National Cancer Institute

Division of Cancer Prevention

The Early Detection Research Network (EDRN)

Scientific Advances (2015-2020)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Contents

Executive Summary

Introduction

Although significant roadblocks have hindered the field of biomarker discovery, the Early Detection Research Network (EDRN) has helped overcome many of them by setting well-defined strategies and milestones focused on solving defined unmet clinical needs. The EDRN has implemented benchmarks to improve biomarker discovery and validation, such as data sharing, use of common data elements, generating multi-disciplinary and multi-institutional collaborations within a cohesive and productive team environment, and putting emphasis on quality control and data replication for all candidate biomarkers for reaching a "go" or "no go" decision. The EDRN attracts excellent academic and industrial scientists by providing access to diverse top-quality assays, clinical specimens, methodological expertise, industrial resources, and financial resources that are not available through other government or industry-based funding mechanisms.

The way the EDRN is organized provides flexibility to respond in a timely fashion to new opportunities and there are few barriers that prevent the EDRN from responding to changes in research priorities. The EDRN has made a major contribution to the research community by providing criteria and standards for validating biomarkers via published validation study protocols designed by EDRN investigators. The Network continues to address a multiplicity of needs in discovery, validation, tissue collection, informatics, public sector collaboration and engaging academia and the private sector. Fulfilling the expectations for rapid discovery and validation of cancer biomarkers requires a continued and sustained investment in biomarker research. The process of bringing new biomarkers to the clinic faces challenges similar to the process of bringing new pharmaceuticals to the clinic, but with the current infrastructure in place, these expectations can be realized in the near future.

Overview and History

In 2000, the National Cancer Institute (NCI) established the EDRN, an investigator-driven network to conduct translational research to identify, develop and validate biomarkers for early cancer detection and risk assessment. This consortium of more than 300 investigators at academic institutions and in the private sector are working collaboratively to bring biomarkers to clinical fruition. These scientists represent diverse disciplines, including genomics, proteomics, metabolomics, bioinformatics, imaging, clinical medicine, and public health. EDRN Principal Investigators frequently comment on the value of having both biomarker discoverers and clinicians within the EDRN where they can learn from each other and exchange ideas. Clinicians provide valuable information to biomarker developers on the clinical context in which a biomarker will be used and the required performance characteristics, which helps them design

their discovery projects. Conversely, biomarker developers inform clinicians on the analytical performance of different classes of biomarkers that helps them design the validation studies.

Since its establishment, the EDRN has been renewed three times, which involved evaluations by external reviewers, NCI leadership and the NCI Board of Scientific Advisors. Although the essential mission of the EDRN, the discovery, development and validation of biomarkers to improve early cancer detection, has remained the same, there have been changes in focus with evolving developments in the field. In 2014, the EDRN Network Consulting Team recommended the EDRN increase its support for imaging as it relates to screening and early detection and to support research that integrates imaging and biomarkers. The NCI Board of Scientific Advisors agreed with this recommendation. In the current EDRN cycle, most of the Clinical Validation Centers and many of the Biomarker Developmental Laboratories include imaging as a significant component of their research. Also, during the last renewal, the Board of Scientific Advisors recommended that more emphasis and a larger fraction of the EDRN resources be devoted to biomarker validation. Consequently, there has been an increase in the percentage of EDRN funds being used to support biomarker validation.

In the current cycle, the EDRN has increased its research on pancreatic cancer, which is now the third leading cause of cancer deaths in the U.S. Another area of increased research by EDRN investigators has been to develop and validate biomarkers and imaging methods that can accurately distinguish an indolent cancer from an early stage cancer that is destined to progress and thereby help reduce the extent of overdiagnosis and overtreatment. Overdiagnosis of prostate, lung and breast cancer present significant clinical challenges that have major impact on patients' health.

As detailed in this progress report, this integrated network has made and continues to make substantial progress on improving methods to detect cancer earlier and has adapted to the evolving needs of the field (e.g., preferential detection of clinically significant disease and integrating biomarkers with imaging). Over its history, EDRN investigators have made significant contributions to the development and validation of 8 Food and Drug Administration (FDA) approved biomarker tests or devices and 19 biomarker tests that are available in Clinical Laboratory Amendment (CLIA) laboratories.

Impact on Cancer Early Detection

Without the EDRN, research into new biomarkers for early cancer detection and risk would have remained on the periphery of research with strong, yet fragmented laboratory studies, many of which would not have been reproduced and validated. The lack of reproducibility of scientific data remains a major challenge and continues to plague scientific data. Indeed, each year thousands of research articles are published on cancer biomarkers, however, much of this literature includes studies that were conducted without appropriate study designs, and only a handful of biomarkers have been approved by the FDA. It is, therefore, important to continue to

have an infrastructure such as the EDRN that systematically assesses biomarkers and selects the most promising ones for transition through rigorous validation for clearly defined clinical uses. Within the EDRN, discovery leads to additional work that confirms and improves the accuracy of the biomarker, which then moves to early clinical validation. Through this approach to translational research, the EDRN has built and implemented a vertically integrated pipeline of biomarkers for cancer early detection and risk assessment.

The EDRN has a mechanism in place that serves as both a "brake" and an "accelerator." Within the EDRN, biomarkers undergo rigorous tests before they are adopted for larger validation studies. Biomarkers that are not effective for the intended clinical objective are not considered further. Each biomarker is tested against the following benchmarks:

1. Is the biomarker assay reproducible in an independent laboratory?
2. Is the biomarker's performance reproducible when checked using independent clinical reference samples?
3. Does the biomarker outperform currently used marker, or add significant value to it?

If the answer to any of these questions is "no", then it is a 'no go' for moving forward.

The EDRN's structure provides a solid approach to translational research. In his 2007 presentation to Congress, NIH Director Elias Zerhouni cited the EDRN as one of the major NIH programs with significant outcomes for the investment. EDRN's approach fits with the NIH's research paradigm for the future, which seeks to transform medicine from curative and reactionary to preemptive and anticipatory. As Dr. Zerhouni testified, "A more predictive, personalized and preemptive form of medicine is no longer just a dream but a vision to strive for, because it can reduce disease burden and its costs while improving individual quality of life." Other NIH institutes have emulated the EDRN model for their translational and clinical programs, e.g. Quantitative Imaging Network, Human Tumor Atlas Network, and Informatics Technology for Cancer Research.

Organizational Structure

The four components of the EDRN have distinct but complementary roles and work synergistically to facilitate the discovery, development, and validation of cancer biomarkers.

1. ***Biomarker Developmental Laboratories (BDLs)***: BDLs discover, develop, and characterize new biomarkers or refine existing biomarkers. Within the EDRN, BDLs are the primary source of new biomarkers or panels of biomarkers on which the EDRN conducts validation studies. They also develop assays to detect candidate biomarkers and conduct pre-validation studies.
2. ***Biomarker Reference Laboratories (BRLs)***: The primary role of the BRLs is to conduct assays for EDRN validation studies. The assays are performed on blinded biospecimens

to minimize bias in the analysis and independently verify the assay performance. BRLs also serve as the primary resource for analytical validation of biomarkers, technological development, standardization, assay refinement and quality control.

3. ***Clinical Validation Centers (CVCs)***: The primary role of the CVCs is to conduct validation studies on biomarkers discovered/developed by both EDRN and non-EDRN investigators. CVCs also provide high-quality, well-annotated biospecimens to the BDLs for biomarker discovery, development and pre-validation studies. The use of biospecimens collected using rigorous standard operating procedures helps minimize false discoveries.

4. ***Data Management and Coordinating Center (DMCC)*:** One of the major roles of the DMCC is to work with the CVCs to conduct biomarker validation studies. The DMCC assists with protocol design, monitors the validation study, and maintains the data and biospecimen tracking system. The DMCC is responsible for analyzing the results of the validation studies, thereby reducing bias as they are independent from the laboratories that discovered the biomarkers. The DMCC provides statistical advice to the BDLs, develops theoretical and applied approaches for simultaneous analysis of multiple markers, and collaborates with the EDRN Informatics Center (described below).

EDRN Steering Committee: The EDRN Steering Committee is composed of all the EDRN Principal Investigators (PIs) and is responsible for overseeing the activities of EDRN and setting priorities. The Steering Committee meets in person twice a year and a subset of PIs, consisting of the EDRN Chair and Co-Chair and the elected Chairs of the Collaborative Groups, have monthly conference calls.

Collaborative Groups: Within the EDRN there are four organ-specific Collaborative Groups — Breast and Gynecologic Cancers (current focus is on breast and ovarian cancers), Colorectal and Other Gastrointestinal Cancers (current focus is on colorectal, esophageal and pancreatic cancers), Lung and Upper Aerodigestive Cancers (current focus is on lung cancer and mesothelioma), and Prostate and Other Urologic Cancers (current focus is on prostate cancer). Every EDRN PI is a member of at least one Collaborative Group, participates in collaborative research projects, and attends monthly conference calls.

Interagency Agreements: The EDRN has collaborations with four other Federal agencies: (1) the National Aeronautics and Space Administration's Jet Propulsion Laboratory (JPL), which supports EDRN informatics; (2) Pacific Northwest National Laboratory (PNNL), which supports the development of proteomic-based assays; (3) the Department of Defense Center for Prostate Disease Research (CPDR), which assists in the development of specific monoclonal antibodies and provides valuable biospecimens collected from subjects with prostatic diseases with high representation of African Americans (30%); and (4) the National Institute of Standards and Technology (NIST), which assists in the development of standards and reference materials (in this cycle, they developed standards for miRNA and cfDNA). The EDRN also works closely

with the private sector to avoid duplication and accelerate the application of biomarkers for diagnostic uses.

EDRN Process for Biomarker Discovery, Development and Validation

Business Model: Biomarker research has generally followed a horizontal approach, which often results in functional "silos" in which investigators develop expertise where depth of knowledge in one specific area is critical. Such a "horizontal" structure fosters excellent solutions for primary scientific problems. However, it often generates barriers in biomarker development and validation when knowledge must be shared between silos. In contrast, the EDRN is organized in a "vertical" structure. In this structure, formal "hand-off" procedures have been designed to ensure that discoveries in one aspect of biomarker development are rapidly and efficiently conveyed to others who require the information. This allows for rapid vetting of ideas, quickly culling out the poor concepts and fostering the rapid acceptance of good concepts (see EDRN 4th and 5th Reports for details: https://edrn.nci.nih.gov/docs).

Biomarker Pipeline - From Discovery to Development to Validation: Each year more than 20,000 papers are published on cancer biomarkers of which 2000 are on early detection. Unfortunately, very few of these biomarkers are validated and become clinically useful tests that are available to patients. The EDRN pipeline includes several important steps to examine validity and clinical usefulness. As shown in Figure 1, many biomarkers fall out of this pipeline due to a variety of reasons. Common factors include (1) the biomarker lacks sufficient sensitivity and/or specificity to be clinically useful, (2) the inability to reproduce the results using another set of biospecimens, (3) the assay has poor analytical reproducibility, and (4) the inability to distinguish early stage cancer from confounding conditions, e.g. pancreatic cancer from pancreatitis. Consequently, the biomarker pipeline remains sparsely populated beyond the initial discovery phase and shares challenges similar to those involved in drug discovery. The EDRN ensures that these challenges are addressed by the appropriate expertise as provided by the various components of EDRN (Figure 2). EDRN investigators have more than 1300 biomarkers (multiple biomarkers as part of panels) at the various stages of the pipeline and some are awaiting validation studies.

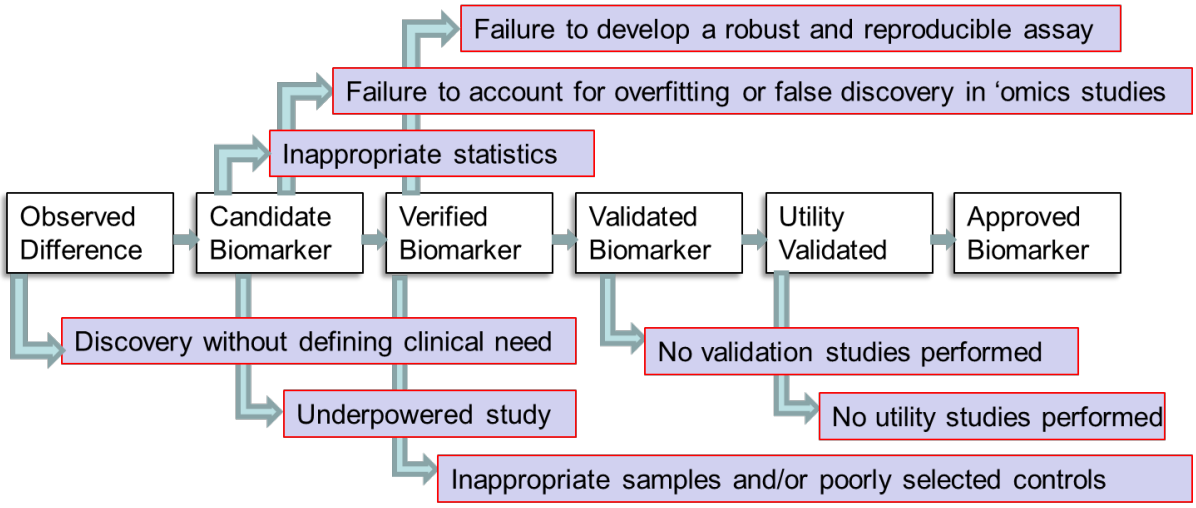


Figure 1: Pitfalls in Biomarker Validation

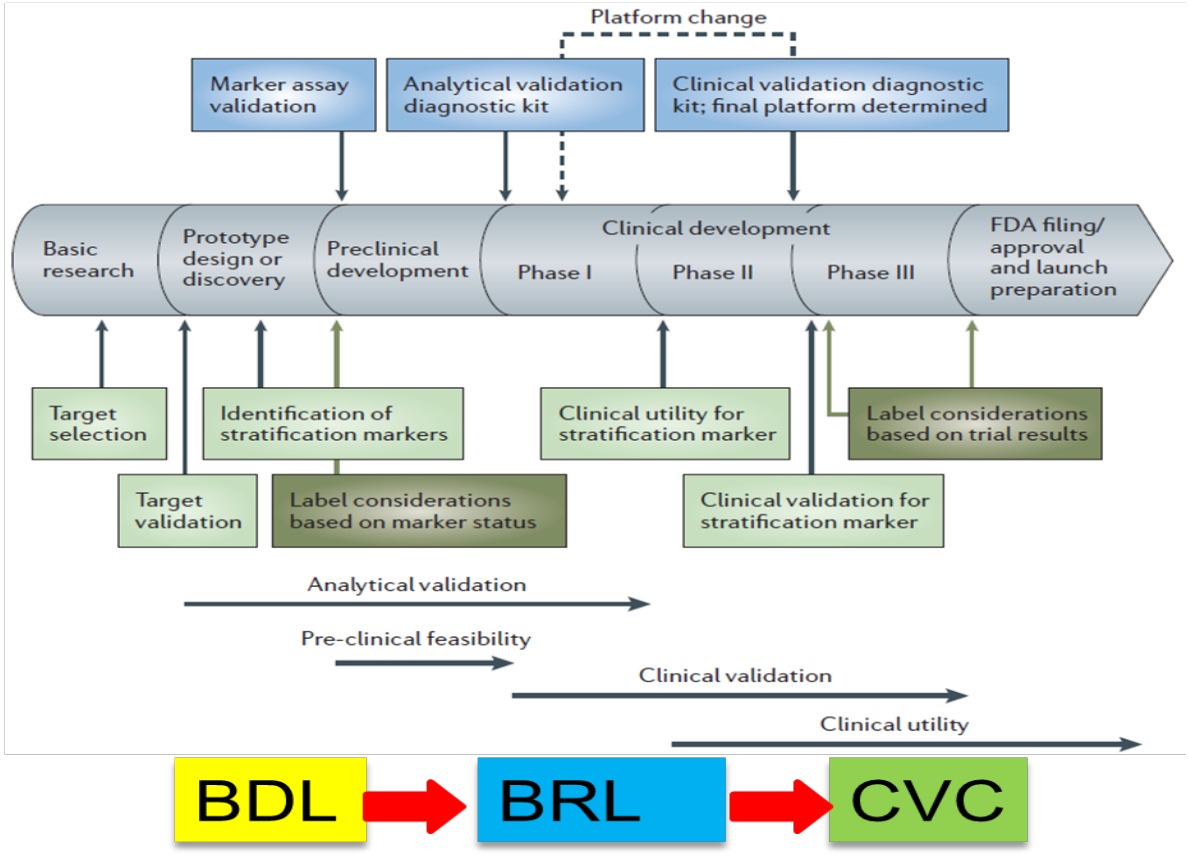
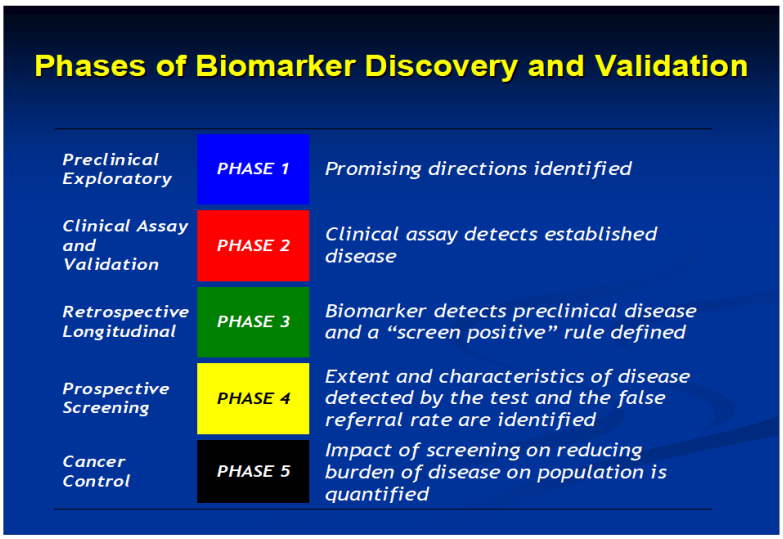


Figure 2: Biomarker Pipeline

Process, Prioritization, and Performance: EDRN DMCC statisticians, led by Margaret Pepe, developed a 5-phase approach to biomarker development that provides a systematic approach to discovery, development, validation and implementation (Figure 3). They also developed a study design approach (PRoBE) that provides a rigorous set of criteria to reduce bias during all phases of biomarker discovery and validation. Together they are used by the EDRN to help inform the "go" or 'no go" decision process and determine which biomarkers to move forward.

The EDRN Biospecimen Reference Sets have been very useful in facilitating the "go' or "no go" decision process. These specimen reference sets are sets of samples with cases and controls statistically powered for a specific intended clinical application, and they allow direct comparisons and assessment of the performance characteristics of individual candidate biomarkers in a blinded fashion. These biospecimen reference sets are described in more detail in the section on EDRN Collaborative Environment. The Collaborative Ovarian Cancer Validation Study is an example of the use of a biospecimen set.



Phases of Biomarker Development for Early Detection of Cancer
Margaret Sullivan Pepe et al., J Natl Cancer Inst. 2001 Jul 18; 93(14): 1054–1061.

Citations: >1300

PRoBE Study Design:
Prospective-Specimen-Collection, **R**etr**o**spective-**B**linded-**E**valuation

Pivotal Evaluation of the Accuracy of a Biomarker Used for Classification or Prediction: Standards for Study Design
Margaret Sullivan Pepe et al., J Natl Cancer Inst. 2008 Oct 15; 100(20): 1432-1438.

Citations: >400

Figure 3: A phased approach to biomarker discovery, validation and implementation.

The EDRN serves not only as an 'accelerator' of the development and validation of biomarkers, but also serves as a 'brake' to unsubstantiated claims. A 6-marker panel for ovarian cancer developed by an investigator from Yale University indicated sensitivity of 95.3% and specificity of 99.4% as compared to CA-125 (72% and 95% respectively) in a case-control study. A similar performance was observed on an independent sample set from GOG (Gynecologic Oncology Group) biorepository. Therefore, a Phase 3 validation study was conducted by EDRN using

Prostate, Lung, Colon and Ovarian Cancer (PLCO) Screening Trial samples to see if the performance will hold on pre-clinical specimens, the intended clinical application. Unfortunately, the panel failed to meet the performance of detecting ovarian cancer in pre-clinical samples.

The EDRN has assembled more than 954 biomarkers in Phase 2 or Phase 3, which are being validated or ready to be validated either individually or as a part a panel (Table 1).

Table 1: EDRN Biomarkers in Phases of Development and Validation

Organ	Phase 1	Phase 2	Phase 3	Phase 4
Bladder	26	26	10	0
Breast	501	315	113	0
Colon	35	26	6	0
Esophagus	12	12	12	1
Head & Neck	8	0	0	0
Liver	51	49	31	0
Lung	179	79	31	1*
Ovary	317	304	99	3
Pancreas	96	89	30	1
Prostate	450	54	21	0
Total by Phase	1675	954	353	6

*- Mesothelioma

Collaborative Approach and Environment

This integrated structure of the EDRN is a unique and important aspect of the network's efficiency and productivity. The bringing together of investigators with expertise in cancer biology and biomarker development (the BDLs) with clinicians having expertise in cancer screening and early diagnosis and with access to appropriate patient populations and specimens (CVCs) ensures that the discovery efforts are performed with specific diagnostic requirements in mind – in what patient population and for what purpose will the biomarkers or imaging modality be used, and what performance (sensitivity and specificity) and accuracy are required to make them clinically useful. Too often, discovery efforts by non-EDRN investigators are not closely aligned with potential clinical applications, e.g., use only late stage cancers or only healthy controls with no confounding conditions. It is notable that more than 50% of the biomarkers or panels being validated by the EDRN CVCs were developed by EDRN BDLs.

Collaborative Groups are an important aspect of the EDRN structure. These EDRN groups are organized around specific cancer types, and all EDRN PIs, co-investigators and many associate members are members of one or more of these collaborative groups. They have monthly conference calls and meet twice a year in person to update each other on their progress and to develop collaborative projects that use the resources of all the investigators. These projects frequently involve comparing the performance of biomarkers from different laboratories in a common set of biospecimens and when appropriate combining these biomarkers to create a panel. These projects are supported by the grantees' set-aside funds, which are restricted to this purpose. Many of these projects are described in this report's section on Research Advances and Collaborative Projects. The design and outcome of a collaborative project on ovarian cancer are outlined in Figures 4 and 5.

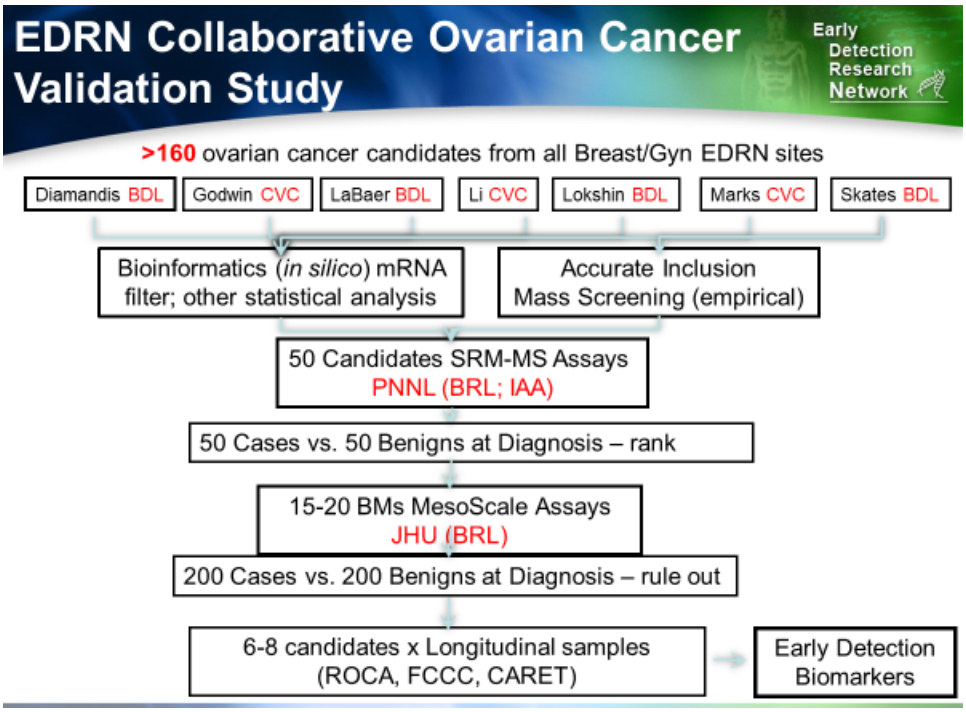


Figure 4: Design of an EDRN Ovarian Cancer Biomarker Project

Comparison of Biomarker Sensitivity at 95% Specificity for Phase II and Phase III Study Results

Marker	Phase II	Phase III			
	All cases	Cases diagnosed ≤6 mo after draw	Cases diagnosed >6–12 mo after draw	Cases diagnosed >12–18 mo after draw	Cases diagnosed >18 mo after draw
CA125	0.73	0.86	0.33	0.12	0.03
HE4	0.57	0.73	0.23	0.18	0.12
Transthyretin	0.47	0.02	0.05	0.12	0.09
CA15.3	0.46	0.45	0.05	0.27	0.03
CA72.4[a]	0.40	0.44	0.14	0.20	0.06
IGFBP2	0.38	0.09	0.00	0.00	0.03
Mesothelin	0.35	0.40	0.00	0.06	0.00
Prolactin	0.34	0.13	0.09	0.12	0.03
Apoliprotein	0.34	0.07	0.05	0.12	0.19
Spondin-2	0.28	0.11	0.14	0.06	0.12
Transferrin	0.23	0.09	0.09	0.00	0.00
MIF	0.15	0.18	0.09	0.00	0.18
B2M	0.05	0.09	0.05	0.00	0.15

[a]Assay changed between phase II and phase III (see Materials and Methods).

Figure 5: Results of an EDRN Ovarian Cancer Biomarker Project

The EDRN program values collective accomplishments and measures its successes on team activities, thus distinguishing itself from other funding mechanisms. Working in teams enhances collaboration and cultivates brainstorming. As a result, more ideas are developed, and productivity improves. Teams often are better at problem solving, finishing difficult tasks and boosting creativity. EDRN also serves as a Hub for several sister programs engaged in biomarker research related to early detection that help enrich the biomarker pipeline for validation by facilitating dialogue and sharing of information (Figure 6).

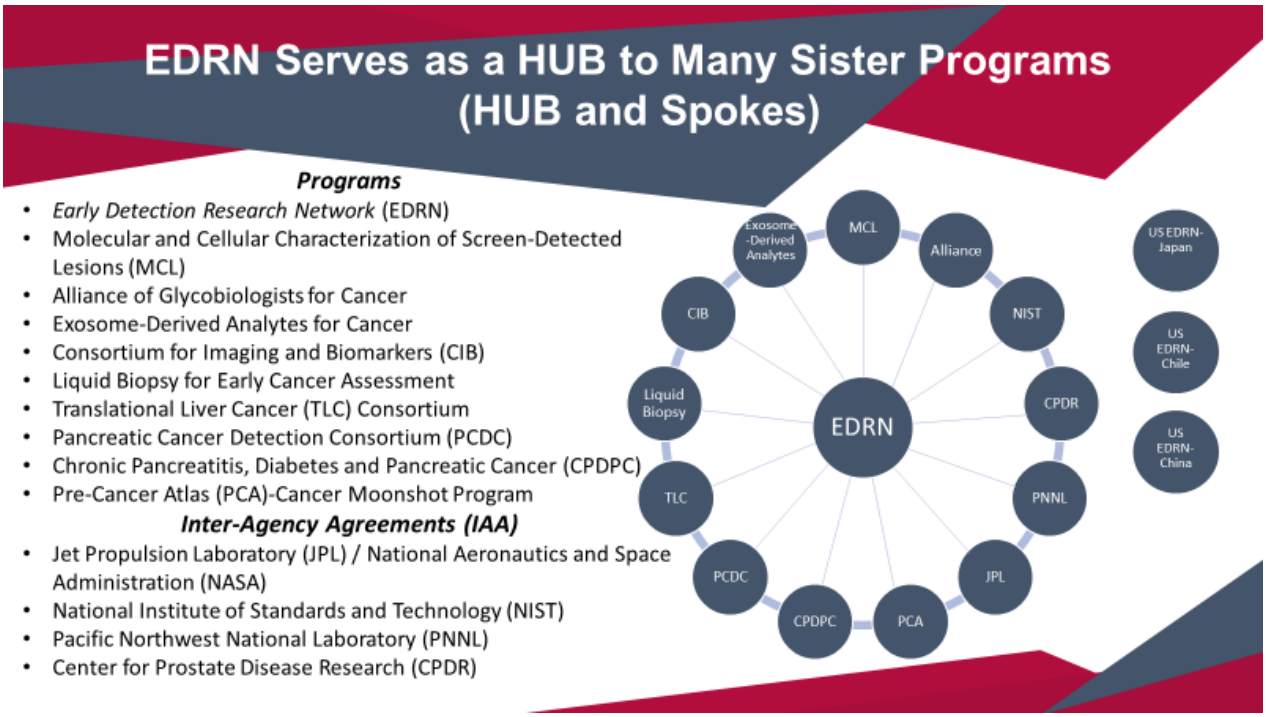


Figure 6: EDRN serves as a biomarker research Hub

Innovative Funding Mechanisms: Set-Aside and Core Funds

Set-aside Funds: EDRN awards include 'set-aside' funds that can only be used for new team and other collaborative projects that take advantage of the expertise, resources, and platforms of several different PIs. These funds account for thirty percent of EDRN investigators' awards. Requests for the use of set-aside funds are reviewed by the EDRN Steering Committee and the release of the funds is contingent upon the advice of the EDRN leadership and authorization by the NCI.

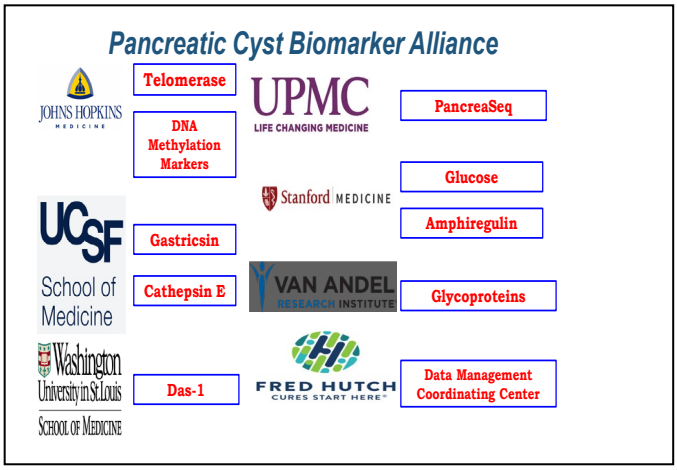
Core or Headquarters Funds: The EDRN has developed innovative funding mechanisms to drive collaboration within the network and with investigators outside of the EDRN. These funds reside at the Data Management and Coordinating Center (DMCC) and are used to support post-award projects. Requests for the release of these funds are reviewed by the EDRN Steering Committee and NCI. They are used primarily to support large multi-center biomarker validation studies that involve patient accrual, biospecimen collections, and assays of defined biomarkers. For example, in this cycle, these funds are being used to support studies to validate stool and blood-based biomarkers for colorectal cancer, blood-based biomarkers for mesothelioma, tissue biomarkers for prostate cancer upgrading, MRI/US-fusion to improve the accuracy of prostate needle biopsies, and uterine lavage tDNA and blood biomarkers for ovarian cancer early detection.

Core Funds are also used to support the coordination of biospecimen collections from multiple centers (both EDRN and non-EDRN) to be used for future biomarker verification and validation. For example, in this cycle, the EDRN's DMCC provided the initial support and continues to provide the infrastructure to support the accrual of patients with new-onset diabetes (NOD), which can be an early symptom of pancreatic cancer in patients who are otherwise asymptomatic. Biospecimens and clinical information from the patients will be used to identify and validate biomarkers to detect pancreatic cancer in patients with NOD.

New-Onset Diabetes Cohort

Among the most compelling needs for pancreatic ductal adenocarcinoma (PDAC) research is to develop a rational, evidence-based strategy to detect this cancer at an early, resectable stage. Currently, patients with new-onset diabetes (NOD) are one of the few "actionable" high-risk groups for PDAC. The three-year cumulative incidence of PDAC in NOD patients is ~0.85%. The NOD study will recruit 10,000 subjects over the age of 50 years with new-onset diabetes to (i) collect clinically annotated biospecimens from pre-symptomatic PDAC subjects and type 2 Diabetes Mellitus controls, (ii) estimate the probability of PDAC in the prospectively assembled NOD cohort, and (iii) establish a specimen reference set to validate emerging tests to identify high risk NOD patients for PDAC. diagnostic workup.

Another collaborative project being supported by EDRN Core Funds is the Pancreatic Cyst Biomarker Validation Study, which will test and validate biomarkers for distinguishing aggressive from non-aggressive pancreatic cysts. Intraductal papillary mucinous neoplasm (IPMN) and mucinous cystic neoplasm (MCN) are high-prevalence lesions and are detected in 0.6 to 1.8% abdominal computed tomography (CT) scans in the U.S. One-third of patients with IPMNs have an associated invasive carcinoma at the time of diagnosis; MCNs can progress to pancreatic ductal adenocarcinoma, and one-third of patients with resected MCNs have cancer. Currently, it is difficult to distinguish precancerous mucinous cysts from benign non-mucinous cysts, and the timing and frequency of malignant progression within the mucinous cysts is unknown. Consequently, there is a need for accurate biomarkers to detect high-grade dysplasia and determine the risk of progression. For this EDRN-funded study, investigators from three consortia (EDRN, the Pancreatic Cancer Detection Consortium (PCDC) and the Chronic Pancreatitis Diabetes and Pancreatic Cancer Consortium) proposed to validate pancreatic cyst fluid biomarkers for the discrimination of patients at high-risk for developing or presenting with pancreatic cancer within a pancreatic cyst.



The markers being tested include genomic markers (KRAS, GNAS, VHL, TP53, PIK3CA, and PTEN); glycomic markers (MUC5AC:WGA, MUC5AC:BGH and endorepellin); telomerase assay; DNA methylation (SOX17, FOXE1, PTCHD2, SLIT2, EYAA4, and SFRP1); amphiregulin expression and glucometer glucose; gastricsin and cathepsin E; and Das-1. Six sites have contributed specimens for this study.

EDRN has also begun a multi-site prospective collection of pancreatic cystic fluids along with blood and plasma from those individuals who develop pancreatic cancer and those who do not.

EDRN Biospecimen Reference Sets

These specimen reference sets are sets of samples with cases and controls statistically powered for a specific intended clinical application to allow the rapid assessment of technologies and biomarkers discovered through a variety of technology platforms. Multiple EDRN sites contribute specimens to these sets, which is critical as single sites rarely have sufficient numbers of early stage cancers. These sets allow the direct comparison and assessment of the performance characteristics of different platforms, as well as the performance characteristics of individual candidate biomarkers using the same specimens in a blinded fashion. For example, the EDRN pancreatic cancer reference set is comprised of serum/plasma samples from subjects with pancreatic cancer (n=60 early stage and 40 late stage cancers), chronic pancreatitis (n=63), acute benign biliary obstruction (n=31), and healthy controls (n=61).

Nine EDRN reference and validation sets are stored at NCI Frederick, which ensures their availability to the entire research community (Table 2: EDRN Biospecimen Reference Sets). Additional information on the individual sets can be obtained by following the link: (https://edrn.nci.nih.gov/resources/sample-reference-sets).

Also, in most instances when the EDRN undertakes a biomarker validation study, additional aliquots of specimens are collected to allow for the validation of future biomarkers. For example, biospecimens from a hepatocellular carcinoma (HCC) biomarker validation study were used to create a biospecimen validation set that contains specimens from 800 patients with HCC and 800 cirrhosis controls.

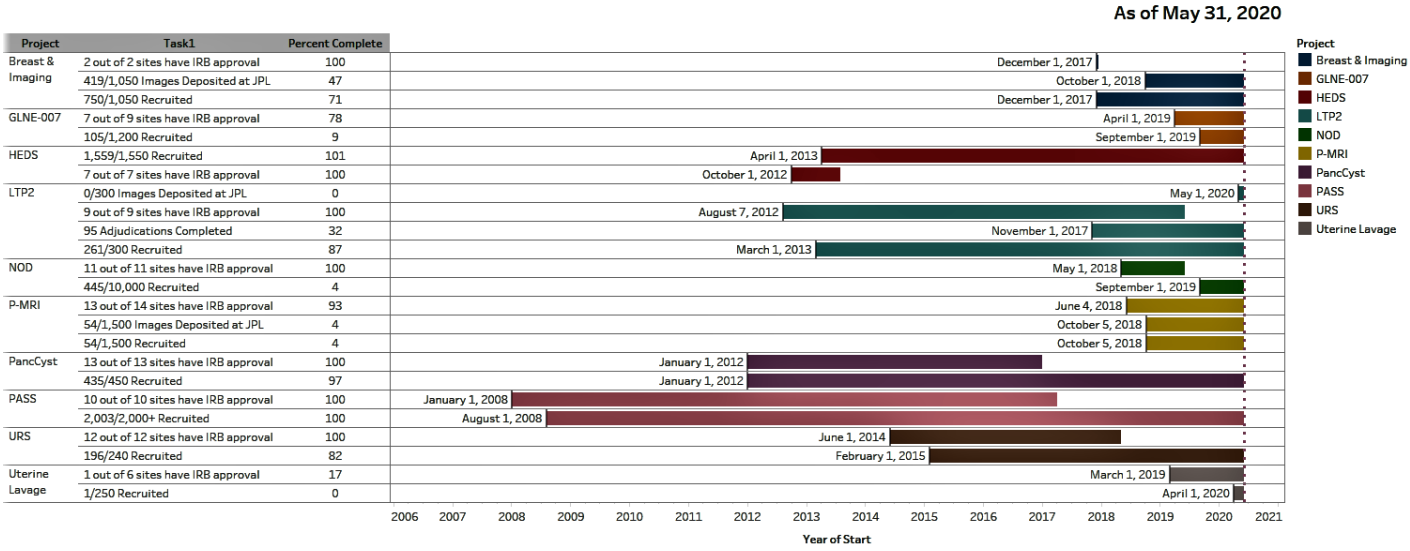
For example, Core Funds are supporting the collection of longitudinal specimens from patients with cirrhosis, many of whom go on to develop HCC. This unique collection will be used to validate biomarkers and algorithms to detect early stage HCC that are currently not detected by ultrasound. HCC accounts for approximately 85-90% of all primary liver cancers. The five-year survival rate for patients detected with early stage HCC is greater than 70% with transplant or resection, but for patients with advanced HCC, the 5-year survival is less than 5%. The fraction of HCC detected early could be increased by improved imaging methods, more sensitive and specific cancer biomarkers and tailoring surveillance protocols based on etiology and

ethnicity/race. Better risk stratification could help identify additional high-risk patients that need to be in surveillance programs. Identifying and improving the surveillance of patients at risk may help reduce mortality due to liver cancer. This prospective collection, EDRN Hepatocellular Carcinoma Early Detection Strategy Study (HEDS), is described in the section on Building Scientific Resources.

Table 2: EDRN Biospecimen Reference Sets

Reference Set	Type of Specimens	Participants #	Participant Groups
Bladder Cancer	Serum, whole urine, DNA from blood	497	Bladder cancer cases Healthy controls High Risk controls
Breast Cancer	Serum, plasma, buffy coat	832	Pre-diagnosis specimens DCIS cases Invasive cancer cases LCIS cases Benign➔later cancer cases Normal➔later cancer cases Benign Disease Atypia controls Benign Disease non-Atypia controls Normal controls
Cancers in Women Endometrium, Ovary, Breast	Serum, plasma	536	Cases (pooled) Controls (individual and pooled)
Colon Cancer	Serum, plasma, whole urine	150	Cases Adenoma controls Normal controls
Liver Cancer	Serum, plasma	871	Cases Controls
Lung Cancer	Serum, plasma	1,205	Cases Controls High risk with CT nodule controls High risk with no CT nodule controls
Pancreatic Cancer	Serum, plasma	255	Cases Controls
Prostate Cancer	Serum, plasma, buffy coat, RNA, supernatant fluid, whole urine	900	Initial Biopsy w/ Cancer cases Repeat Biopsy w/Cancer cases Confirmed but no biopsy controls Initial Biopsy w/o Cancer controls Repeat Biopsy w/o Cancer controls
Prostate Cancer (retrospective)	Serum	663	Cases Controls

EDRN Core Funds are currently used to support collections of biospecimens (Figure 7).



Start Day for each Percent Complete broken down by Project and Task1. Color shows details about Project. Size shows sum of Dur. The marks are labeled by Min Start Date by Project Month.

Figure 7: Ongoing Projects Supported by Core Funds

Scientific Accomplishments

Continuous Improvement

The development of biomarkers and panels of biomarkers for cancer risk, early detection, diagnosis and prognosis by the EDRN is a continuous, iterative process of discovery, verification and validation (Figure 8). These improvements can be incremental or achieved with a breakthrough discovery. Developed and implemented diagnostic tests may provide clinically useful information, but their performances may be less than optimal, e.g., they could benefit from better sensitivity and/or specificity. This is why it is so useful to adopt the principles of continuous improvement.

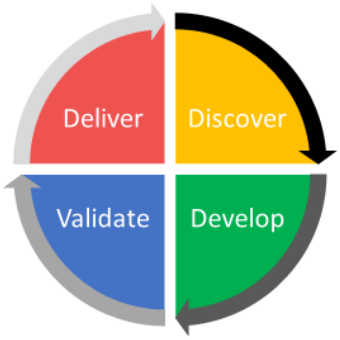


Figure 8: Biomarker Discovery, Development, Validation and Delivery is an Iterative Process

Since these improvements frequently happen beyond a typical five-year funding cycle, it is difficult to delineate the exclusive successes within each five-year cycle. Therefore, while this report focuses on advancements since 2015, where relevant we include progress from previous funding cycles.

The development of the MiPS assay (Mi-prostate score) provides an example of continuous improvement (Figure 9). MiPS helps evaluate a patient's risk of having prostate cancer and the degree of its aggressiveness; it is usually performed after an abnormal PSA test and a digital rectal exam. MiPS combines three biomarkers (serum PSA, urinary PCA3, and urinary TMPRSS2:ERG). With a high Negative Predictive Value (98%) and sensitivity (97%), this test has been shown to avert 27% of unnecessary biopsies. EDRN investigators have made significant contributions to the discovery and validation of these biomarkers.

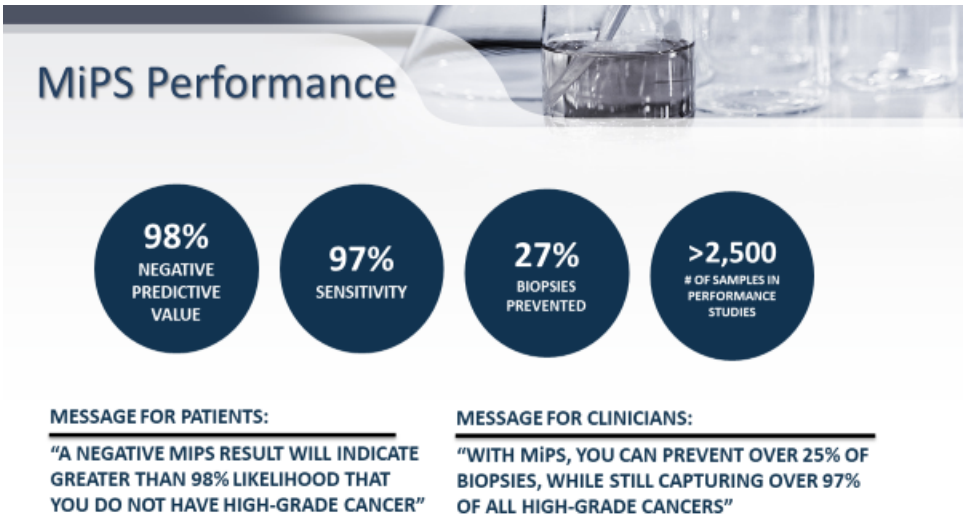


Figure 9. MiPS reduces unnecessary biopsies for prostate cancer by 27%.

FDA-Approved Biomarker Tests and Devices Available in CLIA Laboratories

To improve the clinical utility of PSA for early detection and risk assessment, EDRN investigators validated the utility of PCA3. Prostate cancer antigen 3 (PCA3) is a prostate-specific gene that has been detected in over 90% of prostate cancers. PCA3 mRNA expression was found to be independent of prostate volume and serum PSA and is higher in patients who had larger, more aggressive tumors. EDRN investigators in collaboration with Hologic/GenProbe Co. developed a urine assay, Progensa, which obtained FDA approval in 2012.

EDRN investigators' discovery of frequent recurrent genetic rearrangements, which generate fusion transcripts such as TMPRSS2-ERG, led to the development of new highly specific genetic assays. Genetic rearrangements occur in about 50% of all prostate cancers; TMPRSS2-ERG rearrangement is the most frequent (>90% of all rearrangements). ERG is not expressed in normal prostatic tissue and is detected only in high grade prostatic intraepithelial neoplasia and prostate tumors. The test now is available in a CLIA-certified laboratory.

The primary mission of the EDRN is to develop and validate biomarkers and imaging modalities that are used to improve early cancer detection. One measure of success is the number of these biomarkers that are approved for use in a clinical setting. At the time of the last renewal in 2014, five diagnostic tests to which EDRN investigators made significant contributions had been approved by the FDA (two for prostate cancer, two for ovarian cancer, and one for hepatocellular carcinoma) and 10 EDRN-supported diagnostic tests were in CLIA-certified laboratories.

In the past five years, EDRN investigators have contributed to the development and validation of three FDA approved tests or diagnostic devices; Overa for ovarian cancer, CancerSEEK for ovarian and pancreatic cancer, and EsoCheck for Barrett's esophagus or esophageal cancer.

Overa: EDRN investigators Daniel Chan and Zhen Zhang participated in the development and FDA approval of this test for determining ovarian cancer risk. Overa is specifically designed to help determine which patients with pelvic masses are at low risk for malignancy and to better identify patients who are at high risk for having a malignancy and, therefore, would benefit from care with a specialized gynecologic oncology surgeon. Vermillion, Inc. offers this test.

CancerSEEK: EDRN investigators Kenneth Kinzler, Robert Schoen, Randall Brand, Peter Allen and Samir Hanash participated in the development and testing of CancerSEEK, which is a multianalyte test that simultaneously determines the levels of eight proteins and the presence of cancer gene mutations in circulating DNA. The test is aimed at screening for eight common cancer types that account for more than 60 percent of cancer deaths in the U.S. Five of the cancers covered by the test currently have no screening test. Thrive Earlier Detection Corp. has received FDA's Breakthrough Device designation for the detection of genetic mutations and proteins associated with pancreatic and ovarian cancers.

EsoCheck: EDRN investigator Sanford Markowitz developed this device, which is designed to allow patients to undergo a non-invasive five-minute office-based procedure to detect Barrett's Esophagus (BE) and esophageal cancer without the need for endoscopy. EsoCheck's ability to sample cells from a targeted area of the esophagus has the potential to save lives through the early detection of esophageal abnormalities. PAVmed markets this device.

In the past five years, EDRN investigators have also developed nine new diagnostic tests which are in CLIA-certified laboratories, eight of which are or will soon be in commercial laboratories; MiCheck for prostate cancer, Videssa Breast for breast cancer, DetermaVu for lung cancer, Precepta for lung cancer, Esoguard for Barrett's esophagus, Decipher Prostate Cancer Classifier Test for prostate cancer, urinary RNAs for prostate cancer, metabolite and protein panel for pancreatic cancer, and mucin panel for pancreatic cancer. Four of these are described in more detail below.

Videssa Breast: EDRN investigators Karen Anderson and Joshua LaBaer in collaboration with Provista discovered tumor associated auto-antibody biomarkers which were validated in two large prospective, randomized, double blinded multicenter clinical studies. This test is used in women with abnormal or difficult to interpret mammograms to help inform them whether further diagnostic procedures may be warranted (e.g.,

additional imaging or biopsy) or provide assurance that they likely do not have breast cancer. This test is CLIA approved.

Percepta: EDRN investigator Avrum Spira and Allegro Diagnostic performed the original research that resulted in the development of this CLIA approved test. The test is a 23-gene expression panel that measures mRNA in cells taken from bronchial brushes during bronchoscopy. The Percepta classifier identifies patients with lung nodules who are at low risk of cancer following an inconclusive bronchoscopy result, making it possible to monitor these patients with CT scans in lieu of invasive diagnostic procedure. Validation of this test involved two clinical studies; The Airway Epithelial Genes Expression (AEGIS -1 and AEGIS -2) in the Diagnosis of Lung Cancer. Veracyte Inc. offers the test, which is reimbursed by Medicare. Approximately 1000 tests are being performed per quarter in the U.S. with close to 3000 cumulative tests since July 2019.

Decipher Prostate Cancer Classifier Test: *SChLAP1* and other prostate cancer associated lncRNAs discovered by EDRN investigator Arul Chinnaiyan were licensed to GenomeDx and are included in this classifier test. Decipher test is a tissue-based tumor genomic test that predicts the probability of metastasis within 5 years of radical prostatectomy, and provides an independent assessment of tumor aggressiveness, information that is distinct from that provided by the Gleason score or PSA.

A list of all FDA and CLIA approved biomarkers and devices to which EDRN investigators have made significant contributions are given in Tables 3 and 4.

Table 3: FDA Approved Biomarkers and Devices

Biomarker/Device	Purpose	Year of Approval	EDRN Principal Investigators Industrial Partner
EsoCheck	Allows patients to undergo a non-invasive five-minute office-based procedure to detect Barrett's Esophagus	2019 FDA-cleared tool	Sanford Markowitz, M.D. PAVmed
CancerSEEK	Detection of genetic mutations associated with pancreatic and ovarian cancer.	2019 FDA break through device	Ken Kinzler, Ph.D., Robert Schoen, M.D., Randall Brand, M.D., Peter Allen, M.D., and Samir Hanash, M.D. Thrive Detection Corp.
Overa (5 analytes: CA 125, apolipoprotein A-1, transferrin, follicle-stimulating hormone, human epididymis protein 4)	Prediction of ovarian cancer risk in women with adnexal mass.	2016	Zhen Zhang, Ph.D. and Daniel Chan, Ph.D. Vermillion
%[-2]proPSA	Reduce the number of unnecessary initial biopsies during prostate cancer screening.	2012	Daniel Chan, Ph.D. Beckman Coulter
PCA3 (Prostate Cancer Antigen 3) RNA in urine	Determination of need for biopsy or repeat-biopsy in patients at risk for prostate cancer.	2012	John Wei, M.D. Gen-Probe
Risk of Ovarian Malignancy (ROMA) algorithm	Prediction of ovarian cancer risk in women with pelvic mass.	2011	Steve Skates, Ph.D. Fujirebio Diagnostics
DCP and AFP-L3; a combined panel of biomarkers	Risk assessment for development of hepatocellular carcinoma.	2011	Jorge Marrero, M.D. Wako Diagnostics
OVA1™ (5 analytes: CA 125, prealbumin, apolipoprotein A-1, beta2 microglobulin, transferrin)	Prediction of ovarian cancer risk in women with adnexal mass.	2009	Daniel Chan, Ph.D. and Zhen Zhang, Ph.D. Vermillion

Table 4: Biomarker Tests in Clinical Laboratory Improvement Amendments (CLIA) Laboratories

Biomarker Assay	Purpose	EDRN Principal Investigator CLIA Laboratory
MiCheck (Glypican-1 protein and related signaling molecules)	Differentiate aggressive prostate cancer from non-aggressive cancer and no cancer	Daniel Chan, Ph.D. Minomic, Inc
Videssa (a multi-protein biomarker blood test)	Distinguish benign from malignant breast lesions	Joshua LaBaer, M.D., and Karen Anderson M.D. Provista
DetermaVu	Liquid biopsy test intended to facilitate clinical decision making in lung cancer	Louise Showe, Ph.D. OncoCyte
Percepta (23-gene expression panel)	Detection of lung cancer	Avrum Spira, M.D. Veracyte Inc.
Esoguard (methylated vimentin and cyclin A1)	Detection of Barrett's esophagus	Sanford Markowitz, M.D. PAVmed
Decipher Prostate Cancer Classifier Test (*SChLAP1* and other lncRNAs)	Determination of prostate cancer aggressiveness	Arul Chinnaiyan, M.D., Ph.D. GenomeDx
Protein panel (TIMP1, LRG1 and CA19-9)	Detection of pancreatic cancer	Samir Hanash M.D., Ph.D. Cosmos Wisdom
Mucin panel (MUC4, MUC5AC, MUC16 and MUC 17)	Detection of pancreatic cancer	Surinder Batra, Ph.D. Sanguine Diagnostic and Therapeutics
MiPS (Mi Prostate Score Urine test), Multiplex analysis of TMPRSS2:ERG gene fusion, PCA3 and serum PSA	Detection of prostate cancer	Arul Chinnaiyan, M.D., Ph.D. Gen-Probe
IHC and FISH for TMPRSS2:ERG fusion	Detection of prostate cancer	Arul Chinnaiyan, M.D., Ph.D. Roche

GSTP1 methylation	Decision making regarding repeat biopsies in prostate cancer	David Sidransky, M.D. OncoMethylome
Mitochondrial deletion	Detection of prostate cancer	National Institute of Standards and Technology (NIST) Mitomics
Proteomic panel	Detection of lung cancer	William Rom, M.D., M.P.H. Celera
Aptamer-based markers	Detection of lung cancer	William Rom, M.D., M.P.H. Somalogic
80-gene panel** **(This panel has been refined; Percepta®, a 23-gene classifier, is now available through Veracyte)	Detection of lung cancer	Avrum Spira, M.D., M.Sc. Allegro/Veracyte
Vimentin methylation in stool	Detection of colon cancer	Sanford Markowitz, M.D., Ph.D. LabCorp
Galectin-3 ligand	Detection of advanced adenomas and colon cancer	Robert Bresalier, M.D. BG Medicine
GP73	Risk of hepatocellular carcinoma	Timothy Block, Ph.D. Beckman Coulter
8-gene Panel for Barrett's Esophagus (BE)	Progression Prediction of BE	Stephen Meltzer, M.D. Diagnovus

Ongoing Validation Studies

During this cycle, EDRN CVCs are conducting 15 biomarker and/or imaging validation studies; two on colorectal cancer, two on pancreatic cancer, three on breast cancer, two on ovarian cancer, two on prostate cancer, one on esophageal cancer, and three on lung cancer. Most of these are on track to complete patient accrual and finish the assays by early 2021. A list of these studies is given in Table 5.

Table 5: Ongoing EDRN Validation Studies

Cancer	Principal Investigator(s)	Biomarker(s) or Imaging modality	Status
Colorectal cancer and advanced adenomas	Dean Brenner	1) Methylated vimentin 2) Galectin-3 ligand 3) Hypomethylated LINE 4) Methylated BCAT1/IKZF1	Specimens collected and being assayed. Sufficient specimens from controls and advanced adenomas have been collected. PI and industrial partners are in discussions with the FDA.
Colorectal cancer	Paul Lampe	1) Protein and glycomic hybrid panel (BAG4, IL6ST, VWF, EGFR and CD44) 2) Glycomic hybrid panel +Gallectin-3 ligand	Developed monoclonal Abs and developed Luminex assays Testing in Endoscopy II samples from (Copenhagen).
Esophageal cancer and Barrett's esophagus	Sanford Markowitz	Methylated VIM and CCNA1	Collecting specimens.
Pancreatic cancer	Surinder Batra Randall Brand	1) Protein panel (MUC4, MUC5AC and CA19-9) 2) Protein panel (trefoil factors 1, 2, and 3)	Performing assays on an additional 250 cases and controls.
Pancreatic cancer	Anirban Maitra Samir Hanash	1) Protein panel (CA19-9, TIMP-1 and LRG-1) 2) Protein panel and metabolites	Assays have been performed on pre-diagnostic samples from PLCO and WHI.
Lung cancer – indeterminate pulmonary nodules	Pierre Massion Robert Gillies Mathew Schabath	1) miRNAs in sputum to determine risk 2) Cyfra 21-1 by FSA-BSI 3) Radiomic signature	1) Candidate miRNA panel is being tested. 2) All samples and images collected. Data analysis ongoing
Lung cancer	Avrum Spira	Clinical model vs. clinical model + 30 gene nasal marker panel	Specimen collection is completed, and assays being performed.

Ovarian cancer	Robert Bast	Four biomarker (CA125, HE4, CA72.4 and anti-TP53 autoantibodies) Risk of Ovarian Cancer Algorithm (ROCA)	Completed assays on 2035 samples from a longitudinal collection. These measurements are being used to generate a classification algorithm.
Ovarian cancer	Charles Drescher	Autoantibodies to TP53 and CST (cancer specific transcripts) -derived antigens	Autoantibodies to TP53 assayed in 450 sample set. Assays on CST being conducted.
Breast cancer	Christopher Li	9 Proteomic 12 autoantibodies 16 glycomic	Markers being assayed in WHI and CHS preclinical sample set.
ER+ breast cancer	Christopher Li Karen Anderson	Autoantibodies	Markers being assayed in preclinical samples from CHS.
Prostate cancer	Martin Sanda	Urine T2:ERG/PCA3 + serum PSA (Mi-Prostate Score)	Decision algorithm defined and results being analyzed.
Prostate cancer	John Wei	mpMRI combined with T2:ERG/PCA3/PSA for detection of high-grade disease	IRB approved and patient accrual started.
Lung cancer	Mathew Schabath Robert Gillies	LDCT – radiomic biomarkers (quantitative image-based feature data) for risk assessment and diagnostic discrimination	Analyzed nested case control from NLST. Recruited 400 lung cancer screening patients (collected images and blood).
Breast cancer	Jeffrey Marks John Heine	Radiomics: (1) full field digital mammography (FFDM) images and (2) digital breast tomosynthesis	Images uploaded to data repository. Methods to analyze these images are being developed.

Novel Approaches, Technologies and Resources

The EDRN has built an array of enabling technologies to help discover and develop biomarkers and enrich the pipeline for future validation studies. Integrated genomic and proteomic technologies are yielding highly innovative strategies for identifying candidate biomarkers for early detection. This effort draws upon the multiple disciplines represented within EDRN (i.e., clinical and basic science, technology development, biostatistics and bioinformatics). This cycle, EDRN has focused on leveraging high-throughput technologies that are amenable to use in clinical settings. Some of the novel technologies and approaches are summarized below.

The Nucleic Acid-Programmable Protein Array (NAPPA)

Developed by Joshua LaBaer, this platform opened the possibility of exploiting the natural tumor-antigen signal amplification provided by autoantibodies to identify novel targets that could be used to develop more sensitive early detection biomarker assays. The Videssa Breast test described above is based on results using this platform. This platform has undergone numerous refinements, including the capability to assay glycoproteins. This is a significant advance as many cancer biomarkers are glycoproteins.

Antibody-free Assays for Biomarkers

Employing highly sensitive targeted mass spectrometry-based technologies is an efficient and cost-effective way to rapidly verify potential candidate biomarkers, and further refine a biomarker panel in pre-clinical validation studies, before further investment in the development of expensive, clinical-grade immunoassays. Pacific Northwest National Laboratory (PNNL), an EDRN Reference Laboratory, has developed and applied high-sensitivity reaction monitoring mass spectrometry-based assays to rapidly identify the most promising candidate biomarkers among long lists of candidate biomarkers developed by EDRN BDLs. In the current EDRN cycle, the PNNL has focused on two objectives: 1) quantitative detection of 50+ selected prostate cancer biomarkers in tissue and bodily fluids and validation of their clinical utility; and 2) multiplexed detection of biomarkers from enriched exosomes and/or secreted biomarkers for early detection, diagnosis, and prognosis of cancers and validation of their potential clinical utility. Successful strategies developed for prostate cancer are also being implemented in studies of other cancers, leveraging the collaborative aspects of the EDRN as a network of interacting centers focused on a common goal.

New DNA Methylation Platform for Melt-analysis of Methylated DNA

James Herman's laboratory at the University of Pittsburgh in collaboration with Jeff Wang at Johns Hopkins University have engineered a complex microfluidic platform to detect rarely methylated genes that will be required for a blood-based diagnostic test. This platform automates DNA extraction and methylation on the microfluidic platform, performs PCR, and then analyzes the products by melt analysis. The time to complete all steps from initial DNA extraction to qPCR is reduced from 7 hours to 4.5 hours with the added advantage that all manipulations are handled robotically and should thus be more reproducible than standard lab handling. It is likely

that other epigenetic EDRN labs will be interested in using this technology. Such a device may transform the approach to detecting and analyzing epi-alleles.

Circular RNAs

Arul Chinnaiyan's laboratory at the University of Michigan has cataloged circular RNA (circRNA) in multiple cancers, which suggests these stable structures could serve as cancer markers in blood or urine. They identified circRNA from more than 2,000 clinical cancer samples and cell line panels and demonstrated that the capture RNA sequencing developed for MiOncoSeq was more robust in detecting circRNA than existing methods and that circRNAs were found to be more stable than linear RNAs. The researchers turned their findings into a database called MiOncoCirc, cataloging the reported circRNAs from tumor samples. This compendium is available to the public as a community research resource.

Radiomics

Several EDRN investigators are exploring the use of radiomics to improve the detection of early stage cancers, particularly breast and lung cancers. Radiomics is the process of converting radiographic images into mineable data. The overarching hypothesis of radiomics is that image features describing size, shape and texture, reflect the underlying tumor pathophysiology and hence, can be developed and qualified as biomarkers for risk prediction, diagnostic discrimination, and prognostication. Radiomics is designed to use standard-of-care images, allowing the development and curation of large data sets that are needed for statistical power. For example, with respect to distinguishing between indolent and aggressive lung cancers, investigators have developed a new class of radiomic features (radial gradient and radial deviation features) to characterize the interface at the peri- and intra-tumoral region. Utilizing separate training and test cohorts, they identified a single parsimonious model that contained two highly informative features that differentiated indolent lung cancers (80% 5-year survival) vs. aggressive lung cancers (10% 5-year survival).

The Field Effect as a Platform for Early Cancer Detection

Many cancers arise in a "field" of molecular alterations resulting from exposure to cancer-causing agents (e.g., smoking, hormones, UV light, diet). There are molecular changes in cytologically normal cells that may reflect clonal expansion of cells from which the tumor ultimately develops or may be related to direct effects of the tumor on surrounding tissue, known as "field cancerization."

Measuring the physiological response of the host to exposure within the "field of injury" could provide early markers of individualized cancer risk in relatively accessible proximate tissue. An example of this is the airway 'field of injury' or 'field cancerization' in lung cancer. Smoking (and other inhaled toxins) alters epithelial cell gene expression throughout the respiratory tract, and an aberrant airway epithelial genomic response to and damage from smoking creates a susceptible microenvironment for cancer initiation, an etiologic "field of injury."

EDRN investigator Avi Spira and colleagues are extending the lung cancer "field" to the nasal epithelium (Figure 10).

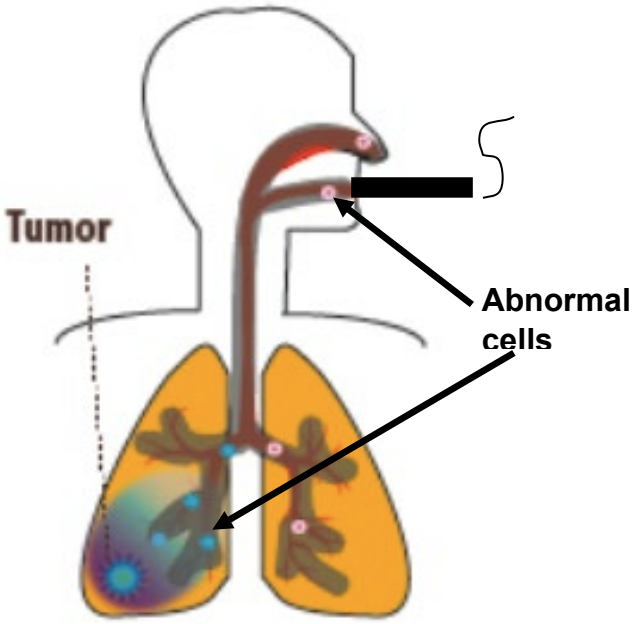


Figure 10: Nasal epithelial gene expression signature associated with lung cancer diagnosis in the indeterminate nodule setting

Research Advances and Collaborative Projects

Within the EDRN there are four organ-specific Collaborative Groups. Every EDRN PI is a member of at least one Collaborative Group, participates in collaborative research projects, and attends monthly conference calls.

Thirty percent of the funds of each EDRN BDL and CVC is set-aside to support collaborative or team projects. These projects involve PIs from multiple EDRN laboratories and centers and frequently include non-EDRN investigators.

Research accomplishments by individual grantees and collaborative projects involving multiple investigators for the four Collaborative Groups are described below.

Colorectal and Other Gastrointestinal Cancers Collaborative Group

In this Collaborative Group there are two CVCs for colorectal cancer, two CVCs for pancreatic cancer, one BDL for pancreatic cancer, one BDL for colorectal cancer, and one BDL for both colorectal and esophageal cancers.

List of EDRN PIs who are members of this collaborative group:

Allen, Peter	Duke University	Pancreas
Batra, Surinder	University of Nebraska Medical Center	Pancreas
Brand, Randall	University of Pittsburgh	Pancreas
Brenner, Dean	University of Michigan	Colorectal
Grady, William	Fred Hutchinson Cancer Research Center	Colon and Esophagus
Guda, Kishore	Case Western Reserve University	Colon and Esophagus
Haab, Brian	Van Andel Research Institute	Pancreas
Kinzler, Kenneth	Johns Hopkins University School of Medicine	Colorectal
Lampe, Paul	Fred Hutchinson Cancer Research Center	Colorectal
Maitra, Anirban	M D Anderson Cancer Center	Pancreas
Markowitz, Sanford	Case Western Reserve University	Colon and Esophagus
Schoen, Robert	University of Pittsburgh Cancer Institute	Colorectal
Stass, Sanford	University of Maryland School of Medicine	Colorectal

This Collaborative Group conducts research on colorectal, pancreatic and esophageal cancers. The main goals are (1) to develop and validate blood-based biomarkers with accuracy comparable to FIT to increase the number of people being screened (stool based testing is rejected by 40% of the population) and to develop and validate ctDNA as a biomarker to monitor for early recurrence of colorectal cancer, (2) to develop and validate biomarkers and imaging

methods to detect pancreatic cancer in high-risk groups, (3) to develop and validate biomarkers and imaging methods to determine which pancreatic cysts are cancerous, and (4) to develop and validate a non-endoscopic method to detect Barrett's esophagus and to distinguish dysplastic from non-dysplastic Barrett's esophagus.

There has been substantial progress in the goal to develop and validate blood-based biomarkers for colorectal cancer with accuracy comparable to FIT. Several blood-based biomarkers or panels of biomarkers have shown sensitivity and specificity that exceeds that of FIT and are being validated in large independent cohorts.

- Drs. Kenneth Kinzler and Robert Schoen have combined aneuploidy with the somatic mutation detection and eight standard protein biomarkers used in CancerSEEK, resulting in a median sensitivity of 80% in the eight cancer types, including colorectal and pancreatic cancer, with a specificity of 99%.
- Dr. Dean Brenner and collaborators have shown that a blood-based panel consisting of galectin-3 ligand, CEA and CYFRA21 have better sensitivity and specificity than FIT for both colorectal cancer and advanced adenomas.
- Dr. Paul Lampe has shown that a five-protein marker panel has a sensitivity of 70% for colorectal cancer at 90% specificity.

There has been substantial progress on the goals to develop and validate biomarkers and imaging methods to detect early stage pancreatic cancer and to develop and validate biomarkers and imaging methods to determine which pancreatic cysts are cancerous. Three groups of investigators have identified biomarkers or panels of biomarkers that significantly improve the accuracy of CA19.9 to detect pancreatic cancer and to determine which pancreatic cysts are cancerous. To validate their performance, EDRN investigators are currently accruing additional patients.

- Drs. Surinder Batra and Randall Brand found that the combination of TFF2, MUC5AC, MUC4 and CA19-9 showed an AUC of 0.96 for differentiating early stage pancreatic cancers from benign controls and TFF3, TFF1, MUC5AC and CA19-9 combination provided an AUC of 0.91 for differentiating early stage pancreatic cancers from chronic pancreatitis.
- Drs. Anirban Maitra and Dr. Samir Hanash used decision tree-based techniques to correctly identify 31 cases with only 1 false positive; in comparison, CA19-9 alone only identified 24 cases when restricting false positives to 1. These findings demonstrate that "an OR rule" using CA199 and the combination of TIMP1 and LRG1 yields better performance than CA199 alone for identifying asymptomatic pancreatic cancer cases.

Dr. Brian Haab and collaborators reported a statistically significant improvement for identifying asymptomatic pancreatic cancer cases by combing sTRA marker with CA19-9 (75% accuracy) over CA19-9 alone (65% accuracy). The improvement was achieved using blinded case/control calls with pre-determined cut-offs and classification rules. The blinded calls gave 95% specificity

and 54% sensitivity. A positive feature of the test is its simplicity: it is a simple combination between CA19.9 and sTRA. Cut-offs can be set for either marker so that the combination test is optimized to detect cancer with high specificity; patients who are elevated in either sTRA or CA19.9 are classified as a 'case.' This simplicity likely contributed to the success of the validation and bodes well for eventual clinical use.

Drs. Sanford Markowitz, William Grady and Kishore Guda have made substantial progress on developing biomarkers that can distinguish dysplastic from non-dysplastic Barrett's Esophagus. A two methylated-marker panel (Up10 and Up35-2) was identified that shows 98% specificity on normal squamous samples, 91% specificity on non-dysplastic Barrett's Esophagus, 48% sensitivity on high grade dysplasia and 57% sensitivity on esophageal adenocarcinoma. When combined with TP53mutation, the 3-marker panel showed 98% specificity on normal squamous and 89% specificity on non-dysplastic Barrett's Esophagus, while showing 56% sensitivity and 76% sensitivity on esophageal adenocarcinoma, respectively. Dr. Markowitz developed EsoCheck, a device that allows patients to undergo a non-invasive five-minute office-based procedure to detect Barrett's Esophagus without the need for endoscopy.

Collaborative Projects on CRC

Steps Towards Validation of Plasma Biomarkers for the Detection of Colorectal Adenoma and Cancer

Participants:

Paul Lampe	Fred Hutchison Cancer Research Center
Ziding Feng	Fred Hutchison Cancer Research Center
Dean Brenner	University of Michigan
Robert Bresalier	M D Anderson Cancer Center
Hans Jørgen Nielsen	University of Copenhagen-Hvidovre Hospital

Aim 1: Define the sensitivity and specificity of specified plasma biomarkers for the detection of advanced adenoma and/or colorectal cancer with samples with positive and negative FIT values.
Aim 2: Develop a combination rule for the markers and compare it with FIT and test whether it has the required minimum 75% sensitivity at ≥70% specificity for colorectal cancer, which would surpass the performance of the currently available blood-based test.
Aim 3: They will test the combination rule fixed in Aim 2 using samples from an EDRN PRoBE-compliant screening trial.

Status: Biospecimens from University of Copenhagen-Hvidovre Hospital are being prepared for shipping to the sites in the US.

Addition of Methylated Markers to CancerSEEK Assay

Participants:

Sanford Markowitz	Case Western Reserve University
William Grady	Fred Hutchinson Cancer Research Center
Robert Schoen	University of Pittsburgh

Aim: Determine whether the addition of circulating methylated DNA can improve the sensitivity of CancerSEEK for early stage colorectal cancer.

Biomarkers for Reducing Mortality of Cancers of the Colon Sandford Markowitz, Robert Schoen, William Grady					
Candidate Biomarker	**Discovery**			**Pre-validation**	**Validation**
	Discovery	Predictive Analysis	Assay Refinement	Blinded Limited Cross-Sectional	Large Cross-Sectional
Collaborative Projects					
Biomarker panel for high risk colon neoplasia, and methylated genes of colorectal cancer risk					
Collaborative Project: Addition of Methylated Markers to CancerSEEK (Markowitz & Schoen)					

ctDNA for the Early Detection and Monitoring of Colorectal Cancer

Participants:

Robert Schoen	University of Pittsburgh Medical Center
Amir Borhani	University of Pittsburgh Medical Center
Brenda Diergaarde	University of Pittsburgh Medical Center

The goal of this project is to collect and analyze the baseline and follow-up computerized tomography (CT) scans from subjects with stage III colorectal cancer (CRC) enrolled in the prospective monitoring study evaluating serial assessment of circulating tumor DNA (ctDNA; clinicaltrial.gov: NCT02842203).

Aim 1: Determine associations between clinical outcome and radiomic characteristics of tumors, as well as morphomic features on pre-operative CT imaging. Radiomic features of tumors and morphomic analysis of body tissues remote from the tumor may be associated with clinical outcome. Using the baseline scans from the monitoring cohort and long-term clinical follow-up

information, the relationship between tumor and tissue characteristics and subsequent risk of recurrence will be assessed.
Aim 2. Perform a longitudinal assessment of morphomic changes on CT imaging in relation to clinical outcome: Longitudinal morphomic changes may be associated with and predict clinical outcome. Using serial assessment of morphomic parameters on CT scanning, the investigator will evaluate changes in these parameters in subjects whose cancer recurs compared to those whose cancer does not recur.
Aim 3: Determine the association of morphomic changes with serial ctDNA levels. Elevated levels of ctDNA may predate overt, radiographic evidence of colorectal cancer recurrence. However, it is possible that morphomic changes may accompany progression to cancer. Longitudinal changes in morphomic features in relation to sequential ctDNA monitoring will be evaluated.

Status:
Currently building a comprehensive dataset for prediction of recurrence that will be applicable for Machine Learning, combining clinical data, longitudinal measurement of biomarkers (ctDNA and CEA) and CT parameters.

Collaborative Projects on Pancreatic Cancer

A Biomarker Bake-off in Early Stage Pancreatic Cancer

Participants:

Randall Brand	University of Pittsburgh
Anirban Maitra	MD Anderson Cancer Center
Ying Huang	Fred Hutchinson Cancer Research Center
Brian Haab	Van Andel Research Institute
Paul Lampe	Fred Hutchinson Cancer Research Center
Samir Hanash	MD Anderson Cancer Center
Surinder Batra	University of Nebraska Medical Center
Anna Lokshin	University of Pittsburgh

The EDRN Pancreas Subgroup developed team projects with the goals of rigorously evaluating candidate biomarkers for pancreatic cancer and determining the performance of novel biomarker combinations. The CVCs were instrumental in assembling a set of sera and plasma samples from cases and controls. The cases were primarily patients with resectable pancreatic ductal adenocarcinoma (PDAC), and a smaller number with advanced PDAC. To enable secondary analyses on other, rarer types of peri-ampullary cancers, the team included samples from cholangiocarcinomas, mucinous cystic tumors, pancreatic neuroendocrine tumors, and ampullary carcinomas. The controls were made up of patients with chronic pancreatitis, benign stricture of

the bile duct, chronic diabetes, or benign pancreatic cyst, as well as subjects with no symptoms. The participating investigators from five different laboratories performed the biomarker assays on the samples. All the investigators were blinded to the diagnostic status of the samples. Dr. Huang at the DMCC at Fred Hutchinson Cancer Research Center evaluated the performance of the markers and assessed potential novel combinations of biomarkers, including cross-laboratory combinations.

Status:

In the first team project, various approaches were applied to develop panels using biomarkers across labs for separating PDACs from benign and healthy controls, targeting optimization of sensitivity at 95% and 90% specificity. This identified a few candidate panels that improve performance over CA19-9 alone. In particular, an 8-marker panel (CA19-9+CA19-9.sTRA+ Thrombospondin+DCD+TIMP1+MUC4+Angiostatin+PSM2) and a 2-marker panel (CA19-9+CA199.sTRA) improved sensitivity at 95% specificity of CA19-9 alone (0.54) to 0.61 and 0.62 and improved sensitivity at 90% specificity of CA19-9 alone (0.61) to 0.69 and 0.70 (as below).

	AUC		**Sen at 95% spe**		**Sen at 90% spe**	
	Naïve	**CV**	**Naïve**	**CV**	**Naïve**	**CV**
CA19-9	0.85	0.85	0.5	0.54	0.54	0.61
8 marker	0.91	0.84	0.79	0.61	0.82	0.69
2 marker	0.86	0.84	0.68	0.62	0.72	0.7

Two tiers of biomarkers (panels) were proposed for evaluation in future pre-diagnostic samples, based on their performance in separating pancreatic cancer from benign controls.

First tier: A panel consisting of CA19-9, CA19-9:sTRA, and MUC16:sTRA was validated in the pancreatic cancer bake-off project as improving over the standard CA19-9 assay alone. Based on pre-specified threshold that ensures high specificity, this panel had sensitivity 53.5% (95% CI=42.3% to 66.2%), specificity 94.3% (95% CI=88.8% to 98.9%).

Second tier: The markers listed in the table below went through independent blinded validation with estimated area under the ROC curve exceeding 0.60.

	Lab	AUC (95% CI)
Thrombospondin	UPMC	0.713 (0.624, 0.790)
LRG1	MD Anderson	0.637 (0.544, 0.723)

TIMP1	MD Anderson	0.635 (0.549, 0.724)
CA19-9:sTRA	Van Andel	0.857 (0.792, 0.916)
MUC5AC:sTRA	Van Andel	0.695 (0.602, 0.768)
MUC5AC	UNMC	0.678 (0.598, 0.757)

Overall, these biomarker studies, involving multiple sample sources, several experimental sites, and independent statistical analyses, demonstrated the effectiveness of the Collaborative Group in performing complex studies in a short time period. The studies also demonstrated the value of having close collaborations between clinical, experimental, and statistical sites. The current team project proposes to examine the performance of these markers on asymptomatic preclinical samples, alone or in combination with CA19-9.

EDRN Pancreatic Cyst Biomarker Validation Study

Participants:
This project is led by Aatur Singhi, University of Pittsburgh.
Other participants:

Michael Goggins	Johns Hopkins University
Walter Park	Stanford University
Charles Craik	University of California San Francisco
Randall Brand	University of Pittsburgh
Brian Haab	Van Andel Research Institute
Koushik Das	Washington University
James Farrell	Yale
Ziding Feng	Fred Hutchinson Cancer Research Center

This project was developed after the 2016 Alliance of Consortia for Pancreatic Cancer meeting. Investigators from three consortia proposed to validate pancreatic cyst fluid biomarkers for the discrimination of patients at high risk for developing or presenting with pancreatic ductal adenocarcinoma within a pancreatic cyst. The markers to be tested include genomic markers, glycomic markers, telomerase assay; SOX17, FOXE1, PTCHD2, SLIT2, EYAA4, and SFRP1; amphiregulin expression and glucometer glucose; gastricsin and cathepsin E; and Das-1.

Aim 1: Assemble a set of biospecimens from 350 pancreatic cysts with diagnostic pathology.
Aim 2: Determine the ability of biomarkers to distinguish mucinous from non-mucinous cysts.
Aim 3: Determine whether the cysts contain advanced neoplasia.

Status:
Aim 1: Specimens from the cysts have been collected and distributed to the testing sites.
Aim 2: Distinguish mucinous from non-mucinous cysts. Results from these blinded assays were analyzed by EDRN DMCC.

Assay (Pancreatic Cyst Biomarker Alliance Investigator)	Mucinous vs. Non-Mucinous Cysts	
	Sensitivity	Specificity
DNA Sequencing: *KRAS, GNAS, VHL, CTNNB1, TP53, PIK3CA & PTEN* (Aatur Singhi)	86%	100%
Protein expression: MUC5AC:WGA, MUC5AC:BGH & endorepellin (Brian Haab)	92%	94%
Amphiregulin expression & glucometer glucose (Walter Park)	100%	72%
Protease activity: Gastricsin & Cathepsin E (Charles Craik)	93%	100%

Aim 3: Determine the presence of advanced neoplasia. Results from these blinded assays were analyzed by EDRN DMCC.

Assay (Pancreatic Cyst Biomarker Alliance Investigator)	Presence vs. Absence of Advanced Neoplasia	
	Sensitivity	Specificity
DNA Sequencing: *KRAS, GNAS, VHL, CTNNB1, TP53, PIK3CA & PTEN* (Aatur Singhi)	88%	100%
DNA Methylation: *SOX17, FOXE1, PTCHD2, SLIT2, EYA4 & SFRP1* (Michael Goggins)	84%	89%
Protein expression: Das-1 (Koushik Das)	91%	96%
Protein activity: Telomerase (Michael Goggins)	74%	93%

Collaborative Projects on Barrett's Esophagus

Assess Utility of Non-Endoscopic Methylation Biomarker Based Detection of Barrett's Esophagus (BE) in an At-Risk Screening Population

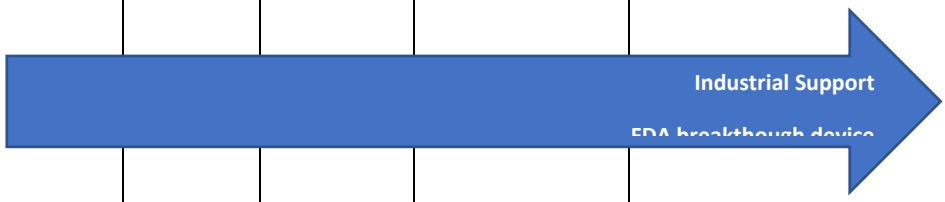
Participants:

Sanford Markowitz	Case Comprehensive Cancer Center
William Grady	Fred Hutchinson Cancer Research Center

The goal is to assess the utility of non-endoscopic methylation biomarker-based detection of Barrett's esophagus (BE) in an at-risk screening population. The Barrett's esophagus translational research network (BETRNet) is conducting a multi-center clinical trial in subjects with chronic gastroesophageal reflux disease (GERD) who meet criteria for BE screening using a molecular epigenetic marker panel developed through EDRN with a novel non-endoscopic balloon-based esophageal sampling device.

Aim 1: Measure the sensitivity and specificity of a two marker EDRN developed panel assay for detecting BE using a balloon device in an adult population with GERD symptoms.

Status:
Recruiting patients and collecting biospecimens using the balloon-based esophageal sampling device.

Biomarkers for Reducing Mortality of Cancers of the Esophagus Sandford Markowitz, Kishore Guda, and William Grady					
Candidate Biomarker	**Discovery**			**Pre-validation**	**Validation**
	Discovery	Predictive Analysis	Assay Refinement	Blinded Limited Cross-Sectional	Large Cross-Sectional
Collaborative Projects					
Methylated DNA biomarkers for detection of Barrett's esophagus (BE), HGD, and EAC, using DNA retrieved by esophageal brushings.					
Methylated DNA and lincRNA biomarkers to distinguish Barrett's esophagus versus progression of Barrett's esophagus to HGD.					
Discovery of methylated DNA loci and/or coding or non-coding RNAs to identify biomarkers able to identify marker negative HGD and EAC of esophageal neoplasia.					
Supplemental Project: Develop an Ion Torrent Assay for methylated Vim and methylated CCNA1.					

Core Fund Project: Assess the utility of non-endoscopic methylation biomarker based detection of BE in an at-risk screening population.					

Prostate and Other Urological Cancers Collaborative Group

In this Collaborative Group there are two CVCs and three BDLs. Investigators from Pacific Northwest National Laboratory and from the Center for Prostate Disease Research, DOD, are also members of this group.

List of EDRN PIs who are members of this collaborative group:

Aebersold, Ruedi	Institute for Molecular Systems Biology	Prostate
Boutros, Paul	The University of California, Los Angeles	Prostate
Chan, Daniel	Johns Hopkins Medical Institutions	Prostate
Chinnaiyan, Arul	University of Michigan	Prostate
Kislinger, Thomas	University of Toronto	Prostate
Leach, Robin	UT Health Science Center at San Antonio	Prostate
Liu, Tao	Pacific Northwest National Laboratory	Prostate
Petrovics, Gorge	Center for Prostate Disease Research, DOD	Prostate
Rodland, Karin	Pacific Northwest National Laboratory	Prostate
Sanda, Martin	Emory University	Prostate
Semmes, John	Eastern Virginia Medical School	Prostate
Tomlins, Scott	University of Michigan	Prostate
Zhang, Hui	Johns Hopkins University School of Medicine	Prostate

The overarching goal of this Collaborative Group is to improve early detection of prostate cancer using molecular markers (RNA, DNA, protein, metabolites) primarily in blood or urine, and to predict the presence of aggressive prostate cancer on histopathology of subsequent biopsy or prostatectomy specimens, either alone or in combination with imaging features. The two clinical problems currently being addressed are (1) developing non-invasive tests to distinguish indolent cancers (histopathological Grade Group I prostate cancers, which do not need treatment) from aggressive cancers (histopathological Grade Groups II, III, IV or V), treatment of which reduces cancer death, and (2) determining whether MRI prostate imaging and biomarkers, used either

alone or in combination with imaging biomarkers, can improve the prediction of cancer extent and aggressiveness to determine suitability for active surveillance or treatment.

Dr. Arul Chinnaiyan's laboratory identified 121 novel, differentially-expressed prostate cancer (PCa) long noncoding RNA (lncRNAs), including SChLAP1, which is overexpressed in a subset of tumors and associated with more aggressive disease. SChLAP1 levels independently predict poor outcomes, including metastasis and prostate cancer-specific mortality. Another class of promising markers are based on circular RNA (circRNA). Candidate prostate cancer circRNAs biomarkers were also detected in urine. The new cancer markers, (lncRNAs and circRNAs) will be added to MiPS-50 panel (my prostate score), which includes the fusion transcript T2-ERG, lncRNA PCA3 and blood PSA and another 40 RNAs, and will be subjected to verification and validation studies.

Dr. Martin Sanda conducted a validation study, which demonstrated that combining urinary T2-ERG and PCA3 at thresholds that preserved 95% sensitivity for detecting aggressive prostate cancer improved specificity from 18% to 39%. He also demonstrated that the combined panel of PCA3, T2-ERG and *phi* test at sensitivity of 97% achieved a specificity of ~45%, as compared to 18% with PSA alone or 27% with *phi* alone.

Dr. Hui Zhang showed that urinary glycosylated proteins, ACPP, CD63, LOX, CLU, PSA are associated with aggressive prostate cancer. Additional markers, which show a great promise but need further development include CS1, PTGD, SERPINA1, LRG1, KLK11, SCGB1A1, AZGP1, CSTA. She also conducted a verification study for fucosylated PSA as a serum marker for aggressive prostate cancer.

Drs. John Semmes, Paul Boutros and Thomas Kislinger combined targeted proteomics with computational biology to discover robust proteomic signatures for prostate cancer. A panel of 34 candidates were verified in an independent cohort. The urine proteomic signature for extracapsular prostate cancer could be used for detection of patients with aggressive cancers.

Drs. Gorge Petrovics and Albert Dobi developed a panel of eight genes (*ERG, GGT1, HDAC1, KLK2, MYO6, PLA2G7, BICD1* and *CACNAID*) that was able to distinguish between prostate cancer patients that progressed to biochemical recurrence from those that did not. In addition, they performed systematic whole genome analyses and identified alterations that differentiate African American (AA) and Caucasian American (CA) prostate cancer genomes. A recurrent deletion on chromosome 3q13.31, centering on the LSAMP locus, was prevalent in tumors from AA men. Interestingly, carriers of this deletion experienced more rapid disease progression. In contrast, PTEN and ERG were significantly lower in prostate tumors from AA compared to prostate tumors from CA. Furthermore, the frequency of inter-chromosomal rearrangements was significantly higher in tumors from AA than from CA. The differentially distributed somatic

mutations in prostate cancer across ancestral groups must be considered in the application of markers for precision medicine.

Drs. Tao Liu and Karen Rodland from Pacific Northwest National Laboratory (PNNL) collaborated with the CPDR team to develop a five-protein classifier which combines FOLH1, KLK3, TGFB1, SPARC, and CAMKK2 with existing clinical and pathological standard of care variables. The classifier demonstrated significant improvement in prediction of which patients are likely to develop distant metastasis, achieving an area under the receiver-operating characteristic curve of 0.92 (0.86, 0.99, $p = 0.001$) and a negative predictive value of 92% in the training/testing analysis. This classifier has the potential to stratify patients based on risk of aggressive, metastatic PCa that will require early intervention compared to low-risk patients who could be managed through active surveillance.

Collaborative Projects on Prostate Cancer

Biomarkers and Clinical Parameters Associated with Gleason Score Upgrading (URS)

Participants:
This study is a multi-institutional study with twelve participating institutes that is led by Drs. Robin Leach, UTHSCSA, Martin Sanda, Emory University, and Paul Boutros, UCLA.

Other participants:

Alan Partin	Johns Hopkins University
Robin Leach	University of Texas Health Science Center at San Antonio
Ian Thompson	University of Texas Health Science Center at San Antonio
John Semmes	Eastern Virginia Medical School
James Brooks	Stanford University Medical Center
Daniel Lin	University of Washington
Dan Mercola	University of California Irvine
Jaime Landman	University of California Irvine
Martin Sanda	Emory University School of Medicine
Eric Klein	Cleveland Clinic
Dipen Parekh	University of Miami Miller School of Medicine
Ashutosh Tewari	Icahn School of Medicine at Mt. Sinai
Juan Miguel Mosquera	Weill Cornell Medicine
Mark A. Rubin	Weill Cornell Medical College
Ziding Feng	Fred Hutchinson Cancer Research Center
Yingye Zhang	Fred Hutchinson Cancer Research Center

The goal of this study is to identify biomarkers that could predict upgrading (Gleason score ≥ 4+3) of patients initially diagnosed with low-risk cancer (Gleason score ≤ 6). The need for such

markers is based on observations that a significant number of men with low-risk prostate cancer (Gleason score ≤ 6) that were managed through active surveillance and eventually elected to undergo therapy (e.g., surgery or radiation therapy) are diagnosed with significant cancers (Gleason score ≥ 4+3). The lack of robust biomarkers to predict the presence of aggressive prostate cancer in this clinical setting contributes to the ongoing over-treatment of low-grade localized prostate cancer. To mitigate this problem, the EDRN GU working group is gathering a cohort of men with low-grade disease (Gleason ≤ 6), who ultimately chose to have a prostatectomy. These biological specimens comprise the Upgrading Reference Set (URS). EDRN URS is currently collecting biologics and clinical information on a cohort of 240 men for the purpose of evaluating tests or prediction tools to identify upgrading amongst patients with an initial biopsy diagnosis of Gleason score ≤ 6 cancer. This is the first and only study that has been designed to specifically investigate prostate cancer upgrading, with most other studies focusing on comparison between two groups, progressors and non-progressors.

Aim: Develop a risk assessment tool using commonly collected clinical information from a series of contemporary radical prostatectomies to predict the risk of prostate cancer upgrading to high grade cancer at radical prostatectomy.

Status:
Samples from this cohort are being subjected to germline whole-genome sequencing for each subject in the cohort to validate polygenic risk-score (PRS) markers with respect to upgrading as previously reported. The goal is to not only validate PRS but to also create a resource for all future studies, including enabling low-cost validation of any further germline-based risk markers. This part of the study is conducted in Paul Boutros' laboratory at UCLA.

Prostate Cancer MRI/Ultrasound Fusion-Guided Biopsy Study

Participants:
This project is led by John Wei, University of Michigan and Martin Sanda, Emory University. Other participants:

Soroush Rais-Bahrami	University of Alabama at Birmingham
Scott Eggener	University of Chicago
Sanoj Punnen	University of Miami
Sandra M. Gaston	University of Miami Miller School of Medicine
Robin J Leach	University of Texas Health Science Center at San Antonio
Dan Yair Lota	UT Southwestern Medical Center at Dallas
Dan Barocas	Vanderbilt University
Aria Olumi	Beth Israel Deaconess Medical Center
Adam Kibel	Brigham and Women's Hospital

Tim McClure	Cornell University
Christopher Filson	Emory University School of Medicine
Ziding Feng	Fred Hutchinson Cancer Research Center
Robert J. Gillies	H. Lee Moffitt Cancer Center and Research Institute
Daniel Chan	Johns Hopkins Medical Institutions
Dan Crichton	NASA Jet Propulsion Laboratory

Ultrasound and MRI are the two main imaging platforms used to aid prostate cancer diagnosis, identify patients who would most likely benefit from active surveillance (AS) and to minimize overtreatment. Image fusion is a process that integrates the data from these technologies to create a single detailed map of the prostate by merging previously captured MRI images with live transrectal ultrasound images to perform targeted biopsies. There has been a dramatic increase in fusion biopsy prostate MRI, but there is no prior validation study of how to best integrate MRI data with US data and with existing validated biomarkers.

Aim 1: Determine if the addition of prostate MRI to T2:ERG/PCA3/PSA improves specificity for detection of high-grade disease.
Aim 2: Create a new panel that optimizes the value of prostate MRI in early detection.
Aim 3: 1,500 patient accrual and prospective data/sample collection.

The commercialization of MRI-US fusion biopsies has resulted in a dramatic increase in the use of MRI-US imaging for prostate cancer detection of aggressive cancer. Given the availability of validated prostate cancer early detection markers, how best to use MRI in the initial prostate biopsy setting is uncertain. The primary aim of this study is to see if the addition of prostate MRI to a panel including PSA, PCA3, TMPRSS2:ERG will significantly improve specificity for high-grade prostate cancer by 10%.

The subsequent exploratory aims will:

1) create an optimal panel of urine and blood biomarkers that will select those cases most likely to benefit from an MRI targeted biopsy,
2) directly compare PSA and urinary biomarkers with MRI to determine which ones are value-added in the setting of initial biopsy,
3) evaluate changes in these biomarkers and MRI to determine if longitudinal changes predict subsequent high-grade prostate cancer, and
4) optimize MRI imaging to improve test performance. Importantly, this study will create a unique, prospective cohort that will become the foundational reference set for a range of future biomarker studies.

Status: Currently, fourteen institutes are participating in the study. Four sites obtained IRB approval and have started enrolling patients. So far, 70 patients have been enrolled in the study.

After the completion of phase 1 (enrollment and testing of 340 patients), EDRN DMCC will conduct an interim analysis. If the results are promising, the study will be expanded to phase 2 and an additional 1,160 patients will be enrolled.

Glycoprotein Biomarkers for the Early Detection of Aggressive Prostate Cancer

Participants:

Hui Zhang	Johns Hopkins University
Lori Sokoll	Johns Hopkins University
Zhen Zheng	Johns Hopkins University

This project aims to determine the performance characteristics of using urinary glycoproteins for the early detection of aggressive prostate cancer (PCa).

Aim 1: Determine the performance of using urinary glycoproteomics and mass spectrometry for the detection of aggressive prostate cancer.

Aim 2: Develop and apply ELISA assays to verify the candidate glycoproteins as non-invasive urinary tests for detecting aggressive prostate cancer.

Status:

By comparing glycoproteins in urine from aggressive (AG) prostate cancer (Gleason score ≥ 8) with non-aggressive (NAG) (Gleason score = 6) the investigators identified differentially expressed glycoproteins. Eight of them, ACPP, CD63, KLK3, KLK11, ANPEP, DSC2, PTGDS, and LRG1, were selected for a pre-validation study. Urine ACPP had a predictive power (AUC=0.739) and consistent outcome was also achieved in two independent analyses where the samples were randomly assigned to discovery and validation sets. When combined with serum PSA testing, its performance was moderately improved resulting in an AUC of 0.824. A urine glycoprotein panel consisted of the down-regulated ACPP with another up-regulated glycoprotein, SERPINA1, successfully differentiated AG PCa from NAG PCa (AUC: 0.782, specificity was 46.9% at 95% sensitivity).

Verification of the data by commercial ELISA of ACPP, KLK3, CD63, KLK11, ANPEP, DSC2, PTGDS, and LRG1 is in progress. While the performances of certain ELISA results were correlated with their glycoproteomic results, the ELISA result for PTGDS was not correlated to its glycoproteomic data, indicating that changes in glycopeptides may be attributed to the glycosylation level. Further analysis was conducted with a developed and evaluated targeted quantitative analysis of the glycopeptides using parallel selected reaction monitoring (SRM) assays. Using the SRM assays, it was possible to verify the association of ACPP with AG PCa, but assays failed to verify PTGDS initial observations.

Status: The plan for the near future is to conduct a validation study on previously collected cohorts such as the PCA3 cohort.

Lung and Upper Aerodigestive Cancers Collaborative Group

In this collaborative group there are two CVCs and four BDLs.

List of EDRN PIs who are members of this collaborative group:

Aberle, Denise	University of California Los Angeles	Lung
Dubinett, Steve	University of California Los Angeles	Lung
Elashoff, David	University of California Los Angeles	Lung
Gillies, Robert	H. Lee Moffitt Cancer Center and Research Institute	Lung
Heine, John	H. Lee Moffitt Cancer Center and Research Institute	Lung
Herman, James	University of Pittsburgh School of Medicine	Lung
Lenburg, Marc	Boston University	Lung
Massion, Pierre	Vanderbilt -Ingram Cancer Center	Lung
Pass, Harvey Ira	New York University School of Medicine	Lung, Mesothelioma
Schabath, Matthew	Lee Moffitt Cancer Center and Research Institute	Lung
Showe, Louise	Wistar Institute	Lung
Spira, Avrum	Boston University	Lung
Stass, Sanford	University of Maryland School of Medicine	Lung
Wang, Tza-Huei	Johns Hopkins Whiting School of Engineering	Lung
Yang, Haining	University of Hawaii	Lung

The primary focus of this Collaborative Group is to develop and validate biomarkers and imaging methods to detect lung cancer among smokers with indeterminate nodules that are detected by low dose CT. Other objectives are (1) to conduct studies using semantic and radiomic image-based features to reduce false positives and distinguish indolent from aggressive pulmonary nodules and (2) to discover and validate biomarkers for the early detection and prognostication of pleural mesothelioma.

Dr. Pierre Massion's Clinical Validation Center is validating biomarkers in collaboration with both EDRN and non-EDRN investigators. The table below summarizes the status of these validation studies.

	Clinical Purpose	Biomarkers	Biospecimens	Phase of Development	Technology	Institution
1	Risk	miRNA signature	Sputum	3	RNA seq	U of Maryland
2	Risk	Gene expression signature	Bronchial Brushings	2	RT-PCR	Veracyte
3	Risk	Autoantibody signature	Serum	3	ELISA	Vanderbilt
4	Risk and diagnosis	Imaging 3D structural analysis	DICOM images	3	Artificial Intelligence	Vanderbilt
5	Diagnosis	ctDNA signature	Blood	3	CAPPSeq	Stanford
6	Diagnosis	C4D, CRP, CYFRA21.1	Blood	3	ELISA	Vanderbilt
7	Diagnosis	FSPG	Molecular imaging	2	PET CT	Vanderbilt
8	Diagnosis	MAYO, CYFRA, Radiomics	Serum and DICOM images	4	BSI, Radiomics	Vanderbilt

Dr. James Herman has conducted Phase 2 studies on a cohort of Chinese subjects presenting with small lung nodules. A four-gene methylation panel of circulating tumor DNA in plasma was found optimal for diagnosis of non-small cell lung cancer showing a sensitivity and specificity of 90% and 71%, respectively, with area under the receiver operating curve (AUC) of 0.88. A recent study has explored measuring these markers in urine in addition to plasma where prediction of lung cancer showed similar performance in both biofluids.

Drs. Avi Spira, Mark Lenburg and Stephen Dubinett previously identified gene-expression changes that are consistent throughout the intrathoracic airway and determined that these genes are enriched among the previously identified changes in the mainstem bronchus of cancer patients, supporting the paradigm of a cancer-related "field of injury" throughout the airway. To understand specifically what cell type(s) contribute to the lung cancer signature, the investigators have refined and are currently validating a biomarker panel in combination with clinical and imaging features. The next steps will be to build a composite biomarker panel and conduct further validation on independent cohorts. One important milestone is that investigators have been able to validate that the lung cancer-associated genes discovered with EDRN funding in the Epithelium Gene Expression in the Diagnosis of Lung Cancer (AEGIS) cohorts are also associated with lung cancer in Detection of Cancer in Military Personnel (DECAMP) cohort. This suggests that the signals are reproducible across cohorts using different measurement technologies and can be extended into the setting of lower disease risk.

Drs. Louise Showe and Kiranmai Gumireddy developed novel, non-invasive blood-based gene signatures that are predictive of diagnosis and prognosis for non-small cell lung cancer (NSCLC) using peripheral blood mononuclear cells from lung cancer patients and high-risk smoking controls. They are currently validating their signature using 600 patient samples collected in the PAXgene system at the site of blood collection. Their preliminary analyses on 242 samples using mRNA and miRNA expression indicates that they are on-target to achieve >90% accuracy. In a

separate study, they have explored the expression of 116 tumor associated antigens and identified AKAP4 expression as a remarkably accurate marker of the presence of a lung cancer. The utility of AKAP4 as a predictive marker for NSCLC has now been further validated in an independent set of samples. Analysis of the combined dataset of 264 NSCLCs and 135 controls gave sensitivities and specificities of 0.92.

Drs. Harvey Pass and Haining Yang are in the process of developing and validating a novel SOMAmer-based proteomic platform (Slow Off-rate Modified Aptamer) in plasma and pleural effusion as diagnostic and prognostic biomarkers for MPM (malignant pleural mesothelioma). SOMAmer reagents consist of a short single-stranded DNA sequence with "protein-like" appendages that allow tight and specific binding to its protein target. The investigators are currently validating an assay that combines a 13 SOMAmer with Fibulin-3 with using new cohorts from the NYU Thoracic Surgery Archives as well as samples from Princess Margaret Cancer Center in Canada and the University of South Glasgow. These investigators are also working to determine the accuracy of high mobility group protein B1 (HMGB1) and its isoforms for the diagnosis of MPM, by comparing the sensitivity and specificity of total HMGB1in pleural effusion to MRP and Fibulin-3.

Collaborative Projects on Lung Cancer

Validation of Biomarkers to Distinguish Malignant from Benign Nodules Detected by CT.

Participants:

Pierre Massion	Vanderbilt University
Avrum Spira	Boston University
Marc Lenburg	Boston University
James Herman	University of Pittsburgh
Steve Dubinett	University of California Los Angeles
Harvey Pass	New York University
Haining Yang	University of Hawaii
Louise Showe	Wistar Institute
Sanford Stass	University of Maryland
Feng Jiang	University of Maryland
Matthew Schabath	H. Lee Moffitt Cancer and Research Institute
James Willey	University of Toledo Medical Center

Aim 1: Establish a cohort of 300 former or current smokers with fully annotated indeterminate lung nodules across 6 medical centers on whom clinical, radiographic and biospecimen repositories are developed and who are followed prospectively until final diagnosis.
Status: 261 patients have been enrolled.

Aim 2: Determine the individually developed assays/biomarkers to distinguish malignant from benign nodules by investigators listed in Aim 1.
Status: Specimens to be sent to investigators in October 2020.

EDRN-DOD Collaboration to Develop and Validate Biomarkers for Lung Cancer in a High-Risk Cohort

Participants:

Avrum Spira	Boston University
Marc Lenburg	Boston University
Pierre Massion	Vanderbilt University
David Elashoff	University of California Los Angeles
Steve Dubinett	University of California Los Angeles
Ignacio Wistuba	MD Anderson Cancer Center

The Detection of Cancer in Military Personnel (DECAMP consortium) is a multidisciplinary translational research initiative established by the Department of Defense (DoD) in 2011 to develop and validate biomarkers for the early detection of lung cancer. Since its inception, EDRN has joined in building resources by providing additional sites and resources to expedite the accruals. There are two ongoing clinical trials recruiting high-risk smokers from 4 military hospitals and 7 VA facilities: (1) DECAMP 1: 500 current and former smokers (age > 45; pack-yrs > 20) with indeterminate pulmonary nodules (7-30mm) on chest CT followed for 2 years until final diagnosis; and (2) DECAMP 2: 800 high-risk smokers (COPD or first degree relative with lung cancer) who are being screened annually for lung cancer (including LDCT) for 4-5 years. Both cohorts have a comprehensive biosample collection protocol including blood (serum, plasma, PAXgene), sputum, urine, nasal and buccal brushings, as well as endobronchial biopsies and brushings collected at time of bronchoscopy. In the screening study, these biosamples are collected annually, with the exception of bronchoscopy-based samples that are collected at two time points in the screening cohort. Importantly, all clinical imaging and biospecimens are being collected under uniform SOPs and stored centrally.

Aim: Characterize spatial and temporal changes in the airway transcriptome among smokers with lung cancer.

Status: Smokers undergoing surgical lung biopsy/resection for pulmonary nodules were recruited at all 4 medical centers in order to collect airway brushings obtained from multiple regions of the intrathoracic airway alongside tumor tissue. The Group has identified gene-expression changes that are consistent throughout the intrathoracic airway (regardless of location), as well as those that change in a gradient-like manner relative to the tumor location. Importantly, genes that change consistently throughout the airway are enriched among the previously identified changes

in the mainstem bronchus of cancer patients, supporting the paradigm of a cancer-related "field of injury" throughout the airway. The investigators used RNA sequencing on laser-microdissected representative cell populations along the squamous cell carcinoma (SCC) pathologic continuum of patient-matched normal basal cells, premalignant lesions, and tumor cells to identify pathways altered with initiation and progression of SCC within individual patients. These studies, by characterizing the process of malignant transformation, will potentially lead to identification of biomarkers for early lung cancer detection as well as novel strategies for targeted chemoprevention of lung cancer.

Validating an Integrated Biomarker and Imaging Approach in the Evaluation of Indeterminate Pulmonary Nodules (IPN)

Participants:

Eric Grogan	Vanderbilt University
Stephen A. Deppen	Vanderbilt University
Pierre P. Massion	Vanderbilt University
Heidi Chen	Vanderbilt University
Melinda Aldrich	Vanderbilt University
Fabien Maldonado	Vanderbilt University
James Herman	University of Pittsburgh School of Medicine
Darryl Bornhop	Vanderbilt University
Timothy Mullett	University of Kentucky

The proposal is to conduct a Phase 3 prospective biomarker validation study in three collection trials: (1) EDRN Lung Team Project 2 (LTP-2), (2) EDRN supplement-funded CanVFun (Cancer Versus Fungus) consortium, and (3) Detection of Early Lung Cancer Among Military Personnel (DECAMP 2) trial. The primary objective of this work is to use biomarkers to improve the accuracy of the evaluation of Indeterminate Pulmonary Nodules (IPN) in the intermediate risk category.

Aim 1: Develop a Biomarker Probability Score (BPS) for lung cancer in patients with IPNs.
Aim 2: Validate the BPS and evaluate its ability to reclassify IPNs.

Status: Accrual of subjects in histoplasmosis endemic areas (4 sites) is continuing following the delay due to the COVID-19 pandemic.

Development of Radiomic Classifiers for Incidental Pulmonary Nodules

Participants:

Matthew Schabath	H. Lee Moffitt Cancer and Research Institute
Robert Gillies	H. Lee Moffitt Cancer and Research Institute

The goal of this project is to develop radiomic classifiers for the management of incidental pulmonary nodules (IPN).

Aim 1: Develop a clinical-radiomics database that includes CT acquisition conditions, extracted radiomic data, pathological data (benign or malignant), radiological impressions, clinical data, genomic data (where available) and patient outcomes (overall survival and progression-free survival).
Aim 2. Develop parsimonious models for diagnostic discrimination and disease behavior. Peritumoral and intratumoral radiomics and patient data will be used to identify a parsimonious model that discriminates between benign and malignant IPNs. Machine-learning and biostatistical approaches, including training and testing, will be applied to identify the most informative sets of quantitative imaging features to differentiate lung cancers versus non-cancerous abnormalities.

Validation of Biomarkers of Risk for the Early Detection of Lung Cancer

Participants:

James Willey	University of Toledo Medical Center
Pierre Massion	Vanderbilt University

The proposal seeks to further develop Low-variant-allele Frequency Actionable Mutation Biomarker (LFAMB) as a biomarker for determining lung cancer risk. The intended use is to first, identify screening eligible patients who have bronchoscopic specimens that may be at low risk and, therefore, may not require additional screening, secondly, to identify patients who do not meet the threshold for CT screening based on lower risk than NLST guidelines, who may have higher risk and, therefore, screening may be of benefit.

Aim 1: Phase 2 biomarker study to develop and validate the Low variant allele Frequency Actionable Mutation Biomarker (LFAMB), a recently discovered test for lung cancer risk that is orthogonal to, and potentially synergistic with, the Lung Cancer Risk Test (LCRT) biomarker.
Status: This phase 2 study has begun.

Validation of Biomarkers of Risk for the Early Detection of Lung Cancer

Participants:

Pierre Massion	Vanderbilt University
Melinda C. Aldrich	Vanderbilt University

The goal of this project is to pilot-test lung cancer screening in a high-risk, under-represented low-income and mostly African American patients. Current efforts have not thus far been able to accomplish this. In this screening study, molecular and genetic strategies for the early detection of lung cancer will be integrated with epidemiology and imaging strategies. The establishment of biomarkers of risk will help identify patients who have early stage lung cancer and allow intervention at a time to improve survival.

Aim 1: Reach out to underserved populations.
Aim 2: Collect and store quality biospecimens for biomarker validation.
Aim 3: Make the repository available to EDRN and the community-at-large, including answering priority goals of the EDRN Lung Cancer Collaborative Group.
Aim 4: Characterize this population at risk for lung cancer risk using epidemiology, imaging, pulmonary function, and biomarkers.
Aim 5: Generate preliminary data for a future application to validate candidate biomarkers of early detection in a larger underserved population that could be done within the larger Southern Community Cohort Study.

Status: Enrollment of subjects from Southern Community Cohort Study in Nashville area completed. To increase enrollment, they are seeking to include in enrollment other minority institutions. Meharry Medical Center has joined.

Integration of Biomarker Signatures from Peripheral Blood for Diagnosis, Prognosis, Remission and Recurrence of Lung Cancer

Participants:

Louise C. Showe	Wistar Institute
Qin Liu	Wistar Institute
Andrew Kossenkov	Wistar Institute
Kiranmai Gumireddy	Wistar Institute

The project aims to transfer the lung cancer biomarker panel developed on the experimental Illumina microarray platform to a clinical assay for the NanoString nCounter system. The second-generation clinical platform is expected to lead to a further improvement in lung cancer screening.

Step 1: Test the NanoString assay with the same samples used to develop the microarray classifier. The custom NanoString panel includes 420 probes identified by the analysis of 600 samples used for the microarray studies.

Status:

The initial test of the new NanoString panel has been tested on a subset of 300 samples (the training set) and the final 200 samples (test set) are in progress. Initial analysis of the training set indicates an accuracy equal to or better than the microarrays and at a sensitivity of 90% the Specificity is 56%. They will complete the validation and then select the subset of probes to be used in step 4.

Step 2: Identify an appropriate standard sample.
Status:
This has been completed. Working with NanoString the investigators designed a highly purified artificial RNA standard that includes sequences of the 420 mRNAs included in the panel. The initial studies calibrated the amount of standard required to provide a signal that was within the range of the PAXgene patient RNAs. The standards serve as a quality control for reagent batches, scanner or technician irregularities.

Step 3: Process 600 training samples on custom array.
Status: They are selecting the minimum NanoString probes needed to maintain accuracy while reducing cost. This will be completed by the end of August 2020 when the validation samples have been completed. The new cartridges with reduced probes will be ordered at this time.

Step 4: Validate the final platform on at least 1400 samples from the existing sample repository
Status:
This is in process and will include samples from five clinical sites plus a set of samples from a collaborator in Israel as well as the 260-plus samples from the EDRN Lung Team Project 2.

Breast and Gynecologic Cancers Collaborative Group

In this Collaborative Group there are one CVC for breast cancer, one CVC for ovarian cancer, one CVC for both breast and ovarian cancer, 3 BDLs for breast cancer, and 2 BDLs for ovarian cancer.

List of EDRN PIs who are members of this collaborative group:

Anderson, Karen	Arizona State University	Breast, Ovarian
Bast, Robert	University of Texas MD Anderson Cancer Center	Ovarian
Birrer, Michael	University of Arkansas Medical Sciences	Ovarian
Drescher, Charles	Fred Hutchinson Cancer Research Center	Breast, Ovarian
Heine, John	H. Lee Moffitt Cancer Center and Research Institute	Breast
LaBaer, Joshua	Arizona State University	Breast, Ovarian
Lewis, Michael	Baylor College of Medicine	Breast, Ovarian
Li, Christopher	Fred Hutchinson Cancer Research Center	Breast, Ovarian

Marks, Jeffrey	Duke University Medical Center	Breast
Paulovich, Amanda	Fred Hutchinson Cancer Research Center	Breast, Ovarian
Shih, Ie-Ming	Johns Hopkins University School of Medicine	Ovarian
Skates, Steven	Massachusetts General Hospital	Ovarian
Tang, Cha-Mei	Creatv MicroTech Inc.	Breast
Zhang, Zhen	Johns Hopkins University School of Medicine	Ovarian

This Collaborative Group conducts research on breast and ovarian cancers and the main goals are: (1) to improve the performance of screening mammography, (2) to distinguish benign from malignant breast lesions, (3) to improve early detection of different molecular subtypes of breast cancer, (4) to develop blood tests for early detection of ovarian cancer, (5) to distinguish benign from malignant pelvic masses, (6) to develop high sensitivity uterine sampling tests for high risk patients, and (7) to develop a strategy combining risk stratification, biomarkers, and secondary diagnostic imaging as a cost-effective screen for ovarian cancer in high risk or general populations.

Drs. Amanda Paulovich and Michael Lewis are working to develop a blood test for early detection of breast cancer that can be used to complement mammography. They have used MS/MS to discover human proteins in mouse plasma from animals with 5 types of xenografted tissues: ER+ tumors, HER2+ tumors, "triple negative" tumors, DCIS, and normal breast tissue. They have identified and prioritized human candidate markers circulating in mouse plasma and 138 human plasma samples. An analysis of the 238 most promising proteins is underway. In collaboration with Dr. Andy Godwin, they are evaluating extracellular vesicles as circulating tumor biomarkers.

Dr. Christopher Li's CVC is conducting a phase 3 validation study to validate biomarkers for early detection of ER+ breast cancer. Their autoantibody and proteomic markers have advanced through three sample sets (WHI discovery, EDRN Reference set and WHI confirmation) and analyses have been completed across these sets to prioritize markers for validation. The autoantibody validation data is currently undergoing statistical analysis. Laboratory assessment of the proteomics biomarkers in a phase 3 validation study using the CHS preclinical set is currently being organized and will begin shortly. Additionally, glycomic biomarkers have been measured in 2 of the 3 sample sets (WHI discovery and EDRN Reference set).

Drs. Joshua LaBaer and Karen Anderson are working on the development of a high-throughput, NAPPA array-based strategy to generate and display synthetic O-linked glycoprotein structures that mimic tumor-specific structural changes. They will use such altered post-translational modifications, which are highly immunogenic, to detect autoantibodies in sera that are specific for glycoproteins as potential biomarkers for the early detection of breast cancer. They have developed a contra-capture platform to generate post-translational modification (PTM) protein

microarrays, which is an improvement of the high-density (HD) NAPPA arrays, displaying 1632 proteins in their unmodified Tn, STn and Core3 glycosylated forms. These are being used to profile anti-glycoprotein autoantibodies (TAAb-AGP) in patients with breast cancer and benign breast diseases to identify early detection biomarkers that will be further validated on independent, blinded cohorts of serum specimens.

Drs. Jeffrey Marks and Cha-Mei Tang are participating in the prospective accrual of 1050 subjects undergoing breast cancer diagnosis obtaining blood, demographic, clinical, and follow-up data as well as breast tomosynthesis radiographic images. The purpose is to determine the presence of Cancer Associated Macrophage-Like (CAML) cells as potential blood biomarkers for the early detection of breast cancer, as well as to extract features from digital mammograms and perform decision fusion analysis to predict the presence of cancer from imaged masses and microcalcifications. More than 750 individuals have been accrued so far and fresh bloods have been analyzed for CAML cell detection.

Drs. Steve Skates and Michael Birrer are conducting studies towards the discovery and development of circulating protein biomarkers as well as the identification of specific mutations in tumor DNA derived from uterine lavage liquids for the early detection of high grade ovarian cancer (HGSOC) in women at normal risk or in women carrying BRCA1 or BRCA2 deleterious mutations (see below under Collaborative Group Projects). Toward that end, >1100 cancer associated proteins were interrogated in serial samples obtained from women prior to the clinical diagnosis of a HGSOC and matched healthy controls. >70 candidates were identified which are currently further analyzed to select an optimal panel of the 20 or fewer best candidates that maximize sensitivity for earliest stage and spectrum of disease, while maintaining a high specificity of at least 95% with the eventual aim of adjusting the cut-off to achieve 98% specificity.

Drs. Robert Bast and Steven Skates, in collaboration with Charles Drescher, are focusing on determining the specificity and positive predictive value for a 4-biomarker ROCA (ROCA2) that includes CA125, HE4, CA72.4 and anti-TP53 autoantibodies in a two-stage strategy for the early detection of ovarian cancer in postmenopausal women at average risk for the disease. This is nested in the ongoing multi-site NROSS screening trial led by Dr. Bast. To date, along the lines of the NROSS trial, 39,688 samples have been obtained from 7,342 postmenopausal women at conventional risk with 4,807 active participants. Twenty-four operations have been prompted by the ROCA algorithm and have detected 15 cases of ovarian cancer with 10 of them (67%) in Stage I or II. This observed significant stage-shift in detection indicates that no more than 3 operations will be required to detect each case of ovarian cancer using this strategy – i.e., a PPV of >30%.

Drs. Zhen Zhang and Ie-Ming Shih are focused on the identification and prioritization of biomarkers to be included in a multivariate classification algorithm for the detection of early

stage and low-volume ovarian cancer. To that end, they have analyzed liquid-based cervical canal cytology samples and plasma samples by mass spectrometry and array-based quantitative proteomic analysis as well as tissue specimens from tubal p53 signature lesions, serous tubal intraepithelial carcinomas (STICs), and HGSOC. Several differentially expressed proteins have been identified in STICS and HGSOC but not in p53 signature lesions, which could be utilized as potential biomarkers for the development of molecular imaging approaches for the early detection of STICS in high-risk women. Furthermore, they have conducted genome-wide comparative methylation analysis among tubal p53 signature lesions, STICs, and HGSOC. Regions of high-confidence STIC-specific differential hypermethylation were identified. Data from this analysis also suggests that most STICs are epigenetically similar to HGSOCs and share hypermethylated DNA regions that warrant further evaluation for potential use as biomarkers for the early detection of HGSOC.

Collaborative Projects on Breast and Ovarian Cancer

Phase 3 Validation of Biomarkers of ER+ Breast Cancer

Participants:

Christopher Li	Fred Hutchinson Cancer Research Center
Karen Anderson	Arizona State University
Paul Lampe	Fred Hutchinson Cancer Research Center

Aim 1: Preliminary validation of proteomic, autoantibody and glycomic markers specific for ER+ breast cancer early detection in the EDRN Reference Set. This set had 115 ER+ cases and 149 controls.
Status: Completed.

Aim 2: The most promising of these markers (9 proteomic, 12 autoantibodies and 16 glycomic markers) was validated in 121 ER+/PR+ ductal cases and 121 matched controls from Women's Health Initiative 1. This validated panel will be used to inform the timing of subsequent mammography in patients with a negative mammogram.
Status: Completed.

Aim 3**:** Validation using preclinical CHS samples: 68 ER+ cases and 204 matched controls from the Cardiovascular Health Study (CHS).
Status: Ongoing.

Circulating Human Tumor-derived Proteins Identified in PDX Models are Contained within Exosomes

Participants:

Amanda Paulovich	Fred Hutchinson Cancer Research Center,
Michael Lewis	Baylor College of Medicine
Andrew Godwin	University of Kansas Medical Center

Aim: Determine whether circulating human tumor-derived proteins identified in PDX models are contained within exosomes.

Status: EV-enriched samples from Dr. Godwin have been received by the Paulovich lab and are undergoing analysis by mass spectrometry.

Circulating Autoantibody Biomarkers for Early Detection of Ovarian Cancer

Participants:

Robert Bast	M D Anderson Cancer Center
Karen Lu	M D Anderson Cancer Center
Karen Anderson	Arizona State University
Charles Drescher	Fred Hutchinson Cancer Research Center
Zhen Zhang	Johns Hopkins University
Steven Skates	Massachusetts General Hospital

The purpose is to conduct a Phase 2 validation study to determine the performance of anti-TP53 AAbs and 15 other AAb biomarkers to distinguish epithelial ovarian cancer (EOC) from healthy individuals and women with benign pelvic masses.

Aim 1: Compare four TP53 autoantibodies plasma assay platforms.
Status:
Five different anti-TP53 AAb assays ((xMAP (MDACC), Luminex SeroMap (FHCRC), Meso Scale Discovery (ASU), RAPID (ASU), and the Roche Elecys Cobas (MDACC)) were tested on diagnostic samples from 502 healthy women, 200 women with benign pelvic masses, and 250 patients with EOC. At 98% specificity, sensitivity ranged from 13.2 - 21.6% across the assays, with the RAPID assay (ASU) demonstrating the greatest sensitivity.

Aim 2: Identify novel autoantibodies to complement CA125 and TP53.
Status: This project is evaluating complementarity of assays for anti-TP53 (RAPID), 15 other AAbs, and HE4 Ag-AAb complexes with each other and with CA125 using the same discovery set utilized in the project described above. At 98% specificity, 70% of the 63 early stage (I-II) EOC cases are positive for CA125. Addition of anti-TP53 detects an additional 3.2%, anti-

CTAG1 3.2% and the combination of both 4.8%. Due to COVID-19 associated delays, assays are still pending for HE4 Ag-AAb complexes at MD Anderson and 4 of the most promising AAbs at Arizona State.

Validate Biomarkers for the Early Detection of Ovarian Cancer

Participants:

Steven Skates	Massachusetts General Hospital
Daniel Chan	Johns Hopkins University
Zhen Zhang	Johns Hopkins University
Karin Rodland	Pacific Northwest National Laboratory
Charles Drescher	Fred Hutchinson Cancer Research Center
Lori Sokol	Johns Hopkins University

This study considered 165 candidate protein markers that had already been identified in previous EDRN research or in the literature for inclusion in a validation study. These were triaged through bioinformatic filters and Acurate Inclusion Mass Screening to identify the top 50 candidates.

Aim 1: Detect 50 candidate protein biomarkers on serum samples from patients with high-grade serous ovarian cancer (HGSOC) (n=50) or benign serous conditions (n=50) using standard LC-SRM and PRISM-SRM.
Status: Eight candidates were selected based on sensitivity at 98% specificity and have been converted to antibody-based assays.

Aim 2: Change the immunoassay platform to the Meso Scale Discovery (MSD) and perform the assays on 200 specimens (100 HGSOC cases:100 benign controls) received from Fred Hutchinson Cancer Reserch Center.
Status: The JHU-BRL has developed high throughput low CV MSD assays to the eight protein candidates selected in Aim 1 with optimization of antibody pairs, dilution, buffers, and multiplexing in three multiplex panels with serum proteins with similar dynamic abundance ranges grouped into the same plex. Assays of the 8 candidate protein bimarkers have been completed and the analysis of the assay data is currently in progress.

tDNA in Uterine Lavage and Serum Proteins for Early Detection of Ovarian Cancer

Participants:
This project is led by Steven Skates, Massachusetts General Hospital.
Other participants:

Amy Bregar	Massachusetts General Hospital,
Charles Drescher	Fred Hutchinson Cancer Research Center
Michael Birrer	University of Arkansas Medical Sciences
Kristin Zorn	University of Arkansas Medical Sciences
Christine Garcia	Kaiser Permanente San Francisco
Bethan Powel	Kaiser-Permanente San Francisco
Robert Bast	MD Anderson Cancer Center
Karen Lu	MD Anderson Cancer Center
Ie-Ming Shih	Johns Hopkins University
Rebecca Stone	Johns Hopkins University
Zhen Zhang	Johns Hopkins University
Daniel Chan	Johns Hopkins University
Jesse Salk	TwinStrand Biosciences
Rosana Risques	University of Washington
Paul Speiser	University of Vienna, Austria
Lucy Gilbert	McGill University, Montreal, Canada
Monica Jones	Ann Arundel Medical Center
Yingqi Zhao	Fred Hutchinson Cancer Research Center

Aim: The relative contributions to detection of epithelial ovarian cancer (EOC) from tumor (t)DNA in uterine lavage (UL) and protein biomarkers from blood using newly available sample collection and high-resolution, NextGen Sequencing detection technologies:

- Duplex sequencing of *TP53* mutations
- McGill Haloplex sequencing of a 23-gene panel
- Serum ovarian cancer proteins tested at MDACC and JHU

Prospective enrollment of 200 women at normal risk with suspected ovarian cancer and 50 women with an inherited *BRCA1* or *BRCA2* deleterious mutation without suspected ovarian cancer who are scheduled for risk-reducing salpingo-oophorectomy. Clinical protocol has been approved with the DMCC designated as the sIRB site of record.

Status:
Currently the recruitment site at Swedish Hospital has been activated and has accrued 13 subjects to date. Although delays have occurred due to single IRB requirements and a lengthy process followed by COVID-19 related shutdowns, three other recruiting sites (Ann Arundel, KP-SF, JHU) have been IRB-approved, with the remaining two recruiting sites soon to follow, and patient accrual at these sites is imminent to begin.

EDRN Pilot Targeted Identification and Collection of Serous Tubal Intraepithelial Carcinoma (STIC) with a Falloposcope

Participants:

Ie-Ming Shih	Johns Hopkins University
Jennifer K. Barton	University of Arizona
Anna Beavis	Johns Hopkins University

This project aims to develop and provide pilot assessment of the falloposcope as an instrument to identify and sample areas of interest in the fallopian tube for detection of serous tubal intraepithelial carcinoma (STIC), a precursor lesion for high-grade serous carcinoma (HGSC) of the ovary.

Aim 1: Develop fluorescence probes to help visualize STICs in fallopian tubes.
Aim 2: Demonstrate *ex vivo* the feasibility of the falloposcope to detect STIC cells in human samples.
Aim 3: Validate if the sampled lesion cells are derived from STIC lesions.

Project 1: Develop and deliver Falloposcope and related documentation.

- Completed the design, building, and testing of 12 cell-acquiring fallopian tube endoscopes (falloposcopes) with console. Each 0.8 mm diameter falloposcope includes multispectral fluorescence and reflectance imaging and a small wire to collect cells.
- The falloposcope system was shipped to JHU; U. Arizona investigators travelled there to assemble and confirm functionality.
- Initial falloposcope images were obtained with mouse tissue and *ex vivo* human fallopian tube surgical discard tissue.
- A user manual for the falloposcope system was written.

Project 2: Develop protocol for cell collection and target staining and experimental contrast agent for *in situ* STIC visualization.

- A protocol for cell collection, dissociation, and affixing on a slide was developed.
- Several laminin C1 antibodies have been tested on cell cultures using immunofluorescence and the best one was selected.
- A large quantity of this antibody was produced and purified, and the antibody has been outsourced for Cy5.5 fluorophore conjugation.
- As a backup strategy, genome-wide methylation beads array was employed to identify other candidate STIC and EOC biomarkers.
- IGFBP2 was identified as a potential protein that is specifically expressed by STIC and ovarian cancer cells. This marker may be combined with laminin C1 for the falloposcope in the future.

Building Scientific Resources

In addition to supporting EDRN Collaborative Group research projects (described above), EDRN core and set-aside funds are used to support biospecimen collections and image repositories from multiple centers (both EDRN and non-EDRN) to be used for future biomarker verification and validation and to develop imaging methods to improve early detection. Following are summaries of these resource projects, including the participating organizations and scientists and the project aims and status.

- Pancreatic Cystic Fluid Reference Set
- Imaging Repository for Pre-Diagnostic and Early Stage Pancreatic Cancers
- A Prospective Study to Establish a New Onset Diabetes (NOD) Cohort
- Hepatocellular Carcinoma Early Detection Study (HEDS)
- Prostate Active Surveillance Study (PASS)
- EDRN Prostate Cancer Tissue Upgrading
- Upgrading Reference Set Phase II
- Breast Cancer Biospecimens and Imaging Reference Set

Pancreatic Cystic Fluid Reference Set

Participants:
This project is being led by Randall Brand, University of Pittsburgh.
Other participants:

Peter Allen	Duke University
Darwin Conwell	Ohio State University
Christopher DiMaio	Mt Sinai Medical Center
Kim Kirkwood	University of California San Francisco
Richard Kwon	University of Michigan
Anne Marie Lennon	Johns Hopkins University
Anirban Maitra	MD Anderson Cancer Center
Nipun Merchant	Vanderbilt University
Walter Park	Stanford University
Shailender Singh	University of Nebraska Medical Center
Jill Smith	Georgetown University
Shivakumar Vignesh	Moffitt Cancer Center
Jordan Winter	Thomas Jefferson University

The objective is to create a reference set consisting of well-characterized cystic fluid and serum/plasma specimens obtained from patients referred to participating academic centers with pancreatic cysts who meet consensus guidelines for consideration of surgical resection. The

primary goal of this reference set is to provide a resource for the development and evaluation of biomarkers for predicting the malignant potential of pancreatic cystic lesions that can be incorporated into clinical management strategies, initially focused on determining who would most benefit for surgical resection.

Status: Recruitment goal: 450 participants (prospective)
Current Enrollment: 435

Imaging Repository for Pre-Diagnostic and Early Stage Pancreatic Cancers

Participants:

Randall Brand	University of Pittsburgh
Ajay Goel	City of Hope
Natalia Khalaf	Baylor College of Medicine
Eugene Koay	MD Anderson Cancer Center
Anirban Maitra	MD Anderson Cancer Center
Walter Park	Stanford University
Michael Rosenthal,	Dana-Farber Cancer Institute
Aatur Singhi,	University of Pittsburgh
Dan Von Hoff	City of Hope
BrianvWolpin	Dana-Farber Cancer Institute
Bechien Wu	Kaiser Permanente Southern California

The goal of the project is to build a multi-institutional imaging repository for pre-diagnostic and early stage pancreatic cancer cases. The repository will be the first of its kind for pancreatic cancer, and will be used to develop specific quantitative imaging tools, which can be applied to validate imaging-based biomarker signals that have shown promise for early detection purposes, as well as image processing methods to improve detection of small pancreatic lesions. The imaging repository will be hosted by NASA's Jet Propulsion Laboratory (JPL) and a Joint Steering Committee will be established to provide oversight of the project and its scientific direction. The repository will initially be accessible by those who contribute cases with annotation from the participating institutions.

Aim 1. Establish a multi-institutional imaging repository for pre-diagnostic and early pancreatic cancer cases with clinical annotation.
Aim 2. Validate quantitative imaging tools for early detection of pancreatic cancer.

Status: 300 cases have been sent from participating sites to MD Anderson Cancer Center prior to transfer to JPL. Image analyses ongoing: (1) Determining the correlation of growth rate parameters with changes in body compartment. (2) Validation of the association of growth rates

with high/low delta in multi-institutional repository.

A Prospective Study to Establish a New Onset Diabetes (NOD) Cohort

Participants:
This project is being led by Suresh Chari and Anirban Maitra, M D Anderson Cancer Center.
Other participants:

David Bradley	The Ohio State University Wexner Medical Center
Randall Brand,	University of Pittsburgh
Ziding Feng	Fred Hutchinson Cancer Research Center
William Fisher	Baylor College of Medicine
Evan Fogel	Indiana University
Steven Hughes	University of Florida
Lynn Matrisian	Pancreatic Cancer Action Network
Stephen Pandol	Cedars Sinai Medical Center
Walter Park	Stanford University
Philip Stella	St. Joseph Mercy Health System
Stephen van den Eeden	Kaiser Permanente Northern California
Bechien Wu	Kaiser Permanente Southern California

Approximately 0.85% of patients with adult onset diabetes will be diagnosed with pancreatic ductal adenocarcinoma (PDAC) within three years of developing diabetes. This type of diabetes (type 3C) is caused by the cancer but these patients are otherwise asymptomatic. The NOD study will recruit 10,000 subjects over the age of 50 years with new-onset diabetes to i) collect clinically annotated biospecimens from pre-symptomatic PDAC subjects and type 2 Diabetes Mellitus controls, ii) estimate the probability of PDAC in the prospectively assembled NOD cohort, and iii) establish a specimen reference set to validate emerging tests to identify high risk NOD patients for PDAC diagnostic workup.

Status: Recruitment Goal: 10,000
Current Recruitment: 445
Three NOD patients have been diagnosed with cancer (as of July 2020).

Hepatocellular Carcinoma Early Detection Study (HEDS)

Participants:
This project is led by Jorge Marrero, UT Southwestern Medical Center.
Other participants

Alex Befeler	Saint Louis University
Ziding Feng	Fred Hutchinson Cancer Research Center
Denise Harnois	Mayo Clinic Jacksonville
Mindie Nguyen	Stanford University
Neehar Parikh	University of Michigan,
Rajende Reddy	University of Pennsylvania
Lewis Roberts	Mayo Clinic
Myron Schwartz	Mount Sinai Hospital

Patients with cirrhosis will be followed for a minimum of 24 months and have biospecimens collected every 6 months. Data will be collected every 6 months: ultrasound, AFP, liver function tests, complete blood counts, MELD scores and any changes in medical history, personal cancer history and family cancer history.

Aim 1: Determine the incidence rate and the performance of ultrasound, and the biomarkers, alpha-fetoprotein (AFP), AFP-L3%, des-gamma carboxy-prothrombin (DCP) and novel biomarkers in detecting preclinical hepatocellular carcinoma (HCC).
Aim2: Establish a biorepository of longitudinally collected biospecimens from this cohort of cirrhotic patients.

Status: Recruitment Goal: 1550 participants (prospective).
Current Recruitment: 1562
87 participants have developed HCC.

Prostate Active Surveillance Study (PASS)

The EDRN formed a partnership with the Canary Foundation to provide coordination and data management for the Prostate Active Surveillance Study (PASS). PASS was launched in 2008 in response to the growing evidence of overtreatment of prostate cancer and a need for tools to tell the difference between aggressive and indolent prostate cancer. PASS is a multi-center study that has enrolled men with early-stage prostate cancer who elected to manage their cancer by being actively monitored.

Participants:
There are 10 clinical sites enrolling patients across the U.S. and Canada in addition to the coordinating center based at the Fred Hutchinson Cancer Research Center. (The EDRN currently supports the coordinating center):

University of Washington
Veterans Affairs Puget Sound Health Care System
University of California in San Francisco
Stanford University – Stanford, California
Beth Israel Deaconess Medical Center
Eastern Virginia Medical School
University of Michigan
Emory University
University of Texas Health Science Center in San Antonio
University of British Columbia

Status:
There are 2002 participants enrolled in PASS, with a median of 5.8 years of follow-up. There are 657 grade reclassifications. More than 16,000 specimens have been used in studies evaluating biomarkers of aggressive prostate cancer. More than fifteen papers have been published (e.g., Performance of PCA3 and TMPRSS2:ERG urinary biomarkers in prediction of biopsy outcome in the Canary Prostate Active Surveillance Study (PASS). *Prostate Cancer Prostatic Dis.* 2019 Jan 21; PMID: 30664734; PMCID: PMC6642858).

EDRN Prostate Cancer Tissue Upgrading

Participants:
This project is led by Robin Leach, UT Health San Antonio and Martin Sanda, Emory University. Other participants:

Ian Thompson,	University of Texas Health Science Center at San Antonio
John Semmes,	Eastern Virginia Medical School
Frances Martin	Eastern Virginia Medical School
Daniel Lin	University of Washington
James Brooks	Stanford University Medical Center
John Wei	University of Michigan School of Medicine
Dan Mercola	University of California Irvine
Jaime Landman	University of California Irvine
Eric Klein	Cleveland Clinic
Dipen Parekh	University of Miami Miller School of Medicine
Ashutosh Tewari	Icahn School of Medicine at Mt. Sinai
Juan Miguel Mosquera	Weill Cornell Medicine
Ziding Feng	Fred Hutchinson Cancer Research

The majority of men with low-risk prostate cancer are currently being managed on active surveillance. Many of these men ultimately elect to undergo therapy because of concerns that they have more aggressive disease than detected by their biopsy. The lack of a robust biomarker to

predict presence of aggressive prostate cancer in this clinical setting contributes to the ongoing over-treatment of low-grade localized prostate cancer. To assist in counseling these men, the EDRN GU working group began gathering a cohort of men with low-grade disease (defined as Gleason 6, ISUP Grade Group I), who ultimately chose to have a prostatectomy. Although the risk of metastasis is extremely low in patients with Gleason score 6 prostate cancers, a significant number of the cancers in these low-risk patients are subject to upgrading after radical prostatectomy (30-50%). Upgrading alone is a negative prognostic factor.

The goal was to identify pre-therapeutic biomarkers (urine, serum and tissue) that could predict upgrading, i.e., detection of high-grade disease in the surgical specimen that had not been detected in diagnostic biopsies. These biological samples comprise the Upgrading Reference Set (URS), and have been gathered using EDRN core funds.

Aim: Prospectively accrue 340 men with Gleason score 6 who subsequently underwent radical prostatectomy.

Status:
Enrollment is nearly complete.

Upgrading Reference Set (phase 2)

Participants:

Robin Leach	University of Texas San Antonio
Paul C. Boutros	University of California Los Angeles

The goal of this project is to improve the identification of men at risk of upgrading their prostate cancer so that curative interventions can be more specifically directed, while avoiding over-treatment of indolent disease.

A series of recent studies has identified associations between the germline genome and clinical features of prostate cancers. The PRACTICAL consortium has identified a 149-variant polygenic risk-score (PRS) that distinguishes a group of men with ~5-fold increased lifetime risk of diagnosis, and another group with ~5-fold decreased lifetime risk (Schumacher et al., 2018). A subset of these have been shown to be associated with increased risk of diagnosis with aggressive disease and with earlier age of diagnosis in a cohort of 6,411 men (1,583 with prostate cancer, 632 of which had aggressive disease) (Seibert et al., 2019). A subset of these have been shown to be univariately associated with outcome in prostate-cancer specific mortality in a cohort of 12,082 patients (1,544 of whom died of prostate cancer) (FitzGerald et al., 2018). Similarly, studies of DNA Damage Repair (DDR) genes such as *BRCA2* and *ATM* have shown that rare-but-damaging

germline (constitutive) polymorphisms are enriched in advanced disease and associated with unique somatic phenotypes.

These studies, along with the rapidly declining costs of DNA sequencing, suggest that, in the near future, germline characterization will be standard-of-care for all newly diagnosed prostate cancers. Indeed, NCCN guidelines now indicate germline testing for all locally-advanced and metastatic patients, in part triggering cascade testing. The utility of germline variants in predicting upgrading from Active Surveillance is not fully clear, but it is likely that future biomarkers – including radiologic ones – will be combined into nomograms or other risk strategies with germline features. We therefore proposed to fully interrogate the germline genome of the URS by whole-genome sequencing to ~60x coverage. This high-depth sequencing will allow testing of the PRS existing germline markers and provide the raw data to allow any future marker to be tested with no analytical costs. It would also provide a heads-up comparator for future non-invasive biomarker studies on this cohort and enrich its overall value. Given this clinical and biomarker context, the goals in the current proposal are two-fold:

Aim 1: Collect tissue, blood, and urine specimens to obtain 195 complete specimen sets under the Upgrading Reference Set (URS) protocol.
Aim 2: Perform Germline whole-genome sequencing for each subject in the cohort to validate the PRS markers with respect to upgrading as previously reported.

The second aim not only serves to validate PRS but will create a resource for all future studies including enabling low-cost validation of any further germline-based risk markers. Through these supplement funds, investigators will be well-positioned to perform numerous validation studies using markers from both the BDL as well as other investigators.

Status:
To date, 375 men have been enrolled. Specimens from these men were then subjected to pre-defined exclusion criteria, including sufficient sample collection processed as required by the SOPs, confirmed Gleason 6 disease on central review of biopsy, and ability to locate previous biopsy material. In addition, some men elected to seek other treatments (e.g. radiotherapy or focal treatment) and therefore were excluded from the study. Of the 375 enrolled men, 316 reached Round 1 (i.e., needed biological specimens were obtained), and of these, 255 have had central pathology review.

Breast Cancer Biospecimens and Imaging Reference Set

Participants:
This project is led by Jeffrey Marks, Duke University.

Other participants:

Cha-Mei Tang	Creatv MicroTech Inc.
John Heine	H. Lee Moffitt Cancer Center and Research Institute Inc.

The goal of this project is the development of a retrospective cohort of 1050 full-field digital mammography images and a prospective cohort of 1050 digital breast tomosynthesis images together with blood samples obtained prior to definitive diagnosis from women referred to diagnostic radiology based on an initial BI-RADS 4 suspicious mammogram. Circulating biomarkers combined with imaging features could allow the development of classification algorithms that can confidently rule out the presence of malignancy in this population without biopsy.

Aim 1: Assemble a well-characterized retrospective set of blood specimens and Full-Field Digital Mammography images to test biomarkers that, in conjunction with mammography image features, can detect and discriminate breast cancer.

Status: Recruitment goal: 1050 participants
Recruitment: complete

Aim 2: Assemble a well-characterized, prospectively collected set of blood specimens and Digital Breast Tomosynthesis images from women designated as BI-RADS 4. Specimen set will be used to test combinations of image features and blood biomarkers for more accurate discrimination of benign versus cancer (*in situ* or invasive) and thereby reduce the number of negative biopsies.

Status: Recruitment goal is 1050 participants (prospective).
Recruitment as of June 2020: 840

The Duke BDL and the Moffitt CVC, together with the Informatics Center at Jet Propulsion Laboratory and the EDRN DMCC, are prospectively acquiring images from 3D-Mammography (tomosynthesis) together with freshly collected serum and plasma to develop a prospective cohort of 1050 individuals with same clinical characteristics. Fresh blood is shipped to Creatv Microtech in real time for rare Cancer Associated Macrophage-Like (CAML) cell assessment. About 840 subjects have been accrued (prior to COVID-19 related shut-down), undergoing breast biopsy triggered by a BI-RADS 4 finding. To date, greater than 80% of these subjects received a benign tissue diagnosis mirroring the false positive rate in this mammographic category.

Conclusion

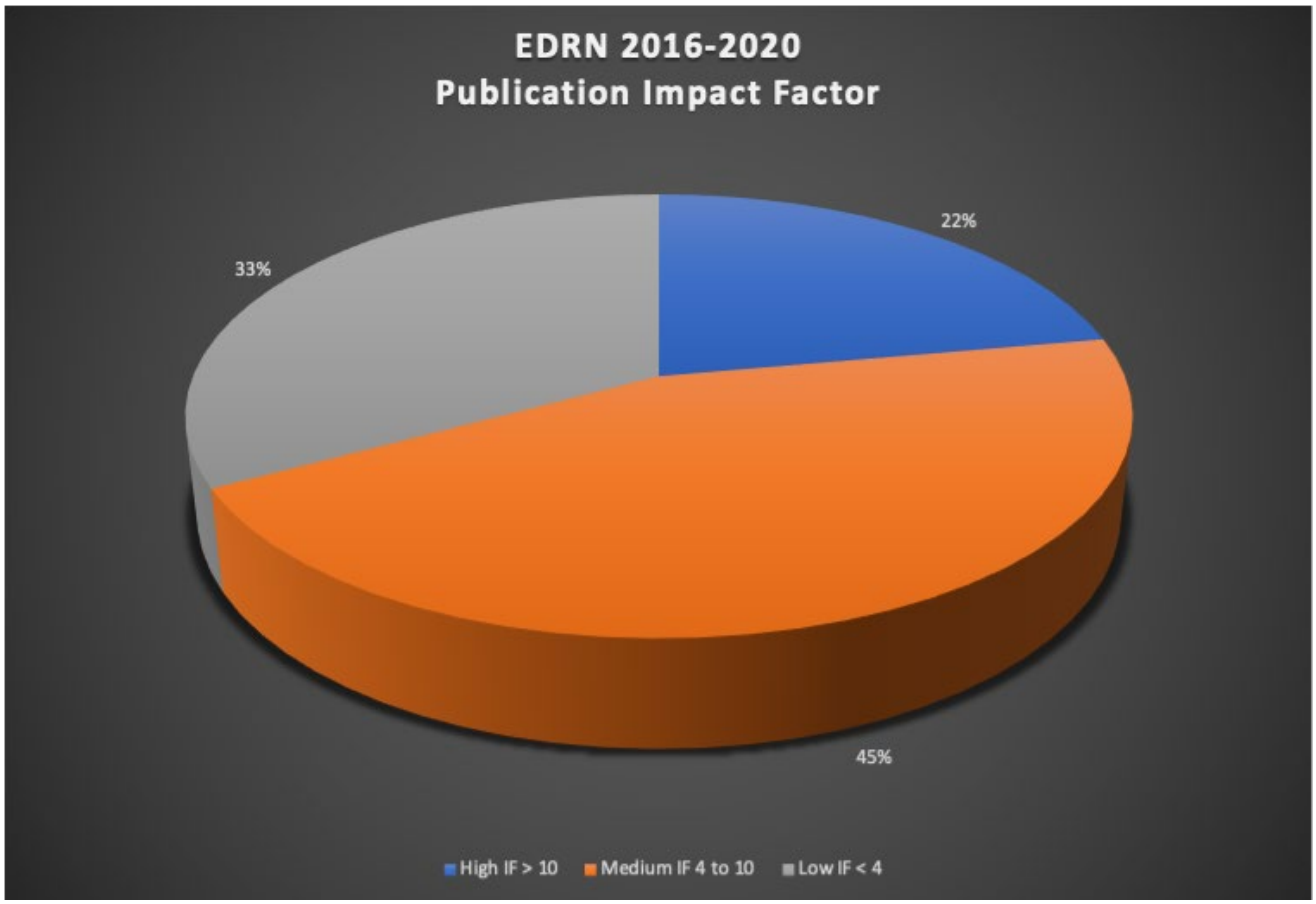
The EDRN structure has fostered a culture of Team Science that has built a strong bond of collaboration and leadership across the network. Most EDRN biomarker developmental and validation research is supported by the individual PI's cooperative agreement and EDRN PIs have the primary responsibility for the conduct of this research. However, a major advantage of a network like the EDRN and its Team Science approach becomes apparent when the investigators meet to discuss their work and establish collaborative projects. Presentation of their recent research results to other EDRN PIs during Collaborative Group and Steering Committee meetings provides them feedback on their ongoing research, allowing adjustments in light of peer input and progress being made by other EDRN PIs. EDRN awards include set-aside funds that can only be used for new team and collaborative projects that take advantage of the expertise, resources, and platforms of several different PIs.

While the organization of the EDRN provides a sound foundation for this high degree of collaboration, its success would not have been possible without the enlightened leadership of NCI program staff, the Chairs and Co-Chairs of the EDRN Executive Committee, and the members of working groups and consulting teams that have provided advice to the EDRN over the years. The vision of NCI leadership to establish such an organization should be congratulated, and this type of structure should be seriously considered for as a model for future large-scale enterprises that require a host of specialties, organizations, and institutions to achieve 'Big Science' discoveries.

The AACR-NCI Think Tank Charting the Future of Cancer Prevention noted in 2008 that "The EDRN should be tapped as a potential partner in the effort to develop response biomarkers. Efficient translational research in prevention requires that trials enroll primarily individuals at high risk. This is another way to take advantage of the EDRN success. The goal of better risk assessment entails research on targets and pathways of the early stages of pre-cancer. Promising agents tested in high-risk individuals for short periods of time can build momentum for some of the needed reforms." The Committee further stated that "Without the EDRN, research into new biomarkers of early cancer detection and risk would have remained on the periphery of research with a strong, but fragmented laboratory presence and little translational interest in the academic scientific community. But with the Network, a new translational paradigm has defined the organization, approaches, and standards by which biomarkers are being developed and assessed. The Network created major focus, energy and new research in the field of early detection. The Network's publications, meetings, funding opportunities and infrastructure have fashioned a new environment for cancer prevention research." AACR is publishing a special issue on the 20th anniversary of EDRN in Cancer Epidemiology, Biomarkers and Prevention, October 2020.

EDRN Publications

Since its inception, EDRN investigators have published more than 3400 articles; 11% in journals with impact factors greater than 10. From 2016-2020, EDRN investigators published more than 555 articles; 22% in journals with impact factors greater than 10. A list of articles published from 2016-2020 is given below, organized by EDRN component.



List of Publications (2016 – 2020)

1. Alemozaffar M, Akintayo AA, Abiodun-Ojo OA, Patil D, Saeed F, Huang Y, Osunkoya AO, Goodman MM, Sanda M, Schuster DM. Fluciclovine PET/CT for Preoperative Staging in Patients with Intermediate to High-Risk Primary Prostate Cancer. J Urol. 2020 Apr 29:101097 JU0000000000001095. Epub ahead of print. PMID: 32347780.
2. Liss MA, Newcomb LF, Zheng Y, Garcia MP, Filson CP, Boyer H, et al. Magnetic Resonance Imaging for the Detection of High-Grade Cancer in the Canary Prostate Active Surveillance Study. J Urol. 2020 Apr 28:101097 JU0000000000001088. Epub ahead of print. PMID: 32343189.
3. Jansen CS, Prokhnevska N, Master VA, Sanda MG, Carlisle JW, Bilen MA, et al. An intra-tumoral niche maintains and differentiates stem-like CD8 T cells. Nature. 2019 Dec; 576(7787): 465-470. doi: 10.1038/s41586-019-1836-5. Epub 2019 Dec 11. PMID: 31827286; PMCID: PMC7108171.
4. Schenk JM, Newcomb LF, Zheng Y, Faino AV, Zhu K, Nyame YA, et al. African American Race is Not Associated with Risk of Reclassification during Active Surveillance: Results from the Canary Prostate Cancer Active Surveillance Study. J Urol. 2020 Apr;203(4):727-733. Epub 2019 Oct 25. PMID: 31651227.
5. Kalapara AA, Verbeek JFM, Nieboer D, Fahey M, Gnanapragasam V, Van Hemelrijck M, et al. Adherence to Active Surveillance Protocols for Low-risk Prostate Cancer: Results of the Movember Foundation's Global Action Plan Prostate Cancer Active Surveillance Initiative. Eur Urol Oncol. 2020 Feb;3(1):80-91. doi: 10.1016/j.euo.2019.08.014. Epub 2019 Sep 26. PMID:31564531.
6. Connell SP, Hanna M, McCarthy F, Hurst R, Webb M, Curley H, et al. A Four-Group Urine Risk Classifier for Predicting Outcome in Prostate Cancer Patients. BJU Int. 2019 May 20;124(4):609–20. doi: 10.1111/bju.14811. Epub ahead of print. PMID: 31106513; PMCID: PMC6851983.
7. McDonald AC, Vira M, Walter V, Shen J, Raman JD, Sanda MG, Patil D, Taioli E. Circulating microRNAs in plasma among men with low-grade and high-grade prostate cancer at prostate biopsy. Prostate. 2019 Jun;79(9):961-968. doi: 10.1002/pros.23803. Epub 2019 Apr 8. PMID: 30958910; PMCID: PMC6520194.
8. Taylor MA, Alemozaffar M, Master VA, Sanda MG, Filson CP. Rise in Node- Positive Prostate Cancer Incidence in Context of Evolving Use and Extent of Pelvic Lymphadenectomy. Clin Genitourin Cancer. 2019 Jun;17(3):e494-e504. doi: 10.1016/j.clgc.2019.01.012. Epub 2019 Jan 26. PMID: 30819637.
9. O'Reilly E, Tuzova AV, Walsh AL, Russell NM, O'Brien O, Kelly S, et al. epiCaPture: A Urine DNA Methylation Test for Early Detection of Aggressive Prostate Cancer. JCO Precis Oncol. 2019;2019:10.1200/PO.18.00134. doi: 10.1200/PO.18.00134. Epub 2019 Jan 14. PMID: 30801051; PMCID: PMC6383793.
10. Liu W, Patil D, Howard DH, Moore RH, Wang H, Sanda MG, Filson CP. Impact of prebiopsy magnetic resonance imaging of the prostate on cancer detection and treatment patterns. Urol Oncol. 2019 Mar;37(3):181.e15-181.e21. doi: 10.1016/j.urolonc.2018.11.004. Epub 2018 Dec 1. PMID: 30514604.
11. Van der Kwast TH, Helleman J, Nieboer D, Bruinsma SM, Roobol MJ; et al. Consistent Biopsy Quality and Gleason Grading Within the Global Active Surveillance Global Action Plan 3 Initiative: A Prerequisite for Future Studies. Eur Urol Oncol. 2019 May;2(3):333-336. doi: 10.1016/j.euo.2018.08.017. Epub 2018 Sep 13. PMID: 31200849.

12. Zhao F, Olkhov-Mitsel E, Kamdar S, Jeyapala R, Garcia J, Hurst R, et al. A urine-based DNAmethylation assay, ProCUrE, to identify clinically significant prostate cancer. Clin Epigenetics. 2018 Nov 23;10(1):147. doi: 10.1186/s13148-018-0575-z. PMID: 30470249; PMCID: PMC6260648.
13. Vicier C, Werner L, Chipman J, Harshman LC, Patil DH, Fichorova RN, Rider JR, Sanda MG, Mucci LA, Sweeney CJ. Elevated Serum Cytokines and Trichomonas vaginalis Serology at Diagnosis Are Not Associated With Higher Gleason Grade or Lethal Prostate Cancer. Clin Genitourin Cancer. 2019 Feb;17(1):32-37. doi: 10.1016/j.clgc.2018.09.022. Epub 2018 Oct 4. PMID: 30348512.
14. Liu W, Patil D, Howard DH, Moore RH, Wang H, Sanda MG, Filson CP. Adoption of Prebiopsy Magnetic Resonance Imaging for Men Undergoing Prostate Biopsy in the United States. Urology. 2018 Jul;117:57-63. doi: 10.1016/j.urology.2018.04.007. Epub 2018 Apr 18. PMID: 29679601.
15. Ankerst DP, Goros M, Tomlins SA, Patil D, Feng Z, Wei JT, Sanda MG, Gelfond J, Thompson IM, Leach RJ, Liss MA. Incorporation of Urinary Prostate Cancer Antigen 3 and TMPRSS2:ERG into Prostate Cancer Prevention Trial Risk Calculator. Eur Urol Focus. 2019 Jan;5(1):54-61. doi: 10.1016/j.euf.2018.01.010. Epub 2018 Feb 13. PMID: 29422418; PMCID: PMC6077104.
16. McDonald AC, Vira M, Shen J, Sanda M, Raman JD, Liao J, Patil D, Taioli E. Circulating microRNAs in plasma as potential biomarkers for the early detection of prostate cancer. Prostate. 2018 May;78(6):411-418. doi: 10.1002/pros.23485. Epub 2018 Jan 31. PMID: 29383739.
17. Sanda MG, Cadeddu JA, Kirkby E, Chen RC, Crispino T, Fontanarosa J, et al. AUA/ASTRO/SUO Guideline. Part II: Recommended Approaches and Details of Specific Care Options. J Urol. 2018 Apr;199(4):990-997. doi: 10.1016/j.juro.2018.01.002. Epub 2018 Jan 10. PMID: 29331546.
18. Elfatairy KK, Filson CP, Sanda MG, Osunkoya AO, Geller RL, Nour SG. In-bore MRI-guided biopsy: can it optimize the need for periodic biopsies in prostate cancer patients undergoing active surveillance? A pilot test-retest reliability study. Br J Radiol. 2018 Apr;91(1084): 20170603. doi: 10.1259/bjr.20170603. Epub 2018 Feb 13. PMID: 29308912; PMCID: PMC5965998.
19. Sanda MG, Cadeddu JA, Kirkby E, Chen RC, Crispino T, Fontanarosa J, et al. Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. Part I: Risk Stratification, Shared Decision Making, and Care Options. J Urol. 2018 Mar;199(3):683-690. doi: 10.1016/j.juro.2017.11.095. Epub 2017 Dec 15. PMID: 29203269.
20. Sanda MG. Patients with Intermediate Risk Prostate Cancer May be Good Candidates for Active Surveillance: Pro. J Urol. 2017 Nov;198(5):997-999. doi: 10.1016/j.juro.2017.08.089. Epub 2017 Sep 22. PMID: 28947083.
21. Sanda MG, Feng Z, Howard DH, Tomlins SA, Sokoll LJ, Chan DW, et al. Association Between Combined TMPRSS2:ERG and PCA3 RNA Urinary Testing and Detection of Aggressive Prostate Cancer. JAMA Oncol. 2017 Aug 1;3(8):1085-1093. doi: 10.1001/jamaoncol.2017.0177. PMID: 28520829; PMCID: PMC5710334.
22. Pellegrini KL, Patil D, Douglas KJS, Lee G, Wehrmeyer K, Torlak M, Clark J, Cooper CS, Moreno CS, Sanda MG. Detection of prostate cancer-specific transcripts in extracellular vesicles isolated from post-DRE urine. Prostate. 2017 Jun;77(9):990-999. doi: 10.1002/pros.23355. Epub 2017 Apr 17. PMID: 28419548; PMCID: PMC5907935.
23. Sowalsky AG, Kissick HT, Gerrin SJ, Schaefer RJ, Xia Z, Russo JW, Arredouani MS, Bubley GJ, Sanda MG, Li W, Ye H, Balk SP. Gleason Score 7 Prostate Cancers Emerge through Branched Evolution of Clonal Gleason Pattern 3 and 4. Clin Cancer Res. 2017 Jul 15;23(14):3823-3833. doi: 10.1158/1078-0432.CCR-16-2414. Epub 2017 Jan 24. PMID: 28119368; PMCID: PMC5511561.

24. O'Malley PG, Nguyen DP, Al Hussein Al Awamlh B, Wu G, Thompson IM, Sanda M, Rubin M, Wei JT, Lee R, Christos P, Barbieri C, Scherr DS. Racial Variation in the Utility of Urinary Biomarkers PCA3 and T2ERG in a Large Multicenter Study. J Urol. 2017 Jul;198(1):42-49. doi: 10.1016/j.juro.2017.01.058. Epub 2017 Jan 20. PMID: 28115190; PMCID: PMC5568076.
25. Pellegrini KL, Sanda MG, Patil D, Long Q, Santiago-Jiménez M, Takhar M, et al. Evaluation of a 24-gene signature for prognosis of metastatic events and prostate cancer-specific mortality. BJU Int. 2017 Jun;119(6):961-967. doi: 10.1111/bju.13779. Epub 2017 Feb 11. PMID: 28107602; PMCID: PMC5444982.
26. Loeb S, Shin SS, Broyles DL, Wei JT, Sanda M, Klee G, et al. Prostate Health Index improves multivariable risk prediction of aggressive prostate cancer. BJU Int. 2017 Jul;120(1):61-68. doi: 10.1111/bju.13676. Epub 2016 Nov 22. PMID: 27743489; PMCID: PMC5392379.
27. Quintana L, Ward A, Gerrin SJ, Genega EM, Rosen S, Sanda MG, et al. Gleason Misclassification Rate Is Independent of Number of Biopsy Cores in Systematic Biopsy. Urology. 2016 May;91:143-9. doi: 10.1016/j.urology.2015.12.089. Epub 2016 Mar 2. PMID: 26944351; PMCID: PMC5836472.
28. Bruinsma SM, Bangma CH, Carroll PR, Leapman MS, Rannikko A, Petrides N,et al. Active surveillance for prostate cancer: a narrative review of clinical guidelines. Nat Rev Urol. 2016 Mar;13(3):151-67. doi: 10.1038/nrurol.2015.313. Epub 2016 Jan 27. PMID: 26813955.
29. Zhang Y, Zhou CK, Rencsok EM, Fall K, Lotan TL, Loda M, Giunchi F, Platz EA, De Marzo AM, Mucci LA, Fiorentino M, Ebot EM. A Prospective Study of Intraprostatic Inflammation, Focal Atrophy, and Progression to Lethal Prostate Cancer. Cancer Epidemiol Biomarkers Prev. 2019 Dec;28(12):2047-2054. doi: 10.1158/1055-9965.EPI-19-0713. Epub 2019 Sep 18. PMID: 31533941; PMCID: PMC6941930.
30. Roychowdhury S, Chinnaiyan AM. Translating cancer genomes and transcriptomes for precision oncology. CA Cancer J Clin. 2016 Jan-Feb;66(1):75-88. doi: 10.3322/caac.21329. Epub 2015 Nov 3. PMID: 26528881; PMCID: PMC4713245.
31. Udager AM, Liu TY, Skala SL, Magers MJ, McDaniel AS, Spratt DE, Feng FY, Siddiqui J, Cao X, Fields KL, Morgan TM, Palapattu GS, Weizer AZ, Chinnaiyan AM, Alva A, Montgomery JS, Tomlins SA, Jiang H, Mehra R. Frequent PD-L1 expression in primary and metastatic penile squamous cell carcinoma: potential opportunities for immunotherapeutic approaches. Ann Oncol. 2016 Sep;27(9):1706-12. doi: 10.1093/annonc/mdw216. Epub 2016 May 23. PMID: 27217541; PMCID: PMC4999561.
32. Shi T, Song E, Nie S, Rodland KD, Liu T, Qian WJ, Smith RD. Advances in targeted proteomics and applications to biomedical research. Proteomics. 2016 Aug;16(15-16):2160-82. doi: 10.1002/pmic.201500449. PMID: 27302376
33. Wang H, Barbieri CE, He J, Gao Y, Shi T, Wu C, Schepmoes AA, Fillmore TL, Chae SS, Huang D, Mosquera JM, Qian WJ, Smith RD, Srivastava S, Kagan J, Camp DG 2nd, Rodland KD, Rubin MA, Liu T. Quantification of mutant SPOP proteins in prostate cancer using mass spectrometry-based targeted proteomics. J Transl Med. 2017 Aug 15;15(1):175. doi: 10.1186/s12967-017-1276-7. PMID: 28810879
34. Zhang P, Gaffrey MJ, Zhu Y, Chrisler WB, Fillmore TL, Yi L, Nicora CD, Zhang T, Wu H, Jacobs J, Tang K, Kagan J, Srivastava S, Rodland KD, Qian WJ, Smith RD, Liu T, Wiley HS, Shi T. Carrier-Assisted Single-Tube Processing Approach for Targeted Proteomics Analysis of Low Numbers of Mammalian Cells. Anal Chem. 2019 Jan 15;91(2):1441-1451. doi: 10.1021/acs.analchem.8b04258. Epub 2018 Dec 28. PMID: 30557009

35. Gao Y, Wang YT, Chen Y, Wang H, Young D, Shi T, Song Y, Schepmoes AA, Kuo C, Fillmore TL, Qian WJ, Smith RD, Srivastava S, Kagan J, Dobi A, Sesterhenn IA, Rosner IL, Petrovics G, Rodland KD, Srivastava S, Cullen J, Liu T. Proteomic Tissue-Based Classifier for Early Prediction of Prostate Cancer Progression. Cancers. 2020 May 17;12(5):E1268. doi: 10.3390/cancers12051268. PMID: 32429558
36. Tsai CF, Zhang, Scholten D, Wang YT, Schultz K, Zhao R, Chrisler WB, Patel DB, Dou M, Jia Y, Reduzzi C, Liu X, Moore RJ, Burnum-Johnson KE, Jacobs JM, Kagan J, Srivastava S, Rodland KD, Wiley HS, Qian WJ, Smith RD, Zhu Y, Cristofanilli M, Liu T, Liu H, Shi T. Facile sample preparation for quantitative single-cell proteomics. Submitted.
37. Wang YT, Shi T, Srivastava S, Kagan J, Liu T, Rodland, KD. Proteomic discovery of protein markers in
38. Neal D.Shore, Christopher M.Pieczonka, JonathanHenderson, James L.Bailen, Daniel R.Saltzstein, Raoul S.Concepcion, Jennifer L.Beebe-Dimmer,Julie J.Ruterbusch, Rachel A.Levin, SandraWissmueller, Thao HoLe, David Gillatt, Daniel W. Chan, Douglas H.Campbell, Bradley J.Walsh. Development and evaluation of the MiCheck test for aggressive prostate cancer. Urologic Oncology, 16April 2020. PMID: 32305266.
39. Hristova V, Sun S, Zhang H, Chan DW. Proteomic analysis of degradation ubiquitin signaling by ubiquitin occupancy changes responding to 26S proteasome inhibition. Clinical Proteomics. 2020 Jan 25;17:2. eCollection 2020. PMID: 31997977, PMCID: PMC6982382.
40. Song J, Merbs SL, Sokoll LJ, Chan DW, Zhang Z. A multiplex immunoassay of serum biomarkers for the detection of uveal melanoma. Clinical proteomics. 2019;16:10. PubMed PMID: 30867659; PubMed Central PMCID: PMC6399902; DOI: 10.1186/s12014-019-9230-8.
41. Wang C, Höti N, Lih TM, Sokoll LJ, Zhang R, Zhang Z, Zhang H, Chan DW. Development of a glycoproteomic strategy to detect more aggressive prostate cancer using lectin-immunoassays for serum fucosylated PSA. Clinical proteomics. 2019;16:13.PubMed PMID: 30996714; PubMed Central PMCID: PMC6451306; DOI:10.1186/s12014-019-9234-4.
42. Hristova VA, Chan DW. Cancer biomarker discovery and translation: proteomics and beyond. Expert review of proteomics. 2019 February;16(2):93-103. PubMed PMID:30556752; PubMed Central PMCID: PMC6635916; DOI: 10.1080/14789450.2019.1559062.
43. Song J, Sokoll LJ, Pasay JJ, Rubin AL, Li H, Bach DM, Chan DW, Zhang Z. Identification of Serum Biomarker Panels for the Early Detection of Pancreatic Cancer. Cancer epidemiology, biomarkers & prevention: a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology. 2019 January;28(1):174-182. PubMed PMID: 30333219; PubMed Central PMCID: PMC6324978.
44. Hemken PM, Sokoll LJ, Yang X, Dai J, Elliott D, Gawel SH, Lucht M, Feng Z, Marrero J A, Srivastava S, Chan DW, Davis GJ. Validation of a novel model for the early detection of hepatocellular carcinoma. Clinical proteomics. 2019 January 16;16:2.PubMed PMID: 30675135; PubMed Central PMCID: PMC6334458.
45. Li QK, Shah P, Tian Y, Hu Y, Roden RBS, Zhang H, Chan DW. An integrated proteomic and glycoproteomic approach uncovers differences in glycosylation occupancy from benign and malignant epithelial ovarian tumors. Clinical proteomics. 2017;14:16.PubMed PMID: 28491011; PubMed Central PMCID: PMC5424371.
46. Sanda MG, Feng Z, Howard DH, Tomlins SA, Sokoll LJ, Chan DW, Regan MM, Groskopf J, Chipman J, Patil DH, Salami SS, Scherr DS, Kagan J, Srivastava S,Thompson IM Jr, Siddiqui J, Fan J, Joon AY, Bantis LE, Rubin MA, Chinnayian AM, Wei JT, Bidair M, Kibel A, Lin DW, Lotan Y, Partin A, Taneja S. Association Between Combined TMPRSS2:ERG and PCA3 RNA Urinary Testing and Detection of

Aggressive Prostate Cancer. JAMA oncology. 2017 August 1;3(8):1085-1093. PubMed PMID: 28520829; PubMed Central PMCID: PMC5710334.
47. Tosoian JJ, Patel HD, Mamawala M, Landis P, Wolf S, Elliott DJ, Epstein JI, Carter HB, Ross AE, Sokoll LJ, Pavlovich CP. Longitudinal assessment of urinary PCA3 for predicting prostate cancer grade reclassification in favorable-risk men during active surveillance. Prostate cancer and prostatic diseases. 2017 September;20(3):339-342. PubMed PMID: 28417979; PubMed Central PMCID: PMC5555773.
48. Loeb S, Shin SS, Broyles DL, Wei JT, Sanda M, Klee G, Partin AW, Sokoll L, Chan DW, Bangma CH, van Schaik RH, Slawin KM, Marks LS, Catalona WJ. Prostate Health Index improves multivariable risk prediction of aggressive prostate cancer. BJU Int. 2017 July 120:61-8. PMID: 27743489.
49. Crutchfield CA, Thomas SN, Sokoll LJ, Chan DW. Advances in mass spectrometry-based clinical biomarker discovery. Clin Proteomics. 2016 Jan 7;13:1. PMID: 26751220.
50. Sokoll LJ, Zhang Z, Chan DW, Reese AC, Bivalacqua TJ, Partin AW, Walsh PC. Do Ultrasensitive Prostate Specific Antigen Measurements Have a Role in Predicting Long-Term Biochemical Recurrence-Free Survival in Men after Radical Prostatectomy? J Urol. 2016 Feb;195(2):330-6. PMID: 26307160.
51. Chambliss AB, Chan DW. Precision medicine: from pharmacogenomics to pharmacoproteomics. Clin Proteomics. 2016 Sep 26;13:25. PMID: 27708556.
52. Sun S, Shah P, Eshghi ST, Yang W, Trikannad N, Yang S, Chen L, Aiyetan P, Höti N, Zhang Z, Chan DW, Zhang H. Comprehensive analysis of protein glycosylation by solidphase extraction of N-linked glycans and glycosite-containing peptides. Nature biotechnology. 2016 January;34(1):84-8. PubMed PMID: 26571101; PubMed Central PMCID: PMC4872599.
53. Coleman RL, Herzog TJ, Chan DW, Munroe DG, Pappas TC, Smith A, Zhang Z, Wolf J. Validation of a second-generation multivariate index assay for malignancy risk of adnexal masses. J Obstet Gynecol. 2016 Jul;215(1):82.e1-82.e11. PMID: 26970494.
54. Loeb S, Shin SS, Broyles DL, Wei JT, Sanda M, Klee G, Partin AW, Sokoll L, Chan DW, Bangma CH, van Schaik RH, Slawin KM, Marks LS, Catalona WJ. Prostate Health Index improves multivariable risk prediction of aggressive prostate cancer. BJU international. 2016 October 15. PubMed PMID: 27743489.
55. Hannigan GD, Duhaime MB, Ruffin MT 4th, Koumpouras CC, Schloss PD. Diagnostic Potential and Interactive Dynamics of the Colorectal Cancer Virome. mBio. 2018 Nov 20;9(6):e02248-18. doi: 10.1128/mBio.02248-18. PMID: 30459201; PMCID: PMC6247079.
56. Gupta S, Lieberman D, Anderson JC, Burke CA, Dominitz JA, Kaltenbach T, Robertson DJ, Shaukat A, Syngal S, Rex DK. Recommendations for Follow-Up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol. 2020 Mar;115(3):415-434. doi: 10.14309/ajg.0000000000000544. PMID: 32039982.
57. Baxter NT, Ruffin MT 4th, Rogers MA, Schloss PD. Microbiota-based model improves the sensitivity of fecal immunochemical test for detecting colonic lesions. Genome Med. 2016 Apr 6;8(1):37. doi: 10.1186/s13073-016-0290-3. PMID: 27056827; PMCID: PMC4823848.
58. Gupta S, Lieberman D, Anderson JC, Burke CA, Dominitz JA, Kaltenbach T, Robertson DJ, Shaukat A, Syngal S, Rex DK. Recommendations for Follow-Up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2020 Mar;158(4):1131-1153.e5. doi: 10.1053/j.gastro.2019.10.026. Epub 2020 Feb 7. PMID: 32044092.

59. Baxter NT, Koumpouras CC, Rogers MA, Ruffin MT 4th, Schloss PD. DNA from fecal immunochemical test can replace stool for detection of colonic lesions using a microbiota-based model. Microbiome. 2016 Nov 14;4(1):59. doi: 10.1186/s40168-016-0205-y. PMID: 27842559; PMCID: PMC5109736.
60. Poneros JM, Faye AS, Barr Fritcher EG, Sen A, Anandasabapathy S, Bresalier RS, Marcon N, Turgeon DK, Appelman H, Normolle D, Morrison LE, Brenner DE, Halling KC. A Multicenter Study of a Fluorescence In Situ Hybridization Probe Set for Diagnosing High-Grade Dysplasia and Adenocarcinoma in Barrett's Esophagus. Dig Dis Sci. 2017 May;62(5):1216-1222. doi: 10.1007/s10620-017-4517-y. Epub 2017 Mar 6. PMID: 28265829; PMCID: PMC6052443.
61. Gao Y, Wang Y-T, Chen Y, Wang H, Young D, Shi T, Song Y, Schepmoes AA, Kuo C, Fillmore TL, Qian W-J, Smith RD, Srivastava S, Kagan J, Dobi A, Srivastava S, Sesterhenn IA, Rosner IL, Petrovics G, Rodland KD, Cullen J, Liu T.: Proteomic Tissue-based Classifier for Early Prediction of Prostate Cancer Progression, Cancers, May 17;12(5):E1268, (2020).
62. Yan W, Jamal M, Tan S-H, Song Y, Young D, Chen Y, Katta S, Ying K, Ravindranath L, Woodle T, Kohaar I, Cullen J, Kagan J, Srivastava S, Dobi A, McLeod DG, Rosner IL, Sesterhenn IA, Srinivasan A, Srivastava S, Petrovics G.: Molecular profiling of radical prostatectomy tissue from patients with no sign of progression identifies ERG the strongest independent predictor of recurrence. Oncotarget, 10, 6466-6483 (2019).
63. Xiao Q, Sun Y, Dobi A, Srivastava S, Wang W, Srivastava S, Ji Y, Hou J, Zhao GP, Li Y, Li H. Systematic analysis reveals molecular characteristics of ERG-negative prostate cancer. Sci Rep. 2018 Aug 27;8(1):12868. doi: 10.1038/s41598-018-30325-9. PMID: 30150711; PMCID: PMC6110738.
64. Cullen J, Young D, Chen Y, Degon, M, Farrell J, Sedarsky J, Baptiste W, Rosen P, Tolstikov V, Kiebish M, Kagan J, Srivastava S, Kuo H-C, Moncur JT, Rosner IL, Narain N, Akmaev V, Petrovics G, Dobi A, McLeod DG, Srivastava S, Sesterhenn IA.: Predicting prostate cancer progression as a function of ERG status, race & obesity in a longitudinal patient cohort. European Urology Focus 4, 818-824 (2018).
65. Rastogi A, Ali A, Tan S-H, Banerjee S, Chen Y, Cullen J, Xavier CP, Mohamed AA, Ravindranath L, Srivastav J, Young D, Sesterhenn IA, Kagan J, Srivastava S, McLeod DG, Rosner IL, Petrovics G, Dobi A, Srivastava S, Srinivasan A.: Autoantibodies against oncogenic ERG protein in prostate cancer: potential use in diagnosis and prognosis in a panel with C-MYC, AMACR and HERV-K Gag. Genes & Cancer 7, 394-413 (2016).
66. Reimers MA, Yip SM, Zhang L, Cieslik M, Dhawan M, Montgomery B, Wyatt AW, Chi KN, Small EJ, Chinnaiyan AM, Alva AS, Feng FY, Chou J. Clinical Outcomes in Cyclin-dependent Kinase 12 Mutant Advanced Prostate Cancer. Eur Urol. 2020;77(3):333-341. PMID: 31640893
67. Parolia A, Cieslik M, Chu SC, Xiao L, Ouchi T, Zhang Y, Wang X, Vats P, Cao X, Pitchiaya S, Su F, Wang R, Feng FY, Wu YM, Lonigro RJ, Robinson DR, Chinnaiyan AM. Distinct structural classes of activating FOXA1 alterations in advanced prostate cancer. Nature. 2019 Jul;571(7765):413-418. doi: 10.1038/s41586-019-1347-4. Epub 2019 Jun 26. PubMed PMID: 31243372; PubMed Central PMCID: PMC6661908.
68. Vo JN, Cieslik M, Zhang Y, Shukla S, Xiao L, Zhang Y, Wu YM, Dhanasekaran SM, Engelke CG, Cao X, Robinson DR, Nesvizhskii AI, Chinnaiyan AM. The Landscape of Circular RNA in Cancer. Cell. 2019 Feb 7;176(4):869-881.e13. doi: 10.1016/j.cell.2018.12.021. PubMed PMID: 30735636.
69. Salami SS, Hovelson DH, Kaplan JB, Mathieu R, Udager AM, Curci NE, Lee M, Plouffe KR, de la Vega LL, Susani M, Rioux-Leclercq N, Spratt DE, Morgan TM, Davenport MS, Chinnaiyan AM, Cyrta J, Rubin MA, Shariat SF, Tomlins SA, Palapattu GS. Transcriptomic heterogeneity in multifocal prostate

cancer. JCI Insight. 2018 Nov 2;3(21). pii: 123468. doi: 10.1172/jci.insight.123468. PubMed PMID: 30385730; PubMed Central PMCID: PMC6238741.

70. Mehra R, Salami SS, Lonigro R, Bhalla R, Siddiqui J, Cao X, Spratt DE, Palapattu GS, Palanisamy N, Wei JT, Chinnaiyan AM, Tomlins SA. Association of ERG/PTEN status with biochemical recurrence after radical prostatectomy for clinically localized prostate cancer. Med Oncol. 2018 Oct 5;35(12):152. doi: 10.1007/s12032-018-1212-6. PubMed PMID: 30291535.
71. Quigley DA, Dang HX, Zhao SG, Lloyd P, Aggarwal R, Alumkal JJ, Foye A, Kothari V, Perry MD, Bailey AM, Playdle D, Barnard TJ, Zhang L, Zhang J, Youngren JF, Cieslik MP, Parolia A, Beer TM, Thomas G, Chi KN, Gleave M, Lack NA, Zoubeidi A, Reiter RE, Rettig MB, Witte O, Ryan CJ, Fong L, Kim W, Friedlander T, Chou J, Li H, Das R, Li H, Moussavi-Baygi R, Goodarzi H, Gilbert LA, Lara PN Jr, Evans CP, Goldstein TC, Stuart JM, Tomlins SA, Spratt DE, Cheetham RK, Cheng DT, Farh K, Gehring JS, Hakenberg J, Liao A, Febbo PG, Shon J, Sickler B, Batzoglou S, Knudsen KE, He HH, Huang J, Wyatt AW, Dehm SM, Ashworth A, Chinnaiyan AM, Maher CA, Small EJ, Feng FY. Genomic Hallmarks and Structural Variation in Metastatic Prostate Cancer. Cell. 2018 Oct 18;175(3):889. doi: 10.1016/j.cell.2018.10.019. PubMed PMID: 30340047.
72. Niknafs YS, Pandian B, Gajjar T, Gaudette Z, Wheelock K, Maz MP, Achar RK, Song M, Massaro C, Cao X, Chinnaiyan AM. MiPanda: A Resource for Analyzing and Visualizing Next-Generation Sequencing Transcriptomics Data. Neoplasia. 2018 Nov;20(11):1144-1149. doi: 10.1016/j.neo.2018.09.001. Epub 2018 Sep 27. PubMed PMID: 30268942; PubMed Central PMCID: PMC6171536.
73. Mehra R, Vats P, Cao X, Su F, Lee ND, Lonigro R, Premkumar K, Trpkov K, McKenney JK, Dhanasekaran SM, Chinnaiyan AM. Somatic Bi-allelic Loss of TSC Genes in Eosinophilic Solid and Cystic Renal Cell Carcinoma. European urology. 2018 October;74(4):483-486. PubMed PMID: 29941307; PubMed Central PMCID: PMC6390848.
74. Kumar-Sinha C, Chinnaiyan AM. Precision oncology in the age of integrative genomics. Nature biotechnology. 2018 January 10;36(1):46-60. PubMed PMID: 29319699; PubMed Central PMCID: PMC6364676.
75. Zhang Y, Pitchiaya S, Cieślik M, Niknafs YS, Tien JC, Hosono Y, Iyer MK, Yazdani S, Subramaniam S, Shukla SK, Jiang X, Wang L, Liu TY, Uhl M, Gawronski AR, Qiao Y, Xiao L, Dhanasekaran SM, Juckette KM, Kunju LP, Cao X, Patel U, Batish M, Shukla GC, Paulsen MT, Ljungman M, Jiang H, Mehra R, Backofen R, Sahinalp CS, Freier SM, Watt AT, Guo S, Wei JT, Feng FY, Malik R, Chinnaiyan AM. Analysis of the androgen receptor-regulated lncRNA landscape identifies a role for ARLNC1 in prostate cancer progression. Nature genetics. 2018 June;50(6):814-824. PubMed PMID: 29808028; PubMed Central PMCID: PMC5980762.
76. Wu YM, Cieślik M, Lonigro RJ, Vats P, Reimers MA, Cao X, Ning Y, Wang L, Kunju LP, de Sarkar N, Heath EI, Chou J, Feng FY, Nelson PS, de Bono JS, Zou W, Montgomery B, Alva A, Robinson DR, Chinnaiyan AM. Inactivation of CDK12 Delineates a Distinct Immunogenic Class of Advanced Prostate Cancer. Cell. 2018 June 14;173(7):1770-1782.e14. PubMed PMID: 29906450; PubMed Central PMCID: PMC6084431
77. Niknafs YS, Pandian B, Iyer HK, Chinnaiyan AM, Iyer MK. TACO produces robust multisample transcriptome assemblies from RNA-seq. Nature methods. 2017 January;14(1):68-70. PubMed PMID: 27869815; PubMed Central PMCID: PMC5199618.
78. Hosono Y, Niknafs YS, Prensner JR, Iyer MK, Dhanasekaran SM, Mehra R, Pitchiaya S, Tien J, Escara-Wilke J, Poliakov A, Chu SC, Saleh S, Sankar K, Su F, Guo S, Qiao Y, Freier SM, Bui HH, Cao X, Malik R, Johnson TM, Beer DG, Feng FY, Zhou W, Chinnaiyan AM. Oncogenic Role of THOR, a Conserved

Cancer/Testis Long Non-coding RNA. Cell. 2017 Dec 14;171(7):1559-1572.e20. doi: 10.1016/j.cell.2017.11.040. PubMed PMID: 29245011; PubMed Central PMCID:

79. Robinson DR, Wu YM, Lonigro RJ, Vats P, Cobain E, Everett J, Cao X, Rabban E, Kumar-Sinha C, Raymond V, Schuetze S, Alva A, Siddiqui J, Chugh R, Worden F, Zalupski MM, Innis J, Mody RJ, Tomlins SA, Lucas D, Baker LH, Ramnath N, Schott AF, Hayes DF, Vijai J, Offit K, Stoffel EM, Roberts JS, Smith DC, Kunju LP, Talpaz M, Cieślik M, Chinnaiyan AM. Integrative clinical genomics of metastatic cancer. Nature. 2017 August 17;548(7667):297-303. PubMed PMID: 28783718; PubMed Central PMCID: PMC5995337
80. Wang X, Qiao Y, Asangani IA, Ateeq B, Poliakov A, CieÅ›lik M, Pitchiaya S, Chakravarthi BVSK, Cao X, Jing X, Wang CX, Apel IJ, Wang R, Tien JC, Juckette KM, Yan W, Jiang H, Wang S, Varambally S, Chinnaiyan AM. Development of Peptidomimetic Inhibitors of the ERG Gene Fusion Product in Prostate Cancer. Cancer Cell. 2017 Apr 10;31(4):532-548.e7. doi: 10.1016/j.ccell.2017.02.017. Epub 2017 Mar 23. PubMed PMID: 28344039; PubMed Central PMCID: PMC5443258.
81. Blattner M, Liu D, Robinson BD, Huang D, Poliakov A, Gao D, Nataraj S, Deonarine LD, Augello MA, Sailer V, Ponnala L, Ittmann M, Chinnaiyan AM, Sboner A, Chen Y, Rubin MA, Barbieri CE. SPOP Mutation Drives Prostate Tumorigenesis In Vivo through Coordinate Regulation of PI3K/mTOR and AR Signaling. Cancer Cell. 2017 Mar 13;31(3):436-451. doi: 10.1016/j.ccell.2017.02.004. PubMed PMID: 28292441; PubMed Central PMCID: PMC5384998.
82. Mani RS, Amin MA, Li X, Kalyana-Sundaram S, Veeneman BA, Wang L, Ghosh A, Aslam A, Ramanand SG, Rabquer BJ, Kimura W, Tran M, Cao X, Roychowdhury S, Dhanasekaran SM, Palanisamy N, Sadek HA, Kapur P, Koch AE, Chinnaiyan AM. Inflammation-Induced Oxidative Stress Mediates Gene Fusion Formation in Prostate Cancer. Cell Rep. 2016 Dec 6;17(10):2620-2631. doi: 10.1016/j.celrep.2016.11.019. PubMed PMID: 27926866; PubMed Central PMCID: PMC5147555.
83. Shukla S, Zhang X, Niknafs YS, Xiao L, Mehra R, Cieslik M, Ross A, Schaeffer E, Malik B, Guo S, Freier SM, Bui HH, Siddiqui J, Jing X, Cao X, Dhanasekaran SM, Feng FY, Chinnaiyan AM, Malik R. Identification and Validation of PCAT14 as Prognostic Biomarker in Prostate Cancer. Neoplasia. 2016 Aug;18(8):489-99. doi: 10.1016/j.neo.2016.07.001. PubMed PMID: 27566105; PubMed Central PMCID: PMC5018094.
84. Udager AM, DeMarzo AM, Shi Y, Hicks JL, Cao X, Siddiqui J, Jiang H, Chinnaiyan AM, Mehra R. Concurrent nuclear ERG and MYC protein overexpression defines a subset of locally advanced prostate cancer: Potential opportunities for synergistic targeted therapeutics. e. 2016 Jun;76(9):845-53. doi:10.1002/pros.23175. Epub 2016 Mar 8. PubMed PMID: 27159573; PubMed Central PMCID: PMC4975940.
85. Qiao Y, Feng FY, Wang Y, Cao X, Han S, Wilder-Romans K, Navone NM, Logothetis C, Taichman RS, Keller ET, Palapattu GS, Alva AS, Smith DC, Tomlins SA, Chinnaiyan AM, Morgan TM. Mechanistic Support for Combined MET and AR Blockade in Castration-Resistant Prostate Cancer. Neoplasia. 2016 Jan;18(1):1-9. doi: 10.1016/j.neo.2015.11.009. PubMed PMID: 26806347; PubMed Central PMCID: PMC4735600.
86. Quigley DA, Dang HX, Zhao SG, Lloyd P, Aggarwal R, Alumkal JJ, Foye A, Kothari V, Perry MD, Bailey AM, Playdle D, Barnard TJ, Zhang L, Zhang J, Youngren JF, Cieslik MP, Parolia A, Beer TM, Thomas G, Chi KN, Gleave M, Lack NA, Zoubeidi A, Reiter RE, Rettig MB, Witte O, Ryan CJ, Fong L, Kim W, Friedlander T, Chou J, Li H, Das R, Li H, Moussavi-Baygi R, Goodarzi H, Gilbert LA, Lara PN Jr, Evans CP, Goldstein TC, Stuart JM, Tomlins SA, Spratt DE, Cheetham RK, Cheng DT, Farh K, Gehring JS, Hakenberg J, Liao A, Febbo PG, Shon J, Sickler B, Batzoglou S, Knudsen KE, He HH, Huang J, Wyatt

AW, Dehm SM, Ashworth A, Chinnaiyan AM, Maher CA, Small EJ, Feng FY. Genomic Hallmarks and Structural Variation in Metastatic Prostate Cancer. Cell. 2018 Jul 26;174(3):758-769.e9. doi: 10.1016/j.cell.2018.06.039. Epub 2018 Jul 19. Erratum in: Cell. 2018 Oct 18;175(3):889. PMID: 30033370; PMCID: PMC6425931.

87. Slack FJ, Chinnaiyan AM. The Role of Non-coding RNAs in Oncology. Cell. 2019 Nov 14;179(5):1033-1055. doi: 10.1016/j.cell.2019.10.017. PMID: 31730848.
88. Tosoian JJ, Chinnaiyan AM. Translating Science to Medicine: When Will the Rubber Meet the Road? Eur Urol. 2019 Nov;76(5):560-561. doi: 10.1016/j.eururo.2019.08.023. Epub 2019 Sep 8. PMID: 31506226.
89. Khoo A, Liu LY, Nyalwidhe JO, Semmes OJ, Vesprini V, Downes MR, Boutros PC, Liu SK & Kislinger T. Proteomic discovery of prostate cancer biomarkers using mass spectrometry. Nature Reviews Urology 2020 (under review)
90. Otto JJ, Correll VL, Engstroem HA, Main BP, Weaver B, Johnson-Pais T, Yang LF, Boutros PC, Kislinger T, Leach RJ, Semmes OJ and Nyalwidhe JO. Targeted Mass Spectrometry of a Clinically Relevant PSA Variant from Post-DRE Urines for Genotype Determination. Proteomics Clinical Applications 2020 (under review)
91. Kishan, Amar U. et al. Local Failure and Survival After Definitive Radiotherapy for Aggressive Prostate Cancer: An Individual Patient-level Meta-analysis of Six Randomized Trials. European Urology, Volume 77, Issue 2, 201 – 208 (2020).
92. Hoey C, Jeyapala R, Boutros PC, Bapat B, Liu SK. Urinary biomarkers in prostate cancer: to the miRnome and beyond. Translational Andrology and Urology; 9(2) (2020).
93. Sinha A, Huang V, Livingstone J, Wang J, Fox NS, Kurganovs N, Ignatchenko V, Fritsch K, Donmez N, Heisler LE, Shiah YJ, Yao CQ, Alfaro JA, Volik S, Lapuk A, Fraser M, Kron K, Murison A, Lupien M, Sahinalp C, Collins CC, Tetu B, Masoomian M, Berman DM, van der Kwast T, Bristow RG, Kislinger T* & Boutros PC*. The Proteogenomic Landscape of Curable Prostate Cancer. Cancer Cell; 35(3):414-427 (2019)
94. Haynes BA, Yang L-F, Huyck RW, Lehrer EJ, Cimring J, Turner JM, Barabutis N, Catravas J, Correll VJ, Wohlgemuth S, McPheat W, Semmes OJ and Dobrian AD. Endothelial to Mesenchymal Transition in Human Adipose Tissue Vasculature Alters the Particulate Secretome and Induces Endothelial Dysfunction. Arteriosclerosis, Thrombosis and Vascular Biology 39:2168-2191 (2019).
95. Macklin A, Khan S & Kislinger T. Recent Advances in Mass Spectrometry Based Clinical Proteomics: Applications to Cancer Research. Clinical Proteomics, 17: 1-25 (2020)
96. Mesci, A., Lucien, F., Huang, X. et al. RSPO3 is a prognostic biomarker and mediator of invasiveness in prostate cancer. J Transl Med 17, 125 (2019)
97. Ray, J., Hoey, C., Huang, X., Jeon, J., Taeb, S., Downes, M.R. ... Liu, S.K. MicroRNA 198 suppresses prostate tumorigenesis by targeting MIB1. Oncology Reports, 42, 1047-1056. (2019).
98. van Dessel, L.F., van Riet, J., Smits, M. et al. The genomic landscape of metastatic castration-resistant prostate cancers reveals multiple distinct genotypes with potential clinical impact. Nat Commun 10, 5251 (2019).
99. Houlahan KE, Shiah YJ, Gusev A, et al. Genome-wide germline correlates of the epigenetic landscape of prostate cancer. Nat Med.;25(10):1615-1626. (2019)
100. Jeon J, Olkhov-Mitsel E, Xie H, Yao CQ, Zhao F, Jahangiri S, Cuizon C, Scarcello S, Jeyapala R, Watson JD, Fraser M, Ray J, Commisso K, Loblaw A, Fleshner NE, Bristow RG, Downes M, Vesprini D, Liu S,

Bapat B, Boutros PC. Temporal stability and prognostic biomarker potential of the prostate cancer urine transcriptome. J Natl Cancer Inst. (2019)

101. Hasegawa T, Glavich GJ, Pahuski M, Semmes OJ, Yang L, Galkin V, Drake R and Esquela-Kerscher A. Characterization and evidence of the miR-888 cluster as a novel cancer network in Prostate. Molecular Cancer Research 16(4), 669-681 (2018).
102. Alfaro A, Ignatchenko A, Ignatchenko A, Sinha A, Boutros PC & Kislinger T. Detecting protein variants by mass-spectrometry: A comprehensive study in cancer cell-lines. Genome Med ; 9(1):62 (2017)
103. Houlahan KE, Shiah YJ, Gusev A, Yuan J, Ahmed M, Shetty A, Ramanand SG, Yao CQ, Bell C, O'Connor E, Huang V, Fraser M, Heisler LE, Livingstone J, Yamaguchi TN, Rouette A, Foucal A, Espiritu SMG, Sinha A, Sam M, Timms L, Johns J, Wong A, Murison A, Orain M, Picard V, Hovington H, Bergeron A, Lacombe L, Lupien M, Fradet Y, Têtu B, McPherson JD, Pasaniuc B, Kislinger T, Chua MLK, Pomerantz MM, van der Kwast T, Freedman ML, Mani RS, He HH, Bristow RG, Boutros PC. Genome-wide germline correlates of the epigenetic landscape of prostate cancer. Nat Med. 2019 Oct;25(10):1615-1626. doi: 10.1038/s41591-019-0579-z. Epub 2019 Oct 7. PMID: 31591588.
104. Sinha A, Huang V, Livingstone J, Wang J, Fox NS, Kurganovs N, Ignatchenko V, Fritsch K, Donmez N, Heisler LE, Shiah YJ, Yao CQ, Alfaro JA, Volik S, Lapuk A, Fraser M, Kron K, Murison A, Lupien M, Sahinalp C, Collins CC, Tetu B, Masoomian M, Berman DM, van der Kwast T, Bristow RG, Kislinger T, Boutros PC. The Proteogenomic Landscape of Curable Prostate Cancer. Cancer Cell. 2019 Mar 18;35(3):414-427.e6. doi: 10.1016/j.ccell.2019.02.005. PMID: 30889379; PMCID: PMC6511374.
105. Houlahan KE, Shiah YJ, Gusev A, Yuan J, Ahmed M, Shetty A, Ramanand SG, Yao CQ, Bell C, O'Connor E, Huang V, Fraser M, Heisler LE, Livingstone J, Yamaguchi TN, Rouette A, Foucal A, Espiritu SMG, Sinha A, Sam M, Timms L, Johns J, Wong A, Murison A, Orain M, Picard V, Hovington H, Bergeron A, Lacombe L, Lupien M, Fradet Y, Têtu B, McPherson JD, Pasaniuc B, Kislinger T, Chua MLK, Pomerantz MM, van der Kwast T, Freedman ML, Mani RS, He HH, Bristow RG, Boutros PC. Genome-wide germline correlates of the epigenetic landscape of prostate cancer. Nat Med. 2019 Oct;25(10):1615-1626. doi: 10.1038/s41591-019-0579-z. Epub 2019 Oct 7. PMID: 31591588.
106. Alfaro JA, Ignatchenko A, Ignatchenko V, Sinha A, Boutros PC, Kislinger T. Detecting protein variants by mass spectrometry: a comprehensive study in cancer cell-lines. Genome Med. 2017 Jul 18;9(1):62. doi: 10.1186/s13073-017-0454-9. PMID: 28716134; PMCID: PMC5514513.
107. Höti N, Lih TS, Pan J, Zhou Y, Yang G, Deng A, Chen L, Dong M, Yang RB, Tu CF, Haffner MC, Kay Li Q, Zhang H. A Comprehensive Analysis of FUT8 Overexpressing Prostate Cancer Cells Reveals the Role of EGFR in Castration Resistance. Cancers. 2020 Feb 18;12(2). doi: 10.3390/cancers12020468. PubMed PMID: 32085441; PubMed Central PMCID: PMC7072180.
108. Cho KC, Clark DJ, Schnaubelt M, Teo GC, Leprevost FDV, Bocik W, Boja ES, Hiltke T, Nesvizhskii AI, Zhang H. Deep Proteomics Using Two Dimensional Data Independent Acquisition Mass Spectrometry. Anal Chem. 2020 Mar 17;92(6):4217-4225. doi: 10.1021/acs.analchem.9b04418. Epub 2020 Feb 26. PubMed PMID: 32058701; PubMed Central PMCID: PMC7255061.
109. Clark DJ, Hu Y, Schnaubelt M, Fu Y, Ponce S, Chen SY, Zhou Y, Shah P, Zhang H. Simple Tip-Based Sample Processing Method for Urinary Proteomic Analysis. Anal Chem. 2019 May 7;91(9):5517-5522. doi: 10.1021/acs.analchem.8b05234. Epub 2019 Apr 8. PubMed PMID: 30924636; PubMed Central PMCID: PMC6512789.
110. Sun S, Hu Y, Ao M, Shah P, Chen J, Yang W, Jia X, Tian Y, Thomas S, Zhang H. N-GlycositeAtlas: a database resource for mass spectrometry-based human N-linked glycoprotein and glycosylation site

mapping. Clin Proteomics. 2019;16:35. doi: 10.1186/s12014-019-9254-0. eCollection 2019. PubMed PMID: 31516400; PubMed Central PMCID: PMC6731604.

111. Wang C, Höti N, Lih TM, Sokoll LJ, Zhang R, Zhang Z, Zhang H, Chan DW. Development of a glycoproteomic strategy to detect more aggressive prostate cancer using lectin-immunoassays for serum fucosylated PSA. Clin Proteomics. 2019;16:13. doi: 10.1186/s12014-019-9234-4. eCollection 2019. PubMed PMID: 30996714; PubMed Central PMCID: PMC6451306
112. Yang W, Ao M, Hu Y, Li QK, Zhang H. Mapping the O- glycoproteome using site-specific extraction of O-linked glycopeptides (EXoO). Mol Syst Biol. 2018 Nov 20;14(11):e8486. doi: 10.15252/msb.20188486. PubMed PMID: 30459171; PubMed Central PMCID: PMC6243375.
113. Höti N, Yang S, Hu Y, Shah P, Haffner MC, Zhang H. Overexpression of α (1,6) fucosyltransferase in the development of castration-resistant prostate cancer cells. Prostate Cancer Prostatic Dis. 2018 Apr;21(1):137-146. doi: 10.1038/s41391-017-0016-7.Epub 2018 Jan 16. PubMed PMID: 29339807; PubMed Central PMCID: PMC5895601.
114. Yang W, Shah P, Hu Y, Toghi Eshghi S, Sun S, Liu Y, Zhang H. Comparison of Enrichment Methods for Intact N- and O-Linked Glycopeptides Using Strong Anion Exchange and Hydrophilic Interaction Liquid Chromatography. Anal Chem. 2017 Nov 7;89(21):11193-11197. doi: 10.1021/acs.analchem.7b03641. Epub 2017 Oct 12. PubMed PMID: 29016103; PubMed Central PMCID: PMC5850954.
115. Höti N, Yang S, Aiyetan P, Kumar B, Hu Y, Clark D, Eroglu AU, Shah P, Johnson T, Chowdery WH, Zhang H, Rodriguez R. Overexpression of Exportin-5 Overrides the Inhibitory Effect of miRNAs Regulation Control and Stabilize Proteins via Posttranslation Modifications in Prostate Cancer. Neoplasia. 2017 Oct;19(10):817-829. doi: 10.1016/j.neo.2017.07.008. Epub 2017 Sep 4. PubMed PMID: 28881308; PubMed Central PMCID: PMC5587889.
116. Zhou J, Yang W, Hu Y, Höti N, Liu Y, Shah P, Sun S, Clark D, Thomas S, Zhang H. Site-Specific Fucosylation Analysis Identifying Glycoproteins Associated with Aggressive Prostate Cancer Cell Lines Using Tandem Affinity Enrichments of Intact Glycopeptides Followed by Mass Spectrometry. Anal Chem. 2017 Jul 18;89(14):7623-7630. doi: 10.1021/acs.analchem.7b01493. Epub 2017 Jul 3. PubMed PMID: 28627880; PubMed Central PMCID: PMC5599242.
117. Yang S, Hu Y, Sokoll L, Zhang H. Simultaneous quantification of N- and O-glycans using a solid-phase method. Nat Protoc. 2017 Jun;12(6):1229-1244. doi: 10.1038/nprot.2017.034. Epub 2017 May 18. PubMed PMID: 28518173; PubMed Central PMCID: PMC5877797.
118. Höti N, Shah P, Hu Y, Yang S, Zhang H. Proteomics analyses of prostate cancer cells reveal cellular pathways associated with androgen resistance. Proteomics. 2017 Mar;17(6). doi: 10.1002/pmic.201600228. PubMed PMID: 28116790; PubMed Central PMCID: PMC5516940.
119. Jia X, Chen J, Sun S, Yang W, Yang S, Shah P, Hoti N, Veltri B, Zhang H. Detection of aggressive prostate cancer associated glycoproteins in urine using glycoproteomics and mass spectrometry. Proteomics. 2016 Dec;16(23):2989-2996. doi: 10.1002/pmic.201500506. PubMed PMID: 27749016; PubMed Central PMCID: PMC5407186.
120. Clark DJ, Schnaubelt M, Hoti N, Hu Y, Zhou Y, Gooya M, Zhang H. Impact of Increased FUT8 Expression on the Extracellular Vesicle Proteome in Prostate Cancer Cells. J Proteome Res. 2020 May 18;. doi: 10.1021/acs.jproteome.9b00578. [Epub ahead of print] PubMed PMID: 32378902.
121. Chen SY, Dong M, Yang G, Zhou Y, Clark DJ, Lih TM, Schnaubelt M, Liu Z, Zhang H. Glycans, Glycosite, and Intact Glycopeptide Analysis of N-Linked Glycoproteins Using Liquid Handling Systems. Anal

Chem. 2020 Jan 21;92(2):1680-1686. doi: 10.1021/acs.analchem.9b03761. Epub 2020 Jan 3. PubMed PMID: 31859482; NIHMSID:NIHMS1553117.
122. Yang W, Song A, Ao M, Xu Y, Zhang H. Large-scale Mapping of Site-specific O-GalNAc Glycoproteome. Nature Protocols. 2020; Accepted.
123. Osmani L, Askin F, Gabrielson E, Li QK. Current WHO guidelines and the critical role of immunohistochemical markers in the subclassification of non-small cell lung carcinoma (NSCLC): Moving from targeted therapy to immunotherapy. Semin Cancer Biol. 2018 Oct;52(Pt 1):103-109. doi: 10.1016/j.semcancer.2017.11.019. Epub 2017 Nov 26. PMID: 29183778; PMCID: PMC5970946.
124. Liu Y, Gonzàlez-Porta M, Santos S, Brazma A, Marioni JC, Aebersold R, Venkitaraman AR, Wickramasinghe VO. Impact of Alternative Splicing on the Human Proteome. Cell Rep. 2017 Aug 1;20(5):1229-1241. doi: 10.1016/j.celrep.2017.07.025. PMID: 28768205; PMCID: PMC5554779.
125. Yang G, Hu Y, Sun S, Ouyang C, Yang W, Wang Q, Betenbaugh M, Zhang H. Comprehensive Glycoproteomic Analysis of Chinese Hamster Ovary Cells. Anal Chem. 2018 Dec 18;90(24):14294-14302. doi: 10.1021/acs.analchem.8b03520. Epub 2018 Dec 3. PMID: 30457839; PMCID: PMC6440468.
126. Yang S, Rubin A, Eshghi ST, Zhang H. Chemoenzymatic method for glycomics: Isolation, identification, and quantitation. Proteomics. 2016 Jan;16(2):241-56. doi: 10.1002/pmic.201500266. Epub 2015 Nov 6. PMID: 26390280; PMCID: PMC4715912.
127. Hu Y, Shah P, Clark DJ, Ao M, Zhang H. Reanalysis of Global Proteomic and Phosphoproteomic Data Identified a Large Number of Glycopeptides. Anal Chem. 2018 Jul 3;90(13):8065-8071. doi: 10.1021/acs.analchem.8b01137. Epub 2018 Jun 11. PMID: 29741879; PMCID: PMC6440470.
128. Toonstra C, Hu Y, Zhang H. Deciphering the Roles of N-Glycans on Collagen-Platelet Interactions. J Proteome Res. 2019 Jun 7;18(6):2467-2477. doi: 10.1021/acs.jproteome.9b00003. Epub 2019 May 15. PMID: 31055923; PMCID: PMC6624648.
129. Dang L, Jia L, Zhi Y, Li P, Zhao T, Zhu B, Lan R, Hu Y, Zhang H, Sun S. Mapping human N-linked glycoproteins and glycosylation sites using mass spectrometry. Trends Analyt Chem. 2019 May;114:143-150. doi: 10.1016/j.trac.2019.02.009. Epub 2019 Feb 13. PMID: 31831916; PMCID: PMC6907083.
130. Sun S, Hu Y, Jia L, Eshghi ST, Liu Y, Shah P, Zhang H. Site-Specific Profiling of Serum Glycoproteins Using N-Linked Glycan and Glycosite Analysis Revealing Atypical N-Glycosylation Sites on Albumin and α-1B-Glycoprotein. Anal Chem. 2018 May 15;90(10):6292-6299. doi: 10.1021/acs.analchem.8b01051. Epub 2018 May 1. PMID: 29671580; PMCID: PMC6467210.
131. McClain A, Sakowski L, Conti M, Zhang H, Li QK. Intranuclear Inclusions in Conventional Clear Cell Renal Cell Carcinoma (ccRCC): Diagnosis and Differential Diagnosis. Arch Urol Res. 2018;2(1):5-7. doi: 10.17352/aur.000003. Epub 2018 Oct 24. PMID: 31565700; PMCID: PMC6764522.
132. Inouye CM, Anagnostou V, Li QK. Primary parotid adenocarcinoma metastasis to the spleen with PIK3CA mutation: cytological findings and review of the literature. Int J Clin Exp Pathol. 2017;10(5):5999-6005. Epub 2017 May 15. PMID: 29263768; PMCID: PMC5733716.
133. Wang H, Li QK, Auster M, Gong G. PET and CT features differentiating infectious/inflammatory from malignant mediastinal lymphadenopathy: A correlated study with endobronchial ultrasound-guided transbronchial needle aspiration. Radiol Infect Dis. 2018 Mar;5(1):7-13. doi: 10.1016/j.jrid.2018.01.002. Epub 2018 Feb 1. PMID: 31692939; PMCID: PMC6831101.

134. Shah P, Yang W, Sun S, Pasay J, Faraday N, Zhang H. Platelet glycoproteins associated with aspirin-treatment upon platelet activation. Proteomics. 2017 Mar;17(6):10.1002/pmic.201600199. doi: 10.1002/pmic.201600199. Epub 2016 Sep 12. PMID: 27452734; PMCID: PMC5441238.
135. Yang S, Clark D, Liu Y, Li S, Zhang H. High-throughput analysis of N-glycans using AutoTip via glycoprotein immobilization. Sci Rep. 2017 Aug 31;7(1):10216. doi: 10.1038/s41598-017-10487-8. PMID: 28860471; PMCID: PMC5578957.
136. Yang S, Zhang L, Thomas S, Hu Y, Li S, Cipollo J, Zhang H. Modification of Sialic Acids on Solid Phase: Accurate Characterization of Protein Sialylation. Anal Chem. 2017 Jun 20;89(12):6330-6335. doi: 10.1021/acs.analchem.7b01048. Epub 2017 May 25. PMID: 28505427; PMCID: PMC5583724.
137. Shu J, Dang L, Zhang D, Shah P, Chen L, Zhang H, Sun S. Dynamic analysis of proteomic alterations in response to N-linked glycosylation inhibition in a drug-resistant ovarian carcinoma cell line. FEBS J. 2019 Apr;286(8):1594-1605. doi: 10.1111/febs.14811. Epub 2019 Apr 2. PMID: 30884134.
138. Toghi Eshghi S, Yang W, Hu Y, Shah P, Sun S, Li X, Zhang H. Classification of Tandem Mass Spectra for Identification of N- and O-linked Glycopeptides. Sci Rep. 2016 Nov 21;6:37189. doi: 10.1038/srep37189. PMID: 27869200; PMCID: PMC5116676.
139. Yang W, Jackson B, Zhang H. Identification of glycoproteins associated with HIV latently infected cells using quantitative glycoproteomics. Proteomics. 2016 Jul;16(13):1872-80. doi: 10.1002/pmic.201500215. Epub 2016 Jun 8. PMID: 27195445; PMCID: PMC5088786.
140. Yang S, Höti N, Yang W, Liu Y, Chen L, Li S, Zhang H. Simultaneous analyses of N-linked and O-linked glycans of ovarian cancer cells using solid-phase chemoenzymatic method. Clin Proteomics. 2017 Jan 13;14:3. doi: 10.1186/s12014-017-9137-1. PMID: 28100988; PMCID: PMC5237303.
141. Zhou Y, Lih TM, Yang G, Chen SY, Chen L, Chan DW, Zhang H, Li QK. An Integrated Workflow for Global, Glyco-, and Phospho-proteomic Analysis of Tumor Tissues. Anal Chem. 2020 Jan 21;92(2):1842-1849. doi: 10.1021/acs.analchem.9b03753. Epub 2020 Jan 3. PMID: 31859488.
142. Lilo MT, Allison D, Wang Y, Ao M, Gabrielson E, Geddes S, Zhang H, Askin F, Li QK. Expression of P40 and P63 in lung cancers using fine needle aspiration cases. Understanding clinical pitfalls and limitations. J Am Soc Cytopathol. 2016 May-Jun;5(3):123-132. doi: 10.1016/j.jasc.2015.07.002. PMID: 27699149; PMCID: PMC5044754.
143. Thomas SN, Zhang H. Targeted proteomic assays for the verification of global proteomics insights. Expert Rev Proteomics. 2016 Oct;13(10):897-899. doi: 10.1080/14789450.2016.1229601. Epub 2016 Sep 1. PMID: 27565203; PMCID: PMC5332399.
144. Li QK. Critical Role of Pathologists in the Accurate Subclassification of Non-Small Cell Lung Carcinoma (NSCLC) for Targeted Therapies: Evidence- Based Practice and the Role of IHC Markers. Diagn Pathol Open Access. 2016;1(3):e105. doi: 10.4172/2476-2024.1000e105. Epub 2016 Dec 31. PMID: 29722354; PMCID: PMC5926242.
145. Lu H. et al. Repeatability of Quantitative Imaging Features in Prostate Magnetic Resonance Imaging. Front Oncol 10:551 (2020).
146. Katchman BA, Chowell D, Wallstrom G, Vitonis AF, LaBaer J, Cramer DW, Anderson KS. Autoantibody biomarkers for the detection of serous ovarian cancer. Gynecol Oncol. 2017 Jul;146(1):129-136. doi: 10.1016/j.ygyno.2017.04.005. Epub 2017 Apr 18. PMID: 28427776; PMCID: PMC5519143.
147. Kaaks R, Fortner RT, Hüsing A, Barrdahl M, Hopper M, Johnson T, Tjønneland A, Hansen L, Overvad K, Fournier A, Boutron-Ruault MC, Kvaskoff M, Dossus L, Johansson M, Boeing H, Trichopoulou A, Benetou V, La Vecchia C, Sieri S, Mattiello A, Palli D, Tumino R, Matullo G, Onland-Moret NC, Gram IT, Weiderpass E, Sánchez MJ, Navarro Sanchez C, Duell EJ, Ardanaz E, Larranaga N, Lundin E, Idahl

A, Jirström K, Nodin B, Travis RC, Riboli E, Merritt M, Aune D, Terry K, Cramer DW, Anderson KS. Tumor-associated autoantibodies as early detection markers for ovarian cancer? A prospective evaluation. Int J Cancer. 2018 Aug 1;143(3):515-526. doi: 10.1002/ijc.31335. Epub 2018 Mar 8. PMID: 29473162; PMCID: PMC6019150.

148. Ewaisha R, Anderson KS. Proteomic Monitoring of B Cell Immunity. Methods Mol Biol. 2016;1403:131-52. doi: 10.1007/978-1-4939-3387-7_6. PMID: 27076128; PMCID: PMC5558855.
149. Ewaisha R, Meshay I, Resnik J, Katchman BA, Anderson KS. Programmable protein arrays for immunoprofiling HPV-associated cancers. Proteomics. 2016 Apr;16(8):1215-24. doi: 10.1002/pmic.201500376. Epub 2016 Apr 4. PMID: 27089055; PMCID: PMC5549685.
150. Katchman BA, Barderas R, Alam R, Chowell D, Field MS, Esserman LJ, Wallstrom G, LaBaer J, Cramer DW, Hollingsworth MA, Anderson KS. Proteomic mapping of p53 immunogenicity in pancreatic, ovarian, and breast cancers. Proteomics Clin Appl. 2016 Jul;10(7):720-31. doi: 10.1002/prca.201500096. Epub 2016 May 17. PMID: 27121307; PMCID: PMC5553208.
151. Buas MF, Li CI, Anderson GL, Pepe MS. Recommendation to use exact P-values in biomarker discovery research in place of approximate P-values. Cancer Epidemiol 2018; 56: 83-89. DOI: 10.1016/j.canep.2018.07.014. PMID: 30099328. PMCID: N/A.
152. Garrison CB, Lastwika KJ, Zhang Y, Li CI, Lampe PD. Proteomic Analysis, Immune Dysregulation, and Pathway Interconnections with Obesity. J Proteome Res 2017; 16: 274-287. DOI: 10.1021/acs.jproteome.6b00611. PMID: 27769113. PMCID: PMC5234688.
153. Pepe MS, Janes H, Li CI, Bossuyt PM, Feng Z, Hilden J. Early-Phase Studies of Biomarkers: What Target Sensitivity and Specificity Values Might Confer Clinical Utility? Clin Chem 2016; 62: 737-42. DOI: 10.1373/clinchem.2015.252163. PMID: 27001493. PMCID: N/A.
154. Zhao W, Fitzgibbon M, Bergan L, Clegg N, Crispin D, Mills GB, McIntosh M. Identifying Abundant Immunotherapy and Other Targets in Solid Tumors: Integrating RNA-seq and Mass Spectrometry Proteomics Data Sets. Cancer J ; 23: 108-114. DOI: 10.1097/PPO.0000000000000258. PMID: 28410298. PMCID: N/A.
155. Dobrolecki LE, Airhart SD, Alferez DG, Aparicio S, Behbod F, Bentires-Alj M, Brisken C, Bult CJ, Cai S, Clarke RB, Dowst H, Ellis MJ, Gonzalez-Suarez E, Iggo RD, Kabos P, Li S, Lindeman GJ, Marangoni E, McCoy A, Meric-Bernstam F, Piwnica-Worms H, Poupon MF, Reis-Filho J, Sartorius CA, Scabia V, Sflomos G, Tu Y, Vaillant F, Visvader JE, Welm A, Wicha MS, Lewis MT. Patient-derived xenograft (PDX) models in basic and translational breast cancer research. Cancer Metastasis Rev. 2016 Dec;35(4):547-573. doi: 10.1007/s10555-016-9653-x. PMID: 28025748; PMCID: PMC5396460.
156. Zhao W, Fitzgibbon M, Bergan L, Clegg N, Crispin D, Mills GB, McIntosh M. Identifying Abundant Immunotherapy and Other Targets in Solid Tumors: Integrating RNA-seq and Mass Spectrometry Proteomics Data Sets. Cancer J ; 23: 108-114. DOI: 10.1097/PPO.0000000000000258. PMID: 28410298. PMCID: N/A.
157. Buas MF, Gu H, Djukovic D, Zhu J, Drescher CW, Urban N, Raftery D, Li CI. Identification of novel candidate plasma metabolite biomarkers for distinguishing serous ovarian carcinoma and benign serous ovarian tumors. Gynecol Oncol. 2016 Jan;140(1):138-44. doi: 10.1016/j.ygyno.2015.10.021. Epub 2015 Oct 30. PMID: 26521694; PMCID: PMC5310763.
158. Leung F, Bernadini MQ, Brown MD, Zheng Y, Molinas R, Bast RC, Jr., Serra S, Diamandis EP, Kulasingam V. Validation of a novel biomarker panel for the detection of ovarian cancer. Cancer Epidemiol Biomarkers Prev, 2016; 25:1333-40. PMID: 27448593.

159. Yang WL, Gentry-Maharaj A, Simmons A, Ryan A, Fourkala EO, Lu Z, Baggerly KA, Zhao Y, Lu KH, Bowtell D, Jacobs I, Skates SJ, He WW, Menon U, Bast RC Jr. Elevation of TP53 Autoantibody Before CA125 in Preclinical Invasive Epithelial Ovarian Cancer. Clinical Cancer Research 2017; 23:5912-5922. PubMed PMID: 28637689; PubMed Central PMCID: PMC5626590.
160. Patriotis C, Simmons AR, Lu KH, Bast RC Jr., Skates SJ. State-of the-Science in Biomarker Research–Ovarian Cancer. In Biomarkers in Cancer Screening and Early Detection, ed. S. Srivastava, John Wiley and Company pp 93-103, 2017.
161. Yang WL, Lu Z, Bast RC Jr. The role of biomarkers in the management of epithelial ovarian cancer. Expert review of molecular diagnostics. 2017; 17:577-591. PubMed PMID: 28468520; PubMed Central PMCID: PMC5823503
162. Mathieu KB, Bedi DG, Thrower SL, Qayyum A, Bast RC Jr. Screening for ovarian cancer: imaging challenges and opportunities for improvement. Ultrasound in obstetrics & gynecology. 2018; 51:293-303. PubMed PMID: 28639753; PubMed Central PMCID: PMC5788737.
163. Elias KM, Guo J, Bast RC Jr. Early Detection of Ovarian Cancer. Hematology/oncology clinics of North America. 2018 December;32(6):903-914. PubMed PMID: 30390764.
164. Skubitz AP, Boylan KL, Geschwind KA, Cao Q, Starr TK, Geller MA, Celestino J, Bast RC, Lu KH, Koopmeiners JS. Simultaneous Measurement of 92 Serum Protein Biomarkers for the Development of a Multi-Protein Classifier for Ovarian Cancer Detection. Cancer Prev Res (Phila) [Epub ahead of print], 2019. PMID: 30709840.
165. Simmons AR, Fourkala EO, Gentry-Maharaj A, Ryan A, Sutton MN, Baggerly K, Zheng H, Lu KH, Jacobs I, Skates S, Menon U, Bast RC Jr. Complementary Longitudinal Serum Biomarkers to CA125 for Early Detection of Ovarian Cancer. Cancer prevention research (Philadelphia, Pa.). 2019 June;12(6):391-400. PubMed PMID: 30967390; PubMed Central PMCID: PMC6548633; DOI: 10.1158/1940-6207.CAPR-18-0377.
166. Bast RC Jr, Matulonis UA, Sood AK, Ahmed AA, Amobi AE, Balkwill FR, Wielgos- Bonvallet M, Bowtell DDL, Brenton JD, Brugge JS, Coleman RL, Draetta GF, Doberstein K, Drapkin RI, Eckert MA, Edwards RP, Elias KM, Ennis D, Futreal A, Gershenson DM, Greenberg RA, Huntsman DG, Ji JXY, Kohn EC, Iavarone C, Lengyel ER, Levine DA, Lord CJ, Lu Z, Mills GB, Modugno F, Nelson BH, Odunsi K, Pilsworth JA, Rottapel RK, Powell DJ Jr, Shen L, Shih IM, Spriggs DR, Walton J, Zhang K, Zhang R, Zou L. Critical questions in ovarian cancer research and treatment: Report of an American Association for Cancer Research Special Conference. Cancer. 2019; 125(12):1963-1972. PubMed PMID: 30835824; PubMed Central PMCID: PMC6557260; DOI: 10.1002/cncr.32004.
167. Nebgen DR, Lu KH, Bast RC Jr. Novel Approaches to Ovarian Cancer Screening. Current oncology reports. 2019; 26;21(8):75. PubMed PMID: 31346778; PubMed Central PMCID: PMC6662655; DOI: 10.1007/s11912-019-0816-0.
168. Guo J, Yang W-L, Pak D, Celestino J, Lu KH, Ning J, Lokshin AE, Cheng Z, Lu Z, Bast RC Jr. Macrophage migration inhibitory factor, osteopontin, and anti-interleukin 8 autoantibodies complement CA125 for detection of early stage ovarian cancer. Cancers 2019; 11(5) pii:E596 doi:10.3390/ cancers 11050596 PMID: 31035430
169. Kobayashi M, Katayama H, Ehsan I, Vykoukal JV, Fahrmann J, Kundnani DL, Yu C-Y, Cai Y, Hsiao F, Yang W-L, Lu Z, Celestino J, Long JP, Do K-A, Lu KH, Ladd JJ, Urban N, Bast RC Jr, Hanash SM. Proteome profiling uncovers an ovarian cancer autoimmune response signature that reflects disease pathogenesis. Cancers 2020; 12:485. PMID: 32092936.

170. Yang W-L, Lu Z, Guo J, Fellman BM, Ning J, Lu KH, Menon U, Kobayashi M, Hanash S, Celestino J, Skates SJ, Bast RC Jr. Human epididymis 4 antigen-autoantibody complexes complement CA125 for detecting early stage ovarian cancer. Cancer 2020; 126:725-736. PMID: 31714597.
171. Kroeger PT Jr, Drapkin R. Pathogenesis and heterogeneity of ovarian cancer. Curr Opin Obstet Gynecol. 2017 Feb;29(1):26-34. doi: 10.1097/GCO.0000000000000340. PMID: 27898521; PMCID: PMC5201412.
172. Jacobs IJ, Menon U, Ryan A, Gentry-Maharaj A, Burnell M, Kalsi JK, Amso NN, Apostolidou S, Benjamin E, Cruickshank D, Crump DN, Davies SK, Dawnay A, Dobbs S, Fletcher G, Ford J, Godfrey K, Gunu R, Habib M, Hallett R, Herod J, Jenkins H, Karpinskyj C, Leeson S, Lewis SJ, Liston WR, Lopes A, Mould T, Murdoch J, Oram D, Rabideau DJ, Reynolds K, Scott I, Seif MW, Sharma A, Singh N, Taylor J, Warburton F, Widschwendter M, Williamson K, Woolas R, Fallowfield L, McGuire AJ, Campbell S, Parmar M, Skates SJ. Ovarian cancer screening and mortality in the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS): a randomised controlled trial. Lancet. 2016 Mar 5;387(10022):945-956. doi: 10.1016/S0140-6736(15)01224-6. Epub 2015 Dec 17. Erratum in: Lancet. 2016 Mar 5;387(10022):944. Erratum in: Lancet. 2016 Mar 5;387(10022):944. PMID: 26707054; PMCID: PMC4779792.
173. Keshishian H, Burgess MW, Specht H, Wallace L, Clauser KR, Gillette MA, Carr SA. Quantitative, multiplexed workflow for deep analysis of human blood plasma and biomarker discovery by mass spectrometry. Nat Protoc. 2017 Aug;12(8):1683-1701. doi: 10.1038/nprot.2017.054. Epub 2017 Jul 27. PMID: 28749931; PMCID: PMC6057147.
174. Hooda J, Novak M, Salomon MP, Matsuba C, Ramos RI, MacDuffie E, Song M, Hirsch MS, Lester J, Parkash V, Karlan BY, Oren M, Hoon DS, Drapkin R. Early Loss of Histone H2B Monoubiquitylation Alters Chromatin Accessibility and Activates Key Immune Pathways That Facilitate Progression of Ovarian Cancer. Cancer Res. 2019 Feb 15;79(4):760-772. doi: 10.1158/0008-5472.CAN-18-2297. Epub 2018 Dec 18. PMID: 30563893; PMCID: PMC6377833.
175. Liu JF, Palakurthi S, Zeng Q, Zhou S, Ivanova E, Huang W, Zervantonakis IK, Selfors LM, Shen Y, Pritchard CC, Zheng M, Adleff V, Papp E, Piao H, Novak M, Fotheringham S, Wulf GM, English J, Kirschmeier PT, Velculescu VE, Paweletz C, Mills GB, Livingston DM, Brugge JS, Matulonis UA, Drapkin R. Establishment of Patient-Derived Tumor Xenograft Models of Epithelial Ovarian Cancer for Preclinical Evaluation of Novel Therapeutics. Clin Cancer Res. 2017 Mar 1;23(5):1263-1273. doi: 10.1158/1078-0432.CCR-16-1237. Epub 2016 Aug 29. PMID: 27573169; PMCID: PMC5332350.
176. Wang S, Blois A, El Rayes T, Liu JF, Hirsch MS, Gravdal K, Palakurthi S, Bielenberg DR, Akslen LA, Drapkin R, Mittal V, Watnick RS. Development of a prosaposin-derived therapeutic cyclic peptide that targets ovarian cancer via the tumor microenvironment. Sci Transl Med. 2016 Mar 9;8(329):329ra34. doi: 10.1126/scitranslmed.aad5653. PMID: 26962158; PMCID: PMC6261358.
177. Dicks E, Song H, Ramus SJ, Oudenhove EV, Tyrer JP, Intermaggio MP, Kar S, Harrington P, Bowtell DD, Group AS, Cicek MS, Cunningham JM, Fridley BL, Alsop J, Jimenez-Linan M, Piskorz A, Goranova T, Kent E, Siddiqui N, Paul J, Crawford R, Poblete S, Lele S, Sucheston-Campbell L, Moysich KB, Sieh W, McGuire V, Lester J, Odunsi K, Whittemore AS, Bogdanova N, Dürst M, Hillemanns P, Karlan BY, Gentry-Maharaj A, Menon U, Tischkowitz M, Levine D, Brenton JD, Dörk T, Goode EL, Gayther SA, Pharoah DPP. Germline whole exome sequencing and large-scale replication identifies FANCM as a likely high grade serous ovarian cancer susceptibility gene. Oncotarget. 2017 Mar 3;8(31):50930-50940. doi: 10.18632/oncotarget.15871. PMID: 28881617; PMCID: PMC5584218.

178. Skates SJ, Greene MH, Buys SS, Mai PL, Brown P, Piedmonte M, Rodriguez G, Schorge JO, Sherman M, Daly MB, Rutherford T, Brewster WR, O'Malley DM, Partridge E, Boggess J, Drescher CW, Isaacs C, Berchuck A, Domchek S, Davidson SA, Edwards R, Elg SA, Wakeley K, Phillips KA, Armstrong D, Horowitz I, Fabian CJ, Walker J, Sluss PM, Welch W, Minasian L, Horick NK, Kasten CH, Nayfield S, Alberts D, Finkelstein DM, Lu KH. Early Detection of Ovarian Cancer using the Risk of Ovarian Cancer Algorithm with Frequent CA125 Testing in Women at Increased Familial Risk - Combined Results from Two Screening Trials. Clin Cancer Res. 2017 Jul 15;23(14):3628-3637. doi: 10.1158/1078-0432.CCR-15-2750. Epub 2017 Jan 31. PMID: 28143870; PMCID: PMC5726402.
179. Perets R, Drapkin R. It's Totally Tubular....Riding The New Wave of Ovarian Cancer Research. Cancer Res. 2016 Jan 1;76(1):10-7. doi: 10.1158/0008-5472.CAN-15-1382. Epub 2015 Dec 15. PMID: 26669862; PMCID: PMC4703449.
180. Skates SJ. EPIC Early Detection of Ovarian Cancer. Clin Cancer Res. 2016 Sep 15;22(18):4542-4. doi: 10.1158/1078-0432.CCR-16-1391. Epub 2016 Jul 14. PMID: 27418634; PMCID: PMC5026579.
181. Anderson L, Razavi M, Skates S, Anderson NG, Pearson TW. Squeezing more value from the analytes we have: personal baselines for multiple analytes in serial DBS. Bioanalysis. 2016 Aug;8(15):1539-1542. doi: 10.4155/bio-2016-0088. Epub 2016 Jun 9. PMID: 27277878.
182. Jacobs IJ, Parmar M, Skates SJ, Menon U. Ovarian cancer screening: UKCTOCS trial - Authors' reply. Lancet. 2016 Jun 25;387(10038):2603-2604. doi: 10.1016/S0140-6736(16)30849-2. PMID: 27353822.
183. Russell MR, Walker MJ, Williamson AJ, Gentry-Maharaj A, Ryan A, Kalsi J, Skates S, D'Amato A, Dive C, Pernemalm M, Humphryes PC, Fourkala EO, Whetton AD, Menon U, Jacobs I, Graham RL. Protein Z: A putative novel biomarker for early detection of ovarian cancer. Int J Cancer. 2016 Jun 15;138(12):2984-92. doi: 10.1002/ijc.30020. Epub 2016 Feb 19. PMID: 26815306; PMCID: PMC4840324.
184. Elias KM, Emori MM, Westerling T, Long H, Budina-Kolomets A, Li F, MacDuffie E, Davis MR, Holman A, Lawney B, Freedman ML, Quackenbush J, Brown M, Drapkin R. Epigenetic remodeling regulates transcriptional changes between ovarian cancer and benign precursors. Version 2. JCI Insight. 2016 Aug 18;1(13):e87988. doi: 10.1172/jci.insight.87988. PMID: 27617304; PMCID: PMC5017158.
185. Pharoah PDP, Song H, Dicks E, Intermaggio MP, Harrington P, Baynes C, Alsop K; Australian Ovarian Cancer Study Group, Bogdanova N, Cicek MS, Cunningham JM, Fridley BL, Gentry-Maharaj A, Hillemanns P, Lele S, Lester J, McGuire V, Moysich KB, Poblete S, Sieh W, Sucheston-Campbell L, Widschwendter M; Ovarian Cancer Association Consortium, Whittemore AS, Dörk T, Menon U, Odunsi K, Goode EL, Karlan BY, Bowtell DD, Gayther SA, Ramus SJ. PPM1D Mosaic Truncating Variants in Ovarian Cancer Cases May Be Treatment-Related Somatic Mutations. J Natl Cancer Inst. 2016 Jan 27;108(3):djv347. doi: 10.1093/jnci/djv347. PMID: 26823519; PMCID: PMC5072371.
186. Gentry-Maharaj A, Glazer C, Burnell M, Ryan A, Berry H, Kalsi J, Woolas R, Skates SJ, Campbell S, Parmar M, Jacobs I, Menon U. Changing trends in reproductive/lifestyle factors in UK women: descriptive study within the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS). BMJ Open. 2017 Mar 6;7(3):e011822. doi: 10.1136/bmjopen-2016-011822. PMID: 28264823; PMCID: PMC5353253.
187. Menon U, McGuire AJ, Raikou M, Ryan A, Davies SK, Burnell M, Gentry-Maharaj A, Kalsi JK, Singh N, Amso NN, Cruickshank D, Dobbs S, Godfrey K, Herod J, Leeson S, Mould T, Murdoch J, Oram D, Scott I, Seif MW, Williamson K, Woolas R, Fallowfield L, Campbell S, Skates SJ, Parmar M, Jacobs IJ. The cost-effectiveness of screening for ovarian cancer: results from the UK Collaborative Trial of Ovarian

Cancer Screening (UKCTOCS). Br J Cancer. 2017 Aug 22;117(5):619-627. doi: 10.1038/bjc.2017.222. Epub 2017 Jul 25. PMID: 28742794; PMCID: PMC5572177.

188. Rosenthal AN, Fraser LSM, Philpott S, Manchanda R, Burnell M, Badman P, Hadwin R, Rizzuto I, Benjamin E, Singh N, Evans DG, Eccles DM, Ryan A, Liston R, Dawnay A, Ford J, Gunu R, Mackay J, Skates SJ, Menon U, Jacobs IJ; United Kingdom Familial Ovarian Cancer Screening Study collaborators. Evidence of Stage Shift in Women Diagnosed With Ovarian Cancer During Phase II of the United Kingdom Familial Ovarian Cancer Screening Study. J Clin Oncol. 2017 May 1;35(13):1411-1420. doi: 10.1200/JCO.2016.69.9330. Epub 2017 Feb 27. Erratum in: J Clin Oncol. 2017 Aug 10;35(23):2722. PMID: 28240969; PMCID: PMC5455461.
189. Kuhn E, Carr SA. Multiplexed Immunoaffinity Enrichment of Peptides with Anti-peptide Antibodies and Quantification by Stable Isotope Dilution Multiple Reaction Monitoring Mass Spectrometry. Methods Mol Biol. 2016;1410:135-67. doi: 10.1007/978-1-4939-3524-6_9. PMID: 26867743.
190. Labidi-Galy SI, Papp E, Hallberg D, Niknafs N, Adlef V, Noe M, Bhattacharya R, Novak M, Jones S, Phallen J, Hruban CA, Hirsch M, Lin DI, Schartz L, Maire CL, Tille, JC, Bowden M, Ayhan A, Wood LD, Scharpf RB, Kurman R, Wang TL, Shih I-M, Karchin R, Drapkin R, Velculescu VE. High grade serous ovarian carcinoma originate in the fallopian tube. Nat Commun. 2017 (8):1093. doi: 10.1038/s41467-017-00962-1. PMID: 29061967; PMCID: PMC5653668.
191. Anglesio MS, Papadopoulos N, Ayhan A, Nazeran TM, Noë M, Horlings HM, Lum A, Jones S, Senz J, Seckin T, Ho J, Wu R-C, Lac V, Ogawa H, Tessier-Cloutier B, Alhassan R, Wang A, Wang Y, Cohen JD, Wong F, Hasanovic A, Orr N, Zhang M, Popoli M, McMahon W, Wood LD, Mattox A, Allaire C, Segars J, Williams C, Tomasetti C, Boyd N, Kinzler KW, Gilks CB, Diaz L, Wang T-L, Vogelstein B, Yong PJ, Huntsman DG, and Shih I-M. Cancer-associated mutations in endometriosis without cancer. N Engl J Med. 2017 May 11. 376(19):1835-1848. doi: 10.1056/NEJMoa1614814. PMID: 28489996; PMCID: PMC5555376.
192. Anglesio MS, Papadopoulos N, Ayhan A, Nazeran TM, Noë M, Horlings HM, Lum A, Jones S, Senz J, Seckin T, Ho J, Wu RC, Lac V, Ogawa H, Tessier-Cloutier B, Alhassan R, Wang A, Wang Y, Cohen JD, Wong F, Hasanovic A, Orr N, Zhang M, Popoli M, McMahon W, Wood LD, Mattox A, Allaire C, Segars J, Williams C, Tomasetti C, Boyd N, Kinzler KW, Gilks CB, Diaz L, Wang TL, Vogelstein B, Yong PJ, Huntsman DG, Shih IM. Cancer-Associated Mutations in Endometriosis without Cancer. N Engl J Med. 2017 May 11;376(19):1835-1848. doi: 10.1056/NEJMoa1614814. PMID: 28489996; PMCID: PMC5555376.
193. Labidi-Galy SI, Papp E, Hallberg D, Niknafs N, Adleff V, Noe M, Bhattacharya R, Novak M, Jones S, Phallen J, Hruban CA, Hirsch MS, Lin DI, Schwartz L, Maire CL, Tille JC, Bowden M, Ayhan A, Wood LD, Scharpf RB, Kurman R, Wang TL, Shih IM, Karchin R, Drapkin R, Velculescu VE. High grade serous ovarian carcinomas originate in the fallopian tube. Nat Commun. 2017 Oct 23;8(1):1093. doi: 10.1038/s41467-017-00962-1. PMID: 29061967; PMCID: PMC5653668.
194. Wu RC, Wang P, Lin SF, Zhang M, Song Q, Chu T, Wang BG, Kurman RJ, Vang R, Kinzler K, Tomasetti C, Jiao Y, Shih IM, Wang TL. Genomic landscape and evolutionary trajectories of ovarian cancer precursor lesions. J Pathol. 2019 May;248(1):41-50. doi: 10.1002/path.5219. Epub 2019 Feb 15. PMID: 30560554; PMCID: PMC6618168.

195. Wang Y, Li L, Douville C, Cohen JD, Yen TT, Kinde I, Sundfelt K, Kjær SK, Hruban RH, Shih IM, Wang TL, Kurman RJ, Springer S, Ptak J, Popoli M, Schaefer J, Silliman N, Dobbyn L, Tanner EJ, Angarita A, Lycke M, Jochumsen K, Afsari B, Danilova L, Levine DA, Jardon K, Zeng X, Arseneau J, Fu L, Diaz LA Jr, Karchin R, Tomasetti C, Kinzler KW, Vogelstein B, Fader AN, Gilbert L, Papadopoulos N. Evaluation of liquid from the Papanicolaou test and other liquid biopsies for the detection of endometrial and ovarian cancers. Sci Transl Med. 2018 Mar 21;10(433):eaap8793. doi: 10.1126/scitranslmed.aap8793. PMID: 29563323; PMCID: PMC6320220.
196. Whelan S, Ophir E, Kotturi MF, Levy O, Ganguly S, Leung L, Vaknin I, Kumar S, Dassa L, Hansen K, Bernados D, Murter B, Soni A, Taube JM, Fader AN, Wang TL, Shih IM, White M, Pardoll DM, Liang SC. PVRIG and PVRL2 Are Induced in Cancer and Inhibit CD8+ T-cell Function. Cancer Immunol Res. 2019 Feb;7(2):257-268. doi: 10.1158/2326-6066.CIR-18-0442. Epub 2019 Jan 18. PMID: 30659054; PMCID: PMC7001734.
197. Pisanic TR 2nd, Cope LM, Lin SF, Yen TT, Athamanolap P, Asaka R, Nakayama K, Fader AN, Wang TH, Shih IM, Wang TL. Methylomic Analysis of Ovarian Cancers Identifies Tumor-Specific Alterations Readily Detectable in Early Precursor Lesions. Clin Cancer Res. 2018 Dec 15;24(24):6536-6547. doi: 10.1158/1078-0432.CCR-18-1199. Epub 2018 Aug 14. PMID: 30108103; PMCID: PMC6295225.
198. Asaka S, Davis C, Lin SF, Wang TL, Heaphy CM, Shih IM. Analysis of Telomere Lengths in p53 Signatures and Incidental Serous Tubal Intraepithelial Carcinomas Without Concurrent Ovarian Cancer. Am J Surg Pathol. 2019 Aug;43(8):1083-1091. doi: 10.1097/PAS.0000000000001283. PMID: 31107721; PMCID: PMC6629487.
199. Song G, Chen L, Zhang B, Song Q, Yu Y, Moore C, Wang TL, Shih IM, Zhang H, Chan DW, Zhang Z, Zhu H. Proteome-wide Tyrosine Phosphorylation Analysis Reveals Dysregulated Signaling Pathways in Ovarian Tumors. Mol Cell Proteomics. 2019 Mar;18(3):448-460. doi: 10.1074/mcp.RA118.000851. Epub 2018 Dec 6. PMID: 30523211; PMCID: PMC6398206.
200. Chen LY, Huang RL, Chan MW, Yan PS, Huang TS, Wu RC, Suryo Rahmanto Y, Su PH, Weng YC, Chou JL, Chao TK, Wang YC, Shih IM, Lai HC. TET1 reprograms the epithelial ovarian cancer epigenome and reveals casein kinase 2α as a therapeutic target. J Pathol. 2019 Jul;248(3):363-376. doi: 10.1002/path.5266. Epub 2019 Apr 23. PMID: 30883733; PMCID: PMC6579655.
201. Uzoma I, Hu J, Cox E, Xia S, Zhou J, Rho HS, Guzzo C, Paul C, Ajala O, Goodwin CR, Jeong J, Moore C, Zhang H, Meluh P, Blackshaw S, Matunis M, Qian J, Zhu H. Global Identification of Small Ubiquitin-related Modifier (SUMO) Substrates Reveals Crosstalk between SUMOylation and Phosphorylation Promotes Cell Migration. Mol Cell Proteomics. 2018 May;17(5):871-888. doi: 10.1074/mcp.RA117.000014. Epub 2018 Feb 8. PMID: 29438996; PMCID: PMC5930406.
202. Pisanic TR 2nd, Asaka S, Lin SF, Yen TT, Sun H, Bahadirli-Talbott A, Wang TH, Burns KH, Wang TL, Shih IM. Long Interspersed Nuclear Element 1 Retrotransposons Become Deregulated during the Development of Ovarian Cancer Precursor Lesions. Am J Pathol. 2019 Mar;189(3):513-520. doi: 10.1016/j.ajpath.2018.11.005. Epub 2018 Dec 13. PMID: 30553834; PMCID: PMC6412403.
203. Xing D, Suryo Rahmanto Y, Zeppernick F, Hannibal CG, Kjaer SK, Vang R, Shih IM, Wang TL. Mutation of NRAS is a rare genetic event in ovarian low-grade serous carcinoma. Hum Pathol. 2017 Oct;68:87-91. doi: 10.1016/j.humpath.2017.08.021. Epub 2017 Sep 2. PMID: 28873354; PMCID: PMC5696063.
204. Fletcher R, Wang YJ, Schoen RE, Finn OJ, Yu J, Zhang L. Colorectal cancer prevention: Immune modulation taking the stage. Biochim Biophys Acta Rev Cancer. 2018 Apr;1869(2):138-148. doi: 10.1016/j.bbcan.2017.12.002. Epub 2018 Jan 31. PMID: 29391185; PMCID: PMC5955808.

205. Cohen JD, Li L, Wang Y, Thoburn C, Afsari B, Danilova L, Douville C, Javed AA, Wong F, Mattox A, Hruban RH, Wolfgang CL, Goggins MG, Dal Molin M, Wang TL, Roden R, Klein AP, Ptak J, Dobbyn L, Schaefer J, Silliman N, Popoli M, Vogelstein JT, Browne JD, Schoen RE, Brand RE, Tie J, Gibbs P, Wong HL, Mansfield AS, Jen J, Hanash SM, Falconi M, Allen PJ, Zhou S, Bettegowda C, Diaz LA Jr, Tomasetti C, Kinzler KW, Vogelstein B, Lennon AM, Papadopoulos N. Detection and localization of surgically resectable cancers with a multi-analyte blood test. Science. 2018 Feb 23;359(6378):926-930. doi: 10.1126/science.aar3247. Epub 2018 Jan 18. PMID: 29348365; PMCID: PMC6080308.
206. Cohen JD, Javed AA, Thoburn C, Wong F, Tie J, Gibbs P, Schmidt CM, Yip-Schneider MT, Allen PJ, Schattner M, Brand RE, Singhi AD, Petersen GM, Hong SM, Kim SC, Falconi M, Doglioni C, Weiss MJ, Ahuja N, He J, Makary MA, Maitra A, Hanash SM, Dal Molin M, Wang Y, Li L, Ptak J, Dobbyn L, Schaefer J, Silliman N, Popoli M, Goggins MG, Hruban RH, Wolfgang CL, Klein AP, Tomasetti C, Papadopoulos N, Kinzler KW, Vogelstein B, Lennon AM. Combined circulating tumor DNA and protein biomarker-based liquid biopsy for the earlier detection of pancreatic cancers. Proc Natl Acad Sci U S A. 2017 Sep 19;114(38):10202-10207. doi: 10.1073/pnas.1704961114. Epub 2017 Sep 5. PMID: 28874546; PMCID: PMC5617273.
207. Tie J, Wang Y, Tomasetti C, Li L, Springer S, Kinde I, Silliman N, Tacey M, Wong HL, Christie M, Kosmider S, Skinner I, Wong R, Steel M, Tran B, Desai J, Jones I, Haydon A, Hayes T, Price TJ, Strausberg RL, Diaz LA Jr, Papadopoulos N, Kinzler KW, Vogelstein B, Gibbs P. Circulating tumor DNA analysis detects minimal residual disease and predicts recurrence in patients with stage II colon cancer. Sci Transl Med. 2016 Jul 6;8(346):346ra92. doi: 10.1126/scitranslmed.aaf6219. PMID: 27384348; PMCID: PMC5346159.
208. Lee B, Lipton L, Cohen J, Tie J, Javed AA, Li L, Goldstein D, Burge M, Cooray P, Nagrial A, Tebbutt NC, Thomson B, Nikfarjam M, Harris M, Haydon A, Lawrence B, Tai DWM, Simons K, Lennon AM, Wolfgang CL, Tomasetti C, Papadopoulos N, Kinzler KW, Vogelstein B, Gibbs P. Circulating tumor DNA as a potential marker of adjuvant chemotherapy benefit following surgery for localized pancreatic cancer. Ann Oncol. 2019 Sep 1;30(9):1472-1478. doi: 10.1093/annonc/mdz200. PMID: 31250894; PMCID: PMC6771221.
209. Robles AI, Traverso G, Zhang M, Roberts NJ, Khan MA, Joseph C, Lauwers GY, Selaru FM, Popoli M, Pittman ME, Ke X, Hruban RH, Meltzer SJ, Kinzler KW, Vogelstein B, Harris CC, Papadopoulos N. Whole-Exome Sequencing Analyses of Inflammatory Bowel Disease-Associated Colorectal Cancers. Gastroenterology. 2016 Apr;150(4):931-43. doi: 10.1053/j.gastro.2015.12.036. Epub 2016 Jan 5. PMID: 26764183; PMCID: PMC5270616.
210. Leibowitz BJ, Yang L, Wei L, Buchanan ME, Rachid M, Parise RA, Beumer JH, Eiseman JL, Schoen RE, Zhang L, Yu J. Targeting p53-dependent stem cell loss for intestinal chemoprotection. Sci Transl Med. 2018 Feb 7;10(427):eaam7610. doi: 10.1126/scitranslmed.aam7610. PMID: 29437148; PMCID: PMC5827930.
211. Tan X, Tong J, Wang YJ, Fletcher R, Schoen RE, Yu J, Shen L, Zhang L. BET Inhibitors Potentiate Chemotherapy and Killing of SPOP-Mutant Colon Cancer Cells via Induction of DR5. Cancer Res. 2019 Mar 15;79(6):1191-1203. doi: 10.1158/0008-5472.CAN-18-3223. Epub 2019 Jan 23. PMID: 30674532; PMCID: PMC6420862.
212. Negm OH, Hamed MR, Schoen RE, Whelan RL, Steele RJ, Scholefield J, Dilnot EM, Shantha Kumara HM, Robertson JF, Sewell HF. Human Blood Autoantibodies in the Detection of Colorectal Cancer. PLoS One. 2016 Jul 6;11(7):e0156971. doi: 10.1371/journal.pone.0156971. PMID: 27383396; PMCID: PMC4934916.

213. Pinsky PF, Schoen RE. Contribution of Surveillance Colonoscopy to Colorectal Cancer Prevention. Clin Gastroenterol Hepatol. 2020 Feb 1:S1542-3565(20)30116-6. doi: 10.1016/j.cgh.2020.01.037. Epub ahead of print. PMID: 32017987.
214. Blum AE, Venkitachalam S, Guo Y, Kieber-Emmons AM, Ravi L, Chandar AK, Iyer PG, Canto MI, Wang JS, Shaheen NJ, Barnholtz-Sloan JS, Markowitz SD, Willis JE, Shyr Y, Chak A, Varadan V, Guda K. RNA Sequencing Identifies Transcriptionally Viable Gene Fusions in Esophageal Adenocarcinomas. Cancer Res. 2016 Oct 1;76(19):5628-5633. doi: 10.1158/0008-5472.CAN-16-0979. Epub 2016 Aug 8. PMID: 27503924; PMCID: PMC5050127.
215. Markowitz SD. Cancer bypasses the lymph nodes. Science. 2017 Jul 7;357(6346):35-36. doi: 10.1126/science.aan8299. PMID: 28684492.
216. Kim J, Do EJ, Moinova H, Bae SM, Kang JY, Hong SM, Fink SP, Joo J, Suh YA, Jang SJ, Hwang SW, Park SH, Yang DH, Ye BD, Byeon JS, Choe J, Yang SK, Markowitz SD, Kim SY, Myung SJ. Molecular Imaging of Colorectal Tumors by Targeting Colon Cancer Secreted Protein-2 (CCSP-2). Neoplasia. 2017 Oct;19(10):805-816. doi: 10.1016/j.neo.2017.07.003. Epub 2017 Sep 5. PMID: 28886423; PMCID: PMC5587890.
217. Morris SM, Davison J, Carter KT, O'Leary RM, Trobridge P, Knoblaugh SE, Myeroff LL, Markowitz SD, Brett BT, Scheetz TE, Dupuy AJ, Starr TK, Grady WM. Transposon mutagenesis identifies candidate genes that cooperate with loss of transforming growth factor-beta signaling in mouse intestinal neoplasms. Int J Cancer. 2017 Feb 15;140(4):853-863. doi: 10.1002/ijc.30491. Epub 2016 Nov 7. PMID: 27790711; PMCID: PMC5316486.
218. Cooper GS, Markowitz SD, Chen Z, Tuck M, Willis JE, Berger BM, Brenner DE, Li L. Evaluation of Patients with an Apparent False Positive Stool DNA Test: The Role of Repeat Stool DNA Testing. Dig Dis Sci. 2018 Jun;63(6):1449-1453. doi: 10.1007/s10620-018-5001-z. Epub 2018 Mar 7. PMID: 29516325; PMCID: PMC5960589.
219. Moinova HR, LaFramboise T, Lutterbaugh JD, Chandar AK, Dumot J, Faulx A, Brock W, De la Cruz Cabrera O, Guda K, Barnholtz-Sloan JS, Iyer PG, Canto MI, Wang JS, Shaheen NJ, Thota PN, Willis JE, Chak A, Markowitz SD. Identifying DNA methylation biomarkers for non-endoscopic detection of Barrett's esophagus. Sci Transl Med. 2018 Jan 17;10(424):eaao5848. doi: 10.1126/scitranslmed.aao5848. PMID: 29343623; PMCID: PMC5789768.
220. Yu M, Maden SK, Stachler M, Kaz AM, Ayers J, Guo Y, Carter KT, Willbanks A, Heinzerling TJ, O'Leary RM, Xu X, Bass A, Chandar AK, Chak A, Elliott R, Willis JE, Markowitz SD, Grady WM. Subtypes of Barrett's oesophagus and oesophageal adenocarcinoma based on genome-wide methylation analysis. Gut. 2019 Mar;68(3):389-399. doi: 10.1136/gutjnl-2017-314544. Epub 2018 Jun 8. PMID: 29884612; PMCID: PMC6565505.
221. Jeun M, Lee HJ, Park S, Do EJ, Choi J, Sung YN, Hong SM, Kim SY, Kim DH, Kang JY, Son HN, Joo J, Song EM, Hwang SW, Park SH, Yang DH, Ye BD, Byeon JS, Choe J, Yang SK, Moinova H, Markowitz SD, Lee KH, Myung SJ. A Novel Blood-Based Colorectal Cancer Diagnostic Technology Using Electrical Detection of Colon Cancer Secreted Protein-2. Adv Sci (Weinh). 2019 Apr 16;6(11):1802115. doi: 10.1002/advs.201802115. PMID: 31179210; PMCID: PMC6548955.
222. Blum AE, Venkitachalam S, Ravillah D, Chelluboyina AK, Kieber-Emmons AM, Ravi L, Kresak A, Chandar AK, Markowitz SD, Canto MI, Wang JS, Shaheen NJ, Guo Y, Shyr Y, Willis JE, Chak A, Varadan V, Guda K. Systems Biology Analyses Show Hyperactivation of Transforming Growth Factor-β and JNK Signaling Pathways in Esophageal Cancer. Gastroenterology. 2019 May;156(6):1761-1774. doi: 10.1053/j.gastro.2019.01.263. Epub 2019 Feb 12. PMID: 30768984; PMCID: PMC6701681.

223. Guo Y, Ayers JL, Carter KT, Wang T, Maden SK, Edmond D, Newcomb P P, Li C, Ulrich C, Yu M, Grady WM. Senescence-associated tissue microenvironment promotes colon cancer formation through the secretory factor GDF15. Aging Cell. 2019 Dec;18(6):e13013. doi: 10.1111/acel.13013. Epub 2019 Aug 6. PMID: 31389184; PMCID: PMC6826139.
224. Pickhardt PJ, Pooler BD, Matkowskyj KA, Kim DH, Grady WM, Halberg RB. Volumetric growth rates of sessile serrated adenomas/polyps observed in situ at longitudinal CT colonography. Eur Radiol. 2019 Sep;29(9):5093-5100. doi: 10.1007/s00330-019-5999-0. Epub 2019 Feb 11. PMID: 30741343; PMCID: PMC6684388.
225. Yu M, Hazelton WD, Luebeck GE, Grady WM. Epigenetic Aging: More Than Just a Clock When It Comes to Cancer. Cancer Res. 2020 Feb 1;80(3):367-374. doi: 10.1158/0008-5472.CAN-19-0924. Epub 2019 Nov 6. PMID: 31694907; PMCID: PMC7002254.
226. Huyghe JR, Bien SA, Harrison TA, Kang HM, Chen S, Schmit SL, Conti DV, Qu C, Jeon J, Edlund CK, Greenside P, Wainberg M, Schumacher FR, Smith JD, Levine DM, Nelson SC, Sinnott-Armstrong NA, Albanes D, Alonso MH, Anderson K, Arnau-Collell C, Arndt V, Bamia C, Banbury BL, Baron JA, Berndt SI, Bézieau S, Bishop DT, Boehm J, Boeing H, Brenner H, Brezina S, Buch S, Buchanan DD, Burnett-Hartman A, Butterbach K, Caan BJ, Campbell PT, Carlson CS, Castellví-Bel S, Chan AT, Chang-Claude J, Chanock SJ, Chirlaque MD, Cho SH, Connolly CM, Cross AJ, Cuk K, Curtis KR, de la Chapelle A, Doheny KF, Duggan D, Easton DF, Elias SG, Elliott F, English DR, Feskens EJM, Figueiredo JC, Fischer R, FitzGerald LM, Forman D, Gala M, Gallinger S, Gauderman WJ, Giles GG, Gillanders E, Gong J, Goodman PJ, Grady WM, Grove JS, Gsur A, Gunter MJ, Haile RW, Hampe J, Hampel H, Harlid S, Hayes RB, Hofer P, Hoffmeister M, Hopper JL, Hsu WL, Huang WY, Hudson TJ, Hunter DJ, Ibañez-Sanz G, Idos GE, Ingersoll R, Jackson RD, Jacobs EJ, Jenkins MA, Joshi AD, Joshu CE, Keku TO, Key TJ, Kim HR, Kobayashi E, Kolonel LN, Kooperberg C, Kühn T, Küry S, Kweon SS, Larsson SC, Laurie CA, Le Marchand L, Leal SM, Lee SC, Lejbkowicz F, Lemire M, Li CI, Li L, Lieb W, Lin Y, Lindblom A, Lindor NM, Ling H, Louie TL, Männistö S, Markowitz SD, Martín V, Masala G, McNeil CE, Melas M, Milne RL, Moreno L, Murphy N, Myte R, Naccarati A, Newcomb PA, Offit K, Ogino S, Onland-Moret NC, Pardini B, Parfrey PS, Pearlman R, Perduca V, Pharoah PDP, Pinchev M, Platz EA, Prentice RL, Pugh E, Raskin L, Rennert G, Rennert HS, Riboli E, Rodríguez-Barranco M, Romm J, Sakoda LC, Schafmayer C, Schoen RE, Seminara D, Shah M, Shelford T, Shin MH, Shulman K, Sieri S, Slattery ML, Southey MC, Stadler ZK, Stegmaier C, Su YR, Tangen CM, Thibodeau SN, Thomas DC, Thomas SS, Toland AE, Trichopoulou A, Ulrich CM, Van Den Berg DJ, van Duijnhoven FJB, Van Guelpen B, van Kranen H, Vijai J, Visvanathan K, Vodicka P, Vodickova L, Vymetalkova V, Weigl K, Weinstein SJ, White E, Win AK, Wolf CR, Wolk A, Woods MO, Wu AH, Zaidi SH, Zanke BW, Zhang Q, Zheng W, Scacheri PC, Potter JD, Bassik MC, Kundaje A, Casey G, Moreno V, Abecasis GR, Nickerson DA, Gruber SB, Hsu L, Peters U. Discovery of common and rare genetic risk variants for colorectal cancer. Nat Genet. 2019 Jan;51(1):76-87. doi: 10.1038/s41588-018-0286-6. Epub 2018 Dec 3. PMID: 30510241; PMCID: PMC6358437.
227. Barault L, Amatu A, Siravegna G, Ponzetti A, Moran S, Cassingena A, Mussolin B, Falcomatà C, Binder AM, Cristiano C, Oddo D, Guarrera S, Cancelliere C, Bustreo S, Bencardino K, Maden S, Vanzati A, Zavattari P, Matullo G, Truini M, Grady WM, Racca P, Michels KB, Siena S, Esteller M, Bardelli A, Sartore-Bianchi A, Di Nicolantonio F. Discovery of methylated circulating DNA biomarkers for comprehensive non-invasive monitoring of treatment response in metastatic colorectal cancer. Gut. 2018 Nov;67(11):1995-2005. doi: 10.1136/gutjnl-2016-313372. Epub 2017 Oct 5. PMID: 28982739; PMCID: PMC5897187.

228. Schmit SL, Edlund CK, Schumacher FR, Gong J, Harrison TA, Huyghe JR, Qu C, Melas M, Van Den Berg DJ, Wang H, Tring S, Plummer SJ, Albanes D, Alonso MH, Amos CI, Anton K, Aragaki AK, Arndt V, Barry EL, Berndt SI, Bezieau S, Bien S, Bloomer A, Boehm J, Boutron-Ruault MC, Brenner H, Brezina S, Buchanan DD, Butterbach K, Caan BJ, Campbell PT, Carlson CS, Castelao JE, Chan AT, Chang-Claude J, Chanock SJ, Cheng I, Cheng YW, Chin LS, Church JM, Church T, Coetzee GA, Cotterchio M, Cruz Correa M, Curtis KR, Duggan D, Easton DF, English D, Feskens EJM, Fischer R, FitzGerald LM, Fortini BK, Fritsche LG, Fuchs CS, Gago-Dominguez M, Gala M, Gallinger SJ, Gauderman WJ, Giles GG, Giovannucci EL, Gogarten SM, Gonzalez-Villalpando C, Gonzalez-Villalpando EM, Grady WM, Greenson JK, Gsur A, Gunter M, Haiman CA, Hampe J, Harlid S, Harju JF, Hayes RB, Hofer P, Hoffmeister M, Hopper JL, Huang SC, Huerta JM, Hudson TJ, Hunter DJ, Idos GE, Iwasaki M, Jackson RD, Jacobs EJ, Jee SH, Jenkins MA, Jia WH, Jiao S, Joshi AD, Kolonel LN, Kono S, Kooperberg C, Krogh V, Kuehn T, Küry S, LaCroix A, Laurie CA, Lejbkowicz F, Lemire M, Lenz HJ, Levine D, Li CI, Li L, Lieb W, Lin Y, Lindor NM, Liu YR, Loupakis F, Lu Y, Luh F, Ma J, Mancao C, Manion FJ, Markowitz SD, Martin V, Matsuda K, Matsuo K, McDonnell KJ, McNeil CE, Milne R, Molina AJ, Mukherjee B, Murphy N, Newcomb PA, Offit K, Omichessan H, Palli D, Cotoré JPP, Pérez-Mayoral J, Pharoah PD, Potter JD, Qu C, Raskin L, Rennert G, Rennert HS, Riggs BM, Schafmayer C, Schoen RE, Sellers TA, Seminara D, Severi G, Shi W, Shibata D, Shu XO, Siegel EM, Slattery ML, Southey M, Stadler ZK, Stern MC, Stintzing S, Taverna D, Thibodeau SN, Thomas DC, Trichopoulou A, Tsugane S, Ulrich CM, van Duijnhoven FJB, van Guelpan B, Vijai J, Virtamo J, Weinstein SJ, White E, Win AK, Wolk A, Woods M, Wu AH, Wu K, Xiang YB, Yen Y, Zanke BW, Zeng YX, Zhang B, Zubair N, Kweon SS, Figueiredo JC, Zheng W, Marchand LL, Lindblom A, Moreno V, Peters U, Casey G, Hsu L, Conti DV, Gruber SB. Novel Common Genetic Susceptibility Loci for Colorectal Cancer. J Natl Cancer Inst. 2019 Feb 1;111(2):146-157. doi: 10.1093/jnci/djy099. PMID: 29917119; PMCID: PMC6555904.

229. Sievers CK, Grady WM, Halberg RB, Pickhardt PJ. New insights into the earliest stages of colorectal tumorigenesis. Expert Rev Gastroenterol Hepatol. 2017 Aug;11(8):723-729. doi: 10.1080/17474124.2017.1330150. Epub 2017 May 26. PMID: 28503955; PMCID: PMC5859121.

230. Rosenthal EA, Shirts BH, Amendola LM, Horike-Pyne M, Robertson PD, Hisama FM, Bennett RL, Dorschner MO, Nickerson DA, Stanaway IB, Nassir R, Vickers KT, Li C, Grady WM, Peters U, Jarvik GP; NHLBI GO Exome Sequencing Project. Rare loss of function variants in candidate genes and risk of colorectal cancer. Hum Genet. 2018 Oct;137(10):795-806. doi: 10.1007/s00439-018-1938-4. Epub 2018 Sep 28. PMID: 30267214; PMCID: PMC6283057.

231. Cooper GS, Markowitz SD, Chen Z, Tuck M, Willis JE, Berger BM, Brenner DE, Li L. Performance of multitarget stool DNA testing in African American patients. Cancer. 2018 Oct 1;124(19):3876-3880. doi: 10.1002/cncr.31660. Epub 2018 Sep 7. PMID: 30193399; PMCID: PMC6226346.

232. Luebeck GE, Hazelton WD, Curtius K, Maden SK, Yu M, Carter KT, Burke W, Lampe PD, Li CI, Ulrich CM, Newcomb PA, Westerhoff M, Kaz AM, Luo Y, Inadomi JM, Grady WM. Implications of Epigenetic Drift in Colorectal Neoplasia. Cancer Res. 2019 Feb 1;79(3):495-504. doi: 10.1158/0008-5472.CAN-18-1682. Epub 2018 Oct 5. PMID: 30291105; PMCID: PMC6359943.

233. Somasundaram S, Forrest ME, Moinova H, Cohen A, Varadan V, LaFramboise T, Markowitz S, Khalil AM. The DNMT1-associated lincRNA DACOR1 reprograms genome-wide DNA methylation in colon cancer. Clin Epigenetics. 2018 Oct 22;10(1):127. doi: 10.1186/s13148-018-0555-3. PMID: 30348202; PMCID: PMC6196572.

234. Evans DR, Venkitachalam S, Revoredo L, Dohey AT, Clarke E, Pennell JJ, Powell AE, Quinn E, Ravi L, Gerken TA, Green JS, Woods MO, Guda K. Evidence for GALNT12 as a moderate penetrance gene for

colorectal cancer. Hum Mutat. 2018 Aug;39(8):1092-1101. doi: 10.1002/humu.23549. Epub 2018 May 28. PMID: 29749045; PMCID: PMC6043371.

235. Neumeyer S, Banbury BL, Arndt V, Berndt SI, Bezieau S, Bien SA, Buchanan DD, Butterbach K, Caan BJ, Campbell PT, Casey G, Chan AT, Chanock SJ, Dai JY, Gallinger S, Giovannucci EL, Giles GG, Grady WM, Hampe J, Hoffmeister M, Hopper JL, Hsu L, Jenkins MA, Joshi A, Larsson SC, Le Marchand L, Lindblom A, Moreno V, Lemire M, Li L, Lin Y, Offit K, Newcomb PA, Pharaoh PD, Potter JD, Qi L, Rennert G, Schafmayer C, Schoen RE, Slattery ML, Song M, Ulrich CM, Win AK, White E, Wolk A, Woods MO, Wu AH, Gruber SB, Brenner H, Peters U, Chang-Claude J. Mendelian randomisation study of age at menarche and age at menopause and the risk of colorectal cancer. Br J Cancer. 2018 Jun;118(12):1639-1647. doi: 10.1038/s41416-018-0108-8. Epub 2018 May 24. PMID: 29795306; PMCID: PMC6008474.
236. Wang X, Dai JY, Albanes D, Arndt V, Berndt SI, Bézieau S, Brenner H, Buchanan DD, Butterbach K, Caan B, Casey G, Campbell PT, Chan AT, Chen Z, Chang-Claude J, Cotterchio M, Easton DF, Giles GG, Giovannucci E, Grady WM, Hoffmeister M, Hopper JL, Hsu L, Jenkins MA, Joshi AD, Lampe JW, Larsson SC, Lejbkowicz F, Li L, Lindblom A, Le Marchand L, Martin V, Milne RL, Moreno V, Newcomb PA, Offitt K, Ogino S, Pharoah PDP, Pinchev M, Potter JD, Rennert HS, Rennert G, Saliba W, Schafmayer C, Schoen RE, Schrotz-King P, Slattery ML, Song M, Stegmaier C, Weinstein SJ, Wolk A, Woods MO, Wu AH, Gruber SB, Peters U, White E. Mendelian randomization analysis of C-reactive protein on colorectal cancer risk. Int J Epidemiol. 2019 Jun 1;48(3):767-780. doi: 10.1093/ije/dyy244. PMID: 30476131; PMCID: PMC6659358.
237. Grady WM, Yu M. Molecular Evolution of Metaplasia to Adenocarcinoma in the Esophagus. Dig Dis Sci. 2018 Aug;63(8):2059-2069. doi: 10.1007/s10620-018-5090-8. PMID: 29766388; PMCID: PMC6597264.
238. Venkitachalam S, Guda K. Altered glycosyltransferases in colorectal cancer. Expert Rev Gastroenterol Hepatol. 2017 Jan;11(1):5-7. doi: 10.1080/17474124.2017.1253474. Epub 2016 Nov 4. PMID: 27781489; PMCID: PMC5520968.
239. Ulrich CM, Gigic B, Böhm J, Ose J, Viskochil R, Schneider M, Colditz GA, Figueiredo JC, Grady WM, Li CI, Shibata D, Siegel EM, Toriola AT, Ulrich A. The ColoCare Study: A Paradigm of Transdisciplinary Science in Colorectal Cancer Outcomes. Cancer Epidemiol Biomarkers Prev. 2019 Mar;28(3):591-601. doi: 10.1158/1055-9965.EPI-18-0773. Epub 2018 Dec 6. PMID: 30523039; PMCID: PMC6420345.
240. Kaz AM, Grady WM. Novel Barrett's esophagus screening assays based on swallowable devices: will they change the game? Transl Gastroenterol Hepatol. 2019 Apr 19;4:25. doi: 10.21037/tgh.2019.04.01. PMID: 31143846; PMCID: PMC6509432.
241. Williams CD, Grady WM, Zullig LL. Use of NCCN Guidelines, Other Guidelines, and Biomarkers for Colorectal Cancer Screening. J Natl Compr Canc Netw. 2016 Nov;14(11):1479-1485. doi: 10.6004/jnccn.2016.0154. PMID: 27799515; PMCID: PMC5117951.
242. Wang T, Maden SK, Luebeck GE, Li CI, Newcomb PA, Ulrich CM, Joo JE, Buchanan DD, Milne RL, Southey MC, Carter KT, Willbanks AR, Luo Y, Yu M, Grady WM. Dysfunctional epigenetic aging of the normal colon and colorectal cancer risk. Clin Epigenetics. 2020 Jan 3;12(1):5. doi: 10.1186/s13148-019-0801-3. PMID: 31900199; PMCID: PMC6942339.
243. Curtius K, Wong CJ, Hazelton WD, Kaz AM, Chak A, Willis JE, Grady WM, Luebeck EG. A Molecular Clock Infers Heterogeneous Tissue Age Among Patients with Barrett's Esophagus. PLoS Comput Biol.

2016 May 11;12(5):e1004919. doi: 10.1371/journal.pcbi.1004919. Erratum in: PLoS Comput Biol. 2017 Mar 17;13(3):e1005439. PMID: 27168458; PMCID: PMC4864310.

244. Anderson S, Poudel KR, Roh-Johnson M, Brabletz T, Yu M, Borenstein-Auerbach N, Grady WN, Bai J, Moens CB, Eisenman RN, Conacci-Sorrell M. MYC-nick promotes cell migration by inducing fascin expression and Cdc42 activation. Proc Natl Acad Sci U S A. 2016 Sep 13;113(37):E5481-90. doi: 10.1073/pnas.1610994113. Epub 2016 Aug 26. PMID: 27566402; PMCID: PMC5027433.
245. Cohen SA, Yu M, Baker K, Redman M, Wu C, Heinzerling TJ, Wirtz RM, Charalambous E, Pentheroudakis G, Kotoula V, Kalogeras KT, Fountzilas G, Grady WM. The CpG island methylator phenotype is concordant between primary colorectal carcinoma and matched distant metastases. Clin Epigenetics. 2017 May 2;9:46. doi: 10.1186/s13148-017-0347-1. PMID: 28469732; PMCID: PMC5414304.
246. Yuan Z, Baker K, Redman MW, Wang L, Adams SV, Yu M, Dickinson B, Makar K, Ulrich N, Böhm J, Wurscher M, Westerhoff M, Medwell S, Moonka R, Sinanan M, Fichera A, Vickers K, Grady WM. Dynamic plasma microRNAs are biomarkers for prognosis and early detection of recurrence in colorectal cancer. Br J Cancer. 2017 Oct 10;117(8):1202-1210. doi: 10.1038/bjc.2017.266. Epub 2017 Aug 15. PMID: 28809863; PMCID: PMC5674097.
247. Kaz AM, Wong CJ, Varadan V, Willis JE, Chak A, Grady WM. Global DNA methylation patterns in Barrett's esophagus, dysplastic Barrett's, and esophageal adenocarcinoma are associated with BMI, gender, and tobacco use. Clin Epigenetics. 2016 Oct 27;8:111. doi: 10.1186/s13148-016-0273-7. Erratum in: Clin Epigenetics. 2017 Mar 1;9:23. PMID: 27795744; PMCID: PMC5082363.
248. Luebeck EG, Curtius K, Hazelton WD, Maden S, Yu M, Thota PN, Patil DT, Chak A, Willis JE, Grady WM. Identification of a key role of widespread epigenetic drift in Barrett's esophagus and esophageal adenocarcinoma. Clin Epigenetics. 2017 Oct 16;9:113. doi: 10.1186/s13148-017-0409-4. PMID: 29046735; PMCID: PMC5644061.
249. Cohen SA, Wu C, Yu M, Gourgioti G, Wirtz R, Raptou G, Gkakou C, Kotoula V, Pentheroudakis G, Papaxoinis G, Karavasilis V, Pectasides D, Kalogeras KT, Fountzilas G, Grady WM. Evaluation of CpG Island Methylator Phenotype as a Biomarker in Colorectal Cancer Treated With Adjuvant Oxaliplatin. Clin Colorectal Cancer. 2016 Jun;15(2):164-9. doi: 10.1016/j.clcc.2015.10.005. Epub 2015 Nov 11. PMID: 26702772; PMCID: PMC4864501.
250. Overman MJ, Morris V, Moinova H, Manyam G, Ensor J, Lee MS, Eng C, Kee B, Fogelman D, Shroff RT, LaFramboise T, Mazard T, Feng T, Hamilton S, Broom B, Lutterbaugh J, Issa JP, Markowitz SD, Kopetz S. Phase I/II study of azacitidine and capecitabine/oxaliplatin (CAPOX) in refractory CIMP-high metastatic colorectal cancer: evaluation of circulating methylated vimentin. Oncotarget. 2016 Oct 11;7(41):67495-67506. doi: 10.18632/oncotarget.11317. PMID: 27542211; PMCID: PMC5341892.
251. Bosch LJ, Luo Y, Lao VV, Snaebjornsson P, Trooskens G, Vlassenbroeck I, Mongera S, Tang W, Welcsh P, Herman JG, Koopman M, Nagtegaal ID, Punt CJ, van Criekinge W, Meijer GA, Monnat RJ Jr, Carvalho B, Grady WM. WRN Promoter CpG Island Hypermethylation Does Not Predict More Favorable Outcomes for Patients with Metastatic Colorectal Cancer Treated with Irinotecan-Based Therapy. Clin Cancer Res. 2016 Sep 15;22(18):4612-22. doi: 10.1158/1078-0432.CCR-15-2703. Epub 2016 Apr 27. PMID: 27121793; PMCID: PMC5026547.
252. Cohen SA, Laurino M, Bowen DJ, Upton MP, Pritchard C, Hisama F, Jarvik G, Fichera A, Sjoding B, Bennett RL, Naylor L, Jacobson A, Burke W, Grady WM. Initiation of universal tumor screening for Lynch syndrome in colorectal cancer patients as a model for the implementation of genetic

information into clinical oncology practice. Cancer. 2016 Feb 1;122(3):393-401. doi: 10.1002/cncr.29758. Epub 2015 Oct 19. PMID: 26480326; PMCID: PMC4724321.
253. Han CJ, Gigic B, Schneider M, Kulu Y, Peoples AR, Ose J, Kölsch T, Jacobsen PB, Colditz GA, Figueiredo JC, Grady WM, Li CI, Shibata D, Siegel EM, Toriola AT, Ulrich AB, Syrjala KL, Ulrich CM. Risk factors for cancer-related distress in colorectal cancer survivors: one year post surgery. J Cancer Surviv. 2020 Jun;14(3):305-315. doi: 10.1007/s11764-019-00845-y. Epub 2020 Mar 12. PMID: 32166576; PMCID: PMC7261242.
254. Böhm J, Pianka F, Stüttgen N, Rho J, Gigic B, Zhang Y, Habermann N, Schrotz-King P, Abbenhardt-Martin C, Zielske L, Lampe PD, Ulrich A, Diener MK, Ulrich CM. Discovery of novel plasma proteins as biomarkers for the development of incisional hernias after midline incision in patients with colorectal cancer: The ColoCare study. Surgery. 2017 Mar;161(3):808-817. doi: 10.1016/j.surg.2016.08.025. Epub 2016 Oct 13. PMID: 27745870; PMCID: PMC5560863.
255. Rho JH, Ladd JJ, Li CI, Potter JD, Zhang Y, Shelley D, Shibata D, Coppola D, Yamada H, Toyoda H, Tada T, Kumada T, Brenner DE, Hanash SM, Lampe PD. Protein and glycomic plasma markers for early detection of adenoma and colon cancer. Gut. 2018 Mar;67(3):473-484. doi: 10.1136/gutjnl-2016-312794. Epub 2016 Nov 7. PMID: 27821646; PMCID: PMC5420499.
256. Garrison CB, Lastwika KJ, Zhang Y, Li CI, Lampe PD. Proteomic Analysis, Immune Dysregulation, and Pathway Interconnections with Obesity. J Proteome Res. 2017 Jan 6;16(1):274-287. doi: 10.1021/acs.jproteome.6b00611. Epub 2016 Nov 14. PMID: 27769113; PMCID: PMC5234688.
257. Rho JH, Ladd JJ, Li CI, Potter JD, Zhang Y, Shelley D, Shibata D, Coppola D, Yamada H, Toyoda H, Tada T, Kumada T, Brenner DE, Hanash SM, Lampe PD. Protein and glycomic plasma markers for early detection of adenoma and colon cancer. Gut. 2018 Mar;67(3):473-484. doi: 10.1136/gutjnl-2016-312794. Epub 2016 Nov 7. PMID: 27821646; PMCID: PMC5420499.
258. Hannigan GD, Duhaime MB, Ruffin MT 4th, Koumpouras CC, Schloss PD. Diagnostic Potential and Interactive Dynamics of the Colorectal Cancer Virome. mBio. 2018 Nov 20;9(6):e02248-18. doi: 10.1128/mBio.02248-18. PMID: 30459201; PMCID: PMC6247079.
259. Gupta S, Lieberman D, Anderson JC, Burke CA, Dominitz JA, Kaltenbach T, Robertson DJ, Shaukat A, Syngal S, Rex DK. Recommendations for Follow-Up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol. 2020 Mar;115(3):415-434. doi: 10.14309/ajg.0000000000000544. PMID: 32039982.
260. Baxter NT, Ruffin MT 4th, Rogers MA, Schloss PD. Microbiota-based model improves the sensitivity of fecal immunochemical test for detecting colonic lesions. Genome Med. 2016 Apr 6;8(1):37. doi: 10.1186/s13073-016-0290-3. PMID: 27056827; PMCID: PMC4823848.
261. Gupta S, Lieberman D, Anderson JC, Burke CA, Dominitz JA, Kaltenbach T, Robertson DJ, Shaukat A, Syngal S, Rex DK. Recommendations for Follow-Up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2020 Mar;158(4):1131-1153.e5. doi: 10.1053/j.gastro.2019.10.026. Epub 2020 Feb 7. PMID: 32044092.
262. Baxter NT, Koumpouras CC, Rogers MA, Ruffin MT 4th, Schloss PD. DNA from fecal immunochemical test can replace stool for detection of colonic lesions using a microbiota-based model. Microbiome. 2016 Nov 14;4(1):59. doi: 10.1186/s40168-016-0205-y. PMID: 27842559; PMCID: PMC5109736.
263. Poneros JM, Faye AS, Barr Fritcher EG, Sen A, Anandasabapathy S, Bresalier RS, Marcon N, Turgeon DK, Appelman H, Normolle D, Morrison LE, Brenner DE, Halling KC. A Multicenter Study of a Fluorescence In Situ Hybridization Probe Set for Diagnosing High-Grade Dysplasia and

Adenocarcinoma in Barrett's Esophagus. Dig Dis Sci. 2017 May;62(5):1216-1222. doi: 10.1007/s10620-017-4517-y. Epub 2017 Mar 6. PMID: 28265829; PMCID: PMC6052443.

264. Kang S, Li Q, Chen Q, Zhou Y, Park S, Lee G, Grimes B, Krysan K, Yu M, Wang W, Alber F, Sun F, Dubinett SM, Li W, Zhou XJ. CancerLocator: non-invasive cancer diagnosis and tissue-of-origin prediction using methylation profiles of cell-free DNA. Genome Biol. 2017 Mar 24;18(1):53. doi: 10.1186/s13059-017-1191-5. PMID: 28335812; PMCID: PMC5364586.
265. Spira A, Yurgelun MB, Alexandrov L, Rao A, Bejar R, Polyak K, Giannakis M, Shilatifard A, Finn OJ, Dhodapkar M, Kay NE, Braggio E, Vilar E, Mazzilli SA, Rebbeck TR, Garber JE, Velculescu VE, Disis ML, Wallace DC, Lippman SM. Precancer Atlas to Drive Precision Prevention Trials. Cancer Res. 2017 Apr 1;77(7):1510-1541. doi: 10.1158/0008-5472.CAN-16-2346. PMID: 28373404; PMCID: PMC6681830.
266. Vachani A, Sequist LV, Spira A. AJRCCM: 100-Year Anniversary. The Shifting Landscape for Lung Cancer: Past, Present, and Future. Am J Respir Crit Care Med. 2017 May 1;195(9):1150-1160. doi: 10.1164/rccm.201702-0433CI. PMID: 28459327; PMCID: PMC5439022.
267. AEGIS Study Team. Shared Gene Expression Alterations in Nasal and Bronchial Epithelium for Lung Cancer Detection. J Natl Cancer Inst. 2017 Jul 1;109(7):djw327. doi: 10.1093/jnci/djw327. PMID: 28376173; PMCID: PMC6059169.
268. Lee JM, Lee MH, Garon E, Goldman JW, Salehi-Rad R, Baratelli FE, Schaue D, Wang G, Rosen F, Yanagawa J, Walser TC, Lin Y, Park SJ, Adams S, Marincola FM, Tumeh PC, Abtin F, Suh R, Reckamp KL, Lee G, Wallace WD, Lee S, Zeng G, Elashoff DA, Sharma S, Dubinett SM. Phase I Trial of Intratumoral Injection of CCL21 Gene-Modified Dendritic Cells in Lung Cancer Elicits Tumor-Specific Immune Responses and CD8+ T-cell Infiltration. Clin Cancer Res. 2017 Aug 15;23(16):4556-4568. doi: 10.1158/1078-0432.CCR-16-2821. Epub 2017 May 3. PMID: 28468947; PMCID: PMC5599263.
269. Beane J, Campbell JD, Lel J, Vick J, Spira A. Genomic approaches to accelerate cancer interception. Lancet Oncol. 2017 Aug;18(8):e494-e502. doi: 10.1016/S1470-2045(17)30373-X. Epub 2017 Jul 26. PMID: 28759388; PMCID: PMC6020676.
270. Pine PS, Lund SP, Parsons JR, Vang LK, Mahabal AA, Cinquini L, Kelly SC, Kincaid H, Crichton DJ, Spira A, Liu G, Gower AC, Pass HI, Goparaju C, Dubinett SM, Krysan K, Stass SA, Kukuruga D, Van Keuren-Jensen K, Courtright-Lim A, Thompson KL, Rosenzweig BA, Sorbara L, Srivastava S, Salit ML. Summarizing performance for genome scale measurement of miRNA: reference samples and metrics. BMC Genomics. 2018 Mar 6;19(1):180. doi: 10.1186/s12864-018-4496-1. PMID: 29510677; PMCID: PMC5838960.
271. Billatos E, Vick JL, Lenburg ME, Spira AE. The Airway Transcriptome as a Biomarker for Early Lung Cancer Detection. Clin Cancer Res. 2018 Jul 1;24(13):2984-2992. doi: 10.1158/1078-0432.CCR-16-3187. Epub 2018 Feb 20. PMID: 29463557.
272. Dhar M, Lam JN, Walser T, Dubinett SM, Rettig MB, Di Carlo D. Functional profiling of circulating tumor cells with an integrated vortex capture and single-cell protease activity assay. Proc Natl Acad Sci U S A. 2018 Oct 2;115(40):9986-9991. doi: 10.1073/pnas.1803884115. Epub 2018 Sep 17. PMID: 30224472; PMCID: PMC6176626.
273. Krysan K, Tran LM, Grimes BS, Fishbein GA, Seki A, Gardner BK, Walser TC, Salehi-Rad R, Yanagawa J, Lee JM, Sharma S, Aberle DR, Spira AE, Elashoff DA, Wallace WD, Fishbein MC, Dubinett SM. The Immune Contexture Associates with the Genomic Landscape in Lung Adenomatous Premalignancy. Cancer Res. 2019 Oct 1;79(19):5022-5033. doi: 10.1158/0008-5472.CAN-19-0153. Epub 2019 May 29. PMID: 31142513; PMCID: PMC6774823.

274. Li R, Ong SL, Tran LM, Jing Z, Liu B, Park SJ, Huang ZL, Walser TC, Heinrich EL, Lee G, Salehi-Rad R, Crosson WP, Pagano PC, Paul MK, Xu S, Herschman H, Krysan K, Dubinett S. Chronic IL-1β-induced inflammation regulates epithelial-to-mesenchymal transition memory phenotypes via epigenetic modifications in non-small cell lung cancer. Sci Rep. 2020 Jan 15;10(1):377. doi: 10.1038/s41598-019-57285-y. Erratum in: Sci Rep. 2020 Mar 4;10(1):4386. PMID: 31941995; PMCID: PMC6962381.
275. Tsay JJ, Wu BG, Badri MH, Clemente JC, Shen N, Meyn P, Li Y, Yie TA, Lhakhang T, Olsen E, Murthy V, Michaud G, Sulaiman I, Tsirigos A, Heguy A, Pass H, Weiden MD, Rom WN, Sterman DH, Bonneau R, Blaser MJ, Segal LN. Airway Microbiota Is Associated with Upregulation of the PI3K Pathway in Lung Cancer. Am J Respir Crit Care Med. 2018 Nov 1;198(9):1188-1198. doi: 10.1164/rccm.201710-2118OC. PMID: 29864375; PMCID: PMC6221574.
276. Dai L, Li J, Tsay JJ, Yie TA, Munger JS, Pass H, Rom WN, Tan EM, Zhang JY. Identification of autoantibodies to ECH1 and HNRNPA2B1 as potential biomarkers in the early detection of lung cancer. Oncoimmunology. 2017 Mar 31;6(5):e1310359. doi: 10.1080/2162402X.2017.1310359. PMID: 28638733; PMCID: PMC5467997.
277. Dai L, Tsay JC, Li J, Yie TA, Munger JS, Pass H, Rom WN, Zhang Y, Tan EM, Zhang JY. Autoantibodies against tumor-associated antigens in the early detection of lung cancer. Lung Cancer. 2016 Sep;99:172-9. doi: 10.1016/j.lungcan.2016.07.018. Epub 2016 Jul 18. PMID: 27565936.
278. Segal LN, Clemente JC, Tsay JC, Koralov SB, Keller BC, Wu BG, Li Y, Shen N, Ghedin E, Morris A, Diaz P, Huang L, Wikoff WR, Ubeda C, Artacho A, Rom WN, Sterman DH, Collman RG, Blaser MJ, Weiden MD. Enrichment of the lung microbiome with oral taxa is associated with lung inflammation of a Th17 phenotype. Nat Microbiol. 2016 Apr 4;1:16031. doi: 10.1038/nmicrobiol.2016.31. PMID: 27572644; PMCID: PMC5010013.
279. Lopatin S, Tsay JC, Addrizzo-Harris D, Munger JS, Pass H, Rom WN. Reduced lung function in smokers in a lung cancer screening cohort with asbestos exposure and pleural plaques. Am J Ind Med. 2016 Mar;59(3):178-85. doi: 10.1002/ajim.22571. Epub 2016 Jan 27. Erratum in: Am J Ind Med. 2016 May;59(5):424. PMID: 26815630.
280. DeCotiis C, Hu Y, Greenberg AK, Huie M, Tsay JC, Pass H, Goldberg JD, Rom WN. Inflammatory cytokines and non-small cell lung cancer in a CT-scan screening cohort: Background review of the literature. Cancer Biomark. 2016;16(2):219-33. doi: 10.3233/CBM-150559. PMID: 26756613.
281. Kossenkov AV, Qureshi R, Dawany NB, Wickramasinghe J, Liu Q, Majumdar RS, Chang C, Widura S, Kumar T, Horng WH, Konnisto E, Criner G, Tsay JJ, Pass H, Yendamuri S, Vachani A, Bauer T, Nam B, Rom WN, Showe MK, Showe LC. A Gene Expression Classifier from Whole Blood Distinguishes Benign from Malignant Lung Nodules Detected by Low-Dose CT. Cancer Res. 2019 Jan 1;79(1):263-273. doi: 10.1158/0008-5472.CAN-18-2032. Epub 2018 Nov 28. PMID: 30487137; PMCID: PMC6317999.
282. Yang L, Zhang Y, Shan W, Hu Z, Yuan J, Pi J, Wang Y, Fan L, Tang Z, Li C, Hu X, Tanyi JL, Fan Y, Huang Q, Montone K, Dang CV, Zhang L. Repression of BET activity sensitizes homologous recombination-proficient cancers to PARP inhibition. Sci Transl Med. 2017 Jul 26;9(400):eaal1645. doi: 10.1126/scitranslmed.aal1645. PMID: 28747513; PMCID: PMC5705017.
283. Huang Q, Yan J, Agami R. Long non-coding RNAs in metastasis. Cancer Metastasis Rev. 2018 Mar;37(1):75-81. doi: 10.1007/s10555-017-9713-x. PMID: 29230620.

284. Kadara H, Sivakumar S, Jakubek Y, San Lucas FA, Lang W, McDowell T, Weber Z, Behrens C, Davies GE, Kalhor N, Moran C, El-Zein R, Mehran R, Swisher SG, Wang J, Zhang J, Fujimoto J, Fowler J, Heymach JV, Dubinett S, Spira AE, Ehli EA, Wistuba II, Scheet P. Driver Mutations in Normal Airway Epithelium Elucidate Spatiotemporal Resolution of Lung Cancer. Am J Respir Crit Care Med. 2019 Sep 15;200(6):742-750. doi: 10.1164/rccm.201806-1178OC. PMID: 30896962; PMCID: PMC6775870.
285. Garland LL, Guillen-Rodriguez J, Hsu CH, Yozwiak M, Zhang HH, Alberts DS, Davis LE, Szabo E, Merenstein C, Lel J, Zhang X, Liu H, Liu G, Spira AE, Beane JE, Wojtowicz M, Chow HS. Effect of Intermittent Versus Continuous Low-Dose Aspirin on Nasal Epithelium Gene Expression in Current Smokers: A Randomized, Double-Blinded Trial. Cancer Prev Res (Phila). 2019 Nov;12(11):809-820. doi: 10.1158/1940-6207.CAPR-19-0036. Epub 2019 Aug 26. PMID: 31451521.
286. Wu AC, Kiley JP, Noel PJ, Amur S, Burchard EG, Clancy JP, Galanter J, Inada M, Jones TK, Kropski JA, Loyd JE, Nogee LM, Raby BA, Rogers AJ, Schwartz DA, Sin DD, Spira A, Weiss ST, Young LR, Himes BE. Current Status and Future Opportunities in Lung Precision Medicine Research with a Focus on Biomarkers. An American Thoracic Society/National Heart, Lung, and Blood Institute Research Statement. Am J Respir Crit Care Med. 2018 Dec 15;198(12):e116-e136. doi: 10.1164/rccm.201810-1895ST. PMID: 30640517; PMCID: PMC6835090.
287. Seijo LM, Peled N, Ajona D, Boeri M, Field JK, Sozzi G, Pio R, Zulueta JJ, Spira A, Massion PP, Mazzone PJ, Montuenga LM. Biomarkers in Lung Cancer Screening: Achievements, Promises, and Challenges. J Thorac Oncol. 2019 Mar;14(3):343-357. doi: 10.1016/j.jtho.2018.11.023. Epub 2018 Dec 4. PMID: 30529598; PMCID: PMC6494979.
288. Billatos E, Duan F, Moses E, Marques H, Mahon I, Dymond L, Apgar C, Aberle D, Washko G, Spira A; DECAMP investigators. Detection of early lung cancer among military personnel (DECAMP) consortium: study protocols. BMC Pulm Med. 2019 Mar 7;19(1):59. doi: 10.1186/s12890-019-0825-7. PMID: 30845938; PMCID: PMC6407252.
289. Billatos E, Vick JL, Lenburg ME, Spira AE. The Airway Transcriptome as a Biomarker for Early Lung Cancer Detection. Clin Cancer Res. 2018 Jul 1;24(13):2984-2992. doi: 10.1158/1078-0432.CCR-16-3187. Epub 2018 Feb 20. PMID: 29463557.
290. Kantrowitz J, Sinjab A, Xu L, McDowell TL, Sivakumar S, Lang W, Nunomura-Nakamura S, Fukuoka J, Nemer G, Darwiche N, Chami H, Tfayli A, Wistuba II, Scheet P, Fujimoto J, Spira AE, Kadara H. Genome-Wide Gene Expression Changes in the Normal-Appearing Airway during the Evolution of Smoking-Associated Lung Adenocarcinoma. Cancer Prev Res (Phila). 2018 Apr;11(4):237-248. doi: 10.1158/1940-6207.CAPR-17-0295. Epub 2018 Jan 30. PMID: 29382653; PMCID: PMC6679600.
291. Khalil AA, Sivakumar S, Lucas FAS, McDowell T, Lang W, Tabata K, Fujimoto J, Yatabe Y, Spira A, Scheet P, Nemer G, Kadara H. TBX2 subfamily suppression in lung cancer pathogenesis: a high-potential marker for early detection. Oncotarget. 2017 Aug 4;8(40):68230-68241. doi: 10.18632/oncotarget.19938. PMID: 28978111; PMCID: PMC5620251.
292. Kang S, Li Q, Chen Q, Zhou Y, Park S, Lee G, Grimes B, Krysan K, Yu M, Wang W, Alber F, Sun F, Dubinett SM, Li W, Zhou XJ. CancerLocator: non-invasive cancer diagnosis and tissue-of-origin prediction using methylation profiles of cell-free DNA. Genome Biol. 2017 Mar 24;18(1):53. doi: 10.1186/s13059-017-1191-5. PMID: 28335812; PMCID: PMC5364586.
293. Spira A, Yurgelun MB, Alexandrov L, Rao A, Bejar R, Polyak K, Giannakis M, Shilatifard A, Finn OJ, Dhodapkar M, Kay NE, Braggio E, Vilar E, Mazzilli SA, Rebbeck TR, Garber JE, Velculescu VE, Disis ML, Wallace DC, Lippman SM. Precancer Atlas to Drive Precision Prevention Trials. Cancer Res. 2017 Apr 1;77(7):1510-1541. doi: 10.1158/0008-5472.CAN-16-2346. PMID: 28373404; PMCID: PMC6681830.

294. Vachani A, Sequist LV, Spira A. AJRCCM: 100-Year Anniversary. The Shifting Landscape for Lung Cancer: Past, Present, and Future. Am J Respir Crit Care Med. 2017 May 1;195(9):1150-1160. doi: 10.1164/rccm.201702-0433CI. PMID: 28459327; PMCID: PMC5439022.
295. AEGIS Study Team. Shared Gene Expression Alterations in Nasal and Bronchial Epithelium for Lung Cancer Detection. J Natl Cancer Inst. 2017 Jul 1;109(7):djw327. doi: 10.1093/jnci/djw327. PMID: 28376173; PMCID: PMC6059169.
296. Lee JM, Lee MH, Garon E, Goldman JW, Salehi-Rad R, Baratelli FE, Schaue D, Wang G, Rosen F, Yanagawa J, Walser TC, Lin Y, Park SJ, Adams S, Marincola FM, Tumeh PC, Abtin F, Suh R, Reckamp KL, Lee G, Wallace WD, Lee S, Zeng G, Elashoff DA, Sharma S, Dubinett SM. Phase I Trial of Intratumoral Injection of CCL21 Gene-Modified Dendritic Cells in Lung Cancer Elicits Tumor-Specific Immune Responses and CD8+ T-cell Infiltration. Clin Cancer Res. 2017 Aug 15;23(16):4556-4568. doi: 10.1158/1078-0432.CCR-16-2821. Epub 2017 May 3. PMID: 28468947; PMCID: PMC5599263.
297. Beane J, Campbell JD, Lel J, Vick J, Spira A. Genomic approaches to accelerate cancer interception. Lancet Oncol. 2017 Aug;18(8):e494-e502. doi: 10.1016/S1470-2045(17)30373-X. Epub 2017 Jul 26. PMID: 28759388; PMCID: PMC6020676.
298. Pine PS, Lund SP, Parsons JR, Vang LK, Mahabal AA, Cinquini L, Kelly SC, Kincaid H, Crichton DJ, Spira A, Liu G, Gower AC, Pass HI, Goparaju C, Dubinett SM, Krysan K, Stass SA, Kukuruga D, Van Keuren-Jensen K, Courtright-Lim A, Thompson KL, Rosenzweig BA, Sorbara L, Srivastava S, Salit ML. Summarizing performance for genome scale measurement of miRNA: reference samples and metrics. BMC Genomics. 2018 Mar 6;19(1):180. doi: 10.1186/s12864-018-4496-1. PMID: 29510677; PMCID: PMC5838960.
299. Dhar M, Lam JN, Walser T, Dubinett SM, Rettig MB, Di Carlo D. Functional profiling of circulating tumor cells with an integrated vortex capture and single-cell protease activity assay. Proc Natl Acad Sci U S A. 2018 Oct 2;115(40):9986-9991. doi: 10.1073/pnas.1803884115. Epub 2018 Sep 17. PMID: 30224472; PMCID: PMC6176626.
300. Krysan K, Tran LM, Grimes BS, Fishbein GA, Seki A, Gardner BK, Walser TC, Salehi-Rad R, Yanagawa J, Lee JM, Sharma S, Aberle DR, Spira AE, Elashoff DA, Wallace WD, Fishbein MC, Dubinett SM. The Immune Contexture Associates with the Genomic Landscape in Lung Adenomatous Premalignancy. Cancer Res. 2019 Oct 1;79(19):5022-5033. doi: 10.1158/0008-5472.CAN-19-0153. Epub 2019 May 29. PMID: 31142513; PMCID: PMC6774823.
301. Li R, Ong SL, Tran LM, Jing Z, Liu B, Park SJ, Huang ZL, Walser TC, Heinrich EL, Lee G, Salehi-Rad R, Crosson WP, Pagano PC, Paul MK, Xu S, Herschman H, Krysan K, Dubinett S. Author Correction: Chronic IL-1β-induced inflammation regulates epithelial-to-mesenchymal transition memory phenotypes via epigenetic modifications in non-small cell lung cancer. Sci Rep. 2020 Mar 4;10(1):4386. doi: 10.1038/s41598-020-61341-3. Erratum for: Sci Rep. 2020 Jan 15;10(1):377. PMID: 32127587; PMCID: PMC7054550.
302. Li R, Ong SL, Tran LM, Jing Z, Liu B, Park SJ, Huang ZL, Walser TC, Heinrich EL, Lee G, Salehi-Rad R, Crosson WP, Pagano PC, Paul MK, Xu S, Herschman H, Krysan K, Dubinett S. Chronic IL-1β-induced inflammation regulates epithelial-to-mesenchymal transition memory phenotypes via epigenetic modifications in non-small cell lung cancer. Sci Rep. 2020 Jan 15;10(1):377. doi: 10.1038/s41598-019-57285-y. Erratum in: Sci Rep. 2020 Mar 4;10(1):4386. PMID: 31941995; PMCID: PMC6962381.

303. Paul R, Schabath MB, Gillies R, Hall LO, Goldgof DB. Hybrid models for lung nodule malignancy prediction utilizing convolutional neural network ensembles and clinical data. J Med Imaging (Bellingham). 2020 Mar;7(2):024502. doi: 10.1117/1.JMI.7.2.024502. Epub 2020 Apr 6. PMID: 32280729; PMCID: PMC7134617.
304. Tunali I, Hall LO, Napel S, Cherezov D, Guvenis A, Gillies RJ, Schabath MB. Stability and reproducibility of computed tomography radiomic features extracted from peritumoral regions of lung cancer lesions. Med Phys. 2019 Nov;46(11):5075-5085. doi: 10.1002/mp.13808. Epub 2019 Sep 23. PMID: 31494946; PMCID: PMC6842054.
305. Tunali I, Gray JE, Qi J, Abdalah M, Jeong DK, Guvenis A, Gillies RJ, Schabath MB. Novel clinical and radiomic predictors of rapid disease progression phenotypes among lung cancer patients treated with immunotherapy: An early report. Lung Cancer. 2019 Mar;129:75-79. doi: 10.1016/j.lungcan.2019.01.010. Epub 2019 Jan 23. PMID: 30797495; PMCID: PMC6450086.
306. Triplette M, Crothers K, Mahale P, Yanik EL, Valapour M, Lynch CF, Schabath MB, Castenson D, Engels EA. Risk of lung cancer in lung transplant recipients in the United States. Am J Transplant. 2019 May;19(5):1478-1490. doi: 10.1111/ajt.15181. Epub 2018 Dec 18. PMID: 30565414; PMCID: PMC6872188.
307. Schabath MB, Cote ML. Cancer Progress and Priorities: Lung Cancer. Cancer Epidemiol Biomarkers Prev. 2019 Oct;28(10):1563-1579. doi: 10.1158/1055-9965.EPI-19-0221. PMID: 31575553; PMCID: PMC6777859.
308. Schabath MB, Aberle DR. MILD trial, strong confirmation of lung cancer screening efficacy. Nat Rev Clin Oncol. 2019 Sep;16(9):529-530. doi: 10.1038/s41571-019-0231-3. PMID: 31118491.
309. Reyes ME, Schabath MB. Optimal lung cancer screening intervals following a negative low-dose computed tomography result. J Thorac Dis. 2019 Sep;11(Suppl 15):S1916-S1918. doi: 10.21037/jtd.2019.08.85. PMID: 31632785; PMCID: PMC6783784.
310. Paul R, Schabath M, Balagurunathan Y, Liu Y, Li Q, Gillies R, Hall LO, Goldgof DB. Explaining Deep Features Using Radiologist-Defined Semantic Features and Traditional Quantitative Features. Tomography. 2019 Mar;5(1):192-200. doi: 10.18383/j.tom.2018.00034. PMID: 30854457; PMCID: PMC6403047.
311. Lu H, Mu W, Balagurunathan Y, Qi J, Abdalah MA, Garcia AL, Ye Z, Gillies RJ, Schabath MB. Multi-window CT based Radiomic signatures in differentiating indolent versus aggressive lung cancers in the National Lung Screening Trial: a retrospective study. Cancer Imaging. 2019 Jun 28;19(1):45. doi: 10.1186/s40644-019-0232-6. PMID: 31253194; PMCID: PMC6599273.
312. Cherezov D, Goldgof D, Hall L, Gillies R, Schabath M, Müller H, Depeursinge A. Revealing Tumor Habitats from Texture Heterogeneity Analysis for Classification of Lung Cancer Malignancy and Aggressiveness. Sci Rep. 2019 Mar 14;9(1):4500. doi: 10.1038/s41598-019-38831-0. PMID: 30872600; PMCID: PMC6418269.
313. Bi WL, Hosny A, Schabath MB, Giger ML, Birkbak NJ, Mehrtash A, Allison T, Arnaout O, Abbosh C, Dunn IF, Mak RH, Tamimi RM, Tempany CM, Swanton C, Hoffmann U, Schwartz LH, Gillies RJ, Huang RY, Aerts HJWL. Artificial intelligence in cancer imaging: Clinical challenges and applications. Version 2. CA Cancer J Clin. 2019 Mar;69(2):127-157. doi: 10.3322/caac.21552. Epub 2019 Feb 5. PMID: 30720861; PMCID: PMC6403009.

314. Balagurunathan Y, Schabath MB, Wang H, Liu Y, Gillies RJ. Quantitative Imaging features Improve Discrimination of Malignancy in Pulmonary nodules. Sci Rep. 2019 Jun 12;9(1):8528. doi: 10.1038/s41598-019-44562-z. PMID: 31189944; PMCID: PMC6561979.
315. Schabath MB. Risk models to select high risk candidates for lung cancer screening. Ann Transl Med. 2018 Feb;6(3):65. doi: 10.21037/atm.2018.01.12. PMID: 29611557; PMCID: PMC5879506.
316. Paul R, Liu Y, Li Q, Hall L, Goldgof D, Balagurunathan Y, Schabath M, Gillies R. Representation of Deep Features using Radiologist defined Semantic Features. Proc Int Jt Conf Neural Netw. 2018 Jul;2018:10.1109/IJCNN.2018.8489440. doi: 10.1109/IJCNN.2018.8489440. Epub 2018 Sep 15. PMID: 30443437; PMCID: PMC6233304.
317. Paul R, Hawkins SH, Schabath MB, Gillies RJ, Hall LO, Goldgof DB. Predicting malignant nodules by fusing deep features with classical radiomics features. J Med Imaging (Bellingham). 2018 Jan;5(1):011021. doi: 10.1117/1.JMI.5.1.011021. Epub 2018 Mar 21. PMID: 29594181; PMCID: PMC5862127.
318. Paul R, Hall L, Goldgof D, Schabath M, Gillies R. Predicting Nodule Malignancy using a CNN Ensemble Approach. Proc Int Jt Conf Neural Netw. 2018 Jul;2018:10.1109/IJCNN.2018.8489345. doi: 10.1109/IJCNN.2018.8489345. Epub 2018 Oct 15. PMID: 30443438; PMCID: PMC6233309.
319. Liu Y, Wang H, Li Q, McGettigan MJ, Balagurunathan Y, Garcia AL, Thompson ZJ, Heine JJ, Ye Z, Gillies RJ, Schabath MB. Radiologic Features of Small Pulmonary Nodules and Lung Cancer Risk in the National Lung Screening Trial: A Nested Case-Control Study. Version 2. Radiology. 2018 Jan;286(1):298-306. doi: 10.1148/radiol.2017161458. Epub 2017 Aug 24. PMID: 28837413; PMCID: PMC5738292.
320. Li Q, Balagurunathan Y, Liu Y, Qi J, Schabath MB, Ye Z, Gillies RJ. Comparison Between Radiological Semantic Features and Lung-RADS in Predicting Malignancy of Screen-Detected Lung Nodules in the National Lung Screening Trial. Clin Lung Cancer. 2018 Mar;19(2):148-156.e3. doi: 10.1016/j.cllc.2017.10.002. Epub 2017 Oct 13. PMID: 29137847; PMCID: PMC5825260.
321. Cherezov D, Hawkins SH, Goldgof DB, Hall LO, Liu Y, Li Q, Balagurunathan Y, Gillies RJ, Schabath MB. Delta radiomic features improve prediction for lung cancer incidence: A nested case-control analysis of the National Lung Screening Trial. Cancer Med. 2018 Dec;7(12):6340-6356. doi: 10.1002/cam4.1852. Epub 2018 Dec 1. PMID: 30507033; PMCID: PMC6308046.
322. Alahmari SS, Cherezov D, Goldgof D, Hall L, Gillies RJ, Schabath MB. Delta Radiomics Improves Pulmonary Nodule Malignancy Prediction in Lung Cancer Screening. IEEE Access. 2018;6:77796-77806. doi: 10.1109/ACCESS.2018.2884126. Epub 2018 Nov 29. PMID: 30607311; PMCID: PMC6312194.
323. Tunali I, Stringfield O, Guvenis A, Wang H, Liu Y, Balagurunathan Y, Lambin P, Gillies RJ, Schabath MB. Radial gradient and radial deviation radiomic features from pre-surgical CT scans are associated with survival among lung adenocarcinoma patients. Oncotarget. 2017 Oct 6;8(56):96013-96026. doi: 10.18632/oncotarget.21629. PMID: 29221183; PMCID: PMC5707077.
324. Shafiq-Ul-Hassan M, Zhang GG, Latifi K, Ullah G, Hunt DC, Balagurunathan Y, Abdalah MA, Schabath MB, Goldgof DG, Mackin D, Court LE, Gillies RJ, Moros EG. Intrinsic dependencies of CT radiomic features on voxel size and number of gray levels. Med Phys. 2017 Mar;44(3):1050-1062. doi: 10.1002/mp.12123. PMID: 28112418; PMCID: PMC5462462.
325. Liu Y, Balagurunathan Y, Atwater T, Antic S, Li Q, Walker RC, Smith GT, Massion PP, Schabath MB, Gillies RJ. Radiological Image Traits Predictive of Cancer Status in Pulmonary Nodules. Clin Cancer

Res. 2017 Mar 15;23(6):1442-1449. doi: 10.1158/1078-0432.CCR-15-3102. Epub 2016 Sep 23. PMID: 27663588; PMCID: PMC5527551.

326. Paul R, Hawkins SH, Balagurunathan Y, Schabath MB, Gillies RJ, Hall LO, Goldgof DB. Deep Feature Transfer Learning in Combination with Traditional Features Predicts Survival Among Patients with Lung Adenocarcinoma. Version 2. Tomography. 2016 Dec;2(4):388-395. doi: 10.18383/j.tom.2016.00211. PMID: 28066809; PMCID: PMC5218828.
327. Cherezov D, Hawkins S, Goldgof D, Hall L, Balagurunathan Y, Gillies RJ, Schabath MB. Improving malignancy prediction through feature selection informed by nodule size ranges in NLST. Conf Proc IEEE Int Conf Syst Man Cybern. 2016 Oct;2016:001939-1944. doi: 10.1109/SMC.2016.7844523. Epub 2017 Feb 9. PMID: 30473607; PMCID: PMC6251413.
328. Napolitano A, Antoine DJ, Pellegrini L, Baumann F, Pagano I, Pastorino S, Goparaju CM, Prokrym K, Canino C, Pass HI, Carbone M, Yang H. Expression of Concern: HMGB1 and Its Hyperacetylated Isoform are Sensitive and Specific Serum Biomarkers to Detect Asbestos Exposure and to Identify Mesothelioma Patients. Clin Cancer Res. 2020 Mar 15;26(6):1529. doi: 10.1158/1078-0432.CCR-20-0338. PMID: 32169964.
329. ICGC/TCGA Pan-Cancer Analysis of Whole Genomes Consortium. Pan-cancer analysis of whole genomes. Version 2. Nature. 2020 Feb;578(7793):82-93. doi: 10.1038/s41586-020-1969-6. Epub 2020 Feb 5. PMID: 32025007; PMCID: PMC7025898.
330. Thorsson V, Gibbs DL, Brown SD, Wolf D, Bortone DS, Ou Yang TH, Porta-Pardo E, Gao GF, Plaisier CL, Eddy JA, Ziv E, Culhane AC, Paull EO, Sivakumar IKA, Gentles AJ, Malhotra R, Farshidfar F, Colaprico A, Parker JS, Mose LE, Vo NS, Liu J, Liu Y, Rader J, Dhankani V, Reynolds SM, Bowlby R, Califano A, Cherniack AD, Anastassiou D, Bedognetti D, Mokrab Y, Newman AM, Rao A, Chen K, Krasnitz A, Hu H, Malta TM, Noushmehr H, Pedamallu CS, Bullman S, Ojesina AI, Lamb A, Zhou W, Shen H, Choueiri TK, Weinstein JN, Guinney J, Saltz J, Holt RA, Rabkin CS; Cancer Genome Atlas Research Network, Lazar AJ, Serody JS, Demicco EG, Disis ML, Vincent BG, Shmulevich I. The Immune Landscape of Cancer. Immunity. 2019 Aug 20;51(2):411-412. doi: 10.1016/j.immuni.2019.08.004. Erratum for: Immunity. 2018 Apr 17;48(4):812-830.e14. PMID: 31433971.
331. Hu X, Fujimoto J, Ying L, Fukuoka J, Ashizawa K, Sun W, Reuben A, Chow CW, McGranahan N, Chen R, Hu J, Godoy MC, Tabata K, Kuroda K, Shi L, Li J, Behrens C, Parra ER, Little LD, Gumbs C, Mao X, Song X, Tippen S, Thornton RL, Kadara H, Scheet P, Roarty E, Ostrin EJ, Wang X, Carter BW, Antonoff MB, Zhang J, Vaporciyan AA, Pass H, Swisher SG, Heymach JV, Lee JJ, Wistuba II, Hong WK, Futreal PA, Su D, Zhang J. Multi-region exome sequencing reveals genomic evolution from preneoplasia to lung adenocarcinoma. Nat Commun. 2019 Jul 5;10(1):2978. doi: 10.1038/s41467-019-10877-8. PMID: 31278276; PMCID: PMC6611767.
332. Baird AM, Easty D, Jarzabek M, Shiels L, Soltermann A, Klebe S, Raeppel S, MacDonagh L, Wu C, Griggs K, Kirschner MB, Stanfill B, Nonaka D, Goparaju CM, Murer B, Fennell DA, O'Donnell DM, Barr MP, Mutti L, Reid G, Finn S, Cuffe S, Pass HI, Opitz I, Byrne AT, O'Byrne KJ, Gray SG. When RON MET TAM in Mesothelioma: All Druggable for One, and One Drug for All? Front Endocrinol (Lausanne). 2019 Feb 26;10:89. doi: 10.3389/fendo.2019.00089. PMID: 30863365; PMCID: PMC6399142.
333. Peters BA, Hayes RB, Goparaju C, Reid C, Pass HI, Ahn J. The Microbiome in Lung Cancer Tissue and Recurrence-Free Survival. Cancer Epidemiol Biomarkers Prev. 2019 Apr;28(4):731-740. doi: 10.1158/1055-9965.EPI-18-0966. Epub 2019 Feb 7. PMID: 30733306; PMCID: PMC6449216.
334. Kossenkov AV, Qureshi R, Dawany NB, Wickramasinghe J, Liu Q, Majumdar RS, Chang C, Widura S, Kumar T, Horng WH, Konnisto E, Criner G, Tsay JJ, Pass H, Yendamuri S, Vachani A, Bauer T, Nam B,

Rom WN, Showe MK, Showe LC. A Gene Expression Classifier from Whole Blood Distinguishes Benign from Malignant Lung Nodules Detected by Low-Dose CT. Cancer Res. 2019 Jan 1;79(1):263-273. doi: 10.1158/0008-5472.CAN-18-2032. Epub 2018 Nov 28. PMID: 30487137; PMCID: PMC6317999.

335. Wang Y, Xu X, Maglic D, Dill MT, Mojumdar K, Ng PK, Jeong KJ, Tsang YH, Moreno D, Bhavana VH, Peng X, Ge Z, Chen H, Li J, Chen Z, Zhang H, Han L, Du D, Creighton CJ, Mills GB; Cancer Genome Atlas Research Network, Camargo F, Liang H. Comprehensive Molecular Characterization of the Hippo Signaling Pathway in Cancer. Cell Rep. 2018 Oct 30;25(5):1304-1317.e5. doi: 10.1016/j.celrep.2018.10.001. PMID: 30380420; PMCID: PMC6326181.
336. Pastorino S, Yoshikawa Y, Pass HI, Emi M, Nasu M, Pagano I, Takinishi Y, Yamamoto R, Minaai M, Hashimoto-Tamaoki T, Ohmuraya M, Goto K, Goparaju C, Sarin KY, Tanji M, Bononi A, Napolitano A, Gaudino G, Hesdorffer M, Yang H, Carbone M. A Subset of Mesotheliomas With Improved Survival Occurring in Carriers of BAP1 and Other Germline Mutations. J Clin Oncol. 2018 Oct 30;36(35):JCO2018790352. doi: 10.1200/JCO.2018.79.0352. Epub ahead of print. PMID: 30376426; PMCID: PMC7162737.
337. Hmeljak J, Sanchez-Vega F, Hoadley KA, Shih J, Stewart C, Heiman D, Tarpey P, Danilova L, Drill E, Gibb EA, Bowlby R, Kanchi R, Osmanbeyoglu HU, Sekido Y, Takeshita J, Newton Y, Graim K, Gupta M, Gay CM, Diao L, Gibbs DL, Thorsson V, Iype L, Kantheti H, Severson DT, Ravegnini G, Desmeules P, Jungbluth AA, Travis WD, Dacic S, Chirieac LR, Galateau-Sallé F, Fujimoto J, Husain AN, Silveira HC, Rusch VW, Rintoul RC, Pass H, Kindler H, Zauderer MG, Kwiatkowski DJ, Bueno R, Tsao AS, Creaney J, Lichtenberg T, Leraas K, Bowen J; TCGA Research Network, Felau I, Zenklusen JC, Akbani R, Cherniack AD, Byers LA, Noble MS, Fletcher JA, Robertson AG, Shen R, Aburatani H, Robinson BW, Campbell P, Ladanyi M. Integrative Molecular Characterization of Malignant Pleural Mesothelioma. Cancer Discov. 2018 Dec;8(12):1548-1565. doi: 10.1158/2159-8290.CD-18-0804. Epub 2018 Oct 15. PMID: 30322867; PMCID: PMC6310008.
338. Korkut A, Zaidi S, Kanchi RS, Rao S, Gough NR, Schultz A, Li X, Lorenzi PL, Berger AC, Robertson G, Kwong LN, Datto M, Roszik J, Ling S, Ravikumar V, Manyam G, Rao A, Shelley S, Liu Y, Ju Z, Hansel D, de Velasco G, Pennathur A, Andersen JB, O'Rourke CJ, Ohshiro K, Jogunoori W, Nguyen BN, Li S, Osmanbeyoglu HU, Ajani JA, Mani SA, Houseman A, Wiznerowicz M, Chen J, Gu S, Ma W, Zhang J, Tong P, Cherniack AD, Deng C, Resar L; Cancer Genome Atlas Research Network, Weinstein JN, Mishra L, Akbani R. A Pan-Cancer Analysis Reveals High-Frequency Genetic Alterations in Mediators of Signaling by the TGF-β Superfamily. Cell Syst. 2018 Oct 24;7(4):422-437.e7. doi: 10.1016/j.cels.2018.08.010. Epub 2018 Sep 26. PMID: 30268436; PMCID: PMC6370347.
339. Bailey MH, Tokheim C, Porta-Pardo E, Sengupta S, Bertrand D, Weerasinghe A, Colaprico A, Wendl MC, Kim J, Reardon B, Kwok-Shing Ng P, Jeong KJ, Cao S, Wang Z, Gao J, Gao Q, Wang F, Liu EM, Mularoni L, Rubio-Perez C, Nagarajan N, Cortés-Ciriano I, Zhou DC, Liang WW, Hess JM, Yellapantula VD, Tamborero D, Gonzalez-Perez A, Suphavilai C, Ko JY, Khurana E, Park PJ, Van Allen EM, Liang H; MC3 Working Group; Cancer Genome Atlas Research Network, Lawrence MS, Godzik A, Lopez-Bigas N, Stuart J, Wheeler D, Getz G, Chen K, Lazar AJ, Mills GB, Karchin R, Ding L. Comprehensive Characterization of Cancer Driver Genes and Mutations. Cell. 2018 Aug 9;174(4):1034-1035. doi: 10.1016/j.cell.2018.07.034. Erratum for: Cell. 2018 Apr 5;173(2):371-385.e18. PMID: 30096302.
340. Kahles A, Lehmann KV, Toussaint NC, Hüser M, Stark SG, Sachsenberg T, Stegle O, Kohlbacher O, Sander C; Cancer Genome Atlas Research Network, Rätsch G. Comprehensive Analysis of Alternative

Splicing Across Tumors from 8,705 Patients. Cancer Cell. 2018 Aug 13;34(2):211-224.e6. doi: 10.1016/j.ccell.2018.07.001. Epub 2018 Aug 2. PMID: 30078747.

341. Nigita G, Distefano R, Veneziano D, Romano G, Rahman M, Wang K, Pass H, Croce CM, Acunzo M, Nana-Sinkam P. Tissue and exosomal miRNA editing in Non-Small Cell Lung Cancer. Sci Rep. 2018 Jul 5;8(1):10222. doi: 10.1038/s41598-018-28528-1. PMID: 29976955; PMCID: PMC6033928.
342. Thorsson V, Gibbs DL, Brown SD, Wolf D, Bortone DS, Ou Yang TH, Porta-Pardo E, Gao GF, Plaisier CL, Eddy JA, Ziv E, Culhane AC, Paull EO, Sivakumar IKA, Gentles AJ, Malhotra R, Farshidfar F, Colaprico A, Parker JS, Mose LE, Vo NS, Liu J, Liu Y, Rader J, Dhankani V, Reynolds SM, Bowlby R, Califano A, Cherniack AD, Anastassiou D, Bedognetti D, Mokrab Y, Newman AM, Rao A, Chen K, Krasnitz A, Hu H, Malta TM, Noushmehr H, Pedamallu CS, Bullman S, Ojesina AI, Lamb A, Zhou W, Shen H, Choueiri TK, Weinstein JN, Guinney J, Saltz J, Holt RA, Rabkin CS; Cancer Genome Atlas Research Network, Lazar AJ, Serody JS, Demicco EG, Disis ML, Vincent BG, Shmulevich I. The Immune Landscape of Cancer. Immunity. 2018 Apr 17;48(4):812-830.e14. doi: 10.1016/j.immuni.2018.03.023. Epub 2018 Apr 5. Erratum in: Immunity. 2019 Aug 20;51(2):411-412. PMID: 29628290; PMCID: PMC5982584.
343. Thorsson V, Gibbs DL, Brown SD, Wolf D, Bortone DS, Ou Yang TH, Porta-Pardo E, Gao GF, Plaisier CL, Eddy JA, Ziv E, Culhane AC, Paull EO, Sivakumar IKA, Gentles AJ, Malhotra R, Farshidfar F, Colaprico A, Parker JS, Mose LE, Vo NS, Liu J, Liu Y, Rader J, Dhankani V, Reynolds SM, Bowlby R, Califano A, Cherniack AD, Anastassiou D, Bedognetti D, Mokrab Y, Newman AM, Rao A, Chen K, Krasnitz A, Hu H, Malta TM, Noushmehr H, Pedamallu CS, Bullman S, Ojesina AI, Lamb A, Zhou W, Shen H, Choueiri TK, Weinstein JN, Guinney J, Saltz J, Holt RA, Rabkin CS; Cancer Genome Atlas Research Network, Lazar AJ, Serody JS, Demicco EG, Disis ML, Vincent BG, Shmulevich I. The Immune Landscape of Cancer. Immunity. 2018 Apr 17;48(4):812-830.e14. doi: 10.1016/j.immuni.2018.03.023. Epub 2018 Apr 5. Erratum in: Immunity. 2019 Aug 20;51(2):411-412. PMID: 29628290; PMCID: PMC5982584.
344. Liu J, Lichtenberg T, Hoadley KA, Poisson LM, Lazar AJ, Cherniack AD, Kovatich AJ, Benz CC, Levine DA, Lee AV, Omberg L, Wolf DM, Shriver CD, Thorsson V; Cancer Genome Atlas Research Network, Hu H. An Integrated TCGA Pan-Cancer Clinical Data Resource to Drive High-Quality Survival Outcome Analytics. Cell. 2018 Apr 5;173(2):400-416.e11. doi: 10.1016/j.cell.2018.02.052. PMID: 29625055; PMCID: PMC6066282.
345. Chen H, Li C, Peng X, Zhou Z, Weinstein JN; Cancer Genome Atlas Research Network, Liang H. A Pan-Cancer Analysis of Enhancer Expression in Nearly 9000 Patient Samples. Cell. 2018 Apr 5;173(2):386-399.e12. doi: 10.1016/j.cell.2018.03.027. PMID: 29625054; PMCID: PMC5890960.
346. Bailey MH, Tokheim C, Porta-Pardo E, Sengupta S, Bertrand D, Weerasinghe A, Colaprico A, Wendl MC, Kim J, Reardon B, Ng PK, Jeong KJ, Cao S, Wang Z, Gao J, Gao Q, Wang F, Liu EM, Mularoni L, Rubio-Perez C, Nagarajan N, Cortés-Ciriano I, Zhou DC, Liang WW, Hess JM, Yellapantula VD, Tamborero D, Gonzalez-Perez A, Suphavilai C, Ko JY, Khurana E, Park PJ, Van Allen EM, Liang H; MC3 Working Group; Cancer Genome Atlas Research Network, Lawrence MS, Godzik A, Lopez-Bigas N, Stuart J, Wheeler D, Getz G, Chen K, Lazar AJ, Mills GB, Karchin R, Ding L. Comprehensive Characterization of Cancer Driver Genes and Mutations. Cell. 2018 Apr 5;173(2):371-385.e18. doi: 10.1016/j.cell.2018.02.060. Erratum in: Cell. 2018 Aug 9;174(4):1034-1035. PMID: 29625053; PMCID: PMC6029450.
347. Huang KL, Mashl RJ, Wu Y, Ritter DI, Wang J, Oh C, Paczkowska M, Reynolds S, Wyczalkowski MA, Oak N, Scott AD, Krassowski M, Cherniack AD, Houlahan KE, Jayasinghe R, Wang LB, Zhou DC, Liu D, Cao S, Kim YW, Koire A, McMichael JF, Hucthagowder V, Kim TB, Hahn A, Wang C, McLellan MD, Al-Mulla F, Johnson KJ; Cancer Genome Atlas Research Network, Lichtarge O, Boutros PC, Raphael B,

Lazar AJ, Zhang W, Wendl MC, Govindan R, Jain S, Wheeler D, Kulkarni S, Dipersio JF, Reimand J, Meric-Bernstam F, Chen K, Shmulevich I, Plon SE, Chen F, Ding L. Pathogenic Germline Variants in 10,389 Adult Cancers. Cell. 2018 Apr 5;173(2):355-370.e14. doi: 10.1016/j.cell.2018.03.039. PMID: 29625052; PMCID: PMC5949147.

348. Malta TM, Sokolov A, Gentles AJ, Burzykowski T, Poisson L, Weinstein JN, Kamińska B, Huelsken J, Omberg L, Gevaert O, Colaprico A, Czerwińska P, Mazurek S, Mishra L, Heyn H, Krasnitz A, Godwin AK, Lazar AJ; Cancer Genome Atlas Research Network, Stuart JM, Hoadley KA, Laird PW, Noushmehr H, Wiznerowicz M. Machine Learning Identifies Stemness Features Associated with Oncogenic Dedifferentiation. Cell. 2018 Apr 5;173(2):338-354.e15. doi: 10.1016/j.cell.2018.03.034. PMID: 29625051; PMCID: PMC5902191.
349. Sanchez-Vega F, Mina M, Armenia J, Chatila WK, Luna A, La KC, Dimitriadoy S, Liu DL, Kantheti HS, Saghafinia S, Chakravarty D, Daian F, Gao Q, Bailey MH, Liang WW, Foltz SM, Shmulevich I, Ding L, Heins Z, Ochoa A, Gross B, Gao J, Zhang H, Kundra R, Kandoth C, Bahceci I, Dervishi L, Dogrusoz U, Zhou W, Shen H, Laird PW, Way GP, Greene CS, Liang H, Xiao Y, Wang C, Iavarone A, Berger AH, Bivona TG, Lazar AJ, Hammer GD, Giordano T, Kwong LN, McArthur G, Huang C, Tward AD, Frederick MJ, McCormick F, Meyerson M; Cancer Genome Atlas Research Network, Van Allen EM, Cherniack AD, Ciriello G, Sander C, Schultz N. Oncogenic Signaling Pathways in The Cancer Genome Atlas. Cell. 2018 Apr 5;173(2):321-337.e10. doi: 10.1016/j.cell.2018.03.035. PMID: 29625050; PMCID: PMC6070353.
350. Ding L, Bailey MH, Porta-Pardo E, Thorsson V, Colaprico A, Bertrand D, Gibbs DL, Weerasinghe A, Huang KL, Tokheim C, Cortés-Ciriano I, Jayasinghe R, Chen F, Yu L, Sun S, Olsen C, Kim J, Taylor AM, Cherniack AD, Akbani R, Suphavilai C, Nagarajan N, Stuart JM, Mills GB, Wyczalkowski MA, Vincent BG, Hutter CM, Zenklusen JC, Hoadley KA, Wendl MC, Shmulevich L, Lazar AJ, Wheeler DA, Getz G; Cancer Genome Atlas Research Network. Perspective on Oncogenic Processes at the End of the Beginning of Cancer Genomics. Cell. 2018 Apr 5;173(2):305-320.e10. doi: 10.1016/j.cell.2018.03.033. PMID: 29625049; PMCID: PMC5916814.
351. Hoadley KA, Yau C, Hinoue T, Wolf DM, Lazar AJ, Drill E, Shen R, Taylor AM, Cherniack AD, Thorsson V, Akbani R, Bowlby R, Wong CK, Wiznerowicz M, Sanchez-Vega F, Robertson AG, Schneider BG, Lawrence MS, Noushmehr H, Malta TM; Cancer Genome Atlas Network, Stuart JM, Benz CC, Laird PW. Cell-of-Origin Patterns Dominate the Molecular Classification of 10,000 Tumors from 33 Types of Cancer. Cell. 2018 Apr 5;173(2):291-304.e6. doi: 10.1016/j.cell.2018.03.022. PMID: 29625048; PMCID: PMC5957518.
352. Liu Y, Sethi NS, Hinoue T, Schneider BG, Cherniack AD, Sanchez-Vega F, Seoane JA, Farshidfar F, Bowlby R, Islam M, Kim J, Chatila W, Akbani R, Kanchi RS, Rabkin CS, Willis JE, Wang KK, McCall SJ, Mishra L, Ojesina AI, Bullman S, Pedamallu CS, Lazar AJ, Sakai R; Cancer Genome Atlas Research Network, Thorsson V, Bass AJ, Laird PW. Comparative Molecular Analysis of Gastrointestinal Adenocarcinomas. Cancer Cell. 2018 Apr 9;33(4):721-735.e8. doi: 10.1016/j.ccell.2018.03.010. Epub 2018 Apr 2. PMID: 29622466; PMCID: PMC5966039.
353. Wang Z, Yang B, Zhang M, Guo W, Wu Z, Wang Y, Jia L, Li S; Cancer Genome Atlas Research Network, Xie W, Yang D. lncRNA Epigenetic Landscape Analysis Identifies EPIC1 as an Oncogenic lncRNA that Interacts with MYC and Promotes Cell-Cycle Progression in Cancer. Cancer Cell. 2018 Apr 9;33(4):706-720.e9. doi: 10.1016/j.ccell.2018.03.006. Epub 2018 Apr 2. PMID: 29622465; PMCID: PMC6143179.

354. Berger AC, Korkut A, Kanchi RS, Hegde AM, Lenoir W, Liu W, Liu Y, Fan H, Shen H, Ravikumar V, Rao A, Schultz A, Li X, Sumazin P, Williams C, Mestdagh P, Gunaratne PH, Yau C, Bowlby R, Robertson AG, Tiezzi DG, Wang C, Cherniack AD, Godwin AK, Kuderer NM, Rader JS, Zuna RE, Sood AK, Lazar AJ, Ojesina AI, Adebamowo C, Adebamowo SN, Baggerly KA, Chen TW, Chiu HS, Lefever S, Liu L, MacKenzie K, Orsulic S, Roszik J, Shelley CS, Song Q, Vellano CP, Wentzensen N; Cancer Genome Atlas Research Network, Weinstein JN, Mills GB, Levine DA, Akbani R. A Comprehensive Pan-Cancer Molecular Study of Gynecologic and Breast Cancers. Cancer Cell. 2018 Apr 9;33(4):690-705.e9. doi: 10.1016/j.ccell.2018.03.014. Epub 2018 Apr 2. PMID: 29622464; PMCID: PMC5959730.
355. Taylor AM, Shih J, Ha G, Gao GF, Zhang X, Berger AC, Schumacher SE, Wang C, Hu H, Liu J, Lazar AJ; Cancer Genome Atlas Research Network, Cherniack AD, Beroukhim R, Meyerson M. Genomic and Functional Approaches to Understanding Cancer Aneuploidy. Cancer Cell. 2018 Apr 9;33(4):676-689.e3. doi: 10.1016/j.ccell.2018.03.007. Epub 2018 Apr 2. PMID: 29622463; PMCID: PMC6028190.
356. Ricketts CJ, De Cubas AA, Fan H, Smith CC, Lang M, Reznik E, Bowlby R, Gibb EA, Akbani R, Beroukhim R, Bottaro DP, Choueiri TK, Gibbs RA, Godwin AK, Haake S, Hakimi AA, Henske EP, Hsieh JJ, Ho TH, Kanchi RS, Krishnan B, Kwiatkowski DJ, Lui W, Merino MJ, Mills GB, Myers J, Nickerson ML, Reuter VE, Schmidt LS, Shelley CS, Shen H, Shuch B, Signoretti S, Srinivasan R, Tamboli P, Thomas G, Vincent BG, Vocke CD, Wheeler DA, Yang L, Kim WY, Robertson AG; Cancer Genome Atlas Research Network, Spellman PT, Rathmell WK, Linehan WM. The Cancer Genome Atlas Comprehensive Molecular Characterization of Renal Cell Carcinoma. Cell Rep. 2018 Apr 3;23(1):313-326.e5. doi: 10.1016/j.celrep.2018.03.075. Erratum in: Cell Rep. 2018 Jun 19;23(12):3698. PMID: 29617669; PMCID: PMC6075733.
357. Chiu HS, Somvanshi S, Patel E, Chen TW, Singh VP, Zorman B, Patil SL, Pan Y, Chatterjee SS; Cancer Genome Atlas Research Network, Sood AK, Gunaratne PH, Sumazin P. Pan-Cancer Analysis of lncRNA Regulation Supports Their Targeting of Cancer Genes in Each Tumor Context. Cell Rep. 2018 Apr 3;23(1):297-312.e12. doi: 10.1016/j.celrep.2018.03.064. PMID: 29617668; PMCID: PMC5906131.
358. Seiler M, Peng S, Agrawal AA, Palacino J, Teng T, Zhu P, Smith PG; Cancer Genome Atlas Research Network, Buonamici S, Yu L. Somatic Mutational Landscape of Splicing Factor Genes and Their Functional Consequences across 33 Cancer Types. Cell Rep. 2018 Apr 3;23(1):282-296.e4. doi: 10.1016/j.celrep.2018.01.088. PMID: 29617667; PMCID: PMC5933844.
359. Jayasinghe RG, Cao S, Gao Q, Wendl MC, Vo NS, Reynolds SM, Zhao Y, Climente-González H, Chai S, Wang F, Varghese R, Huang M, Liang WW, Wyczalkowski MA, Sengupta S, Li Z, Payne SH, Fenyö D, Miner JH, Walter MJ; Cancer Genome Atlas Research Network, Vincent B, Eyras E, Chen K, Shmulevich I, Chen F, Ding L. Systematic Analysis of Splice-Site-Creating Mutations in Cancer. Cell Rep. 2018 Apr 3;23(1):270-281.e3. doi: 10.1016/j.celrep.2018.03.052. PMID: 29617666; PMCID: PMC6055527.
360. Peng X, Chen Z, Farshidfar F, Xu X, Lorenzi PL, Wang Y, Cheng F, Tan L, Mojumdar K, Du D, Ge Z, Li J, Thomas GV, Birsoy K, Liu L, Zhang H, Zhao Z, Marchand C, Weinstein JN; Cancer Genome Atlas Research Network, Bathe OF, Liang H. Molecular Characterization and Clinical Relevance of Metabolic Expression Subtypes in Human Cancers. Cell Rep. 2018 Apr 3;23(1):255-269.e4. doi: 10.1016/j.celrep.2018.03.077. PMID: 29617665; PMCID: PMC5916795.
361. Knijnenburg TA, Wang L, Zimmermann MT, Chambwe N, Gao GF, Cherniack AD, Fan H, Shen H, Way GP, Greene CS, Liu Y, Akbani R, Feng B, Donehower LA, Miller C, Shen Y, Karimi M, Chen H, Kim P, Jia P, Shinbrot E, Zhang S, Liu J, Hu H, Bailey MH, Yau C, Wolf D, Zhao Z, Weinstein JN, Li L, Ding L, Mills GB, Laird PW, Wheeler DA, Shmulevich I; Cancer Genome Atlas Research Network, Monnat RJ Jr,

Xiao Y, Wang C. Genomic and Molecular Landscape of DNA Damage Repair Deficiency across The Cancer Genome Atlas. Cell Rep. 2018 Apr 3;23(1):239-254.e6. doi: 10.1016/j.celrep.2018.03.076. PMID: 29617664; PMCID: PMC5961503.

362. Gao Q, Liang WW, Foltz SM, Mutharasu G, Jayasinghe RG, Cao S, Liao WW, Reynolds SM, Wyczalkowski MA, Yao L, Yu L, Sun SQ; Fusion Analysis Working Group; Cancer Genome Atlas Research Network, Chen K, Lazar AJ, Fields RC, Wendl MC, Van Tine BA, Vij R, Chen F, Nykter M, Shmulevich I, Ding L. Driver Fusions and Their Implications in the Development and Treatment of Human Cancers. Cell Rep. 2018 Apr 3;23(1):227-238.e3. doi: 10.1016/j.celrep.2018.03.050. PMID: 29617662; PMCID: PMC5916809.
363. Campbell JD, Yau C, Bowlby R, Liu Y, Brennan K, Fan H, Taylor AM, Wang C, Walter V, Akbani R, Byers LA, Creighton CJ, Coarfa C, Shih J, Cherniack AD, Gevaert O, Prunello M, Shen H, Anur P, Chen J, Cheng H, Hayes DN, Bullman S, Pedamallu CS, Ojesina AI, Sadeghi S, Mungall KL, Robertson AG, Benz C, Schultz A, Kanchi RS, Gay CM, Hegde A, Diao L, Wang J, Ma W, Sumazin P, Chiu HS, Chen TW, Gunaratne P, Donehower L, Rader JS, Zuna R, Al-Ahmadie H, Lazar AJ, Flores ER, Tsai KY, Zhou JH, Rustgi AK, Drill E, Shen R, Wong CK; Cancer Genome Atlas Research Network, Stuart JM, Laird PW, Hoadley KA, Weinstein JN, Peto M, Pickering CR, Chen Z, Van Waes C. Genomic, Pathway Network, and Immunologic Features Distinguishing Squamous Carcinomas. Cell Rep. 2018 Apr 3;23(1):194-212.e6. doi: 10.1016/j.celrep.2018.03.063. PMID: 29617660; PMCID: PMC6002769.
364. Saltz J, Gupta R, Hou L, Kurc T, Singh P, Nguyen V, Samaras D, Shroyer KR, Zhao T, Batiste R, Van Arnam J; Cancer Genome Atlas Research Network, Shmulevich I, Rao AUK, Lazar AJ, Sharma A, Thorsson V. Spatial Organization and Molecular Correlation of Tumor-Infiltrating Lymphocytes Using Deep Learning on Pathology Images. Cell Rep. 2018 Apr 3;23(1):181-193.e7. doi: 10.1016/j.celrep.2018.03.086. PMID: 29617659; PMCID: PMC5943714.
365. Way GP, Sanchez-Vega F, La K, Armenia J, Chatila WK, Luna A, Sander C, Cherniack AD, Mina M, Ciriello G, Schultz N; Cancer Genome Atlas Research Network, Sanchez Y, Greene CS. Machine Learning Detects Pan-cancer Ras Pathway Activation in The Cancer Genome Atlas. Cell Rep. 2018 Apr 3;23(1):172-180.e3. doi: 10.1016/j.celrep.2018.03.046. PMID: 29617658; PMCID: PMC5918694.
366. Schaub FX, Dhankani V, Berger AC, Trivedi M, Richardson AB, Shaw R, Zhao W, Zhang X, Ventura A, Liu Y, Ayer DE, Hurlin PJ, Cherniack AD, Eisenman RN, Bernard B, Grandori C; Cancer Genome Atlas Network. Pan-cancer Alterations of the MYC Oncogene and Its Proximal Network across the Cancer Genome Atlas. Cell Syst. 2018 Mar 28;6(3):282-300.e2. doi: 10.1016/j.cels.2018.03.003. PMID: 29596783; PMCID: PMC5892207.
367. Ellrott K, Bailey MH, Saksena G, Covington KR, Kandoth C, Stewart C, Hess J, Ma S, Chiotti KE, McLellan M, Sofia HJ, Hutter C, Getz G, Wheeler D, Ding L; MC3 Working Group; Cancer Genome Atlas Research Network. Scalable Open Science Approach for Mutation Calling of Tumor Exomes Using Multiple Genomic Pipelines. Cell Syst. 2018 Mar 28;6(3):271-281.e7. doi: 10.1016/j.cels.2018.03.002. PMID: 29596782; PMCID: PMC6075717.
368. Pine PS, Lund SP, Parsons JR, Vang LK, Mahabal AA, Cinquini L, Kelly SC, Kincaid H, Crichton DJ, Spira A, Liu G, Gower AC, Pass HI, Goparaju C, Dubinett SM, Krysan K, Stass SA, Kukuruga D, Van Keuren-Jensen K, Courtright-Lim A, Thompson KL, Rosenzweig BA, Sorbara L, Srivastava S, Salit ML. Summarizing performance for genome scale measurement of miRNA: reference samples and metrics. BMC Genomics. 2018 Mar 6;19(1):180. doi: 10.1186/s12864-018-4496-1. PMID: 29510677; PMCID: PMC5838960.

369. Morris S, Vachani A, Pass HI, Rom WN, Ryden K, Weiss GJ, Hogarth DK, Runger G, Richards D, Shelton T, Mallery DW. Whole blood FPR1 mRNA expression predicts both non-small cell and small cell lung cancer. Int J Cancer. 2018 Jun 1;142(11):2355-2362. doi: 10.1002/ijc.31245. Epub 2018 Jan 30. PMID: 29313979; PMCID: PMC5901395.
370. Romero R, Sayin VI, Davidson SM, Bauer MR, Singh SX, LeBoeuf SE, Karakousi TR, Ellis DC, Bhutkar A, Sánchez-Rivera FJ, Subbaraj L, Martinez B, Bronson RT, Prigge JR, Schmidt EE, Thomas CJ, Goparaju C, Davies A, Dolgalev I, Heguy A, Allaj V, Poirier JT, Moreira AL, Rudin CM, Pass HI, Vander Heiden MG, Jacks T, Papagiannakopoulos T. Keap1 loss promotes Kras-driven lung cancer and results in dependence on glutaminolysis. Nat Med. 2017 Nov;23(11):1362-1368. doi: 10.1038/nm.4407. Epub 2017 Oct 2. PMID: 28967920; PMCID: PMC5677540.
371. Birse CE, Tomic JL, Pass HI, Rom WN, Lagier RJ. Clinical validation of a blood-based classifier for diagnostic evaluation of asymptomatic individuals with pulmonary nodules. Clin Proteomics. 2017 Jul 5;14:25. doi: 10.1186/s12014-017-9158-9. PMID: 28694742; PMCID: PMC5498919.
372. Bononi A, Yang H, Giorgi C, Patergnani S, Pellegrini L, Su M, Xie G, Signorato V, Pastorino S, Morris P, Sakamoto G, Kuchay S, Gaudino G, Pass HI, Napolitano A, Pinton P, Jia W, Carbone M. Germline BAP1 mutations induce a Warburg effect. Cell Death Differ. 2017 Oct;24(10):1694-1704. doi: 10.1038/cdd.2017.95. Epub 2017 Jun 30. PMID: 28665402; PMCID: PMC5596430.
373. Fahrmann JF, Grapov DD, Wanichthanarak K, DeFelice BC, Salemi MR, Rom WN, Gandara DR, Phinney BS, Fiehn O, Pass H, Miyamoto S. Integrated Metabolomics and Proteomics Highlight Altered Nicotinamide- and Polyamine Pathways in Lung Adenocarcinoma. Carcinogenesis. 2017 Mar;38(3):271-280. doi: 10.1093/carcin/bgw205. Epub 2017 Jan 3. PMID: 28049629; PMCID: PMC5862279.
374. Fahrmann JF, Grapov D, Phinney BS, Stroble C, DeFelice BC, Rom W, Gandara DR, Zhang Y, Fiehn O, Pass H, Miyamoto S. Proteomic profiling of lung adenocarcinoma indicates heightened DNA repair, antioxidant mechanisms and identifies LASP1 as a potential negative predictor of survival. Clin Proteomics. 2016 Oct 27;13:31. doi: 10.1186/s12014-016-9132-y. PMID: 27799870; PMCID: PMC5084393.
375. Carbone M, Adusumilli PS, Alexander HR Jr, Baas P, Bardelli F, Bononi A, Bueno R, Felley-Bosco E, Galateau-Salle F, Jablons D, Mansfield AS, Minaai M, de Perrot M, Pesavento P, Rusch V, Severson DT, Taioli E, Tsao A, Woodard G, Yang H, Zauderer MG, Pass HI. Mesothelioma: Scientific clues for prevention, diagnosis, and therapy. CA Cancer J Clin. 2019 Sep;69(5):402-429. doi: 10.3322/caac.21572. Epub 2019 Jul 8. PMID: 31283845.
376. McCambridge AJ, Napolitano A, Mansfield AS, Fennell DA, Sekido Y, Nowak AK, Reungwetwattana T, Mao W, Pass HI, Carbone M, Yang H, Peikert T. Progress in the Management of Malignant Pleural Mesothelioma in 2017. J Thorac Oncol. 2018 May;13(5):606-623. doi: 10.1016/j.jtho.2018.02.021. Epub 2018 Mar 8. PMID: 29524617; PMCID: PMC6544834.
377. Chen C, Huang X, Yin W, Peng M, Wu F, Wu X, Tang J, Chen M, Wang X, Hulbert A, Brock MV, Liu W, Herman JG*, Yu F. Ultrasensitive DNA Hypermethylation Detection Using Plasma for Early Detection of NSCLC: A Study in Chinese Patients With Very Small Nodules. Clin Epigenetics 2020 Mar 5;12(1):39. doi: 10.1186/s13148-020-00828-2, PMID: 32138766.
378. Liu B, Ricarte-Filho J, Mallisetty A, Villani C, Kottorou AE, Rodgers KP, Chen C, Ito T, Holmes K, Gastala N, Valyi-Nagy K, David O, Gaba RC, Ascoli C, Pasquinelli M, Feldman LE, Massad MG, Wang TH, Jusue-Torres I, Benedetti E, Winn RA, Brock MV, Herman JG*, Hulbert A. Detection of Promoter

DNA Methylation in Urine and Plasma Aids the Detection of Non-Small Cell Lung Cancer. Clin Cancer Res 2020 May 19; doi: 10.1158/1078-0432.CCR-19-2896. PMID: 32430478 Online ahead of print.

379. O'Keefe, Christine M; Kaushik, Aniruddha M; Wang, Tza-Huei. Highly Efficient Real-Time Droplet Analysis Platform for High-Throughput Interrogation of DNA Sequences by Melt. Anal Chem 2019: 91; 11275-11282, PMID 31356737
380. O'Keefe CM, Giammanco D, Li S, Pisanic TR, Wang TJ. Multilayer microfluidic array for highly efficient sample loading and digital melt analysis of DNA methylation. Lab Chip. 2019 Jan 29;19(3):444-451. doi: 10.1039/c8lc01189c. PMID: 30623957; PMCID: PMC6363116.
381. Deppen SA, Massion PP, Blume J, Walker RC, Antic S, Chen H, Durkin MM, Wheat LJ, Grogan EL. Accuracy of a Novel Histoplasmosis Enzyme Immunoassay to Evaluate Suspicious Lung Nodules. Cancer Epidemiol Biomarkers Prev 2019; 28: 321-326. DOI: 10.1158/1055-9965.EPI-18-0169. PMID: 30341097. PMCID: N/A.
382. Kammer MN, Kussrow AK, Webster RL, Chen H, Hoeksema M, Christenson R, Massion PP, Bornhop DJ.. Compensated Interferometry Measures of CYFRA 21-1 Improve Diagnosis of Lung Cancer.. (Abstract) ACS Comb Sci 2019; 21(6): 465-472. PMID: 31022347. PMCID: N/A.
383. Phelps HM, Pierce JM, Murphy AJ, Correa H, Qian J, Massion PP, Lovvorn HN. FXR1 expression domain in Wilms tumor. J Pediatr Surg 2019; 54: 1198-1205. DOI: 10.1016/j.jpedsurg.2019.02.030. PMID: 30894247. PMCID: N/A.
384. Seijo LM, Peled N, Ajona D, Boeri M, Field JK, Sozzi G, Pio R, Zulueta JJ, Spira A, Massion PP, Mazzone PJ, Montuenga LM. Biomarkers in Lung Cancer Screening: Achievements, Promises, and Challenges. J Thorac Oncol 2019; 14: 343-357. DOI: 10.1016/j.jtho.2018.11.023. PMID: 30529598. PMCID: N/A.
385. Spalluto LB, Lewis JA, LaBaze S, Sandler KL, Paulson AB, Callaway-Lane C, Grogan EL, Massion PP, Roumie CL. Association of a Lung Screening Program Coordinator With Adherence to Annual CT Lung Screening at a Large Academic Institution.. (Abstract) Am J Coll Radiol 2019; : 1546-. PMID: 31499025. PMCID: N/A.
386. Tunali I, Gray JE, Qi J, Abdalah M, Jeong DK, Guvenis A, Gillies RJ, Schabath MB. Novel clinical and radiomic predictors of rapid disease progression phenotypes among lung cancer patients treated with immunotherapy: An early report. Lung Cancer 2019; 129: 75-79. DOI: 10.1016/j.lungcan.2019.01.010. PMID: 30797495. PMCID: N/A.
387. Yang X1,2, Su W3, Chen X4, Geng Q5, Zhai J6, Shan H1, Guo C2, Wang Z2, Fu H6, Jiang H6, Lin J2, Lagisetty KH2, Zhang J1, Li Y1, Yang S1, Massion PP7, Beer DG2, Chang AC2, Ramnath N8,9, Chen G10.. Validation of a serum 4-microRNA signature for the detection of lung cancer.. (Abstract) Transl Lung Cancer Res 2019; (5): 636-648. PMID: 31737499. PMCID: PMC6835096.
388. Ajona D, Okrój M, Pajares MJ, Agorreta J, Lozano MD, Zulueta JJ, Verri C, Roz L, Sozzi G, Pastorino U, Massion PP, Montuenga LM, Blom AM, Pio R. Complement C4d-specific antibodies for the diagnosis of lung cancer. Oncotarget 2018; 9: 6346-6355. DOI: 10.18632/oncotarget.23690. PMID: 29464077. PMCID: N/A.
389. Ferreiro-Iglesias A, Lesseur C, McKay J, Hung RJ, Han Y, Zong X, Christiani D, Johansson M, Xiao X, Li Y, Qian DC, Ji X, Liu G, Caporaso N, Scelo G, Zaridze D, Mukeriya A, Kontic M, Ognjanovic S, Lissowska J, Szołkowska M, Swiatkowska B, Janout V, Holcatova I, Bolca C, Savic M, Ognjanovic M, Bojesen SE, Wu X, Albanes D, Aldrich MC, Tardon A, Fernandez-Somoano A, Fernandez-Tardon G, Le Marchand L, Rennert G, Chen C, Doherty J, Goodman G, Bickeböller H, Wichmann HE, Risch A, Rosenberger A, Shen H, Dai J, Field JK, Davies M, Woll P, Teare MD, Kiemeney LA, van der Heijden EHFM, Yuan JM, Hong YC, Haugen A, Zienolddiny S, Lam S, Tsao MS, Johansson M, Grankvist K, Schabath MB, Andrew

A, Duell E, Melander O, Brunnström H, Lazarus P, Arnold S, Slone S, Byun J, Kamal A, Zhu D, Landi MT, Amos CI, Brennan P. Fine mapping of MHC region in lung cancer highlights independent susceptibility loci by ethnicity. Nat Commun 2018; 9: . DOI: 10.1038/s41467-018-05890-2. PMID: 30254314. PMCID: N/A.

390. Jones CC, Mercaldo SF, Blume JD, Wenzlaff AS, Schwartz AG, Chen H, Deppen SA, Bush WS, Crawford DC, Chanock SJ, Blot WJ, Grogan EL, Aldrich MC. Racial Disparities in Lung Cancer Survival: The Contribution of Stage, Treatment, and Ancestry. J Thorac Oncol 2018; 13: 1464-1473. DOI: 10.1016/j.jtho.2018.05.032. PMID: 29885480. PMCID: N/A.
391. Li Q, Balagurunathan Y, Liu Y, Qi J, Schabath MB, Ye Z, Gillies RJ. Comparison Between Radiological Semantic Features and Lung-RADS in Predicting Malignancy of Screen-Detected Lung Nodules in the National Lung Screening Trial. Clin Lung Cancer 2018; 19: 148-156.e3. DOI: 10.1016/j.cllc.2017.10.002. PMID: 29137847. PMCID: N/A.
392. Li Y, Xiao X, Han Y, Gorlova O, Qian D, Leighl N, Johansen JS, Barnett M, Chen C, Goodman G, Cox A, Taylor F, Woll P, Wichmann HE, Manz J, Muley T, Risch A, Rosenberger A, Arnold SM, Haura EB, Bolca C, Holcatova I, Janout V, Kontic M, Lissowska J, Mukeria A, Ognjanovic S, Orlowski TM, Scelo G, Swiatkowska B, Zaridze D, Bakke P, Skaug V, Zienolddiny S, Duell EJ, Butler LM, Houlston R, Soler Artigas M, Grankvist K, Johansson M, Shepherd FA, Marcus MW, Brunnström H, Manjer J, Melander O, Muller DC, Overvad K, Trichopoulou A, Tumino R, Liu G, Bojesen SE, Wu X, Marchand LL, Albanes D, Bickeböller H, Aldrich MC, Bush WS, Tardon A, Rennert G, Teare MD, Field JK, Kiemeney LA, Lazarus P, Haugen A, Lam S, Schabath MB, Andrew AS, Bertazzi PA, Pesatori AC, Christiani DC, Caporaso N, Johansson M, McKay JD, Brennan P, Hung RJ, Amos CI. Genome-wide interaction study of smoking behavior and non-small cell lung cancer risk in Caucasian population. Carcinogenesis 2018; 39: 336-346. DOI: 10.1093/carcin/bgx113. PMID: 29059373. PMCID: N/A.
393. Magarik MA, Walker RC, Gilbert J, Manning HC, Massion PP. Intracardiac Metastases Detected by 18F-FSPG PET/CT. Clin Nucl Med 2018; 43: 28-30. DOI: 10.1097/RLU.0000000000001883. PMID: 29076915. PMCID: N/A.
394. Maiga AW, Deppen SA, Massion PP, Callaway-Lane C, Pinkerman R, Dittus RS, Lambright ES, Nesbitt JC, Grogan EL. Communication About the Probability of Cancer in Indeterminate Pulmonary Nodules. JAMA Surg 2018; 153: 353-357. DOI: 10.1001/jamasurg.2017.4878. PMID: 29261826. PMCID: N/A.
395. Nakajima EC, Frankland MP, Johnson TF, Antic SL, Chen H, Chen SC, Karwoski RA, Walker R, Landman BA, Clay RD, Bartholmai BJ, Rajagopalan S, Peikert T, Massion PP, Maldonado F. Assessing the inter-observer variability of Computer-Aided Nodule Assessment and Risk Yield (CANARY) to characterize lung adenocarcinomas. PLoS One 2018; 13: . DOI: 10.1371/journal.pone.0198118. PMID: 29856852. PMCID: N/A.
396. Tindle HA, Stevenson Duncan M, Greevy RA, Vasan RS, Kundu S, Massion PP, Freiberg MS. Lifetime Smoking History and Risk of Lung Cancer: Results From the Framingham Heart Study. J Natl Cancer Inst 2018; 110: 1201-1207. DOI: 10.1093/jnci/djy041. PMID: 29788259. PMCID: N/A.
397. Wood DE, Kazerooni EA, Baum SL, Eapen GA, Ettinger DS, Hou L, Jackman DM, Klippenstein D, Kumar R, Lackner RP, Leard LE, Lennes IT, Leung ANC, Makani SS, Massion PP, Mazzone P, Merritt RE, Meyers BF, Midthun DE, Pipavath S, Pratt C, Reddy C, Reid ME, Rotter AJ, Sachs PB, Schabath MB, Schiebler ML, Tong BC, Travis WD, Wei B, Yang SC, Gregory KM, Hughes M. Lung Cancer Screening, Version 3.2018, NCCN Clinical Practice Guidelines in Oncology. J Natl Compr Canc Netw 2018; 16: 412-441. DOI: 10.6004/jnccn.2018.0020. PMID: 29632061. PMCID: N/A.

398. Yeo J, Morales DA, Chen T, Crawford EL, Zhang X, Blomquist TM, Levin AM, Massion PP, Arenberg DA, Midthun DE, Mazzone PJ, Nathan SD, Wainz RJ, Nana-Sinkam P, Willey PFS, Arend TJ, Padda K, Qiu S, Federov A, Hernandez DR, Hammersley JR, Yoon Y, Safi F, Khuder SA, Willey JC. RNAseq analysis of bronchial epithelial cells to identify COPD-associated genes and SNPs. BMC Pulm Med 2018; 18: . DOI: 10.1186/s12890-018-0603-y. PMID: 29506519. PMCID: N/A.
399. Li Q, Kim J, Balagurunathan Y, Liu Y, Latifi K, Stringfield O, Garcia A, Moros EG, Dilling TJ, Schabath MB, Ye Z, Gillies RJ. Imaging features from pretreatment CT scans are associated with clinical outcomes in nonsmall-cell lung cancer patients treated with stereotactic body radiotherapy. Med Phys 2017; 44: 4341-4349. DOI: 10.1002/mp.12309. PMID: 28464316. PMCID: N/A.
400. Liu Y, Balagurunathan Y, Atwater T, Antic S, Li Q, Walker RC, Smith GT, Massion PP, Schabath MB, Gillies RJ. Radiological Image Traits Predictive of Cancer Status in Pulmonary Nodules. Clin Cancer Res 2017; 23: 1442-1449. DOI: 10.1158/1078-0432.CCR-15-3102. PMID: 27663588. PMCID: PMC5527551.
401. Massion PP, Healey GF, Peek LJ, Fredericks L, Sewell HF, Murray A, Robertson JF. Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer. J Thorac Oncol 2017; 12: 578-584. DOI: 10.1016/j.jtho.2016.08.143. PMID: 27615397. PMCID: PMC5367043.
402. Qian J, Chen H, Ji X, Eisenberg R, Chakravarthy AB, Mayer IA, Massion PP. A 3q gene signature associated with triple negative breast cancer organ specific metastasis and response to neoadjuvant chemotherapy. Sci Rep 2017; 7: . DOI: 10.1038/srep45828. PMID: 28387221. PMCID: PMC5384279.
403. Walker R, Deppen S, Smith G, Shi C, Lehman J, Clanton J, Moore B, Burns R, Grogan EL, Massion PP. 68Ga-DOTATATE PET/CT imaging of indeterminate pulmonary nodules and lung cancer. PLoS One 2017; 12: . DOI: 10.1371/journal.pone.0171301. PMID: 28182730. PMCID: N/A.
404. Atwater T, Cook CM, Massion PP. The Pursuit of Noninvasive Diagnosis of Lung Cancer. Semin Respir Crit Care Med 2016; 37: 670-680. DOI: 10.1055/s-0036-1592314. PMID: 27732989. PMCID: PMC5317274.
405. Atwater T, Massion PP. Biomarkers of risk to develop lung cancer in the new screening era. Ann Transl Med 2016; 4: . DOI: 10.21037/atm.2016.03.46. PMID: 27195276. PMCID: PMC4860477.
406. Boutaud O, Sosa IR, Amin T, Oram D, Adler D, Hwang HS, Crews BC, Milne G, Harris BK, Hoeksema M, Knollmann BC, Lammers PE, Marnett LJ, Massion PP, Oates JA. Inhibition of the Biosynthesis of Prostaglandin E2 By Low-Dose Aspirin: Implications for Adenocarcinoma Metastasis. Cancer Prev Res (Phila) 2016; 9: 855-865. DOI: 10.1158/1940-6207.CAPR-16-0094. PMID: 27554763. PMCID: PMC5093073.
407. Crawford EL, Levin A, Safi F, Lu M, Baugh A, Zhang X, Yeo J, Khuder SA, Boulos AM, Nana-Sinkam P, Massion PP, Arenberg DA, Midthun D, Mazzone PJ, Nathan SD, Wainz R, Silvestri G, Tita J, Willey JC. Lung cancer risk test trial: study design, participant baseline characteristics, bronchoscopy safety, and establishment of a biospecimen repository. BMC Pulm Med 2016; 16: . DOI: 10.1186/s12890-016-0178-4. PMID: 26801409. PMCID: N/A.
408. Harrigan RL, Yvernault BC, Boyd BD, Damon SM, Gibney KD, Conrad BN, Phillips NS, Rogers BP, Gao Y, Landman BA. Vanderbilt University Institute of Imaging Science Center for Computational Imaging XNAT: A multimodal data archive and processing environment. Neuroimage 2016; 124: 1097-1101. DOI: 10.1016/j.neuroimage.2015.05.021. PMID: 25988229. PMCID: N/A.
409. Hawkins S, Wang H, Liu Y, Garcia A, Stringfield O, Krewer H, Li Q, Cherezov D, Gatenby RA, Balagurunathan Y, Goldgof D, Schabath MB, Hall L, Gillies RJ. Predicting Malignant Nodules from

Screening CT Scans. J Thorac Oncol 2016; 11: 2120-2128. DOI: 10.1016/j.jtho.2016.07.002. PMID: 27422797. PMCID: N/A.

410. Massion PP, Healey GF, Peek LJ, Fredericks L, Sewell HF, Murray A, Robertson JFR. Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer. Journal of Thoracic Oncology 2016; 12(3): 578-584. DOI: 10.1016/j.jtho.2016.08.143. PMID: 27615397. PMCID: PMC5367043.
411. Newman AM, Lovejoy AF, Klass DM, Kurtz DM, Chabon JJ, Scherer F, Stehr H, Liu CL, Bratman SV, Say C, Zhou L, Carter JN, West RB, Sledge GW, Shrager JB, Loo BW, Neal JW, Wakelee HA, Diehn M, Alizadeh AA. Integrated digital error suppression for improved detection of circulating tumor DNA. Nat Biotechnol 2016; 34: 547-555. DOI: 10.1038/nbt.3520. PMID: 27018799. PMCID: PMC4907374.
412. Rahman SM, Ji X, Zimmerman LJ, Li M, Harris BK, Hoeksema MD, Trenary IA, Zou Y, Qian J, Slebos RJ, Beane J, Spira A, Shyr Y, Eisenberg R, Liebler DC, Young JD, Massion PP. The airway epithelium undergoes metabolic reprogramming in individuals at high risk for lung cancer. JCI Insight 2016; 1: . DOI: 10.1172/jci.insight.88814. PMID: 27882349. PMCID: N/A.
413. Schabath MB, Massion PP, Thompson ZJ, Eschrich SA, Balagurunathan Y, Goldof D, Aberle DR, Gillies RJ. Differences in Patient Outcomes of Prevalence, Interval, and Screen-Detected Lung Cancers in the CT Arm of the National Lung Screening Trial. PLoS One 2016; 11: . DOI: 10.1371/journal.pone.0159880. PMID: 27509046. PMCID: PMC4980050.
414. Silvestri GA, Tanner NT, Kearney P, Vachani A, Massion PP, Porter A, Springmeyer SC, Fang KC, Midthun D, Mazzone PJ; PANOPTIC Trial Team. Assessment of Plasma Proteomics Biomarker's Ability to Distinguish Benign From Malignant Lung Nodules: Results of the PANOPTIC (Pulmonary Nodule Plasma Proteomic Classifier) Trial. Chest. 2018 Sep;154(3):491-500. doi: 10.1016/j.chest.2018.02.012. Epub 2018 Mar 1. PMID: 29496499; PMCID: PMC6689113.
415. Mazzone PJ, Sears CR, Arenberg DA, Gaga M, Gould MK, Massion PP, Nair VS, Powell CA, Silvestri GA, Vachani A, Wiener RS; ATS Assembly on Thoracic Oncology. Evaluating Molecular Biomarkers for the Early Detection of Lung Cancer: When Is a Biomarker Ready for Clinical Use? An Official American Thoracic Society Policy Statement. Am J Respir Crit Care Med. 2017 Oct 1;196(7):e15-e29. doi: 10.1164/rccm.201708-1678ST. PMID: 28960111; PMCID: PMC5803661.
416. Codreanu SG, Hoeksema MD, Slebos RJC, Zimmerman LJ, Rahman SMJ, Li M, Chen SC, Chen H, Eisenberg R, Liebler DC, Massion PP. Identification of Proteomic Features To Distinguish Benign Pulmonary Nodules from Lung Adenocarcinoma. J Proteome Res. 2017 Sep 1;16(9):3266-3276. doi: 10.1021/acs.jproteome.7b00245. Epub 2017 Aug 8. PMID: 28731711; PMCID: PMC6339813.
417. Richmond BW, Brucker RM, Han W, Du RH, Zhang Y, Cheng DS, Gleaves L, Abdolrasulnia R, Polosukhina D, Clark PE, Bordenstein SR, Blackwell TS, Polosukhin VV. Airway bacteria drive a progressive COPD-like phenotype in mice with polymeric immunoglobulin receptor deficiency. Nat Commun. 2016 Apr 5;7:11240. doi: 10.1038/ncomms11240. PMID: 27046438; PMCID: PMC4822073.
418. Farkas JZ, Smith GT, Webb GF. A dynamic model of CT scans for quantifying doubling time of ground glass opacities using histogram analysis. Math Biosci Eng. 2018 Oct 1;15(5):1203-1224. doi: 10.3934/mbe.2018055. PMID: 30380307.
419. Hassanein M, Hight MR, Buck JR, Tantawy MN, Nickels ML, Hoeksema MD, Harris BK, Boyd K, Massion PP, Manning HC. Preclinical Evaluation of 4-[18F]Fluoroglutamine PET to Assess ASCT2 Expression in Lung Cancer. Mol Imaging Biol. 2016 Feb;18(1):18-23. doi: 10.1007/s11307-015-0862-4. PMID: 25971659; PMCID: PMC4644503.

420. Su J, Liao J, Gao L, Shen J, Guarnera MA, Zhan M, Fang H, Stass SA, Jiang F. Analysis of small nucleolar RNAs in sputum for lung cancer diagnosis. Oncotarget. 2016 Feb 2;7(5):5131-42. doi: 10.18632/oncotarget.4219. PMID: 26246471; PMCID: PMC4868676.
421. Balasenthil S, Huang Y, Liu S, Marsh T, Chen J, Stass SA, KuKuruga D, Brand R, Chen N, Frazier ML, Jack Lee J, Srivastava S, Sen S, McNeill Killary A. A Plasma Biomarker Panel to Identify Surgically Resectable Early-Stage Pancreatic Cancer. J Natl Cancer Inst. 2017 Aug 1;109(8):djw341. doi: 10.1093/jnci/djw341. PMID: 28376184; PMCID: PMC6059209.
422. Pine PS, Lund SP, Parsons, JR, Vang LK, Mahabal AA, Cinqyini L, Kelly SC, Kincaid H, Crichton DJ, Spira A, Liu G, Gower AC, Pass HI, Coparaju C, Dubinett SM, Krysan K, Stass SA, KuKuruga D, Van Keuren-Jensen K, Courtright-Lim A, Thompson KL, Rosenzweig BA, Sorbara L, Srivastava S, And Salit ML. Summarizing Performance for Genome Scale Measurement of miRNA: Reference Samples and Metrics. BMC Genomics. (In Press)
423. Ma J, Guarnera MA, Zhou W, Fang H, Jiang F. A Prediction Model Based on Biomarkers and Clinical Characteristics for Detection of Lung Cancer in Pulmonary Nodules. Transl Oncol. 2017 Feb;10(1):40-45. doi: 10.1016/j.tranon.2016.11.001. Epub 2016 Nov 24. PMID: 27889655; PMCID: PMC5126145.
424. Leng Q, Lin Y, Jiang F, Lee CJ, Zhan M, Fang H, Wang Y, Jiang F. A plasma miRNA signature for lung cancer early detection. Oncotarget. 2017 Dec 5;8(67):111902-111911. doi: 10.18632/oncotarget.22950. PMID: 29340099; PMCID: PMC5762367.
425. Gupta C, Su J, Zhan M, Stass SA, Jiang F. Sputum long non-coding RNA biomarkers for diagnosis of lung cancer. Cancer Biomark. 2019;26(2):219-227. doi: 10.3233/CBM-190161. PMID: 31450489.
426. Pine PS, Lund SP, Stass SA, Kukuruga D, Jiang F, Sorbara L, Srivastava S, Salit M. Cell-based reference samples designed with specific differences in microRNA biomarkers. BMC Biotechnol. 2018 Mar 20;18(1):17. doi: 10.1186/s12896-018-0423-4. PMID: 29554888; PMCID: PMC5859499.
427. Carbone M, Kanodia S, Chao A, Miller A, Wali A, Weissman D, Adjei A, Baumann F, Boffetta P, Buck B, de Perrot M, Dogan AU, Gavett S, Gualtieri A, Hassan R, Hesdorffer M, Hirsch FR, Larson D, Mao W, Masten S, Pass HI, Peto J, Pira E, Steele I, Tsao A, Woodard GA, Yang H, Malik S. Consensus Report of the 2015 Weinman International Conference on Mesothelioma. J Thorac Oncol. 2016 Aug;11(8):1246-1262. doi: 10.1016/j.jtho.2016.04.028. PMID: 27453164; PMCID: PMC5551435.
428. Napolitano A, Antoine DJ, Pellegrini L, Baumann F, Pagano I, Pastorino S, Goparaju CM, Prokrym K, Canino C, Pass HI, Carbone M, Yang H. HMGB1 and Its Hyperacetylated Isoform are Sensitive and Specific Serum Biomarkers to Detect Asbestos Exposure and to Identify Mesothelioma Patients. Version 2. Clin Cancer Res. 2016 Jun 15;22(12):3087-96. doi: 10.1158/1078-0432.CCR-15-1130. Epub 2016 Jan 5. PMID: 26733616; PMCID: PMC4867109.
429. Carbone M, Shimizu D, Napolitano A, Tanji M, Pass HI, Yang H, Pastorino S. Positive nuclear BAP1 immunostaining helps differentiate non-small cell lung carcinomas from malignant mesothelioma. Oncotarget. 2016 Sep 13;7(37):59314-59321. doi: 10.18632/oncotarget.10653. PMID: 27447750; PMCID: PMC5312314.
430. Yoshikawa Y, Emi M, Hashimoto-Tamaoki T, Ohmuraya M, Sato A, Tsujimura T, Hasegawa S, Nakano T, Nasu M, Pastorino S, Szymiczek A, Bononi A, Tanji M, Pagano I, Gaudino G, Napolitano A, Goparaju C, Pass HI, Yang H, Carbone M. High-density array-CGH with targeted NGS unmask multiple noncontiguous minute deletions on chromosome 3p21 in mesothelioma. Proc Natl Acad Sci U S A. 2016 Nov 22;113(47):13432-13437. doi: 10.1073/pnas.1612074113. Epub 2016 Nov 9. PMID: 27834213; PMCID: PMC5127333.

431. Larson D, Powers A, Ambrosi JP, Tanji M, Napolitano A, Flores EG, Baumann F, Pellegrini L, Jennings CJ, Buck BJ, McLaurin BT, Merkler D, Robinson C, Morris P, Dogan M, Dogan AU, Pass HI, Pastorino S, Carbone M, Yang H. Investigating palygorskite's role in the development of mesothelioma in southern Nevada: Insights into fiber-induced carcinogenicity. J Toxicol Environ Health B Crit Rev. 2016;19(5-6):213-230. doi: 10.1080/10937404.2016.1195321. PMID: 27705545; PMCID: PMC5062041.
432. Pellegrini L, Xue J, Larson D, Pastorino S, Jube S, Forest KH, Saad-Jube ZS, Napolitano A, Pagano I, Negi VS, Bianchi ME, Morris P, Pass HI, Gaudino G, Carbone M, Yang H. HMGB1 targeting by ethyl pyruvate suppresses malignant phenotype of human mesothelioma. Oncotarget. 2017 Apr 4;8(14):22649-22661. doi: 10.18632/oncotarget.15152. PMID: 28186988; PMCID: PMC5410252.
433. Chen Z, Gaudino G, Pass HI, Carbone M, Yang H. Diagnostic and prognostic biomarkers for malignant mesothelioma: an update. Transl Lung Cancer Res. 2017 Jun;6(3):259-269. doi: 10.21037/tlcr.2017.05.06. PMID: 28713671; PMCID: PMC5504120.
434. Carbone M, Yang H. Mesothelioma: recent highlights. Ann Transl Med. 2017 Jun;5(11):238. doi: 10.21037/atm.2017.04.29. PMID: 28706906; PMCID: PMC5497108.
435. Szymiczek A, Pastorino S, Larson D, Tanji M, Pellegrini L, Xue J, Li S, Giorgi C, Pinton P, Takinishi Y, Pass HI, Furuya H, Gaudino G, Napolitano A, Carbone M, Yang H. FTY720 inhibits mesothelioma growth in vitro and in a syngeneic mouse model. J Transl Med. 2017 Mar 15;15(1):58. doi: 10.1186/s12967-017-1158-z. PMID: 28298211; PMCID: PMC5353897.
436. Guo Z, Carbone M, Zhang X, Su D, Sun W, Lou J, Gao Z, Shao D, Chen J, Zhang G, Hu J, Chen K, Wang F, Pass HI, Yu H, Napolitano A, Yang H, Mao W. Improving the Accuracy of Mesothelioma Diagnosis in China. J Thorac Oncol. 2017 Apr;12(4):714-723. doi: 10.1016/j.jtho.2016.12.006. Epub 2016 Dec 19. PMID: 28007630; PMCID: PMC5567857.
437. Mao W, Zhang X, Guo Z, Gao Z, Pass HI, Yang H, Carbone M. Association of Asbestos Exposure With Malignant Mesothelioma Incidence in Eastern China. JAMA Oncol. 2017 Apr 1;3(4):562-564. doi: 10.1001/jamaoncol.2016.5487. Erratum in: JAMA Oncol. 2017 Apr 1;3(4):568. PMID: 27918607; PMCID: PMC5569880.
438. Bononi A, Yang H, Giorgi C, Patergnani S, Pellegrini L, Su M, Xie G, Signorato V, Pastorino S, Morris P, Sakamoto G, Kuchay S, Gaudino G, Pass HI, Napolitano A, Pinton P, Jia W, Carbone M. Germline BAP1 mutations induce a Warburg effect. Cell Death Differ. 2017 Oct;24(10):1694-1704. doi: 10.1038/cdd.2017.95. Epub 2017 Jun 30. PMID: 28665402; PMCID: PMC5596430.
439. Bononi A, Giorgi C, Patergnani S, Larson D, Verbruggen K, Tanji M, Pellegrini L, Signorato V, Olivetto F, Pastorino S, Nasu M, Napolitano A, Gaudino G, Morris P, Sakamoto G, Ferris LK, Danese A, Raimondi A, Tacchetti C, Kuchay S, Pass HI, Affar EB, Yang H, Pinton P, Carbone M. BAP1 regulates IP3R3-mediated Ca2+ flux to mitochondria suppressing cell transformation. Nature. 2017 Jun 22;546(7659):549-553. doi: 10.1038/nature22798. Epub 2017 Jun 14. PMID: 28614305; PMCID: PMC5581194.
440. Pastorino S, Yoshikawa Y, Pass HI, Emi M, Nasu M, Pagano I, Takinishi Y, Yamamoto R, Minaai M, Hashimoto-Tamaoki T, Ohmuraya M, Goto K, Goparaju C, Sarin KY, Tanji M, Bononi A, Napolitano A, Gaudino G, Hesdorffer M, Yang H, Carbone M. A Subset of Mesotheliomas With Improved Survival Occurring in Carriers of BAP1 and Other Germline Mutations. J Clin Oncol. 2018 Oct 30;36(35):JCO2018790352. doi: 10.1200/JCO.2018.79.0352. Epub ahead of print. PMID: 30376426; PMCID: PMC7162737.

441. McCambridge AJ, Napolitano A, Mansfield AS, Fennell DA, Sekido Y, Nowak AK, Reungwetwattana T, Mao W, Pass HI, Carbone M, Yang H, Peikert T. Progress in the Management of Malignant Pleural Mesothelioma in 2017. J Thorac Oncol. 2018 May;13(5):606-623. doi: 10.1016/j.jtho.2018.02.021. Epub 2018 Mar 8. PMID: 29524617; PMCID: PMC6544834.
442. Carbone M, Adusumilli PS, Alexander HR Jr, Baas P, Bardelli F, Bononi A, Bueno R, Felley-Bosco E, Galateau-Salle F, Jablons D, Mansfield AS, Minaai M, de Perrot M, Pesavento P, Rusch V, Severson DT, Taioli E, Tsao A, Woodard G, Yang H, Zauderer MG, Pass HI. Mesothelioma: Scientific clues for prevention, diagnosis, and therapy. CA Cancer J Clin. 2019 Sep;69(5):402-429. doi: 10.3322/caac.21572. Epub 2019 Jul 8. PMID: 31283845.
443. Carbone M, Yang H, Gaudino G. Does Chromothripsis Make Mesothelioma an Immunogenic Cancer? J Thorac Oncol. 2019 Feb;14(2):157-159. doi: 10.1016/j.jtho.2018.11.006. Epub 2018 Dec 28. PMID: 30598368; PMCID: PMC6526534.
444. Gaudino G, Xue J, Yang H. How asbestos and other fibers cause mesothelioma. Transl Lung Cancer Res. 2020 Feb;9(Suppl 1):S39-S46. doi: 10.21037/tlcr.2020.02.01. PMID: 32206569; PMCID: PMC7082251.
445. Kobrinski DA, Yang H, Kittaneh M. BAP1: role in carcinogenesis and clinical implications. Transl Lung Cancer Res. 2020 Feb;9(Suppl 1):S60-S66. doi: 10.21037/tlcr.2019.11.24. PMID: 32206571; PMCID: PMC7082261.
446. Traverso A, Wee L, Dekker A, Gillies R. Repeatability and Reproducibility of Radiomic Features: A Systematic Review. Int J Radiat Oncol Biol Phys. 2018 Nov 15;102(4):1143-1158. doi: 10.1016/j.ijrobp.2018.05.053. Epub 2018 Jun 5. PMID: 30170872; PMCID: PMC6690209.
447. Fowler EEE, Smallwood A, Miltich C, Drukteinis J, Sellers TA, Heine J. Generalized breast density metrics. Phys Med Biol. 2018 Dec 19;64(1):015006. doi: 10.1088/1361-6560/aaf307. PMID: 30523909; PMCID: PMC7034052.
448. Fowler EE, Smallwood A, Khan N, Miltich C, Drukteinis J, Sellers TA, Heine J. Calibrated Breast Density Measurements. Acad Radiol. 2019 Sep;26(9):1181-1190. doi: 10.1016/j.acra.2018.10.009. Epub 2018 Dec 10. PMID: 30545682; PMCID: PMC6557684.
449. Fowler EEE, Smallwood AM, Khan NZ, Kilpatrick K, Sellers TA, Heine J. Technical challenges in generalizing calibration techniques for breast density measurements. Version 2. Med Phys. 2019 Feb;46(2):679-688. doi: 10.1002/mp.13325. Epub 2019 Jan 11. PMID: 30525207; PMCID: PMC6367025.
450. Liu Y, Kim J, Balagurunathan Y, Hawkins S, Stringfield O, Schabath MB, Li Q, Qu F, Liu S, Garcia AL, Ye Z, Gillies RJ. Prediction of pathological nodal involvement by CT-based Radiomic features of the primary tumor in patients with clinically node-negative peripheral lung adenocarcinomas. Med Phys. 2018 Jun;45(6):2518-2526. doi: 10.1002/mp.12901. Epub 2018 Apr 29. PMID: 29624702; PMCID: PMC6161827.
451. Beichel RR, Smith BJ, Bauer C, Ulrich EJ, Ahmadvand P, Budzevich MM, Gillies RJ, Goldgof D, Grkovski M, Hamarneh G, Huang Q, Kinahan PE, Laymon CM, Mountz JM, Muzi JP, Muzi M, Nehmeh S, Oborski MJ, Tan Y, Zhao B, Sunderland JJ, Buatti JM. Multi-site quality and variability analysis of 3D FDG PET segmentations based on phantom and clinical image data. Med Phys. 2017 Feb;44(2):479-496. doi: 10.1002/mp.12041. PMID: 28205306; PMCID: PMC5834232.
452. Oh H, Rice MS, Warner ET, Bertrand KA, Fowler EE, Eliassen AH, Rosner BA, Heine JJ, Tamimi RM. Early-Life and Adult Anthropometrics in Relation to Mammographic Image Intensity Variation in the

Nurses' Health Studies. Cancer Epidemiol Biomarkers Prev. 2020 Feb;29(2):343-351. doi: 10.1158/1055-9965.EPI-19-0832. Epub 2019 Dec 11. PMID: 31826913; PMCID: PMC7007347.

453. Nimmakayala RK, Seshacharyulu P, Lakshmanan I, Rachagani S, Chugh S, Karmakar S, Rauth S, Vengoji R, Atri P, Talmon GA, Lele SM, Smith LM, Thapa I, Bastola D, Ouellette MM, Batra SK, Ponnusamy MP. Cigarette Smoke Induces Stem Cell Features of Pancreatic Cancer Cells via PAF1. Gastroenterology. 2018 Sep;155(3):892-908.e6. doi: 10.1053/j.gastro.2018.05.041. Epub 2018 Jun 2. PMID: 29864419; PMCID: PMC6120776.
454. Sinha J, Cao Z, Dai J, Tang H, Partyka K, Hostetter G, Simeone DM, Feng Z, Allen PJ, Brand RE, Haab BB. A Gastric Glycoform of MUC5AC Is a Biomarker of Mucinous Cysts of the Pancreas. PLoS One. 2016 Dec 19;11(12):e0167070. doi: 10.1371/journal.pone.0167070. PMID: 27992432; PMCID: PMC5167232.
455. Kaur S, Smith LM, Patel A, Menning M, Watley DC, Malik SS, Krishn SR, Mallya K, Aithal A, Sasson AR, Johansson SL, Jain M, Singh S, Guha S, Are C, Raimondo M, Hollingsworth MA, Brand RE, Batra SK. A Combination of MUC5AC and CA19-9 Improves the Diagnosis of Pancreatic Cancer: A Multicenter Study. Am J Gastroenterol. 2017 Jan;112(1):172-183. doi: 10.1038/ajg.2016.482. Epub 2016 Nov 15. PMID: 27845339; PMCID: PMC5365072.
456. Smolsky J, Kaur S, Hayashi C, Batra SK, Krasnoslobodtsev AV. Surface-Enhanced Raman Scattering-Based Immunoassay Technologies for Detection of Disease Biomarkers. Biosensors (Basel). 2017 Jan 12;7(1):7. doi: 10.3390/bios7010007. PMID: 28085088; PMCID: PMC5371780.
457. Gautam SK, Kumar S, Cannon A, Hall B, Bhatia R, Nasser MW, Mahapatra S, Batra SK, Jain M. MUC4 mucin- a therapeutic target for pancreatic ductal adenocarcinoma. Expert Opin Ther Targets. 2017 Jul;21(7):657-669. doi: 10.1080/14728222.2017.1323880. Epub 2017 May 29. PMID: 28460571; PMCID: PMC5706649.
458. Aithal A, Junker WM, Kshirsagar P, Das S, Kaur S, Orzechowski C, Gautam SK, Jahan R, Sheinin YM, Lakshmanan I, Ponnusamy MP, Batra SK, Jain M. Development and characterization of carboxy-terminus specific monoclonal antibodies for understanding MUC16 cleavage in human ovarian cancer. PLoS One. 2018 Apr 30;13(4):e0193907. doi: 10.1371/journal.pone.0193907. PMID: 29708979; PMCID: PMC5927449.
459. Chao DT, Shah NH, Zeh HJ 3rd, Singhi AD, Bahary N, McGrath KM, Fasanella KE, Zureikat AH, Whitcomb DC, Brand RE. Overweight or Obese Individuals at Eighteen Years of Age Develop Pancreatic Adenocarcinoma at a Significantly Earlier Age. Gastroenterol Res Pract. 2018 Jun 5;2018:2380596. doi: 10.1155/2018/2380596. PMID: 29967636; PMCID: PMC6008748.
460. Cannon A, Thompson C, Hall BR, Jain M, Kumar S, Batra SK. Desmoplasia in pancreatic ductal adenocarcinoma: insight into pathological function and therapeutic potential. Genes Cancer. 2018 Mar;9(3-4):78-86. doi: 10.18632/genesandcancer.171. PMID: 30108679; PMCID: PMC6086006.
461. Banerjee K, Kumar S, Ross KA, Gautam S, Poelaert B, Nasser MW, Aithal A, Bhatia R, Wannemuehler MJ, Narasimhan B, Solheim JC, Batra SK, Jain M. Emerging trends in the immunotherapy of pancreatic cancer. Cancer Lett. 2018 Mar 28;417:35-46. doi: 10.1016/j.canlet.2017.12.012. Epub 2017 Dec 12. PMID: 29242097; PMCID: PMC5801196.
462. Hall BR, Cannon A, Atri P, Wichman CS, Smith LM, Ganti AK, Are C, Sasson AR, Kumar S, Batra SK. Advanced pancreatic cancer: a meta-analysis of clinical trials over thirty years. Oncotarget. 2018 Apr 10;9(27):19396-19405. doi: 10.18632/oncotarget.25036. PMID: 29721211; PMCID: PMC5922405.

463. Qazi AK, Siddiqui JA, Jahan R, Chaudhary S, Walker LA, Sayed Z, Jones DT, Batra SK, Macha MA. Emerging therapeutic potential of graviola and its constituents in cancers. Carcinogenesis. 2018 Apr 5;39(4):522-533. doi: 10.1093/carcin/bgy024. PMID: 29462271; PMCID: PMC5888937.
464. Aithal A, Rauth S, Kshirsagar P, Shah A, Lakshmanan I, Junker WM, Jain M, Ponnusamy MP, Batra SK. MUC16 as a novel target for cancer therapy. Expert Opin Ther Targets. 2018 Aug;22(8):675-686. doi: 10.1080/14728222.2018.1498845. Epub 2018 Jul 26. PMID: 29999426; PMCID: PMC6300140.
465. Barkeer S, Chugh S, Batra SK, Ponnusamy MP. Glycosylation of Cancer Stem Cells: Function in Stemness, Tumorigenesis, and Metastasis. Neoplasia. 2018 Aug;20(8):813-825. doi: 10.1016/j.neo.2018.06.001. Epub 2018 Jul 6. PMID: 30015157; PMCID: PMC6037882.
466. Jahan R, Macha MA, Rachagani S, Das S, Smith LM, Kaur S, Batra SK. Axed MUC4 (MUC4/X) aggravates pancreatic malignant phenotype by activating integrin-β1/FAK/ERK pathway. Biochim Biophys Acta Mol Basis Dis. 2018 Aug;1864(8):2538-2549. doi: 10.1016/j.bbadis.2018.05.008. Epub 2018 May 16. PMID: 29777904; PMCID: PMC6047753.
467. Carmicheal J, Kaur S, Batra SK, Ganti AK. Hunting for transcription factors: STAT3 decoy in non-small cell lung cancer. Transl Lung Cancer Res. 2018 Sep;7(Suppl 3):S254-S257. doi: 10.21037/tlcr.2018.09.06. PMID: 30393616; PMCID: PMC6193924.
468. Barkeer S, Chugh S, Karmakar S, Kaushik G, Rauth S, Rachagani S, Batra SK, Ponnusamy MP. Novel role of O-glycosyltransferases GALNT3 and B3GNT3 in the self-renewal of pancreatic cancer stem cells. BMC Cancer. 2018 Nov 22;18(1):1157. doi: 10.1186/s12885-018-5074-2. PMID: 30466404; PMCID: PMC6251200.
469. Chugh S, Barkeer S, Rachagani S, Nimmakayala RK, Perumal N, Pothuraju R, Atri P, Mahapatra S, Thapa I, Talmon GA, Smith LM, Yu X, Neelamegham S, Fu J, Xia L, Ponnusamy MP, Batra SK. Disruption of C1galt1 Gene Promotes Development and Metastasis of Pancreatic Adenocarcinomas in Mice. Gastroenterology. 2018 Nov;155(5):1608-1624. doi: 10.1053/j.gastro.2018.08.007. Epub 2018 Aug 4. PMID: 30086262; PMCID: PMC6219903.
470. Pothuraju R, Rachagani S, Junker WM, Chaudhary S, Saraswathi V, Kaur S, Batra SK. Pancreatic cancer associated with obesity and diabetes: an alternative approach for its targeting. J Exp Clin Cancer Res. 2018 Dec 19;37(1):319. doi: 10.1186/s13046-018-0963-4. PMID: 30567565; PMCID: PMC6299603.
471. Ma P, Beatty PL, McKolanis J, Brand R, Schoen RE, Finn OJ. Circulating Myeloid Derived Suppressor Cells (MDSC) That Accumulate in Premalignancy Share Phenotypic and Functional Characteristics With MDSC in Cancer. Front Immunol. 2019 Jun 19;10:1401. doi: 10.3389/fimmu.2019.01401. PMID: 31275327; PMCID: PMC6594197.
472. Khatri I, Ganguly K, Sharma S, Carmicheal J, Kaur S, Batra SK, Bhasin MK. Systems Biology Approach to Identify Novel Genomic Determinants for Pancreatic Cancer Pathogenesis. Sci Rep. 2019 Jan 15;9(1):123. doi: 10.1038/s41598-018-36328-w. PMID: 30644396; PMCID: PMC6333820.
473. Nimmakayala RK, Batra SK, Ponnusamy MP. Unraveling the journey of cancer stem cells from origin to metastasis. Biochim Biophys Acta Rev Cancer. 2019 Jan;1871(1):50-63. doi: 10.1016/j.bbcan.2018.10.006. Epub 2018 Nov 9. PMID: 30419314; PMCID: PMC6347501.
474. Carmicheal J, Hayashi C, Huang X, Liu L, Lu Y, Krasnoslobodtsev A, Lushnikov A, Kshirsagar PG, Patel A, Jain M, Lyubchenko YL, Lu Y, Batra SK, Kaur S. Label-free characterization of exosome via surface enhanced Raman spectroscopy for the early detection of pancreatic cancer. Nanomedicine. 2019 Feb;16:88-96. doi: 10.1016/j.nano.2018.11.008. Epub 2018 Dec 11. PMID: 30550805; PMCID: PMC6532067.

475. Chaudhary S, Ganguly K, Muniyan S, Pothuraju R, Sayed Z, Jones DT, Batra SK, Macha MA. Immunometabolic Alterations by HPV Infection: New Dimensions to Head and Neck Cancer Disparity. J Natl Cancer Inst. 2019 Mar 1;111(3):233-244. doi: 10.1093/jnci/djy207. PMID: 30615137; PMCID: PMC6410958.
476. Jahan R, Ganguly K, Smith LM, Atri P, Carmicheal J, Sheinin Y, Rachagani S, Natarajan G, Brand RE, Macha MA, Grandgenett PM, Kaur S, Batra SK. Trefoil factor(s) and CA19.9: A promising panel for early detection of pancreatic cancer. EBioMedicine. 2019 Apr;42:375-385. doi: 10.1016/j.ebiom.2019.03.056. Epub 2019 Apr 5. PMID: 30956167; PMCID: PMC6491718.
477. Banerjee K, Gautam SK, Kshirsagar P, Ross KA, Spagnol G, Sorgen P, Wannemuehler MJ, Narasimhan B, Solheim JC, Kumar S, Batra SK, Jain M. Amphiphilic polyanhydride-based recombinant MUC4β-nanovaccine activates dendritic cells. Genes Cancer. 2019 May;10(3-4):52-62. doi: 10.18632/genesandcancer.189. PMID: 31258832; PMCID: PMC6584211.
478. Bhatia R, Gautam SK, Cannon A, Thompson C, Hall BR, Aithal A, Banerjee K, Jain M, Solheim JC, Kumar S, Batra SK. Cancer-associated mucins: role in immune modulation and metastasis. Cancer Metastasis Rev. 2019 Jun;38(1-2):223-236. doi: 10.1007/s10555-018-09775-0. PMID: 30618016; PMCID: PMC6614013.
479. Park WG, Li L, Appana S, Wei W, Stello K, Andersen DK, Hughes SJ, Whitcomb DC, Brand RE, Yadav D, Habtezion A; Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer. Unique circulating immune signatures for recurrent acute pancreatitis, chronic pancreatitis and pancreatic cancer: A pilot study of these conditions with and without diabetes. Pancreatology. 2020 Jan;20(1):51-59. doi: 10.1016/j.pan.2019.11.008. Epub 2019 Nov 25. PMID: 31791885; PMCID: PMC6983346.
480. Carmicheal J, Patel A, Dalal V, Atri P, Dhaliwal AS, Wittel UA, Malafa MP, Talmon G, Swanson BJ, Singh S, Jain M, Kaur S, Batra SK. Elevating pancreatic cystic lesion stratification: Current and future pancreatic cancer biomarker(s). Biochim Biophys Acta Rev Cancer. 2020 Jan;1873(1):188318. doi: 10.1016/j.bbcan.2019.188318. Epub 2019 Oct 30. PMID: 31676330; PMCID: PMC6980327.
481. Dalal V, Carmicheal J, Dhaliwal A, Jain M, Kaur S, Batra SK. Radiomics in stratification of pancreatic cystic lesions: Machine learning in action. Cancer Lett. 2020 Jan 28;469:228-237. doi: 10.1016/j.canlet.2019.10.023. Epub 2019 Oct 17. PMID: 31629933; PMCID: PMC6927395.
482. Gautam SK, Kumar S, Dam V, Ghersi D, Jain M, Batra SK. MUCIN-4 (MUC4) is a novel tumor antigen in pancreatic cancer immunotherapy. Semin Immunol. 2020 Feb;47:101391. doi: 10.1016/j.smim.2020.101391. Epub 2020 Jan 14. PMID: 31952903; PMCID: PMC7160012.
483. Pothuraju R, Rachagani S, Krishn SR, Chaudhary S, Nimmakayala RK, Siddiqui JA, Ganguly K, Lakshmanan I, Cox JL, Mallya K, Kaur S, Batra SK. Molecular implications of MUC5AC-CD44 axis in colorectal cancer progression and chemoresistance. Mol Cancer. 2020 Feb 25;19(1):37. doi: 10.1186/s12943-020-01156-y. PMID: 32098629; PMCID: PMC7041280.
484. Carmicheal J, Atri P, Sharma S, Kumar S, Chirravuri Venkata R, Kulkarni P, Salgia R, Ghersi D, Kaur S, Batra SK. Presence and structure-activity relationship of intrinsically disordered regions across mucins. FASEB J. 2020 Feb;34(2):1939-1957. doi: 10.1096/fj.201901898RR. Epub 2020 Jan 5. PMID: 31908009; PMCID: PMC7018569.
485. Singhi AD, Wood LD, Parks E, Torbenson MS, Felsenstein M, Hruban RH, Nikiforova MN, Wald AI, Kaya C, Nikiforov YE, Favazza L, He J, McGrath K, Fasanella KE, Brand RE, Lennon AM, Furlan A, Dasyam AK, Zureikat AH, Zeh HJ, Lee K, Bartlett DL, Slivka A. Recurrent Rearrangements in PRKACA and PRKACB in Intraductal Oncocytic Papillary Neoplasms of the Pancreas and Bile Duct.

Gastroenterology. 2020 Feb;158(3):573-582.e2. doi: 10.1053/j.gastro.2019.10.028. Epub 2019 Oct 31. PMID: 31678302; PMCID: PMC7010554.
486. Ganguly K, Rauth S, Marimuthu S, Kumar S, Batra SK. Unraveling mucin domains in cancer and metastasis: when protectors become predators. Cancer Metastasis Rev. 2020 Jun 2. doi: 10.1007/s10555-020-09896-5. Epub ahead of print. PMID: 32488403.
487. Tang H, Partyka K, Hsueh P, Sinha JY, Kletter D, Zeh H, Huang Y, Brand RE, Haab BB. Glycans related to the CA19-9 antigen are elevated in distinct subsets of pancreatic cancers and improve diagnostic accuracy over CA19-9. Version 2. Cell Mol Gastroenterol Hepatol. 2016 Feb 1;2(2):201-221.e15. doi: 10.1016/j.jcmgh.2015.12.003. PMID: 26998508; PMCID: PMC4792034.
488. Reatini BS, Ensink E, Liau B, Sinha JY, Powers TW, Partyka K, Bern M, Brand RE, Rudd PM, Kletter D, Drake R, Haab BB. Characterizing Protein Glycosylation through On-Chip Glycan Modification and Probing. Anal Chem. 2016 Dec 6;88(23):11584-11592. doi: 10.1021/acs.analchem.6b02998. Epub 2016 Nov 15. PMID: 27809484; PMCID: PMC5290727.
489. Barnett D, Liu Y, Partyka K, Huang Y, Tang H, Hostetter G, Brand RE, Singhi AD, Drake RR, Haab BB. The CA19-9 and Sialyl-TRA Antigens Define Separate Subpopulations of Pancreatic Cancer Cells. Sci Rep. 2017 Jun 22;7(1):4020. doi: 10.1038/s41598-017-04164-z. PMID: 28642461; PMCID: PMC5481434.
490. Ivry SL, Sharib JM, Dominguez DA, Roy N, Hatcher SE, Yip-Schneider MT, Schmidt CM, Brand RE, Park WG, Hebrok M, Kim GE, O'Donoghue AJ, Kirkwood KS, Craik CS. Global Protease Activity Profiling Provides Differential Diagnosis of Pancreatic Cysts. Clin Cancer Res. 2017 Aug 15;23(16):4865-4874. doi: 10.1158/1078-0432.CCR-16-2987. Epub 2017 Apr 19. PMID: 28424202; PMCID: PMC5712228.
491. Klamer Z, Staal B, Prudden AR, Liu L, Smith DF, Boons GJ, Haab B. Mining High-Complexity Motifs in Glycans: A New Language To Uncover the Fine Specificities of Lectins and Glycosidases. Anal Chem. 2017 Nov 21;89(22):12342-12350. doi: 10.1021/acs.analchem.7b04293. Epub 2017 Nov 3. PMID: 29058413; PMCID: PMC5700451.
492. Chao DT, Shah NH, Zeh HJ 3rd, Singhi AD, Bahary N, McGrath KM, Fasanella KE, Zureikat AH, Whitcomb DC, Brand RE. Overweight or Obese Individuals at Eighteen Years of Age Develop Pancreatic Adenocarcinoma at a Significantly Earlier Age. Gastroenterol Res Pract. 2018 Jun 5;2018:2380596. doi: 10.1155/2018/2380596. PMID: 29967636; PMCID: PMC6008748.
493. Root A, Allen P, Tempst P, Yu K. Protein Biomarkers for Early Detection of Pancreatic Ductal Adenocarcinoma: Progress and Challenges. Cancers (Basel). 2018 Mar 7;10(3):67. doi: 10.3390/cancers10030067. PMID: 29518918; PMCID: PMC5876642.
494. Klamer Z, Hsueh P, Ayala-Talavera D, Haab B. Deciphering Protein Glycosylation by Computational Integration of On-chip Profiling, Glycan-array Data, and Mass Spectrometry. Mol Cell Proteomics. 2019 Jan;18(1):28-40. doi: 10.1074/mcp.RA118.000906. Epub 2018 Sep 26. PMID: 30257876; PMCID: PMC6317472.
495. Barnett D, Hall J, Haab B. Automated Identification and Quantification of Signals in Multichannel Immunofluorescence Images: The SignalFinder-IF Platform. Am J Pathol. 2019 Jul;189(7):1402-1412. doi: 10.1016/j.ajpath.2019.03.011. Epub 2019 Apr 23. PMID: 31026417; PMCID: PMC6616976.
496. Haab BB, Klamer Z. Advances in Tools to Determine the Glycan-Binding Specificities of Lectins and Antibodies. Mol Cell Proteomics. 2020 Feb;19(2):224-232. doi: 10.1074/mcp.R119.001836. Epub 2019 Dec 17. PMID: 31848260; PMCID: PMC7000120.
497. Butner JD, Elganainy D, Wang CX, Wang Z, Chen SH, Esnaola NF, Pasqualini R, Arap W, Hong DS, Welsh J, Koay EJ, Cristini V. Mathematical prediction of clinical outcomes in advanced cancer

patients treated with checkpoint inhibitor immunotherapy. Sci Adv. 2020 Apr 29;6(18):eaay6298. doi: 10.1126/sciadv.aay6298. PMID: 32426472; PMCID: PMC7190324.
498. Avila S, Smani DA, Koay EJ. Radiation dose escalation for locally advanced unresectable intrahepatic and extrahepatic cholangiocarcinoma. Chin Clin Oncol. 2020 Feb;9(1):10. doi: 10.21037/cco.2019.12.05. Epub 2019 Dec 19. PMID: 32008331; PMCID: PMC7277074.
499. Park PC, Choi GW, M Zaid M, Elganainy D, Smani DA, Tomich J, Samaniego R, Ma J, Tamm EP, Beddar S, Koay EJ. Enhancement pattern mapping technique for improving contrast-to-noise ratios and detectability of hepatobiliary tumors on multiphase computed tomography. Med Phys. 2020 Jan;47(1):64-74. doi: 10.1002/mp.13769. Epub 2019 Nov 19. PMID: 31449684; PMCID: PMC7065272.
500. Kamyabi N, Bernard V, Maitra A. Liquid biopsies in pancreatic cancer. Expert Rev Anticancer Ther. 2019 Oct;19(10):869-878. doi: 10.1080/14737140.2019.1670063. Epub 2019 Sep 26. PMID: 31533487; PMCID: PMC6824837.
501. Staal B, Liu Y, Barnett D, Hsueh P, He Z, Gao C, Partyka K, Hurd MW, Singhi AD, Drake RR, Huang Y, Maitra A, Brand RE, Haab BB. The sTRA Plasma Biomarker: Blinded Validation of Improved Accuracy Over CA19-9 in Pancreatic Cancer Diagnosis. Clin Cancer Res. 2019 May 1;25(9):2745-2754. doi: 10.1158/1078-0432.CCR-18-3310. Epub 2019 Jan 7. PMID: 30617132; PMCID: PMC7246054.
502. Singhi AD, Koay EJ, Chari ST, Maitra A. Early Detection of Pancreatic Cancer: Opportunities and Challenges. Gastroenterology. 2019 May;156(7):2024-2040. doi: 10.1053/j.gastro.2019.01.259. Epub 2019 Feb 2. PMID: 30721664; PMCID: PMC6486851.
503. Fahrmann JF, Bantis LE, Capello M, Scelo G, Dennison JB, Patel N, Murage E, Vykoukal J, Kundnani DL, Foretova L, Fabianova E, Holcatova I, Janout V, Feng Z, Yip-Schneider M, Zhang J, Brand R, Taguchi A, Maitra A, Brennan P, Max Schmidt C, Hanash S. A Plasma-Derived Protein-Metabolite Multiplexed Panel for Early-Stage Pancreatic Cancer. J Natl Cancer Inst. 2019 Apr 1;111(4):372-379. doi: 10.1093/jnci/djy126. PMID: 30137376; PMCID: PMC6449169.
504. Bernard V, Semaan A, Huang J, San Lucas FA, Mulu FC, Stephens BM, Guerrero PA, Huang Y, Zhao J, Kamyabi N, Sen S, Scheet PA, Taniguchi CM, Kim MP, Tzeng CW, Katz MH, Singhi AD, Maitra A, Alvarez HA. Single-Cell Transcriptomics of Pancreatic Cancer Precursors Demonstrates Epithelial and Microenvironmental Heterogeneity as an Early Event in Neoplastic Progression. Clin Cancer Res. 2019 Apr 1;25(7):2194-2205. doi: 10.1158/1078-0432.CCR-18-1955. Epub 2018 Nov 1. PMID: 30385653; PMCID: PMC6445737.
505. Bernard V, Kim DU, San Lucas FA, Castillo J, Allenson K, Mulu FC, Stephens BM, Huang J, Semaan A, Guerrero PA, Kamyabi N, Zhao J, Hurd MW, Koay EJ, Taniguchi CM, Herman JM, Javle M, Wolff R, Katz M, Varadhachary G, Maitra A, Alvarez HA. Circulating Nucleic Acids Are Associated With Outcomes of Patients With Pancreatic Cancer. Gastroenterology. 2019 Jan;156(1):108-118.e4. doi: 10.1053/j.gastro.2018.09.022. Epub 2018 Sep 19. PMID: 30240661; PMCID: PMC6434712.
506. Capello M, Vykoukal JV, Katayama H, Bantis LE, Wang H, Kundnani DL, Aguilar-Bonavides C, Aguilar M, Tripathi SC, Dhillon DS, Momin AA, Peters H, Katz MH, Alvarez H, Bernard V, Ferri-Borgogno S, Brand R, Adler DG, Firpo MA, Mulvihill SJ, Molldrem JJ, Feng Z, Taguchi A, Maitra A, Hanash SM. Exosomes harbor B cell targets in pancreatic adenocarcinoma and exert decoy function against complement-mediated cytotoxicity. Nat Commun. 2019 Jan 16;10(1):254. doi: 10.1038/s41467-018-08109-6. PMID: 30651550; PMCID: PMC6335434.
507. Koay EJ, Lee Y, Cristini V, Lowengrub JS, Kang Y, Lucas FAS, Hobbs BP, Ye R, Elganainy D, Almahariq M, Amer AM, Chatterjee D, Yan H, Park PC, Rios Perez MV, Li D, Garg N, Reiss KA, Yu S, Chauhan A,

Zaid M, Nikzad N, Wolff RA, Javle M, Varadhachary GR, Shroff RT, Das P, Lee JE, Ferrari M, Maitra A, Taniguchi CM, Kim MP, Crane CH, Katz MH, Wang H, Bhosale P, Tamm EP, Fleming JB. A Visually Apparent and Quantifiable CT Imaging Feature Identifies Biophysical Subtypes of Pancreatic Ductal Adenocarcinoma. Clin Cancer Res. 2018 Dec 1;24(23):5883-5894. doi: 10.1158/1078-0432.CCR-17-3668. Epub 2018 Aug 6. PMID: 30082477; PMCID: PMC6279613.

508. Ideno N, Yamaguchi H, Ghosh B, Gupta S, Okumura T, Steffen DJ, Fisher CG, Wood LD, Singhi AD, Nakamura M, Gutkind JS, Maitra A. GNASR201C Induces Pancreatic Cystic Neoplasms in Mice That Express Activated KRAS by Inhibiting YAP1 Signaling. Gastroenterology. 2018 Nov;155(5):1593-1607.e12. doi: 10.1053/j.gastro.2018.08.006. Epub 2018 Aug 22. PMID: 30142336; PMCID: PMC6219919.
509. Koay EJ, Owen D, Das P. Radiation-Induced Liver Disease and Modern Radiotherapy. Semin Radiat Oncol. 2018 Oct;28(4):321-331. doi: 10.1016/j.semradonc.2018.06.007. PMID: 30309642; PMCID: PMC6402843.
510. Elganainy D, Holliday EB, Taniguchi CM, Smith GL, Shroff R, Javle M, Raghav K, Kaseb A, Aloia TA, Vauthey JN, Tzeng CD, Herman JM, Koong AC, Krishnan SX, Minsky BD, Crane CH, Das P, Koay EJ. Dose escalation of radiotherapy in unresectable extrahepatic cholangiocarcinoma. Cancer Med. 2018 Oct;7(10):4880-4892. doi: 10.1002/cam4.1734. Epub 2018 Aug 27. PMID: 30152073; PMCID: PMC6198206.
511. Ng SP, Koay EJ. Current and emerging radiotherapy strategies for pancreatic adenocarcinoma: stereotactic, intensity modulated and particle radiotherapy. Ann Pancreat Cancer. 2018 Aug;1:22. doi: 10.21037/apc.2018.07.03. Epub 2018 Aug 13. PMID: 30198024; PMCID: PMC6124686.
512. Amer AM, Zaid M, Chaudhury B, Elganainy D, Lee Y, Wilke CT, Cloyd J, Wang H, Maitra A, Wolff RA, Varadhachary G, Overman MJ, Lee JE, Fleming JB, Tzeng CW, Katz MH, Holliday EB, Krishnan S, Minsky BD, Herman JM, Taniguchi CM, Das P, Crane CH, Le O, Bhosale P, Tamm EP, Koay EJ. Imaging-based biomarkers: Changes in the tumor interface of pancreatic ductal adenocarcinoma on computed tomography scans indicate response to cytotoxic therapy. Version 2. Cancer. 2018 Apr 15;124(8):1701-1709. doi: 10.1002/cncr.31251. Epub 2018 Jan 25. PMID: 29370450; PMCID: PMC5891375.
513. Riquelme E, Maitra A, McAllister F. Immunotherapy for Pancreatic Cancer: More Than Just a Gut Feeling. Cancer Discov. 2018 Apr;8(4):386-388. doi: 10.1158/2159-8290.CD-18-0123. PMID: 29610286.
514. Koay EJ, Hall W, Park PC, Erickson B, Herman JM. The role of imaging in the clinical practice of radiation oncology for pancreatic cancer. Abdom Radiol (NY). 2018 Feb;43(2):393-403. doi: 10.1007/s00261-017-1373-3. PMID: 29110053; PMCID: PMC5832555.
515. Tang C, Hobbs B, Amer A, Li X, Behrens C, Canales JR, Cuentas EP, Villalobos P, Fried D, Chang JY, Hong DS, Welsh JW, Sepesi B, Court L, Wistuba II, Koay EJ. Development of an Immune-Pathology Informed Radiomics Model for Non-Small Cell Lung Cancer. Sci Rep. 2018 Jan 31;8(1):1922. doi: 10.1038/s41598-018-20471-5. PMID: 29386574; PMCID: PMC5792427.
516. Castillo J, Bernard V, San Lucas FA, Allenson K, Capello M, Kim DU, Gascoyne P, Mulu FC, Stephens BM, Huang J, Wang H, Momin AA, Jacamo RO, Katz M, Wolff R, Javle M, Varadhachary G, Wistuba II, Hanash S, Maitra A, Alvarez H. Surfaceome profiling enables isolation of cancer-specific exosomal cargo in liquid biopsies from pancreatic cancer patients. Ann Oncol. 2018 Jan 1;29(1):223-229. doi: 10.1093/annonc/mdx542. PMID: 29045505; PMCID: PMC6248757.

517. Goggins MG, Lippman SM, Constantinou PE, Jacks T, Petersen GM, Syngal S, Maitra A. Intercepting Pancreatic Cancer: Our Dream Team's Resolve to Stop Pancreatic Cancer. Pancreas. 2018 Nov/Dec;47(10):1175-1176. doi: 10.1097/MPA.0000000000001165. PMID: 30325853; PMCID: PMC6193263.
518. Bhattacharyya S, Pradhan K, Campbell N, Mazdo J, Vasantkumar A, Maqbool S, Bhagat TD, Gupta S, Suzuki M, Yu Y, Greally JM, Steidl U, Bradner J, Dawlaty M, Godley L, Maitra A, Verma A. Altered hydroxymethylation is seen at regulatory regions in pancreatic cancer and regulates oncogenic pathways. Genome Res. 2017 Nov;27(11):1830-1842. doi: 10.1101/gr.222794.117. Epub 2017 Oct 6. PMID: 28986391; PMCID: PMC5668941.
519. Cohen JD, Javed AA, Thoburn C, Wong F, Tie J, Gibbs P, Schmidt CM, Yip-Schneider MT, Allen PJ, Schattner M, Brand RE, Singhi AD, Petersen GM, Hong SM, Kim SC, Falconi M, Doglioni C, Weiss MJ, Ahuja N, He J, Makary MA, Maitra A, Hanash SM, Dal Molin M, Wang Y, Li L, Ptak J, Dobbyn L, Schaefer J, Silliman N, Popoli M, Goggins MG, Hruban RH, Wolfgang CL, Klein AP, Tomasetti C, Papadopoulos N, Kinzler KW, Vogelstein B, Lennon AM. Combined circulating tumor DNA and protein biomarker-based liquid biopsy for the earlier detection of pancreatic cancers. Proc Natl Acad Sci U S A. 2017 Sep 19;114(38):10202-10207. doi: 10.1073/pnas.1704961114. Epub 2017 Sep 5. PMID: 28874546; PMCID: PMC5617273.
520. Capello M, Bantis LE, Scelo G, Zhao Y, Li P, Dhillon DS, Patel NJ, Kundnani DL, Wang H, Abbruzzese JL, Maitra A, Tempero MA, Brand R, Firpo MA, Mulvihill SJ, Katz MH, Brennan P, Feng Z, Taguchi A, Hanash SM. Sequential Validation of Blood-Based Protein Biomarker Candidates for Early-Stage Pancreatic Cancer. J Natl Cancer Inst. 2017 Apr 1;109(4):djw266. doi: 10.1093/jnci/djw266. PMID: 28376157; PMCID: PMC5441297.
521. Allenson K, Castillo J, San Lucas FA, Scelo G, Kim DU, Bernard V, Davis G, Kumar T, Katz M, Overman MJ, Foretova L, Fabianova E, Holcatova I, Janout V, Meric-Bernstam F, Gascoyne P, Wistuba I, Varadhachary G, Brennan P, Hanash S, Li D, Maitra A, Alvarez H. High prevalence of mutant KRAS in circulating exosome-derived DNA from early-stage pancreatic cancer patients. Ann Oncol. 2017 Apr 1;28(4):741-747. doi: 10.1093/annonc/mdx004. PMID: 28104621; PMCID: PMC5834026.
522. Lech Pedersen N, Mertz Petersen M, Ladd JJ, Lampe PD, Bresalier RS, Davis GJ, Demuth C, Jensen SØ, Andersen CL, Ferm L, Christensen IJ, Nielsen HJ. Development of blood-based biomarker tests for early detection of colorectal neoplasia: Influence of blood collection timing and handling procedures. Clin Chim Acta. 2020 Aug;507:39-53. doi: 10.1016/j.cca.2020.03.035. Epub 2020 Apr 6. PMID: 32272156.
523. Yang JD, Addissie BD, Mara KC, Harmsen WS, Dai J, Zhang N, Wongjarupong N, Ali HM, Ali HA, Hassan FA, Lavu S, Cvinar JL, Giama NH, Moser CD, Miyabe K, Allotey LK, Algeciras-Schimnich A, Theobald JP, Ward MM, Nguyen MH, Befeler AS, Reddy KR, Schwartz M, Harnois DM, Yamada H, Srivastava S, Rinaudo JA, Gores GJ, Feng Z, Marrero JA, Roberts LR. GALAD Score for Hepatocellular Carcinoma Detection in Comparison with Liver Ultrasound and Proposal of GALADUS Score. Cancer Epidemiol Biomarkers Prev. 2019 Mar;28(3):531-538. doi: 10.1158/1055-9965.EPI-18-0281. Epub 2018 Nov 21. PMID: 30464023; PMCID: PMC6401221.
524. Zheng Y. Study Design Considerations for Cancer Biomarker Discoveries. J Appl Lab Med. 2018 Sep;3(2):282-289. doi: 10.1373/jalm.2017.025809. PMID: 30828695; PMCID: PMC6391721.
525. Wang L, Luedtke AR, Huang Y. Assessing the incremental value of new biomarkers based on OR rules. Biostatistics. 2018 Dec 26. doi: 10.1093/biostatistics/kxy070. Epub ahead of print. PMID: 30590454.

526. Kim S, Huang Y. Combining biomarkers for classification with covariate adjustment. Stat Med. 2017 Jul 10;36(15):2347-2362. doi: 10.1002/sim.7274. Epub 2017 Mar 9. PMID: 28276080; PMCID: PMC5459674.
527. Maziarz M, Cai T, Qi L, Lok AS, Zheng Y. Evaluating longitudinal markers under two-phase study designs. Biostatistics. 2019 Jul 1;20(3):485-498. doi: 10.1093/biostatistics/kxy013. PMID: 29912281; PMCID: PMC6587940.
528. Class CA, Ha MJ, Baladandayuthapani V, Do KA. iDINGO-integrative differential network analysis in genomics with Shiny application. Bioinformatics. 2018 Apr 1;34(7):1243-1245. doi: 10.1093/bioinformatics/btx750. PMID: 29194470; PMCID: PMC6030922.
529. Yan Q, Bantis LE, Stanford JL, Feng Z. Combining multiple biomarkers linearly to maximize the partial area under the ROC curve. Stat Med. 2018 Feb 20;37(4):627-642. doi: 10.1002/sim.7535. Epub 2017 Oct 30. PMID: 29082535; PMCID: PMC6469690.
530. Ha MJ, Banerjee S, Akbani R, Liang H, Mills GB, Do KA, Baladandayuthapani V. Personalized Integrated Network Modeling of the Cancer Proteome Atlas. Sci Rep. 2018 Oct 8;8(1):14924. doi: 10.1038/s41598-018-32682-x. PMID: 30297783; PMCID: PMC6175854.
531. Cooperberg MR, Brooks JD, Faino AV, Newcomb LF, Kearns JT, Carroll PR, Dash A, Etzioni R, Fabrizio MD, Gleave ME, Morgan TM, Nelson PS, Thompson IM, Wagner AA, Lin DW, Zheng Y. Refined Analysis of Prostate-specific Antigen Kinetics to Predict Prostate Cancer Active Surveillance Outcomes. Eur Urol. 2018 Aug;74(2):211-217. doi: 10.1016/j.eururo.2018.01.017. Epub 2018 Feb 9. PMID: 29433975; PMCID: PMC6263168.
532. Tayob N, Stingo F, Do KA, Lok ASF, Feng Z. A Bayesian screening approach for hepatocellular carcinoma using multiple longitudinal biomarkers. Biometrics. 2018 Mar;74(1):249-259. doi: 10.1111/biom.12717. Epub 2017 May 8. PMID: 28482112; PMCID: PMC5677596.
533. Kim J, Do KA, Ha MJ, Peterson CB. Bayesian inference of hub nodes across multiple networks. Biometrics. 2019 Mar;75(1):172-182. doi: 10.1111/biom.12958. Epub 2018 Aug 23. PMID: 30051914; PMCID: PMC6393214.
534. Zhou QM, Dai W, Zheng Y, Cai T. Robust Dynamic Risk Prediction with Longitudinal Studies. Stat Theory Relat Fields. 2017;1(2):159-170. doi: 10.1080/24754269.2017.1400418. Epub 2017 Nov 27. PMID: 29335682; PMCID: PMC5766050.
535. Liu D, Cai T, Lok A, Zheng Y. Nonparametric Maximum Likelihood Estimators of Time-Dependent Accuracy Measures for Survival Outcome Under Two-Stage Sampling Designs. J Am Stat Assoc. 2018;113(522):882-892. doi: 10.1080/01621459.2017.1295866. Epub 2017 Feb 28. PMID: 30555194; PMCID: PMC6291304.
536. Wang L, Huang Y. Evaluating classification performance of biomarkers in two-phase case-control studies. Stat Med. 2019 Jan 15;38(1):100-114. doi: 10.1002/sim.7966. Epub 2018 Sep 12. PMID: 30209824; PMCID: PMC6317859.
537. Wang L, Huang Y, Feng Z. Strategies for validating biomarkers using data from a reference set. Biostatistics. 2019 Aug 17:kxz031. doi: 10.1093/biostatistics/kxz031. Epub ahead of print. PMID: 31420985.
538. Kundu MG, Harezlak J, Randolph TW. Longitudinal Functional Models with Structured Penalties. Stat Modelling. 2016 Apr;16(2):114-139. doi: 10.1177/1471082X15626291. Epub 2016 Feb 17. PMID: 28316508; PMCID: PMC5354471.

539. Marsh TL, Janes H, Pepe MS. Statistical inference for net benefit measures in biomarker validation studies. Biometrics. 2019 Nov 16:10.1111/biom.13190. doi: 10.1111/biom.13190. Epub ahead of print. PMID: 31732971; PMCID: PMC7228830.
540. Wang Y, Zhao YQ, Zheng Y. Learning-based biomarker-assisted rules for optimized clinical benefit under a risk constraint. Biometrics. 2019 Dec 13:10.1111/biom.13199. doi: 10.1111/biom.13199. Epub ahead of print. PMID: 31833561; PMCID: PMC7292743.
541. Huang Y, Laber E. Personalized Evaluation of Biomarker Value: A Cost-Benefit Perspective. Stat Biosci. 2016;8:43-65. doi: 10.1007/s12561-014-9122-4. Epub 2014 Nov 21. PMID: 27446505; PMCID: PMC4938856.
542. Bantis LE, Yan Q, Tsimikas JV, Feng Z. Estimation of smooth ROC curves for biomarkers with limits of detection. Stat Med. 2017 Oct 30;36(24):3830-3843. doi: 10.1002/sim.7394. Epub 2017 Aug 7. PMID: 28786136; PMCID: PMC5679135.
543. Zheng Y, Brown M, Lok A, Cai T. IMPROVING EFFICIENCY IN BIOMARKER INCREMENTAL VALUE EVALUATION UNDER TWO-PHASE DESIGNS. Ann Appl Stat. 2017 Jun;11(2):638-654. doi: 10.1214/16-AOAS997. Epub 2017 Jul 20. PMID: 28943991; PMCID: PMC5604898.
544. Borges KA, Dai J, Parikh ND, Schwartz M, Nguyen MH, Roberts LR, Befeler AS, Srivastava S, Rinaudo JA, Feng Z, Marrero JA, Reddy KR. Rationale and design of the Hepatocellular carcinoma Early Detection Strategy study: A multi-center longitudinal initiative of the National Cancer Institute's Early Detection Research Network. Contemp Clin Trials. 2019 Jan;76:49-54. doi: 10.1016/j.cct.2018.11.008. Epub 2018 Nov 12. PMID: 30439517; PMCID: PMC7086481.
545. Maziarz M, Heagerty P, Cai T, Zheng Y. On longitudinal prediction with time-to-event outcome: Comparison of modeling options. Biometrics. 2017 Mar;73(1):83-93. doi: 10.1111/biom.12562. Epub 2016 Jul 20. PMID: 27438160; PMCID: PMC5250577.
546. Fu R, Wang P, Ma W, Taguchi A, Wong CH, Zhang Q, Gazdar A, Hanash SM, Zhou Q, Zhong H, Feng Z. A statistical method for detecting differentially expressed SNVs based on next-generation RNA-seq data. Biometrics. 2017 Mar;73(1):42-51. doi: 10.1111/biom.12548. Epub 2016 Jun 8. PMID: 27276420; PMCID: PMC5151178.
547. Bantis LE, Feng Z. Comparison of two correlated ROC curves at a given specificity or sensitivity level. Stat Med. 2016 Oct 30;35(24):4352-4367. doi: 10.1002/sim.7008. Epub 2016 Jun 20. PMID: 27324068; PMCID: PMC5297391.
548. Payne R, Yang M, Zheng Y, Jensen MK, Cai T. Robust risk prediction with biomarkers under two-phase stratified cohort design. Biometrics. 2016 Dec;72(4):1037-1045. doi: 10.1111/biom.12515. Epub 2016 Apr 1. PMID: 27037494; PMCID: PMC5045782.
549. Koopmeiners JS, Feng Z. Group sequential testing of the predictive accuracy of a continuous biomarker with unknown prevalence. Stat Med. 2016 Apr 15;35(8):1267-80. doi: 10.1002/sim.6790. Epub 2015 Nov 4. PMID: 26537180; PMCID: PMC4777674.
550. Tretiakova MS, Wei W, Boyer HD, Newcomb LF, Hawley S, Auman H, Vakar-Lopez F, McKenney JK, Fazli L, Simko J, Troyer DA, Hurtado-Coll A, Thompson IM Jr, Carroll PR, Ellis WJ, Gleave ME, Nelson PS, Lin DW, True LD, Feng Z, Brooks JD. Prognostic value of Ki67 in localized prostate carcinoma: a multi-institutional study of >1000 prostatectomies. Prostate Cancer Prostatic Dis. 2016 Sep;19(3):264-70. doi: 10.1038/pcan.2016.12. Epub 2016 May 3. PMID: 27136741; PMCID: PMC5536893.

551. Fong Y, Yin S, Huang Y. Combining biomarkers linearly and nonlinearly for classification using the area under the ROC curve. Stat Med. 2016 Sep 20;35(21):3792-809. doi: 10.1002/sim.6956. Epub 2016 Apr 5. PMID: 27058981; PMCID: PMC4965290.
552. Huang Y. Evaluating and comparing biomarkers with respect to the area under the receiver operating characteristics curve in two-phase case-control studies. Biostatistics. 2016 Jul;17(3):499-522. doi: 10.1093/biostatistics/kxw003. Epub 2016 Feb 16. PMID: 26883772; PMCID: PMC4915610.
553. Tayob N, Do KA, Feng Z. Unbiased estimation of biomarker panel performance when combining training and testing data in a group sequential design. Biometrics. 2016 Sep;72(3):888-96. doi: 10.1111/biom.12480. Epub 2016 Feb 4. PMID: 26845527; PMCID: PMC4974170.
554. Newman LA, Stark A, Chitale D, Pepe M, Longton G, Worsham MJ, Nathanson SD, Miller P, Bensenhaver JM, Proctor E, Swain M, Patriotis C, Engstrom PF. Association Between Benign Breast Disease in African American and White American Women and Subsequent Triple-Negative Breast Cancer. JAMA Oncol. 2017 Aug 1;3(8):1102-1106. doi: 10.1001/jamaoncol.2016.5598. PMID: 28006062; PMCID: PMC5796807.
555. Tayob N, Lok AS, Do KA, Feng Z. Improved Detection of Hepatocellular Carcinoma by Using a Longitudinal Alpha-Fetoprotein Screening Algorithm. Clin Gastroenterol Hepatol. 2016 Mar;14(3):469-475.e2. doi: 10.1016/j.cgh.2015.07.049. Epub 2015 Aug 7. PMID: 26260109; PMCID: PMC4744807.
556. Zhao YQ, Zhu R, Chen G, Zheng Y. Constructing dynamic treatment regimes with shared parameters for censored data. Stat Med. 2020 Apr 30;39(9):1250-1263. doi: 10.1002/sim.8473. Epub 2020 Jan 17. PMID: 31951041.