36th EDRN Steering Committee Meeting (Virtual)

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October 27-28, 2020

Early Detection Research Network (EDRN): Program Objectives

An investigator-initiated infrastructure to:

- Support the development and validation of early detection biomarkers and markers of progression

- Interaction among academic, clinical and industrial leaders

- Standardize biomarker validation criteria

- Develop quality assurance in biomarker measurement

- Bring biomarkers to clinical use

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EDRN: Organizational and Operational Structure

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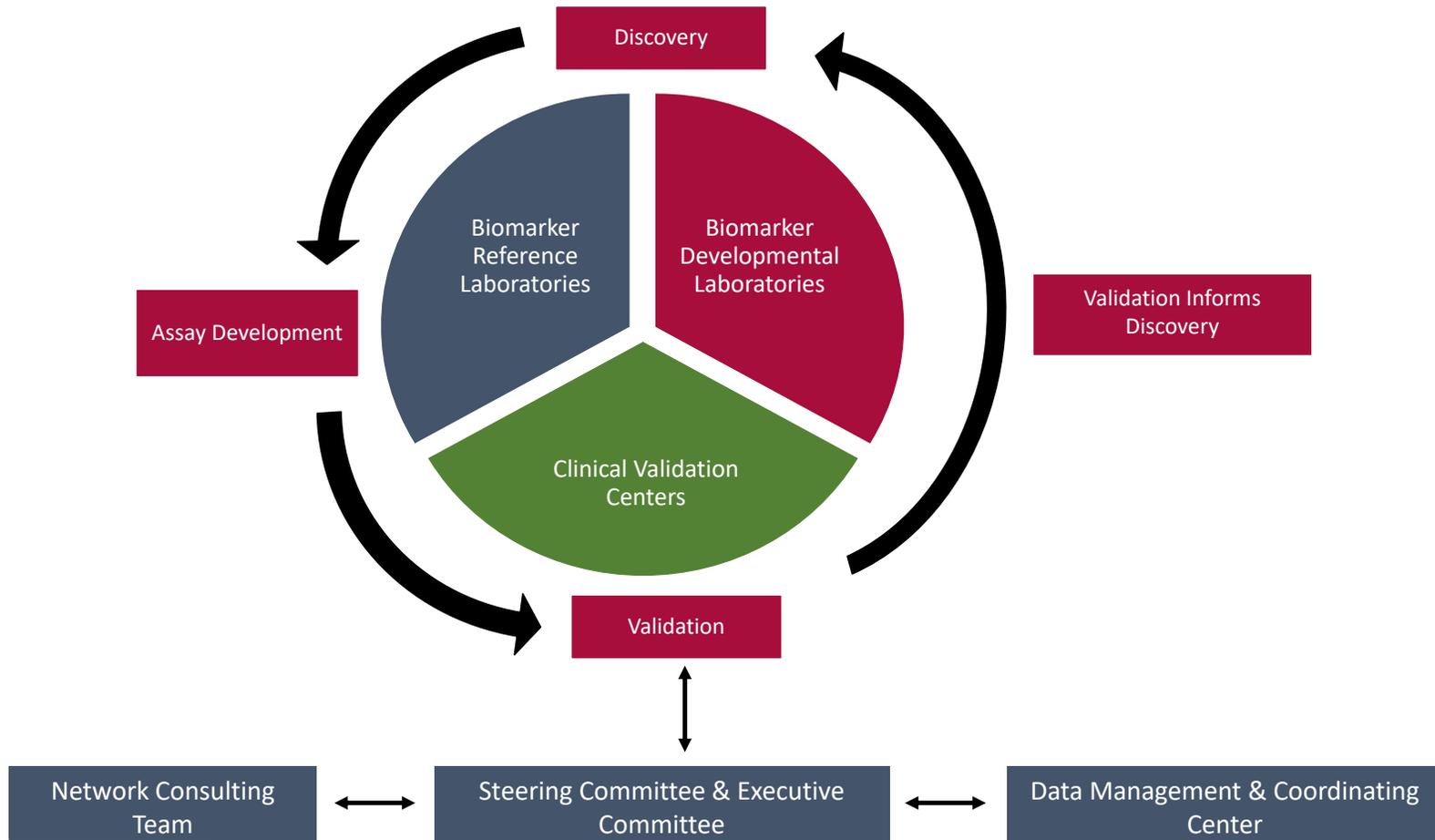
36th EDRN Meeting Topics
Charge to the Steering Committee

- How should we target sensitivity and specificity for clinical utility?
  - Session 1: Target Sensitivity and Specificity for Clinical Utility
- How can modeling help us determine likely impact of new biomarkers in realistic dissemination scenarios?
  - Session 2: Modeling, Biomarkers and Implementation Science
- How should biomarkers be deployed to narrow cancer disparities?
  - Session 3: Health Disparity and Biomarker Research
- How can we evaluate clinical utility in a timely and cost-efficient manner?
  - Session 4: Study Designs for Clinical Utility Evaluation

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What Target Sensitivity and Specificity Might Confer Clinical Utility?

- How does disease incidence/prevalence factor into the calculation?

- How should the clinical context be factored in?

- How do the clinical consequences of a positive biomarker test in cases (true positive) compare with the cost associated with a positive biomarker test in controls (false positive)

- How should we measure and project cost/benefit ratios?

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Modeling, Biomarkers and Implementation Science

◆ Given limited data on clinical outcomes can modeling help us to translate performance of biomarkers to outcomes such as incidence, metastases, lives saved and quality of life?

◆ Can modeling be used to assess the likely impact of new biomarkers in realistic dissemination scenarios affect by population heterogeneity and system factors?

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Health Disparity and Biomarker Research

◆ How do we make sure that new biomarker-based tests narrow rather than widen the minority and gender gap in cancer detection and deaths?

◆ How can EDRN collaborate with existing research program(s) addressing different racial and ethnic populations and examining the genetic differences among these populations to promote the role of validated biomarkers for cancer risk prediction and early detection?

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Study Designs for Clinical Utility Evaluation

- ◆ How can we validly reduce the time and cost of prospective studies to evaluation clinical utility?

- ◆ What are the plusses and minuses of Risk Scores versus Surrogate Endpoints?
  - ◆ Surrogate Endpoints (Surrogates: stage shift, reducing biopsy, etc.)

- ◆ What are the tradeoffs between Perfect Study (RCT) versus Near-Perfect (NP) (Prospective, one arm) Designs?

- ◆ How will realistic adoption scenarios affect these tradeoffs?

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Expectations

◆ Prepare 2-3 pages summary of each session

◆ Prepare a position paper on the topics covered during this meeting for wide circulation

◆ Like 5-Phase Guidelines for Biomarker Discovery and Validation, consider preparing a manuscript for publication for adoption by the extramural community

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