EDRN-Public-Private Partnership Guidelines

I. Background:

In September 2007, the Early Detection Research Network (EDRN) sponsored a **Public-Private Partnership Workshop** in Ann Arbor, Michigan in which industry representatives were asked to join EDRN members and give their views on the challenges and benefits of partnering with academia and the government. The discussions were specifically designed to center around those investigators whose research interests lie in the field of biomarker discovery, development, validation, and ultimately, clinical/diagnostic use.

In today's market, more than ever, cooperation with industry is becoming the norm in scientific research. The forces behind this push for partnership are many…economic factors certainly play a large role, but consumers are increasingly demanding faster growth in the areas of personalized medicine, while sponsors are realizing that partnership means less redundancies, duplication, and waste. Additionally, each member of the partnership possesses their own unique "core" competencies that, when taken together, can synergistically produce a product greater than the individual members alone.

There are three basic types of partnerships that EDRN could be engaged in or could facilitate:

One-to-One
This is the traditional model for partnering and is how many of the partnerships have occurred so far. The agreement governing this type of partnership is generally straightforward as there are only two parties negotiating the agreement. The one-to-one model often falls short, however, due to the fact that successful biomarker technologies most likely will encompass multiple markers and these markers may not be discovered by a single researcher at one institution. Therefore, more complex one-to-many or many-to-many models may be more applicable for biomarker PPPs.

One-to-Many: In general, this model involves one industrial partner and multiple research institutions to help develop projects, identify biomarkers, and/or participate in validation studies using the industry partner's proprietary reagents, assays, technologies, or biomarkers. The agreement(s) for these partnerships is more cumbersome and must account for the needs of multiple

parties and potentially IP from multiple sources. Different scenarios could be imagined in which each party is contributing different resources to the project.

Many-to-Many: Perhaps the most complicated (and potentially the most productive) model is the many-to-many model that involves many industrial partners and many investigators at different research institutions. The benefit of this type of partnership is that several biomarkers can be analyzed at one time with a standardized sample/specimen set. The potential for combining biomarkers to create a more powerful prognostic/diagnostic test can be realized with a many-to-many (or one-to-many) approach. The agreement(s) for these partnerships entails complicated IP issues as considerations must be made for separate IP rights from multiple sources.

In any of the partnership models described above, it is easy to recognize a "win-win" situation, however, it may not be easy to achieve. There are stumbling blocks and barriers all along the way to full partnership agreements. Although the scientists involved in the research may be willing and ready to bring their expertise and skills together in a collaborative effort, the administrative and legal issues surrounding these agreements may take upwards of one year to settle and, ultimately, slow the progress of the project.

In order to address these issues, the attendees at the September 2007 meeting made a list of suggestions/recommendations/comments on how to streamline the agreement process. These were discussed in an open forum during the workshop and, subsequently, presented in review form to the entire EDRN Steering Committee attendees later in the week. Their final recommendations are outlined in this document below.

II. Recommendations:

A). Roles and Responsibilities of EDRN:

(1). The liaison and 'honest broker':

It was agreed by all parties in the discussion forum that EDRN can play a major role in advancing the collaboration and partnering of industry with academia and perhaps, even industry with industry. EDRN has much experience in facilitating and forming collaborative efforts. Its infrastructure is set up and designed to encourages and rewards its own members for their collaborative work through their cooperative agreement funding policies. However, EDRN

may be able to further collaborative research by (1) allowing companies to realize the full value of their new products or platforms and their research investments (i.e., by validating their products in large scale assays with "gold standard" specimens); (2) connecting the research community to new products, reagents, technologies and services that industry can provide; and (3) perhaps, most importantly, acting as the *honest broker*.

The role of the *honest broker* is vital in keeping with the idea of encouraging all parties to set appropriate terms and conditions at the very outset of any partnering agreement. Being the conduit of "transparency" and ensuring that all parties understand their roles/responsibilities as well as their rights may be one of the most important contributions that EDRN can make in advancing and streamlining collaborative efforts. Since cooperative agreements and contracts are the "bread and butter" of its funding opportunities, EDRN has the experience necessary to outline, streamline, and clarify the documentation required to undertake collaborative efforts.

(2). The provider/curator of 'gold standard' specimens:
EDRN has the infrastructure that allows for the standardized collection of biospecimens. These specimens are collected, stored, and maintained from a variety of sites under rigorous protocols.
EDRN can play a major role in partnering by providing the "gold standard" of specimens for the testing and validation of biomarkers from various sources and from panels contributed by various sources. Cross validation studies can be performed using the same standardized samples and comparison data can be obtained, analyzed, and disseminated rapidly.

B). Responsibilities of Collaborating Parties:

When setting up collaborations (one-to-one, one-to-many, many-to-many), specific documentation is to be outlined and agreed upon by all parties that will include the areas described below. Clarity and understanding of these issues will lead to greater *supportive trust* among the stakeholders. A template agreement could be formulated by EDRN in conjunction with industry to streamline these arrangements.

(1). Resources and Contributions to the project: Clear documentation describing the contribution of specimens, reagents, labor, supplies, and resources

is to be outlined and agreed upon at the outset of the partnership. These can be set up similarly to the Statement of Work (SOW) of a contract.

In turn, the recipients (investigators, companies, etc.) of the resources who are utilizing the "gold standard" repository specimens will be obliged to share the resulting data with EDRN.

(2).Success/non-success of the project:

Clear definitions/milestones/goals and metrics of the project's successes are to be outlined and made available for all parties. These are to be negotiated and agreed upon by all partners prior to any collaborative research or transfer of materials or data.

Clear definitions of action(s) to be taken when the goals/milestones are not met in a timely fashion are to be written and agreed upon at the outset of the collaborative project.

(3). Data sharing/statistical support:

There must be agreement and written documentation on how the data will be shared among the collaborators; on the "language of the data" and the analysis of combined datasets; which partners will be responsible for the statistical support; which partners will have access to the data; and, when; and how the data will be used for regulatory filings or further development, etc.

C). Intellectual property on biomarkers:

Perhaps regulation of intellectual property (IP) is the most difficult area for agreement. There are many scenarios in which IP becomes an issue in the biomarker discovery and validation phases of collaborative research.

(1). Individual Biomarkers:

If EDRN is to evaluate an individual biomarker from an individual source, then IP is maintained by the source as EDRN claims no IP. This, of course, is not problematic. Difficulties arise when there are multiple biomarkers contributed by various investigators or sources that are to be evaluated as a panel by EDRN.

Additionally, if a pre-existing single, individual biomarker with IP rights established for one use is now used for a completely different indication, e.g.

prostate-specific antigen (PSA) used for breast cancer screening, then IP rights may be sought for this marker on its completely new application.

(2). Panel of Biomarkers:

For many contributors of biomarkers to a panel, the overwhelming recommendation by the September 2007 Workshop forum was to establish written documentation ensuring that:

No one partner or contributor will claim IP on the panel of markers they were contributing to. Each partner may claim and keep IP on their individual biomarker but the panel remains IP-free.

To help achieve this outcome and ensure fair and equitable results to all parties, EDRN's role would be to publish positive results on the biomarker panel as promptly as possible, i.e., through press releases as well as full manuscript publications.

Another possible scenario that was less popular with the discussants but, nonetheless under consideration, was the idea of "shared" IP. In this situation, the parties contributing biomarkers to the panel would each share in the IP of the combined panel. Although this seems to be an equitable and fair resolution, the legal aspects of this arrangement are more daunting as each individual party/company/institute would have to agree to the shared IP.