

NATIONAL BIOMARKER INITIATIVE WORKING GROUP REPORT

Pre-amble

A small working group (SWG) was asked to recommend a plan to TFRI for a pan-Canadian biomarker initiative to include, as a first step, the organizing of a focused workshop of interested researchers in October.

The SWG met on Thursday September 20th, 2007 in Montreal, and comprised Victor Ling (Vancouver), Anne-Marie Mes-Masson (Montreal), Pat Shaw (Toronto), Susan Lees-Miller (Calgary), Peter Watson (Victoria). The group completed a preliminary analysis of the complete list of EOIs and LOIs submitted by BC, Alberta (Calgary) and Quebec Nodes, which included a large number of biomarker projects. Lee Hartwell (Seattle) joined the meeting by teleconference to describe existing international efforts in biomarkers, with a particular focus on work he is leading in the US in the discovery of serum proteomic markers, and to talk about how TFRI's initiative might contribute.

Scope / Policy Considerations

In recognition of the importance of choosing TFRI projects which can provide early successes, the SWG recommends a process to choose a few projects that can:

1. be designed in phases
2. with priority being given to projects based on their 'readiness' for operation
3. which can share resources to accelerate the pace of a project, and
4. which define specific time-driven deliverables with 'impact'

To ensure the selection of the best projects the SWG identified a number of guiding principles for the biomarker workshop to consider (see box overpage).

Potential Participants

To ensure the success of the workshop, the SWG recommends that invitations are issued for between 30 – 40 people. The SWG recommends that invitations are issued to key investigators across Canada, including Ontario investigators who have not yet been asked to submit LOIs, and investigators with existing national programs. To ensure maximum benefit from the workshop the SWG recommends that champions be identified from at least five tumour sites which can generate discussion papers for presentation at the workshop (see Appendix 1). Other sites interested in preparing discussion papers could be encouraged to do so for a future workshop.

TFRI Biomarker Workshop

The purpose of the proposed workshop is threefold. First, is to build consensus on key characteristics of a successful TFRI national biomarker initiative using the guiding principles articulated overpage as a starting point. Second, is to challenge cancer type / interdisciplinary groups to prioritize a competitive strategy for their theme / area. Thirdly, the workshop should open up for a discussion on each of the group's competitive strategy. That discussion should initially look for areas of synergy between different group's proposals, and potentially lead to a discussion which prioritizes each of the group's proposals. The SWG recognizes that there may not be an opportunity to prioritize preliminary proposals, in which case, self-identified groups may be invited by TFRI Co-ordinating committee to prepare a more detailed proposal after the end of the workshop.

Guiding Principles for Selection of Biomarker Projects

Proposed Projects should consider the following criteria:

1. **Build on Strengths / Opportunities:**
 - a. The importance of clinical question described in terms of
 - i. Cancer type and status of the current biospecimen collections and mechanisms for collection
 - ii. Clinical impact & improved outcomes, and
 - iii. The potential for payback to the healthcare system;
 - b. The opportunity offered by small focused project or a large scale initiative described in terms of
 - i. The intellectual synergies / capacity that will be created, and
 - ii. The willingness of researchers to collaborate effectively.
2. Identify **the phase(s) of disease** to be studied. For example:
 - a. high risk pre-cancer precursors
 - b. pre-invasive disease
 - c. invasive disease
 - d. specific therapy targeted disease
3. Identify the **type of deliverable to be produced** by project end, including:
 - a. Risk biomarkers
 - b. Response biomarkers
 - c. Toxicity biomarkers
 - d. Imaging biomarkers
4. Describe fully how the project will **build partnerships**, by
 - a. Engaging ongoing clinical programs (clinical trials / screening / genetic / imaging)
 - i. Especially with respect to pre-agreement with partners on priority and use of resources created before and during course of the project
 - b. Leveraging existing and new funding partners
 - c. Involvement of policy partners
 - d. How Cancer Agencies & RHAs will implement discoveries in the health care system
5. How a Canada-wide project would help **overcome gaps / limitations / challenges** including:
 - a. Availability of pathology time & resources
 - b. Quality and collection of clinical data / standardization
 - c. Logistics and availability of control samples
6. Identify the type of specimen(s) that would be the primary focus for biomarker detection and that might be collected.
7. A description of the **nature of the impact at project end**, in terms of
 - a. Timeframe
 - b. Financial consequences of impact
 - c. Clinical impact / Change in management of disease
 - d. Public awareness
8. The opportunity to **leave a 'footprint'** at project end described in terms of
 - a. Sustainability of the team / network
 - b. Availability of team / infrastructure / resources for future projects.

Appendix 1
Guidance to Champions preparing a Discussion Paper

Why is a pan-Canadian biomarker initiative necessary for your tumour site?

The purpose of each discussion paper is to create one or more starting points for discussion of the key questions to be addressed. As a general guide, discussion papers should not be more than three pages provided in bullet form, and should address the following topics / issues:

1. What are the clinical problems and key clinical questions that would be 'biomarked'?
2. What are the unique resources / strengths in Canada to address these issues (unique relative to the world, with respect to the health care systems, and which may be novel or innovative).
3. Why now? Comment on the current environment, other complementary or competing initiatives, and what a pan-Canadian biomarker initiative could deliver in a 3 – 5 year time frame.
4. What barriers / challenges would need to be overcome to achieve a successful outcome?
5. Summary. What are initial thoughts for next steps?