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**Office of the Director
National Cancer Institute (NCI)
National Institutes of Health**

**Cancer Bioinformatics Grid (caBIG)/National
Biospecimen Network (NBN) Pilot Teleconference:
Discussion of NBN Pilot “Phase 0” Scope**

**July 1, 2005
11:00 a.m. - 12:00 p.m. EDT**

SUMMARY

List of Participants

Greg Eley	Booz Allen Hamilton (BAH)
Paul Fearn	Memorial Sloan-Kettering Cancer Center (MSKCC)
Ian Fore	National Center for Bioinformatics (NCICB)
Mariana González del Riego	Rose Li and Associates (RL&A)
Andrew Hruszkewycz	Organ Systems Branch, NCI
Rakesh Nagarajan	Washington University
Steve O’Krepky	RL&A
Mark Rubin	Dana Farber Cancer Institute
Julie Schneider	Office of Technology and Industrial Relations (OTIR), NCI
Sharon Settnik	Science Applications International Corporation (SAIC)

Introductions and Review of Agenda

Julie Schneider thanked everyone for their participation and invited participants to introduce themselves. She then reviewed the goals of the teleconference as follows: (1) To review the need and framework for revisiting the scope of the NBN Pilot project; and (2) to discuss, modify, and confirm the revised scope. For additional meeting details, refer to the agenda (Attachment 1).

Discussion

Ian Fore further explained that the purpose of this teleconference was to ensure that the scope of the NBN Pilot project is well-defined for the benefit of the NBN Pilot core team, the Prostate SPOREs, and the contractor who will be supporting the biorepository coordinating system. Additionally, developing clear, concrete objectives and relevant documentation (to be reviewed and approved by users) would guarantee the project’s success. He added that a brief assessment of the status of current activities should also be addressed during this teleconference.

Mark Rubin underscored the fact that the NBN Pilot project remained as an abstract concept to Prostate SPORE investigators. To obtain their input would first require that the project and its workflow be understood. He proposed that a concrete scenario of how the system will be utilized

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be presented to Prostate SPORE investigators. One such pilot would entail contacting the 11 sites and gathering the clinical data associated with a prostatectomy cohort (i.e. staging, Gleason score, outcome data, etc.) This data would then be assembled to determine what common data elements (CDEs) are in each institution's database. Furthermore, a nomogram study could be published based on aggregated data. Another added benefit of such an exercise would be the effective use of resources between now and the end of September 2005 (the period prior to the arrival of the contractor); data would be gathered at a relatively low cost and the retrospective study would likely begin on time. Paul Fearn agreed that this specific scenario would be an ideal way to generate CDEs for the IPBS/NBN Pilot. Julie Schneider commented that the Prostate SPORE principal investigators (PIs) would be receptive to this example because of the possibility of publication and the current limitations on resources. Ian Fore noted that such a pilot could be added to the objectives of the IPBS/NBN Pilot, but that the resources and money needed to conduct such a study would have to be considered.

Greg Eley announced that the 11 Prostate SPOREs had been awarded caBIG Year 2 Evaluation Project funding. In order to receive such funding, a set of steps would have to be followed including the generation of statements of work (SOW) and the completion of a requirements analysis. The information could be obtained from each site, but further discussion within NCICB would have to take place to determine the best way to complete this effort. With respect to the above-discussion, Greg Eley mentioned that it may be possible to build in the nomogram study into the SOWs. However, each site would have to be responsible for collecting their own information, which would require that some level of internal resources be available to researchers. For caBIG's purposes, the scope of the project would have to be delineated carefully. His only concern was that caBIG funding would have to be in place by the September-October IPBS/NBN Pilot timeframe. Paul Fearn suggested that they discuss this matter further at the upcoming SPORE Workshop since a good strategy to overcome this obstacle was needed.

The discussion turned to the July 11, 2005 Prostate SPORE Task Force for NBN Implementation meeting that would take place during the SPORE Workshop. Mark Rubin reiterated that, based on time limitations and previous discussions with the Prostate SPORE PIs, a concrete example should be used to explain the NBN Pilot concept to meeting participants. He also suggested that lay terms be used during the presentation period; technical jargon, such as "use cases," should be avoided as much as possible or carefully defined. As a result, Mark Rubin and Paul Fearn agreed to coordinate the content of their respective presentations.

Julie Schneider suggested that the slide presentation include a simplified overview and a straightforward explanation of the project scope and purpose, a high-level summary of accomplishments to date (e.g., workflows and use cases) and the goals of the next 3-4 months. It was also recommended that the NBN Pilot Executive Summary and materials from the Biorepository Coordinating System request for proposals (RFP) pre-conference presentation be available to meeting participants.

Greg Eley thought that the group may find John Gilbertson's white paper on caTISSUE annotations useful as it describes the goals and requirements of the informatics platform to a scientific audience. Julie Schneider agreed that the document should be circulated to the group.

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In addition, she and other members of the core team encouraged NCICB and BAH staff to attend the July 11, 2005 Task Force on NBN Implementation and IPBS Committee Meeting.

In drafting the slide presentation, Sharon Settnek urged participants to consider defining the type of system and tools being built, what the system will allow researchers to do (e.g., queries), and the data to be collected (e.g., clinical outcomes and biomarker data). Feedback from the Prostate SPOREs will inform the core team how data will be submitted by each site and what the interface needs will be. This information in turn will determine whether a federated, centralized, or hybrid approach should be pursued. Furthermore, a brief update on accomplished tasks and an explanation of what is expected from the sites should be given. A question and answer period should follow the presentation. Teleconference participants agreed with these suggestions.

Ian Fore felt that the Prostate SPORE PIs needed to play a more central role as stakeholders since they own the outcome of this project's inception phase. Sharon Settnek further suggested that a users group meeting be held monthly. Prostate SPORE representatives would then be able to provide their input on new requirements and/or priorities on a regular basis. Paul Fearn pointed out that two Prostate SPORE groups had been formed last year to lead the IPBS/NBN Pilot and address related issues: The Task Force, a clinical oversight body that meets monthly, and a group of informatics representatives that meets on an as-needed basis.

Sharon Settnek also recommended that the workflows and use case diagrams not be presented in detail. She added that it would be better to do so when individual system requirements were sought. One of the problems recently discovered during a review of the use cases is that management of data identifiers must be established between all of the integrated systems and modules. Consequently, it would be prudent to review the site visit summaries completed for each SPORE and the caBIG Tissue Bank and Pathology Tools Workspace (TBPTW) surveys completed last year, prior to approaching Prostate SPOREs sites about their systems. Paul Fearn agreed with this suggestion and added that the caBIG Year 2 Evaluation Project funds would be available to learn more about the Prostate SPOREs' specimen tracking systems and conduct a gap analysis to develop an interoperability system.

Julie Schneider reminded participants that the CD created and distributed at the January 30, 2005 Prostate SPORE Task Force Informatics meeting in Houston, Texas contained the TBPTW surveys, the Prostate SPORE site visit summaries, and other relevant documents. In addition, these documents would be available on the Prostate SPORE NBN Pilot Intranet site in the near future. However, she noted that, although many Prostate SPOREs granted permission to share their data, not every institution had done so.

Towards the end of the discussion, Julie Schneider also suggested that a preliminary draft slide presentation based on the Biorepository Coordinating System RFP pre-proposal conference slides be drafted by NCI staff as a starting point and sent to Mark Rubin and Paul Fearn for further development. Participants agreed to hold a teleconference on July 6, 2005 to provide input on the presentation, which would be provided to them prior to the teleconference. It was suggested that the link to the Prostate SPORE NBN Pilot Web site be included in the presentation and that copies of the NBN Pilot Executive Summary be available at the meeting.

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Discussion of Next Steps

The group agreed on the following action items/next steps:

- A teleconference will be set up for July 6, 2005 to discuss the NBN Pilot presentation to be given at the upcoming SPORE Workshop Task Force on NBN Implementation and IPBS Committee meeting on July 11, 2005. In preparation for this teleconference, the NBN Pilot Executive Summary and draft slide presentation will be disseminated to core team members.
- Sharon Settnek will email the latest versions of the workflows and the use cases to Mariana González del Riego so that they can be posted on the Prostate SPORE NBN Pilot Web site.
- Mariana González del Riego will provide the link to the Prostate SPORE NBN Pilot Web site to participants so that they can easily access the latest workflows and use cases.

Teleconference Adjournment

The teleconference was formally adjourned at 12:15 pm EDT.

Attachment 1

**Office of the Director
National Cancer Institute (NCI)
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**National Biospecimen Network (NBN) Pilot Teleconference:
Discussion of NBN Pilot “Phase 0” Scope**

**July 1, 2005
11:00 a.m. - 12:00 p.m. EDT**

AGENDA

Purpose

To refine the scope for different stages of the NBN Pilot, both before and after the contractor is selected.

Participants

Harshawardhan Bal	Booz Allen Hamilton (BAH)
Angelo DeMarzo	Johns Hopkins University (JHU)
Greg Eley	BAH
Paul Fearn	Memorial Sloan-Kettering Cancer Center (MSKCC)
Ian Fore	NCI Center for Bioinformatics (NCICB)
Mariana González del Riego	Rose Li and Associates (RL&A)
Andrew Hruszkewycz	Organ Systems Branch, NCI
George Komatsoulis	NCICB
Rakesh Nagarajan	Washington University
Steve O’Krepky	RL&A
Mark Rubin	Dana Farber Cancer Institute
Julie Schneider	Office of Technology and Industrial Relations (OTIR), NCI
Sharon Settnek	Science Applications International Corporation
John Speakman	MSKCC
Bruce Trock	JHU
Mark Watson	Washington University

Agenda

1. Review need and framework for revisiting scope.
2. Discuss, modify, and confirm the revised scope detailed on the next page.

Note: Headings 1-5 are the objectives. Activities associated with a given objective are listed under each heading.

Proposed Project Inception – Phase 0 (Deliverables to be completed by 9/30)

1. Understand what to build
 - a. Agree on the scope of developing informatics systems to support biomarker studies.
 - b. Continue discussions with biomarker scientists only in the context of this refined scope.

Attachment 1

- c. Develop project charter based on the “Executive Summary.”
 - d. Develop a presentation for the SPORE meeting (July 11) regarding project goals, plans, system usage etc. This presentation should follow the outline of the project charter.
2. Identify key system functionality
 - a. Complete first iteration workflows and high-level use cases. Obtain input from Prostate SPORE clinicians and pathologists.
 - b. Prioritize use cases.
 - c. Characterize strawperson dataset required for the IPBS study as a mockup spreadsheet.
 3. Determine at least one possible solution architecture
 - a. Evaluate caBIG tools (caTissue CORE, Clinical Annotation, caTIES, caIntegrator, etc.) for fit with needs and identify gaps.
 - b. Discuss data submission, retrieval, and system interfaces with each Prostate SPORE NBN Pilot site.
 - c. Draft high-level architecture options. These will be revisited with the contractor who may also have additional options.
 4. Understand costs, schedule, and risks
 - a. How does employing caBIG tools affect costs, schedule, and risks?
 - b. Understand diversity of CDEs used at different sites.
 5. Decide on the development process and tools
 - a. Employ caBIG-compliant process and tools.