DRAFT

Office of the Director
National Cancer Institute (NCI)

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

July 22, 2005
3:00 p.m. – 4:00 p.m. EDT

SUMMARY

List of Participants

Angelo DeMarzo	Johns Hopkins University (JHU)
Greg Eley	BAH
Paul Fearn	Memorial Sloan-Kettering Cancer Center (MSKCC)
Samson Fines	MSKCC
Ian Fore	NCI Center for Bioinformatics (NCICB)
Mariana González del Riego	Rose Li and Associates (RL&A)
Andrew Hruszkewycz	Organ Systems Branch, NCI
Steve O'Krepky	RL&A
Mark Rubin	Dana Farber Cancer Institute
John Speakman	MSKCC
Bruce Trock	JHU

Introductions and Review of Agenda
On behalf of Julie Schneider, Ian Fore and Mariana González del Riego welcomed participants and invited them to introduce themselves. Ian Fore then proceeded to review the objectives of the teleconference as follows: To review the goals of the caBIG Year 2 Evaluation Project in the context of the caTISSUE core and NBN Pilot timelines; discuss the steps required for caBIG funding of each Prostate SPORE institution; and develop a framework for a generic task list. For additional teleconference details, refer to the agenda and slide presentation (Attachments 1 and 2, respectively).

Overview
Samson Fines, a pathologist from MSKCC, introduced himself to the group as a new member of the Prostate SPORE Task Force for NBN Implementation Core Team. He recently joined the Genitourinary/Pathology Department at MSKCC. Prior to this appointment, he worked closely with Angelo DeMarzo as a Clinical Fellow in the Department of Pathology of Johns Hopkins University.

Mark Rubin then gave a brief overview of the NBN Pilot project. He began by stating that the Inter-SPORE Prostate Biomarker Study (IPBS) proposal was developed by the Prostate SPOREs about 3.5 years ago. This effort was led by Bruce Trock (IPBS principal investigator [PI], JHU) and Tim Thompson (Baylor College of Medicine). The proposal consisted of a prospective study to determine the clinical value of biomarkers previously evaluated for prostate cancer. At about

this time, the NBN Blueprint also was being developed. The concept stressed the role of human biospecimens in the advancement of cancer research and the importance of granting researchers access to well annotated samples. It was felt that the IPBS possessed the criteria needed to test some of the key aspects of the NBN. Thus, in the past year, the IPBS proposal was revised by Bruce Trock (e.g., it now consists of both a prospective and retrospective biomarker analysis and the details of specimen collection have been developed) and submitted to a scientific peer review. The logistics of data sharing and informatics also have been examined among the Prostate SPORE institutions with assistance from the caBIG team. Further information on this project can be found in the NBN Pilot executive summary and the Prostate SPORE NBN Pilot website (http://prostatenbnpilot.nci.nih.gov).

Paul Fearn added that all 11 Prostate SPOREs responded to the caBIG Year 2 Evaluation Project request for proposals earlier this year with the intent of serving as adopters of caTISSUE core (i.e., a tissue bank management tool being developed by the caBIG Tissue Banks and Pathology Tools Workspace [TBPTW]) either by adopting it in its entirely or "wrapping" to it. He further emphasized that this adopter role would leverage the IPBS prospective study.

Greg Eley then provided an overview of caBIG. He stated that caBIG helps develop tools and standards to enable cancer researchers to better leverage and share informatics. caBIG is comprised of several workspaces including the clinical trials, TBPTW, and integrative cancer research studies as well as cross-cutting domains to fund infrastructure development. Altogether, the purpose is to create tools and interoperable software that communicate across a federated system. Greg Eley further explained that once all the Prostate SPORE adopter system units are linked together and the federated system is accessed, information will be gathered from all 11 sites, but it will appear as a one-entity search to the user.

Greg Eley expended on the goals of this teleconference. He mentioned that the needs of caTISSUE core adopters had to be determined. In addition, the group's plans for the tool (once it is developed) had to be clarified. Finally, caBIG's expectations needed to be understood and logistics for the successful adoption of caTISSUE core addressed. Greg Eley underscored the necessity of sharing data via the grid by caBIG tool adopters. With respect to the NBN Pilot, it was not expected that the scientific data be shared; rather he suggested that a catalog of tissue types entered into caTISSUE core by the Prostate SPOREs could be posted to the grid. Paul Fearn inquired whether BAH could provide a data sharing agreement since explicit authorization to share the requested data across the grid would have to be obtained from the Prostate SPORE PIs. Greg Eley agreed to help with this aspect. He also noted that those institutions new to caBIG can utilize a master agreement that describes how business with caBIG is conducted. In addition, for each institution, another type of agreement is developed. He proposed to bring the BAH legal team together with the NCI and SPORE representatives to assist in this process.

Greg Eley described the process of obtaining a contract. A statement of work (SOW) will be created and a fixed-price contract issued immediately thereafter. Once institutions contractually agree to adopt caTISSUE core, caBIG will review contract requirements and deliverables with each adopter to include costs, access to data generated by the project, submission of information, and other deliverables. Due to the fixed-price aspect of the contract, payment will be rendered only after a deliverable is submitted and accepted. Paul Fearn inquired about those sites that do

not have the required staff resources to complete deliverables in the proposed timeframe. In those cases, the respondent replied that the institutions can seek outside help from a contractor, caBIG developer, Prostate SPORE, or other institution.

Discussion

Ian Fore began the discussion by presenting a list of project risks as follows:

- Timing of NBN Pilot with caTISSUE core
- Determination of integration approach
- Verification of adoption plan
- Usage of caTISSUE core beyond the study

Additional questions posed to participants included:

- What will happen to retrospective data acquired as part of the study and stored in caTISSUE core?
- How will the integration of connectivity be handled for universities that do not have the appropriate resources?
- How can the system being developed for the NBN Pilot through caBIG be reused for future projects?

One of the main concerns shared by Ian Fore was the current caTISSUE core developer and adopter timeline. Greg Eley explained that developers (Washington University) first relied on adopters (Indiana University, Duke University, Thomas Jefferson University, University of Pennsylvania, Northwestern University, Wake Forrest University) to create specifications and document all information in a computer science capacity. At that point, the development of caTISSUE core was initiated. The prototype will be completed by the end of September/beginning of October 2005 and the release of a stable version of the software is expected to be available by the end of December 2005. Paul Fearn inquired whether it would be possible to map to the tool before December 2005. NCICB representatives replied that, although it would be possible, caTISSUE core development would have to run its course independent of the NBN Pilot timeline. Ian Fore further mentioned that contributions to the development of caTISSUE core still could be made by NBN Pilot participants.

Ian Fore also reminded participants of the need to consider an integration approach (i.e., how connectivity would be provided between the different Prostate SPORE sites). He noted that there are a couple of APIs to caTISSUE core that could be considered. He also announced that a meeting with the caBIG architecture team will be held the following Monday to discuss this issue. In addition, Ian Fore mentioned it was important to ensure which tools would meet the NBN's pilot's querying needs the best: caTISSUE core (which can handle specimen data), or the clinical annotations module (which handles clinical annotations data). Bruce Trock explained that the sites that will be providing retrospective samples to the IPBS will first review their own tissue resources and databases to assess how many patients and samples are available that meet the eligibility criteria. The general sample data then will be posted to a catalog that the PIs would review. Subsequently, a retrospective sample set will be selected based on the sample data provided. Paul Fearn added that the clinical annotations module would not be needed. Instead, a check box should be added to caTISSUE core to denote whether any clinical follow-up data are available rather than including the follow-up data itself.

Greg Eley asked where most of the data for the queries would come from. Bruce Trock explained that most of the participating institutions already have databases that collect these data. Greg Eley then asked about the timeline for compiling such data into a single common system, sharing data, and executing the queries. Bruce Trock responded that work on the pilot will be initiated as soon as funding is received from the NCI. Andrew Hruszkewycz informed participants that such funding should come through by October 1, 2005.

The possibility of having to develop an ad hoc catalogue system to avoid delaying the initiation of the IPBS until the necessary caTISSUE tools became available, was discussed. Recognizing that the ad hoc system would not as beneficial as the final caBIG solution, the advantages of this plan were pointed out as follows: The NBN Pilot timeline would not be delayed and data still would be retained. It also was observed that once the caBIG tools are available, the data then could be used to test the new system. Greg Eley added that, in the case that NCICB could not provide the full version of caTISSUE core to the Prostate SPOREs in time, it was fortuitous that one of the annotation tools already developed by the Cooperative Prostate Cancer Tissue Resource (CPCTR) (created for prostate cancer research) could serve as an interim tool. Paul Fearn mentioned that the retrospective study data is very valuable even though the focus of the NBN pilot is on prospective samples and data. He also observed that if the development of caTISSUE core were to be completed over the summer, then it would be possible to run the NBN Pilot query in the fall. However, if the development of caTISSUE core were to be completed by a later date and an ad hoc catalogue developed, the NBN Pilot team could focus on the distribution of samples for the prospective study. Ian Fore then pointed out that marrying the catalogue with caTISSUE core will require careful consideration upfront to determine whether the mental models being discussed are in fact the same or different. He then inquired whether the development of an ad hoc catalogue would fall under the caBIG umbrella. Paul Fearn replied that the process of mapping towards the implementation of caTISSUE core is within the scope of the caBIG effort. However, if the “last mile” effort fell outside scope, the Prostate SPOREs would have to absorb those costs.

Ian Fore again asked about the end-product of the NBN Pilot study and the use of caTISSUE core to future projects. Paul Fearn replied that the shipping and receiving aspects of the tissue sample handling system as well as an up-to-date catalog of samples across institutions will be legacy items that can be used in future projects. Mark Rubin added that the possibility of extending the use of the tool to other organ site SPOREs could be explored.

Next Steps

The group then discussed the next steps of the Prostate SPORE caTISSUE core adopter process as outlined below.

- Establishment of caBIG Year 2 Evaluation Project contracts with Prostate SPOREs
  - Creation of a task list for each one of the institutions involved
  - Completion of master agreements (BAH contract personnel will reach out to each of the Prostate SPOREs to address this.)
  - Agreement by each Prostate SPORE site of what they can and cannot accomplish.
  - Release of a SOW by caBIG to be signed by each of the Prostate SPOREs.

  - Release of a Task Order that will describe funding and required deliverables
  - Initiation of period of performance (Note: All work outlined in the Task Order will need to be completed within the period of performance.)
- Information to be relayed to caBIG about the NBN Pilot
  - Specific dates when the retrospective and prospective portions of the IPBS will be completed
  - Steps required for each Prostate SPORE site to bring their data to a common, centralized format
- Information to be provided to Prostate SPORE representatives by caBIG
  - A more detailed caTISSUE core timeline
  - Feedback on how the NBN Pilot timeline and the caBIG timeline will intersect with each other
  - caBIG training information posted on the caBIG website to be reviewed by adopter institutions to better understand how caBIG operates
  - A presentation of the latest version of caTISSUE core to ensure the current queries and reports will meet NBN Pilot requirements (i.e., that the data required for both retrospective and prospective studies are being captured)

At the conclusion of the teleconference, Ian Fore and Greg Eley underscored the need to hold another conference call in the near future to further discuss the above-described steps. In addition, Paul Fearn also suggested that the other Prostate SPORE sites be invited to participate in future discussions.

Adjournment
The teleconference was officially adjourned at 4:05 pm EDT.

Attachment 1

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

National Biospecimen Network (NBN) Pilot Teleconference: Discussion of NBN Pilot "Phase 0" Scope

July 22, 2005
3:00 p.m. - 4:00 p.m. EDT

AGENDA

Purpose

To review the goals of the caBIG Year 2 Evaluation Project in the context of the caTISSUE core and NBN Pilot timelines, discuss the steps required for caBIG funding of each Prostate SPORE institution, and develop a framework for a generic task list.

Participants

Harshawaradan Bal	Booz Allen Hamilton (BAH)
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)
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
John Speakman	MSKCC
Bruce Trock	JHU
Mark Watson	Washington University

Agenda

- Review of caBIG Year 2 Evaluation Project goals
    - What are needs of the Prostate SPORE NBN Pilot? (NBN Pilot perspective)
    - What are the needs of caBIG? (caBIG perspective)
- caTISSUE core development timeline (will drive short-, medium-, and long-term goals)
- NBN development timelines
- caBIG logistics
    - Steps required for caBIG funding of each institution
- Develop framework for generic task list

NBN Pilot - caTISSUE adoption

July 22, 2005

Issues/Risks we need to understand

- Timing it right with caTISSUE
- Determine integration approach
- Verify the proposed adoption plan
- Usage beyond the study

Timing relative to caTISSUE

- caTISSUE must be allowed to run its current course
  - Development
  - Current adoption

Integration approach

- Will caGRID provide the infrastructure?
- Comparison of caTISSUE API with API generated from UML model via caCORE SDK.
- Work with architecture group - meeting planned for Monday

Other uses of what we build

- Other uses of what we build
- What do we get beyond the study?
- What value does it have
  - How?
  - When?

caTISSUE APIs

Grid query

Data loading