Clinical and Translational Imaging Informatics Project

Application Overview

Imaging-based cancer research is in the beginning phase of an integrative-biology revolution. It is now feasible to extract large sets of quantitative image features relevant to prognosis or treatment across three complementary research domains: in vivo clinical imaging, pre-clinical imaging, and digital pathology. These high-dimensional image feature sets can be used to infer clinical phenotypes or correlate with gene–protein signatures. This type of analysis, however, requires large volumes of image data. In this project, we propose to develop and deploy software that supports a comprehensive and reusable exploration and fusion of imaging, clinical, and molecular data. Within these three research domains, only one, clinical imaging, has made some progress in terms of establishing a framework and standards for informatics solutions. For pre-clinical imaging and digital pathology, there are no such standards that allow for the seamless viewing, integration, and analysis of disparate data sets to produce integrated views of the data, quantitative analysis, data integration, and research or clinical decision support systems.

This research theme has been systematically explored by the NCI Imaging Informatics Working Group, as a joint effort by NCI extramural staff and CBIIT staff. In addition, these informatics needs were well articulated at the Imaging Informatics Working Group Workshop held on March 5th, 2013 and April 14th, 2015 that were in conjunction with the Quantitative Imaging Network (QIN) annual meetings. At these workshops, QIN members leveraged their experience to explore novel informatics solutions for pre-clinical imaging, co-clinical trials, and digital pathology, and validated the needs met by the projects.

Some of the relevant, high-level takeaways from the workshop can be summarized as follows:

Standards

- The lack of standards in pre-clinical and pathology prevents the ability to share and leverage data across studies and institutions.
- There are differences between the domains, and therefore there should be careful consideration of where there are commonalities in semantic interoperability, and where there is not.

Community Engagement & Needs Identification

- Identify cross-NCI needs and gaps, and work with projects that represent both internal and broader community needs.
- Engaging the broader community is important, in order to gain consensus on needs and gaps. Working with professional societies is helpful in this regard.
- Standards Development Organizations (SDOs) may also be helpful partners.
- Keep the initial group working on a standards project small; use the wider community to validate and credential what is developed.

Incentivizing Adoption

- NCI should incorporate data sharing requirements into grants.
- NCI could create and fund projects that can only be successful if standards are utilized / developed (i.e., "pose questions that can only be answered through increased standardization").

Strategy
The overarching goal of this project is to establish an informatics infrastructure that demonstrates the benefit and feasibility of data interoperability across the three domains: Genomics, Diagnostic Imaging, and Digital Pathology. The intent is to identify and address the interoperability needs to support specific research objectives, with the goal of demonstrating the need to scale up. The scope is limited to pilot data sets, and the intent is only to demonstrate the infrastructure. Creation of more robust tools that leverage the interoperability and infrastructure created in this project would be supported through extramural support after the benefit of scaling up has been demonstrated.

Three complementary projects were proposed and approved.

1. **Digital Pathology: Integration of TCIA and TCGA** - The first project will address interoperability for digital pathology data, improve integration and analytic capabilities between TCIA and TCGA, and raise the level of interoperability to create the foundation required for pilot demonstration projects in each of the targeted research domains: clinical imaging, pre-clinical imaging, and digital pathology imaging.

2. **DICOM Standards for Small Animal Imaging; Use of Informatics for Co-clinical Trials** – The second project will address the need for standards in pre-clinical imaging, and test the informatics created in project 1 for decision support in co-clinical trials.

3. **Pilot Challenges**: The third project will also leverage the work done in project 1 to further enhance the informatics and infrastructure in several “Pilot Challenges.” These challenges will be designed to develop knowledge extraction tools and compare decision support systems for the three research domains, which will now be represented as a set of integrated data from TCIA and TCGA. The intent is not to specifically implement a rigorous “Grand Challenge”, but rather to develop “Pilot Challenge” projects. These would utilize limited data sets for proof-of-concept, and test the informatics infrastructure needed for such “Grand Challenges” that would be scaled up and supported by extramural initiatives later in 2014 and beyond.

CBIIT has worked extensively for several years in the area of data standards for both clinical research and healthcare, working with the community and Standards Development Organizations (SDOs), such as the Clinical Data Interchange Standards Consortium (CDISC), Health Level 7 (HL7) and the International Organization for Standardization (ISO). From that work, EVS and caDSR are harmonized with the BRIDG, SDTM, and HL7 RIM models. Standardized Case Report Forms (CRFs), including those for imaging, have also been created. This work provides the bioinformatics foundation for semantic interoperability in digital pathology and co-clinical trials integrated with clinical and patient demographic data and data contained in TCIA / TCGA.

**Support**

- Application Support email

**Presentations, Demos and Other Materials**

- caMicroscope Videos
- DataScope Video

**Documentation and Training**

- Digital Pathology and Integrative Query System Documentation
- Challenge Management System Documentation