|  | Transitioning for Deployment in Oncology Clinical Trials  |
|--|---|
| OIN  | Volume 4, Issue 1   |
| QIN  | QIN Welcomes New Team Members   |
|  | The Eastern Cancer Oncology Group and American College of Radiology Imaging Network<br>(ECOG-ACRIN) joins the QIN under the leadership of Mitchell Schnall. Their research will bring a<br>combined benefit of quality assurance expertise and imaging/datasets/resources for open scientific<br>evaluation and leverage ECOG-ACRIN's clinical trial development structure to enable prospective<br>testing for methods developed by the QIN.   |
| Special points of  |   |
| interest:  | In addition, two Canadian teams from the <b>University Health Network and the University of British</b><br><b>Columbia</b> joined the QIN under the respective leaderships of David Jaffray and Francois Benard.  |
| New Members  | David Jaffray's team will advance hypoxia PET imaging by creating global standards for image acquisition so that images obtained from different hospitals can be directly compared and combined   |
| Challenge Guidelines   | into a single study. Francois Benard's team project goal will be to improve the accuracy of PET/CT in measuring radiotracer uptake in tumors of various shapes or sizes in comparison to ctDNA/genomic  |
| Challenge Flow Chart   | biomarkers from sequencing data.  |
| 2016 QIN Face-to-Face     Preview                                  | The University of Chicago team led by Maryellen Giger will develop quantitative image-based   |
| Other Challenge     Community Activities     Funding Opportunities | phenotypes for use in predicting response to therapy and ultimately aiding in patient management. The research builds on their 25-year history of taking innovation to the clinical setting by extending prior development, validation, and translation of quantitative image analysis for computer aided diagnosis to  |
| Funding Opportunities  | the post-diagnosis, predictive component in order to assess response to therapy.  |
| Inside this issue:   | The second <b>Stanford University</b> team joining the QIN is under Sandy Napel's leadership and will develop a Quantitative Imaging feature pipeline, a cloud-based, open source platform that will give researchers free access to capabilities that will hasten the introduction of quantitative image biomarkers into single– and multi-center clinical trials.   |
| Policy and Guidelines <b>2</b>                                     | Hugo Aerts's team from the <b>Dana-Farber Cancer Institute</b> joins the QIN with work involving genotype and imaging phenotype biomarkers in lung cancer. This group has recently demonstrated that radiomic biomarkers have strong prognostic performance in large cohorts of lung and head and neck cancer patients, and are associated with the underlying gene-expression and somatic mutation patterns.   |
| Challenges Tasks2ForceChallenge Flow Chart3                        | Fred Prior and his team from the <b>University of Arkansas for Medical Sciences</b> will bring broad experience in imaging informatics to expand the existing TCIA platform and computational resources by providing leading edge research services to QIN researchers. Their goal it to develop and deploy software and services to drive advanced quantitative image analysis and biomarker development.  |
| 2016 QIN Face-to- 3  | Congratulations to QIN Renewal Teams  |
| Face Meeting<br>Executive Committee <b>4</b><br>Report             | The following team members recently were renewed for participation in the QIN. The QIN looks forward to supporting their continued efforts to advance quantitative imaging for cancer research and development as we move forward to deployment in clinical application: Brain Ross - University of   |
| Clinical Trials 4<br>Community Activities                          | Michigan, Daniel Rubin - Stanford University, Thomas Yankeelov - Vanderbilt University, Paul Kinahan - University of Washington.  |
| Challenge Activities <b>4</b>                                      | <b>QIN Challenge Tasks Force Mission</b><br>The QIN has been conducting a variety of network-wide projects, collectively referred to as<br>"challenges." In order to streamline the challenge process and garner the potential value of challenges<br>in benchmarking of quantitative tools, comparison of methods, and driving consensus, the <b>QIN</b>   |
| Funding Opportunities <b>5</b>                                     | <ul> <li>Executive Committee recommended the creation of a task force to develop policies and procedures for conduct of computational challenges in a more organized fashion within the network.</li> <li>The QIN Challenge Task Force (CTF) created in July 2015 and is composed of Keyvan Farahani (NCI), Jayashree Kalpathy-Cramer (MGH), and John Buatti (University of Iowa) who serve as co-Chairs of the QIN-CTF, representatives from each of the five QIN Working Groups, and selected NCI program staff. The CTF is charged with the task of developing a framework of policies and processes for the management of challenges in the QIN.</li> </ul> |

## QIN Challenge Task Force (cont.)

In order to consider a framework for developing policy and guidelines that will facilitate the effective management of future challenge activities, the CTF collected information on current and past QIN challenges. The survey of current and past QIN challenges identified two categories of projects, all currently referred to as challenges. Because of the specific task in each project and how they will be evaluated and reported, CTF considered it important to subdivide these activities into Challenges and Collaborative Projects (CCPs), as defined below:

**QIN Computational Challenge**: A multisite test of computational algorithms designed to perform image processing and/or analysis for a given task, with direct technical or clinical relevance to QIN projects, using designated training and test data sets, relevant physical or clinical reference standards, and evaluation metrics. QIN challenges may be further divided into the following categories:

**Technical Challenge** – tests performance characteristics of algorithms based on physical standards and metrics (e.g., image markup, spatial or functional accuracy, repeatability, etc.). A Technical Challenge may test the performance of a tool or a method. The immediate outcome of a Technical Challenge would be a set of tools, or class of methods, for

technical assessment and the resulting annotations or other data types.

**Clinical Challenge** – tests performance characteristics of algorithms based on clinical standards or criteria for decision support in evaluation of response to therapy. A Clinical Challenge may test performance of a tool or a method. The immediate outcome of a Clinical Challenge would be a set of tools or methods for clinical assessment and the resulting data.

**QIN Collaborative Project**: An analytical study of tools, techniques, scientific and clinical parameters, or otherwise survey opinions of members engaged in common studies. Cataloging the outcomes of such projects may provide a useful resource to current and future members of the QIN, NCI, and the greater scientific community.

#### **Guidelines for Challenges and Collaborative Projects**

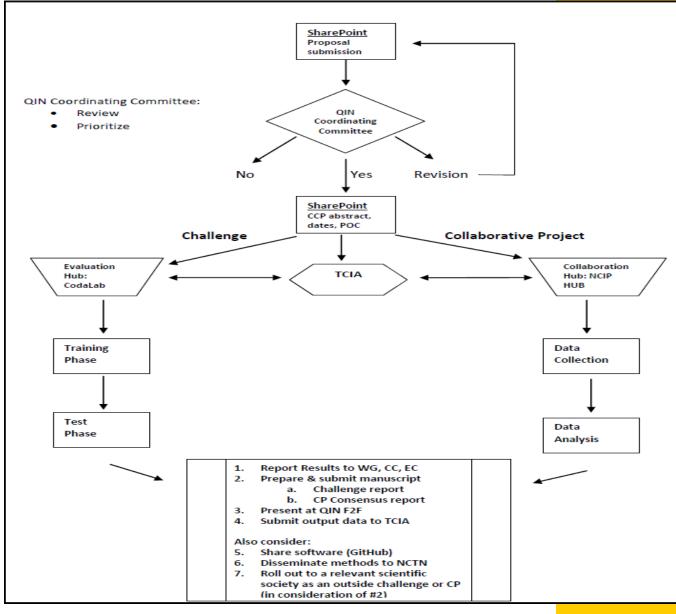
The CTF convened its first meeting on July 7, 2015 to construct the planning phases for how to move forward with a policy and supporting guidelines that would leverage current experiences encountered with challenges and put forth a management process to ensure that the most productive attributes from future challenges direct the QIN to align with its mission for deployment in clinical applications. During the course of several months, the tasks force moved forward with assembling what was necessary for a policy and process framework for conducting challenges and collaborative projects (CCPs).

Components for conducting a CCP and associated administrative and informatics support was considered for process improvement that entailed preparation for proposing a CCP, proposal submission, proposal review, posting and preparation, execution, participation, and how CCP results will be captured based on the "evaluation metrics" that were proposed in an approved application. Additional administrative aspects for the guidelines included CCP reporting for conflict resolution, peer-review publication of CCP reports, and presentations at the QIN annual meeting.

Management of the process will involve the **Coordinating Committee**, in collaboration with NCI program staff, to provide oversight for QIN Challenges and Collaborative Projects. This will include review and prioritization of proposals, recommendations for amendment of proposed projects prior to their execution, monitoring of the process, review of final reports, and relevant communications with the **Executive Committee**.

The CTF has presented drafts of the current policy and guidelines to the Executive Committee for review and has obtained considerable feedback to ensure that the process build consensus. The next QIN Newsletter will describe how the process will be implemented and monitored, following the process flow chart for CCPs (see next page). The goal is to establish a best-practice on how the network will conduct future CCPs to ensure alignment with the overall objective of the QIN and share CCP products more openly and effectively through an open science approach.

#### Process Flow Chart for QIN Challenge and Collaborative Projects



### 2016 QIN Face-to-Face Meeting

The 2016 QIN Face-to-Face Meeting will emphasize methods the network will use to incorporate Challenges and Collaborative Projects (CCPs) as a developmental activity to validate and test algorithms and analytical studies of tools, techniques, scientific and/or clinical parameters. In some instances, collaborative projects will be used to survey opinions of members engaged in common studies.

QIN members will be encouraged to provide input on how CCPs could be central and vital to network-wide activities that will concern specific scientific tasks related to the greater clinical mission of the network. If exercised properly, CCPs would represent organized efforts among QIN member teams to help compare various computational approaches to a given task or develop consensus on analytic methods. One of the overarching goals of the 2016 QIN Face-to-Face Meeting will be to build consensus on how CCPs can provide the network with data to adequately test tools. Publishing the findings associated with CCPs could be an effective outreach instrument to galvanize support from interested communities involved in translational oncology and cancer precision medicine.

## **Executive Committee Report**

2015 has been an very active year the **Executive Committee (EC)** with high profile accomplishments to support the mission of the QIN. The following are several high profile program activities accomplished by the EC:

- Productive participation for the 2015 QIN Face-to-Face Annual Meeting and follow-up on breakout session recommendations,
- Organizing the ACRIN QIN Team for the advancement of ECOG-ACRIN data sharing to provide imaging resources for the QIN and the greater scientific community with regard to both prospective studies of clinical trials data, as well as retrospective studies involving legacy datasets,
- Outreach to scientific professional societies and organizations, and the Cancer Cooperative Groups,
- The voting in for several new associate members and the establishment of an International Liaison Committee,
- Engaging IROC to identify clinical trial opportunities and function with the National Clinical Trials Network,
- Establishment of the QIN Challenge Task Force,
- Ratification of the QIN Challenges and Collaborative Projects guidelines, form, process, timeline, and informatics support,
- A very successful program participation in 2015 RSNA Conference with **Quantitative Imaging Biomarker Alliance (QIBA)**.

# **Clinical Trials Community Activities**

The **Clinical Trials Design and Development (CTDD)** Working Group has been working diligently to build a bridge with the national clinical trials community. CTDD Working Group had a productive year with following accomplishments:

- Soon to be reviewed Radiation Oncology manuscript,
- Planning has started for STIRQI with an initial draft from Richard Wahl,
- Auto-PERCIST challenge is ongoing with QIN sites participation,
- The Auto-PERCIST demonstration at the Annual RSNA meeting was a success and well received by the imaging community,
- A Invited session "Advanced Quantitative Imaging for the Radiation Oncologist: Response Assessment and Targeting for Clinical Trials and Practice, A View from the NCI's Quantitative Imaging Network" was submitted for ASTRO 2016 Annual meeting by Hui-Kuo Shu and John Buatti and selected by the first (and most difficult) round of review; and is likely to be a part of ASTRO 2016 annual meeting,
- The group is also working on a PERCIST 1.0 summary paper to be submitted to Radiology.

#### Future SPIE, AAPM, and NCI Challenge Collaboration

Planning talks are be conducted to set the stage for future SPIE, AAPM, and NCI challenge for 2017. The goal is to establish a working relationship with scientific professional societies to engage NCI on software challenges for cancer imaging research and development. NCI is very interested in expanding the TCIA as a research resource for future software challenge activities that support cancer imaging research and the advancement of precision medicine.

#### MICCAI Workshop and Challenges- Munich Germany

MICCAI 2015 Workshop and Challenges in Imaging and Digital Pathology were held on Oct 9 in conjunction with the annual meeting of the society for Medical Image Computing and Computer Assisted Interventions (MICCAI). For a second year, CIP collaborated with co-organizers from MGH, Stony Brook Cancer Center, Technical University of Munich, and University of Bern, to conduct a morning workshop on "Computational Imaging in Precision Medicine," followed by three challenge sessions on low- and high-grade gliomas in the afternoon. The goals of the workshop was to consider the requirements and resources for open science approaches to development of systems and benchmarking of software tools for clinical decision support. Invited speakers included Andre Dekker (the Netherlands), Jens Kleesiek (Germany), Henning Muller (Switzerland), Jayashree Kalpathy-Cramer (USA), and Joel Saltz (USA). Challenges included the segmentation of nuclei in digital pathology images (Challenge 1), Combined Imaging and Digital Pathology Primary Tumor Classification (Challenge 2), and Guess the Primary (Challenge 3). More information about this event can be found on the TCIA wiki page on challenges: <a href="https://wiki.cancerimagingarchive.net/display/Public/">https://wiki.cancerimagingarchive.net/display/Public/</a>

## **Funding Opportunities**

The NCI and NIH - BD2K has provided a expanded set of funding opportunities for QIN team members to benefit from where they can aligned support in various areas of the research domains for translational research for oncology clinical development.

**Quantitative Imaging for Evaluation of Response to Cancer Therapies (U01)**: http://grants.nih.gov/grants/guide/pa-files/PAR-14-116.html

Academic Industry Partnership (AIP) allows teams to partner with industry to develop new imaging systems and methods, including informatics/databases: http://grants.nih.gov/grants/guide/pa-files/PAR-13-169.html

**Oncology Co-Clinical Imaging Research Resources to Encourage Consensus on Quantitative Imaging Methods and Precision Medicine (U24):** http://grants.nih.gov/grants/guide/pa-files/PAR-15-266.html

Image-Guided Drug Delivery (R01): http://grants.nih.gov/grants/guide/pa-files/PAR-16-044.html

**Trans NCI Informatics Initiative for Imaging** where you have the option of applying for supplement, a U01, or a U24. http://grants.nih.gov/grants/guide/pa-files/PAR-12-287.html

**ITCR - Advanced Development of Informatics Technologies for Cancer Research and Management (U24)**: http://grants.nih.gov/grants/guide/pa-files/PAR-15-331.html

**ITCR - Early-Stage Development of Informatics technologies for Cancer Research and Management (U01)**: https://www.google.com/?gws\_rd=ssl#q=Par-15-332

**ITCR - Sustained Support for Informatics Resources for Cancer Research and Management (U24)**: http://grants.nih.gov/grants/guide/pa-files/PAR-15-333.html

ITCR - Development of Innovative Informatics Methods and Algorithms for Cancer Research and Management (R21): http://grants.nih.gov/grants/guide/pa-files/PAR-15-334.html

**Proteogenomic Data Analysis Centers for Clinical Proteomic Tumor Analysis Consortium (U24)**: http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-15-023.html

**Exploratory/Developmental Bioengineering Research Grants (EBRG) (R21)**: http://grants.nih.gov/grants/guide/pa-files/PA-16-040.html

NIH BIG DATA to KNOWLEDGE (NIH - BD2K): https://datascience.nih.gov/bd2k/announcements

- Big Data to Knowledge (BD2K) Development of Software Tools and Methods for Biomedical Big Data in Targeted Areas of High Need (U01)
- Early Stage Development of Technologies in Biomedical Computing, Informatics, and Big Data Science (R01)
- Extended Development, Hardening and Dissemination of Technologies in Biomedical Computing, Informatics and Big Data Science (R01)
- Early Stage Development of Technologies in Biomedical Computing, Informatics, and Big Data Science (R43/R44)
- Early Stage Development of Technologies in Biomedical Computing, Informatics, and Big Data Science (R41/R42)