

# **QIN Setting the Stage for Translating Tools and Methods for Oncology Clinical Trials**

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## **QIN New Team Members**

The QIN welcomes two team members from Memorial Sloan Kettering Institute and the University of Texas Southwest Medical Center. The Memorial Sloan Kettering team lead by Dr. Amita Dave endeavors to develop, optimize and validate novel DW-MRI acquisition and modeling methods that address non-Gaussian water diffusion, perfusion effects through diffusion kurtosis imaging, non-Gaussian intravoxel incoherent motion imaging; and provide more specific measures of tissue structure and biology. Additionally, the team will develop and implement advanced image processing tools to maximize the biologic information from the tumor and tissue provided by the imaging data. The team will also address urgent and unmet needs in clinical trials for recurrent and metastatic head and neck cancers.

The University of Texas Southwestern team propose to validate a non-invasive perfusion imaging technique, Arterial Spin Labeled (ASL) MRI, to evaluate treatment response in patients with advanced brain tumors (glioma) or advanced kidney cancer (metastatic renal cell carcinoma). Current radiological assessment of treatment outcomes predominantly relies on changes in tumor size, however, the vascular effects caused by many therapeutic agents at the microscopic level precede well before noticeable changes in tumor size. ASL can be used as an early imaging marker to predict tumor responsiveness to treatment far sooner than observable tumor size changes, thereby, informing and guiding clinical decisions to maintain or change treatments that may be ineffective and potentially toxic.

## **QIN Prepares to Meet with the National Clinical Trials Network for Translation**

The CTDD Working Group will hold QIN-NCTN monthly planning meetings for the Alliance Group this November in Chicago. The planned meeting presents a unique opportunity for QIN to work constructively to lay the ground work with the NCTN for integrating QIN into clinical trials. The QIN would like to establish a framework pathway for directing QIN members to specific disease sites, incentivizing individual QIN U01s toward specific trials and groups to help increase participation and determine how best to test quantitative imaging tools in national clinical trials.

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**From the “Director”**

## **CTDD Working Group – PathCT**

Because of the QIN and NCTN joint meeting in December 2016 and the QIN Face-to-Face Meeting held in April 2017, the CTDD Working Group initiated a PathCT focus group to start the process of putting in place an implementation framework to evaluate existing tools to assess integration into clinical trials. There was unified agreement among members of the NCTN and QIN teams for early tool integration planning process with clinical trial development. It was specifically noted that the time from early concept development to trial implementation typically take 1 - 1.5 years or more and there might be opportunities for earlier integration of QIN tools into emerging NCTN trials. Early integration strategy might be feasible if image collection is already planned, image data requirements for the tool are not too restricted or challenging, and central image analysis is possible. The PathCT focus group drafted a QIN Tool Readiness Template to begin the process for the evaluation. The template captures specific information such as tool name, description, ability to share the tool for deployment, and collect information on tool performance testing, validation, and results. This activity is a first attempt to collect information that would be pertinent for making educated assessments for readiness evaluation.

## **Setting the Stage for Translation - QIN Toolx Challenge**

Keyvan Farahani, Program Director for Challenges and Collaborative Projects, introduced the QIN Tool Exchange Collaborative Project to the QIN. The goal is to start conducting systematic evaluation of user experience with QIN software tools. Development, optimization, and validation of quantitative imaging software tools that can aid in prediction or evaluation of response to cancer therapy is a central theme of the QIN. An overarching programmatic goal of the network is to utilize appropriate QIN tools in clinical trials in oncology. Although QIN teams have developed tools, some maybe distinct to their scientific quantitative metric application, making dissemination and utilization across different research environments challenging for deployment in clinical trials. As a precursor to potential deployment of QIN tools in clinical trials, collaborative projects could provide a useful mechanism for peer evaluation for the utility of QIN tools in like environments. Conducting systematic evaluations of user experiences with QIN software tools through a tool exchange (Toolx) collaborative project could provide a bridge solution. The motivation, purpose, approach, and the overall design of the Toolx will have four distinct phases with time periods are currently being reviewed and refined by the Executive and Coordination Committees for implementation in the future.

## **QIBA-QIN Collaboration**

During the annual meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) held in June 2017, a joint meeting was convened with QIN, QIBA, SNMMI, the imaging industry, and others to discuss how QIN tools and QIBA profiles can work together to promote the adoption of quantitative imaging tools and methods in clinical trials. Central to the deliberation were several issues such as roles of each participant group would take on to execute a plan, how to reduce industrial barriers to adopting quantitative imaging, how best could tools and profiles be united, selecting the appropriate clinical trial process, standardization of methods, and site qualification. Consensus was reached on a position paper to inform the imaging community on how best to overcome barriers to translation and commercialization of quantitative imaging with a focus on implementing potential solutions. In addition, the meeting provided an opportunity for the group to discuss how pharma could be engaged to promote quantitative imaging methods in clinical trials. Emphasis was placed on how to expose pharma to the benefits of quantitative imaging methods in clinical trials where performance attributes associated with imaging scanners could enhance clinical trial function and optimize its business model via correlative study utilization.

## **QIN Infomercials Coming Soon**

The Cancer Imaging Program plans to design and develop QIN infomercial videos to educate the public on aspects of the QIN, its purpose, and provide visual context for how tools and methods can support oncology clinical trials. Over a period of one year, videos from QIN team projects, the 2017 Annual Face-to-Face Meeting, and selected individuals were collected with the goal of constructing the infomercial using video editing software.

The Program Staff will convene a small infomercial committee to start the process of constructing a story board with scripts to convey the message for why quantitative imaging tools and methods will be important for oncology clinical trials. The infomercials will not only be used to inform the public but also NCI Senior Program Leadership on the program's contribution to cancer research. QIN teams who have completed videos on their projects are encouraged to send them to George Redmond ([gr34m@NIH.GOV](mailto:gr34m@NIH.GOV)), the QIN Communications Coordinator, for future video development planning efforts to expand communication to the public. QIN Infomercials are a unique opportunity for the network to build an important connection with public, researchers, administrators, and patients and we hope to have each team represented in this collective effort.

## **QIN New Public Website**

Program staff and contractor support has been very busy developing a new public facing QIN Website. The website will complement the QIN SharePoint moving forward as content builds for the network. Content for the website will provide easy point-click-and view screens with landing page access to the mission, goals, teams, network structure, and request for application instruction for parties interested in joining the network. The tool bar search will merge information associated with the Cancer Imaging Program official public website to broaden programmatic content information dissemination. QIN specific tool bar information will be readily available for cooperative agreements, QIN activities, selected QIN publications, clinical translational activities, and QIN Annual Meeting notifications. The website will enhance information content for the network and will be a welcome informatics addition for the TCIA Website, QIN LABS Website, and NCIP-Hub.

## **International Associate Member Updates**



The QIN welcomes Finbarr O'Sullivan with the University College Cork as a new QIN Associate Member from Ireland. Dr. O'Sullivan is Professor of Statistics at UCC and the Head of School of Mathematical Sciences. Dr. O'Sullivan maintains a strong collaboration with the Positron Emission Tomography Imaging Group at the University of Washington, where he holds an appointment as Affiliate Professor of Radiology. He also collaborates with other researchers on other imaging projects in the US and Ireland. Among these researchers are The American College of Radiology Imaging Network and the University of Wisconsin, where he also holds an appointment as affiliate professor of statistics. His QIN application focus is metabolic

imaging of cancer and its response to therapy using PET. Rapid development of technologies for quantitative image data capture in biology and medicine are increasing, specially, for diagnostic medical information consisting of in-vivo sequences of 3-D (volumetric) imaging data. However, local biologic variability of the target, as well as fundamental restrictions in resolution characteristics (often related to dosimetry considerations) produce data that are limited by noise. Advances in instrumentation and data generation capabilities have far out-paced the development of statistical analysis tools capable of extracting useful scientific information from data. This is especially the case with technologies used for in-vivo imaging studies with PET, fMRI and dynamic contrast CT. We welcome Dr. O'Sullivan and his ability to meet these challenges.

Tata Memorial Hospital (TMH), Mumbai, is a leading cancer specialty hospital in India and an associate member of the QIN. Their patient volumes are very large, they have advanced image acquisition protocols and high quality

clinical data. The MGH team has been working closely with TMH to evaluate tools developed as part of MGH's participation in the QIN. The tools developed by the MGH team include semi-automatic and deep learning based automatic segmentation measurement of tumor burden in gliomas, tools for multi parametric MR analysis in brain tumors (including tools for DSC, DCE and diffusion analysis), radiomics pipeline and tools for risk stratification. The goal of this collaborative project is to evaluate the performance and utility of these tools at TMC. The tools have been made available as Slicer modules, python packages and Docker containers. We are currently evaluating the automatic tumor segmentation tools. Our goals are to evaluate the entire pipeline of tools on cohorts of high and low-grade glioma patients over the next year.

## **QIN Publications**



QIN and JMI will honor Dr. Larry Clarke in the upcoming special issue that will focus on quantitative imaging methods and translational development. There was a great turnout of submitted papers that are currently under review.

## **Funding Opportunities**

PAR-17-093, Academic-Industrial Partnership to Translate and Validate in-vivo Cancer Imaging Systems (R01), was recently published on December 21, 2016. The purpose of this Funding Opportunity Announcement (FOA) is to stimulate translation of scientific discoveries and engineering developments in imaging or spectroscopic technologies into methods or tools that address problems in cancer biology, risk of cancer development, diagnosis, treatment, and/or disease status. A distinguishing feature of this FOA is the formation of an academic-industrial partnership, which is a strategic alliance of investigators in academic, industrial, and any other entities to work together as partners to identify and translate a technological solution or mitigate a cancer-related problem. The goals for proposed technologies are imaging applications in clinical trials, clinical research, non-clinical research, and/or patient care. Among other possibilities, participant's may include pre-clinical imaging investigations or investigations that combine patient specimens and pre-clinical methods, or optimizations of methods across different commercial platforms, sites, or time.

## **From the QIN Director**

As we move from summer into fall, the mood here in the QIN program team is mixed. On the one hand, we are very excited about the opportunity that the upcoming interaction with the Alliance Clinical Trials Group. QIN members have been invited to participate in the Nov 2 – 4 meeting in Chicago of this group. Larry Schwartz, MD (Columbia University) has been instrumental in organizing the interaction. The QIN members will have the opportunity to present information on validated tools developed by the network and to listen to the needs of oncologists conducting clinical trials. The meeting should be a springboard for moving QIN therapy-response tools closer to clinical utility

The enthusiasm expressed by this opportunity, however, is tempered by the extreme difficulty in funding those applications to QIN that receive highly enthusiastic scores from study section. Paylines are going down for R01 awards, and acceptable scores for U-awards are likewise falling. The current budget problems experienced by NIH are filtering down to this program. We realize that this is very frustrating to the investigators seeking to enter or continue activities in the network. It is frustrating to program staff as well, and there is no easy, short-term answer to this problem. All we can say is we continue to search. Right now, I want to encourage each of you to have the perseverance to continue to apply even if applications with remarkably good scores are overlooked by NCI management. The success of QIN has come because each team member is doing his/her job to make the network successful.

