

The Quantitative Imaging Network (QIN) Update

A woman in a white lab coat is shown in profile, looking at a computer monitor. The monitor displays several medical images, including brain scans and anatomical diagrams, with various data points and graphs overlaid. The background is a blurred office or laboratory setting.

Janet Eary, MD
Robert Nordstrom, PhD
Lalitha Shankar, MD, PhD

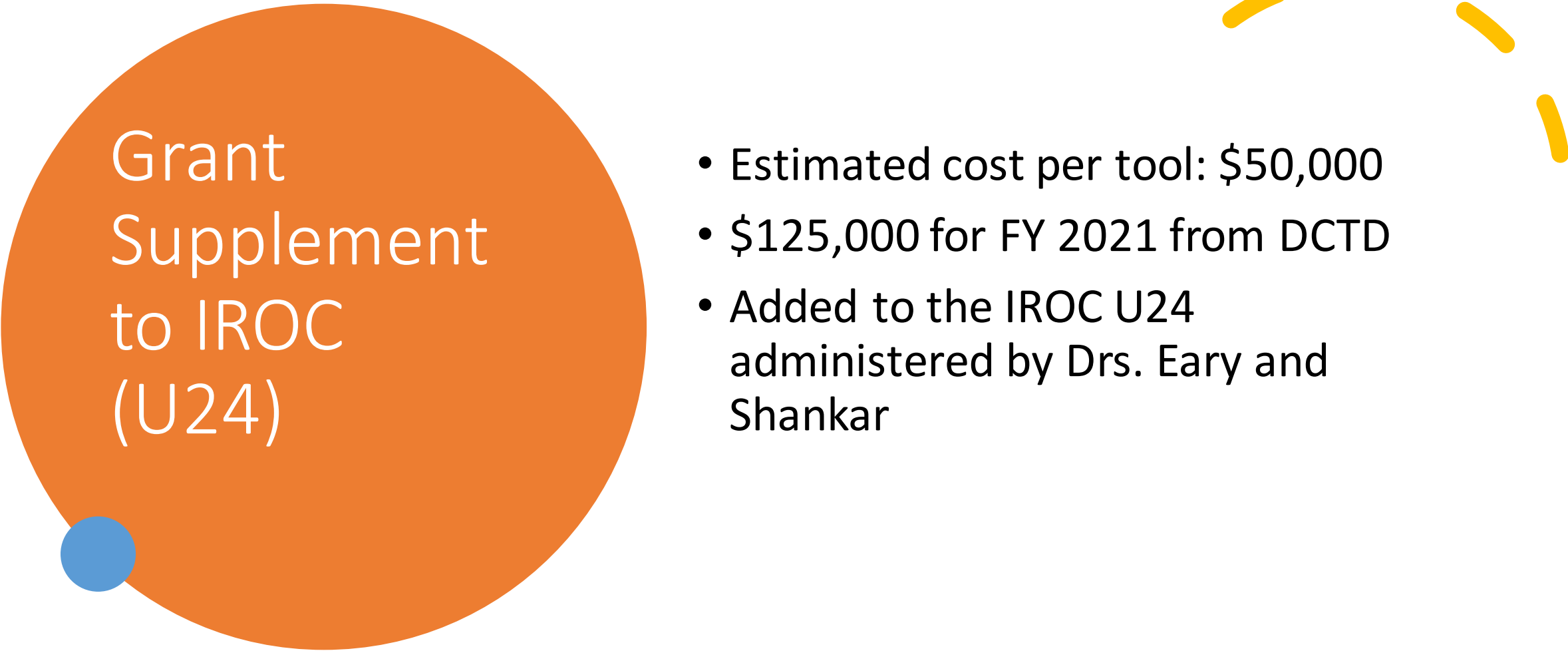
CTAC
July 14, 2021

The QIN – CTAC Timeline History

- July 2018: Presentation of QIN to the Clinical Trials and Translational Research Advisory Committee (CTAC)
- September 2018 – July 2019: QIN – CTAC Working Group formed
 - QIN, CTAC, and NCI representatives
- March 2020: Report to CTAC from Working Group
 - 6 recommendations
- June 2020: Recommendations enacted

CTAC Working Group Recommendations

1. Form an Oversight Committee to assess QIN Tool for clinical validation.
 - NCTN, IROC, and QIN participation, NCI leadership.
 - Create Fit for Purpose Requirements for QIN Tools
2. Provide opportunities for QIN and NCTN engagement.
3. Promote and incentivize QIN tool development and readiness for NCTN.
4. Ensure that all stakeholders understand the utility of incorporating QIN tools in appropriate trials.
5. Ensure NCTN sites are ready to open trials that include QIN tools.
6. Support image banking and data sharing with metadata from NCTN trials (TCIA)



Grant Supplement to IROC (U24)

- Estimated cost per tool: \$50,000
- \$125,000 for FY 2021 from DCTD
- Added to the IROC U24 administered by Drs. Eary and Shankar



Process...over
the past 6
months

- NCI-QIN-CTAC working group established – with representation from CIP and CTEP
- QIN tool shortlist for evaluation developed by Dr. Nordstrom
- Tool developers present fit for purpose to NCI-QIN-CTAC working group - ongoing

IROC Tool Assessment Process

Leaders:

Dr. Michael Knopp
(IROC PI)

Dr. Lalitha Shankar
(CIP Clinical Trials Branch
Chief)



Tool presentation to Oversight Committee,
determination of tool fit for purpose



Assess and shortlist available trial image data sets



IROC team tests tool on 2 or more data sets with
ongoing communication with the tool developer




Timeline: 3 months with initial report at 6 weeks



Performance assessed in
various scenarios

Imaging device types
Patient BMI artifacts
Clinical imaging software and
workflows

Quantitative Imaging Tools under evaluation

- IB Clinic: a suite of tools for processing MRI perfusion images
 - Kathleen Schmainda, Medical College of Wisconsin
 - Lung Segmentation: Lung tumor automatic segmentation
 - Larry Schwartz, Binsheng Zhau, Columbia University
 - Miviewer: annotate, outline, and measure urinary bladder tumors
 - Lubomir Hadjiyski, University of Michigan
 - autoPERCIST: PET image tumor response evaluation criteria
 - Richard Wahl, Washington University
 - qDWI Phantom: two quantitative phantoms with known ADC
 - Tom Chenevert, University of Michigan
 - ePAD: quantitative imaging informatics platform to support clinical trials imaging
 - Daniel Rubin, Stanford University
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QIN Tools Ready for Clinical Trials (An Example)



IB Clinic® 2.0 User Manual

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IB Clinic is an FDA-cleared set of tools to perform and streamline brain image post-processing.

- Standardized algorithms
- Default settings to allow generation of parametric images
- Automatic brain mask generation
- Automatic contrast leakage correction
- Integration with multiple PACS to access acquired data and distribute results
- Automatic arterial/vascular input function generation
- Longitudinal reporting

Certifications

Imaging Biometrics, LLC is ISO 13485 certified. IB Clinic and its modules are cleared by the US FDA and have also declared CE Marking.



Contacting Imaging Biometrics

For assistance, contact the IB Customer Service Department by phone at 262.439.8252 (US) or send email to support@imagingbiometrics.com.

In the European Community, contact us at:



Imaging Biometrics, LLC (www.imagingbiometrics.com)
5 Chestnut Close
Down Ampney
Gloucestershire GL7 5RA, UK

Workflow

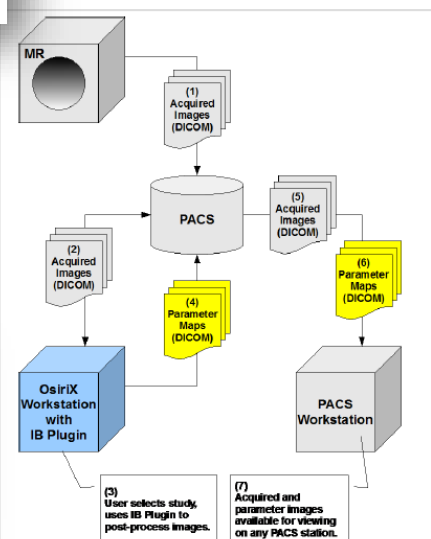


Figure 3. Workflow for using IB Clinic within a PACS environment.

Additional QIN tool Program Support Activity

- NOSI created to link imaging tool development with Academic/Industrial Partnership (PAR-21-206)
 - Bring commercial interests to quantitative imaging tool clinical translation
- Small Business Research Contract (SBIR) created for business entry into clinical translation of quantitative imaging tools
 - Three contracts are being negotiated

Conclusions

- The process envisioned by the QIN – CTAC committee is well underway for identifying and submitting QIN quantitative imaging tools to IROC for testing and evaluation in clinical trials data.
- Tools continue to be brought forward for committee fit for purpose consideration

- Thank You CTAC!