

## **Leveraging the CTSA Program to Support Imaging Biomarker Development**

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**(No Relevant COI Disclosures)**

## **Clinical and Translational Science Awards (CTSA)**

- **Launched in 2006 by NCRR**
- **55 sites in 28 states and DC as of 2010**
- **Strategic Goals**
  1. **Build national clinical / translational capacity**
  2. **Training / career development**
  3. **Enhance consortium-wide collaborations**
  4. **Improve community and national health status**
  5. **Advance T1 research (discovery to clinical testing)**
- **Consortium organizational structure**
  - **Steering and Strategic Goal Committees**
  - **14 Key Function Committees (Translational)**
- **CTSA facilitated scientific activities**
  - **Core and training activities**
  - **Planning and pilot awards (≈\$10 – 50K, or more)**

## Clinical and Translational Science Awards (CTSA)



## CTSA Imaging Working Group (CTSA IWG)

- **Housed within the Translational KFC**
  - **Mission:** develop infrastructure to facilitate advancements of novel translational research and technologies through the consortium in collaboration with the NIH; bidirectional integration of basic & clinical research to improve care & health
- **IWG Chair Daniel Sullivan, MD; Supported by RSNA**
- **Membership open to CTSA's (awarded and planned) and "interested parties" (industry included)**
- **Organizational structure**
  - **Steering Committee**
  - **3 Subgroups within the CTSA IWG**
    - **Cores and Education (Macura and Reynolds)**
    - **Imaging Informatics (Erickson)**
    - **Clinical Trials and UPICT (Dorfman)**

## **CTSA IWG Subgroup Activities and CTSA Strategic Goals**

- **IWG Subgroups: All five strategic goals to some extent**
- **Cores / Education: Build capacity; Training and career development**
  - Inform institutional imaging cores so as to optimize performance
  - Educate clinical and translational scientists and providers (imaging and others) regarding emerging imaging technologies and imaging's roles and capabilities in translational research
- **Imaging Informatics: Build capacity; Enhance collaborations**
  - Develop & deploy inter-operable imaging informatics infrastructure enabling optimal sharing of research-related, image-derived data & information

## **CTSA IWG Subgroup Activities and CTSA Strategic Goals**

- **Clinical Trials / UPICT: Enhance collaborations; Advance T1 research**
  - Trial design including standardized image acquisition; development of relevant imaging endpoints; strategies for handling imaging PHI; and mechanisms for managing image-based response assessments.
  - Development of Uniform Protocols for Imaging in Clinical Trials (UPICT).

## **UPICT: (Uniform Protocols for Imaging in Clinical Trials)**

**UPICT facilitates the development and maintenance of consistent imaging protocols for use in clinical trials ...**

**... so that signal is a consequence of the intervention under investigation rather than to some artifact of the manner in which the imaging is conducted.**

**As many subjects are enrolled in trials after baseline imaging has been performed, there may be value in UPICT protocols being used in clinical practice.**

## **UPICT Protocols & QIBA Profiles**

**UPICT Protocols describe how subjects (*and potentially patients*) should be imaged so as to achieve reproducible qualitative, semi-quantitative, and/or quantitative endpoints (*and potentially clinical test results*) when those tests are performed utilizing systems that meet specific performance claims. These specific performance claims are inherent in the QIBA Profiles.**

**QIBA Profiles describe how specific performance claims are achieved when targets (inanimate and/or living) are imaged under specific conditions (including, but not limited to, imaging system requirements and imaging protocols). The imaging protocols used for the living targets are the UPICT Protocols.**

## **Leveraging Current CTSA IWG Activities Towards Imaging Biomarkers**

- **UPICT**
  - Enabling IT infrastructure established
  - Standard Template (v 1.0) – completed, potential improvements based on use
  - Oncologic vCT (Lung) – in progress
  - Oncologic FDG-PET/CT (Whole Body) – in progress
  - Oncologic vCT (Whole Body) – to be implemented, near term
  - AD / MCI MRI (Brain) – committee being organized
  - Airspace Disease CT – committee being organized
  - Suggestions for additional foci and volunteers welcomed
- Discussion during this year's RSNA regarding linking imaging data (phenotypes) with "omics" repositories
- Individual CTSA site projects (to be catalogued)

## **Leveraging Potential CTSA IWG Activities Towards Imaging Biomarkers**

- Providing tools to CTSA sites to facilitate local activities
  - UPICT protocols, IT, technologies (in c/w industry)
  - Enabling imaging scientists (and collaborators) to compete for local CTSA planning and pilot funds
  - Organizing CTSA sites to develop data necessary (but "missing") for UPICT protocols / QIBA profiles
- Develop & deploy tools to facilitate linkage between imaging and other data (locally and nationally)
  - "omics" repositories
  - Clinical outcomes data
- Training imaging scientists to travel the path towards imaging biomarker validation / qualification
- Facilitating a national focus on imaging as a biomarker
  - Linkage of standardized image data with existing national repositories

## **Migration From “Test” to “Biomarker”**

- **Pre-sampling patient / subject status (characteristics and pre-test management)**
- **± provocative maneuvers**
- **Sample acquisition (fluid, tissue, specimen, cells, data)**
- **Sample management post-acquisition**
- **Sample processing (and reconstruction)**
- **Sample post-processing and analysis**
- **Interpretation of analytic output (clinical relevance)**
- **Output archival specifications**
- **Integration into scientific and/or clinical decision-making**
  
- **Requirements (standardization):**
  - **Stipulated test platform performance (QIBA Profiles)**
  - **Stipulated SOPs for the use of the test platform (UPICT Protocols)**
  - **QC and audit for each**
  
- **Outcome – Widespread acceptance as biomarker (validation)?**