QIBA Queries

• How might current NIH Initiatives benefit from QIBA Biomarker Development?
  • Plan activities to align with the NIH goals
  • Make a case to potential future funders

• Translation to Clinical Research & Practice?
• Updates
The challenges...

- Many diseases lack effective prevention strategies, diagnostics, or treatments
  - Options fail to consider key differences among individuals: genes, lifestyle, environment
- Need to look beyond the genome
Scientific Opportunities in the AoU Cohort Program

- Develop quantitative estimates of risk for a range of diseases by integrating environmental exposures, genetic factors and gene-environment interactions
- Identify the causes of individual variation in response to commonly used therapeutics (pharmacogenomics)
- Discover biological markers that signal increased or decreased risk of developing common diseases
- Create a platform to enable trials of targeted therapies

Main Awardees So Far

Anticipate new “community partner” awards to begin mid ’17
All of Us Nears Launch

- A “soft”, iterative launch is scheduled for this month.
- At least one Healthcare Provider Organization (HPO) will go live with All of Us enrollment followed by more HPOs as the summer progresses.
- National launch is targeted for Fall 2017.

Sharing Health Data Electronically

- Sync for Science (S4S) is a technology that will provide research participants a way to submit their EHR data to All of Us.
- RSNA Image Share is a medical image sharing platform. Image Share is patient centered and patient controlled.

Collaboration: Define technical specifications for imaging data to be shared in a scalable approach using the S4S model of automated, scalable, patient-controlled workflow.
Budget Estimates & Funding

Five-year Plan Budget Estimates

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Funding Provided through 21st Century Cures Act

Sign up for updates:

https://www.nih.gov/allofus-research-program
Definition of Precision Medicine - Oncology
(Doug Lowy, MD, Acting Director, NCI)

Where the individual characteristics of the patient are sufficiently distinct, *interventions can be concentrated on those who will benefit*, sparing expense and side effects for those who will not.

Components of PMI-Oncology

- *Developing and expanding clinical therapy trials* in precision oncology
- Improving *predictive oncology*: by overcoming drug resistance, determining effective combination targeted therapy, and advancing immunotherapy
- Sharpen our ability to diagnose cancer at its earliest *stages*, when it is usually most treatable
- Building a national cancer *knowledge system* that integrates cancer genomic information, clinical information, and laboratory model information
Planned NCI-QIBA Collaboration

- NCI-Radiation Research Program* and the NCI-Cancer Imaging Program:
  - Have funded several investigators (mostly limited-institution clinical trials) exploring a variety of advanced and/or quantitative imaging techniques aimed at improving the process and/or outcomes of radiation therapy for cancer.
  - NCI is now in the process of establishing an informal working group of NCI-funded investigators, experts from QIBA and the Quantitative Imaging Network (NCI-QIN), for brainstorming and assisting these investigators in advancing their efforts to larger multi-institutional clinical trials to definitively evaluate/establish the clinical benefit of quantitative imaging techniques.

* B. Vikram, MD, Chief, Clinical Radiation Oncology Branch (Vikramb@mail.nih.gov) - involves monthly T-cons.

NIH Cancer Moonshot

- President Obama’s (2016) $1 billion initiative “to achieve a decade’s worth of progress in five years.”
- Supports 7 areas for cutting edge research opportunities, among which are:
  - Early Cancer Detection - evaluation of minimally invasive screening assays
  - Genomic Analysis of Tumor & Surrounding Cells
  - Enhanced Data Sharing
  - FDA - Oncology Center of Excellence - combining skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices.
  - Pediatric Cancer

AND

- VP’s Exceptional Opportunities in Cancer Research Fund - focused on high-risk, high-return research identified by the collaborative work and new ideas stimulated by the research community
Federal Cancer Moonshot Initiative Includes RSNA QIBA Profiles

‘Two RSNA Quantitative Imaging Biomarkers Alliance (QIBA) profiles relevant to cancer have been referenced and supported by the federal Cancer Moonshot initiative to increase efforts to prevent, diagnose and treat cancer’:

- 18F-fluorodeoxyglucose (FDG) PET/CT measurements
- CT tumor volume measurements.

Dan Sullivan, RSNA News, January 2017

(Off shoot of Intra-Agency Working Group on Medical Imaging)

NICHD Human Placenta Project

- Goal is to understand placenta development and function across pregnancy
- Emphasis on development of translational technology for use in women
- Large focus on technology development with heavy investment in imaging – MRI and Ultrasound
- Launched in Spring of 2014
- First awards made in late fall of 2015
Funding Opportunities

FY15 R01/R21: Technology (Imaging)
FY15 U01: Technology + environment
FY16 Omics
FY17 Existing Datasets
FY18 Technology beyond standard assessments (Novel imaging allowed)

This complements our substantial investment in investigator-initiated research!

Distribution of FY15 Projects

- 4D Power Doppler that allows visualization of the utero-placental circulation
- Modified MRI that allows measurements of oxygenation and perfusion without the need for contrast agents, manages breathing artifacts, etc.
- Novel methods for isolation of placental vesicles and evaluation of their cargo
- Placental RNA Analysis
- Automated Ultrasound data reads

Investments to date >$53 Million
QIBA Biomarkers: Translation to Clinical Research

CT Volumetry/Cancer – NCI, NINDS, NIDDK, NHLBI, NICHD

FDG-PET (SUV)/Cancer – NCI, NINDS, NIDDK, NHLBI, NICHD

Dynamic Contrast Enhancement MRI/Cancer – NCI, NINDS, NIDDK, NHLBI, NICHD

Perfusion/Diffusion/Flow MRI Biomarker – NINDS, NCI, NICHD

➢ Diffusion-Weighted Magnetic Resonance Imaging (DWI) Profile
  (90-day Public Comment ends 7/28/17)
QIBA Biomarkers: Translation to Clinical Research

CT Lung Density Biomarker – NCI, NHLBI

FDG-PET/Amyloid Biomarker – NINDS

fMRI Biomarker – NINDS, NICHD

MR Elastography Biomarker – NCI, NIDDK

US Shear Wave-Speed/Volume Blood Flow Biomarkers - NCI, NIDDK, NICHD

SPECT Biomarker – NCI, NHLBI

Interagency Working Group, Medical Imaging

• Est. 2015 by Congressional Committee on Science (co-chaired by NIH and NSF Directors), which oversees National Science & Technology Council (NSTC).

• Coordinate & develop Federal investment in medical imaging R&D - goal to improve health of Americans and economic vitality and commercial interest and participation in MI

• Co-chaired by NIBIB and NIST

• Participants: Academia, Professional Societies, Industry, Patient Advocates (2015-2016)

• IWGMI considered data standardization & sharing, quantitative imaging, machine-assisted image recognition & interpretation / “deep learning”

Member Agencies: NIH, NIST, NSF, FDA, DOE, DOD, NASA, FBI, VA, CMS, OMB, OSTP, & Treasury
Interagency Working Group on Medical Imaging (IWGMI)

- **High-value imaging** was selected as focus for December 2006 *White House* blog
- **Roadmap addresses**: data standardization, artificial intelligence, **high-value techniques**, best practices for researchers and clinicians
- Roadmap report is currently under agency review and clearance
- September 2017 symposium on IWGMI and *diagnostic cockpit* planned by Academy of Radiology & Biomedical Imaging Research

NIH Partnerships

1. QIN (NCI): focusing on imaging-derived quantitative measurements of responses to drugs and/or radiation therapy, and/or image-guided interventions (IGI)
2. Medical Device Innovation Consortium (MDIC Board has *ex officio* NIH, FDA & CMS representatives)
3. Trans-NIH/FDA Medical Device Interest Group
4. NIH-NASA Biomedical Research Partnership (NIBIB: new liaison IC)
THANK YOU