

# SG1 National Clinical and Translational Research Capability

- Mission of the National Clinical and Translational Research Capability Strategic Goal Committee:
  - to improve all processes related to the development, approval, activation, enrollment, and completion of clinical trials.
- Methods to develop and implement data-driven process improvement include
  - pilot and mature cross-consortium studies to validate and implement measurements of process milestones and completion times
  - development of standardized definitions of metrics to be used as tools for process evaluation and improvement
  - annual workshop each June to exchange lessons learned and best practices

# PIs for SG#1

- Mary Dysis                      University Washington
- Daniel Ford                      Johns Hopkins
- James Heubi                      Cincinnati

# SG1 Priorities

- Initial focus has been on study activation process
- Other working groups:
  - IND/IDE Support
  - Measuring research participant experience
  - Recruitment of research participants
  - Work environment for research coordinators

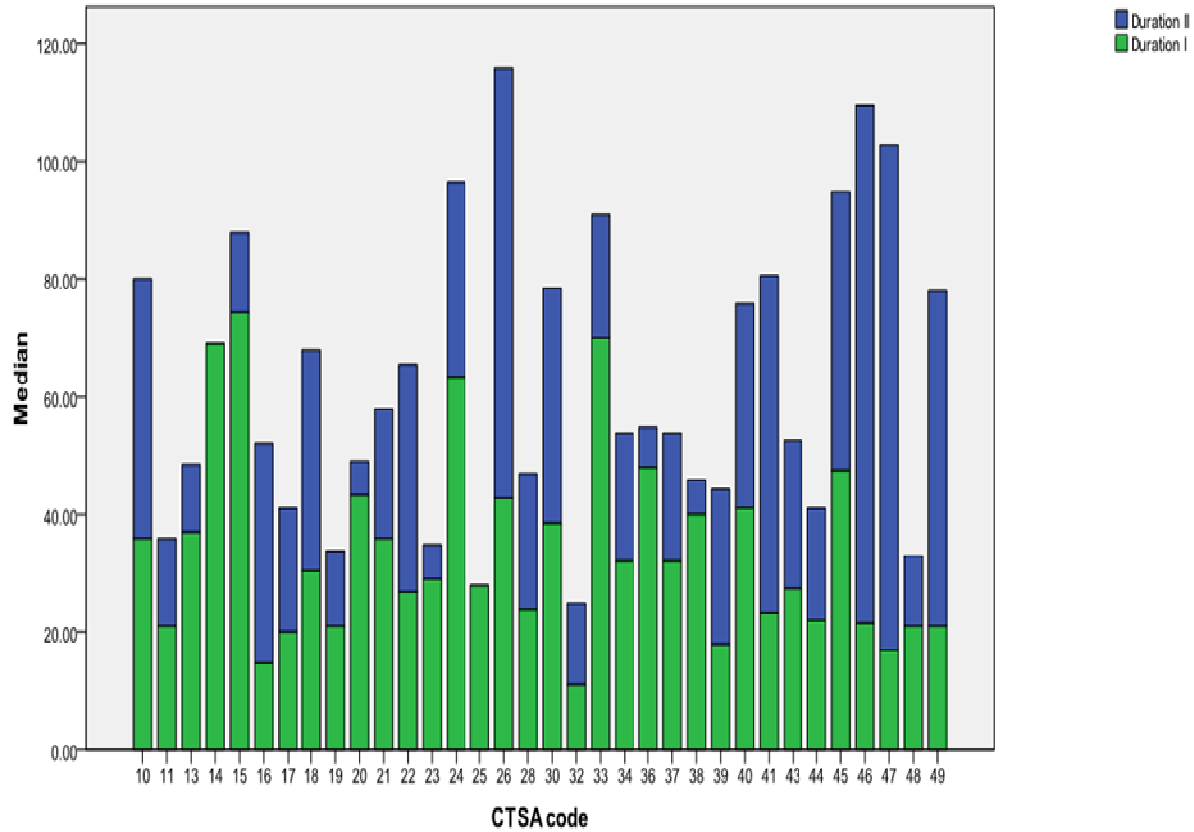
# Highlights of Accomplishments

- Workshops
- Papers planned
- Contracting pilot is underway
- Reports for Task Forces
  - IND/IDE Regulatory
  - Research Coordinator Environment
- Champions of Change

# CTSA IRB Pilot

- Completed IRB Pilot
  - 34 sites participated
  - Data quality was less than optimal
    - Only 44% of 425 final protocols had all dates present
  - Median duration of 64 days from submission to approval
  - Huge variation in times within total duration because IRBs organized differently
  - Some protocols have longer time to approval (protocols with children, Phase I, etc)

# Duration of Phase in IRB Review



# Metrics of IRB Performance Study Team Members

## IRB Subgroup

Co-Chairs

Ray Hutchinson (U Michigan)

Kathleen Uscinski

(Yale University)

Coordinator

DJ McCloskey (NCRR)

## Metric, Analysis, and Mapping

Co-Chairs

Marc Drezner (U Wisconsin)

William Trochim (Weill-Cornell)

Coordinator

DJ McCloskey (NCRR)

## Data Coordinators

Susan Bankowski (OHSU)

Data Coordinators from 31 sites

## REDCap (Vanderbilt)

Paul Harris

Gordon Bernard

## Statistical Team (Weill-Cornell)

William Trochim

Françoise Vermeylen

Cath Kane

# Vision for 2 Years

- Complete pilots and identify reliable, valid measures to assess time to activate multicenter clinical trials at each institution
- Select an independent group to manage data collection and posting of performance metrics for each CTSA institution
- Complete at least one pilot to create metrics for investigator initiated and single center studies

# Vision for 2 Years

- Provide data that CTSA institutions meet the 90 day study activation time 90% of the time
- Work towards meeting a 60 day study activation time 90% of the time
- Complete a white paper addressing value of US academic centers in relation to community and international sites for clinical research (quality of investigators, quality of data, meeting recruitment goals) Still being debated

# Vision for 2 years

- Pilot test at least one approach for measuring the quality of IRB review
- Create tool to measure experience of research participants (satisfaction with consent process, respect from study staff, met expectations, contribution to science)
- Create working group focused on research participant recruitment and retention with expertise in direct recruiting of patients, health care policy, community engagement, health care communications and IT.
  - Create a preliminary set of tools for use locally and nationally to enhance recruitment and retention

# Vision for 7 Years

- Functional website describing study initiation metrics
  - Achieve 90% approval by 30 days
  - Performance ratings of study sponsors
- Will have national master contract used in 50% of commercial – AHC agreements
- Create multiple clinical research networks with single IRB
- Metrics documenting improvements of “patients” perception of participation in research and recruitment rates
- Document high levels of satisfaction for research participants across the CTSA consortium and willingness to participate in a future study

# Vision for 20 years

- A system to continuously measure study activation and other clinical research processes to identify and address barriers as soon as possible
- Possibilities
  - Certified clinical research teams with reduced regulatory burden
  - National clinical research networks that have ability to support research and rapid diffusion of results into clinical practice
  - All health professionals will have training on basics of clinical research leading to positive attitudes toward research and reinforcement for participating

# SG#1 Administrative Supplements

- Yale/Mayo Paired Supplement
  - Develop models for leveraging each institution's strengths to identify and share best practices for study startup
- U Washington
  - Work with the Cystic Fibrosis Foundation database to identify high and low performing sites in terms of study activation and recruitment and try to understand why the sites are different

# How can PI's help?

- Create urgency to change at your institution
- Be advocate for Champion of Change within your institution – help find and support that leader
- Help to increase the quality of the data on IRB/Contracting
- Be sensitive in how you communicate any data on performance times,
  - pilot data is on median of 11 clinical trial protocols per site
- Help to enhance data quality
- CTSA should take the lead in communicating results and improving skills/performance of research teams