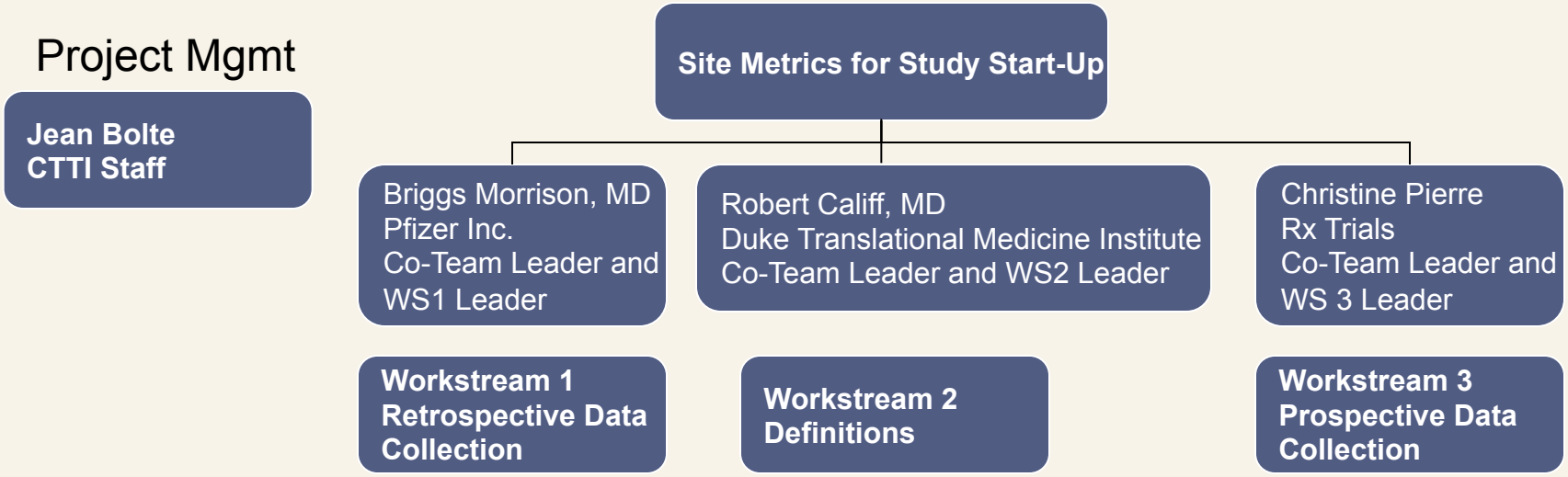
Site Metrics for Study Start-Up Project Overview

May 4, 2011

Project Goal

To identify core data elements that should be collected by all clinical trial sites to allow measurement and improvement of important timeframes for study start-up

Project Organization



Project approved by CTTI Executive Committee 24-Sept-2010

Received authoritative determination from the Duke IRB that this research does not qualify as *human subjects research* on 25-October 2010

Workstream 1: Retrospective Data Collection

Objective

To complete an analysis of the current state of study start-up at sites participating in multicenter clinical trials, including the range of variability in performance using cycle time metrics and a variety of stratifications

Data Collection

- Invitations to participate sent 3-Nov -2010
- Data received from 18 organizations representing:
  - Academic
  - CRO-ARO
  - Biotechnology
  - Device
  - Government
  - Investigators
  - Pharmaceutical
- Data submitted for a 12 month consecutive period
- Results will be reported in the next presentation

Workstream 2 – Expert Meeting May 4, 2011

Objective

- **Through expert meeting with key stakeholders**
  - **Define appropriate site start up metrics to be prospectively collected and analyzed**
  - **Include a standard, specific and measureable definition for each metric**
  - **Agree on set of metrics for inclusion in prospective data collection pilot**

Proposed metrics for today's discussion was developed by a working group in collaboration with CTTI staff

WS-2 Working Group Representation

Academic Institutions	
- Duke University	Rob Califf, Swati Chakraborty
- UCSF	Clay Johnston
- University of Michigan	Dan Ford
Pharmaceutical Companies	
- Pfizer	Briggs Morrison, Soo Bang
US Government	
- FDA	Barabara Buch, Jonathan Helfgott, Susan Libenhaut
- NIH	Andrea Denicoff, Jonathan Kagan
CROs	
- ICON	Julian Rimmer
- Quintiles	Amy Kissam, Debbie Liske
Biotechnology Companies	
- Amgen	Brian York
Device/Diagnostics Companies	
- J&J Device	Lori Lonzetta
Clinical Investigator Groups)	
- RX Trials, Inc.	Christine Pierre
Standard Setting Organizations	
- CDISC	Becky Kush

Workstream 3 Prospective Data Collection

- **Prospective data collection pilot**
  - **Focus is on sites reporting their own data**
  - **Output from today's meeting will help inform the planning and implementation of Workstream 3**
    - **Metrics to be collected**
    - **Strategies for success & potential barriers**
    - **Recommended requirements for an electronic data collection tool for use by sites for reporting requested data**
    - **Site identification and recruitment**
  - **Timeline**
    - **Initiation of data collected targeted for Sept 2011**
    - **Duration and scope of pilot TBD**

QUESTIONS??