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CTSU Operational Support Services for the ET-CTN

Early Drug Development Meeting
April 21, 2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Presentation Agenda

- Describe the Objectives of Consolidating ET-CTN Support Services
- Provide an Overview of CTEP/CTSU Support Services
- Describe Integration Points Between Systems and Organizations

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Transition to Network Model

- Shift from the U01 independent organization arrangement to the Network model requires common support infrastructure
- Leverage CTSU's original objective to harmonize practices and increase efficiencies within the Cooperative Group model.
- Maximize use of same policies, procedures and systems for ET-CTN and National Clinical Trials Network (NCTN).
  - Site can be a member of both ET-CTN and NCTN

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Objectives of Consolidated Support Services

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- Support efficient and timely activation and conduct of clinical trials that meet all regulatory requirements*
- Support collaborations among ET-CTN member institutions and investigators*
- Facilitate member interactions and communications and enable centralized access to trial documentation by ET-CTN member institutions and investigators*
- Help to ensure adequate accrual and increase the rate of accrual to trials
- Improve reporting and tracking of trial accrual
- Reduce cost burden by eliminating redundant systems and processes

** From ET -CTN RFA and Guidelines*

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Common Network Support – Policies, Procedures, and Tools

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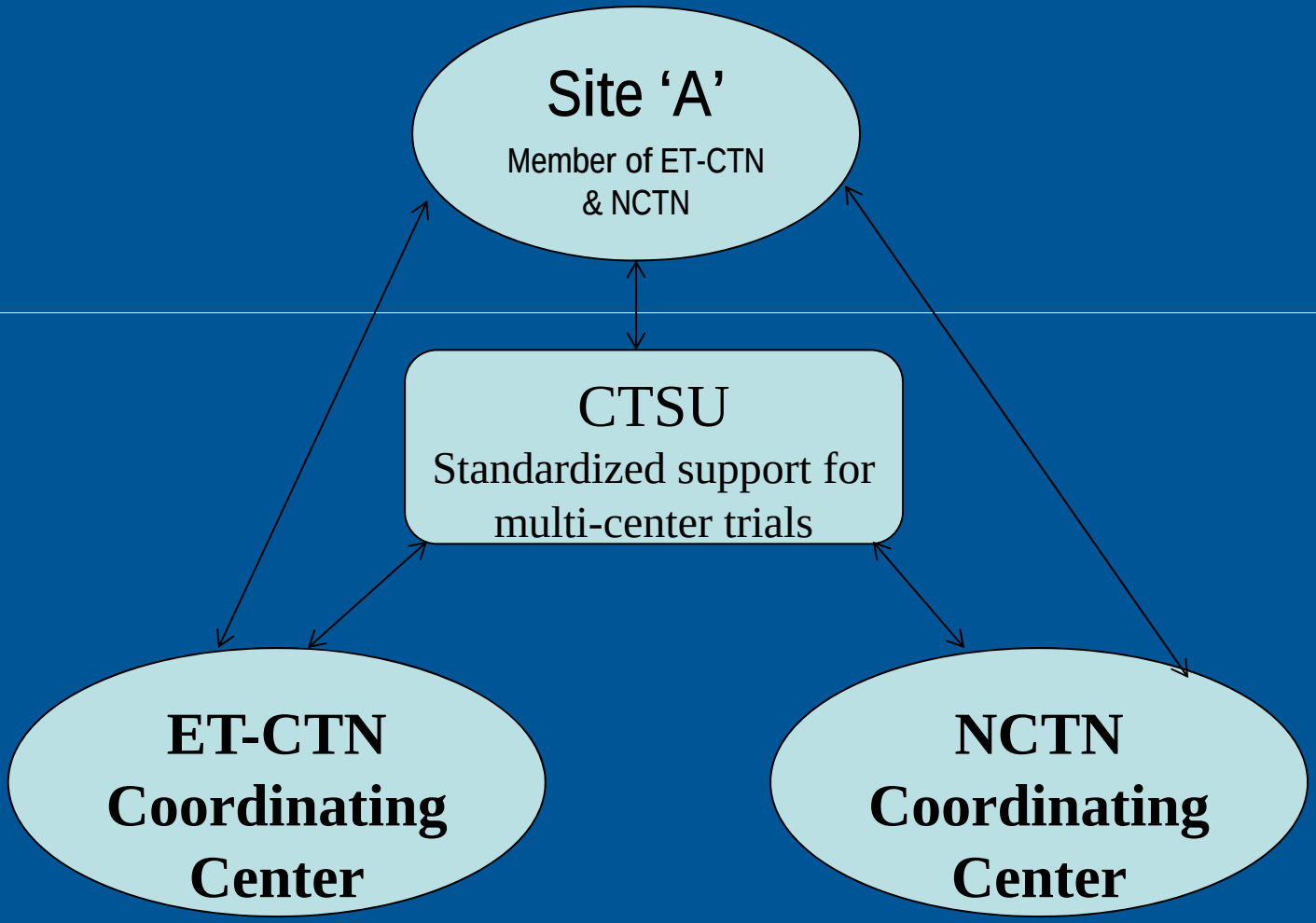

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CTEP/CTSU Support Services

- Investigator Registration (IR)
- CTEP Identity and Access Management (IAM) Account Management & Associate Registration
- Single Sign-On (SSO) Integration using CTEP-IAM
- Institutional and Person Roster Maintenance via the Regulatory Support System (RSS)
- Centralized Regulatory Processing and Study Requirements Management via RSS
- Oncology Patient Enrollment Network (OPEN)
- CDMS Support Center & General Support

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Investigator Registration

- Rationale
  - Ensure compliance with FDA and OHRP regulations
  - Required to submit IRB approvals, enroll patients, treat patients, receive agents, and act as study leadership
- Requirements
  - All MDs or DOs will register with the Pharmaceutical Management Branch (PMB) at CTEP
  - Annual Registration
  - ***Strongly*** encourage creation of CTEP-IAM account (additional online process)

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Associate (non-investigator) Registration

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- Required for system access (ex. Rave and OPEN)
- Completed through the CTEP-IAM process
- Annual re-registration

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Identity Access Management (CTEP-IAM)

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- Web-based system to provide Authentication and Authorization to CTEP/CTSU systems
  - Provides username, password, and role
- Utilizes NIH password standards to ensure system security
  - Passwords must be updated every *60 days*
  - Format requirements (length, case, letters, #'s, special characters)
- Single Sign On (SSO) for CTEP/CTSU systems

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Single Sign On Capability (SSO)

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- Allows access to CTEP/CTSU systems
  - Rave
  - OPEN/Interactive Web Response System (IWRS)
  - caAERS (adverse event reporting and monitoring)
  - Regulatory Support System (RSS)
  - OEWG Timeline Reports
  - OAOP (online investigational agent ordering)
- *Could be used for ET-CTN systems/websites*

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ET-CTN
Institution and Person Rosters

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- Institutions –
  - ALL ET-CTN participating sites MUST be listed on Grant
  - CTEP will manage Institution Roster based on Grant
  - Grant must be amended to add/delete member institutions
- Investigators and Associates –
  - Management
    - Central - ET-CTN Coordinating Center identifies individuals
    - Delegation - ET-CTN Member site are delegated rights to maintain staff for their institution
  - In ALL cases the ET- CTN coordinating center MUST validate their membership
  - Person rosters must be updated annually

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Regulatory Services

- ET-CTN Coordinating Center establishes study participation requirements
- CTSU Regulatory Support office collects and maintains all study participation materials
- Requirements for study participation
  - ET-CTN Member
  - (C)IRB approval
  - Study specific requirements required by ET-CTN coordinating center (ex. study specific training/credentials)
- Linked to patient registration system (OPEN)
  - Site can NOT enroll a patient until ALL requirements are met

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Oncology Patient Enrollment Network (OPEN)

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- Web-based patient registration system with 24/7 access
- Set-up
  - Core set of standard requirements
  - Study specific requirements established by ET-CTN coordinating center
  - Theradex sets up forms
  - Must be caDSR /CDE compliant
- Verifies that all study requirements have been met before patient can be registered
- Link to IWRS - for slot reservation capability and cohort management
- Data re-use - Credentialing and demographic data entered in OPEN transferred to Rave and caAERS

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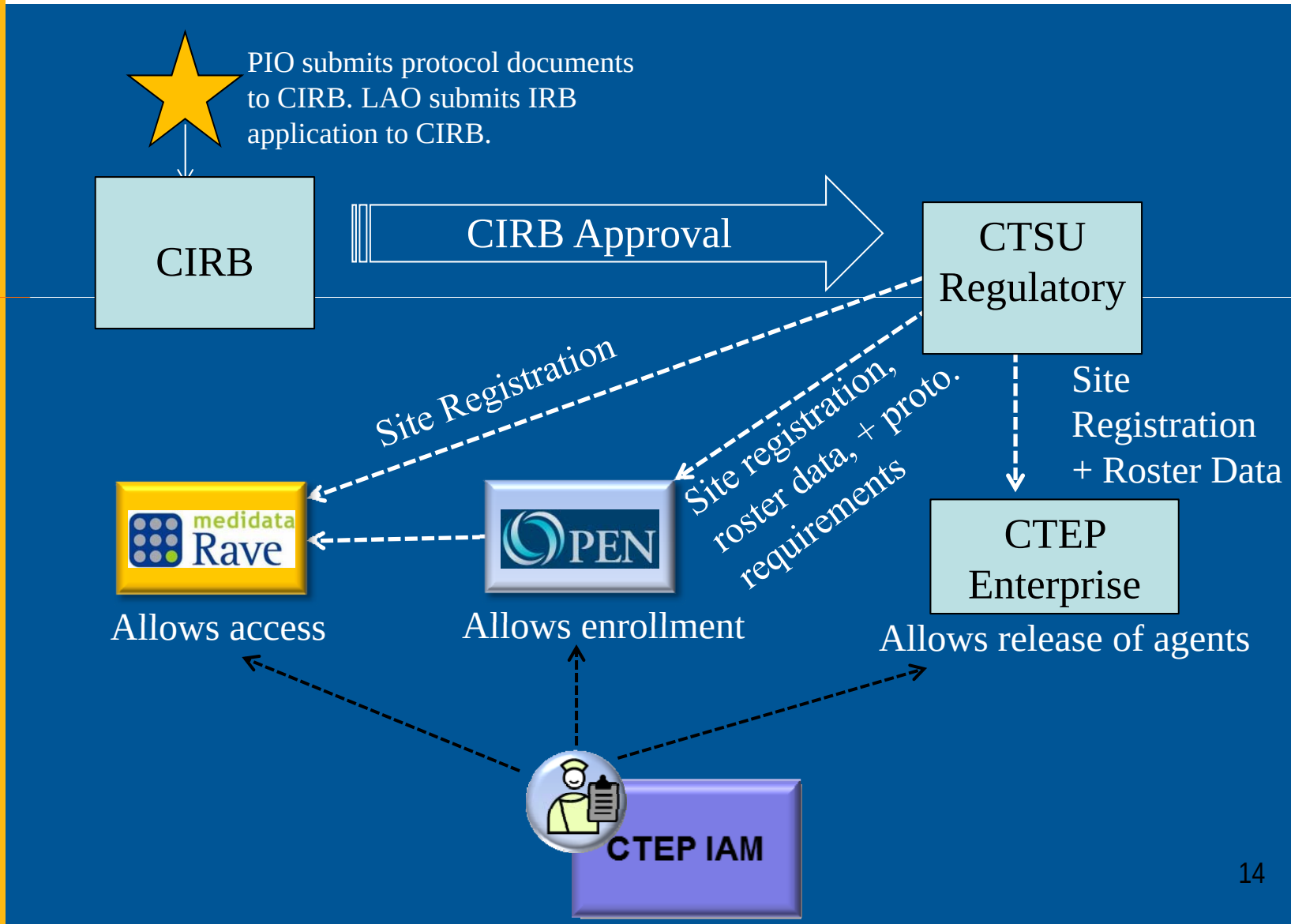
Integrated Infrastructure



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Other Services

- CDMS Support Center (CSC)
  - Supports integration of Rave as common CDMS system across NCI-supported trials
- Protocol support
  - Posting and distribution of protocol documents
  - Logistical language for regulatory, OPEN, and Rave
- Help Desk support
  - M-F: 9 am to 8:30 pm ET
- Communication support
  - CTSU Website
  - CTSU Bi-Monthly Broadcast
  - Targeted announcements

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Benefits of Integration

- Central credential of investigators and management of regulatory data
  - Assures compliance
  - Eliminates need to modify protocol to add or withdraw participants
  - Allows for wider distribution of protocols
  - Decreases time to activate and accrue to protocols
- Central patient registration
  - Provides common system for all clinical sites
  - Improves reporting
  - Allows for integration with the common CDMS

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Questions?