CTSU Operational Support Services for the ET-CTN
Early Drug Development Meeting
April 21, 2013
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
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.
Objectives of Consolidated Support Services

- 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
Common Network Support – Policies, Procedures, and Tools

Site ‘A’
Member of ET-CTN & NCTN

CTSU
Standardized support for multi-center trials

ET-CTN
Coordinating Center

NCTN
Coordinating Center
<table>
<thead>
<tr>
<th>CTEP/CTSU Support Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Investigator Registration (IR)</td>
</tr>
<tr>
<td>• CTEP Identity and Access Management (IAM) Account Management &amp; Associate Registration</td>
</tr>
<tr>
<td>• Single Sign-On (SSO) Integration using CTEP-IAM</td>
</tr>
<tr>
<td>• Institutional and Person Roster Maintenance via the Regulatory Support System (RSS)</td>
</tr>
<tr>
<td>• Centralized Regulatory Processing and Study Requirements Management via RSS</td>
</tr>
<tr>
<td>• Oncology Patient Enrollment Network (OPEN)</td>
</tr>
<tr>
<td>• CDMS Support Center &amp; General Support</td>
</tr>
</tbody>
</table>
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)
# Associate (non-investigator) Registration

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

- 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
## Single Sign On Capability (SSO)

- 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
ET-CTN

Institution and Person Rosters

- 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
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
**Oncology Patient Enrollment Network (OPEN)**

- 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
PIO submits protocol documents to CIRB. LAO submits IRB application to CIRB.

CIRB

CIRB Approval

CTSU Regulatory

Site Registration

Site registration, roster data, + proto. requirements

Allow access

Rave

allows enrollment

OPEN

Allow release of agents

CTEP Enterprise

CTEP IAM
## 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
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
Questions?