Delegation of Tasks Log Update and Demo

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Goals and Objectives

- review the FDA Guidelines for tracking study team members

- Discuss Delegation of Tasks Log protocol designation and connection to the Registration and Credential Repository

- Demonstration of the DTL application

- Describe the development process for DTL development/deployment and FDA report capability
Delegation of Tasks Log – WHY??

- FDA Guidance documents
- Statement of Investigator (FDA 1572 FAQ)
- Investigator responsibilities
- 21 CFR 312.53 - selection of investigators
NCI’s Registration and Credential Repository and Delegation of Tasks Log Applications - Timelines

- July 31, 2017: RCR released to production
- August 24, 2017: DTL released to production
- September 2017: Begin DTL Pilot Phase
- October 2017: Enhanced reporting capabilities
- December 2017: Deploy RCR Feature Enhancements
- February 2018: Extend DTL Pilot
- 3Q 2018: First RCR Registration cycle complete
Delegation of Tasks Log

- Online application within the CTSU website that is used to define and maintain people and tasks at the protocol and site level

- Identify Clinical Investigator (CI) for each protocol

- Complete list of study team for the protocol at the site

- Record study-specific responsibilities

- Verify qualifications of study personnel

- Record of protocol-specific training (if applicable)
Delegation of Tasks Log Implementation

- Ongoing protocol process
  - LPO amends protocol to include updated CTSU language including RCR and DTL information
  - LPO generates and submits DTL template through CTSU application to CTEP PIO
  - CTEP reviews/approves DTL template and notifies LPO
  - LPO “activates” template
  - Sites have 60 days from the “activation” of the template by the LPO to complete their site and protocol-specific DTL
    - Failure to get approved DTL in 60 days = Site Registration Status → PENDING
Delegation of Tasks Log Implementation

- New Protocols
  - LPO submits DTL template with protocol
  - DTL template reviewed/approved at time of protocol review at CTEP
  - DTL can be “activated” with protocol activation
    - Sites required to have IRB approval submitted prior to DTL submission
      - Allows appropriate system checks to happen
      - DTL approval required for site approval
      - CI required to sign with any significant updates (minimum annually)
Delegation of Tasks Log Integration

• Integrates across CTEP CORE systems
  • OPEN – controls LOV for selection of enrolling, treating, consenting persons
  • RAVE – controls write access
  • RSS
    • Required for site registration approval
    • Enforces person registration types and roster affiliations
    • RSS flags protocols that have DTL available
Delegation of Tasks Log Protocols

• Initial pilot consisting of 2 protocols
  EA8143
  A051301

• 8 additional protocols to follow
  A021502   S1605
  EA5142   S1418 (?)
  NRG-GI004 (?)   AEWS1221
  NRG-HN004 (?)   AALL1331
Site-Protocol Registration Report Workflow

CTEP IAM
Identification Authentication
Manages an individual’s user account and password

RCR
NCI Person Registration
Verifies an individual’s credentials for study participation

DTL
Research Activity Assignments
Assigns an individual to study activities at a specific site

Restricts research activity assignments

Output
Form FDA 1572
NCI Biosketch
Financial Disclosure Form (FDF)

NCI Site-Protocol Registration Report
Site-Protocol Delegation of Tasks Logs
- Summary Log
- Signed Logs
Clinical Investigator:
- Form FDA 1572
- NCI Biosketch
- FDF
Sub-Investigator (1):
- NCI Biosketch
- FDF
Sub-Investigator (2):
- NCI Biosketch
- FDF
Sub-Investigator (...):
- NCI Biosketch
- FDF

Site-Protocol Delegation of Tasks Summary Log
Site-Protocol Delegation of Tasks Signed Logs
Delegation of Tasks Log Demo
QUESTIONS ???
DTL Reference Slides
References

- 21 CFR 312.53 - Selecting investigators and monitors
Site DTL Status vs. Task Status

**DTL Status**

- **Initiated:** DTL started but not submitted for CI Signature
- **Awaiting CI Approval:** DTL completed but pending CI signature
- **Unapproved:** The last person with a mandatory role is no longer active, or other failed check
- **Approved:** All required tasks assigned and DTL signed by CI
- **Retired:** The DTL is no longer active due to a new version (terminal status)

**Task Status**

- **Active:** The assignee has an active CTEP status, active roster status on a participating roster, appropriate registration type, and completed any required training
- **Pending:** The assignee has a suspended CTEP status, suspended on last participating site roster, task training not complete
- **Awaiting CI Approval:** Task requires CI to re-sign the DTL
- **Inactive:** CTEP status is other than active or suspended, last participating roster status is withdrawn, no longer at the appropriate registration level, or by manual update
<table>
<thead>
<tr>
<th>TASK</th>
<th>DESCRIPTION</th>
<th>Primary</th>
<th>Requires CI Approval</th>
<th>Mandatory or Optional</th>
<th>Limited to single person at the site</th>
<th>Registration Type</th>
<th>Rostering Required</th>
<th>Audit Validation Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Investigator</td>
<td>Investigator at site responsible for signing the DTL for a given protocol and with overall responsibility for the study conduct at the site</td>
<td>Y</td>
<td>Y</td>
<td>M</td>
<td>Y</td>
<td>IVR</td>
<td>Y</td>
<td>System</td>
</tr>
<tr>
<td>DTL Administrator</td>
<td>Manages DTL after CI signature</td>
<td>Y</td>
<td>Y</td>
<td>M</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Y</td>
<td>System</td>
</tr>
<tr>
<td>Treating or Crediting Investigator (enrolling)</td>
<td>Investigator listed in OPEN as having responsibility for subject treatment</td>
<td>N</td>
<td>Y</td>
<td>M</td>
<td>N</td>
<td>IVR</td>
<td>Y</td>
<td>System</td>
</tr>
<tr>
<td>Consenting Person</td>
<td>Person listed in OPEN as having responsibility for consent</td>
<td>N</td>
<td>Y</td>
<td>M</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Y</td>
<td>System; Site Audit</td>
</tr>
<tr>
<td>Drug Shipment Investigator</td>
<td>In OPEN the investigator that will receive CTEP distributed agent for the enrollment</td>
<td>N</td>
<td>Y</td>
<td>O</td>
<td>N</td>
<td>IVR</td>
<td>Y</td>
<td>System</td>
</tr>
<tr>
<td>H&amp;P Assessments</td>
<td>Conducts Physical Exam and assessments</td>
<td>N</td>
<td>N</td>
<td>M</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Y</td>
<td>Site Audit</td>
</tr>
<tr>
<td>Eligibility Assessment</td>
<td>Verification of eligibility</td>
<td>N</td>
<td>Y</td>
<td>M</td>
<td>N</td>
<td>IVR, NPIVR</td>
<td>Y</td>
<td>Site Audit</td>
</tr>
<tr>
<td>Tox, Assessment</td>
<td>Assess adverse events</td>
<td>N</td>
<td>Y</td>
<td>M</td>
<td>N</td>
<td>IVR, NPIVR</td>
<td>Y</td>
<td>Site Audit</td>
</tr>
<tr>
<td>Rave CRA</td>
<td>Rave write access; responsible for data management and uploads of central monitoring documents; and using Rave-CTEP-AERS safety reporting tools</td>
<td>N</td>
<td>N</td>
<td>M*</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Y</td>
<td>System</td>
</tr>
<tr>
<td>End Point Assessment</td>
<td>Assess study end points</td>
<td>N</td>
<td>Y</td>
<td>M</td>
<td>N</td>
<td>IVR, NPIVR</td>
<td>Y</td>
<td>Site Audit</td>
</tr>
<tr>
<td>OPEN Registrar</td>
<td>OPEN registration access</td>
<td>N</td>
<td>N</td>
<td>M*</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Y</td>
<td>System</td>
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<tr>
<td>Rave Investigator</td>
<td>Rave investigator sign-off. Role needed to access Rave and signoff on CRFs. Currently, maintained as part of the RSS roles by roster owner (on a participating roster at</td>
<td>N</td>
<td>Y</td>
<td>O</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Y</td>
<td>System</td>
</tr>
</tbody>
</table>
Current NCI DTL Tasks List (2/2)

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
<th>N</th>
<th>O</th>
<th>Y</th>
<th>IVR, NPIVR, AP</th>
<th>Site Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Study/Site Contact</td>
<td>Listed as point of contact for the study</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Site Audit</td>
</tr>
<tr>
<td>Regulatory Contact</td>
<td>Site staff responsible for regulatory submissions and maintaining essential documents</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Site Audit</td>
</tr>
<tr>
<td>Study-related interventions</td>
<td>Responsible for coordinating and/or administering study-related interventions and procedures</td>
<td>N</td>
<td>N</td>
<td>O</td>
<td>N</td>
<td>IVR, NPIVR, AP, A</td>
</tr>
<tr>
<td>Source Documentation Completion</td>
<td>Responsible for collecting data on study-related assessments</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
<td>Y</td>
</tr>
<tr>
<td>Investigational Product Accountability</td>
<td>Tracking of distribution and return of investigational product</td>
<td>N</td>
<td>N</td>
<td>M</td>
<td>N</td>
<td>IVR, NPIVR, AP, A</td>
</tr>
<tr>
<td>Pathology/ Lab Support</td>
<td>Pathology-lab support</td>
<td>N</td>
<td>N</td>
<td>O</td>
<td>N</td>
<td>IVR, NPIVR, AP, A</td>
</tr>
<tr>
<td>RT/Imaging-Support</td>
<td>RT/Imaging support (primarily TRIAD related, but could be other)</td>
<td>N</td>
<td>N</td>
<td>O</td>
<td>N</td>
<td>IVR, NPIVR, AP, A</td>
</tr>
<tr>
<td>Patient Screening/ Recruiting</td>
<td>Responsible for screening and recruiting of subjects</td>
<td>N</td>
<td>N</td>
<td>O</td>
<td>N</td>
<td>IVR, NPIVR, AP</td>
</tr>
<tr>
<td>Agent Prescribing</td>
<td>Responsible for writing an order for a patient that is not a CTEP IND agent</td>
<td>N</td>
<td>N</td>
<td>O</td>
<td>N</td>
<td>IVR, NPIVR</td>
</tr>
<tr>
<td>IND Prescribing</td>
<td>Responsible for writing an order for a patient that is a CTEP IND agent</td>
<td>N</td>
<td>Y</td>
<td>M</td>
<td>N</td>
<td>IVR</td>
</tr>
</tbody>
</table>

*Mandatory if using OPEN/Rave for the protocol