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

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

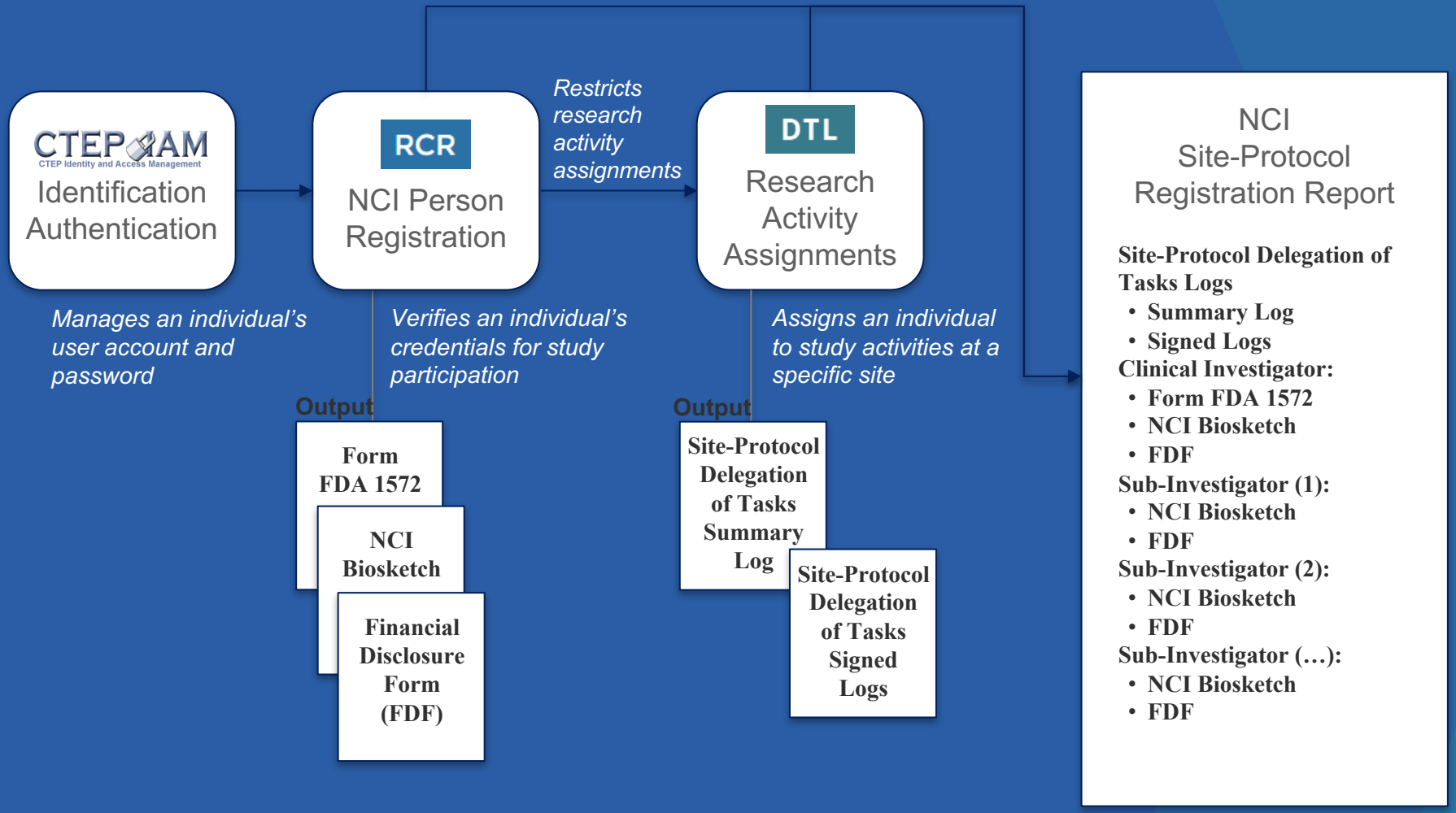
- Integrates across CTEP CORE systems
  - OPEN – controls LOV for selection of enrolling, treating, consenting persons
  - RAVE – controls write access
  - RSS
    - Required for site registration approval
    - Enforces person registration types and roster affiliations
    - RSS flags protocols that 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



Delegation of Tasks Log Demo

QUESTIONS ???

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www.cancer.gov/espanol

DTL Reference Slides

References

- Frequently Asked Questions – Statement of Investigator (Form FDA 1572) - http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf
- Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects http://www.fda.gov/downloads/drugs/guidancecompliancereglatorinformation/guidance/ucm187772.pdf
- 21 CFR 312.53 - Selecting investigators and monitors
- Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf

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

Current NCI DTL Tasks List (1/2)

TASK	DESCRIPTION	Primary	Requires CI Approval	Mandatory or Optional	Limited to single person at the site	Registration Type	Rostering Required	Audit Validation Rule
Clinical Investigator	Investigator at site responsible for signing the DTL for a given protocol and with overall responsibility for the study conduct at the site	Y	Y	M	Y	IVR	Y	System
DTL Administrator	Manages DTL after CI signature	Y	Y	M	N	IVR, NPIVR, AP	Y	System
Treating or Crediting Investigator (enrolling)	Investigator listed in OPEN as having responsibility for subject treatment	N	Y	M	N	IVR	Y	System
Consenting Person	Person listed in OPEN as having responsibility for consent	N	Y	M	N	IVR, NPIVR, AP	Y	System; Site Audit
Drug Shipment Investigator	In OPEN the investigator that will receive CTEP distributed agent for the enrollment	N	Y	O	N	IVR	Y	System
H&P Assessments	Conducts Physical Exam and assessments	N	N	M	N	IVR, NPIVR	Y	Site Audit
Eligibility Assessment	Verification of eligibility	N	Y	M	N	IVR, NPIVR	Y	Site Audit
Tox. Assessment	Assess adverse events	N	Y	M	N	IVR, NPIVR	Y	Site Audit
Rave CRA	Rave write access; responsible for data management and uploads of central monitoring documents; and using Rave-CTEP-AERS safety reporting tools	N	N	M*	N	IVR, NPIVR, AP	Y	System
End Point Assessment	Assess study end points	N	Y	M	N	IVR, NPIVR	Y	Site Audit
OPEN Registrar	OPEN registration access	N	N	M*	N	IVR, NPIVR, AP	Y	System
Rave Investigator	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	N	Y	O	N	IVR, NPIVR	Y	System

Current NCI DTL Tasks List (2/2)

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

*Mandatory if using OPEN/Rave for the protocol