Managing Delegation of Tasks Logs

Matthew Boron, RPh
PMB, CTEP, NCI

November 2, 2018
## Registration and Credential Repository (RCR) Update

<table>
<thead>
<tr>
<th>Registration Type</th>
<th>Correct Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>28</td>
</tr>
<tr>
<td>AP</td>
<td>15717</td>
</tr>
<tr>
<td>IVR</td>
<td>19836</td>
</tr>
<tr>
<td>NPIVR</td>
<td>1215</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>36796</strong></td>
</tr>
</tbody>
</table>
Registration and Credential Repository (RCR) ... more to come

- Enhanced RC and back-up RC functionality
- Reports (site protocol reports – with DTLs, 1572 reports)
- Review of profile details (HSP / GCP / licensing)
Delegation of Tasks Log (DTL) - What is it?

• documents the delegation of tasks by the site Clinical Investigator (CI) to appropriately trained site staff at the clinical site for a protocol

• For select protocols, a signed DTL is required to obtain an approved site registration and enroll subjects in OPEN

• required for select protocols as determined by the CTEP or the Division of Cancer Prevention (DCP)
What Studies Require One?

- CTEP Investigational New Drug (IND) application, and/or that support FDA registration
- Information on DTL requirements is included in the protocol webpages [See CTSU members’ website → Protocols or Regulatory Tabs → Protocol Requirements subtab]
- DTL activation notices will be in Bi-monthly Broadcasts and/or targeted broadcasts when a new DTL is activated on an existing study
ALLIANCE protocols requiring a Delegation of Tasks Log

• 15 study DTLs activated

  • **A021502**: Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair

  • **A051301**: A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma of the Activated B-cell Subtype

  • **A021602**: Randomized, Double-Blinded Phase III Study of CABozantinib Versus Placebo IN Patients with Advanced NEuroendocrine Tumors After Progression on Everolimus (CABINET)
When does the DTL have to be Completed?

• For newly activated studies, the DTL must be complete prior to obtaining an approved site registration status.

• For already active studies, registered sites have 60 calendar days to complete the DTL after activation of the amendment to retain an approved site registration status.

• For new versions of the DTL on a study, registered sites have 60 calendar days to complete the DTL update to retain an approved site registration status.
Requirements for Assigning Tasks

- All tasks on the DTL require the assignee to have an active CTEP registration status
- Most tasks are limited to individuals on a participating roster at the site and registered in the Registration and Credential Repository (RCR)
- While there is a core set of required tasks, optional tasks may vary between studies
- The Site DTL Browser and Master Task List provide more detail on requirements for DTL assignment
Delegation of Tasks Log – who should I add?

• IVR (INVESTIGATOR)
  • CTEP-Sponsored treatment trials
    • M.D., D.O., international equivalent
  • DCP-Sponsored trials / some CTEP non-treatment trials
    • Multiple different healthcare professionals
Delegation of Tasks Log – who should I add?

**INVESTIGATOR ONLY**

- Clinical Investigator
- Drug Shipment Investigator
- IND prescribing (investigational arm and SOC arms)
- Treating / Enrolling person
Delegation of Tasks Log – who should I add?

NPIVR (Non-Physician Investigator)

• Mid-level providers
  • Examples, not limited to:
    • APN
    • PA
    • PharmD
    • NP
    • MPH
    • Etc.
Delegation of Tasks Log – who should I add?

NPIVR (Non-Physician Investigator)

• Eligibility
• End point assessment
• Enrolling/Treating (CTEP non-treatment trials and some DCP studies)
• History and Physical
• Toxicity Assessment
• Agent Prescribing -- maybe
• Rave Investigator – maybe
Delegation of Tasks Log – who should I add?

**AP (Associate Plus)**

- CRA / RN / Pharmacist
- RAVE roles (also requires role assignment in RSS)
- NCTN/ETCTN/LAPS/LAO/Site Administrators
- Auditor
- Registrar – OPEN (also requires role assignment in RSS)
Delegation of Tasks Log – who should I add?

AP (Associate Plus)

• Delegation of Tasks Log Administrator
• Consenting
• Investigational Product Accountability
• OPEN Registrar
• RAVE CRA
Delegation of Tasks Log Update

• Email communications
  • CI and DTLA(s)
  • CI approval required tasks
  • Annual (30, 14 and 1 day prior to due date)
Delegation of Tasks Log Issues

• RCR registration suspended
  • Person will not be in LOVs for OPEN/DTL
  • Last person on a required task ➡ DTL will change to unapproved and Site Registration status will be set to PENDING
  • Can no longer be Site Protocol PI (IRB PI)
Delegation of Tasks Log Questions

• Staff covering multiple sites – cloning

• Clinical Investigator practicing at multiple sites – What is reasonable?

• Changes to DTL – CI signature Required?

• General DTL site navigation – CI dashboard
Delegation of Tasks Log on the Horizon

- Bulk assignment / removal
- Bulk signing
- Dashboard for CI to help navigate signing of documents
- Local tasks – still looking into this
Where can I find Help?!?
Questions??