UC BRAID Contracting Initiative

Improving Processes

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Goals & Approach

• Increasing attention to clinical research administration performance

• Goals:
  – Drive performance improvement initiatives
  – Identify best practices and models to be adopted

• Collected 581 new contracts and 246 amendments over 18 months in REDCap
New Contracts: Average Time Between Minimum Documents Received, First Comments Provided, and Contract Terms Finalized

Area for improvement?

Chief delays?

Days

- Campus A (n=178)
  - Minimum Documents Received: 33 days
  - First Comments Provided: 46 days

- Campus B (n=130)
  - Minimum Documents Received: 7 days
  - First Comments Provided: 29 days

- Campus C (n=128)
  - Minimum Documents Received: 28 days
  - First Comments Provided: 59 days

- Campus D (n=94)
  - Minimum Documents Received: 6 days
  - First Comments Provided: 15 days

- Campus E (n=36)
  - Minimum Documents Received: 18 days
  - First Comments Provided: 44 days

- All sites (n=566)
  - Minimum Documents Received: 21 days
  - First Comments Provided: 39 days
Test Article

New Contracts (n=581)

- Drug: 89%
- Device: 10%
- Both Drug & Device: 1%
PI- vs. Sponsor-initiated Contracts: Average Time Between Minimum Documents Received and Contract Terms Finalized*

<table>
<thead>
<tr>
<th>Days</th>
<th>PI-initiated</th>
<th>Sponsor-initiated</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>49.5</td>
<td>49.5</td>
</tr>
<tr>
<td>10</td>
<td>70.4</td>
<td>70.4</td>
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</tbody>
</table>

*New Contracts

PI-initiated studies take 42% longer
UCOP Master Agreements: New Contracts

Average Time Between Minimum Documents Received and Contract Terms Finalized

<table>
<thead>
<tr>
<th></th>
<th>Without Master</th>
<th>With UCOP Master Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>73 days</td>
<td>39 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>=47% decrease</td>
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</tbody>
</table>

218 (38%) UCOP Master Used
362 (62%) No UCOP Master
Clinical Research Organizations (CROs)

New Contracts (n=566)

- Contracting With CRO: 34%
- No CRO: 66%

Average Time Between Minimum Documents Received and Contract Terms Finalized

<table>
<thead>
<tr>
<th></th>
<th>No CRO (n=376)</th>
<th>Contracting w/ CRO (n=189)</th>
</tr>
</thead>
<tbody>
<tr>
<td>57 days</td>
<td></td>
<td>65 days</td>
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<tr>
<td>=14% increase</td>
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</tbody>
</table>
Number of Contract Terms Finalized Same Day or Before Final Documents/Approvals* Received (n=581)

*Examples include:
Coverage Analysis
IRB approval
Approved budget
Economic Interest and Financial Disclosure
Next Steps

• Continue to increase # of master agreements
• Strengthen cross-campus collaboration
• Improve process with respect to CROs
• Identify tools and resources to expedite PI-initiated studies
• Compare results with benchmarks from other institutions
Partnerships - Thanks

Contracting Working Group: Erick Jenkins (lead), Jennifer Ford, Hillary Kalay, Helene Orescan, Rachael Sak, Irene Shin, Tam Tran

Evaluation consultation and data analysis support: Terry Nakazono, John Fontanesi, Pamela Davidson (UCLA CTSI-Evaluation Sciences Program), Nate Buscher (Program Manager, UC BRAID)

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