UC BRAID Contracting Initiative

Improving Processes

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October 15, 2013
Background

- Increasing attention to clinical research administration performance
- Benchmarking and comparative reporting used to identify performance strengths and gaps
- Drive performance improvement initiatives
- Part of a broader initiative to standardize National CTSA Common Metrics
Project Goals

• Provide a pragmatic approach to metrics and data collection
• Provide benchmarks for comparison and opportunities for collective learning
• Identify best practices and models that can be adopted
Rationale

A collaborative approach provides greater benefits to each participant than could be accomplished alone.
What we did: Harmonization

• Harmonized definitions for contracting processes
• Ensured contract types to be tracked are comparable
• Harmonized metrics and data to be collected
• Created guidelines to facilitate uniform interpretation and data entry
What we did: Data collection

• Developed and tested simple, easy to use tool in REDCap
• Initiated data collection July 2013 on all new projects
• 221 contracts entered (as of October 6th)
• 78 contracts completed (as of October 6th)
## Characteristics of Contracts

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Contracts (n=221) Completed (%)</td>
<td>78 (35)</td>
</tr>
<tr>
<td>Contract Type (n=217)</td>
<td></td>
</tr>
<tr>
<td>New (%)</td>
<td>152 (70)</td>
</tr>
<tr>
<td>Amendment to Existing Contract (%)</td>
<td>65 (30)</td>
</tr>
<tr>
<td>Contracting with a Clinical Research Organization (n=218)</td>
<td></td>
</tr>
<tr>
<td>Yes (%)</td>
<td>46 (21)</td>
</tr>
<tr>
<td>Contracting with Academic Medical Center (n=217)</td>
<td></td>
</tr>
<tr>
<td>Yes (%)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Test Article (n=213)</td>
<td></td>
</tr>
<tr>
<td>Drug (%)</td>
<td>184 (86)</td>
</tr>
<tr>
<td>Device (%)</td>
<td>26 (12)</td>
</tr>
<tr>
<td>Both Drug &amp; Device (%)</td>
<td>3 (1)</td>
</tr>
</tbody>
</table>
For Those Contracts Completed (n=73)*, Average No. of Days Between:

- Minimum Documents Received and Contract Terms Finalized (12.2)
- Contract Terms Finalized and Fully Executed Contract (14.5)
- Minimum Documents Received and Fully Executed Contract (26.7)

*Completed contracts with no days reported were excluded from this analysis.
## Characteristics of Contracts (cont.)

<table>
<thead>
<tr>
<th>Description</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCOP Master Agreement Used (n=206)</td>
<td></td>
</tr>
<tr>
<td>Yes (%)</td>
<td>68 (33)</td>
</tr>
<tr>
<td>Campus Master Used (n=206)</td>
<td></td>
</tr>
<tr>
<td>Yes (%)</td>
<td>13 (6)</td>
</tr>
<tr>
<td>Reliance campus - another campus is negotiating (n=218)</td>
<td></td>
</tr>
<tr>
<td>Yes (%)</td>
<td>5 (2)</td>
</tr>
<tr>
<td>Sponsor or UC PI Initiated Trial (n=217)</td>
<td></td>
</tr>
<tr>
<td>Sponsor (%)</td>
<td>202 (93)</td>
</tr>
<tr>
<td>UC Primary Investigator (%)</td>
<td>14 (6)</td>
</tr>
<tr>
<td>Non-UC Investigator (%)</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>
Average No. of Days between Minimum Documents Received and Fully Executed Contract (n=73)*

*Completed contracts with no days reported were excluded from this analysis.
What the Pilot Data Tell Us

For all contracts

• The ratio of new to amended contract types is 70/30
• About 21% contracted with a CRO
• About 23% used existing terms and conditions
• About 33% used a UCOP Master Agreement
• The majority of trials (93%) are sponsor-initiated
What the Pilot Data Tell Us

For completed contracts

• Mean no. of days between minimum documents received and fully executed contract is 25*

• Those using existing terms and conditions had an average of 33 days completion time compared to 26 days for those that didn’t

* Note – Reflects data collection period of 7 weeks, as data collection goes on we anticipate time to execution to move toward industry standard of 60 – 72 days.
Limitations/Caveats

- Coverage analysis will adversely impact the contracting process
- Small sample size, short duration of collection
- The executed contracts represent early completed sample and represent atypical outcome. Industry standard is closer to 60 – 72 days
Next Steps

• Continue data collection & tracking
• Assess contracting practices at each campus for
  – Processes that can be leveraged across campuses
  – Processes that don’t work and their causes
• Assess long-term solutions/technologies for continuous tracking
• Finish data collection by June 30, 2014 and begin data analysis
Partnerships - Thanks

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

**Evaluation consultation and data analysis support:** Terry Nakazono, Pamela Davidson (UCLA CTSI-Evaluation Sciences Program)

**Informatics/REDCap support:** Martin Lai (UCLA-CTSI Informatics Core)