UC BRAID Contracting Initiative

Improving Processes

Helene Orescan, Pamela Davidson, Jennifer Ford, Erick Jenkins, Hillary Kalay, Terry Nakazono, Rachael Sak, Irene Shin, Tam Tran

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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

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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

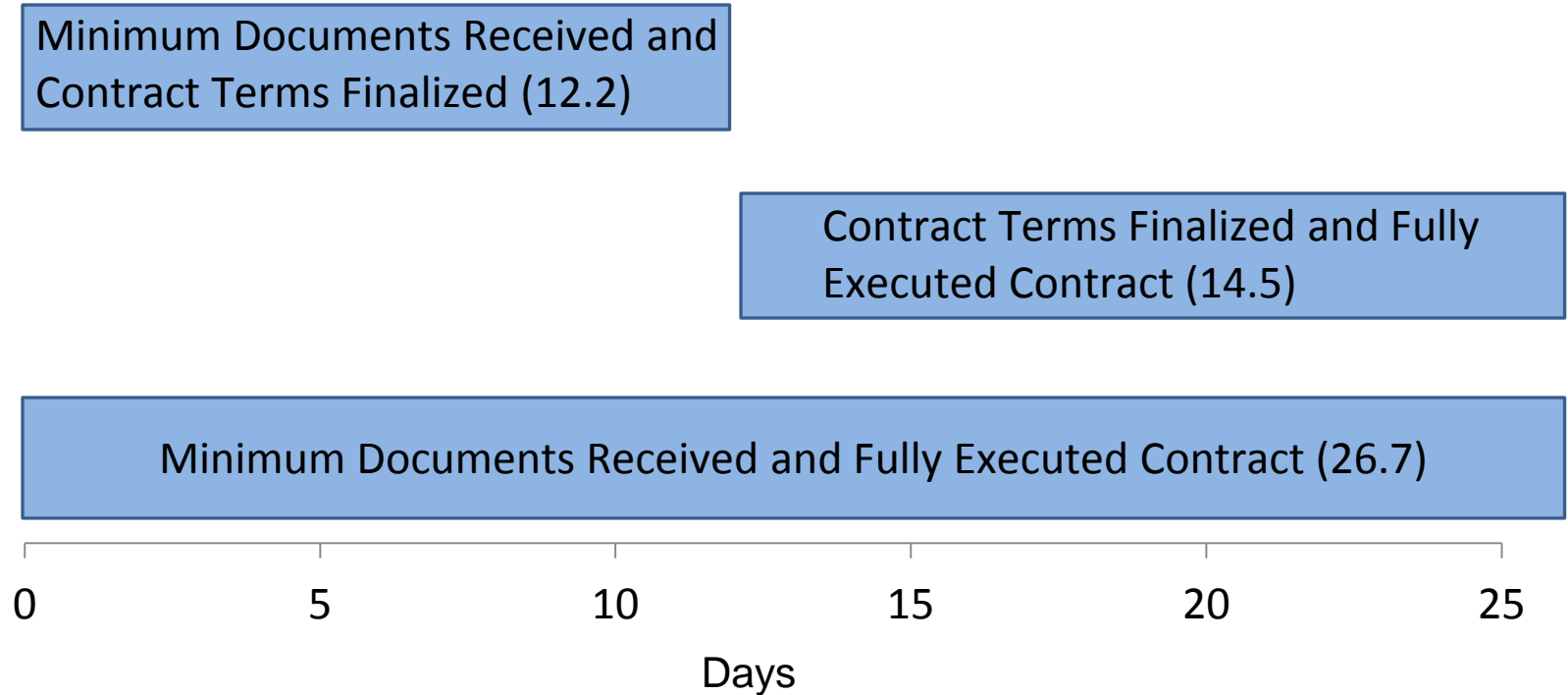- Created guidelines to facilitate uniform interpretation and data entry

What we did: Data collection

- Developed and tested simple, easy to use tool in REDCap

- Initiated data collection July 2013 on all <u>new projects</u>

- **221** contracts entered (as of October 6th)

- **78** contracts completed (as of October 6th)

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Characteristics of Contracts

	Total
Total Contracts (n=221) Completed (%)	78 (35)

Contract Type (n=217)
    New (%)
    Amendment to Existing Contract (%)
	152 (70)
	65 (30)

Contracting with a Clinical Research Organization (n=218) Yes (%)	46 (21)
Contracting with Academic Medical Center (n=217) Yes (%)	3 (1)

Test Article (n=213)
    Drug (%)
    Device (%)
    Both Drug & Device (%)
	184 (86)
	26 (12)
	3 (1)

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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)

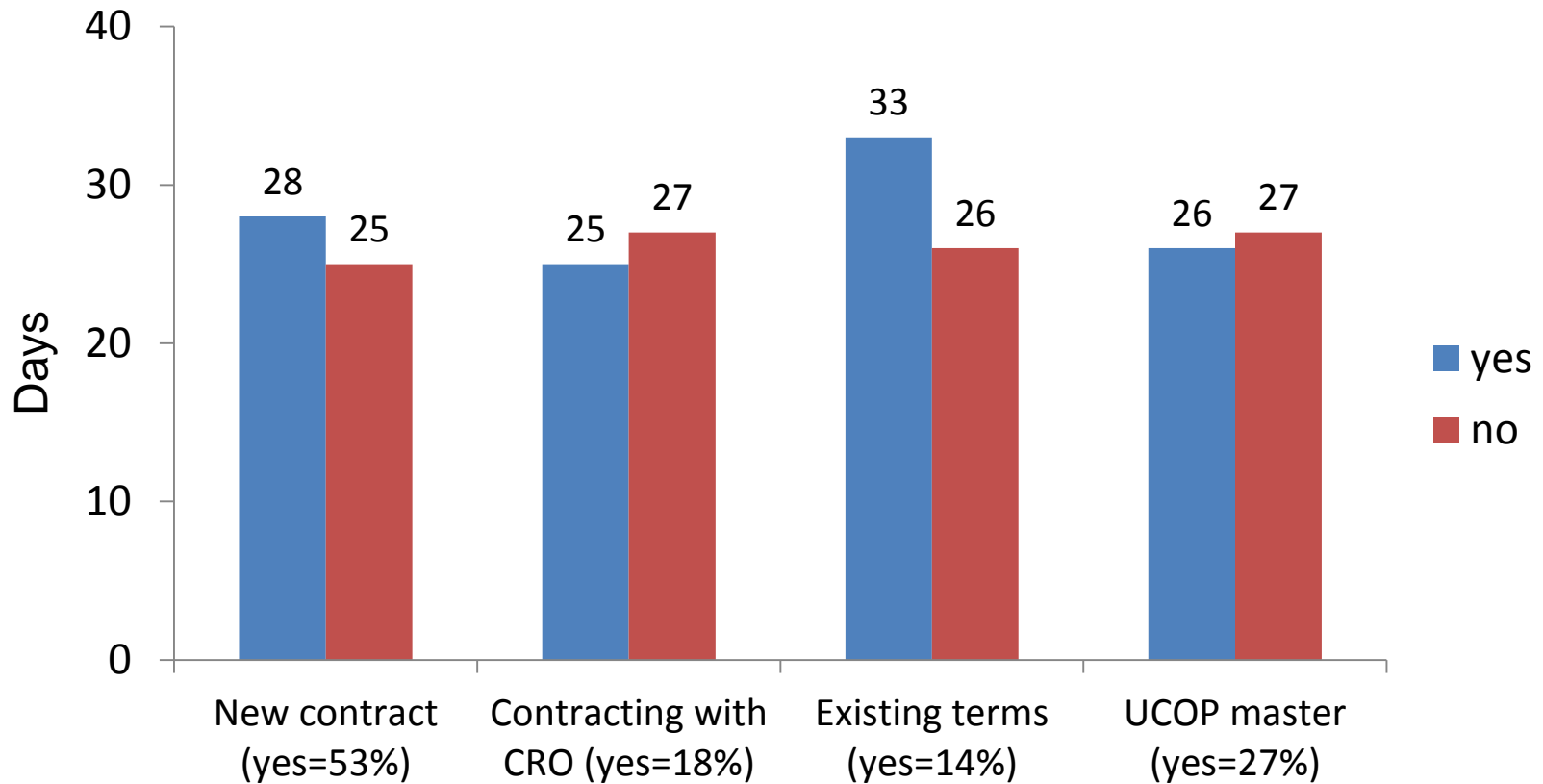|					
0	5	10	15	20	25

Days

*Completed contracts with no days reported were excluded from this analysis.

Characteristics of Contracts (cont.)

	Total
UCOP Master Agreement Used (n=206) Yes (%)	68 (33)
Campus Master Used (n=206) Yes (%)	13 (6)
Reliance campus - another campus is negotiating (n=218) Yes (%)	5 (2)

Sponsor or UC PI Initiated Trial (n=217)
    Sponsor (%)
    UC Primary Investigator (%)
    Non-UC Investigator (%)
	202 (93)
	14 (6)
	1 (1)

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.

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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

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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

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Partnerships - Thanks

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