How Does a Master CDA Affect Timelines?

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Background

This study feasibility process usually starts with the sponsor (SP) or clinical research organization (CRO) establishing a confidentiality agreement (CDA). A considerable amount of time is spent between the SP/CRO and the site's legal team negotiating language for a CDA for every study a site takes under consideration.

We believe having a master confidentiality agreement (mCDA) in place can streamline the ability for Covance to share study specific information with University of Kansas Cancer Center (KUCC), thereby reducing time and site administrative burden, and ultimately decreasing study start-up time.

Goals

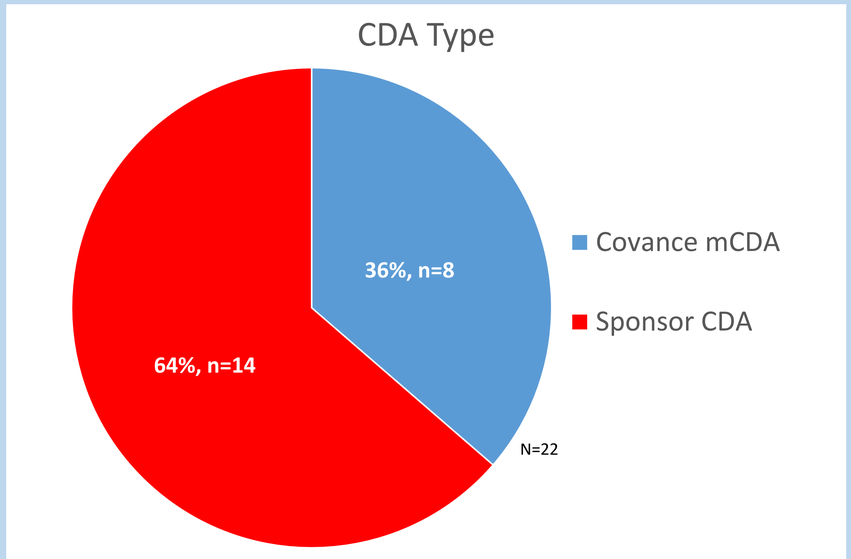
- Reduce the administrative burden on the legal teams at KUCC and Covance by establishing a mCDA.
- Evaluate the acceptance rate by sponsors for using the Covance mCDA.
- Compare the time to confidentiality agreement execution between using the mCDA versus using a sponsor specific CDA.

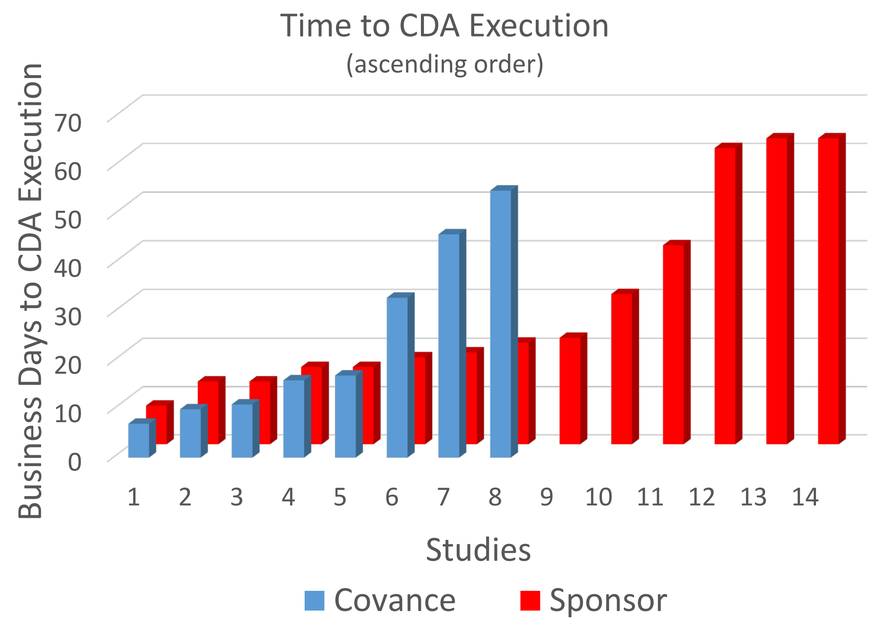
Methods

KUCC and Covance negotiated and executed a mCDA (renewed in 2018). The mCDA includes a one-page addendum template which requires trial specific information for each new opportunity.
From July 1, 2018 through June 23, 2019, there were twenty-two (22) study opportunities meeting these evaluation criteria:

- Covance approached KUCC with new a trial opportunity.
- Covance discussed with SP mCDA use.
- KUCC did not have mCDA with SP.
- Trials in which KUCC expressed interest.
- Trials for which CDAs were executed.

Results





Avg. days to CDA execution:	24	29

Lessons Learned

- With the establishment of a mCDA, Covance was able to initiate trial discussions with KUCC an average of **5 business days faster** than when the mCDA was not used.
- Most (63%) of the mCDA addendums were executed in 17 business days or less.

Of note, one SP required its own CDA, which was a standard template previously used with KUCC. When these studies (n=4) were excluded, the time for SP CDA execution increased to 35 days.

Future Direction

- Continue to capturing the acceptance rate of the Covance mCDA.
- Evaluate how the time to CDA execution may correlate with the time to study activation.
- Consider analyzing the detailed timepoints of non-mCDA negotiations as support for increasing mCDA acceptance

We would like to acknowledge the University of Kansas Medical Center Research Institute staff for their work in negotiating and executing the master CDA .

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