Category: Trial Start Up/Closure – Completed Project

How Does a Master CDA Affect Timelines?

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1. Background

Having a master confidentiality agreement (mCDA) in place streamlines the ability to share study specific information with a site. Master agreements, in general, decrease time to activation and reduce the time and administrative burden on site research teams. The first step in any study feasibility process for a sponsor or CRO, is to determine if a site is interested and capable of conducting that clinical trial. That process usually starts with establishing a confidentiality agreement between either the site and sponsor or the site and CRO.

Many sites have specific legal language or confidentiality term requirements. A considerable amount of time is spent between the sponsor/CRO and the site's legal team negotiating language for a confidentiality agreement. Since this process is being performed for every study a site takes under consideration, there is a significant amount of time spent on the negotiation of confidentiality agreements by both parties.

2. Goals

- Reduce the administrative burden on the legal teams at the University of Kansas Cancer Center (KUCC) and Covance by establishing a mCDA with addendum.
- Evaluate the acceptance rate by sponsors for using the Covance mCDA.
- Compare the time to confidentiality agreement execution between using the mCDA addendum versus using a sponsor specific CDA.

3. Solutions and Methods

The University of Kansas and Covance negotiated and executed a mCDA, most recently renewed in 2018. When Covance was awarded a study, Covance first presented the mCDA to the sponsor for review. Sponsors either accepted or rejected use of the Covance mCDA prior to study specific information being shared. The mCDA includes a one-page addendum template which required entry of trial specific information for each new study. If the mCDA was accepted by the sponsor, KUCC was sent the mCDA addendum for signature.

4. Outcomes and Future Directions

From July 1, 2018 through April 19, 2019, there were twenty (20) study opportunities which met these evaluation criteria:

- Trial opportunities for which Covance was seeking research site interest and capability.
- Covance discussion with sponsor about mCDA use.
- Trials in which KUCC was interested.
- Trials for which CDAs were executed.

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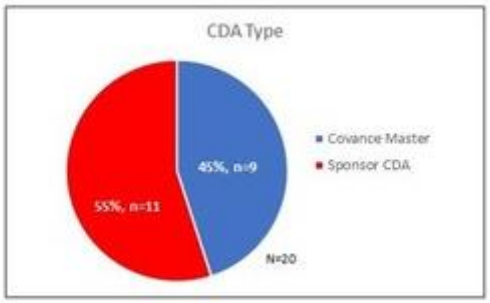
Nearly half of sponsors accepted the mCDA (see figure).



Acceptance of the Covance mCDA (9)

- 23 business days on average to fully execute the mCDA addendum
- 67% were executed in 17 business days or less

Use of sponsor CDA (11)

- 30 business days on average to fully execute the sponsor CDAs
- 36% of these CDAs took an average of 55 business days to execute

Sponsor acceptance of the Covance mCDA resulted in achieving a fully executed mCDA addendum 7 business days faster on average than obtaining a sponsor specific CDA.

Using a mCDA template decreases the ever-growing administrative burden on sites and study teams by eliminating the time to negotiate. Quickly executing the CDA allows Covance to quickly engage with a site to initiate the trial start up process.

We will continue to evaluate the acceptance by sponsors of the Covance mCDA and comparing timelines from CDA receipt to execution.