SITE-SPONSOR CONSORTIUM

INDUSTRY REPORT

Accelerating Clinical Trials through Streamlined Confidential Disclosure Agreements and Processes

A Site-Sponsor Consortium Initiative

Contents

Accelerating Clinical Trials through Streamlined Confidential Disclosure Agreements and Processes

The Site-Sponsor Consortium is a collaborative, equally weighted coalition of sponsors, CROs, and commercial and institutional research sites. Our mission is to expedite clinical research—while upholding the highest ethical and legal standards—by co-creating process efficiencies and breaking down operational silos to improve site performance, streamline trial execution, and support the delivery of safe, effective therapies.

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Introduction

Study startup delays remain a persistent challenge in clinical research, often undermining the timely delivery of therapies to patients. One key—but sometimes overlooked—operational bottleneck is the execution of Confidential Disclosure Agreements (CDAs), which can create unnecessary friction at the earliest stage of a clinical trial.

Recognizing that simplification of CDAs could serve as a meaningful foundation for accelerating study startup timelines across the industry, Site-Sponsor Consortium members selected CDA streamlining as their inaugural, industry-wide initiative. This report details the Consortium's recommendations for the most efficient CDA processes and proposes a bilateral CDA template designed to balance operational speed with mutual protection.

Why Focus on CDAs?

A CDA, also referred to as a Non-Disclosure Agreement (NDA), is a legal contract that restricts the use and dissemination of proprietary or sensitive information shared between parties. In clinical research, sponsors and CROs typically require a signed CDA before disclosing trial protocols to clinical research sites as part of the trial-site feasibility process, to ensure the confidentiality of scientific, commercial, or strategic details.

CDAs differ substantially from Clinical Trial Agreements (CTAs). While CTAs are comprehensive contracts that define operational, financial, and legal obligations—including payment terms, data handling, and liability—CDAs allow for a site to evaluate materials necessary to determine their interest in and the feasibility of performing the trial, if selected. These materials, such as the study protocol and budget, are confidential and must be protected from unauthorized disclosure. Once the site signs the CTA, that contract then governs the confidentiality obligations.

The Case for Simplification

There are compelling reasons to keep CDAs minimally burdensome. First, as described, CDAs are preliminary in scope and are not intended to create an ongoing operational relationship; instead, they enable the initial exchange of confidential information prior to any formal collaboration. Second, they have a direct operational impact on study startup timelines. Internal reviews of sponsor and CRO metrics indicate that delays in CDA execution can delay study startup at a site by weeks or even months. Third, despite the competitive and regulated nature of the clinical research industry, most stakeholders agree that excessive negotiations of CDAs contribute little to legal protection Optimizing how CDAs are reviewed and executed can have a material impact on overall trial timelines.

Master CDAs—pre-negotiated agreements between a sponsor/CRO and a site/institution—have proven to be the most efficient solution, as they cover confidentiality needs for future feasibility activities and studies. However, operational efficiency is also affected by whether CDAs are unilateral (protecting only sponsor information, namely the clinical trial protocol) or bilateral (protecting both sponsor and site information, such as sites' competitive advantages related to patient populations). Although creating the simplest possible CDA template is a goal, true efficiency is only achieved with bidirectionality. Bilateral (mutual) CDAs can help eliminate delays at sites that require mutual protection.

Streamlined CDA Recommendations

In response to these perspectives, the Consortium has developed two complimentary deliverables that embrace efficiency while also retaining strong legal protection:

1. Streamlined CDA processes, with practical guidance for sponsors, CROs, and sites; and
2. A master Mutual CDA template—reviewed by the Consortium's sponsors, CROs, and sites—which is structured to meet the needs of both parties named in the agreement and minimize negotiation.

Notes on Scope

Master CDAs are efficient precisely because they are broad in coverage. Protocol-specific, compound-specific, and investigator-specific CDAs should be discontinued in favor of master CDAs between companies/institutions.

This document pertains specifically to clinical trial feasibility CDAs. If a sponsor and a physician wish to engage in a relationship where a site-based physician serves as a subject-matter expert, a separate CDA should be executed by the physician or their employer.

The processes outlined here are most applicable to Phase 2a through Phase 4 clinical trials conducted at U.S.-based sites but can be used to inform other organizational uses.

Notes on Format

Several organizations suggested click-through CDAs as the most efficient delivery method. There are several reasons this method has not been recommended, however. First, the Consortium heard on many occasions that the name of the site entity was frequently incorrect, and so sites often need to request editable versions. Second, most institutional sites have designated signatories; when a CDA is sent as a click-through signature to site personnel who are not authorized to sign legal agreements, the site needs to request a version be sent via other electronic means for signature. Third, more sites are requesting that the CDAs be mutual so that their information and commercial advantages cannot be shared, and the CDAs that are sent to sites are often not mutually protective. Fourth, state-funded institutions often require that legal agreements specify their own state as the governing law and/or jurisdiction, which then requires negotiation and slows study startup. The Consortium's recommended CDA template remains silent on governing law and jurisdiction for U.S. entities.

Execution Recommendations

Electronic CDA signatures are strongly recommended, as they can substantially reduce turnaround time and enable faster study startup. When routing for electronic execution, it is important to ensure that all redline edits have been agreed upon and that the final version is the one being signed. All parties should also agree on the electronic platform for execution, including who routes the document and the order of signatures.

The electronic signature solution does not need to be compliant with FDA 21 CFR Part 11, as CDAs and similar legal contracts are not subject to this regulation. 21 CFR Part 11 was designed to govern electronic records and signatures that are required by FDA regulations to be created, maintained, or submitted for FDA-regulated products. CDAs (and CTAs) are legal agreements that establish terms for confidentiality between parties but are not regulatory records under the scope of Part 11. The validity and enforceability of electronic signatures on CDAs are governed by general electronic signature laws, such as the U.S. Electronic Signature in Global and national Commerce (E-SIGN) Act and the Uniform Electronic Transactions Act (UETA). These statutes ensure that electronically signed contracts are recognized as legally binding, provided that the parties can verify attribution and consent.

Notes on Effective Communication

Where a CDA process step assigns a task to a centralized department, the Consortium recommends using a dedicated email address (e.g., contracts@company.com) for related communications. This approach applies equally to sponsors, CROs, and sites, as it facilitates more effective collaboration across organizations and protects against lost or delayed communications due to staff absence or turnover.

Consortium-Endorsed CDA Processes

As noted previously, the Consortium is strongly in favor of Master CDAs, and the master Mutual CDA template created is the preferred form. However, recognizing that adoption may be slow, Consortium members across organizational types developed best practices for streamlining CDA procedures when there is either no master CDA in place or when the CDA received is not bilaterally protective.

Processes for Sponsors and CROs

During review of sponsor and CRO processes for trial-specific CDAs, it was evident that both systems were similar enough to be harmonized. The two most streamlined process options are:

Option 1
A link to the electronic feasibility questionnaire is emailed to the site, accompanied by a confidentiality notice.

By receiving the email, the site and its personnel are considered bound by confidentiality. This allows the site to proceed directly to the questionnaire without additional steps.

Option 2
An electronic CDA is emailed to the site.

This is a click-through process where the site acknowledges agreement to confidentiality terms by clicking a button. Upon acceptance, the site is immediately directed to the feasibility questionnaire via an electronic survey system.

Knowing that Option 2 may not work if the site's entity name is incorrect, if legal jurisdiction is not acceptable, or if the CDA received is not mutual, the following alternative process is recommended when a site does not accept the confidentiality terms as presented in Option 1 or Option 2:

Release

An editable electronic CDA is sent to the site for redline revisions.

Negotiation

A centralized team of CDA specialists negotiates the agreement. Once finalized, the agreement is sent to the site for signature.

Tracking

A site ID specialist (or equivalent) handles all administrative tasks (e.g., signatures, filing) and negotiates within predefined parameters. Legal is only involved for exceptions beyond standard policy.

In all cases, a contract management system is used to manage the full contract lifecycle, including search, request, creation, review, and approval.

Processes for Institutional Sites

Although not the most common approach, the following is the most streamlined process identified by institutional sites, which includes academic medical centers, cancer centers, and healthcare systems.

Of note, most institutions require that legally binding agreements, such as CDAs, are executed by an authorized signatory—typically a corporate officer or designated institutional official. Investigators are generally not parties to the agreement and are often not authorized to sign; however, they may sign under a "Read and Acknowledged" line.

Due to these requirements, institutional sites typically do not accept click-through CDAs and instead request editable versions. The most efficient process for handling these requests is:

1. **Receipt**
   Site personnel receive the CDA and forward it to the appropriate centralized team or authorized signatory.
2. **Review**
   The CDA is reviewed and redlined as needed (e.g., correcting entity names, updating correspondence addresses). Negotiation is only required for substantive issues such as legal jurisdiction or agreement terms.
3. **Return and follow-up**
   Site personnel return a partially executed CDA to the client and follow up until a fully executed version is received.

Processes for Commercial Sites

Commercial sites—also known as independent research sites, site networks, site management organizations, and integrated research organizations—have historically been less likely to negotiate CDAs, focusing instead on CTAs. However, as more commercial sites become embedded within hospitals or backed by private equity investors, there is a growing trend toward requesting mutual (bidirectional) CDAs. Accordingly, the following process includes optional steps that can be tailored to each site's needs and resources:

1. **Initial review**
   Site personnel receive the CDA and, if needed, forward it to an owner, manager, or legal counsel for review.
2. **Signature routing**
   Once approved, the site sends a partially executed CDA to the sponsor or CRO and follows up until a fully executed version is received.
3. **Tracking and follow-Up**
   The staff member responsible for CDA coordination—typically a clinical research coordinator or business development specialist—logs the trial opportunity in an electronic tracking system and may follow up on trial award status as needed.

Conclusion

CDAs should be a gateway to collaboration, not a first roadblock. By simplifying and standardizing CDA processes across stakeholders, the industry collectively takes another step toward decreasing operational inefficiencies in clinical research. The Consortium encourages sponsors and CROs to adopt the master Mutual CDA template as their own, sites to accept this template without negotiation when received, and all parties to examine and update their processes to be as efficient and effective as possible.

The Site-Sponsor Consortium's commitment to clarity and operational excellence is a call to action: Let us replace bottlenecks with a harmonized, forward-thinking approach toward accelerating therapeutic delivery. As one Consortium member noted: *"Every day saved in startup is a day gained for patients awaiting treatments."*

Consortium-Endorsed Master Mutual CDA Template

A Master Mutual CDA template can be downloaded here.

While broad industry adoption of this template across sponsors, CROs, and sites is an aspirational goal, it can also serve immediate, practical purposes. The template is designed to enable faster CDA—and thus study startup—timelines without compromising legal protections. In the near term, individuals may use it as a conversation tool to explore incremental changes to their current organizational procedures. For example, a sponsor leader could propose transitioning to mutual/bilateral CDAs, while a site representative might recommend accepting non-specific governing laws.