# A "Holistic" e-Clinical System: Be Wary of Managing Clinical Development With Blinders On

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If we were to survey all sponsors and CROs, asking what their biggest cost drivers have been since they have started conducting clinical trials, they would all mention the same thing – paper. Paper storage, maintenance and global express mailing drive total study costs up tremendously. Why is paper study management so costly?

- Paper forces duplicate copies of the same document in multiple locations (and many companies still keep "shadow files"), as opposed to one centralized location where all parties can access study documents on demand.
- Paper creates bigger inefficiencies – not providing a place to retain the same information about investigative sites and vendors – forcing those involved in the study to collect the same data (CVs, Medical Licenses, etc) repetitively.

Despite the efforts in recent years to streamline this by leveraging electronic solutions[1], many challenges in pushing towards digitization of clinical information have not been addressed[2]. The main reason for this lack of development can be attributed to trial sponsors reapplying the same processes they use with paper documents to electronic documents, without fully leveraging the extent of technological reach. Some of these inefficiencies and proposed enhancements to clinical platforms are as follows:

Imagine a complete set of clinical information for one study. There are three main states in which the content can exist in this cloud of information:

1. Initial: A document has arrived in your system from external sources (sites, CRAs, vendors and other parties) involved in the study. For each individual study, this intake activity occurs at every step of the clinical process such as feasibility, study start up and TMF.

2. Shared: When the same information exists across multiple steps of the clinical process. For example, site qualification or CVs that can be found in feasibility, can also be found in study start-up and TMF.
3. Archive: In formation is mostly static and is used primarily for reference purposes and rarely viewed by study teams.

What process improvements can be made using modern technology around these main content states to make the overall process more efficient?

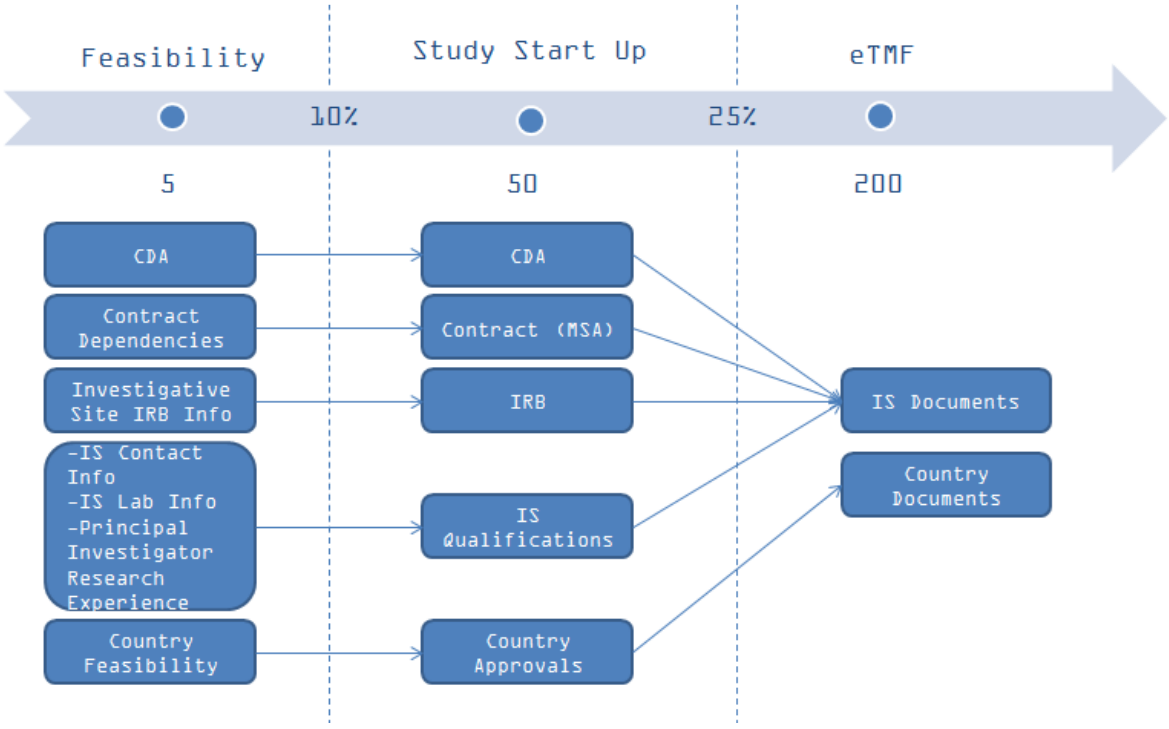
One of the main activities of the intake stage is reviewing incoming documents and capturing their metadata. If we were to examine the process of reviewing one document, we would see that about half of that time is spent on reviewing document content and the other half on entering the metadata. Much of the information being coded as metadata comes from the document content itself; however, this metadata is being manually re-typed, costing companies time and money.

What if there was a way to eliminate the need to re-type this information? Believe it or not, we can do that today if we start leveraging all the different formats of electronic data capture, which already exists. Some of the more popular formats are dynamic web forms or "smart forms" and dynamic PDFs. Tools such as Survey Monkey or Checkbox are examples of such dynamic form creators. What if we could create these types of dynamic forms directly in e-clinical platforms? If a platform produces a dynamic form, for say a monitoring report, logically, it should be able to import information filled in in this report as well. By providing multiple ways for site staff and CRAs to complete their content (feasibility questionnaires or monitoring visit reports) in an electronic format from the start, we can inherently benefit from having the platform automatically import the content from completed forms as metadata into its database. This will ultimately accelerate the document review time by a large margin.

When thinking of a holistic e-clinical platform, one should not be imagined without a built-in feature that can assist users in creating dynamic forms – web forms that can work

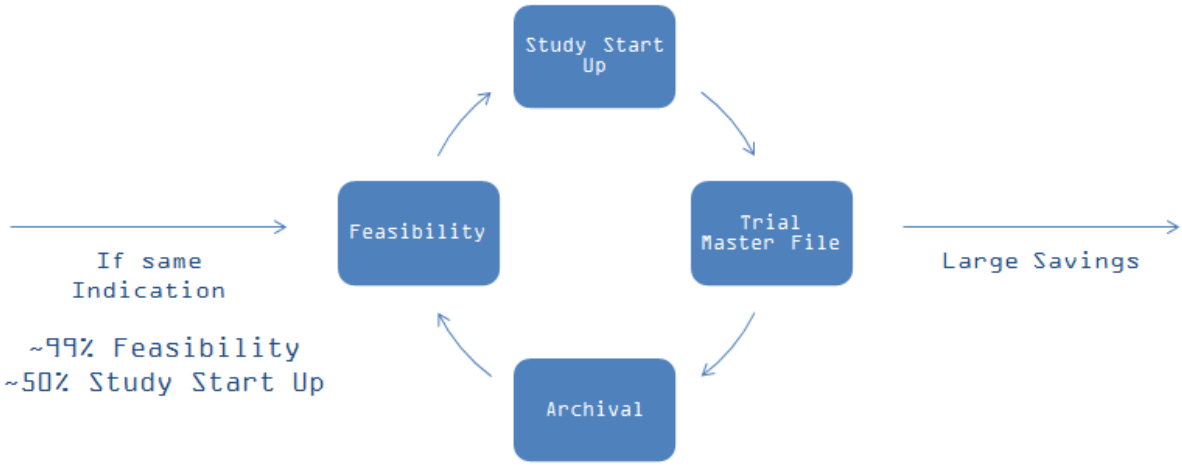
directly in a browser or dynamic PDF forms which can be completed locally on a desktop – and sent when internet is available. Having this built-in feature will introduce significant efficiency improvements including increased reviewer productivity, as they will now code minimal metadata, bypassing paper inventory hassles, avoiding paper scanning, etc.

Another essential characteristic of a holistic e-clinical system is the ability to connect clinical data across study processes such as feasibility, study start-up, TMF, safety and study archiving. Based on clinical trials that we have supported, we've identified that pieces of clinical information are commonly being copied manually between these steps[3]. In feasibility, for example, the information collected for an individual investigative site applies to about five different types of content or document types. Once this site is selected for further consideration, these five document types get copied from feasibility to study start-up by CRO staff. Similarly, we've identified that about 50 different types of documents gets copied from study start-up to TMF manually, daily, for each investigative site[3].



Reports show that about 10% of data in study start-up came from feasibility and about 25% of data in TMF came from study start-up[3]. If we had a platform that could share information collected between all steps of the process automatically, these 10% of efforts saved in study start-up and 25% saved in TMF would add up to a sizeable increase in efficiency and cost savings.

Additionally, the process of going from one study for the same indication to another was examined:




Reports indicate that much of the information from feasibility and about 50% of the information from study start-up of the first study could be re-used in the second study as investigators would not have to provide their information again, benefitting both CROs and sites. This finding constitutes another essential characteristic of a holistic e-clinical platform – its ability to search and re-use information from historic studies for the upcoming ones. Millions of hours have been invested into collecting clinical data for closed studies and, for many companies, this bank of information currently collects dust in cold storages in shapes of CDs, DVDs, hard drives and, of course, paper. These piles of dusty hardware actually contain a wealth of valuable intelligence such as: information about investigative sites you have previously worked with, vendors and laboratories with their proven track record as well as IRBs and ECs with their requirements and committee meeting schedules. This intelligence data can be extremely useful when planning

upcoming individual studies as well as entire clinical programs. The next generation of e-clinical systems needs to help us leverage this historic information – help us view it, filter it, and re-use it.

Proper management of post-closing study information will have an impact not only on individual companies but also on the industry in its entirety. The industry is moving forward towards more open information sharing[4]. Non-profits such as TransCelerate are already working on establishing the foundation for it[5]. However, in order to effectively streamline global clinical information, it is imperative that all players collecting clinical data contribute to this common pool of knowledge. Implementing an efficient archiving strategy and analytics (mentioned above) directly within clinical platforms will make it easier for these platforms to exchange information with the new public industry-wide databases such as TransCelerate's Investigator Database. This will help CROs and sponsors consume the latest clinical information as soon as it becomes available and also help them become more effective contributors to the industry's future.

The entire processing methodology of electronic clinical information needs to be reevaluated in light of the latest technological advancements. The clinical industry is gradually moving from paper to electronic format, yet many times as a point solution. How are we going to capitalize on this move? Many of the inefficiencies that have been acceptable with paper can now be eliminated with electronic data capture and processing. This is a great opportunity to re-examine old processes and invent more efficient clinical research processes by leveraging all that the modern technology now offers. The "holistic" e-clinical solution is not a futuristic dream. Technology tools to create it already exist. It is up to us to drive the innovation behind it.

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