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Embarking on a Decentralized Clinical Trial Journey – A Data Manager's Guide

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Decentralized clinical trials (DCTs), once considered innovative, have now become an established methodology to support a patient and site centric approach in clinical research. DCTs leverage technology and re-imagined clinical practices to allow sites to support their patients offsite rather than having a patient return to the clinic for each visit, additionally allowing for electronic data capture between scheduled visits. This methodology is supported by a number of different elements such as eConsent, telemedicine, wearable devices, eCOA platforms, virtual physician consultation and home visits.

It needs to be understood that DCTs are a spectrum, not an absolute; whilst full DCTs have been conducted with success (CHIEF-HF & VERKKO[1, 2]) the majority of DCTs will aim to implement a hybrid design with a mix of on-site and home visits for the patients. These hybrid designs increase flexibility for patients to fit a clinical trial into their lives, increase diversity, allow for trials to be monitored centrally and future proof protocols against any force majeures.

Whilst DCTs are well understood as a concept their implementation is still relatively new, with a large number of stakeholders still developing DCTs through trial and error as opposed to established best practices; however, increasingly sponsors are looking to leverage DCTs to support their drug development cycle. This paper looks to guide those within data management who are about to embark on a DCT journey, or those simply looking to understand more with a specific focus on how data managers should look to operationalize these elements. Indeed, the very structure of how DCT project teams are structured can be difficult to define due to their complex operational considerations and cross functional nature but it is vital an operational structure is agreed to deliver these trials. This paper will support the tooling of those individuals involved, allowing for pertinent questions to be asked to ensure a well thought through and robust clinical system is implemented to successfully support DCTs.

When should DCTs be considered?

When designing a DCT strategy for a trial, it is important to ensure that the design fits the needs of the study, the patients and adds measurable value to the trial design. It also needs to be designed in a way that allows the study to collect all required data such as primary and secondary endpoints and provides the evidence required to answer the regulatory questions.

When creating a DCT strategy for a study, a number of factors need to be considered to ensure that the best fit DCT design for the protocol, patients and sites is achieved. Some of these considerations include:

- **Patient population and patient journey** ensuring the patient population is able to participate within the DCT design by mapping out the end-to-end patient journey. For example, age, diversity, disease severity, socioeconomic status and access to the internet should all be considered and incorporated within the design. The advantage of a DCT is that it can design accessible solutions around the needs of the specific patient population thus increasing access to clinical trials.

- **Protocol specific information** such as therapeutic area, investigational product and dosing regimen. For example, is the investigational product suitable to be administered, stored and managed in the patient's home. Some investigational products are better suited to a DCT design such as oral and self-administered products.

- **Protocol specific design** such as study phase, primary endpoints and study schedule of assessments, including checking which of these can be and are suitable to be completed in the patient's home. For example, with the support of DCT solutions such as eConsent, eCOA, telemedicine, devices/wearables, home healthcare, remote monitoring and patient concierge services where appropriate.

- **Geographical footprint, local healthcare practices, country regulations and acceptance of the proposed DCT solutions.** Some aspects of DCTs may be feasible in some countries but not others, enforcing the need to consider a hybrid approach for the study.

- **Data collection and data flow** for the study, including how the data will be captured, curated, and consumed.

We need to ensure the DCT strategy and design is truly patient centric and is giving patients flexibility and choice on how they want to participate in a clinical trial without excluding patients that may wish to complete their visits at a site in the traditional way. The DCT strategy and design should be clearly documented in the protocol and informed consent form, including the location of where visits are allowed to be completed, how data will be collected and by whom.

Site Centricity – maintaining Site engagement within a DCT design

One key consideration of DCT strategy is ensuring the site is seen as a critical stakeholder to ensure the trial is successful – they should be seen as a partner of research rather than an end user –empowering sites and increasing site centricity. This is a key advantage noted when a DCT design is proposed; however, by implementing technologies typically associated with DCTs it can lead to increased technology and process complexity for sites, thus leading to data quality issues and potentially trial disengagement. How these systems are interconnected could mean the difference between success and failure of a trial, and therefore it is critical that, as part of the DCT strategy, the site is at the forefront of consideration during design.

Understanding how the site will interact with the different tools in a logical order will maximize site centricity and help to reduce site burden; this can be considered as the site flow (an example is in diagram 1 below). To demonstrate from an operational aspect, if consent through an eConsent platform is utilized this will lead to a significant divergence in the traditional paradigm of patient registration in a clinical trial (traditionally IRT). This has implications downstream for the collection of data for other systems such as IRT and EDC platforms – the utilization of integration can mean that once a patient is created in the eConsent platform this data can then be integrated to both IRT and EDC to save the site from the burden of having to re-enter this data, with the added benefit of also mitigating potential entry errors.

This functionality can be further developed by using the primary system to trigger actions in other systems. For example, if a patient has to complete pre-randomization questionnaires as the final criteria to be considered eligible for the trial; integrations can be utilized between the eCOA, IRT and EDC platform to ensure once the patient is randomized within eCOA (leveraging a successful randomization response from the IRT vendor) this information can be automatically updated across the two other platforms as needed. From a site's perspective, they will have been able to update three separate systems through interactions with a single system. If this interconnectivity had not been designed, it could lead to sites having to utilize three different platforms, which can generate end user frustration. It needs to be emphasized that it is crucial the study team fully understand how the site will interact with the trial systems and that the interconnectivity follows a logical progression, or else you could be left with a system that is at best, ineffective, or at worst, unworkable.

The utilization of site networks (a group of clinical sites represented under one entity) within DCTs can further augment the site centricity experience, as they can provide valuable input upfront into the setup of the trial to ensure those who will be running the trial understand, but have also added value to the system proposed. Furthermore, as site networks are re-used for further DCTs, a common knowledge can be built upon allowing for future trials to focus on novel elements rather than having a significant training burden explaining consistently used elements. For example, the involvement of national pharmacies in the US has expanded the way that medications can be provided allowing sites more flexibility in the way they can provide support to their patients during clinical trials to the advantage of both sites and patients.

It is clear to see the benefits created for sites through interconnecting these clinical systems, it does however increases the burden in relation to the validation of these proposed systems – it is simply not enough to test the systems in isolation as within the trial they do not function in this fashion. It highlights the requirements for a holistic review of the whole system architecture as a single organism, including its relevant interactions. This will ensure the team has the greatest confidence in the system will work in real world settings. Whilst it is often not possible to account for all potential scenarios that can occur in trials, it is vital adequate time is proportioned to this task. This becomes even more significant in DCTs, as the systems used will include real time capture technologies, therefore, if an error is noted that impacts the ability to complete transactions, there will be a critical need to have this resolved. What this means is that the team needs to not only robustly test the system but also have an agile change management process that can be rapidly deployed to support any critical issues noted during the live trial. If these principles can be adhered to, DCTs will create real site centricity benefits for the trial rather than just a token phrase.
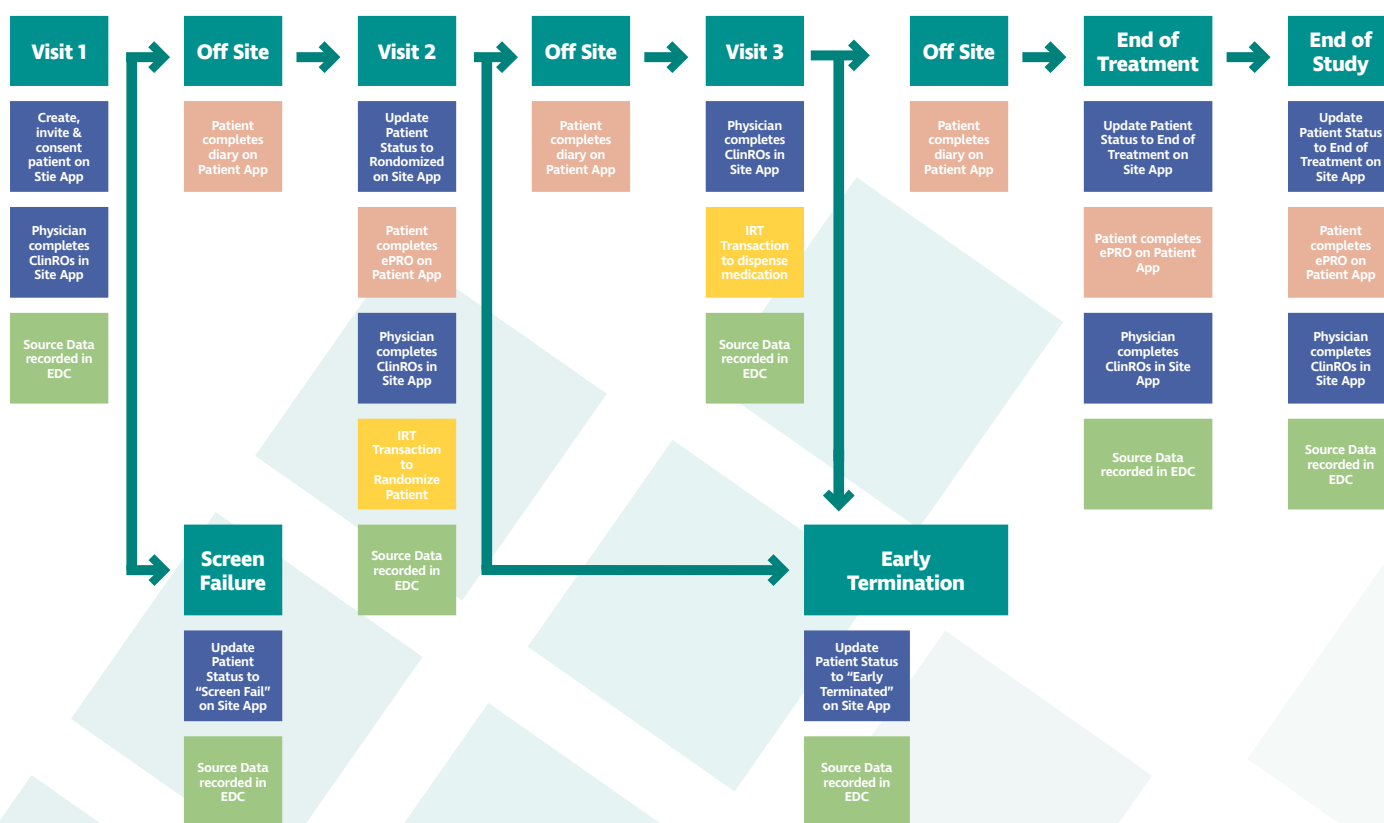
Diagram 1: Example of a site flow indicating the sites use of different systems within a clinical trial.

Empowering The Patient Through DCTs

The DCT approach provides a potential for greater patient engagement. One such benefit is that by creating trial paradigms that limit or no longer rely on site attendance, the trial can reach a wider and broader audience who may have previously not had the option to partake in clinical research. This can only be seen as beneficial for potential populations or indications that have previously been difficult to bring into brick-and-mortar sites, although thought needs to be given to access, connectivity and usability issues for the different participants. For example, those with fine motor issues may struggle to utilize hand held devices and as such it may be worthwhile to engage with patient advocacy groups early in development to look at the accessibility of such devices to ensure they are fit for purpose. This ability to reach wider groups can also positively impact sponsors by increasing enrollment rates, thus shortening time to reach recruitment goals. This increased diversity of DCTs can help support calls from regulators who now expect sponsors to take further action to reach such groups, such as the FDA, who have drafted guidance that a "Race and Ethnicity Diversity Plan"[3] needs to be submitted early in the clinical development process.

While the nature of a decentralized trial should theoretically increase inclusivity, if done right, measures should be taken to ensure that there are no unintended consequences affecting the representation of particular subgroups. For example, the implementation of DCTs may present new challenges for certain subgroups of populations who are less able to access digital technology or easily understand more complex tests and procedures or any potential issues of understanding complex shipments of at-home medication. Another example is that utilizing social media platforms for patient recruitment, this could lead to certain biases in the populations who would support such trials. Furthermore, it is possible that using innovative new technology requiring internet access and a different patient engagement approach, such as using Apple watches to track step count, will favour certain populations, which can lead to under-representation in other patient populations.

Designing adaptive solutions that reduce the patient burden and aim to maximize patient engagement will lead to improved patient experience, higher patient retention and better trial performance. The different stakeholders involved in clinical trials, including both sponsor and sites, need to collaborate to create safe and ethical clinical trials, as well as promote a more efficient clinical trial process. Additionally, this collaboration is needed to increase the adoption and scaling of DCTs by designing patient-centric approaches and defining the data flow, similar to creating a patient flow chart, which will facilitate the data collection, validation, storage and analysis.

Maximizing Value by Centralizing Traditional Site Activities

Recruiting study participants in clinical trials has always been a challenging and demanding process. Existing technologies leveraged during the pandemic have shown their worth by offering the opportunity to improve patient engagement and recruitment, such as by using e-recruiting methods, which involves leveraging the power of the internet to enroll qualified candidates for clinical trials in a more timely and efficient manner than traditional advertising.

Remote recruitment plays a crucial role in the enablement of DCTs. It is important for digital recruitment to have a robust flow, clear eligibility criteria outlined, in addition to developed questionnaires and processes to achieve diversity within the trial protocol. Screening technology creates a sophisticated way to find qualified patients for clinical trials and web-based recruiting systems provide a more efficient and cost-effective means of obtaining clinical study participants than traditional advertising methods. Both of these online methods allow individuals to find trials suitable for themselves rather than the traditional way where sites putting forward certain trials to the pool of patients they are able to access – this may empower patients to find trials that suit their needs providing they have the means and knowhow to do so. Even if online measures are used to support solely pre-screening, whereby individuals interested in the trial can register interest and complete certain elements of pre-screening online, this can help support the site find additional individuals to enroll in the trial.

eConsent can be utilized to support DCTs as the patient and investigator no longer need to be on site to have the patient provide consent to support a clinical trial, which allows much more flexibility in the process and improves participant engagement. It is crucial sponsors can provide an eConsent system whereby the participant will always have continuous access to the eConsent system or a paper informed consent form (ICF) copy and allow them to interact with the eConsent device or application and understand the trial conditions and information.

Furthermore, within a DCT environment, systems should allow for electronic signatures so that informed consent can be performed remotely within a validated and secure system. For eConsent carried out in a country that does not recognize electronic signatures, a mechanism such as 'print-to-sign' should be utilized to allow the confirmed eICF to document the necessary wet ink signature. Ideally this also includes the means to scan the signed documents to close the loop between digital and non-digital manifestations.

Data management teams have an important role to play for ensuring data integrity and validation. Systems should allow real-time updates, connection to source data, and finally, incorporate data security measures and set regular integrity controls (e.g., audit trails, encryption). Furthermore, system interoperability and centricity are encouraged to identify and proactively follow up on missing or inconsistent data or even flagging data outliers and potential protocol deviations. To achieve this, data management teams will need both seamless system synchronization, as previously mentioned, along with data management risk mitigation strategies to ensure data's validity, accuracy and integrity or be provided with role-based access to the different systems that fulfill the DCT needs.

Data Capture Considerations Within Decentralized Clinical Trials

There has been exponential growth of data collection systems and technologies that offer solutions for clinical trials, however, there is complications around the ability for one system to provide all aspects of data capture for a DCT. Whilst some organizations are becoming more equipped to handle an increasingly large portfolio of DCT elements, sponsors may find that they are having to manage a number of vendors to meet the requirements of the protocol. In addition, there is an expectation as part of DCTs that multiple external data sources such as wearables will be utilized as well, which generates a significant volume of data. Therefore, it has never been more critical for the team to understand the data captured in these trials and ensure they can be analyzed in an elegant way to enable key insights for clinical trials.

As a result, there are specific needs data management should consider:

- The enablement of easy and flawless systems integration wherever possible
- The creation of measurable endpoints
- To ensure only data that is essentially needed for the trial protocol is collected (from both a data and operational perspective)

- Whether the utilization of a clinical data repository will be needed to handle the number and volume of third-party data expected
- Completing a Risk Management Framework
- Provisioning for around the clock service desk support to cover any unexpected issues from the patients and sites

Any clinical data generated must follow a robust and structured framework, as most parts of decentralized clinical trials are using electronic systems and tools for data capture and analysis. Naturally, these computerized systems used for clinical data collection, validation, and analysis must comply with ICH GCP and local regulations. The key responsibility of data managers is to create well-defined data collection, handling, and management procedures. This, of course, may vary depending on the capabilities offered by each system.

Data collection in DCTs is performed either by site personnel or more extensively by non-site personnel as the hybrid setup mandates. The collection and management of clinical data from non-site personnel, such as participants and caregivers using mobile devices including smartphones, tablet applications, wearables, and sensors (e.g., glucose monitors, smart pills), is challenging as we need to consider electronic data collection and analysis (eSource). What is more, within data management, establishing a vigorous infrastructure that allows connectivity in the DCT systems network is essential.

The ability to centrally monitor patient entered data in real time, for example a patient diary, allows for vastly improved compliance compared to traditional methods as long as a robust oversight plan is implemented. It should be expected of the eCOA platform that reminders can be sent to the patient to act as a prompt. However, the system must also be able to provide real time reports to allow the site, a central monitor or potential concierge call service to also prompt the patient to ensure it is completed. In addition, the aggregation of this data should provide insights into specific trends of patients, sites and countries to support future intervention within the current trial and considerations for future trials.

A possible way to handle eSource data, along with eCRF/EDC-based data, may be via graphical visualizations of aggregated data to monitor trends and mark potential errors early on. More specifically, it is a case of examining data trends over time across sites and participants to identify inconsistent patterns, data outliers, or skewed distributions. On top of this, data managers can develop a risk-based approach framework, where data validation tools are customized and designed to ensure created data is reliable, accurate and of high quality and integrity, and also that the tools and systems used are fit for purpose. Additionally, when it comes to eSource data or data gathered from electronic records during data collection, the team needs to consider a data management plan, which outlines and specifies the data flow, including the data format, origin, and accessibility rights. One fundamental layer is the identification of critical data, which are meaningful for the study analysis, which call for the development of a data collection and validation plan customized to the measurable endpoints of each DCT.

The multiple sources and volume of data expected in DCT can put strain on existing IT infrastructure and this becomes further complicated with the expectation of having systems where certain stakeholders can enter, review or be blinded to certain data. As of today, few platforms support the delivery of clinical trial data to stakeholders as well as providing the appropriate tools and user experiences for various stakeholders to carry out their business functions. As a result, until better tools emerge, teams should look to leverage data aggregation tools that ingest data from multiple sources and generate data for action by each stakeholder.

Finally, the accuracy, and precision of remote sensor measurements, documentation of all new processes created, and clear definition of the storage, archival and retrieval of source documents and electronic information are critical in the DCT remote setting. Clinical trial participants are often required to travel long distances to attend visits, perform procedures, or undertake measurements expected by the protocol design. Overcoming challenges like distance whilst ensuring the health and safety of participants can be tackled with home health. In these cases, during the home health visits, the data flow is triggered once the healthcare professional or nurse inputs participant study data directly into a system or application. Moreover, the data collected during home health visits may be directed into the electronic case report form (eCRF) or via other medical/wearable devices.

Implications of DCTs on Data Review

When thinking about the data review for DCTs or elements of it, we may need to start looking at ways we need to work differently to ensure the data quality is as expected. The data may not be visible in an EDC as we are used to (unless you are planning to integrate); instead, it could be stored in different systems and external datasets and transferred as listings. As most of the data will rely solely on the patient providing the information outside of a controlled environment, we need to consider how reliable and compliant the data is. Can we add any steps to ensure it meets the requirements of the protocol? What are the regulatory recommendations on collecting and storing these types of data? The big question is what data is required, and how will it be analyzed? Careful consideration maybe required, especially when generated by wearable devices as these create vast volumes of data that could impact the results or the potential to overcompensate.

Historically data validation has been implemented in the EDC to account for the transcription errors expected when sites transcribe source data. However, a significant consideration with DCTs is that there is an increase of source data captured directly by the patients which raises concerns about the ability for teams to go back and potentially query and correct such data. Therefore, it is imperative any patient facing data capture platforms use functionality to restrict erroneous data capture where possible; for example ensuring a field is only present once a leading question has been answered yes – this will assist to ensure no conflicting data is entered – with no understanding of which is correct.

Furthermore, with the increase in real time data entry restrictions can be placed on the system to ensure compliance with the trial. For example, in a scenario where a patient inputs data to the eCOA platform to access their eligibility for joining the trial in real time (e.g., by scoring high enough on a questionnaire), the patient is only randomized in the IRT system if the score has been met – thus removing the potential for human error and creating efficiency improvements.

When reviewing and cleaning these types of data the system collating the data could, where possible, provide checks for discrepant data. Not all systems will have the ability to implement this level of reliability checking, which in turn could lead to a lot of questionable data; in this instance, standalone software and/or the use of programming tools to identify discrepancies, non-compliance and potential safety concerns would need to be used in the same way we have developed edit checks for EDC.

Vendor Management to setup DCTs for success

Incorporating virtual elements into the traditional model requires a clear vision for how the various technologies, platforms, and other "site-less" elements will flow together with minimal intervention; however, the potential challenges of managing multiple vendors are often overlooked. Sponsors should ensure vendors are selected primarily to support their individual protocol needs careful considerations should also be taken into relation to ease of vendor management, auditing, and scalability in today's evolving clinical trial landscape, with the main focus on system interoperability, security, and data protection.

During the vendor selection process it is vital the data flow of clinical data is well understood. Mapping out the data flow (see diagram 2 for an example) can support the teams understanding and alignment on the plan, as well as allowing the opportunity to raise any concerns with the proposed solution. Key consideration needs to be given to understand how the different elements of the vendor clinical data will flow to ensure it is fit for purpose for the trial's needs – extensive conversations with your partners needs to take place to ensure this is clear. At a glance stakeholders will also be able to check that they are able to access the data as and when and if they need it. To summarize, a detailed data flow map should outline the transfer of data between stakeholders, including all third-party vendors contracted for data collection, data handling, data management and/or parties in which data processing is required. It's also important to note that regulatory bodies often expect such data flow diagrams to be incorporated into trial documentation.
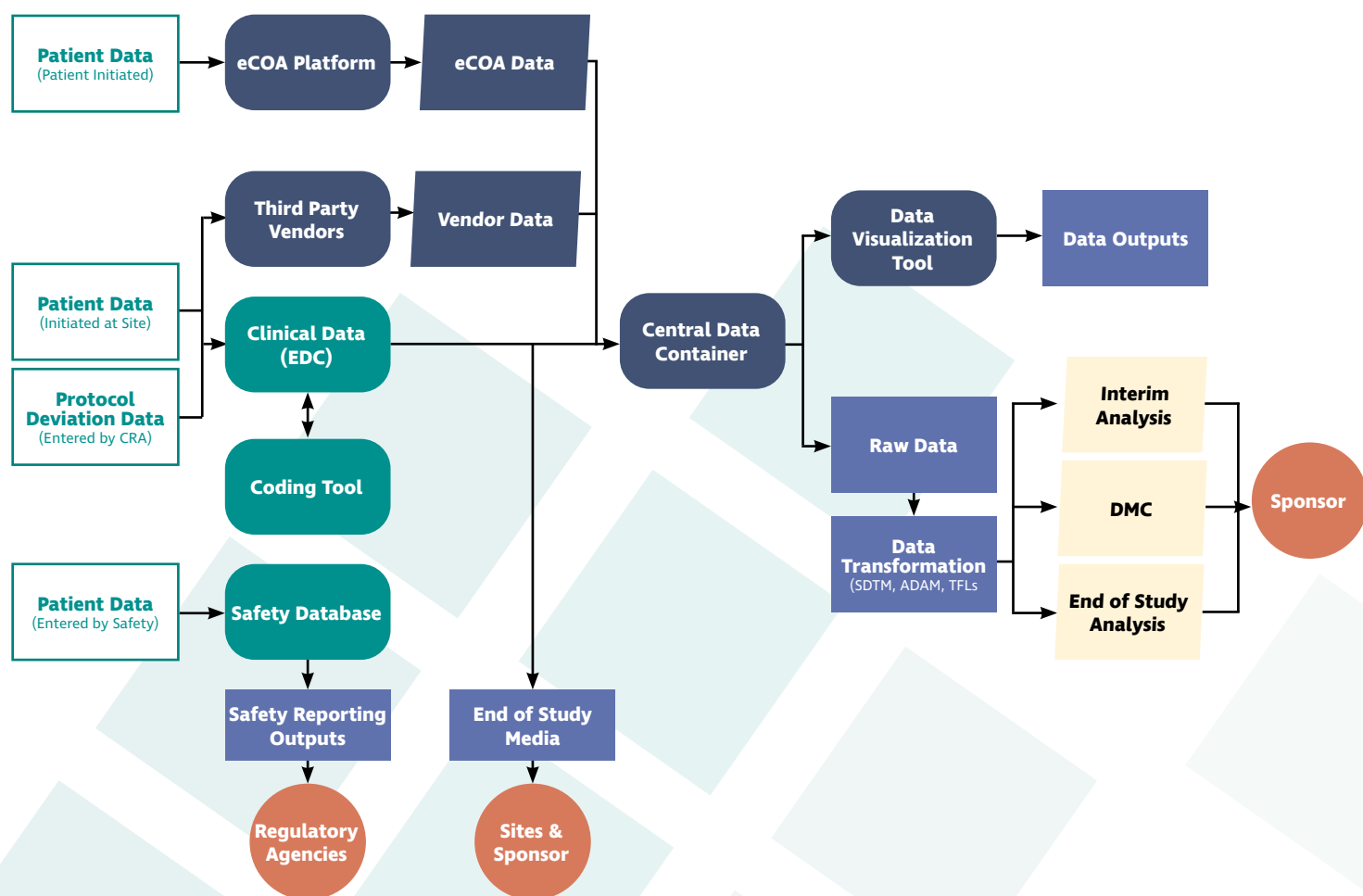
Diagram 2: Example of the clinical data flow for a clinical trial

For the majority of sponsors, DCTs will involve a vendor selection process to provision the required technology and it can be deceptively difficult to navigate the ever-evolving landscape of the different options available. When evaluating vendors, it is important to maintain a vigorous risk assessment process to ensure data security, one such consideration involves additional security checks such as cyber threat protection.

As best practice, study teams should engage early to begin a study-level sourcing strategy and vendor selection process. Data management teams need to set in place a framework for vendor selection that outlines:

- Vendor validation and auditing, to ensure vendors have the appropriate capabilities, skills and quality systems necessary to perform the services required.

- Scope of work and a task ownership matrix, which identifies all tasks that may arise during the execution of a clinical study and the associated roles and responsibilities.

- Vendor oversight and deliverable monitoring, such as lab results or any other type of external data based on the contractual agreement.

- A robust reporting model that allows data review and validation of the collected data points.
- Standard operating procedures (SOPs) developed to describe processes to reduce operational challenges and address any process-related concerns.
- Applicable risk-based management principles, adding efficiency to the auditing process by categorizing the risk categories of vendors.
- A vendor list template, with all the relevant information for the vendor and the contractual agreement.

Creating guidance documents and developing a clear monitoring plan can provide a good baseline for ensuring quality results.

Another consideration is to ensure patients and sites are able to view their data as needed throughout the course of the trial and can receive a copy after the study, therefore, it is important chosen vendors have a robust end of study media solution so that information can be retained, as specified in the ICH GCP guidance.

The Impact of Regulators on DCT Trials

In a highly regulated industry, it is no surprise that DCT's may add new regulatory considerations to our trials as currently regulatory processes were designed with traditional study design in mind. A significant consideration while designing DCTs is a good regulatory framework, regulators are increasingly interested in using patient outcomes as primary endpoints (e.g., pain scores, inhaler use, number of episodes (pain, cough, or spasms)), which means collecting additional clinical assessments using eDiaries and other technology outside of conventional methods.

Some regulatory authorities are more conservative, reactive, and tend to focus on compliance with current regulations. An example of this is eConsent, which is not yet fully accepted globally, therefore, flexibility needs to be built in to the DCT take this into account. It is important to understand the regulations in each country intended to be used in the trial before making a decision to implement a DCT to ensure the trial can be delivered as expected. Furthermore, the regulatory landscape is complex and under continuous evaluation, so, information must be up to date to ensure ongoing compliance. The systems utilized will also need to include a level of flexibility to ensure regulatory considerations can be accounted for in each country. Thus, the more countries that are to be included in the trial the more flexibility is needed in the DCT solution which can increase the technological burden required from the different platforms. Ideally data management should be included early on in the country selection for a trial to ensure there is a level of harmonization in those selected – where feasible.

In a typical trial, the site would explain the trial, ensure the patient is fully informed about who has access to the data collected, if it is intended to be re-used and how they can withdraw consent if they no longer wish for it to be included or stored, meet regularly with the participant, answer any questions they have and run through the study procedures. In a DCT the participant is expected to complete study procedures, answer questions electronically and submit information independently. Therefore, consideration must be given by the sponsor and possibly CRO on how they will ensure these conversations can still occur whilst the patient may not be at site – potentially through video conferencing or online chat support directing patient questions to sites.

Analyzing and Mitigating Risks of DCTs

The industry is now well acquainted with a risk-based approach to clinical trials; as has been noted throughout this paper, it is imperative that a robust risk analysis of any DCT methodologies is performed to ensure they are fit for purpose and sufficient backups are in place. However, the implementation of DCT elements themselves can be used to de-risk protocols to allow data capture to continue if the patient cannot attend the site. Secondly, the methodologies that support DCTs allow for greater visibility of ongoing data capture this can further enhance the trial through increased central monitoring. As an example, the primary endpoint for a trial could be self-reported eDiary data compared at baseline to a critical window during the treatment period – therefore with a patient completing an eDiary daily a review of compliance could be performed across sites and any outliers flagged to sites to remind patients of their commitments. Furthermore, during the critical period any missed entries could be escalated for more prompt support to ensure compliance does not drop significantly highlighting DCTs ability to protect the endpoints of trials. In another example whereby heart rate is continuously monitored by a wearable device, an alert flag could be put in place for certain low and high threshold which may be able to pre-emptively detect any safety issues with the patients highlighting DCTs ability to support the safety of the patients on trial. As part of the management of this increased volume of data it is also now a requirement that data management fully understand the data containers setup to ingest, consume and curate this data. If the database architecture cannot handle these effectively then this process can become a suboptimal system that impacts on the running of the trial.

The above highlights the greater impact the data management function can have on the successful running of a trial. When a DCT methodology is proposed for a trial, it is key that data management are involved within the protocol development to ensure their expertise is taken into account. Regulators expect details of how the trial will be conducted and therefore it is important that data management are a key stakeholder in supporting this process to ensure the most logical, well-rounded solution is incorporated so that a robust protocol is created that can successfully support the DCT elements of the trial.

A risk analysis should consider all technological elements of the trial to ensure that if a failure occurred in a system, it would not inhibit the core function of the trial – for example, dispensation of medication and alternative contingency planning is in place for such scenarios. By performing the risk analysis, a proportional response and potential backup solution can be generated to ensure the smooth running of the trial. If these backup methods can collect data in the same fashion as the electronic counterpart this will streamline the data capture solution. For example, if an eDiary is utilized then thought must be given to how the patient would capture this information if they are unable to complete the electronic version, such as contacting the site to give their daily information and allowing the site to enter it into the platform. If it is possible for the site to enter the same data in the same area as in the scenario of eConsent (once the technical issue is resolved) this will then allow for one file to be provided at the end of the trial, which will include all records rather than capturing this information elsewhere (such as EDC), avoiding the creation of multiple datasets for the same data. Whilst preparing contingency and mitigation planning, it is important to design this within a multi-disciplinary review to ensure the integrity and equivalence of the collection methods is not affected.

A Cornerstone of DCT Success: Training

Whilst this paper has raised points in relation to implementation of DCTs, a key facet of the delivery is the training of the individuals who will utilize this system. The solution proposed could be streamlined, efficient and well thought out, however, if sites are not adequately trained it could cause issues in implementation. Given this potential for issue, it is imperative that thought is given to how sites will receive training on the system itself – an investigator meeting is a traditional approach for training provisioning. This can be further supplemented with ongoing support from the clinical team or central monitors – whose role is to support the sites. This means that there is a requirement for the clinical team to have knowledge of these technical systems, empowering the clinical team to proactively support their sites to ensure minimal disruption to the trial. In addition, a helpdesk should be established, one in which individuals can reach out to for any technical issues that the devices utilize, as failure with these devices could mean missing data, which would mean that data can no longer form part of the analysis. Furthermore, time should be taken to review the tickets raised to the helpdesk on a periodic basis to look for patterns of issues that could result in revisions to the systems or further site training. Conducting training solely at startup will set up the trial for failure – training within DCTs needs to be seen as an ever-evolving ongoing objective.

It is also important that the cross functional team overseeing the solution are actively reviewing the system and the data it captures to ensure it is fit for purpose; a governance structure could be implemented to support such a review, which could utilize key performance indicators (KPIs) (such as how many tickets have been raised for errors) and review of the data generated to ensure all is as expected. This will allow the team to proactively identify concerns, allowing them to address them with a minimal impact on the trial. This should focus primarily on patient safety and key endpoints in a risk-based approach.

Concluding remarks

The aim of this paper has outlined the considerations important in data management when transitioning to a DCT and should help teams raise pertinent questions. The industry has seen the benefits that DCTs bring to the patient and site and it is now expected these are included as standard in trials in the future. Therefore, as data managers it is imperative we understand the key considerations to ensure these trials are built for purpose and have the necessary flexibility to ensure success. The more frequently DCTs are adopted in the industry the more knowledge we can share with the regulators and vice versa. The technical investment DCTs require will naturally bring data management to the forefront of clinical development to offer their skills and expertise and it is therefore imperative data management are in a position to contribute and further innovate within this space.

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