Megasite solutions

Objective

To understand use cases and operational feasibility of a megasite model, defined as a decentralized model that involves a central site(s) overseeing remote study conduct for a large region or country and in what cases this model offers most benefit to study participants, sites, and sponsors.

Methods

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To understand use cases and feasibility of a megasite model, workshops were held with cross-functional subject matter experts to identify potential benefits as well as operational, regulatory, and legal considerations that dictate model viability.

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This included considerations for in what situations CRO partners may provide investigative site services and what protocol designs are most amenable to oversight by a central coordinating.

3

Learnings from an ongoing case study operating with a megasite model was also examined to identify lessons learned and understand global acceptability based on regulatory feedback.

Results

- Centralizing remote study conduct under a megasite has he potential to reduce start up timelines and costs related to investigator fees and monitoring which has benefit to sponsors. The model also has the opportunity to improve diversity and inclusivity, allowing patients to participate remotely from a broader geographic area and include patients who may not have access to traditional brick and mortar clinics.
- Findings from the workshop indicated that megasite models are optimal for non-interventional, observational, low-risk studies driven by patient reported outcomes. These studies can incorporate technologies such as eConsent and virtual study platforms that allow participants to provide all required study data remotely without impact to patient safety.
- Studies that include medical oversight, investigational product or require treatment decisions to be made by the enrolling investigator are not ideal for this approach but may be evaluated based on the risk profile of the drug or product under study and the type of services that are being included to ensure patient safety. Consumer health studies that are minimal risk may benefit from a megasite approach.
- Additionally, studies that incorporate remote contact with study participants (e.g. televisits) may be subject to local laws concerning telehealth.
- Local data privacy requirements must be considered as participants may be required to share personal information with the coordinating site and the acceptability of this will be determined by local laws, including whether this information can be shared across regional boundaries as well as where this data is stored and who is permitted access to it.
- The role of megasite may be filled by coordinating sites or virtual site/CRO partners, selected based on protocol and regulatory requirements. When considering whether a CRO partner can fulfill the roll of the investigative site, considerations such as corporate practice of medicine and other local/regional laws must be evaluated.
- When determining whether a central coordinating site is suitable, the site should be assessed for their ability to oversee a large number of participants. Sites must also have the resources and bandwidth to manage study activities remotely, oversee data being provided by patients and follow up with study participants as needed to ensure compliance to study data collection requirments.
- Study coordination services can benefit coordinating sites, reducing burden by supporting the site with these activities while allowing the coordinating investigator to focus on oversight, including any aspects concerning patient safety. Study coordination services also offer benefit by ensuring conduct of study is managed in a consistent manner and have the ability to offer participants more white-glove support.
- A recent case study utilizing a megasite approach for a 10-year follow up study found that regulatory acceptance of the model was country specific. The study included the option for global oversight by a CRO megasite or for a local in-country PI to be selected to provide oversight for participants in their region. Participants in the interventional trial are invited to participate in the long term follow up study by their enrolling investigator and transferred to the applicable long term follow up site. The study includes 27 countries and 11,000 participants. The global CRO megasite has been accepted by regulatory authorities in 12 countries spanning North America, Europe and Asia which includes study oversight and direct contact with participants to collect bi-annual questionnaires. To date 15 countries declined acceptance of the global megasite and approved oversight by in-country national coordinating sites instead. Some of these countries have required oversight by national coordinating site but have approved the CRO partner to contact participants to obtain questionnaire responses.
- The following countries in Asia were activated and enrolled patients: Japan, Australia, India, Malaysia and Taiwan.

Conclusion

- A megasite model presents the opportunity to realize efficiencies in study startup and improve inclusivity by removing geographic barriers to participation.
- However, protocol and regulatory requirements (eg. telehealth and data privacy) must be considered to determine if a megasite model is fit for purpose and it's acceptance will be country-specific, dependent on the site selected to fulfill the role of PI and the associated responsibilities.