Feasibility Assessments: What Investigators Need to Know

The feasibility of clinical trial involves a thorough assessment of the potential and practicality of conducting a particular trial within a specified geographic area to ensure a project's success in terms of timeline, target achievement, cost management, and various other essential factors. The extent of feasibility outreach can constitute an initial assessment phase that provides a preliminary understanding of the disease prevalence and standard of care. In contrast, an extensive feasibility analysis encompasses patient criteria, site capabilities, regulatory requirements, and potential execution challenges, thus enabling informed decision-making while paving the way for a successful clinical trial execution and delivery.[1] Clinical Research Malaysia (CRM) provides a centralised feasibility assessment to sponsors and contract research organisations (CROs) to match clinical trials with the right investigators and sites in Malaysia. CRM provides reliable insights and up-to-date information that covers the hospitals in the public, private, and academia to ensure that potential centres and institutions are tapped into the study.[2]

This article offers key insights to investigators, underscoring the importance of feasibility assessments, the impact of feasibility on successful clinical trials, and recommendations for improving feasibility responses.

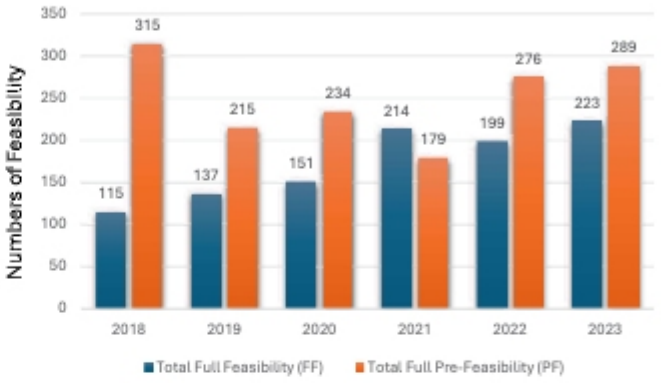

Figure 1: Total full feasibility and pre-feasibility from 2018–2023

Feasibility Growth and Its Importance

Over the period spanning from 2018 to 2023, the growth of feasibilities conducted by CRM has been significant (Figure 1). In line with this, there has also been an increasing number of sponsors and Contract Research Organisations (CROs) conducting feasibility studies through CRM. Based on the annual customer satisfaction survey reported in the CRM Annual Report 2022, 94% of the respondents rated "good" and "very good" for CRM's complimentary feasibility service.

There are a few components that should be considered by clinical investigators when responding to feasibility questionnaires, such as population profile and access,[3] facilities and equipment accessibility, and investigators' experience.[2] Usually, each of the components has a weight assigned based on the sponsors' evaluation of the site's strengths and weaknesses and allows for objective comparison. Hence, due consideration should be given to each of the components in completing the questionnaires to meet the feasibility objective and facilitate site selection.

Estimating Potential Patient Population

A vital aspect of feasibility assessment is identifying the availability of patients with a certain disease condition specific to a particular trial. Investigators' considerations encompass a thorough review of the study design, inclusion/exclusion criteria for patient recruitment, the current standard of care, frequency of visits, invasiveness level of the trial, and the provision of reimbursement for study-related procedures.[1] Furthermore, correctly identifying the available patient pool, while exercising caution on underestimation, and ensuring realistic projections of patient numbers are crucial aspects to consider. References from Clinical Practice Guidelines (CPG), up-to-date patient registries,[4] and the availability of databases such as the Malaysian Health Data Warehouse (MyHDW) platform, could provide vital data during feasibility assessments. The integration of Electronic Medical Records (EMR) within hospitals supports investigators in providing real-time patient pool for a certain disease condition, further translating to a more reliable recruitment projection that ultimately meets the recruitment targets set.

Resources and Infrastructure

Assessing infrastructure in healthcare institutions is crucial in determining the site's ability to conduct clinical trials.[5] A thorough evaluation enables sponsors and investigators to anticipate and proactively address challenges during the feasibility stage. Having basic and adequate facilities such as freezer and fridge for investigational product storage and centrifuge with regular calibration taking place, will increase the chances of sites being selected during the feasibility assessment. Considering Malaysia's resource allocation and population distribution, certain sites may lack essential diagnostic capabilities or long waiting times at diagnostic units. The sites' readiness to utilize outsourcing services offers a valuable alternative for obtaining timely results. In addition, it also helps in mitigating the prolonged turnaround time of test results and alleviates overcrowding issues at public hospital laboratories. CRM provides the support to connect sponsors and CROs for the outsourcing services to ensure a successful trial.

Investigators' Experience and Competing Studies

Investigators' experience and their familiarity with the study protocols are vital for successful studies.[6] In addition, identifying competing studies involving similar patient populations is crucial for patient recruitment. Investigators are encouraged to share their trial experience and disclose any ongoing or planned trials within the same patient pool at a particular locality. This could prevent challenges in recruiting patients for different trials which taps into the same patient pool especially if both trials are taking place at the same time. CRM continuously provides training to the study teams to uphold the quality of trial conduct and adherence to the protocol. The trainings include Nurturing New Talents in Sponsored Research, GCP refresher courses, Protocol Compliance Workshop, and Patient Recruitment and Retention Workshops.

Challenges and Strategies

One of the challenges in meeting Sponsors' requirements includes short timelines given to investigators to complete feasibility questionnaires, especially if the study is under the bidding stage by a CRO or if it's a rescue study for an ongoing trial that is already happening in other parts of the world. Sponsors may also set short timelines to meet specific business objectives and address seasonal considerations, such as disease outbreaks, which require rapid trial initiation and completion. With digitalisation playing a larger role in clinical research, sponsors and CROs are introducing new digital platforms to implement feasibility assessments. Unfamiliarity with the use of these platforms among investigators also poses challenges in responding to feasibility in a timely manner. To address this, CRM feasibility team and onsite study coordinators support the investigator in completing the feasibility questionnaire, with input from investigators. Guidelines on navigating the feasibility platform and support in gathering information from other departments, such as the laboratory and pharmacy are provided. This collaborative effort expedites the feasibility process, leading to quicker site start-up if the sites are selected.

Other strategies aimed at improving feasibility timelines include the use of e-signatures in Confidential Disclosure Agreements (CDA)[8] and utilising online questionnaires/surveys from sponsors. E-signature is legally recognised under the Electronic Commerce Act 2006 (ECA) in Malaysia. E-signature offers flexibility that can aid in recordkeeping, improve efficiency and deadlines, and reduce the overall timeline for feasibility assessment. The incorporation of e-signatures and online surveys aligns with CRM and the industry's focus on operational efficiency in clinical trials.

Conclusion

Details and information shared by investigators in feasibility assessments carry a huge weight in sponsors' decisions in site selection. Significant aspects including the availability of the patient pool, basic facilities, relevant investigator experience, and upcoming competing trials will also ensure that they can deliver the trial and meet the expectations of sponsors. Feasibility assessments enable investigators to anticipate and address challenges in clinical trials, which could facilitate resource utilisation and the development of effective strategies in trial initiation. At the end of the day, a good feasibility assessment and response translates into successful clinical trials. CRM continuously supports investigators in feasibility assessments and endeavours to ease communication between the investigator and sponsor throughout the process.

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Nur Ain binti Amir

Nur Ain binti Amir graduated from Universiti Putra Malaysia with a Bachelor of Science in Cell and Molecular Biology. She is currently pursuing a master's degree in Neuroscience from the same institute. She holds the position of Feasibility Specialist at Clinical Research Malaysia. In this role, she collaborates with doctors, pharmaceutical companies, and Clinical Research Organisations to conduct feasibility studies for clinical trials.

Email: nur.ain@clinicalresearch.my

Shu Hui, Cheng

Shu Hui is currently a Senior Feasibility Specialist at Clinical Research Malaysia. She has her bachelor's degree with honours in Medical Biotechnology from both Sunway University Malaysia and Lancaster University UK. She has the experience in medical diagnostic as well as research and development field.

Liew Eu, Koh

Liew Eu graduated from Universiti Sultan Zainal Abidin with a Bachelor of Animal Production and Health (Hons) and later went on to obtain her master's degree in Biomedical Science from Universiti Sains Malaysia. She had experience in the diagnostic lab before joining Clinical Research Malaysia and now she works as a feasibility specialist at CRM.

Nur Aziemah, Ab.Ghani

Nur Aziemah is currently working as a feasibility specialist at Clinic Research Malaysia. She has experience working in molecular microbiology wet lab research, before working as a study coordinator in clinical trials. She earned her bachelor's degree with honours in microbial biotechnology from The University of Queensland.