CRM's role in making smooth conduct of Investigator Initiated Research in Malaysia

Mohd Murad Intan Munirah, Abd Muis Siti Nuralis, Abd Rahman Nurul Atiqah

Clinical Research Malaysia

ABSTRACT

Introduction: In Investigator-Initiated Research (IIR), the investigator conceives the research, develops the study protocol, and is responsible as the sponsor and investigator of the study. This abstract looks into Clinical Research Malaysia's (CRM) role in facilitating the IIR hybrid studies, which were IIR funded by non-government organizations. **Methods:** This retrospective pilot study is based on CRM's IIR hybrid data that our legal team reviewed and endorsed from 2020 to July 2023. During study start-up, CRM facilitates the review of Clinical Trial Agreements (CTAs), ensuring the terms and provisions of the agreement are clear, fair, and reasonable. The legal department reviews CTAs within 14 calendar days, as per its Standard Operating Procedures. **Results:** Out of 383 CTAs that were reviewed and endorsed by CRM during the period, 46 were IIR hybrid, in which the majority were observational studies funded by international organizations. Essential clauses that were reviewed in CTA include contracting parties' obligations and rights, indemnification, protection of confidential information, intellectual property and clinical trial governance in respect of the applicable laws and regulations in the country. CRM Study Coordinators (SCs) support in IIR hybrid is limited to the study budget allocation. CRM SCs have supported 7 IIR hybrid studies, responsible for compiling documents for ethics submission, facilitating data entry and coordination of trial-related activities at the site, all as delegated and in accordance with the Good Clinical Practice guidelines. **Conclusion:** CRM's support via legal review and clinical operations aims to ensure IIR hybrid studies are delivered with speed, quality and reliability.