

CRM Study Coordinators – Making a Difference in Clinical Trial Conduct in Malaysia

The clinical trial industry is developing rapidly in Malaysia. Since 2012 there have been more than 2000 clinical trials across different Therapeutic Areas, hence promoting Malaysia as a preferred country for sponsored clinical trials. The commitment to deliver clinical trials with Speed, Reliability and Quality is the essence to this success. This achievement is critically delivered by the invisible hands of Study Coordinators (SC).

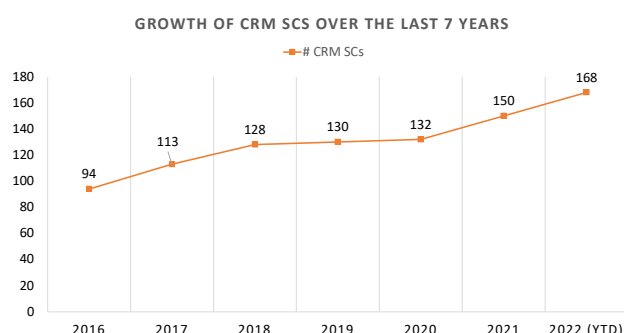
Although the Principal Investigators (PI) are responsible for the clinical trial conduct, very often the success of these studies relies on the study team which consists of SCs. SCs are specialised research professionals working with the PI to support, facilitate, and coordinate daily clinical trial activities and play a critical role in the conduct of the study. It is essential that SCs and PIs work hand in hand to ensure study conduct is in accordance with the protocol and principles of Good Clinical Practice (GCP).

CRM SCs support investigators at site to quicken the start-up process (from submission of Ethics Committee approval to site initiation) by assisting to collect and compile relevant documents within 14 days of request. The SCs are also trained to adhere to study timeline including PD reporting, SAE reporting, data entry etc. to ensure the study processes are carried out in a timely manner.

Growth of CRM Study Coordinators

A study published by Papke A. et. al shows that adding a coordinator to a research team significantly improves subject recruitment numbers, enhances subject retention, and increases general study efficiency.¹

In 2012, CRM had 22 SCs placed throughout Malaysia at various sites conducting industry-sponsored research; this number has grown to more than 160 SCs in 2022, placed mainly at Ministry of Health (MOH) hospitals, few MOH clinics and private hospitals. CRM has received increasing interest to support investigators and sites in Ministry of Higher Education (MOHE) hospitals and private hospitals over the years. The growth of CRM SCs over the span of 7 years is as illustrated in Graph 1.



Graph 1: Growth of CRM SCs over the last 7 years

CRM Initiative – Boosting Excellent Study Coordinator Service

In ensuring high quality SC service is provided to stakeholders, CRM conducts regular trainings and provides opportunities to further develop the SCs, continually evaluating the quality of service through Performance Management System (PMS) and treat customer's feedback as gold nuggets to be more effective in answering their needs.

a) Training for CRM SCs

The pharma industry does recognize that the performance quality of sites varies dramatically. Jim Kremidas, executive director of Association of Clinical Research Professionals (ACRP) believes the root cause of this variance is the lack of consistency in how staff, including principal investigators (PIs) and SCs at sites are screened, hired, trained, and validated for their competency.²

With ISO 9001:2015, CRM has strengthened and standardized our services with proper Standard Operating Procedure (SOP) ensuring the right candidate is hired, trained and the delivery of the studies is similar across the country. Having an efficient SOP in place minimizes errors, clears the way forward by avoiding uncertainties, and serves as a vital tool to transfer knowledge and skill.³

It is recommended GCP certified personnel to refresh their GCP every three years to stay updated with current regulations, standards, and guidelines.⁴ CRM mandates that all SCs must be equipped with the adequate knowledge and GCP certification to perform their duties. Internal Post GCP Assessment Test (PGAT) is also incorporated as part of quality metrics to ensure SCs are tested on GCP knowledge every three years post GCP certification.

CRM has developed structural training programs to support the onboarding process for SCs especially those with no prior experience in clinical research. Training for SCs continues even after the probation period. This includes the yearly Training to Improve Performance of Study Coordinators (TIPS) introduced in 2019. The training modules are designed to meet expectation of the industry with support from Sponsors/CROs to deliver the trainings to SCs. There are also regional Continuous Medical Education (CME) conducted monthly for SCs to share their knowledge and best practices.

The continuous training also includes our in-house newsletter called "Q-Bites". It contains practical knowledge focussing on GCP, local Ethics Committee guidelines, regulatory guidelines in conducting high quality study which can be applied to SC's tumultuous daily life at work.

b) Adequate supervision by Line Manager

To ensure we maintain our service quality, the line managers conduct supervisory visits on quarterly basis to provide guidance

and support to the SCs throughout the year. The work performance of the SCs is appraised by the respective line managers at least every 6 months through the structural mid-year performance and year-end performance review system.

c) Opportunities for career development

CRM creates opportunities for the SCs to grow their careers in a transparent, competence-based systems as depicted in Diagram 2. These career tracks allow CRM to increase job satisfaction of the SCs as each employee can grow their individual passion and career.

Development of our Talent Pool – grow from within

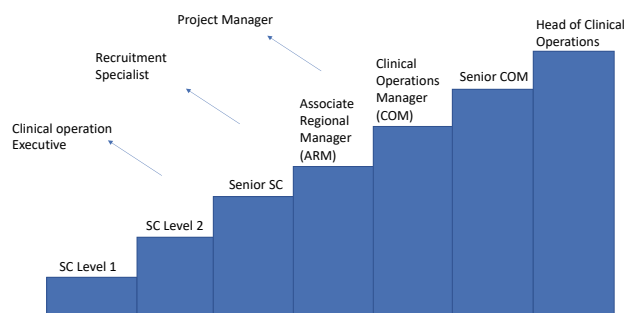


Diagram 2: Career Advancement Ladder for SCs within Clinical Operations Department

Customer Satisfaction Survey on SC Services

In 2021, CRM conducted Customer Satisfaction Survey (CSS) through a third-party company, Vase.ai. The online survey was conducted between Dec 2021 and Jan 2022. The nationwide survey covered four services provided by CRM including the Study Coordinator service. 234 respondents from stakeholders such as Investigators, Sponsors and CRO have taken part in the survey and the detailed breakdown is as shown in Figure 1.

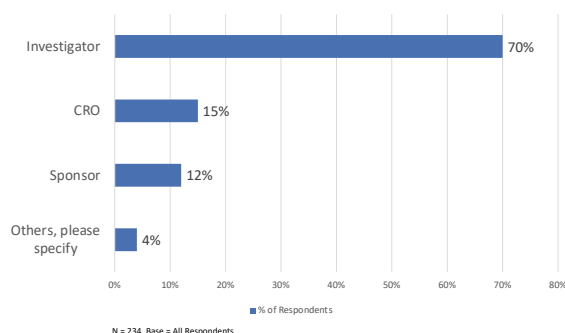


Figure 1: Respondents for Customer Satisfaction Survey 2021



211 out of 234 respondents have experience in engaging with CRM SCs for their clinical trials. The respondents rated CRM SCs performance at site on three areas:

1. Knowledge and compliance of study protocol and GCP.
2. SC's competency in performing delegated tasks and helpfulness in subject recruitment activities.
3. Speed/responsiveness to perform delegated tasks and maintenance of Investigator Site File (ISF) within the timelines.

Figure 2 shows the detailed ratings provided by respondents.

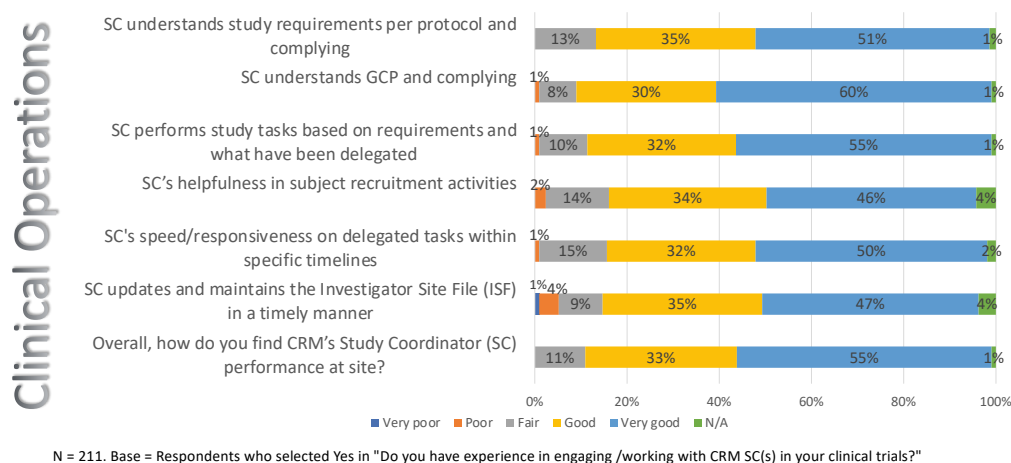


Figure 2: Respondents Ratings



Through the initiatives conducted by CRM, the customers gave 89% satisfactory rate (rated 'Good and above') towards CRM SC services. Feedback was received that the top three areas for improvement are related to workload management, retention of SCs and training and development. CRM values the feedback from respondents and has taken action to mitigate the issues. One of the new strategies introduced in 2022 is the hiring of additional SCs that are mobile and support site with high activities. New trainings including effective communication was carried out to improve the communication skills of the SCs. In addition to this, CRM credits the outstanding performance of the company to its people. The people are the greatest asset to the organisation and CRM has implemented new schemes in 2022 to improve the employee's status and benefit in the company.

Conclusion

The SCs are the invisible hands in clinical trials who contributes to the success of each trial and provides supports to the Investigators. Finding qualified candidates for SC position can be quite challenging⁵. However, with proper skills and knowledge equipped

to each SC by CRM, they can carry out the clinical trials not only at a high quality, but also maintain high integrity throughout the trial conduct.

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Nor Hafiza Johari graduated from Universiti Putra Malaysia with Bachelor of Science (Hons) Biology. She started her career as a full-time study coordinator, managing trials from few therapeutic areas. Currently she is the Clinical Operations Manager working with Clinical Research Malaysia (CRM). For the past 10 years, she is engaging with different sponsors, CROs, investigators, and trial sites to assist on the trial conduct and later demonstrated her capabilities through people management.



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