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Introducing Quality Management System (QMS) for Expediting Health Research Programme

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Abstract

This paper explains the role of quality management system (QMS) in management of health research programmes. While QMS is widely applied in clinical trials, laboratories and industries, lesser is known about its use for management of health research programme. Here, the authors describe the introduction of a QMS under India TB Research Consortium, the flagship programmes of In dian Council of Medical Research (ICMR) for tackling TB and its impact in advancing the health research agenda of the ITRC in a structured way leading to major successful outcomes of national importance. The QMS can ensure timely completion of the hea lth research programmes with quality research thus emphasizing a need for introduction of the system in all major health research programmes.

Keywords- quality management system,Tuberculosis,India Tuberculosis Research Consortium

Commentary/Short Communication

Quality management system (QMS) is a well-known process to ensure that all activities related to the concerned programme adhere to the established guidelines and standards leading to reliable and credible outcome. While this has been introduced in many areas like clinical research/trial, industries laboratories1, less is known about its use/ incorporation for management of the health research systems. In this communication, we present the details of the introduction of the QMS in execution of a mission mode program for all its activities.

In clinical research, a robust Quality Management System (QMS) inbuilt as a mandatory comprehensive framework into all stages from protocol design to data analysis and reporting ensuring compliance with regulatory requirements, data integrity, operational efficiency, ultimately leading to credibility and ethical compliance of clinical trials, particularly in vaccine research where public health outcomes are directly impacted and has legal implications.2,3 However, the QMS in management of research programmes is not a common feature. Tuberculosis (TB) is one of the highest killer from a single infectious disease worldwide, and Indian bears one third of the total TB global burden. Therefore, a mission mode programme "India Tuberculosis Research Consortium" (ITRC) a flagship program of ICMR focused on advancing technology and product development in a time bound manner for tackling tuberculosis across four thematic areas of research (Diagnosis, Therapy, Vaccines, Epidemiology & Implementation Research (Build), was launched.4

While stringent regulations and thus the mandate of quality systems exist in pharmaceutical industry, there was no institution-wide well defined framework for quality management system (QMS) for managing research Programmes. Therefore, a quality management system was built in as part of the ITRC programme to meet its defined goals and achieving its objectives in a time bound manner while ensuring quality in all research projects. This required a defined plan for executing the activities including landscape analysis for identification of advance research leads in various thematic areas of TB research, formation of working groups in all thematic areas for identification of research priorities as per the need of the national TB Elimination Programme (NTEP), development of protocols, selection of research sites through defined criteria, project

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review mechanisms, approval processes till sanction of the projects. Stringent monitoring for enhanced compliance by expediting activities with quality driven research processes was built-in for timely execution and completion. The QMS ensured that the programme meets its stated objectives and mandate and that all activities not only adhere to its timelines but also followed standard guidelines and rules (GFR and administrative) of the organization and met defined milestones, achieved desired outcomes in a multi-pronged approach. The QMS for research management included a structured mechanism with defined standard operating procedures (SOPs)/workflows for various research management processes for execution of research projects while meticulously keeping track of all projects not only for its timely completion but also execution of all activities including enrollments, interventions and follow-up with proper documentation in a time bound manner. An effective QMS with clear communication for fostering collaborations with all stakeholders was ensured. An independent timely review based on performance indicators and suggestions for improvisation and risk mitigation plans was critical in timely completion of the projects. Technical and clinical feedback and efficient administrative support helped in achieving defined milestones in a timely manner. This programme has met its objectives despite covid-19 pandemic resulting in completion of the various projects in all thematic areas within stipulated timeframe.

This demonstrated that introducing QMS for research management can help increase efficiency and result in quality driven outputs. These QMS elements were aligned with the mission mode objectives and were essential tool for meeting the target driven goals. Risk based QMS with emphasis on protocol development through following stringent Quality by design (QbD) approach, critical independent expert review, ensuring adequate due diligence, risk mitigation strategies, independent planned audits, and competence enhancement of the research teams significantly developed a strong and sustainable a system, which mostly lacks in larger research programs of national and international relevance. Introduction of QMS under ITRC, since inception in 2016, has led to successful development of key tools some of which have been adopted and are being used under NTEP contributing to strengthening health systems for tackling TB.5–15

It would be worth noting that one of the largest regulatory vaccine trials on Tuberculosis, enrolling more than 12000 participants spanning 18 sites from 6 states of India and with over 3 years of follow up was successfully conceptualized, conducted and completed under ITRC as per stringent regulatory norms with QMS in place since inception, setting an example of national health research capacity and capabilities for conducting quality research of such level. The study underwent intense scrutiny independent auditing as per ICH GCP at each step, mega funding management as per administrative directives demonstrating exemplary conduct of this one of a kind unique vaccine study.16

The capacity building of the sites for undertaking large regulatory trials especially vaccine trials was another big achievement under ITRC. The publications emerging out of the research have not only generated evidence but also resulted in some major policy level decisions by MoHFW. The successful completion of projects without much delay despite Covid-19 pandemic demonstrated the core importance of the QMS for research management and thus emphasizes the need for such a system in major research management programme.

Conclusion

The well designed, integrated and comprehensive QMS deployed in the large scale health research program of national importance, in a mission mode resulted in realization of several projects accelerated with great vigor and credibility following highest levels of compliance and well established procedures. Under the ITRC, over hundred projects were undertaken, since 2016 with promising researchers and institutions. These projects were monitored closely for satisfactory progress and timely tracking through use of project trackers, regular project update meetings, expert sessions, mentoring programs and systematic follow up with respective stakeholder. This resulted in establishment of successful clinical research network sites across India, capable of undertaking and delivering high quality research work through implementation and monitoring of sustainable process flows which may be scaled in health research programs for innovative and reliable solutions for Tuberculosis disease management.

Conflict of Interest: None

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