Monitoring Platform

Monitoring in brief

For any trial to reach its conclusion, monitors are crucial. Whereas auditing serves a quality assurance (QA) function, monitoring provides quality control (QC), through which study conduct is checked, step by step. Simply put, monitors aim to detect issues and rectify them, preventing existing errors from recurring, and new ones from developing. Before, during, and after the trial, monitors assess whether what is planned, described, and approved is realised as intended.

Every trial must be conducted, recorded, and reported correctly, meaning that it should adhere to protocol, Standard Operating Procedures, Good Clinical Practice, and the relevant regulatory requirements – all of these being aspects of QC. Monitoring was developed internationally as a profession to render trials more cost effective, of higher quality, and ultimately to help them reach conclusive results. Monitors are effectively guardians of both processes and people. They oversee that trial data is accurate, complete, and verifiable, while checking that the rights of participants are protected. When both processes and people are protected in this way, more trials can run to completion.

What role does monitoring play in clinical research?

Besides overseeing the progress of a clinical trial, monitoring provides the trial participants with protection and ensures data integrity. This key quality control activity is critical for fulfilling Good Clinical Practice (GCP). Monitoring should be considered early on in the study development and carried out throughout the trial. It should also be tailored to the potential harm or risk of the study and performed in a smart and agile manner. Well conducted monitoring adds undeniable value to any study.

What does the platform offer stakeholders?

The Monitoring Platform supports clinicians who are assuming the sponsor’s role and responsibilities of setting up and carrying out monitoring, as it is tailored to their particular study. This support from the platform is especially valuable for national, multicentre, investigator-driven studies or trials, for which the communication, coordination, and harmonisation aspects are decisive. Monitoring teams from across the country can rely upon the Monitoring Platform to provide relevant expertise and services, such as documentation and tools. Finally, the platform aims to be the primary contact point for Swiss and/or foreign stakeholders with expertise in monitoring.

What key project is the platform embarking on?

Adopting a risk-based strategy for the monitoring of clinical trials has become the standard, reinforced by the recommendations given in the integrated addendum to the GCP of the International Conference on Harmonisation (ICH-GCP E6 (R2)). The Monitoring Platform will provide updated tools for implementing this risk-based approach, by adapting the current version of the risk-analysis calculator and the accompanying guideline (as provided in the Guidelines for Good Operational Practice/GGOP, Appendix 3). New versions of Appendix 3 are expected for 2019.

What else does the platform plan to bring about?

Harmonising the monitoring processes for Swiss multicentre, investigator-initiated studies is another task taken over by the Monitoring Platform. For this purpose, various documents related to the monitoring function will be developed, such as a guideline for the development of a monitoring plan, a template for such a monitoring plan, and templates for monitoring visit reports. The Monitoring Platform also aims to improve the quality and coordination of national multicentre studies by providing aid to clinicians (academic sponsors) to initiate the monitoring of their study. As a first step, a roadmap describing the communication flow will be set up.
What are typical challenges in the field of monitoring?
Because the financial resources of investigator-driven clinical studies are often limited, monitoring activities may be relegated to the background. A compromise has to be found so that quality monitoring can still be carried out, even when the budget is tight. Such a compromise could be fostered by adopting a risk-based approach, while preserving the monitors’ autonomy and independence from investigators.
Since the Monitoring Platform will focus its efforts on national multicentre studies, a considerable, yet rewarding challenge remains – handling Swiss diversity, in particular its administrative, political, and linguistic differences.

How is the SCTO involved?
The SCTO Platforms were established in 2017 in line with the SCTO’s ultimate goal of supporting the successful development of new therapies and improving existing treatments. To optimise clinical research, our platforms are to serve as centres of excellence that focus on eight key fields: auditing, education, data management, monitoring, project management, regulatory affairs, monitoring, and statistics and methodology.

The SCTO liaises with and between these individual platforms and supports them in their activities. Accordingly, the SCTO will publish regular updates on the objectives and output of these platforms as they continue to develop.

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