promedim
Technology Enhanced Medical Monitoring

case study

Raising the compliance bar for 24/7 medical coverage with the help of technology

Medical oversight is frequently cited as a deficiency in agency inspections of Sponsors and Contract Research Organisations. Here we give an example how medical monitoring can be enhanced with a technology solution to provide effective medical oversight, raising the compliance bar and making medical monitoring as efficient as possible for sponsor and study medics alike.

> "Investigators very happy with speed of response and ease of contact with Promedim Medical Monitors"
>
> Senior Clinical Research Coordinator
> US Cancer Centre

Struggling to provide medical coverage

A small biotechnology company specializing in oncology medicines, approached Promedim for help with medical monitoring of a planned Phase 3 oncology program. The company asked for Promedim's support to address a major internal audit finding.

The internal GCP audit reviewed the company's early clinical trial documentation, including their Medical Monitoring Plan, to help them prepare for the Phase 3 program. During review of study documentation, the biotechnology company had contracted only a Chief Medical Officer to provide medical coverage.

Whilst absolutely qualified, the auditor found that this single physician with just their personal cellphone number listed on the study protocol, was insufficient to provide robust medical support to the studies as they could not ensure they were available and could not demonstrate their availability 24/7 for the duration of the study.

The auditor raised this as a major finding with respect to their provision of medical oversight, and failure to ensure proper monitoring.

Why was this raised as a finding?

GCP requires the sponsor – or delegate – to provide "readily available" medical oversight. We have seen this regularly interpreted by agencies and auditors that companies running clinical trials must have a robust team and processes in place with qualified, trained physicians available to support the study.

Medical oversight is required to not only support trial sites and study staff in answering protocol or IMP-related questions but importantly to support other health professionals who may be required to attend to the study patient in an emergent medical condition – and give advice on the IMP. A single physician is insufficient in an inspector's eyes to provide comprehensive round-the-clock coverage.

> By integrating Promedim's technology and medical team services with the client's medical support, the Phase 3 oncology study completed successfully with demonstrable 24/7 coverage throughout the study duration.

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Technology enhanced medical monitoring

To address this finding and to support compliance with GCP, Promedim provided technology enhanced medical monitoring services to the organization to enable the Phase 3 oncology study to progress. The trial was conducted in Europe, US and Australia with the contracted Chief Medical Officer, based in the US, assigned as the first point of call during US office hours. Promedim' s oncology experienced medical team, using promedim24 mobile technology, delivered seamless back up medical coverage outside of US office hours ensuring 24/7 medical coverage.

Rather than carrying around hard copies of study documentation and risking delays in response or referencing out of date revisions, promedim24 also enabled the medics to access controlled study documentation including protocols, and medical monitoring plans on the move through their mobile devices.

Strengthening GCP, ICH E6 compliance

promedim24, the industry-leading physician management technology, is the world's first plug and play GCP compliant, validated cloud-based application for medical oversight of clinical trials that continually manages global medic availability 24/7 across multiple studies.

During the study, the application allowed the medical team to have real-time visibility of medics that were available to take emergency calls or to answer any study queries. Critical coverage alerts ensured coverage levels were maintained as required by the Medical Monitoring Plan.

Evidence of availability was demonstrated by audit trail with a downloadable medical coverage report for inclusion within the TMF and to support GCP inspection.

Next level: Efficiency / Transparency and Compliance

By integrating Promedim's technology and medical team services with the client's medical support, the Phase 3 oncology study completed successfully with demonstrable 24/7 coverage throughout the study duration.

The clearly documented audit trail with continuous medic availability provided next level compliance and Sponsor transparency, whilst providing the medical team with real-time visibility of medical coverage across multiple time zones

Making the life of a medical monitor easier

Promedim's technology raises the bar for quality and reduces risk to your business. By providing real time updates and eliminating costly management of manual rotas/schedules it is a highly cost effective and scalable solution that allows medics "on the move" access to current study documentation secured within a fully validated 21 CFR Part 11 environment.

24+

24/7/365 Medical Monitoring for Clinical Trials

Promedim's advanced cloud-based technology, integrated with our global control centre ensures that trial investigators and healthcare providers have rapid, 24/7/365 emergency access to relevant medical expertise, high-quality advice, and unrivalled customer service.

It continually manages global medic availability in-real time 24/7, with a continuous audit trail of medic availability providing next-level compliance and Sponsor transparency.
Make your life easier and raise the compliance bar

Please contact the Promedim team to find out how we can make your life easier and raise the bar.

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