

## 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.



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Investigators wish all studies had a Promedim style oversight.

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Quality Officer  
Global CRO



## Providing emergency medical coverage for a Global Intensive Care Study

Ensuring around the clock coverage for medical emergencies in any clinical study can be a challenging and costly venture to have fully qualified and therapeutically experienced medics readily available 24/7/365 on the off-chance a call comes from an investigator, out of business hours, to discuss an emergency situation.

More challenging still, is when you are expecting calls at all times – for example in an intensive care study or research in an emergency situation where discussions on enrolment or dose escalation can occur anytime day or night.

## Medical services – any time, any place

Promedim were asked to support a sponsor investigating a new biologic molecule to be used in the intensive care setting. The sponsor had an extensive US-based medical team but needed medical back-up in the rest-of-world especially given the sites were in Australia, Asia and Europe –as well as the US.

Promedim was able to take on this challenge by utilising our full medical services offering by providing:

- Promedim medical monitors with intensive care experience
- Integration of both Sponsor and Promedim medical teams through our promedim24 technology
- Promedim control centre to triage and route calls to those medics who were available

By using promedim24 technology this enabled:

- The Promedim control centre to see the medics who were available for calls in real-time, and vital for patient safety
- Physicians to have access to the latest study specific documents, including protocol, on the go via a mobile app wherever they were
- The Sponsor's quality team to demonstrate physician availability 24/7/365, through a continuous audit trail in a subsequent regulatory agency inspection



“ The combination of promedim24 technology allowed integration of the sponsor medical team together with Promedim medical experts to ensure a high-quality, cost-effective medical monitoring solution for a clinical study in critically ill patients. ”

## Promedim's study success

- Medical coverage was provided 24/7 throughout the study duration.
- Over 250 calls were routed, with up to 10 calls per day.
- All eligible patients were discussed in real-time without missing an opportunity for investigator contact or compromising patient safety.
- Each call was passed in real-time to an available physician answering to the highest scientific standards to ensure the sponsor's credibility with investigators remained, facilitating hitting the recruitment goals ahead of schedule and with the clinical trial data supporting a successful product application for the use in that indication.

## Ready for any challenge

The combination of promedim24 technology allowed integration of the sponsor medical team together with Promedim medical experts to ensure a high-quality, cost-effective medical monitoring solution for a clinical study in critically ill patients.

## case study



### 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.

**promedim**  
Technology Enhanced Medical Monitoring