IMS Health & Quintiles are now IQVIA™

OPERATIONALIZING 30-MINUTE ECG REVIEW

Addressing the unique post-marketing cardiac safety monitoring requirements of an autoimmune disease product

THE CHALLENGE

Reports of serious adverse events (SAEs) post-approval

- Customer needs to respond to regulatory guidance issued on **rigorous monitoring of cardiac safety** by clinics six hours post-dose, with reporting requirements varying across geographies – because of the risk of transient bradycardias and heart block after the first dose, the FDA heightened the recommended level of cardiovascular monitoring of all patients after their first dose
- At the time, no clinical services provider had resources in place to facilitate expedited analysis

THE SOLUTION

Develop and operationalize novel global processes

ECG equipment provided to clinics for **on-site safety reviews**. Immediate calls via helpdesk to resolve any queries and facilitate prompt reporting.

ECG analysis processes and systems customized for **expedited reporting within just 30 minutes** (versus the industry standard of 48-72 hour turnaround time).

- **MD support available 24/7 and 365 days a year** for expedited ECG review and on-call support – and call center support for technical troubleshooting
- 100% of all ECGs are reviewed by our team of **board-certified cardiologists**

THE RESULTS

Expertise to meet post-marketing/Phase IV needs for near real-time ECG reporting

Successful roll out implemented across >200 clinics in the U.S. and Canada

Since 2012, IQVIA met the required **30-minute turnaround time with >98% accuracy across >4000 ECGs**

Delivery model has since been duplicated across other studies for other sponsors

CONTACT US

iqvia.com/contactus