SCCR's Monitoring Program
Pioneering New Frontiers in Clinical Research Oversight

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BACKGROUND

SCCR's Monitoring Program is designed to provide meticulous monitoring oversight for investigator-initiated trials (IIT) and other human research studies deemed to carry more than minimal risk. Our program fills a crucial gap in ensuring the integrity and safety of research endeavors. We offer a comprehensive suite of other monitoring services: Risk-based Monitoring, Risk Assessments, Monitoring Plan Creation, Remote and On-site monitoring visits, 100% Source Data Verification , Regulatory Document Review, and Sponsor monitoring oversite.

FDA's regulations requires the sponsor to ensure proper monitoring of investigation(s), and that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND. For IITs, the Investigator is equal to the Sponsor. (21CFR 312.50 and 812.40).

ICH E6. v. 2.0 states that the purposes of trial monitoring are to verify that:

a. The rights and well-being of human subjects are protected
b. The data is accurate, complete, and verifiable from source documents.
c. The trial is in compliance with the currently approved protocol/amendment(s), GCP, and applicable regulatory requirement(s).

METHODS

Our Monitoring Program follows the FDA's recommendation of using a **Risk-Based Approach**. At the protocol design stage, together we identify critical data and processes essential for ensuring subject safety and maintaining data integrity. Once these elements are identified, we conduct a risk assessment to determine how to identify, track, and manage potential risks. These strategies and procedures are then outlined in the study's monitoring plan.

RESULTS

In 2024, we monitored over 15 studies across more than 20 sites, covering multiple therapeutic areas including Dermatology, BMT, Pediatric Oncology, CIT, and others. Through our monitoring efforts, we successfully identified and resolved potential risks and instances of noncompliance. See the table below:

Category	#Minor	#Major	Reportable
Protocol Deviations	136	7	1
Unreported Safety Events	53	6	**5**
GCP and Regulatory Noncompliance	**> 300**	18	4
Informed Consent Errors	90	**25**	4
15# Corrective And Preventative Actions (CAPAs) were created and successfully implemented as result of the findings above.			

KEY TAKEAWAYS

Our program provides critical oversight for IITs and other human research studies, ensuring the integrity and safety of these endeavors. Our experienced staff offers tailored, risk-based monitoring to meet FDA and ICH E6 guidelines.

Early involvement by the SCCR monitoring team ensures that study staff and the PI understand their regulatory responsibilities, study procedures, and the monitoring plan.

ACKNOWLEDGEMENTS

We would like to extend our gratitude to our external partners, whose collaboration and trust in our program have been instrumental in refining and streamlining our monitoring processes. This enables us to better support study teams and provide the most effective monitoring solutions.

CONTACT

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