



FHI Clinical is dedicated to continually improving the clinical trial process which increasingly includes the use of artificial intelligence (AI). Our adoption of AI tools is guided by our global policy on AI to ensure responsible and ethical use and to protect data confidentiality and maintain integrity and compliance with relevant regulations. We understand the unique opportunities and challenges that AI represents in the clinical trial space and believe it must be utilized in ways that ensure the safety, security, and overall well-being of the participants.

Some areas where FHI Clinical has already begun to incorporate AI to improve our processes include:

- Contracts & Legal – accelerate the start-up process
- Project management – record and track communication including key decisions and actions
- Clinical Monitoring – improve quality by drafting and comparing documentation based on a protocol design
- Data Management – improve data accuracy by assisting with local lab reference range management
- Biostatistics – generate SDTM datasets more efficiently
- Regulatory – track global regulatory updates
- Quality Assurance – review and compare SOPs for more effective internal and external audits

As AI continues to improve and become incorporated into more of the clinical trial process, FHI Clinical believes the human element remains core to our approach. While AI may lead to faster start-up times, more accurate site selection, and more efficient monitoring, we know that human supervision and review remain crucial. Our experts continue to engage with AI to make sure we are using it in ways that improve our sponsors' experience, maintain the safety and security of our trial participants, and stay true to our mission to help all people live longer, healthier lives.