

## ELECTRONIC RESEARCH INFORMATION AND COMPLIANCE (eRIC)

### CHALLENGE/SITUATION

Protecting human clinical trial participants is important, especially for stakeholder committees, such as the Institutional Review Board (IRB) and the research committees, who review those trials for ethics and drug efficacy on a continuous basis. However, these processes and workflows are complex. It involves time-sensitive communication across various stakeholders; timely alerts and notifications; data integrity/quality assurance; data consistency; monitoring protocol statuses and lifecycles; audit trails and reporting, all of which have the potential to impede overall efficiency. There is a clear requirement for a solution that would facilitate communication and exchange information; create automation and collaboration; and decrease redundancy and human errors due to poor version control and paper-dependent tactics, while protecting the rights and welfare of the people who participate in research.

### APPROACH

The solution needed to eliminate redundancy and human risk for errors; minimize liability; increase standardization; streamline meeting logistics; make it easier to comply with standards; maintain an audit trail; and control access. It needed to automate and centralize the clinical trial registration process on a single platform; reduce clinical trial setup time; and increase standardization.

### SOLUTION

eRIC is a paperless, electronic system that automates the submission, tracking, and reviewing of scientific regulatory and compliance information required for the safe conduct of human subject research. eRIC easily routes forms for approvals; securely collects electronic signatures; quickly views user tasks; submits protocol application forms and easily attaches related documents; enters protocol data into protocol application templates and informed consent forms; and automatically saves updated information.

eRIC modules include protocol, meeting, documents and review management; electronic signature; alerts/notifications; reporting; IRB task facilitation; and interfaces. It is a single-source collaboration platform that aids the process of reviewing research protocols and related materials.



### BENEFITS

eRIC delivers a diversified and convenient solution for research administrative tasks and meeting logistics; decreases workload and alleviates administrative burdens; improves human subject protection and animal care; complies with regulatory and good practice standards; facilitates collaboration among research teams and improves the overall clinical trial process; and minimizes the risk for human error. eRIC currently has 160 Active Protocols and about 75 Active Users. eRIC facilitates and enables discourse on the U.S. health research policy; promotes real-time interaction between regulatory agencies and research communities; improves overall public trust in pre-clinical and clinical research processes; maximizes Return on Investment (ROI); and is compliant with caBIG® Bronze, Section 508, and Title 21, Code of Federal Regulations (CFR) Part 11.