Lighthouse Institute | Product Brief: *CRICIT*

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Purpose

Clinical Research Information Core for Integrity and Tracking (CRICIT) systems are custom-built software applications designed to streamline the processes involved in conducting clinical research. These systems provide a robust infrastructure for managing a multitude of data workflows and operational demands of research projects. CRICIT systems are developed with a primary focus on maintaining fidelity to research protocols while facilitating efficient data collection, reporting, and analysis.

The development of CRICIT systems is guided by the Knowledge to Action (KTA) cycle (Straus, Tetroe, Graham, 2013), a knowledge translation framework commonly used in healthcare to bridge research and practice, which we adapt to translate research protocols into custom software. This conceptual framework ensures that the software aligns with the specific objectives and workflows of each research project. The process begins by identifying the data requirements and workflows essential for research activities, often using grant applications or similar documentation as the foundation. These inputs are translated into a comprehensive implementation protocol, which outlines how the research will be conducted in real-world settings. This protocol also serves as the blueprint for the development of a CRICIT system, ensuring that the software remains aligned with project goals.

By translating project objectives into actionable workflows and tools, CRICIT systems are uniquely designed to uphold the integrity of research protocols. This alignment not only enhances the accuracy and efficiency of data collection but also supports the validity and reliability of research findings. The CRICIT development team includes staff with expertise in behavioral health treatment, software engineering, statistics, and research methodology, ensuring systems are technically robust, aligned with research best practice, and considers the participants' experience. The team's interdisciplinary approach brings valuable insights that support the diverse needs of project stakeholders.

Development Lifecycle of CRICIT Systems

The lifecycle of a CRICIT system encompasses several critical stages, starting with collaboration between researchers and software developers to establish a comprehensive vision and plan. Following this, the system is developed, tested rigorously, and implemented in the research environment. During implementation, ongoing monitoring and adjustments are made to accommodate real-world usage and any changes to the research protocol. As the system matures and stabilizes, the frequency of changes and interactions typically decreases, allowing for smoother operation and maintenance. This iterative process ensures that CRICIT systems are not only functional but also adaptable, meeting the evolving needs of the research project while maintaining the highest standards of data integrity and usability.

Features

CRICIT systems are designed to seamlessly handle essential research processes while offering full customization to meet the unique requirements of individual studies. Commonly included features are

tailored to align with the specific workflows and objectives of each project. This flexibility ensures that CRICIT systems can support a wide range of research needs with precision and efficiency.

Customizable features include:

- Recruitment tracking
- Screening
- Consent
- Complex and simple randomization
- Enrollment
- Scheduling
- Locator forms
- Participant tracking
- Retention effort tracking
- Payments
- Multi-site management
- Print mailing labels
- Reports
- Process automation
- Role-based data access
- Audit log
- API integration with external software systems

Common Research Challenges Addressed with CRICIT

Research Challenge	CRICIT Solution
Tracking people & tasks over time	Collect and access longitudinal data
Multiple software to address needs for screening, tracking, follow-up, treatment adherence, incentives, billing	Robust software handles complicated tasks in one application
Simple to complex randomization scheme	Program in CRICIT or link to applications (e.g., urn randomization)
Adjusting data collection & adherence protocols	Easily edit or add new components & reports
Onboarding staff with various roles	Intuitive interface for onboarding & assigning roles
Limited data access options	Multiple ways to access and export data
Protocol information is in multiple places	Protocol information is embedded in CRICIT
Time and effort to produce CONSORT Diagrams	On-demand, real time CONSORT diagram
Access to data analytics & software development teams' time	Training of project level staff to do basic functions like editing, new modules, and report writing

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