Project Title: Accelerating Clinical Trials: From Protocol to System Readiness Using Interoperability Standards and Intelligent Automation

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Project Description

Clinical trials face persistent bottlenecks. First, the time required to translate an approved protocol into a functioning data collection system: configuring case report forms and mapping data requirements remains manual and error-prone, typically taking months. Second, once trials are running, data collection itself is inefficient. Despite the digitisation of healthcare, most trials still rely on manual transcription from electronic health records (EHR) to research databases, a process that duplicates effort, introduces errors, and burdens clinical staff.

Electronic source (eSource) approaches, where clinical data flows directly from EHRs into trial systems, offer a solution. Yet large-scale, standards-based implementations remain rare. The problem is compounded by precision medicine trials, which demand increasingly granular data across heterogeneous EHR systems. There is no standardised pathway from protocol specification to automated data collection.

This doctoral research, in collaboration with Mela Solutions, addresses a central question: ***How can we automate the translation of clinical trial protocols into executable data collection configurations, minimising setup time and improving data quality?***

The project will develop and evaluate a model-driven approach that bridges protocol specifications, EHR data availability, and EDC system configuration. By leveraging interoperability standards from both the healthcare (HL7 FHIR) and clinical trials domains, the research will create a generalisable framework for rapid, standards-based trial deployment.