



Human Performance

Skill acquisition of personnel is a key factor in the safe and effective deployment of a clinical research protocol. Proficiency can only be gained through experience. Research personnel can “practice” in a simulated environment, working through their personal “learning curve,” without placing subjects (or data) at risk.



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High-Fidelity
 Simulation of Clinical
 Research
 Protocols

DUKE UNIVERSITY HUMAN SIMULATION AND PATIENT SAFETY CENTER

Duke University Human Simulation and Patient Safety Center is pioneering the use of high-fidelity simulation in the deployment of clinical research protocols.

Our methods make clinical trials safer for patients and less costly for sponsors. We can quickly replicate any clinical location.

Our investigative group, the Research Organization on Clinical Trials (ROCT) is building evidence supporting the use of high-fidelity simulation in two distinct phases of protocol development: (1) pre-enrollment walkthroughs and (2) research personnel training.

The potential impact of these training methods include: improved patient safety, fewer protocol amendments, few data queries, improved data quality, and faster completion of studies.

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Walkthroughs

Protocol developers observe their study performed by research personnel in a simulated clinical setting PRIOR to subject enrollment. Walkthroughs highlight potential protocol errors and inefficiencies early in the development cycle (thereby minimizing subject exposure, minimizing amendments and improving study “usability”). Any clinical setting can be replicated.



Personnel Training

Proper performance of a clinical trial depends upon complex, intertwined behaviors. Complex human behaviors demonstrate “learning curves” (where performance improves with repetition). Training research personnel in simulated environments allow monitors, coordinators, and investigators to make mistakes without risk to enrolled subjects or data integrity. Upon conclusion of simulation training, the research personnel are closer to optimal performance when subject enrollment begins.

High-Fidelity Simulation

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