

User Acceptance Testing and RTSM System Validation

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4G Clinical is a cutting-edge [randomization and trial supply management \(RTSM\) company](#) focused on simplifying and accelerating the study start-up process through offering the [4th generation of RTSM technology](#). The company was founded in October 2015 by RTSM pioneers, engineers and marketing experts to solve operational and supply chain challenges that have plagued this industry for years. Ultimately, 4G's mission is to bring crucial medicines to those who need them, faster. Headquartered in the heart of the Boston biotech corridor, in Wellesley, MA, 4G Clinical has facilities and staff around the globe, and offers expertise and advisory services to bio/pharmaceutical companies and contract research organizations. For more information, visit www.4gclinical.com.

When implementing a randomization and trial supply management (RTSM) system for a clinical trial, there is a shared responsibility between the RTSM vendor and sponsor organizations to ensure the system performs as intended according to predefined requirements. The vendor is responsible for ensuring the system is properly validated to perform to requirements prior to the client accepting the system for use. According to guidance documents, regulations and industry best practices, the sponsor is responsible for supplier oversight, validation of the system in their environment (i.e. fitness for use) and to plan for risk and mitigation. This whitepaper outlines a proposed strategy for sponsors to follow that demonstrates joint responsibility for ensuring overall RTSM validation, without duplicating the efforts already taken by their vendor and ensuring proper oversight by the sponsor company.

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