Article

Achieving Faster, Simpler Validation Through Crowdsource UAT

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Demonstrating the safety and quality of a clinical trial protocol requires systematic data collection practices and reliable data integrity. A Trial Master File (TMF) acts as a repository for all documents relevant to a trial's conduct, and an electronic TMF (eTMF) can offer several advantages over its traditional counterpart, including improved tracking, streamlined collaboration, and simpler and more secure storage. Having a well-delineated TMF or eTMF in place is crucial to a study's regulatory success, as the accessibility and trackability these systems afford is considered essential to achieving Good Clinical Practice (GCP) standards.

Validating the features and functionality of an eTMF is both required by regulators and crucial to optimizing trial management. User acceptance testing (UAT), the phase of software validation during which actual users operate a platform to ensure it can perform as expected in real-world scenarios, can represent a significant lift for vendors and sponsors. Traditionally, this testing is performed one of two ways: either through in-house testing or by way of a third-party vendor. Although these models can provide valuable insights into a technology's usability, each can also create compounding burden for a UAT protocol as both trials and the technologies supporting them grow more complex.

Crowdsource UAT is a validation model that enables testing via real, external users. An approach most often seen in the larger tech space, crowdsource UAT can offer several potential advantages for the clinical trial industry — with access to more users, crowdsourcing can often result in faster testing, as well as more reliable flagging of issues and bugs. This, coupled with the advantages users themselves can experience through the in-system training offered by testing, can help position organizations for a more streamlined, comprehensive UAT and technology deployment.

eTMF and UAT regulatory requirements

For sponsors intending to use an eTMF platform as the system of record for a trial's regulated documents, adequately validating the platform is critical. In Subpart C of the FDA's CFR 21 Part 11, the agency states that any executed validation for a computerized system should be based on a justified, documented risk assessment; this requirement is reinforced by guidance issued under an ICH GCP addendum released in 2018. The EMA has likewise required that any qualification and validation activities conducted for computerized systems be based on a documented risk assessment, noting that "it is not acceptable to use computerized systems in clinical trials for which the validation status is not confirmed, or for which appropriate documentation on system validation cannot be made available to GCP inspectors."

While a sponsor may rely on qualification documentation provided by an eTMF vendor, ultimate responsibility for this qualification lies with the sponsor. A sponsor may choose to engage in additional validation and qualification activities beyond what a vendor recommends, and must re-validate systems which have undergone upgrades, which can introduce new complexity to subsequent validation cycles. Although any changes or upgrades to a system may not automatically result in added evaluation, each new element of a system must be reviewed for inclusion in validation moving forward. Ultimately, with each new

upgrade and validation cycle comes an increase in the volume and workload for UAT execution. This is true for both in-house validation activities and outsourced ones, with additional oversight required for the latter.

Crowdsource UAT: Results, benefits, and future considerations

The ability to quickly implement data capture technologies in support of clinical trials is vital in the modern pharmaceutical development landscape. The IQVIA Digital Trial Management Suite (DTMS), a cloud-based platform that convenes several integrated applications designed to accelerate traditional, hybrid and decentralized trials, offers digital solutions that support precision planning and intelligent automation to create and maintain an inspection-ready eTMF. As part of a recent pilot project, IQVIA implemented a crowdsourcing model by building a bespoke, vendor-managed crowdsource eTMF tenant for use in system upgrade cycles. In its pilot, IQVIA supported participating clients in conducting a portion of their UAT using the tenant, sharing their test execution objective evidence, as well as any reported defects, with other participating clients, thereby reducing the validation workload of each. The intention of the crowdsource model was not to replace existing validation requirements in their entirety, but rather to focus on activities pertaining to core functionalities and features of the eTMF.

IQVIA built and defined its crowdsource UAT process comprehensively, drafting an SOP and crowdsource-specific UAT scripts for participating clients. As part of its script development, IQVIA has built in defect escalation and resolution pathways for any potential script failures, as well as materials outlining the execution of crowdsource-specific UAT training. The process for crowdsource validation is similar to traditional system validation, with a few key divergences. For the crowdsource process, participating clients will use a single multi-client tenant, with the vendor leading UAT training for all testers. Following the release and provision of all validation documentation associated with a crowdsource project, the vendor is responsible for assigning UAT scripts to each client for execution. At the conclusion of the project, the vendor will review, consolidate, and release all of the objective evidence to all participating clients.

By driving joint cross-client UAT activities during upgrade cycles, IQVIA found that its crowdsource model may afford eTMF vendors the ability to better support their clients while collectively expending fewer resources. For example, if a vendor identifies UAT scripts for inclusion during an eTMF upgrade cycle, it may choose to divide those scripts across four clients during the validation process, assigning five scripts to each. This approach effectively lowers each client's workload by 75 percent, along with establishing a larger pool of users across four distinct clients.

Conclusion

While more traditional methods of UAT validation are likely to result in a steady increase in workload with each new upgrade cycle, crowdsource validation can, over time, reduce workloads through objective evidence exchange. A gradual increase in workload is still possible with crowdsource UAT; however, overall burden for individual clients will be markedly lower than for those engaging in traditional validation methods. IQVIA's long-term plan is to continue to build confidence in the model through increasing client buy-in, generating more client feedback, and continuing to scale, with a focus on achieving iterative improvements. Although IQVIA has thus far only executed crowdsource validation once in the context of an individual upgrade, it has already begun implementing key learnings from the process for future client projects, including shifting more control to clients regarding user permissions in order to further shorten time windows.

Ultimately, the crowdsource UAT model represents a viable alternative to traditional UAT models, allowing clients to reduce their individual validation workloads during eTMF upgrade cycles. By enabling shorter validation timeframes and increased defect detection, crowdsource UAT may serve to greatly reduce the burden of eTMF upgrade and launch activities, simplifying and streamlining the process for vendors and sponsors alike.

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