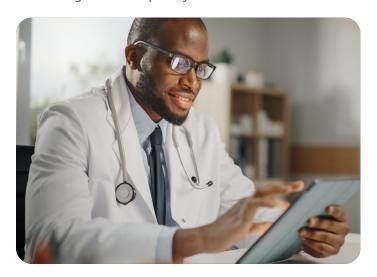**IQVIA TECHNOLOGIES**

Crowdsource UAT: An Opportunity for Future Validation

User acceptance testing (UAT) is a crucial step in validating an organization's chosen electronic Trial Master File (eTMF) system — this phase of validation, conducted before a system goes live or prior to significant upgrades, is the last and best means of flagging issues and ensuring regulatory adherence. In the clinical trial space, most UAT exercises are conducted either by third-party testers or in-house. While each approach has its merits, both also have the potential to create significant burden for a sponsor as technologies and trials grow in complexity.

In a recent webinar, IQVIA, a leading health information technology and clinical research company, introduced a new validation model for eTMF patterned after approaches used within the larger tech space. Its crowdsource UAT model drives joint, cross-client UAT activities during upgrade cycles, offering eTMF vendors the ability to better support their clients while those clients collectively expend fewer resources. This is because while more traditional methods of UAT validation are likely to result in a steady increase in workload with each new upgrade cycle, crowdsourced validation can, over time, reduce workloads through objective evidence exchange. By utilizing crowdsource UAT, multiple sponsors can divide a workload, perform their assigned tasks, and receive combined, comprehensive, anonymized data from their eTMF vendor at the end of a validation cycle.

Qualifying an eTMF's core features and functionality is required by regulators in the U.S., Europe, and beyond. These mandates, coupled with the potential pitfalls of insufficient validation — time and money lost, mid-trial, from issues arising with an eTMF — make crowdsource UAT an attractive option, owing to both its reduced individual workload and access to larger numbers of testers. Through 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.

IQVIA's crowdsource UAT pilot is ongoing and designed to complement its comprehensive technology platforms, which support on-site, hybrid and decentralized studies. To learn more about IQVIA's site suite of technologies, click here or email OrchestrateYourTrials@iqvia.com.