Fact Sheet

Centralized User Acceptance Testing (cUAT)

GxP-compliant user acceptance testing for sponsors implementing new systems or introducing new studies on existing systems

The challenge

When you implement Interactive Response Technology (IRT), electronic Clinical Outcomes Assessment (eCOA) or other new technology systems, they need to be thoroughly tested as part of User Acceptance Testing (UAT). Such testing must be performed before those systems go into production, and handled by an independent organization to avoid any buy-in.

- Without proper UAT, critical issues such as incorrect medications or dosages being assigned to participants may occur during the trial. This can cause patient safety issues and impact the success of the trial
- Incorrect IRT/eCOA data affects the quality of data in downstream systems, such as Electronic Data Capture (EDC), Clinical Trial Management Systems (CTMS), and others
- The cost of fixing errors found during the trial can be very costly and possibly lead to regulatory agency audit findings, trial delays or cancellation, and reputational damage, along with all the costs to remediate these issues

The solution

Ensure compliance with independent UAT for Good Practices (GxP)

IQVIA's Centralized UAT (cUAT) service provides an independent capability for UAT of systems like IRT, eCOA and others used during clinical trials. Our cUAT team:

- Performs a review of User Requirement Specifications (URS) for accuracy before the finalization of URS
- Coordinates with stakeholders for these systems to ensure test cases test the appropriate areas of that system
- Writes independent test cases, reviews them, and executes all test cases before confirming system go live
- Maintains documentation for traceability evidence and future audits

Your benefits

Reduce your trial expenses by conducting proactive, independent UAT prior to launch

We specialize in this type of user acceptance testing to take the burden off you. This focus allows us to deliver the services efficiently and cost-effectively to your organization with minimal effort needed from your end. Our cUAT services:

1. Help your organization ensure that critical issues are identified before systems like IRT and eCOA go live to capture data for trials
2. Save you time and study budget by identifying and re-testing as part of our UAT process until required functionalities working as per expectation
3. Ensure patient safety by executing independent UAT before approving system go-live
4. Maintain validated state of the system by engaging with vendors and customers for re-UAT before any enhancement releases

Our capabilities

Our cUAT team's capabilities include:

- 15 UAT specialists
- Vast experience of performing 800+ UATs for various clinical systems
- UAT expertise on IRT systems for blinded and unblinded studies, eCOA systems, Web reports, Spirometry, LogPad and SitePad devices
- SLC process adherence with documentation availability for reference in future:
  - » Standard Risk Assessment and Control document
  - » Requirement Traceability document
  - » Execution Summary Report (ESR)
  - » Evidence of Traceability Report (EOT)
  - » Creation of UAT Computer System Validation binder for future reference

"I want to express gratitude for your team's cooperation in the initial studies, where the eCOA UAT was successfully delivered. Your team's dedication and flexibility were crucial. A special thanks to the operational team for their successful delivery of the UATs. Our team has provided very positive feedback about this collaboration. We value your efforts and are excited about the prospect of further collaboration and strengthening our partnership in the coming year."

Director of Clinical Solutions for a large pharma

Reach out to schedule a consultation about independent UAT of your IRT, eCOA or clinical system.

IQVIA TECHNOLOGIES

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