

QMENTA Launches Central Review in line with FDA Real-Time Clinical Trials Requirements for Imaging

Central Review addresses the longitudinal consistency problem that derails long-duration oncology and CNS trials

BOSTON MA, MA, UNITED STATES, June 23, 2026 /EINPresswire.com/ -- The FDA's Real-Time Clinical Trials (RTCT) initiative does not change what can go wrong in an imaging trial. It changes when sponsors find out. Under legacy models, protocol deviations and QC failures were back-end problems managed at closeout. Under RTCT, they are financially material the moment they occur. Most central reading infrastructure was not built for that.

QMENTA today announced Central Review, an end-to-end platform covering site upload, blinded multi-reader assessment, adjudication, QA, and locked database export in a single 21 CFR Part 11-compliant system.

The Problem Most Vendors Have Not Solved

Sponsors running long-duration neuro-oncology trials focus on reader supply: how many qualified radiologists can be recruited and retained. Aly H. Abayazeed, MD, Neuroradiologist and Founder and CEO of QRadAI, argues that misses the harder problem.

"Sponsors ask how many readers you have. That is the wrong question," said Dr. Abayazeed. "A reader joining a trial two years in is not going to manually pull and re-measure every prior scan. They are busy, paid a flat fee per study regardless of the number of priors they have to evaluate, and they will read what is in front of them. Each reader transition adds a little more variability. Over years of a trial, that accumulates and it is invisible until the data does not hold up. The system has to do the heavy lifting. It must seamlessly facilitate evaluation by automatically linking all prior studies and surfacing critical data based on established response criteria, ensuring accurate time-point categorization while remaining intuitive enough for the reviewer to easily dig deeper into the patient history when necessary."

Central Review is built around this model. Every scan is linked across all timepoints for the same subject. A complete longitudinal electronic Case Report Form (eCRF) is viewable as a single table with one-click export to PDF, fully audit-trailed. The reader who opens a worklist two years into a trial sees the same complete picture as the reader who was there at baseline.

That continuity depends on getting everything upstream right. The workflow is designed around what readers, sponsors, and regulators actually need:

- No IT project, no VPN, no hard drives: sites upload via browser, Python SDK, or direct PACS connector, with automated de-identification built in.
- Reader blinding enforced by the platform, not managed by process: role-based access and dedicated worklists by design.
- Adjudication built into the workflow, with every event captured in the audit trail: no email coordination, no gaps between systems.

A Platform Regulators Can Audit

Central Review inherits 21 CFR Part 11, EU Annex 11, HIPAA, GDPR, ISO 13485, and GxP compliance from the QMENTA Platform, which holds FDA 510(k) clearance and zero nonconformities across all external pharmaceutical partner audits.

Upcoming Webinar and Free Trial

QMENTA hosts a live webinar on June 25, 2026 at 12:00 PM ET featuring Dr. Abayazeed and Paulo Rodrigues, PhD, CTO and co-founder at QMENTA, demonstrating subject-linked reads and longitudinal eCRF export. Register at <https://neuroimaging.qmenta.com/webinar/one-click-between-timepoints-one-table-for-the-whole-subject>.

QMENTA also offers a two-month trial with free cloud credits at www.qmenta.com.

About QMENTA

QMENTA provides the governed imaging layer connecting scanners, sites, models, and regulators into a single auditable system for regulated clinical trials. QMENTA is an AI Orchestration Fabric purpose-built to turn imaging operations from a source of trial risk into a source of competitive advantage, accelerating the time from first scan to regulatory submission. Over 16 million imaging files have been managed across more than 250 sites globally, serving NIH, Amylyx, UCSF, Bayer, Alzamend Neuro, and ICON. Offices in Boston and Barcelona.

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