CASE STUDY

Streamlining Medical Imaging to Support Alzheimer's Disease Phase II Trial

A neuro focused Mid-Size Biopharmaceutical Company initiated a phase 2 alzheimer's disease clinical trial. It was a randomized, double-blind, multi-center, placebo-controlled trial evaluating the safety, tolerability and activity of a compound in 100 adults with dementia or late mild cognitive impairment (MCI) due to AD, over 6 months of treatment.

The trial was designed to evaluate tolerability in this patient population while also assessing efficacy measures and diverse, disease-relevant markers to allow for evaluation and correlation of imaging-based markers, neurobiological changes, functional measures, and cognitive outcomes in a broad group of people with AD.

Situation

The sponsor had identified a Key Opinion Leader (KOL) in the neurology and translational neurology field. Established CROs and Imaging Core Labs were not chosen for the execution of the trial due to agility and budget challenges, as well as the scientific flexibility in supporting the assessment of state-of-the art imaging-based objectives.

However, the KOL and academic CRO's lacked the technological infrastructure to acquire and manage large imaging study; and lacked the experience to translate the use of academically developed analysis tools in a highly controlled and regulated environment.

Challenge

The clinical trial evaluated 100 adults with dementia or late mild cognitive impairment (MCI). The trial was designed for the evaluation and correlation of imaging-based markers from large quantities of clinical imaging data acquired across 13 sites.

Being able to deploy state-of-the-art, complex, image processing tools in a protected, secure and inspection-ready environment, was of utmost importance.

Solution

QMENTA's industry leading scientific team and all-in-one software solution was employed to efficiently streamline the imaging workflow, including collection, management, and analysis of all trial's imaging data.

QMENTA's solution enabled:

- **Seamless aggregation** of multimodality image data across 13 sites. Patient's DICOM images are automatically sorted based on the database Randomized IDs, and a ML/AI tool automatically organizes data based on the different sequences, instead of manually validating naming of files.
- **De-Identification** tools automatically remove protected health information (PHI) from DICOM images, while preserving offset dates such as age at scan.
- **Automated Protocol adherence and Quality Assurance** automatically validates that all parameters of the uploaded imaging data are compliant with the predefined imaging protocol, quickly identifying missing data or inconsistencies. Automatically extracted image quality measures assist in preserving data quality and accelerate the identification of cropped or noisy images.
- **Quantitative image analysis** of MRI Imaging for the assessment of volumetric changes, as well as diffusion and functional connectivity mapping.
- **Automation of manual tasks** lowering the risk of intra/inter-reader variability and transcription errors.
- **QMENTA unified cloud infrastructure** is a secure and scalable technology infrastructure that connects patients, sites, sponsors, and partners, together, in a single environment. One place to manage all imaging data, from start to finish, reducing site burden and overall costs.
- **Complete, efficient end-to-end management** of imaging data enabling deadlines to be met.

Key Highlights

- **Enrollment Adjustment**: Enrolled patients increased to 100, from the initially planned 50 patients from 5 sites (initial constraints on budget and time).

  While using QMENTA ecosystem, it was rapidly clear that data acquisition challenges were simplified. The sponsor had the confidence to increase the studied population without significantly increasing site burden or risk.

- **Secure Image Data Transfer and Management:** One of the sites followed a different file naming convention, which was immediately identified and had no impact in database reconciliation.

  Automated de-identification preserved technical acquisition details such as TE, TR, or even private tags with diffusion gradient encoding information.

- **Imaging Data Validation and Quality Assurance:** Automated quality checks along the imaging workflows allowed to preserve data quality and integrity along every step of the process, facilitating a quick database lock and data scrubbing turnaround times.

- **Quantitative Imaging Objectives/Endpoints:** The combination of our AI experts and proprietary technology permitted the combination of third-party 'gold standard' algorithms with state of the art imaging workflows in an efficient and compliant manner.

  We provided a fast, almost real-time, turn-around time for all quantitative imaging endpoints.

  Initial image processing design included the cross-sectional evaluation of changes on whole-brain and regional (hippocampal) brain atrophy as assessed by volumetric Magnetic Resonance Imaging (vMRI).

  Our sientific team guided in the use of a longitudinal processing stream reducing the test-retest variability, and therefore increasing the overall quality and confidence in the imaging results.

  QMENTA's scientific team worked together with the sponsor and PI to apply further exploratory image processing algorithms such as resting state Connectomic Maps or white matter lesion segmentation, unlocking additional value in the data.

- **Imaging Data Traceability and Scrubbing:** Although the Randomization ID protocol changed through the course of the trial (naming convention for second timepoint changed), the flexible database allowed for instant mapping of the timepoints, without any further manual entry.

  Our database interoperability allowed for the easy reconciliation between collected and analyzed data to the trial EDC, easily identifying which patients dropped through the trial, due to COVID-19 or other reasons.

  A comprehensive and unified view of the acquired data and the image analysis results allowed for full control and visibility along every step of the process.

- **Documentation:** Our scientific team quickly provided reconciliation, QA, closeout report and other documentation.

- **Regulatory Support / audit?:** Our Quality and Regulatory teams together with QMENTA's Platform helped ensure the safeguard of trial's data and provided solutions to ensure sponsor's regulatory compliance.

In June 2020, the trial completed enrollment and dosed 96 participants despite delays from COVID-19 pandemic.

State-of-the-art medical imaging outcomes were delivered with high quality, reliability and accuracy, all in a secure and inspection-ready infrastructure.

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US Headquarters

1 International Place, Suite 3700
Boston, Massachusetts 02110
+1 339 368 8040

EU Offices

C/ Roger de Llúria 46, Pral. 1ª
08009 Barcelona, Spain
+34 933 282 007

qmenta_inc

@QMENTA_Inc

www.qmenta.com