median
The Imaging Phenomics Company®

Case study:

Managing medical images in oncology trials:

How automation can improve data consistency/value, and streamline study workflow

Background

Managing medical images in clinical trials can have a number of pitfalls that can potentially jeopardize trial results. With regulators and payers asking for higher quality and a greater quantity of evidence from clinical trials[1], requirements are becoming more stringent and effectively managing the growing amount of data as well as the increasing complexity of the imaging workflow present new risks.

Our innovative response to this situation is to use a high level of automation at different stages of the imaging workflow.

Automation in imaging workflow:

The Median solution

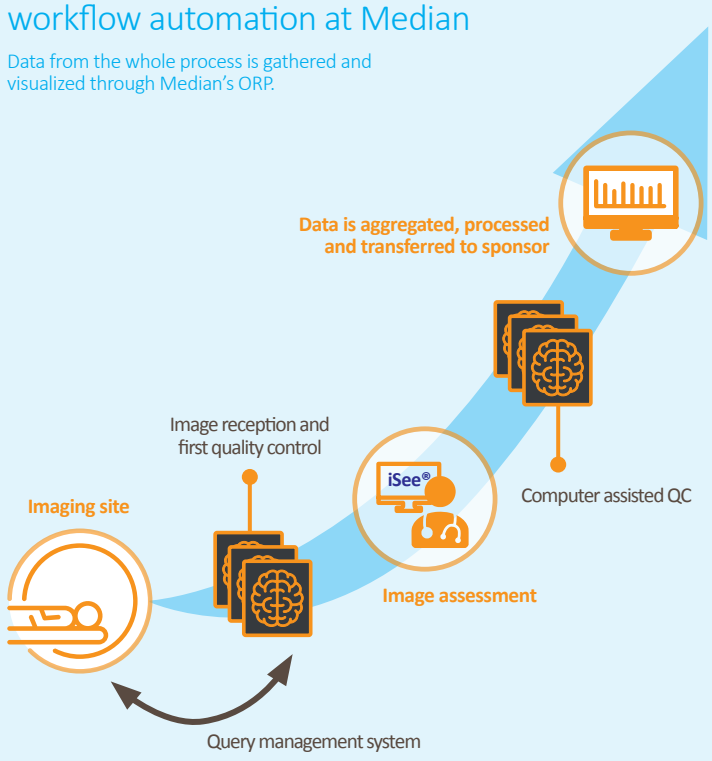
For oncology trials, imaging is used as a primary and/or secondary endpoint to evaluate drug efficacy. At Median, we understood that imaging data is critical to trial success and therefore we implemented a high level of automation in the studies we support.

1 **We increase imaging data consistency and value by** reducing and better managing queries, helping radiologists assess images more accurately while decreasing inter- and intra-reader variability and checking the quality of image assessment according to specific imaging criteria depending on trial design and cancer indication;

2 **We streamline study workflow by** improving operations transparency through status/metrics based follow up of the workflow.

The different steps of imaging workflow automation at Median

Data from the whole process is gathered and visualized through Median's ORP.



Sources:

[1] https://www2.deloitte.com/content/dam/insights/us/articles/22934_intelligent-clinical-trials/DI_Intelligent-clinical-trials.pdf

Automated query management

Image reception and initial quality control are two crucial steps in ensuring the best possible assessment of each patient time point. To ensure the efficient treatment of queries opened with imaging sites – a possibly complex and iterative process – Median has developed a complete solution based on the JIRA software. Thanks to this automation, all repetitive tasks and reminders are managed automatically, leaving more time to our imaging experts to focus on core issues related to intricate image quality parameters. This reduces the time spent between image reception and read assessment by 15% and avoids unnecessary queries later on in the imaging workflow, while still providing readers with the best possible quality images to make their assessment.

Computer-aided image reading using Median's proprietary platform iSee®

Our proprietary imaging platform iSee® helps radiologists during their image assessment by assisting in lesion/region of interest (ROI) identification, and by quantifying/automatically tracking lesions across time points.

iSee® limits reader subjectivity, increases lesion measurement accuracy and reproducibility, streamlines data management and decreases data queries while providing routine or advanced imaging biomarkers and delivering superior reporting.

Computer-assisted quality control of image assessment

At Median, images get a second computer-assisted quality control after the reading assessment step. This ensures that radiologists have correctly followed study criteria. This computer-assisted evaluation flags the most recurrent issues so that they can be corrected quickly by readers. This allows our imaging experts to save 75% of the time they spent on this task before.

Automated progress visualization using the Tableau Online Reporting Portal

Clinical trial imaging workflows generate a huge quantity of data. Consolidation, processing and visualization of this data is key to identifying risks and improving decision-making capabilities for sponsors and imaging CROs.[1]

Median's proprietary Online Reporting Portal (ORP) is a configurable system providing advanced analytics. Each report provides status and performance metrics, evolution charts and data trackers that can be filtered and exported. The ORP includes specific reports to monitor four essential activities:

— Site management
— Image collection
— Query management
— Read management

Median's ORP plays an important role in efficient decision making and risk mitigation. As it can be followed and leveraged in real time by study sponsors, the tool also provides a useful transparency about Median's operations.

"Consolidation, processing and visualization of imaging workflow data is key to identifying risks and improving decision-making"

Benefits

Automating imaging workflows provides more meaningful data, limits reading variability and enhances reproducibility. It also enables efficient monitoring ensuring high quality assessment data for better informed decisions, including Go/No Go decisions.

Our optimized and standardized processes reinforce image management and quality control with automated checks conducted as early as possible and throughout the entire data collection process. Automation technology also provides seamless interoperability with clinical trial management and electronic data collection systems.

Moreover, automation makes it possible for imaging experts and readers to add more value to the workflow with their unique knowledge and expertise, while ensuring robust data consistency and reducing the time to deliver results to sponsors.

About us

As an imaging CRO, Median Technologies has unmatched clinical, technological and operational experience and expertise in oncology trials. With our offices based in the US, Europe and China, we operate globally to deliver best-in-class end-to-end imaging services for your Phase I to III oncology trials. We have a unique knowledge of the various standard imaging criteria used in clinical trials covering all solid tumor cancer indications, and we also provide innovative imaging biomarkers to ease Go/NoGo decisions in early phase studies. Median Technologies works with large pharma and biotech companies as well as global CROs, has a recognized track record with Phase III studies and has successfully passed FDA and China NMPA audits. We nicely complement the experience of global CROs we partner with by bringing our unique expertise in oncology imaging. We excel in all areas of managing oncologic images in clinical trials. There are many excellent reasons for selecting Median Technologies as your imaging CRO. Contact us to learn more!

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