

Rave Imaging and Oncology

Introduction

The use of medical imaging in clinical trials is growing rapidly. In therapeutic areas such as oncology, the importance of a streamlined, efficient, and reliable imaging workflow is even most important in studies where imaging outcomes contribute to the primary or secondary endpoints. Unfortunately, processes and systems for managing medical images within the context of clinical trials are generally decoupled and have not advanced at the pace that medical imaging could support.

Protocol Checks on Images

While receiving medical images in a timely and efficient manner is important, receiving the right images is even more important.

Imaging has advanced image edit checks that can be run on images before they ever leave the site. This ensures that you only receive the right images, at the right time, rather than wasting time with images that did not meet the imaging protocol and cannot be reviewed.

Imaging can check for any of the following:

- Modality
- Slice Thickness
- Description (Study or Series)
- and other parameters...



Imaging adds significant value to all aspects of the oncology imaging process including:

- Integrated Assessment Criteria Derivations such as RECIST 1.1 and iRECIST
- Protocol Checks on Images
- Advanced Workflow Management w/Blinding and Adjudication
- Image Viewing Tools

Advanced Workflow Management

Once the right images are submitted to Rave Imaging, the real value can be recognized.

Imaging includes sophisticated workflow management capabilities that match the workflow needs for your trial. Workflow options can be configured on a trial-by-trial basis, ensuring that each of your trials operates according to its design and not solely to match the capabilities, or lack thereof, of the system(s) used to manage the data.

Workflow management highlights include:

- Blinded Reviews
- Double Blinded Review w/ Adjudication
- Conditional based workflow triggers

RECIST

RECIST (Response Evaluation Criteria In Solid Tumors) is a set of published rules and guidelines that define when and how patients within an oncology clinical trial respond during the treatment period.

Imaging allows you to manage oncology trials in a very structured and powerful manner.

- eCRFs to support RECIST and other response criteria (irRC, RANO, Cheson, Lugano, etc)
- Workflow to support image QC, multiple reads and flexible adjudication criteria
- Optional integration with state-of-the-art viewing tools



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Rave Data Capture and Management

It Starts with Data Capture

Rave Data Capture and Management powers today's targeted therapies – all of the data, all of the protocol, in once place. , going beyond clinic and lab data to also include data from sensors, apps, images, genomics and RWE (Real World Evidence)

By capturing and integrating such a wide array of study data, **Rave Data Capture and Management** also automates many of the most challenging data management workflows across randomization, supply, coding, and safety. It is now possible for a patient to be electronically consented, randomized, provided their first supply, and automatically be coded – all in their first visit.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including over 950 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers— from study design and planning through execution, management and reporting.

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