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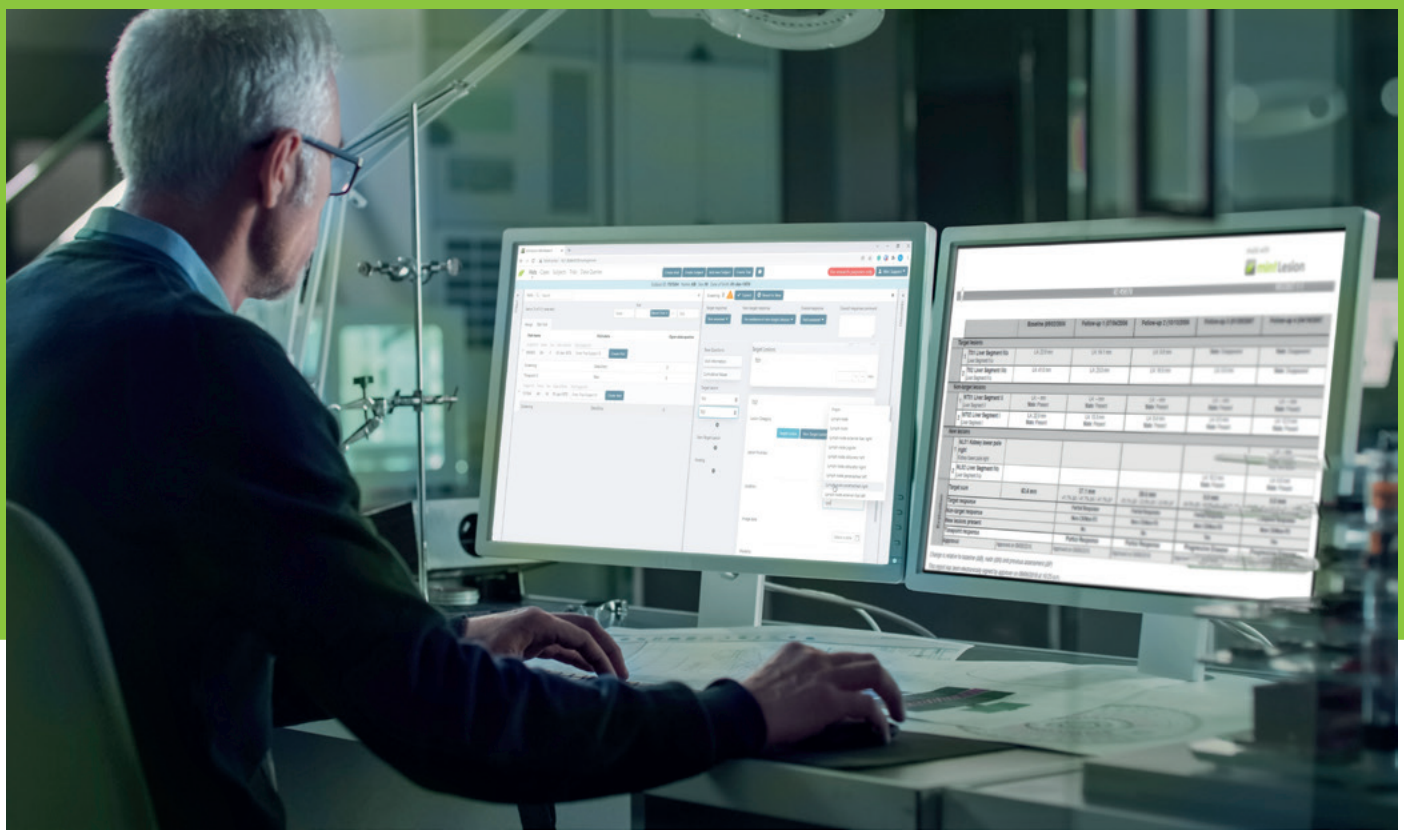


Mitigating Investigational Site Queries

Real-Time Verification of Tumor Response Assessments

As clinical trial timelines from patient enrollment to data submission continue to get shorter in the global effort to bring new therapies to patients faster, the oncology clinical trial community faces tremendous pressure to keep up with the transforming landscape.

Continuously evolving response criteria and complex protocol designs make the reporting process increasingly challenging for investigational sites participating in clinical trials. Disparity in response criteria across indications coupled with limited available information on how to operationalize a response criterion often leads to discrepancies across sites with regard to data interpretation. Combined, this may cause discordance in trial data as a whole.

Given the vast amount of data and documentation that each site must generate as well as the multitude of personnel involved in the oversight of each aspect of a patient's data file, remaining vigilant on each nuanced response criteria rule and response requirement is not often feasible. This is where a research tool with real-time response criteria evaluation, such as Mint Response Analytics becomes invaluable.

Minimizing errors in key critical datapoints, reducing the burden of effort

Mint Response Analytics supports clinical trials by enabling the assessments derived from radiological and clinical data analysis to be captured using Response Assessment CRFs in an EDC model or with a simple Microsoft Excel-based interface. Utilizing mint Lesion™ response assessment read templates (e.g., RECIST 1.1, iRECIST, Lugano, RANO, etc.), the data quality is improved through the real-time data verification. Consequently, Mint Response Analytics mitigates time-intensive data queries from CROs to investigational sites by providing the study teams entering or verifying source data with a real-time feedback, as well as clarity in interdisciplinary communication.

Main features

- Patient journey monitoring from the initial Baseline visit through all visits with longitudinal tracking of response assessment
- Rules-based algorithms deriving the protocol-specific response assessment based on the values captured in accordance with the criteria requirements
- Guided response assessment with real-time conformity checks advising the user on non-compliance with the response criteria, including checks for:
    - Criteria-specific parameters (e.g., maximum number of Target Lesions or minimum Target Lesion size)
    - Missing lesion locations when first reported
    - Missing status assessments for previously reported disease sites
- Tracking of lesion locations as initially entered over time without the need to re-enter the lesion placeholder at each visit
- Tracking of the correct comparator (Baseline or Nadir) for response determination
- Comprehensive response calculation algorithm for overall response and disease compartments (e.g., Target, Non-Target, New).

Mint Response Analytics for EDC Reporting

Convenience and simplicity of use

Response assessment data are entered via eCRFs modeling traditional EDC type formats. Furthermore, the Mint Response Analytics can be integrated with your existing trial EDCs for tumor response assessment reporting.

Clean and reliable data

The response criteria templates in conjunction with a workflow specifically crafted for the data reporting at investigational sites is enhanced with real-time conformity checks and rules frameworks to ensure entered data meets response criteria requirements.

Seamless workflow

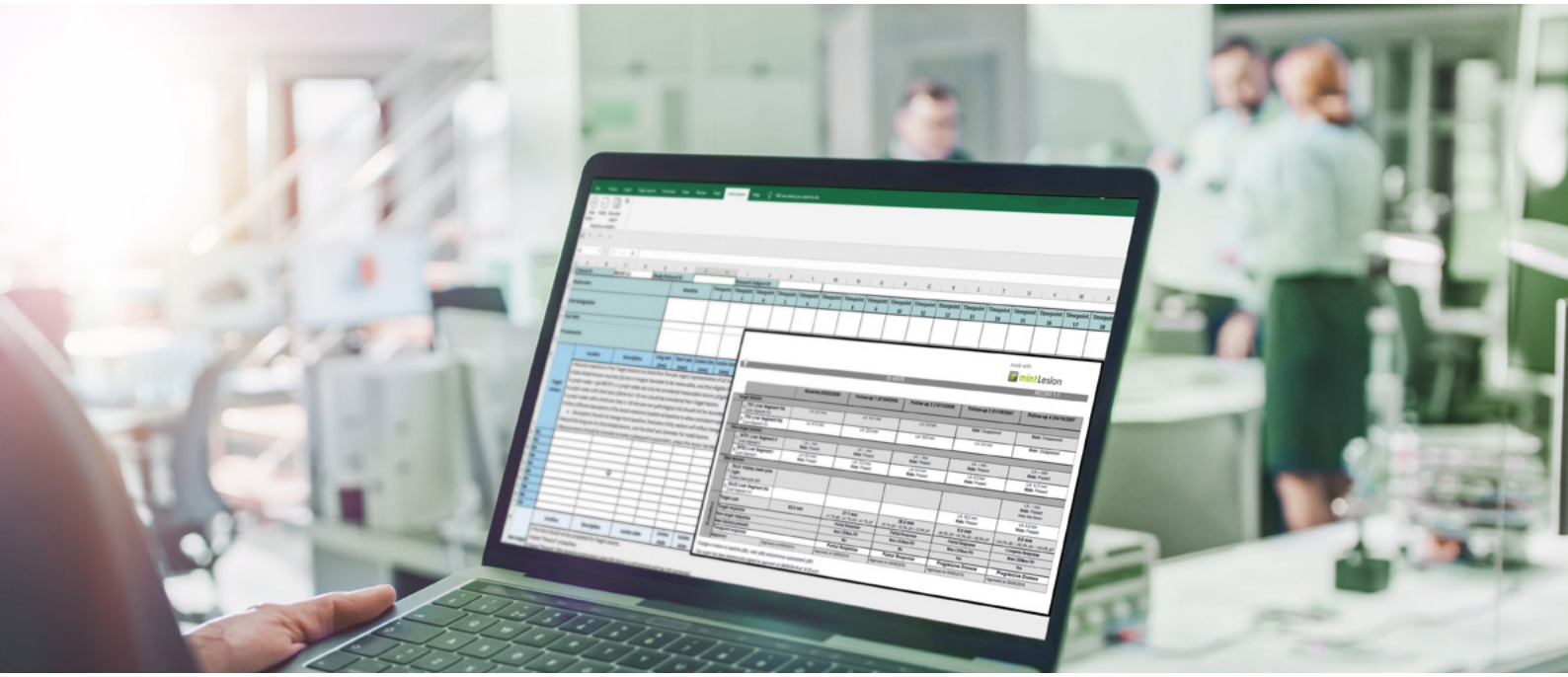
The workflow of data entry, source data verification, data review and Principal Investigator approval is supported by data-point querying and communication. Audit-trailing and real-time export of data queries and their status enable an efficient work organization.

Prospective quality control

The real-time checking of response assessment compliance in conjunction with derived response assessment values introduces quality control measures prospectively at the time of data entry rather than reactively after the data is reported.

Workload and cost reduction

Reduction of costly operational efforts to ensure data quality in turn reduces the workload of study teams and treating investigators in responding to data queries. Improving the operational and cognitive workload at the investigational sites allows the study teams to focus on patient care while also meeting the clinical trial specific needs in data reporting.



Data Verification with an Easy-to-Use Microsoft Excel Add-In

mint Lesion™ data quality through the real-time input data control

The Mint Response Analytics Add-In enables users to enter and verify clinical trial response assessment data in a Microsoft Excel document. Once the data (e.g., image scan date, lesion measurements and locations, etc.) are entered into the document, mint Lesion™ software will run conformity checks and derive response assessments using the preconfigured criteria template algorithms. Upon verification, the data is reported in the same Microsoft Excel file.

Familiar interface

The Mint Response Analytics Add-In is easy to use as it utilizes the Microsoft Excel functionality, familiar to most users.

Training on response criteria

The tool provides an easy and sustainable means for study teams at investigational sites, CROs and sponsors to become familiar with the nuances of published response criteria, offering a practical hands-on training and engaging the user with the real-time feedback to correct reporting errors.

About mint Lesion™

mint Lesion™ is Mint Medical's state-of-the-art software platform for radiological diagnostics, reporting and analysis that assures data uniformity by generating reliable, high-quality data – reported in a consistent, compliant, and structured way. mint Lesion™ provides a platform to support imaging and clinical data response assessment in clinical trials with a solution that is compliant, road-tested, and highly configurable while also maintaining the leading edge of new response criteria and disease assessment evaluation. Together with its ancillary platforms, such as Mint Response Analytics, mint Lesion™ maximizes data alignment, increases data comparability and minimizes discordance between site and central reads.

About Mint Medical

Mint Medical is an innovation-driven company for the standardized and computer-assisted review of medical images and clinical data that provides solutions for oncological radiological diagnostics and therapy progress evaluation in clinical routine, clinical research, and clinical trials. As a Brainlab company, Mint Medical is working on further process automation and more efficient data extraction from diagnostic images by integrating anatomical mapping and context-based AI algorithms.

Discover more: www.mint-medical.com