MEDIDATA | Rave

WHITE PAPER

Innovations in Clinical Trial Imaging – Today and Beyond

Advances in Image and Data Quality Control and Analysis

AUTOMATIC OUTLIER DETECTION IN IMAGING DATA

Using sophisticated statistical algorithms and machine learning analytics, it is possible to interrogate imaging data for outliers, data anomalies, and trends. The system automatically learns the proper ranges for all data elds and detects outliers and ags any data outside of the acceptable parameters. This can be used to:

- Uncover data entry errors
- Identify patterns in reader assessments (for instance if adjudicated cases always support one reader over another)
- Spot a lack of standardization of applied read criteria

Such algorithms can help detect these issues early on, allowing sponsors, CROs and/or core labs the ability to remediate these issues before there is a large impact to the data.

MONITORING READER PERFORMANCE

Despite the application of standardized criteria on how images should be interpreted, many measures require radiologists to make some subjective judgements. Thus, there is always some level of variability in assessments from one reader to the next. These variations can be mitigated by introducing a third reader to adjudicate differences between the two primary readers, however even in these situations, reader performance needs to be monitored carefully to ensure that readers are accurately applying the chosen criteria.

Algorithms can be developed that can automatically identify patterns that suggest a deviation from the imaging criteria, allowing early remediation of these issues. Ideally, the results are presented in a dashboard and updated in real time, proactively to identifying anomalies before they become systemic issues.

CORRELATING IMAGING DATA WITH CLINICAL DATA

Because historically, imaging data and clinical data reside in two different systems that are not integrated, it has been onerous for Sponsors to analyze both data sets together. Even when imaging and EDC systems are integrated, as is the case with Rave Imaging and ith Rav howtsedss shouleom p009≥aabss cEasy (e0 0 0 asSponif the)18 (ousghthe da)5 (ta)to identifyi10 ( )]TJ0

RAVE IMAGING HAS RE-ENGINEERED CLINICAL TRIAL MANAGEMENT

Medidata Rave Imaging is changing the way the industry thinks about imaging in clinical trials. Our system's intelligent workflows simplify image and data collection and are configured to immediately perform edit checks and de-identification during the image upload process. It then automates the distribution and review process after upload, per the protocol design to ensure that the most accurate data is distributed to the right users at the right time.

This automated and structured approach helps study managers meet their study goals by:

- Reducing the query rate, dramatically
- Supporting on-time completion of all image-related steps in the clinical trial
- Minimizing the risk, error-rate, and complexity of medical image management
- Minimizing data entry and workflow steps

Rave Imaging works with any network, any image format, and any data set, making it a truly scalable system.

For more information on how Rave Imaging can transform image management in clinical trials, visit our website, www.medidata.com.

Endnotes

1. https://www.hipaajournal.com/what-is-considered-protected-health-information-under-hipaa/

2. https://gdpr-info.eu/art-4-gdpr/

3. "Clinical Trial Imaging Endpoint Process Standards: Guidance for Industry," US Food and Drug Administration, April, 2018.

4. Assessment results performed by Saliency Algorithm.

5. Rizzo S, Botta F, Raimondi S, et al. Radiomics: the facts and the challenges of image analysis. Eur Radiol Exp. 2018;2(1):36. Published 2018 Nov 14.

6. Meng, Yiming et al., "Application of Radiomics for Personalized Treatment of Cancer Patients, " Cancer Management and Research, 2019:11 10851 – 10858.

7. Rizzo S, Botta F, Raimondi S, et al. Radiomics: the facts and the challenges of image analysis. Eur Radiol Exp. 2018;2(1):36. Published 2018 Nov 14.

8. Meng, Yiming et al., "Application of Radiomics for Personalized Treatment of Cancer Patients, "Cancer Management and Research, 2019:11 10851 – 10858.