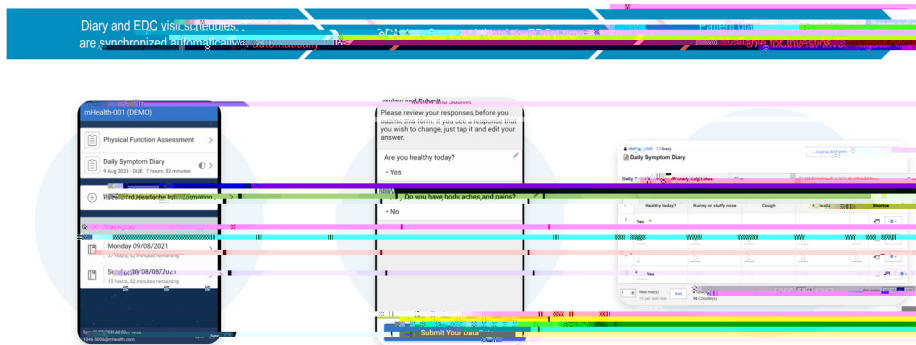# Overcoming challenges of disparate
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A platform approach: Rave EDC and Rave RTSM for informed decision making
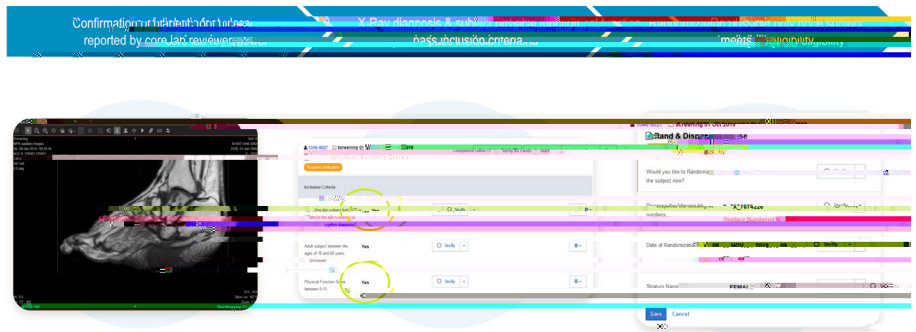
HAVE INCLUSION REQUIREMENTS BEEN MET?

Subject is eligible and has passed pre-screening.

Using Medidata's Rave RTSM, the sponsor was able to capture and integrate eCOA via eDiaries to inform decision-making throughout the course of the trial. Patient-reported outcomes which were restricted to speci c dates to prevent data entry errors were synchronized into Rave EDC in real time, as well as automatic calculation of patient diary scores to allow the sponsor to make go/no-go decisions as part of inclusion and exclusion criteria.

CAN PATIENT BE ENROLLED AND RANDOMIZED?

X-ray con rms grade 3 foot ulcer. Diary data shows no increase in pain. Dispense kit.

Value of Uni ed Rave EDC and RTSM

Real-time visibility and data insights

Cross platform reporting

Improved decision-making

Automated action and edit checks

Streamlined subject randomization

Automated dispensation

Instant disquali cation of subjects who didn't meet inclusion criteria

Reduced risk and improved subject safety

The sponsor's second decision phase included reviewing and managing imaging data. With Medidata's unifed platform, patient imaging and assessment were synchronized to Rave EDC which automatically confrmed diagnosis for eligibility and enrollment per the protocol. Only post-confrmation of inclusion criteria was the subject allowed to be randomized with automatic dispensation. Rave EDC blocked attempts at randomization when the subject did not meet eligibility criteria, adding a layer of security, while seamless data fow removed the need to log in anywhere else.

SHOULD TREATMENT BE CONTINUED?

Confrmed worsening of diabetic foot ulcer. Subject is discontinued and recommended for surgery.

Continuous monitoring of subjects and information fow informed the sponsor of the needed discontinuation of subjects, early termination, and whether to enroll into an open label extension, as well as recommendation for further treatment.

Unlock the power of a unifed platform for treatment assignment and management

Medidata's unifed platform of Rave RTSM and Rave EDC allowed the sponsor to overcome logistical complexities inherent in patient randomization by streamlining and condensing processes. By instantly randomizing then enabling dispensation to enrolled patients in real time, double entry and data reconciliation was eliminated, increasing the sponsor's overall data integrity, improved insights, and allowing for faster and more accurate go/no-go decision making. With one integrated solution, Rave RTSM and Rave EDC provided a more seamless patient journey and sponsor experience to meet the desired outcomes of a successful trial.

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences. Discover more at www.medidata.com and follow us @medidata. Contact us at info@medidata.com | +1 866 515 6044