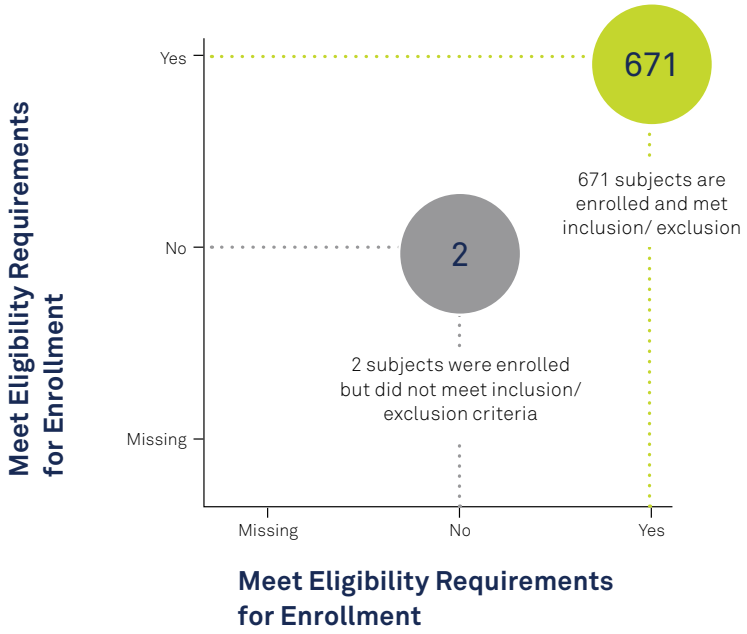
Eliminating the Guesswork from Critical Decision Making: A Case Study

When data is entered incorrectly, human error is the primary reason. Unfortunately, sometimes this is discovered not when critical decisions are being made, but when reconciliation and cleaning of the data are taking place later in the clinical trial/ process. If a patient appears to have met inclusion criteria based on faulty data, this potentially can lead to a serious scenario and certainly a protocol violation which must be reported. More importantly, it can have severe consequences to patients.



Overcoming challenges of disparate systems and limited data visibility

With four key decision points that required a broad range of data throughout the course of their study, the sponsor of a Diabetic Foot Ulcer trial needed a solution for a single, unified central database to lower the risk of human error. Compiling solutions including eCOA, medical imaging, and physician assessments across disparate data sources introduced risks for protocol violation from human error associated with multiple data entry. A platform with synchronized data capture and automated randomization functionality would provide on-demand access and complete visibility for their study teams to help inform go/no-go decisions without fear of data validity.

Clinical Trial Case Study:

Phases and Decision Points

1

Pre-Screening

Decision Point 1

Patient eDiary data collected to confirm baseline assessment.

2

Screening

Decision Point 2

Diagnosis confirmed via imaging and physician assessment of pain. Inclusion criteria met.

3

Randomization & Conduct

Decision Point 3

Significant deterioration of diagnosis; possible surgical intervention. Inclusion criteria failure.

4

Extension Phase

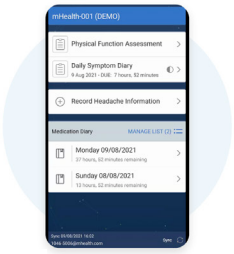
Decision Point 4

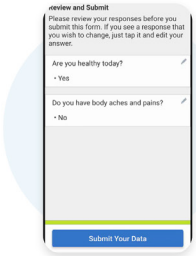
Confirmation of eDiary compliance and controlled diagnosis management required for OLE.

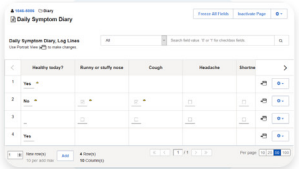
A platform approach: Rave EDC and Rave RTSM for informed decision making

HAVE INCLUSION REQUIREMENTS BEEN MET?

Diary and EDC visit schedules are synchronized automatically → eCOA data flows real-time into EDC → Patient diary score immediately available for Investigator decision





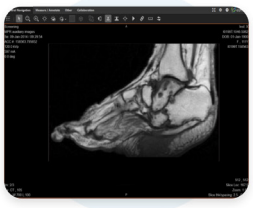


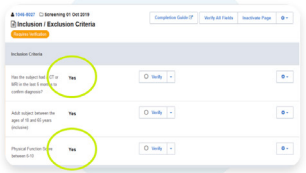
Subject is eligible and has passed pre-screening.

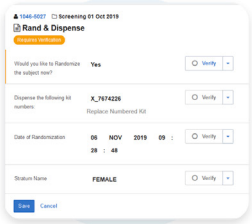
Using Medidata's Rave RTSM, the sponsor was able to capture and integrate eCOA via eDiaries to inform decision-making throughout the course of the trial. Patient-reported outcomes which were restricted to specific dates to prevent data entry errors were synchronized into Rave EDC in real time, as well 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?

Confirmation of diabetic foot ulcer reported by core lab reviewer → X-Ray diagnosis & subject physical function pass inclusion criteria → Randomization possible only once subject meets eligibility







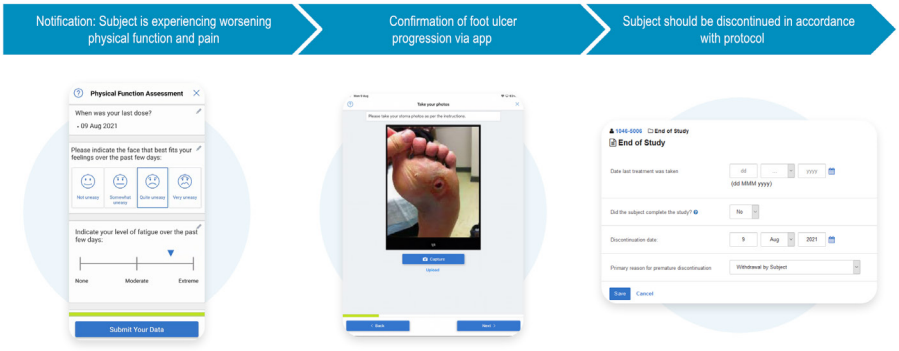
X-ray confirms grade 3 foot ulcer. Diary data shows no increase in pain. Dispense kit.

Value of Unified 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 disqualification 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 unified platform, patient imaging and assessment were synchronized to Rave EDC which automatically confirmed diagnosis for eligibility and enrollment per the protocol. Only post-confirmation 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 flow removed the need to log in anywhere else.

SHOULD TREATMENT BE CONTINUED?



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

Continuous monitoring of subjects and information flow 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 unified platform for treatment assignment and management

Medidata's unified 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's unified platform of Rave RTSM and Rave EDC allowed the sponsor to overcome logistical complexities inherent in patient randomization by streamlining and condensing processes.

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.