SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

SMARTSIGNALS eCOA

Signant's Scale Management Expertise Facilitates Endpoint Accuracy & Reliability in Psoriatic Arthritis Trial

SUMMARY:

Signant leveraged its scale management and digital health science expertise to acquire and implement a proprietary scoring algorithm required to measure safety and efficacy in a psoriatic arthritis (PsA) trial.

TRIAL SUMMARY:

- **Study Phase:** Phase II
- **Therapeutic Area:** Immunology
- **Indication:** Psoriatic arthritis
- **Participant Population:** Adults
- **Number of Participants:** 195
- **Number of Sites:** 60
- **COAs:** 19
- **Countries:** 9
- **Languages:** 12

INTRODUCTION:

A biotechnology company requested Signant's electronic clinical outcome assessment (eCOA) solutions, digital health science and scale management expertise to support the measurement strategy for a global Phase II psoriatic arthritis trial. The study protocol required the electronic data capture of 18 clinical outcome assessments (COAs), including those needed for the assessment of the American College of Rheumatology (ACR) response criteria which were used as the primary endpoint. The schedule of activities required careful planning and collaboration, scale management expertise, and creative project delivery solutions for which Signant was prepared.

CHALLENGES:

- The primary endpoint (ACR response criteria) was a complex composite of participant-reported outcome measures (PROMs), clinician-reported outcomes (ClinROs), and laboratory data, and it was important that this value could be calculated accurately.
- Participant eligibility at the screening and randomization visits was determined based on a complex ClinRO: the number of tender and swollen joints assessed by a clinician.
- The protocol included a large number of COAs that required electronic implementation according to best practice and industry standards, including complex clinical assessments such as the Leeds Enthesitis Index (LEI), Leeds Dactylitis Index (LDI), and the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index.
- Participants were required to take the study medication twice a day, with the study requiring a method to monitor self-reported adherence to study medication intake.

SOLUTIONS:

- Signant consulted with the sponsor and their contract research organization (CRO) partner to propose an optimal eCOA implementation strategy, ensuring robust data collection from participants and clinicians and that critical study milestones such as first participant first visit (FPFV) could be met on time.
- Our dedicated Scale Management team leveraged its extensive scale management expertise and resources to identify, acquire, and implement all COAs included in this protocol, including those for the ACR response criteria assessment.
- Signant utilized our library implementation of the 66/68 swollen and tender joint count (66/68 STJC) to electronically capture the required data using a clinician-friendly homunculus for easy joint selection and assessment, and automatically calculated scores in the background to reduce manual errors.
- Complex clinical assessments such as LEI, LDI, and SPARCC were implemented electronically using user-friendly interactive body maps for the clinician to easily select the required digit, and with guidance images and instructions incorporated into a single solution for easy reference.
- Participants were reminded to take the study medication using a custom application developed specifically for the requirements of the study, that incorporated alarms and notifications and allowed them to record medication intake twice daily, providing adherence metrics to the sites and sponsor.

RESULTS:

- ✓ The trial, ongoing through 2025, launched on time with a scientifically robust eCOA data capture strategy designed to ensure accurate data collection and endpoint reliability.
- ✓ Signant successfully licensed and implemented a large number of assessments from multiple copyright holders, demonstrating technical and clinical expertise and satisfying the copyright owner's requirements.
- ✓ Even when a complex eCOA design is required, Signant adds value by navigating challenging design processes and applying creative approaches to mitigate impacts on a trial's timeline.

ABOUT SIGNANT HEALTH

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