

CASE STUDY:

Signant SmartSignals eConsent

OVERVIEW:

A top pharmaceutical company in Japan was implementing eConsent for the first time and selected Signant Health's eConsent solution after testing multiple vendors.

The study needed a flexible, digital solution to help the study team support the advanced document management required for Japanese pediatric trials, accommodate multiple consent forms, and implement user-specific language requirements.

TRIAL SUMMARY:

Study Phase: Phase II

Therapeutic Area: CNS - Psychiatry

Patient Population: Pediatric

Number of Patients: 300+

Number of Sites: 60+

Countries: 1

Languages: 2

CHALLENGES:

This study presented a number of unique challenges:

01

MULTIPLE CONSENT FORMS NEEDED FOR CHILDREN AND LARS

Both pediatric patients and legally authorized representatives (LARs) were required to sign study documents. Japanese regulations required the child to sign to confirm their assent to participate, and one or both parents (or authorized guardians), to sign to confirm consent to participate.

02

MULTIPLE ACCOUNTS NEEDED TO ACCOMMODATE CHILDREN & LAR

Information needed to be presented using different written Japanese character sets based on the age of the reader: Hiragana for children aged 6-17 and Kanji for adults 18 and above.

03

KEEP CHILDREN ENGAGED AND INFORMED

Eight unique consent forms needed to be managed for 300+ pediatric patients and their LARs.

SOLUTIONS:

01

ADVANCED DOCUMENT MANAGEMENT & TRANSLATIONS

Our solution was configured to accommodate the different written language requirements for the different age groups, resulting in 8 unique consent forms. Signant SmartSignals eConsent successfully tracked status changes for the multiple consent forms created, providing the study team optimal visibility on patient enrollment.

02

MANAGE MULTIPLE ACCOUNTS

Our solution enabled separate access for the parent and for each of the 300+ pediatric patients. This allowed a user flow that enabled pediatric patients to sign a separate assent form, while allowing one or both parents to independently sign consent forms.

03

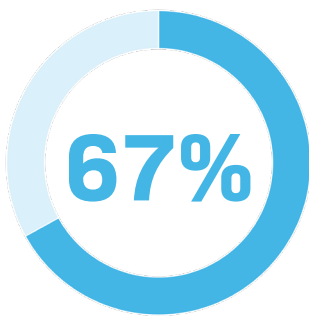
MULTI-MEDIA CAPABILITY

Signant's Creative Services leveraged Signant SmartSignals eConsent multimedia capabilities to incorporate custom, age-appropriate animations and audio throughout the consenting process to increase patient engagement and comprehension.

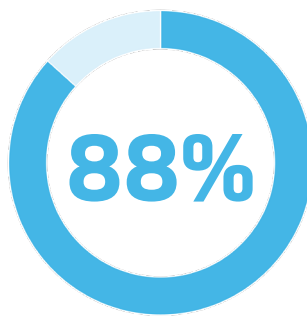
BENEFITS OF SIGNANT'S eCONSENT:

- **Meet cultural & language needs**
From translations and localizations to delivering devices on time, Signant's teams and solutions understand and accommodate global needs – an expertise that would prove essential for this study.
- **Improve overall comprehension**
Signant's eConsent solution was designed to support all learning styles and uses engaging multimedia to convey complex study information.
- **Managing multiple consent forms and updates**
Signant's eConsent solution ensures the correct ICF version of consent documents is always used. Only minor edits were required on the eICF to accommodate individual site requirements.

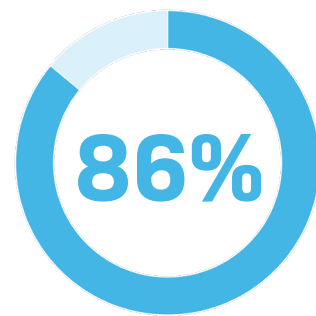
RESULTS:



Signatures completed electronically



Sites that used Signant SmartSignals eConsent



Sites that chose to use an electronic signature as opposed to a digitized (screen drawn) signature or a wet ink signature (using print-to-sign).

ABOUT SIGNANT HEALTH



Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. For more information, please visit www.signanthealth.com.