

CASE STUDY:

SMARTSIGNALS™ eConsent

The digital tool proves to be a valuable approach to speed access to treatment using remote consent from legally authorized representatives (LARs).

OVERVIEW:

A top pharmaceutical company wanted to perform a US-based study using Signant's eConsent solution in which the technology would enable faster access to treatment for patients unable to consent personally through a legally authorized representative (LAR).

The customer needed a flexible tool that would safely and securely enable LARs to consent remotely on behalf of unconscious adult patients.

CHALLENGES:

This study presented a number of unique challenges:

01

PATIENT NEEDS TO BE IN COMA

Inclusion criteria required patients to have a specific condition that resulted in them arriving at an emergency room in a comatose state, and therefore, unable to provide written, informed consent to participate in the study and receive a new treatment.

02

LAR CONSENT NEEDS TO BE DONE REMOTELY

Treatment administration must occur when the patient is still in a coma and the LAR may not be present at the emergency room.

03

THE PATIENT NEEDS TO RE-CONSENT

When the patient regains consciousness, they must be able to personally re-consent to continue participating in the study.

SOLUTIONS:

01

BYOD CAPABILITY FOR LAR

SmartSignals eConsent is a web-based platform that allows a LAR to consent on behalf of the comatose patient using any web-connected device.

02

REMOTE CONSENTING AVAILABLE FOR LAR

The site used SmartSignals eConsent to allow the LAR and investigator to securely, remotely access the study, treatment, and consenting information before capturing their signature on the study consent forms.

03

ACCOMMODATE RE-CONSENTING

Signant's system managed and reported re-consenting workflow for patients when they regained consciousness, providing independent consent to participate. Intuitive dashboards made it easy for site staff and sponsors to oversee the re-consent process.

BENEFITS OF SIGNANT'S eCONSENT:**— Compatible on any device**

SmartSignals eConsent can be rapidly deployed on provisioned and personal (BYOD) devices alike. The ability to fully access eConsent from any web-connected device or computer was critical for the LARs to consent quickly and remotely using their own smartphone, tablet, or PC.

— User-friendly remote consent

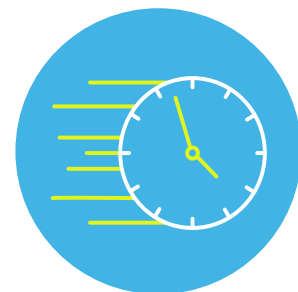
Usernames and passwords are automatically generated and securely sent. For this study, emails were sent to the LARs with user credentials, allowing them to quickly access, sign in, and complete the consenting process remotely.

RESULTS:

The sponsor found Signant's eConsent solution to be a viable solution to facilitate remote LAR consent in emergency situations.



Features of eConsent, including version control, remote access, and rapid consent dramatically reduce burdens on the site and LARs.



LARs successfully and remotely consented on the patient's behalf to enroll them into the study, allowing them to receive vital treatment in a timely fashion.

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.