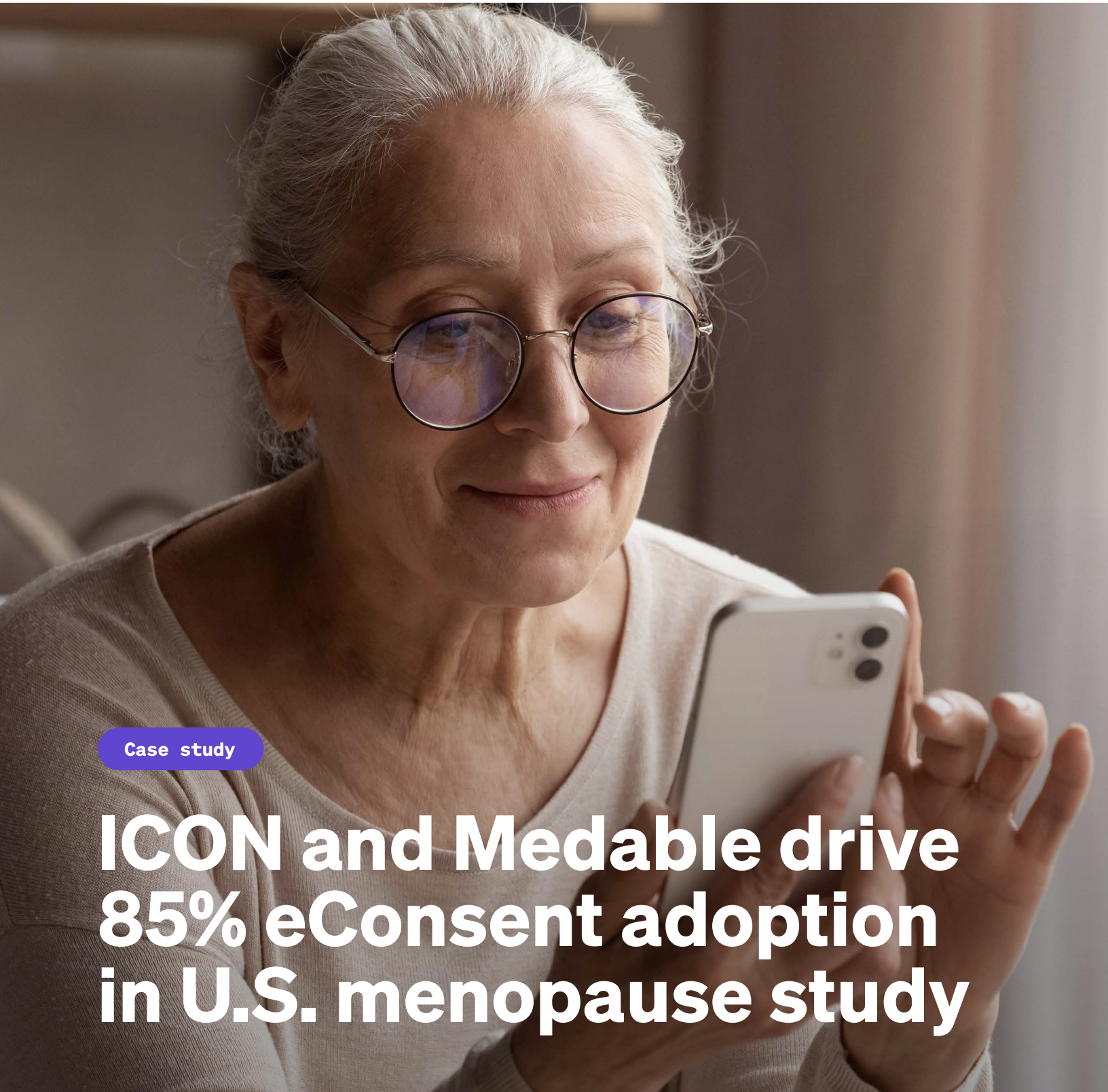
Partner: ICON (CRO) on behalf of a global pharma company

Therapeutic area: Menopause / Women's health

Solutions used: Total Consent (Medable eConsent solution), eCOA and TeleVisit

Countries/Locales: United States (English and Spanish)

Participants: 1,222



Case study

ICON and Medable drive 85% eConsent adoption in U.S. menopause study

Partner study overview

In partnership with ICON, Medable supported a client in the delivery of a U.S. only women's health trial for menopausal participants.

With a protocol that contained 13 assessments repeated on a regular basis throughout the schedule of assessments, the study demanded both participant and site engagement from the outset. Enabling the sites to consent participants with eConsent allowed for improved study communication, oversight of consent, and an enhanced participant onboarding experience into both the study and the technology platform.

Both Medable and ICON focused on a simplistic approach to training as well as providing a hand-on concierge support service to the sites in order to provide a frictionless experience. The strategy yielded significant success in both participant and site-level adoption of consent, laying the groundwork for increased levels of patient adherence to the complex protocol requirements.

Key outcomes and insights

100%

eConsent adoption among 18 sites

Achieved full compliance with the study's digital workflow

85.4%

of enrolled participants consented electronically by Medable's Total Consent

Among the total 1,222 participants, 1,044 consented electronically

The top enrolling site enrolled 170 patients, with

91%

of them opting to consent to the study using Total Consent

Demonstrated that training, when tailored and simple for sites to consume, combined with hands-on site support delivered jointly with the CRO team significantly improves site adoption of technology.

Understanding the challenge

The study team faced three primary hurdles:

1

Ensuring high eConsent
uptake among a diverse participant base in both English and Spanish speaking patient populations. Enabling a smooth onboarding process to the study and technology.

2

Coordinating training
across 40+ sites to ensure sites could adopt the technology with limited additional burden and felt confident to present eConsenting to the participants

3

Maintaining site engagement
throughout the enrollment period ensuring sustained technology adoption

Given the complexity of the protocol and high level of electronic based assessments(eCOAs), the study team understood the importance of a smooth onboarding and consent process to reduce any potential resistance to electronic based data collection workflows.

Medable's solution

Joint deployment with ICON's concierge team
Medable and ICON delivered a collaborative training and onboarding approach that was both strategic and site-specific:

Concierge-led rollout
ICON's internal concierge group partnered with Medable to reinforce consistent site support across all US regions.

Customized study training
Medable's internal team developed study-specific eConsent training modules tailored to the trial's unique requirements.

CRA enablement
Clinical Research Associates (CRAs) were directly equipped with training and materials to support consistent site-level implementation.

This study illustrates exactly why tailored training delivered in a site focused manner, combined with an educated CRA workforce able to support the sites is critical for the successful adoption of any study technology. When sites are supported and confident, adoption follows, enabling positive outcomes even from demanding study protocols with high levels of patient facing data collection assessments."

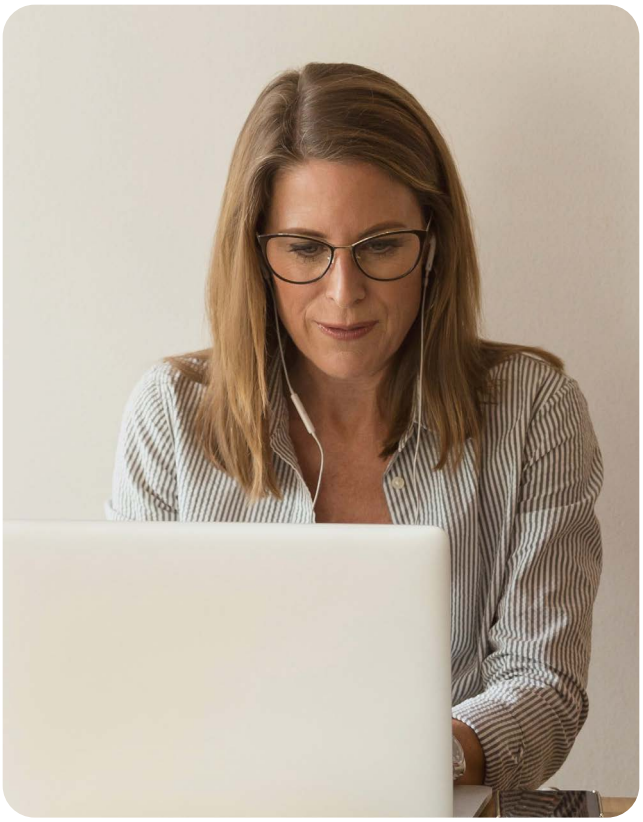
Jade Borsberry
Customer Success Lead
Medable

Conclusion

By aligning training efforts, tailoring onboarding resources, and closely partnering with the CRO, Medable enabled a seamless eConsent rollout in a challenging U.S. focused study in a patient population

With 85.4% of participants opting into electronic consent and 18 sites achieving full compliance, the effort offers a compelling case for the use and deployment of eConsent in the future.

If you'd like to speak to someone at Medable about improving eConsent adoption in your next study, **connect with our experts.**



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