

# Accelerating eConsent Adoption During COVID-19

## MedStar Health Research Institute Applies CTTI's Decentralized Clinical Trials Recommendations

### SUMMARY

[MedStar Health Research Institute](#) is the research division of MedStar Health, the largest healthcare provider in Maryland and the Washington, D.C., region with more than 300 care locations. The Institute used CTTI's Decentralized Clinical Trials recommendations to launch an electronic case platform where patients could give informed consent to studies electronically.

### GOAL(S)

MedStar Health Research Institute wanted to improve its interactions with patients to reduce their burden while still meeting clinical trial regulatory requirements. To that end, they sought to launch an electronic case platform that allowed the Institute's research participants to e-consent to studies via an electronic device with supportive assistance available as needed. The platform would mean fewer site visits for patients and increased efficiency, but getting it right was critical so that participants felt comfortable and well informed throughout the virtual process.

### CHALLENGES

E-consent has been around for years, but the research industry has historically been slow to adopt the technology. However, all that changed when the COVID-19 pandemic upended the industry, requiring modern approaches to be implemented at lightning speed to ensure trial continuity and patient safety. Traditional methods of in-person informed consent became particularly problematic in the pandemic, as face-to-face discussions may have exposed researchers and patients to increased risk of contracting and spreading the virus. The MedStar Health Research Institute's original plan, which involved launching e-consent slowly to give patients a toe-in-the-water experience with the process, suddenly had to be fast-tracked.

### SOLUTION(S)

CTTI's suite of Decentralized Clinical Trials (DCT) [recommendations and resources](#) are intended to facilitate the adoption and appropriate use of mobile technology in clinical trials. They offer legal, regulatory and practical considerations for integrating these technologies into trials in a way that improves engagement, enrollment, retention, and overall trial quality. For the MedStar Health Research Institute, the recommendations were invaluable to guide their e-consent adoption.

### TAKING ACTION

In alignment with CTTI's DCT recommendations, MedStar Health Research Institute began by exploring e-consent vendors, ultimately choosing one with which they had a long history and existing experience. With the vendor in place, MedStar Health sought institutional review board (IRB) input. During the presentation to the IRB, the MedStar Health e-consent team presented on the goals of the e-consent platform, explaining that all of the same information would be communicated to the patient as in a traditional consent engagement. They also explained the Institute's intent to offer both e-consent and paper consent, so participants uncomfortable with technology could opt for a traditional consent approach. Importantly, the team messaged to the IRB that e-consent was not intended to replace important discussions with patients and site staff – such conversations will always be an important research component and irreplaceable by a device.

With approval from the IRB, the Institute developed a test architecture that they would eventually pilot. To ensure research coordinators could understand the platform's functions and features, MedStar Health stood up a robust training program for its platform. With the intended phased approach to launching e-consent no longer viable due to COVID, they needed to go straight to a live pilot with active feedback in real time as patients consented (versus a demo approach for an inactive trial).

One snag the e-consent team encountered was related to web browser updates. After several months of the MedStar Health Research Institute's e-consent platform functioning beautifully, Apple's Safari browser had a version release that prevented third-party cookies, disrupting the e-consent experience. Apple had alerted business users of the change, but released its update sooner than planned, which resulted in a complete crippling of MedStar Health's e-consent platform for anyone using Apple products. In response, the team was forced to rebuild and revalidate its platform, a multi-month process. During that time, only patients using non-Apple products could participate in e-consent. Fortunately, the issue was eventually resolved, but the experience is a cautionary tale of the need to stay abreast of technology when implementing decentralized approaches and plan resources appropriately.

### IMPACT

Today, the MedStar Health Research Institute offers an entirely paperless consent approach from beginning to end, as well as a traditional approach for anyone that opts. Patient feedback to date has been largely positive, and the Institute is enjoying improved efficiencies and higher engagement due to reduced participant burden.

### ADVICE

The consenting phase of research is a critical time, as it represents the beginning of the journey with a patient. The experience these patients have matters to overall trial outcomes, including engagement and retention. Adopting e-consent is a way to create a much less burdensome experience, and there are numerous resources, including CTTI's, to support sponsors along the way. At the same time, it is important to always stay mindful of preferences in different patient groups. Despite positive feedback, the Institute still sees patients who either struggle to sign virtually or aren't comfortable with the experience. Active, continuous communication is essential – e-consent should be leveraged as an option to improve and enrich the patient experience, never to alienate or create distance.

### ORGANIZATION

MedStar Health

### CONTACT

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## **ORGANIZATION TYPE**

Clinical Investigator/Site

## **IMPLEMENTATION DATE**

2019

## **TOPIC**

Decentralized Clinical Trials

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