CRIO

Case Study

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INNOVO RESEARCH: USING CRIO ECONSENT TO FACILITATE A 200% INCREASE IN ENROLLMENT

Innovo Research adopts eConsent to Improve Research Enrollment and Value-Based Care Delivery

OVERVIEW

Innovo Research, Inc. is running several cancer screening studies for high-risk patients that involve biospecimen collection. As a research partner to health care organizations that operate within value-based care delivery frameworks, Innovo views these studies not only as valuable contributions to research, but also as tools to improve patient compliance with best practices, and therefore outcomes. Using CRIO's integrated remote eConsent solution, Innovo Research was able to increase enrollment on these studies by a factor of 3.5x.

CHALLENGE

Innovo Research is a clinically integrated research organization that partners with health systems to deliver clinical research in support of population health and value-based care. Innovo Research offers sponsors a single point of contact to run studies at multiple locations, using a network wide, EMR integrated database for feasibility and recruiting. As a multi-site operator, Innovo Research utilizes CRIO's eSource, eISF and CTMS solution to standardize workflows, drive quality, embed patient safety at point of capture, and centralize management.

Recently, at one of the sites, Western Washington Medical Group, Innovo Research secured two separate cancer screening studies. These studies targeted patients not previously diagnosed with cancer but having certain risk factors. For each study, the research team consents the patient, then collects and curates medical record information, and, if the patient is eligible, collects biospecimen samples. After the study visit, the patient performs the recommended standard of care for cancer screening. The research team then tracks the patients' outcomes over a multi-year period.

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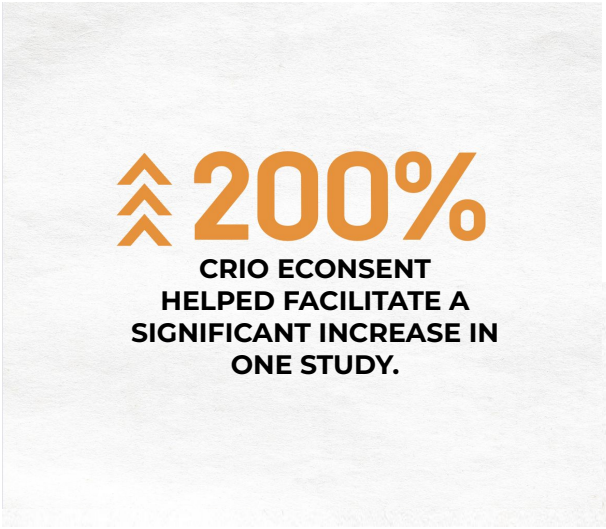
These studies embody Innovo Research's commitment to integrating care and research. Through study participation, the research team has a powerful tool to engage patients and encourage compliance with standard of care, in turn improving health outcomes for their partners.

However, one barrier to enrollment was the fact that the teams had to ask patients to come into the clinic to sign the consent form prior to their standard of care screening procedure. This required scheduling a 1.5-hour visit, creating "leakage" in the funnel, as patients would often no-show, or repeatedly reschedule. The research team was also constrained by lack of space, which limited the number of openings and often prevented the patient from being able to get into the clinic and have their blood work drawn prior to their standard of care scan, disqualifying the patient from participating.

SOLUTION

During the studies, CRIO released its remote-enabled eConsent solution. This solution allows sites to convert the IRB-approved Informed Consent template into a fillable PDF that the team could route to the patient for remote signature. The solution renders the PDF in a variety of screens, including cell phones, and utilizes a system-generated PIN code to verify patient identity.

One of the best features of CRIO eConsent is that it's integrated into the eSource solution. It has built in versioning, so when the study coordinator initiates a visit, the first thing the eSource solution does is compare the subject's most recently executed ICF form to the latest study version, and generate an initial or re-consent procedure using the up-to-date version. This eliminates the need for the study team to maintain a separate login, and eliminates re-consent deviations.



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Stephanie Abbott PharmD, Senior Director of Clinical Operations at Western Washington Medical Group (WWMG), recognized the potential of CRIO's remote consent tool to enhance enrollment and the patient experience. With remote eConsent, if a patient expresses interest in participating in the study, the research coordinator can then send the eConsent to the patient, reviewing it with them live. After the patient signs, the research coordinator can countersign, then collect the required medical history.

This new process eliminates the need to schedule a 1.5 hour on-site visit; instead, the coordinator simply has to schedule a 15 minute biospecimen collection visit. This makes the scheduling much more flexible while giving the patient assurance that he or she meets study criteria and will not "waste" a visit.

OUTCOMES

eConsent is currently used for two cancer screening studies at WWMG – **Screening Study 1 and Screening Study 2**. eConsent has been used for Screening Study 1 since its startup with all patients; however, it was introduced to Screening Study 2 after about a year of enrollment and has made a significant positive impact on enrollment. WWMG has been specifically leveraging remote eConsent to facilitate enrollment. **The primary reasons patients opt for remote consent are:**

- they do not have time to come into the office to execute a consent form prior to an SOC procedure that is part of the study; and/or
- to reduce the amount of time that they spend in the office.

SCREENING STUDY 1

60.4% of patients who have consented to this study have chosen to use remote eConsent.
7 patients have been consented after hours to accommodate work and/or personal schedules.

SCREENING STUDY 2

The Screening Study 2 has been enrolling since June of 2022 at WWMG, the use of eConsent was introduced on April 27th, 2023.

62% of patients who have enrolled in Screening Study 2 since, have chosen remote consent. From April to May, use of eConsent helped to facilitate a greater than **200% increase in enrollment** in the Screening Study 2 study.

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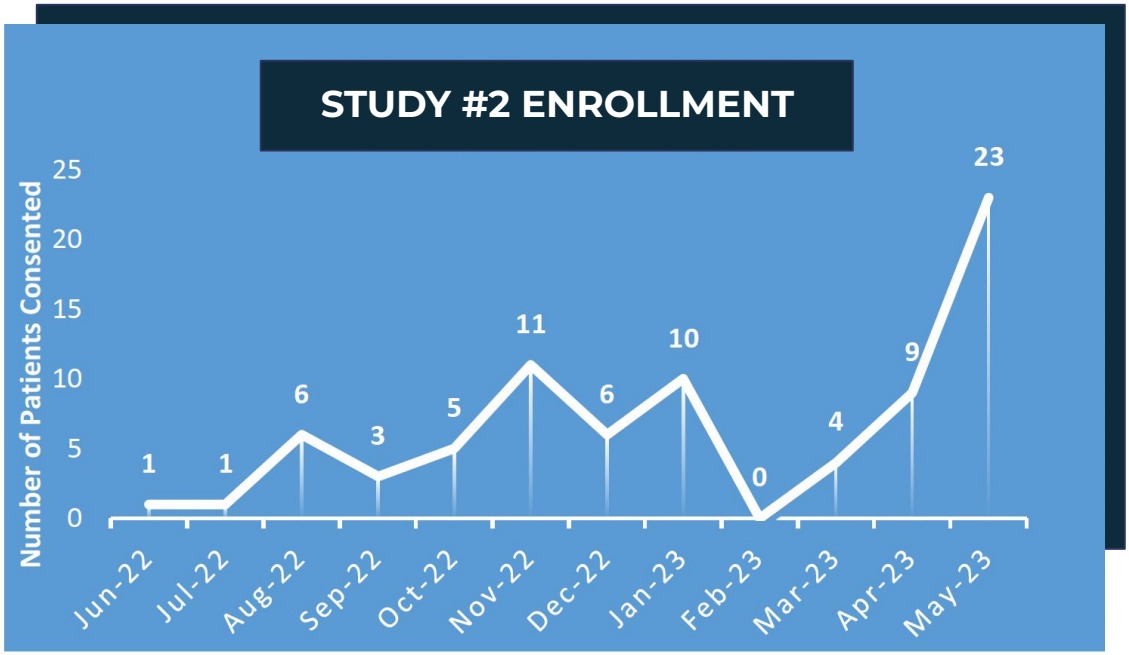
In the year prior to implementing eConsent, WWMG enrolled 5 patients per month on average in Screening Study 2. In May alone, WWMG enrolled 23 patients in Screening Study 2. While there isn't sufficient data at this point to project how that number will progress, the site is confident that eConsent will continue to support consistent enrollment metrics.



Data sourced from CRIO logs and compiled by Heloisa Stager, current as of 24JUN2023

Dr. Abbott attributes this sharp increase entirely to the new process. "When our team is able to engage with patients on the phone, that's when we have the most success obtaining consent and collecting data. At that point, patients are assured of eligibility and have a much lower visit burden."

With CRIO's integrated patient stipend solution, the research team can guarantee on-the-spot reimbursement once the patient's blood draw has been completed. And, because the on-site study visit is only 15 minutes, the team is often able to synchronize the study visit with the standard of care procedure that follows, allowing the patient to do everything at once, further improving compliance with care.

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Besides improving the patient experience, CRIO's solution also improves the staff experience. CRIO gives study team members the flexibility to work from home and frees them of administrative tasks, allowing them to focus more on patient care. The CRIO platform improves continuity of care delivery to patients, sponsors and partner providers.

Dr. Abbott is looking forward to CRIO's pending release of its Medical Records API, which will let study teams pull in medical records from other institutions within minutes. This will enable Innovo Research to get records instantaneously from research volunteers who are not current patients of the practice, thus expanding Innovo Research's reach.

CONCLUSION

Using CRIO's integrated eConsent-eSource solution, Innovo Research has a tool they can deploy to improve enrollment significantly, while protecting patient safety and ensuring data quality at point of capture. This helps Innovo Research deliver significant value to pharmaceutical and device sponsors and their partner health systems at the same time, helping them achieve the vision of integrating research into care delivery and population health management.

ABOUT THE PROFILE

Innovo Research ("Innovo") is a provider-sponsored, provider-led network of high-performing Accountable Care Organizations (ACOs) that utilize clinical research as part of their population health strategy. Its integrated approach supports both the triple aim aspirations of its partner ACOs as well as their research interests. Innovo brings value to sponsors and CROs by applying systems, infrastructure, and organizational support to access more patients, reduce inefficiencies, better match patients to clinical trials, and enroll faster. The clinical integration of research results in better outcomes for patients, lower costs for the healthcare industry, higher patient engagement, and a diversified revenue source for partner ACOs. Innovo is where research meets patient care for better outcomes. For more information, please visit https://www.innovoresearch.com.

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Innovation is at the heart of everything we do. Our mission is to streamline clinical research to bring new medications to market faster. We have created a holistic paperless platform for conducting clinical trials that will reduce data errors, streamline regulatory workflows and accelerate timelines. Today, CRIO supports more than 1000 global medical research sites. For more information about CRIO, visit www.clinicalresearch.io.