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eConsent Readiness in 24 Countries

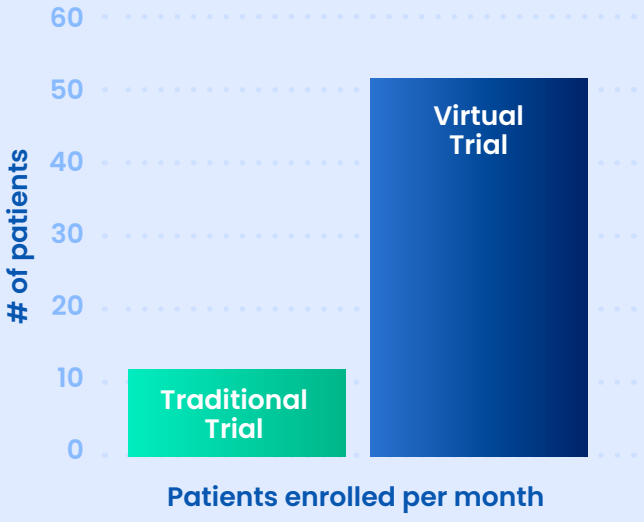


Shifts in the eConsent Regulatory Landscape

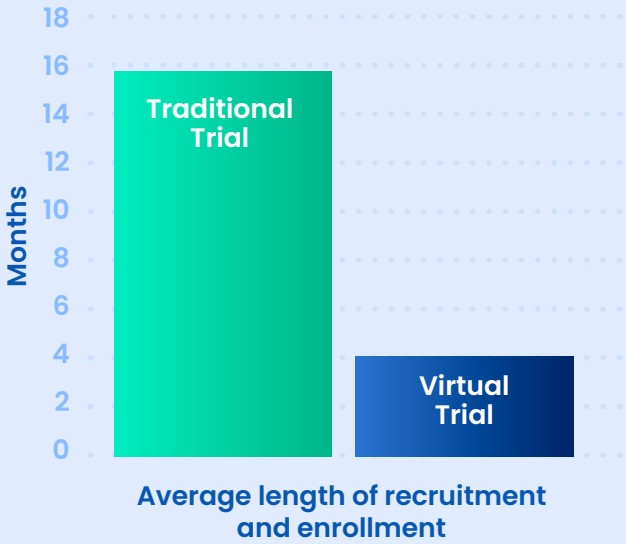
Regulatory bodies across different countries are gradually shifting towards a more favorable stance for eConsent adoption. For instance, the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have published guidelines encouraging the use of electronic processes like eConsent in clinical trials to enhance participant understanding and engagement, while also expediting the trial process.

Alongside the benefits of eConsent, sponsors must consider data privacy and compliance with ethical standards when conducting trials according to regional mandates. This white paper covers the eConsent adoption landscape, country-specific legislation, and the practicalities of using eConsent in your clinical trial.

eConsent can increase enrollment speed



eConsent can reduce enrollment timelines



Reference: https://www.sciencedirect.com/science/article/pii/S2451865420300740

Market trends

Castor researched eConsent in 24 countries spread across the globe. Results showed that 46% (11/24) of countries had national legislation allowing eConsent and eSignature. When we included countries whose federal legislation deferred to international guidance, the percentage rose to 79% (19/24). Many countries without national eConsent legislation allowed eSignatures and had organizations working to legislate eConsent.

Although the number of countries we researched was relatively small, results suggest that guidance around eConsent and eSignature is active internationally and gaining more influence at national levels.

Alongside our work, organizations like the Decentralized Trials & Research Alliance (DTRA) are making these findings more accessible through features like their Global Conduct Map.[88]

eConsent adoption has been growing worldwide. Experts predict eConsent in healthcare will grow at a compound annual growth rate of approximately 10% from 2023 to 2031, with the market expected to reach $996.61 million by 2031. While the North American countries hold most of the market share, other regions continue to grow in adoption.[99]



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Country-specific guidance

Country	eConsent	eSignature
Australia	✓	✓
Austria	✓ *	✓ ^
Belgium	✓	✓
Brazil	✗	✓ ^
Canada	−	−
China	−	✓ ^
Denmark	✓	✓
Finland	✓ *	✓ +
France	✓ *	✓ +
Germany	✓ *	✓ +
India	−	✓ ^
Ireland	✓ *	✓ +
Israel	✓	✓
Italy	✓ *	✓ +
Japan	✓	✓
The Netherlands	✓ *	✓ +
Poland	✓ *	✓
Singapore	✓	✓
Spain	✓	✓
South Korea	✓	✓
Sweden	✓	✓
Switzerland	✓	✗
United Kingdom	✓	✓
United States of America	✓	✓

Key:

- ✓ Allowed
- ✗ Not allowed
- − Ethics committees decide

Exceptions:

* per EU Clinical Trials Regulation (CTR) (536/2014)

\+ per eIDAS Regulation

^ per General legislation

Australia

National guidance updated in July 2023 allows eConsent with approval from human research ethics committees and eSignatures that accurately document the time, date, and authenticity.[5] Australia's National Health and Medical Research Council requires a respectful consenting process, straightforward eConsent materials, and time for participants to review materials.[6]

Austria

The Austrian "Medicinal Products Act" requires trials to follow EU Clinical Trials Regulation (CTR) (536/2014), which allows written consent by both electronic and paper mediums[7]. According to the "Signature and Trust Services Act" of 2016, Austrian legislation accepts qualifying eSignatures instead of written forms.[8]

Belgium

National legislation allows both eConsent and eSignatures. Belgium conducts a disproportionate number of trials for its population size due to many research centers and hospitals, quick regulatory approval processes, and investigator expertise.[9] Even though the EU Clinical Trials Regulation (2022) is leveling the playing field, Belgium is working hard to continue to lead through innovative trial designs and digitalization.[10]

Brazil

Brazil's national legislation requires written informed consent forms and signatures. Final approval for informed consent rests with local ethics committees.[11] Brazil's provisional measure 2.200-2 allows eSignatures under certain conditions. This legislation doesn't have specific guidance for clinical research.[12]

Canada

According to the guidance from Health Canada, informed consent must be documented by a "written, signed and dated informed consent form." However, each research ethics board (REB) has its own rules.[13] For example, the University of Calgary accepts both eConsent and eSignatures.[14] Health Canada recommends supplementing written documentation with audio aids, visual aids, or video presentations.

China

Chinese legislation published in 2020 requires written or oral (situational) consent.[15] However, in 2021, China's Center for Drug Evaluation allowed eConsent under certain circumstances.[16] eSignatures are legally binding in China but are not applicable when other laws do not allow electronic documentation. In other words, eSignatures are acceptable only in situations where eConsent is valid.[17]

Denmark

Guidance from the Danish Medicines Agency allows eConsent. eSignatures are also allowed if they comply with ICH E6 (R2) guidelines.[18] In 2021, the Danish Medicines Agency started a project encouraging the adoption of decentralized clinical trial (DCT) elements (including eConsent) to improve trial accessibility and help research teams recruit and retain participants.[19]

Finland

Finland follows the EU Clinical Trials Regulation (CTR)(536/2014), which allows written consent by both electronic and paper mediums. eSignatures must align with guidance from the eIDAS regulation.[20] Finnish citizens can access health information electronically through the Finnish National Health Information System (Kanta). While Kanta is not yet supporting clinical trials, it may help reduce hesitancy over eConsent adoption.[21]

France

Public Health Code Chapter II, Article L11322-1 requires that informed consent be collected in writing.[22] However, Article 1365 of the French Civil Code defines writing as "a series of letters, characters, numbers, or any other signs or symbols with an intelligible meaning, regardless of their medium.[23] eConsent must align with the EU Clinical Trials Regulation (CTR) (536/2014), and eSignatures must follow guidance from the eIDAS regulation.

Germany

Germany leads the EU in the number of clinical trials per year and has launched efforts to improve digitalization, including testing the use of AI, in clinical research.[24,25] German legislation requires informed consent procedures to align with the EU Clinical Trials Regulation (CTR) (536/2014), which allows written consent by both electronic and paper mediums. eSignatures must follow guidance from the eIDAS regulation. Information presented to participants during the consent process must include the essence, meaning, and scope of the clinical trial.[26]

India

Indian legislation allows audio-visual aids to complement the consent process but does not specify the legality of eConsent. Advocates call for guidance and clarity around eConsent from regulatory bodies. Despite the vagueness, many clinical trials in India do use eConsent.[27] The Information Technology Act allows "electronic signatures" the same legal status as handwritten signatures.[28]

Ireland

Irish legislation requires informed consent procedures to align with the EU Clinical Trials Regulation (CTR) (536/2014). CTR allows written consent by both electronic and paper mediums. eSignatures must follow guidance from the eIDAS regulation. Ireland's Health Products Regulatory Authority (HPRA) requires informed consent interviews to be conducted by either the investigator or a registered health professional.[29]

Israel

Israel's Ministry of Health allows eConsent as part or all of the informed consent process. The guidance recommends face-to-face meetings as best practice for informed consent but allows eConsent as long as the materials and processes help participants completely understand the trial, assess their knowledge, and verify their full consent. Legislation allows digital signatures.[30]

Italy

Italian legislation requires informed consent procedures align with the EU Clinical Trials Regulation (CTR) (536/2014). CTR allows written consent by both electronic and paper mediums. Italy's "Provisions for informed consent and advance directives" law requires informed consent not to be limited to acceptance or rejection but ongoing throughout treatment.[31]

Japan

In 2023, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) published guidance allowing "written consent" by electromagnetic means. eSignatures adhering to Japan's regulatory requirements are also allowed.[32] Per Japan's "Act on Electronic Signatures and Certification Business," valid eSignatures must be traceable to the signatory and confirm any alterations.[33]

The Netherlands

Dutch legislation requires informed consent procedures to align with the EU Clinical Trials Regulation (CTR) (536/2014), allowing written consent by electronic and paper mediums. eSignatures must follow guidance from the eIDAS regulation. A bill introduced to parliament in 2020 recommended national legislation on eConsent by the Medical Scientific Research Involving Human Subjects Act (WMO).[34]

Poland

In 2023, Poland introduced the Act on Clinical Trials of Medicinal Products for Human Use ("Act").[35] The Act aligns federal legislation with the EU Clinical Trials Regulation (CTR) No 536/2014, which allows written consent by both electronic and paper mediums. Polish legislation also allows electronic biometric signatures for consent in clinical trials.[36]

Singapore

Singapore's Health Sciences Authority (HSA) allows eConsent as a supplement or replacement (when appropriate) for paper-based informed consent.[37] eSignatures must comply with Singapore's Personal Data Protection Act and Electronic Transactions Act.[38,39] Although local institutional review boards (IRBs) ultimately approve eConsent, researchers must also submit materials to federal regulatory bodies.

Spain

In 2023, the Spanish Agency for Medicines and Medical Devices (AEMPS) published guidance allowing eConsent in clinical research. eSignature is also allowed, given it follows EU directives for signatures with a high security level.[40]

South Korea

Guidance issued by South Korea's Ministry of Food and Drug Safety (MFDS) allows both eConsent and eSignatures in clinical research.[41] In late 2020, South Korea updated its Electronic Signature Act (ESA). The new ESA allows eSignatures as long as they are verifiable and identify the signatory.[42]

Sweden

According to the Swedish Medical Products Agency (MPA), eConsent is possible as long as it complies with best practices for informed consent. eSignatures are also possible on appropriate systems.[43] Sweden's Ethical Review Act requires informed consent to be voluntary, explicit, specific to the research, and thoroughly documented.[44]

Switzerland

In Switzerland, national regulatory bodies are currently debating the legality of eSignatures. Researchers may use eConsent to convey information to participants, but the legislation allows only a handwritten signature on paper to give legal consent.[45]

United Kingdom

The UK is among the global leaders in the number of trials conducted annually and plans to continue strengthening its position through digitizing clinical research delivery.[46] eConsent and eSignature are legal in the UK for clinical trials of investigational medical products. eSignatures must follow UK eIDAS regulations.[47] The Health Research Authority, a separate governmental body established to streamline research regulations and protect patients, provides extensive guidance on ethical informed consent materials.[48]

United States of America

Guidance from the FDA and the Department of Health and Human Services Office for Human Research Protections (OHRP) allow both eConsent and eSignature.[49] The Code of Federal Regulations (CFR) lays out specific information for requirements of informed consent (45 CFR 46.116), elements of informed consent (21 CFR 50.25), and electronic records and signatures (21 CFR Part 11).[50]

Guidelines for successful eConsent adoption

Successful eConsent adoption requires a nuanced approach, with input from sites, participants, regulatory agencies, sponsors, CROs, ethics committees, and technology partners. Convincing all stakeholders that eConsent is significantly better than paper is critical to gaining traction in the research community (Figure 1).



eConsent needs to be 10x better than the traditional consent process. That's based on an old rule of thumb: if you want to displace an incumbent, you must be 10x better. This is specifically true for eConsent.

– Derk Arts, CEO of Castor

Webinar

Navigating successful eConsent adoption from sponsor to site

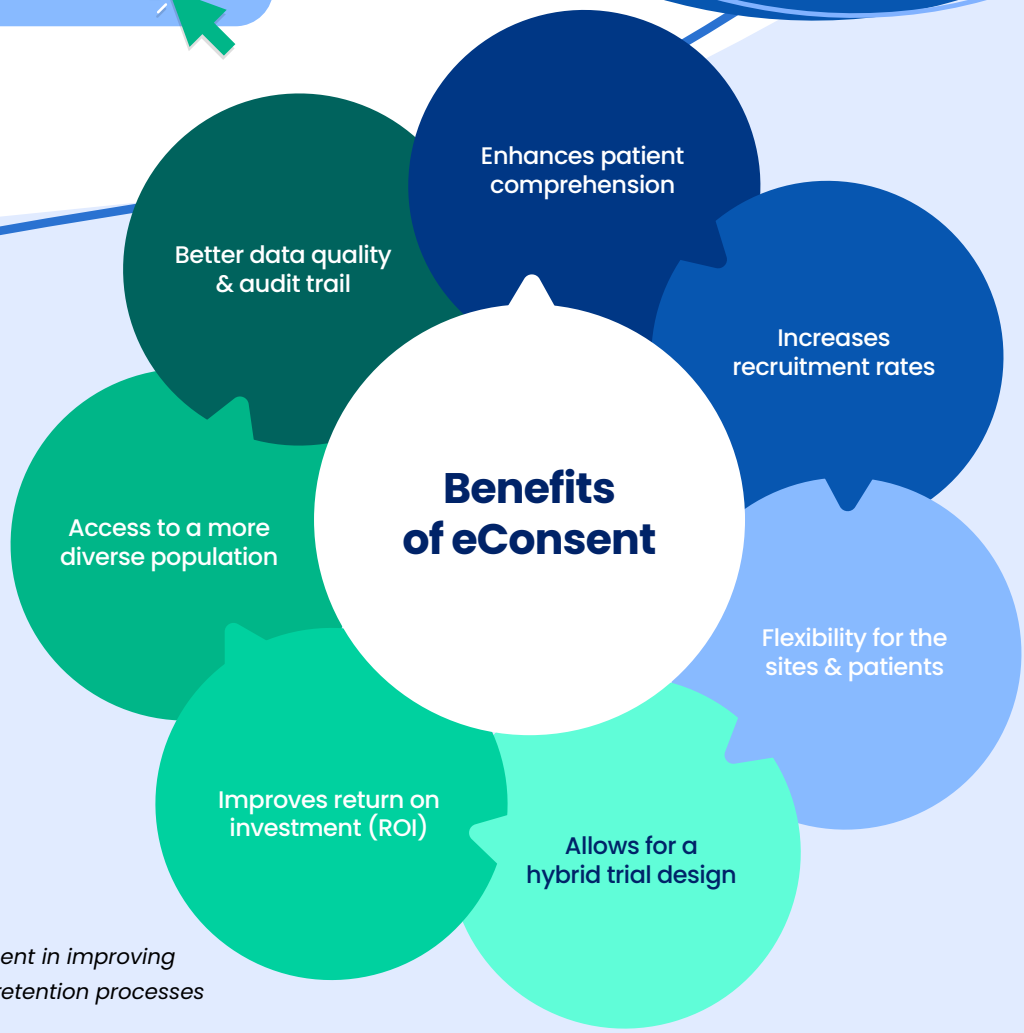


Figure 1. Benefits of eConsent in improving existing recruitment and retention processes

Preparing sites for eConsent adoption

Sites are more likely to use eConsent tools that simplify their work. If researchers need to log into their account, set up an account with a participant, and then navigate a tricky interface, they are much more likely to advocate for a traditional paper consent form. Participants, too, will likely ask for paper if eConsent feels bulky or difficult.

Digital tools that adapt to site and participant expectations help ease the transition. Castor's eConsent tool is easy to use in its digital format. Still, researchers can print the signature form for participants who prefer to sign on paper or for sites that require a printed signature for regulatory approval.

Castor's eConsent tool can be used in a variety of situations, making it ideal for the sites to use during the transition to eConsent.

Including site representatives in trial design and introducing eConsent early will also help ensure successful adoption. Site representatives have the expertise and experience to pinpoint potential barriers to eConsent adoption during an upcoming trial. Addressing these concerns during the design stage is simpler than scrambling to fix them after the trial begins.

Making the most of eConsent in your trial



Enhancing patient workflow

eConsent works in many different situations and is scalable for patients. For example, patients can opt to receive emails with the consent form and updates on study activity but are not required to submit their email for trial enrollment.

eConsent can include multimedia elements and comprehension questions to enhance patient understanding and be used on a variety of devices. Face-to-face calls between patients and providers add a personal touch during remote consent.

Simplifying site workflow

eConsent can automatically send patients reminders to complete consent material and surveys after they sign forms. This is in direct contrast to a traditional clinical trial workflow, where researchers initiate follow-up. eConsent provides the same prompts regardless of whether the tool is used on-site or remotely, which helps ensure continuity and prevents confusion. Researchers can manage settings easily within the eConsent tool.

Users can build electronic consent forms using an intuitive text editor within the platform. The form builder allows users to quickly incorporate multi-media content, comprehension questions, agreements and more into their consent forms.

Versioning enables users to update documents and archive out of date material, to ensure participants are only signing current, IRB-approved materials. New versions of consent forms can be electronically sent to participants for signature, eliminating the need for travel to the study site for reconsents.

Improving regulatory compliance

Castor's eConsent increases consent validity and provides a clear audit trail of the entire process. The eSignature option is 21 CFR part 11 compliant and uses an approved authentication method to ensure the validity of signatures. Researchers can also set up eConsent to accept legally authorized representative (LAR) eSignatures.

Personally Identifiable Information (PII) entered into eConsent is stored securely and encrypted so sponsors can't link it to patients. Castor's servers comply with data protection regulations such as the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act (HIPAA) in the U.S.

Interoperability and integrations help data flow

Data entered into Castor's eConsent tool populates in real-time in the EDC system. Researchers can use Castor's application programming interface (API) to connect securely with other systems, including devices, wearables, and electronic health records (EHRs). With Castor's modular portfolio, researchers can choose which tools to use and scale up when necessary.

Multilanguage support for international trials

Customizing the consent process is essential for international trials, where languages may vary by trial site. Castor's eConsent tool has forms available in different languages, and staff can set up multiple landing pages within a single trial. Patients can see information on their trial site and in their language without searching for what they need.

Our customer success story

Essity, a global health company, partnered with Castor and Link2Trials to test their novel bladder-sensing device to help adults with urinary incontinence.

Because they conducted the trial during the COVID-19 pandemic and needed to include a vulnerable population, they chose eConsent to enroll participants – reducing the risk of infections through travel and on-site meetings.

However, researchers couldn't conduct the entire trial remotely. The protocol required on-site measurements, which researchers entered into Castor's EDC platform. Since Castor has an integrated platform, data from in-person visits and remote tools flowed into a central repository, where researchers could trace, monitor, analyze, and use it for real-time decision-making.

There is no one-size-fits-all-sites solution for trial technology, so having a flexible solution with remote and on-site applications is essential. In this case, the hybrid model was successful – enrollment took only four months, and the retention rate was 100%.

Our customer success story

The COVID-RED study with Julius Clinical is another example of how eConsent can improve trial recruitment and enrollment.

Julius Clinical needed to recruit 20,000 participants to test their system for early symptom detection of COVID-19. Nearly half of the participants had to be from high-risk populations, who were especially hesitant to risk travel to trial sites. Using Castor eConsent and other remote tools in their workflow, Julius Clinical recruited over 17,824 participants in just 15 weeks.

Ready, set, go: Using eConsent in your clinical trial

After reviewing regulatory guidance and legislation, the next step is designing your trial around eConsent. Including key stakeholders like sites in the discussion and offering a flexible platform to support their workflows will ensure eConsent adoption throughout the trial. Readiness must happen at both the regulatory and site level.

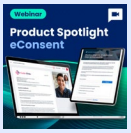
eConsent adoption will carry clinical research into a more efficient, patient-friendly era. The best time to implement eConsent is sooner rather than later. Schedule a demo with Castor today to learn how to use eConsent in your trial.

Schedule a demo with Castor today

to learn how to use eConsent in your trial.

Additional resources

Want to know more? Check out the following resources.



Learn more about eConsent features and see a demo: Product Spotlight: Dive deep into Castor's eConsent.



Hear how eConsent addresses core concerns of site staff: Download with Derk: Understand barriers to eConsent adoption from site & sponsor perspectives.



Read how decentralized clinical trial technology like eConsent helps digital therapeutics companies conduct clinical trials: Don't Overengineer It: Hybrid Designs Overcome Barriers in DTx Clinical Trials



Stock up on tips for navigating post-market clinical follow-up under new requirements: Preparing for Post-Market Clinical Follow-Up Under EU MDR



Watch how to prioritize patient-centricity in trial design and implementation: Harnessing the power of Patient-centric Technologies.

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