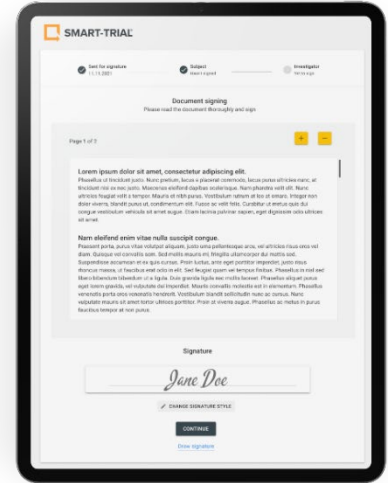


How to Use eConsent Efficiently in Medical Device Studies

We will commence the Webinar a few minutes past the hour to allow our many participants time to join.



Today's Hosts



Páll Jóhannesson
Chief Executive Officer

SMART-TRIAL



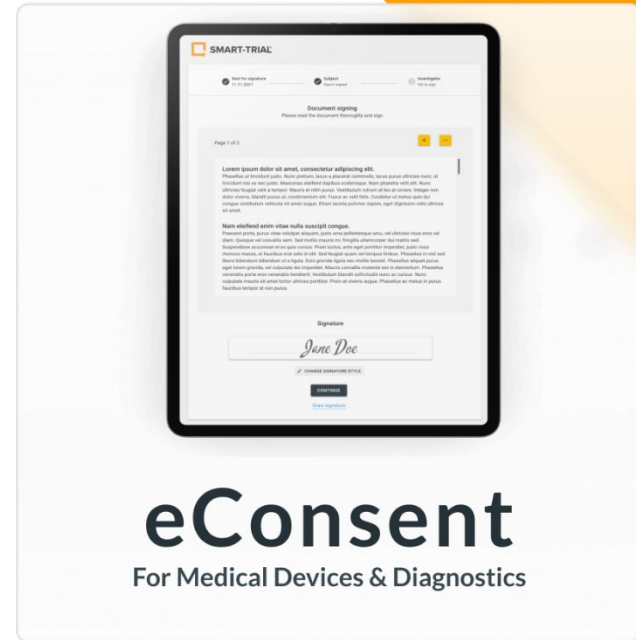
Adam Steadman
Chief Commercial Officer – Americas

SMART-TRIAL

New SMART-TRIAL eConsent Add-On

Collect consent from subjects electronically, **out-of-the-box**

- Bypass setup cost and time
- 100% control of your eConsent process
- Tamper-free eIDAS compliant signatures
- Improved patient experience
- Manage and oversee all informed consent in one place
- Audit trail with full traceability



Today's Agenda

- What is eConsent?
- Why eConsent?
- Key Considerations for Implementation
- Use Cases
- SMART-TRIAL eConsent



Audience

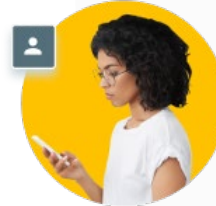
Question

What is eConsent?

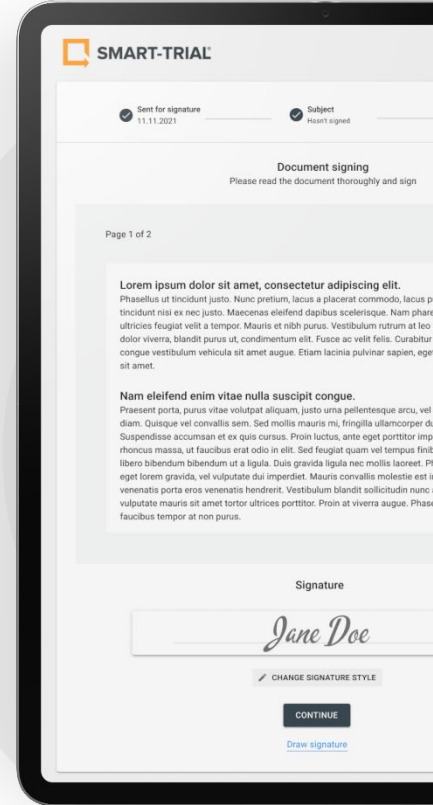
- A simple way to acknowledge one's consent to participate in a clinical investigation or other research activity by electronic means.
- Utilizing eSignatures to replace the traditional wet/ink signature to confirm consent for participation.
- Recent accelerated acceptance and use through Decentralized Clinical Trials (DCTs) and Direct To Patient studies (DTP)



Clinical Investigator

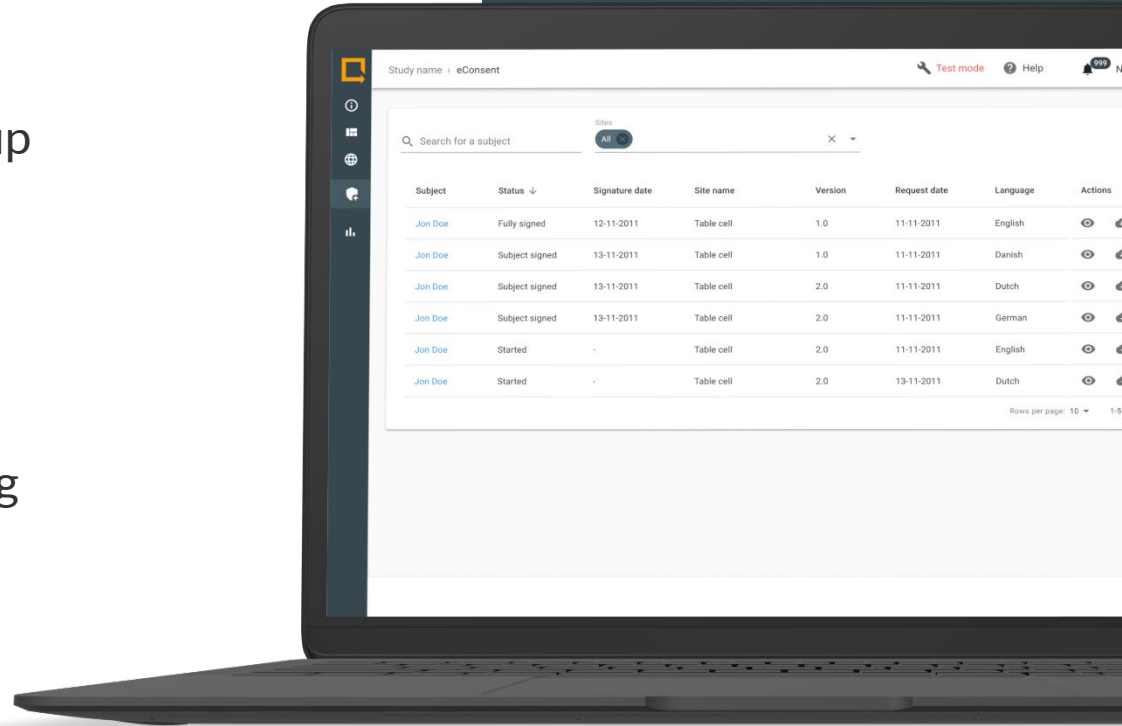


Subject



Why eConsent?

- Electronic storage and back-up
- 2-step authentication
- Documentation of necessary privacy law confirmations
- Consent version control
- Reduced in-person monitoring



The Basics: Consenting

ISO 14155:2020

and

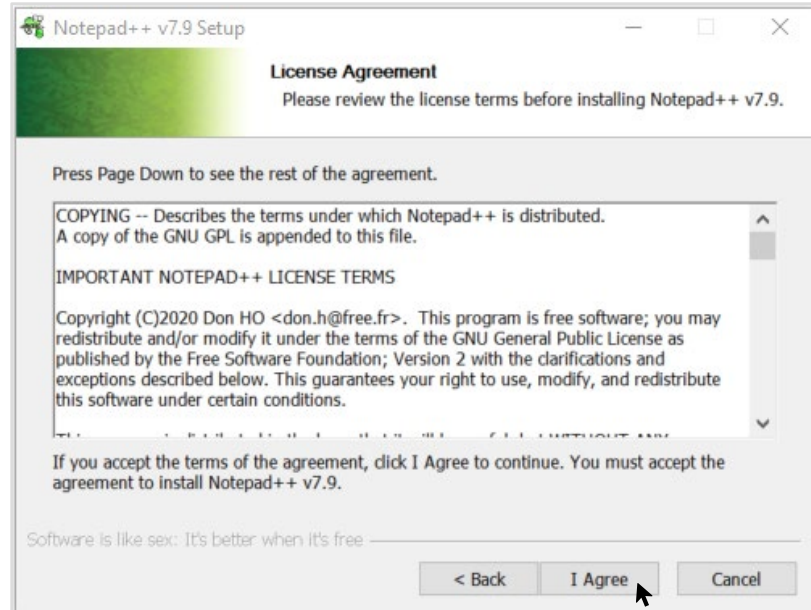
ISO 20916:2019

use the same definition

- 3.27
- informed consent
- process by which an individual voluntarily confirms willingness to participate in a particular clinical investigation, after **having been informed of all aspects of the investigation that are relevant to the decision to participate**

Design your use of eConsent to maximize adherence to the principles of informed consent

Inform about all aspects of the investigation that are relevant to the decision to participate by the volunteer



eConsent can be dangerous in wrong hands

Key Considerations for eConsent Implementation

1. Study/site location
2. In-person consenting preferable
3. The right technology
4. Setup and test with actual users
5. No study is too big (or too small)



Use Case #1

Clinical Investigation

- Class III Implantable device
- 15 sites in France, Germany, USA, Italy.
- One year study with five-year follow-up
- 200 patients, mainly older
- Mid-study protocol change
- EDC used – SMART-TRIAL

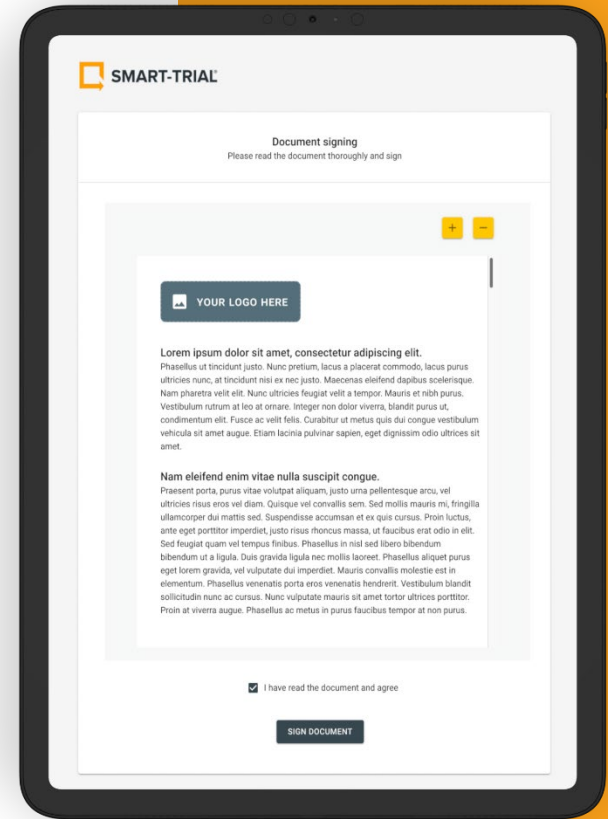
Considerations

- Older population, less comfortable with technology
- Initial consenting should be in-person
- 14155:2020 5.8.2 (j) ensure important new information is provided to new and existing subjects throughout the clinical investigation, which may relate to the subject's willingness to continue participation in the clinical investigation



Efficiencies

- eConsent to record consent, using subject's own device in-person
- CRAs to focus on site-only verification procedures
- Consent to be monitored by the team member(s) who are conducting central review
- Mid-study protocol change may impact already consented patients. These patients can be consulted, educated and re-consented remotely if appropriate
- As the eConsent feature is integrated into SMART-TRIAL, configuration literally takes minutes, and the privacy elements related to PII in the patients email address are blinded



Use Case #2

Registries & Retrospective

- Class III Implantable device
- 100 sites in Europe and the USA
- Device CE marked in 2018
- Expecting FDA PMA Q2/2023
- 1,600 patients, mainly older
- EDC used – SMART-TRIAL

Considerations

- CE Marking will be renewed under MDR and additional evidence is required. US study will only end after CE marking submission is to be made. Cannot afford to temporarily take product off EU market.
- Focus is on largest body of data coming from real world population in Europe, but these patients have not been consented.
- Prospective registry meets needs for ongoing collection of safety and effectiveness data



Efficiencies

- Setup of registry database in SMART-TRIAL along with ePRO for various QoL and satisfaction measurements.
- Quick and trackable remote consent of past patients
- Consent to be monitored by the team member(s) who are conducting central review
- New patients can join the registry after completion of the US IDE study or upon implantation of the CE marked product in Europe using the same registry database and the efficiencies of using eConsent in the previous use case for clinical investigations will be achieved



USE Case: DIAGNOSTICS STUDIES

Use of eConsent in a simple diagnostic study

DESCRIPTION

Early detection study for various cancers
Single blood draw, five year follow up
125 sites, 12,000 patients
US, Canada, Germany, UK,
Netherlands, Poland, Hungary, Spain

CONSIDERATIONS

- By diagnostics standards, this type of trial is relatively big, and can range from ~10,000 volunteers to >50,000 volunteers. The principals are the same, the multipliers make all the difference
- Sample sizes are very large so as to statistically power and prove that earlier predictions of low-incidence diseases are detected accurately
- Clinical site monitoring is potentially the largest study cost

EFFICIENCIES

- An EDC system with integrated ePRO can be quickly and efficiently set up in SMART-TRIAL. As the eConsent feature is integrated into SMART-TRIAL, configuration literally takes minutes, and the privacy elements related to PII in the patients email address are blinded.
- All volunteers must complete at least one on-site visit – for the blood draw - when eConsent can be used to record their consent. This may be done using their own phone or tablet or can be facilitated by any kind of web-enabled browser at the site.
- As this will be a PMA submission in the USA, there will be a BiMo (Bioreserach Monitoring Program) audit by the FDA. Focus will be on whether subjects were adequately consented. Without eConsent, “interim” or “early detection” visits will have to be conducted at all 125 sites, driving significant study cost. With eConsent, visits will be limited to aberrations identified by the central review as part of the integrated RBM strategy.
- Follow-up visits using the ePRO features are facilitated efficiently, and changes to consent driven by the process are easily recorded.

USE Case: Stand-alone (Bring your own EDC)

Use of eConsent in a non-SMART-TRIAL study

DESCRIPTION

Delivery device study to be conducted by top 10 Pharma company
EDC provided by a subsidiary of an Aerospace manufacturer

CONSIDERATIONS

- The manufacturer's device team are the "one percenters" – they have little say in corporate decisions that may impact them. Company has understandably mandated one EDC system for all trials, due to drug based CDISC and drug coding requirements.
- The device team have to conduct studies to meet CE marking requirements for the transdermal patch but have limited budgets and want to use the existing base of customers enrolled in the pre-existing registry.

EFFICIENCIES

- As patients have already started using the device in combination with their prescription, and have already consented to inclusion in the registry, the target volunteer pool, while finite, is well identified and clinical research aware.
- Patients can be targeted efficiently, and appropriate EC approved written communications can be used to inform all aspects of the investigation that are relevant to the decision to participate in this additional study. Patients will likely not be required to revisit the site for this requirement alone.
- eConsent can be configured and validated in a stand-alone database in just a few hours.
- Consent can be monitored by the team member(s) who are conducting central review as part of the integrated RBM strategy for the device study, reducing or eliminating the need for onsite visits.
- Cost of using eConsent is marginal when compared to cost of onsite clinical monitoring

SMART-TRIAL

eConsent

01

What is eConsent?

- A simple way to acknowledge consent
- Replacing the traditional wet/ink signature
- Recent accelerated acceptance through DCT & DTP

02

Why eConsent?

- Electronic storage and back-up
- 2-step authentication
- Documentation of necessary privacy law confirmations
- Consent version control
- Reduced in-person monitoring

03

Key Considerations

1. Study/site location
2. In-person consenting preferable
3. The right technology
4. Setup and test with actual users
5. No study is too big (or too small)

Q&A

Thank You!

For further information or eConsent demo



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