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2020: A milestone for patient informed consent.

2020 is the year of major changes in the way that clinical trials are conducted, as the EU No 536/2014 Regulation becomes applicable.

Informed consent is a mandatory requirement for enrolling any person in a clinical trial. According to ClinicalTrials.gov, 316,844 studies are listed with locations in all 50 States and in 209 countries. An impressive number if we look back in 2000 when only 1,255 studies were registered. Traditionally, clinical trials are paper-based and focused on physical meetings, meaning higher costs reflected at the end in the price of the new drugs on the market.

As the research landscape changes rapidly, online tools can be used effectively to interact with patients in a convenient, user-friendly way, providing information accessible over time. Subject recruitment, reminders, online adverse reaction reports in real-time are just a few examples where Information and Communication Technology (ICT) can bring important benefits, allowing pharmaceutical companies and clinical trial sponsors to focus on the research while the patient stays at the center of decision-making. Data privacy and data reliability are fundamental and capturing valid information may be difficult to control.

In which cases do researchers need to provide an informed consent form?

When the research involves:
- Patients
- Children
- Incompetent/Incapacitated persons
- Healthy volunteers
- Immigrants
- Others

When the research uses/collects:
- Human Genetic Material
- Biological samples
- Personal data

Consent should be a continuing process, especially in long-term trials or projects where participants should be informed of anything new related to the trial.

Regulatory requirements

EU Clinical Trials Regulation No 536/2014

FDA 21 CFR Part 50 Protection of Human Subjects
FDA 21 CFR Part 11

GDPR

EU Clinical Trials Regulation

Art.29 (1) Informed consent shall be written, dated and signed by the person performing the interview and by the subject (...).

FDA requirements

Informed consent shall be documented by the use of a written consent form approved by Institutional Review Board (IRB) and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form. (21 CFR 50.27(a).) When obtaining informed consent, informed consent must be documented by a signed and dated written consent form except under two specific circumstances, as described in FDA's regulations at 21 CFR 56.109(c). (21 CFR 50.27.) When written informed consent is required, the use of electronic, including digital, signatures is permitted under FDA's regulations, provided it is in compliance with applicable regulations (21 CFR Part 11).

Research staff should obtain informed consent before any trial procedures, and throughout the trial. Whenever there are changing elements to the trial that could change the participants' decision to keep moving forward, they should express again their consent to continue with the study.
Besides the clinical trials, the informed consent is required for Medical Device Clinical Investigations as well. The FDA recently published a Guidance Document intended to help sponsors address common challenges faced in clinical investigations. Patient engagement and retention, participant commitments, and protocol compliance are just a few factors contributing to increased time and cost, increased burden and risk exposure to study participants and delays in patient access to beneficial medical technologies.

Adobe Sign and Intesi Group Digital Signature

Let's look at how Adobe Sign and Intesi Group address the challenges of electronic informed consent, helping Life Sciences to stay compliant with EU Clinical Trials Regulation, GDPR and FDA Guidance for IRBs, Clinical Investigators and Sponsors.

The communication of the information provided to the patient should be documented.

Signed by the subject PRIOR to the participation in Clinical Trial.

Subject should receive a copy.

Improving the consent process for staff and patients is what we guarantee. The signature process couldn't be easier with Adobe Sign and Intesi Group.
The patients can easily read the form on the tablet, understand what they are consenting to and simply sign electronically. Authenticated staff can self-sign the form after that and a timestamp is automatically applied.

Once the consent form is signed, it can be automatically archived in the Electronic Health Record (EHR) System. In addition to the electronic consent form, an audit report is generated capturing who created the document, date and time of the signatures and other important information to meet regulatory compliance requirements.

Benefits

A simple calculation for a hospital with around

19,500

consents per month

and two pages per consent form at a

US$ 0.30

per page

results in

US$ 140,400

per year.

In addition to that we should consider the physical archiving cost, as these papers should be preserved for the entire period of the final drug or therapy on the market.

Key takeaways

1. New regulatory requirements come into force impacting Life Sciences companies.
2. Adobe Sign with Intesi Group digital signature help drive compliance.
3. Digital signatures support cost reduction, data integrity and a seamless user experience.

Engage with one of our specialists to find out how we can help your company to implement new requirements for Informed Consent.

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