



Genius ENGAGE™

the electronic Informed Consent

Edition November, 2016

Why use electronic informed consent versus paper?

- **Electronic consenting of patients** using an array of digital elements and process efficiencies provides :
 - **insight into patients' understanding**
 - **increases regulatory compliance** and
 - **reduces quality risks.**
- The **interaction with the site is enhanced** by using a system that **enables patients to self-educate** with the aid of media support and prompts them **to ask questions**
- **Sponsors/CROs can monitor regulatory issues** by viewing a **complete audit trail**, which will show precisely **when patients viewed** the information, **how long** they took to review the ICF, what **additional questions** they had, and their **degree of retention** of the information given.

Why use electronic informed consent versus paper ?

- Importantly, it is currently **difficult to monitor what version of a paper ICF a patient has signed** if the study has protocol amendments containing adverse events that were not previously noted
- **eICF systems** can be used to **notify both the clinical sites and the patients** for follow-up in these situations
- Finally, from a site monitoring standpoint, **digitally stored ICF documents** are **easily stored and reviewed by the authorized personnel**, via a web portal

Genius ENGAGE™: how it works ?



Genius ENGAGE™: features

- Fully digital workflow combined with Genius eTMF
- Once the the **site specific version of the ICF** has been approved and filed into **Genius eTMF™**, than **Genius Engage™** is triggered to provide Investigator and patient of **the appropriate version of the ICF**, for reading and signature
- **Manage multi-language and multi-sites ICFs**
- **Investigator and Patient** can together proceed and **sign the Informed Consent**
- **Complemented with an «understanding» questionnaire** for patient

Genius ENGAGE™: features

- **Track each state of a patient IC process**, from creating the placeholder content till the digital/electronic signed Informed Consent
- Overview of all **ICFs lifecycles for each site** and resume the work on it
- **ICFs and supportive materials** like PDF, (PPT), Video and Audio **directly on the App** on the mobile device
- **No data are stored on the mobile device**
- Local language **Text To Speech** option to read the **ICF text**
- **Digital Signature by DocuSign** or electronic signature process

Genius ENGAGE™ : workflow

- **Patient can share and discuss the IC content with his family members and/or GP** via the controlled access (private PIN) to the web portal
- **After the electronic signing** process by the patient, the investigator and/or by the witness , when needed, **the ICF will be send as a PDF copy to both the investigator and patient**
- **Additionally a wet-ink signature** can be applied too on the printed copy of the electronically signed ICF

Genius ENGAGE™: questionnaire for patient

- Managed by Genius eTMF
- Unlimited amount of questions and languages
- Only if the questionnaire is answered correctly the ICF can be signed successfully
- The answers to the questionnaire are saved in Genius eTMF

The screenshot displays a 'Patient Quiz' interface. On the left, a progress list shows five items, all marked with a red 'X' indicating incorrect answers:

- 0 First Question ❌
- 1 Second Title ✅
- 2 Third Title ✅
- 0 Read & Understood ❌
- 1 Time & Clarification ❌
- 2 Voluntary ❌
- 3 Agreement ❌
- 4 Risks ❌

The main content area shows a question: "Did you explained the patient the study purpose?". Below it is a text block with placeholder text: "Lorem ipsum dolor sit amet, consetetur sadipscing elitr, sed diam nonumy eirmod tempor invidunt ut labore et dolore magna aliquyam erat, sed diam voluptua. At vero eos et accusam et justo duo dolores et ea rebum. Stet clita kasd gubergren, no sea takimata". A yellow box labeled "Your Answer:" is empty. At the bottom, there is a "SAVE ANSWER" button and a red envelope icon.

A second screenshot below shows a question: "I confirm that I have read and understood the information sheet for the Study mentioned above and to have had the opportunity to ask questions." Below it is the same placeholder text block. The "Your Answer:" box contains two radio button options: "Yes, I confirm" and "No, I don't confirm". At the bottom, there is a "SAVE ANSWER" button and a red envelope icon.

Genius ENGAGE™: benefits for participants

- Better understanding of risks and benefits
- Less pressure and anxiety
- Evaluated comprehension
- Improved learning through animation and visual imagery
- More engagement
- Multiple language support
- Clear and easy study explanation

Genius ENGAGE™: benefits for researchers

- True Informed Consent
- More Compliant Participants
- Reduced complex & time-consuming explanations
- Convenience
- Paperless
- Higher Enrollment
- Increased capability

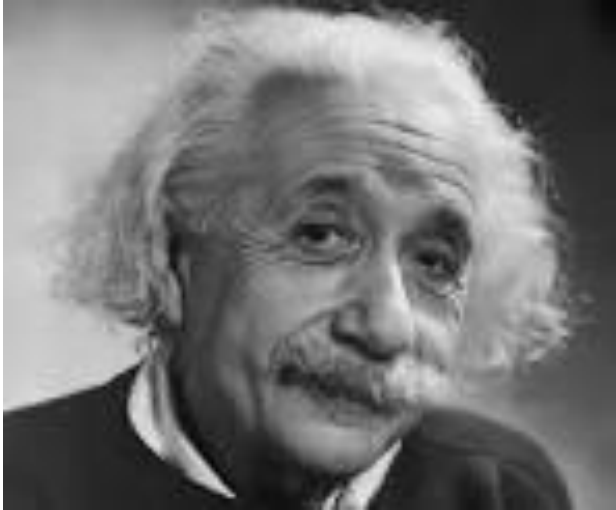
Genius ENGAGE™: benefits for Sponsors/CROs (1)

- Real-time updates of enrollment
- Avoid reporting errors
- Remote control of ICFs
- Avoid the risk of wrong ICF version submitted to patients
- On-time filing into the eTMF of the AOR of the signed eICF
- Allows data entry into eCRF only post eICF signature

Genius ENGAGE™: benefits for Sponsors/CROs (2)

- Establish a **consistent and aligned process** for **Health Authorities and Ethics Committees** to **improve** review/approval process
- **Reduces inspection findings**
- **Reduces or eliminates on-site consent monitoring activities**
- **Reduces or eliminates corrective actions for audit/inspection consent findings**
- **Improves patient recruitment**
- **Reduces dropout rates** for complex studies

Conclusions



We shall not expect that things will change ...
if we keep doing the same things !

(Albert Einstein)



The Human Digital CRO



For more information on Genius ENGAGE™

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