Where Science, Quality & Ethics Meet

EFGCP eConsent Initiative

eConsent Survey for Sponsors and Vendors

This document gives an overview of the questions and related information of the on-line eConsent Survey for Sponsors and Vendors.
Completion of survey needs to be done on-line using the following link
https://form.jotform.com/231433206735046

Click on the below section to navigate

Survey Introduction

Introduction

We are gathering information regarding industry experience, perceptions, and expectations around the use of electronic informed consent (eConsent) in clinical trials. Your responses will help inform strategies for improving the use of this technology for the benefit of participant, sites, and sponsors.

The survey should take approximately 15-20 minutes to complete. Your responses are anonymous unless you chose, at the end, to provide your email for further involvement in this research or related initiatives from the European Forum for Good Clinical Practice.

EFGCP eConsent initiative is a non-profit multistakeholder initiative focusing on harmonizing terminologies and processes associated with eConsent, to increase insight in different stakeholder value models and to provide a consistent country-level overview of acceptance/non-acceptance of certain eConsent aspects. A common misunderstanding on eConsent is that it is about remote consenting or electronic signatures, however these are just some of the features that could be used for eConsent. A glossary of various eConsent digital features has been created by the EFGCP eConsent team and can be accessed here.

Organization Information

1. Please indicate if you are a Sponsor or Vendor
   - Sponsor
   - Vendor

2. In what country is your company headquartered?
   - Select a country

3. In what country are you personally based?
   - Select a country

4. What is the approximate size of your company?
   - Fewer than 50 employees
   - 50-499 employees
   - 500-999 employees
   - 1000-9,999 employees
   - 10,000 or more employees

Survey Questions

5. Please indicate your experience with electronic informed consent (eConsent)
   - We do not have experience with eConsent
   - We have piloted eConsent
   - We have implemented eConsent frequently
   - We use eConsent in all studies

6. What is the most important factor driving a decision to use eConsent technology in organization?

	Not at all	Somewhat important	Very important	Essential
Patient-centricity				
Improve compliance and quality of consent process				
That it enables decentralized trials				
Integration with other clinical systems				
Improvement of recruitment rate				
Reduction of drop out				

7. To what extent is each of the following a barrier to your organization's adoption of eConsent?

	Not at all	Somewhat of a barrier	A significant barrier
Challenges with eConsent platform			
High cost			
Regulatory approval concerns			
Delay in timelines			
Lack organization delivery structure and process			
Poor site adoption			

   7.1. In case you have designated "challenges with eConsent Platform" and/or "Lack organization delivery structure and process" as "A significant barrier", please provide additional information below, or any additional comments

8. Do you have any experience working with any country where eConsent has been deployed as default consent method?
   - Yes
   - No

If the answer is “yes”

8.1. Please indicate the country (please hold ctrl key to select multiple countries)

9. Remote Consent - What is your experience for participant authentication?
   - QTSP (Qualified Trust Service Provider) ID Verification
   - Live Video with Investigator
   - Two factors (via SMS, Call, Authenticator,...)
   - Exchange of a random code in conjunction with a phone call with identity control
   - CAPTCHA (Completely Automated Public Turing Test to tell Computers and Humans Apart) after participants create their accounts
   - Other

10. In your experience, which of these types of information is typically required for submission and approval with IRBs/ECs? (Check all that apply)
    - System privacy and security documentation
    - Storyboards of multi-media content used to supplement the consent documents
    - Attestation that eICF is identical to paper ICF
    - System-printed PDF of document
    - Screenshots of digitized content
    - Access to the electronic platform for IRB/EC preview
    - other

11. How frequently have you deployed each of the following features with eConsent ?

	Never	On a few studies	Frequently	Most or all studies
Knowledge Check				
Videos				
Content flags (e.g. mark unfamiliar words, sections)				
Comment boxes (e.g. free text fields, note logs)				
Chat box				
Dictionary/glossary				
Links to other websites (e.g. disease information)				

12. We would also like an assessment of the importance or value of each feature:

	Not at all useful	Adds some value to participant consent	Is extremely useful	Do not know/ No opinion
Knowledge Check				
Videos				
Content flags (e.g. mark unfamiliar words, sections)				
Comment boxes (e.g. free text fields, note logs)				
Chat box				
Dictionary/glossary				
Links to other websites (e.g. disease information)				

13. Would you be interested in participating in future research (interviews or focus groups) or initiatives regarding eConsent?
    - Yes
    - No

    If the answer is "*yes*"

    13.1. Thank you for your interest in supporting eConsent. Please provide your name, organization and email address to be contacted
        - First name
        - Last name
        - Organization
        - email

Terms of Use and Data Protection Policies

Please find below the Data Protection Policies.

Thank you for confirming your agreement by ticking the box at the bottom of this page before clicking on the « submit » button.
Once your results are submitted, you will not be able to make changes anymore.

If you want to receive your survey submission results by email, please tick the box below and enter your email in the field that will appear. This email address will be used to send the results automatically by Jotform and stored in JotForm, it will however not be used by EFGCP to contact you.

Survey Data

Survey Submission Results tick box

- I want to receive my survey submission results by email

If you ticked the above "*I want to receive my survey submission results by email*", please enter your Email below.

By participating in this survey, you are consenting to have your responses used in the analysis and a publication of the results, if applicable. However, your responses will not be identified by name or any other identifying information.

Your data will be provided to the EFGCP eConsent Database workstream carrying out the analysis of the results. The information will be handled by EFGCP within the framework of the eConsent Initiative according to the EFGCP Privacy Policy. If you have additional questions on data privacy policy or you might want to have your personal data deleted or amended, you can contact the EFGCP Data Protection Officer of the EFGCP in writing at secretariat@efgcp.eu.

In the scope of this survey, EFGCP will process your data as data controller for the purposes that were presented to you. The legal basis for processing your personal data is consent (Article 6(1)(a) of Regulation (EU) 2016/679). Your data will be processed according to the EFGCP Privacy Policy.

All data will be used exclusively within the framework of the EFGCP eConsent initiative.

In case you have accepted to be contacted, within this survey, you agree for your personal data to be stored and accessible only to EFGCP Staff Members in the JotForm system and made accessible to the EFGCP eConsent Database WS Lead(s) and EFGCP eConsent initiative lead. You have the right to ask your personal data to be amended or deleted by contacting secretariat@efgcp.eu.

EFGCP will provide its services in a professional and compliant manner using best efforts to protect personal data. When sharing your personal data for the purpose of the eConsent Initiative to the participating stakeholders, EFGCP will implement appropriate safeguards. Each participating stakeholder is an independent controller and has agreed to carry out the tasks assigned to it in this Initiative with care and diligence applying their own safeguards for the received personal data. The parties hereto acknowledge and agree that nothing in this statement contained, and nothing done pursuant hereto by participating stakeholders shall be deemed to constitute a direct or indirect guarantee by EFGCP of any liability. EFGCP cannot be held responsible for any data leaks, IT issues, hacks, misuses, or any harms to you, your organizations or your activities, due to your involvement in the eConsent Initiative Activities.

Personal Data Gathered (if agreed):

- Name, Surname, Organization
- E-mail Address

Agreement tick box

- I agree to Terms of Use and Data Protection Policies