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Effective eConsent Strategies for Every Study: Utilizing the eConsent Fit-for-Purpose Study Framework

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Designing eConsent for Each Study from a Stakeholders' Value, Not Technology Perspective

To date, eConsent adoption and tangible study data about eConsent outcomes are limited.

The most crucial factor contributing to this is that there is no one-size-fits all eConsent model. Each indication, each study, each study population, each site and each participant might have different needs. Multiple factors further complicate this: disconnects in understanding what eConsent entails, limited insight into the benefits and challenges for different stakeholders, and uncertainties regarding the impact of various eConsent platform and operational aspects. Additionally, the lack of effective, comparable metrics and analysis methodologies poses significant obstacles for study teams aiming to deploy eConsent.

A step-by-step evaluation per study is critical to explore and define the eConsent objectives for a particular study, to identify the best eConsent aspects to implement on the study, to define the metrics and measurements of success, and to analyze and report on its effectiveness.

The European Forum Good Clinical Practices (EFGCP) eConsent Initiative, comprised of over 50 companies, developed the eConsent Fit-for-Purpose Study Framework to guide stakeholders through this evaluation. This framework benefits sponsors (commercial and non-commercial) by providing a structured and harmonized approach to address the potential shortcomings highlighted above, and may benefit other stakeholders including sites, ethics committees (ECs), health authorities (HAs), participants, vendors, and any other partner interested or involved in eConsent.

A Common Understanding of eConsent is Crucial

Informed consent is a process between the participant and site personnel – the two key players – but the sponsor and other parties also have important roles to drive, support, and verify the accuracy of the process.

The term 'eConsent' is the overarching terminology for the traditional informed consent process supported by one or more digital features[1]. It is important to understand that the consent process does not change; the same consent process steps are still applicable, as shown in Figure 1.

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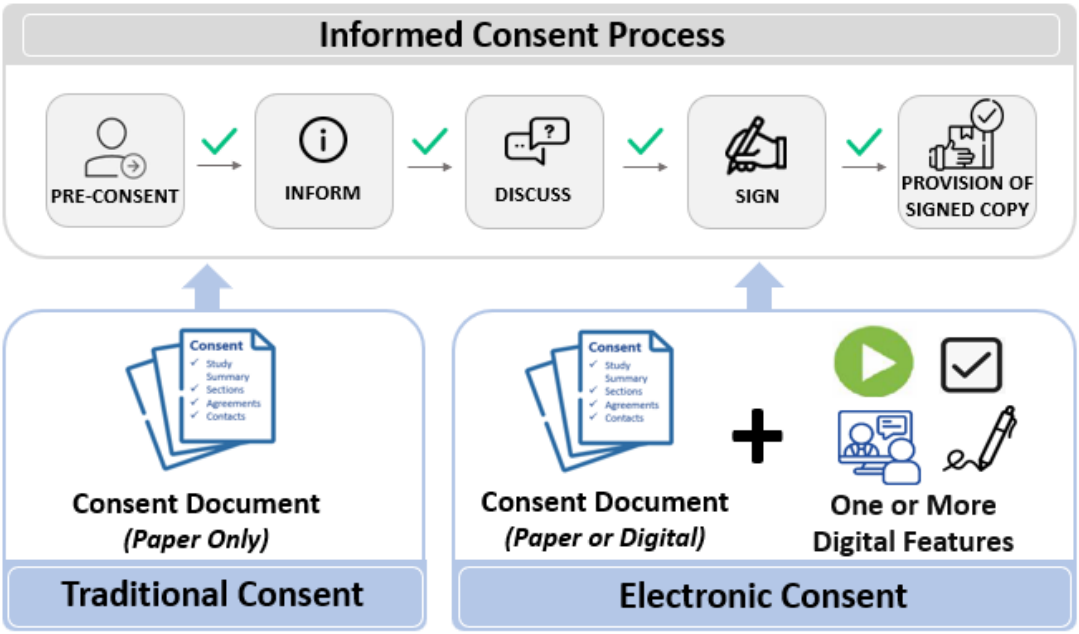

***Figure 1**: eConsent Definition and Examples of eConsent Digital Features. **Source**: EFGCP.*

There are many disconnects regarding eConsent with some misconceptions outlined in Figure 2. For example, eConsent is often confused with remote consent but they are two different concepts. Remote consent refers to the location of the participant and investigator during the consent process and that they are not in the same physical location. A remote consent process could be conducted entirely on paper (not eConsent) or by using digital features (eConsent).

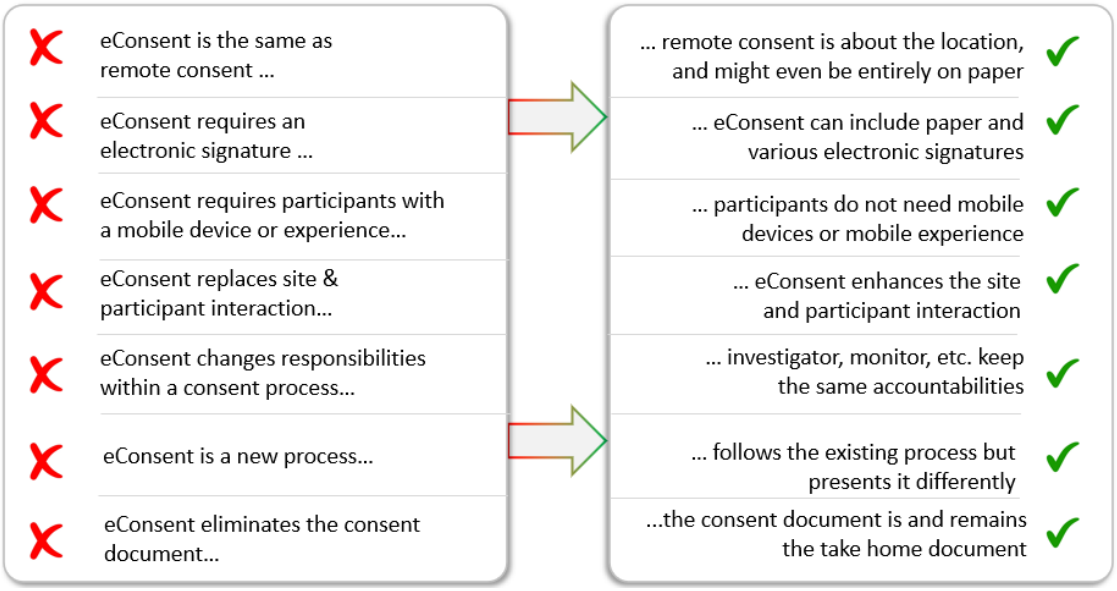

***Figure 2**: Some Common eConsent Misunderstandings. **Source**: EFGCP*

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A 5-Step Process Flow to Enable a Fit-for-Purpose eConsent for Your Study

The eConsent Fit-for-Purpose Study Framework consists of five process steps and a Go/No Go decision point to design, measure and analyze the right eConsent for your study, and generate impactful study data on eConsent (see Figure 3). Depending on the organization strategy, variations might exist in the overall process flow. For example, the process steps might not be done at a study level but at the program level, or the Go/No Go decision point might not be applicable if the implementation of eConsent is mandatory within an organization.

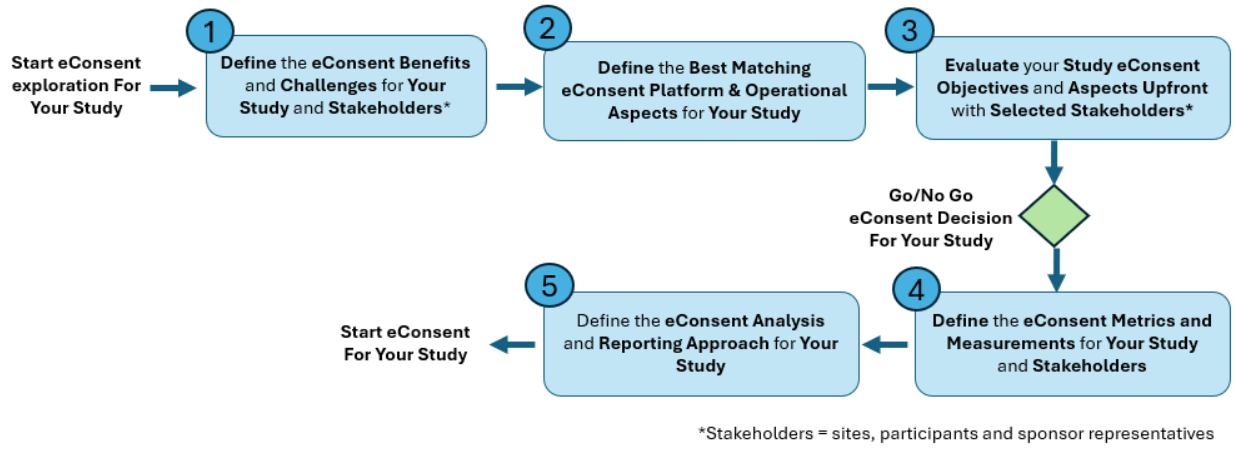

***Figure 3**: eConsent Fit-for-Purpose Study Framework Overview.* ***Source:** EFGCP.*

In the following sections some highlights of each step are provided.

Step 1: Define the eConsent Benefits and Challenges for Your Study and Stakeholders

In total, *18 potential eConsent benefits* were identified and their impacts were assessed on the sponsor, site and participant level. Vendors and other third parties were not listed as they fall under the responsibility of the sponsor or site (Figure 4).

Potential eConsent Benefits	Sponsor	Site	Participant
Enhancing participant preparedness in advance	+++	+++	+++
Improving consistent and complex information sharing	+++	+++	+++
Enhancing access, recruitment and diversity	+++	+++	+++
Enhancing autonomy for vulnerable/ specialized participant groups	+++	+++	+++
Improving participants' understanding	+++	+++	+++
Reducing participants' dropouts	+++	+++	+++
Enhancing the ability for flexible communication channels	+++	+++	+++
Increasing the quality of consent data	+++	+++	+
Improving compliance with the consent process	+++	+++	+
Improving tracking and insights into optional consents	+++	+++	+
Improving oversight and real-time insights	+++	+++	/
Enabling integration with other systems	+++	+++	/
Reducing on-site consent auditing and inspection activities	+++	+++	/
Reducing on-site consent monitoring activities	+++	+	/
Enhancing continuous improvement of consent content	+++	+	+
Supporting sites to have a more tailored discussion with the participant	+	+++	+++

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Potential eConsent Benefits	Sponsor	Site	Participant
Improving consent storage	+	+++	+++
Improving consent archival for sites	+	+++	/
Impact Legend - impact can be direct or indirect			
+++	*The benefit has a **significant impact** on the stakeholder.*		
+	*The benefit has **some impact** on the stakeholder.*		
/	*The benefit has **no impact** on the stakeholder.*		

***Figure 4**: Potential Cross-Stakeholder eConsent Benefits Impact Overview. **Source:** EFGCP.*

All potential benefits have an impact on both sponsors and sites, either directly or indirectly. Benefits that directly impact the participant such as improved preparedness and enhanced access also indirectly benefit the site and sponsor.

Some benefits are indirectly linked with nearly all other benefits. For instance, if information sharing or participants' understanding is improved, the quality of consent data and compliance with the consent process will likely improve too.

In total, *16 potential eConsent challenges* were identified and impact on stakeholders assessed (see Figure 5). These challenges are not necessarily the same as risks and are not meant to discourage the use of eConsent but are important to consider and proactively mitigate.

Potential eConsent Challenges	Sponsor	Site	Participant
Resisting technology adoption by sites	+++	+++	+++
Resisting technology adoption and/or limited technology skills of participants	+++	+++	+++
Navigating the complex usability of eConsent platforms	+++	+++	+++
Navigating a variety of electronic devices	+++	+++	+++
Dealing with incompatible IT infrastructure at the site	+++	+++	+
Extending submission and approval timelines	+++	+++	+
Extending the development timelines	+++	+++	+
Correcting errors in linkage EDC ID and Consent ID	+++	+++	/
Navigating the wide range of eConsent platforms	+++	+++	/
Increasing administrative workload and training	+++	+++	/
Increasing heterogenous oversight and deployment	+++	+++	/
Increasing consent data review activities	+++	+++	/
Limiting availability of integrated systems	+++	+++	/
Increasing complexity to navigate multiple stakeholders	+++	+	/
Increasing impact on budget and resources	+++	+	/
Impacting site relationships with participants	+	+++	+++
Impact Legend - impact can be direct or indirect			
+++	*The challenge has **a significant impact** on the stakeholder that **needs consideration and action to be taken**.*		
+	*The challenge has **some impact** on the stakeholder that **needs consideration and action to be taken.***		
/	*The challenge has **no impact** on the stakeholder.*		

***Figure 5**: Potential Cross-Stakeholder eConsent Challenges Impact Overview. **Source:** EFGCP.*

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A benefit can also present a challenge. For example, while eConsent can enhance access, recruitment, and diversity, it might also introduce a new diversity barrier for participant populations that lack basic digital literacy skills[2].

Environmental impact was not categorized as either a benefit or challenge. This is because both a reduction in paper printouts (due to digital availability) and an increase in paper printouts (due to more supporting consent materials like glossary, video scripts, quizzes) might be applicable. Additionally, the environmental impact of electronic devices on waste is not yet clear.

Step 2: Define the Best Matching eConsent Platform and Operational Aspects for Your Study

The EFGCP eConsent Initiative has developed a list of over 60 different terminologies for eConsent platform aspects, including digital features and eConsent operational aspects. This standardization aims to create a common and consistent nomenclature for eConsent[1, 3]. Digital features represent the foundation of eConsent and which digital features have a significant impact on a particular benefit is demonstrated in Figure 6.

	Pre-Consent Acknowledgment	Educational content	Comprehension Content	Comprehension Confirmation	Communication channels	Consent Document Copy	Identity/authentication	Documentation/Log	Signed Consent Upload	Paper Consent Tracking	Confirmation of Participation	Metadata Insights and Metrics	Business Intelligence	Notifications
Enhancing participant preparedness in advance	x	x	x		x	x								x
Improving consistent and complex information sharing		x	x		x									
Enhancing access, recruitment and diversity	x	x	x		x	x								
Enhancing autonomy for vulnerable/specialized participant groups	x	x	x		x	x								
Improving participants' understanding		x	x	x	x									
Reducing participants' dropouts		x	x	x	x									
Enhancing the ability for flexible communication channels					x									
Increasing the quality of consent data									x	x	x	x	x	
Improving compliance with the consent process	x		x	x			x	x	x	x	x	x	x	
Improving tracking and insights into optional consents									x	x	x	x	x	
Improving oversight and real-time insights	x		x	x			x	x	x	x	x	x	x	
Enabling integration with other systems	x				x		x			x	x			
Reducing on-site consent auditing and inspection activities	x			x			x	x	x	x	x	x		
Reducing on-site consent monitoring activities	x			x			x	x	x	x	x	x	x	
Enhancing continuous improvement of consent content			x	x								x		
Supporting sites to have a more tailored discussion with the participant			x	x				x				x		
Improving consent storage						x			x					
Improving consent archival for sites						x			x					

Figure 6: *eConsent Digital Features and Benefits Overview.* ***Source:*** *EFGCP.*

Overall, benefits that directly impact participants (e.g. upfront preparedness, understanding, autonomy) are best supported by Educational and Comprehension Content digital features such as videos and quizzes. In contrast, sponsor benefits, like quality of data, process compliance, and oversight are best enabled by digital features like Confirmation of Participation (e.g. electronic acknowledgment, the different eIDAS eSignatures) or Signed Consent Upload. Mitigating the identified challenges for a particular study upfront is crucial. For example, for studies with budget and resource constraints the use of expensive multimedia digital features (e.g. videos, quizzes) might be less appropriate. For studies conducted in many countries and with diverse populations and cultures (highly heterogenous oversight), flexibility in deployment of digital features may be recommended on a per site/participant basis.

Apart from eConsent digital features, several other eConsent platform and operational aspects are important to consider in line with the selected eConsent benefits and challenges for a particular study.

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Some examples are determining the type of data to be electronically collected (e.g. personal, non-personal, or aggregated data), who will have electronic access to which type of data, the type of devices to be used (provisioned or use of participant/site own electronic devices), and the location of the participant/investigator for the different consent process steps.

A template to identify the benefits and challenges for your study, along with the best matching aspects or mitigation approaches, is included in the framework.

Step 3: Evaluate Your Study eConsent Objectives and Aspects Upfront with Selected Stakeholders

Cross-checking your assumed eConsent objectives, platform aspects, and operational aspects for your study upfront with some selected stakeholders is highly recommended. Frequently, assumptions made by the sponsor do not align with how sites and participants – the consent process owners – experience the impact of eConsent on the consent process.

Various stakeholder evaluation methodologies can be used, such as surveys, group meetings, and interviews. Given that only "selected" stakeholders are involved in this upfront check, and to avoid misinterpretations and ensure a good understanding of the rationale behind each answer, it is recommended that interviews or group meetings are used.

The outcome of this upfront evaluation combined with your overall challenge mitigation approach will drive the final decision about whether to proceed or not with deploying eConsent in your study. In case of negative feedback from stakeholders, updates to the defined eConsent platform or operational aspects may need to be considered to address their concerns.

Step 4: Define the eConsent Metrics and Measurements for Your Study and Stakeholders

In total, nine potential eConsent Key Performance Indicators (KPIs) have been identified to measure all of the potential eConsent benefits and potential eConsent challenges (see Figure 7). Detailed quantitative and qualitative measurements for each of these KPIs are described in the framework.

Monitor Experience	Site Experience	Recruitment Rate
Sponsor Experience	Inspection/Audit Findings	Dropout Rate
Participant Experience	Consent Protocol Deviations	Investments/Savings

Figure 7: Potential eConsent Key Performance Indicators (KPIs) for Your Study

Most measurements are qualitative since the data reporting capabilities related to consent activities within eConsent platforms or within sponsor systems are currently limited or fragmented and require careful interpretation to avoid drawing incorrect conclusions.

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Step 5: Define the eConsent Analysis and Reporting Approach for Your Study

There are different ways in which you can analyze your defined KPIs for your study. For example, all participants and sites are offered eConsent versus only a select group of participants and sites. Each analysis approach has its advantages and disadvantages.

The timing of assessment might also vary depending on the KPIs. For example, collecting participants' and sites' experience is recommended as soon as possible after the eConsent experience while impact on inspection/audit findings or dropout rates will be evaluated at the end of the study. Creating an eConsent study evaluation report is highly recommended. Such a report not only facilitates the sharing of learnings and best practices with internal stakeholders, but also provides valuable insights for external stakeholders. Raising industry awareness of your results through publications is also advisable given the current limited availability of eConsent study data and low adoption rates. It is crucial to clearly describe the eConsent digital features, the platform and operational aspects deployed in your study, as well as your analysis approach, to ensure accurate interpretation and broad applicability.

Successful eConsent Adoption Requires a Fit-for-Purpose Approach and Industry Engagement

Using digital features to support the informed consent process (i.e. eConsent) can bring value for all stakeholders involved and has the potential to mitigate many of the traditional quality and compliance issues noted with the paper consent process (e.g. 4th highest cause of all critical inspection findings and 5th highest cause of all critical site findings[4]).

However, there is no one-size-fits-all eConsent model. Each study, each site, each participant might have their own needs. It is important to define the targeted eConsent objectives for each study and its stakeholders so that the right eConsent can be designed. For example, in one study the focus might be to reduce on-site consent monitoring activities or improve tracking and insight into optional consents (predominantly benefiting the sponsor); in contrast another study might aim to enhance participants' upfront preparedness or autonomy.

Defining your eConsent objectives clearly for your study upfront is fundamental and drives which eConsent platform and operational aspects best match your needs, which metrics and measurements to implement, and how to generate impactful study data about eConsent that can support other stakeholders' considerations and use of eConsent. Documenting your intent to use eConsent as early as possible and starting from the draft study documents (e.g. draft study design) is highly recommended to maximize the support and input of your stakeholders. The industry perspective on EC and HA related study documents and an overall recommendation of which eConsent operational and platform aspects should be included in which study document is available on the EFGCP eConsent website[5, 6].

Lack of concrete study data on eConsent remains one of the biggest challenges to eConsent adoption to date [6, 7, 8, 9]. We hope that with this eConsent Fit-for-Purpose Study Framework we are one step closer to closing this gap. It is now in the hands of the stakeholders to make it happen and give eConsent the place it deserves in the research community.

Supplemental Information

The entire EFGCP eConsent Fit-for-Purpose Study Framework is available at the EFGCP eConsent website Access to Supplemental Information.

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