Where Science, Quality & Ethics Meet

EFGCP eConsent Initiative

eConsent Fit-for-Purpose Study Framework

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1. INTRODUCTION

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, identify the best eConsent aspects to implement on the study, define the metrics and measurements of success, and analyze and report on its effectiveness.

The 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

*Throughout the text, when the term participant or site is used it may include other stakeholders (see Appendix A for details of other stakeholders)

2. WHAT IS eCONSENT

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 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.

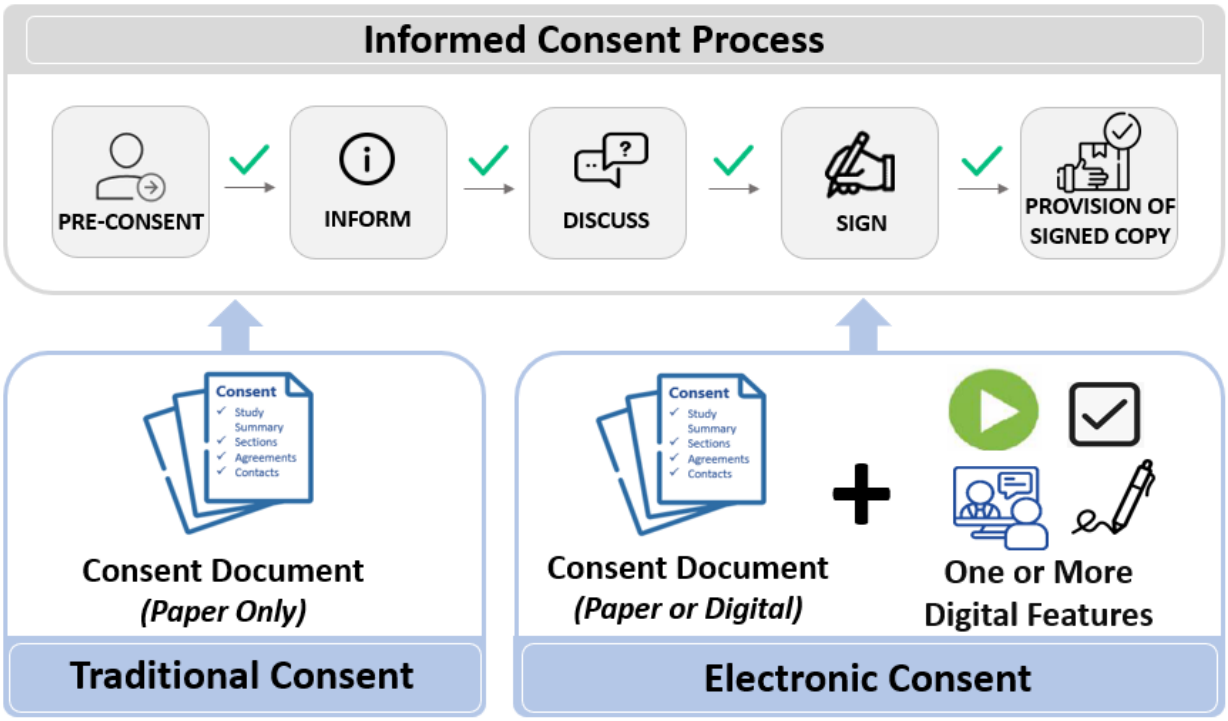

Figure 1: eConsent Definition and Some Examples of eConsent Digital Features

There are many disconnects regarding eConsent with some misconceptions as 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).

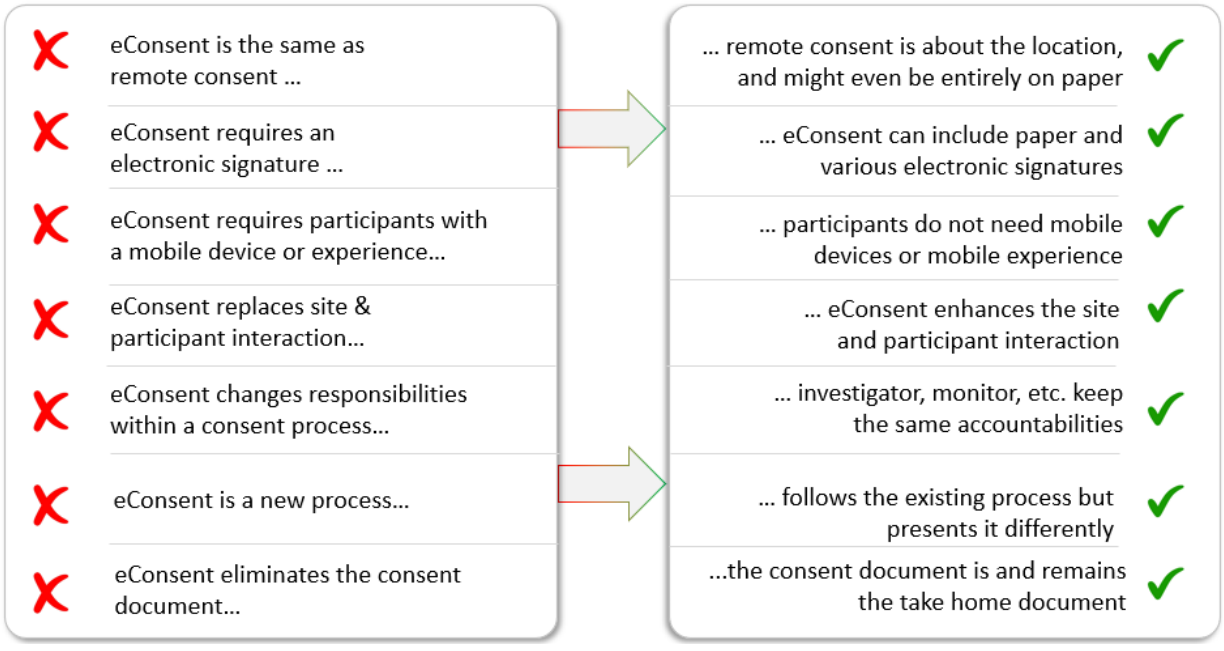

Figure 2: Some Common eConsent Misunderstandings

A list of over 60 different eConsent platform aspects, including digital features, and eConsent operational aspects have been developed to standardize the eConsent nomenclature and enable a common understanding (See Appendix A, Glossary of eConsent Platform and Operational Aspects).

3. eCONSENT FIT-FOR-PURPOSE STUDY FRAMEWORK OVERVIEW

The 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 about eConsent (see Figure 3).

Depending on the organization strategy, variations might exist in the overall process flow. For example, steps might not be done at a study level, or Go/No Go decision might not be applicable if the implementation of eConsent is mandatory within an organization Each study has its own needs and requirements – there is no one-size-fits-all eConsent – and considering this framework can help to define the best eConsent for your study.

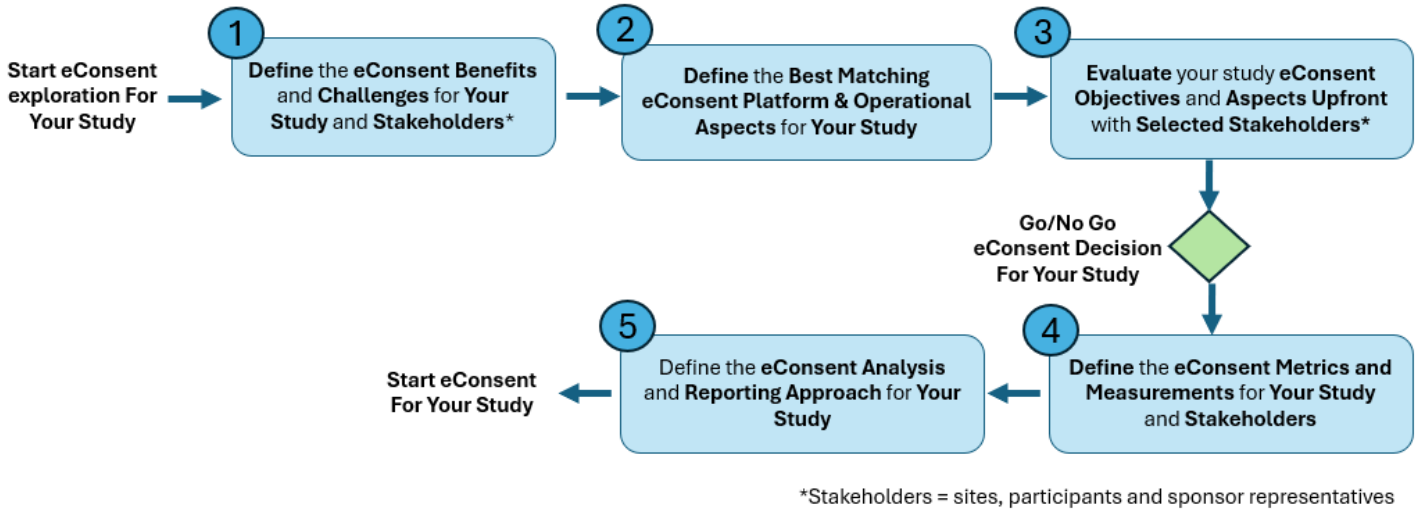

Figure 3: eConsent Fit-for-Purpose Study Framework Overview

Informing your stakeholders and documenting your intent to use eConsent as early as possible, starting from the draft study documents (e.g. draft study design, draft protocol) is highly recommended to maximize the support and input of your stakeholders. In Appendix B, an overall recommendation of which eConsent operational and platform aspects should be included in which study document is referenced.

4. STEP 1: DEFINE THE eCONSENT BENEFITS AND CHALLENGES FOR YOUR STUDY AND STAKEHOLDERS

4.1. Introduction

To define the eConsent objectives for your study, it is important to consider both the targeted eConsent benefits and challenges for your study and stakeholders.

In total, 18 potential eConsent benefits and 16 potential eConsent challenges were defined. Using generic terms such as "engaging" or "efficiencies" were avoided, and the focus was to have more concrete and specific benefits and challenges.

The impact of each benefit and challenge has been assessed on the following stakeholders: 1) sponsors, 2) sites and 3) participants. Vendors (technology providers, CRO's) or other third parties are not listed as they fall under the responsibility of either sponsor or site.

In the following sections, an overview of the cross-stakeholder benefits and challenges is provided with some additional explanations. Corresponding templates are also present in Appendix C and Appendix D.

4.2. Potential Cross-Stakeholder Benefits Impact Overview

Potential eConsent Benefits	Sponsor	Site	Participant	Descriptions*
Enhancing participant preparedness in advance	+++	+++	+++	Sharing upfront consent information with participants, including the option to share with their relatives, could facilitate a more efficient, tailored, and GCP compliant process. The details to be shared (e.g. complete informed consent or just a summary page) and the methodology of sharing (e.g. via email, download from a website) may vary depending on the study.
Improving consistent and complex information sharing	+++	+++	+++	Utilizing digital educational content (e.g. video, glossary) can facilitate a more consistent, more complete, and easier way to explain complex procedures and concepts to participants (e.g. DNA analysis). Complexity of clinical trials and procedures tends to also increase with novel technologies and operational models being introduced.
Enhancing access, recruitment and diversity	+++	+++	+++	Providing various digital communication channels can enable broader access, increase inclusion and diversity of participants, and offer alternative ways for sites to reach a wider participant community (e.g. community screening events, websites).
Enhancing autonomy for vulnerable/ specialized participant groups	+++	+++	+++	Vulnerable/specialized participant populations (e.g. visually impaired individuals, illiterate individuals, children) often rely on the assistance of others to comprehend and make informed decisions about their participation in clinical trials. Providing digital educational content (e.g. audio, video) can foster greater autonomy to independently understand the details of the trial and determine whether or not they want to participate.
Improving participants' understanding	+++	+++	+++	Using digital educational content (e.g. tiered content, glossary) or comprehension content (e.g. flag unfamiliar terms, quizzes) may enhance participants' understanding of the clinical trial.
Reducing participants' dropouts	+++	+++	+++	Improved clinical trial understanding by participants could decrease participants dropping out.
Enhancing the ability for flexible communication channels	+++	+++	+++	Provision and incorporation of digital communication channels may enhance use of mobile healthcare, remote consenting, etc.
Increasing the quality of consent data	+++	+++	+	Electronic management of consent/reconsent data can reduce missing participant consent data (e.g., not all elements checked by participants, missing dates/names), reduce errors in dates or wrong versions provided, etc.
Improving compliance with the consent process	+++	+++	+	Using electronic systems to manage various stages of the consent process (confirming interest, informing, discussing, signing, and providing signed documents) can improve the correctness/accuracy of the overall process and ensure compliance with regulatory requirements. For example, it can reduce the risk of backdating paper consent forms, and it can enable more secure, restricted, and controlled storage and access of personal data compared with paper filing.
Improving tracking and insights into optional consents	+++	+++	+	Electronic management and access to participant's agreements (or refusals) for optional consents (e.g. bio-sampling, secondary use of data for other studies, re-contact for other studies) can improve tracking and insight into participants' decisions for sponsors and sites.

Potential eConsent Benefits	Sponsor	Site	Participant	Description*
Improving oversight and real-time insights	**+++**	**+++**	**/**	Electronic management and access to consent data in one system can provide better, more easily searchable, immediate insight and oversight of the overall consent status (e.g., consent withdrawal, completed consent amendments). There may be variations depending on which or how the data is captured (e.g. uploaded paper consent, electronic confirmation that consent was signed) but having it all electronically available can support improved oversight and real-time insight.
Enabling integration with other systems	**+++**	**+++**	**/**	Electronic management of consent data can enable integration with other systems (e.g. RTSM/IRT, EDC, bio sample systems, courier/home nurse systems, tele-visit systems). This allows the consent process to be fully integrated into the clinical trial process, enabling automatic verifications (e.g., no medication can be assigned if the consent process was not completed) or even reduce other monitoring activities by automating certain processes.
Reducing on-site consent auditing and inspection activities	**+++**	**+++**	**/**	Electronic management and remote access of consent data by auditors/Inspectors, can reduce or even eliminate the necessity for on-site consent auditing and inspection activities.
Reducing on-site consent monitoring activities	**+++**	**+**	**/**	Electronic management and remote access of consent data by the monitor can reduce or even eliminate the necessity for on-site consent monitoring activities.
Enhancing continuous improvement of consent content	**+++**	**+**	**+**	Electronic insight and easy access to what was not understood, which text is confusing or not clear, rationale for consent withdrawal, etc. might generate insights into what should be improved content-wise in the consent document for the participant.
Supporting sites to have a more tailored discussion with the participant	**+**	**+++**	**+++**	Electronic insight into time spent on various consent sections, words looked up in the glossary, words/phrases marked as unfamiliar, quiz results, etc., can support the site to focus on unclear or overlooked areas, and enable a more tailored discussion with the participant.
Improving consent storage	**+**	**+**	**+**	Electronic distribution of consent materials to participants (e.g. via email) may aid longer term storage and easier retrieval of information. System generated consent material may ensure sites don't misfile or misplace paper copies/versions and can enable search.
Improving consent archival for sites	**+**	**+++**	**/**	Electronic management of consent material allows sites to have improved access to the archived, signed document and to comply with regulatory requirements.
* Descriptions sometimes include one or more examples of digital features, for all relevant digital features see Section 5.2.				
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.

All benefits indicated have an impact on sponsors, and in most cases the impact is significant. Benefits directly impacting participants' and sites' consent process (e.g. improved access, improved information sharing between participant and site) also indirectly benefit the sponsor. The only benefits with a low sponsor impact are the ones directly linked with site responsibilities, such as consent storage, consent archive, or supporting sites to have a more tailored discussion with the participant.

Similarly, all benefits have an impact on sites, and in most cases the impact is significant. The only benefits with a low site impact are those directly linked to sponsor responsibilities such as on-site consent monitoring activities and enhancing continuous improvement of consent content.

Some benefits, such as "Increasing the quality of consent data" and "improving compliance with the consent process" are also indirectly influenced by most other benefits. For example, if information sharing or participant's understanding is improved, the consent data quality and consent process compliance are likely to improve as well.

A template to define the targeted benefits for your study is present in Appendix C.

4.3. Potential Cross-Stakeholder Challenges Impact Overview

Challenges are not necessarily the same as risks and are not to discourage the use of eConsent, but they are important to consider and to proactively mitigate (see Section 5.4).

Potential eConsent Challenges	Sponsor	Site	Participant	Description
Resisting technology adoption by sites	+++	+++	+++	Technologies often present challenges, increase workload and frustration for sites, which may impact their willingness to adopt another technology. Reluctance may be driven by actual experience or impressions from others.
Resisting technology adoption and/or limited technology skills of participants	+++	+++	+++	Some participants may not feel comfortable using technology and/or may not have the basic digital literacy skills to use eConsent, potentially limiting the diversity of the participant population using the technology.
Navigating the complex usability of eConsent platforms	+++	+++	+++	Some eConsent platforms may be complex, difficult to use, not intuitive, and not self-explanatory. Bad technology is worse than no technology.
Navigating a variety of electronic devices	+++	+++	+++	The format of electronic devices can affect the accessibility and readability of consent content.
Dealing with incompatible IT infrastructure at the site	+++	+++	+	Some sites may experience challenges with connecting, stability issues, or difficulties activating non-site applications. Additionally, if sites have their own eConsent platform, this can add complexity and may even result in the site being excluded from the study.
Extending submission and approval timelines	+++	+++	+	eConsent material review and approval by Ethics Committees and Health Authorities may require longer submission and approval timelines. High variability might also exist between countries, which can impact study start timelines. Paper is always a backup solution or alternative to limit the impact on study start timelines.
Extending the development timelines	+++	+++	+	Development and readiness of eConsent material may take more time compared with that of paper consent material.
Correcting errors in linking EDC ID and Consent ID	+++	+++	/	In most cases, except with integrated systems, a manual activity is required by the site to link the subject ID (EDC ID, RTSM ID) to the consent ID, which can result in errors.
Navigating the wide range of eConsent platforms	+++	+++	/	Multiple eConsent platforms are available, each with their own functionality and requirements, making it complex and cumbersome for sites to manage.
Increasing administrative workload and training	+++	+++	/	eConsent as another system to be used and trained on may increase the workload for the site and sponsor. This might also require additional staff to support administrative tasks and provide coverage (e.g. holidays).
Increasing heterogenous oversight and deployment	+++	+++	/	There may be different approaches at the country, site, and participant levels (e.g., electronic signature or electronic collection of personal data may not be allowed by regulations, some participants may prefer not to sign electronically, etc) within a study, which drives a more heterogenous oversight and deployment.
Increasing consent data review activities	+++	+++	/	More consent data collected and available to review may impact workload and potentially introduce additional findings that were not visible on paper.
Limited availability of integrated systems	+++	+++	/	Integrations with systems with other suppliers such as RTSM/IRT, EDC, etc. might still be limited.
Increasing complexity to navigate multiple stakeholders	+++	+	/	Various internal and external stakeholders (e.g. IT, privacy, procurement, vendors) need to be engaged with by the sponsor to coordinate overall strategy, processes and change management.
Increasing impact on budget and resources	+++	+	/	More investments may be needed for sponsors and potentially for sites.
Impacting site relationships with participants	+	+++	+++	Especially for remote consent, some sites may feel that this will impact their communication, interactions and 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

A template to define the potential challenges for your study is present in Appendix D.

4.4. Additional Considerations

Important to note is that some benefits are also listed as challenges. For example, eConsent can enhance access, recruitment, and diversity but might also introduce a new diversity barrier for participant populations that do not have basic digital literacy skills[2]. Clearly defining both eConsent benefits and challenges for your study is crucial to proactively address and enable the most optimal eConsent platform and operational aspects for your study (see Sections 5.2 and 5.3).

Environmental impact was not categorized as either 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.

Challenges linked with non-validated or non-secure eConsent platforms, such as e.g. potential personal data breaches, are not listed as having a validated, secure, and compliant platform is a fundamental prerequisite. As a note, more secure personal data storage and restricted access, compared with paper filings, might even be enabled by eConsent platforms, and was covered under the benefit 'Improving compliance with the consent process".

Capabilities to support multiple tasks (e.g. eConsent, ePRO) on a single electronic device (e.g. provisioned or participants' own device) can also have an impact and is covered under eConsent Device Deployment, see Section 5.3.

5. STEP 2: DEFINE THE eCONSENT PLATFORM AND OPERATIONAL ASPECTS TO SUPPORT THE TARGETED eCONSENT OBJECTIVES FOR YOUR STUDY

5.1. Introduction

eConsent is an umbrella term covering many different approaches; there is no one-size-fits-all eConsent. A glossary of over 60 different eConsent platform and operational aspects, including descriptions and examples, has been created by the European Forum GCP eConsent Initiative and can be found in Appendix A.

Selecting the eConsent platform and operational aspects that can best support the targeted eConsent benefits, while also considering the challenges identified for your study, are described in the following sections.

5.2. eConsent Digital Features and Benefits Overview

eConsent digital features are one of the most fundamental eConsent platform aspects, as without a digital feature there is no eConsent. A list of the most common digital features has been defined (Appendix A) and their impact has been evaluated for each potential eConsent benefit and shown in Figure 6.

Each digital feature impacts the benefits to varying degrees. Only digital features that significantly enhance the beneficial outcomes of eConsent by demonstrating clear and measurable improvements of changes are shown in Figure 6. Some digital features (e.g. eConsent Platform Training Content, Non-Study, Non-Consent Related Content and Artificial Intelligence) are not listed, as they have no significant direct impact, and they support the correct use of the eConsent platform, and/or are still in the early stages of implementation/utilization and impact assessment is unknown.

The eConsent Benefits and Digital Features Study Template (Appendix C), that was referred to before, can also be used to define the digital features in line with the targeted benefits for your study.

	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 (Click Here to view a Larger Version)

5.3. Additional eConsent Platform and Operational Aspects

Some digital features are fundamental for certain benefits. For example, in the case of electronically sharing consent information in advance to enhance participant preparedness, a digital feature “pre-consent acknowledgment” could ensure that the participant has agreed upfront to having their email address collected in the eConsent platform, if the upfront sharing is done via email from the eConsent platform. Alternatively, the provision can also be done outside the eConsent platform and separately by the site.

Next to eConsent digital features, other eConsent platform aspects and eConsent operational aspects might be considered for your study (see Appendix A for a list of all aspects). Some key aspects to consider are described below.

It is important to note that several eConsent platform and operational aspects are not yet relevant at this stage, but an overall check of the complete list of aspects might still be useful. Operational eConsent aspects are often also applicable for the traditional consent process.

eConsent Device Deployment (Operational Aspect)

There are usually 2 options for eConsent device deployment: 1) use of participant's/site's own electronic device or 2) use of a provisioned electronic device. For both options, eConsent can be accessed either at the same location, not at the same location or a mixed location (for more details, see below "eConsent participant/investigator location"). In most cases, provisioned electronic devices or sites' own electronic devices are used for "at the same location" eConsent activities, and use of participants' own electronic device is for "not at the same location" eConsent activities.

Both options of device deployment have benefits and challenges that need to be carefully evaluated in line with the targeted eConsent objectives for your study. For instance, using participants' own electronic devices can eliminate the need for additional, unfamiliar devices. However, the eConsent software might not be compatible with all devices, participants may lack the digital skills to access the eConsent application, or they may be unwilling to use their own devices for a clinical study. Additionally, sites might need to address software issues on a variety of unfamiliar devices. On the other hand, provisioned electronic devices might imply additional distribution and administrative logistics for the site and participants (in case of home use). A mixed approach, where both device deployment options are offered for eConsent, may be preferred.

Another important factor linked with device deployment is the capability to use the same electronic device for multiple study activities (e.g. eConsent, eCOA). This reduces the need for multiple devices for different applications, reduces overall cost, and simplifies device management. In the case of high enrolling sites or when multiple participants are expected to come on the same day, however, having more devices at the site is recommended.

If printing of the eConsent form is required, it is recommended to verify printing capabilities and ease of device and printing activation to ensure that the electronic device can be connected to a printer. If this is not possible, sites or participants need to be instructed to access the eConsent platform via their desktop or laptop computer for printing to their printer.

eConsent Participant/Investigator Location (Operational Aspect)

There are 3 options for eConsent participant/investigator location: They are 1) at the same location, 2) not at the same location, or 3) in a mixed location (i.e. some consent process steps are at the same location, but other process steps are not). For simplicity, we focus on the first 2 options in the description below, but a similar evaluation is applicable depending on which consent process step is done at which location.

Both options have benefits and challenges. For example, in Europe[3], at least one physical interaction between participant and investigator (i.e. at the same location) for eConsent is recommended or a good rationale needs to be provided to explain why it is not needed in your study. Items often raised are e.g. non-verbal symptoms might be less visible in a video or phone call, identity authentication and verification might be more complex for new or first-time connections between investigator and participant, and not all participants might have appropriate electronic devices or the necessary digital skills to conduct a video call.

Alternatively, being able to have the consent process (or certain steps) not done at the same location also offers several advantages related to access, easier follow-up, etc. for participant and investigator.

A mixed location model for the site personnel might also be considered, where one site staff (e.g. nurse) is at the same location as the participant (e.g. at a local facility, at home), while the investigator joins via video call.

eConsent Stakeholders (Operational Aspect) and eConsent Stakeholders Accounts (Platform Aspect)

Several stakeholders can directly or indirectly support the participant during the consenting process: e.g. participant related stakeholders (e.g. legal authorized representatives, parent), or non-participant related stakeholders (e.g. witness, translator), or miscellaneous stakeholders (e.g. pregnant female of a male participant, nursing care staff in a retirement home).

It is important that these stakeholders have access to the eConsent platform and can fulfill their responsibilities using their eConsent stakeholder account, where applicable.

eConsent Data Types (Platform Aspect) and eConsent Data Access (Operational Aspect)

There are three options for eConsent data types: 1) personal data, 2) non-personal data or 3) aggregated data. The first two options are the most critical ones as different requirements might exist on electronic collection and storage of personal data within a country, site, or even participants might have personal preferences. For example, local regulations might require that personal data is stored on local servers, or participants might not want their personal data stored in a system that is not owned by the site. In general, if personal data are shared electronically outside the site, an additional layer of access control is recommended. For example, if signed eConsent is shared via email, a PIN or another layer of access control might be required for download.

eConsent data access by different stakeholders is closely linked to the different data types. For example, can the monitor electronically access eConsent personal data using his/her account, or will access via his/her account be limited to non-personal data, and access to personal data is only allowed through the site? Data access considerations can also be linked with the location of the participant/investigator. For example, participants might have only electronic access during the consenting process if it is being completed at the same location, but not afterwards. In this scenario, participants will receive a paper copy of the signed consent document to take home, regardless of whether signed on paper or electronically.

There might also be differences at the local, site, or participant level of who can access eConsent personal data. Additional instructions on personal data access might also be included in monitoring guidelines (e.g. personal data should not be reviewed in public areas).

5.4. eConsent Challenges Mitigation Approaches

Mitigating the identified challenges for a particular study (see Section 4.3: “Potential cross-stakeholder challenges impact analysis”) upfront is crucial.

The template described earlier “eConsent Challenges Assessment Study Template” (see Appendix D) contains potential challenge mitigation approaches per challenge and can be used to document the mitigation strategy and overall outcome (accepted, not accepted) for your study.

For example, for studies with budget and resource constraints, expensive multimedia digital features (e.g. videos, quizzes) might be less appropriate. For global studies with diverse cultures, heterogeneous oversight and deployment of eConsent solutions and features may be recommended per site/participant.

Overall, eConsent challenge mitigation approaches can be divided in 4 areas:

1. Selection of the right eConsent digital features, other platform aspects, and operational aspects
    - For example, advanced multimedia educational content (e.g. video) or comprehension content (e.g. quiz) are more expensive and time-consuming compared with simple digital feature examples (e.g. tiered content).
2. Selection of the right eConsent vendor platform
    - There are multiple different vendors, each with their own characteristics. Select an intuitive, self-explanatory, easy-to-use-, platform to support the digital features, platform aspects, and operational aspects defined for your study.
3. Change management strategies and supporting material
    - Invest in change management strategies both for internal and external stakeholders, and create simple, clear, and easy-to-understand stakeholder benefits and value material.
4. Upfront stakeholder assessment
    - Assess your targeted eConsent benefits and challenge mitigation approaches upfront with selected stakeholders to confirm (or not) your study assumptions. This is described in detail in Section 4 and completion of the challenge outcome assessment (accept, not accept) will only be finalized afterwards.

6. STEP 3: EVALUATE WITH SELECTED STAKEHOLDERS THE TARGETED eCONSENT OBJECTIVES AND ASPECTS FOR YOUR STUDY

6.1. Introduction

The eConsent objective and aspects (platform, operational) have been defined for your study. eConsent platform vendor(s) that can best support your study have been contacted and you have a good view on how you want to deploy the different eConsent aspects in line with the vendor capabilities.

An upfront evaluation with selected stakeholders is highly recommended to confirm or cross-check your assumed eConsent objectives and related eConsent platform and operational aspects. This also allows you to further tailor and update your eConsent platform and operational aspects, if required.

6.2. eConsent Stakeholders' Evaluation Methodology

Using the targeted eConsent benefits and aspects defined for your study, create the related questions that you want to have answered or cross-checked.

Since the goal of this upfront evaluation is to check whether your study eConsent assumptions are correct, it is recommended to have detailed and open questions to cover the targeted benefits and selected digital features, platform aspects, and operational aspects to enable a good perspective on fit for your study, and the underlying rationale. Preferably, include practical and tangible examples showcasing the vendor capabilities that you are considering, to ensure a correct understanding.

Internal sponsor departments (e.g. participant and/or site engagement departments) or specialized vendors can support with developing the questions for participants and sites. Different methodologies can be used to address these questions or provide the answers you are looking for.

Figure 7 shows the most common methodologies, including their advantages and disadvantages.

Methodologies	Advantages	Disadvantages
Surveys (electronic, on paper)	Low resource and time-intensive Potential for large audience	• High risk of misunderstanding • Limited insight into feedback and no rationale • Potential low response rate
Group Meetings (video call, face-to-face)	Detailed insight into feedback and rationale	• High resource and time-intensive • Limited audience (few people) • Potential for vocal person intimidating others
Interviews (video call, face-to-face)	Detailed insight into feedback and rationale	• Very high resource and time-intensive • Personal opinion of one person

Figure 7: Different methodologies to collect stakeholders' feedback

Preferably selected sites (if feasible, from the actual study), participants, and sponsor representatives (e.g. from different countries) are involved in this upfront evaluation step.

Depending on the stakeholder, some additional considerations might be needed. For example, sponsor representatives can be brought together at a global level, while for participants a local approach might be more relevant to enable feedback in their own local language.

As only "selected" stakeholders are involved, either interviews or group meetings would be recommended as the methodology. Surveys as methodology are more appropriate for the overall eConsent analysis of the study when the goal is to reach all participants, sites and sponsor stakeholders involved (see Section 7).

6.3. Go/No Go eConsent Decision for Your Study

The outcome of this upfront evaluation with selected stakeholders is a critical step to get an idea of participants, sites, and sponsor representatives' perspectives.

In case of negative feedback from stakeholders, updates to the defined eConsent platform or operational aspects might be considered to address their concerns.

Outcomes can be documented on the challenge outcome assessment (Appendix D) and drive the overall Go/No Go eConsent decision for your study.

7. STEP 4: DEFINE THE eCONSENT METRICS AND MEASUREMENTS FOR YOUR STUDY AND STAKEHOLDERS

7.1. Introduction

In this section, we will focus on defining eConsent metrics and qualitative and quantitative measurements (i.e. Key Performance Indicators) to evaluate and measure the eConsent objectives and eConsent platform and operational aspects defined for your study. The lack of study data about eConsent is one of the biggest challenges to date, as often no measurements or metrics are included for eConsent, while concrete study data about eConsent are fundamental to support overall eConsent deployment.

Methodologies and questions that were defined in section 6.2 to explore and evaluate eConsent assumptions with selected stakeholders might be re-used and/or reframed. However, several other metrics and measurements are added that can be considered for the overall and actual study evaluation about eConsent for all stakeholders involved.

7.2. eConsent Key Performance Indicators

In total, nine eConsent Key Performance Indicators (KPIs) have been defined to measure all the 18 potential eConsent benefits and 16 potential eConsent challenges. For an overview of how each KPI is linked with the individual benefits and challenges, see Appendix E.

KPIs can include quantitative or qualitative measurements and an overview is shown in Figure 8.

Key Performance Indicators	Description	How to measure?
Monitor Experience	Measuring impact of eConsent on monitoring activities	• Use surveys, group meetings, and interviews to collect data on eConsent monitor experience (e.g. impact on informed consent review, platform usability, platform issues). • Develop additional reporting capabilities for platforms if needed (e.g. eConsent platform or internal company reporting tools) to enable measurement of eConsent monitoring activities (e.g. time spent by the monitor on site versus remotely on consent activities).
Sponsor Experience	Measuring impact of eConsent on sponsor activities (not monitor)	• Use surveys, group meetings, and interviews to collect data on eConsent experience of data management, regulatory, IT, privacy, procurement, and other staff (roles outside of monitoring).
Participant Experience	Measuring impact of eConsent on participant	• Use surveys, group meetings, and interviews to collect data on participants' experience with eConsent (e.g. participant satisfaction). • Identify metrics from eConsent platform, such as participant training time, time spent in the eConsent platform by participants, participant's helpdesk metrics (if applicable), can also provide some insights. However, these need to be interpreted with the necessary precaution (educated assumptions). Comparison with paper-based methods may also be challenging due to limited available data.
Site Experience	Measuring impact of eConsent on site activities	• Use surveys, group meetings, and interviews to collect data on eConsent experience of sites (e.g. site-participant relationship, site workload). • eConsent platform metrics, such as site training time, time spent by site staff on the eConsent platform, site's helpdesk metrics (if applicable), can also provide some indication. However, these need to be interpreted with the necessary precaution (educated assumptions). Comparison with paper-based methods may also be challenging due to limited data available.
Inspection/Audit Findings	Measuring impact of eConsent on consent inspection/audit findings	• Specify number and classification of inspection/audit findings related to eConsent activities. • Verify number of CAPA (Corrective and Preventive Actions), including the time from setup to closure and any additional required actions.
Consent Protocol Deviations	Measuring impact of eConsent on consent protocol deviations	• Analyze number of eConsent protocol deviations, if available. Informed consent is often a specific category of protocol deviations (e.g. missing date, issue with signature, wrong version).
Recruitment Rate	Measuring impact of eConsent on recruitment numbers	• Use surveys, group meetings, and interviews to collect data on the impact of recruitment and/or increased access from participants and sites. • Using overall participants' recruitment data can be difficult/challenging due to the multi-factor/complex nature of the recruitment process.
Dropout Rate	Measuring impact of eConsent on drop out numbers	• Use surveys, group meetings, and interviews to collect impact on dropout rate from participants. • Using overall participants' drop data can be difficult/challenging as dropout is a multi-factor/complex process.
Investments/ Savings	Measuring impact of eConsent on investments or savings (e.g. resources, cost)	Use sponsor surveys and internal company reporting systems to measure eConsent impact on • Investments: e.g. resources allocation, eConsent platform and related integration costs, and other expenses (e.g. site or participant reimbursement associated with eConsent) • Savings: e.g. linked with other KPIs (e.g. reduced resources/time spent linked with reduced audit/inspection findings, reduced or less frequent on-site monitoring visits linked with reduced on-site consent monitoring activities)

Figure 8: Key Performance Indicators Overview including quantitative and qualitative measurements.

7.3. Additional Considerations

Most eConsent KPIs are qualitative measurements as to date, data reporting capabilities related to consent activities in platform or internal companies are limited or fragmented and require careful interpretation to not draw incorrect conclusions.

For generating overall eConsent data for your study, it is important that all stakeholders provide their input. Depending on the size of the study and stakeholders involved, surveys might be a more appropriate methodology compared with interviews or group meetings (see Figure 7).

8. STEP 5: DEFINE THE eCONSENT ANALYSIS AND REPORTING APPROACH FOR YOUR STUDY

8.1. Introduction

In this section we will cover different ways on how you can analyze your defined Key Performance Indicators for your study and create a study eConsent evaluation report for internal and/or external stakeholders.

8.2. eConsent Analysis and Reporting Approach

There are different approaches on how to analyze the impact of eConsent digital features and other eConsent platform aspects and operational aspects for your study. The 2 most common approaches, including their advantages and disadvantages, are shown in Figure 9.

eConsent Study Implementation Approach	eConsent Analysis Approach	Advantages	Disadvantages
All participants/sites of the study are offered eConsent	*Related to Participants'/Sites' Experience KPIs* • Participant/site experience is evaluated by questioning the impact of various eConsent aspects versus the non-digital or traditional format. • The same participant might also evaluate different formats: e.g. initial consent as eConsent, reconsent without any digital features. • For participants/sites that do not want to use eConsent, the exact rationale can also be collected. *Related to monitor/sponsor experience KPIs and other KPIs* • Monitor/sponsor experience is evaluated by questioning the impact of various eConsent aspects compared with the traditional consent process. • Other KPIs might be evaluated by comparing them with historical data of other comparable studies: e.g. inspection/audit findings related to consent, dropout rates.	Perspective of ALL stakeholders involved in the study (e.g. all participants, all sites, all monitors).	Less simple comparison methodology, no group comparison.
Selected group of participants/sites of the study are offered eConsent	*Related to Participants'/Sites' Experience KPIs* • Participant/site experience is evaluated in line with the consenting format received. • For evaluating impact on traditional paper consent process, equivalent paper documents (e.g. quiz) might need to be provided or questions specifically tailored (e.g. would upfront provision of information be helpful). *Related to monitor/sponsor experience KPIs and other KPIs* • Impact of monitor/sponsor experience and other KPIs can be evaluated in the different groups.	More straightforward comparison methodology	• Perspective of a selected group of study participants and sites • Evaluation of traditional consent approach might be more difficult for certain aspects • Potential bias within the study on how participants are informed

Figure 9: eConsent Study Analysis Approach

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. Some measurements might also be embedded in the consent process. For example, if questions to check the understanding of the participants are included, the site should have the opportunity to address any inadequate understanding prior to finalizing the consent process.

Creating an eConsent study evaluation report at the end of your study to summarize your outcomes is highly recommended. This is not only for sharing learnings and best practices with internal stakeholders, but such information can also be very beneficial for external stakeholders, such as Ethics Committees.

As to date, eConsent study data are limited, we would recommend also raising industry awareness of your results, e.g. via publications. Important to note is to clearly describe the eConsent digital features, platform aspects, and operational aspects which were deployed in your study and your analysis approach.

8.3. Additional Considerations

Novel technologies and approaches can have a significant impact on how the process is traditionally done and might require time before their real impact can be assessed. Lessons learned from eConsent pilots can generate insight into what works well and what doesn't for certain studies, participant populations, and sites, and create the data needed for broader eConsent adoption.

8.4. Start eConsent For Your Study

The eConsent study design has been finalized and you are ready to implement eConsent in your study, taking into account that the appropriate study documentation and Ethics Committees and/or Health Authorities approvals are also in place. Recommendations of which eConsent platform or operational aspects should be documented in which study document can be found in Appendix B.

9. CLOSING REMARKS

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[4].

However, there is no one-size-fits-all eConsent. Each study, each indication, each study population, each site, each participant might have their own needs and it is important to define the targeted eConsent objectives for each study. For example, for one study the focus might be predominantly on the sponsor, for example, to reduce the on-site consent monitoring activities or improve tracking and insight into optional consents. While for another study the focus might be more on the participant and site interaction, and thus, enhancing the ability for flexible communication channels or supporting sites to have a more tailored discussion with the participant.

Clearly defining your eConsent objectives for your study is fundamental and will also drive which eConsent platform and operational aspects best match, which metrics and measurements to implement, and how to generate impactful study data about eConsent that can support other stakeholders to also consider eConsent.

Lack of concrete study data on eConsent remains one of the biggest challenges for eConsent adoption (and other DCT elements). There is either an absence of, or limited eConsent measurements in studies that deploy eConsent[5]. Additionally, the analysis and reporting methodology is often fragmented with limited insight into the eConsent design used (e.g. no information about eConsent digital features, platform aspects, and operational aspects used), or limited insight into the measurement and analysis methods, making it rather impossible to compare or interpret the results[6,7].

With this framework, sponsors (commercial, non-commercial) have a tool to change and bridge the eConsent adoption gap and enable a Fit-for-Purpose eConsent for each study, while also generating impactful study data about eConsent to support broader adoption. What still needs to be done is to start using the framework and make it happen. It is now in the hands of the stakeholders to make it happen and give eConsent the place it deserves in the research community.

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APPENDIX A:
GLOSSARY OF eCONSENT TERMS

The Glossary of eConsent Terms developed by EFGCP eConsent initiative contains over 60 different terminologies to describe various eConsent platform aspects and eConsent operational aspects. The below figures represent the eConsent platform and operational aspects including digital features terminologies (See Figure A.1), the eConsent operational aspects terminologies (See Figure A.2), the digital features terminologies categorized per stakeholder group (See Figure A.3) and the descriptions and some examples of each digital feature term (See Figure A.4).

More details (e.g. descriptions and examples of other aspects) can be found in the "EFGCP Glossary of eConsent Terms"[8] and the supporting article "eConsent: Why Language Matters"[9].

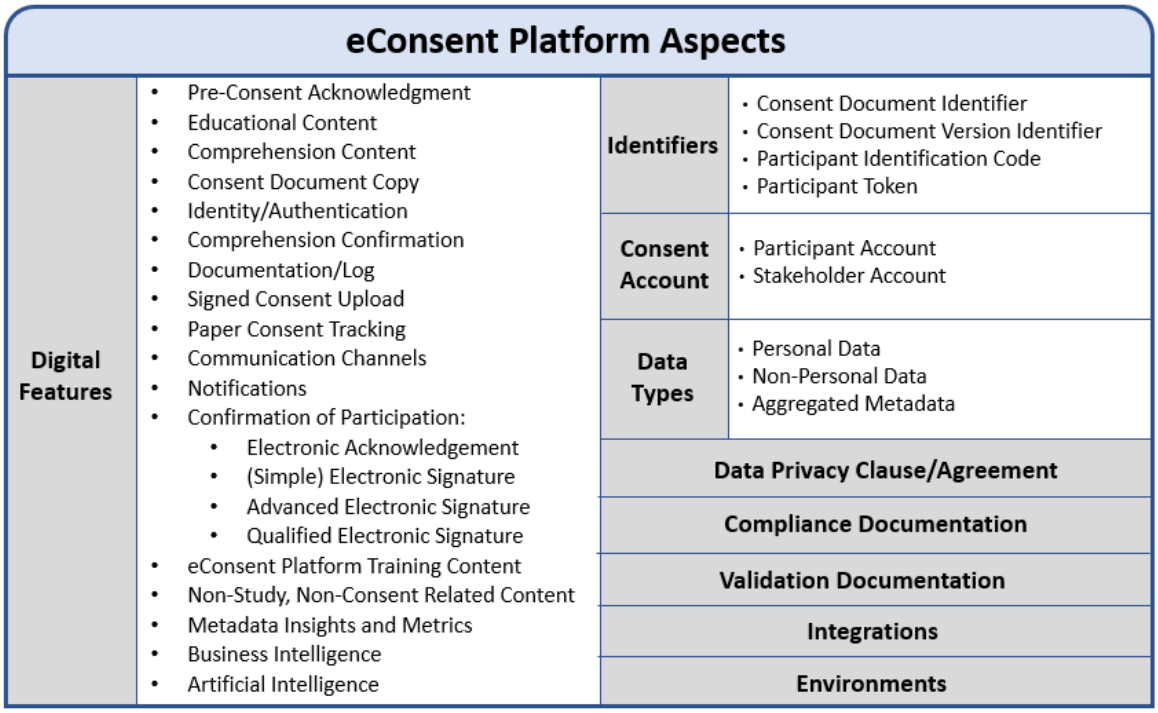

Figure A.1. eConsent Platform Aspects (including Digital Features)

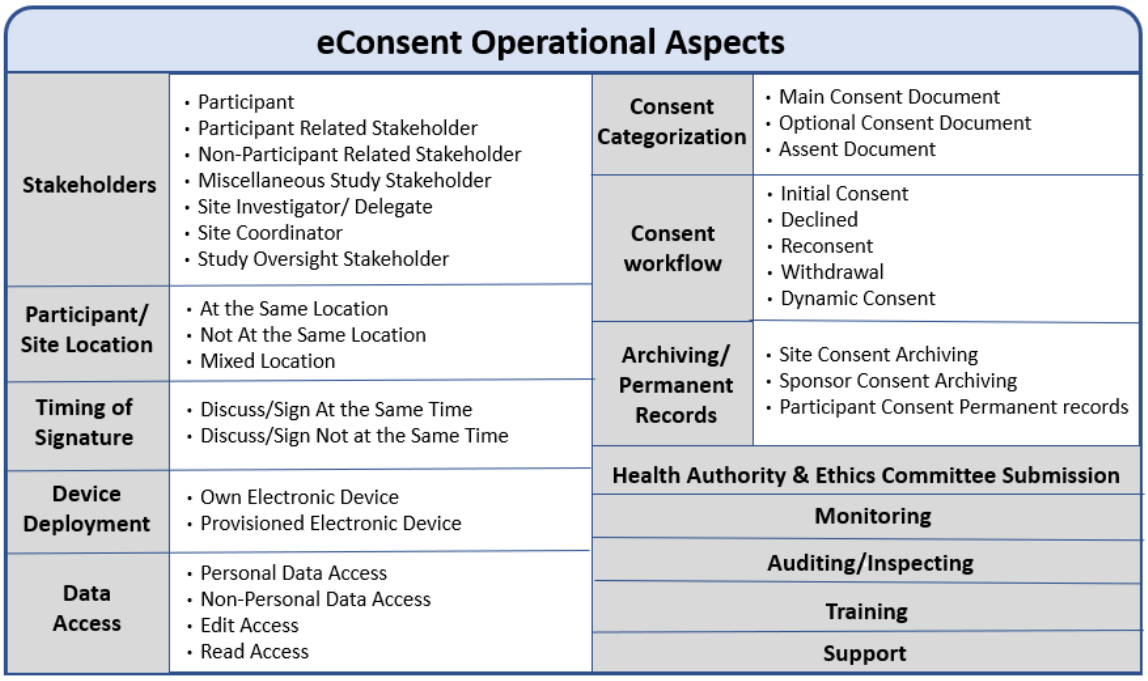

Figure A.2. eConsent Operational Aspects

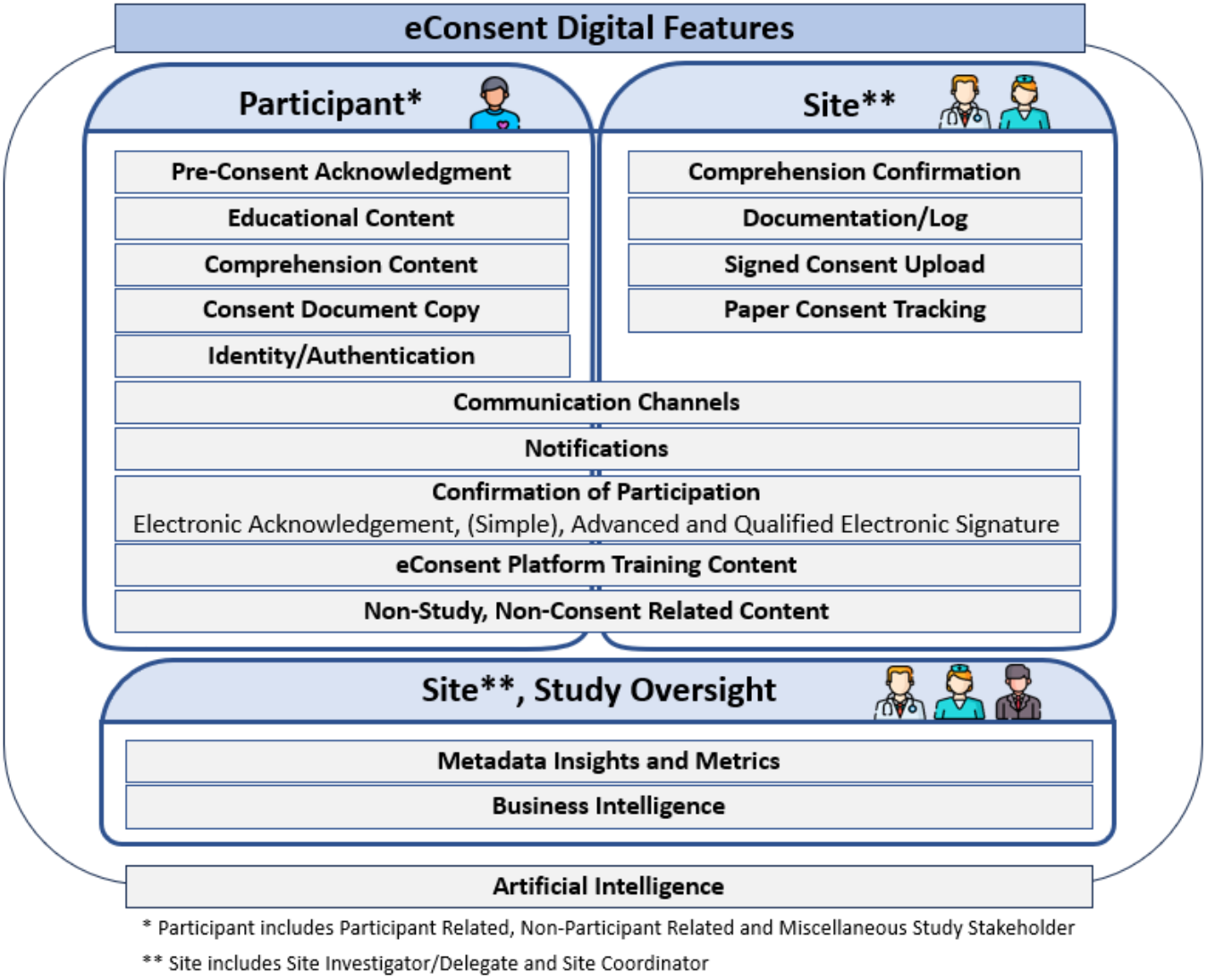

Figure A.3: eConsent Digital Features Per Stakeholder Group.

Digital Features	Definition of Digital Features	Examples of Digital Features
Pre-Consent Acknowledgment	Digital acknowledgment but can also be a more formal confirmation/ agreement from the participant that study consent information can be presented to the participant to begin the consent process. This is predominantly applicable when the consent process is started when participant and site investigator/delegate are not at the same location. Digital confirmation/agreement might include the collection and use of participant personal data (e.g., email, phone number) for sharing the study consent information.	Digital confirmation / agreement collected via e.g. digital recruitment portals, or study registration website.
Educational Content	Digital educational consent content that the participant can read, watch, hear, etc but that does not allow an interaction from the participant beyond consuming the content.	Video, audio, visuals, dictionary/glossary, Frequently Asked Questions, tiered content (organized into sections, drill downs), etc.
Comprehension Content	Digital interactive consent content where an interaction of the participant might be, or is required, to check comprehension.	Quiz, content flags, comment/free text boxes, section/ chapter-based confirmation/attestation of understanding.
Consent Document Copy	A paper or electronic copy of the consent document(s). This can include the informed consent form (unsigned or signed) and any other accompanying consent documents. The information about the clinical trial should be a physical hard copy or electronic copy in a format that can be downloaded. The copy should be available immediately to the trial participant.	Printed or downloadable participant fully signed informed consent form
Identity/ authentication	Digital methodologies that are used to identify/authenticate the participant during the consent process. Different methods might be required depending on the study, country, etc.	Locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.
Comprehension Confirmation	Digital interactive consent content for the site investigator/delegate to close the loop on any questions, concerns, or knowledge gaps from the participant. This feature is closely linked with the participant's comprehension content features and is meant to address and document actions taken.	Site confirmation box or site comments box linked with participant's comprehension content digital feature (e.g., quiz, content flags).
Documentation/ Log	Digital log for the site to capture specific information about the participant's consent process.	Site note logs, site comment fields/boxes.
Signed Consent Upload	Capability for the site to upload a fully signed, paper consent document (wet ink signature management). This might include confirmation that it is an exact copy of the original document.	Upload signed paper consent capability
Paper consent tracking	Capability for the site to document or confirm one or more steps of the paper consent process (e.g., discuss, sign, provision of signed copy), and create digital transparency for the overall consent process. For countries where the fully signed paper consent cannot be uploaded, this can be useful to document that the signature process has been finalized, optional consents agreed/not agreed, etc.	Site data fields to capture the paper consent process
Communication channels	Digital communication channel between the participant and site to share consent information, to ask questions, to discuss, to sign, etc. These communication channels may be incorporated within the eConsent platform or reside outside of it.	Email, web portal, video call, using electronic devices such as PC, smartphones, tablets.
Notifications	Digital consent notifications/messages for the participant and/or site related to the consent process	Notifications on remote consent activities, notifications on availability of reconsent
eConsent platform training content	Supporting digital content or guidance for participant or site to help with navigating and using the eConsent platform	How-to-use eConsent App/plaform instructions for participants, mock eConsent app/plarform for sites where they can consent a mock participant, digital consent training content
Non-study, non-consent related content	Non-study, non-consent related content that is part of the eConsent platform and visible to the participant and/or site. It is important to decide how to handle updates related to non-study, non-consent related content. For example, will changes to the name of an icon (e.g., "Help" icon of participant's app is renamed to "Questions") result in updates to study documents and/or trigger a submission?	Platform/ Application user interface content, profile information, general settings (e.g., language), privacy policies, terms & conditions
Metadata insights and metrics	Generated insights regarding usage of the eConsent platform on various aspects of an individual participant or group of participants. Generation of information may be passive or active	Time registrations/ insights (e.g., per section, overall review time, reconsent), use of functionalities (e.g., video, Frequently Asked Questions), repeating questions that appear across various participants, etc.

Digital Features	Definition of Digital Features	Examples of Digital Features
Business Intelligence	Overviews of eConsent status for an individual participant or across participants at a site, country, regional and global level. Access level depends on the role (e.g., global roles will have access at a global level).	Dashboard, reports, alerts triggered e.g., by consent status thresholds.
Artificial Intelligence	• Artificial Intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals (definition of EMA Reflection Paper on the use of Artificial Intelligence (AI) in the Medicinal Product Lifecycle). • AI can impact various eConsent aspects and the overall consent process. It can cover a broad set of algorithms, which enable computers to mimic human intelligence, and range from simple if-then rules and decision trees, to more advanced subsets of AI like Machine Learning (ML) and deep learning.	AI-powered chatbots for consent questions, ML-algorithms for consent personalization and optimization.
Confirmation of participation	Digital methods used by the participant and site investigator/delegate to confirm participation in the study. This includes 4 types of digital features: an electronic acknowledgement, simple electronic signature, advanced electronic signature, and qualified electronic signature.	Examples linked with the 4 types of Confirmation of Participation Digital Features: • Electronic acknowledgement: recording of names and tick boxes to confirm participation (no real signature), implicit consent unless opted out. • eIDAS simple electronic signatures: a handwritten signature drawn by finger or stylus on an electronic device, a username and password, an uploaded picture of a handwritten signature on a paper form. These are all examples without biometric data included. • eIDAS advanced electronic signatures: a simple electronic signature combined with multi-factor authentication (e.g., registration code, security questions) or biometric data collection (e.g., fingerprints, facial recognition, retina scan, voice recognition). • eIDAS qualified electronic signatures: locally approved/certified identity/signature applications and software, e.g., Belgian eID software/Itsme with linked electronic signature.

Figure A.4 eConsent Digital Features Definitions and Examples

APPENDIX B:
eCONSENT STUDY DOCUMENTS RECOMMENDATIONS OVERVIEW

Various eConsent platform and operational aspects (see Appendix A) have been evaluated on whether these eConsent aspects need to be documented or not in the following 9 study documents:

- Protocol
- HA Submission Cover Letter
- EC Submission Cover Letter
- Participant-Related eConsent Documents
- Informed Consent Document
- Site eConsent Documents
- Monitoring Plan
- Data Management Plan
- Platform/Vendor Due Diligence Documents

For each study document, a detailed table with recommendations about various eConsent platform and operational aspects are listed in the "EFGCP eConsent Study Documents Recommendations" document.

APPENDIX C:
eCONSENT BENEFITS AND DIGITAL FEATURES ASSESSMENT STUDY TEMPLATE

Potential eConsent Benefits	Targeted Benefit for Your Study (Yes/No)	Proposed eConsent Digital Features and Other Platform and Operational Aspects for Your Study
Enhancing participant preparedness in advance	<sponsor populates this per study>	<sponsor populates this per study>
Improving consistent and complex information sharing	<sponsor populates this per study>	<sponsor populates this per study>
Enhancing access, recruitment, and diversity	<sponsor populates this per study>	<sponsor populates this per study>
Enhancing autonomy for vulnerable/specialized participant groups	<sponsor populates this per study>	<sponsor populates this per study>
Improving participants' understanding	<sponsor populates this per study>	<sponsor populates this per study>
Reducing participants' dropouts	<sponsor populates this per study>	<sponsor populates this per study>
Enhancing the ability for flexible communication channels	<sponsor populates this per study>	<sponsor populates this per study>
Increasing the quality of consent data	<sponsor populates this per study>	<sponsor populates this per study>
Improving compliance with the consent process	<sponsor populates this per study>	<sponsor populates this per study>
Improving tracking and insights into optional consents	<sponsor populates this per study>	<sponsor populates this per study>
Improving oversight and real-time insights	<sponsor populates this per study>	<sponsor populates this per study>
Enabling integration with other systems	<sponsor populates this per study>	<sponsor populates this per study>
Reducing on-site consent auditing and inspection activities	<sponsor populates this per study>	<sponsor populates this per study>
Reducing on-site consent monitoring activities	<sponsor populates this per study>	<sponsor populates this per study>
Enhancing continuous improvement of consent content	<sponsor populates this per study>	<sponsor populates this per study>
Supporting sites to have a more tailored discussion with the participant	<sponsor populates this per study>	<sponsor populates this per study>
Improving consent storage	<sponsor populates this per study>	<sponsor populates this per study>
Improving consent archival for sites	<sponsor populates this per study>	<sponsor populates this per study>

More details on how to use this study template can be found in Section 4.2 and 5.2.

APPENDIX D:
eCONSENT CHALLENGES ASSESSMENT STUDY TEMPLATE

Potential eConsent Challenges	Study Likelihood (High, Medium, Low, Not Applicable)	Potential Challenge Mitigation Approaches	Study Mitigation Approach	Study Assessment Outcome (Accept, Not Accept)
Resisting technology adoption by sites	<sponsor populates this per study>	Assess upfront the eConsent platform with the sites and targeted benefits. Create easily understandable one-page material on use of platform and targeted benefits.	<sponsor populates this per study>	<sponsor populates this per study>
Resisting technology adoption and/or limited technology skills of participants	<sponsor populates this per study>	Create easily understandable one-page or very simple guidance on use/navigation of eConsent platform and benefits (compared with paper), consider providing upfront. Do not call it a training as risk that it is considered more complex/ cumbersome.	<sponsor populates this per study>	<sponsor populates this per study>
Navigating the complex usability of eConsent platforms	<sponsor populates this per study>	Select best vendor platform in line with the targeted objectives, requirements, ease-of-use, etc, intuitive UX/UI, information easily available with minimum amount of navigation, fit for purpose based on the study workflows.	<sponsor populates this per study>	<sponsor populates this per study>
Navigating a variety of electronic devices	<sponsor populates this per study>	Select eConsent platforms that conform to web accessibility standards (e.g. compatible with screen readers, sufficient contrast, etc.), consider web responsive experience for patients, including text size adjustments, line carriage adjustments, allowing "dark mode".	<sponsor populates this per study>	<sponsor populates this per study>
Dealing with incompatible IT infrastructure at the site	<sponsor populates this per study>	Assess upfront the eConsent platform with the sites. Consider providing additional IT infrastructure/devices to the site.	<sponsor populates this per study>	<sponsor populates this per study>
Extending submission and approval timelines	<sponsor populates this per study>	Collaborate with Ethics Committees/Institutional Review Boards to encourage adoption and comfort for eConsent review. Select platform vendor that allows automation of review materials and/or allows access to review materials directly in the product, streamline approval by proving simple PDF matches source document.	<sponsor populates this per study>	<sponsor populates this per study>
Extending the development timelines	<sponsor populates this per study>	Select best vendor platform with minimal lag between paper and eConsent readiness.	<sponsor populates this per study>	<sponsor populates this per study>
Correcting errors in linkage EDC ID and Consent ID	<sponsor populates this per study>	Select platform with better integrations across products, interoperability, user trainings on integrations and data flow.	<sponsor populates this per study>	<sponsor populates this per study>
Navigating the wide range of eConsent platforms	<sponsor populates this per study>	Select best vendor system in line with the requirements, ease-of-use, etc.	<sponsor populates this per study>	<sponsor populates this per study>
Increasing administrative workload and training	<sponsor populates this per study>	Consider change management strategies, user-friendly interface, updated trainings and documentation, bite-sized training modules, in-product trainings, just-in-time trainings.	<sponsor populates this per study>	<sponsor populates this per study>
Increasing heterogenous oversight and deployment	<sponsor populates this per study>	Assess upfront and document openness for use of eConsent platform and different approaches by the site and their participants. Consider selecting a system that is flexible to incorporate and support the different approaches (e.g. paper consent upload, paper consent documented, site-owned eConsent platforms).	<sponsor populates this per study>	<sponsor populates this per study>
Increasing consent data review activities	<sponsor populates this per study>	Select best vendor platform in line with requirements, ease-of-use, etc.	<sponsor populates this per study>	<sponsor populates this per study>

Potential eConsent Challenges	Study Likelihood (High, Medium, Low, Not Applicable)	Potential Challenge Mitigation Approaches	Study Mitigation Approach	Study Assessment Outcome (Accept, Not Accept)
Limiting availability of integrated systems	<sponsor populates this per study>	Select vendor platform with better integrations across products, interoperability (e.g. if a product has not integrated with other systems before, there is still interoperability functionality that would enable it).	<sponsor populates this per study>	<sponsor populates this per study>
Increasing impact on budget and resources	<sponsor populates this per study>	Create Return of Investment (ROI) analysis on up-front investment versus return over time, mobilize eConsent champions to help evangelize and problem-solve, etc. See also section 7 on Key Performance Indicators.		<sponsor populates this per study>
Impacting site relationships with participants	<sponsor populates this per study>	Create easy understandable one-pager that indicates the benefits with specifically focus on connections, it does not reduce connection but provide alternative ways to support and increase connection with participant.		<sponsor populates this per study>

More details on how to use this study template can be found in Sections 4.3, 5.4 and 6.3.

APPENDIX E:
eCONSENT KEY PERFORMANCE INDICATORS, BENEFITS AND CHALLENGES OVERVIEW

	Monitor Experience	Sponsor Experience	Site Experience	Participant Experience	Inspection/Audit Findings	Consent Protocol Deviations	Recruitment Rate	Dropout Rate	Investments/Savings
eConsent Potential Benefits									
Enhancing participant preparedness in advance			x	x					
Improving consistent and complex information sharing			x	x					
Enhancing access, recruitment and diversity			x	x			x		
Enhancing autonomy for vulnerable/specialized participant groups			x	x					
Improving participants' understanding			x	x					
Reducing participants' dropouts			x	x				x	
Enhancing the ability for flexible communication channels			x	x					
Increasing the quality of consent data	x	x	x		x	x			
Improving compliance with the consent process	x	x	x		x	x			
Improving tracking and insights into optional consents	x	x	x						
Improving oversight and real-time insights	x	x	x						
Enabling integration with other systems	x	x	x						
Reducing on-site consent auditing and inspection activities	x	x	x		x	x			
Reducing on-site consent monitoring activities	x				x	x			
Enhancing continuous improvement of consent content	x	x				x			
Supporting sites to have a more tailored discussion with the participant			x						
eConsent Potential Challenges									
Resisting technology adoption by sites			x						
Resisting technology adoption and/or limited technology skills of participants				x					
Navigating the complex usability of eConsent platforms	x	x	x	x					
Navigating a variety of electronic devices			x	x					
Dealing with incompatible IT infrastructure on the site	x		x						
Extending submission and approval timelines	x	x	x						
Extending the development timelines	x	x	x						
Correcting errors in linkage EDC ID and Consent ID	x	x	x						
Navigating the wide range of eConsent platforms	x	x	x						
Increasing administrative workload and training	x	x	x						
Increasing heterogenous oversight and deployment	x	x	x						
Increasing consent data review activities	x	x	x						
Limiting availability of integrated systems	x	x	x						
Increasing complexity to navigate multiple stakeholders	x	x	x						
Increasing impact on budget and resources	x	x	x						x
Impacting site relationships with participants			x	x					

More details of this overview can be found in Section 7.2.

ENLARGED FIGURE 6 (ECONSENT DIGITAL FEATURES AND BENEFITS OVERVIEW)

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	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					