

**EUFEMED-HEALIXIA Joint Conference - 22 May 2025**

**Mastering increasing complexity in developing innovative therapies**

# **eConsent Done Right: A Fit-for-Purpose Study Framework**

**Hilde Vanaken, PhD, Eng, MsC**

Head European Forum GCP eConsent Initiative  
Head TCS Industry Leaders Life Sciences



# The Informed Consent – A Fundamental Clinical Trial Process



A **process** between a **trial participant** and **investigator** by which a **trial participant** **voluntary confirms** their **willingness to participate** in a trial after having been **informed** and been provided with the opportunity **to discuss** **all aspects of the trial** that are **relevant to the participant's decision to participate** (ICH GCP)

**Without Consent – No Participants – No Clinical Trials**

# The Electronic Informed Consent (eConsent) - Not a New Concept

## ***Some Data of My Own eConsent Journey***

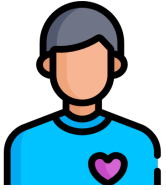
- 2013: Launched **J&J First Global Phase III eConsent Study**\*
- 2015-2017: Initiated and released **Transcelerate eConsent Implementation Guideline** \*\*
- 2016: Supported **FDA eConsent Guidance**
- 2018: Supported **MHRA/HRA eConsent Position Paper**
- 2022: Supported **EMA Recommendation Paper on Decentralized Elements**

*\*eConsent Study Provides Insight to Shape Industry Adoption, Applied Clinical Trials 2016, Author Hilde Vanaken.*

*\*\*Awareness and collaboration across stakeholder groups important for eConsent achieving value-driven adoption, TIRS 2019, Authors Hilde Vanaken et al.*

# eConsent – Some Feedback of Stakeholders

## Some Stakeholder Feedback Data of *My Own* eConsent Journey



**+ 80% of participants** found the **video** and **quiz** to help their **understanding**

**73% of participants** felt eConsent help **understanding** the clinical trial



**77% of sites** reported that eConsent **improved the consenting process**

**Sites felt eConsent improved data quality** and allowed a more **tailored discussion** with participants

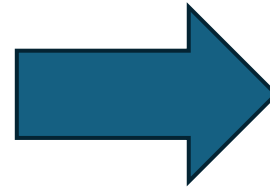
**2013:** data of J&J phase III study with 76 participants and 13 sites\*

**2016:** Data of Transcelerate participant survey with 3045 respondents and Transcelerate site advisory group virtual sessions with 8 sites\*\*

\*eConsent Study Provides Insight to Shape Industry Adoption, Applied Clinical Trials 2016, Author Hilde Vanaken.

\*\*Awareness and collaboration across stakeholder groups important for eConsent achieving value-driven adoption, TIRS 2019, Authors Hilde Vanaken et al.

# eConsent - Where Are We Today?



**WHY?**

# eConsent – What Is Hampering eConsent Implementation?

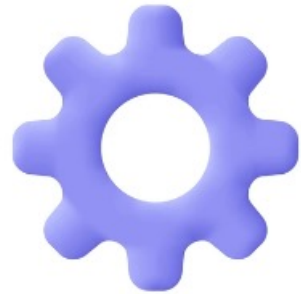
Many Different Interpretations



Many Disconnects



Many Unclear Processes



Limited Stakeholders Value Insights



# eConsent – Some Common Misunderstandings



eConsent is the same as remote consent ...



eConsent requires an electronic signature ...



eConsent requires participants with a mobile device or experience...



eConsent replaces site & participant interaction...



eConsent changes responsibilities within a consent process...



eConsent is a new process...



eConsent eliminates the consent document...



... remote consent is about the location, and might even be entirely on paper



... eConsent can include paper and various electronic signatures



... participants do not need mobile devices or mobile experience



... eConsent enhances the site and participant interaction



... investigator, monitor, etc. keep the same accountabilities



... follows the existing process but presents it differently



...the consent document is and remains the take home document



# eConsent – Some Disconnects



Use of eSignatures European Countries Is Acceptable!

Please see relevant footnotes for responses marked with an asterisk. A footnote may be raised even though no response is given.	AT	BE	BG	CY	CZ	DE BfArM	DE PEI	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK
Q12: Is it possible to use electronic signatures instead of wet ink? If yes, please specify in the footnotes which eIDAS category is expected for the electronic signature.	Yes *	Yes *			Yes *	Yes *		Yes *	Yes *	*	Yes *	Yes *	Yes *	Yes *	Yes *	Yes		Yes *		Yes *			Yes	Yes *	Yes *	*		Yes *	Yes *	*	Yes *

\*National provision overview of EMA Recommendation Paper on Decentralized Elements in Clinical Trials, 13 December 2022.



eSignature Improves Participant Understanding

The method of signing does not have any impact on participant understanding

• ? ? ?  
**Bringing  
Clarity in  
eConsent!**



European Forum for Good  
Clinical Practices (EFGCP)

**eConsent Initiative**

# European Forum GCP eConsent Initiative - Mission



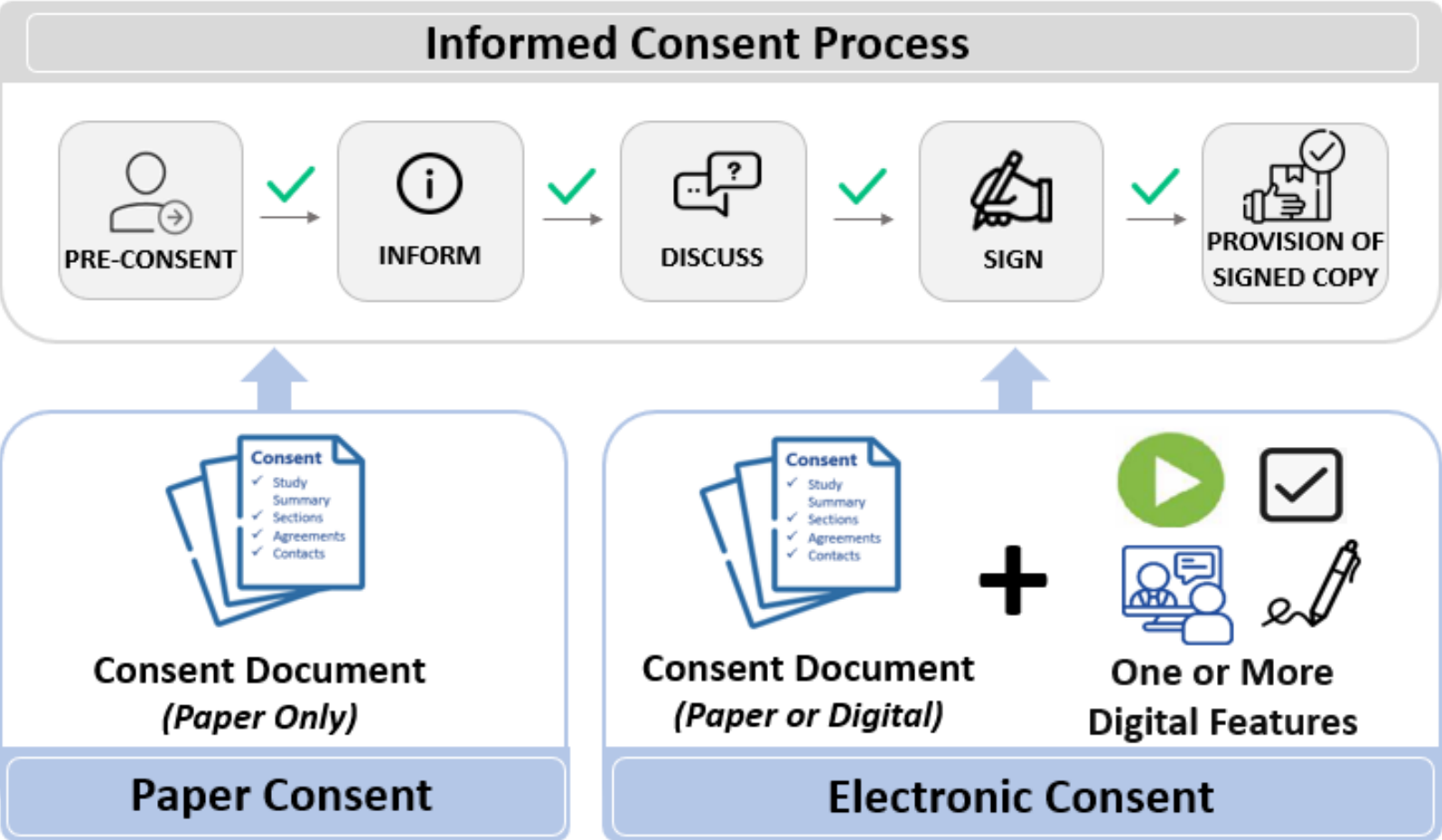
Non-Profit Multi-Stakeholder Initiative

to HARMONIZE **eConsent Terminologies** and **Study Documents Needs**  
to INCREASE INSIGHT in **Stakeholder's Value Models** and **Country Needs**  
to PROVIDE a **Fit-for-Purpose eConsent Study Framework**

Initiative launched in September 2022

+50 Organizations - 6 Workstreams – Global Initiative

# What is eConsent?



eConsent =  
Traditional Consent  
Process Supported  
by One or More  
Digital Features

**eConsent is an  
Umbrella Term**

# Harmonization of eConsent Terminologies



## Glossary of eConsent Terms

### General Information

In the dynamic landscape of eConsent, forging a common understanding of various aspects of eConsent through harmonized terms represents the foundational stride toward clarity and consensus.

Widespread misunderstandings result in conflicting messages on acceptance and non-acceptance of eConsent, lack of clarity regarding study document requirements, and incomplete insights into benefits and challenges posed to stakeholders.

To enable a common understanding and facilitate adoption of eConsent, the multi-stakeholder, nonprofit European Forum for Good Clinical Practice (EFGCP) eConsent Initiative developed a Glossary of eConsent Terms to standardize the nomenclature and terminology used to describe eConsent.

Firstly, and most important, "eConsent" is an overarching term and there are multiple different eConsent models – there is no one-size-fits-all. The main point of commonality between all models is "the use of one or more digital" and definition of eConsent.

Secondly, as there is no one-size-fits-all underlying platform and operational aspects, this glossary in the following 2

- **eConsent Platform Aspect** and underlying data and to eConsent platform aspect characteristics and communication
- **eConsent Operational Aspect** management. These aspects examples include terminology

These aspects should not be taken as platform and operational aspects

The focus of this glossary was



## eConsent - Why Language Matters

December 20, 2023

By Hilde Vanaken, Rebecca Zeising, Bethany Pryskei and Liz Goodman

### Fostering common eConsent terminologies enriches communication and understanding across all stakeholders

Ask a group of industry professionals to describe 'eConsent' and you will get a variety of answers. Some of these answers may reflect a limited understanding of eConsent, and some may even propagate misconceptions around the use of eConsent. A recent poll at the DIA 2023 Global Annual Meeting's eConsent session<sup>1</sup> asked attendees about the use of eSignature: 78% responded that eConsent requires an electronic signature, propagating a common misconception around the varied uses of eConsent.

Widespread misunderstandings result in conflicting messages around the acceptance of eConsent, lack of clarity regarding study documents required for Health Authority and Ethics Committee submissions<sup>2</sup>, and incomplete insights about the benefits and challenges posed to stakeholders.

Having harmonized terminologies to describe the platform and operational aspects of eConsent is critical to eliminate misconceptions and to enable transparency and a common understanding between all stakeholders. This was precisely the focus and intent when developing the Glossary of eConsent terms, one of the deliverables of the multi-stakeholder, non-profit European Forum for Good Clinical Practice (EFGCP) eConsent Initiative<sup>3</sup>. Where applicable, references to existing terminologies are incorporated in the glossary<sup>4,5</sup>.

In addition, the glossary can also serve as a general knowledge base of key aspects to consider for sponsors and vendors when deploying eConsent. Of note, even within our group of industry experts from over 50 different organizations, we had several "eureka" moments as we learned from each other's experiences.

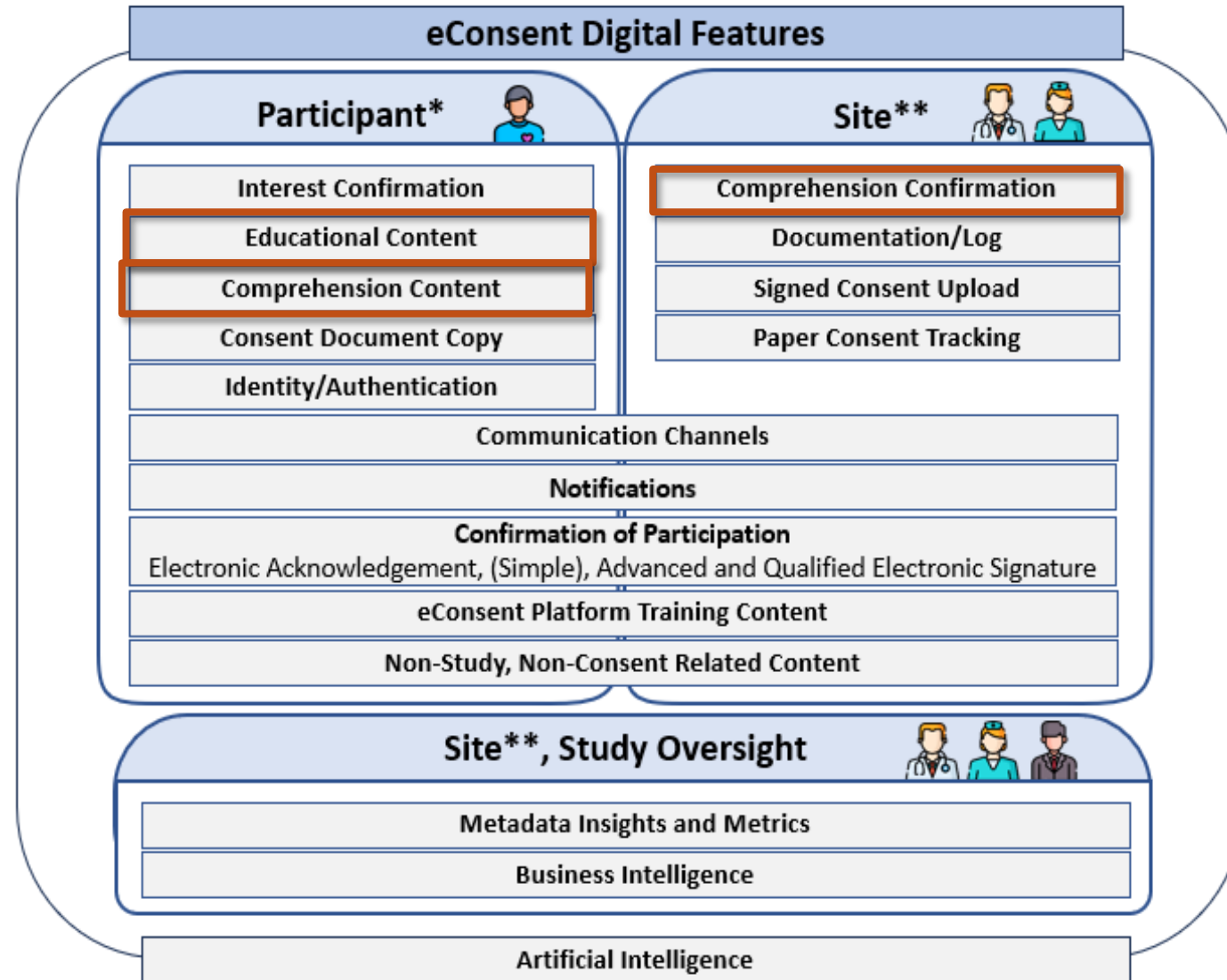
eConsent Platform Aspects													
Digital Features	<ul style="list-style-type: none"> <li>• Pre-Consent Acknowledgment</li> <li>• Educational Content</li> <li>• Comprehension Content</li> <li>• Consent Document Copy</li> <li>• Identity/Authentication</li> <li>• Comprehension Confirmation</li> <li>• Documentation/Log</li> <li>• Signed Consent Upload</li> <li>• Paper Consent Tracking</li> <li>• Communication Channels</li> <li>• Notifications</li> <li>• Confirmation of Participation:                             <ul style="list-style-type: none"> <li>• Electronic Acknowledgement</li> <li>• (Simple) Electronic Signature</li> <li>• Advanced Electronic Signature</li> <li>• Qualified Electronic Signature</li> </ul> </li> <li>• eConsent Platform Training Content</li> <li>• Non-Study, Non-Consent Related Content</li> <li>• Metadata Insights and Metrics</li> <li>• Business Intelligence</li> <li>• Artificial Intelligence</li> </ul>												
	<table border="1"> <tr> <th>Identifiers</th> <td> <ul style="list-style-type: none"> <li>• Consent Document Identifier</li> <li>• Consent Document ID</li> <li>• Participant Identifier</li> <li>• Participant Token</li> </ul> </td> </tr> <tr> <th>Consent Account</th> <td> <ul style="list-style-type: none"> <li>• Participant Account</li> <li>• Stakeholder Account</li> </ul> </td> </tr> <tr> <th>Data Types</th> <td> <ul style="list-style-type: none"> <li>• Personal Data</li> <li>• Non-Personal Data</li> <li>• Aggregated Metadata</li> </ul> </td> </tr> <tr> <th>Data Privacy Clause/Policy</th> <td></td> </tr> <tr> <th>Compliance Documents</th> <td></td> </tr> <tr> <th>Validation Documents</th> <td></td> </tr> </table>	Identifiers	<ul style="list-style-type: none"> <li>• Consent Document Identifier</li> <li>• Consent Document ID</li> <li>• Participant Identifier</li> <li>• Participant Token</li> </ul>	Consent Account	<ul style="list-style-type: none"> <li>• Participant Account</li> <li>• Stakeholder Account</li> </ul>	Data Types	<ul style="list-style-type: none"> <li>• Personal Data</li> <li>• Non-Personal Data</li> <li>• Aggregated Metadata</li> </ul>	Data Privacy Clause/Policy		Compliance Documents		Validation Documents	
	Identifiers	<ul style="list-style-type: none"> <li>• Consent Document Identifier</li> <li>• Consent Document ID</li> <li>• Participant Identifier</li> <li>• Participant Token</li> </ul>											
	Consent Account	<ul style="list-style-type: none"> <li>• Participant Account</li> <li>• Stakeholder Account</li> </ul>											
	Data Types	<ul style="list-style-type: none"> <li>• Personal Data</li> <li>• Non-Personal Data</li> <li>• Aggregated Metadata</li> </ul>											
	Data Privacy Clause/Policy												
Compliance Documents													
Validation Documents													
	Integrations												
	Environments												

**Glossary of eConsent Terms with 64 eConsent Platform & Operational Aspects Terms**  
Simple and clear terms with descriptions and examples

eConsent Operational Aspects						
Stakeholders	<ul style="list-style-type: none"> <li>• Participant</li> <li>• Participant Related Stakeholder</li> <li>• Non-Participant Related Stakeholder</li> <li>• Miscellaneous Study Stakeholder</li> <li>• Site Investigator/ Delegate</li> <li>• Site Coordinator</li> <li>• Study Oversight Stakeholder</li> </ul>	<table border="1"> <tr> <th>Consent Categorization</th> <td> <ul style="list-style-type: none"> <li>• Main Consent Document</li> <li>• Optional Consent Document</li> <li>• Assent Document</li> </ul> </td> </tr> <tr> <th>Consent workflow</th> <td> <ul style="list-style-type: none"> <li>• Initial Consent</li> <li>• Declined</li> <li>• Reconsent</li> <li>• Withdrawal</li> <li>• Dynamic Consent</li> </ul> </td> </tr> </table>	Consent Categorization	<ul style="list-style-type: none"> <li>• Main Consent Document</li> <li>• Optional Consent Document</li> <li>• Assent Document</li> </ul>	Consent workflow	<ul style="list-style-type: none"> <li>• Initial Consent</li> <li>• Declined</li> <li>• Reconsent</li> <li>• Withdrawal</li> <li>• Dynamic Consent</li> </ul>
	Consent Categorization	<ul style="list-style-type: none"> <li>• Main Consent Document</li> <li>• Optional Consent Document</li> <li>• Assent Document</li> </ul>				
Consent workflow	<ul style="list-style-type: none"> <li>• Initial Consent</li> <li>• Declined</li> <li>• Reconsent</li> <li>• Withdrawal</li> <li>• Dynamic Consent</li> </ul>					
Participant/Site Location	<ul style="list-style-type: none"> <li>• In the Same Location</li> <li>• Not in the Same Location</li> <li>• Mixed Location</li> </ul>	Health Authority & Ethics Committee Submission				
Timing of Signature	<ul style="list-style-type: none"> <li>• Discuss/Sign At the Same Time</li> <li>• Discuss/Sign Not at the Same Time</li> </ul>	Monitoring				
Device Deployment	<ul style="list-style-type: none"> <li>• Own Electronic Device</li> <li>• Provisioned Electronic Device</li> </ul>	Auditing/Inspecting				
Data Access	<ul style="list-style-type: none"> <li>• Personal Data Access</li> <li>• Non-Personal Data Access</li> <li>• Edit Access</li> <li>• Read Access</li> </ul>	<table border="1"> <tr> <th>Training</th> <td></td> </tr> <tr> <th>Support</th> <td></td> </tr> </table>	Training		Support	
Training						
Support						
	Archiving/Permanent Records	<ul style="list-style-type: none"> <li>• Site Consent Archiving</li> <li>• Sponsor Consent Archiving</li> <li>• Participant Consent Permanent records</li> </ul>				

\*Supporting article: eConsent Why Language Matters, Applied Clinical Trials Dec 2023, Author Hilde Vanaken et al.

# Example - 20 different eConsent Digital Features Terms



**Digital features terms cluster individual digital feature examples based on their characteristics and commonalities**

\* Participant includes Participant Related, Non-Participant Related and Miscellaneous Study Stakeholder

\*\* Site includes Site Investigator/Delegate and Site Coordinator

# Example – “Confirmation of Participation” Digital Feature Term

## 1.12. CONFIRMATION OF PARTICIPATION

### 1.12.1. ELECTRONIC ACKNOWLEDGEMENT

Description:

Digital methods used by the participant and site investigator/delegate, other than a signature or equivalent, to confirm participation in the study.

Examples:

Recording of names and tick boxes to confirm participation (no real signature), implicit consent unless opted out.

Primary stakeholders involved:

Participants, Sites.

### 1.12.2. (SIMPLE) ELECTRONIC SIGNATURE

Description:

Any data in electronic form that is used by the signatory to identify themselves.

No biometric data are used. This term is used in regulations and study templates.

Other countries and regions might use the term “eSignature” but to describe the actual implementation of the eSignature (see examples below).

Examples:

A handwritten signature drawn by a picture of a handwritten signature on an electronic device.

To illustrate different local/regional categorizations, a “(simple) Electronic signature by FDA regulation” is a (simple) Electronic signature by FDA regulation.

Primary stakeholders involved:

Participants, Sites.

### 1.12.3. ADVANCED ELECTRONIC SIGNATURE

Description:

An electronic signature that is uniquely linked to the signatory, is capable of identifying the signatory, is created using a process that the signatory is able to control, and is detectable (~ European eIDAS regulation definition<sup>7</sup>).

Other countries and regions might use the term “Advanced eSignature” but to describe the actual implementation of the eSignature (see examples below).

Examples:

Simple electronic signatures (see 1.12.2) combined with multi-factor authentication (e.g., registration code, security questions) or biometric data collection (e.g., fingerprints, facial recognition, retina scan, voice recognition).

Primary stakeholders involved:

Participants, Sites.

### 1.12.4. QUALIFIED ELECTRONIC SIGNATURE

Description:

An advanced electronic signature that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures. (~ European eIDAS regulation definition<sup>7</sup>).

Other countries and regions might use other categorizations; hence it is important to not simply use the term “Qualified eSignature” but to describe the actual implementation of the eSignature (see examples below).

Examples:

Locally approved/certified identity/signature applications and software, e.g., Belgian eID software/Itsme with linked electronic signature.

Primary stakeholders involved:

Participants, Sites.

*Examples on how to describe in detail are included in the Glossary of eConsent Terms*

**An eSignature is Not an eSignature Everywhere!**

For example, a “**handwritten signature on an electronic device**”

(Europe)  
eIDAS Simple  
eSignature

(US)  
NOT an  
eSignature

**Always describe in detail to ensure correct understanding regardless of local/regional categorizations**

# Example - eConsent “ Location” Term

## 2. Participant/Site Location

### 2.1. AT THE SAME LOCATION

Description:

Refers to a participant and site investigator/delegate being physically at the same location to conduct all steps of the consent process.

Note - The location of both the participant (or the person acting on behalf of the participant) and the investigator is fundamental. Other stakeholders may also support the participant or investigator throughout this process (e.g. participant-related stakeholders, etc – see section B1) and may or may not be in the same location as the participant

Examples:

Investigator site (most common), participant’s home or primary address (e.g., university home for a student), pharmacy, community health center.

### 2.2. NOT AT THE SAME LOCATION

Description:

Refers to a participant and site investigator/delegate not being at the same location to conduct all steps of the consent process (interest confirmed, inform, discuss, sign and provision of signed copy). If all consent process steps are done not in the same location, it is often also referred to as “remote” consent.

Note - The location of both the participant (or the person acting on behalf of the participant) and the investigator is fundamental. Other stakeholders may also support the participant or investigator throughout this process (e.g. participant-related stakeholders, etc – see section B1) and may or may not be in the same location as the participant

Examples:

Interaction is usually supported by a “Communication Channels” digital feature (see section 1.10, examples are email, chatbot, video call), but it might also be done using traditional paper processes and couriers (no digital feature involved).

### 2.3. MIXED LOCATION

Description:

Refers to a participant and site investigator/delegate where some consent process steps are done in the same location, while others are not conducted in the same location.

Note - The location of both the participant (or the person acting on behalf of the participant) and the investigator is fundamental. Other stakeholders may also support the participant or investigator throughout this process (e.g. participant-related stakeholders, etc – see section B1) and may or may not be in the same location as the participant

Examples:

Sharing of the consent information with participant is done via email (Not in the Same Location) while the discussion with the site investigator/delegate is done at the investigator site (In the Same Location).

“In person” does not mean  
the same for everyone

**\* eConsent operational aspects terms are usually also applicable for the paper consent process**



# Example – “Protocol” Selected As Submission Document

% of organizations per organization type that selected "Protocol"					
eConsent Platform and Operational Aspects	All	EC	Pharma	Acad Instit	Vendor
Participants' use of digital features (high-level reference)	64%	69%	41%	93%	50%
Participants' type of digital features*	49%	69%	24%	77%	9%
Sites' use of digital features (high-level reference)	58%	58%	42%	75%	44%
Sites' type of digital features*	45%	58%	30%	56%	0%
Use of eSignature (high-level reference)	47%	50%	25%	77%	36%
Type of eSignature*	37%	50%	29%	45%	25%
Participants' access to fully eSigned form*	29%	40%	13%	55%	10%
Use of wet-ink signature	28%	50%	20%	33%	11%
Electronic storage of wet-ink signed document*	37%	50%	17%	50%	20%
Linkage of wet-ink signature with electronic consent record*	36%	60%	17%	50%	20%
Electronic data storage of PII data	50%	80%	27%	83%	25%
Electronic data storage of non-PII data	47%	83%	33%	56%	0%
Participants' remote identification methods	46%	64%	23%	73%	33%
Location of consent discussion	64%	69%	33%	100%	60%
Use of provisioned mobile device	64%	58%	54%	92%	33%
Details of provisioned mobile device*	32%	30%	33%	38%	0%
Use of participants' own mobile device	44%	36%	50%	43%	33%
Remote monitor access to PII data	67%	56%	58%	100%	50%
Remote monitor access to non-PII data	76%	67%	75%	100%	33%
Participants' remote consent withdrawal	47%	42%	45%	88%	18%
Platform validation	51%	33%	42%	78%	25%
Platform integrations with study systems	75%	67%	57%	86%	33%
Platform integrations with site systems	52%	44%	56%	56%	25%
Sites' training	50%	40%	60%	67%	40%
Participants' training	34%	44%	20%	64%	17%
Sites' access to a helpdesk	44%	25%	60%	80%	0%
Participants' access to a helpdesk	28%	20%	27%	44%	22%
Participants' helpdesk measures linked to privacy*	31%	29%	22%	67%	14%

Different opinions on all aspects whether to report or not in the protocol “between” but also “within” the same organizational types even within the same country

Multiple Answer Categorization		
High (+70% of organizations)	Partial (between 25-50% of organizations)	Not selected (0%)
Moderate (between 50-70% of organizations)	Low (less 25% of organizations)	

# eConsent Study Documents Recommendations

**Recommendations drafted for  
9 study documents**

## Table of Contents

- 1. INTRODUCTION .....2
- 2. WHAT IS eCONSENT .....3
- 3. PROTOCOL .....4
  - 3.1. Description .....4
  - 3.2. eConsent Recommendations for Protocol .....4
- 4. HEALTH AUTHORITY SUBMISSION COVER LETTER.....4
  - 4.1. Description .....4
  - 4.2. eConsent Recommendations for Health Authority Submission Cover Letter .....4
- 5. ETHICS COMMITTEE SUBMISSION COVER LETTER.....5
  - 5.1. Description .....5
  - 5.2. eConsent Recommendations for Ethics Committee Submission Cover Letter .....5
- 6. PARTICIPANT RELATED eCONSENT DOCUMENTS .....6
  - 6.1. Description .....6
  - 6.2. eConsent Recommendations for Participant Related eConsent Documents .....6
- 7. INFORMED CONSENT DOCUMENT .....8
  - 7.1. Description .....8
  - 7.2. eConsent Recommendations for Informed Consent Document .....8
- 8. SITE eCONSENT DOCUMENTS.....9
  - 8.1. Description .....9
  - 8.2. eConsent Recommendations for Site eConsent Documents .....9
- 9. MONITORING PLAN .....10
  - 9.1. Description .....10
  - 9.2. eConsent Recommendations for Monitoring Plan .....10
- 10. DATA MANAGEMENT PLAN .....10
  - 10.1. Description .....10
  - 10.2. eConsent Recommendations for Data Management Plan .....10
- 11. PLATFORM/VENDOR DUE DILIGENCE DOCUMENTS .....11
  - 11.1. Description .....11
  - 11.2. eConsent Recommendations for Platform/Vendor Due Diligence Documents .....11
- 12. ADDITIONAL CONSENT DOCUMENTS .....12
- 13. REFERENCES.....13
- APPENDIX A: GLOSSARY .....14
- APPENDIX B: eCONSENT .....15

- Protocol
- Health Authority Submission Cover Letter
- Ethics Committee Submission Cover Letter
- Participant-related eConsent Documents
- Informed Consent Document
- Site eConsent Documents
- Monitoring Plan
- Data Management Plan
- Platform/Vendor Due Diligence Documents

## 3. PROTOCOL

### 3.1. Description

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents (Definition from ICH GCP E6 R3)<sup>2</sup>.

### 3.2. eConsent Recommendations for Protocol

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	Digital Features	Participants' Digital Features	High Level	High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent).
		Participants'/ sites' Confirmation of Participation	High Level	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.
		Participants' Remote Identity/Authentication		Description of methods used to remotely identify/authenticate the participant during the consent process: e.g. locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.
eConsent Operational Aspects	Participant/Site Location	Full Remote Consent Process	High Level	High level reference in case of absence of any physical interaction between the participant and site investigator for the consent process.
	Consent Workflow	Participants' Remote Withdrawal Process		Description that a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.
The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).				

There might be cases where sites are using their own eConsent platform, the sponsor will need to consider whether this detail should be part of the protocol or be documented somewhere else.

# ECs, Sponsors & Vendors Perspectives about eConsent

## ***Ethics Committees Survey***

- **49** Ethics Committees respondents
- **15 different countries**, 70% of Europe
- **35% never received an eConsent**

## ***Sponsors/ Vendors Survey***

- **42** respondents (67% sponsors, 33% vendors)
- **26% no eConsent experience** (36% sponsors, 7% vendors)

Important factors in your approval process

Minimal signature requirements for on-site, remote with video, remote with phone call

Barriers

Drivers

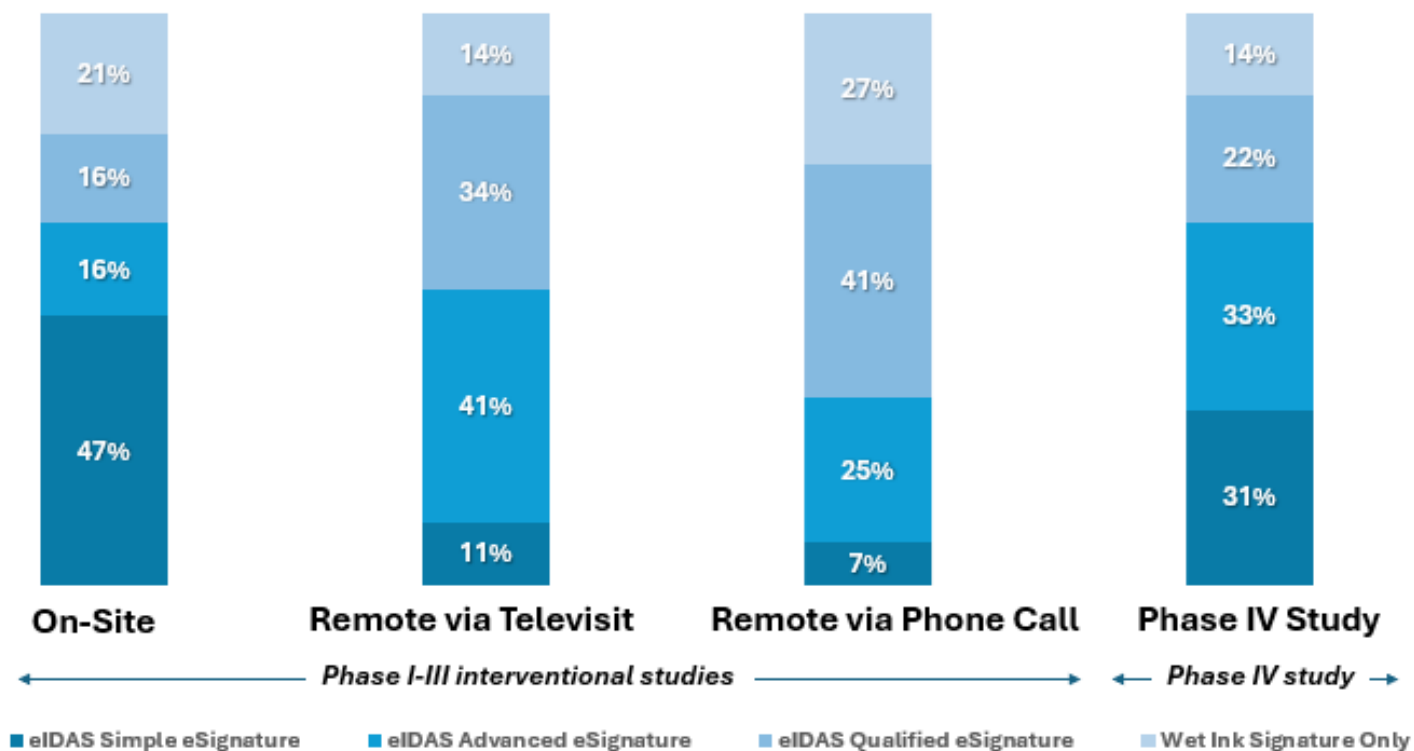
Material required for submission

Personal data hosting requirements

Digital features usage and value

Remote participant identification methods

# Example – Some results of Ethics Committees Survey



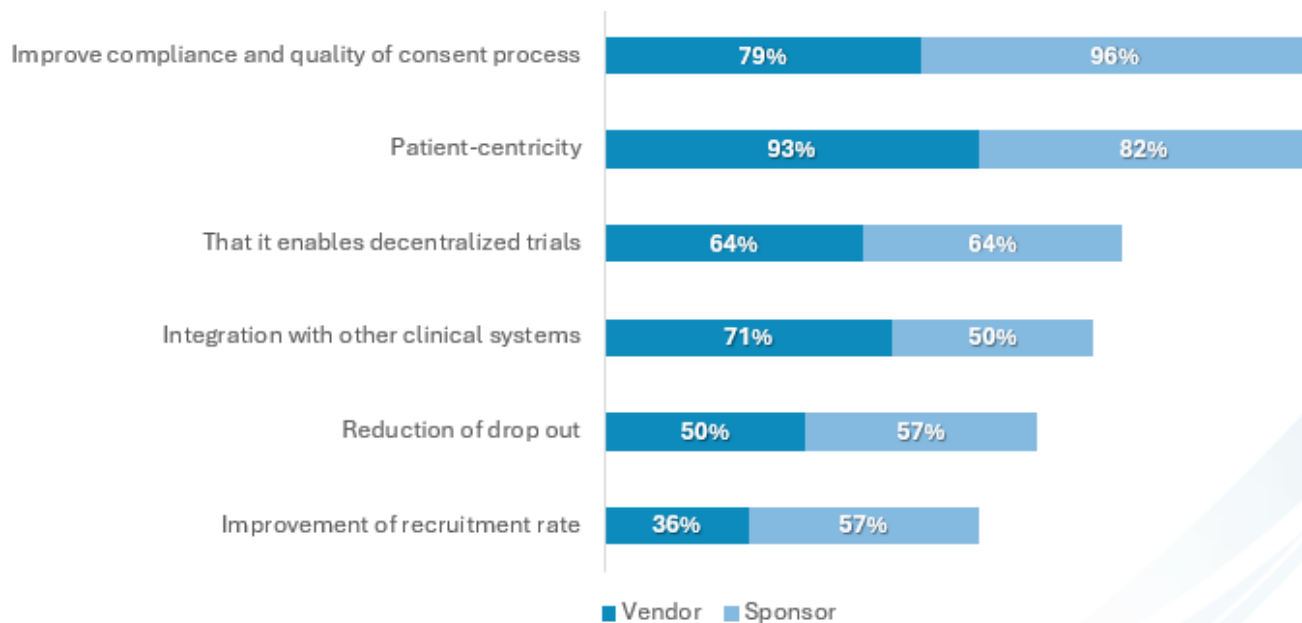
Some examples of differences between European and North American Ethics Committees respondents



	North American ECs (#= 9)	European ECs (# = 26)
Experience with eConsent	78%	65%
Personal Data Must be Stored On Site	44%	77%
Paper Option is Needed	78%	65%
<b>Minimal Consent Signature Requirement On Site:</b>		
- Simple eSignature	33%	53%
- Advanced eSignature	33%	12%
- Qualified eSignature	11%	24%
- Wet Ink Signature	22%	13%

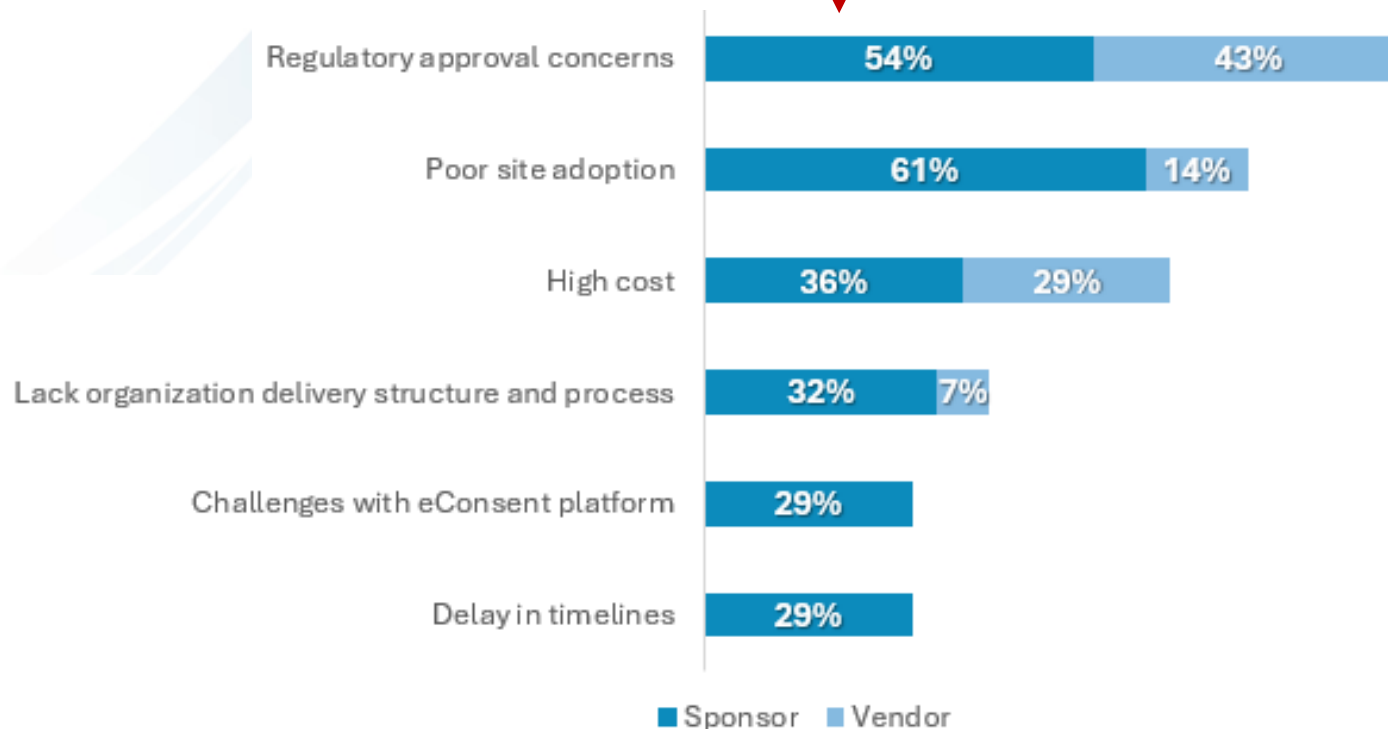
More stringent eSignature requirements when moving from on-site to remote workflows

# Example – Some Results of Sponsors & Vendors Survey



Most important factors driving eConsent for sponsors and vendors

Significant barriers to eConsent adoption for sponsors and vendors



# eConsent Fit-for-Purpose Study Framework

## TABLE OF CONTENTS

TABLE OF CONTENTS	1
1. INTRODUCTION	2
2. WHAT IS eCONSENT	3
3. eCONSENT FIT-FOR-PURPOSE STUDY FRAMEWORK OVERVIEW	5
4. STEP 1: DEFINE THE eCONSENT BENEFITS AND CHALLENGES FOR YOUR STUDY AND STAKEHOLDERS	6
4.1. Introduction	6
4.2. Potential Cross-Stakeholder Benefits Impact Overview	6
4.3. Potential Cross-Stakeholder Challenges Impact Overview	8
4.4. Additional Considerations	9
5. STEP 2: DEFINE THE eCONSENT PLATFORM AND OPERATIONAL ASPECTS TO SUPPORT THE TARGETED eCONSENT OBJECTIVES FOR YOUR STUDY	
5.1. Introduction	
5.2. eConsent Digital Features and Benefits Overview	
5.3. Additional eConsent Platform and Operational Aspects	
5.4. eConsent Challenges Mitigation Approaches	
6. STEP 3: EVALUATE WITH SELECTED STAKEHOLDERS THE TARGETED eCONSENT OBJECTIVES / STUDY	
6.1. Introduction	
6.2. eConsent Stakeholders' Evaluation Methodology	
6.3. 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	
7.2. eConsent Key Performance Indicators	
7.3. Additional Considerations	

APPLIED  
CLINICAL TRIALS

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

August 12, 2024

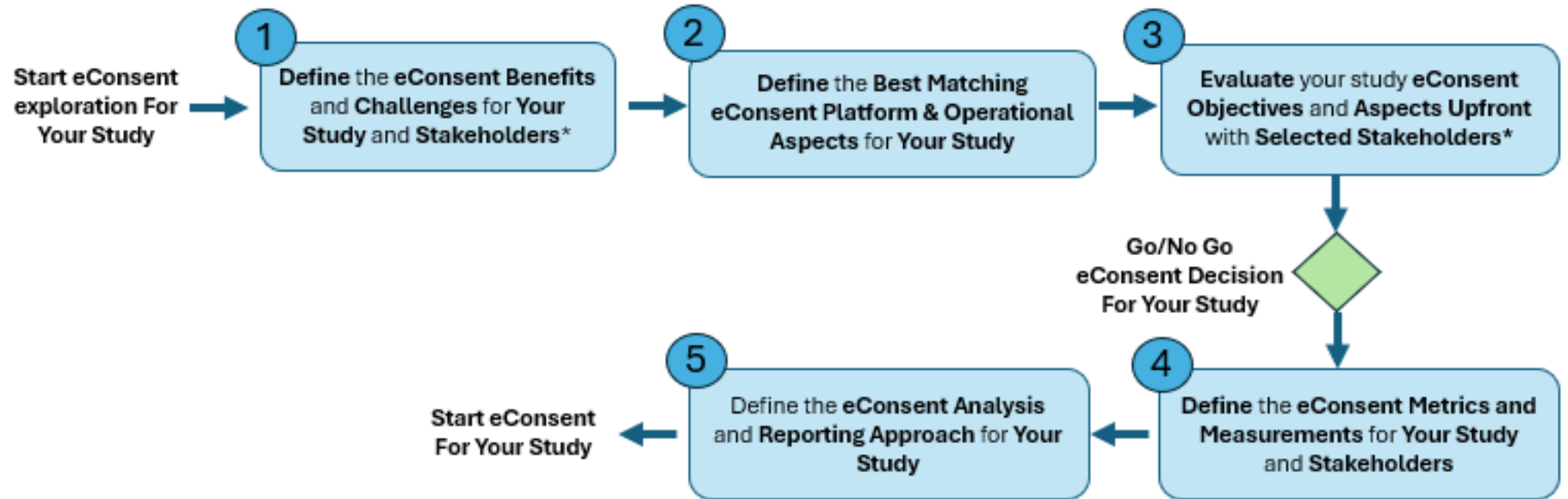
By Hilde Vanaken, Bethany Pryskei, Reamonn Madden, Katrin Ong, Hanna Preus, Ri Zeising, Petra Ochabova, Liz Goodman, Edwin Cohen, Jo Dewhurst, Silvia Chia, Tina

### Designing eConsent for Each Study from a Stakeholders' Va 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

5-step process to **define and design the right eConsent for a particular study** and to **generate effective and comparable eConsent study outcomes**



\*Stakeholders = sites, participants and sponsor representatives

\* Supporting Article: Effective eConsent Strategies for Every Study. Applied Clinical Trials Aug 2024, Author Hilde Vanaken et al.

# Detail – Step 1 & 2 of eConsent Fit-for-Purpose Study Framework

**Step 1 - Define the eConsent Benefits and Challenges for Your Particular Study and Stakeholders**

CROSS-STAKEHOLDER ECONSENT BENEFITS IMPACT OVERVIEW			
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	-		
Improving consent storage	-		
Improving consent archival for sites	-		

CROSS STAKEHOLDER ECONSENT CHALLENGES IMPACT OVERVIEW			
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 on the site	+++	+++	+++
Extending submission and approval timelines	+++	+++	+
Extending the development timelines	+++	+++	+

	Pre-Consent Acknowledgment	Educational content	Comprehension Content	Comprehension Confirmation	Communication channels	Consent Document Copy	Identity/Authentication	Documentation/Log	Signed Consent Upload	Paper Consent Upload	Confirmation of Participation	Metadata Insights and Metrics	Business Intelligence	Notifications
Increasing consent data review activities	x	x	x	x	x									x
Limiting availability of integrated systems		x	x		x									
Increasing complexity to navigate multiple systems	x	x	x		x	x								
Increasing impact on budget and resources		x	x	x	x									
Impacting site relationships with participants					x									
Enhancing participant preparedness in advance														
Improving consistent and complex information sharing														
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				
Reducing on-site consent auditing and inspection activities	x						x	x	x	x	x	x		
Reducing on-site consent monitoring activities	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					
Improving consent archival for sites									x					

**Step 2 – Define the Best Matching eConsent Platform and Operational Aspects for the Targeted eConsent Benefits**

# Key Take Aways

## eConsent Can Bring Value to All Stakeholders Involved

- |                 |                    |
|-----------------|--------------------|
| ↑ Readability   | ↑ Transparency     |
| ↑ Understanding | ↑ Quality          |
| ↑ Consistency   | ↑ Compliance       |
| ↑ Autonomy      | ↑ Privacy          |
| ↑ Accessibility | ↑ Interoperability |
| ↑ Insights      | ↑ Reusability      |

*Values vary depending on eConsent Digital Features used.*

**But**

- **Without a common understanding, conversations become meaningless**
- **Be transparent on what you are doing, communicate with your stakeholders**
- **There is NO one-size-fits-all eConsent. Each study, each site, each participant might have different needs**
- **Generation of effective and comparable eConsent study data is key for adoption**



**Thank You!**

Interested to Know More or Any  
Feedback on eConsent Tools?

[hilde.vanaken@efgcp.eu](mailto:hilde.vanaken@efgcp.eu)

[hilde.vanaken@tcs.com](mailto:hilde.vanaken@tcs.com)



eConsent tools