eConsent Initiative

Demystifying Uncertainties, Disconnects and Challenges

Hilde Vanaken
Head, European Forum GCP eConsent Initiative
Head, TCS Pharma R&D Transformation

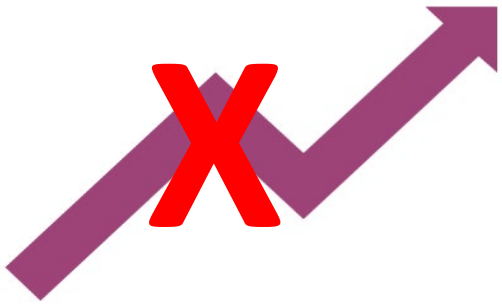
Electronic Informed Consent (eConsent) - Not a New Concept

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*****
- 2022: Request of **European Forum GCP** to support eConsent adoption in Europe

** 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.*
**** All guidelines are publicly available on official websites of FDA, MHRA, EMA, Transcelerate*

Where Are We With eConsent?



eConsent adoption is limited

Many Different Interpretations

Many Disconnects

Many Unclear Processes

Limited Stakeholders Value Insights

Launch of European Forum GCP eConsent Initiative

European Forum GCP eConsent Initiative

Non-Profit Multistakeholder Initiative
Launched in September 2022
+50 Organizations - 6 Workstreams – Global Initiative

to **HARMONIZE eConsent Terminologies** and **Study Documents Needs**

to **INCREASE INSIGHT** in **Stakeholder's Value Models** and **Country Needs**

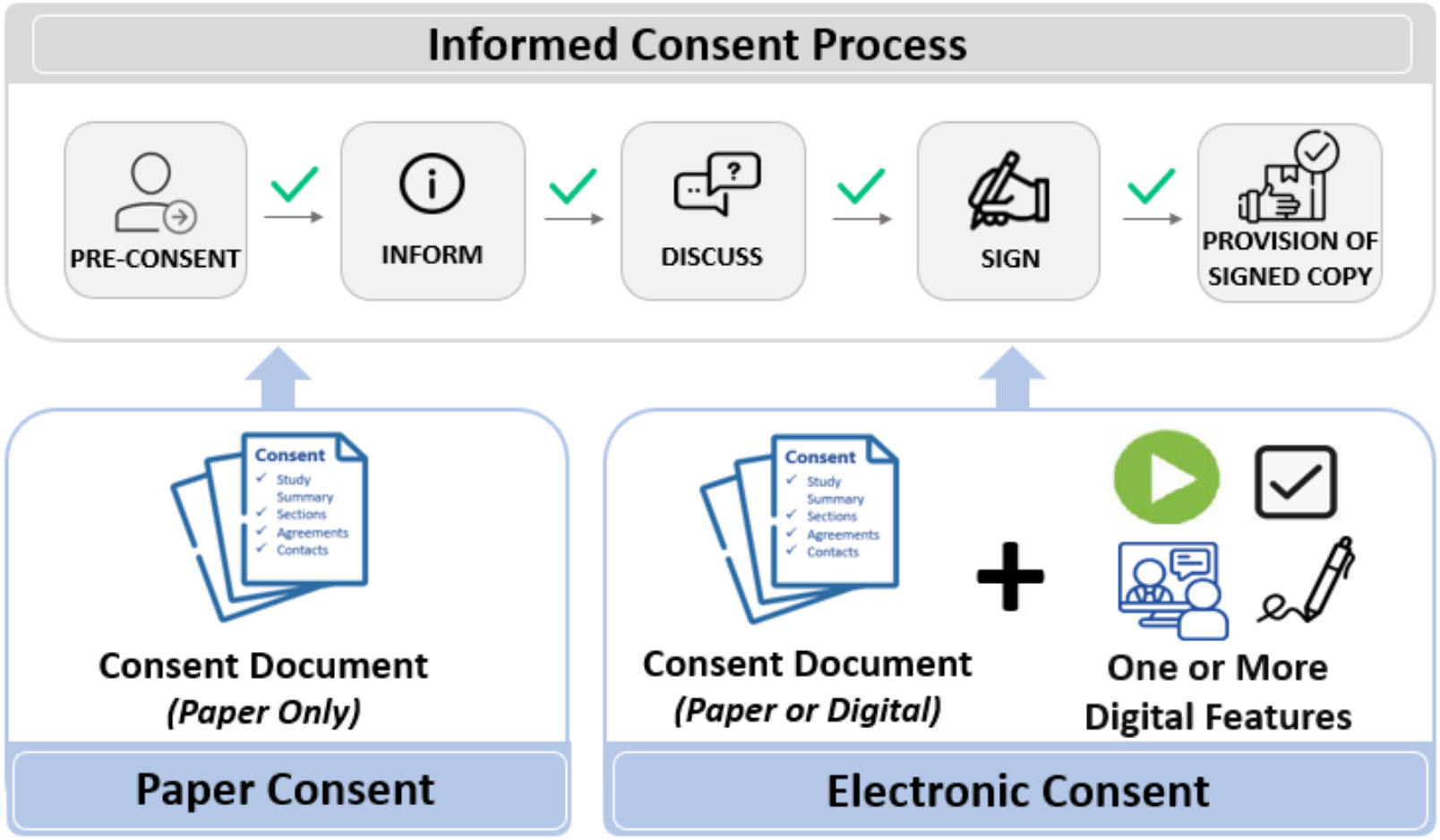
to **PROVIDE** a **Fit-for-Purpose eConsent Study Framework**

Suite of Tools Released December 2024

Existing cross-industry eConsent guidelines and initiatives were referenced, where applicable (e.g., EMA DCT, TransCelerate, EUCROF, iConsent, IMI Trials@Home)

Tool 1: EFGCP eConsent Glossary

eConsent Definition



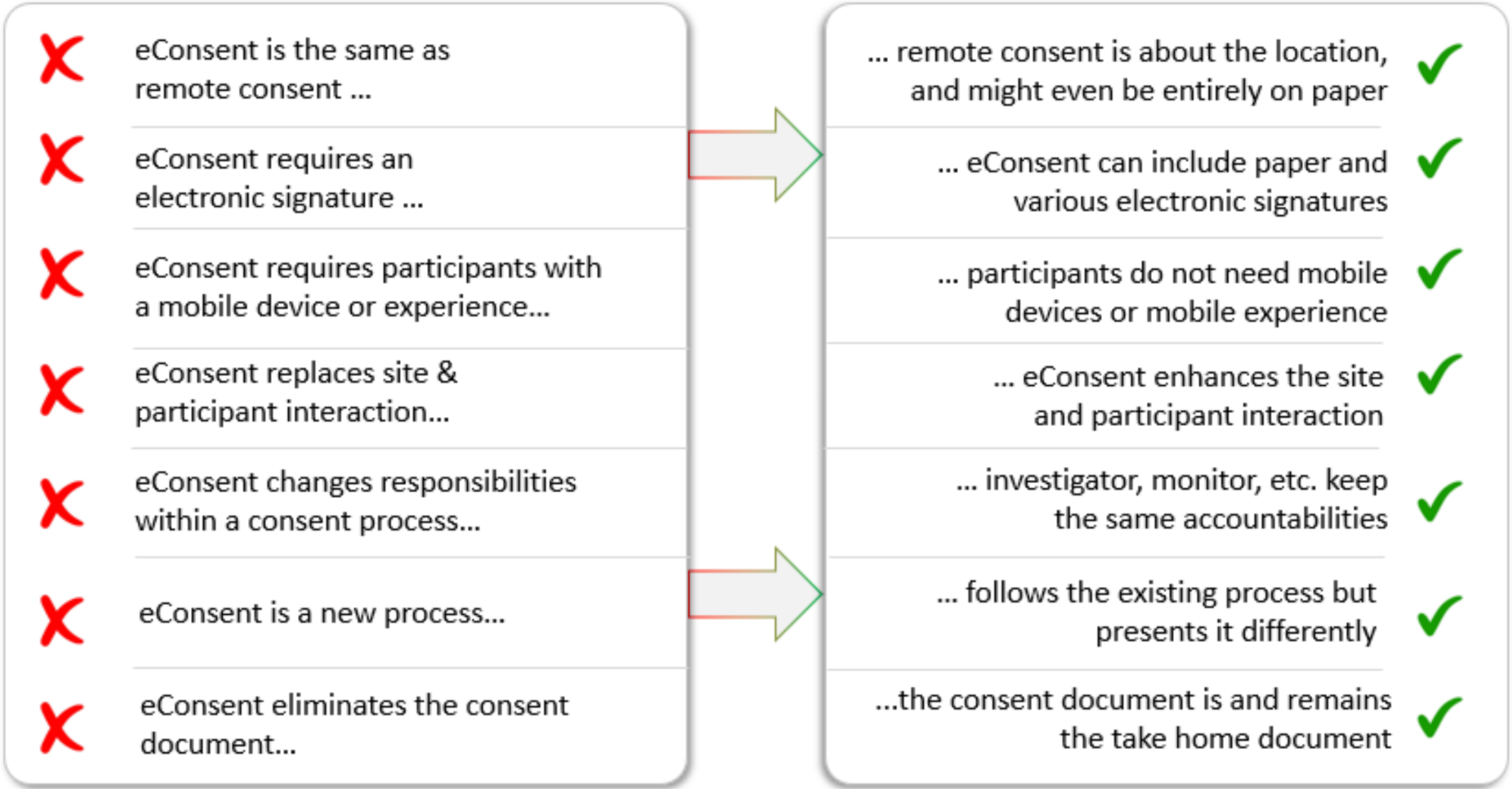
eConsent is the Traditional Consent Process Supported by One or More Digital Features

eConsent is an Umbrella Term

**Article "eConsent Why Language Matters", Applied Clinical Trials Dec 2023, Author Hilde Vanaken et all.*

Tool 1: EFGCP eConsent Glossary

Some Common Misunderstandings



Tool 1: EFGCP eConsent Glossary

64 Platform & Operational eConsent Terms

1.12. CONFIRMATION OF PARTICIPATION

1.12.1. ELECTRO

Description:
Digital methods us
participation in the

Examples:
Recording of name

Primary stakeholde
Participants, Sites.

1.12.2. (SIMPLE)

Description:
Any data in electro
is used by the sign

No biometric data
regulations and stu

Other countries an
eSignature" but to

Examples:
A handwritten sign
picture of a handw

To illustrate differ
electronic device"
electronic signatur

Primary stakeholde
Participants, Sites.

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**

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

Description:
Refers to a particip
process (interest c
in the same locatio

Note - The locatio
fundamental. Oth
participant-related

Examples:
Interaction is usua
chatbot, video call)

2.3. MIXED L

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"

Physical meeting or video call?

** Article "eConsent Why Language Matters", Applied Clinical Trials Dec 2023, Author Hilde Vanaken et all.*

Tool 2: EFGCP eConsent Study Documents Recommendation

Surveys on Industry Perspectives about HA & ECs eConsent Document Needs

Category	Sub-Category	Should ECs (or HAs) be informed about the following aspects
eConsent Platform Aspects	Digital Features	Participant's use of digital features
		Participant's type of digital features*
		Site's use of digital features
		Site's use of digital feat
	eSignature/Wet Ink Signature	Use of eSignature
		Type of eSignature*
		Participants' access to a
		Use of wet-ink signatur
		Electronic storage of we
		Linkage of wet-ink signa
	Remote Identification Methods	Participants' remote ide
	Remote Consent withdrawal	Participants' remote cor
	Electronic Data Storage	Electronic data storage
		Electronic data storage
	Platform validation	Platform validation
	Platform integration	Platform integrations w
		Platform integrations w
eConsent Operational Aspects	Location	Location of consent disc
	Training	Participants' training
		Sites' training
	Helpdesk	Participants' access to a
		Participants' helpdesk m
		Sites' access to a helpde
	Device Deployment	Use of participants' own mobile device
		Use of provisioned mobile device
		Details of provisioned mobile device*
	Remote Monitor Access	Remote monitor access to PII data
		Remote monitor access to non-PII data

+60 Organizations Responsed

28 eConsent Aspects Questions

and

Should HA/EC be informed or not + rationale?

In which HA/EC document, it should be described?

Should HA/EC approve or not?

NOT ONE QUESTION HAD 100% CONSENSUS

** Article "Navigating eConsent Submissions: Who, What, Where and Why?", Applied Clinical Trials Nov 2023, Author Hilde Vanaken et all.*

Tool 2: EFGCP eConsent Study Documents Recommendation

Recommendations for 9 Study Documents Developed

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)[2].

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.

9 study documents

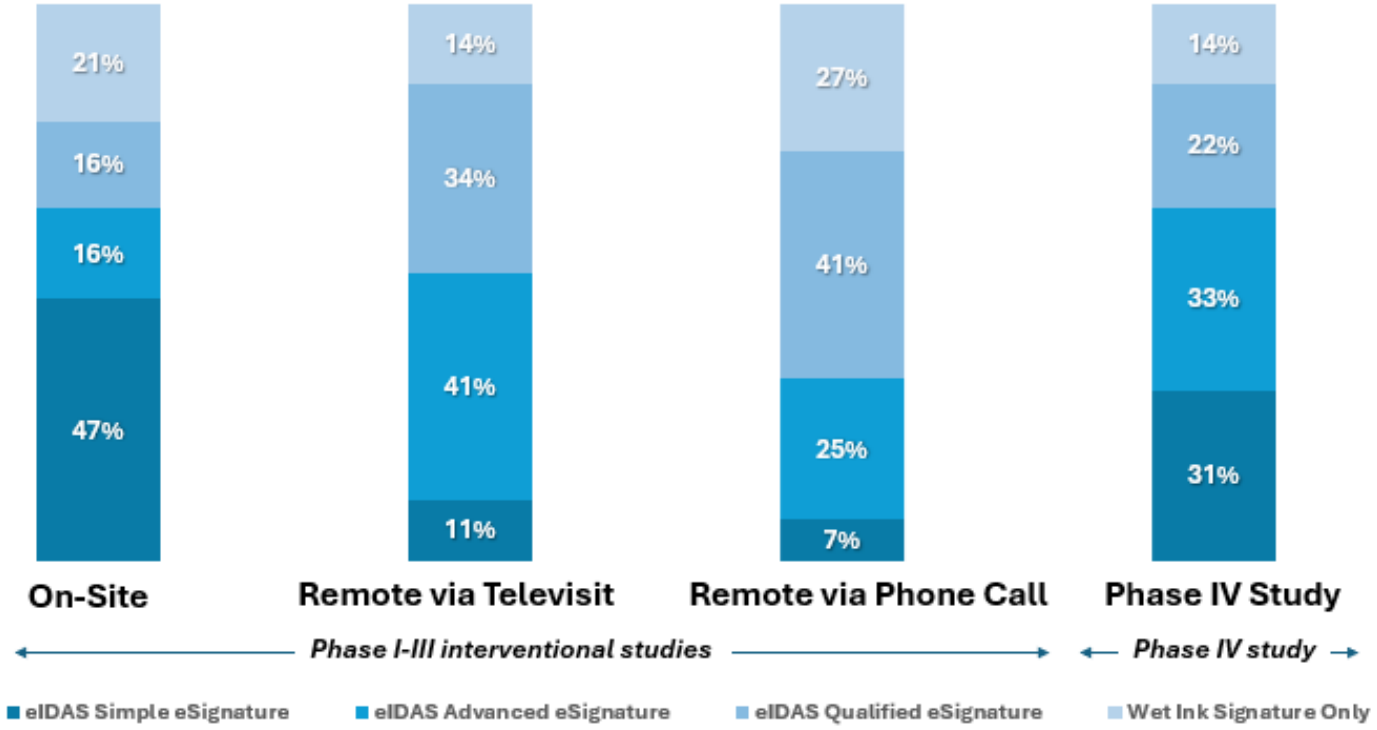
- Protocol
- HA Submission Cover Letter
- EC Submission Cover Letter
- Participant Related eConsent Docs
- Informed Consent Doc
- Site eConsent Docs
- Monitoring Plan
- Data Management Plan
- Platform/Vendor Due Diligence Docs

**Tool referenced official HA guidelines: e.g., SwissMedic and SwissEthics DCT Positioning Paper, 10 Feb 2025*

Tool 3: EFGCP eConsent Fit for Purpose Study Framework

Surveys on Ethics Committees, Sponsors and Vendors Perspective

Type of eSignature required can vary depending of location and study phase



Data of EC survey (49 responses)

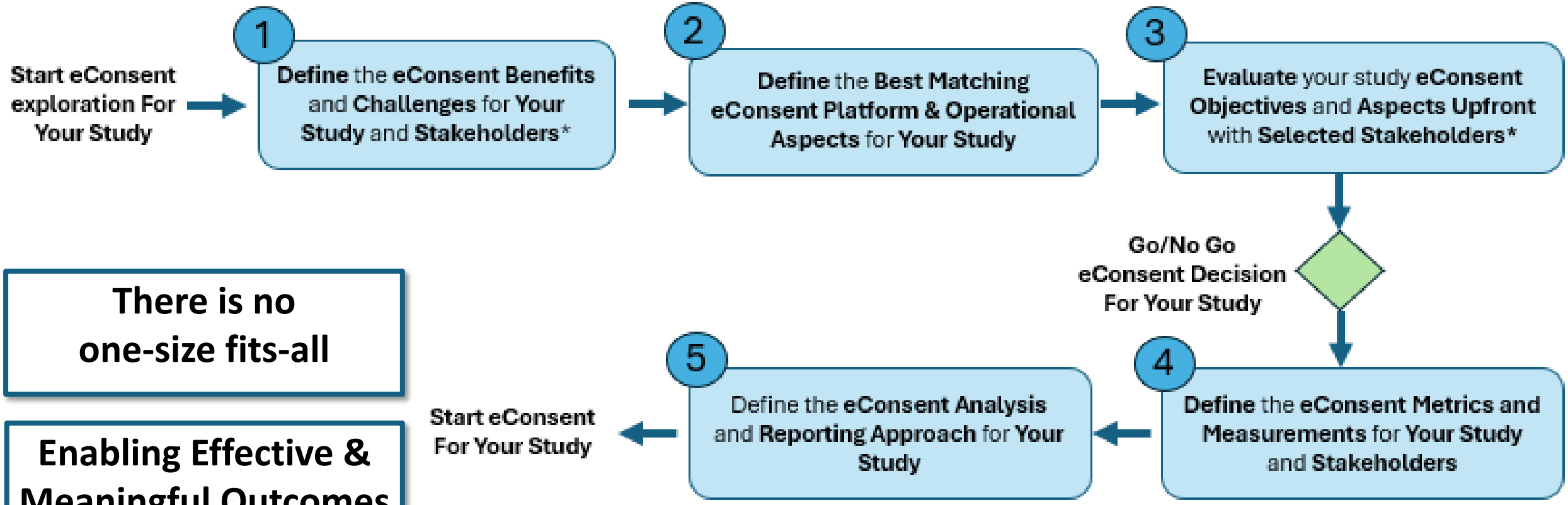
	North American ECs (#= 9)	European ECs (# = 26)
Experience with eConsent	78%	65%
Personal Data Must be Stored On Site	44%	77%
Paper Option is Needed	78%	65%
Minimal Consent Signature Requirement On Site:		
- Simple eSignature	33%	53%
- Advanced eSignature	33%	12%
- Qualified eSignature	11%	24%
- Wet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

Differences and Commonalities between European & North American ECs

** Article: "Understanding Acceptability of eConsent from a Global, Ethical and Industry Perspective", Applied Clinical Trials Oct 2024, Author Hilde Vanaken et all.*

Tool 3: EFGCP eConsent Fit for Purpose Study Framework

5-Step Process to Define the Right eConsent For Your Study & Its Stakeholders



There is no one-size fits-all

Enabling Effective & Meaningful Outcomes

*Stakeholders = sites, participants and sponsor representatives

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

Tool 3: EFGCP eConsent Fit for Purpose Study Framework

Define Benefits & Challenges (Step 1 A, B) and Best Matching Aspects (Step 2)

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	+		

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

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			
Correcting errors in linkage EDC ID an			
Navigating the wide range of eConser			
Increasing administrative workload a			
Increasing heterogenous oversight an			
Increasing consent data review activit			
Limiting availability of integrated syst			
Increasing complexity to navigate mu			
Increasing impact on budget and reso			
Impacting site relationships with part			

	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					

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

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

My Learnings & Perspective

Addressing eConsent Challenges Requires a Fundamental Change in the Entire Consent Development and Execution Process

Interested to know more & how?
(hilde.vanaken@efgcp.eu or hilde.vanaken@tcs.com)