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What experience do you have with eConsent?

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Unraveling all Disconnects, Misconceptions and Uncertainties about eConsent: *European Forum GCP eConsent Initiative*

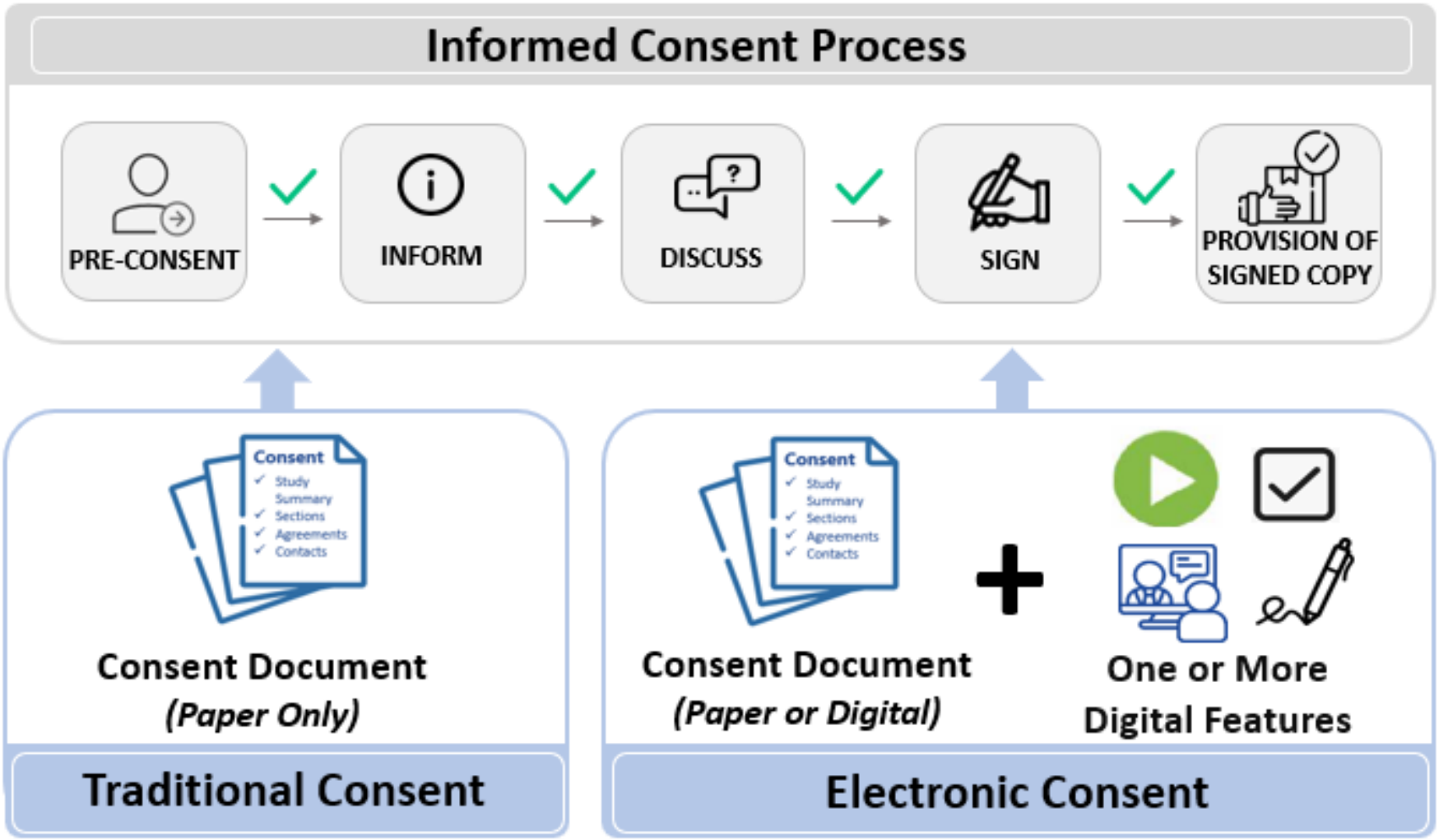
Hilde Vanaken, PhD, Eng, MsC

Head European Forum GCP eConsent Initiative

Common eConsent Misunderstandings

✗ eConsent is the same as remote consent …	… remote consent is about the location, and might even be entirely on paper ✓
✗ eConsent requires an electronic signature …	… eConsent can include paper and various electronic signatures ✓
✗ eConsent requires participants with a mobile device or experience…	… participants do not need mobile devices or mobile experience ✓
✗ eConsent replaces site & participant interaction…	… eConsent enhances the site and participant interaction ✓
✗ eConsent changes responsibilities within a consent process…	… investigator, monitor, etc. keep the same accountabilities ✓
✗ eConsent is a new process…	… follows the existing process but presents it differently ✓
✗ eConsent eliminates the consent document…	…the consent document is and remains the take home document ✓

eConsent is an Umbrella Term

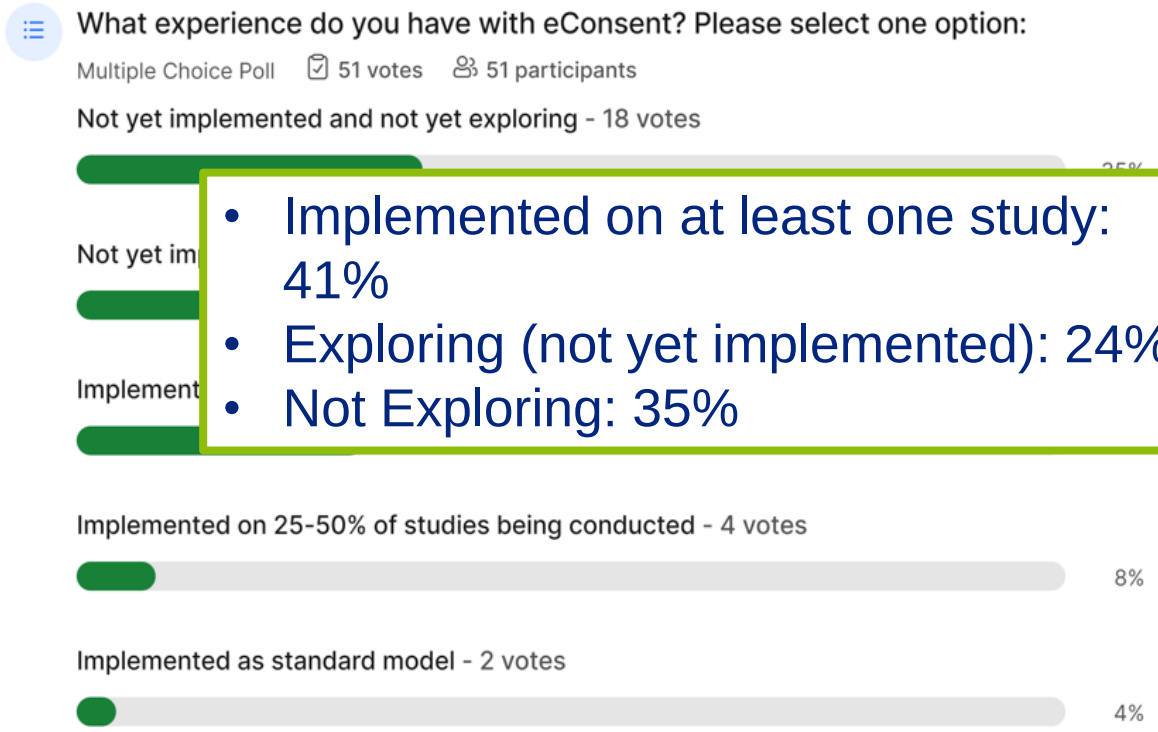


eConsent = Traditional Consent Process Supported by One or More Digital Features

eConsent Experience in Industry

DIA 2023 eConsent Audience Poll

(eConsent session with FDA, MHRA, EFGCP & chair Roche)



- Implemented on at least one study: 41%
- Exploring (not yet implemented): 24%
- Not Exploring: 35%

2023 eConsent Surveys

(EFGCP Study Docs eConsent Surveys)

Implemented on at least one study

- Pharma: ~80%
- Academic Institutes: ~22%
- Vendors: ~85%

eConsent is 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: Request of **European Forum GCP** to help with eConsent in Europe

Numerous interpretations, conflicting messages, limited stakeholder insight

**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.*

European Forum GCP eConsent Initiative

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

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-
"the use of one or more digital
and definition of eConsent.

Secondly, as there is no one-siz
underlying platform and operat
this glossary in the following 2

- **eConsent Platform Aspects** and underlying data and te eConsent platform aspects characteristics and commo
- **eConsent Operational Aspe** management. These aspect examples include terminolo

These aspects should not be loc
platform and operational aspec

The focus of this glossary was n

Applied Clinical Trials

eConsent -Why Language Matte

December 20, 2023

By Hilde Vanaken, Rebecca Zeising, Bethany Pryski 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[1] 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[2], 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[3]. Where applicable, references to existing terminologies are incorporated in the glossary[4-15].

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

eConsent Platform Aspects

Digital Features	• Pre-Consent Acknowledgment
	• Educational Content
	• Comprehension Content
	• Consent Document Copy
	• Identity/Authentication
	• Comprehension Confirmation
	• Documentation/Log
	• Signed Consent Upload
	• Paper Consent Tracking
	• Communication Channels
	• Notifications
	• Confirmation of Participation:
	  • Electronic Acknowledgement
	  • (Simple) Electronic Signature
	  • Advanced Electronic Signature
	  • Qualified Electronic Signature
	• eConsent Platform Training Content
	• Non-Study, Non-Consent Related Content
	• Metadata Insights and Metrics
	• Business Intelligence
	• Artificial Int
		Identifiers	• Consent Document Identifier
			• Consent Document Version Identifi
			• Participant Identification Code
			• Participant Token

		Consent Account	• Participant Account • Stakeholder Account
		Data Types	• Personal Data • Non-Personal Data • Aggregated Metadata
		Data Privacy Clause/Agreement	
		Compliance Documentation	
		Validation Documentation	
		Integrations	

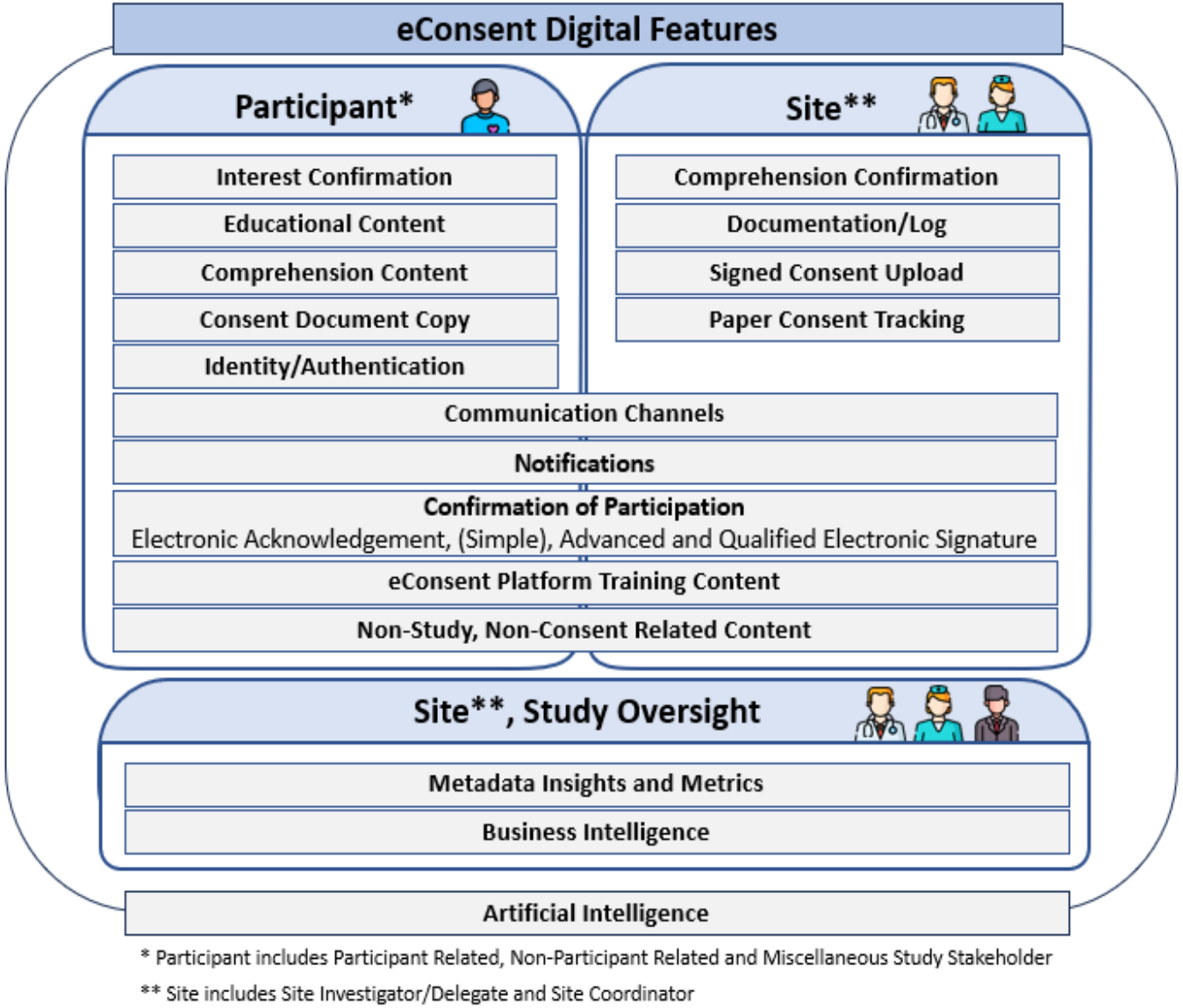
eConsent Operational Aspects

Stakeholders	• Participant • Participant Related Stakeholder • Non-Participant Related Stakeholder • Miscellaneous Study Stakeholder • Site Investigator/ Delegate • Site Coordinator • Study Oversight Stakeholder	**Consent Categorization**	• Main Consent Document • Optional Consent Document • Assent Document
Participant/ Site Location	• In the Same Location • Not in the Same Location • Mixed Location	**Consent workflow**	• Initial Consent • Declined • Reconsent • Withdrawal • Dynamic Consent
Timing of Signature	• Discuss/Sign At the Same Time • Discuss/Sign Not at the Same Time	**Health Authority & Ethics Committee Submission**	
Device Deployment	• Own Electronic Device • Provisioned Electronic Device	**Monitoring**	
Data Access	• Personal Data Access • Non-Personal Data Access • Edit Access • Read Access	**Auditing/Inspecting**	
		Training	
		Support	
		Archiving/ Permanent Records	• Site Consent Archiving • Sponsor Consent Archiving • Participant Consent Permanent records

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

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

Example – Digital Features Terms (~ Platform Aspects Terms)



- Terms **cluster** individual digital feature examples based on **their characteristics and commonalities**
- **Describe the example** to avoid misunderstanding.
  - E.g. "**Not eSignature"** but "**handwritten signature on an electronic device"**:

(Europe)
eIDAS Simple eSignature

(US)
NOT an eSignature

Example – Stakeholders & Location (~ Operational Aspects Terms)

1. Stakeholders

1.1. PARTICIPANT

Description:
An individual who participates in a clinical study, either as a recipient of the investigational product(s) or as a control (Trial Participant definition of ICH GCP E6 (R3)[6]).

Other terms used are e.g., subject, trial participant.

Examples:
Patient, healthy volunteer, minor, etc.

1.2. PARTICIPANT RELATED STAKEHOLDER

Description:
An individual related to the participant who is involved in the consent process and can confirm the participant's participation in the [illegible] the participant's confirmation to participate.

Examples:
Legally authorized/[illegible] of kin, etc.

1.3. NON-PAR[illegible]

Description:
An individual that is [illegible] sing role in the consent process. They may confirm [illegible] their participation in the consent process is separately documented.

Examples:
Translator, impartial witness

1.4. MISCELLANEOUS STUDY STAKEHOLDER

Description:
An individual that is directly or indirectly linked with the participant and may sign off on a separate document and/or their involvement is separately documented next to the consent process. They might not be part of the overall consent process.

Examples:
Pregnant female partner of a male participant, nursing care staff in retirement house not acting as a caregiver.

All stakeholders should be considered

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 part[illegible] onsent process (interes[illegible] ne not in the same loca[illegible]

Note - The loca[illegible] ator is fundamental. C[illegible] s (e.g. participant-rela[illegible] ant

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

Operational Aspects terms are often also applicable on the traditional consent process

ECs and HAs eConsent Submission Docs - Industry Perspective

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 features
	eSignature/Wet Ink Signature	Use of eSignature
		Type of eSignature*
		Participants' access to a fully eSigned form*
		Use of wet-ink signature
		Electronic storage of wet-ink signed document*
		Linkage of wet-ink signature with electronic consent record*
	Remote Identification Methods	Participants' remote identification methods
	Remote Consent withdrawal	Participants' remote consent withdrawal
	Electronic Data Storage	Electronic data storage of PII data
		Electronic data storage of metadata metrics (non-PII data)
	validation	Platform validation
	integration	Platform integrations with study systems
		Platform integrations with site systems
		Location of consent discussion
		Participants' training
		Sites' training
		Participants' access to a helpdesk

- **HA and EC Submission Docs Surveys with 28 questions** on various eConsent platform & operational aspects
  - **Should HA (or EC) to be informed or not + rationale?**
  - In **which HA (or EC) submission doc** to document?
  - **Should HA (or EC) approve or not?**
- **63 organizations** completed the **ECs** Docs Survey
- **58 organizations** completed the **HAs** Docs Survey
- **Not one single question had 100% consensus**

	All Organizations				ECs responses alone				All vs ECs
	#	ECs Should be Informed	ECs should NOT be informed	Don't know	#	ECs Should be Informed	ECs should NOT be informed	Don't know	Aligned/ not aligned
reference) (Q1)	63	97%	3%	0%	13	100%	0%	0%	Aligned
timedia tiered consent, video, audio,	61	97%	3%	0%	13	100%	0%	0%	Aligned
rence) (Q2)	63	79%	14%	6%	13	92%	8%	0%	Aligned
, alerts, confirmation boxes) (Q2A)	50	80%	16%	4%	12	100%	0%	0%	Aligned
	63	87%	13%	0%	13	77%	23%	0%	Aligned
A)	55	84%	11%	5%	10	80%	10%	10%	Aligned
erson handout) (Q3B)	55	93%	7%	0%	10	100%	0%	0%	Aligned
	63	63%	37%	0%	13	62%	38%	0%	Aligned
	40	68%	25%	8%	8	75%	25%	0%	Aligned
B)	40	63%	20%	18%	8	63%	25%	13%	Aligned
during the consent process (Q5)	63	86%	11%	3%	13	77%	23%	0%	Aligned
ent review time) (Q6)	63	48%	44%	8%	13	46%	46%	8%	No consensus
check, local certified system) (Q7)	63	83%	11%	6%	13	85%	8%	8%	Aligned
remote) (Q8)	63	79%	19%	2%	13	100%	0%	0%	Aligned
	63	75%	21%	5%	13	92%	8%	0%	Aligned
only access electronic consent	47	72%	17%	11%	12	83%	8%	8%	Aligned
	63	65%	25%	10%	13	85%	15%	0%	Aligned
dentifiable Information (PII) (Q11)	63	62%	25%	13%	13	69%	23%	8%	Aligned
dentifiable Information? (e.g., questions	63	33%	40%	27%	13	46%	38%	15%	No consensus
nsent system/platform (Q13)	63	75%	24%	2%	13	92%	8%	0%	Aligned
	63	56%	38%	6%	13	46%	46%	8%	Not aligned
c systems? (e.g., EDC, RTSM) (Q15)	63	44%	41%	14%	13	69%	31%	0%	Not aligned

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

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%

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)	

Different organization types had different opinions on whether to report or not a certain aspect in the protocol

eConsent Study Documents Recommendations

Table of Contents

- 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

Recommendations drafted for **9 study documents**

3. PROTOCOL

3.1. Description

A document that describes the [illegible] 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)[3].

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 eConsent Expectations and Perspectives

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

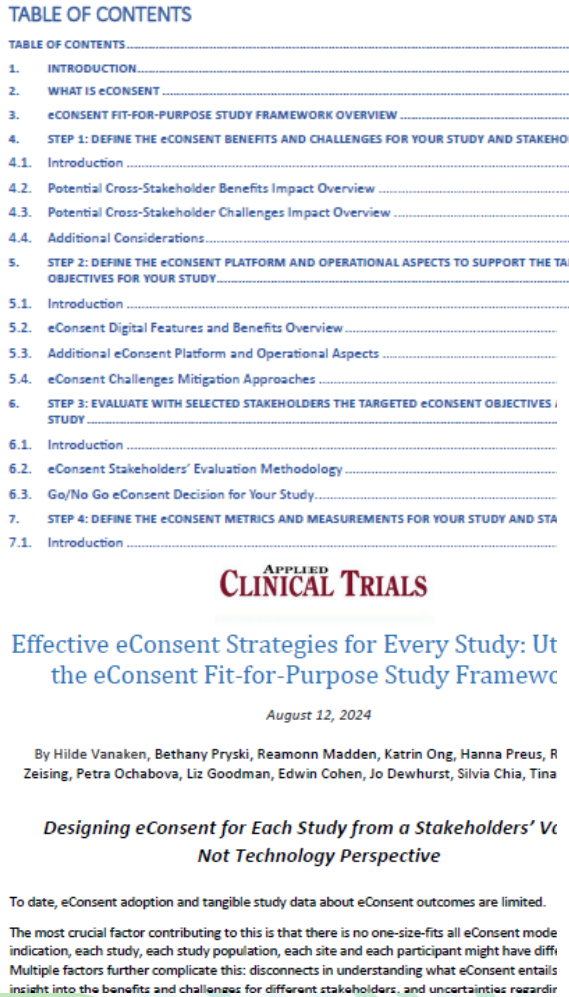
Personal data hosting requirements

Digital features usage and value

Remote participant identification methods

Article and Results Ready to Publish

eConsent Fit-for-Purpose Study Framework



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APPLIED CLINICAL TRIALS

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

August 12, 2024

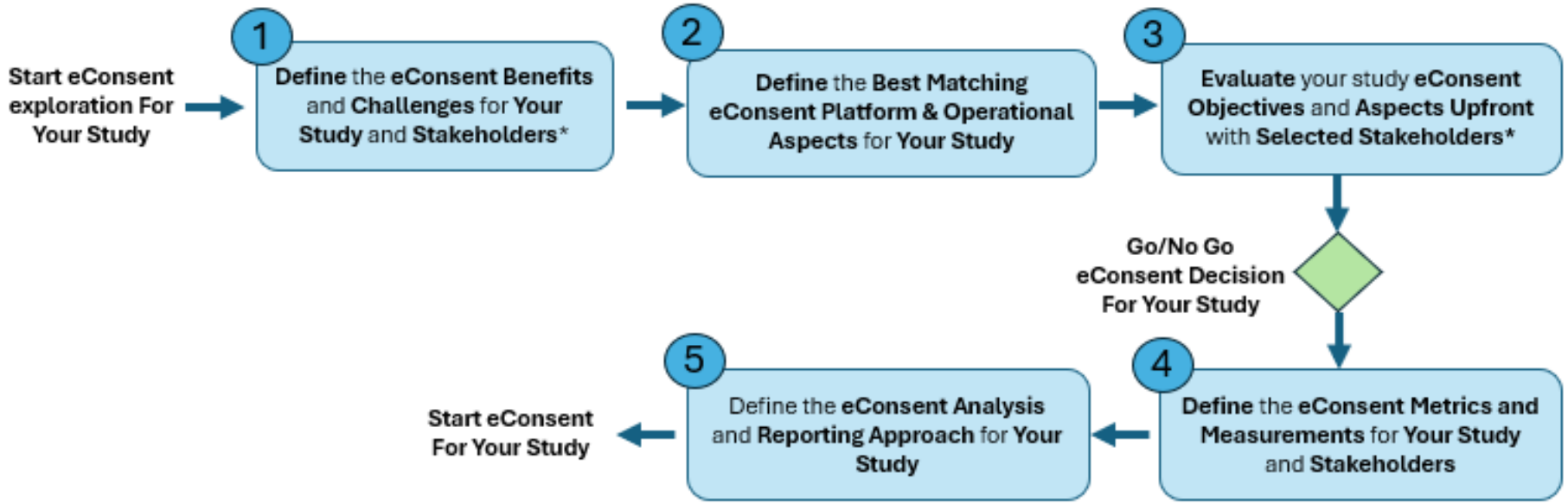
By Hilde Vanaken, Bethany Pryski, Reamonn Madden, Katrin Ong, Hanna Preus, R
Zeising, Petra Ochabova, Liz Goodman, Edwin Cohen, Jo Dewhurst, Silvia Chia, Tina

***Designing eConsent for Each Study from a Stakeholders' Vc
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 mode
indication, each study, each study population, each site and each participant might have diff
Multiple factors further complicate this: disconnects in understanding what eConsent entails
insight into the benefits and challenges for different stakeholders, and uncertainties regardir

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 all.*

Step 1 & Step 2 – Some More Details

- Step 1 - Define the Benefits and Challenges for your Particular Study and Its Stakeholders
- Step 2 – Define the Best Matching eConsent Platform and Operational Aspects

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			
Re			
En			
In			
Improving compliance with the consent process			
Improving tracking and insights into optional consent			
Improving oversight and real-time insights			
Enabling integration with other systems			
Reducing on-site consent auditing and inspection acti			
Reducing on-site consent monitoring activities			
Enhancing continuous improvement of consent conte			
Supporting sites to have a more tailored discussion w			
Improving consent storage			
Improving consent archival for sites			

18 Potential Benefits

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 appr			
Extending the development tim			
Correcting errors in linkage EDC ID and Consent ID			
Navigating the wide range of eConsent platforms			
Increasing administrative workload and training			
Increasing heterogenous oversight and deployment			
Increasing consent data review activities			
Limiting availability of integrated systems			
Increasing complexity to navigate multiple stakeholders			
Increasing impact on budget and resources			
Impacting site relationships with participants			

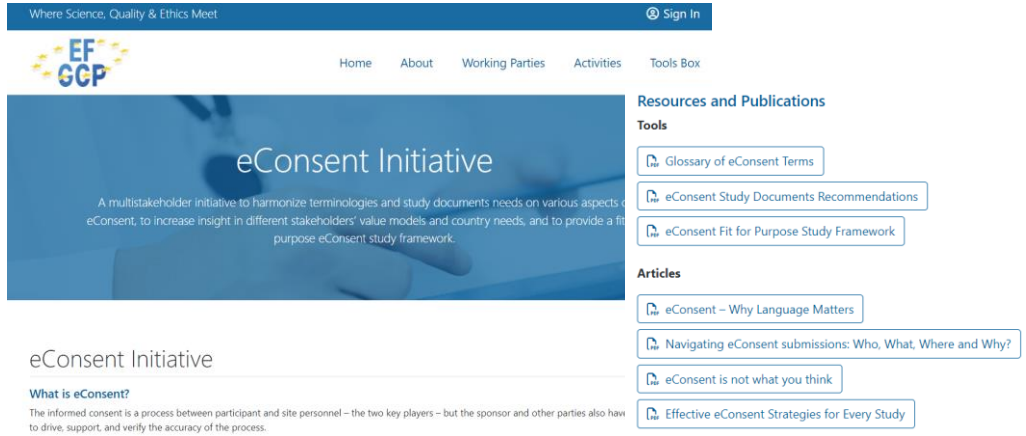
16 Potential Challenges

	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														
Increasing the quality of														
Improving compliance w														
Improving tracking and i														
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					

Best Matching Digital Features/Benefits

Key Take Aways

- Without a Common Understanding, Conversations Become Meaningless
- There is NO one-size-fits-all eConsent
- Effective and Comparable eConsent data are the fuel for broader adoption
- Flexibility for Sites and Participants – the 2 Consent Drivers - is Key



A suite of eConsent tools is available at efgcp.eu

Will You Join the Journey to bring eConsent to the place it deserves?

Any feedback on eConsent tools, please let me know!

Thank You

Interested to Know More?

Hilde.vanaken@efgcp.eu

EMA – eConsent in National Provision Overview*

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
Q11: Is a physical face to face meeting between the trial participant and the PI or a member of the research team always mandatory during the consent procedure (even if the rest is conducted remotely)?	No	No			No *	Yes *		No *	*	*	No *	No	No *	No *	Yes *	No		No *		No			No	No *	No	No	Yes *	No	No	*	No
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 *	*	Yes *

All countries allow eIDAS electronic signatures (simple, advanced or qualified eSignature) and 2 countries require a physical face to face meeting between participant and PI during consent procedure: Belgium (but exceptions possible) and Hungary.

**EMA Recommendation Paper on Decentralized Elements in Clinical Trials, 13 December 2022.*

Why eConsent?

Zabir Macci

Director, Strategy & Solution Engineering

IQVIA Patient Technologies

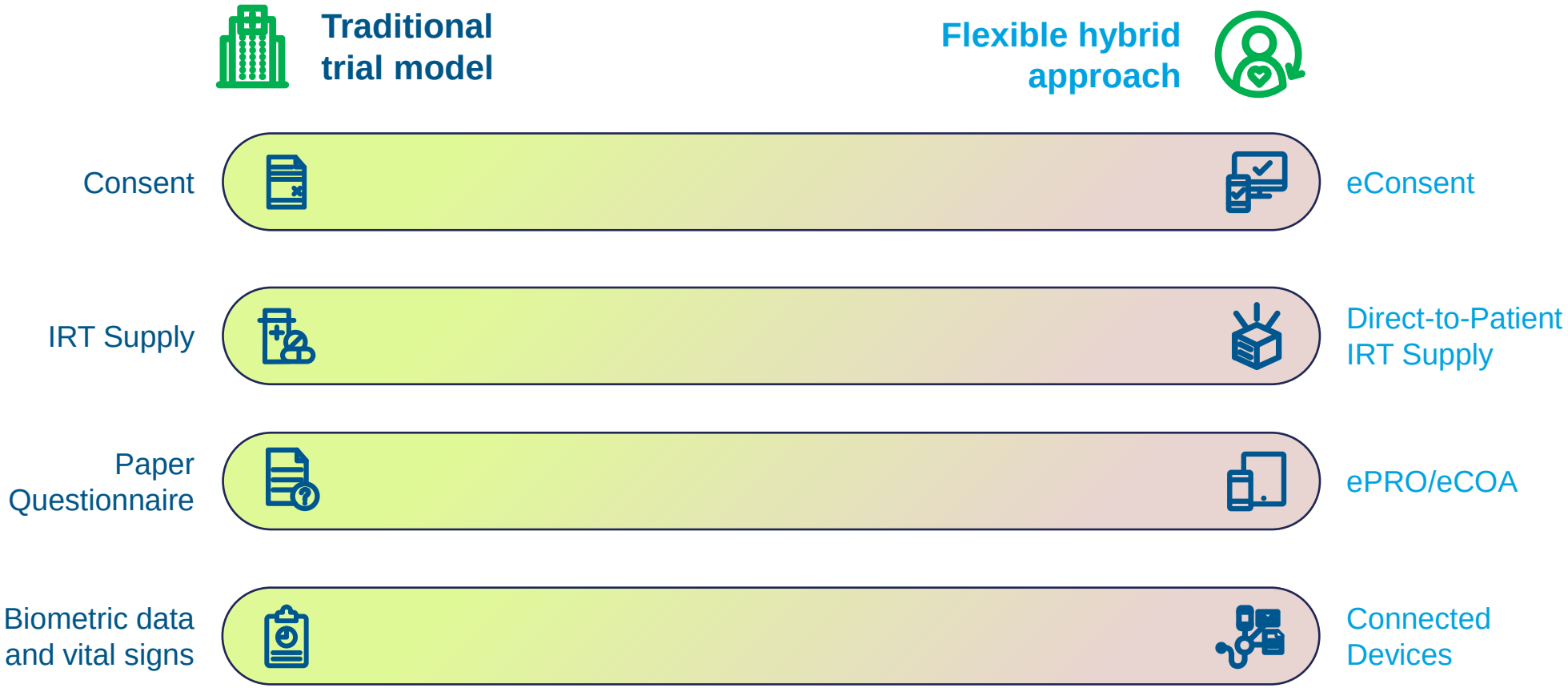
The burden of clinical trials participation

Estimated **70% of participants** live
>2 hours away from trial sites

Resulting in **>135 miles/2+ hours traveled** to and from site for each visit

Simplifying and improving the participant experience

Flexible, scalable, proven technology solutions



Benefits of eConsent Use

Improved Quality

- Protocol and regulatory compliance
- Consistent delivery of information

Improved Efficiencies

- CRA efficiency
- Remote monitoring

Patient Centricity

- Interactive reading experience
- Improved comprehension
- Better compliance, better retention

Data Integrity & Transparency

- Comprehensive audit trail
- Specificity and analytics

eConsent benefits stakeholders & eliminates hidden costs

Proven value for all stakeholders in the clinical trial process

Participants

- View multimedia education & flag question areas
- Better understand risks and benefits
- Tablet easier to hold
- Higher levels of satisfaction
- Better adhere to protocol

Hidden cost:
Decline consent, drop out, non-protocol compliance

Trial Staff

- Eliminate repetition in explanations and providing own definitions
- Version and document management
- Automatically record consent notes
- Streamlined re-consents

Hidden cost:
Manual tracking, deviations, Time managing CRA visits & inspections

Monitors

- View real-time consent status across sites globally
- Easily access detailed audit trails
- Rely on date/time stamps
- Access optional consent element reporting

Hidden cost:
Travel to sites, “blind” to consent source until on site, deviations

Sponsor

- Assured of the integrity of the consent process
- Fewer consent-related audit findings
- Provides valuable consent analytics
- Global signature compliance with 2 modalities

Hidden cost:
Timeline creep, carbon impact, CONQ, loss of biosamples

Top 5 Business Challenges solved with eConsent

1. **Patient comprehension & retention**
   - Interactive reading experience
   - Improved comprehension
   - Better compliance, better retention
   - Consistent delivery of information & reading analytics
2. **Complex consenting**
   - Seamless management of complex document collections and consenting events
   - eConsent that fits to your trial
3. **Improved quality**
   - Consent related deviations, Protocol and regulatory compliance
   - Comprehensive audit trail
   - Accurate biosample consent tracking
4. **Global eConsent & DCT capabilities**
   - Globally compliant signature modalities
   - Regulatory navigation
   - Remote eSignature capabilities to meet DCT needs
   - Remote Legally Authorised Representatives
5. **Efficiencies - remote monitoring**
   - CRA efficiency
   - Remote monitoring

Complete Consent Case Study

Reduction in consent related deviations and findings

Situation

- ❑ Paper processes are prone to human error
- ❑ *One of the most common observations collected from issued FDA Form 483s is inadequate subject protection; informed consent issues
- ❑ **Average consent related critical and major deviations across all IQVIA trials is 14%**

Solution

IQVIA Complete Consent solution:

- ➢ Eliminates risk of incomplete ICF fields
- ➢ Reduces risk of misdating or inaccurate paper consenting notes by site staff
- ➢ Eliminates risk of signing incorrect ICF versions
- ➢ Eliminates risk of patient reconsenting to new ICF versions

Results

- Across nearly 100 IQVIA trials implementing eConsent shows only 6% critical and major deviations resulting in:

57%

reduction in critical and major ICF related deviations

eConsent Site Engagement Strategy

Framework for managing a successful eConsent adoption

Engage early with Sites

Early discussion with sites at **feasibility / selection** to assess capabilities and acceptability, identify and remove potential roadblocks

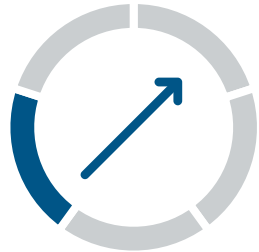
Educate and Onboard Sites

Training webinars, site guides and a practice environment available to sites – provide multiple, flexible means for sites to learn about eConsent and share feedback

Build a Monitor Advocacy Program

Monitors must be involved **"front line"** to promote **eConsent benefits,** and have the support of **eConsent SMEs**

Establish an Escalation Process



Timely detection of issues and **escalation** to secure tailored support from **the project team leaders from site selection throughout conduct**

Incorporate Ongoing Process Improvement

Leverage patient and site surveys to evaluate and improve site adoption, continual communication through **regular governance** meetings

Real World Experience of Implementing eConsent

Mingyue Xuan

Executive Director, Clinical Data Management

eikon therapeutics

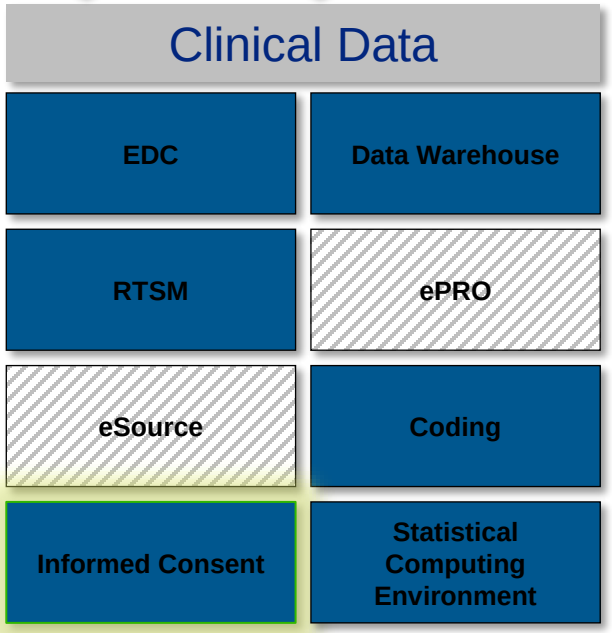
Agenda

- Journey with eConsent
- Key Consideration & Challenges
- Overall Benefits & Impacts for Data Management

SCDM Live

About eikon therapeutics

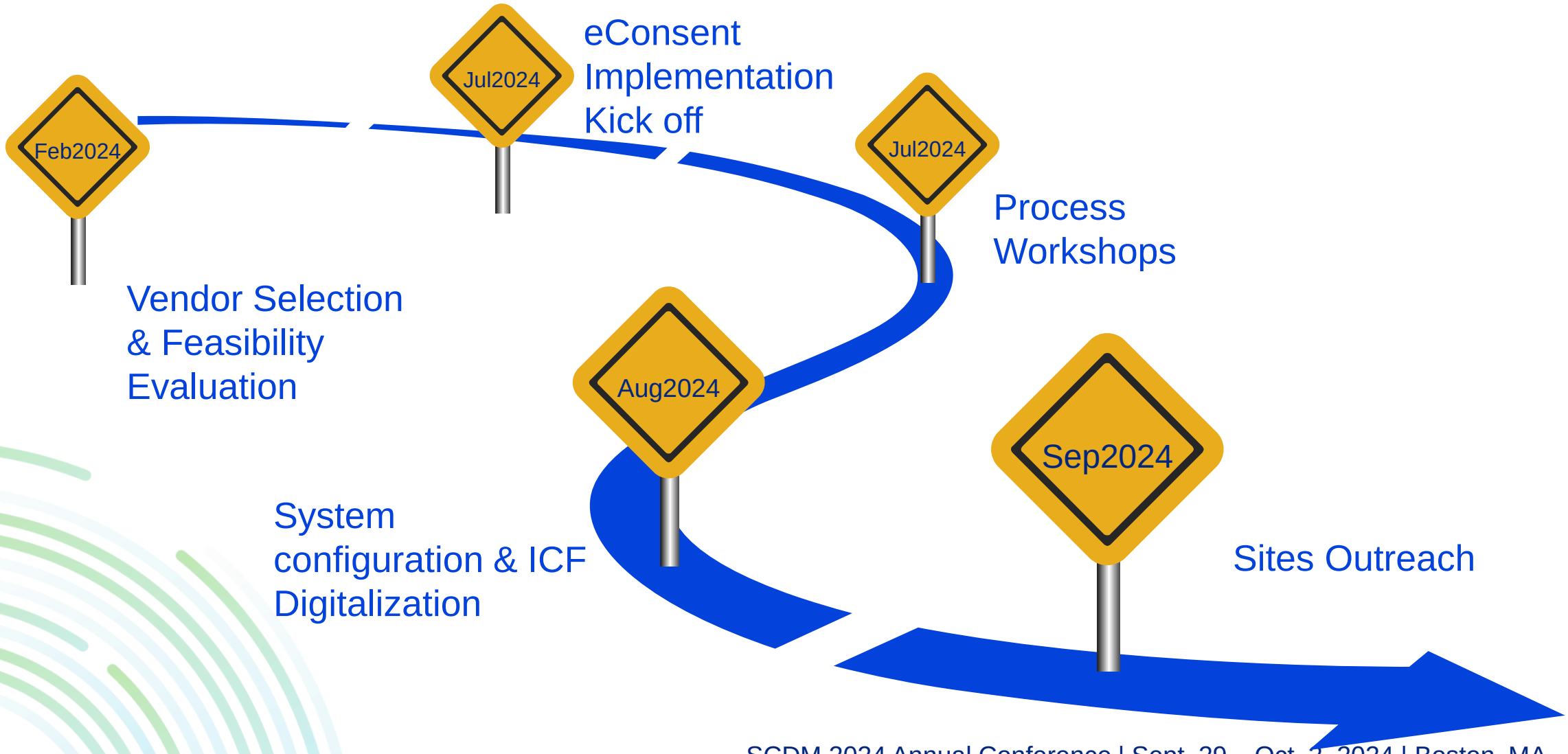
- Scientific Research, Data Analytics, Engineering
- Single Molecule Tracking(SMT) Technology
- Clinical development team started to form in Jul 2022
- Successfully implemented **Wave1** key clinical systems platform **within 6 months**
- **Wave2** Journey starts with eConsent, SSU, etc



2023-Wave 1

2024-Wave 2

Journey with eConsent Implementation



SCDM Live

Key Considerations with eConsent Implementation

Focus Area	eConsent Compliance
Focus Area	eSignature
Focus Area	Processes & Procedures
Focus Area	System requirement & Integration
Focus Area	Sites & Patients Consideration

eConsent Regulatory Compliance

US

- ❑ eConsent must include all elements of informed consent as require by HHS and FDA
  - Common Rules(1991, revised 2018)
  - HHS and/or FDA Regulations (Element of ICF and documentation requirements):
    -45 CFR Part 46.116
    -21CFR Part 50.25
    -45CFR Part 46.117 and 21CFRPart50.27
    -21CFR Part 50.20
- ❑ eSignature requirement
  - 21CFR Part 11[13]
  - A Wet ink paper signature equivalent.
  - No particular method is mandated

ROW

- Country by country evaluation
  - eIDAS 910[12]
  - EU's GDPR
  - eSignature compliance with 21CFR Part 11[13]: Africa
  - Qualified signature required: Germany, Austria
  - Certification of eSignature required: Costa Rica
  - Not allow eSignatures
    - E.g. Bulgaria, Czech Republic, Hungary, Switzerland, France… etc.
  - Physical signoff required
- Regulation might be changed all the time
- Temporary regulations during Pandemic

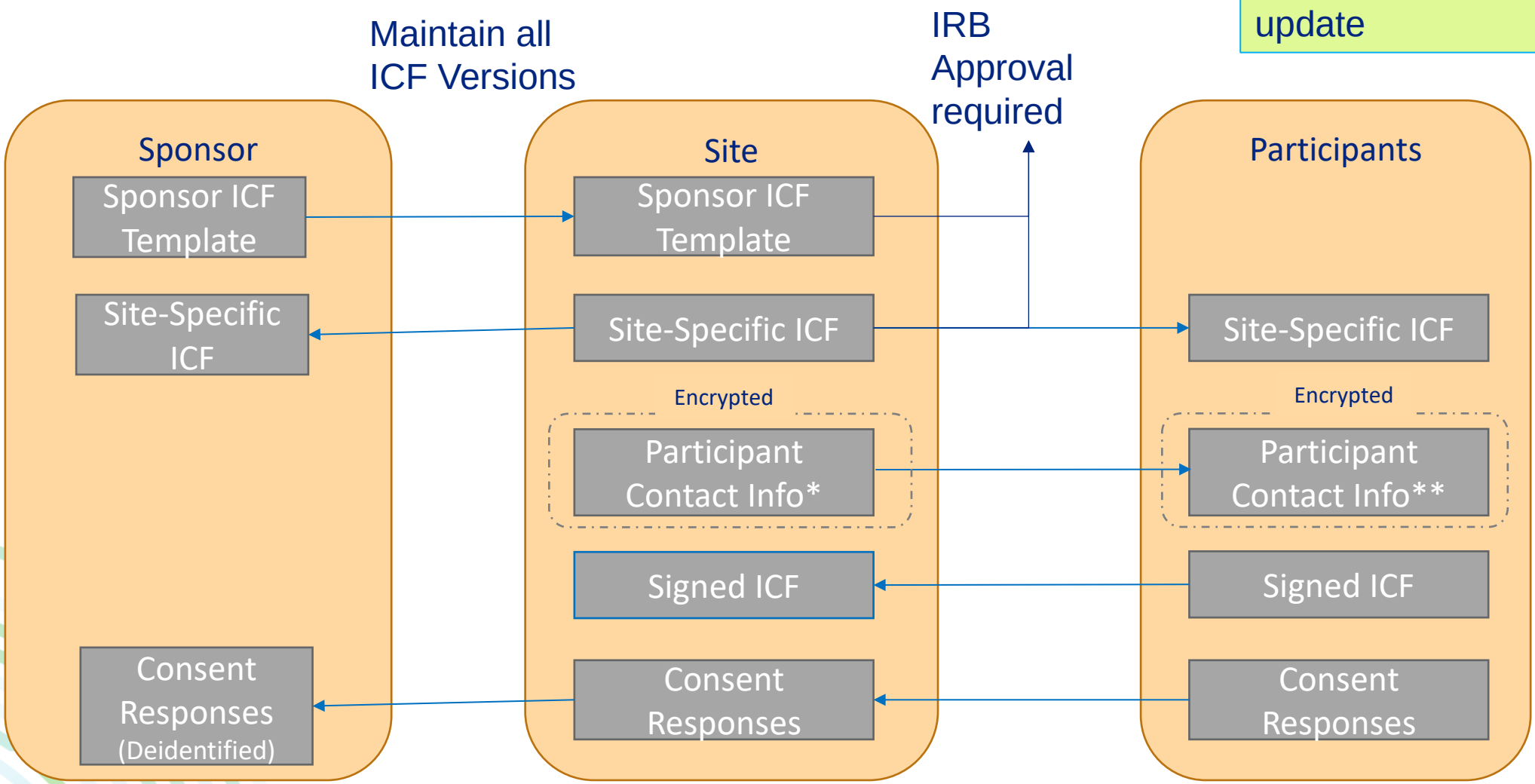
eSignature (EU Categorization)

- Simple electronic Signature
- Advanced electronic signature
- Qualified Signature

SCDM Live

eConsent Stakeholders' Data Flow

SOPs/Processes update



eConsent System Consideration

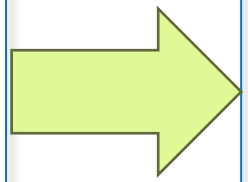
- Stored in a secure, HIPAA-compliant system
- Sign on a device: Provisioned Device VS BYOD
- Be able to manage multiple versions of ICF
- Be able to manage Protocol amendments
- Support Multi-media
- Be able to meet Data privacy requirement (GDRP)
- Support Multiple roles access
- System integration (CTMS, RTSM, EDC, eTMF… etc.)
- Archival

Site & Patient Consideration

- Site outreach
- Sites/Patients System Training
- Language translation
- On-site VS Remote
- Hybrid Model: eConsent + Paper Consent

eConsent Benefit & Data Management Impact

- Better comprehension of ICF by patients
- Eliminate any travel constraint during the informed consent process
- Accelerate the study and startup
- Real time consent capture
- Integration with other Data Collection/study management systems
- Central location and audit trail of managing all ICFs



- Improve patient's enrollment
- Reduce Drop off rate
- Improve Long term Recall of ICF
- Reduce the consent related protocol deviations
- Avoid data entry delay of reconsent
- Synchronize the timing to trigger protocol amendment related changes in multiple systems
- Reduce data review challenges due to the multiple protocol amendments or country specific amendments requirement
- Improve overall quality of data collection
- Reduced manual effort/errors of ICF management
- Easy for regulatory auditing

Key Takeaways

Implementing eConsent improves the participants' experience and the overall quality of trial conduct.

- Carefully planning of eConsent implementation is critical. There are many considerations.
- Being flexible and a backup plan is always needed
- Keeping Regulatory requirement and guidance in mind
- Involving Key Stakeholders early and understanding their need

References

- eCFR :: 45 CFR Part 46 (July 19, 2018) -- Protection of Human Subjects
- https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50
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- Electronic_Informed_Consent_Implementation_Guide_Practical_Considerations_Version_1.0___March_2021_2.pdf (eucrof.eu)
- https://gdpr-info.eu/