NVFG – eConsent @ Janssen

Jessica Riley, *Shells*
Artwork from Reflections Art in Health

David Fauvart - Janssen Clinical Innovation
October 8th, 2019

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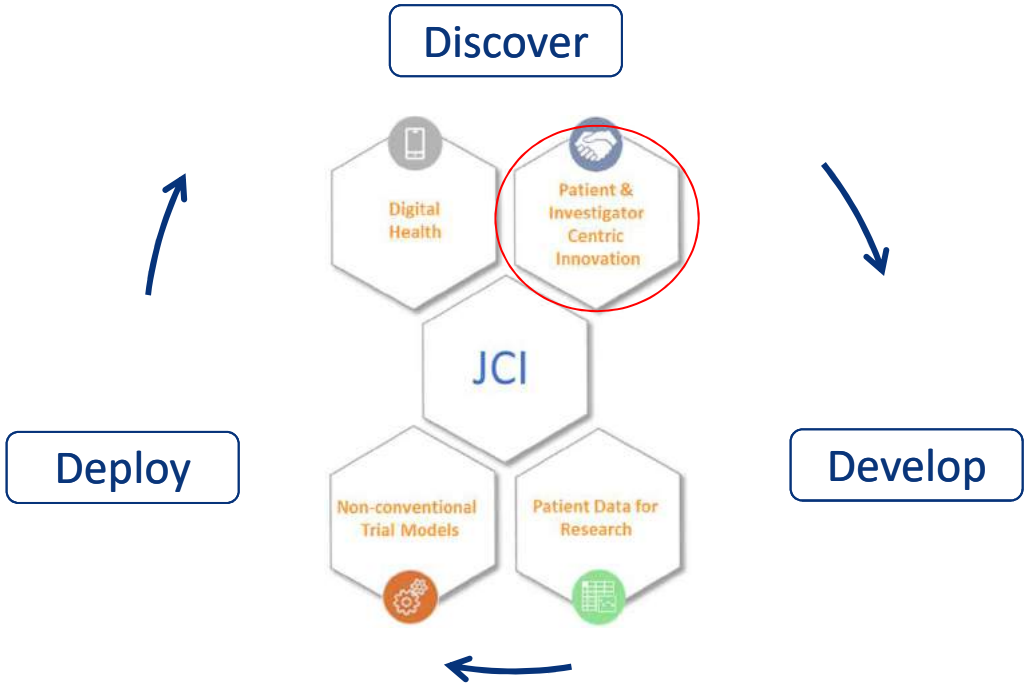
Janssen Clinical Innovation (JCI)

"Bringing Clinical Trials into the 21st century"



Informed Consent...

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Electronic Informed Consent...

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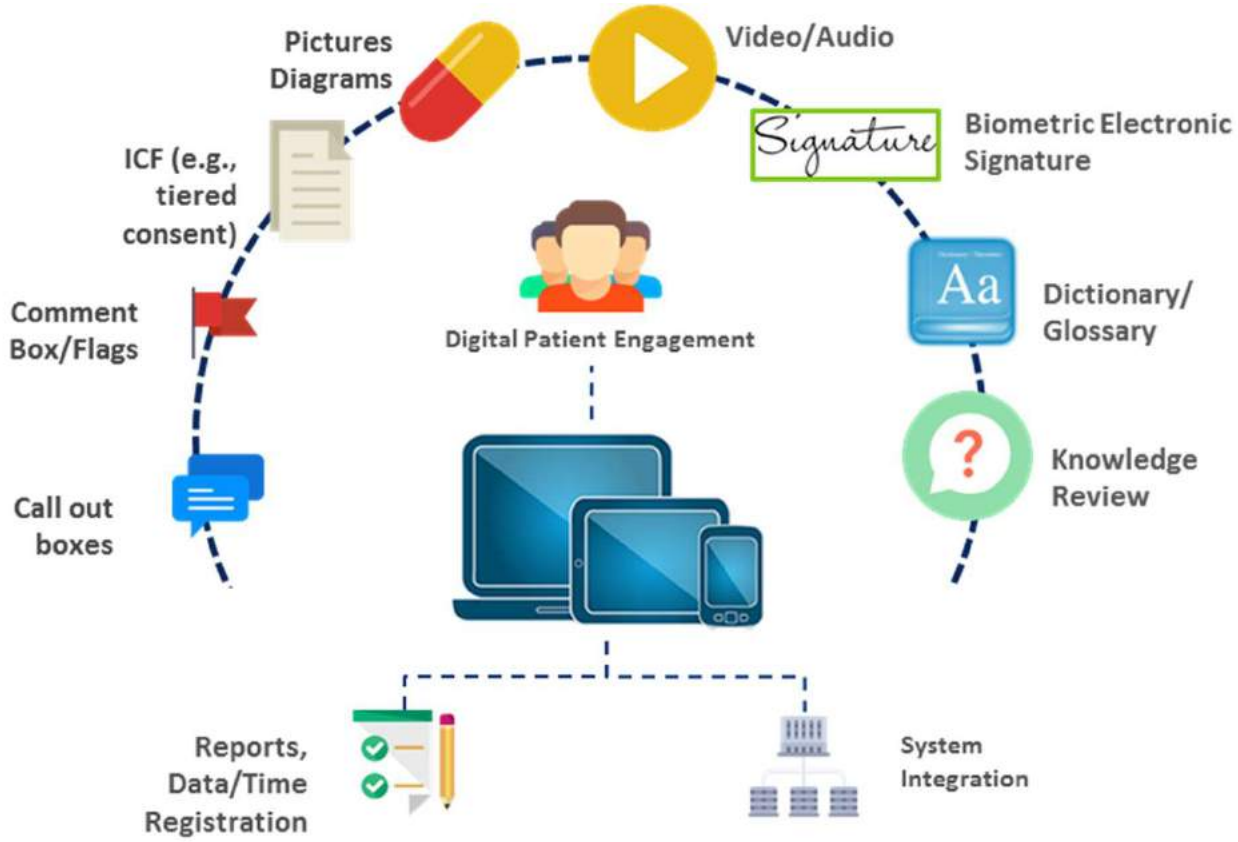
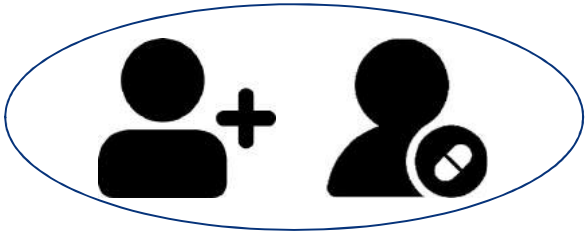
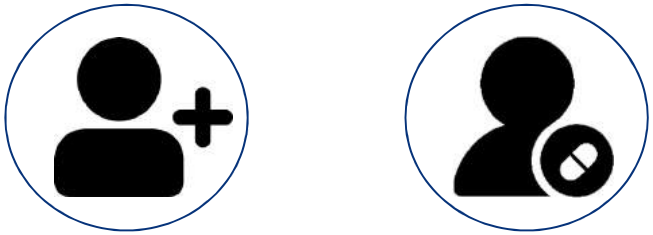

Pictures
Diagrams
Video/Audio
Signature
Biometric Electronic
Signature
ICF (e.g.,
tiered
consent)
Comment
Box/Flags
Digital Patient Engagement
Aa
Dictionary/
Glossary
Call out
boxes
?
Knowledge
Review
Reports,
Data/Time
Registration
System
Integration

eSignature ⟷ Print2Sign

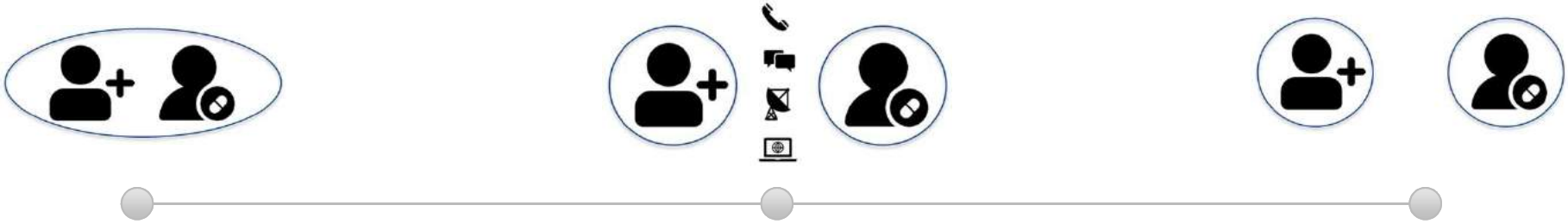
eConsent ≠ Remote consent



Investigator and subject
are co-located
at time of consenting



Investigator and subject
are **not** co-located
at time of consenting

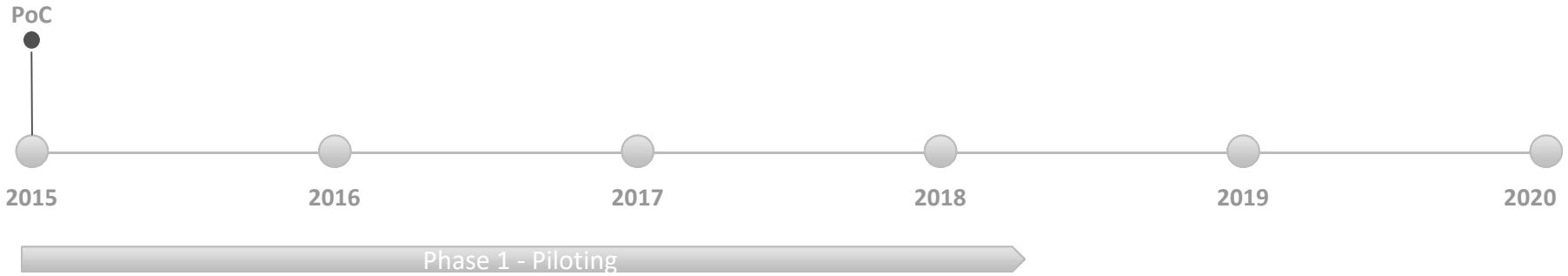


eConsent

Hybrid

Remote Consent

eConsent @ Janssen



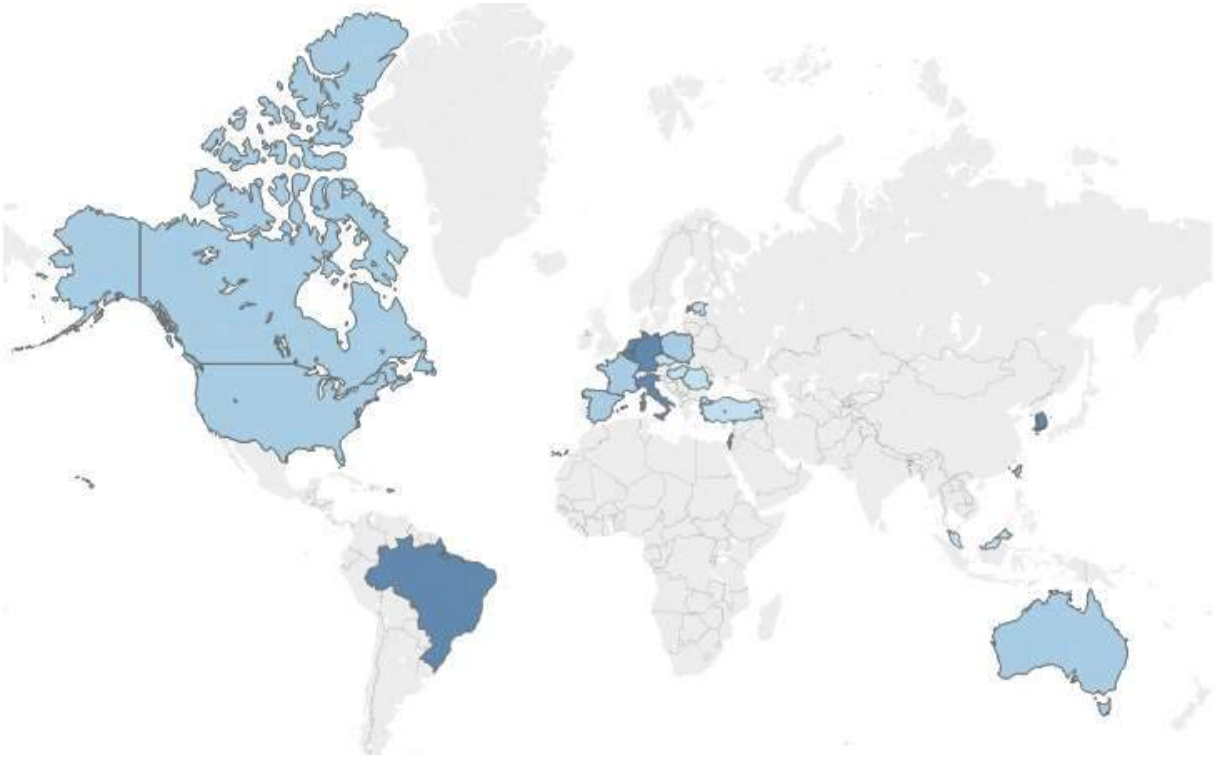
4+ years

eICF used in **10+** trials

eICF used in **14+** countries

eICF used in **95+** sites

eICF used by **500+** patients



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eSignature mainly used in US, Canada and Australia

Print2Sign mainly used in EU

Janssen eConsent Pilot Example 1:

Study with 76 eConsented patients, 13 sites, US & Hungary[1]

Patient Feedback

Collected via questionnaire

100% rated eConsent as **easy to very easy to use**
26% above 60 yrs

60% indicated **increased understanding as a key advantage**, next to

- ✓ I can be better prepared for the discussion with my doctor/site staff
- ✓ I can replay the video/repeat the process until I'm clear on what the trial is about

Very high satisfaction scores for the multimedia components, highlighting ...

- 96% video
- 94% knowledge review
- 92% handwritten signature on eDevice
- 90% mark unfamiliar words

74% **preferred eConsent** over traditional paper

Site Feedback

Collected via questionnaire

100% rated eConsent as **easy to very easy to use**

77% indicated that **eConsent improved the consenting process**

Reported **eConsent as an useful tool** for patients, highlighting...

- 69% Improved understanding
- 69% Improved engagement
- 62% Increased retention
- 38% Improved desire to enroll and willingness to stay in trial

Time impact on consenting process varied...

- **46%** no impact
- **31%** decrease or significant decrease
- **23%** increased

... noting that the ease of using eConsent improved over time

Note: Phase 3 Diabetes Study

1. Vanaken, H; Applied Clinical Trials. Aug 2016

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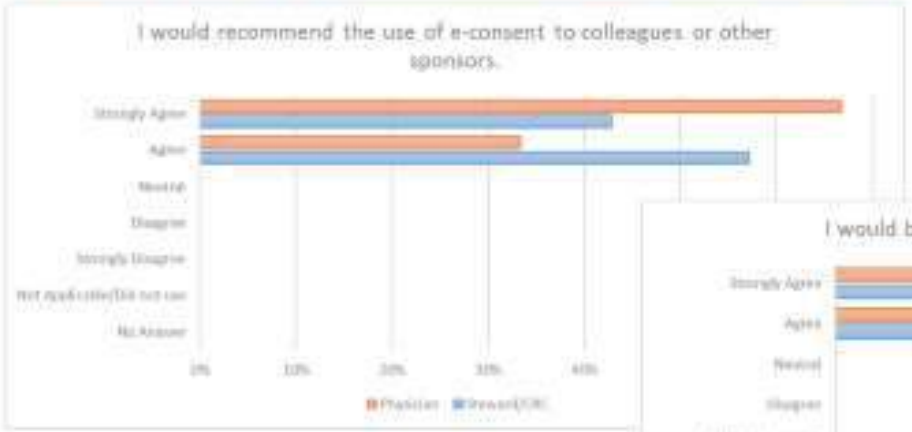
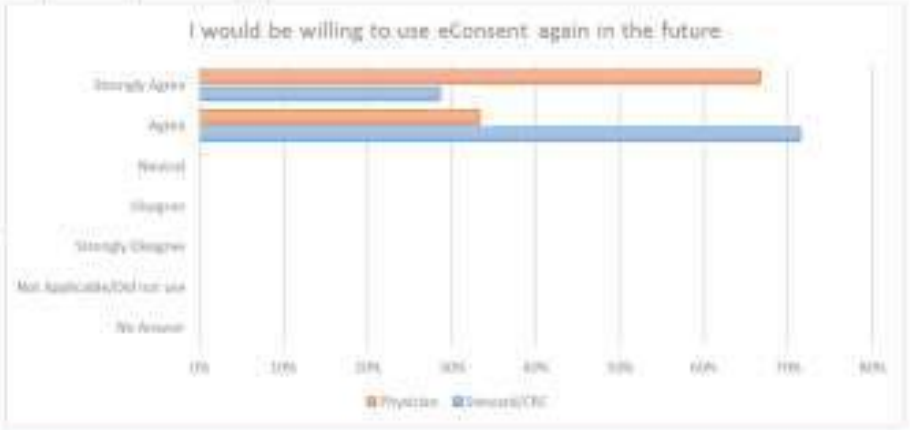
Janssen eConsent Pilot Example 3:

Study with 52 eConsented patients, 1 site, Belgium





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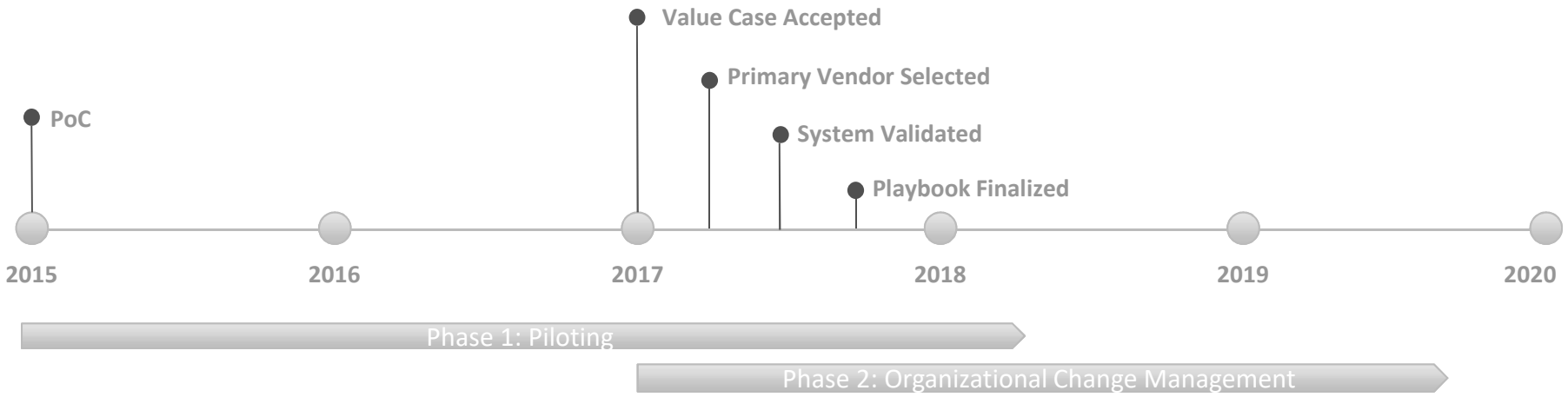
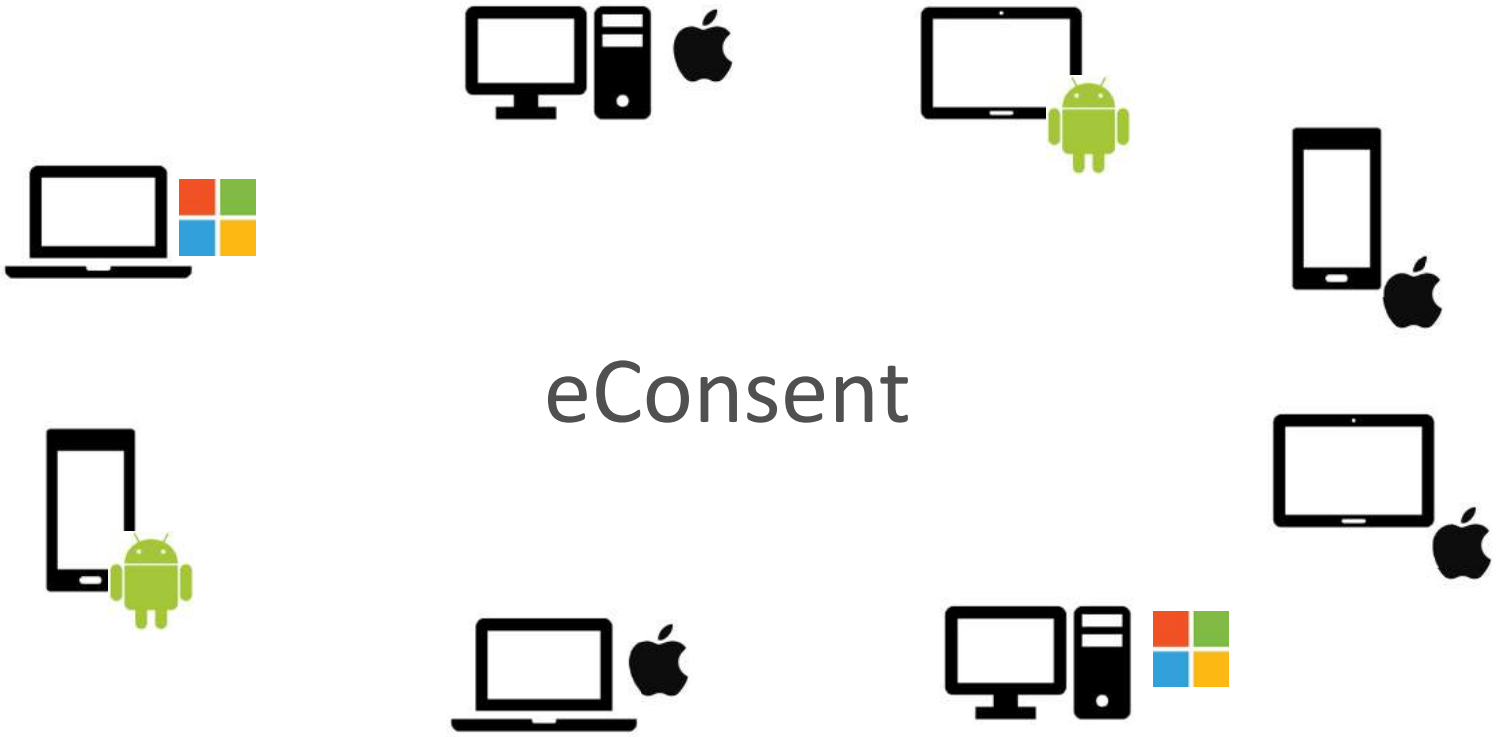
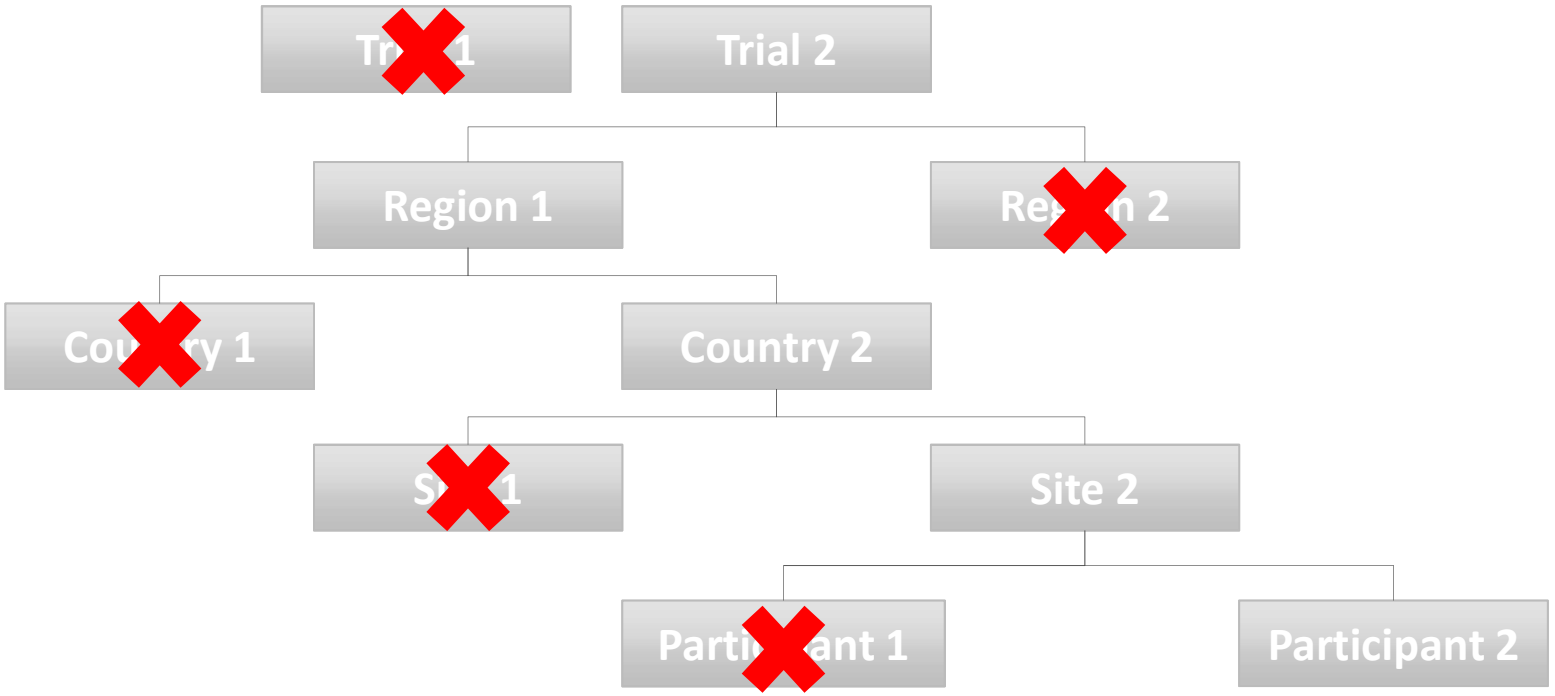
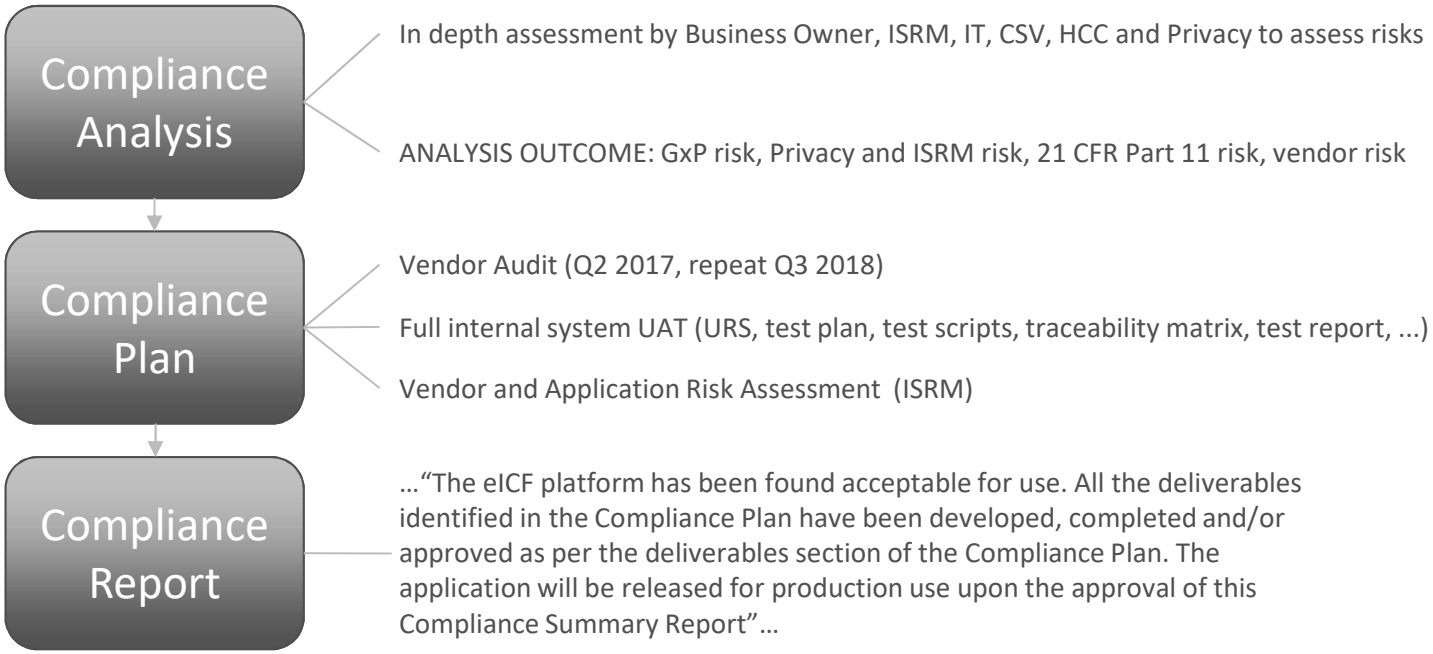



eConsent


Trial 2
Region 1
Country 2
Site 2
Participant 1
Participant 2

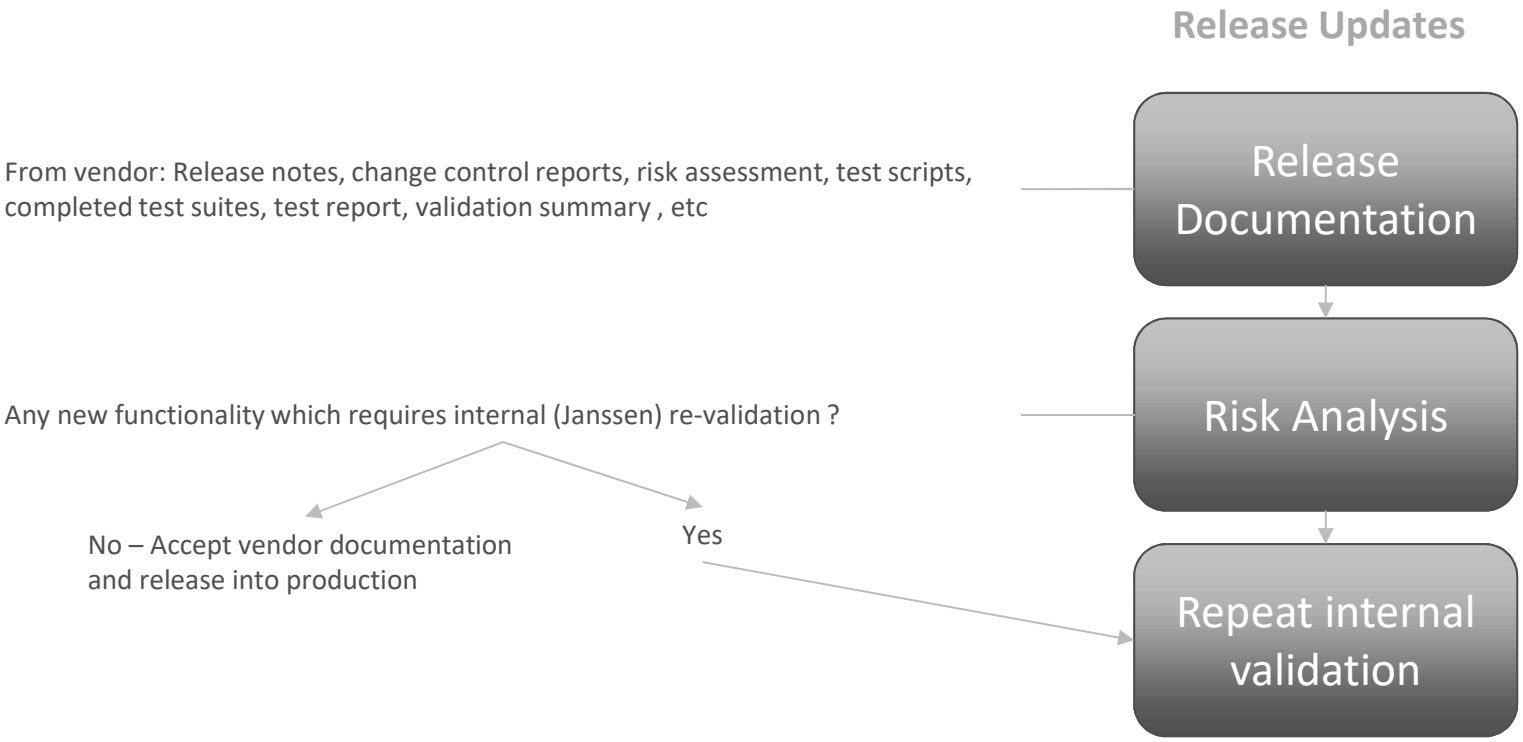
Validation Approach*

Initial Validation



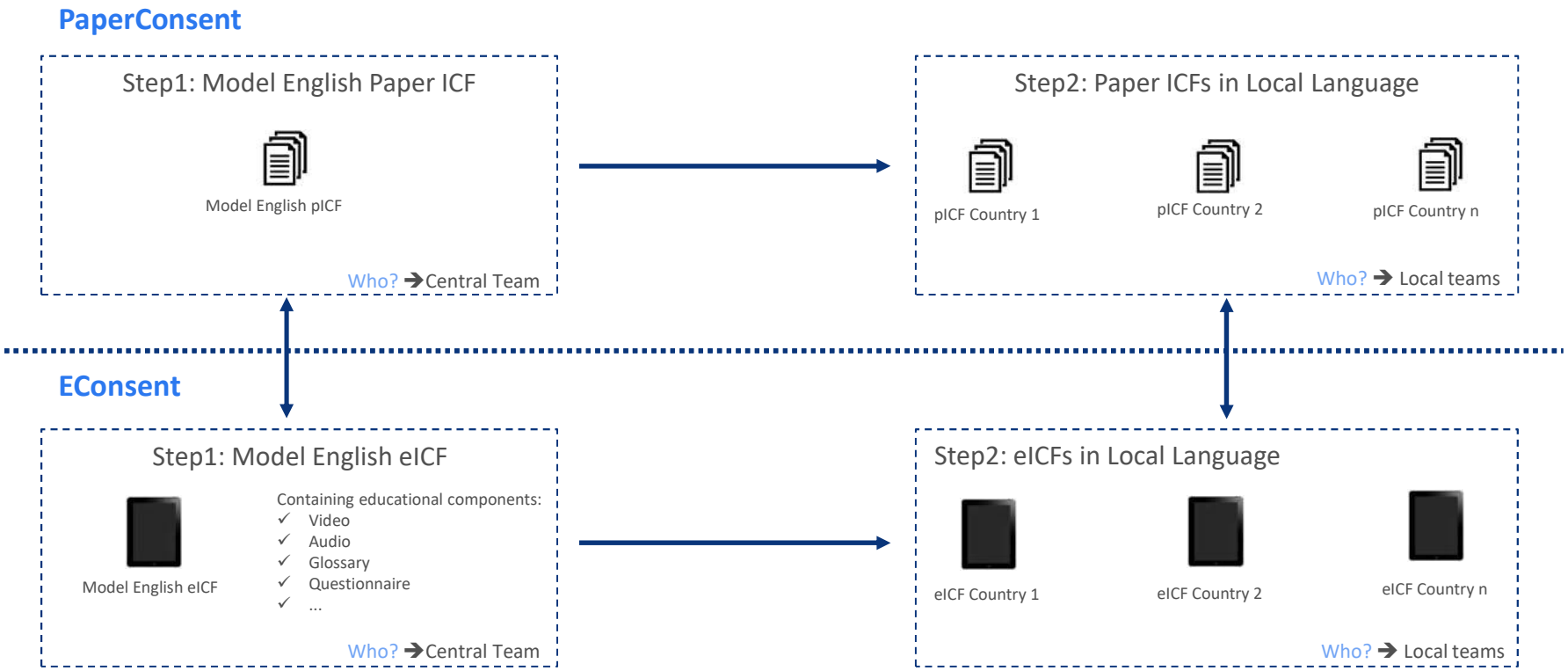
*According to Janssen SDLC SOP

Validation Approach*



*According to Janssen SDLC SOP

Development of an eICF



IEC and HA submission

Vendor prepared, submission-ready package containing:

- ✓ Cover letter, including attestation letter
- ✓ Transcript of the Glossary of terms (if applicable)
- ✓ Transcript of the Video Story Board (if applicable)
- ✓ Transcript of the Comprehension questionnaires (if applicable)
- ✓ eICF screenshots
- ✓ Login credentials for IRB/IEC and HA personnel wishing to view the eICF directly in the system
- ✓ Certificates of translation
- ✓ GDPR compliance statement
- ✓ Privacy Policy (sponsor)

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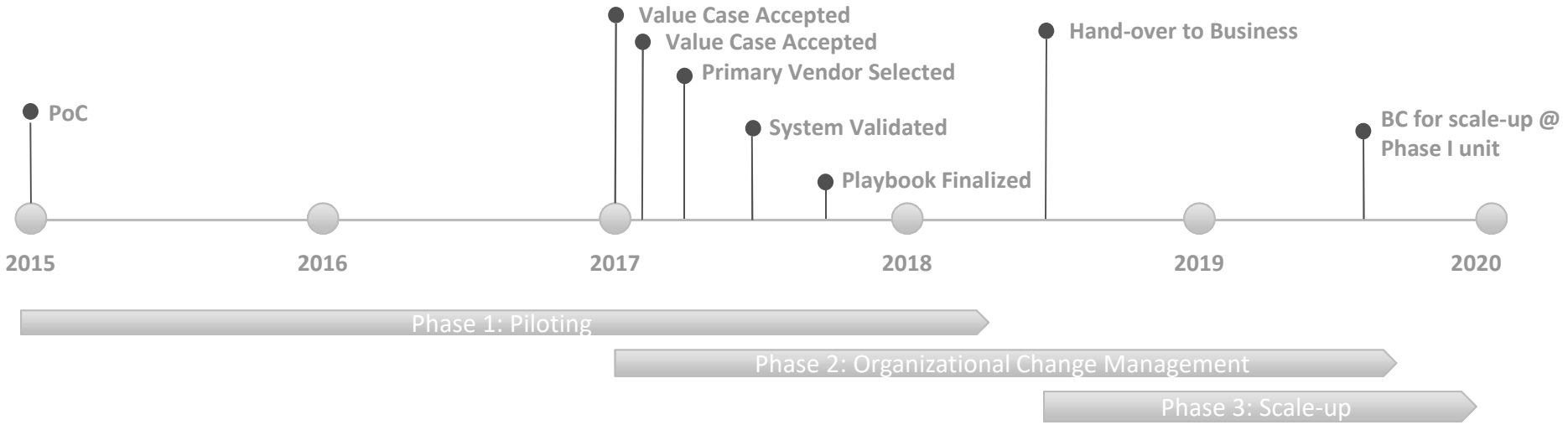


eConsent – Regulation and Guidance

General/Overarching	
ICH/GCP	21 CFR Part 11, 50 and 56
EU CTD/CTR + Translations into national laws	EMA - Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials
eIDAS	GDPR

eConsent specific	
US - FDA - Use of Electronic Informed Consent Questions and Answers – 2016	https://www.fda.gov/downloads/drugs/guidances/ucm436811.pdf
Swiss Ethics – eICF guidance - 2017	
EU – HRA and MHRA - Joint statement on seeking consent by electronic methods – 2018	https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

Medicines & Healthcare products Regulatory Agency

eConsent in Clinical Trials of IMP

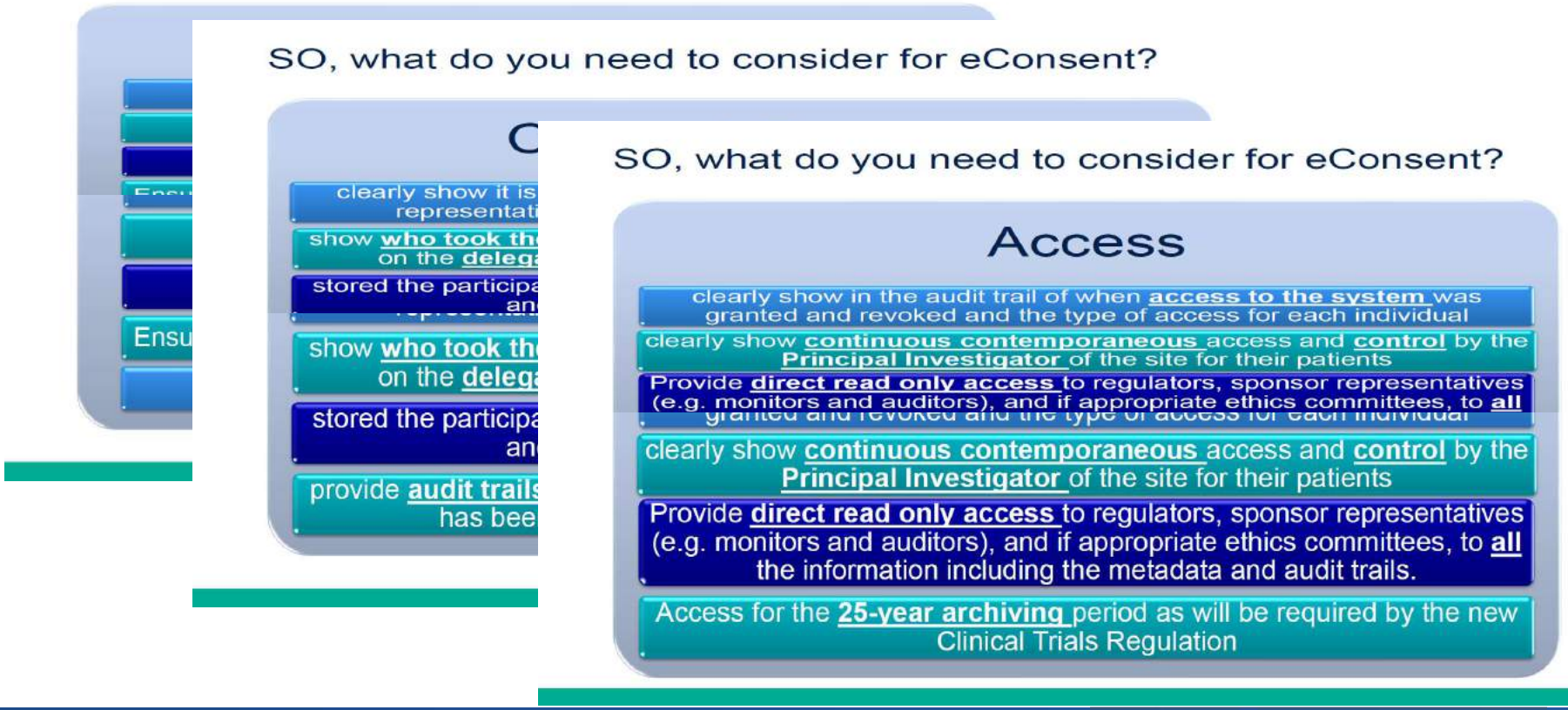
Jennifer Martin, GCP Operations Manager and Lead Senior GCP Inspector
Clive Collett, Ethics Policy Manager HRA
EFGCP Webinar September 2019

CPRD NIBSC

Issue with other eSystems

- Lack of audit trails (audit trials not switched on or not effective)
- No direct read only access for regulators and sponsor representatives
- Incorrect access controls for staff (e.g. sponsor staff given research site access to eCRF to make manual changes to data)
- Poor validation/lack of validation resulting in systems not fit for purpose (e.g. IRT systems not built as per the protocol / do not correctly dose adjust based on protocol criteria / need manual process for protocol compliance)
- Systems not released appropriately (e.g. before MHRA/REC approval)
- Poor validation/lack of validation resulting in systems not fit for purpose (e.g. IRT systems not built as per the protocol / do not correctly dose adjust based on protocol criteria / need manual process for protocol compliance)
- Systems not released appropriately (e.g. before MHRA/REC approval)
- Archive of flat PDF files and not the metadata and audit trials
- No access allowed by the system providers to audit/inspect the software/platform supplied

SO, what do you need to consider for eConsent?



Back-up

Simple

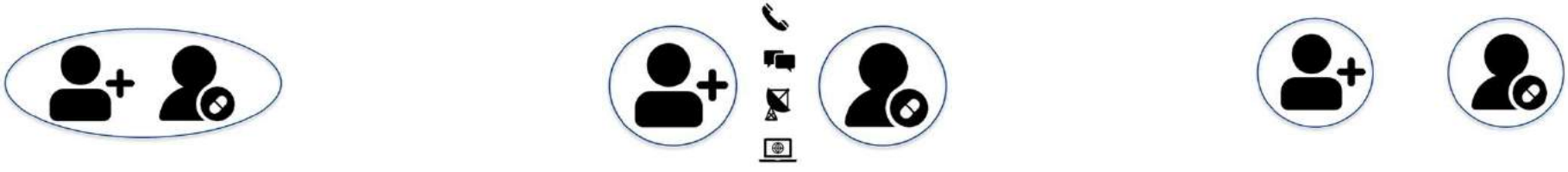
- ✓ Data in electronic form
- ✓ Attached to other data in electronic form
- ✓ Used by the signatory to sign

Advanced

- ✓ Uniquely linked to the signatory
- ✓ Capable of identifying the signatory
- ✓ Allows the signatory to retain control
- ✓ Linked to the document in a way that any subsequent change of the data is detectable

Qualified

- ✓ Created by a qualified signature creation device
- ✓ Based on a qualified certificate for electronic signatures.

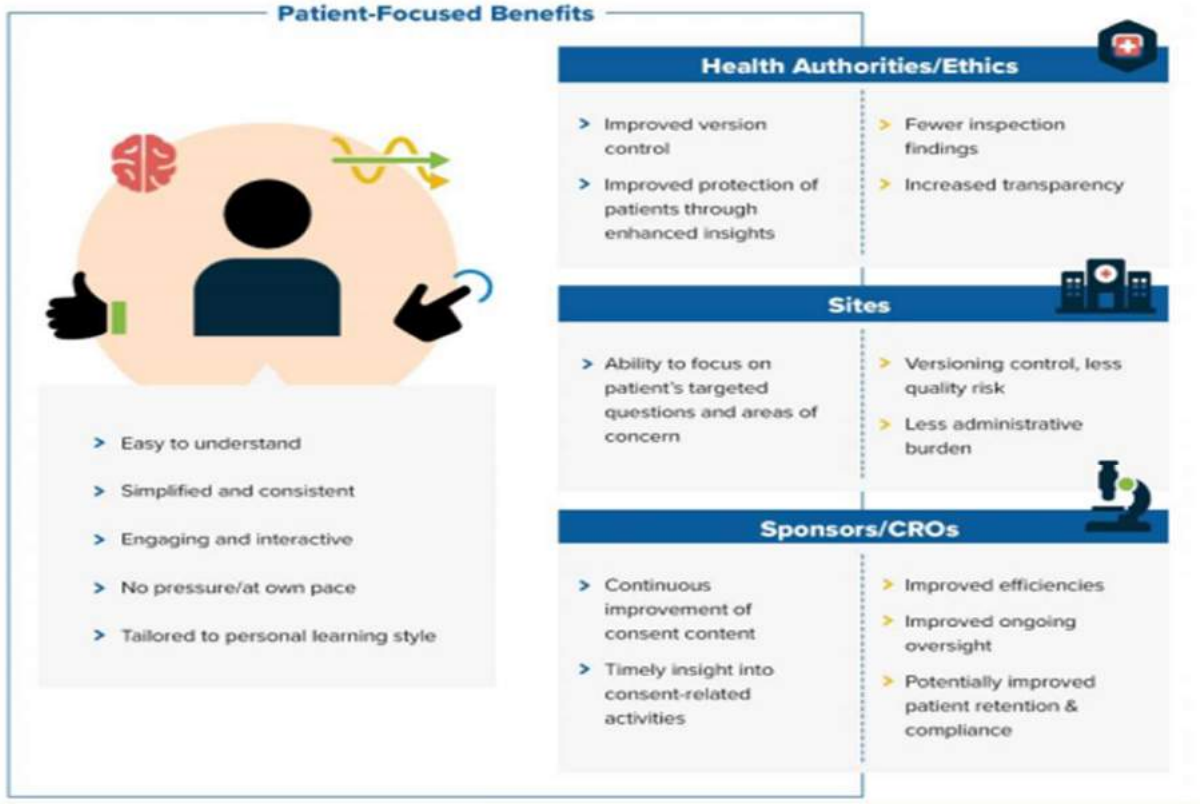


Simple

Advanced

Qualified

Benefits of eConsent



Source = TransCelerate Biopharma Inc.