Electronic Consent:

Obtaining & Documenting Informed Consent When the Patient is Not in the Room

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Agenda

- Industry Shifts & The Evolution of Data
- Defining eConsent and Suitability
- Requirements and Best Practices
- The Patient Experience and Impact to Current Processes
- Overcoming Adoption Barriers
- Question and Answer Period

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Industry Shifts

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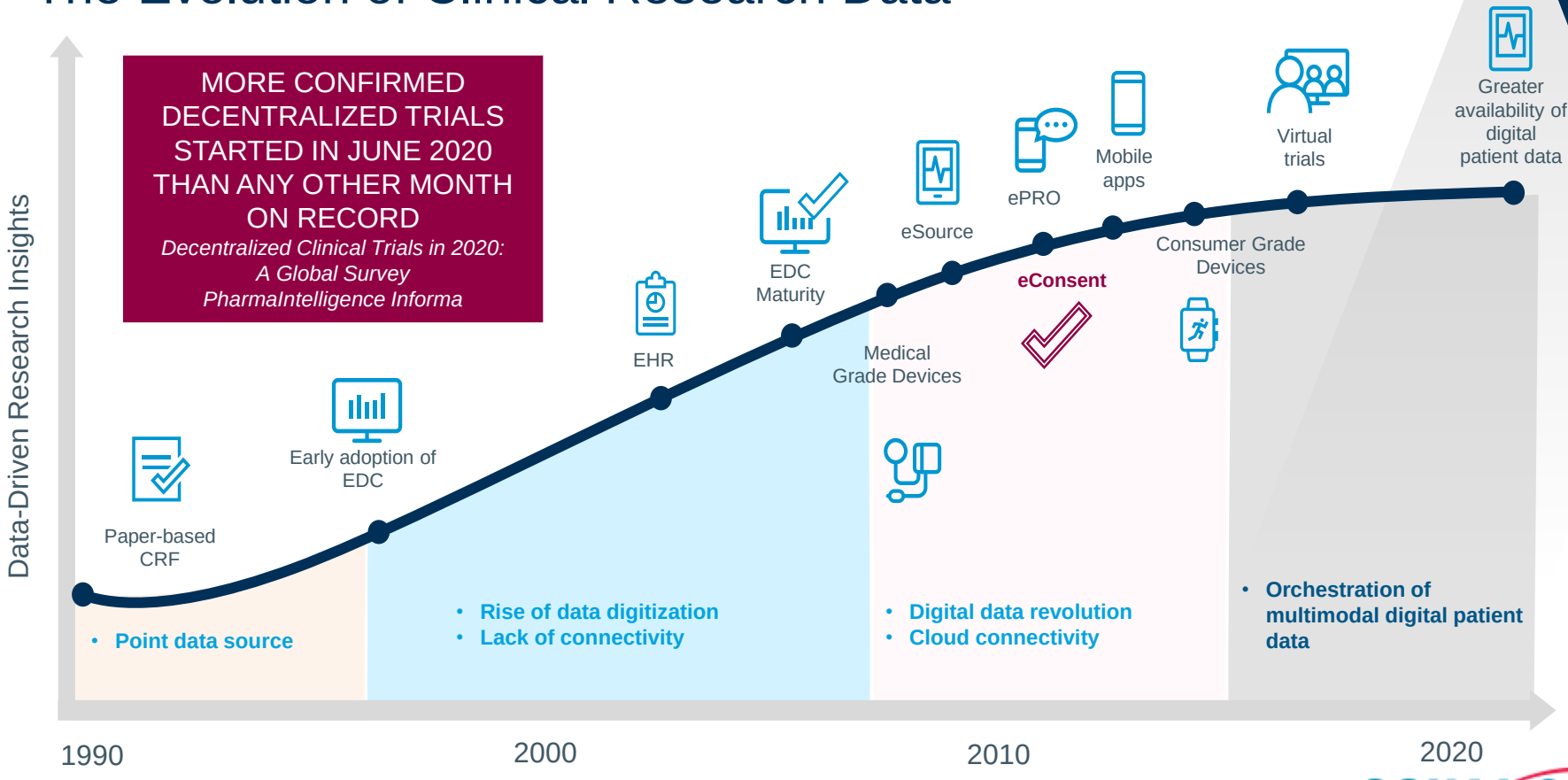
The Evolution of Clinical Research Data



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eConsent Defined

THE **DIGITIZATION** OF THE **CONSENTING PROCESS**

A **DYNAMIC** AND **CONFIGURABLE** MULTI-MEDIA SOLUTION

ENABLES SHIFT OF **TRIAL ACTIVITIES INTO THE HOME**

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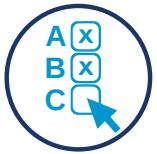
eConsent Multimedia Components

SIGNATURE INTEGRATION

DocuSign, Adobe Sign, Free-form signatures

LANGUAGE OPTIONS

Select language of preference for audio content



KNOWLEDGE CHECKS

Provide knowledge checks to patients to ensure understanding and identify gaps for discussion

DOWNLOADABLE ICF

Store and log any sessions recorded in a secure environment

VIDEO/ AUDIO CONTENT

Integrate video training and audio recording into the app

SUMMARY BOXES

Providing section highlights

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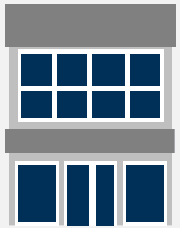
Benefits



Sponsor/ CRO

- Decreased inspection findings due to improved version control
- Improved oversight via immediate notification of signed consent
- Timely monitoring of informed consent data
- Reduced CRA time on site

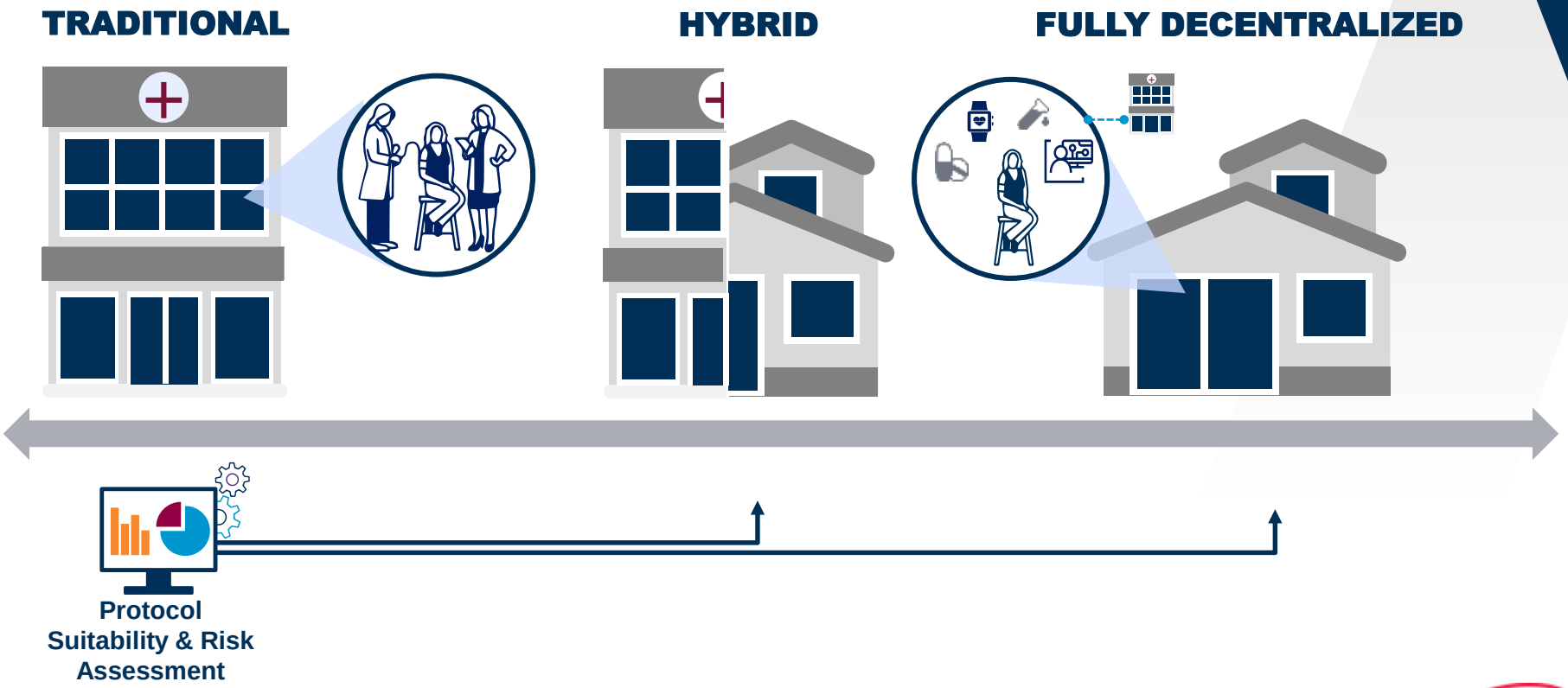
Site

- Facilitates version tracking leading to fewer inspection findings
- Ensures consistent messaging to all participants
- Reduced administrative burden

Patient

- Self paced learning
- Ability to complete remotely
- Family, caregiver, LAR involvement in consent review
- Informed of updated information in timely manner

The eConsent Continuum



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Subject Suitability

Pediatric	Language and presentation must be understandable to a child
Rare Disease	Reduced need for long distance travel and patient inconvenience
Visually Impaired	Patient should have the choice of paper based or eConsent

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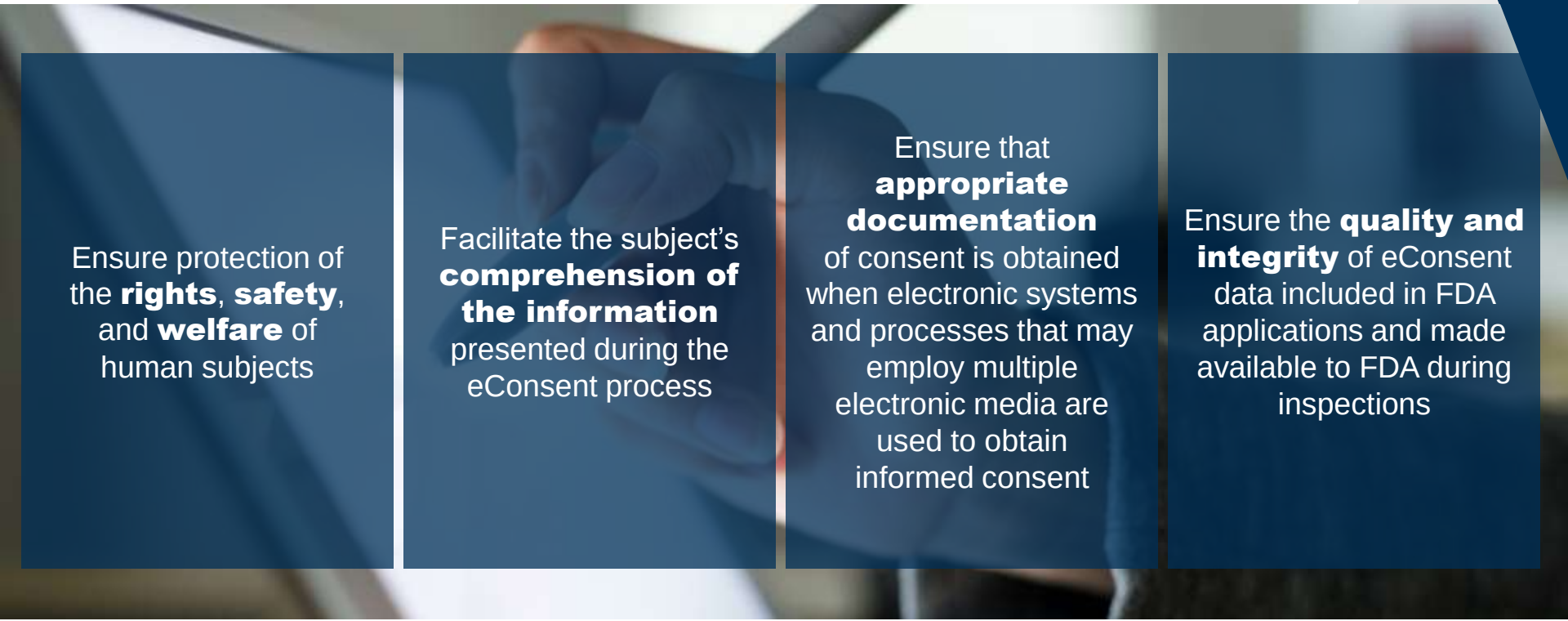
Regulatory Requirements

Modality Changes, Requirements Do Not:



Ensure protection of the **rights**, **safety**, and **welfare** of human subjects

Facilitate the subject's **comprehension of the information** presented during the eConsent process

Ensure that **appropriate documentation** of consent is obtained when electronic systems and processes that may employ multiple electronic media are used to obtain informed consent

Ensure the **quality and integrity** of eConsent data included in FDA applications and made available to FDA during inspections

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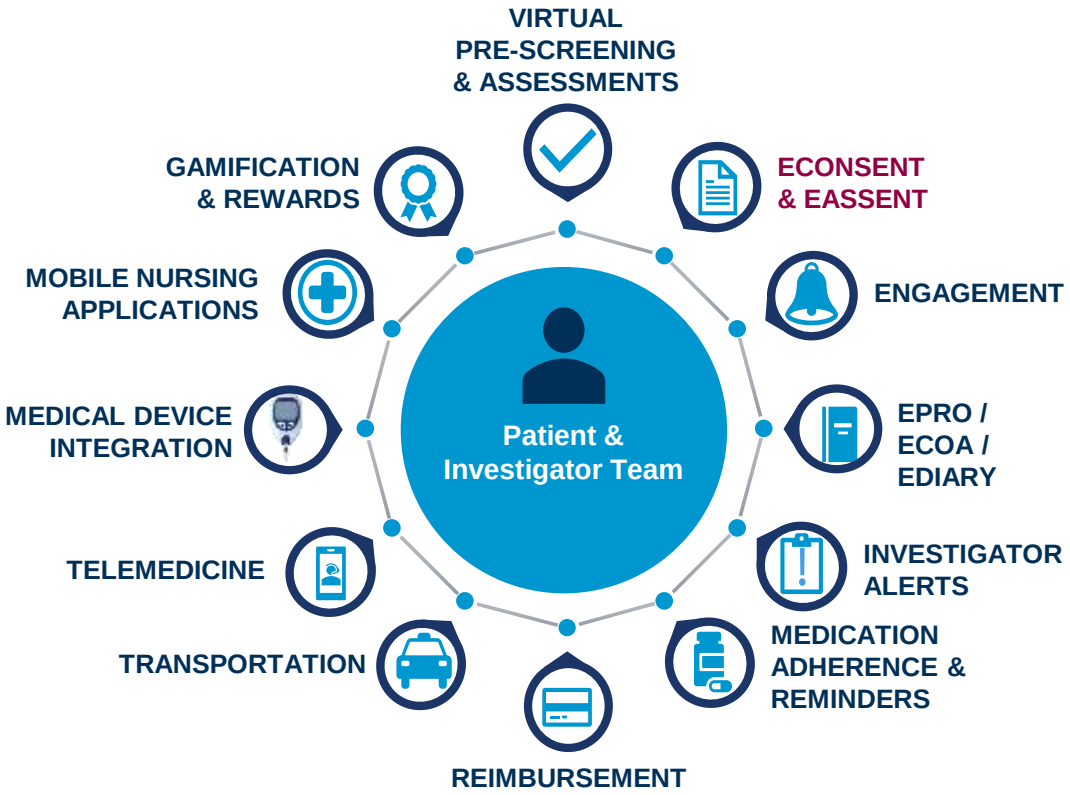
Technology Platform Requirements



- **21 CRF Compliant**
- **Restricted Access**
- **Secure**
- **Capture Date of Signature**

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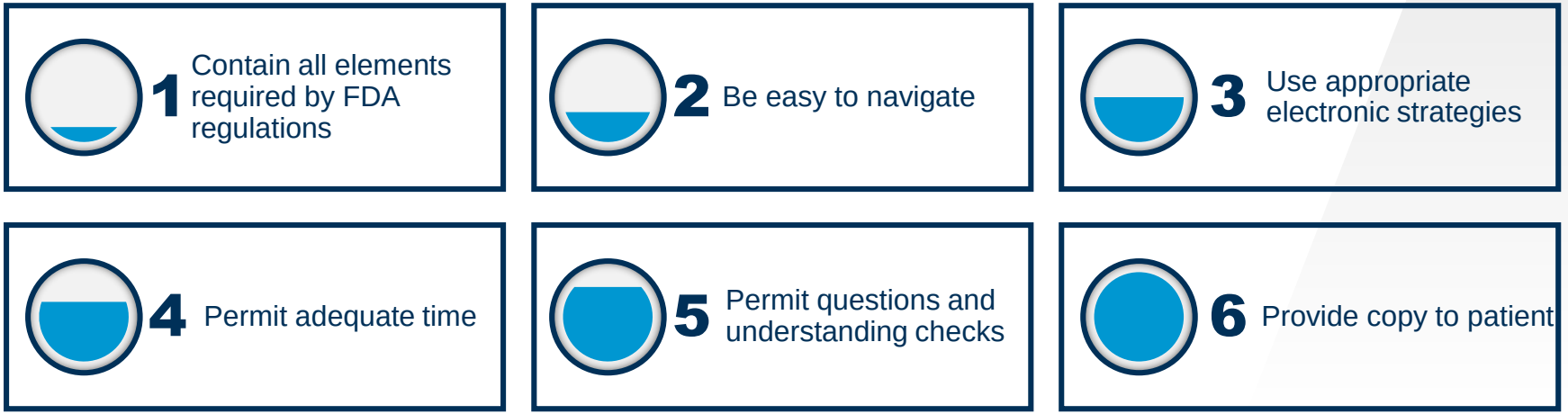
Presenting eConsent to Participants

OHRP and FDA, eIC Must:



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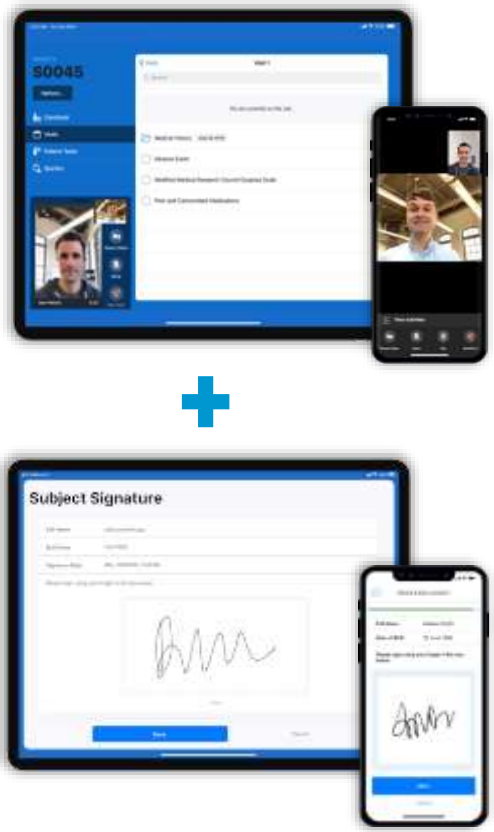
eConsent Administration



SUPPORT PATIENT ENGAGEMENT PROCESSES

Support the consenting process and discussion, ensure understanding

SCREEN SHARING

Allow the clinician to share any documents for discussion

LIVE DISCUSSION/INSTANT MESSAGING

Use other methods of communication for preference

TEAM CALLING

Support sessions that include the patient, caregivers, LAR and clinicians

SUPPORT TECHNOLOGY NAVIGATION

Support patients with technology navigation as required

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Impact to Study Start-Up

Process Flow

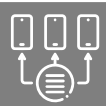
Decision to use eConsent

Standard process ICF development

Materials provided for EC submission

EC submission/ approval

eConsent release to Platform



Device provisioning

Site and Patient training

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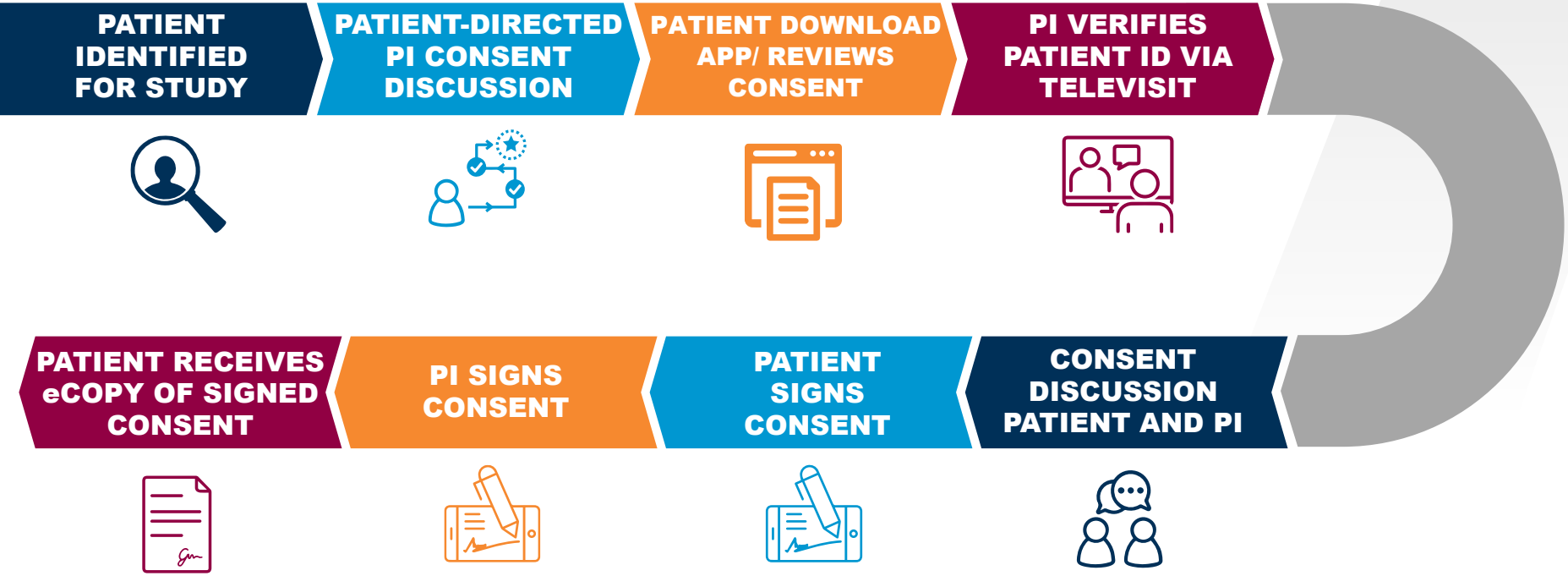
The Patient Experience: Remote



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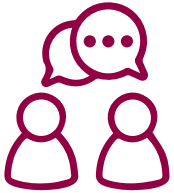
The Patient Experience: Onsite

1. PATIENT IDENTIFIED FOR STUDY

2. PATIENT REVIEWS CONSENT WITHIN PATIENT APP

3. PATIENT AND PI CONSENT DISCUSSION



4. PATIENT SIGNS CONSENT

5. PI SIGNS CONSENT

6. PATIENT RECEIVES COPY OF SIGNED CONSENT

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Centralized Monitoring of eConsent

1 CRA logs into platform

2 Verifies that the approved version of the consent is available

3 Verifies approved version used for each participant

4 Reviews source documents pertaining to consent

5 Verifies against EDC data

6 Review/collects regulatory documentation

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Overcoming Adoption Barriers

- Demonstrate success to ease concerns
- Gather participant feedback
- Build awareness around unchanged requirements and similarities to paper-based process
- Further regulatory guidance will ease concerns

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Key Messages

eConsent enhances the patient experience

A change in how consent is administered, not process

Fundamental principles and requirements do not change

Protocol and Subject Suitability must be assessed

Paper ICF
- Complex language
- Long forms

Electronic Consent
- User-friendly navigation and content
- Review at patients own pace
- Integrated tools
- Targeted discussions
- Improved version control

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References

eConsent: Implementation Guidance (eConsent Initiative).
Transcelerate BioPharma Inc.
https://www.transceleratebiopharmainc.com/wp-content/uploads/2017/10/eConsent-Implementation-Guidance.pdf

Decentralized Clinical Trials in 2020: A Global Survey
PharmaIntelligence Informa

Use of Electronic Informed Consent: Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors
Office for Human Research Protections, Food and Drug Administration
https://www.fda.gov/media/116850/download

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Question & Answer

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