phuse·virtual

Single Day Event

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Technology Enablement for Decentralized Clinical Trials

phuse.global

Highlighting Known Data Points …

1 out of 2 Investigators participate in clinical research only once

Less than 5% of patients participate in clinical research

30% patients screened, fail to meet study-specific protocol requirements

48% of studies take significantly longer time to meet enrolment targets

70% patients live more than 2 hours of travel from research site

In 50% of trials, patients find it difficult to stay enrolled due to poor health

About 20% of patients drop out in clinical trials

85% of clinical trials fail to retain enough patients

Decentralized Clinical Trial

- Virtual
- Digital
- Remote
- Site-less
- Direct-to-Patient

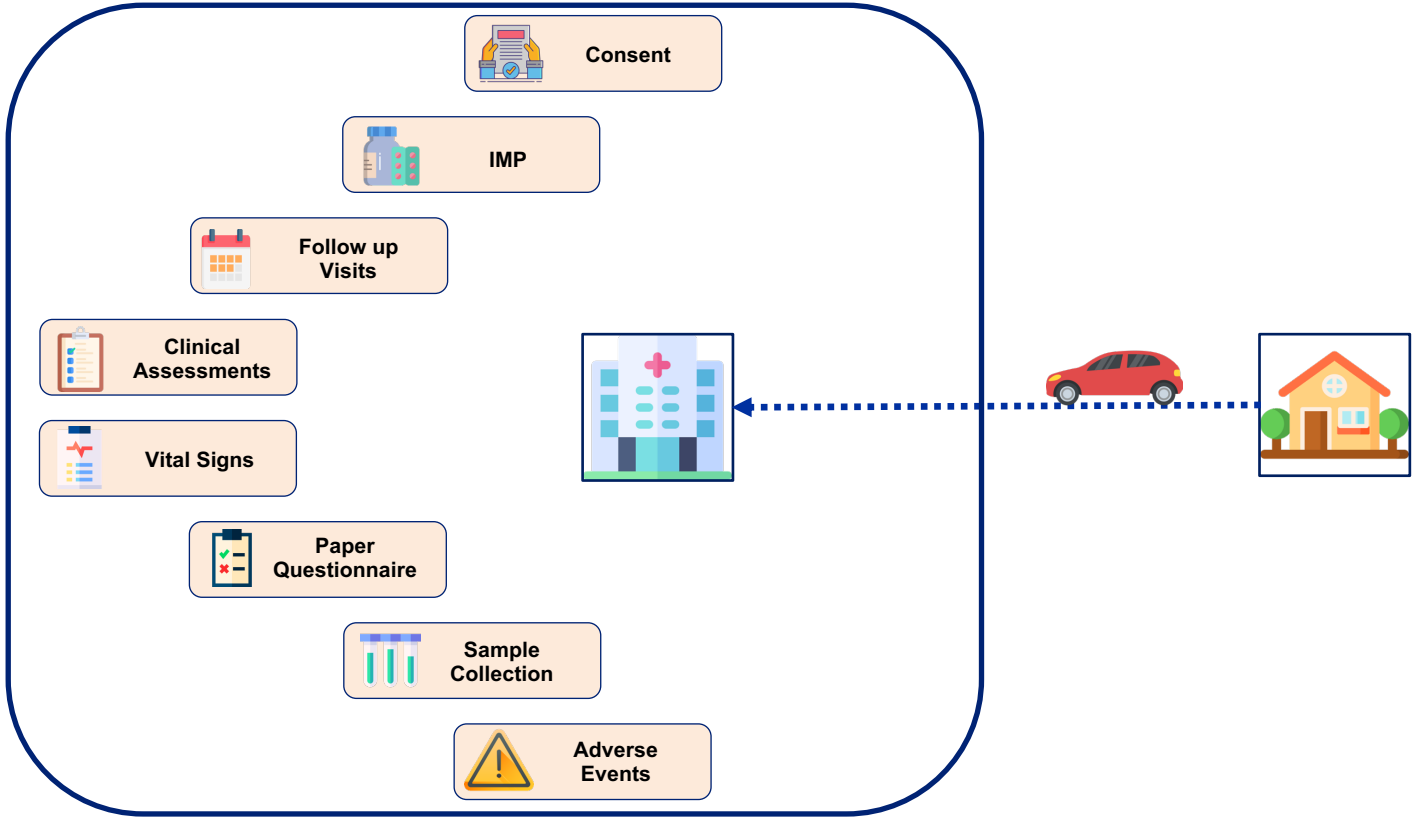
GOAL

Make Clinical Trial Easier for Patients, Caregivers and Industry

- **Patient Centricity**
- **Population Diversity**
- **Patient Recruitment**
- **Patient Retention**
- **Remote Data Collection**
- **Reduced SDVs**
- **Additional Capacity at Site**

Decentralization is a transformational philosophy for the conduct of clinical trials; fewer in-clinic visits; patient and caregiver burden is reduced; and a wide range of digital technologies deployed

Traditional Clinical Trial Is Site-centric



Patient-centric Decentralized Clinical Trial

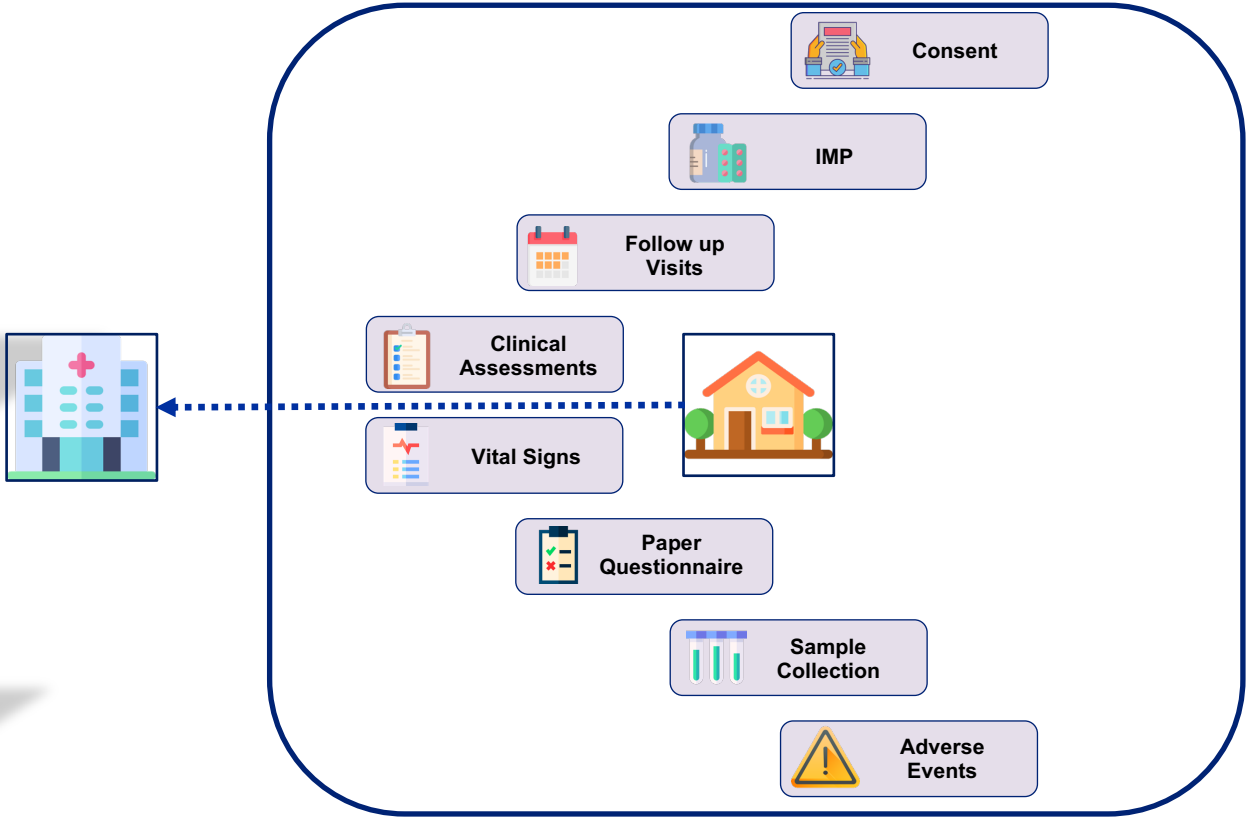
Decentralisation does not mean

- absence of healthcare professionals
- eliminating physical patient contact

It is about looking at areas where digital technology, mix of in-clinic & tele-visits, and other novel solutions can help

Regulator's view

- More frequent, sensitive, and objective measures from digital tech help teams answer research questions faster and cheaper.



Technology Solutions Around The Patient

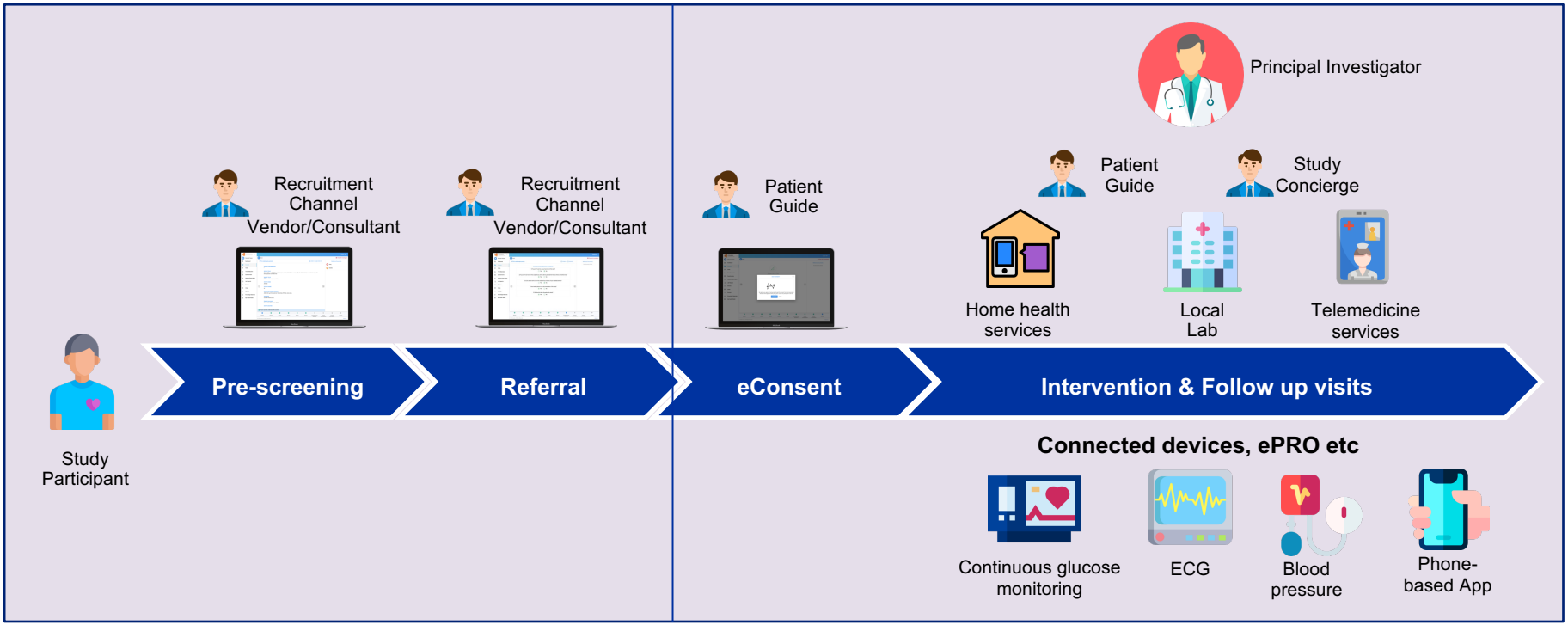
Site-Based

Home-Based

Consent	*eConsent*
IMP	*Direct To Patient IMP*
Follow-up Visits	*Text / Video Chats / Tele-visits*
Vital Signs	*Devices / Wearables*
Paper Questionnaire	*ePRO / eCOA*
Sample Collection	*Home Health Nurse*
Adverse Events	*eAdverse Events Reporting*

Reduce The Burden For Both Patient & Site

Patient-Centric Study Conduct Infrastructure



eRecruitment

Accelerate Enrolment

1

Patient / Caregiver lands on eRecruitment App via digital lead gen

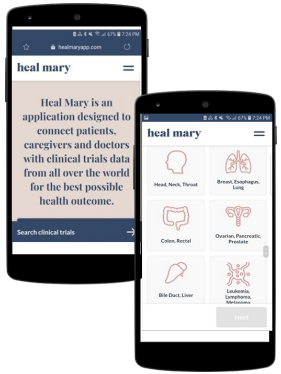
Uses search criteria to identify trials

Finds a trial, if key criteria is met, expresses willingness to join trial

Patient is then onboarded on e-consent portal

Doesn't find a trial - given an option to opt-in for future matching

Notified as soon as additional trials matching trial is available

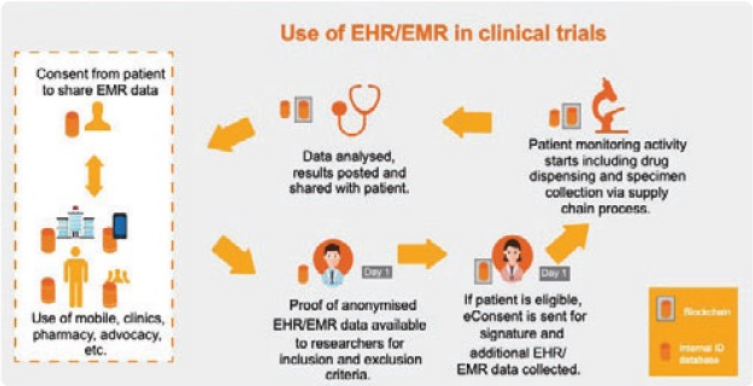


2

The PHUSE Blockchain Phase II Project (Report dated 02 Dec 2020)

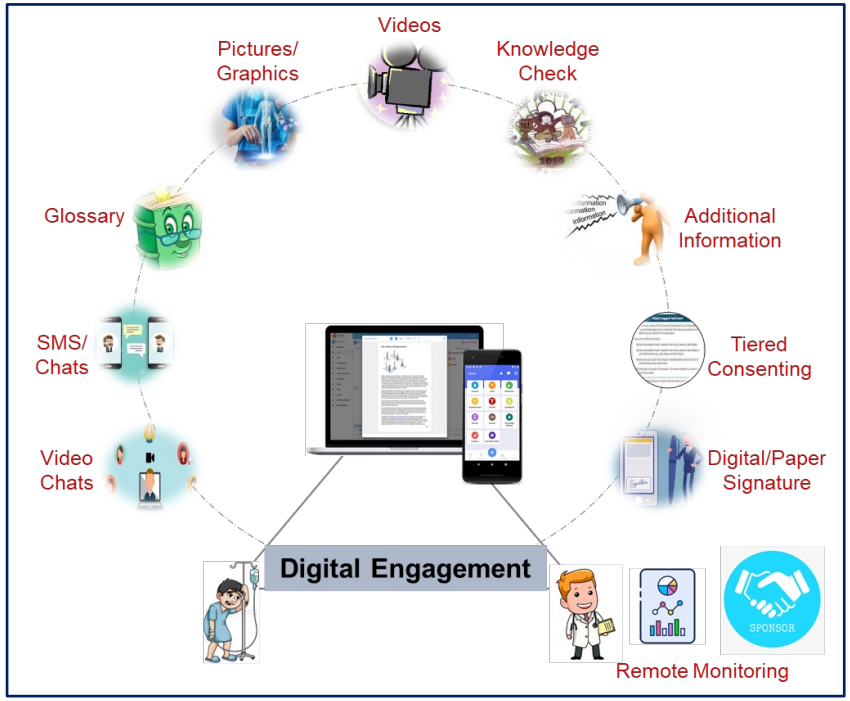
PoC study for accessing and sharing sensitive patient data for pre-screening of patients for clinical trial participation

Use Case: Patient recruitment for clinical trials



eConsent

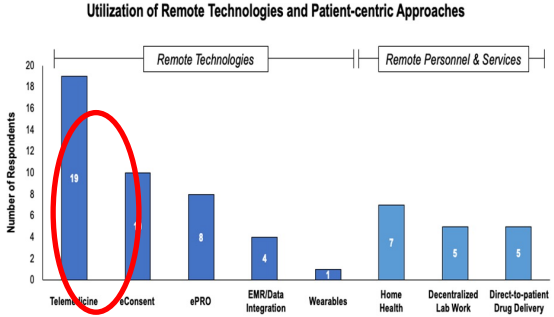
Increase Comprehension



Perceived barriers towards adoption

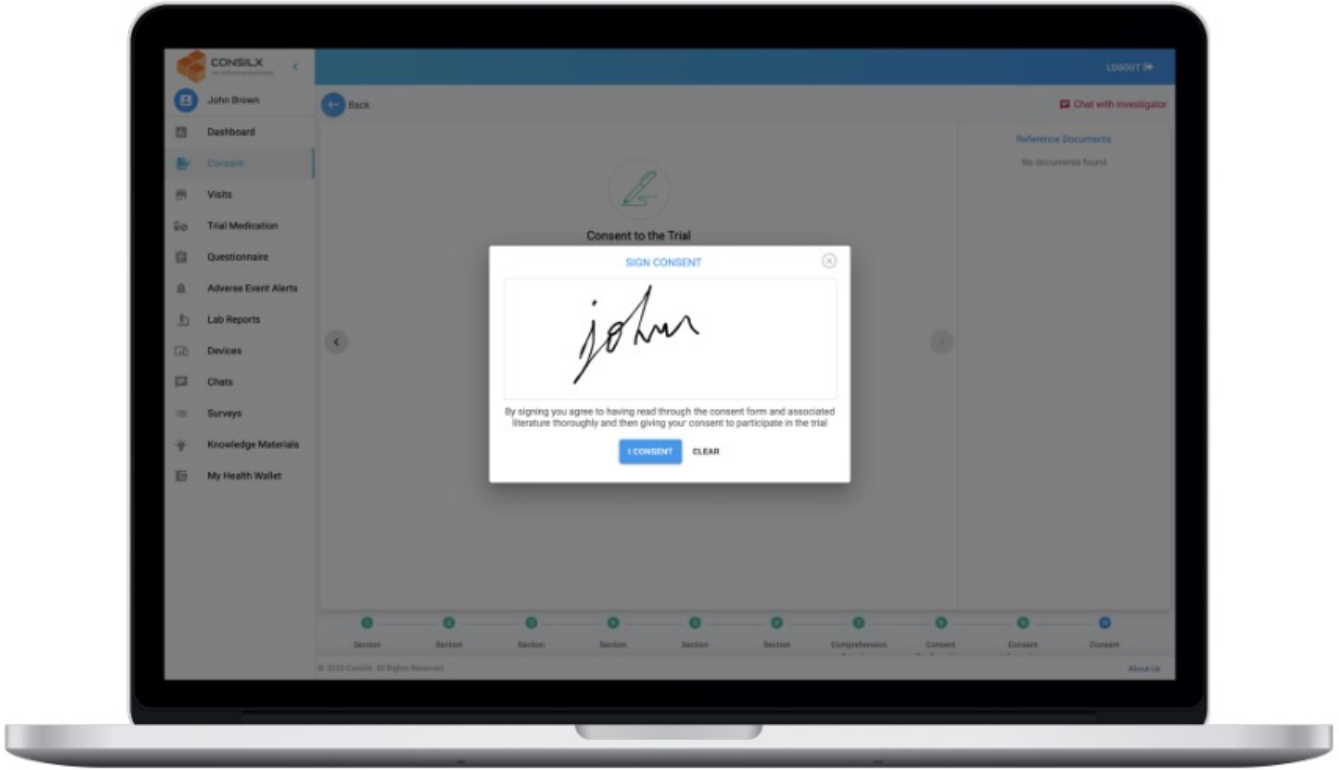
- *Literacy*
- *Tech Savviness*
- *Confidentiality, Integrity*
- *Cost Effectiveness*

Survey conducted by Tufts on impact of Covid-19 on future of trial execution



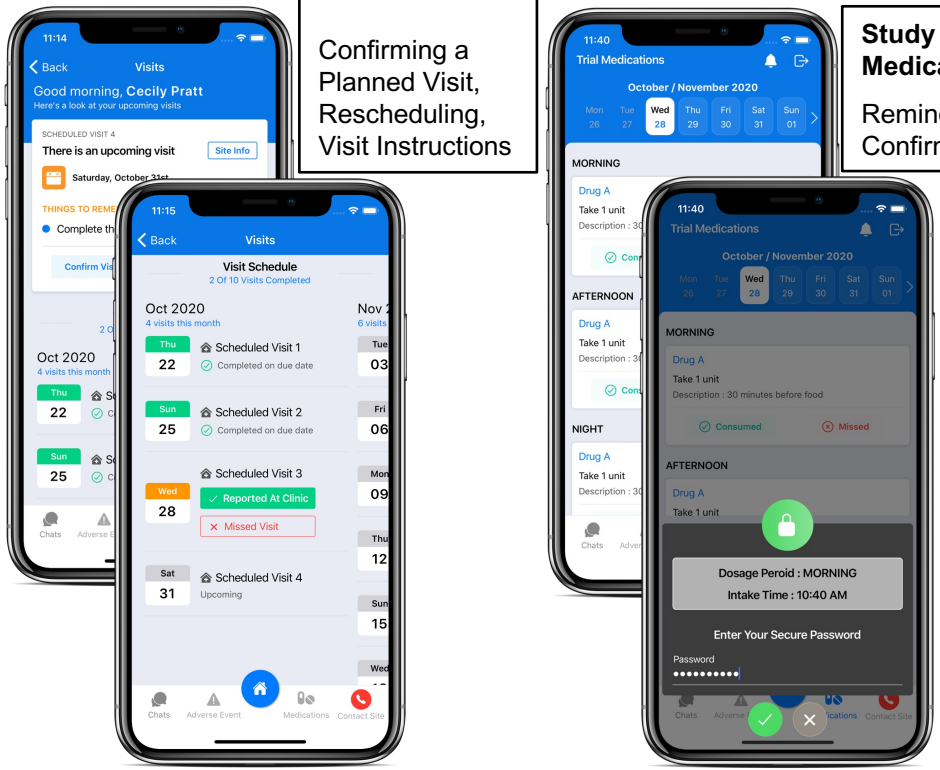
eConsent Platform: Quick View

Increase Comprehension



Patient Engagement Apps

Influence Behaviour



Visits Trackers

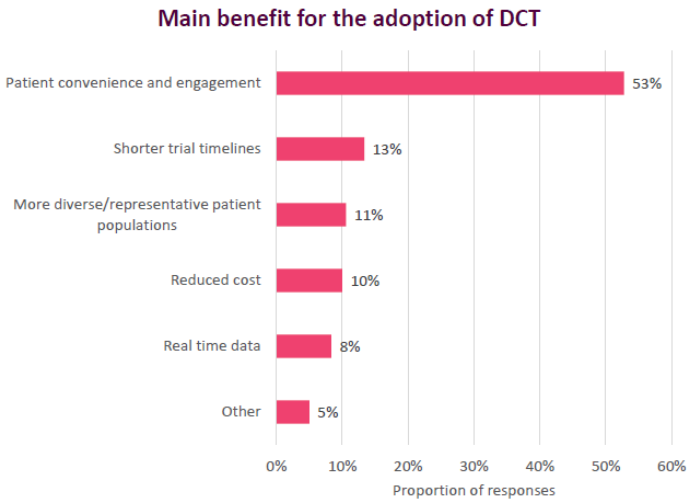
Confirming a Planned Visit, Rescheduling, Visit Instructions

Study Medications

Reminders, Confirmation

Benefits of DCTs

Patient centricity is recognized as the biggest asset of a decentralized study

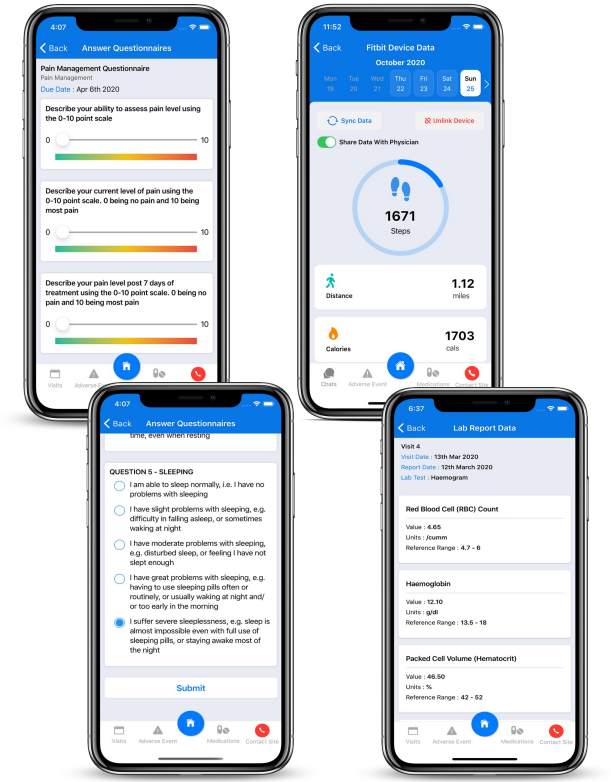


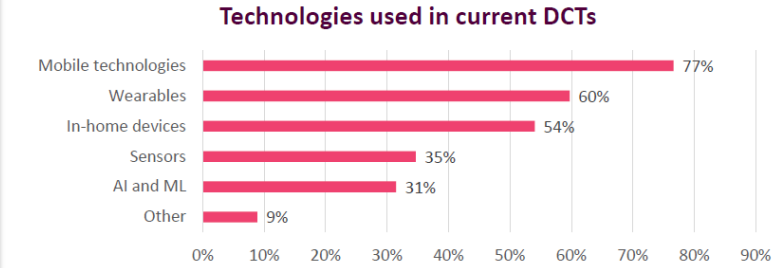
Source: Informa Connect; NEJM Catalyst

Direct Data Collection Solutions

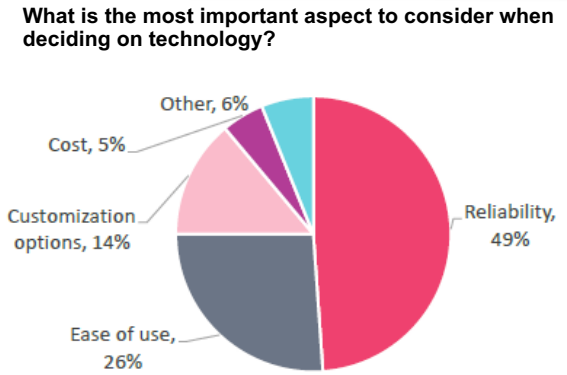
Remote, Real-time, Accurate Data

- eSource
- Adverse events alerts
- Patient diaries
- Questionnaires
- QoL
- Surveys
- Symptoms
- Images
- Videos
- Devices
- Wearables
- Lab / 3rd parties





Source: Informa Connect; CTTI



Source: Informa Connect; CTTI

IRB Approved Proof of Value Study Conducted By HITLAB, A Digital Health Research Lab (Nov 2008)

Patients

In numbers

- **75%** participants needed no support to setup
- **87%** patients completed consent remotely
- **86%** compliance to completing questionnaires
- **75%** medication adherence reporting

What worked?

- Usability: navigation, understanding, layout
- Perform trial activities remotely
- In-app activities, reminders promoted adherence
- AE reporting feature preferred over other methods
- Viewing own data drives engagement & retention: one place, immediate access, share with care providers
- Security element of blockchain made users feel more comfortable and secure

Recommendations

- 100% interested in owning their medical records
- 86% interested in sharing data with other trials
- Additional features: Payment, site travel logistics

87% participants would recommend LifeLedger™ for future clinical trials

Investigators

What worked?

- Usability: dashboards, navigation. Even for less technically-savvy
- eConsent and re-consent feature. Blockchain expected to address security concerns.
- Expect patient adherence and retention to improve
- AE alert feature and timestamping helps track timely responsiveness
- Real time data hit all the right points
- Record events electronically (including visits), connect with other devices enhances overall PX
- Reduces paper storage
- Real time research allows changes in protocol as needed

Recommendations

- Tailoring dashboard, data collection fields and app for specific populations will improve adoption
- Timestamping when data is submitted would be useful information

Expressed desire to extend the app to their clinical trials

Sponsors

What worked?

- Delivers value to clinical trial sponsorship
- Blockchain helpful to solve known impediments to data-driven clinical trials.
- Reporting AE is an important tool and will help sponsors to understand safety issues quickly
- With blockchain, one can verify the sources of the data and where its coming from including reproducibility
- Data immutability and provenance are important to the sponsor
- The big benefit is the regulatory authorities could take the audit from this product at face value
- LifeLedger™ could potentially save significant money in streamlining the auditing process

LifeLedger™ can help make trial auditing faster with significant savings

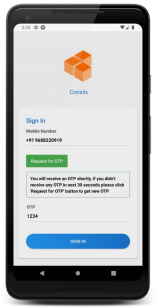
eConsent Deployment In A COVID-19 Sero-prevalence Community Study (Aug 2020)

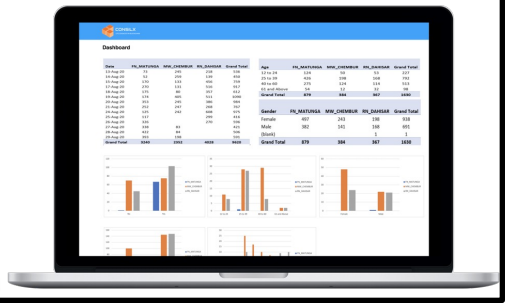
- Mumbai City
- 3 Slum Areas
- 3 Non-slum Areas
- 75 Field Volunteers
- 14 Days of Field Work
- 12,663 Participants Registered
- 8,142 Consented

The Solution

eConsent App

- Multiple languages
- Multi-media support
- LAR option
- Off-line data capture
- Data sharing
- KPI dashboard





Outcomes Delivered

- Successful identification and enrolment of eligible volunteers for the survey
- Digital process delivering operational efficiency in large scale community-based survey
- Real-time sharing of signed informed forms (pdf) with subjects through whatsapp / email
- Real-time SMS notification on subjects mobile phones about their consenting status
- Reports for daily reconciliation of subjects with lab database
- Performance reports within an hour post completion of survey for management review
- Test results shared with subjects within 3 days post sample collection
- Target (8000) achieved in 14 days; significantly lesser duration compared with previous rounds by the same sponsor using paper-based consenting process

An Open-label Safety & Acceptability Study Of A Medical Device on 30 Volunteers (Feb 2021)

	Visit #1	Visit #2	Visit #3	Visit #4	Visit #5
Protocol-defined Location	**In-Clinic** 	**In-Clinic** 	**At-Home** 	**At-Home** 	**At-Home** 
Procedures	Consent Screening	Enrolment Baseline assessments IP administration Pain assessment Acceptability questionnaire AE assessment	Follow-up visit Pain assessment AE assessment	Follow-up visit Pain assessment AE assessment	Follow-up visit Pain assessment AE assessment
Solution / platform used	**eConsent** **eSource**	**eSource** **Direct data collection tools**	**Tele-visit** **Text & Video chat** **eSource** **eQuestionaire**	**Tele-visit** **Text & Video chat** **eSource** **eQuestionaire**	**Tele-visit** **Text & Video chat** **eSource** **eQuestionaire**

Outcomes

- Digitized all components involved in the conduct of the hybrid study (consent, data collection, acceptability, safety & pain assessments)
- Seamless experience in onboarding volunteers, executing consent at site, sharing the signed consent form with the volunteers on email
- Online data collection using eSource modules and real-time insights on missed data or if there were any issues
- Subjects completed pain assessment electronically – VAS; all data points related to timing of administration & measurements are tracked
- Tele-visit was successfully used to contact the subject for visits #3, #4, & #5 and AE assessments
- Effective coordination of multiple In-clinic and Tele-visits; real-time data visibility was well received by the study team and sponsor

phuse-sponsored Technology Case Study

Blockchain Technology Phase II Project Report (dated 02 Dec 2020)

eConsent

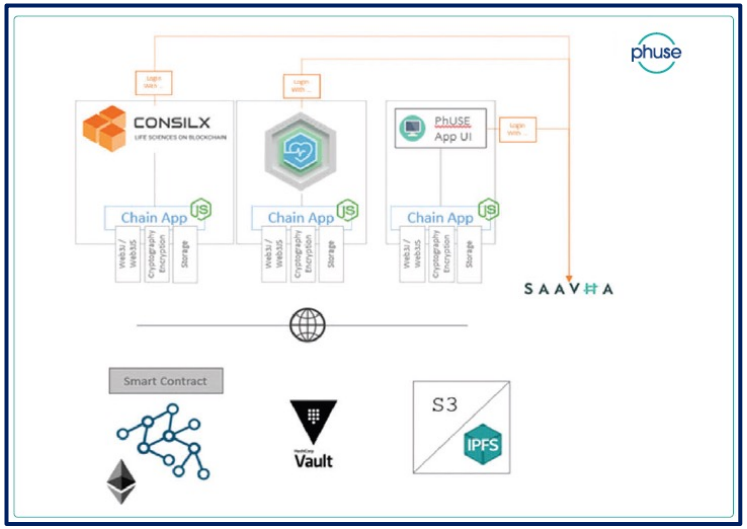
Sub-Workgroup #3: eConsent (ICF)

Problem: **How to track all the versions of signed ICF**

Desired methodology: defining the data, data standards, limitations, benefits and results

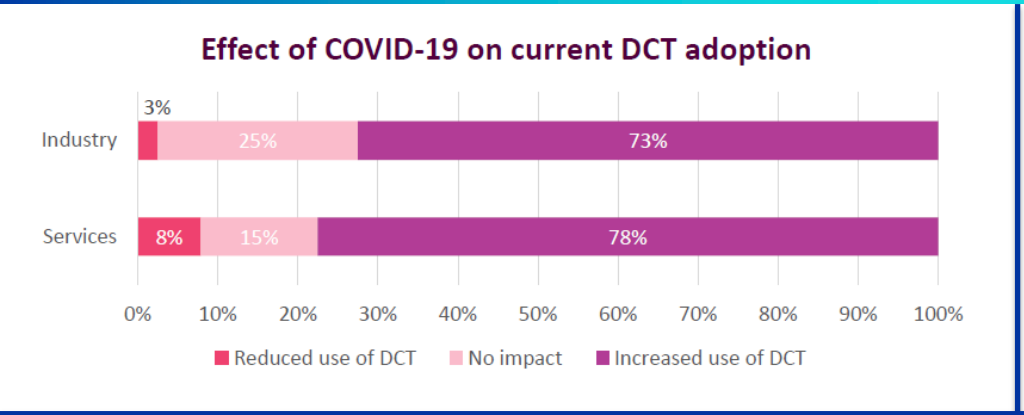
Considerations:
- Patient matching to the different versions of ICF
- Tracking/flagging of missing ICF
- DB interface

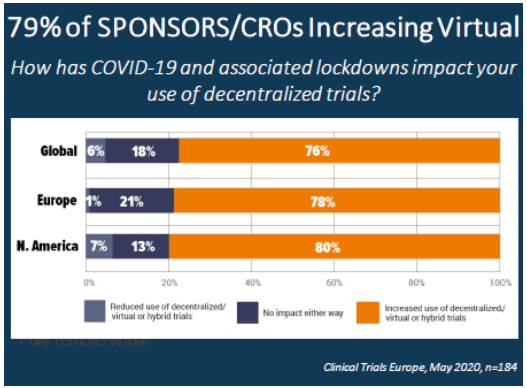
Deliverables:
- User interface (APP/website)
- Written protocol

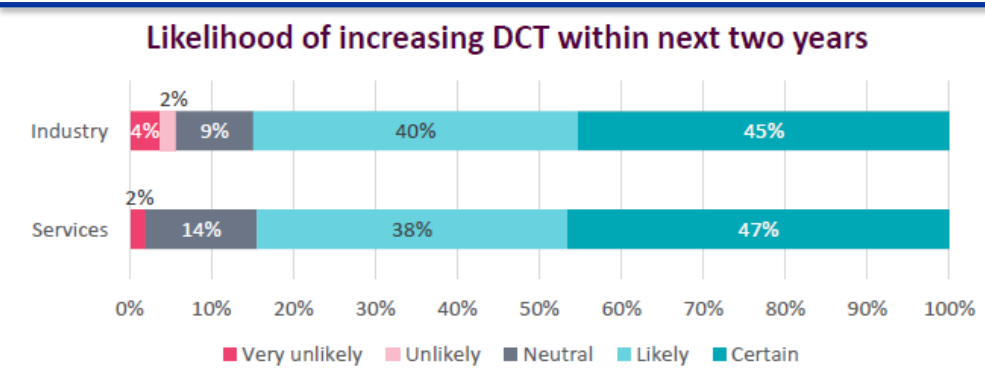


Consilx led this project, lending technology from their end-to-end eConsenting platform. Consilx leveraged the SAAVHA patient ID and connected to the local site ID, ensuring documentation and updates surfaced in the user's dashboard and were fed back to sites to manage the appropriate patient on-boarding process.

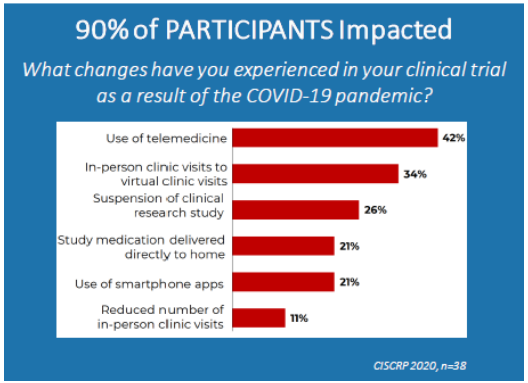
Pandemic Accelerated Discussions On Decentralized Clinical Trials



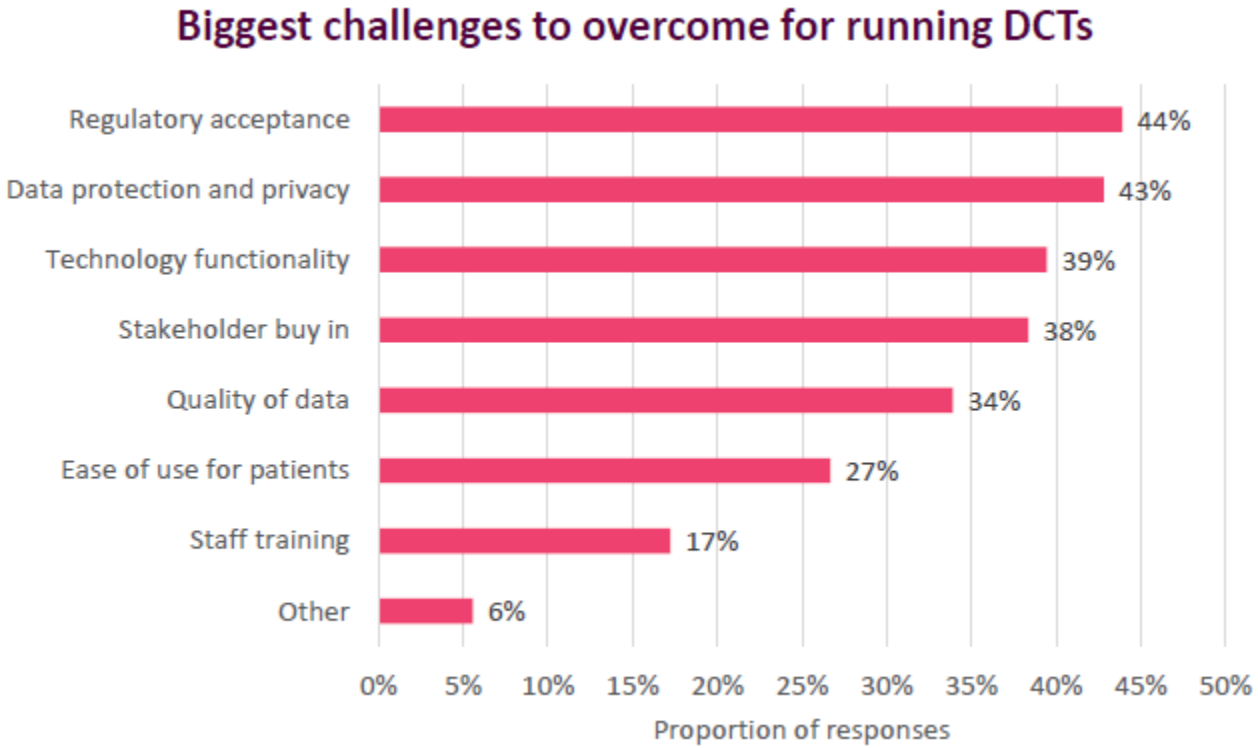




Source: Informa Connect; CTTI



Adapting Decentralized Trials …



Source: Informa Connect; CTTI

Collaboration is the Key

Thank you …

The Global Healthcare Data Science Community

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