Session III: Sponsor Perspectives – What's Working Now?

Facilitated by Megan Doyle, Amgen

10:40 a.m. – 12:15 p.m. EDT

Overview

Panelists

- **Robert "Joe" Mather**, Pfizer
- **Alma Chavez**, Duke Clinical Research Institute
- **Scott Askin**, Novartis
- **Adam Hartman**, NINDS
- **Isaac Rodriguez-Chavez**, ICON

Session Objectives

- Understand from sponsor perspective what works and what doesn't for specific DCT solutions
- Discuss how to ensure DCT solutions are considered during study design, including as opportunities to streamline trials and reduce participant burden
- Identify considerations for effective and efficient safety monitoring in DCTs

Please share questions, comments, and ideas in the chat throughout the session

CTTI

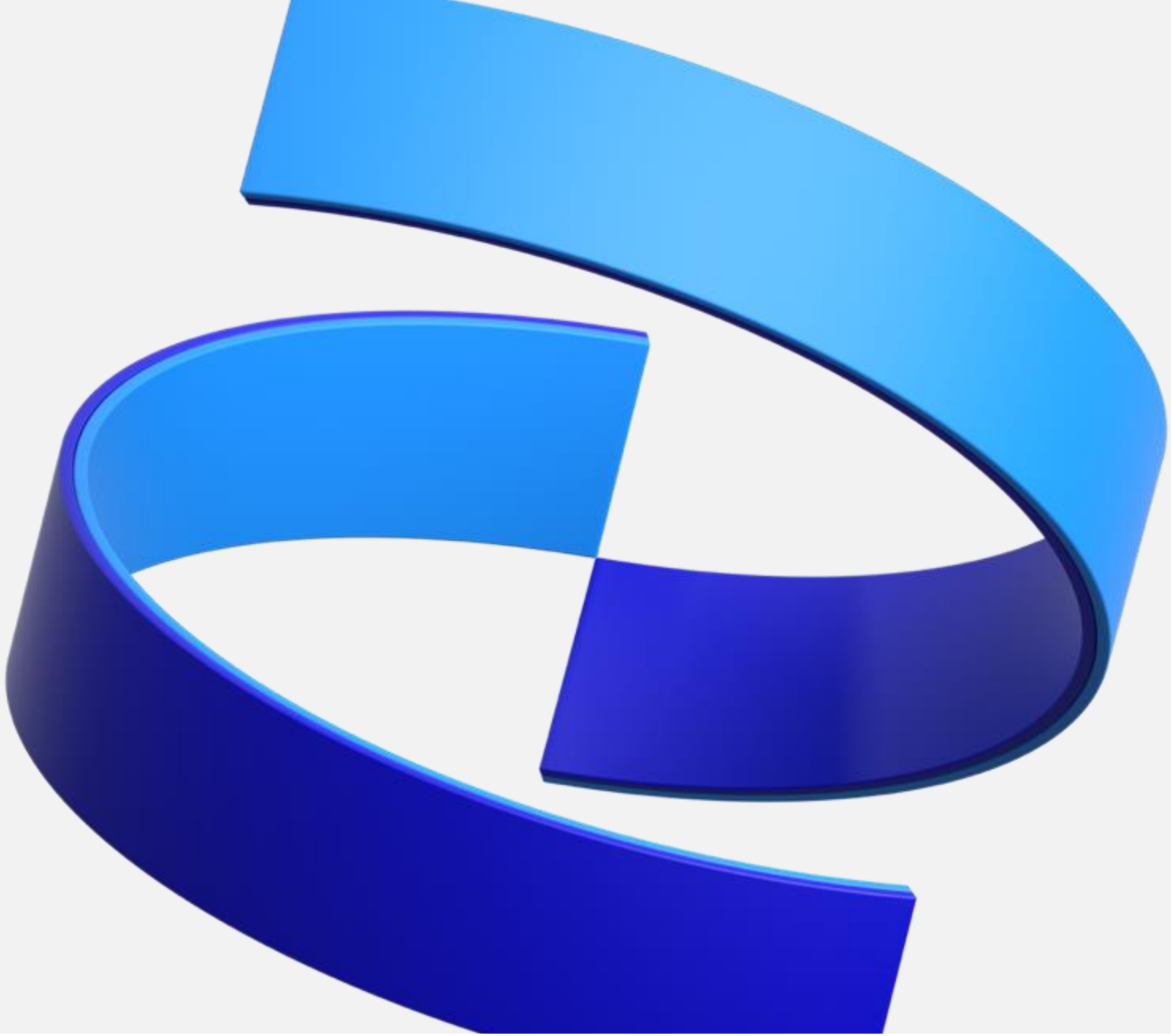
CTTI Case Study #1

Implementing a Decentralized Clinical Trial at Scale for COVID-19 Symptom Monitoring

Joe Mather
Executive Director
Head of Advanced Science Group

Early Clinical Development

August 26, 2021



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- This presentation is intended for non-promotional scientific purposes only and may contain information on products or indications currently under investigation and/or that have not been approved by the regulatory authorities
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Agenda

1. Introduction
2. Case Study
3. Key Learnings
4. Summary

Decentralized or Flexible Clinical Trials

The FDA recently defined DCTs as the **decentralization of clinical trial operations where technology is used to communicate with study participants and collect data**

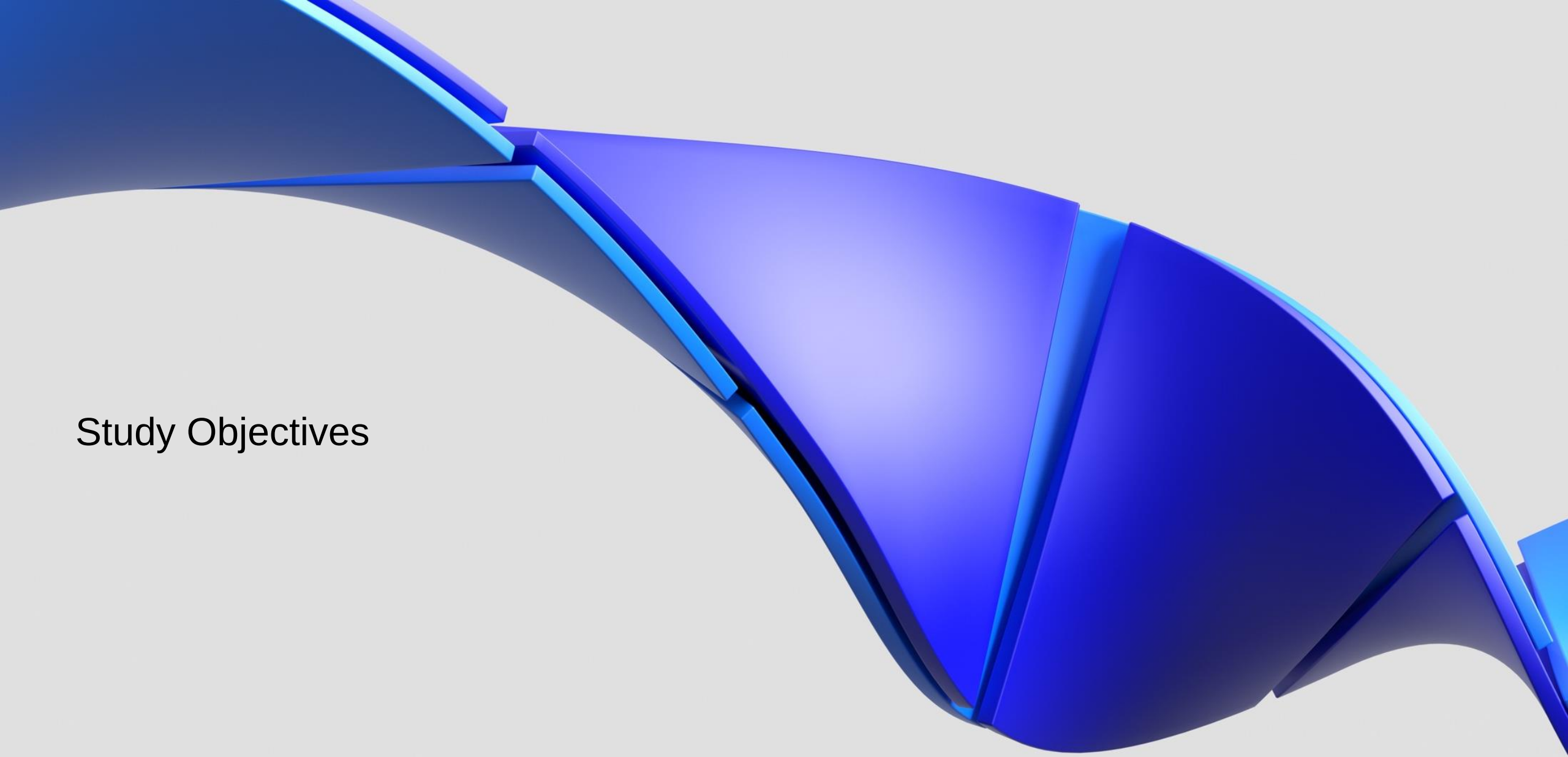
Key elements of a decentralized or flexible trial design include:

- eConsent (electronic informed consent)
- **Remote eConsent**
- **ePRO (patient reported outcomes or diaries)**
- Home Health or Telehealth
- Direct to participant drug or investigational medical product delivery

- **Participant self-collected samples**
- **Sensors/wearables**
- **Remote monitoring**
- Remote source document review and source data verification
- Direct data capture (quality & reliability)

- *May provide patients more flexibility to participate in studies or recruit broader patient populations*
- *Heavy reliance on participant or caregivers to complete study activity*
- *Higher burden on vendors, technologies and site to ensure GCP guidelines are followed, that data quality and integrity as well as privacy and security are maintained and to ensure audit readiness throughout the study*
- ***Critical need for study and site management & support systems***

Study Objectives



A Decentralized Clinical Trial at Scale for COVID-19 Symptom Monitoring

Primary objective build a voice and symptom algorithm(s) for detection and monitoring of SARS-CoV-2 illness and characterize the link between symptoms and voice features of SARS-CoV-2 positive participants

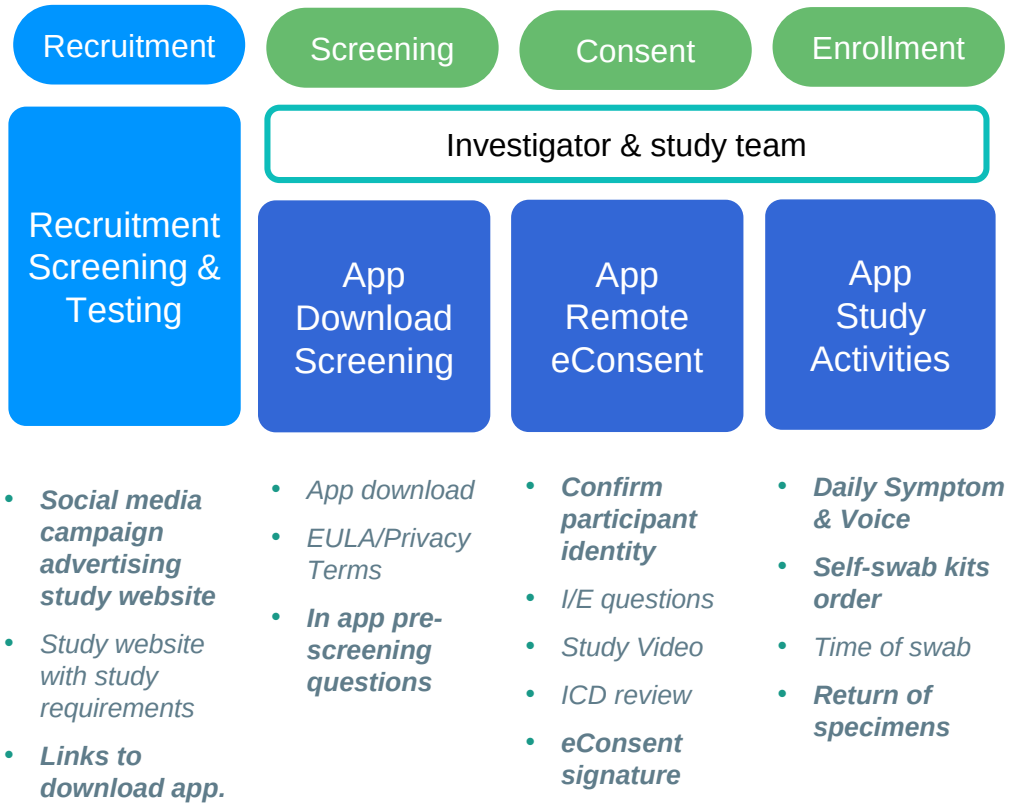
Secondary objectives will assess **app compliance**; quality of voice recordings; **infection rates for SARS-CoV-2**/Influenza/RSV & **feasibility of self-swabbing**

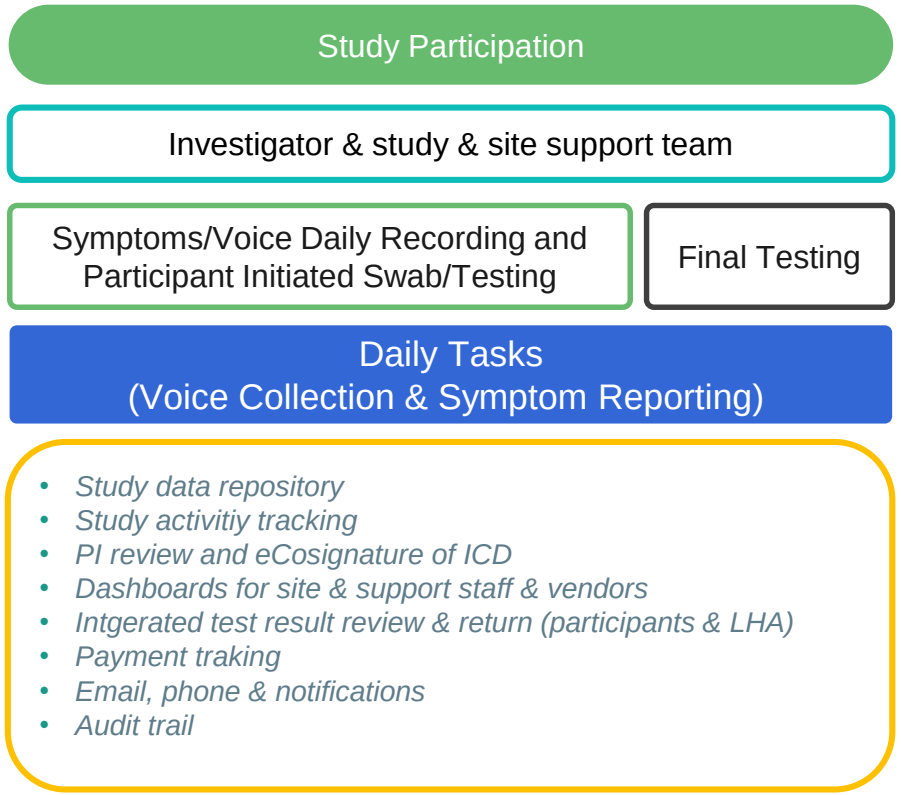
BOYD App enabling remote ID verification, screening, consenting, symptom and voice recordings, and recording of self-swabbing

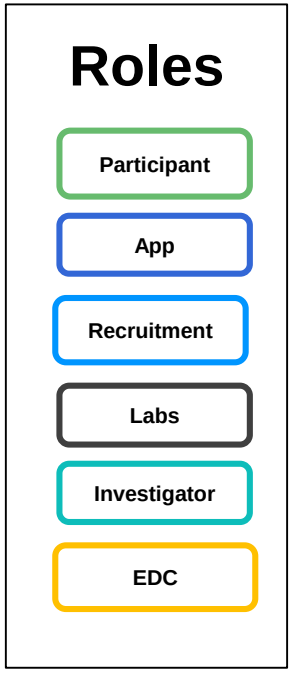
Impact:

- Characterizing **self-reported voice and symptom** profiles for acute respiratory illnesses and **enabling their early detection** benefits vaccine development
- This study models concepts of **efficient and flexible clinical trials**: web-based participant recruitment, enhanced participant engagement and remote sample collection
- This observational study will assess technology and its performance to **enable deployment in future interventional studies**.

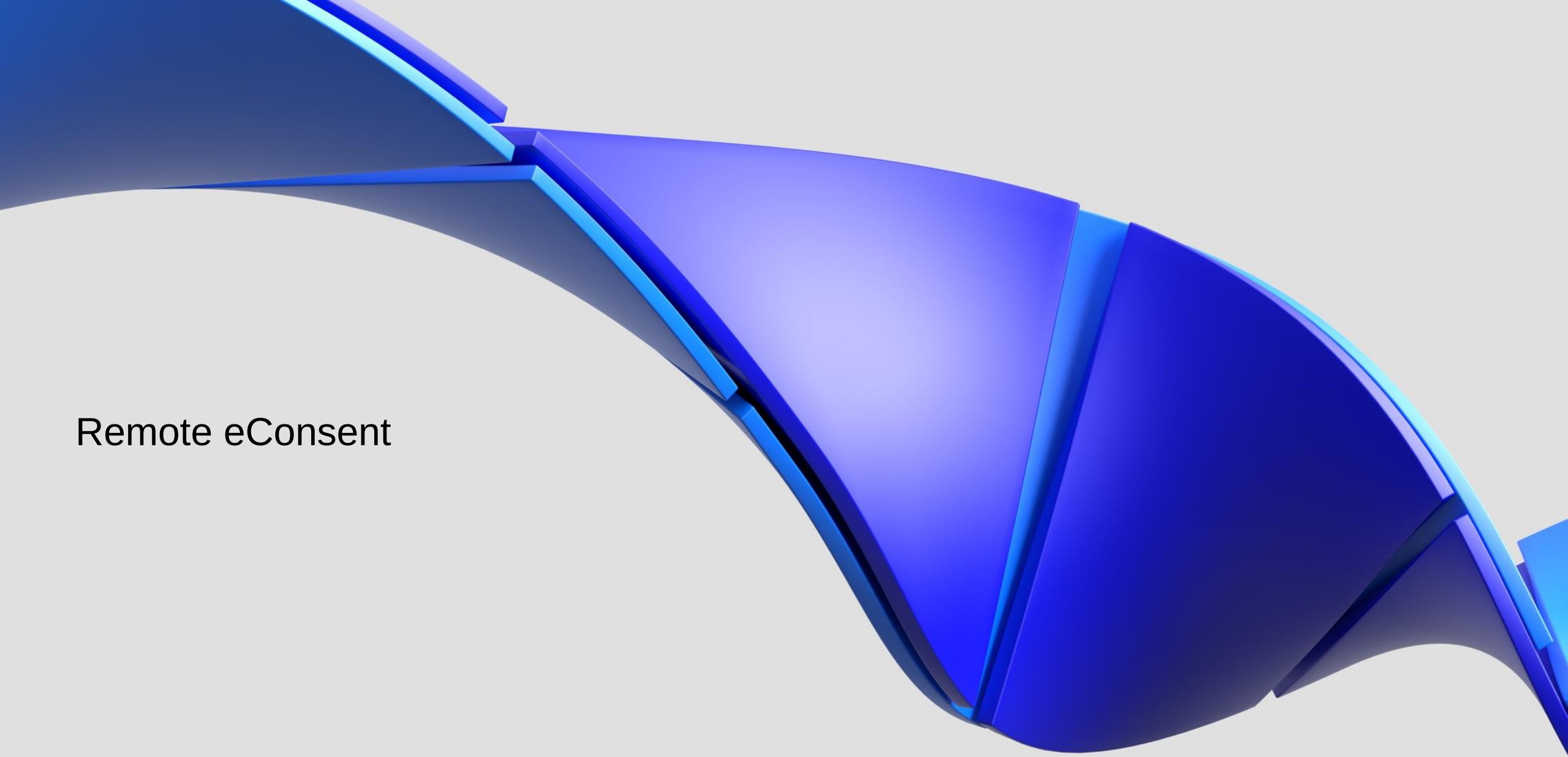
Study Concept







Remote eConsent



Remote eConsent

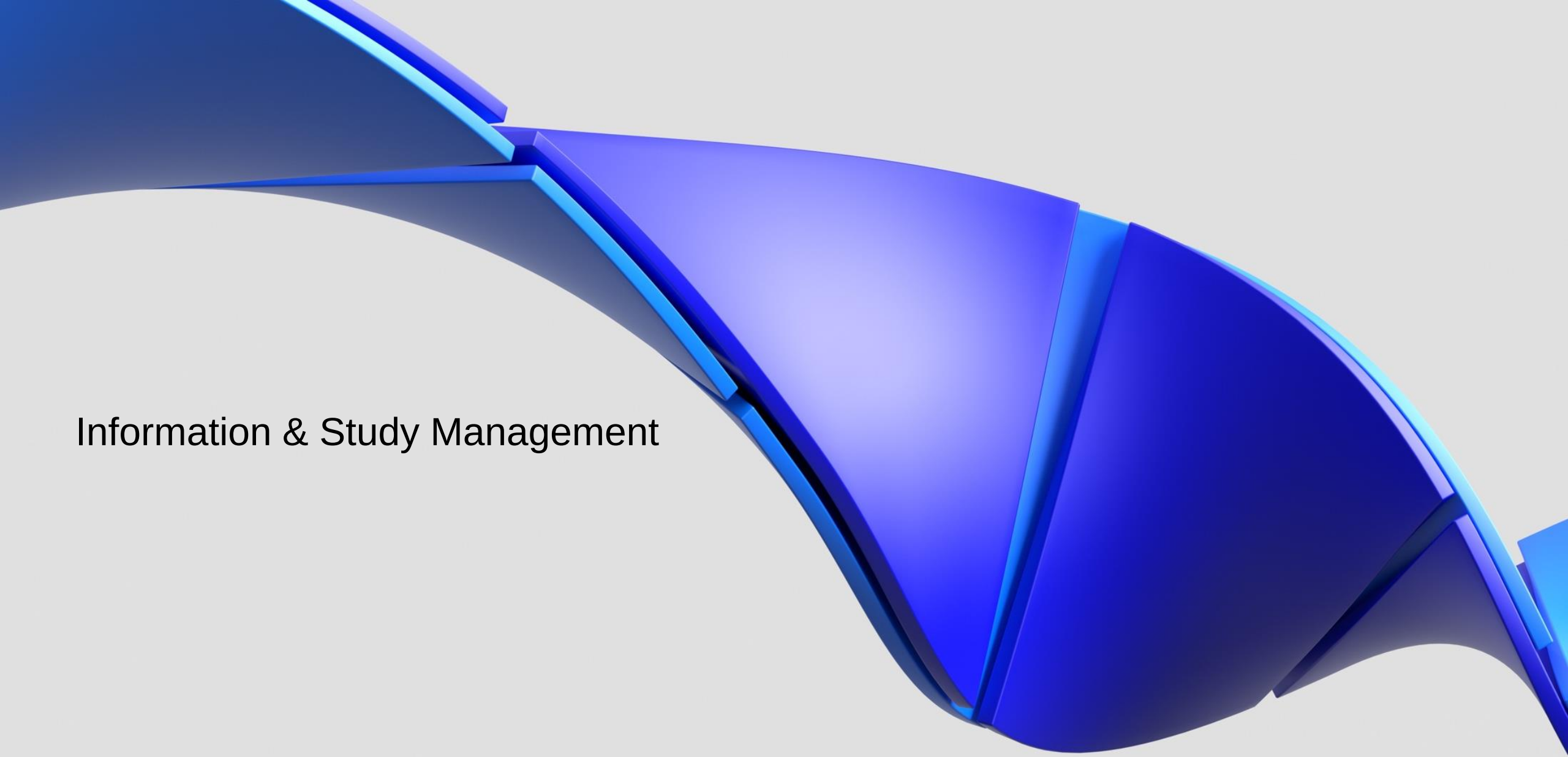
Remote eConsent

- eConsent on mobile app; fully remote and decentralized process
- Remote and automated identity verification in app- based on public data in of individuals
- Study video in app to inform participant
- Confirmation of individual's understanding of the protocol elements and risks of the study
- Opportunity to ask questions and contact the investigator
- Relatively simple inclusion and exclusion requirements for study participation

Considerations for Future Trials

- Dual approach with alternative for remote consent through secure video conference where participant can meet with site staff and show proof of identity
- Interventional drug trials will need to consider more strict identity verification field checks if using automated ID verification service
- Secure communications will allow participant questions in real time to reduce loss or screen failures

Information & Study Management



Study Management

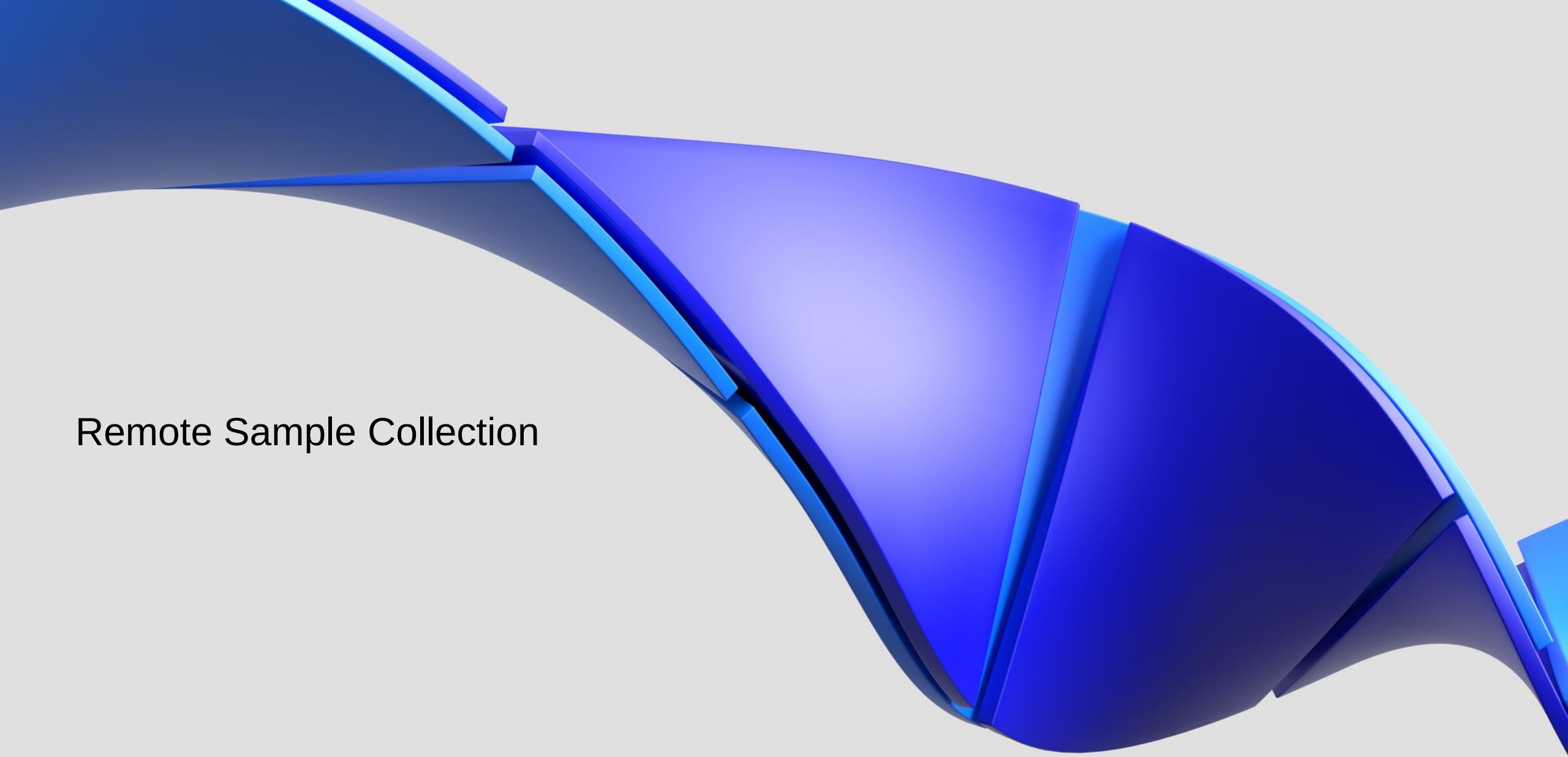
Study Implementation

- Mobile App available on iOS and Android phones; dependent on OS requirements (acoustic quality)
- Participants enrolling with older models of Android phones; hardware on phones results in issues with voice recordings
- Operational team portals for site, vendors and study team to manage and monitor study
- Operational & study tracking reports
- Patient addresses and courier delivery services
- Virtual payment cards for participant payments
- Data triggered payments based on eDiary compliance
- Site support for compensation support to participants

Considerations for Future Trials

- Regulatory barriers (currently a COVID-19 guidance from FDA)
- Option to procure phones for participants to streamline type of device used and enhance participant study experience
- eConsent tools capable for capturing remote signatures, future studies
- Site capabilities and compliance of tools (e.g., DocuSign, etc.); secure messaging platforms to contact participants
- Not all participants may have bank accounts (requirement for virtual payment cards)
- Access to account registration emails and record of instructions available for both vendor and site to help resolve issues

Remote Sample Collection



At home biospecimen collection

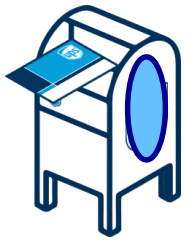
Study Implementation

- Two at-home self swab kits were sent directly to participant's home in single shipment to reduce costs and time
- Sample collection and shipping Instructions included in the box
- Return of results direct to the participant via HIPAA compliant mechanism and site reporting to required health authorities

Considerations for Future Trials

- Participant confusion on whether both swabs should be taken at once; consider shipping separately based on study design considerations
- Engagement of participants to complete both swabs at different time intervals is challenging - consider less samples or have additional site reminders; flexible collection options
- Some kits may get lost or stolen; no accurate way to tracking to understand confirmation of receipt

Shipping, shipping, shipping!



Summary

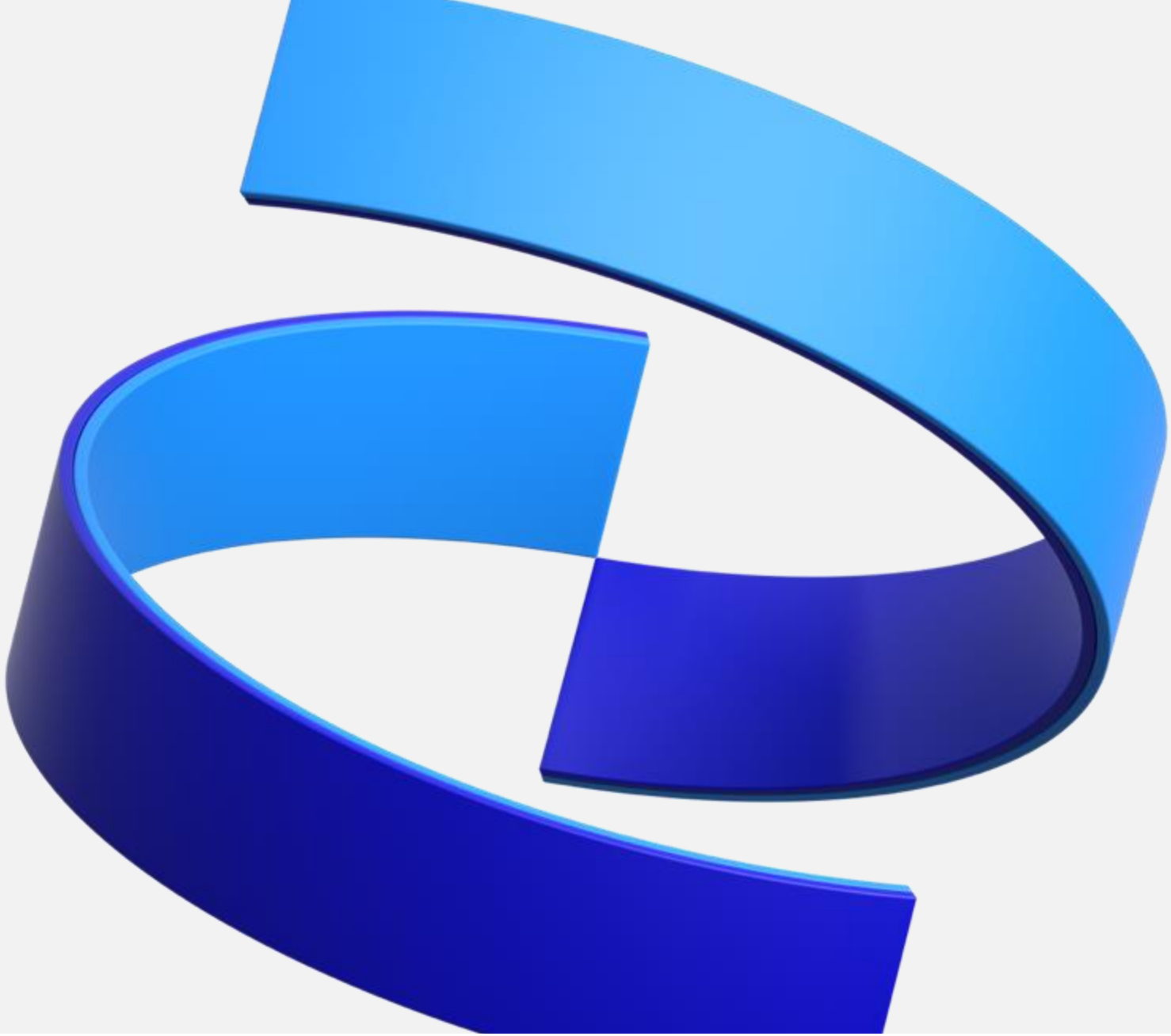
- The primary objective of the study is to obtain data to build a voice and symptom algorithm based on patient-reported symptoms, voice and PCR test results
- This study models the concepts of **efficient and flexible clinical trials**: web-based participant **recruitment**, enhanced **participant engagement**, and **remote sample collection**
- If successful, we hope that characterizing **self-reported voice and symptom** profiles for acute respiratory illnesses will **enable their early detection** and would benefit future vaccine development programs
- We have **demonstrated** some of the technical and operational hurdles we have overcome in implementing **a fully decentralized study at scale** under tight timelines
- Future clinical studies will benefit from technical and operational systems that enabled the study

Further Considerations

- Does your organization understand the risks associated with the study?
- Do you have the systems to collect, monitor and audit the quality of data collected?
- Do the patients understand what is being asked of them?
- Does the data collected meet the quality requirements for the study?
- Does the investigator and site have capacity to run the study?
- Do you have the vendor, site support and study monitoring systems in place?

Expect the unexpected!

Thank You



Acknowledgements

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- Robb Linde

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Christopher Eliopulos

Parthena Psyllos

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- William Gruber
- Demetris Zambas
- Timothy McCarthy

Special thanks to the investigators, site staff and vendors that made this possible!

Study Status

Milestones

- **Study launched April 15th, 2021**
- 1,241 of 6,250 participants enrolled in 28 days!
- **50% enrollment completed by June 30th, 2021**

Enrollment

Total 3,514 enrolled including screen failures

- 404 have screen failed
- 105 participants are currently enrolled in the study now
- **2,737 have completed their eDiary** activities/the study
- **268** have been discontinued
- **Demographic, diversity recruitment objectives are on track with goals**

BOYD App enabling remote ID verification, screening, consenting, symptom and voice recordings, and recording of self-swabbing

PROACT Xa

CTTI Decentralized Clinical Trials Expert Meeting

August 26, 2021

Duke Clinical Research Institute | FROM THOUGHT LEADERSHIP TO CLINICAL PRACTICE

PROACT Xa

Sponsor Perspectives – What's Working Now?

PROACT Xa Trial Design

Patients with On-X aortic valve replacement >3 months prior (n=1000)

Randomize

Apixaban 5 mg BID Apixaban 2.5 mg BID in selected patients	Open Label	**Continued warfarin** INR goal 2.0 – 3.0

2 year follow-up (≥800 patient-years in each arm)

Primary endpoint: composite of valve thrombosis or valve-related thromboembolism

Secondary endpoints: components of primary composite endpoint, major bleeding

Co-Primary Analyses:

1) Apixaban non-inferior to warfarin with absolute NI margin of 1.7%/patient-year
2) Apixaban primary outcome 95% CI below objective performance criteria (OPC) of 3.4%/patient-year

Study considerations - details (public access)

PROACT Xa

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Si

Home > Search Results > Study Record Detail

Trial record **1 of 1** for: proact xa

Previous Study | Return to List | Next Study

PROACT Xa - A Trial to Determine if Participants With an On-X Aortic Valve Can be Maintained Safely on Apixaban

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04142658

Recruitment Status : Recruiting
First Posted : October 29, 2019
Last Update Posted : August 12, 2021

See Contacts and Locations

Sponsor:
CryoLife, Inc.

Collaborator:
Duke Clinical Research Institute

Information provided by (Responsible Party):
CryoLife, Inc.

American Heart Journal
Volume 227, September 2020, Pages 91-99

Trial Design

Rationale and design of PROACT Xa: A randomized, multicenter, open-label, clinical trial to evaluate the efficacy and safety of apixaban versus warfarin in patients with a mechanical On-X Aortic Heart Valve ☆, ☆☆, ☆☆☆

Oliver K. Jawitz MD MHS [a,b], Tracy Y. Wang MD MHS MSc [a], Renato D. Lopes MD PhD [a], Alma Chavez BSN [a], Brittanny Boyer BS CCRP [c], Hwasoon Kim PhD [a], Kevin J. Anstrom PhD [a], Richard C. Becker MD [d], Eugene Blackstone MD [e], Marc Ruel MD MPH [f], Vinod H. Thourani MD [g], John D. Puskas MD [h], Marc W. Gerdisch MD [i], Douglas Johnston MD [e], Scott Capps MS [c], John H. Alexander MD MHS [a], Lars G. Svensson MD PhD [e]

Objectives

PROACT Xa

- Understand from sponsor perspective what works and what doesn't for specific DCT solutions
- Discuss how to ensure DCT solutions are considered during study design, including as opportunities to streamline trials and reduce participant burden
- Identify considerations for effective and efficient safety monitoring in DCTs

Landscape Scan for CTTI DCT Update Project

Completed 16 April 2021

CTTI Landscape Scan

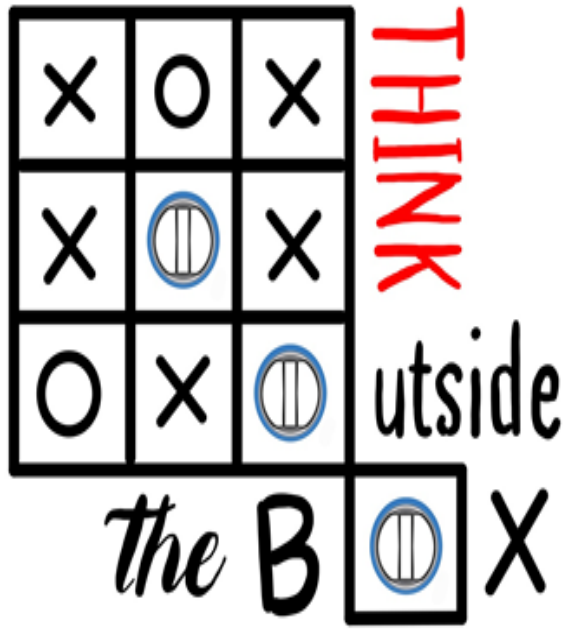
I. High Level Findings

Anticipated Benefits of DCT Solutions Adoption

- Higher participant enrollment, compliance, satisfaction and retention
- Broader geographic reach (e.g. rare disease)
- Shorter drug development timelines
- Cost savings
- Data captured in real world settings, improving the validity and generalizability of results
- Decentralized elements can be used selectively on a fit for purpose basis for a given trial

Barriers to Decentralized Clinical Trial (DCT) Solutions Adoption

- Variations in global legal and regulatory requirements and uncertainty around future change
- Technology platform variations across sites
- Lack of data demonstrating cost vs benefit
- Lack of data demonstrating impact on and preferences/needs of sites and participants
- Need for practitioners to share methods and evidence for those methods
- Need for change management within sponsor organizations
- Need for new processes and procedures to optimize implementation of DCT elements

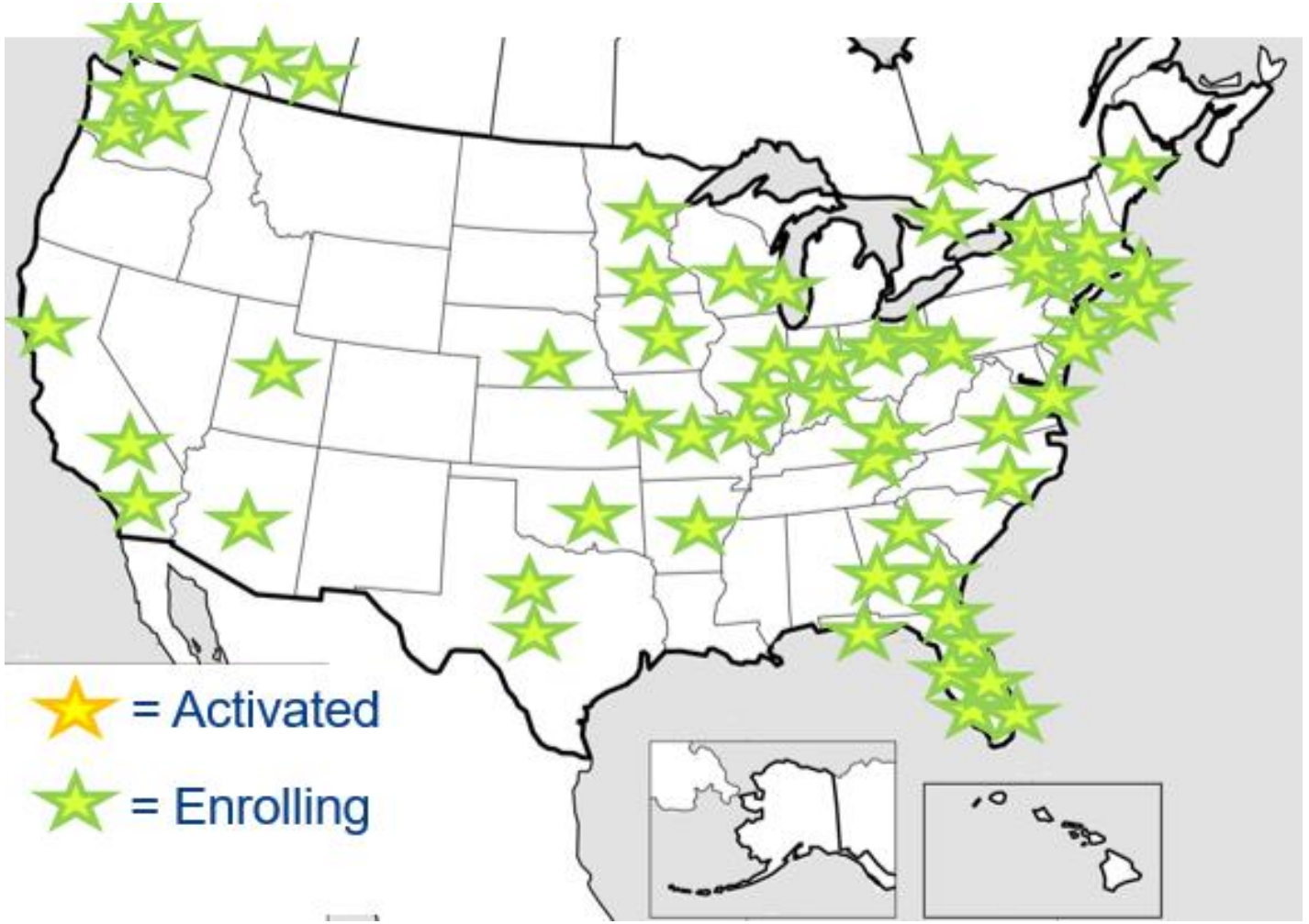


Sponsor Perspective: Overview of “Deliverables”

PROACT Xa

Significant timelines:

- 02/Sep/2019 - Study May Proceed
- 15/Jan/2020 - protocol finalized
- *23/Mar/2020 - Investigators Meeting*



Stakeholders

- CryoLife
- Duke Clinical Research Institute (DCRI)
- ThermoFisher / Fisher BioServices
- WCG / local Institutional Review Boards
- Investigative Sites
- Patients / participants
- Anyone & Everyone

Not Documented, Not Done

Sponsor Perspective: Overview of "Deliverables"

PROACT Xa

Significant timelines:

- 02/Sep/2019 - Study May Proceed
- 15/Jan/2020 - protocol finalized
- *23/Mar/2020 - Investigators Meeting*
- 24/Apr/2020 - 1st site activated
- 04/May/2020 - 1st participant enrolled
- 26/Aug/2021 - 54 sites activated

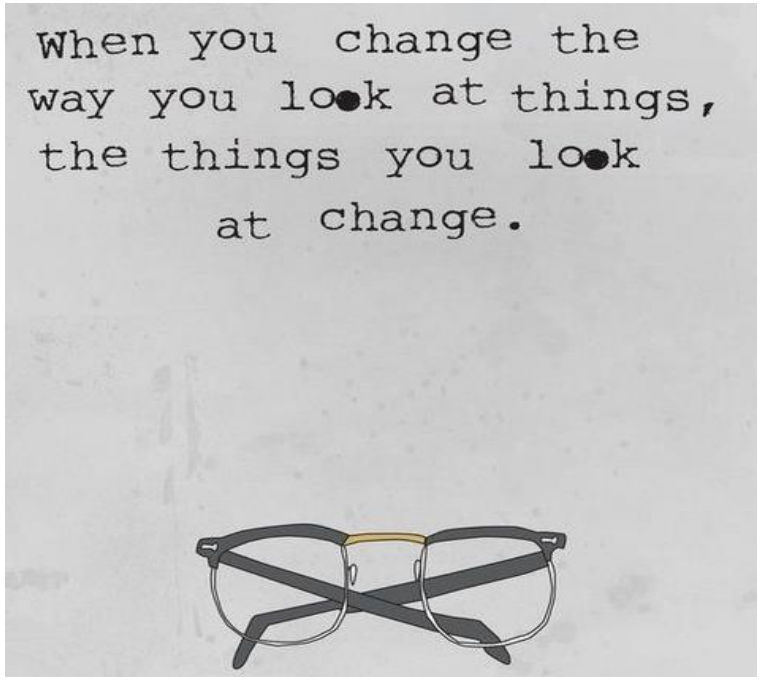
  # participants enrolled

Objectives

- Understand from sponsor perspective what works and what doesn't for specific DCT solutions

- Discuss how to ensure DCT solutions are considered during study design, including as opportunities to streamline trials and reduce participant burden

- Identify considerations for effective and efficient safety monitoring in DCTs



COMMUNICATION

PROACT Xa

Decentralized Clinical Trials Multi-Stakeholder Expert Meeting

Sponsor Perspectives – What's Working Now?

Scott Askin, *Global Program Regulatory Director, RA Innovation*

Presented at CTTI Workshop 26th August 2021

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Agenda

- **Identifying DCT Opportunities**
  - A Systematic Evaluation of the Portfolio
- **Case Study**
  - Lesson's Learned from the Trial
- **Why is Moving to Scale Challenging**
  - Complexity & Risk
- **Lesson's Learned - A European Perspective**
  - Areas still to be Addressed

Identifying DCT Opportunities

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Systematic Evaluation of the Portfolio

Identifying near-term Trials that may benefit from DCT Implementation

- **Background:** Agreement with Development Units to systematically evaluate whether upcoming trials could benefit from DCT elements
- **Purpose:** Understand what trials are interested in DCT elements and reasons for low / lack of interest
- **Scope:** Interventional trials (Phase II-III) with planned FPFV within the next year
- **Format:** Qualitative self-assessment of interest in DCT elements

What teams were asked;

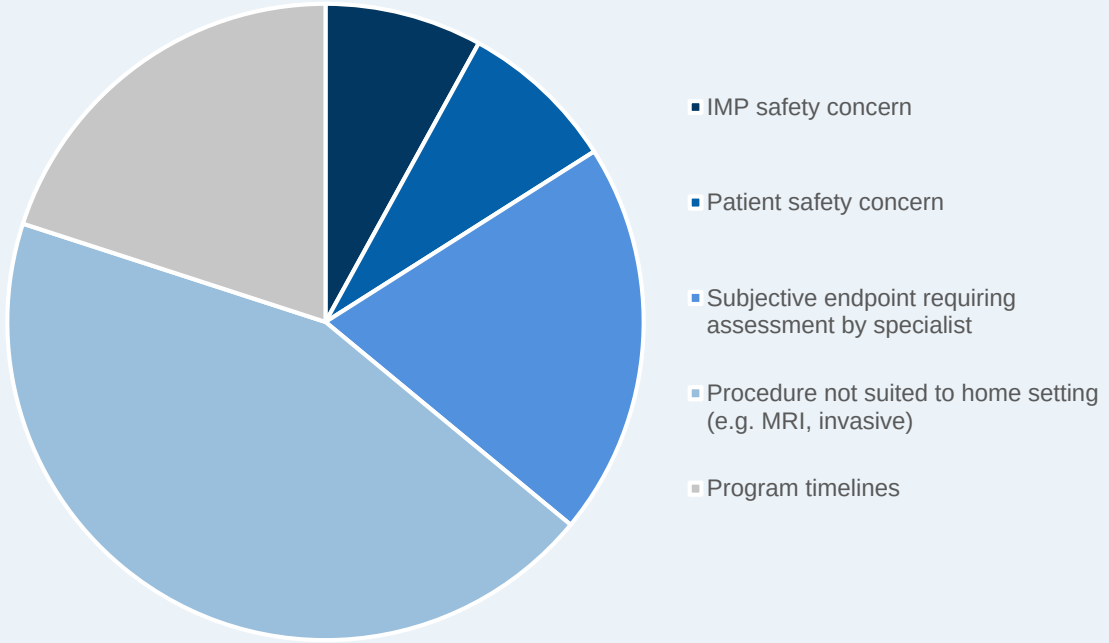
- How could your target patient population (*& caregivers)* benefit by incorporating remote trial options?
- Could the study treatment be administered at home, either self-administered or with support of a nurse?
- Could the objectives of the trial be reliably measured using DCT remote option(s)

Outcome of Systematic Evaluation

Of the trials evaluated, 19 expressed an interest in implementing 1 or more DCT elements

- Greatest interest was in Offsite Healthcare Professionals *(i.e. Home Nursing)*
- Direct to Patient Drug Shipments also featured very heavily in interest & value to trials
- Use of Telemedicine not featured as heavily as anticipated
- Local Healthcare Providers (HCPs) also perceived as adding value to trials

- Rational for not considering DCT:



Next Steps; Deeper dive into trials that expressed interest to support implementation, & further investigate those trials not expressing interest to determine rational (i.e. lack of awareness, disease related etc)

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Case Study

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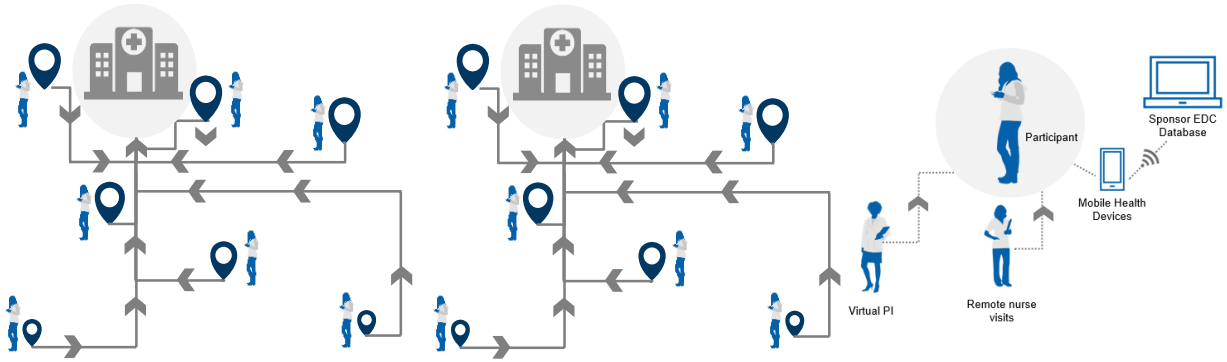
Global Phase III, *open label extension*

Adolescent & Adult Sickle Cell Disease patients participate via Traditional on-Site model for first year after which, at selected sites & with PI's discretion, and based on defined criteria, patients offered a switch to a Hybrid approach

Traditional Onsite	"Hybrid Approach" (*Onsite+Offsite*)



Year 1 → *Years 2 to 5*

- Patients attend at least bi-annual visits *(in-person)* at their existing site, throughout the trial

- Monthly visits take place in between these, where patients may be offered remote visits supported by offsite Healthcare Professionals & a telemedicine platform, along with other services listed

Telemedicine Platform	Remote Study Coordinator	Home Nursing / Phlebotomist	Local Health Care Provider (HCP) Support	Biosample Collection
Direct-to-Patient Investigational Medicinal Product (IMP) Management	Direct-to-Patient Study Supplies Shipment *(Non-IMP)*	Sensors and Mobile Devices	Electronic Patient Reported Outcomes (ePRO)	Patient Engagement Tools
Patient Direct Messaging	eConsent/Remote Consent	Patient Compensation / Reimbursement	Treatment Adherence / Compliance	Digital Recruitment

Implemented in the Trial *Not implemented in the Trial*

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Key Learnings so Far?

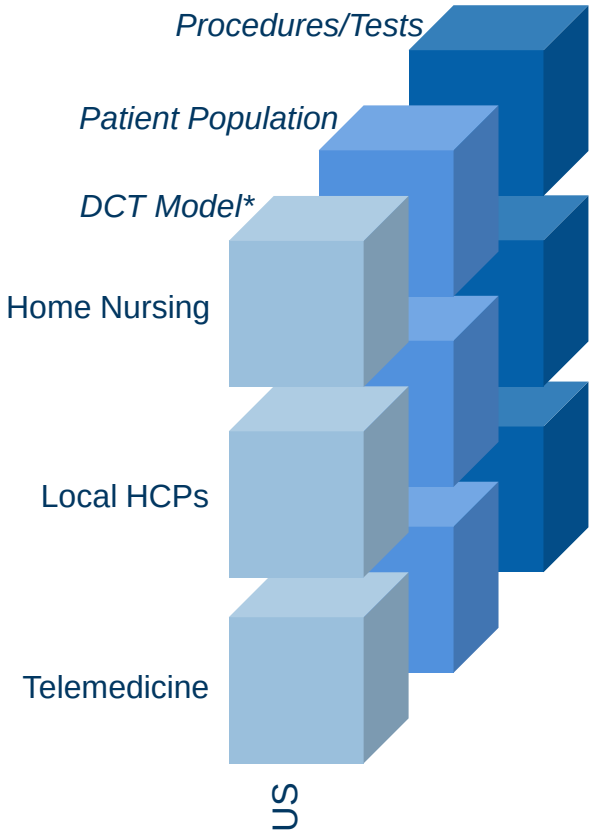
Learnings primarily relate to trial initiation & set up activities as implementation of the remote DCT elements are in their relative infancy

- Tri-party agreement/contracts, which are recommended by EMA in the case of Home Nursing/Offsite Healthcare Professionals, take time to implement
- Privacy is often raised as a concern, but GDPR interpretation differs across EU National Competent Authorities, so tailored solutions may be required
- An “Operations Manual” has been required as part of the Clinical Trial Application in some countries, so early assessments of local requirements are encouraged
- Transportation of IMP to the patient’s home requires additional effort to demonstrate stability
- Go/No Go criteria required to support PI in decision making that enables patients to transition to home visits

Why is Moving to Scale Challenging?

Complexity & Risk Increase with Scale!

1 Country x 3 Technologies/Services = 9 Items to Evaluate



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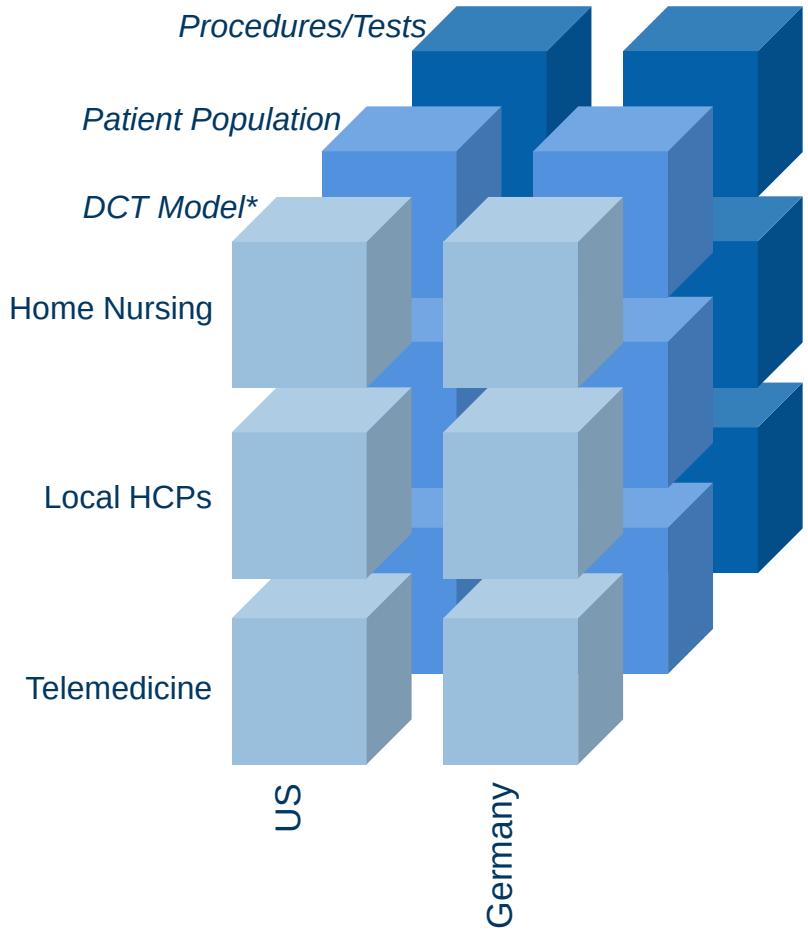
**DCT Model = Fully Remote, Hybrid, Side-by-Side*

Complexity & Risk Increase with Scale!

2 Countries x 3 Technologies/Services = 18 Items to Evaluate



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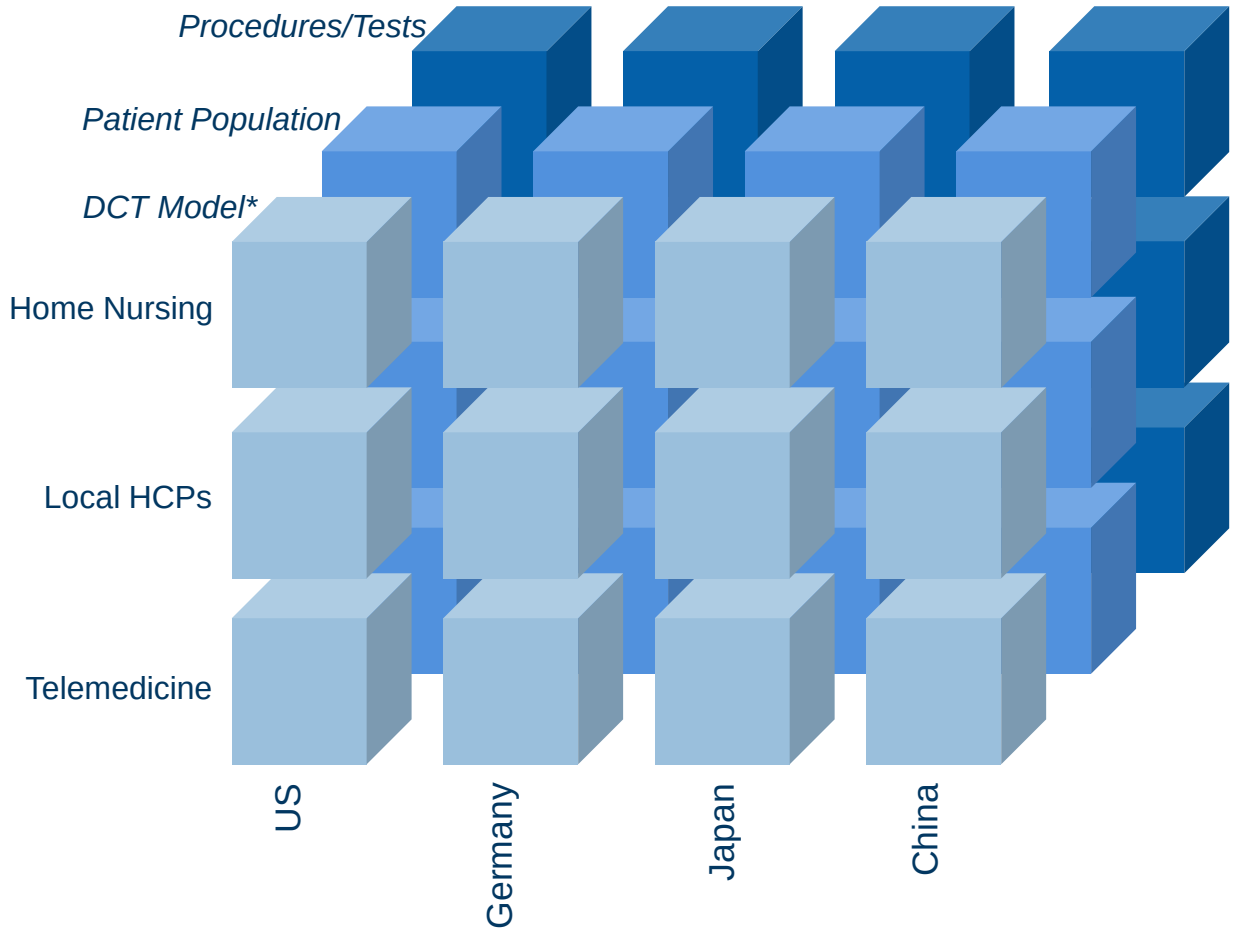
**DCT Model = Fully Remote, Hybrid, Side-by-Side*

Complexity & Risk Increase with Scale!

4 Countries x 3 Technologies/Services = 36 Items to Evaluate



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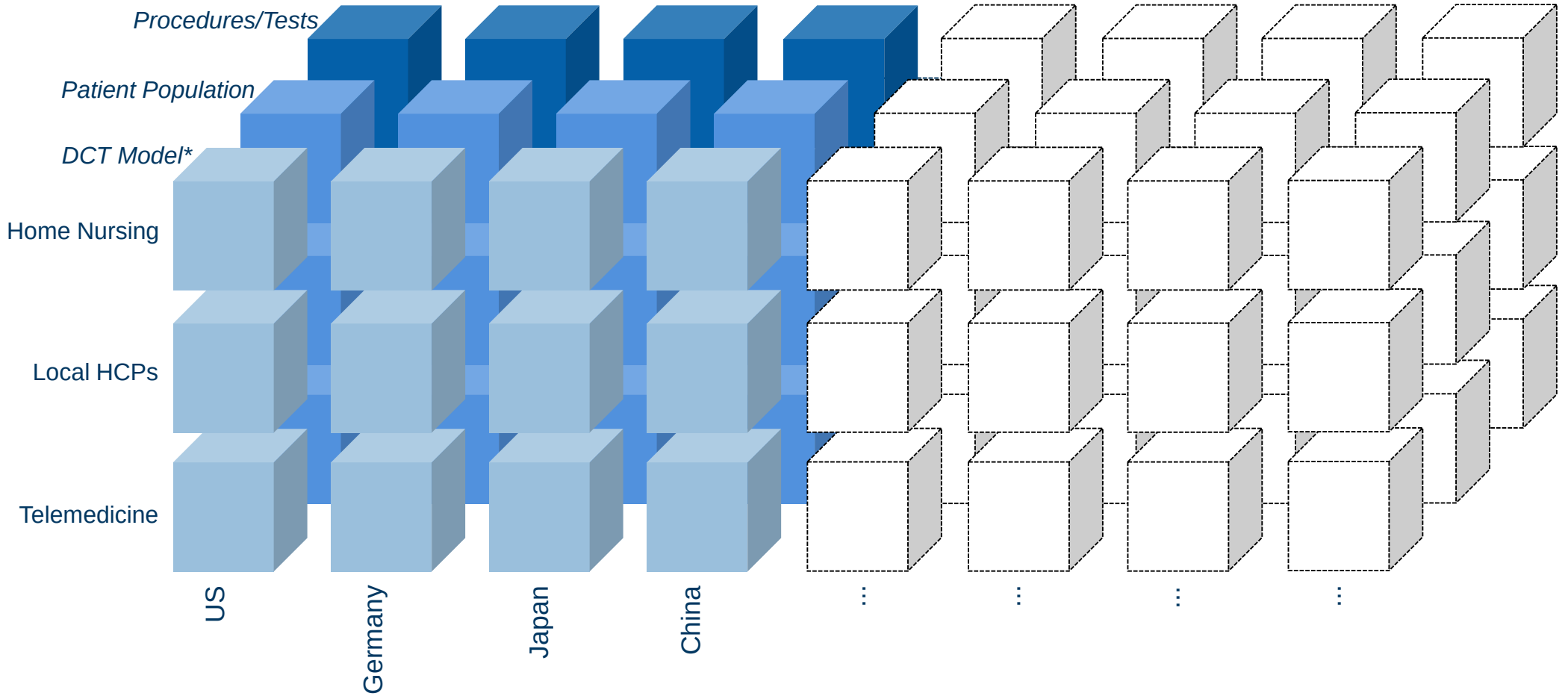
*DCT Model = Fully Remote, Hybrid, Side-by-Side

Complexity & Risk Increase with Scale!

8 Countries x 3 Technologies/Services = 72 Items to Evaluate



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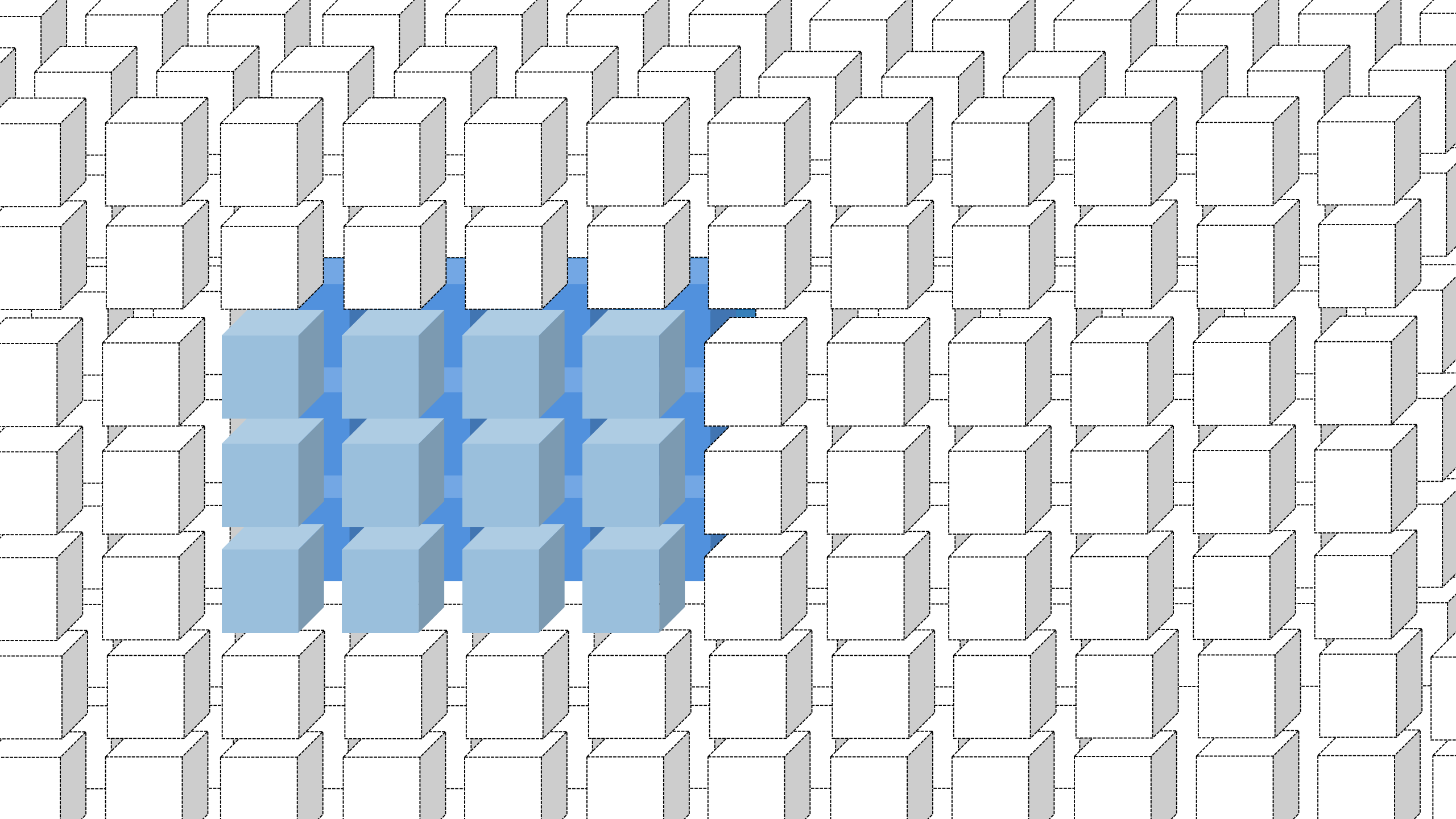
*DCT Model = Fully Remote, Hybrid, Side-by-Side



Lesson's Learned - A European Perspective

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Consolidated Lesson's Learned & Feedback

The benefits of DCTs with its enabling technologies are broadly endorsed and the need for global adoption is recognized, however,....

- Health Authorities advise 1) "Baby Steps", 2) Early advice meetings, 3) Describing DCT elements in CTA Cover Letters
- Compliance with ICH GCP guidelines for digital approaches is critical, but not well defined
- Demonstration of Investigator oversight of Patients, Local HCPs & offsite health care providers is required

- Data quality & Investigator Control of data must be ensured for all digital approaches
- Comparability between onsite and remotely assessed endpoints is critical
- Some HA's require/prefer initial visits to be conducted on site
- Risk assessments requested for DCT elements being implemented

- **Whilst COVID-19 has increased the awareness of DCT and demonstrated some feasibility, it hasn't "flipped the switch" regarding Health Authority acceptance**
- **Not all countries are in the same place: understanding, experience and stage of guideline development**
- **Complexity is driven by many factors, in addition, not everything is under the responsibility of HAs**

Back-Up

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Spotlighting some Key European DCT Activities

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DCT Projects in the Nordics

Initiatives in Sweden and Denmark

MPA DKMA

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Virtual clinical trials project starting now

The Medical Products Agency (MPA) has been allocated 1.8 million SEK from Vinnova (the innovation agency in Sweden) to launch a one-year pilot study to explore the current premises and additional requirements that would be necessary to implement virtual clinical trials in Sweden in a safe and efficient way.

- Our assessment is that exclusively employing digital technique will benefit patients, but also scientists and the researching pharmaceutical companies, which will become especially evident in these Covid-19 times, says Gunilla Andrew-Nielsen, responsible for the project at the MPA.

It is anticipated that virtual clinical trials can reform how clinical research is performed both in Sweden and internationally.

-The possibility of virtual clinical trials would enable participation in clinical trials for more patients and subsequently broaden the foundation for developing new medicinal products. For instance, we know that approximately 70 percent of a potential population is not being considered and offered the opportunity to be screened for a trial due to geographical reasons. The virtual methodology also aims to produce more equal and economically sustainable clinical trials in Sweden, says Jenny Söderberg, project manager of the pilot study.

The pilot study will be conducted in both a theoretical and practical context and in close collaboration with the traditional stakeholders initiating, planning and implementing clinical trials. During early summer 2020, aided by several external reference groups, the project group will map how well virtual clinical trial requirements are supported by current regulations and define areas that are indistinct and unpredictable. The MPA is assessed to have an important and prominent role in this context as the government agency responsible for approving and overseeing clinical trials.

As a part of the pilot project, one or several pilots will be conducted during the fall of 2020 to explore present practical foundations, but also to compile important experiences. Since the project became official, there has been extensive interest to participate and actively contribute.

-This is an important signal concerning that these issues are current and relevant amongst those it primarily affects, says Jenny Söderberg.

The MPA homepage will continuously publish information regarding and results from the project. It is currently possible to report interest concerning taking part in the reference groups during the spring of 2020.

The pilot project is expected to be ongoing until February 2021.

More information (in Swedish) about the project can be found at:
https://www.lakemedelsverket.se/sv/tillstand-godkannande-och-kontroll/klinisk-provning/lakemedel-for-manniskor/virtuella-kliniska-lakemedelsprovningar

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Denmark's **DKMA** has initiated an industry forum to have open dialogue with the research community, including hospitals, patient associations, CROs and pharma, on the topic of decentralization

Sweden's **MPA** has developed a pilot program, where they plan to initiate up to 5 DCT trials in Sweden. Free trial application and Scientific Advice is also provided to successful applicant

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

August 2020

Lægemiddelstyrelsens dialogforum vedr. den digitale udvikling og decentralisering af kliniske forsøg med lægemidler.

Baggrund:

Kliniske forsøg med lægemidler er under accelererende udvikling når det kommer til digitalisering og decentralisering. Med dette forstås brugen af digitale værktøjer (digitalt samtykke, elektroniske konsultationer, elektroniske systemer til dataindsamling, medicinsk udstyr, etc.), som sekundært understøtter, at patienter ikke i samme grad som for traditionelle kliniske forsøg er afhængige af fysisk at skulle tilgå en hospitalsafdeling (decentralisering).

Denne udvikling tænkes at være med til at sikre en bredere repræsentation af forsøgspersoner samt lette inklusion og fastholdelse af patienter i kliniske forsøg. Lægemiddeludvikling er desuden ekstraordinær kapitalkrævende og den digitale udvikling kan potentielt holde omkostningerne nede til gavn for både patienter og samfund.

Lægemiddelstyrelsen ønsker at imødegå denne udvikling ved oprettelse af et dialogforum i samarbejde med Trial Nation. Dette forum skal garantere et stærkt samspil mellem myndigheder, forskere og industri og sikre en passende og rettidig udvikling af de regulatoriske rammer, således at Danmark kan fastholde en stærk position inden for klinisk forskning til gavn for patienterne.

Deltagere i dialogforum:

Følgende interessenter er inviteret til deltagelse af én repræsentant, som forventes at være forankret i Danmark. Ved workshops og andre faglige aktiviteter forventes der deltagelse med relevante eksperter.

Repræsentanter fra forskningsmiljøet:

- GCP-enheden
- Dermato-Venerologisk Afdeling og Videncenter for Sårheling, Bispebjerg Hospital
- CASTLE, Cancer Late Effect Research, Center for Surgery and Cancer, Rigshospitalet

Repræsentant fra patientforeninger:

- Danske Patienter

Kontraktvirksomheder (CRO):

- IQVIA

Industri:

- Novo Nordisk
- LEO Pharma A/S
- Bristol-Myers Squibb (BMS)
- GlaxoSmithKline A/S (GSK)

Øvrige organisationer:

- Lægemiddelindustriforeningen
- Dansk Biotek
- Apotekerforeningen

Kommissorium, digital udvikling og decentralisering af kliniske forsøg med lægemidler.

Side 1 af 2

NOVARTIS | Reimagining Medicine

Innovative Medicines Initiative

Europe's Partnership for Health

- IMI1 programme (2008-2013), the total budget was €2 billion
- IMI2 programme (2014-2020), the total budget was €3.276 billion
- Innovative Health Initiative *(replacement for IMI*), has a proposed budget of €2.4 billion

- ~50% comes from the European Commission
- ~50% comes from EFPIA (IMI 1 & 2) and COCIR, EFPIA, EuropaBio, MedTech Europe and Vaccines Europe (IHI)

Under IMI 1 & 2

€5.3bn	168	5 244	>7 000	>3 800
BUDGET	PROJECTS	PARTICIPANTS	PROJECT OUTPUTS	PUBLICATIONS

https://www.imi.europa.eu/

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Centre of Excellence for Remote & Decentralized Clinical Trials

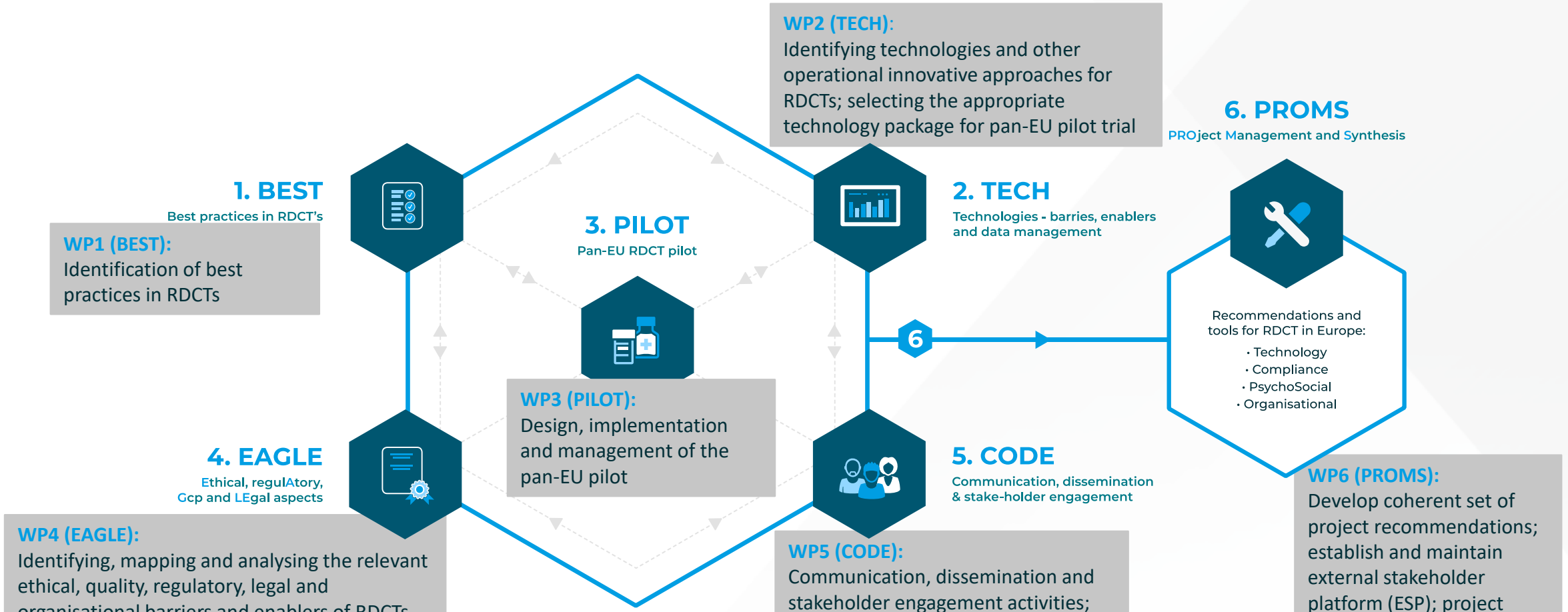
Trials@Home aims to reshape clinical trial design, conduct and operations, by developing and piloting standards, recommendations and tools for the definition and operationalization of remote decentralized clinical trials (RDCTs) in Europe

Key objectives:

- Defining the best practices for the conduct of RDCTs.
- Identifying technologies and other operational innovative approaches for RDCTs and selecting the appropriate technology package to be used for the pan-EU pilot.
- Designing and running a pan-EU pilot, comparing the scientific and operational quality of the RDCT with traditional trial approaches and evaluating the feasibility of the RDCT.
- Identifying, mapping and analysing the relevant ethical, quality, regulatory, legal and organisational barriers and enablers of RDCTs.
- Consulting with stakeholders and promoting the outcomes from the Trials@Home consortium through targeted communication, dissemination and training activities.
- Providing recommendations with supporting tools for implementing RDCTs in Europe and contributing to the update of ICH guidelines on RDCTs.

Project Organization: Work packages

The six Work Packages (WPs) of Trials@Home and their interdependencies



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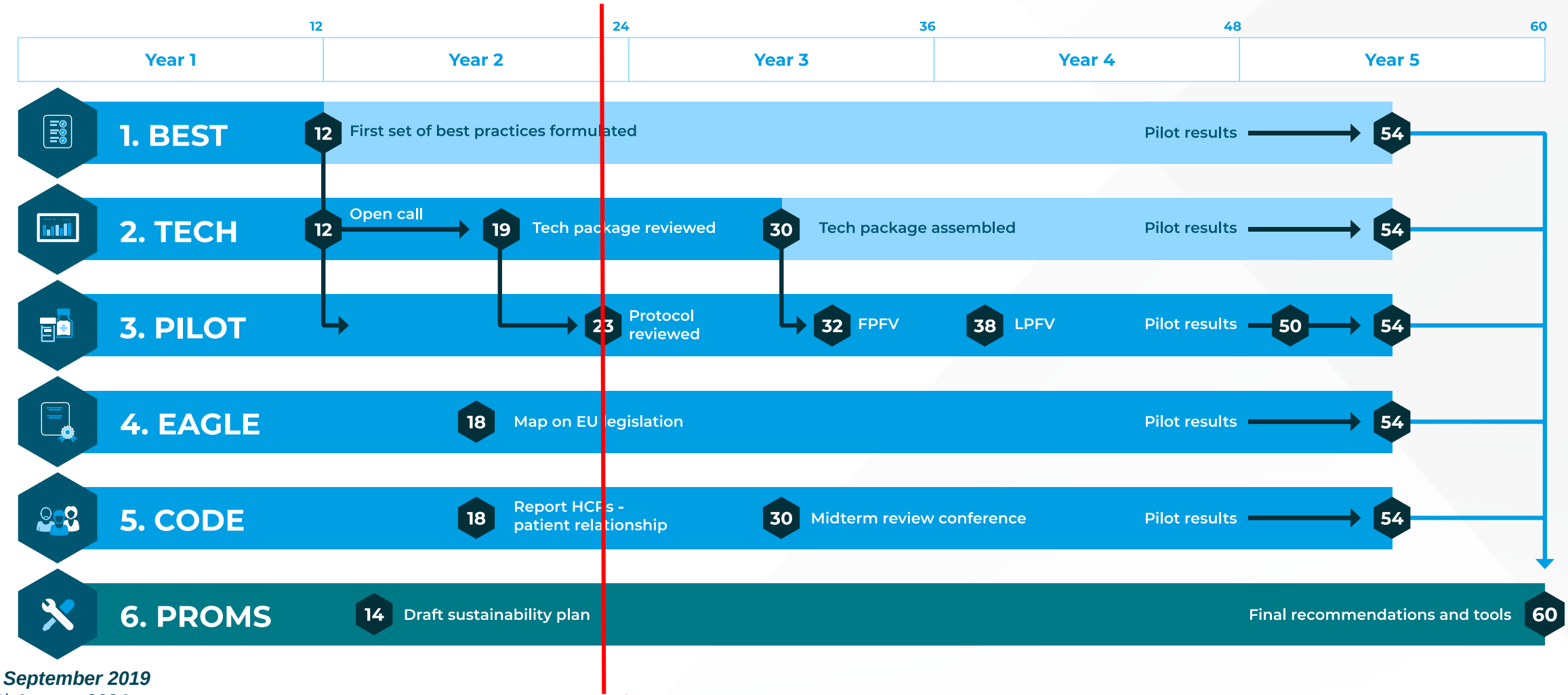
IMI DCT Topic – Overall Timing



1st September 2019
31st August 2024

We are here

TRIALS @HOME

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Panel Discussion

- **Megan Doyle**, Amgen (Moderator)
- **Scott Askin**, Novartis
- **Alma Chavez**, Duke Clinical Research Institute
- **Adam Hartman**, NINDS
- **Robert “Joe” Mather**, Pfizer
- **Isaac Rodriguez-Chavez**, ICON