



DTRA
DECENTRALIZED TRIALS
&
RESEARCH ALLIANCE

LEADERSHIP COUNCIL

Business Meeting

March 2nd, 2023

AGENDA

Welcome!

Initiatives & Forum

- Team Updates from 2C, 4C, 3A
- Co-Labs
- DTRA Circles
- Regulatory Forum Update
 - OSTP/ONC RFI
 - ASCO/FDA 1572 Modernization

DTRA Membership

- Leadership Council Expectations
- Member Benefits
- DTRA Annual Meeting 2023
 - Engagement Opportunities
- TGIF-DCT Clubhouse
- Upcoming Leadership Meetings

REMINDERS



CHATHAM HOUSE RULE

Participants are free to use today's information, but do not attribute to any individual participant



RAISE YOUR VIRTUAL HAND

Use the Zoom feature to indicate wanting to comment



NON-COMMERCIAL SPACE

The online collaboration platform provides the appropriate space to share capabilities

CURRENT MEMBERS

accenture

Advanced Clinical

ADVARRA

agios

AMGEN

astellas

Boehringer
Ingelheim

Bristol Myers Squibb

CardieX

Care
Access

careevolution
HEALTHCARE TECHNOLOGY

castor

CITELINE

CLARIO.

Michael Smith
Health
Research BC
CLINICAL TRIALS BC

CMIC
Pharmaceuticals & Biotech

Cognizant

Cogstate

CSL Behring

Curebase

CVS
Health.

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Datacubed
Health

Davita
Clinical Research

EDETEK

Eisai

EmVenio
RESEARCH

EQUIDEUM

Everest Group

EVERSANA

FasterCures
A CENTER OF THE NIAH INSTITUTE

FDA

flatiron.

Genetic Alliance

Global Genes
It's Not In Your Genes

greenphire

GSK

Halloran
CONSULTING GROUP

ICON

Influss Health

IQVIA



Janssen
Johnson & Johnson

JNP MEDI
MedicalData. Secured.

Lightship

Lilly

MAYO
CLINIC

McKinsey
& Company

mdgroup

Medable

MEDIDATA

merative

NOVOTECH
The Age-Proof CEO

ORACLE

Otsuka

parexel.

PMTRIALS
QUALITY MOBILE RESEARCH

Pfizer

PPD

pwc

REALTIME
CLINICAL TRIAL MANAGEMENT SYSTEMS

Roche

sanofi

Science 37

sema4

SEQSTER

VA
U.S. Department
of Veterans Affairs

SHEARWATER
HEALTH

SIGNANT HEALTH

STAND
UP TO
CANCER
standuptocancer.org

sunovion

Syneos
Health

Takeda

TEMPUS

THREAD

UBC
UNIVERSITY OF BRITISH COLUMBIA

Inspired by patients.
Driven by science.

Velocity
CLINICAL RESEARCH

Verana Health

veradigm.

verily

VERISTAT

vivoSense

w

WORLDWIDE
CLINICAL TRIALS

xCures

ZS

DTRA ORGANIZATIONAL UPDATE



Welcome New DTRA Team Member

Jane Myles, Program Director, DTRA

INITIATIVE TEAMS

UPDATE

Claudine Paccio

DTRA - INITIATIVE OVERVIEW


Initiatives

The 12 Priorities delve deeper into each of the Priorities to identify the framework to pursue our shared goals and develop strategic solutions. Click on each Initiative, or access in the DTRA Community.


1A GLOSSARY




1B KEY PERFORMANCE INDICATORS




1C CHANGING THE NORM



2A BEST PRACTICES HANDBOOK




2B MAPPING THE PATIENT JOURNEY



2C TECHNOLOGY & DATA STRATEGY



3A CROWDSOURCE EVIDENCE OF IMPACT



3B KNOWLEDGE-SHARING PLAYBOOK



3C DCT CURRICULUM




4A GLOBAL CONDUCT MAP



4B COLLABORATE ON REGULATORY GAPS



4C DATA CONNECTIVITY



SELECT INITIATIVE SUMMARY

DTRA Glossary

Live at www.dtra.org/1a-glossary



Join Now

Glossary

Industry Terms and Definitions

Please enter a clinical research word in the alphabetically below.

Search Glossary

A B C D E F G H I J K L

All Forms Foundational Outcomes

A

Adverse Event (AE) Foundational

Adverse event means any untoward medical occurrence associated with the use of a d

KPIs

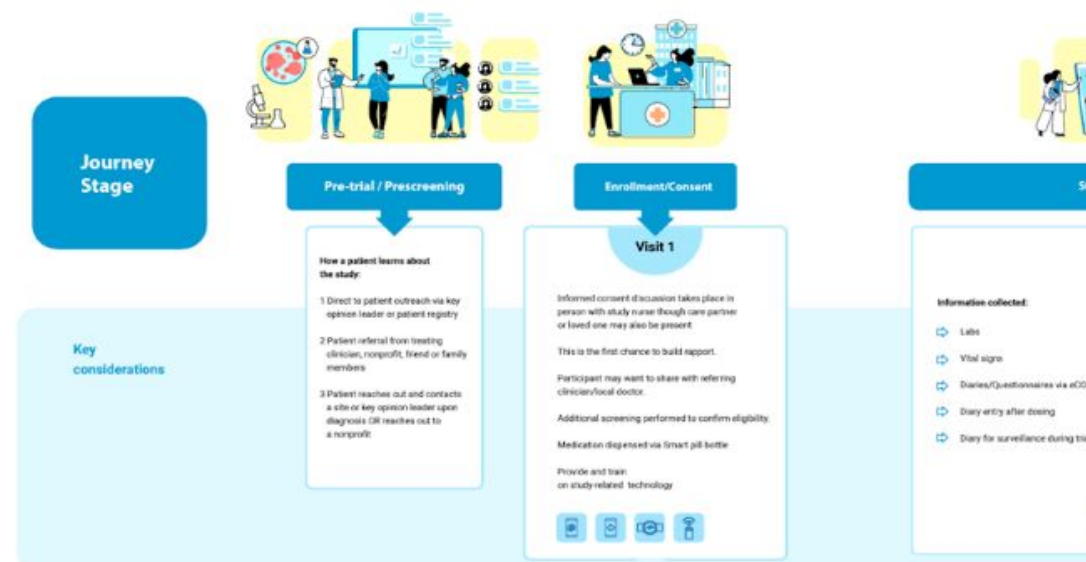
Live for DTRA Members at www.dtra.org/key-performance-indicators

Number	Stakeholder	Metric	Calculation Method
1	Patient, sites	Likelihood to engage in a DCT	Net Promoter Score (NPS), a metric of likelihood to recommend a product, a score for your customer experience.
2	Patient, sites, sponsor	Patient drop out % for a "patient decision"	% of patients who have been randomized (1 visit) and has left the trial due to "p

Patient Journey Maps

Live at www.dtraresources.org

Vaccine map now live



Best Practices Rubric

Live at www.dtraresources.org/rubrics



1. EVIDENCE OF SUCCESS

Best practices should have measurable and demonstrable success. This dimension is meant to help teams consider whether there is a track record of successful outcomes from the use of the practice. Teams should evaluate the data to determine the fit for their situation. KPIs and tangible outcomes are at the heart of evaluating best practices for DCT.



2. IMPROVING PATIENT EXPERIENCE

DTRA - INITIATIVE OVERVIEW

Foundational Initiatives: DCT Standards				Supporting DCT with Education and Adoption			
1A	Glossary	PUBLISHED AND COMMUNICATED	complete	1C	Changing the Norm	Whitepaper completed.	Q1
2B	Mapping the Patient Journey	3 Maps created and completed: Oncology, Rare Disease, & Vaccines	complete	3B	Knowledge Sharing Playbook	Spreadsheet populated with information Final graphic will be Tubestop	Q2
2C	Data & Technology Strategy	3 of 4 areas of focus completed	Q2	3C	DCT Curriculum	Module list created with specific details behind each one Overview module 1 outline completed	Q2
Measuring Success with DCT				Removing Barriers			
1B	KPIs	version 1.0 published internal to DTRA for feedback	Q1	4A	Global Conduct Insight Map	Spreadsheet APAC / EU / US: Regulatory is comprehensive Information on Privacy (just GDPR, China) Content visualization underway	Q1
2A	Best Practices	version 1.0 rubric PUBLISHED Evaluation process to be finished	Q1	4B	Regulatory Gaps	Completed gaps and added to 3C spreadsheet Team is being dissolved and migrated into the DTRA Regulatory Forum	complete
3A	Crowdsharing Evidence of Impact	Slide deck from 3A: Crowdsourcing Evidence workstream along with a document citing links to the publications that were referenced.	Q1	4C	Data Connectivity	Team meetings underway after the rescope	Q2

PRIORITY INITIATIVE 2C

DATA & TECHNOLOGY STRATEGY

Status Updates

Toni Hofhine

TECHNOLOGY & DATA STRATEGY

Deliverable:

DCT Clinical Data Strategy framework that outlines modern data requirements, data flow, data channels, data curation and insight generation to improve end-to-end data accessibility, reliability, integrity, and traceability across study phases

Key Initiative/Focus Areas - 3 of 4 Completed

Focus Area	DTRA Definition Provided	Notes
DCT Technology	Outline of established (and novel) technologies used to support decentralized trial execution	2C Initiative
User Ecosystem	Outline of relevant users/personas that can comprise the execution of decentralized trials	2C Initiative
Privacy, Ethical, & Legal Considerations	Outline of key considerations (globally) related to data capture and data use in decentralized trials	2C Initiative + input/feedback from interested 4C
Data Capture & Accessibility	Outline of different data capture methods/modes and associated accessibility requirements required for effective execution of clinical trial activities in a remote setting	2C Initiative + input/feedback from interested 4C

2C Team Members:

PM: Open
 Co-lead: Toni Hofhine, CardieX
 Co-Lead: Kim Williams, Datacubed
 John Storey, MRN
 Charisa Scott, Amgen
 Camila Matheny, Medable
 Helen Greta, IQVIA

4C Team Members:

Venkat Setti, AstraZeneca
 Sneha Sundet, Agios Pharmaceuticals
 John Graves, Equideum Health
 John Stuart,
 Eldawud Reem, Kearney
 Greg Jones, Oracle
 Kishori Khokarale, ZS

Team Dependencies:

1A Glossary
 2B Patient Journey Maps
 4B Regulatory Gaps
 4C Data Connectivity

DCT TECHNOLOGY & USER ECOSYSTEM - 2C TEAM

Overall Status ●

Deliverable Timeline

Completed on January 31, 2023

Challenge

Deliver a comprehensive list of technology used in a decentralized trials

Solution

Identify key technology used by trial milestone, provide a definition, integrated trial roles with identified ecosystem users/personas

DCT Technology & User/Personal Ecosystem Grid by Trial Milestone							
	Trial Planning	Trial Startup		Patient Recruitment & Consent		Trial Conduct	Trial Close Out & Reporting
	Site Feasibility	Trial Startup	Pre-trial / Prescreening	Patient Recruitment	Consent/Screening/Enrollment	Study Conduct	Study Close Out
Definition	Site feasibility is the process of evaluating the possibility of conducting a clinical trial or study, at a particular site. The monitoring team conducting the feasibility, also ensures that the trial can be conducted at the proposed site from an ethical and regulatory perspective.	Start-up occurs after protocol development and includes various tasks that enable trial execution. This phase includes system identification and set-up, development of key study materials (eg consent), and several activities to enable site readiness for patient enrollment such as regulatory submissions, investigator file compilation, and receipt of devices/kits/supplies.	Pre-trial or prescreening is the general identification of a patient population for any clinical trial.	Recruitment is the identification of patients for a specific IRB-approved clinical trial protocol using the inclusion/exclusion criteria.	Participant consent to study enrollment.	Conduct occurs from first patient in through last patient out.	Close out occurs at the time the database is locked followed by submissions and back to regulatory/ethics, statistical analysis, etc.
Actions	Intersect with 1A glossary team						
Integrated Trial Roles	Site, IRB & EC, Sponsor/CRO, Country Regulatory Designee	Site, Patient, Sponsor/CRO, IRB & EC, Country Regulatory Designee	Site, Patient, Country Regulatory Designee	Site, IRB & EC, Patient, Sponsor/CRO	Site, Patient	Site, Sponsor/CRO, Site Monitoring, Patient	Site, Sponsor/CRO, Country Regulatory Designee
User/Persona Ecosystem	Study or site startup team (CRA, PM, Feasibility Mgr, Patient Recruitment, Regulatory), IRB/EC, Study Management Team (CRO, Sponsor, SMO)	Site staff (CRC, PI, Sub-I, Pharmacist, Phlebotomist), Study Management Team	Site Staff, Patient Recruitment, RWD/RWE, Study Management Team	Site Staff, Patient Recruitment, IRB/EC, Study Management Team	Site Staff, Technology Teams, Study Management Team, Patient Recruitment	Site Staff, Patient Recruitment, RWD/RWE, Study Management Team, Technology Teams	Site Staff, Regulatory, Study Management Team, Technology Teams, IRB/EC
DCT Technology	Router/WiFi Geomapping Investigator data bank (RWD patient populations and RWD secondary arms)	Site: eConsent, Prescreening, eSource, eISF, eCOA, IRT, Clinical Trial Payments, Telemedicine, CTMS, LMS Sponsor: CTMS, eTMF, EDC Patient: ePRO, sensors/mobile devices	Pre-screener for trial Direct to patient (diagnostics) Investigator data bank (RWD patient populations and RWD secondary arms)	Recruitment database	eConsent Remote consent (telemedicine) Direct/remote to patient (diagnostics) Lab reports to EDC/CTMS/IRT/RWD Medical device sensors (RPM) Virtual visits	eSource eQMS/CAPA Risk based monitoring Analytics (data lake/warehouse) Clinical Trial Payments, Telemedicine, Patient Compliance (alerts/reports)	eSource, CTMS, EDC, eTMF, eISF, eCOA, wearables/sensors Pharmacovigilance, eArchiving

DCT TECHNOLOGY - 2C TEAM

DCT Technology & User/Personal Ecosystem Grid by Trial Milestone							
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User/Persona Ecosystem	Study or site startup team (CRA, PM, Feasibility Mgr, Patient Recruitment, Regulatory), IRB/EC, Study Management Team (CRO, Sponsor, SMO)	Site staff (CRC, PI, Sub-I, Pharmacist, Phlebotomist), Study Management Team	Site Staff, Patient Recruitment, RWD/RWE, Study Management Team	Site Staff, Patient Recruitment, IRB/EC, Study Management Team	Site Staff, Technology Teams, Study Management Team, Patient Recruitment	Site Staff, Patient Recruitment, RWD/RWE, Study Management Team, Technology Teams	Site Staff, Regulatory, Study Management Team, Technology Teams, IRB/EC
DCT Technology	Router/WiFi Geomapping Investigator data bank (RWD patient populations and RWD secondary arms)	<u>Site</u> : eConsent, Prescreening, eSource, eISF, eCOA, IRT, Clinical Trial Payments, Telemedicine, CTMS, LMS <u>Sponsor</u> : CTMS, eTMF, EDC <u>Patient</u> : ePRO, sensors/mobile devices	Pre-screener for trial Direct to patient (diagnostics) Investigator data bank (RWD patient populations and RWD secondary arms)	Recruitment database	eConsent Remote consent (telemedicine) Direct/remote to patient (diagnostics) Lab reports to EDC/CTMS/IRT/RWD Medical device sensors (RPM) Virtual visits	eSource eQMS/CAPA Risk based monitoring Analytics (data lake/warehouse) Clinical Trial Payments, Telemedicine, Patient Compliance (alerts/reports)	eSource, CTMS, EDC, eTMF, eISF, eCOA, wearables/sensors Pharmacovigilance, eArchiving

PRIVACY, ETHICAL, & LEGAL CONSIDERATIONS

Overall Status ●

Deliverable Timeline

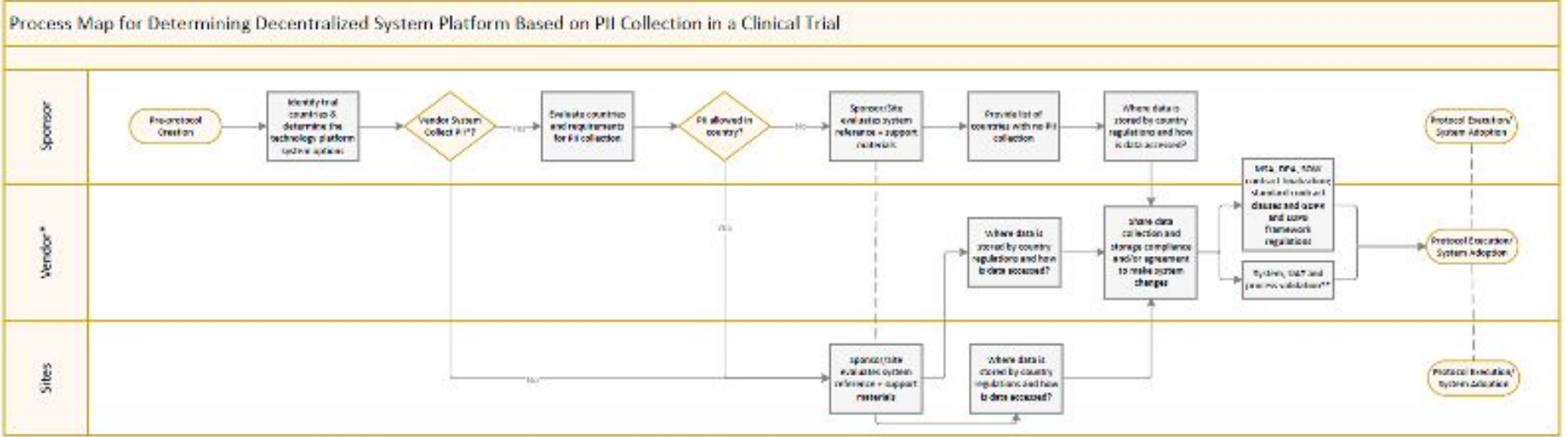
Completed on January 31, 2023

Challenge

Deliver a solution that encompassed the global consideration for privacy, ethical, and legal data collection

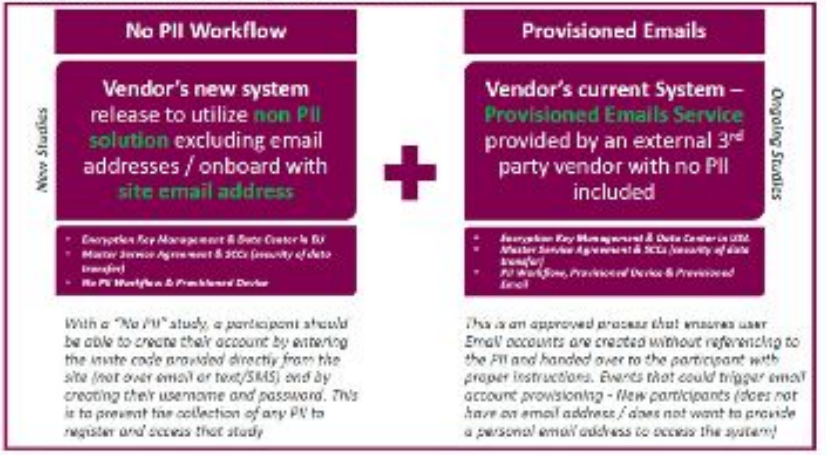
Solution

Adopt the System Agnostic Technical Solutions concept (donated to DTRA by AstraZeneca) on how PII data collection could be fully avoided in any region
The team will develop a process map to clarify stakeholder and system needs



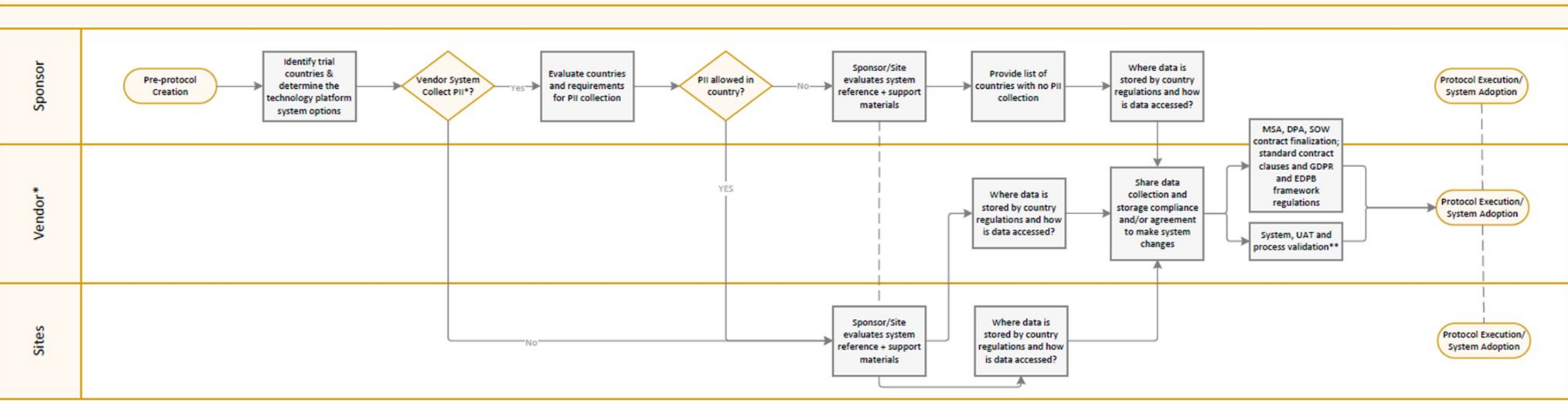
System Agnostic Technical Solutions

Participant invites and registration without collecting identifiable information



PRIVACY, ETHICAL, & LEGAL CONSIDERATIONS

Process Map for Determining Decentralized System Platform Based on PII Collection in a Clinical Trial



PRIORITY INITIATIVE 4C

DATA CONNECTIVITY

Status Updates

Munther Baara

DATA CONNECTIVITY

Vision:

Define and provide an agnostic data framework for DCTs clinical data life cycle maintaining quality and integrity to enable near real-time data driven decision-making, across all trial phases (I to IV), and therapeutic areas. **The framework will provide an approach(es) for data connectivity, standardization, reliability, and interoperability.**

Deliverable:

Agnostic strategy to manage clinical data flow through its life cycle including controlled access, acquisition, curation, processing, reporting, dissemination, and data flow across the CT ecosystem, while maintaining compliance to applicable regulation.

- **A toolkit** (Architecture, blueprint, etc). **to provide approaches on how to manage clinical data** in different scenarios
- **Flexible and configurable clinical data orchestration and workflow** based on events
- Specific to full and hybrid DCTs

Values:

- Reduce manual redundancy, fragmentation, and error of multiple entries of the same data in different systems
- Single source of truth (i.e. what constitutes an electronic source for DCT)
- Near real-time access to data
- Faster decision making
- Decrease the variety of touchpoints and entry-points by streamlining and automating technology ecosystems

4C Team Members:

Co Lead: Open

Co Lead: Munther Baara, Edetek

PM: Moulik Shah, Advanced Clinical

Sneha Sundet, Agios Pharmaceuticals

Thomas Healy, PPD

Jordan Simpson, Merative

Venu Mallarapu, eClinical

Rick Greenfield, RealTime CTMS

Kishori Khokarale, ZS

Tianna Umann, Microsoft

David Enarson, Mayo Clinic*

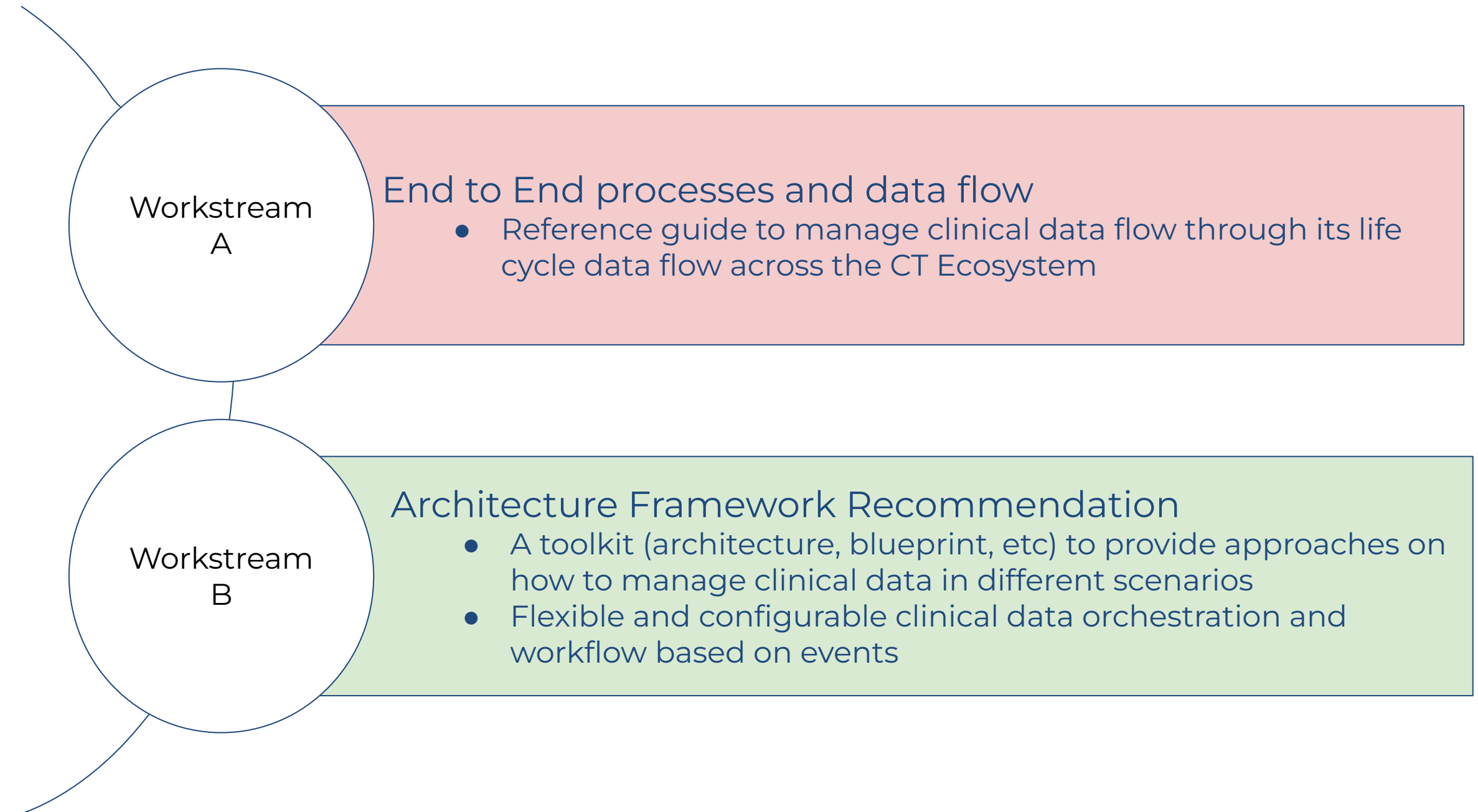
Justin Gundelach, Mayo Clinic*

Rebecca Kottschade, Mayo Clinic*

*New Members

PROPOSED WORKSTREAMS

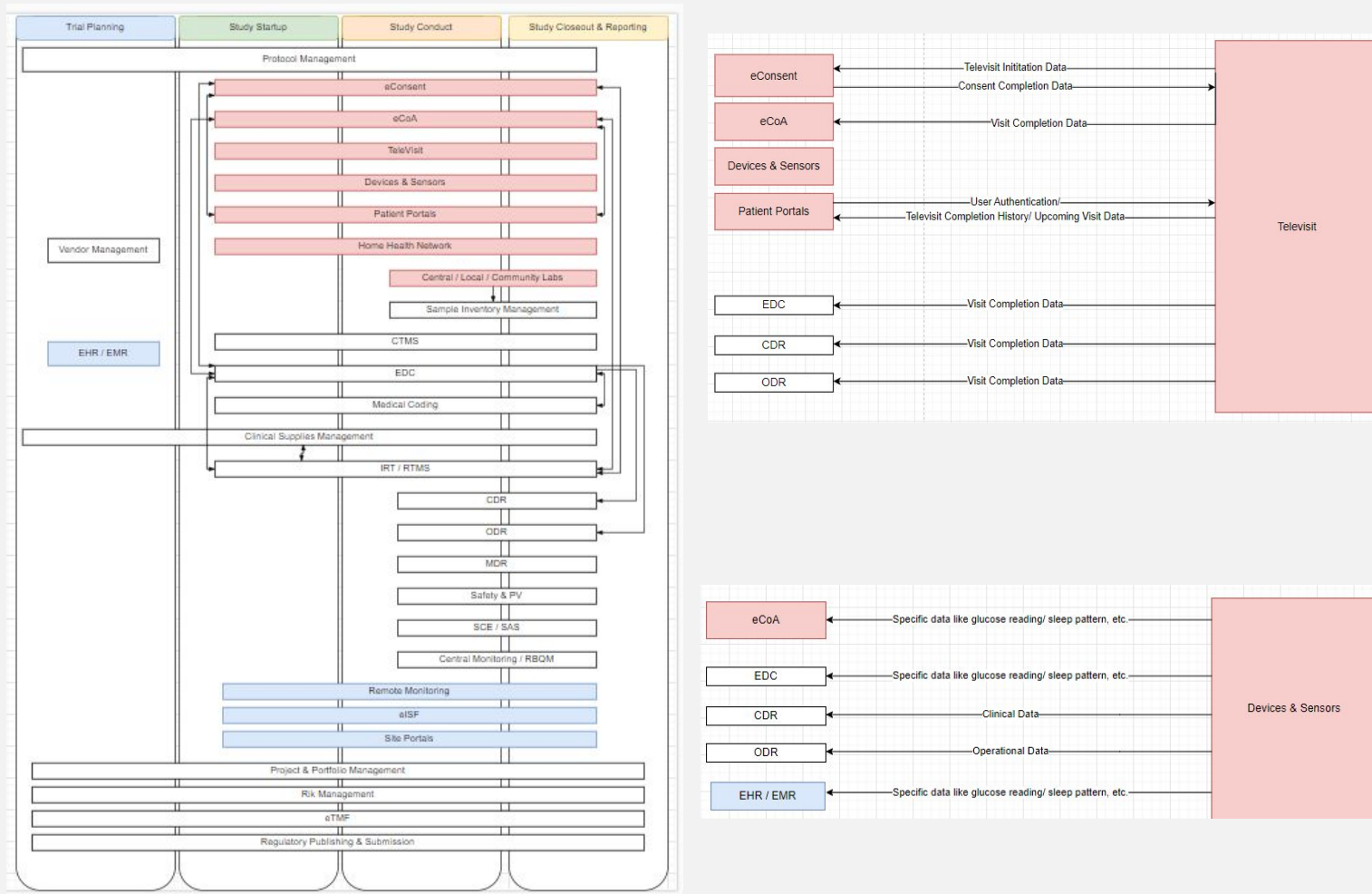
Workstream Deliverables



INFORMATION DATAFLOW AND DATA EXCHANGE FRAMEWORK

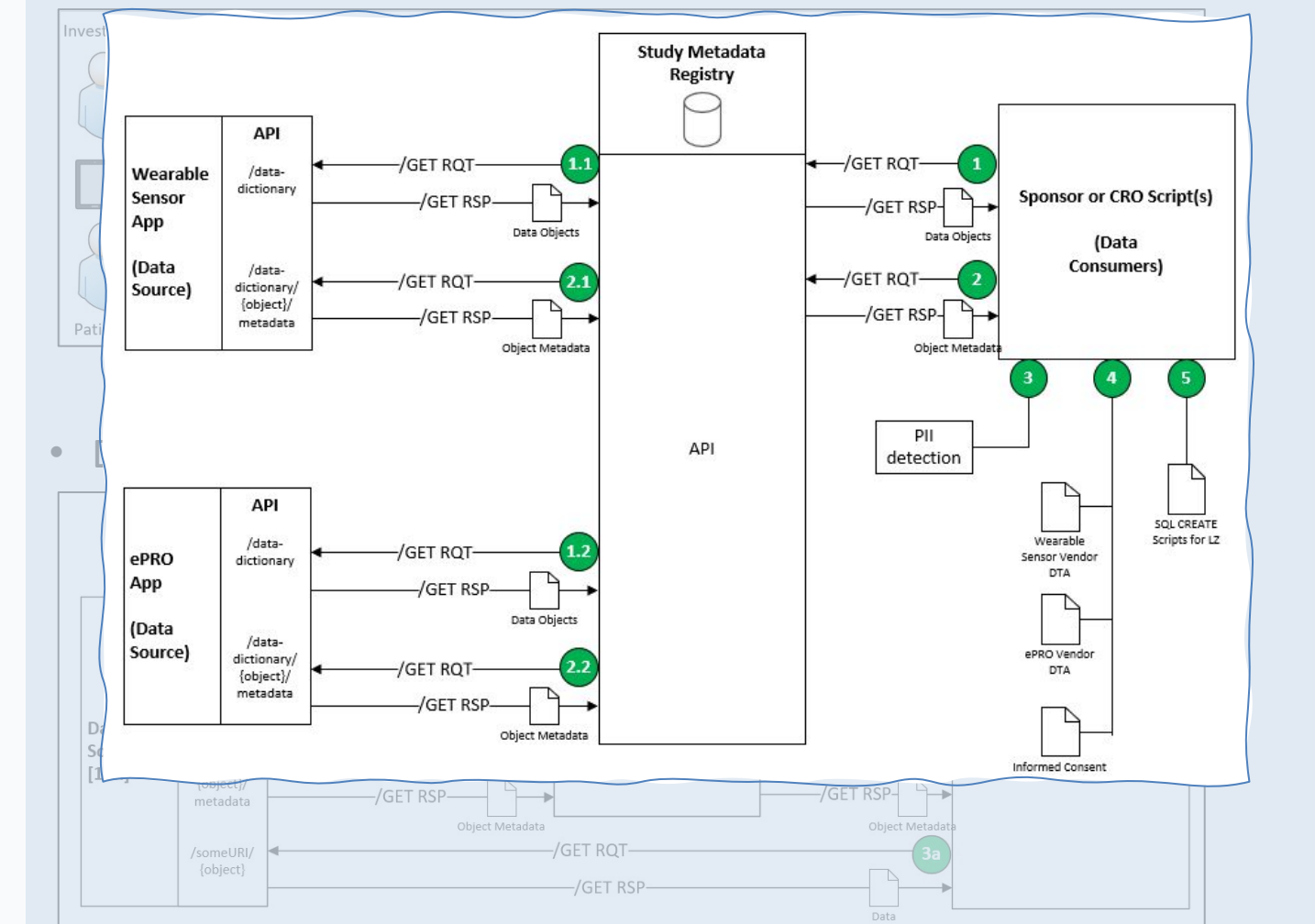
Information Dataflow

- Capturing where the data flows from each of the system
- Capturing what type of data flows from each of the system






Data Exchange Framework

- An event notification service – real-time process
- Use Case – eConsent and EDC



STATUS AND TIMELINE



	January 2023	February 2023	March 2023	April 2023	May 2023	June 2023
Team Restart						
Workstream Breakout						
Workstream Consolidation (2C + 4C)						

Major Accomplishment

- Workstream created and deliverables defined
- Operating mechanism setup complete
- Initial review of 2C deliverable completed

Key Considerations

- This initiative will have to take a phased approach
 - Phase 1 is focused on clinical patient data
- Member/participant count for the overall workstream is low

PRIORITY INITIATIVE 3A

EVIDENCE OF IMPACT

Status Updates

Caroline Redeker

OVERVIEW AND GOALS

High Level Description:

- Identify where data, use cases & evidence exists demonstrating the impact of decentralized research and make broadly available for the research community

Actions to deliver:

- Conduct secondary and primary research with key stakeholders across the DCT ecosystem
- Crowdsourcing for additional data and evidence
- Primary research to better understand education needs
- Draw expertise from stakeholders within DTRA and beyond including global investigators and patient voices

TIMELINE, WORKSTREAMS, AND KEY MILESTONES

	October 2021	November 2021	December 2021	...	September 2022	November 2022
Key Milestones	Initiative Kick Off ★	DTRA Inaugural Annual Meeting ★				Final Readout DTRA Annual Meeting ★
Desk Research	[Blue bar spanning from start of October 2021 to end of December 2021]					
Internal Interviews (DTRA)	[Blue bar spanning from start of October 2021 to end of December 2021]					
External Interviews*		[Blue bar spanning from start of November 2021 to end of September 2022]				
Regulatory Validation (DTRA)		[Blue bar spanning from start of November 2021 to end of September 2022]				
Synthesis & Presentation				[Blue bar spanning from start of September 2022 to end of November 2022]		

METHODS UTILIZED TO CROWDSOURCE, ANALYZE, AND COMPILE EVIDENCE



Survey DTRA participants

Conducted survey to crowdsource evidence of impact and **received ~60 responses** from DTRA & industry participants

- Responses received from life sciences sponsors, CROs and technology vendors



Desk Research

~34 citable articles on DCT impact collated by:

- Crowdsourcing from DTRA Initiative 3A members
- Additional research and collaboration conducted by Boston University studies (with DTRA Oversight)
- Resulted in overlapping information



Additional Interviews

~8 interviews were conducted to gather detailed evidence of Impact

- Interviewee roles ranged from strategy, operations and technology teams



Evidence Compilation & Synthesis

Initiative members helped synthesize DCT impact across 7 categories

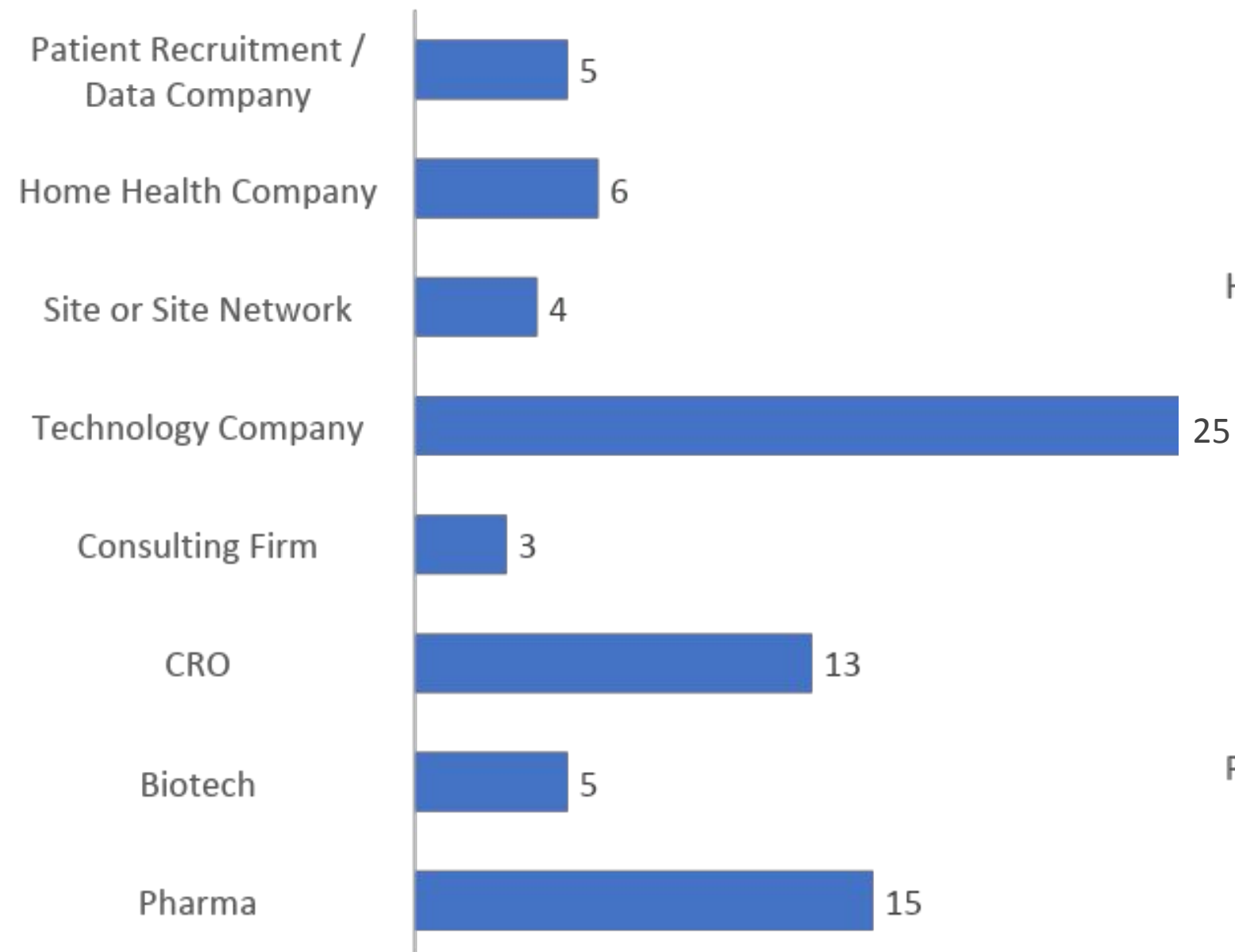
Further validation and input received on the readout presentation from DTRA leadership and partner organizations (e.g. SCRS)

INPUT FROM PHARMA/BIOTECH, DEVICE, CROs, DCT PROVIDERS, MOBILE SITES

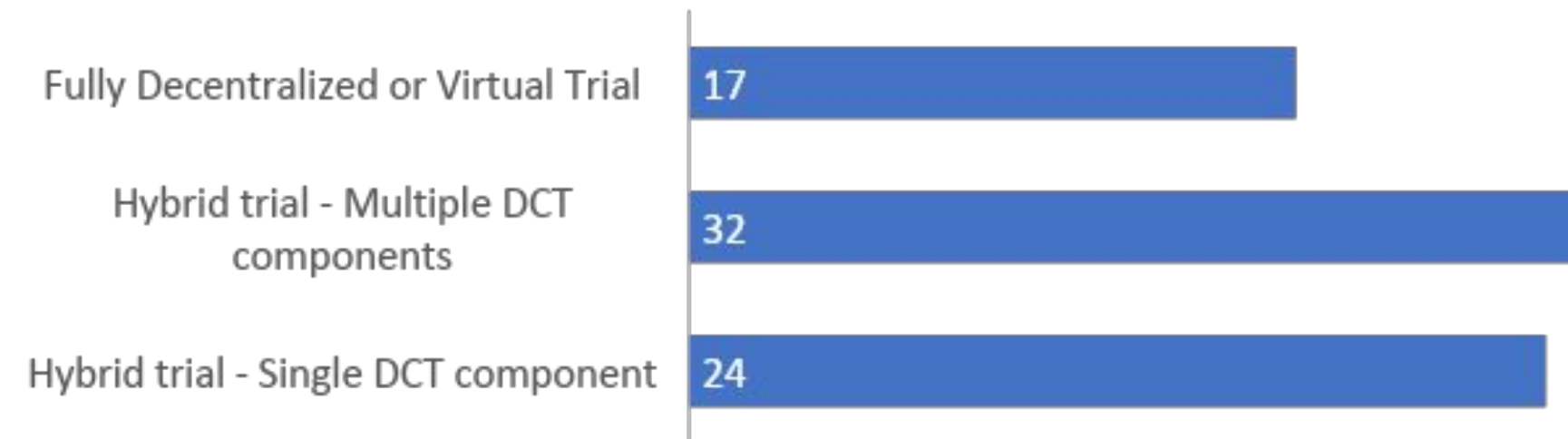
Initiative 3A Survey: Response Summary

N = Number of respondents

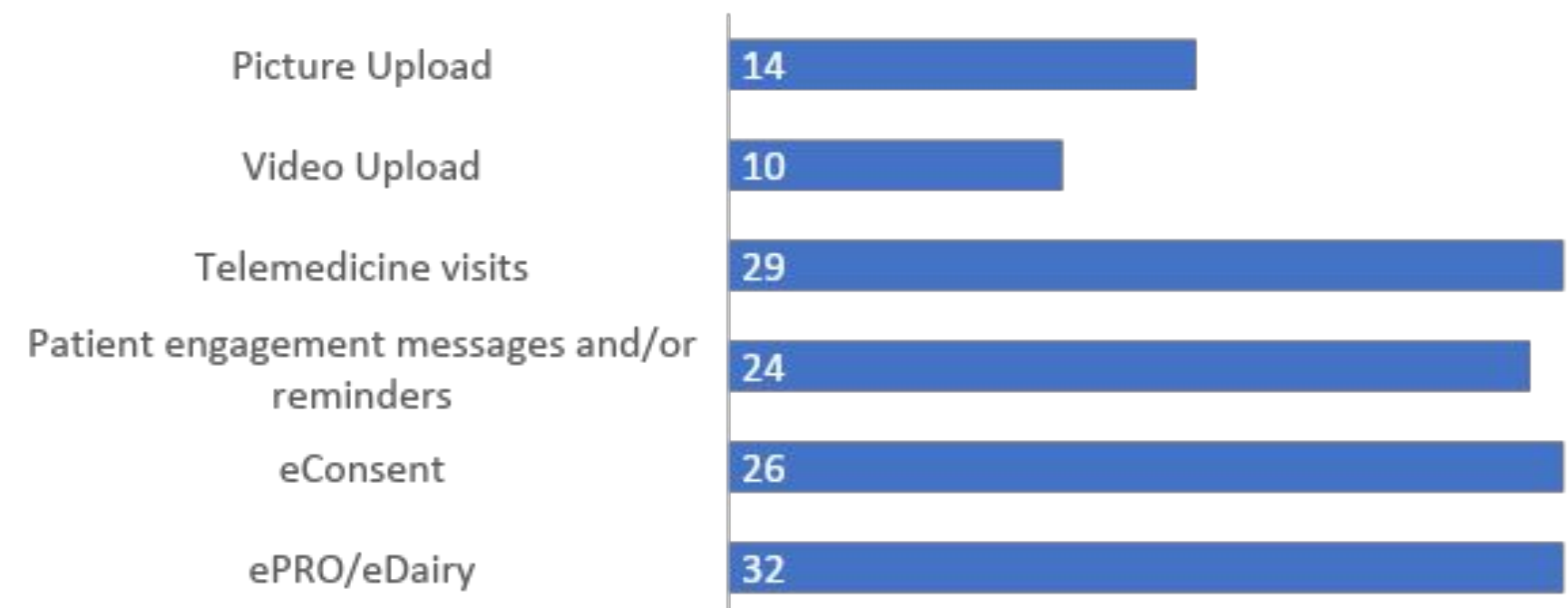
Company Representation



Trial Type Supported



DCT Components Utilized



DATA LIMITATIONS AND REGULATORY CLARITY

Acknowledgement of data limitations:

- Data site largely derived from experience at pharma sponsors and DCT providers, but currently lacking site perspective
- Most of what has been collected is **operational data** and only some of it is published data. Most DCT claims are operational in nature and hence difficult to find published evidence of impact
 - Even operational data is limited; companies do not have measurements in place to capture this level of detail within their studies
- Global regulatory differences in operating DCT continues to evolve
 - It is also unclear to many in the industry what will change coming out of COVID-19 era
 - What will be acceptable to regulatory authorities vs. what will revert by region and country
 - Site feedback includes confusion over their role in oversight when a patient is seen in the home or outside of the site with another provider

SOURCE AND CATEGORIZATION OF EVIDENCE

Initiative 3A: Research Process



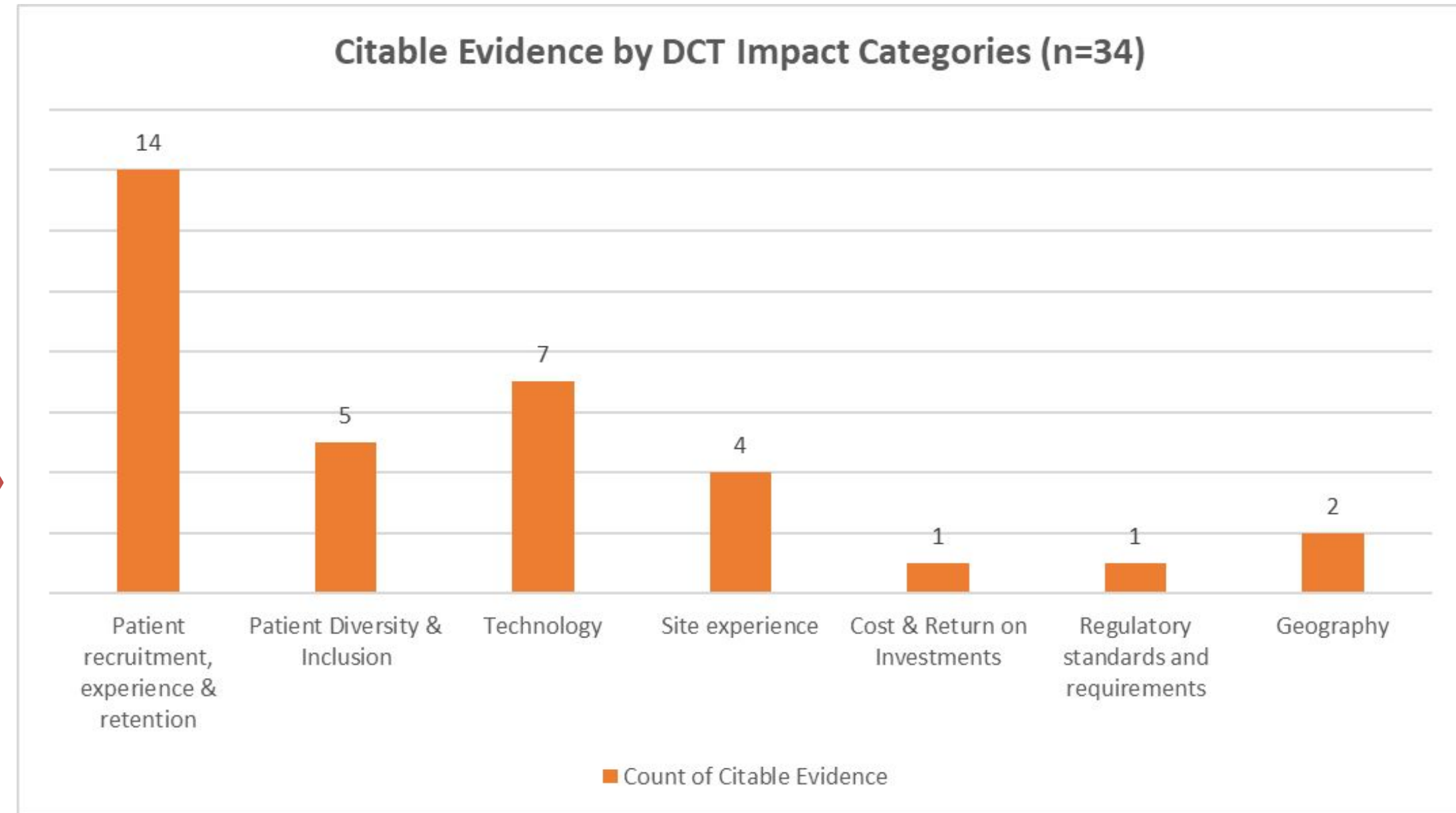
60 respondents surveyed across DTRA member companies including pharma, biotech, CROs, DCT technology companies and others



+35 publications reviewed by initiative members; collaborated with Boston University for validation and additional research



8 follow-up interviews with DTRA members to collect detailed evidence of DCT impact



Shows robust usage evidence on DCT methods; proof points for adding value to stakeholders still emerging

EXECUTIVE SUMMARY:

7 CATEGORIES FROM 34 CITABLE EVIDENCES

Despite limitations in tracking decentralized technologies & their impact, available sources suggest increasing adoption

Impact Category #	Impact Category	Summary	# of Citable Evidences
1	Patient Recruitment, Experience, & Retention	There have been many patient surveys with results indicating that patients prefer having the option of remote vs. in-person site visits (published and unpublished data)	14
2	Patient Diversity & Inclusion	With fewer site visits and digitally-enabled recruitment, there are clear emerging proof points that DCTs support DEI objectives and broader patient access to and participation in clinical trials	5
3	Technology	In addition of traditional systems using in Clinical trials (for e.g., EDC), there is significant increase in use of newer technologies to support decentralized trials in the recent years. However, the evidence captured on impact from these technologies has been quite limited	7
4	Site Experience	Sites are increasingly supporting DCT methods but call out some key challenges on the road to adoption including technology integration and compensation	4
5	Cost & Return of Investment	Despite limitations in tracking decentralized technologies & their impact, available sources suggest increasing adoption; Industry overall needs to be purposeful in measuring ROI from DCT technology investments	1
6	Regulatory Standards and requirements	please refer to output from DTRA 4B: Collaborate on Regulatory Gaps	1
7	Geography	General recognition into DCT benefits along with early investments being seen across APAC countries; Various European countries are at different stages in adoption and approval of DCTs	2

SUMMARY



What are our findings?

- **Overall high evidence of use for DCTs globally** (80% of our survey participants reported DCT usage)
 - Most in hybrid model, not fully decentralized
- Despite adoption of DCT research methods, **proof points on early value to stakeholders is still emerging**

DCT Impact Quotes

“ There is a sweet spot to hit with hybrid DCTs - it's about finding the right balance – *Rajesh Ghosh, Head of Digital Safety and Decision support at Genentech*

When we got hit by COVID, DCTs are what kept us going
Shobha Dhadda, Global head of Clinical Operations, EISAI



What is our critical observation?

- **No forum in the industry available to collect evidence** of DCT impact and disseminate systematically
- Many times, the **evidence available is operational in nature**, or **evidence points are captured in a scattered manner** from multiple stakeholders within the R&D organization, making it difficult to be reported
- **There is a need for collaboration** with other organizations, such as TransCelerate, CTTI, ACRP, etc
 - Many organizations working with sites, pharma, regulatory agencies = more effective together
- **There is an opportunity to be the repository/provider** of tracking tools for the industry

Team suggests DTRA becoming a centralized hub to collect evidence of DCT impact

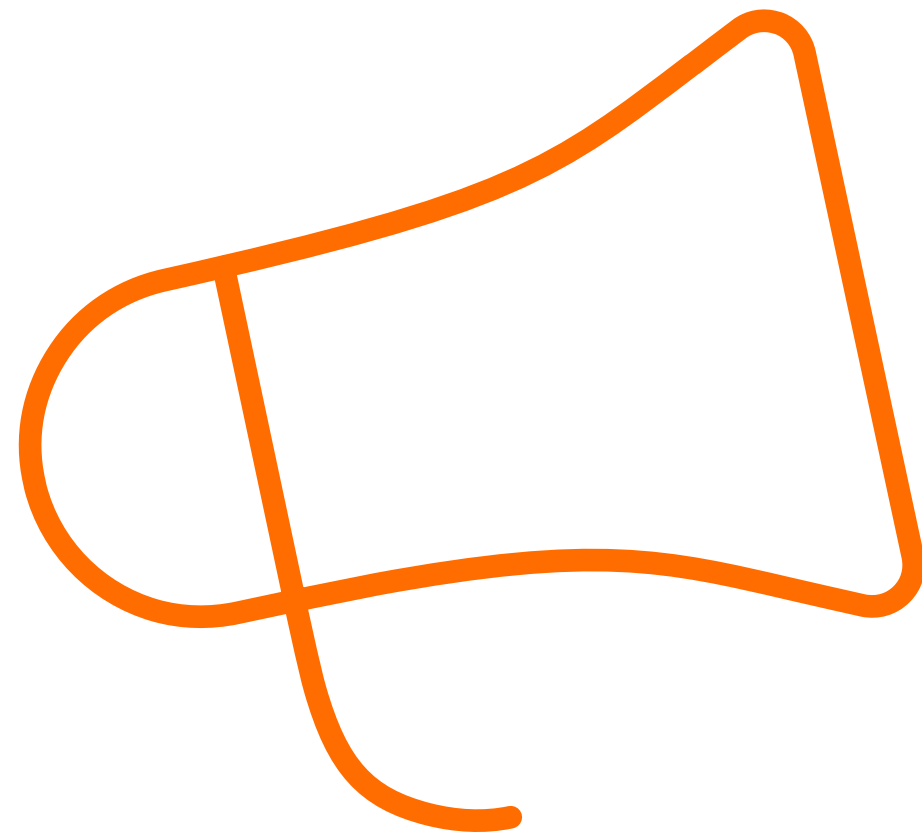


NEXT STEPS

Call to Action

Initiative team **recommend an ongoing process to share DCT impact evidence** in a standardized format

DTRA has accepted this recommendation and is working on an submission process & a library to share resources



DTRA CONSIDERATION FOR FUTURE



Communicate with DTRA Members and Industry the need for standardization, measurement of effectiveness and ROI



Develop a tracking framework and offer it as a free way for people to track their metrics in a standardized manner that provides reports they can generate and provide to their management team

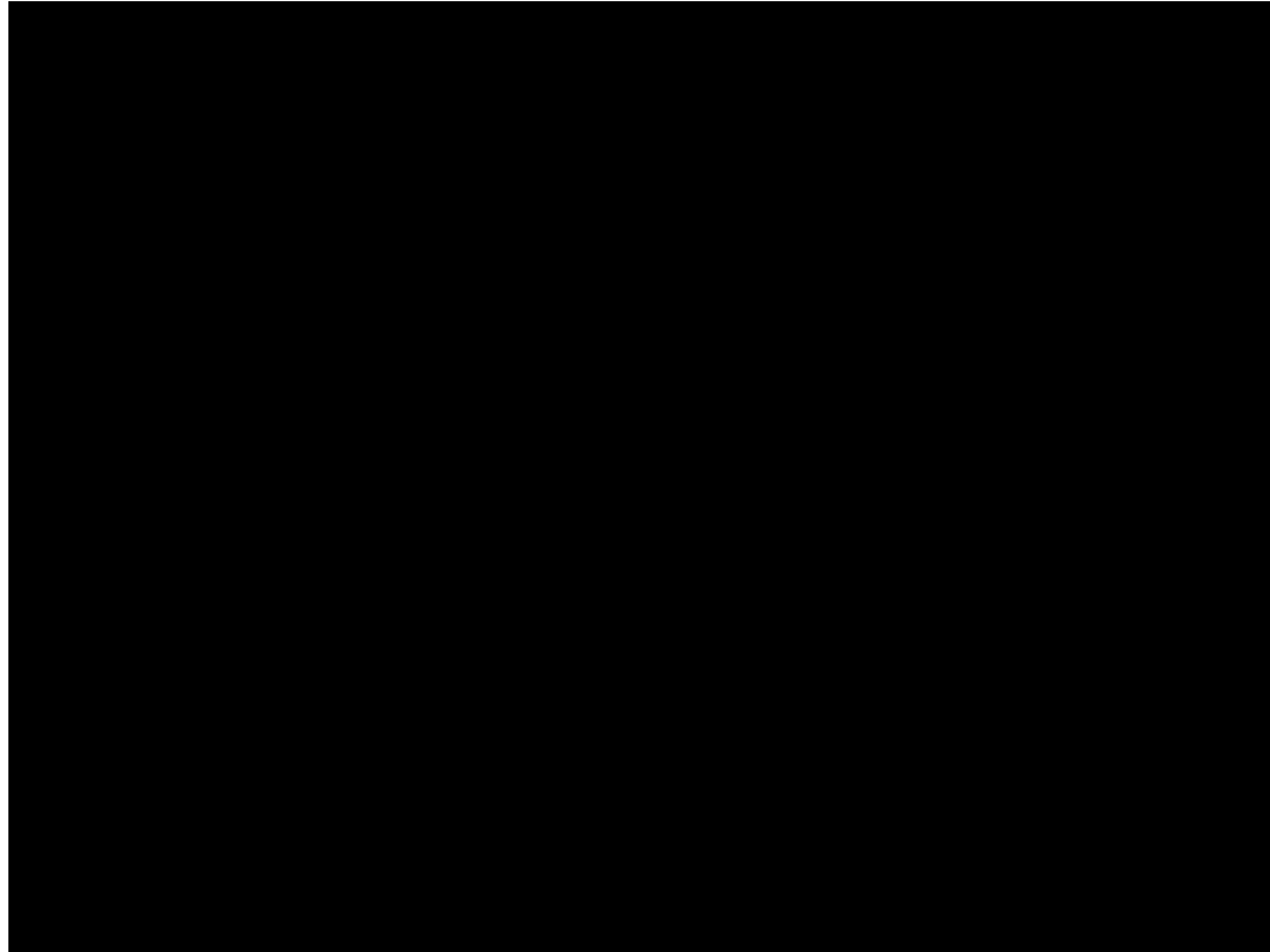


De-Identify the data but use on an aggregated basis to collectively track for the Industry across programs
May be sorted by phase, DCT component, therapeutic indication, country, etc

Win-win for clinical research teams and the Industry

CROWDSOURCING EVIDENCE OF IMPACT

Evidence of Impact Report & Reference Documents available now at
www.dtra.org



CO-LABS

Opportunities for new member-driven initiatives

Smaller teams

Narrow-ish scope

Not yet chartered initiatives

May work on recommendations to solve problems ID'd by initiatives

Target - 3-4 month timeframe to recommendations

Operate more like a sprint team

TWO NEW CO-LABS

Target Duration: 3 months to recommendations

Propose 5-7 core team members

1572 Needs

Aim to kick off by 15 March

SCOPE:

Recommendations on if/how to best include DCT-specific roles and needs (eg. local labs, local imaging, local HCPs) using 1572 and or other forms

Alternative Site Models

Aim to kick off by 30 March

SCOPE:

Recommendations on site selection / qualification, training and oversight, delegation of authority (prioritize 2-3 initial areas)

DTRA CIRCLES

The Challenge

Enable deeper member engagement

- DTRA receives many inbound messages from colleagues at a member company asking to get involved

Help more colleagues connect with their peers from across the industry

- Shared learnings
- New opportunities

Proposed Solution

Micro-communities of functional leaders from across member organizations

- Examples may include:
 - Diversity leaders
 - Monitoring leads for DCT
 - Data Management leads for DCT
 - Supply Chain leads for DCT
 - Other

Provide space for connecting and sharing

- Quarterly meet-ups
- Online connections

DTRA CIRCLES

Please respond to the Poll Question on your screen:

What are the top 2 "Circles" where DTRA should begin to form function-specific communities?

DTRA CIRCLES

1. What initial Circles would be most meaningful?
Diversity? Monitoring for DCT? Data management for DCT?
Others?
2. What would you need in order to help engage your colleagues in Circles?
Engage via LC, member database, social, or all of the above?
3. What collaboration platforms are accessible for your organization?
Slack?

REGULATORY FORUM

Rasika Kalamegaham

OSTP/ONC RFI UPDATE

- Listening Session with OSTP/ONC Representatives held on 1/23
- Topics discussed were:
 - *How might decentralized research be used to enhance equitable participation in emergency clinical trials?*
 - *How might regulatory flexibility help accelerate emergency clinical trials using decentralized methods?*
 - *How might we develop a pilot or demonstration project to use decentralized research for emergency clinical trials in a 6-12 month timeframe?*
- DTRA responded to the RFI with a summary of the listening session

ASCO/FDA - 1572 MODERNIZATION

*“What is it that you **want** to do, that you **think** you can not do?”*

2 upcoming webinars

- March 20, 2023
- April 24, 2023

QUESTIONS?

YOUR DTRA MEMBERSHIP

MEMBERSHIP

Leadership Council Basic Expectations

- Attend LC Meeting and Annual Meeting or assign an Alternate
- Communicate and collaborate to share DTRA updates and engagement opportunities with your organization
- Respond to calls to action

MEMBERSHIP

DTRA Designated Contacts

Take a moment and complete [this form](#) to update the DTRA on the appropriate Points of Contact at your Organization

- Leadership Council
- Leadership Council Alternate
- Marketing/Communications
- Financial

MEMBERSHIP BENEFITS



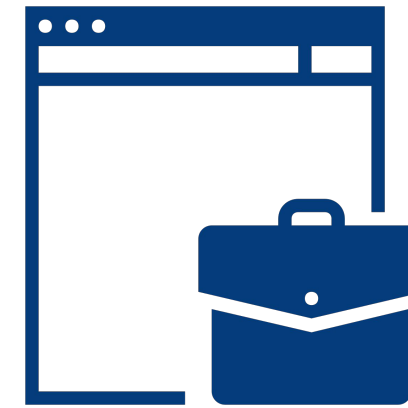
Leadership Council
Representation



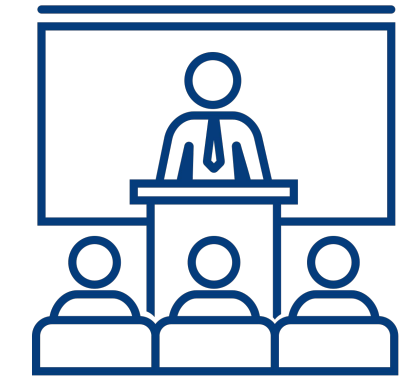
Collaboration &
Volunteer
Opportunities



Curated News &
Member Updates



Complimentary
Listings on the Job
Board



2 Registration Passes
to DTRA Annual
Meeting



Access to Everest
Group's curated
clinical development
technology research



Sponsorship
Opportunities at
Annual Meeting



Professional
Networking with
Industry Leaders



Eligibility to be a
guest on
TGIF-DCT



Access to
Membership
Community

MEMBER BENEFITS

Everest Group Partnership

- Access to curated clinical development technology research
- Opportunity to schedule a call with their clinical technology analysts

dtra.memberclicks.net/everest-group-reports

DTRA
DECENTRALIZED TRIALS
&
RESEARCH ALLIANCE

Everest Group[®]

Everest Group | DTRA Partnership

DTRA Organizational Members may now access the curated clinical development technology research reports from Everest Group. This membership benefit provides access to their life sciences technology research reports and provides access to insights to improve clinical development.

NOTE: These reports are not for external use outside of DTRA Member Organizations.

[Access FAQ Document](#) [Access Reports Here](#)

MEMBERSHIP

Biotech Members: Seeking your Input

DTRA aims to include representatives from all stakeholder groups

Seeking to increase biotech participation and ensure needs are included when identifying and solving for DCT adoption challenges

- Would you be willing to be part of a Zoom advisory session?
 - Potential members, key biotech challenges
 - 1 hour - Week of March 6
 - Contact secretariat@dtra.org

CALL TO ACTION

Engagement Opportunities

Three open opportunities to get involved with DTRA

- Co-Labs
- DTRA Circles
- Biotech Advisory Input Session
- Registry of Decentralized Studies Input Session

Please complete the form [HERE](#)



DTRA
DECENTRALIZED TRIALS
&
RESEARCH ALLIANCE

2023
ANNUAL
MEETING

SAVE THE DATE

DTRA 2023 Annual Meeting

Encore Hotel, Boston, MA

November 5-8, 2023

Membership in 2023 include 2 Basic Registration Passes

ENGAGEMENT OPPORTUNITIES

We look forward to your organization being represented
at the 2023 Annual Meeting

Connect your Marketing Teams with the DTRA Secretariat to discuss event opportunities



EXTERNAL DTRA UPDATES: Q1-Q2

EuroVulcan	Paris	March 15, 2023
Society for Translational Oncology	New York	March 23, 2023
AACR	Orlando	April 16, 2023
Informa - DCT Conference	Boston	April 19, 2023
ACRP	Dallas	April 28, 2023
DIA dTrials	China	April 21, 2023
DGE - DCT Conference	Philadelphia	May 10, 2023
FDA/AdvaMed	Washington DC	May 11, 2023
American Psychiatric Association	San Francisco	May 20, 2023
BIO International Convention	Boston	June 5, 2023
Informa - DCT Week	Virtual	June 5, 2023
Digital Health in Clinical Trials	San Francisco	June 6, 2023
DIA Annual Meeting	Boston	June 27, 2023

TGIF-DCT CLUBHOUSE

Fridays at 12:00 PM EST

Join each week to hear from passionate leaders in the DCT & Clinical Research community sharing insight and vision into the future of research

TGIF-DCT is where you can hear from peer DTRA Initiative Leaders around the work they have been delivering

Want to be a guest or have a great topic you'd love to see discussed?
[Submit this form](#)

TGIF-DCT CLUBHOUSE

Tomorrow @ 12p EST

Patient Advisory Boards for Decentralized Trials

with Jane Myles, Alicia Staley, and Jen Horonjeff

Recognize Rare Disease Day as we talk to leaders at the forefront of patient advisory boards to inform decentralized trials

TGIF-DCT → PODCAST

- All weekly TGIF-DCT recordings will be distributed via Podcast
 - All new episodes in 2023
 - Most listened prior episodes
- Sponsorship opportunities will be available

DECENTRALIZED TRIALS AND CLINICAL RESEARCH

PODCAST





DTRA
DECENTRALIZED TRIALS
&
RESEARCH ALLIANCE

UPCOMING MEETINGS

2023 Leadership Council Meetings

- June 15, 2023
- September 14, 2023
- December 14, 2023

Initiative Updates All-Hands Meeting

- Last Thursday of each month
- Email secretariat@dtra.org to be added to the invite

2023 Annual Meeting

- November 5-8, 2023 (Boston)