DTRA
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Leadership Council

Business Meeting

June 15, 2023

Agenda

DTRA Membership

- Leadership Council Expectations
- Member Benefits
- DTRA Annual Meeting 2023
  - Engagement Opportunities
- DIA Annual Meeting
  - Panel
  - Member Meet-Up
- TGIF-DCT Clubhouse
- DTRA Podcast
- Regulatory Forum Update
  - NIH/NCATS RFI
  - FDA Draft Guidance
- Save the Dates

Initiatives & Forum

- Initiative Team Updates
  - 2C
  - 4C
- Co Labs
  - 1572 Needs
  - Alternative Site Models
- DTRA Circles

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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

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Current Members

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Your DTRA Membership

Paige Altrogge, Amir Kalali, Craig Lipset

Membership

Leadership Council Basic Expectations

- Attend LC Meeting & Annual Meeting or assign an alternate to do so
  - Share the deck internally with other members of your organization
- Communication and collaborate to share DTRA updates and engagement opportunities with your organization
- Respond to Calls to Action

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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

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Save the Date

DTRA 2023 Annual Meeting

Encore Hotel, Boston, MA

November 5-8, 2023

Membership in 2023 include 2 Basic Registration Passes

Programming Sneak Peak

A View from Washington: Driving Decentralized Trials in the US Research Ecosystem

- Perspectives from US Govt Agencies on DCT adoption

Recent Data on Site Adoption Trends & Barriers

- Site perspectives and needs to help with adoption

Global Adoption of DCTs

- Facts & Figures - What needs to happen to drive scale across continents?

Programming Asks

Do you know of a patient who can share a compelling perspective of the impact of DCT in their life?

- Nominate by sending information over to secretariat@dtra.org

Do you have any themes you'd like to see on the Main Stage at DTRA 2023?

- Send details over to secretariat@dtra.org

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

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DIA 2023 Panel

DIA 2023 GLOBAL ANNUAL MEETING BOSTON, MA | JUNE 25-29

DCT Meta Collaboration to Improve Decentralized Trials Panel

June 27 - 1:15 - 2:15 PM ET

Susan Landis
Executive Director
ACRP

Kim Hawkins
Global Head of Clinical Project Operations & Dossier Delivery, Sanofi; Project Lead, IMI Trials@Home

Rob DiCicco
Vice President Portfolio Management
TransCelerate BioPharma

Sara Calvert
Director of Projects
CTTI

Jane Myles
Program Director
DTRA

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MEMBER MEETUP AT DIA
Crescendo Bar at the Omni Boston
Tuesday, June 27, 2023
5:30 pm

RSVP here!

External DTRA Updates: Q2-Q4

BIO International Convention	Boston, MA	June 5-8, 2023
HITlab Innovators Summit 2023	New York, NY	June 20-23, 2023
DIA Annual Meeting	Boston, MA	June 25-29, 2023
Operationalize: Decentralize Clinical Trials Event	Philadelphia, PA	September 13-14, 2023
Fierce DCT Summit	Philadelphia, PA	September 26-28, 2023
OCT-NE	Boston, MA	October 1-2, 2023
SCRS Annual Summit	Hollywood, FL	October 6-8, 2023
SCDM Annual Meeting	San Diego, CA	October 8-12, 2023
SCOPE EU	Barcelona, Spain	October 17-18, 2023
DTRA Annual Meeting	Boston, MA	November 5-8, 2023
CNS Summit	Boston, MA	November 8-11, 2023
Informa Europe	Barcelona, Spain	November 29-30, 2023
Node Health	New York, NY	December 7-8, 2023

TGIF-DCT Clubhouse

Friday's at 12:00 PM ET

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 to the greater community.

Want to be a guest? Have a great topic to share?
Submit this form for consideration!

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TGIF-DCT Clubhouse Upcoming Events

Friday's at 12:00 PM ET

Friday, June 16, 2023
Conference Updates
Craig Lipset, Amir Kalali, Jane Myles

Join us to hear the highlights from all of the Conferences happening in June.

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Decentralized Trials and Clinical Research Podcast

Now available on your favorite podcast player!

All weekly TGIF-DCT recordings will be distributed on-demand via our podcast

- All new episodes in 2023
- Most listened prior episodes

Sponsorship opportunities will be available

Find it on the DTRA website or on your favorite podcast player!

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TransCelerate Digital Data Flow Discussion Forum

Opportunity to work with DTRAs Partner Organization

TransCelerate is hosting a regular Discussion Forum for clinical technology solution providers seeking to become actively involved in further development of Digital Data Flow (DDF) solutions, including the CDISC Unified Study Definitions Model (USDM) and the Study Definitions Repository (SDR) Reference Implementation.

If interested, complete the form linked here, and consider joining the DTRA Data Management Circle to connect with your peers on this topic.

- Next meeting is on 6/20 at 12:00 PM ET

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DTRA Regulatory Affairs Council

Rasika Kalamegham

NIH/NCATS RFI Update

- Listening Session with NIH/NCATS Representatives held on 4/24
- Topics discussed were:
  - *What are the challenges and opportunities for institutions in a network to fully leverage decentralized approaches in a multi-center trial?*
  - *How might leading institutions develop their own central/virtual site capabilities, technology, and processes?*
- DTRA responded to the RFI on behalf of the DTRA Community with input from the Listening Session

FDA Guidance

- The FDA has released their draft guidance document around decentralized trials.
  - This guidance provides recommendations for sponsors, investigators, and other stakeholders regarding the implementation of decentralized clinical trials (DCTs) for drugs, biological products, and devices.
- DTRA has put out a call to action for comments to be shared as we review the guidance and prepare to share comments with the FDA.

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Regulatory Engagement Updates

Upcoming Meetings

Save the Date

2023 Leadership Council Meetings

- September 14, 2023
- November 8, 2023 (onsite in Boston)
- 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, MA)

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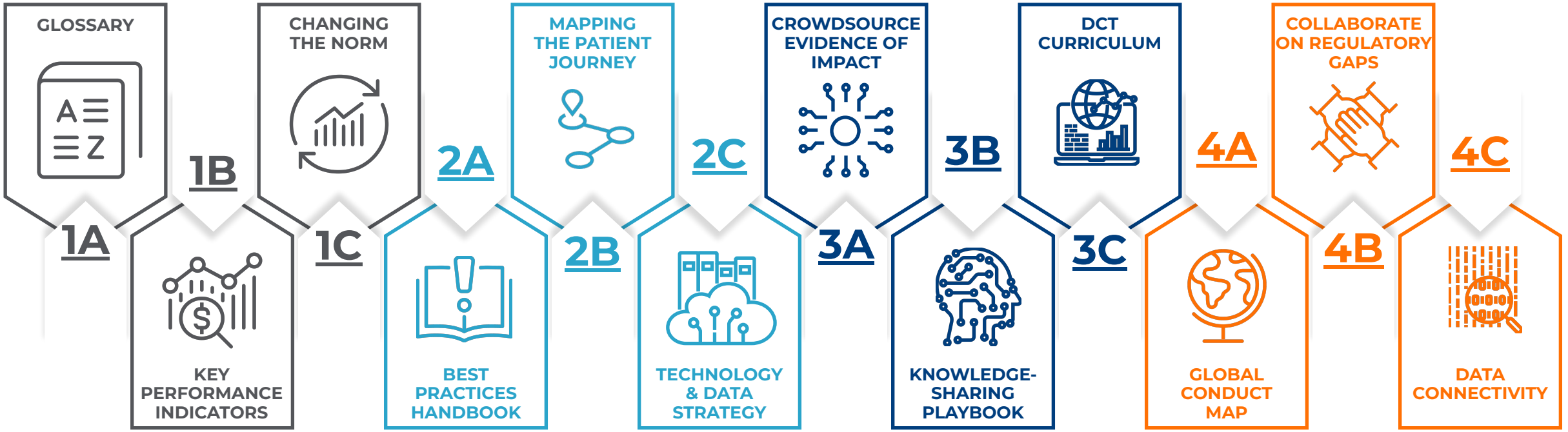
Initiative Teams Update

Claudine Paccio

Initiative Overview

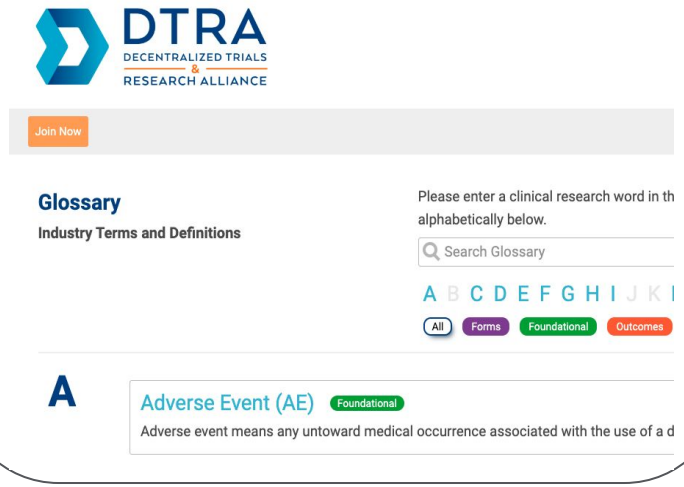


The 12 Initiatives delve deeper into each of the Priorities to identify the framework to pursue our shared goals and develop strategic solutions. Click on each Initiative for more information, or access at www.dtra.org.

Select Initiative Summary

DTRA Glossary

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



KPIs

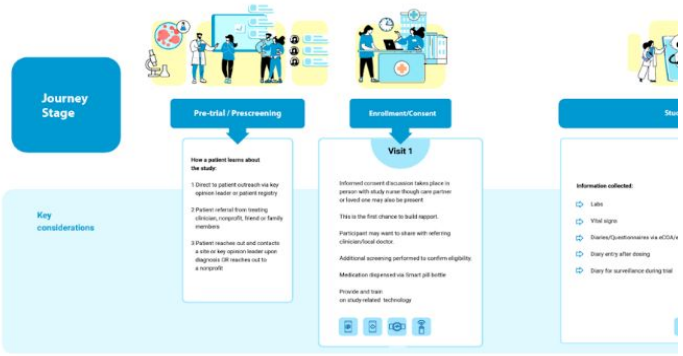
Live for DTRA Members at www.dtra.org/key-performance-indicators

Number	Stakeholder	Metric	Calculation Method
1	Patient, sites	Likelihood to engage in a DCT	Net Promoter Score (NPS), a metric likeliehood to recommend a product, a score for your customer experienc
2	Patient, sites, sponsor	Patient drop out % for a "patient decision	% of patients who have been randon 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

Evidence of Impact

Live at https://www.dtra.org/evidence-of-impact

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Initiative Overview

Foundational Initiatives: DCT Standards		
Glossary	Glossary is available on the DTRA website … *Content Council to review feedback*	COMPLETED
Mapping the Patient Journey	3 Maps (Oncology, Rare Disease, & Vaccines) available on the DTRA website … *Interactive template pending*	COMPLETED
Data & Technology Strategy	Deliverables completed … *Digitization pending*	JUNE
Measuring Success with DCT		
KPIs	KPIs are available on the DTRA website … *Possible upcoming Circle*	COMPLETED
Best Practices	Rubric is available on the DTRA website … *Evaluation process & BP Identification pending*	COMPLETED
Crowdsourcing Evidence of Impact	Deliverable results available on the DTRA website … *Recommendations under review*	COMPLETED
Supporting DCT with Education and Adoption		
Changing the Norm	Survey on Barriers and Whitepaper completed … *Closeout pending*	JUNE
Knowledge Sharing Playbook	Spreadsheet populated with information … *Final graphic (tubestop) pending*	JULY
DCT Curriculum	Module list w. details completed; Overview of Module 1 Outline competed … *Closeout pending*	JUNE
Removing Barriers		
Global Conduct Insight Map	Spreadsheet populated with information; Air-table complete … *Digitization pending*	COMPLETED
Regulatory Gaps	Gaps added to the 3C spreadsheet … *Team has migrated to the Regulatory Forum*	COMPLETED
Data Connectivity	Deliverables in progress	AUGUST

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Priority Initiative 2C
Data and Technology Strategy

Camila Matheny

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

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

2C Team Members:

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,

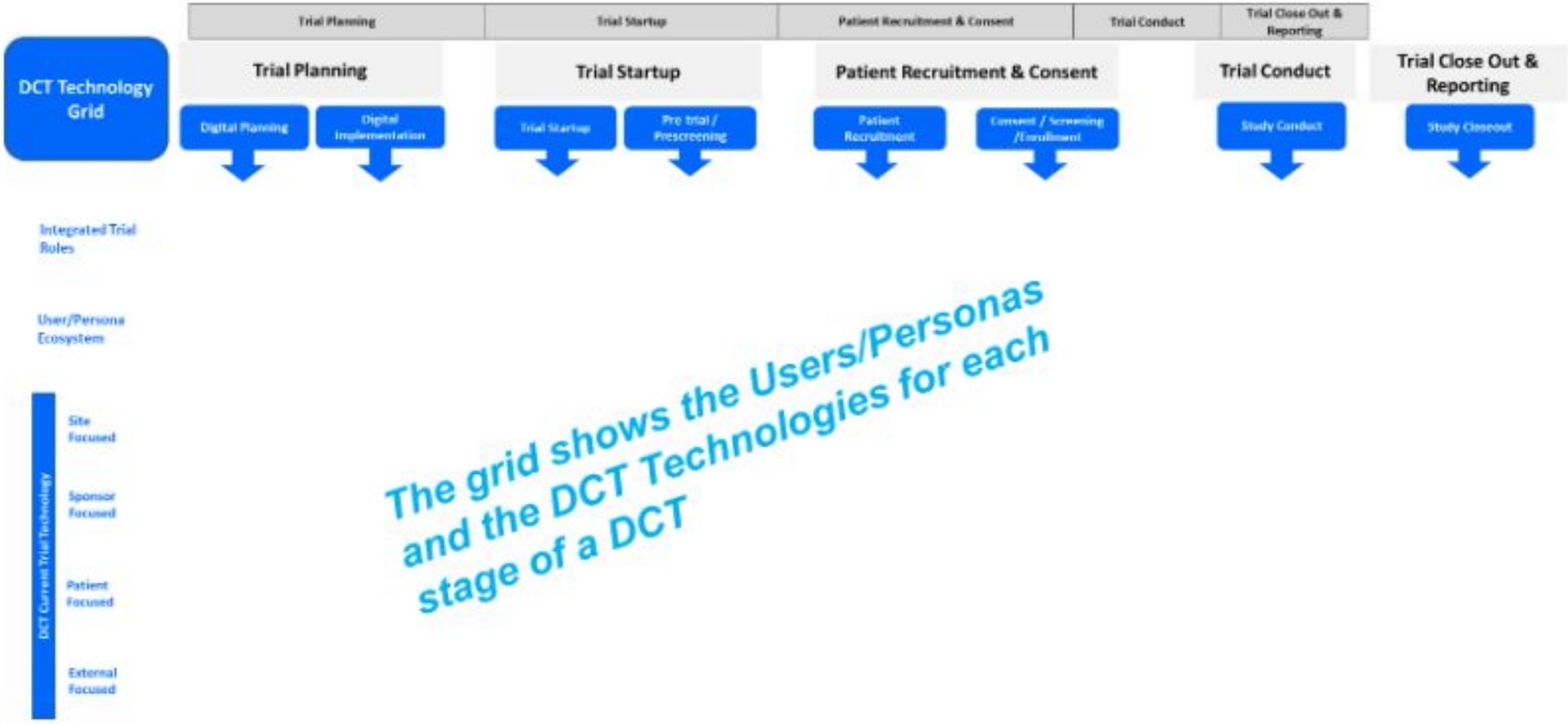
Eldawud Reem, Kearney

Greg Jones, Oracle

Kishori Khokarale, ZS

Focus Area: DCT Technology & User Ecosystem Grid

Challenge: Deliver a comprehensive list of technology used & identify the users/personas that intersect in each stage of a DCT



Focus Area: Privacy, Ethical, and Legal Considerations

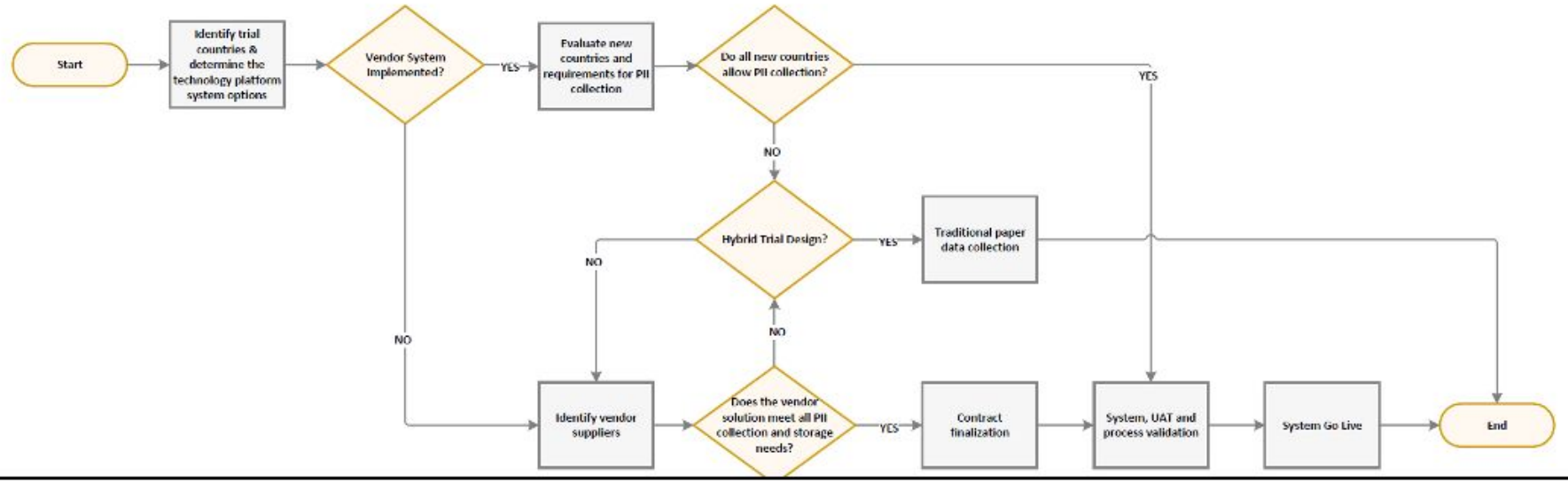
Deliver a solution that encompassed the global considerations for privacy, ethical, and legal data collection.

Tool to facilitate decisions on global trials where PII is collected

Determination of a Decentralized System Platform Based on PII Collection in a Clinical Trial*

There are many privacy, ethical, and legal considerations with global patient data capture and data use in decentralized clinical trials. Shown below is a process map to assist sponsors determine the optimal decentralized system platform based on the ability to collect personally identifiable information (PII) for a decentralized clinical trial.

* Note: For eConsent, signature and name will be required as PII in every country, based on country permissions for use of eConsent.



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Priority Initiative 4C Data Connectivity

Moulik Shah
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

4C Team Members:

Co Lead: Moulik Shah, Advanced Clinical

Co Lead: Munther Baara, Edetek

PM: Claudine Paccio, DTRA

Sneha Sundet, Agios Pharmaceuticals

Thomas Healy, PPD

Jordan Simpson, Merative

Venu Mallarapu, eClinical

Rick Greenfield, RealTime CTMS

Proposed Workstreams

Workstream Deliverables

Workstream A

End to End processes and data flow

- Reference guide to manage clinical data flow through its life cycle data flow across the CT Ecosystem

Workstream B

Architecture Framework Recommendation

- 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

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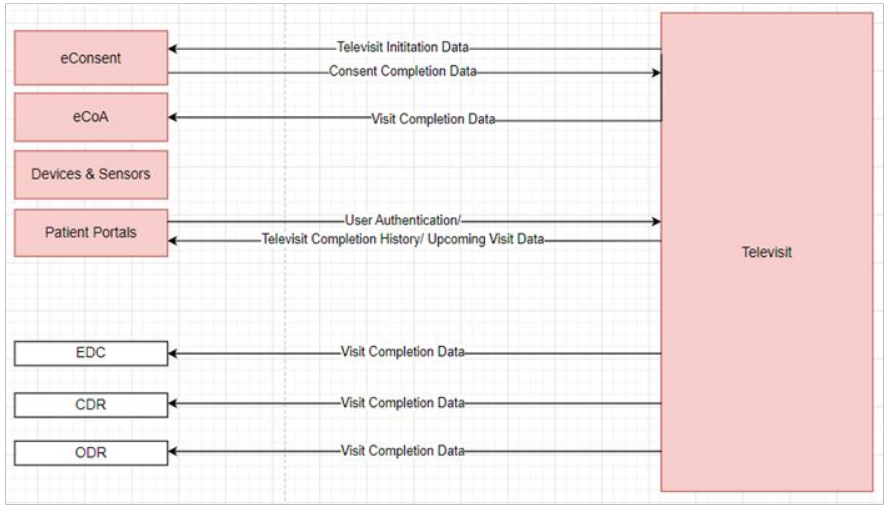
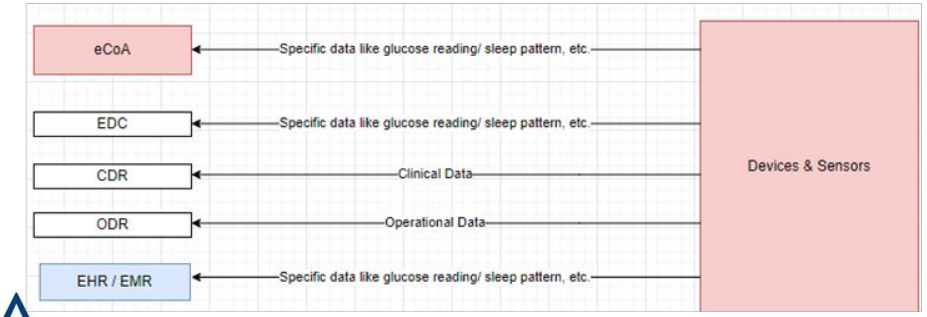
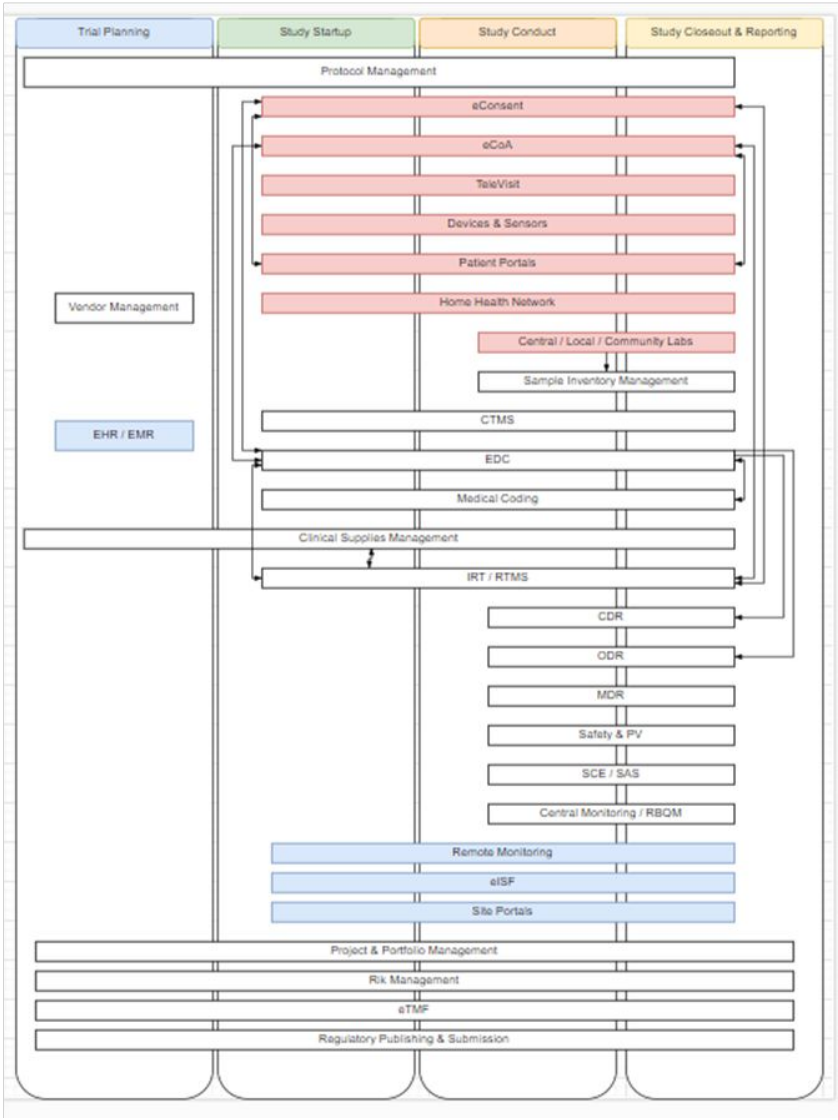
Information Dataflow and Data Exchange Framework

Capturing where the data flows & what type of data flows from each of the systems







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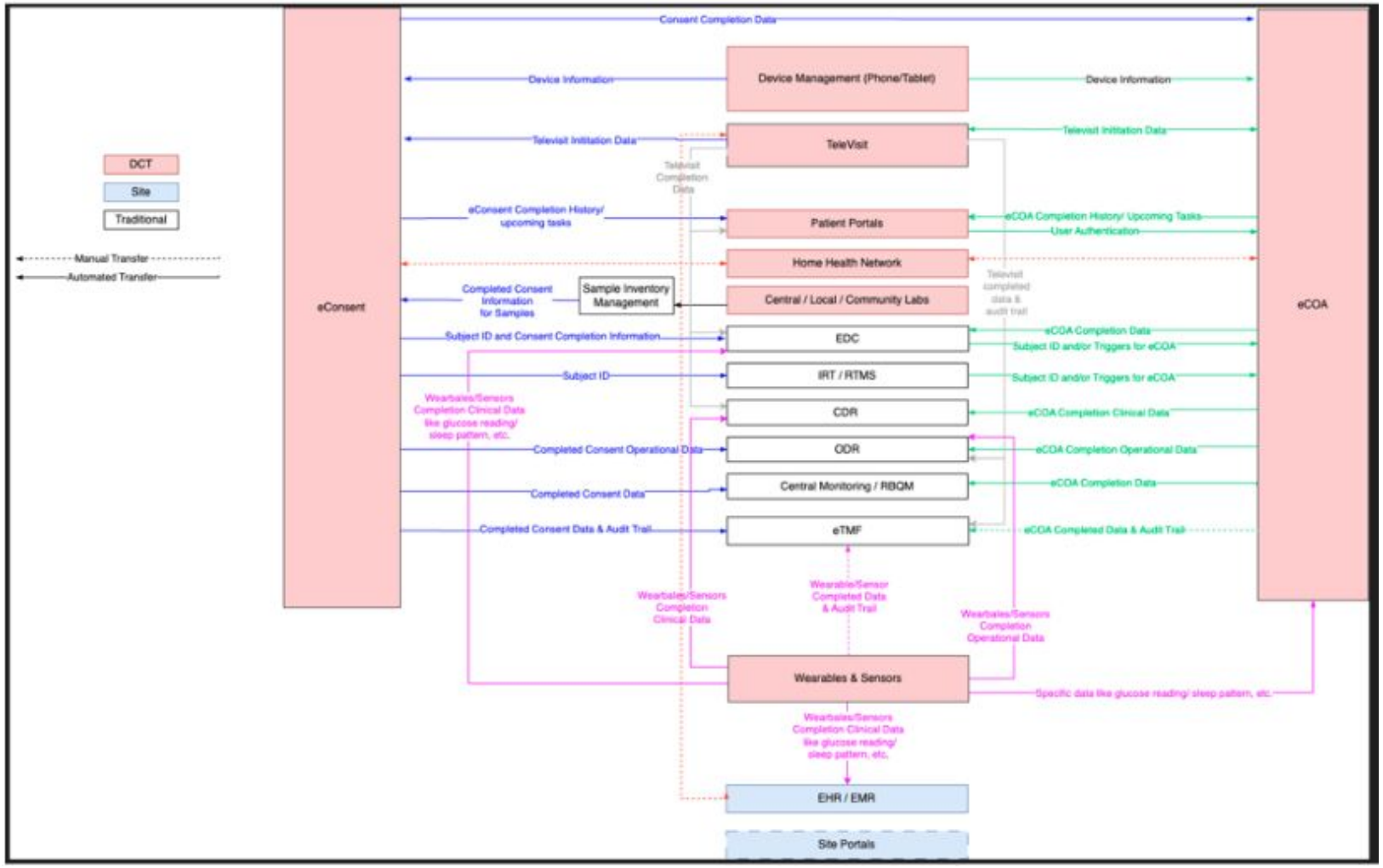
Information Dataflow and Data Exchange Framework

Data Flow across DCT Systems

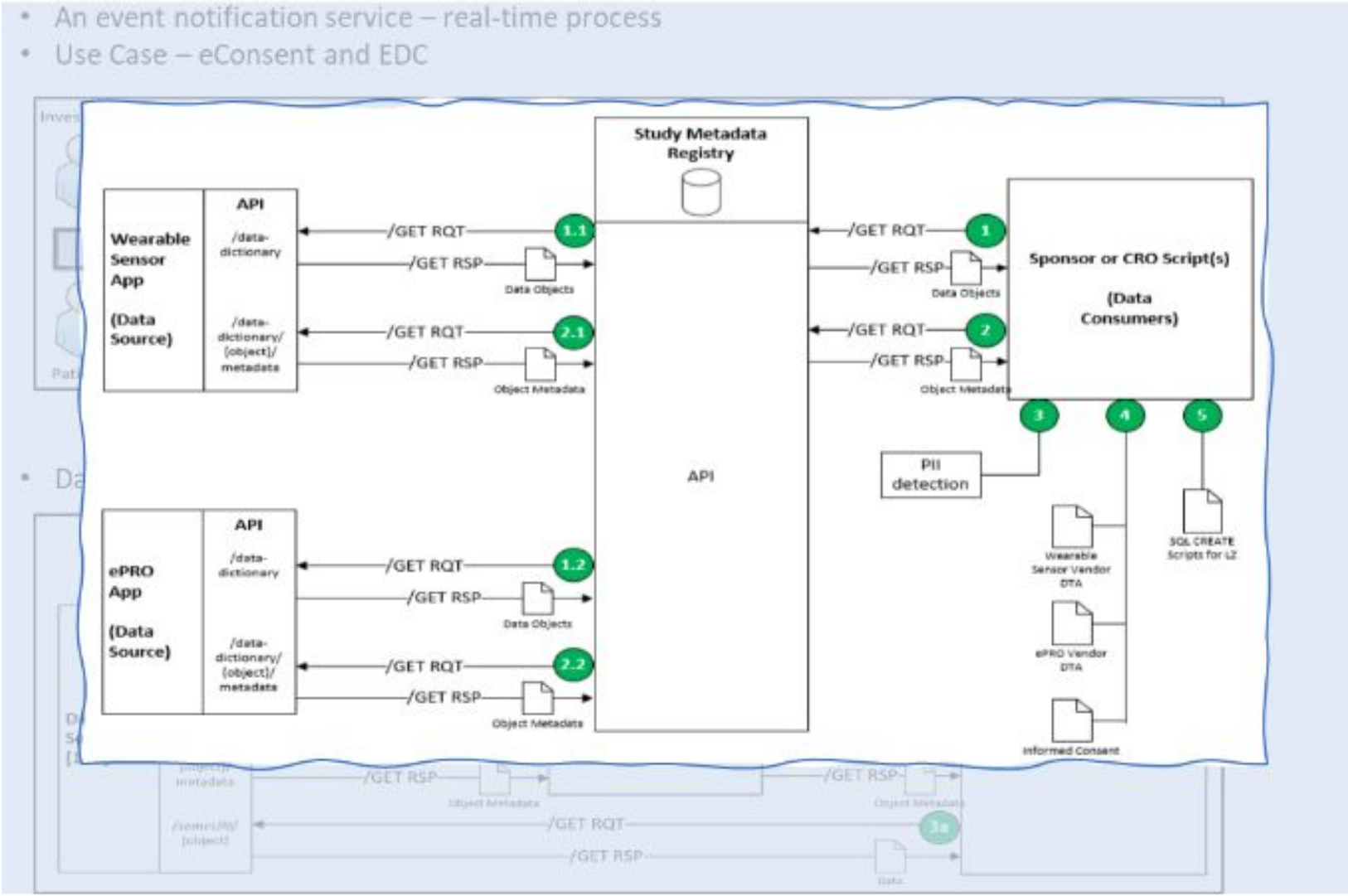
Our focus was to map out cross-system interaction of DCT systems (as identified in the table above) with the rest of the systems in the ecosystem.

Please note that only systems that interact with the DCT systems are represented in the diagram below.

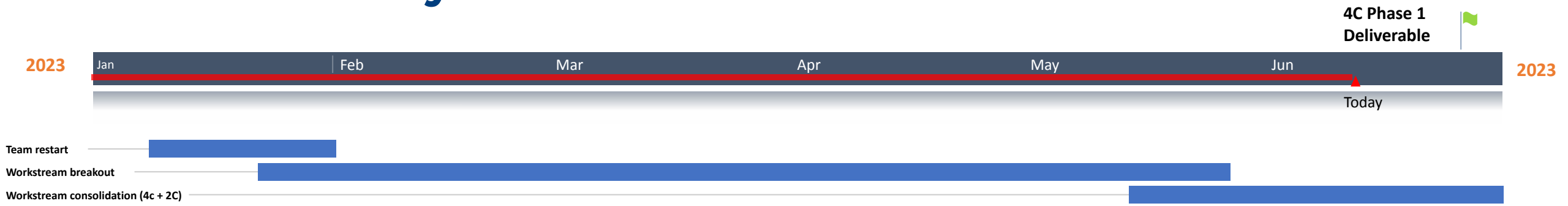


Data Exchange Framework

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



Data Connectivity Status & Timeline



End to End Processes & Data Flow

- Table of Contents
  - Executive Summary
  - Clinical Study Phases & Activities
  - Regulatory Guidance & Implication
  - Key systems used on typical Decentralized Clinical Trial
- Digitization of deliverable estimated for August

Architecture Framework Recommendation

- Documentation is completed
- Proof of Concept (POC) is being worked on
  - eConsent with EDC prototype
- FDA Guidance leverage
- End of August Delivery

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Co Labs

Jane Myles

Co Labs: Initial Focus

Testing the model for scalability

1572 Needs

Kicked Off 3 Apr

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

Kicked off 17 Apr

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

- Mobile sites, Pharmacy based sites, etc

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1572 CoLab: Timeline Expectations

15 Jun: DTRA Reg Council / FDA meeting to discuss DCTs

GOAL: Include any key recommendations / questions re 1572

- **1 Jun:** Expect pre-read materials sent to FDA

- 30 May: MVP Draft Deliverables shared across sub-teams
  - **≤6 weekly meeting to get to MVP**

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1572 Needs Co Lab

Lauren Tobe, Rebecca Kottschade

Recommendations on who fits where
Traditional and DCT Roles: Creating a Reference tool

	Traditional Documentation	DCT Analogue	DCT Recommendation
Central lab	1572 Field 4 (Clinical Labs)	Central lab	1572 Field 4 (Clincial Labs)
Local Lab	1572 Field 4 (Clinical Labs)	Local Lab	1572 Field 4 (Clincial Labs)
Local Radiolgy Lab	1572 Field 4 (Clinical Labs)	Local Radiolgy Lab	Other (Comment)
eCOA raters	Delegation of Authority Log	eCOA raters	Delgation of Authority Log
Sub-investigators	1572 Field 3 (Facilities where research wi…	Virtual Investigators	1572 Field 1: Name of Investigator
Network sites	1572 Field 6 (Sub-Investigators)	Network Sites	Task Log (DCT Guidance)
		Mobile research sites	Task Log (DCT Guidance)
		Pharmacy research sites	Task Log (DCT Guidance)
Primary Care MD	Other (Comment)	Primary Care MD	Task Log (DCT Guidance)
CRC (Clinical Research Coordinator)	Delegation of Authority Log	Virtual CRC	Delgation of Authority Log
Home Health Nurses - SOC Procdures (signs a	Delegation of Authority Log	Home Health Nurses - SOC Procdu	Task Log (DCT Guidance)
Home Health Nurses - IP admin	Delegation of Authority Log	Home Health Nurses - IP admin	Delgation of Authority Log
Home Health Nurses - Protocol Specific Asses	Delegation of Authority Log	Home Health Nurses - Protocol Spe	Delgation of Authority Log

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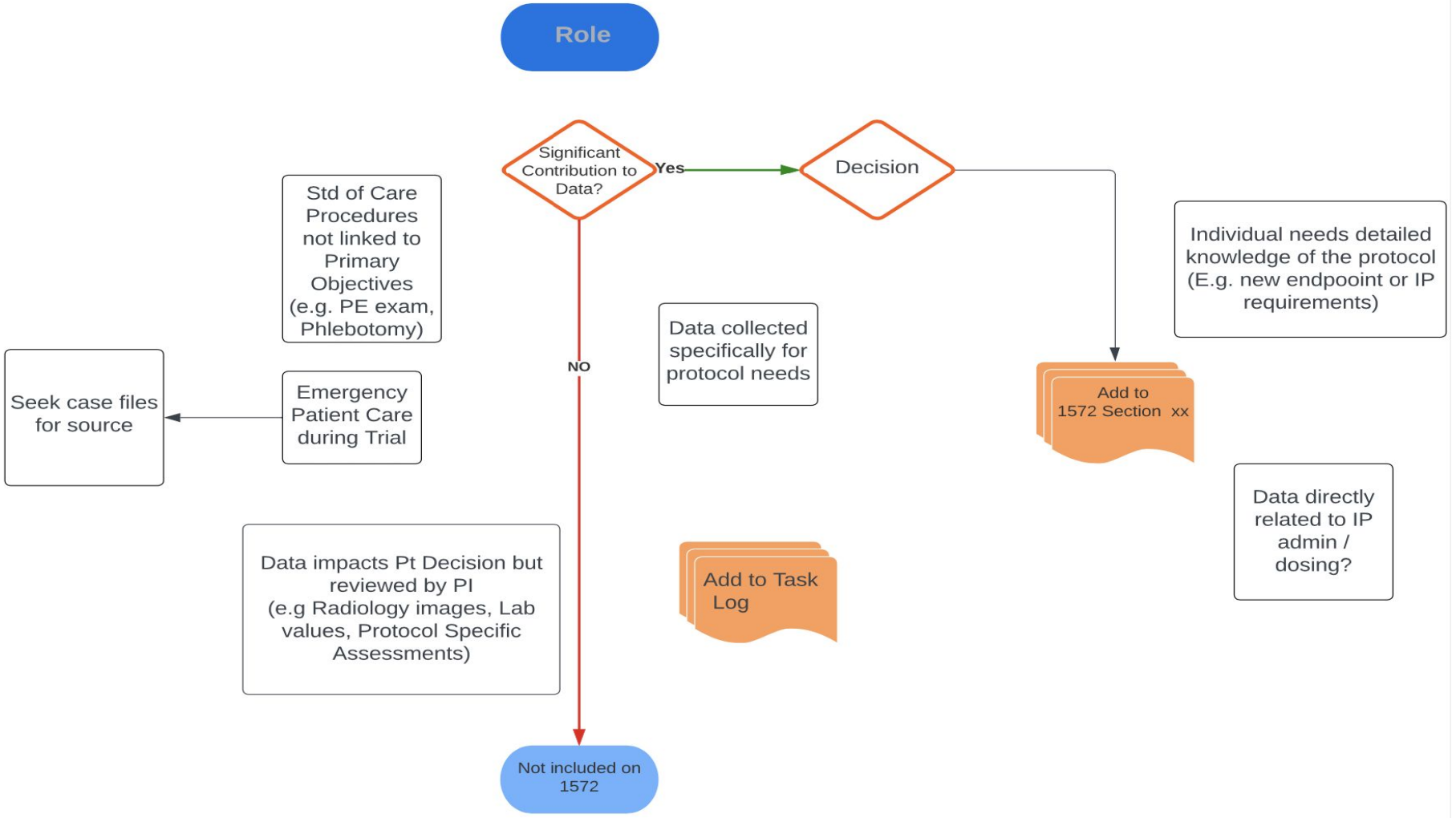
Clarifying What is a Significant Contribution to Data
Creating a Reference Tool to Guide Decision Making



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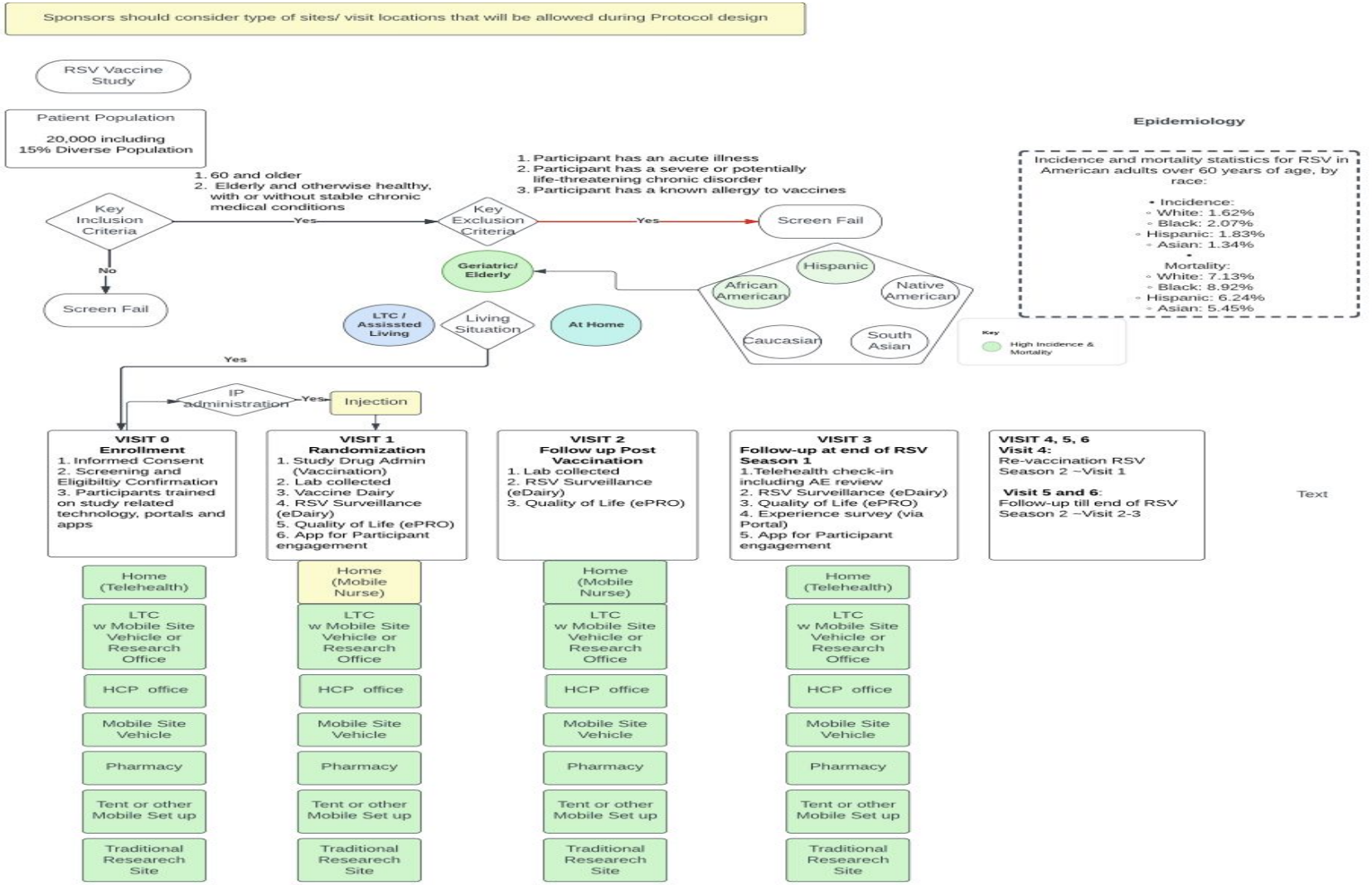
Alternative Sites Co Lab

Sandeep Bhat, Darcy Forman

Selection: What site model fits your study need?

Creating a guide to models, what they do, how they help



Demonstrating PI Oversight of Alternative Sites:
Creating Training and Oversight Checklists

Oversight by PI			
	Category	**Task**	**Considerations**
☐	Site Set Up	Site staff training on DCT Components	Provide and document appropriate staff training
☐	Regulatory / Ethics Approvals	Site readiness	Study is approved to proceed
☐	DCT System Go Live	Study Platform go-live	Study is ready for patient enrollement / data entry
☐	Regulatory and ethical submissions and approvals		Regulatory and ethical submissions and approvals When are DCT implementation changes considered a substantial or non-substantial modification?
☐	Patient Recruitment (DTP or other)	Participant awareness of trial / Patient recruitment	eConsent, remote and in person, with known and unknown investigators Participant identity verified prior to consent signature Include consent to release medical records (if needed) Appropriate version of consent used Include biomarker / biosample / tissue asay consent language to enable consent tracking at a per patient level.
☐			Remote setting. Considerations for hand off between Patient Pre-screen and Patient screening. Relationship / engagement solutions if site is hybrid or a rully remote option is used. Participant identity verified prior to consent signature Include consent to release medical records (if needed) Appropriate version of consent used

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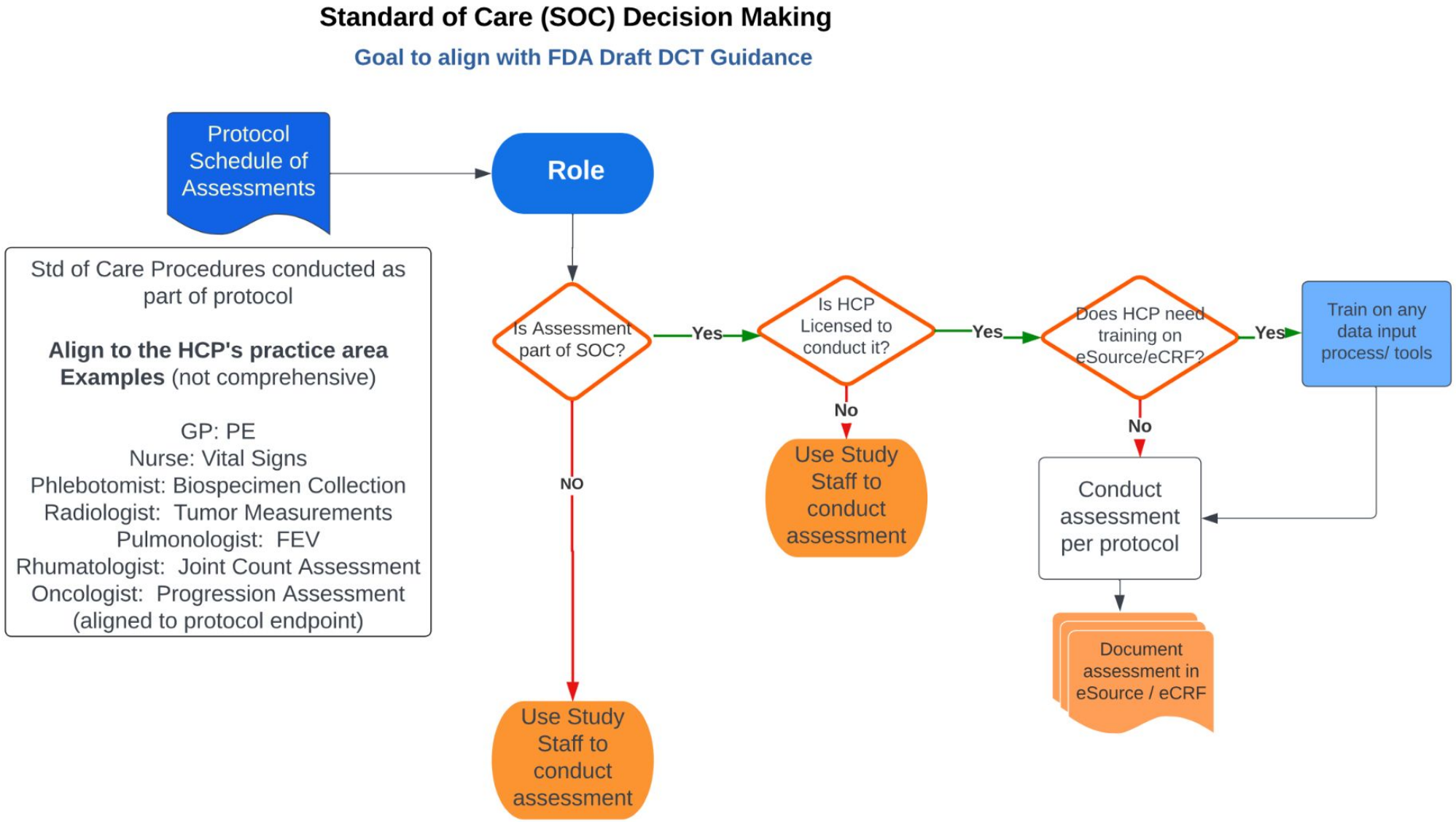
What is SOC: A Framework to Support Decision Making



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Site Adoption Needs: Digging Deeper

Significant interest across membership stakeholders to better understand how to support site adoption

What are some specific needs? Are they similar across site types?

- Are there tools / training / other assets to support adoption?

CoLab Scoping stage - ACRP shared survey data from 2022 (9 Jun)

Next steps - Determine the best method to gather more information

- Listening sessions?
- Co-created survey, executed with partners?

Please contact Secretariat / Jane if interested in supporting this work. Seeking:

- PM
- CoL
- Team Members

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DTRA Circles

Jane Myles

DTRA Circles

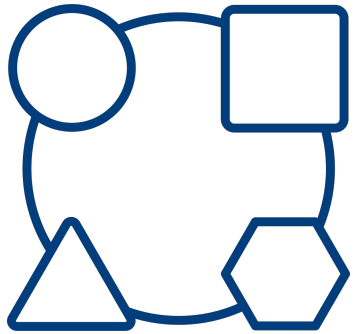
Enabling deeper member engagement by creating space to connect with peers

4 Micro Communities of functional leaders have been kicked off!

To join any of these Circles, complete this form or email secretariat@dtra.org

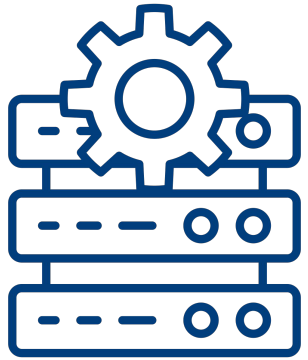
Real World Data & DCTs

Next Virtual Meet-up: June 19 1:00 PM ET



Diversity

Next Virtual Meet-up: August 8 3:00 PM ET



Data Management

Next Virtual Meet-up: June 20 12:00 PM ET

Patient Recruitment

Next Virtual Meet-up: June 23 11:00 AM ET

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