DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

Leadership Council

Business Meeting

September 14, 2023

Agenda

DTRA Membership

- Maximizing Membership Benefits
- DTRA Annual Meeting 2023
- Open Forum
- Regulatory Forum Update

Initiatives & Forum

- 4C Initiative Update
- CoLab Updates
- 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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DTRA Organizational Update

Welcome Donna, new Program Coordinator at DTRA!

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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

Organizational Membership in 2023 include 2 Basic Registration Passes

Register here!

Programming Sneak Peak

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

- Perspectives from US Gov't Agencies on DCT adoption

Recent Data on Site Adoption Trends & Barriers

- Site perspectives and needs to help with adoption

Global Adoption of DCTs

- Trends on the journey to scale

Government Agency Speakers Sneak Peak

Leonard Sacks, MD
Associate Director for Clinical Methodology, Office of Medical Policy, CDER
FDA

Grail Sipes
Assistant Director for Biomedical Regulatory Policy, Health & Life Sciences Division
OSTP

Stephen Konya
Senior Advisor to the Deputy National Coordinator for Health IT and Innovation
Portfolio Lead
ONC

Gina Conenello
Biologist
BARDA/HHS

Christopher Hartshorn
Chief, Digital & Mobile Technologies Section
National Institutes of Health

Monique Al
Coordinating/Special Advisor
CCMO

Paul Kluetz
Deputy Director, Oncology Center of Excellence
FDA

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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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New DTRA Website

- Better navigation for users
- Easier access to resources
- Ready to scale and support additional resources and work created by DTRA

TubeStop

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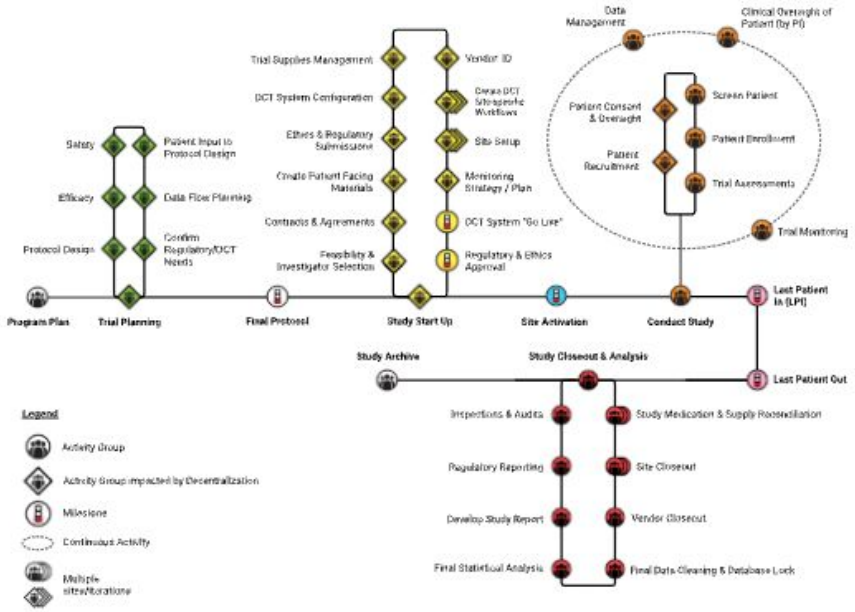
PRIORITIES AND INITIATIVES | 2023 ANNUAL MEETING | CONNECT | ABOUT | NEWS | CONTACT | DTRA COMMUNITY



The DCT Playbook

The DCT Tubestop Map is a digital end-to-end process map to support DCT trial planning and execution, with key process steps across the plan, setup, conduct, and close stages of trials and resources from DTRA and our Partner Orgs to help you along the journey.

Learn More

External DTRA Updates: Q2-Q4

Operationalize: Decentralize Clinical Trials Event	Philadelphia, PA	September 13-14, 2023
DPHARM	Boston, MA	September 20-22, 2023
MRCT / National Academies: Diversity Convergence Summit	Washington DC	September 22, 2023
Fierce DCT Summit	Philadelphia, PA	September 26-28, 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
C3 Summit	Princeton, NJ	October 19, 2023
Trials@Home Annual Meeting	Brussels, Belgium	October 24-25, 2023
OCT-NE	Boston, MA	November 1-2, 2023
DTRA Annual Meeting	Boston, MA	November 5-8, 2023
CNS Summit	Boston, MA	November 8-11, 2023
DIA Innovating Clinical Trials in Europe	Virtual	November 15-16, 2023
Informa Europe	Barcelona, Spain	November 29-30, 2023
FDA/CTTI Public Workshop to Enhance Clinical Study Diversity	Virtual	November 29-30, 2023
PRIM&R Annual Meeting	Washington DC	December 6, 2023
Node Health	New York, NY	December 7-8, 2023

TGIF-DCT Clubhouse

Fridays 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

Fridays at 12:00 PM ET

Friday, September 15, 2023

Data on Our Terms: The Key to Patient Empowerment
Craig Lipset, Amir Kalali, Jane Myles, Christine Von Raesfield

Join us to discuss a future where patients are the decision makers about who has access to their data, and where trials are a part of their care options by design.

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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 to prior episodes

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

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Upcoming Meetings

Save the Date

2023 Leadership Council Meetings

- November 8, 2023 (on-site 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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Open Forum

Jane Myles, Craig Lipset, Amir Kalali

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DTRA Regulatory Affairs Council

Steve Walker

FDA Draft Guidance

Thank you to the Community for the collaborative effort put forth to help craft DTRAs response to the FDA Draft DCT Guidance.

- Your Organizations comments and being part of our Community Session helped craft our submission.

DTRA Response to FDA Draft Guidance is linked here.

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Additional Responses on DTRA's Docket

DTRA Regulatory Affairs Council has begun working on & submitted responses to these guidances

- CDRH - Increasing Patient Access to At-Home Use Medical Technologies
  - Guidance Link
  - DTRA Comments submitted 8/30/2023
- WHO - Guidance for Clinical Trials Response
  - Guidance Link
  - Response due 9/15/2023

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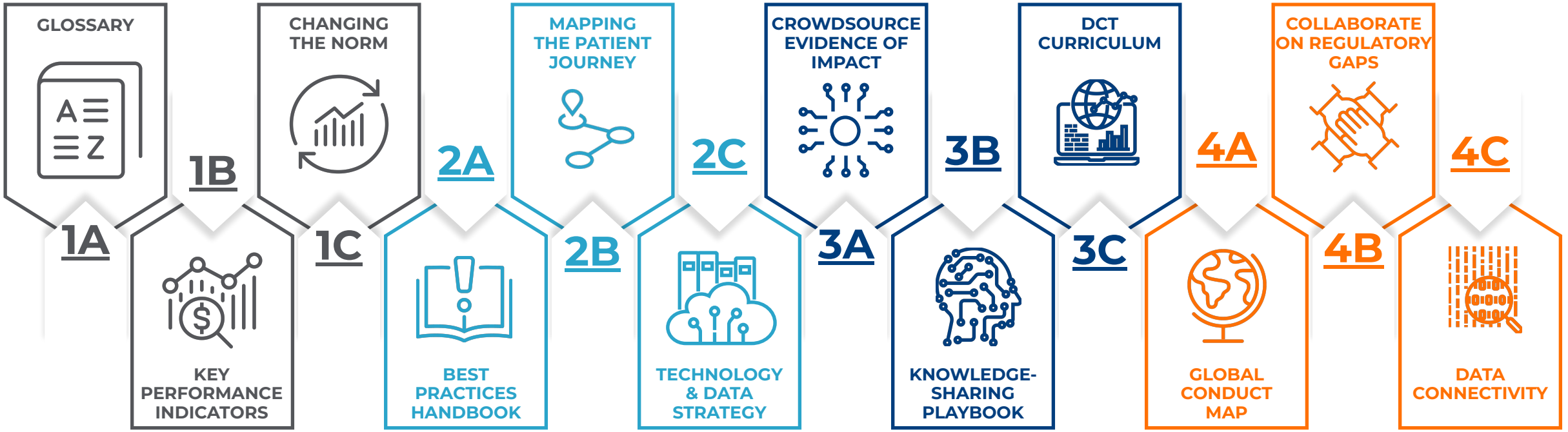
Initiative Teams Update

Jane Myles

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.

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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: Jane Myles, DTRA

Sneha Sundet, Agios Pharmaceuticals

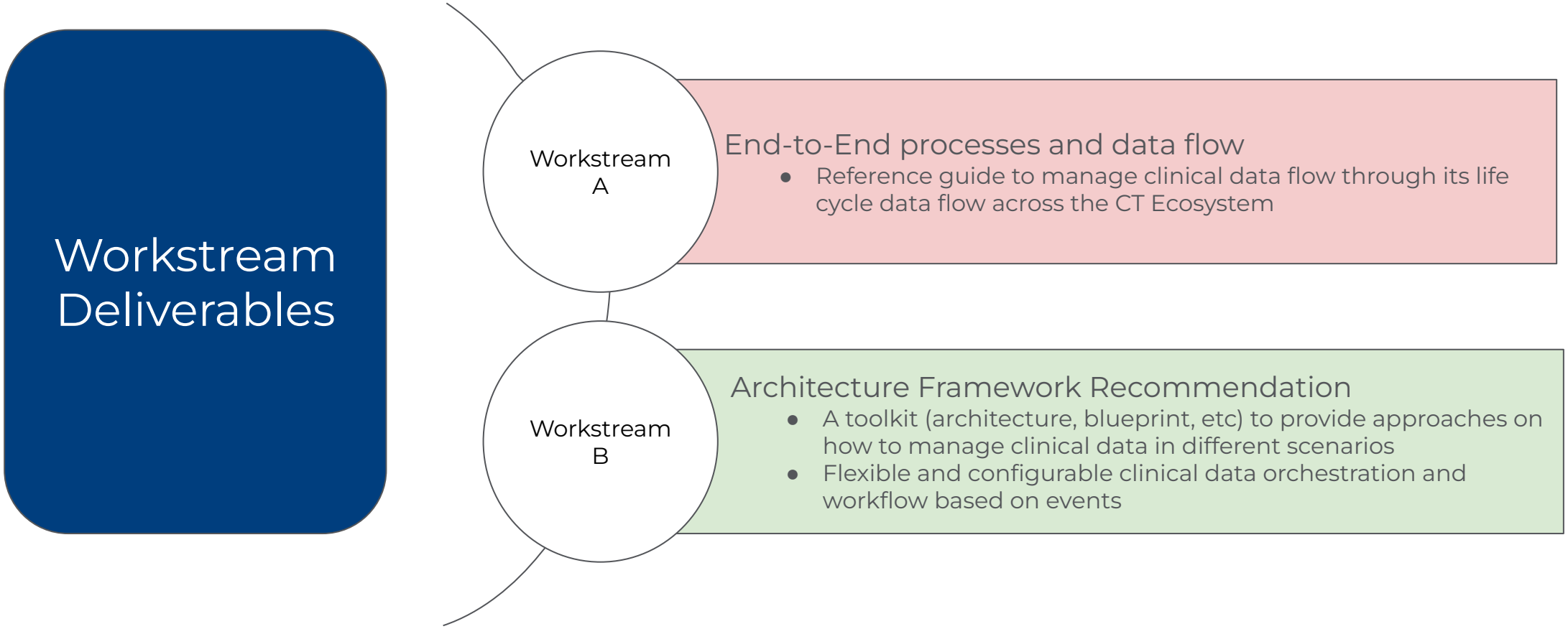
Thomas Healy, PPD

Jordan Simpson, Merative

Venu Mallarapu, eClinical

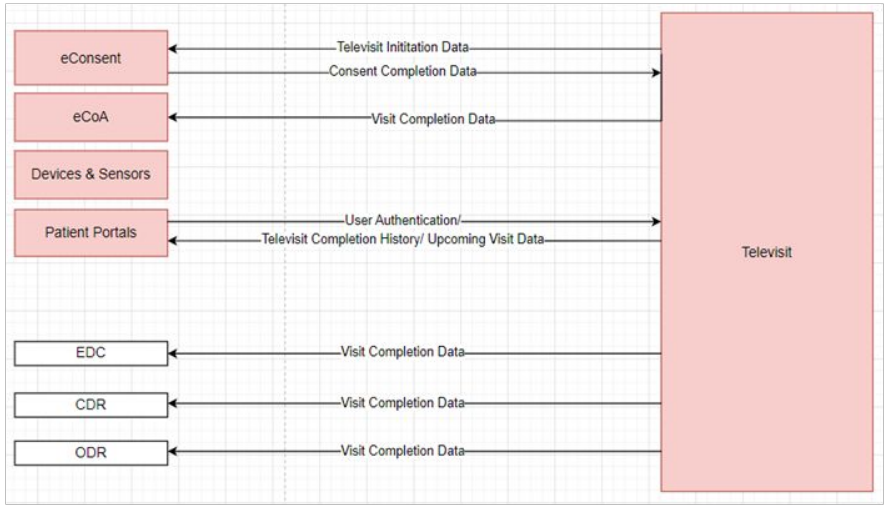
Rick Greenfield, RealTime CTMS

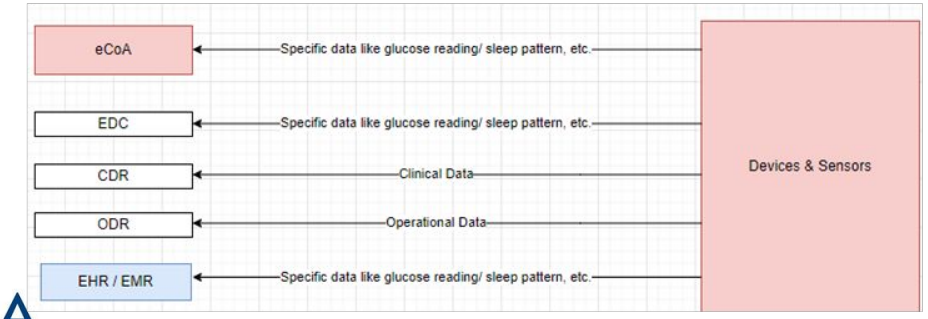
Workstreams

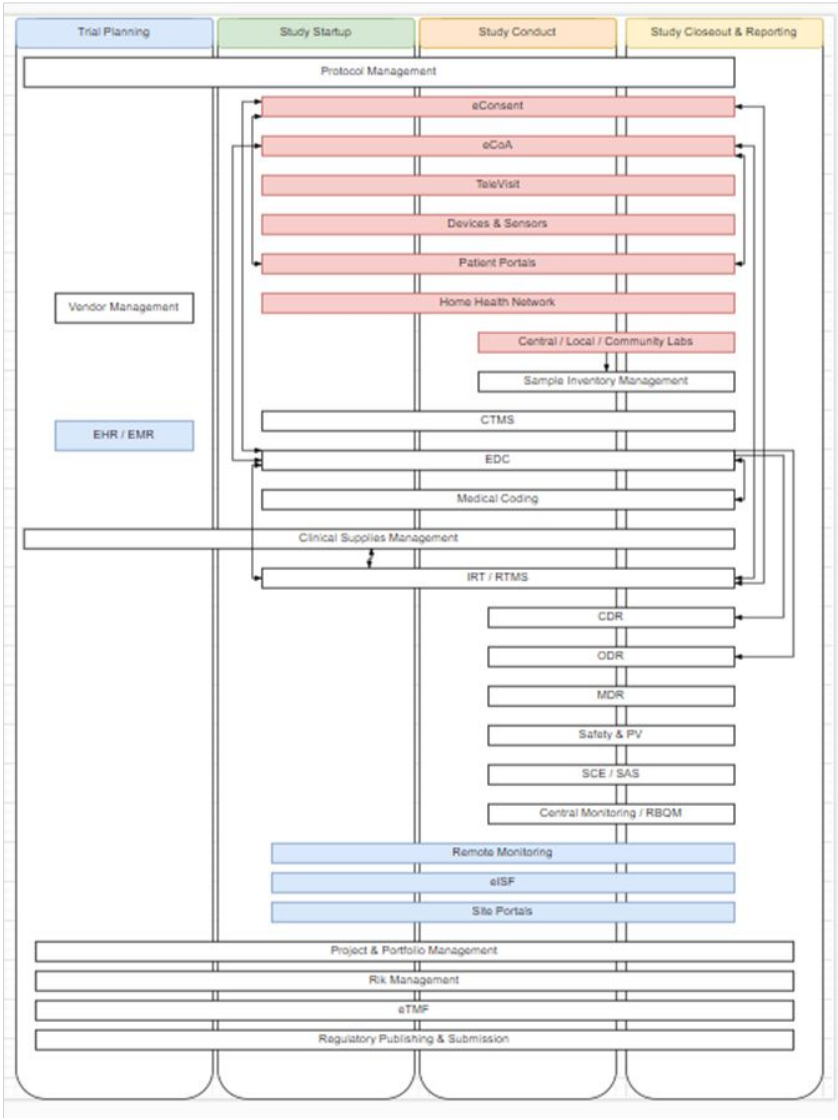


Information Dataflow and Data Exchange Framework

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







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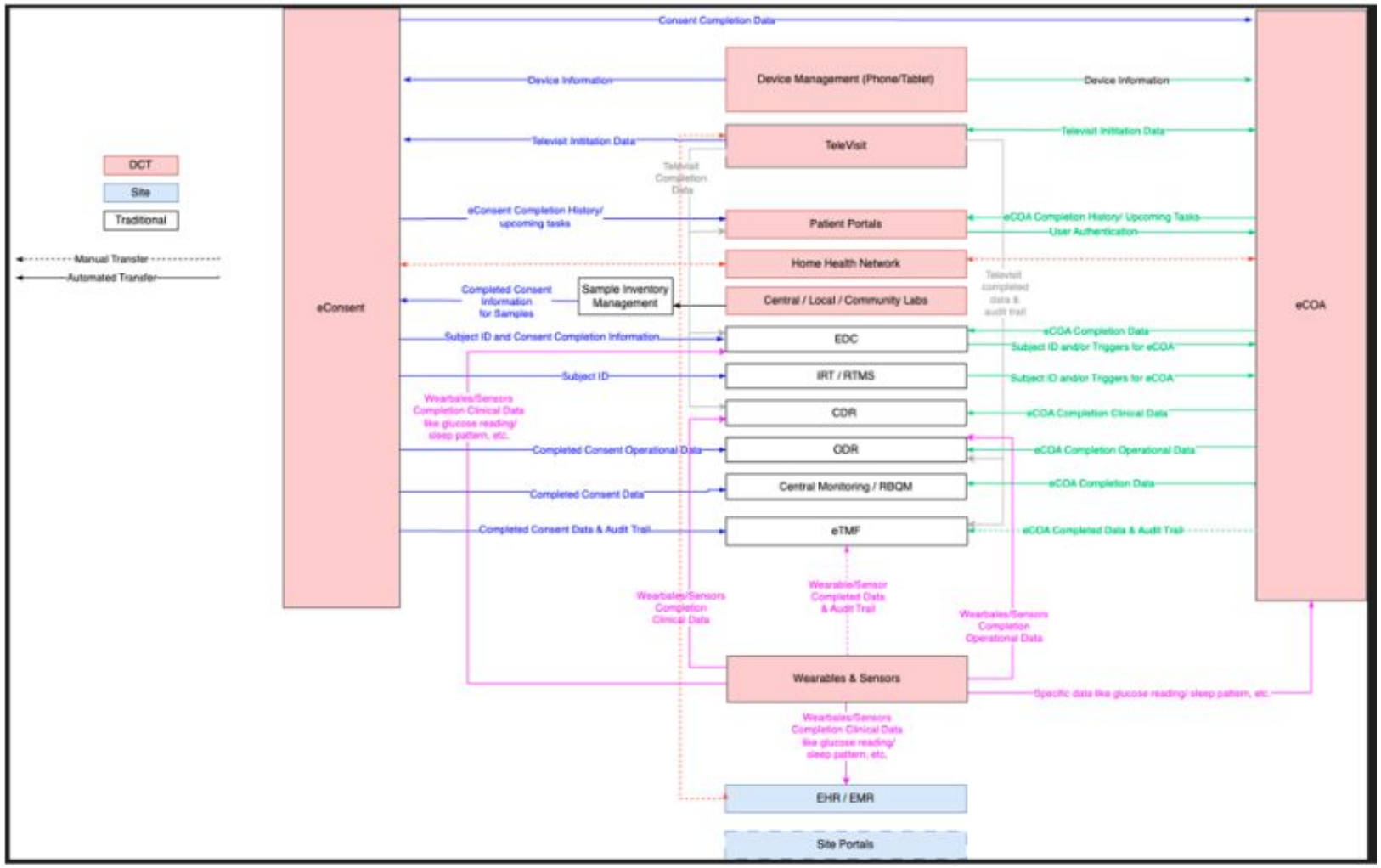
Information Dataflow and Data Exchange Framework

Data Flow across DCT Systems

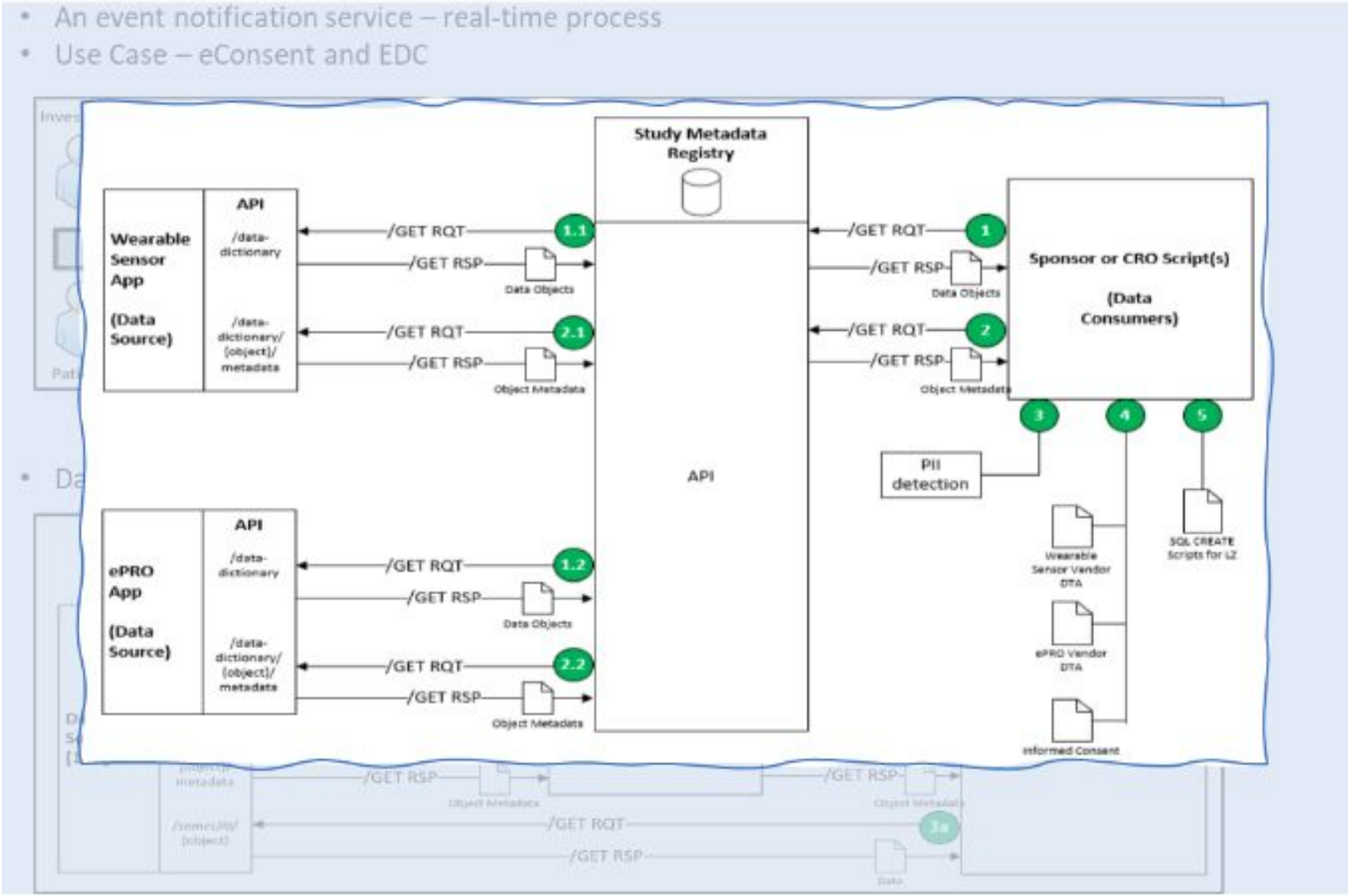
Our focus was to map out cross-system interaction of DCT systems (as identified in the table above) with the rest of the systems in the ecosystem.

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



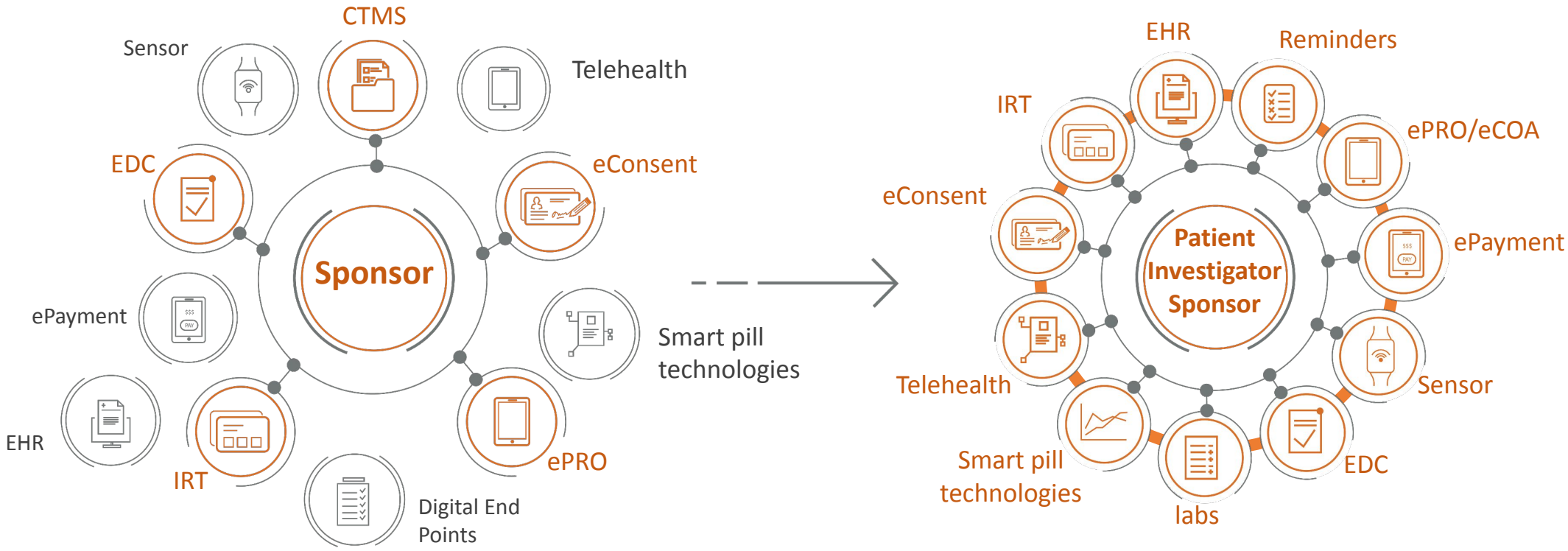
Data Exchange Framework

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



Information Dataflow and Data Exchange Framework

Connecting eConsent, ePRO, IRT, ePayment, Televisit, EDC, Patient devices, Patient portal, CTMS and other systems into one integrated ecosystem



Reduce manual, redundant and fragmented effort

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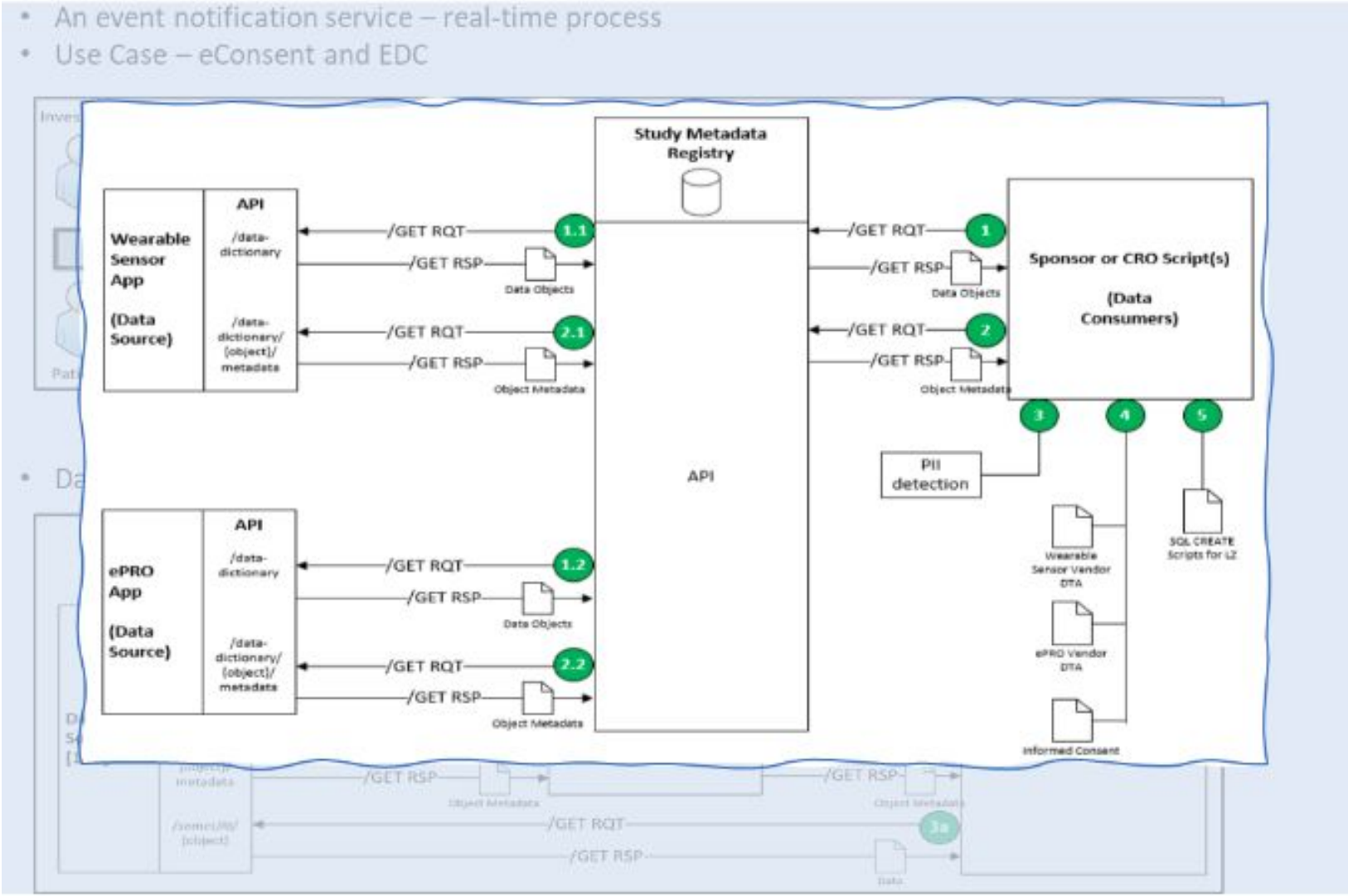
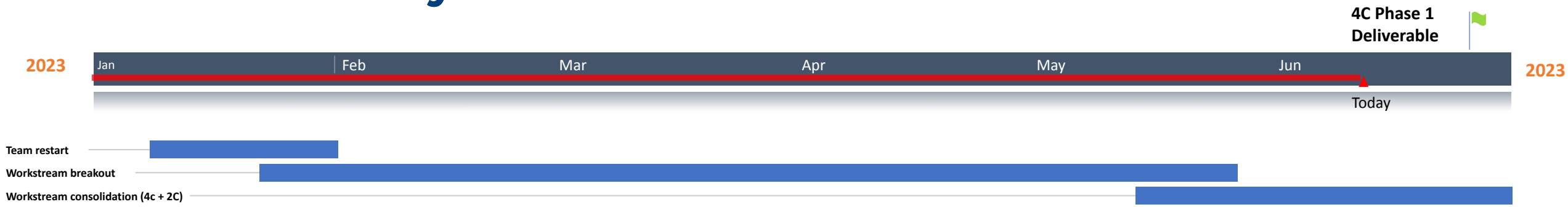
Data Exchange Framework

- 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

EDETEK REALTIME CLINICAL TRIAL MANAGEMENT SYSTEMS merative ThermoFisher SCIENTIFIC

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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 Needs Co Lab

Lauren Tobe, Rebecca Kottschade

1572 Needs CoLab

Testing the model for scalability

Kicked off 4 Apr. Completed August.

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

DELIVERABLES:

Create recommendations for 1572 / regulatory form completion to document

- conduct of decentralized trial assessments
- oversight responsibility for decentralized trial assessments
- use of virtual sites / metasites, mobile nursing services, retail pharmacy, local community physicians, local imaging centers, local labs and appropriate documentation guidance

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Resource Table - Traditional and DCT Roles and Documentation Recommendations

	Traditional Documentation	DCT Trial Related Role / Activity	DCT Recommendation
Investigator	1572 Field 1: Name of Investigator	Investigator	1572 Field 1: Name of Investigator
Virtual Investigator	1572 Field 1: Name of Investigator	Virtual Investigator	1572 Field 1: Name of Investigator
Central lab	1572 Field 4 (Clinical Labs)	Central lab	1572 Field 4 (Clincial Labs)
Local Lab	1572 Field 4 (Clinical Labs)	Local Lab	Task Log (DCT Guidance)
Local Radiolgy Lab	Other (Comment)	Local Radiolgy Lab	Task Log (DCT Guidance)
eCOA raters	Delegation of Authority Log	eCOA raters (not HCP Providers)	Delgation of Authority Log
Sub-investigators	1572 Field 6 (Sub-Investigators)	Virtual Investigators	1572 Field 6 (Sub-Investigators)
Network sites	1572 Field 3 (Facilities where research will be conducted_	Network Sites	1572 Field 3 (Facilities where research will be conducted)
		Mobile research sites	1572 Field 3 (Facilities where research will be conducted)
		Pharmacy research sites : SOC Assessment/ HCP Activities asacting as another location for Traditional Research Site	Task Log (DCT Guidance)
		Pharmacy research Site acting as full site	1572 Field 1: Name of Investigator
		Pharmcy research site acting as another location for Traditional Research Site Conducting Protocol Specific Activites	Delgation of Authority Log
		Pharmacy Research Site: Low Risk IP Admin (SOC Tasks)	Task Log (DCT Guidance)
		Pharmacy Research Site: High Risk IP Admin	Delgation of Authority Log
Primary Care MD	Other (Comment)	Primary Care MD/ HCP acting as another location for traitional site: SOC Assessment	Task Log (DCT Guidance)
		Primary Care MD/ HCP acting as another location for traitional site: : Protocol Specific Assessment	Delgation of Authority Log
		Primary Care MD/ HCP acting as the PI	1572 Field 1: Name of Investigator
CRC (Clinical Research Coordinator)	Delegation of Authority Log	Virtual CRC	Delgation of Authority Log
Home Health Nurses - SOC Proodures (signs and symptoms)	Delegation of Authority Log	Home Health Nurses - SOC Assessment (signs and symptoms)	Task Log (DCT Guidance)
Home Health Nurses - IP admin	Delegation of Authority Log	Home Health Nurses - Low Risk IP Admin	Task Log (DCT Guidance)
		Home Health Nurses - High Risk IP admin	Delgation of Authority Log
		Hone Healh nursse conducting SOC activities.	Task Log (DCT Guidance)
Home Health Nurses - Protocol			

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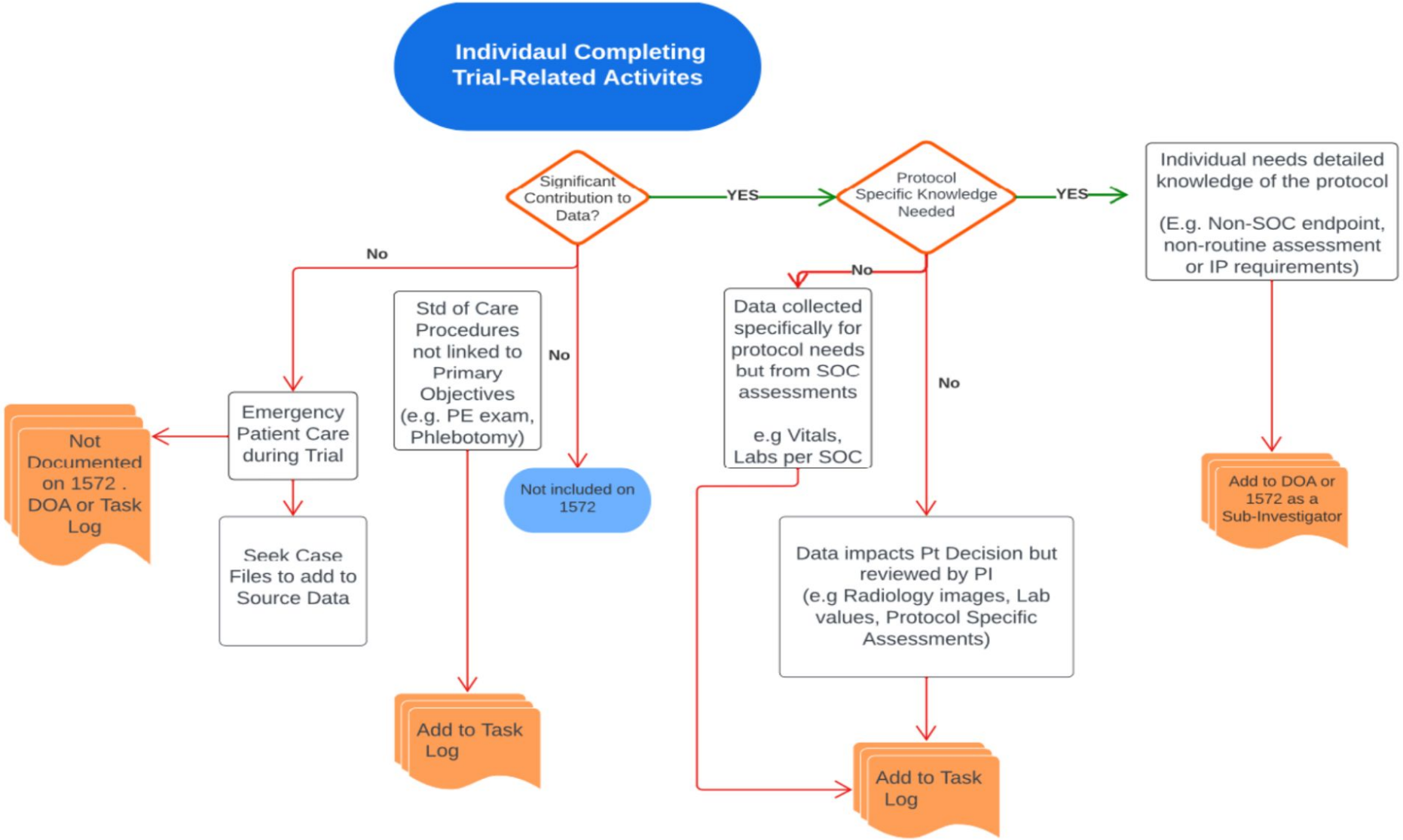
Decision elements to determine appropriate documentation of delegated trial-related activities



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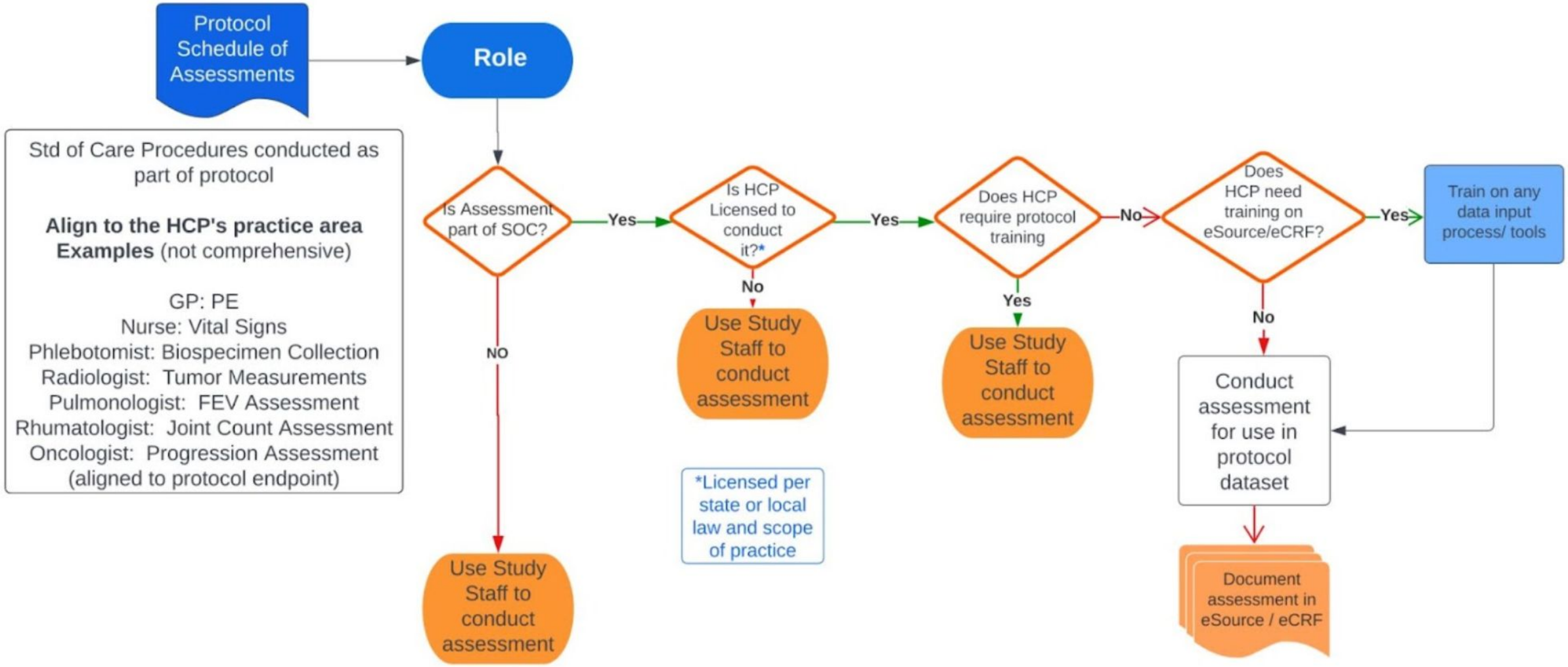
Decision Elements regarding Standard of Care Practice



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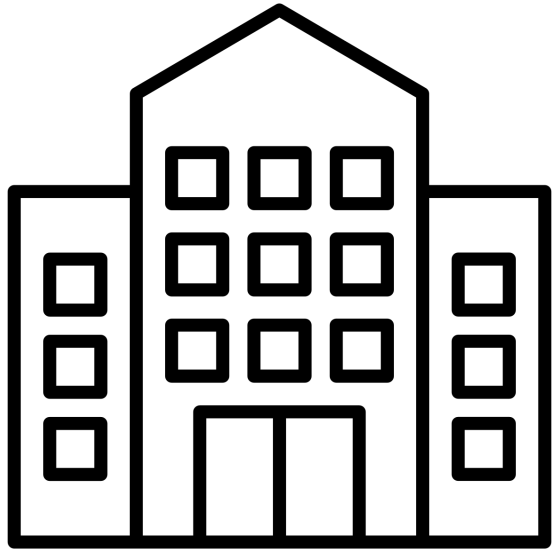
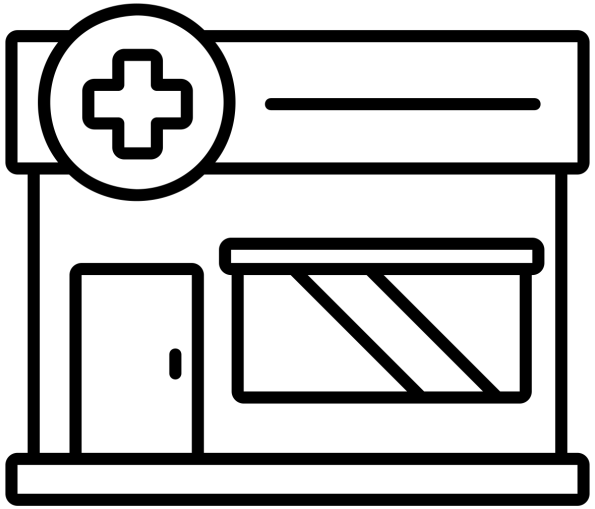
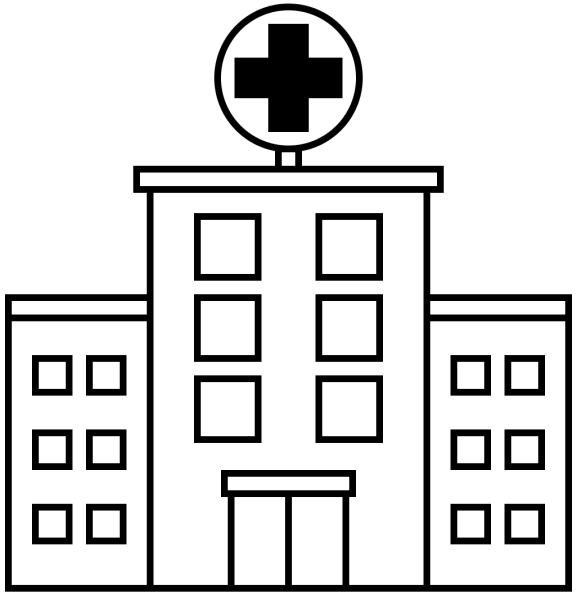
Scenarios for PI Oversight and Delegation of Trial-Related Activities



Traditional Research Site
Visit 0 - eConsent at Site
Visit 3 - Telehealth Follow Up
Visit 6 - Telehealth Follow Up



Pharmacy
Visit 2 – Follow up labs
Visit 4 - RSV Vaccine Dose
Visit 5 - Follow up labs



Primary Care Physician
Visit 1 - Initial Visit in Clinic,
initial RSV Vaccine and labs
RSV Event - HCP Involvement

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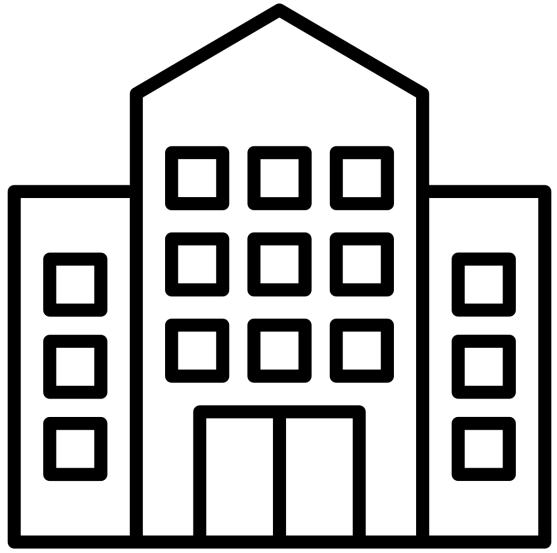
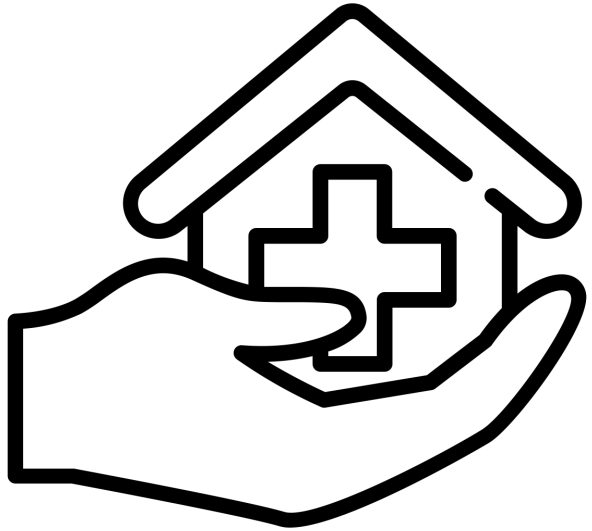
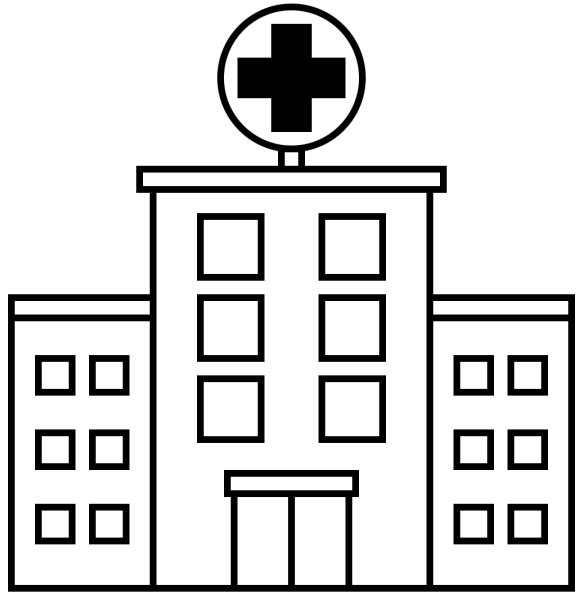
Scenarios for PI Oversight and Delegation of Trial-Related Activities



Traditional Research Site
Visit 1 - Initial visit at site



Home Health Care
Visit 2 – Labs drawn, physical exam
Visit 4 – Labs drawn, physical exam
Visit 6 – Labs drawn, physical exam



Health Care Provider Practice
Visit 3
Visit 5
Visit 7

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Completed 1572 Form and Additional Page for RSV Trial Site per Briefing Document

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: March 31, 2025
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator: Dr. Tom Petty

Address 1	Address 2		
Perfection Clinical Research Inc.	123 Main Street		
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Sunrise	FL	USA	33351

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select one of the following.)*

☒ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility: Perfection Clinical Research Inc.

Address 1	Address 2		
123 Main Street			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Sunrise	FL	USA	33351

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — CONTINUATION PAGE for Item 4

Name of Clinical Laboratory Facility: Labcorp Central Laboratory Services Limited

Address 1	Address 2		
8211 SciCor Drive			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Indianaopolis	IN	USA	46214

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — CONTINUATION PAGE for Item 5

Name of IRB: Advarra

Address 1	Address 2		
6100 Merriweather Drive	Suite 60046214		
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Columbia	MD	USA	46214

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

Steven Ferrone, MD

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select **one** of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☐ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

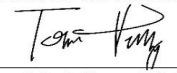
I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR	Sign
		

(**WARNING**: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

FORM FDA 1572 (3/22) **PREVIOUS EDITION IS OBSOLETE.** **Page 2 of**

Example of a combined Delegation of Authority and Task Log for RSV Trial Site per Briefing Document

	Delegation of Authority and Task Log								
Protocol Title:	Vaccine trial to prevent Respiratory Syncytial Virus (RSV)								
Name		**Protocol Training Needed**	**Is Assessment SOC?**	**Study Role Designation**	**Location of Clincial Trial Activites**	**Start Date**	**End Date**	**Delegated Responsibilities**	**Tasks Completed**
Lena Love, RN	Study Coordinator	Yes	NA	Study Site Team Member	Perfection Clinical Research Inc. 123 Main Street, Sunrise FL 33351	6/1/2023		Patient Pre-Screening Patient Informed Consent Patient Screening Med Hx / Con Med RSV Vax Administration AE / SAE Reporting	NA
Dr. Steve Ferrone, MD	Sub-Invstigator	Yes	NA	Study Site Team Member	Perfection Clinical Research Inc. 123 Main Street, Sunrise FL 33351	6/1/2023		Patient Informed Consent Patient Screening Med Hx / Con Med RSV Vax Administration All Study Visit procedures	NA
Marilyn Martin, RN	Study Nurse (Pharmacy Based)	Yes	NA	Pharmacy Site Team Mer	Walgreens 6401 W Commercial Blvd, Tamarac, FL 33319	6/1/2023		Med Hx / Con Med RSV Vax Administration Study Assessments for V2,3,4,5,6	NA
Michael Campbell, PharmD	Study Pharmacist (Pharmacy Based)	Yes	NA	Pharmacy Site Team Mer	Walgreens 6401 W Commercial Blvd, Tamarac, FL 33319	6/1/2023		Med Hx / Con Med RSV Vax Administration Study Assessments for V2,3,4,5,6	NA
Dr. Stevie Nicks, MD	HCP	No	Yes	HCP treating patient	12651 W Sunrise Blvd Suite 202, Su	7/23/2023	7/30/2023	NA	PE, Labs, Rx for RSV
PI Signature	*Tom Petty*	**Date**	7/23/2023						

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Alternative Sites Co Lab

Shivi Stanley

Alternative Site Models

Testing the model for scalability

Kicked off 17 Apr. Target end date 15 Sept.

SCOPE:

Recommendations on site selection / qualification, Key Considerations for using the alternative site models, training and oversight, (~7 initial models)

- Mobile sites, Pharmacy based sites, Mobile Nursing, Patient Service Centers, etc

Key Lessons learned:

- Working meeting model
- Momentum is hard to sustain in summer

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Defining Alternative Site Models: What and Why

Goal: Clarify Different Site Models and the problems they solve

Target audience: Internal Team Members (e.g. study teams, procurement) and Customers

Site Model	Accountable Owner	Input Partner(s)
Mobile Research Site (site on wheels)	Jenn Embury	Hassan Kadhim
Pharmacy Based Sites	Sandeep Bhat	John Campbell?
Research assessments go to patient (e.g. mobile nursing)	Tajuna Barron	Deb Guattery
Pop-up sites	Jenn Embury	Hassan Kadhim
Lab Based Sites/ Patient Service Centers	Kristin Andrews	Jane Myles
PCP Community Based Sites (e.g. Community based health centers, Onc centers, Tribal Research Centers)	Jane Myles	Jenn Embury
Naive research sites - IRO	Elizabeth White	Kristen Andrews

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Alternative Sites: What and Why

1. What is alternative/ non-traditional site model called?

2. What problems does this model aim to solve in trials?

☐	Patient Recruitment	☐	Increase diverse participation / recruitment
☐	Patient Retention	☐	Increase geographic reach for sites to patients
☐	Improve patient accessibility	☐	Reduce site burden / resource utilization
☐	Increase access to rare disease patients	☐	Increase access to de novo / new investigators
☐	Decrease patient burden (e.g. financial, time, etc)	☐	Other:
☐	Increase access to underserved / underrepresented patients		

3. Where are these site models available for use in trials? NOTE: Assume US is a given

☐	Canada	☐	Japan
☐	Mexico	☐	China
☐	France	☐	Australia
☐	Italy	☐	South Korea
☐	Germany	☐	India
☐	Spain	☐	Singapore
☐	Belgium	☐	Taiwan

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Alternative Sites: Research Naive Site

Alternative Sites: What and Why

1. What is alternative/ non-traditional site model called?

Local Laboratory / Biospecimen Collection Site (e.g. LabCorp or Quest Patient Service Center)

2. What problems does this model aim to solve in trials?

☐	Patient Recruitment	☒	Increase diverse participation / recruitment
☒	Patient Retention	☒	Increase geographic reach for sites to patients
☒	Improve patient accessibility	☐	Reduce site burden
☐	Increase access to rare disease patients	☐	Reduce resource utilization
☒	Decrease patient burden (e.g. financial, time, etc)	☐	Increase access to de novo / new investigators
☒	Increase access to underserved / underrepresented patients	☐	Other:

3. Where are these site models available for use in trials? NOTE: Assume US is a given

☐	Canada	☐	Japan
☐	Mexico	☐	China
☐	France	☐	Australia

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Alternative Sites: Creating Visual Deliverables

ALTERNATIVE SITE MODEL

RESEARCH NAIVE SITE - IRO INTEGRATED RESEARCH ORG

WHAT IS A RESEARCH NAIVE SITE?

A NEW TO RESEARCH MD WHO MAY BE DOING 1 TRIAL OR BE IN TRAINING TO BE A FULL PI.

WHAT PROBLEMS DOES THIS MODEL AIM TO SOLVE IN TRIALS?

Patient
...recruitment
...retention
...accessibility

Access
...to rare disease patients
...to diverse patients
...to underserved/represented
...to geographic reach for sites
...to de novo/new investigators

Cost
...financial burden

HOW CAN THIS SITE MODEL BE USED IN TRIALS?

- ✓ As an HCP location
- ✓ As an additional location for a traditional site
- ✓ Integrated/satellite site from PI
- ○
- ○

WHERE ARE THESE SITE MODELS AVAILABLE FOR USE IN TRIALS?

SPECIAL CONSIDERATIONS/LIMITATIONS

INVESTIGATIONAL PRODUCT PREPARATION

IP prep, handling, and storage will depend on sponsor/site capabilities. If entire staff is research naiive:

- Research experienced vendor meta-site, if sponsor allows, could receive/store/prep admin at the home or in HCP office.
- IP and home nurse administrators
- If patient's HCP is research trained, IP can be shipped/stored/prepped in office

INVESTIGATIONAL PRODUCT ADMINISTRATION

IP route of admin & safety profile will provide guardrails for admin

- If IP is injectable or infusion, proper licensure for HCP administering is required
- Proper supplies to handle severe reactions - crash cart supplies as appropriate for IP.

PRIVACY

- Minimal considerations
- Medical practice accustomed to privacy concerns or within the patients home

ACCESS

- Water and electricity will be essential to conduct any medical related study visit
- Technology needed for eDiaries

BIOSPECIMEN COLLECTION

Lab processing usually requires protocol knowledge and training. The blood draw could be separated from the processing/shipping if needed.

- Third party vendor to ship supplies directly to patients house for home nurse to use to draw, process, and ship to a central lab
- Could be outsourced to a third party lab

TRIAL SPECIFIC ASSESSMENTS

- Of and patient monitoring
- With protocol training
- 's office
- Remote study team coordinate with HCP office
  - Remote study coordinator
  - Remote mentor PI

MEDICAL WASTE MANAGEMENT

Minimal considerations - lots of options in US

- Home Health Nurse can take waste for central disposal
- HCP office can handle waste
- Medical waste can be picked up/shipping to appropriate vendor

PI OVERSIGHT

CONTENT NEEDED

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CoLabs - Coming Next

Site Adoption Challenges

Cross-Partner collaboration - ACRP, SCRS, DTRA

Many different topics considered

- Change Management
- Technology needs
- Training Needs

Annual survey to measure change over time (adoption, concerns, needs)

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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

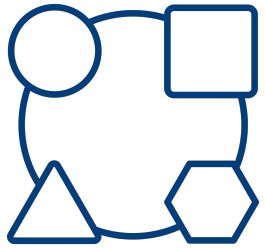
Enabling deeper member engagement by creating space to connect with peers

6 Micro Communities of functional leaders are currently running and always recruiting new members.

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

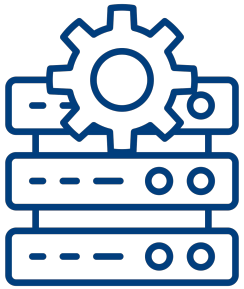
Real World Data

Next Virtual Meet-up:
Oct 12 at 2:00 PM ET



Diversity

Next Virtual Meet-up:
Oct 3 at 3:00 PM ET



Data Management

Next Virtual Meet-up:
Oct 10 12:00 PM ET

Patient Recruitment

Next Virtual Meet-up:
Oct 13 11:00 AM ET

Patient Voice

Next Virtual Meet-up:
Sept 28 2:00 PM ET

KPIs/ Metrics

Next Virtual Meet-up:
Nov 15 3:00 PM ET

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