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&  
RESEARCH ALLIANCE

# All Hands Meeting

September 28, 2023



# Agenda

- Welcome
- DTRA Resources - Tubestop Introduction
  
- CoLab Updates
  - Alternative Site Models
  - Site Adoption Needs
  
- Circles Updates: Metrics & KPIs
  
- DTRA Annual Meeting - Preview!

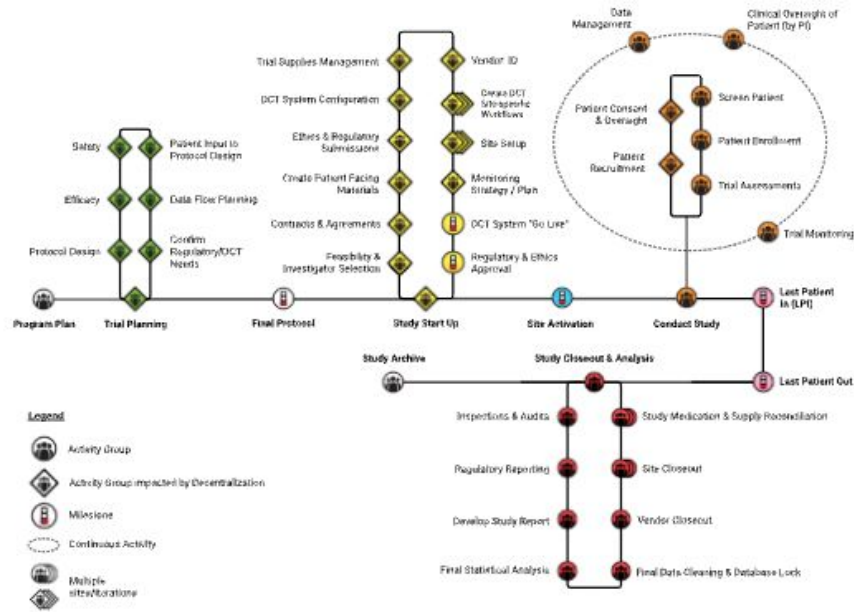


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# **DCT Tubestop Overview**

Jane Myles & Paige Altrogge





## The DCT Playbook

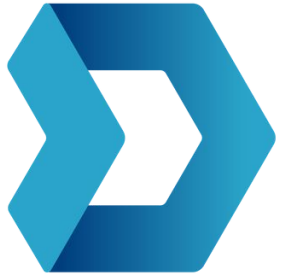
The DCT Tubestop Map is a digital end-to-end process map to support DCT trial planning and execution, with key process steps across the plan, setup, conduct, and close stages of trials and resources from DTRA and our Partner Orgs to help you along the journey.

[Learn More](#)

# 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 to 4 month timeframe to recommendations
- Operate more like a sprint team



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# Alternative Sites CoLab

Shivi Stanley, Darcy Forman



# Alternative Site Models

## What are they? How to Use them?

### **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

# 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  |
|---|
| Mobile Research Site (site on wheels)   |
| Pharmacy Based Sites  |
| Research assessments go to patient<br>(e.g. mobile nursing)   |
| Pop-up sites  |
| Lab Based Sites/<br>Patient Service Centers   |
| PCP Community Based Sites<br>(e.g. Community based health centers, Onc<br>centers, Tribal Research Centers) |
| Integrated Research Organizations (IRO)   |



# 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
- 
- 



## SPECIAL CONSIDERATIONS/LIMITATIONS



### INVESTIGATIONAL PRODUCT PREPARATION

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

- Research experienced vendor meta-site, if sponsor allows, could receive/store/prepare 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



### PRIVACY

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



### 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



### 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



### 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.



### ACCESS

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



### 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



### PI OVERSIGHT

CONTENT NEEDED

# CoLabs - Coming Next

## Site Adoption Challenges

Site listening session- Partnering between ACRP, SCRS, DTRA

Objective: Prioritization / Roadmap for specific adoption needs:

- Change Management Support
- BYOT
- Roles / Responsibilities and RACIs (Sponsor, Site, DCT Provider)

Consider an annual survey to measure change over time  
adoption, concerns, needs



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# Circles Update

Paige Altrogge



# 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. KPIs & Metrics is kicking off in September!

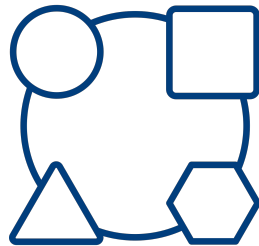
To join any of these Circles, [complete this form](#) or email [secretariat@dtra.org](mailto:secretariat@dtra.org)



**Real World Data**

Next Virtual  
Meet-up:

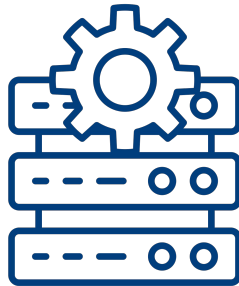
Oct 12 at 2:00 PM ET



**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**

First Virtual  
Meet-up:



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# DTRA Annual Meeting

Paige Altrogge





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**2023  
ANNUAL  
MEETING**

**Register Now - Price Increase on 9/30!**

**MEMBERSHIP FEE INCLUDES 2 REGISTRATIONS! Check with your LC to see if you can attend.**

DTRA 2023 Annual Meeting  
Encore Hotel, Boston, MA  
November 5-8, 2023

# 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

# 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*





# Thank you for your time!

We'll be skipping October's meeting due to the Annual Meeting! We hope to see you there.



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