



DTRA
DECENTRALIZED TRIALS
&
RESEARCH ALLIANCE

Leadership Council

Onsite at the Annual Meeting

November 8, 2023





DTTRA
DECENTRALIZED TRIALS
&
RESEARCH ALLIANCE

Introductions



Agenda

DTRA Activities

- Initiatives
- Co Labs
- Circles
- Future Areas of Focus

Maximize your Membership

- 2024 Membership
- How to help get information into your organization

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



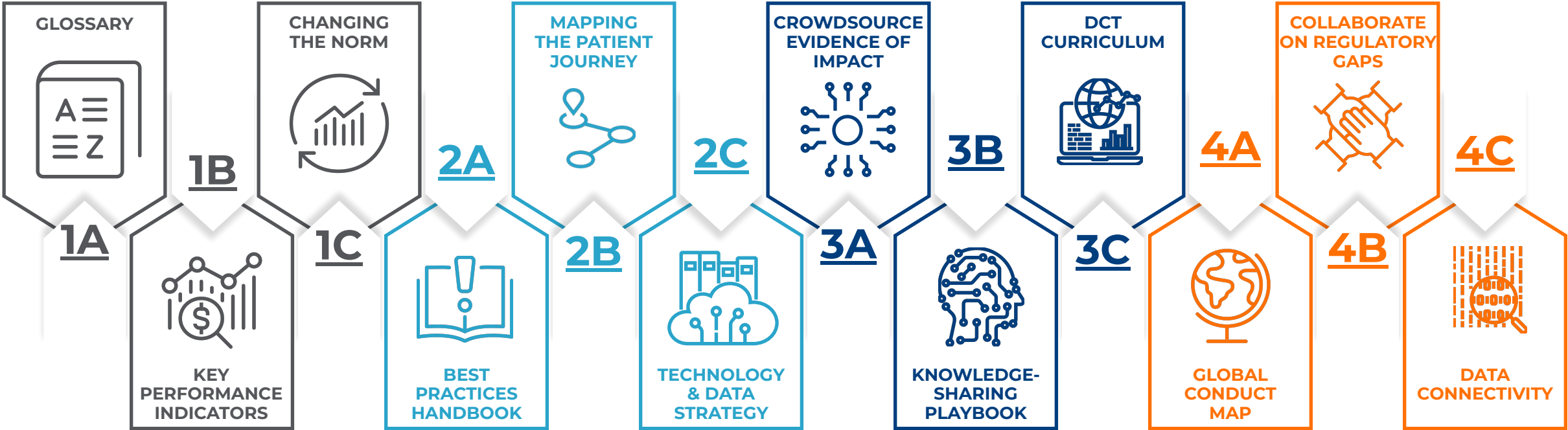
NON COMMERCIAL SPACE

The online collaboration platform provides the appropriate space to share capabilities

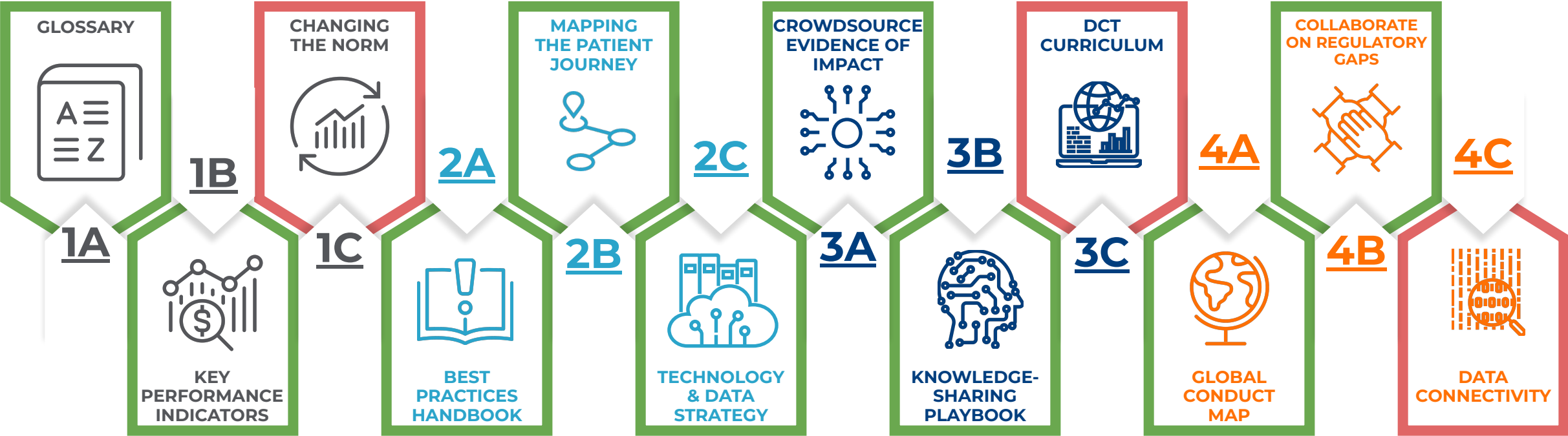
Current Members



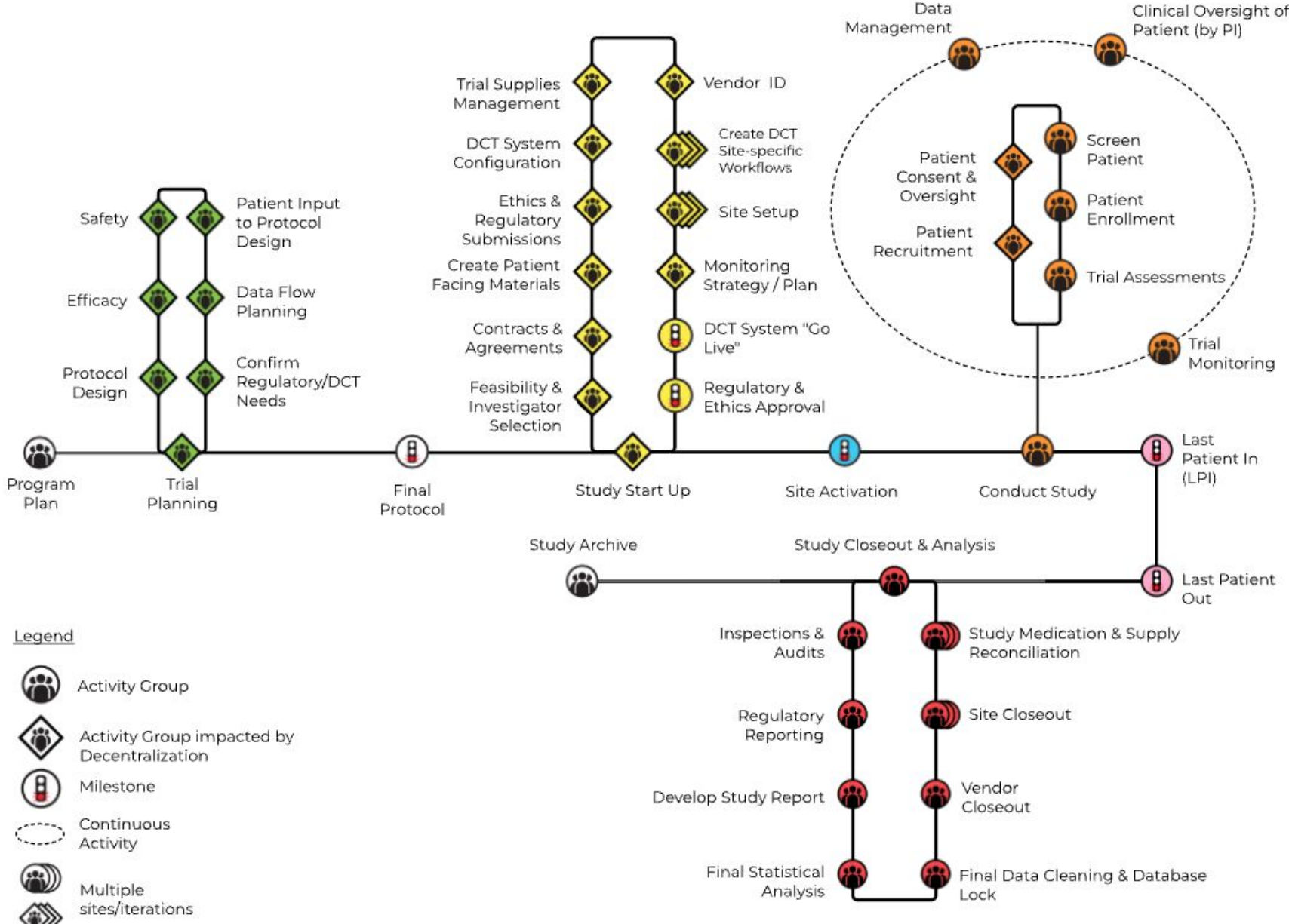
Initiatives Close-Out



Digitization of Deliverables



TubeStop



Poll - Tubestop Map

- Have you used the DCT Tubestop map?
- What would help your team members use the map?

Resource Library



Become a member

My profile

PRIORITIES AND INITIATIVES

DCT TUBESTOP

2023 ANNUAL MEETING

CONNECT

ABOUT

NEWS

CONTACT

DTRA COMMUNITY



Resource Library

Resource Library

A Comprehensive Collection of DTRA Content and Resources Supporting the Adoption of DCTs

Resource Library

Find resources, white papers, case studies, and more with the DTRA Resource Library.

Explore Resources



Resource Library

What is the DTRA Resource Library?

DTRA has created a library of resources, ranging from white papers and peer-reviewed journal articles to regulatory documents that can be used by our greater DCT community. The library is sortable by therapeutic area, topic, type of publication, and more. Please share resources with DTRA that you think should be part of this library so we can continue to grow and expand this repository.

Resource Type	Search...
General Topic	Rainbow SPARX: A novel approach to addressing depression in sexual minority youth View
Solution / Service Offering	The mPower study, Parkinson disease mobile data collected using ResearchKit View
Region	Pharmaceutical perspective: how digital biomarkers and contextual data will enable therapeutic environments View
Therapeutic Area	Incorporating site-less clinical trials into drug development: a framework for action View
Phase	Facebook Advertising to Recruit Young, Urban Women into an HIV Prevention Clinical Trial View
Trial Type	Clinical trials go virtual, big pharma dives in View

Add your Resources to the Library



Submitting Your Resource

Choose descriptive tags to categorize to this resource. Select all that apply.

Resource Type

- Case Study
- White Paper
- Peer Reviewed Journal Article
- Guidance Document
- Regulatory Document
- Non-Peer Reviewed Article

General Topic

- Evidence of Impact
- Evidence of Adoption
- KPIs
- ROI
- Diversity Equity and Inclusion
- Patient Voice

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

CoLab: Regulatory Documents in DCTs

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

Alternative Site Models

Testing the model for scalability

Kicked off 17 Apr. Completed October.

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

DELIVERABLES:

- What problem does this approach solve?
- Where can you use it?
- What do you need to consider
 - IP management and administration
 - PI Oversight
 - Patient considerations (e.g. privacy, comfort, etc)

CoLabs - Coming Next

- Site Adoption Challenges
 - Roles / Responsibilities / RACIs
 - Process: Including site input to trial design / planning
- Use of DHT in DCTs
 - Create example protocols and review guide
 - Seek feedback from Ethics committees , sites, patient groups?
 - Develop some tools to guide decision making for study teams/ DHT developers
- Patient Recruitment and DCT
- What's different? Processes / tools to support successful recruitment

DTRA Circles

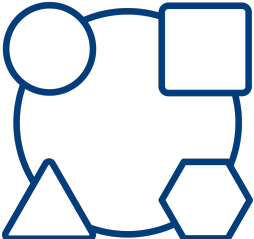
Enabling deeper member engagement by creating space to connect with peers

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



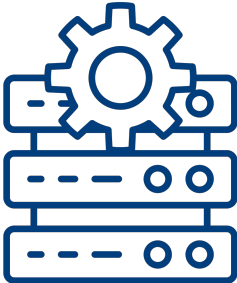
Real World Data

38 Members
5 Virtual Meetings



Diversity

80 Members
5 Virtual Meetings



Data Management

47 Members
5 Virtual Meetings



Patient Recruitment

78 Members
5 Virtual Meetings



Patient Voice

33 Members
3 Virtual Meetings



KPIs/ Metrics

24 Members
2 Virtual Meetings

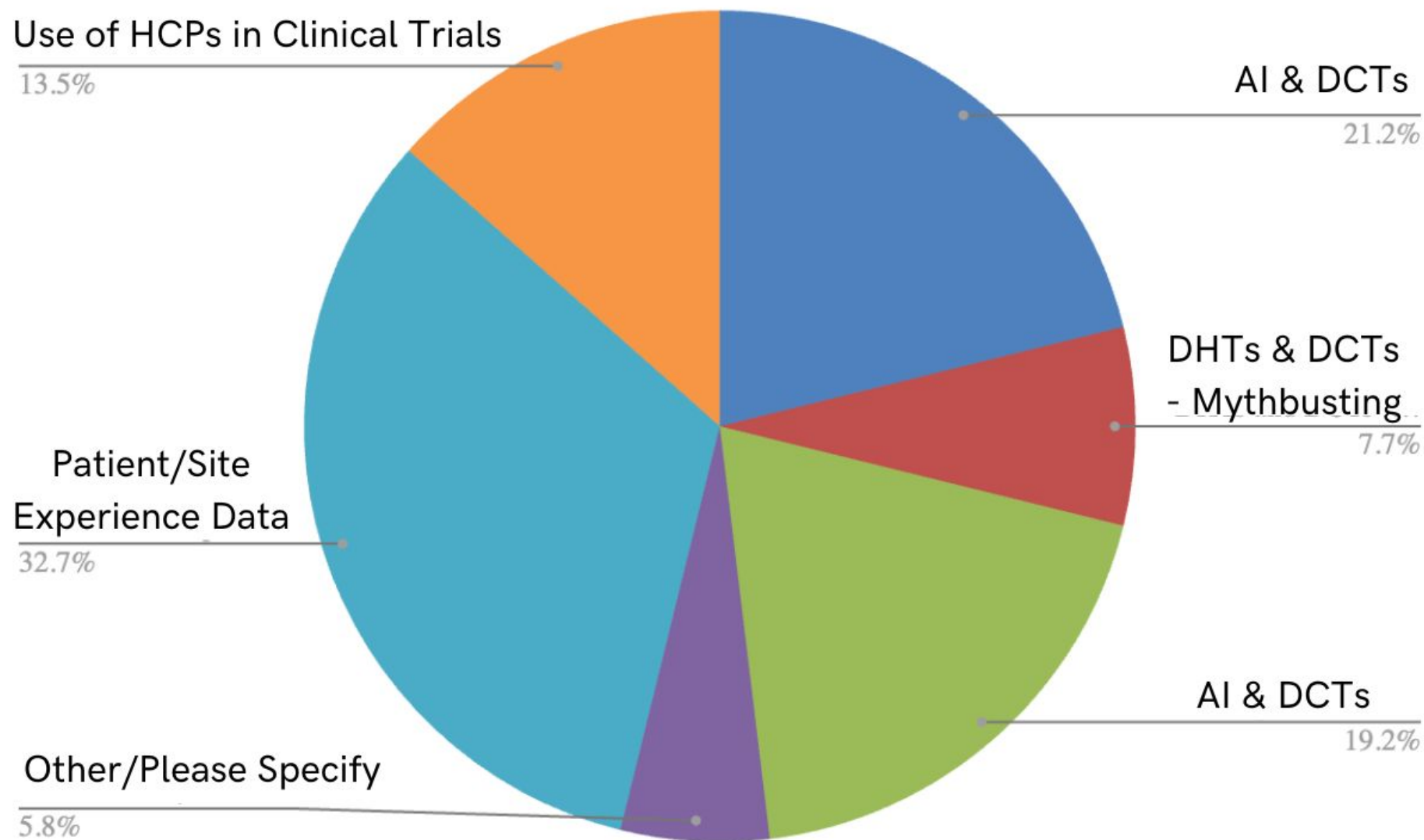
DTRA Circles - What's next?

- Geographic / Regional Circles
 - Japan
 - Western EU / UK
- AI and DCT?
- DHTs in DCT?
- What's next in trial modernization?

2024 Areas of Focus

- Patient / site experience data
- Use of HCPs in clinical trials
 - Stakeholder Perspectives
 - How to make it a reality
- DHTs and DCTs - Myth busting and Decision Support
- Patient Recruitment in DCTs
- How-to guides for teams to operationalize
 - how to build in optionality
 - how to measure impact (data needs, analytic framework)
- AI in DCTs

2024 Areas of Focus





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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

How do you share DTRA's opportunities and deliverables?

Open Discussion

Membership Benefits



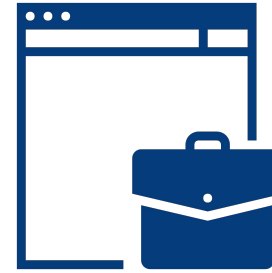
Leadership Council Representation



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

2024 Membership

Dues will remain at \$30,000 for the 2024 Membership Year

Invoices will be issued the week of December 4 for processing

Save the Date

DTRA 2024 Annual Meeting
Encore Hotel, Boston, MA

2nd week of November 2024

Organizational Membership in 2024 includes 2 Basic Registration Passes

Final Leadership Council Meeting for 2023

Thursday, December 14

12:00 - 2:00 PM ET

Social/Networking Time amongst peers



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