DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

DTRA Initiatives

Monthly ‘all hands’ meeting

April 27, 2023

DTRA INITIATIVES AGENDA

- Welcome & Agenda - Claudine
- 2B Mapping the Patient Journey: deep dive – Richie Kahn
- 2A Best Practices – Mike DeMarco
- Update from team 4C Data Connectivity– Munther Baara
- Circles and CoLabs – Jane

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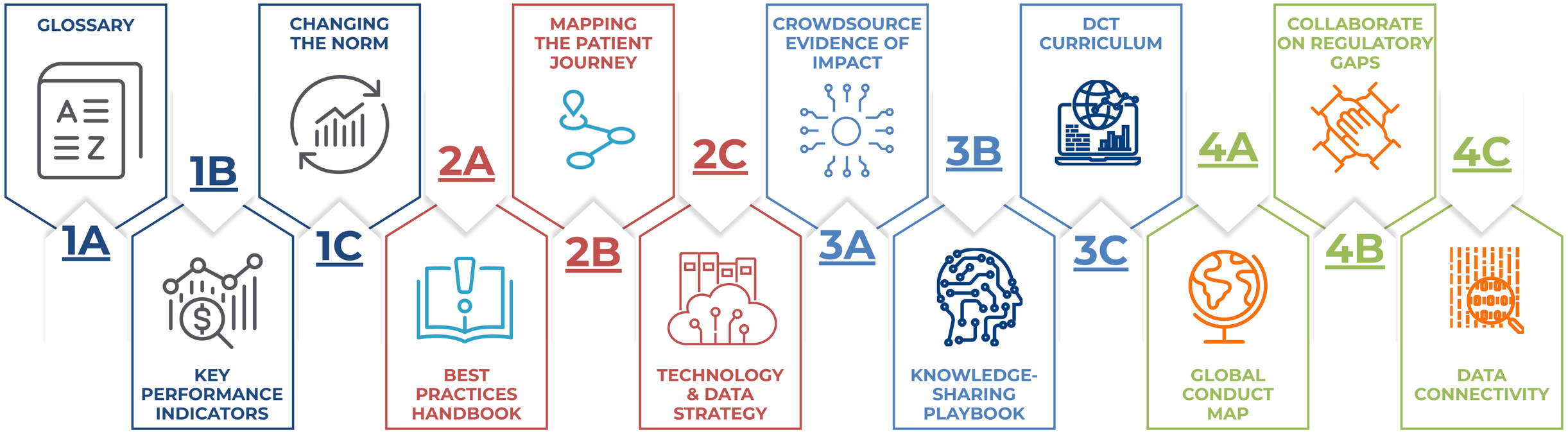
DTRA INITIATIVES AGENDA

Initiative Overview



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 for more information, or access at www.dtra.org.

Initiative Teams

12

Priorities

315

Leaders in Decentralized Research

125

Global Organizations

Volunteers from our Member Organizations are assembled on Initiative Teams to work together to achieve a deliverable that contributes to the larger goal of the Priority.

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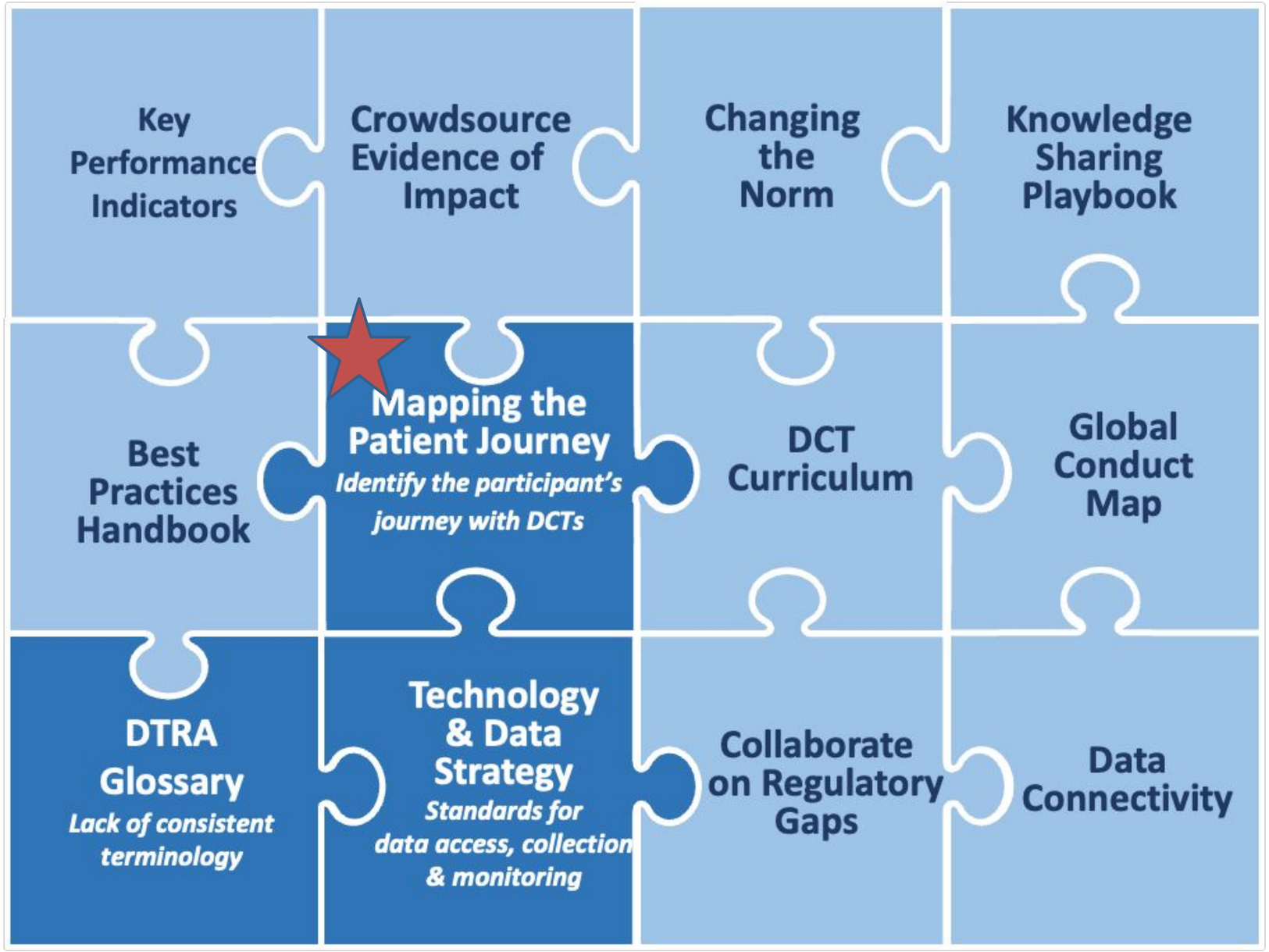
SETTING FOUNDATIONAL DCT STANDARDS



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DTRA Initiative 2B Patient Journey Overview

April 27, 2023

Presenting: Richie Kahn, Canary Advisors (Co-Lead)

Deena Bernstein, Datacubed (PM)

Alicia Staley, Medidata (Co-Lead)

DTRA Initiative 2B Patient Journeys Maps

Background

- **2B's intended audience, or the user of this journey map** is any clinical development leader at CROs, pharmaceutical and device companies, as well as technology and other vendors.

- **The user's "job-to-be-done":** The user is all clinical research stakeholders. The Journey Maps are intended to the used in the early stages of designing a clinical trial. We looked for best practices to incorporate elements of patient-focused, decentralized clinical trials into their trial. Armed with this information, stakeholders can evangelize decentralization to the rest of their org.

- **Our goal:** Our goal is to promote the widespread adoption of decentralized trials, in a way that is thoughtful and patient-centric. Guides stakeholders to use decentralized trials when it makes the most sense for optimizing a clinical trial experience for patients.

A successful patient journey map will help our users:

- Understand the patient experience, potential pain points / pitfalls, and ultimately lead to a more patient-friendly trial design.
- Provide optionality for patients when and where in their journey it makes sense.
- Educate others within an org and promote the adoption of decentralized options to their teams.

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DTRA Initiative 2B Patient Journeys Maps

Overview

If there's one silver lining to the pandemic as it relates to clinical research, it's that we've learned the traditional way of running studies and recruiting patients isn't the ideal way or necessarily the only way. While patients have generally been satisfied with DCTs, what they really want is optionality along the patient journey.

By better incorporating the patient perspective along the way, we can reduce unnecessary barriers and burdens and increase the likelihood that studies are completed on time and according to budget.

Recognizing that no two patient journeys are the same, this is intended to read teach the industry about the journeys of clinical trial participants in a vaccine, oncology, and rare disease trial.

Methodology

The journeys depicted here are a result of conversations with multiple patients representative of the disease states being depicted as well as lessons learned from industry leaders in decentralized bringing their experience and expertise to the exercise.

These visualizations will make it easier to understand and contextualize the decentralized patient journey across multiple phases of research and indications of interest.

DTRA Initiative 2B Patient Journeys Maps

Overview

Oncology, Rare Disease, and Vaccine Studies

These therapeutic areas were chosen because oncology is the largest chunk of the R&D pipeline; rare disease is a rapidly expanding area of development; and vaccine studies are more front and center than ever as a result of COVID-19.

While DCT isn't right for every trial, by thoughtfully incorporating elements as appropriate we have the power to democratize research and brin clinical trials to large swaths of the population that wouldn't otherwise have access.

DTRA Initiative 2B Patient Journeys Maps

Overview

Journey stage	How is the patient feeling?	What are the patient's pain points?	What DCT components might help?
-----	-----	-----	-----
Pre-trial / pre-screening Patients learn about their new diagnosis through their care team, usually after a precipitating event. Patients learn about the study through their care team (%), social media (%), advocacy groups (%), and other patients (%).	**Patients ask whether the trial makes sense for them** Will this trial help me? (%) What are the potential risks or downsides? (%) How might participation affect my family, my work? (%) How will this research help future patients? (%)	**Barriers prevent many patients from accessing trials.** Awareness is the #1 issue, as most oncologists are not aware of all trials. Additional barriers include long travel distances (%), frequent visits (%), etc...	**This trial is hybrid.** Patients must attend a mix of televisits and in-person visits. Sponsors and sites must provide and support eConsent, eCOA, ePRO, smart pill technologies, and patient portals.

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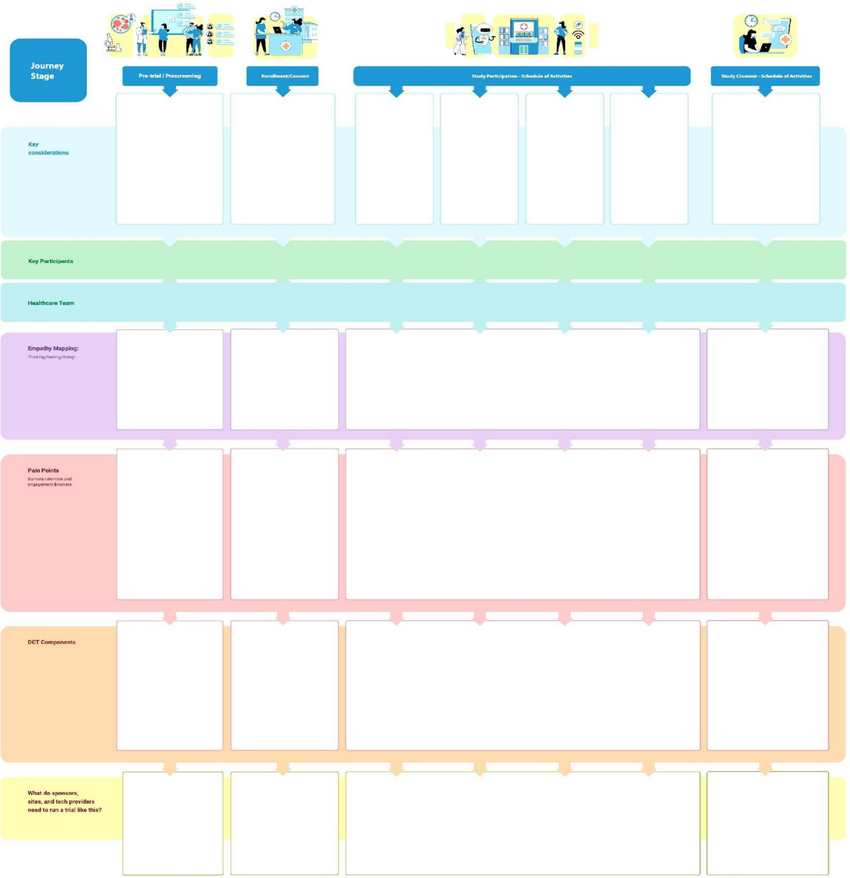
DTRA Initiative 2B Patient Journeys Maps

Overview

How to use the Journey Maps:

- **Maps hosted DTRA website**
  - Oncology
  - Rare Disease
  - Vaccine
  - Empty Template
  - https://dtraresources.org/
- **Use at early study design** stage (before a protocol is written)
- **Evaluate where DCT's make the most sense**
  - Do not overburden Site and Patient
- **Build out your DCT strategy using map and align with protocol designing**



DTRA Initiative 2B Patient Journeys Maps

Overview

Each journey map outlines:

Key considerations from interviews with the patient
and/or
What characteristics do these patients have that may affect their ability to participate in a DCT?

Travel, transportation, travel to site, technology use, access to tech and internet

Example from Oncology

- Needs flexibility
- Needs to be able to continue working
- Will need to take time off for treatment
- Concerns about insurance
- Concerns about down time (how long will meds affect ability to work)

Example from Rare Disease

- Often experience vision loss
- Many unable to drive
- Used to working with a KOL (Dr they know)
- Patient works full time
- Tech savvy but CT naive

RSV Vaccine

- Seasonal and Multi Country
- Age
- Fear of Technology (Not Savvy)
- Lack of understanding (RSV, Vaccine)
- Concerns about risk and long-term safety
- Scheduling
- Transportation

DTRA Initiative 2B Patient Journeys Maps

Overview

During each journey stage, Key Considerations were highlighted including which DCT method could be used.

DCT Tech/methods:	Oncology	Rare Disease	Vaccine
- eDiary (ePRO)	✓	✓	✓
- eConsent portal			✓
- Participant engagement app		✓	✓
- Wearable (Smartwatch)	✓	✓	
- Telehealth Visit	✓	✓	✓
- Home Health Nurse visit	✓		
- Smart Pill Bottle	✓		
- Study related Technology portal		✓	✓
- Additional diary (eCOA)	✓	✓	✓
- Give back Data	✓	✓	✓
- Thank you for Participating	✓	✓	✓

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DTRA Initiative 2B Patient Journeys Maps

Overview

Each of the journey maps take you through the same *Journey stages* and highlights which DCT Tech/method can be used:

- Pre-Trial/Prescreening
- Enrollment/Consent
- Study Participation – Schedule of Activities
- Study Closeout – Schedule of Activities

DTRA Initiative 2B Patient Journeys Maps

Overview

Each of the journey maps highlight the following during each Journey stage:

- **Key Considerations**
- **Key Participants**
- **Healthcare team**
- **Empathy Mapping** (thinking/feeling/doing)
- **Pain Points** (barriers to retention and engagement blockers
- **DCT Components**
- **What do sponsors, sites, and tech providers need to run a trial like this?**

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DTRA Initiative 2B Patient Journeys Maps

Overview

What do sponsors, sites, and tech providers need to run a trial like this?

	Pre-Trial/Prescreening	Enrollment/Consent	Study Participation	Study Closeout
Oncology	• Access to software to support eConsent, eCOA, ePRO, smart pill tech, patient portals	• Site needs software for eConsent	• Site needs ability to connect to patient via Telehealth • Site and patients need access to patient portal, telehealth tools, and smart pill solutions	• Patient needs long term access to trial information. • Site needs to support patients long term access
Rare Disease	• Buy in from internal teams and support with change management strategies • Education on how DCTs add value and keep the role of the site as important as it is now • Access to fit-for-purpose technology – hardware and software	• Provide and explain the options to participants they know what is best for them. • Sites might need hardware (eg iPad) to support the use of software tools such as eConsent		
Vaccines	• Access to participant recruitment and referral portal/apps • Collateral: participant brochures in waiting rooms etc for the population to explain the trial	• Access to software to support eConsent • Training options on-demand for site staff	• Access to tech for collecting data electronically (eCOA, ePRO, eDiary, portal) • Sites need ability to connect with participant via telehealth and ability to engage via app • Site need home healthcare nurses (own staff or offered by study sponsor) • Sites need training options on-demand, tech specialists for problem solving, transparency on privacy and security concerns (tech safeguards for hacking networks) • Sponsors need transparency on regulatory landscape	

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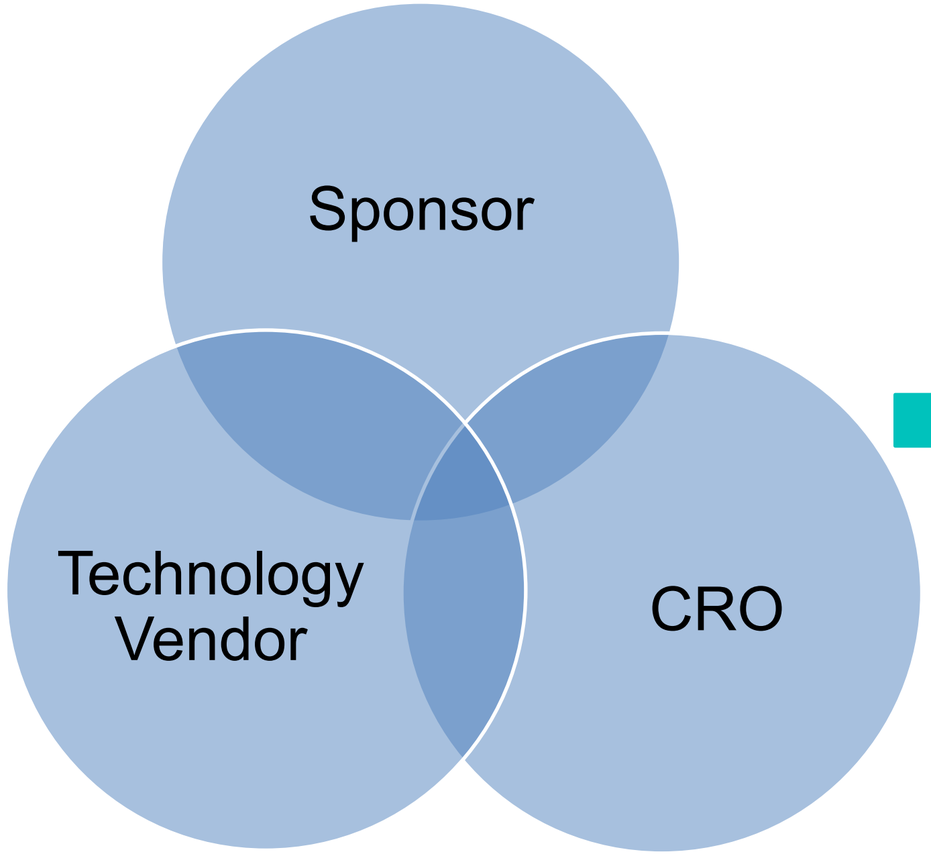
DTRA Initiative 2B Patient Journeys Maps

Overview



Designed to be use and shared as tool by all stakeholders considering DCT's:

Use Journey mapping early in study design

Build out the Journey using REAL patient feedback

Be Mindful of optionality

Think about study logistics

Don't overburden Sites or Patients with too many DCT's

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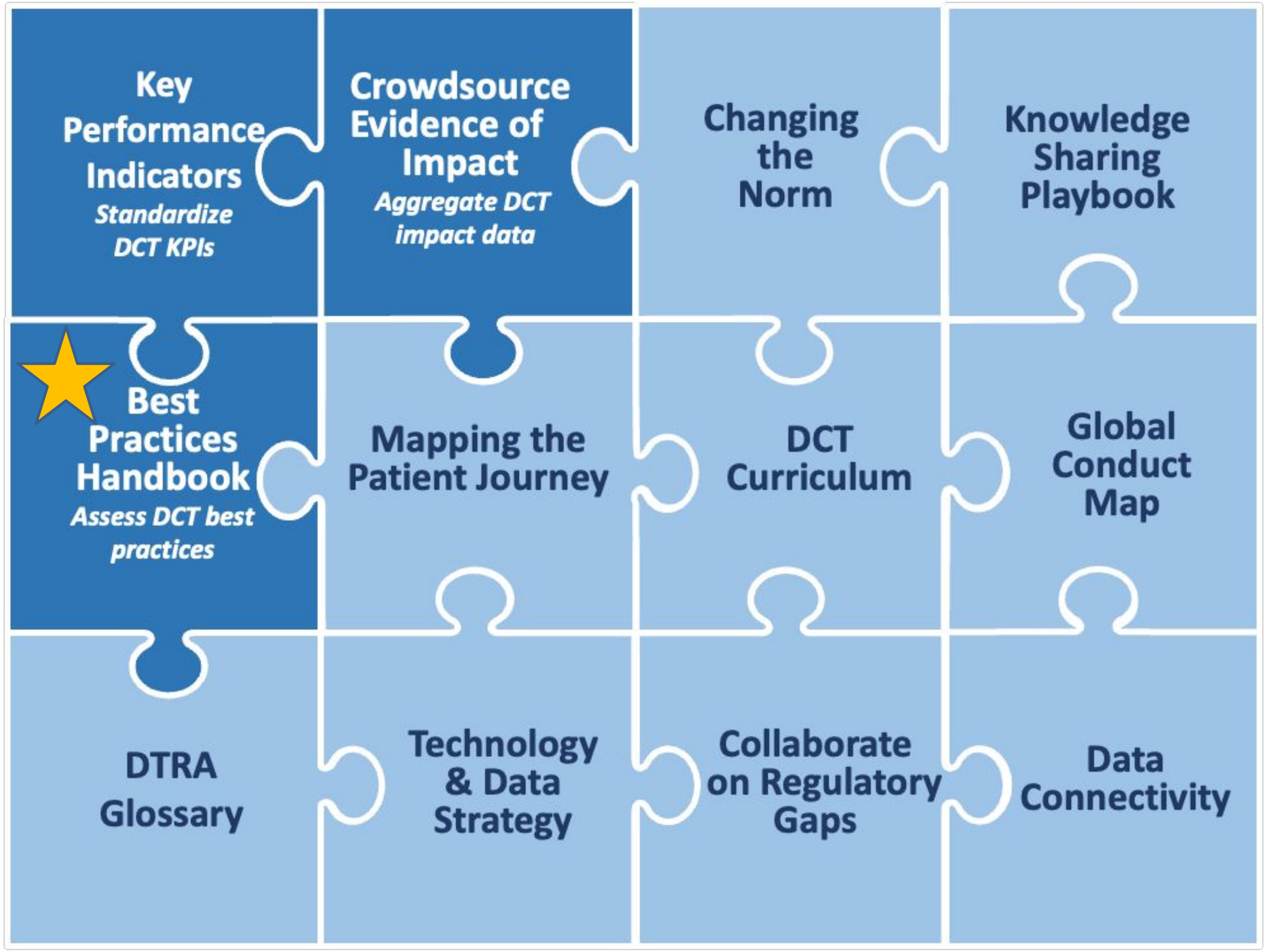
DTRA Initiative 2B Patient Journeys Maps

Questions?

MEASURING SUCCESS WITH DCTs



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DTRA Initiative 2A Best Practices Closeout

March 2023

Presenting: Mike DeMarco, PwC (Co Lead)

Arry Balachandran, Capgemini (PM)

Dan DeBonis, formally Signant Health (CoLead)

DTRA Initiatives

Initiative Deliverable Closeout Document

- **Section 1:** Overview on Initiative
- **Section 2:** Overall approach taken to reach deliverable (ie surveys, key inputs, etc.
- **Section 3:** Summary of Deliverable
- **Section 4:** Call to action and/or DTRA next steps

DTRA Initiative 2A Best Practices

Overview

Problem:

Stakeholders are unaware of how and where to share & find best practices to address conduct of decentralized research

Mission:

To provide stakeholders with a defined path to classify best practices, and a single point of access for knowledge sharing and distribution

Deliverable:

The 2a project stream have aligned on our scope and a clarification of our deliverables. They may now be summarized as:

- ❑ **Best Practices Evaluation Rubric** - criteria by which DTRA will evaluate DCT practices to determine if they are suitable for publication as a 'best practice'
- ❑ **Best Practices Evaluation Guidance Document** - supporting context / information to assist best practice evaluators throughout the review process to drive consistent engagement and quality reviews
- ❑ **Best Practices Evaluation Process** - consistent evaluation process in which DCT practices are submitted, peer-reviewed, and approved for publication as a 'best practice'

Actions Taken:

- ✔ A number of workstream discussion sessions to shape and create an initial strawman view of the Rubric principles
- ✔ Allocation of those dimensions for sub-workstreams to discuss, detail and form clarity around what was important to consider
- ✔ As the material was developed a small group to bring the structure and style together to ensure that this was a usable and easily communicated set of principles, with some 1-2-1 interviews with SMEs across each dimension following offline feedback to refine and complete
- ✔ Wider group (DTRA) review, feedback and refinement until we had our first version of the Rubric.
- ✔ Once the Rubric was completed, we undertook a similar approach to determining a process for Rubric evaluation. This has gone as far as an initial draft of the suggested process.

DTRA DECENTRALIZED TRIALS & RESEARCH ALLIANCE

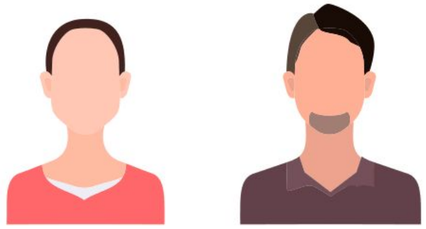
Recognition of team members

Team Member Name	Initiative Role	Company
Arry Balachandran	PM	Capgemini Invent
Mike DeMarco	Co-Lead	PWC
Dan DeBonis	Co-Lead	Signant Health
Eric Kaurs		Advanced Clinical
Theo Emmanuel-Mari		Amgen
Meadhbh Kerr		Bionical Emas
Keli Platco		ClinOne
Jenna McDonnell		PPD
Juan Pablo de Olaguibel		Roche
Priyanka Sawant		TCS
Craig Nash		UBC
Lewis Millen		UCB Biosciences
Alex Burrington		Vertex
Linda King		Astellas
Danielle Horton		Astellas
Cindie Kazmer		IQVIA
Amber Bickford		Agios
Lauren Tochacek		UCB
Mileysa Ponce Rios		Pfizer
Les Yates		Thread
Andrew Nguyen		Thread

DTRA Initiative 2A Rubric Creation

Overall Approach

Step 1: Consider the Users



A number of group workstream workshops to understand:

- Who would be seeking best practice
- What would they look for
- What guidance would they need

A consideration of the role of DTRA

- How would we identify best practice
- What criteria would we consider

Step 2: Sub Team Analysis

- ❑ Created a process and vision for the rubric and our approach
- ❑ Created sub teams across some initial dimensions that we felt were key areas to explore
- ❑ Kick off and sub team set up individual workshops and discussions
- ❑ We considered and researched existing guidance from other Industry organisations

ACRO CELEBRATING 20 YEARS

CLINICAL TRIALS TRANSFORMATION INITIATIVE

FDA

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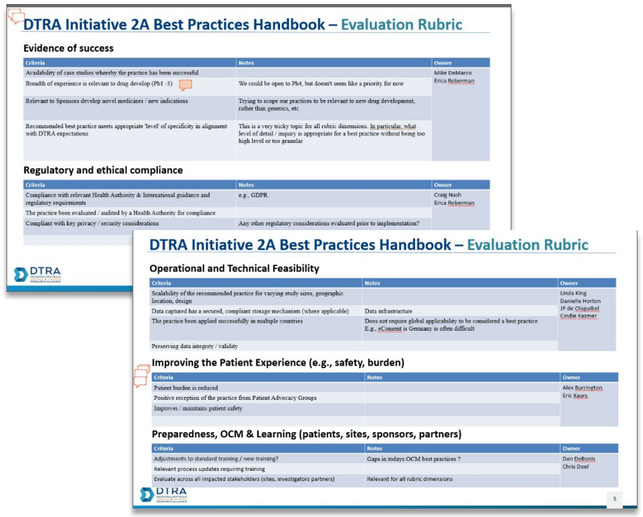
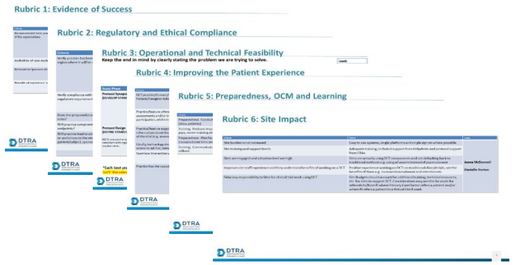
DTRA Initiative 2A Rubric Creation

Step 3: Draft and review

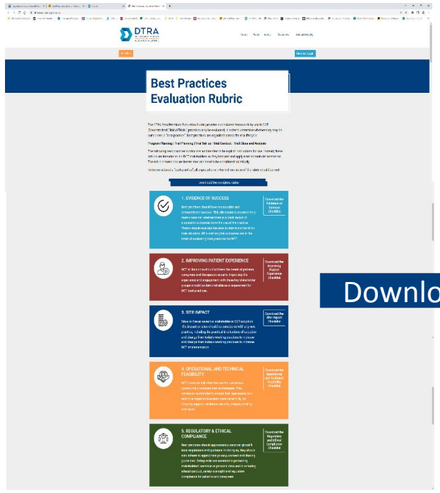


- ❑ Drafted within workstreams and reviewed with the group in weekly sessions
- ❑ Also issued to the wider group for comment and input

Step 4: Create, Refine and Publish



- ❑ Final draft reviewed by DTRA
- ❑ Branded and downloadable content created
- ❑ Website Publish and download available



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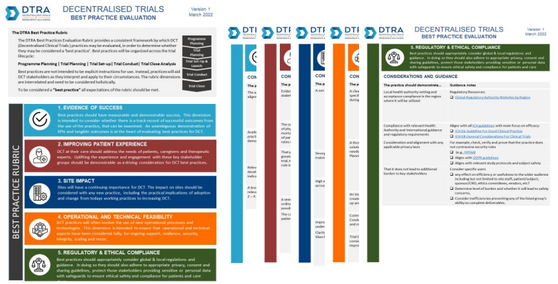

DTRA Initiative 2A Rubric

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DECENTRALISED TRIALS
BEST PRACTICE EVALUATION

Version 1
March 2022

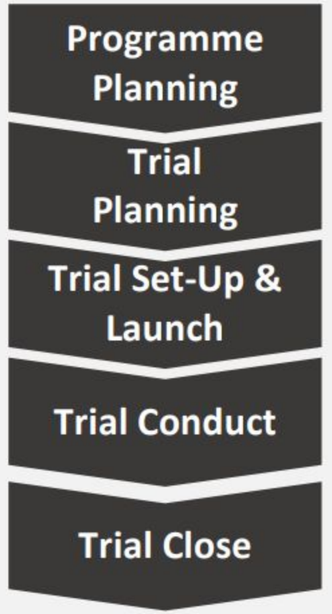
The DTRA Best Practice Rubric

The DTRA Best Practices Evaluation Rubric provides a consistent framework by which DCT (Decentralised Clinical Trials) practices may be evaluated, in order to determine whether they may be considered a 'best practice'. Best practices will be organized across the trial lifecycle:

Programme Planning | Trial Planning | Trial Set-up| Trial Conduct| Trial Close Analysis

Best practices are not intended to be explicit instructions for use. Instead, practices will aid DCT stakeholders as they interpret and apply to their circumstances. The rubric dimensions are interrelated and need to be considered holistically.

To be considered a **"best practice"** all expectations of the rubric should be met.



DTRA Initiative 2A Rubric

Best practices will aid DCT stakeholders as they interpret and apply their circumstances

The Rubric dimensions are interrelated and need to be considered holistically

To be considered a “best practice” all expectations of the rubric should be met

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DTRA Initiative 2A Rubric

Dimension 1: Evidence of Success

Is there a track record of successful outcomes from the use of the practice

How was success Measured?
Qualitative and or quantitative

Relevance to new drug development

Applicable across all study phases

1. EVIDENCE OF SUCCESS

Best practices should have measurable and demonstrable success. This dimension is intended to consider whether there is a track record of successful outcomes from the use of the practice, that can be examined. An unambiguous demonstration of KPIs and tangible outcomes is at the heart of evaluating best practices for DCT.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
The appropriate 'level' of detail in alignment with DTRA expectations	Reference DTRA Best Practices evaluation form. A template 'best practice' has been documented, including the: ❑ Best practice in the form of a checklist questionnaire ❑ Additional context regarding the best practice (e.g. why should it be considered a best practice, what is the value to Sponsor / site / patients) ❑ Relevant case study in which the proposed best practice was used
Availability of case studies whereby the practice has been successfully demonstrated	How was success measured? ❑ Consider both qualitative and / or quantitative values that were captured from successful implementation of the proposed practice ❑ Consider size, relevance and future reuse of the selected case studies
Relevance to sponsors who are developing new treatments, digital therapeutics and devices	❑ Consider whether the scope of practices will be relevant to new drug development, rather than generics, etc.. ❑ Future recommendations may expand to include best practices for other organizations (e.g. sites, patients).
A breadth of applicability that is relevant to drug development across all study phases	❑ If proposed practices are overly specific to an individual phase, the relevance to the DTRA community will be diminished.

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DTRA Initiative 2A Rubric

Dimension 2:
Improving the Patient Experience

Address the needs of the patients, caregivers, and therapeutic experts

Opportunity to reduce the burden of participation

Positive feedback from stakeholders

Patients have greater access to information

Seamless interaction with ordinary care

Increase the diversity of patients recruited

2. IMPROVING PATIENT EXPERIENCE

DCT at their core should address the needs of patients, caregivers and therapeutic experts. Uplifting the experience and engagement with these key stakeholder groups should be demonstrable as a driving consideration for DCT best practices.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
The opportunity to reduce the number of physical assessments and/or physical site visits and reduce the burden of participation, whilst maintaining high rates of trial activity adherence	❑ Reduction of physical visits to the hospital can be a key driver here, but it should be kept in mind that some patients will prefer the hyper-care of a physical trial setting. ❑ Patient optionality is key to truly minimizing the burden of participation.
Evidence of positive feedback from key stakeholders.	❑ DCT practices are evaluated and receive positive approval from stakeholders including Patient/Caregiver Advocacy/Therapeutic experts. ❑ Teams should recognize that some patients may not consider a DCT an optimal trial experience (e.g. patients for whom the hyper-care of a clinical trial is desirable). ❑ Patient experience feedback and data should be collected early and often throughout the trial
That patients are empowered with greater access to information about the trial, the schedule of events and their role in the conduct of the trial	❑ Supporting patients not only improves their experience, it enhances their ability to drive the desired study data collection and compliance thus meeting the primary goals of the study. ❑ Technology should employ design principles to allow data collection (e.g. push notifications and reminders). ❑ Explain how technology has been leveraged to ensure patients will have greater access to ad-hoc, remote engagements with the site team
A seamless interaction with patient's ordinary care routine, wherever possible	❑ Features are implemented in such a way that data collection is integrated within patient's daily routine (e.g. application reminders, triggers, etc.).
The capacity to increase the diversity of patients recruited	❑ Diversity of patient populations (including age, gender, ethnicity, race) is a prime potential benefit of DCTs. Steps should be taken to ensure trial design and recruitment strategy provides enhanced opportunities for diverse patient participation. ❑ **IMPORTANT:** Decentralization can also introduce a new type of bias, towards adherent/motivated/technologically literate patients. Steps should be taken to avoid this bias wherever possible

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DTRA Initiative 2A Rubric

Dimension 3:
Site Impact

Impact of sites considered with any new practice

Net reduction in burden for site and patients

Site compliance with minimal training and support

High engagement & adoption levels across sites

Improved site staff experience

Site budget and payment considerations

3. SITE IMPACT

Sites will have a continuing importance for DCT. The impact on sites should be considered with any new practice, including the practical implications of adoption and change from today's working practices to increasing DCT.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
A net reduction in burden for both patients and sites	❑ Burden may increase in some areas and decrease in others. Capture the details of this change. ❑ Easy to use systems, single platforms and access across systems where possible. ❑ Reduce data entry redundances while supporting a single point of source documentation. ❑ Reduce CRO Site Management time, CRA time on site, time to issue resolution. ❑ increase risk-based monitoring without sacrificing patient safety or data integrity. ❑ Trigger corrective action to data queries, non-compliance, and issue identification early and resolve/re-train site quickly. ❑ Reduced sponsor contacts across studies and disciplines.
Strong site compliance with minimal training and support	❑ Technology should be simple to use, intuitive and require minimal training ❑ If training is necessary, then it should be available "on-demand" through the life of the study ❑ Technical support from Helpdesks and protocol support from CRAs in local language
High engagement and adoption levels across sites.	❑ Sites are not defaulting back to traditional methods ❑ Measure and demonstrate improved uptake of new processes with visibility of the patient flow ❑ Operational performance by Sites includes, but is not limited to, compliance with protocol, regulations, patient safety, data quality and data integrity ❑ Demonstrate the benefits of improved engagement (e.g. recruitment and retention) including site engagement and feedback around operational and feasibility
Improved site staff experience and understanding of the benefits	❑ Positive experience working on DCTs vs traditional clinical trials, demonstrated through feedback from stakeholders.
Clarity of the fiduciary responsibility to Sites for clinical trial work using DCT	❑ Site Budgets should account for additional resources required for sites to support DCT. ❑ Considerations may need to be made for referrals to/from PI where Primary Care Doctor refers a patient and/or where PI refers a patient to a virtual site if used. ❑ Payment considerations for example with regard to increase remote SIV, site management call or remote

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DTRA Initiative 2A Rubric

Dimension 4: Operational and Technical Feasibility

Ensure that operational and technical aspects have been considered fully

Clear problem statement

Defined strategy

Implementation plan

Controlled delivery with tracking and KPIs

Trial close requirements for improvement

4. OPERATIONAL AND TECHNICAL FEASIBILITY

DCT practices will often involve the use of new operational processes and technologies. This dimension is intended to ensure that operational and technical aspects have been considered fully, for ongoing support, resilience, security, integrity, scaling and reuse.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
A clear problem statement, addressing specific challenges or needs, developed during Programme Planning.	❑ Is the problem clearly defined? E.g. ○ Reduce Patient/Caregiver burden ○ Increase/Ensure Patient Safety ○ Increase Patient Retention/Reduce Drop-Out ○ Improve Data Quality/Integrity ○ Reduce/Eliminate manual entry/human error ❑ Identify all stakeholders who can help solve the problem (e.g., Vendor collaboration is key to risk/benefit analysis with coordination of all DCT capabilities/services)?
A thoroughly defined strategy, including solutions to specific challenges or needs, has been developed during Trial Planning.	❑ Include only what is required, and: ○ Mitigate risks of both operational and technical challenges when considering multiple solutions ○ Align with data privacy guidance and data security at the local country and site level (see dimension 5) ○ Ensure blinding/unblinding requirements will not be impacted by the solution(s) ❑ Keep the end in mind and takes a holistic approach to DCT solutions ❑ Ensure the solution is fit for use for the patient population and does not require patients to have their own devices and hardware in order to participate?
An implementation plan has been created and followed through Trial Set-up and Launch	❑ Document the Study Build Plan and Launch Plan ❑ Collaboratively modify the plans as needed ❑ Ensure all stakeholders are aligned with the plan
Controlled delivery throughout Trial Conduct phase with suitable tracking and measures	❑ Document Roles/Responsibilities. ❑ Document how to measure performance and/or compliance (Patient, Site, Vendor). ❑ Track issues and trends, improvements
Trial Close requirements have been considered to allow for continual improvement.	❑ Analyse operational data to assess evidence of impact and define future improvements. ❑ Analyse site and patient survey data to understand experience and ID future improvements. ❑ Site survey / feedback process is built into the trial deployment plan, including questions on implementation / integration with other systems, ease of use, time to train,

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DTRA Initiative 2A Rubric

Dimension 5:
Regulatory & Ethical Compliance

Consider global and local regulations and guidance

Local health authority vetting and acceptance

Compliance with relevant health authority

Consideration with privacy laws

No additional burden

5. REGULATORY & ETHICAL COMPLIANCE

Best practices should appropriately consider global & local regulations and guidance. In doing so they should also adhere to appropriate privacy, consent and sharing guidelines, protect those stakeholders providing sensitive or personal data with safeguards to ensure ethical safety and compliance for patients and care givers.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
Local health authority vetting and acceptance compliance in the region where it will be utilized	Regulatory Resources: ❑ Global Regulatory Authority Websites by Region
Compliance with relevant Health Authority and International guidance and regulatory requirements	Aligns with all ICH guidelines with main focus on efficacy: ❑ ICH E6-Guideline For Good Clinical Practice ❑ ICH E8-General Considerations For Clinical Trials
Consideration and alignment with any applicable privacy laws	For example, check, verify and prove that the practice does not contravene security rules ❑ (e.g., HIPAA) ❑ Aligns with GDPR guidelines ❑ Aligns with relevant study protocols and subject safety
That it does not lead to additional burden to key stakeholders	Consider specific users ❑ any effect on efficiency or usefulness to the wider audience including but not limited to site staff, patient/subject, sponsor/CRO, ethics committees, vendors, etc.? ❑ Determine level of burden and whether it will lead to safety concerns, ❑ Consider inefficiencies preventing any of the listed group's ability to complete deliverables.

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DTRA Initiative 2A Best Practices

2 aspects of our work are partially progressed

1. We agreed that there needs to be a ongoing process to allow the rubric to be defined in an ongoing way through feedback and learnings.
   This will be part of the Content Council.

2. Best Practice Process needs to be developed to allow for best practice to be Identified, evaluated against our rubric and added to a library of content and guidance
   This process has been drafted

3. Best Practices need to be identified and taken through the process and begin populating the repository within DTRA.
   This identification has only partially begun

Recommendations

The 2 a team began to face a little uncertainty around the next steps and actions. Since completing the rubric we now have 3 recommended actions to proceed.

The Rubric
Should exist on the DTRA site and be reviewed quarterly against feedback, emerging thoughts and refined as necessary. It should be owned and maintained by a DTRA team.

Process and best practice identification
Before progressing with this process, some questions that we feel we need to examine before this can progress:

1. Who are the users / stakeholders who will nominate, assess and approve, search and utilise best practices ?
2. Is there an intention to store best practices within a DTRA library or repository? How does this repository evolve (new or changed practices)

Based on the above – what is the right process and who operates it for:

- Submission/ identification
- approval and publish
- refine and update
- search and utilise

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DTRA Initiative 2A Best Practices

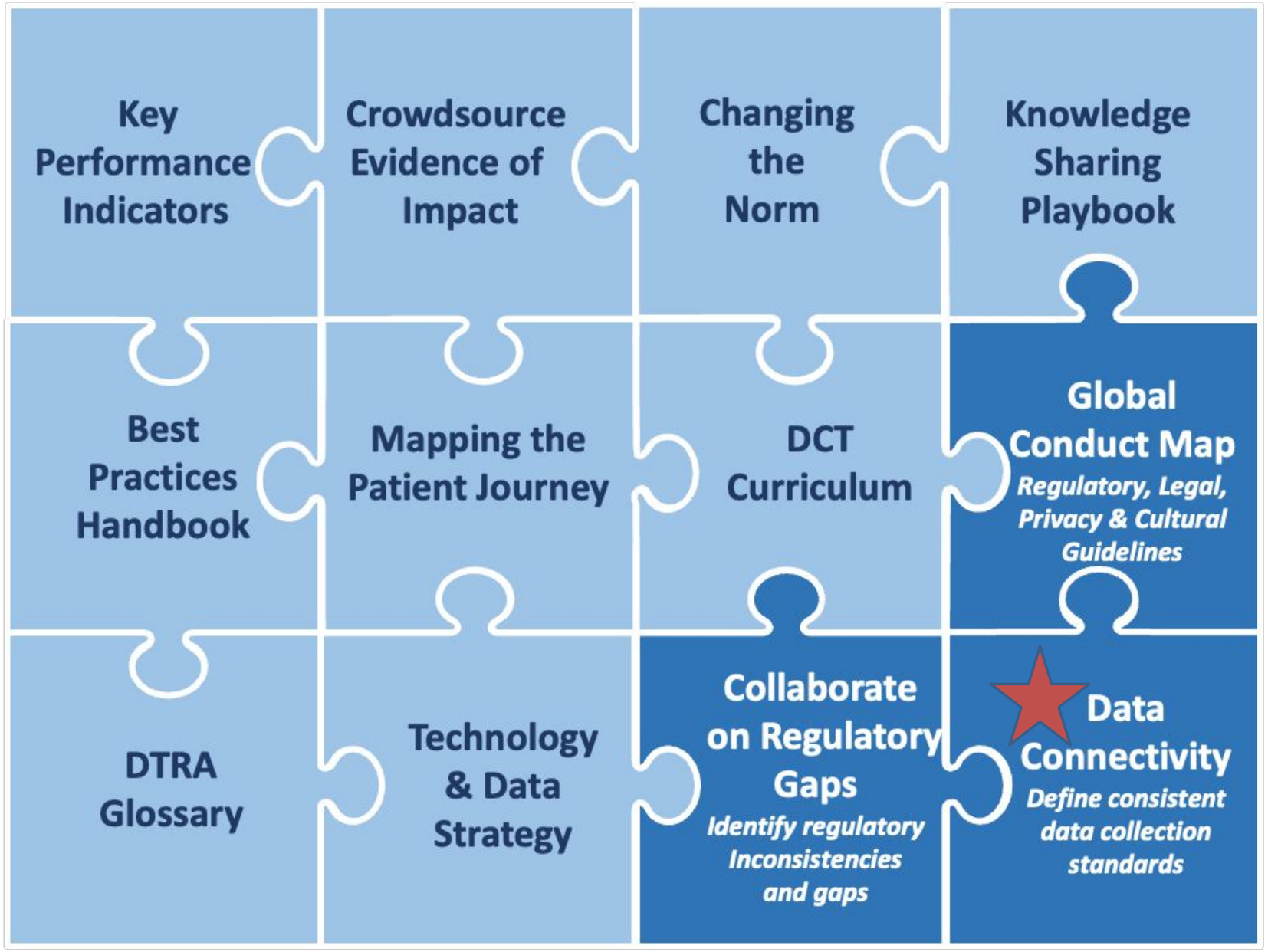
Appendix / Supporting documents

https://dtraresources.org/rubrics/

DTRA Initiative 2A Best Practices

Questions?

REMOVING BARRIERS TO ADOPTION



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4C Data Connectivity:

Presenting: Munther Baara, Edetek (CoLead)

Moulik Shah, Advanced Clinical (CoLead & PM)

DTRA Initiative 4C 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

Value:

- 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 a DCT)
- Near-real time access to data
- Faster decision making
- Decrease the variety of touchpoints and entry-points by streamlining and automating technology ecosystems

Team Members:

- ✔ Co-Lead: Munther Baara, EDETEK
- ✔ Co-Lead: Moulik Shah, Advanced Clinical
- ✔ PM: Claudine Paccio, DTRA
- ✔ Sneha Sundet, Agios
- ✔ Thomas Healy, PPD
- ✔ Jordan Simpson, Merative
- ✔ Venu Mallarapu, eClinical
- ✔ Rick Greenfield, Realtime CTMS
- ✔ Kishori Khokarale, ZS
- ✔ Tianna Umann, Microsoft

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Proposed workstreams

Workstream deliverables

Workstream A

End to End Processes and Dataflow

- 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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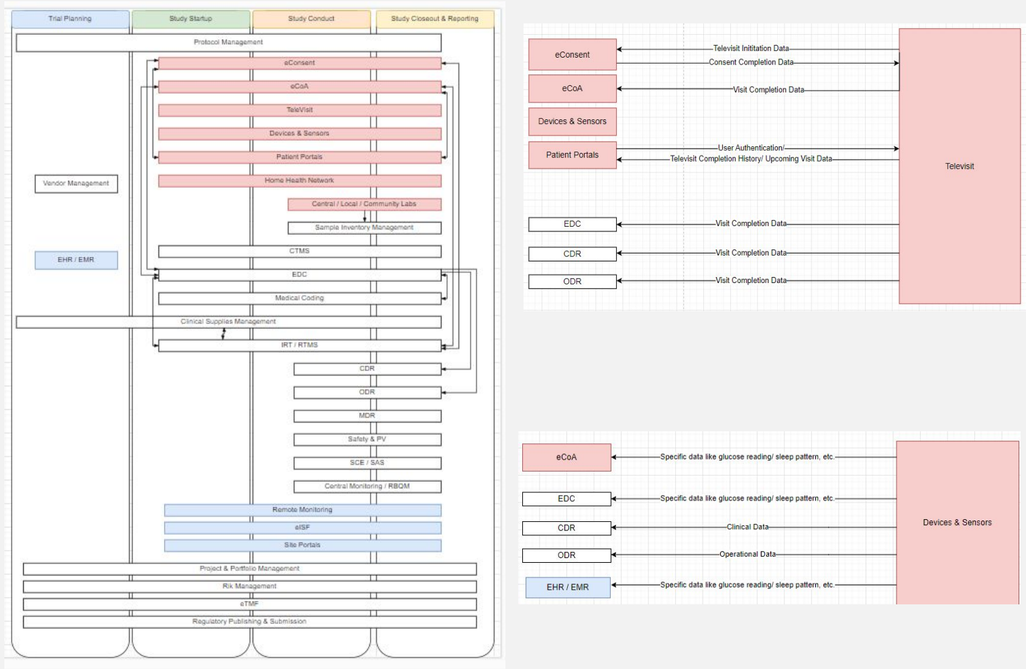
Information Dataflow and Data Exchange Framework

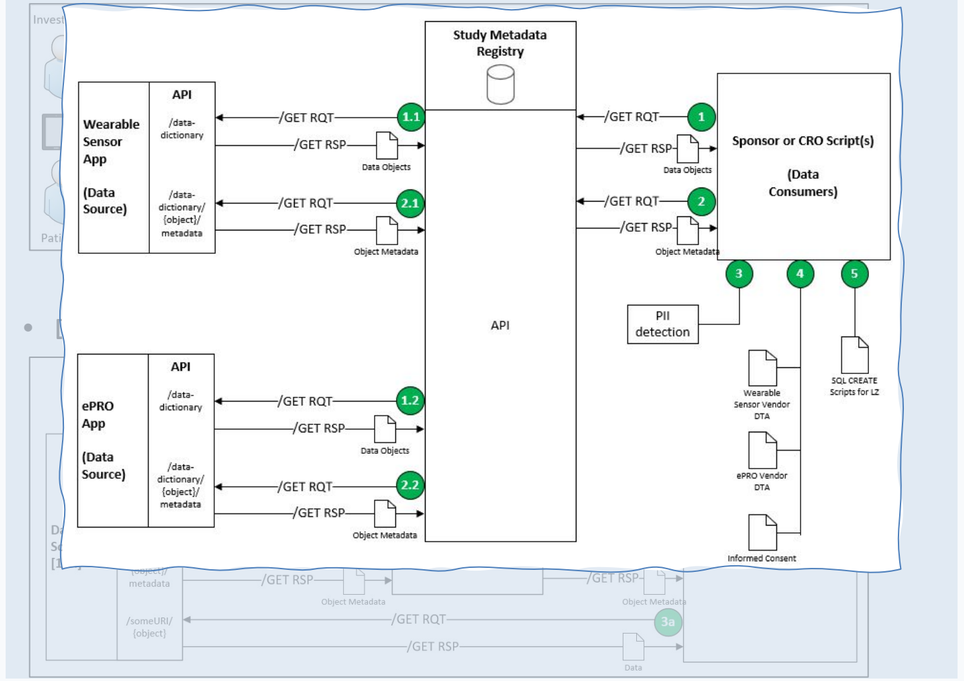
Information Dataflow

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



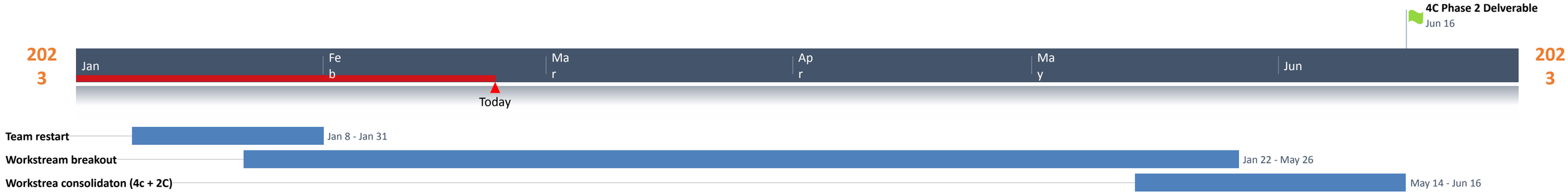
Data Exchange Framework

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



Overall Status

4C Status and Timeline



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 focused on clinical patient data**
- Member/participant count for the over all workstream is small

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Co Labs - Update and Up Next

Jane Myles

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

Co Lab Progress

1572 Needs

- Kicked off on April 4!

SCOPE:

Recommendations on when/how to best include DCT-specific roles and needs

- eg local labs, local imaging, local HCPs, using 1572 and or other forms.
- Questions to raise to FDA with proposed solutions

Alternative Site Models

- Kickoff scheduled for April 27

SCOPE:

Recommendations on using alternative site models, such as pop up sites, in-pharmacy sites, mobile sites, research metasites

- site selection
- qualification
- training
- oversight

Co Labs - Up Next

Defining Site Needs: Research Project

Aim to kick off by mid May

SCOPE:

Design and sponsor a survey to gather information around what sites need to help drive adoption and use of DCT Methods

- DO NOT repeat prior surveys. Aim for more specificity on friction / barriers
- Target respondents are site staff. May need a partner org (e.g. SCRS or ACRP)

NEXT STEPS: Define Co Leads & open opportunity to join to membership

- **NOTE:** This Co Lab will likely lead to future Initiative work or Co Labs to define solutions

Circles Update

Jane Myles

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

Circles: Status Update

- Diversity Circle kicked off 10 Apr
  - 41 members signed up
  - EU, NA and SA participation. Discussion lead by Angela Radcliffe (BMS)
  - Slack channel is getting some traction
- Data management Circle kicked off 18 Apr
  - 25 members signed up
  - NA and EU participation. Discussion led by Michael Underhill (Astellas)
  - Aiming to drive slack channel engagement
- Patient Recruitment Circle kicking off Apr 28
  - 44 members signed up
  - 26 members accepted mtg invitation. Discussion to be led by Kelly McKee (Medidata)
  - Aiming to drive slack channel engagement

COMING NEXT!

- **Join a *Circle*!**
- **Come to the *Clubhouse***
- **Next meeting, Thursday May 25th**

Thank You!

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