DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

DTRA Initiatives Monthly Meeting

February 23, 2023

DTRA INITIATIVES AGENDA

- Welcome & Agenda - Claudine
- DTRA Initiatives Core Strategy - Claudine & Jane
- Update from team 2C Data & Technology Strategy – Toni
- Update from team 4C Data Connectivity – Munther/Moulik
- DTRA SCOPE presentation– Jane, Caroline (3A), Jonathan (4B)
- Upcoming Q1 DTRA agenda
  - Conferences
  - Clubhouse events

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DTRA - INITIATIVE OVERVIEW

Priorities

DTRA's member stakeholders have identified 4 Priorities to define the work of the Alliance to support our mission to accelerate the adoption of patient-focused, decentralized clinical trials and research.

1. **Definitions**
   Establish common nomenclature and definitions, archetypes, and KPIs around the practice of decentralized research.

2. **Best Practices**
   Identify and promote best practices in decentralized research.

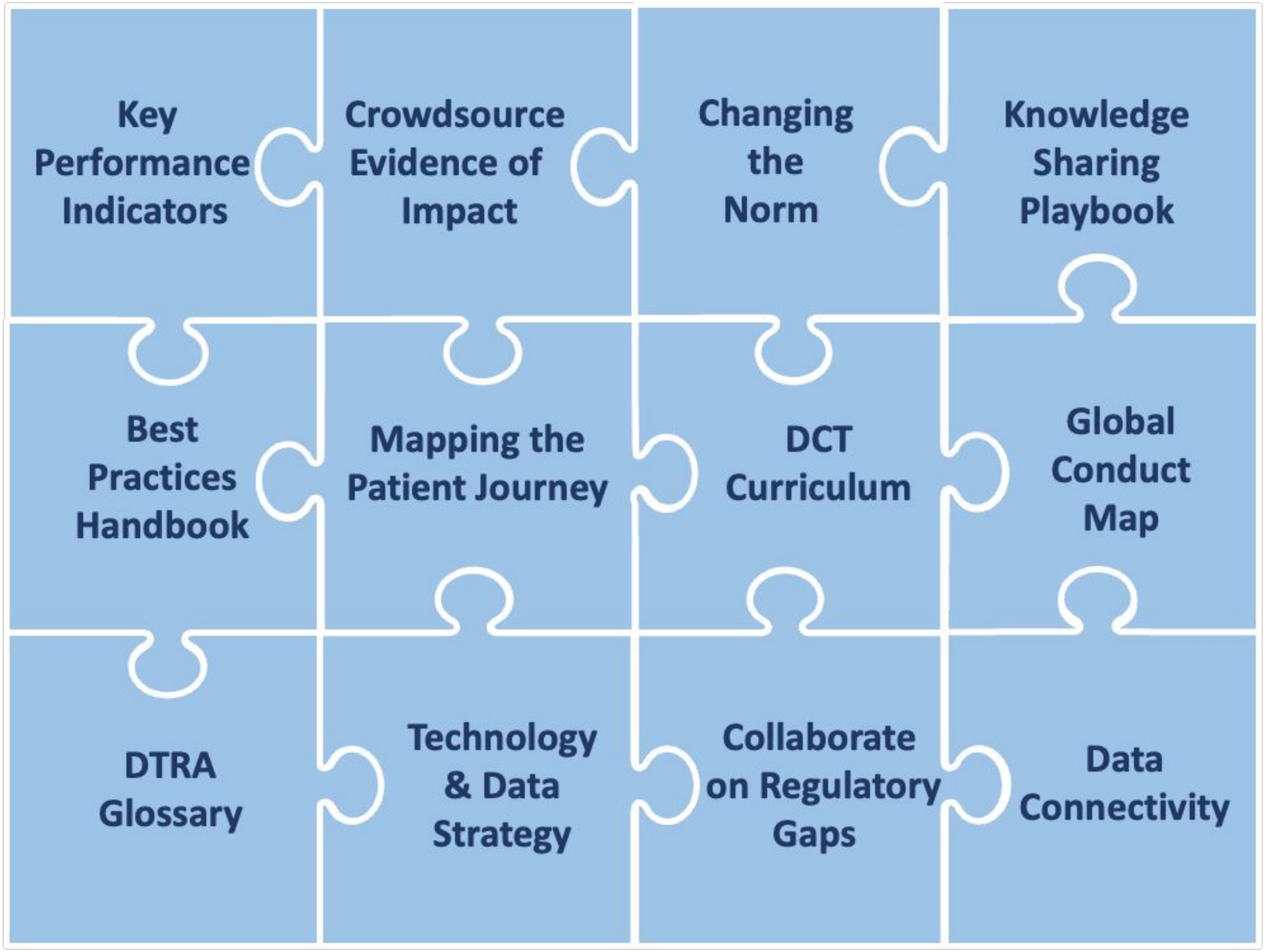
3. **Education**
   Build knowledge repository and mechanisms for information sharing.

4. **Removing Barriers**
   Identify barriers to decentralized research implementation and establish roadmaps to their resolution.

DTRA - INITIATIVE OVERVIEW – Phase 1 2022

All 12 Initiatives are interconnected and interdependent

Together they create a framework to support DCT adoption



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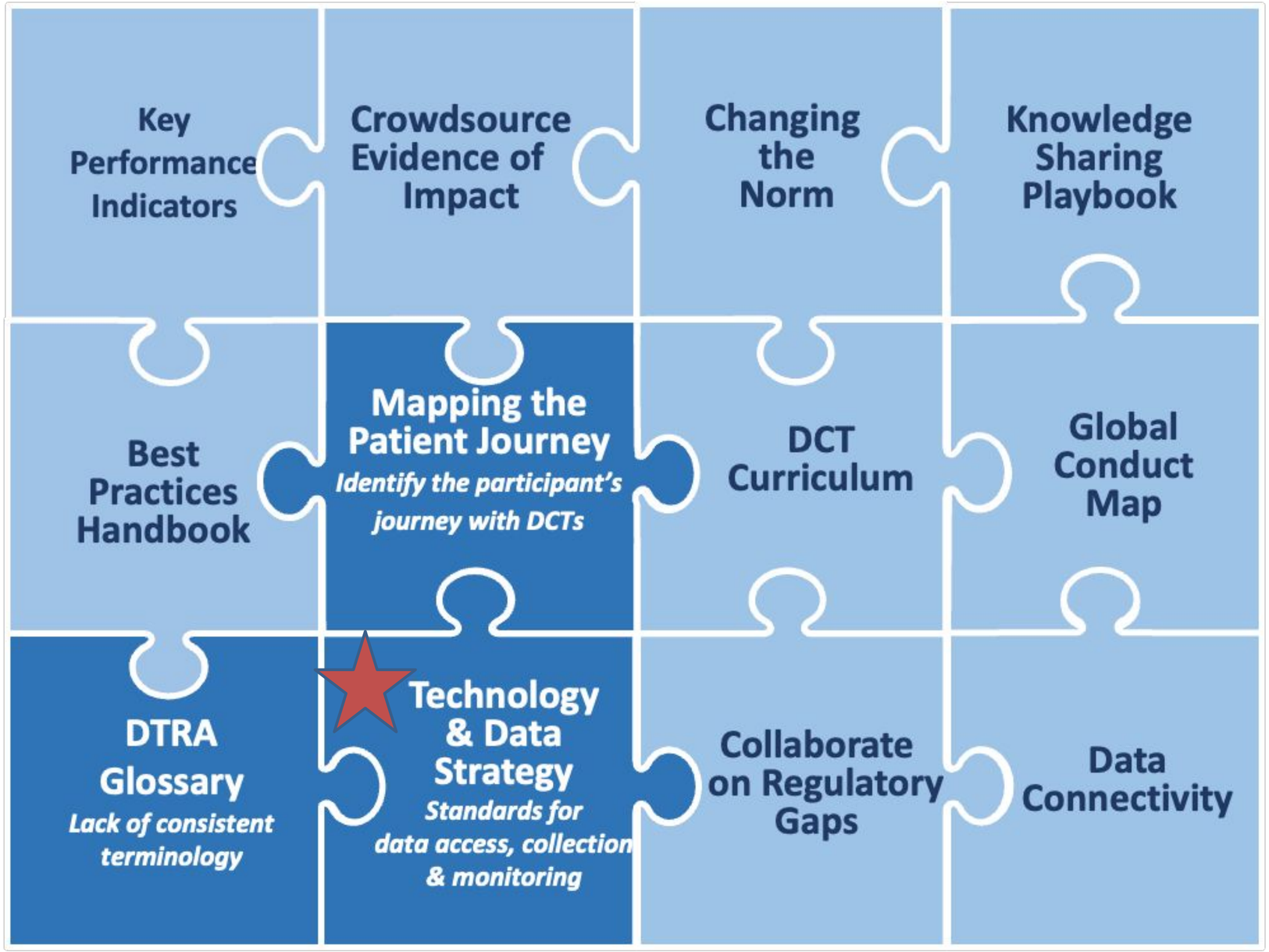
SETTING FOUNDATIONAL DCT STANDARDS



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2C Priority Initiative

Status Updates

February 2023

DTRA Initiative 2C Technology & Data Strategy

Deliverable:

'DCT Clinical Data Strategy' framework that outlines modern data requirements, data flow, data channels, data curation and insight generation to improve end-to-end data accessibility, reliability, integrity, and traceability across study phases

Key Initiatives/Focus Areas – 3 of 4

Focus Area	DTRA Definition Provided	Notes
DCT Technology	Outline of established (and novel) technologies used to support decentralized trial execution	2C initiative
User Ecosystem	Outline of relevant users/personas that can comprise the execution of decentralized trials	2C initiative
Privacy, Ethical & Legal Considerations	Outline of key considerations (globally) related to data capture and data use in decentralized trials	2C initiative + input/feedback from interested 4C
Data Capture & Accessibility	Outline of different data capture methods/modes and associated accessibility requirements required for effective execution of clinical trial activities in a remote setting	2C initiative + input/feedback from interested 4C

2C Team Members:

- ✔ PM: Open
- ✔ Co-lead: Toni Hofhine, CardieX
- ✔ Co-Lead: Kim Williams, Datacubed
- ✔ John Storey, MRN
- ✔ Charisa Scott, Amgen
- ✔ Camila Matheny, Medable
- ✔ Helen Greta, IQVIA

4C Team Members:

- ✔ Venkat Setti, AstraZeneca
- ✔ Sneha Sundet, Agios Pharmaceuticals
- ✔ John Graves, Equideum Health
- ✔ John Stuart,
- ✔ Eldawud Reem, Kearney
- ✔ Inez Jones, Oracle
- ✔ Kishori Khokarale, ZS
- ✔ 1A Glossary

Team Dependencies:

- ✔ 2B Patient Journey Maps
- ✔ 4B Regulatory Gaps
- ✔ 4C Data Connectivity

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DCT Technology & User Ecosystem - 2C Team

Overall Status:

Deliverable Timeline:
Completed on 31 January 2023

Challenge:
Deliver a comprehensive list of technology used in a decentralized trial. Identify the users/personas that intersect in a decentralized trial.

Solution:
Identify key technology used by trial milestone, provide a definition, integrated trial roles with identified ecosystem users/personas.

	DCT Technology & User/Personal Ecosystem Grid by Trial Milestone						
	Trial Planning	**Trial Startup**		**Patient Recruitment & Consent**		**Trial Conduct**	**Trial Close Out & Reporting**
	Site Feasibility	**Trial Startup**	**Pre-trial / Prescreening**	**Patient Recruitment**	**Consent/Screening/Enrollment**	**Study Conduct**	**Study Close Out**
Definition	Site feasibility is the process of evaluating the possibility of conducting a clinical trial or study, at a particular site. The monitoring team conducting the feasibility, also ensures that the trial can be conducted at the proposed site from an ethical and regulatory perspective.	Start-up occurs after protocol development and includes various tasks that enable trial execution. This phase includes system identificatoin and set-up, development of key study materials (eg consent), and several activities to enable site readiness for patient enrollment such as regulatory submissions, investigator file compilation, and receipt of devices/kits/supplies.	Pre-trial or prescreening is the general identification of a patient population for any clinical trial.	Recruitment is the identification of patients for a specific IRB-approved clinical trial protocol using the inclusion/exclusion criteria.	Participant consent to study enrollment.	Conduct occurs from first patient in through last patient out.	Close out occurs at the time the database is locked followed by submissions and back to regulatory/ethics, statistical analysis, etc.
Actions	**Intersect with 1A glossary team**						
Integrated Trial Roles	Site, IRB & EC, Sponsor/CRO, Country Regulatory Designee	Site, Patient, Sponsor/CRO, IRB & EC, Country Regulatory Designee	Site, Patient, Country Regulatory Designee	Site, IRB & EC, Patient, Sponsor/CRO	Site, Patient	Site, Sponsor/CRO, Site Monitoring, Patient	Site, Sponsor/CRO, Country Regulatory Designee
User/Persona Ecosystem	Study or site startup team (CRA, PM, Feasibility Mgr, Patient Recruitment, Regulatory), IRB/EC, Study Management Team (CRO, Sponsor, SMO)	Site staff (CRC, PI, Sub-I, Pharmacist, Phlebotomist), Study Management Team	Site Staff, Patient Recruitment, RWD/RWE, Study Management Team	Site Staff, Patient Recruitment, IRB/EC, Study Management Team	Site Staff, Technology Teams, Study Management Team, Patient Recruitment	Site Staff, Patient Recruitment, RWD/RWE, Study Management Team, Technology Teams	Site Staff, Regulatory, Study Management Team, Technology Teams, IRB/EC
DCT Technology	Router/WiFi Geomapping Investigator data bank (RWD patient populations and RWD secondary arms)	Site: eConsent, Prescreening, eSource, eISF, eCOA, IRT, Clinical Trial Payments, Telemedicine, CTMS, LMS Sponsor: CTMS, eTMF, EDC Patient: ePRO, sensors/mobile devices	Pre-screener for trial Direct to patient (diagnostics) Investigator data bank (RWD patient populations and RWD secondary arms)	Recruitment database	eConsent Remote consent (telemedicine) Direct/remote to patient (diagnostics) Lab reports to EDC/CTMS/IRT/RWD Medical device sensors (RPM) Virtual visits	eSource eQMS/CAPA Risk based monitoring Analytics (data lake/warehouse) Clinical Trial Payments, Telemedicine, Patient Compliance (alerts/reports)	eSource, CTMS, EDC, eTMF, eISF, eCOA, wearables/sensors Pharmacovigilence, eArchiving

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DCT Technology - 2C Team

	DCT Technology & User/Personal Ecosystem Grid by Trial Milestone						
	Trial Planning	**Trial Startup**		**Patient Recruitment & Consent**		**Trial Conduct**	**Trial Close Out & Reporting**
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DCT Technology	Router/WiFi Geomapping Investigator data bank (RWD patient populations and RWD secondary arms)	Site: eConsent, Prescreening, eSource, eISF, eCOA, IRT, Clinical Trial Payments, Telemedicine, CTMS, LMS Sponsor: CTMS, eTMF, EDC Patient: ePRO, sensors/mobile devices	Pre-screener for trial Direct to patient (diagnostics) Investigator data bank (RWD patient populations and RWD secondary arms)	Recruitment database	eConsent Remote consent (telemedicine) Direct/remote to patient (diagnostics) Lab reports to EDC/CTMS/IRT/RWD Medical device sensors (RPM) Virtual visits	eSource eQMS/CAPA Risk based monitoring Analytics (data lake/warehouse) Clinical Trial Payments, Telemedicine, Patient Compliance (alerts/reports)	eSource, CTMS, EDC, eTMF, eISF, eCOA, wearables/sensors Pharmacovigilence, eArchiving

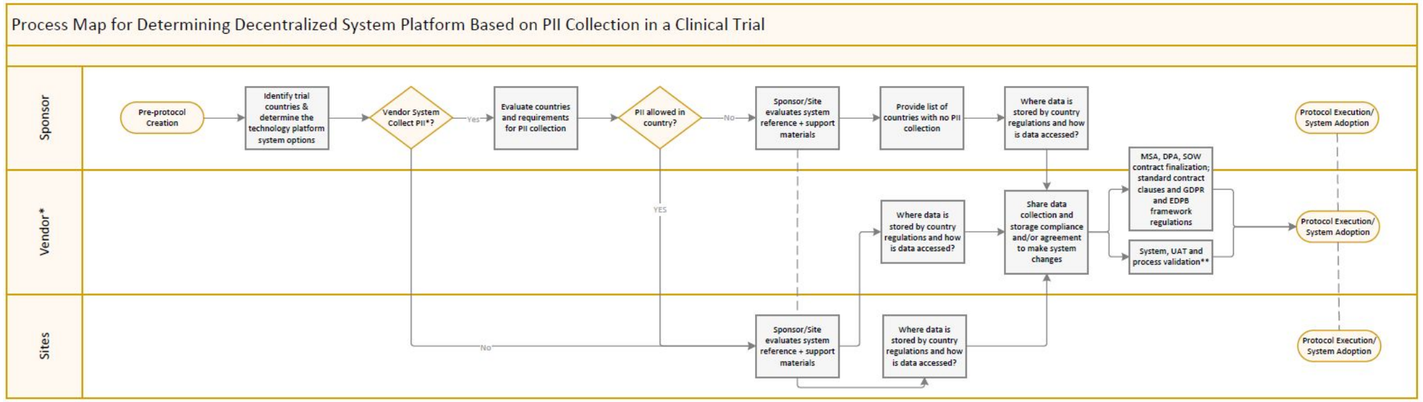
Privacy, Ethical, Legal Considerations - 2C + 4C Teams

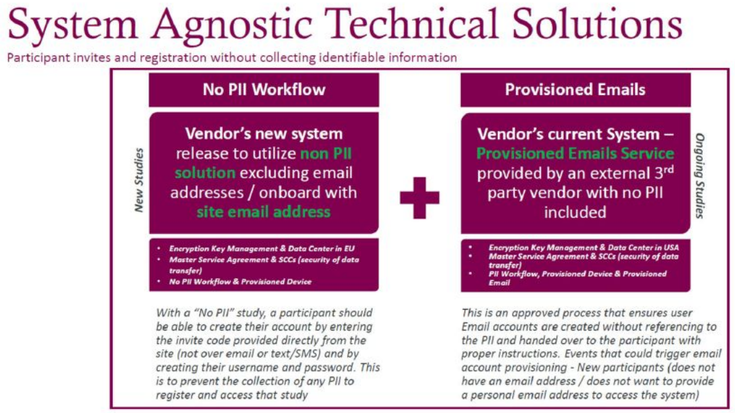
Overall Status:

Deliverable Timeline:
Completed on 31 January 2023

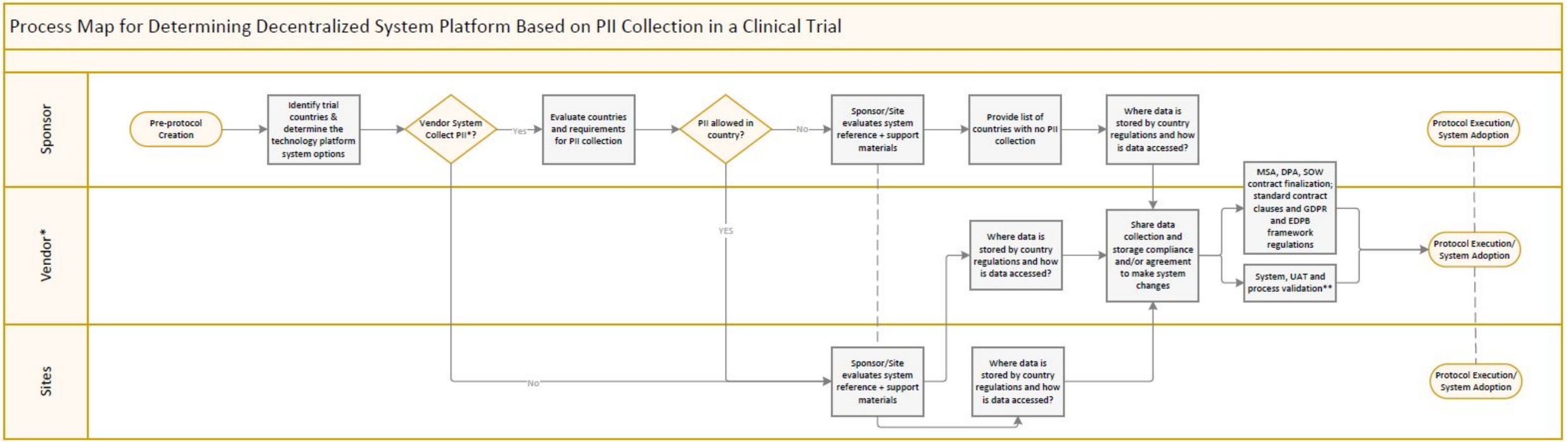
Challenge:
Deliver a solution that encompassed the global considerations for privacy, ethical, and legal data collection.

Solution:
Adopt the System Agnostic Technical Solutions concept donated to the DTRA by AstraZeneca on how PII data collection could be fully avoided in any region, and back track this process to develop a process map on how to identify across sponsor, vendor, and site where and what system platform is needed to be compliant.





Privacy, Ethical, Legal Considerations - 2C + 4C Teams



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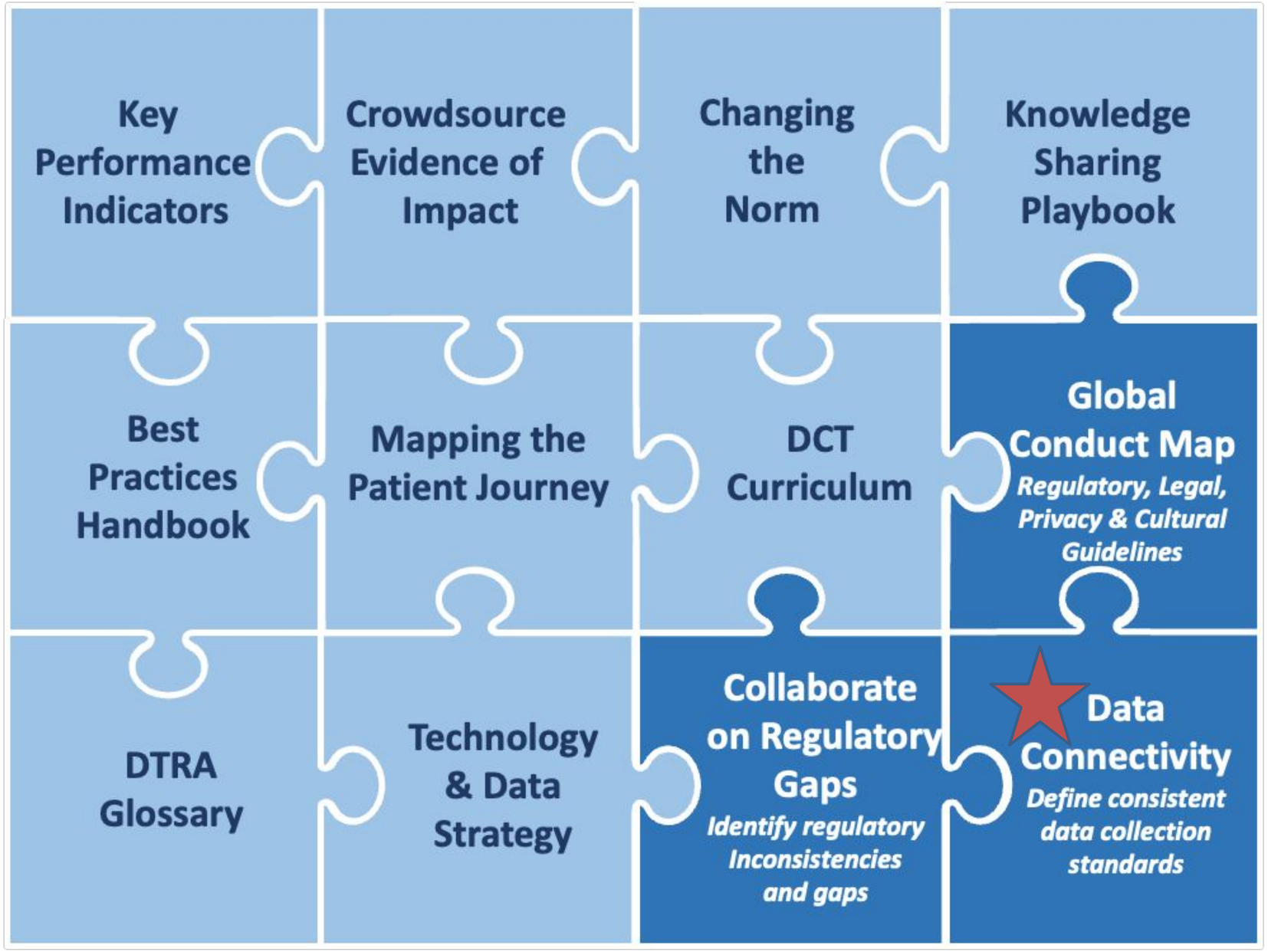
REMOVING BARRIERS TO ADOPTION



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4C Data Connectivity:

Feb 2023

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

Proposed workstreams

Workstream deliverables

Workstream A

End to End processes and data flow

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

Workstream B

Architecture framework recommendation

- A toolkit (Architecture, blueprint, etc.) to provide approaches on how to manage clinical data in different scenarios
- Flexible and configurable clinical data orchestration and workflow based on events

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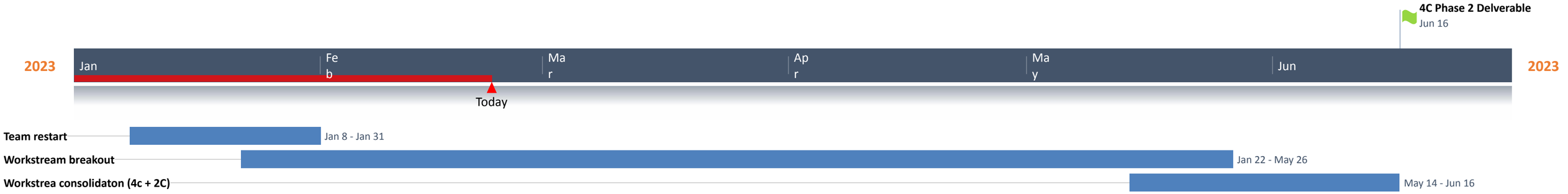
Overall Status

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 low
  - Still missing a co-lead

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CROSS INDUSTRY INITIATIVES TO EASE DCT ADOPTION: UPDATES FROM DTRA

February 9, 2023

AGENDA

- Welcome
- DTRA Overview
- Initiative Teams Presentation
  - Evidence of Impact
  - Regulatory Gaps
- Q&A
- Wrap Up

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OUR PRESENTERS

Craig Lipset
Co-Chair
DTRA

Caroline Redeker
SVP, Corporate Development
Advanced Clinical

Jonathan Andrus
President & COO
CRIO

Jane Myles
Co-Lead, DCT Playbook
DTRA

EVIDENCE OF IMPACT

Caroline Redeker

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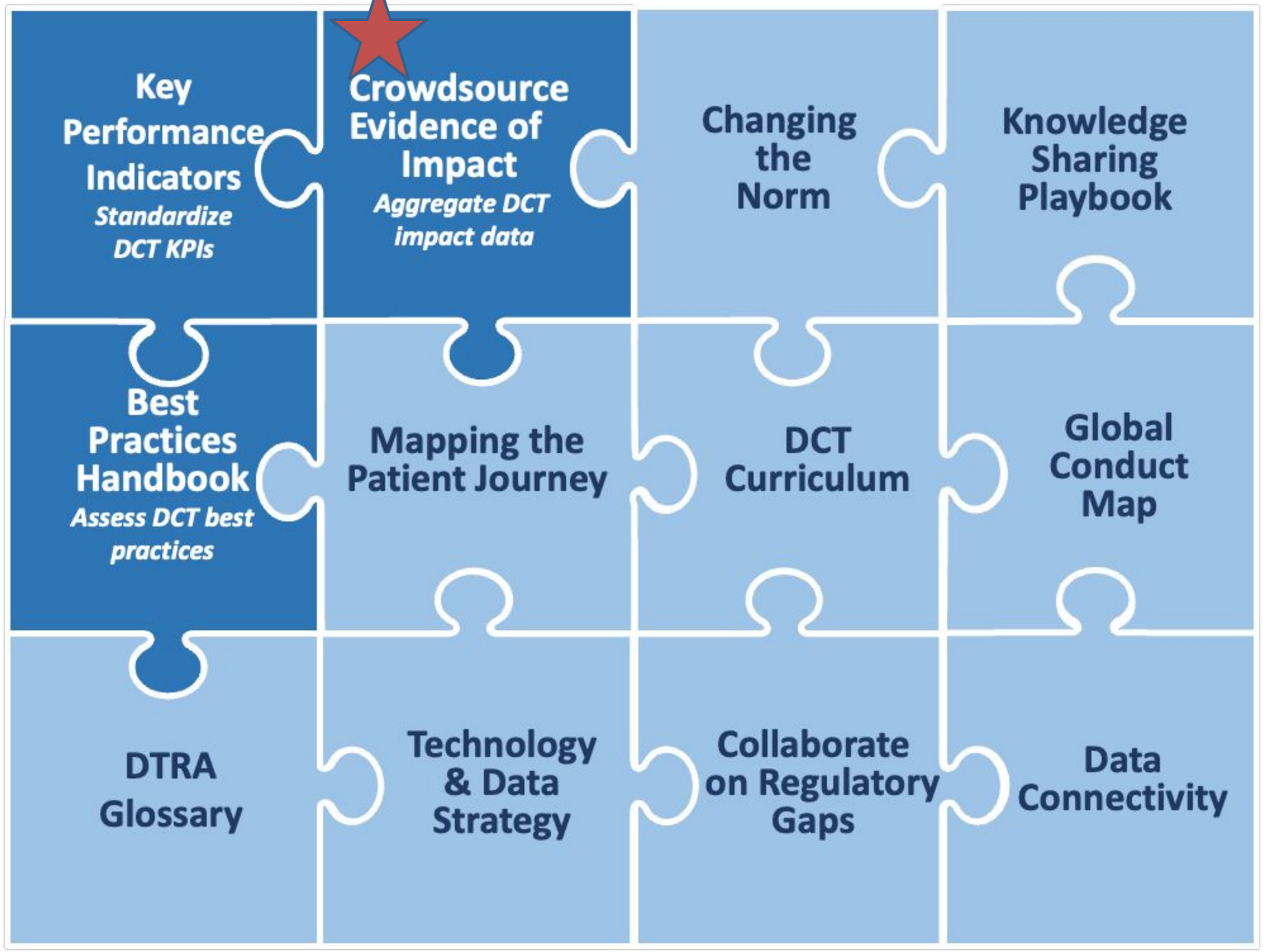
MEASURING SUCCESS WITH DCTs



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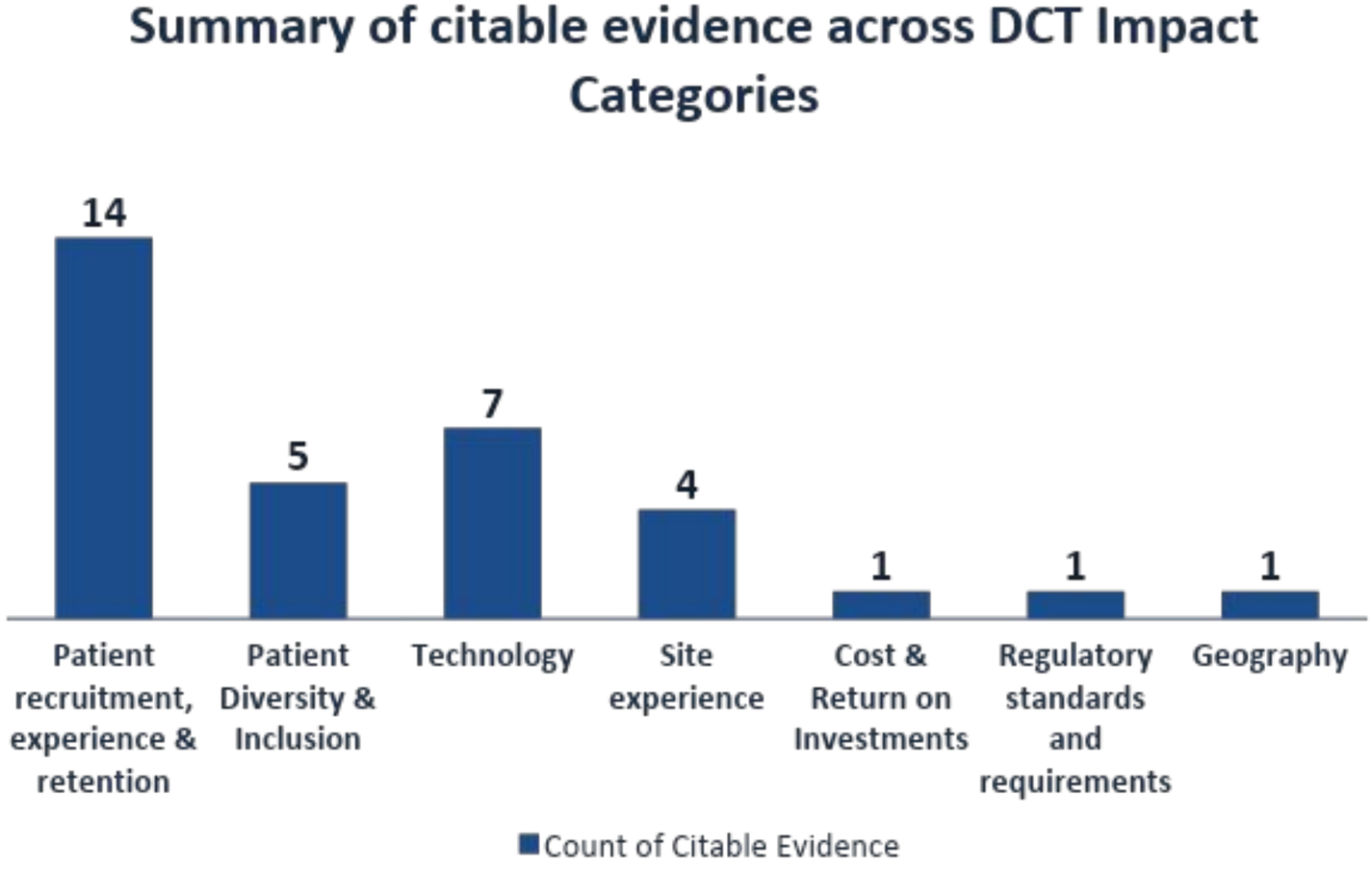
EVIDENCE OF IMPACT

60+ respondents surveyed

+35 publications reviewed

8 follow-up interviews with DTRA members



Robust evidence on usage of decentralized trial methods, Limited initial proof points on stakeholder value

CROWDSOURCING EVIDENCE OF IMPACT: SUMMARY

What are our findings?

- **Overall high evidence of use for DCTs globally** (80% of our survey participants reported DCT usage)
  - Most in hybrid model, not fully decentralized
- Despite usage of decentralized research methods, **proof points on early value to stakeholders is still emerging**

DCT Impact Quotes

There is a sweet spot to hit with hybrid DCTs - it's about finding the right balance – *Rajesh Ghosh, Head of Digital Safety and Decision support at Genentech*

When we got hit by COVID, DCTs are what kept us going
Shobha Dhadda, Global head of Clinical Operations, EISAI

What is our critical observation?

- **No forum in the industry available to collect evidence** of DCT impact and disseminate systematically
- Many times, the **evidence available is operational in nature**, or **evidence points are captured in a scattered manner** from multiple stakeholders within the R&D organization, making it difficult to be reported
- **There is a need for collaboration** with other organizations, such as TransCelerate, CTTI, ACRP
  - Many organizations working with sites, pharma, regulatory agencies = more effective together
- **There is an opportunity to be the repository/provider** of tracking tools for the industry

We suggest DTRA becoming a centralized hub to collect evidence of DCT impact

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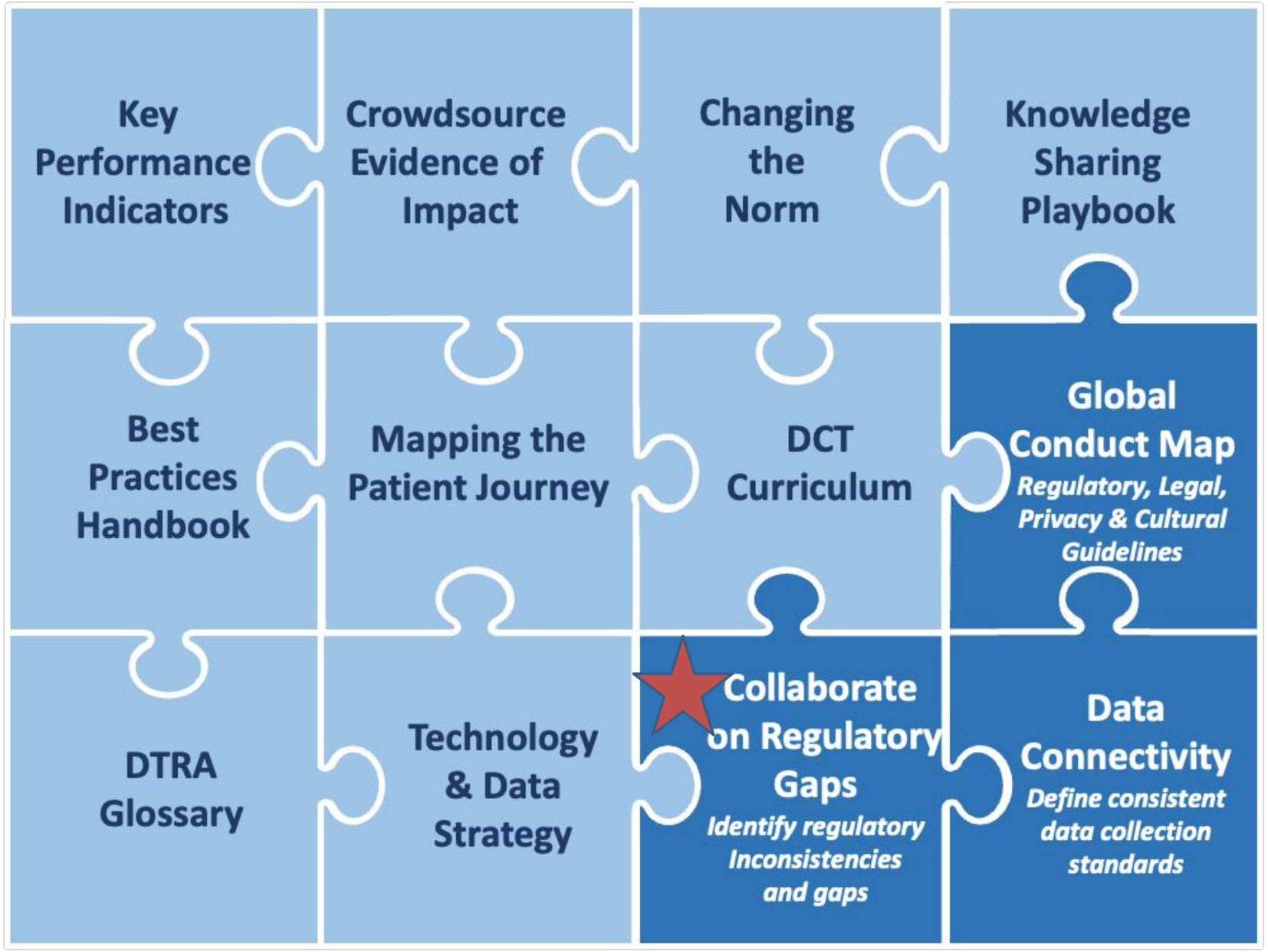
REGULATORY GAPS

Jonathan Andrus

REMOVING BARRIERS TO ADOPTION



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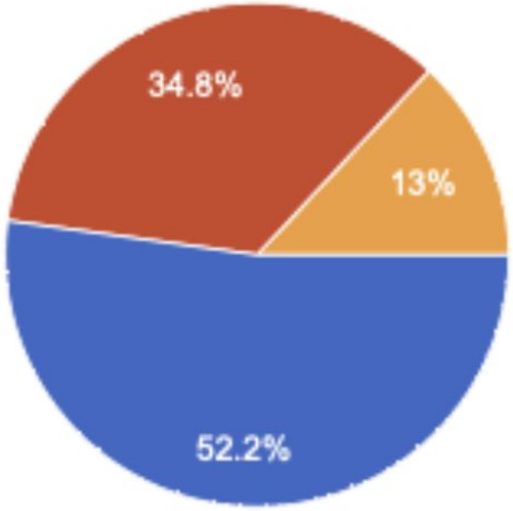
COLLABORATE ON REGULATORY GAPS

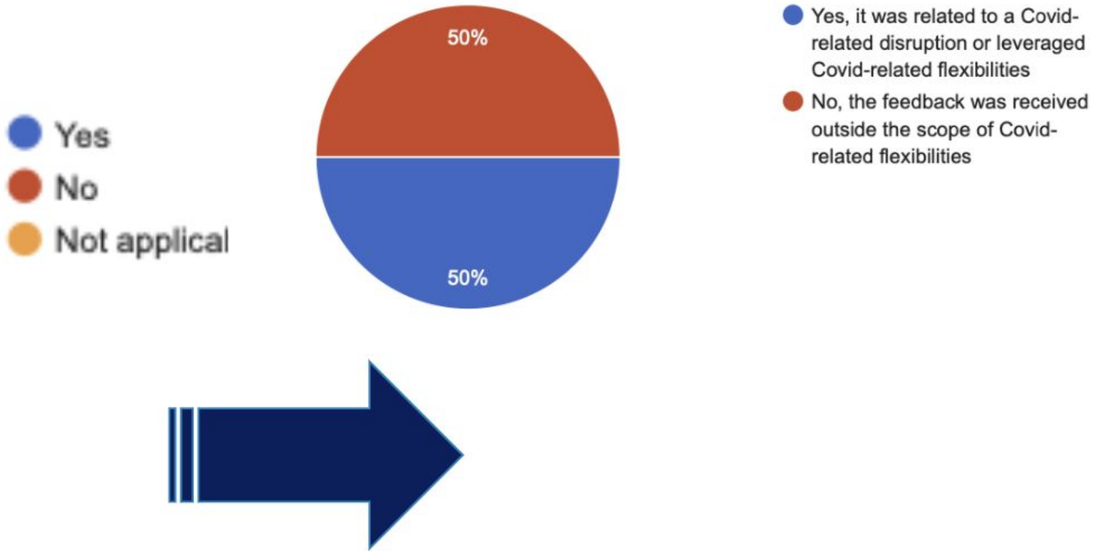
Regulatory Interaction Survey to DTRA members

- 25 respondents (80% Pharma)
- Generally, Health Authorities have been receptive

Health Authority Questionnaire Highlights

Have you sought regulatory feedback from a health authority concerning elements of trial decentralization?





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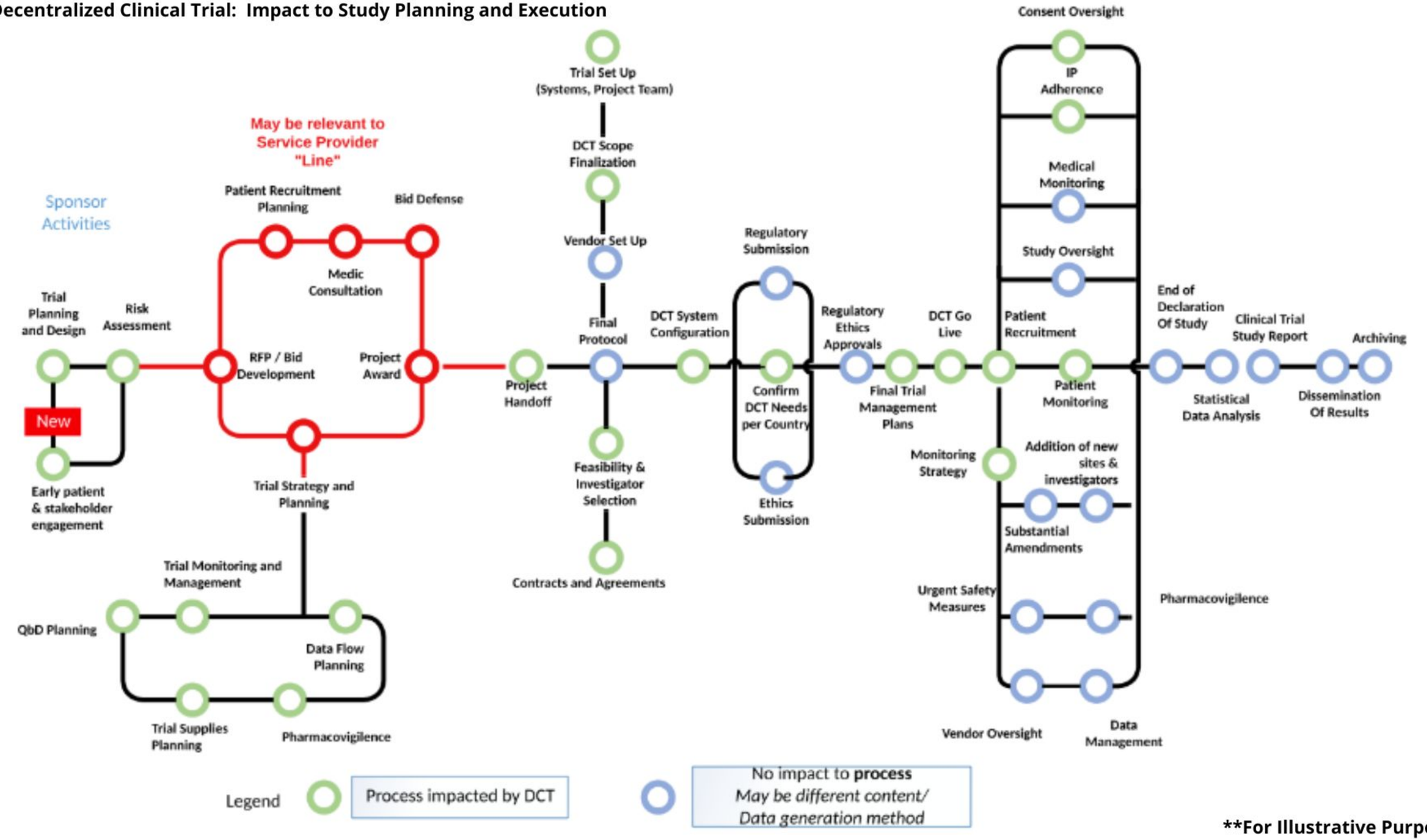
MIND THE GAP: DRAFT FRAMEWORK

Decentralized Clinical Trial: Impact to Study Planning and Execution



**For Illustrative Purposes Only

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BRIDGING THE GAPS

- Detailed regulatory gap analysis conducted across all project stages
- DTRA Regulatory Affairs Council (RAC) providing proactive engagement with global health authorities
- Upcoming FDA listening session
  - Determine areas of collaboration and partnership between FDA and DTRA
  - Additional Health Authority listening sessions planned

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DTRA - INITIATIVE OVERVIEW

Foundational Intiatives: DCT Standards			
1A	Glossary	PUBLISHED AND COMMUNICATED	**complete**
2B	Mapping the Patient Journey	3 Maps created and completed: Oncology, Rare Disease, & Vaccines	**complete**
2C	Data & Technology Strategy	3 of 4 areas of focus completed	**Q2**
Measuring Success with DCT			
1B	KPIs	version 1.0 published internal to DTRA for feedback	**Q1**
2A	Best Practices	version 1.0 rubric PUBLISHED Evaluation process to be finished	**Q1**
3A	Crowdsharing Evidence of Impact	Slide deck from 3A: Crowdsourcing Evidence workstream along with a document citing links to the publications that were referenced.	**Q1**

Supporting DCT with Education and Adoption			
1C	Changing the Norm	Whitepaper completed.	**Q1**
3B	Knowledge Sharing Playbook	Spreadsheet populated with information Final graphic will be Tubestop	**Q2**
3C	DCT Curriculum	Module list created with specific details behind each one Overview module 1 outline completed	**Q2**
Removing Barriers			
4A	Global Conduct Insight Map	Spreadsheet APAC / EU / US: Regulatory is comprehensive Information on Privacy (just GDPR, China) Content visualization underway	**Q1**
4B	Regulatory Gaps	Completed gaps and added to 3C spreadsheet Team is being dissolved and migrated into the DTRA Regulatory Forum	**complete**
4C	Data Connectivity	Team meetings underway after the rescope	**Q2**

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COMING NEXT!

Month	Initiative Output	Conference	Conference Content	DTRA Clubhouse Content	Web Publication
January	✔ **3A Evidence of Impact** ✔ **4B: Regulatory Gaps**				✔ **Patient Journey: Vaccine** ✔ **Best Practices Rubric**
February	• 1C Changing the Norm (survey & whitepaper)	✔ **SCOPE 2/6-2/9)**	✔ **Reg Gap assessment**	✔ **2A: Best Practices Rubric**	• Evidence of Impact (tbd) • Everest Research Homepage • Publish ONC / OSTP response (TBD)
Q1/early Q2	• Tubestop v1 draft (3B & 4B) • Launch DTRA Library resource	• DIA EU (TBD)	TBD – DTRA Overview	• Changing the Norm: whitepaper/survey • Regulatory Insight Map	• 4A: Regulatory Insights Map)TBD) • Website – new look

- Look for the DTRA Newsletters!
- **Next meeting, March 30th**

Thank You!

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Extra slides

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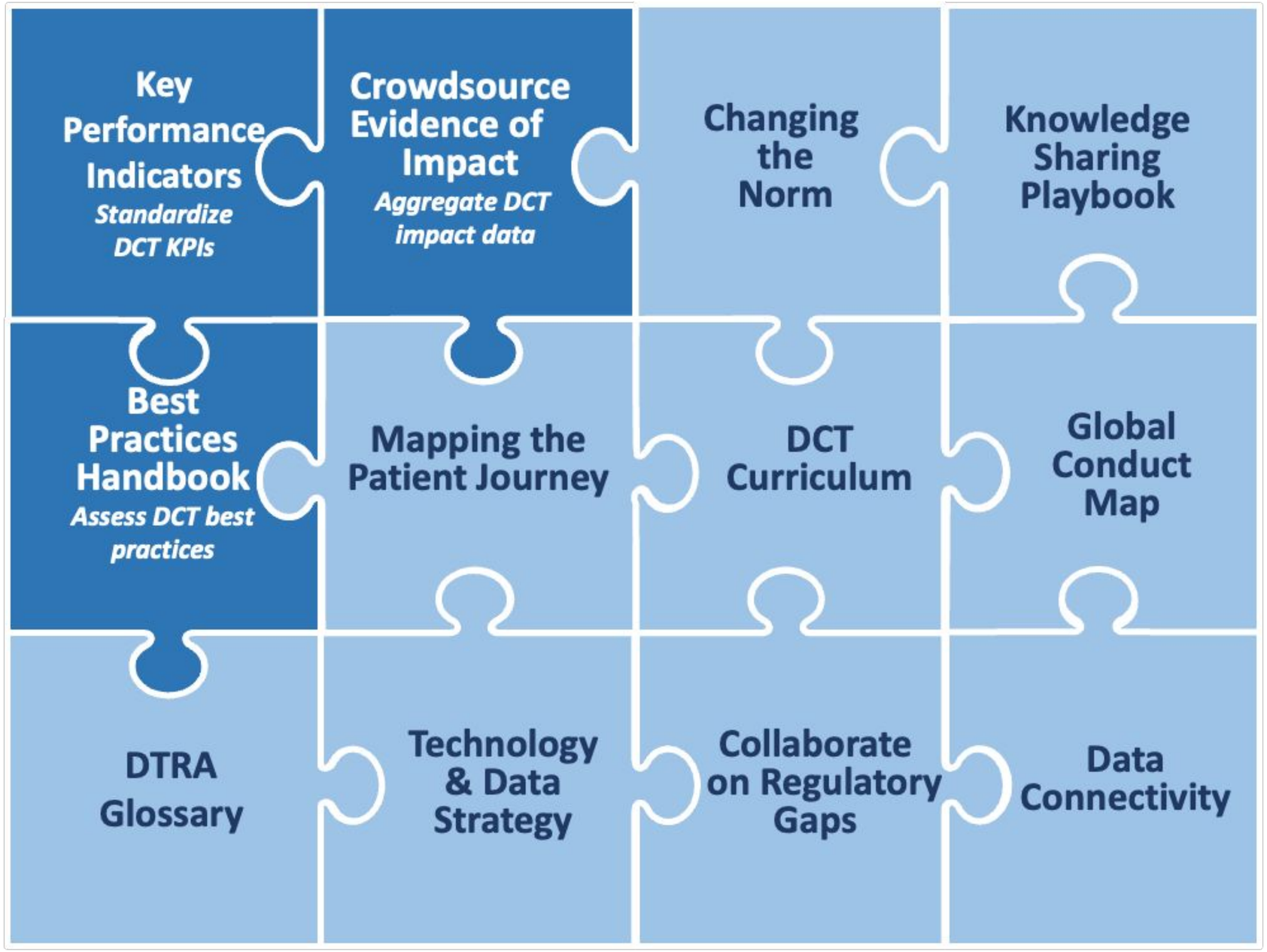
INITIATIVES:
GOVERNANCE & CONTINUITY

Phase 1 Initiatives	***Adoption of Initiatives***	***Phase 2 Initiatives***
Completed:		
Content Council Oversight		
• 1A: Glossary • 1B: Key Performance Indicators • 2B: Mapping the Patient Journey • 2A: Best Practices Handbook • !C; Changing the Norm • 3A: Evidence of Impact • 4A: Global Conduct Insights Map	• CONTENT REVIEW BASED ON FEEDBACK (1A, 1B) • FINDING & POSTING BEST PRACTICES (2A) • FINDING & POSTING CASE STUDIES (1C, 3A) • APPLYING THE DELIVERABLES (1B, 1C, 4A, 4B)	
In progress:		
Regulatory Council Oversight		
4B Regulatory Gaps	IDENTIFYING REGULATORY GAPS (4B)	
Education Committee Oversight		
3B DCT Playbook	TUBESTOP CREATION	
3C DCT Curriculum	CURRICULUM ON LMS	
Data & Technology Committee Oversight		
2C Data & Tech Strategy 4C Data Connectivity	STRATEGY AND ALIGNMENT BETWEEN INITIATIVES	

MEASURING SUCCESS WITH DCTs



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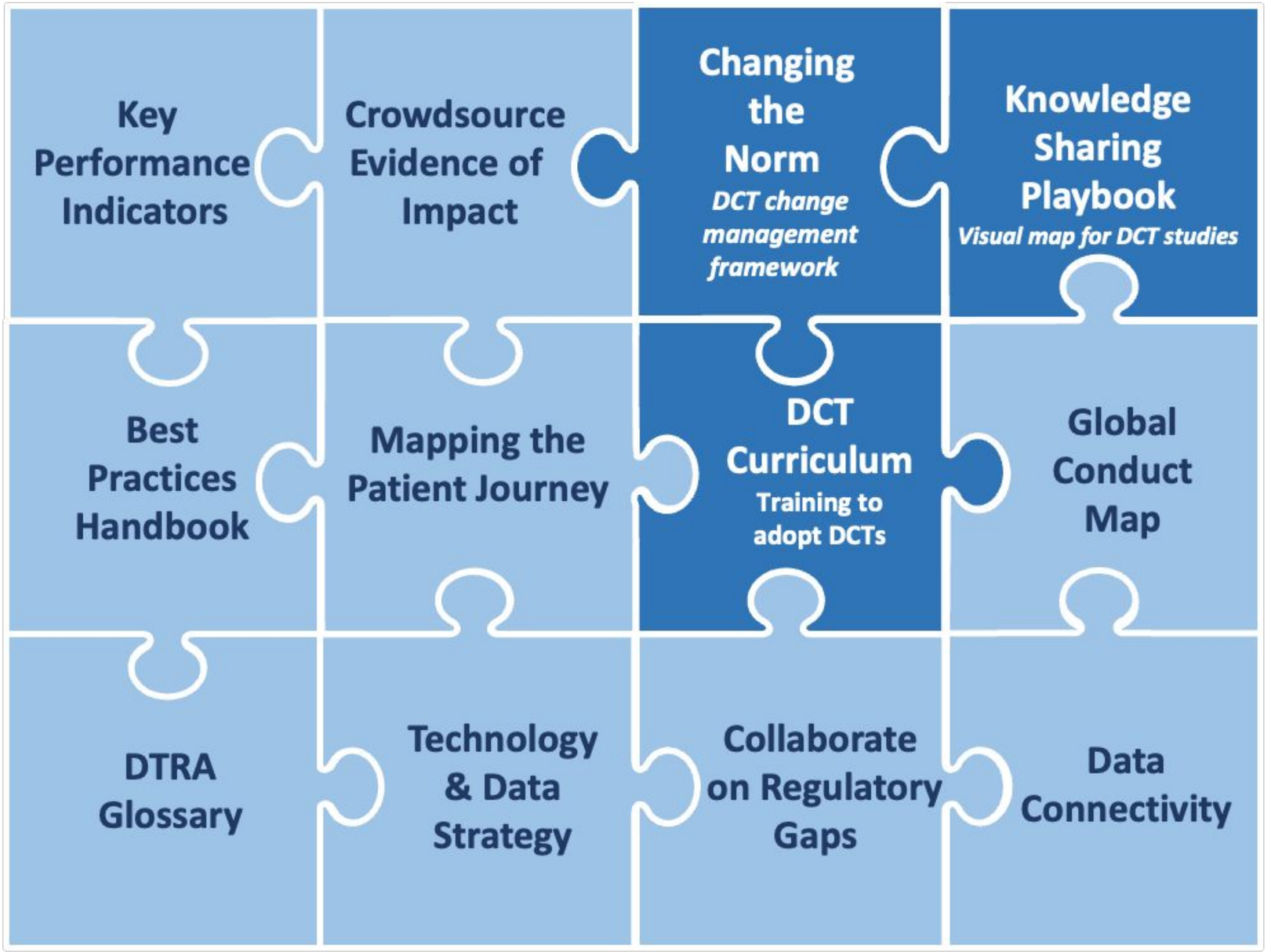
SUPPORTING DCT EDUCATION AND ADOPTION



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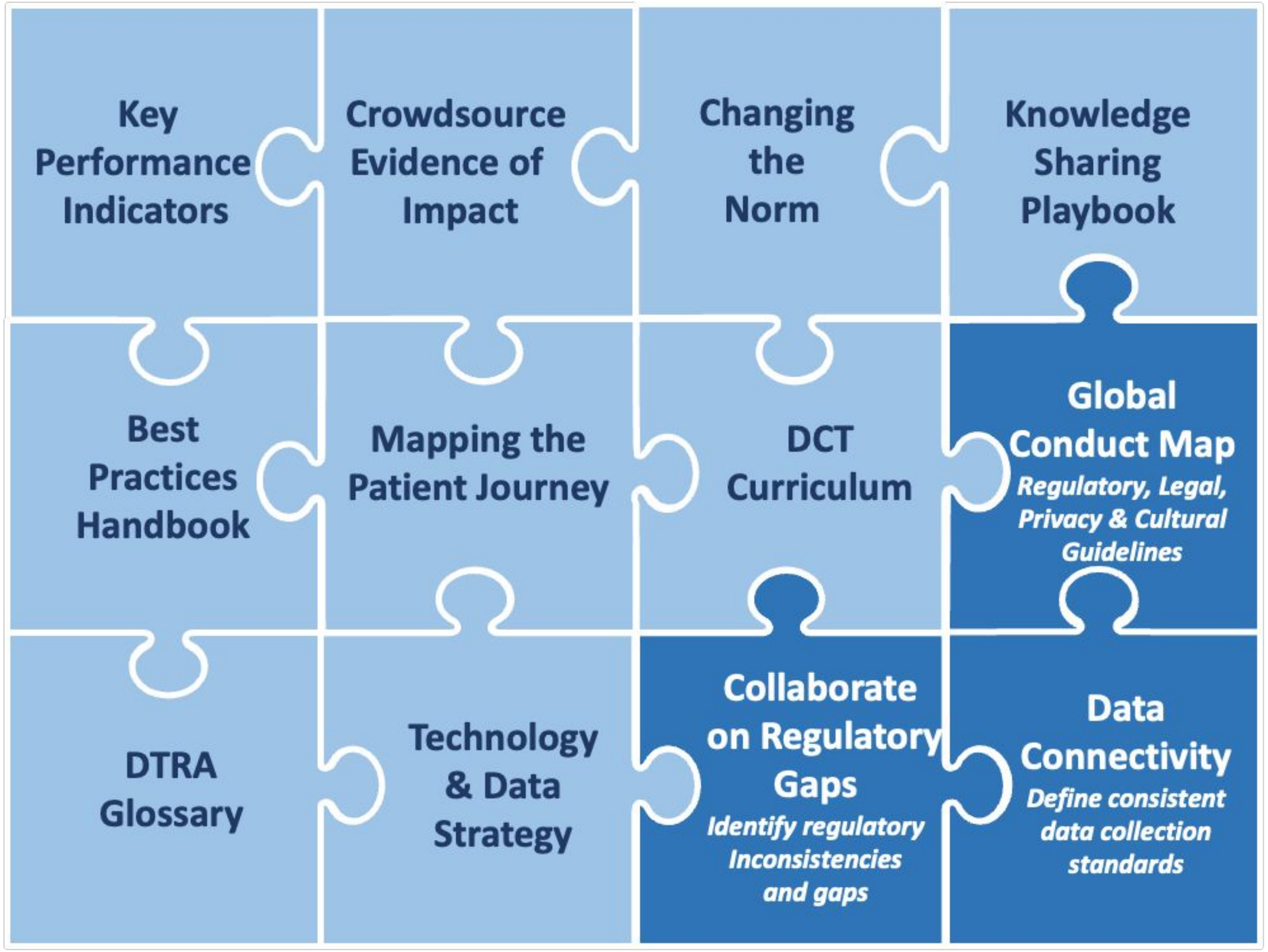
REMOVING BARRIERS TO ADOPTION



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CONTENT COUNCIL

Decision making review body to maintain current, relevant content.
Comprised of 7-10 engaged SMEs
Time Commitment - >1 d/m

Current Scope

- Glossary
- Key Performance Indicators
- Changing the Norm
- Best Practices Handbook
- Mapping the Patient Journey
- Crowdsource Evidence of Impact
- Global Conduct Map

Expectations

- Review feedback asynchronously
- Monthly meeting to make decisions
- Ensure content reflects current state
- Support adoption through relevant content

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STEERING COMMITTEES

Peer Review Forum offering input and guidance on deliverables and/or gaps
Each committee is comprised of 3-5 Leadership Council Members
Time commitment - 1-2 Meetings/Quarter

Technology & Data Strategy Steering Committee
Data Connectivity, Technology & Data Strategy

Education Steering Committee
Knowledge Sharing Playbook
DCT Curriculum

Regulatory Steering Committee
Collaborate on Regulatory Gaps

Expectations

- Enable successful outcomes and deliverables
- Quarterly Review Meetings
- Discuss issues, challenges, and/or needs
- Identify next steps and ownership

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