DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

DTRA Initiatives Monthly Meeting

January 26, 2023

DTRA INITIATIVES AGENDA

- Welcome & Agenda - Claudine
- DTRA Initiatives Core Strategy - Claudine & Jane
- Co-Labs – Jane
- OSTP overview - Jane
- Regulatory Council update – Jane
- Update from 2C & 4C – Toni & Moulik
- Upcoming Q1 DTRA agenda
  - Conferences
  - Clubhouse events

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DTRA - INITIATIVE CORE STRATEGY

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

In progress:

Regulatory Council Oversight

4B Regulatory Gaps

Education Committee Oversight

3B DCT Playbook

3C DCT Curriculum

Data & Technology Committee Oversight

2C Data & Tech Strategy

4C Data Connectivity

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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

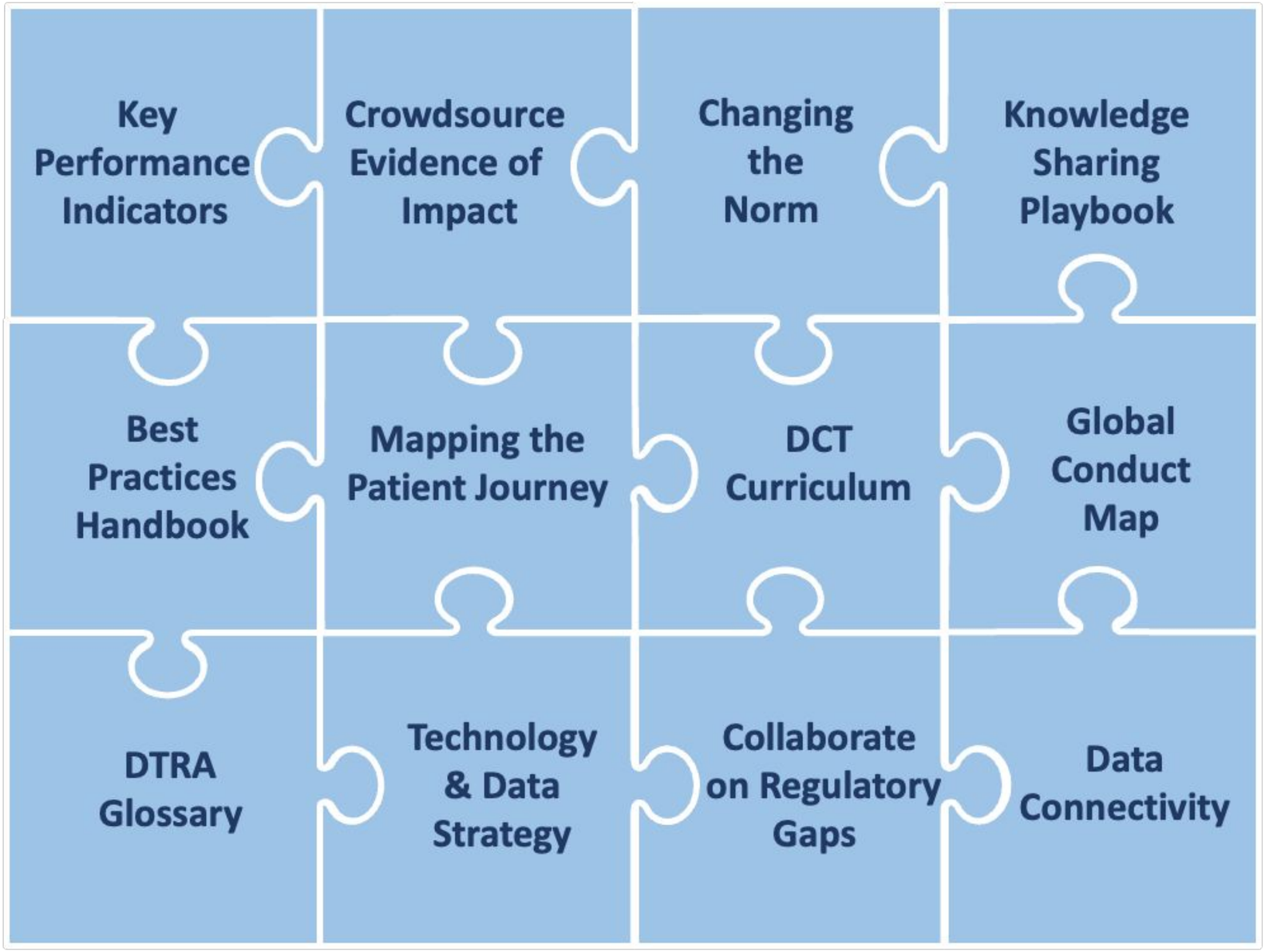
Removing Barriers

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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DTRA - INITIATIVE OVERVIEW

Foundational Intiatives: DCT Standards			
1A	Glossary	PUBLISHED AND COMMUNICATED	**complete**
2B	Mapping the Patient Journey	3 Maps crated and completed: Oncology, Rare Disease, & Vaccines	**complete**
2C	Data & Technology Strategy	Team meetings underway after the rescope	**Q2**
Measuring Success with DCT			
1B	KPIs	version 1.0 ready 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 Need to settle on final graphic (Tubestop - draft idea)	**Q2**
3C	DCT Curriculum	Module list created with specific details behind each one Content of modules not complete	**Q2**
Removing Barriers			
4A	Global Conduct Insight Map	Spreadsheet APAC / EU / US: Regulatory is comprehensive Not a lot of information on Privacy (just GDPR, China)	**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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DTRA – OSTP overview

Response to Emergency Clinical Trials RFI (#87 FR 64821)
Submitted to White House Office of Science and Technology Policy (OSTP)

Background

The Office of Science and Technology Policy (OSTP) has issued a Request for Information (RFI) to ensure that coordinated and large-scale clinical trials can be efficiently carried out to address outbreaks of disease and other emergencies (Emergency Clinical Trials - ECT)

- Some DTRA members participated in public listening sessions week of 9 Jan
- OSTP / ONC specifically sought more DTRA Member input - 23 Jan session

DTRA MEMBER PANEL DISCUSSIONS

- *How might decentralized research be used to enhance equitable participation in emergency clinical trials?*
- *How might regulatory flexibility help accelerate emergency clinical trials using decentralized methods?*
- *How might we develop a pilot or demonstration project to use decentralized research for emergency clinical trials in a 6-12 month timeframe?*

DTRA – Regulatory Council Update

New members joined (Dec 22)

- Co-Leads and PM from Initiative team 4B (Regulatory Gaps)
- Individuals from regulatory groups in member orgs

Activities

- Proactive outreach
- Reactive response
- Co-creation of regulatory guidance / policy (TBD)

DTRA – Regulatory Council Members

Rasika Kalamegham, Genentech, Inc.
Jonathan Andrus, CRIO
Dylan Bechtle, Janssen Research and Development
Rob Berlin, GSK
Kari Forsaith, Vertex Pharmaceuticals Incorporated
Danielle Friend, Janssen Research & Development
Martine Dehlinger Kremer, ICON
Steve Walker, CSL Behring

DTRA : Co-Labs

Problem Statement: There are areas of need not currently addressed by existing Initiative Teams. We need a mechanism to allow interested members to contribute to solutions help close these gaps.

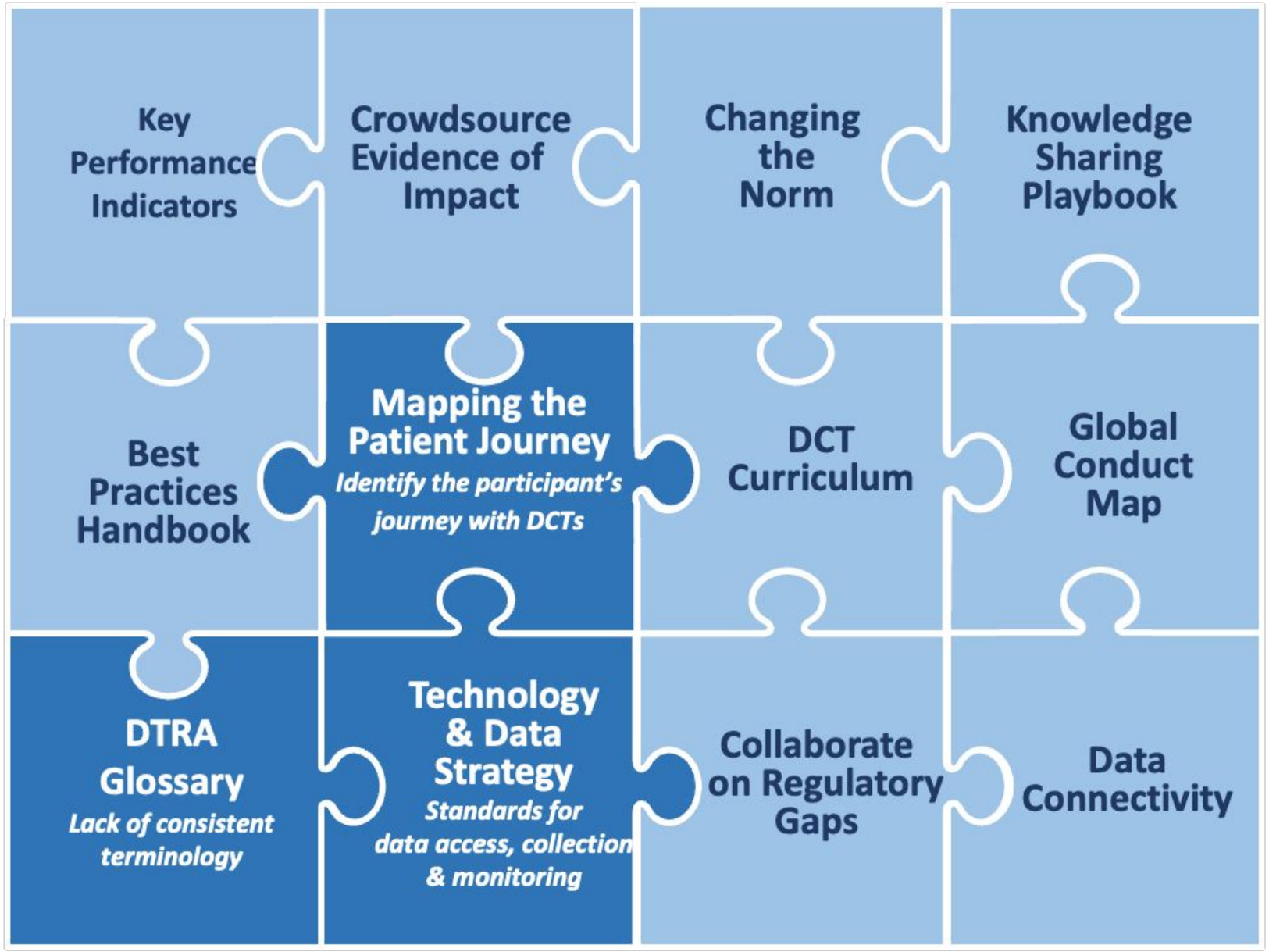
Potential Priority Areas
1 1572s and oversight - Gaps in current guidance
2 Site Needs - Best practices and gaps
3. Open registry of DCT for benchmarking
4. Environmental Sustainability and DCTs
5. Diversity & DCTs

DTRA : Co-Labs

Next Steps

- Finalize priority topics (by 31 Jan)
- Create a light PM framework / toolkit (by 6 Feb)
- Call for volunteers (mid Feb)

SETTING FOUNDATIONAL DCT STANDARDS



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2C PRIORITY INITIATIVE STATUS UPDATES

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 (In Progress):

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
- ✔ Greg Jones, Oracle
- ✔ Kishori Khokarale, ZS

Team Dependencies:

- ✔ 1A Glossary
- ✔ 2B Patient Journey Maps
- ✔ 4B Regulatory Gaps
- ✔ 4C Data Connectivity

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DTRA INITIATIVE 2C TECHNOLOGY & DATA STRATEGY

Overall Status: 

Deliverable Timeline: Complete on 27 January 2023

	DCT Technology Grid by Trial Milestone						
	Site Feasibility	**Trial Startup**	**Pre-trial / Prescreening**	**Patient Recruitment**	**Consent/Screening/Enrollment**	**Trial Conduct**	**Trial 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							
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

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.

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DTRA INITIATIVE 2C TECHNOLOGY & DATA STRATEGY

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User/Persona Ecosystem							
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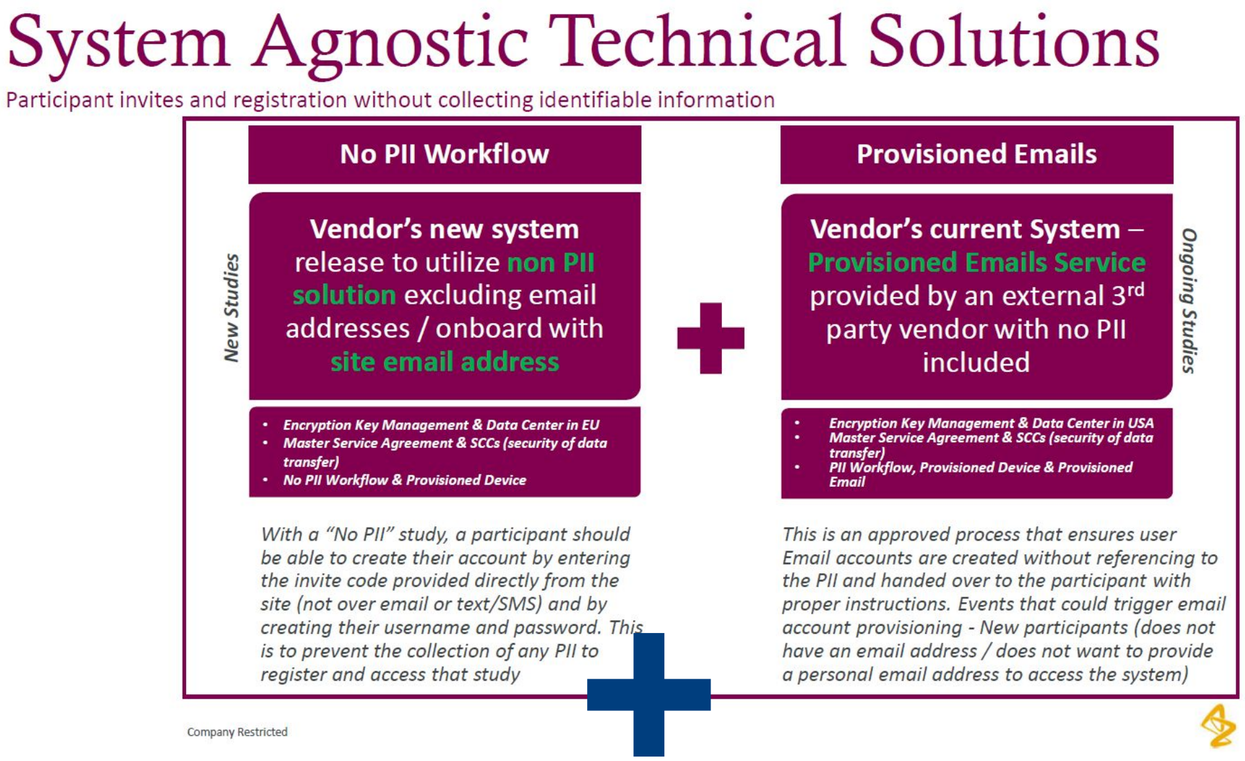
PRIVACY, ETHICAL, & LEGAL CONSIDERATIONS - 2C + 4C

Overall Status:

Deliverable Timeline:

Finalize on 27 Jan 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.

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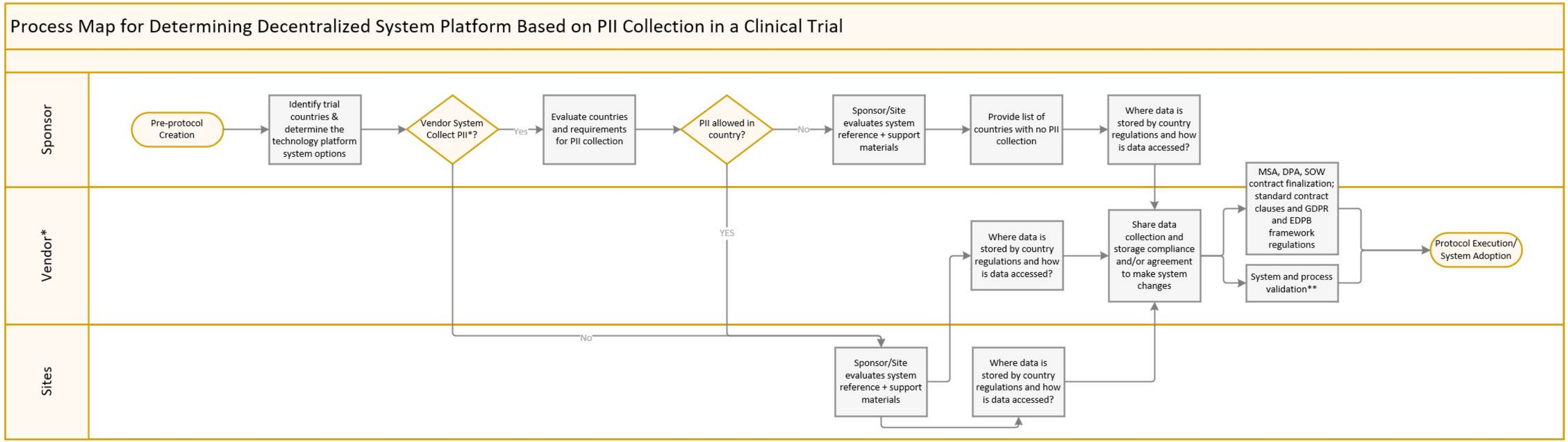
Privacy, Ethical, Legal Considerations - 2C + 4C Teams

Overall Status:

Deliverable Timeline: Finalize on 27 Jan 2023



* Note: For eConsent, signature and name will be required as PII in every country.
**Note: May be performed in parallel or precede the contract finalization based on study protocol and regional regulations.

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4C DATA CONNECTIVITY

VISION

Agnostic data framework for DCT clinical data life cycle, maintaining quality and integrity to enable near real-time data-driven decision-making

✓ Data connectivity standardization
✓ Data reliability
✓ Data interoperability

DELIVERABLE

- **Strategy to manage clinical data flow**
  - Across clinical trial lifecycle & ecosystem
  - Compliant to applicable regulations
- A toolkit approach to **manage clinical data** across scenarios
  - Architecture, blueprint
- **Flexible and configurable** data handling
- Event based **workflow**

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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)	• BIO Investors (2/6-2/9)	DTRA Overview	• 2A: Best Practices Rubric	• Evidence of Impact (tbd) • Everest Research Homepage • Publish ONC / OSTP response (TBD)
		• SCOPE 2/6-2/9)	Reg Gap assessment		
March	• 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 Newsletter next week!
- Next meeting, February 23rd

Thank You!

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SCOPE 2023 PRESENTATION - CROSS INDUSTRY INITIATIVES TO EASE DCT ADOPTION: UPDATES FROM DTRA

Craig Lipset
Co-Chair
DTRA

Caroline Redeker
SVP, Corporate Development
Advanced Clinical

Jonathan Andrus
President & COO
CRIO

Jane Myles
Co-Lead, DCT Playbook
DTRA

Thursday, February 9th | 12:00 PM

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Extra slides

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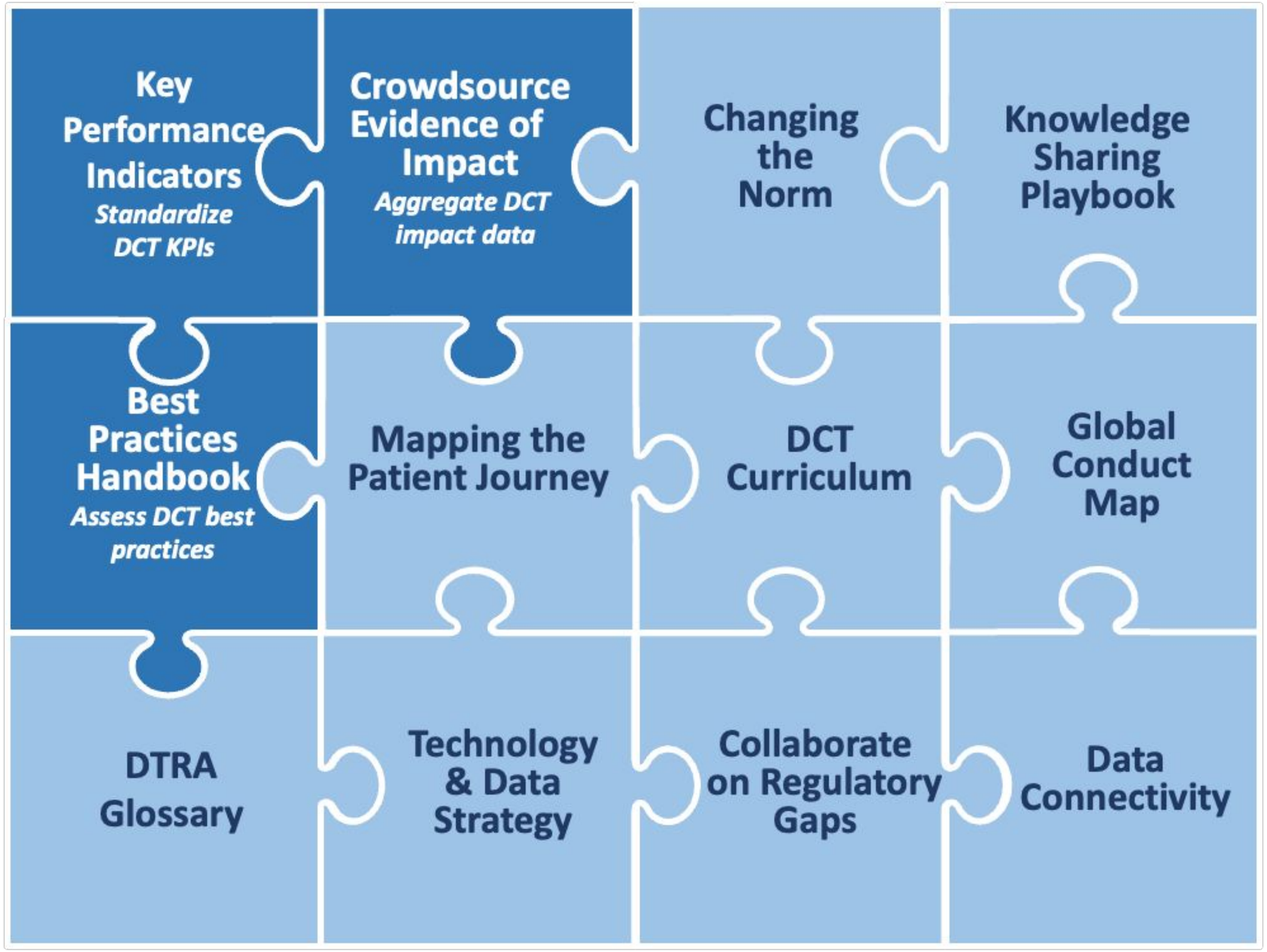
INITIATIVES:
GOVERNANCE & CONTINUITY

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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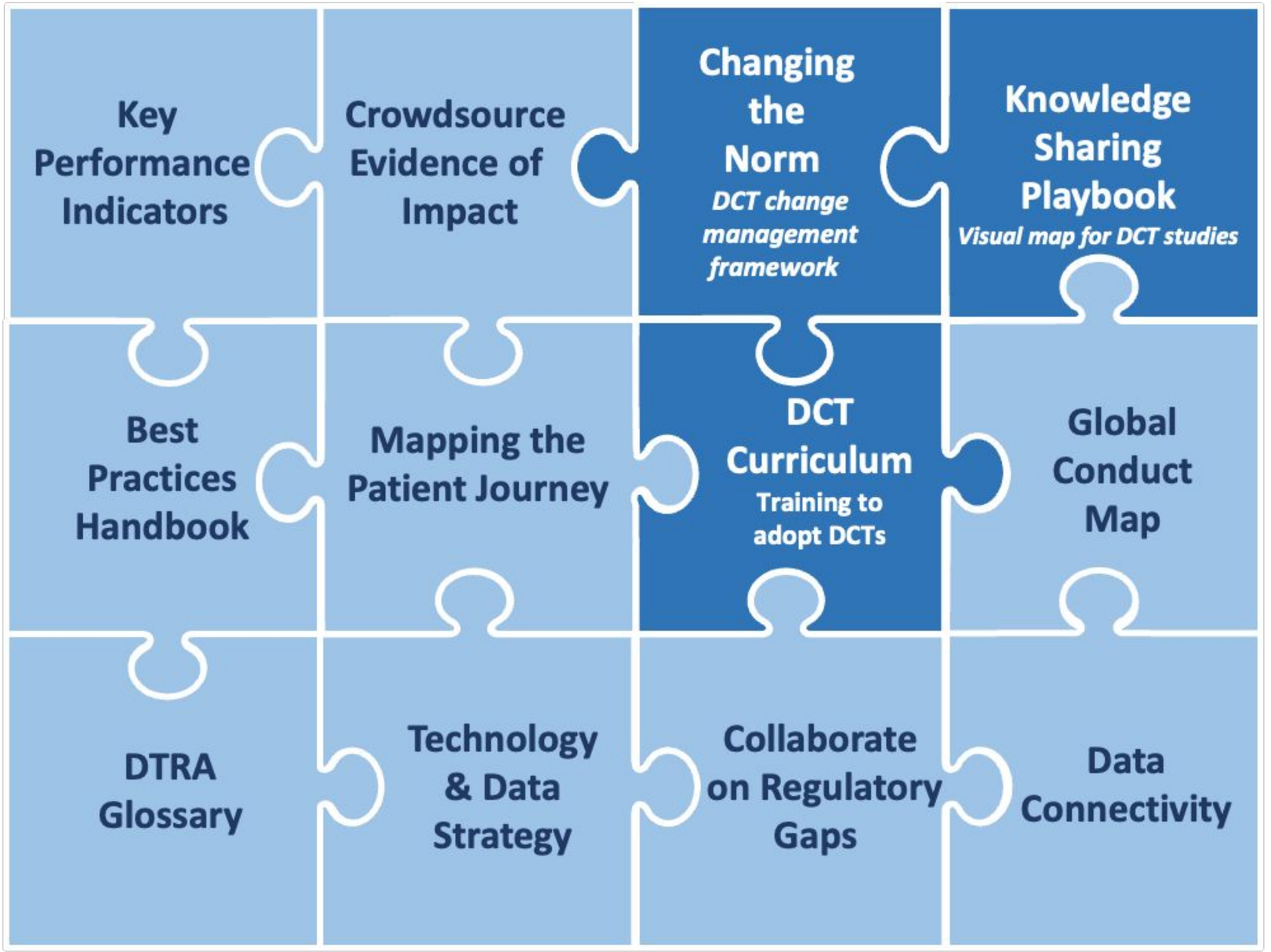
SUPPORTING DCT EDUCATION AND ADOPTION



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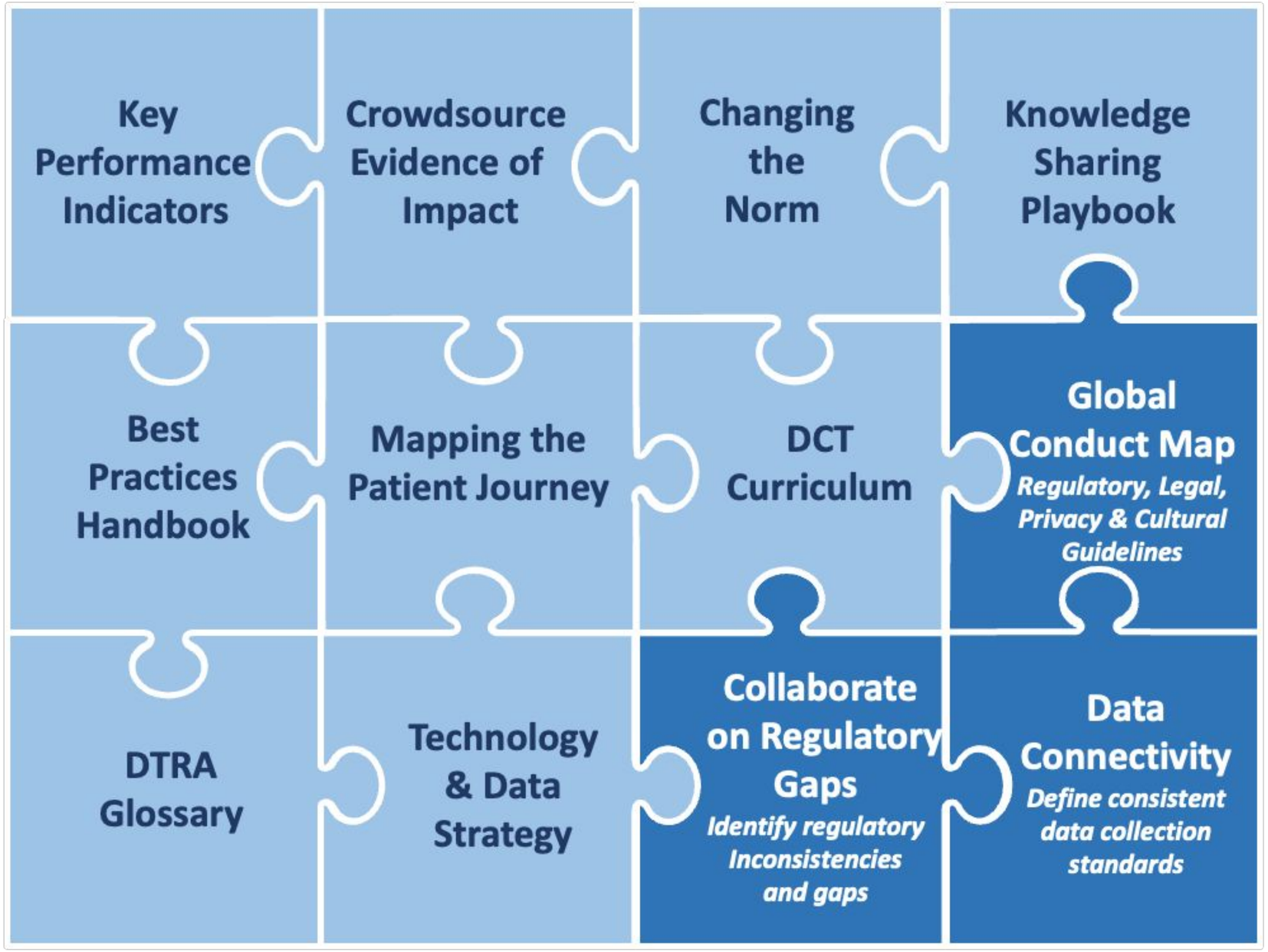
REMOVING BARRIERS TO ADOPTION



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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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