

DTRA Initiatives

Monthly 'all hands' meeting

March 30, 2023

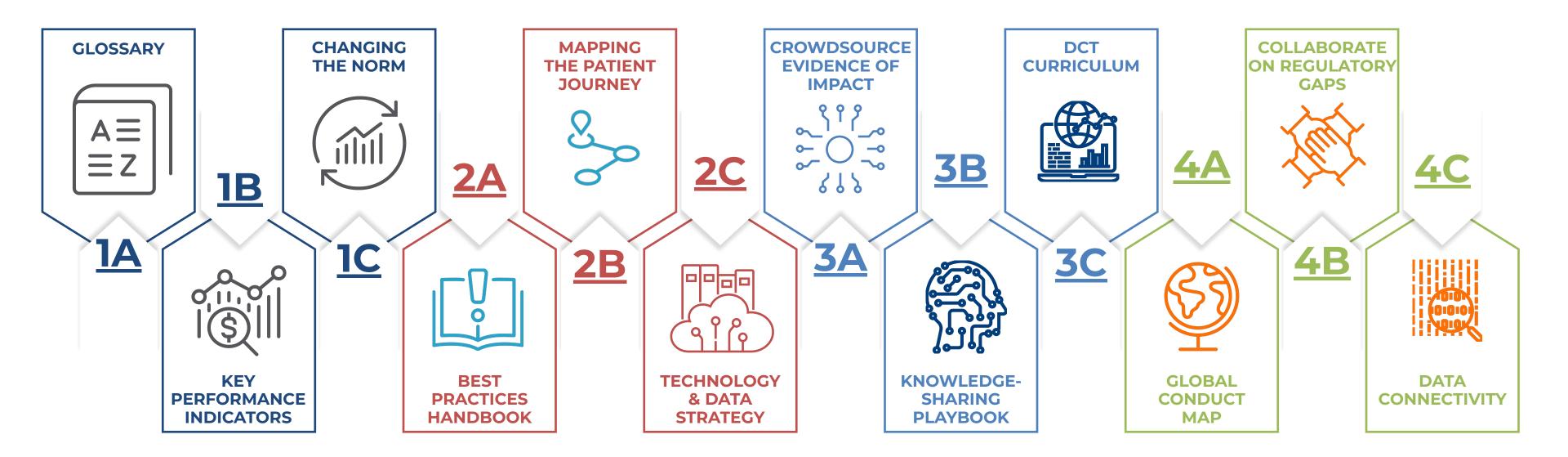


DTRA INITIATIVES AGENDA

- Welcome & Agenda Claudine
- 1B KPIs: User case review Anna
- Update from team 2C Data & Technology Strategy Toni
- Update from team 4C Data Connectivity Munther/Moulik
- Content Council Update- Jane
- DTRA updates
 - Circles
 - Clubhouse events



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.



DECENTRALIZED TRIALS & RESEARCH ALLIANCE



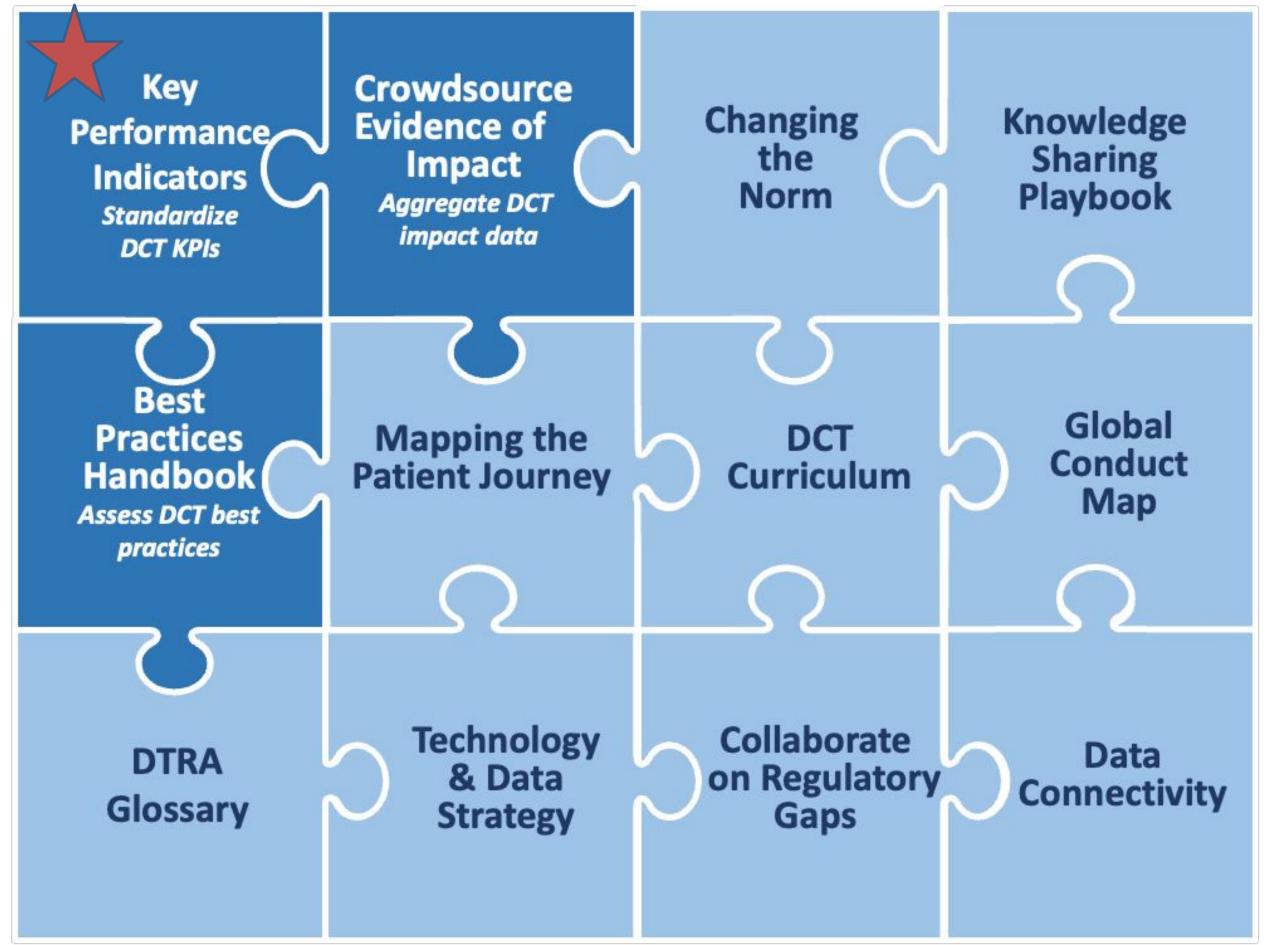
Volunteers from our Member Organizations are assembled on Initiative Teams to work together to achieve a deliverable that contributes to the larger goal of the Priority.





Global Organizations

MEASURING SUCCESS WITH DCTs







DTRA Initiatives 1B KPIs: Use case/deep dive with CATORI Study

Co-Leads: Anna Yang (Roche/Genentech), Shelly Barnes (UBC) Mar 30, 2023



DTRA 1B KPIs

Problem:

Different organizations tracking and reporting inconsistent quantitative and qualitative measurement of DCT impact; Impacts speed of stakeholders working together and limits benchmarking or aggregation to drive uptake

Deliverable:

Establish clear DCT Benchmarks that highlight the productivity and impact of DCTs following the standard language from the definition's glossary

Actions

- KPIs were posted to internal DTRA Community in Q2 '2022
- Feedback requested from DTRA members
- KPIs being applied in a 'Use Case'



DTRA Team 1B: Final Draft for KPIs for DCTs FOR DTRA INTERNAL MEMBERS ONLY

	Stakeholder	Metric	Calculation Method	
1	Patient, sites	Likelihood to engage in a DCT	Net Promoter Score (NPS), a metric that uses customers' likelihood to recommend a product, service, of The scale is rated from 0 (not at all likely) to 10 (extremely likely). - Promoters: score of 9 or 10 - Passives: score of 7 or 8 - Detractors: score of 0 to 6 NPS = Total % of promoters – total % of detractors	
2	Patient, sites, Sponsor	Patient drop out % - for a "patient decision"	% of patients who have been randomized / intent to treat (at least 1 visit) and has left the trial due to "	
3	Patient, sites, Sponsor	Number of adverse events reported per number of randomized participants	Total number of AE and SAE reported per number of randomized participants	
4	Sites, Sponsor	Speed: enrollment rate	Number of patients enrolled per month / site or Period between first patient enrolled to last patient or met the LPI or not (Y/N) + margin by which you have met the LPI	
5	Sites, Sponsor	Variance vs target population group	For each domain (geographic, ethnicity, disease types, age, commute) and per study: - Define target - Calculate gap (in % pts) Geography: +/- 50 miles from a PI Ethnicity: 25% enrolled are categorized as part of the ethnic "minorities" Commute: >1hour	
6	Sites, Sponsor	Referral base increase due to patients engaged in DCT	Gap of referred patient pool (within total HCP patient pool)	
7	Sponsor	More patients/site: % of total patients enrolled per site	Average number of patients enrolled in CT per site	
8	Sponsor	Database lock timelines	Database lock - LPLV (telehealth visit in the case of DCT)	
9	Sponsor	Protocol deviations number	% of patient having at least one protocol deviation (different level of severity)	
10	Patients	Re-inclusion of patient in CT due to DCT facility	% of additional eligible patients that can be reached	

- Plans for the document: Release internally first to DTRA community on May 4, 2022 with the intention to release to the public at the end of 2022.
- Directions for use: Please run these metrics through a DCT use case and provide feedback on if metric makes sense and/or if additional context for use is needed. Please provide feedback via Basecamp and the co-leads, Shelly Barnes (UCB) and Anna Yang (Roche), will meet to review feedback. Thank you!



	Scope of Metric
e, or organization as a score for your customer experience.	 Eligible patient prior to joining a CT Patient enrolled in standard CT, eligible for DCT
o "patient decision"	All DCT, split to distinguish full DCT vs hybrid DCT
	All DCT
	All DCT, calculate it at trial level, site level and sponsor
	All DCT
	Investigator site participating in DCT
	All DCT
	All DCT
	All DCT
	All DCT

DTRA Team 1B: Final Draft for KPIs for DCTs FOR DTRA INTERNAL MEMBERS ONLY

KPIs assess operational performance and effectiveness of DCTs

ENROLLMENT

1. Likelihood to engage in a DCT	2. Dropout % du
4. Enrollment rate SITE SPONSOR	3. Number of AE
5. Variance vs Target Population Group SITE SPONSOR	9. Protocol Devia
6. Referral Base Increase SITE SPONSOR	8. Database lock
7. More patients per site SPONSOR	

10. Re-inclusion of Patient in CT due to DCT PATIENT



OPERATIONS

due to Patient Decision

AE per Randomized Participants

PATIENT SITE SPONSOR

viation #s sponsor

ck times **SPONSOR**

STAKEHOLDER

PATIENT SITE SPONSOR

CONSOLIDATED METRICS AS OF MARCH 30, 2022 Pending Feedback from DTRA Community

	Stakeholder	Metric
1	Patient, sites	Likelihood to engage in a DCT
2	Patient, sites, Sponsor	Patient drop out % for a "patient decision"
3	Patient, sites, Sponsor	Number of adverse events reported per number of randomized participants
4	Sites, Sponsor	Speed - Enrollment Rate
5	Sites, Sponsor	Variance Vs. target population group
6	Sites, Sponsor	Referral base increase due to patient engagement in DCT
7	Sponsor	More patients/site - % of total patient enrolled per site
8	Sponsor	Database lock timelines
9	Sponsor	Protocol deviations number
10	Sponsor DTRA	Re-inclusion of patient in CT due to DCT facility

DECENTRALIZED TRIALS

RESEARCHALLIANCE

Scope of Metric

- Eligible patient prior to joining a CT Patient enrolled in standard CT, eligible for DCT
- All DCT, split to distinguish full DCT vs Hybrid DCT
- All DCT
- All DCT, calculated at a trial level, site level, and sponsor
- All DCT
- Investigator sites participating in DCT
- All DCT
- All DCT
- All DCT
- All DCT

DTRA 1B KPIs

Use Case: CATORI

CATORI is a Genentech-sponsored observational study looking to define the current care pathways available for American Indian or Alaskan natives requiring specialty care (oncology, neurology or ophthalmology)

Hybrid trial (n=150)

- Has both brick & mortar sites and virtual site
- Open to patients anywhere no need to live on tribal land/close to a physical site to participate

More information available at: https://www.catoristudy.com/

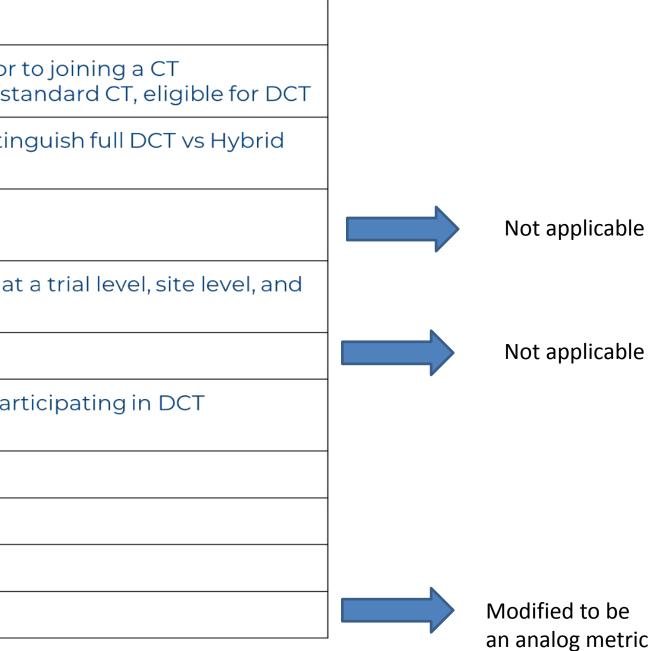


CONSOLIDATED METRICS

		1	
	Stakeholder	Metric	Scope of Metric
٦	Patient, sites	Likelihood to engage in a DCT	Eligible patient prior Patient enrolled in st
2	Patient, sites, Sponsor	Patient drop out % for a "patient decision"	All DCT, split to distin
3	Patient, sites, Sponsor	Number of adverse events reported per number of randomized participants	All DCT
4	Sites, Sponsor	Speed - Enrollment Rate	All DCT, calculated a sponsor
5	Sites, Sponsor	Variance Vs. target population group	All DCT
6	Sites, Sponsor	Referral base increase due to patient engagement in DCT	Investigator sites par
7	Sponsor	More patients/site - % of total patient enrolled per site	All DCT
8	Sponsor	Database lock timelines	All DCT
9	Sponsor	Protocol deviations number	All DCT
10	<mark>Sponsor</mark>	Re-inclusion of patient in CT due to DCT facility	All DCT

All 10 KPIs may not be applicable in every trial





	Stakeholder	Metric	Calculat
1	Patient, sites	Likelihood to engage in a DCT	Team 1B: calculatio
			 CATORIC Transc Questi Measu Son Son Captu This main trade



ation Method

: use net promoter score (NPS)-type ion.

application:

celerate Study Participant Feedback tionnaire (SPFQ) ured through surveying patients me 0-4 scale questions me Y/N questions ured at predefined time intervals nethod is not unique to DCTs - captured ditional trials

	Stakeholder	Metric	Calcula
2	Patient, sites, Sponsor	Patient drop out % for a "patient decision"	Team 1B been rar and has
			 CATORI Will s Calcuto to "page



ation Method

B: calculate the % of patients who have andomised / intent to treat (at least 1 visit) s left the CT for a "patient decision"

application:

survey Curebase virtual site(s) ulate % of patients who leave the DCT due patient decision"

	Stakeholder	Metric	Calculat
3	Patient, sites, Sponsor	Number of adverse events reported per number of randomized participants	Team 1B: per numl
			 CATORI a Not ap not co

Not applicable

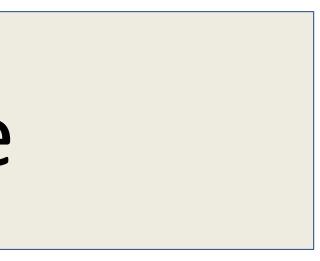


ation Method

: Total number of AE and SAE reported ober of randomised participants

application:

pplicable because safety information is ollected (non-interventional setting)



	Stakeholder	Metric	Calculation Me
4	Sites, Sponsor	Speed - Enrollment Rate	 Team 1B: Number of pa Period betwee Met the LPI or met the LP
			 CATORI application Collected through Rate of enrolling (patients per mission)



lethod

atients enrolled per month / site **or** een first patient enrolled to last patient **or** or not (Y/N) + margin by which you have

ation:

ough Sponsor (GNE) or CRO (Curebase) Iment at virtual site vs physical site month)

	Stakeholder	Metric	Calculation Me
5	Sites, Sponsor	Variance Vs. target population group	Team IB: For eac types, age, comr - Define target (e - Calculate gap (e
			 CATORI application Not applicable to enrolling model be targeted

Not applicable

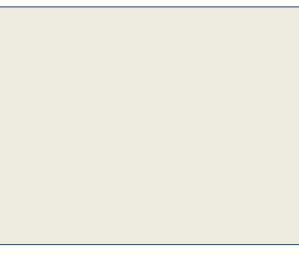


lethod

ch domain (geographic, ethnicity, disease mute) and per study: (eg: want to enroll 15% AA) (eg: we historically enroll only 5% AA)

ation:

ne because CATORI is a study dedicated minority patients - there is no variance to



	Stakeholder	Metric	Calculation Meth
6	Sites, Sponsor	Referral base increase due to patient engagement in DCT	Team 1B: Gap of refe patient pool)
			 CATORI application Collected by CRC Comparison of: Distance from patient (tradition Distance from because the value



hod

erred patient pool (within total HCP

n: O (Curebase)

n a brick & mortar site to a brick & mortar tional distance) n a brick & mortar site to a virtual patient **virtual patient can come from a Ily unlimited location** (DCT distance)

	Stakeholder	Metric	Calculation Meth
7	Sponsor	More patients/site - % of total patient enrolled per site	Team 1B: Average nu
			 CATORI application Collected by spor



hod

number of patients enrolled in CT per site

onsor (GNE) or CRO (Curebase)

	Stakeholder	Metric	Calculation
8	Sponsor	Database lock timelines	Team 1B: Data DCT)
			CATORI applCollected t



n Method

abase lock - LPLV (telehealth visit in the case of

lication: through Sponsor (GNE)

	Stakeholder	Metric	Calculation Meth
9	Sponsor	Protocol deviations number	% of patient having level of severity)
			CATORI applicationCollected throug



hod

g at least one protocol deviation (different

o**n:** gh Sponsor (GNE)

	Stakeholder	Metric	Calculation Method
10	Sponsor	Re-inclusion of patient in CT due	Team 1B: % of additional elig
		to DCT facility	 CATORI application: Collected through CRO (Analogue measure to de mechanisms this patien participate We will measure the use Reimbursement suppor device, wifi access, etc), (

Analog Measurement



ligible patients that can be reached

(Curebase) letermine what other support nt population needs to be able to

e of: Transportation support, rt, Tech access support (ie providing a CRC data entry for participants who

DTRA Initiative 1B KPIs

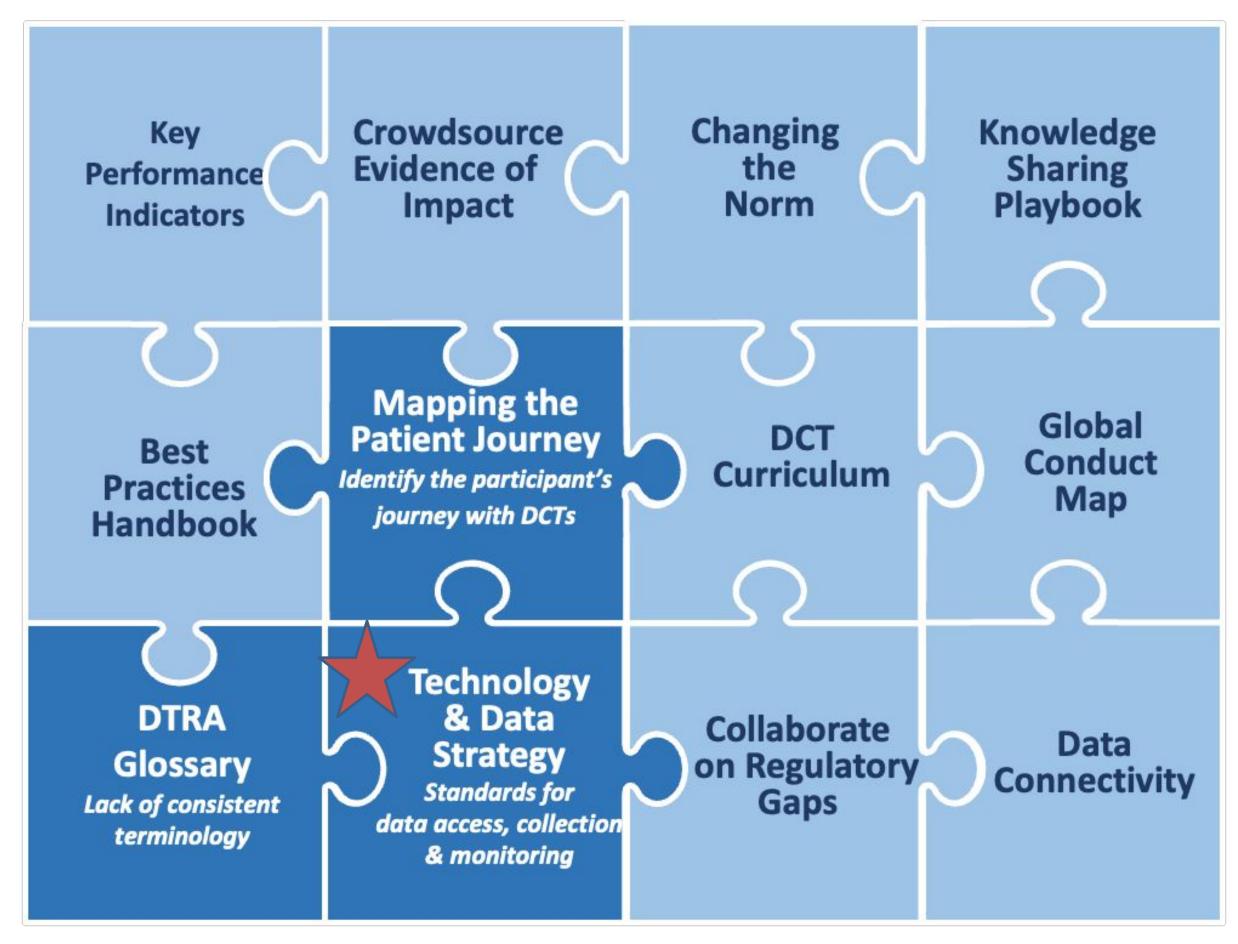
DEEP DIVE INTO METRICS

Questions?



23

SETTING FOUNDATIONAL DCT STANDARDS







2C Priority Initiative Status Updates

March 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 Completed, with a

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/feed
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/feed



edback from interested 4C

edback 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
- Clawud Reem, Kearney
 Dependencies:
 Kishori Khokarale, ZS 1A Glossary
 2B Patient Journey Maps
 4B Regulatory Gaps
- 4C Data Connectivity

DCT Technology & User Ecosystem - 2C Team

Overall Status:

Deliverable

Timeline: Completed on 31 January 2023

		DCT Technology &	User/Personal Eco	system Grid by Tr	ial Milestone		
	Trial Planning	Trial Start	up	Patient Recr	uitment & Consent	Trial Conduct	Tr
	Site Feasibility	Trial Startup	Pre-trial / Prescreening	Patient Recruitment	Consent/Screening/Enrollment	Study Conduct	
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 process of the process of from	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 or contation an necous of dev ces/ke /survies	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 criferia.	Participant consent to study enrollment.	Conduct occurs from first patient in through last patient out.	Clo tim loc sub to r sta
Actions				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 Cou Des
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, Pharmast, Phlebotomist), Study Manageme Team	Site cationatie less of sat, RV RWE, Study Manage of Team	Site Souff, Patiens Recrument, Study Management Team	Site Staff, Technology Teams, Study Management Team, Patient Recruitment	Site Staff, Patient Recruitment, RWD/RWE, Study Management Team, Technology Teams	Site Stu Tea
DCT Technology	Router/WiFi Geomapping Investigator data bank (RWD patient populations and RWD secondary arms)	<u>Site</u> : eConsent, Prescreening, eSource, eISF, eCOA, IRT, Clinical Trial Payments, Telemedicine, CTMS, LMS <u>Sponsor</u> : CTMS, eTMF, EDC <u>Patient</u> : ePRO, sensors/mobile devices	(diagnostics) Investigator data bank (RWD	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)	eSc eTN wea Pha eAr



Challeng

e:

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

Trial Close Out & Reporting Study Close Out

Close out occurs at the time the database is locked followed by submissions and back to regulatory/ethics, statistical analysis, etc.

ite, Sponsor/CRO, Country Regulatory Designee

Site Staff, Regulatory, Study Management Feam, Technology Feams, IRB/EC

eSource, CTMS, EDC, eTMF, eISF, eCOA, wearables/sensors Pharmacovigilence, eArchiving

Draft Solution:

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

Final Solution:

We challenged the final toolset of our deliverable. We agreed that using the milestone draft solution is a great template to build upon the Patient Journey template and create a new a 'layer' of DCT technology and User/Persona Ecosystem.

Work ahead:

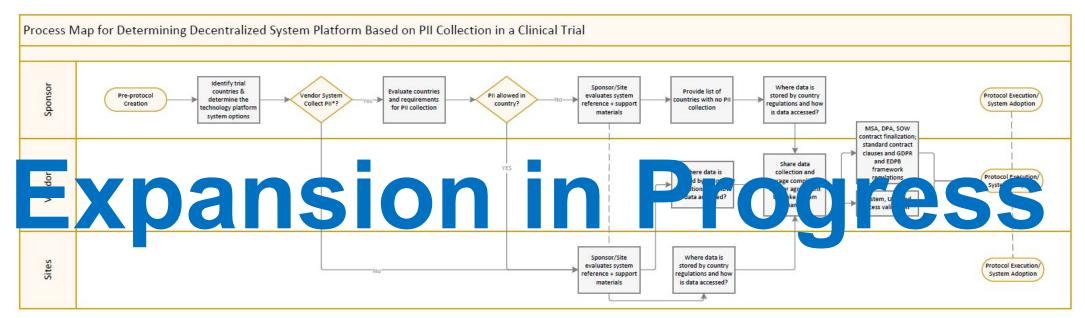
Obtain the original Patient Journey template to map out our new 'layers', as though they were tabs in a notebook.

Regroup with the 1A Glossary Team on creating new definitions across the final milestones of a DCT.

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

Overall Status:

Deliverable Timeline: Completed on 31 January 2023



System Agnostic Technical Solutions

Participant invites and registration without collecting identifiable information **Provisioned Emails** No PII Workflow Vendor's new system Vendor's current System release to utilize non PII Provisioned Emails Service solution excluding email provided by an external 3rd party vendor with no PII addresses / onboard with site email address included t & Data Center in EU With a "No PII" study, a participant should This is an approved process that ensures use be able to create their account by entering Email accounts are created without referencing to the invite code provided directly from the the PII and handed over to the participant with site (not over email or text/SMS) and by proper instructions. Events that could trigger emo account provisioning - New participants (does not creating their username and password. This have an email address / does not want to provide is to prevent the collection of any PII to register and access that study a personal email address to access the system)





Challeng

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

Solutio

n:

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.

We also challenged the final toolset of our process map deliverable. We agreed that this could use additional vetting to draw out more of the decision making.

Work ahead:

Expanding our scope to provide additional branches to ensure the process is inclusive of today's DCT environment where hybrid is a reality and PII can be accommodated.

Identifying where this intersects with the 4C team with their solution, with this possibly existing as a tool to determine how PII management is factored per trial/region.

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

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Will need assistance to bring the 2C and 4C team members and others across DTRA together and execute this final jointly shared initiative. Moulik and Toni are able to provide guidance, but collectively, 2C and 4C may not have sufficient team members engaged to execute this final initiative.



dback from interested 4C

edback from interested 4C

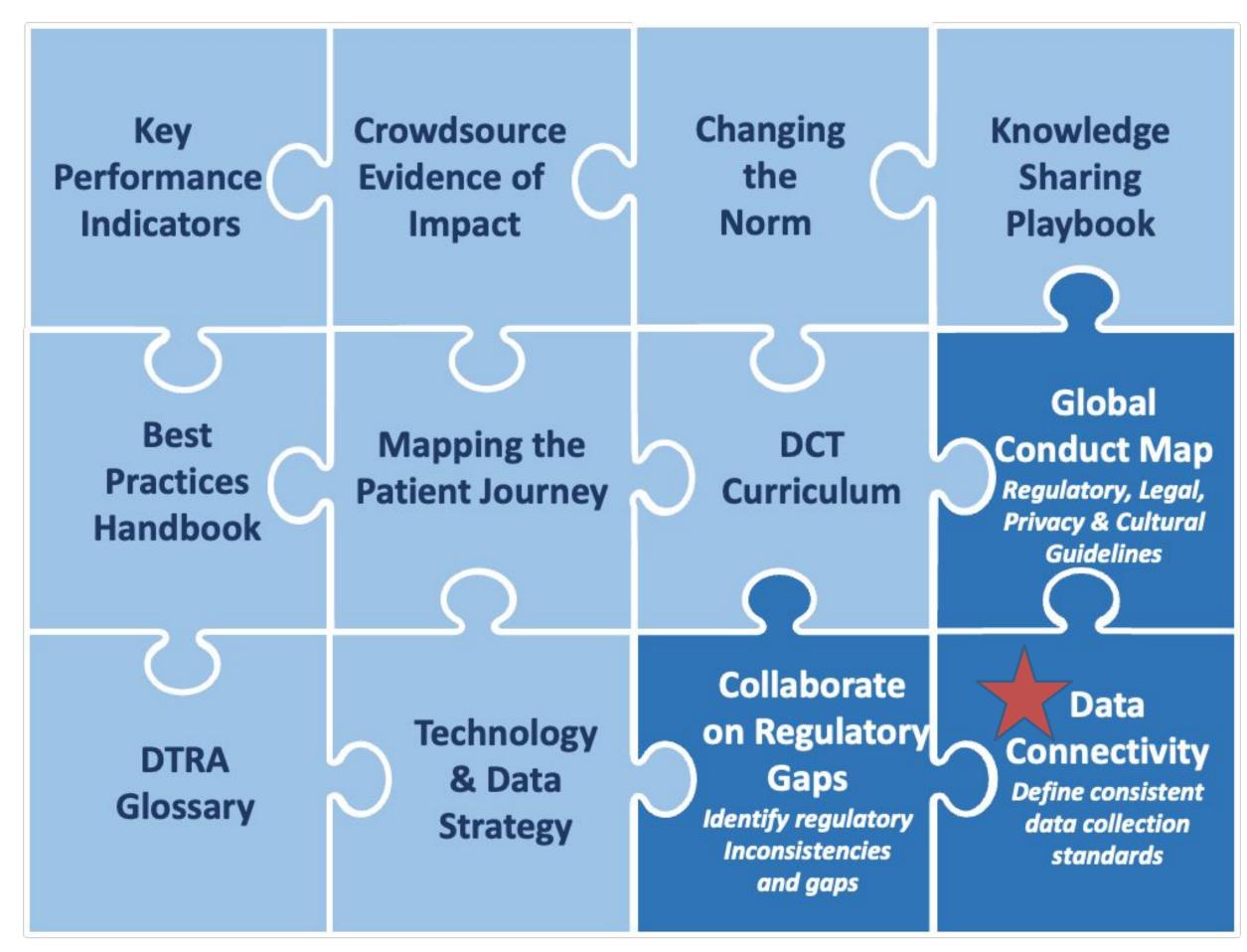
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 4B Regulatory Gaps
- 4C Data Connectivity

REMOVING BARRIERS TO ADOPTION







Content Council Operational Model and Scope

30 March 2023 Jane Myles



PROBLEM STATEMENT

- The DTRA is committed to maintaining current digital content aligned to Priority Areas and based on Initiative deliverables.
- As initiative deliverables are achieved and approved, the initiative teams will dissolve and/or evolve
- DTRA needs to establish a process / resource to curate and update digital content following the publication of initial deliverables.



CURRENT STATE

- Initiative teams are struggling with equitable commitment and contribution from members.
- Some initiative teams are nearing or at initial deliverable completion, and members want to move off the teams.

DESIRED FUTURE STATE

Deliverables are handed off and updates are managed by a small group to maintain up-to-date / relevant content

THE CONTENT COUNCIL



CONTENT COUNCIL

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

Current Scope

Initiative collateral that has been developed / released as V1 to DTRA.org website

- content

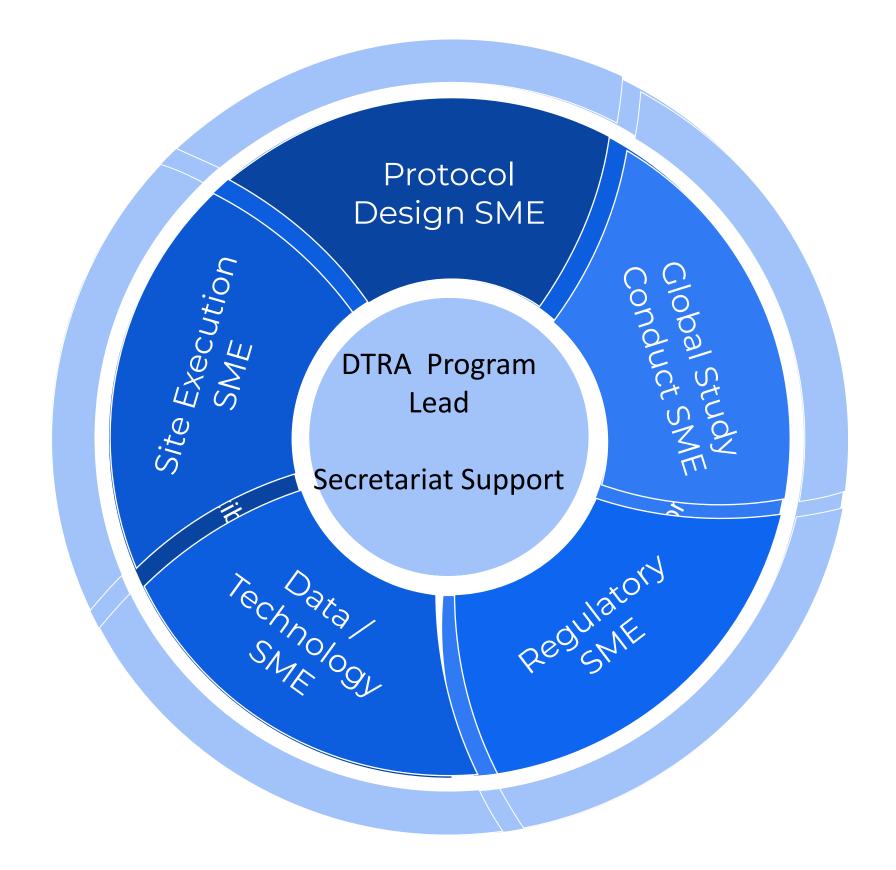


Expectations

Review feedback asynchronously Bi-monthly meeting to make decisions Ensure content reflects current state knowledge / evidence Support adoption through relevant

Proposed Structure

- Asynchronous review
- Bi-monthly meetings
 - Structured agenda
 - \circ DTRA chair
 - Clear decision making model
 - $\circ~$ e.g. Prior initiative lead or PSC agress?
- Decision outputs to HighTouch for changes
 - $\circ~$ Post website go-live
 - Within 5 business days of mtg





Initial Scope (Q1 2023)

• 1A: Glossary updates

- Feedback forms and input from IMI / CiteLine, etc
- 1B: Metrics and KPIs
 - Feedback form input and any team feedback on utility / ease of use (Survey?)
- 1C: Once whitepaper is in digestible form, Content Council will ensure information remains relevant. They can 'sunset' the information if it gets dated.

2A: Best Practices Rubric

update versions of the rubric or sunset portions that become not useful

• 2B - Patient Journey Maps and Template

• *Review Feedback from teams*



Q2 2023 Scope

• 3A: Evidence of impact

- Library submissions (ie to journals / case studies with DTRA Secretariat Curation?)
- Creation of a case study template?

4A: Regulatory Conduct Map

Objective assessment tool for visualization in progress (TAG) but not yet begun

4B: Regulatory Gap Assessment

• Specifically, focus on including links to any Regulatory guidelines a





CIRCLES: Functional Collaboration



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
- First three areas of focus:
 - Diversity Leads for DCT
 - Patient Recruitment leads for DCT
 - Data Management leads for DCT
- Provide space for connecting and sharing

 - Bi-Monthly or Quarterly meet-ups • Online connections

DTRA CIRCLES Who

- Team members of DTRA Members who work on the functional challenges daily with
 - DCT focus
 - No level limitation
 - From any region
 - Share challenges
 - Share solutions
 - Ask questions

- <u>Complete Form</u> to express interest
- DTRA is helping ID best meeting time / 2. cadence
 - DTRA will add you to a Slack channel for each Circle (e.g. Diversity / Data Mgt)
- 3.
- 4. Ask for Volunteers from Circle to 'lead' each meeting

- All-hands mtg (Oct) DTRA Annual Mtg (Nov)
- Shared lessons learned

How

Outputs:

DTRA - INITIATIVE OVERVIEW

Foundatio	nal Intiatives: D	OCT 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 D	СТ	
1B	KPIs	version 1.0 published internal to DTRA for feedback	Q1
2 A	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.	complete

ipporti	ng DCT with Educ	ation 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	
emoving 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	complet	
4C	Data Connectivity	Team meetings underway after the rescope	Q2	



COMING NEXT!

• Look for the CoLabs Launch!

• Next meeting, April 27th



