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Behind Multisite Trials Coordinating Center: Building and Sustaining Effective Data Coordinating Centers (DCCs)

TALK 1 – ROLES AND RESPONSIBILITIES IN EFFECTIVE DCC FORMATION AND OPERATIONS

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Center for Biostatistics
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The Ohio State University

What Does It Take to Build an Effective DCC?

- DCCs are central to data integrity, study quality and reliable trial execution.
- Building a DCC requires clear roles, defined structure, and coordinated processes
- **Central Question =>** What roles, structures, and processes make a DCC reliable, transparent, and efficient?
  - Core functions of a DCC
  - Team structure and roles
  - Lessons learned from building a new DCC

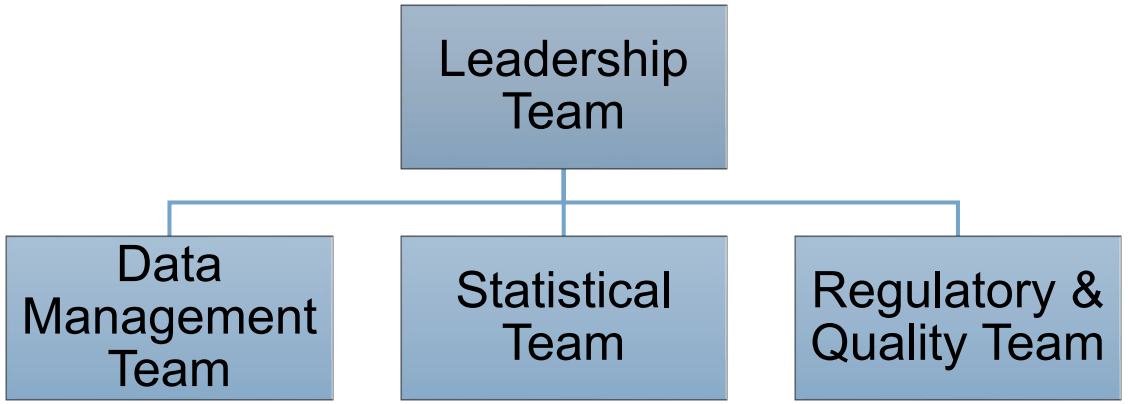
It is the job of the CC to constantly "herd cats" and keep everyone focused on the larger agenda of the consortium while seeking to understand and meet the professional objectives of all collaborators (Rolland et al. 2011)

Core Functions of a DCC

- **Study design & protocol development** — input on endpoints, randomization, feasibility
- **Data management** — collection systems, database build, EDC oversight
- **Quality control & assurance** — edit checks, query management, site auditing
- **Statistical analysis** — analysis plans, interim monitoring, final reporting
- **Regulatory & compliance oversight** — IRB coordination, adverse event reporting, TMF management (in coordination with clinical arm)
- **Project/operations management** — timelines, budgets, site communications

How to Structure a DCC (Org Chart Overview)

- Leadership Team
- Data Management Team
- Statistical Team
- Regulatory & Quality Team
- Other necessary components



How to Structure a DCC (Org Chart Overview)

- **Leadership Team**
  - Principal Investigator / DCC Director — scientific vision, sponsor/stakeholder relations, accountability
  - Operations or Administrative Director — day-to-day execution, resource management, cross-functional integration
- **Data Management Team**
  - Data Manager / Lead — system design, standards, workflow oversight
  - Data Coordinators — site support, query resolution, data entry oversight
  - Clinical/Biomedical Informatics / IT — EDC build, system validation, integration
- **Statistical Team**
  - Lead Biostatistician — SAP development, DSMB support, analysis oversight
  - Statistical Programmers / Analysts — SAS/R programming, table/figure/listing production
- **Regulatory & Quality Team**
  - Regulatory Affairs Specialist — IRB submissions, amendments, compliance tracking
  - QA/QC Specialist — SOPs, audit readiness, internal monitoring
- **Other necessary components**
  - Single point of contact
  - Escalation/remediation plan
  - Communication Plan
  - Evaluation Plan (optional, but recommended)

Lessons Learned (New DCC Experience)

- **Build structure early**
  - Need infrastructure early (***including a strong clinical trial management system!***)
  - SOP development activities are essential
  - Intentional planning
- **Invest in capacity and time**
  - Need protective time to identify opportunities and develop proposals
  - Need Institutional support (***it is hard to secure funding for building infrastructure*!)**
  - Time to mature and earn recognition ***(funding priority given to applicants that are ready from the outset)***
- **Build the right team**
  - Need to invest in management/coordination capacity, not just scientific roles ***(data coordinators with years of experience)***
  - Need clinician expertise integrated into DCC work
- **Learn the ecosystem (ongoing self-education)**
  - Different funding mechanisms
  - National networks and expectations
- **Ensure coordination**
  - Importance of clear communication structure across teams and sites
- **Establish a collaborative environment; complemental to clinical coordination**
  - ***It is difficult to "convince" clinical researchers of the need for a DCC; "we underscore how our process complements the clinical coordination center"* (Abebe et al. ConCTC 2019)**

Key Takeaways

- **DCC are built on:**
  - Clear roles
  - Defined structures
  - Well-articulated processes *(including a strong communication plan)*
- **Leverage:**
  - Institutional infrastructure
  - Established track record
  - Clinician expertise
- **Success depends on:**
  - Strong coordination
  - Integrated teams
  - Reliable, transparent processes *(promote a culture of trust, openness and inclusivity)*

References

- Rolland B, Smith BR, Potter JD. Coordinating centers in cancer epidemiology research: the Asia Cohort Consortium coordinating center. Cancer Epidemiol Biomarkers Prev. 2011 Oct;20(10):2115-9. doi: 10.1158/1055-9965.EPI-11-0391. Epub 2011 Jul 29. PMID: 21803842; PMCID: PMC3189300.
- Abebe et al., Creating an academic research organization to efficiently design, conduct, coordinate, and analyze clinical trials: The Center for Clinical Trials & Data Coordination. Contemporary Clinical Trials Communications. Volume 16, 2019.
- Kim, H. The Invisible Infrastructure of Multisite Clinical Research: Why Data Coordinating Centers Matter, Society for Clinical Trials Newsletter, March 6, 2026. LinkedIn, https://www.linkedin.com/pulse/invisible-infrastructure-multisite-clinical-dumie.

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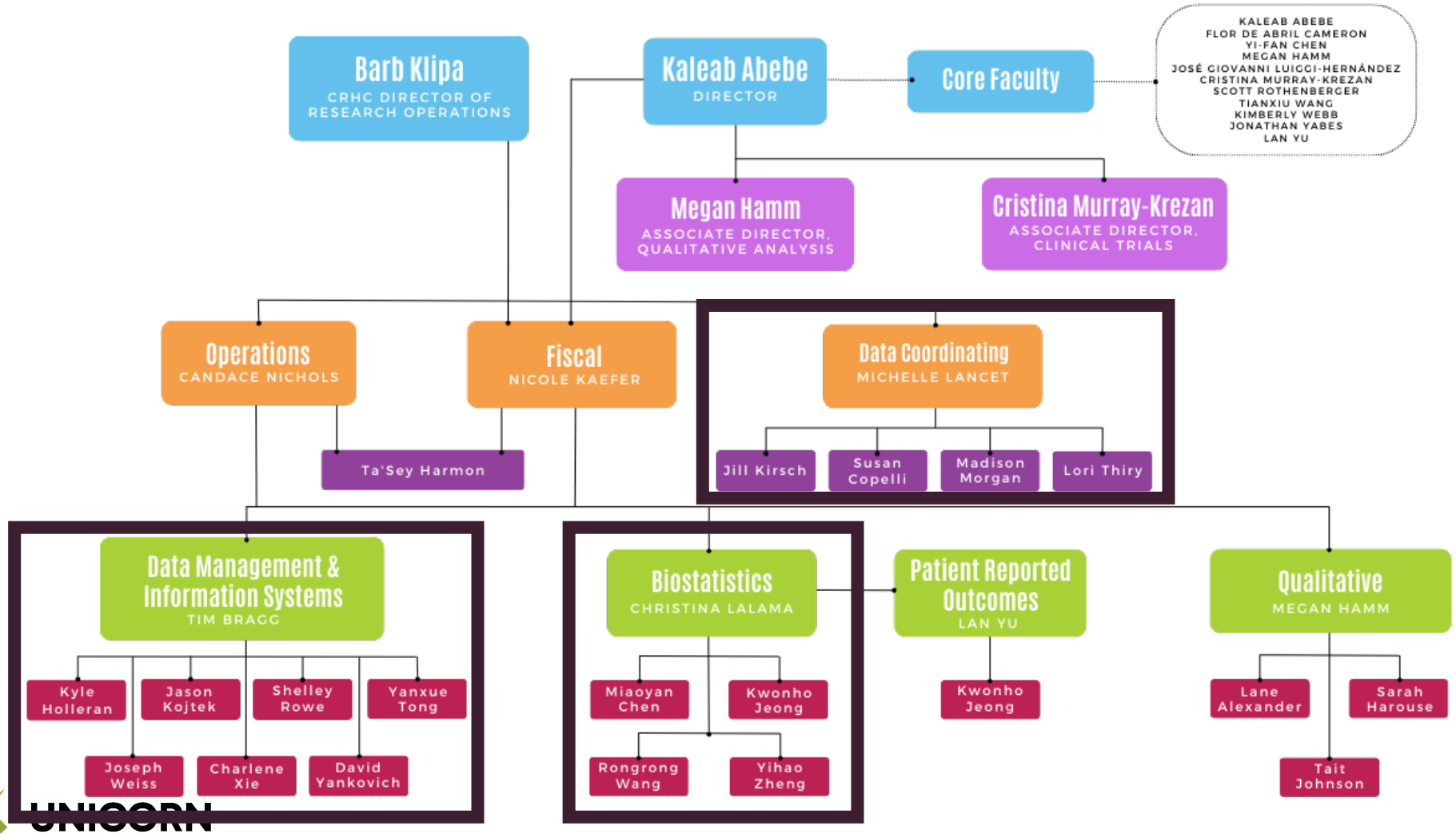
TALK 2 – CAREER PATHWAYS INTO DCCS

Kaleab Z. Abebe, PhD
Director, Center for Biostatistics & Qualitative Methodology
University of Pittsburgh School of Medicine

DCC Structure Overview — Center for Biostatistics & Qualitative Methodology

- CBQM:
  - A multidisciplinary research support center with 25+ years of serving University of Pittsburgh investigators and 1000+ research projects in our portfolio
  - We support investigators by providing world-class biostatistics, qualitative research, data management, and **data coordinating center** expertise to carry out high-quality clinical and translational research

DCC Structure Overview — Center for Biostatistics & Qualitative Methodology



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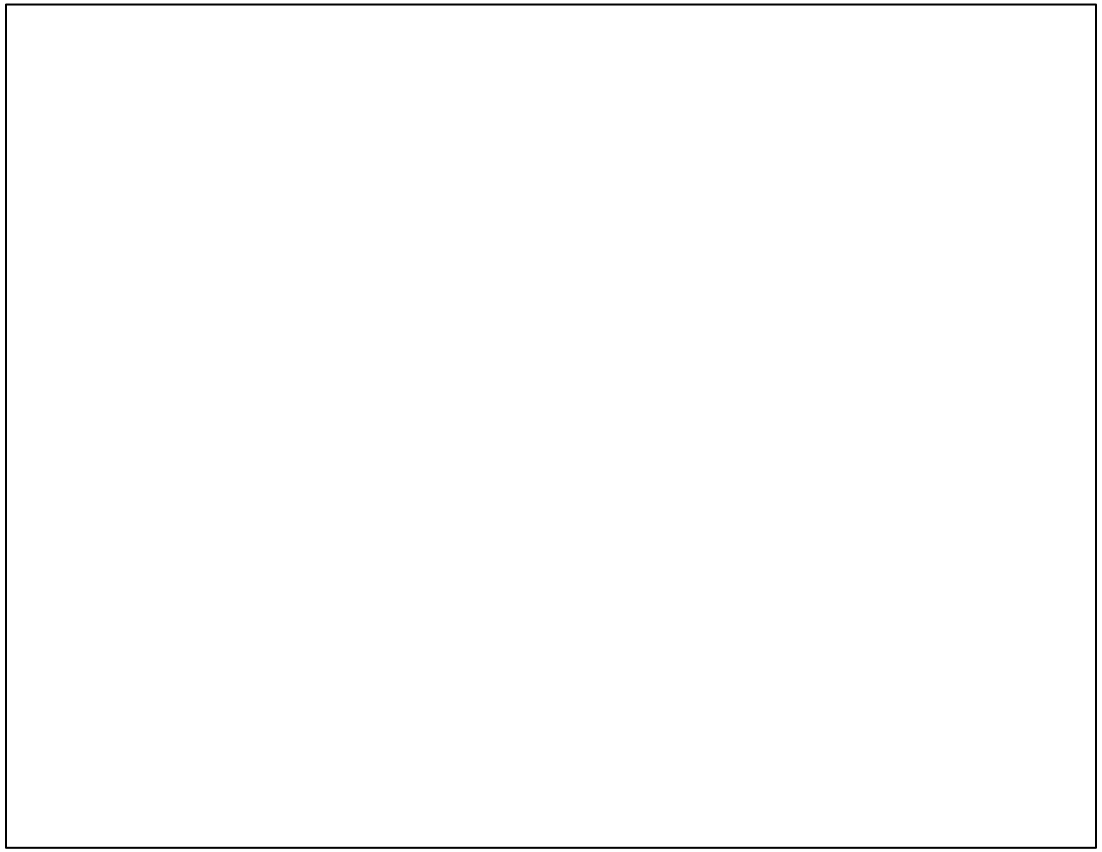
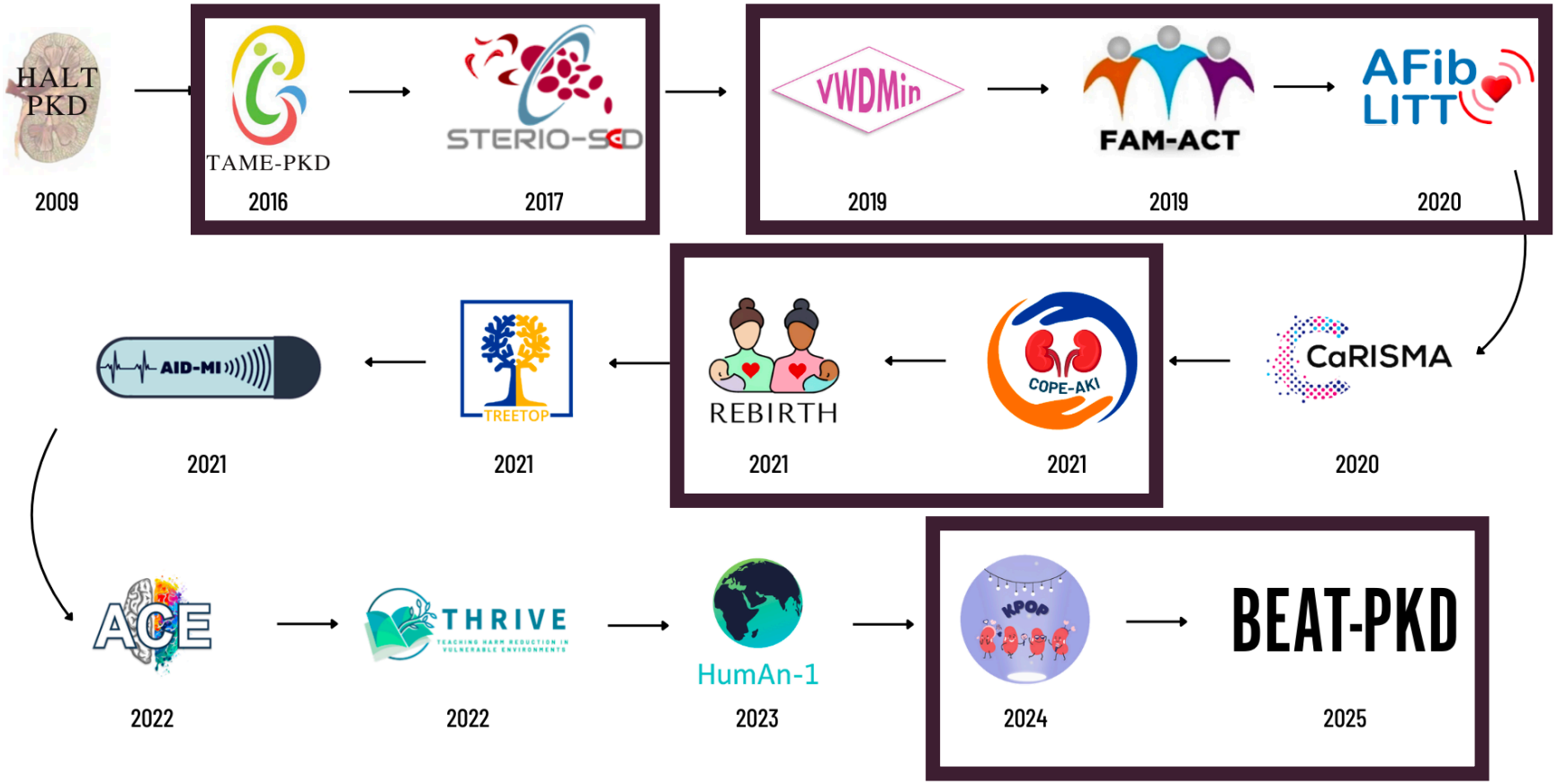
DCC Structure Overview — Center for Biostatistics & Qualitative Methodology

- CBQM-DCC:
  - Goal is to provide expertise in clinical trial design, conduct, and analysis.
  - Leverages strong statistical and data management/information system infrastructure to address key aspects of clinical trials management



DCC Structure Overview — Center for Biostatistics & Qualitative Methodology



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Strategies for Promotion and Advancement for Faculty and Staff

- Overarching Issues
  - RCTs can take a lot of time → few publications until the end
  - DCCs are still relatively new and unknown → questions around promotion and tenure
  - DCCs are large teams comprised of many staff → how to further their careers without dedicated funding

Strategies for Promotion and Advancement for Faculty and Staff

Advice for Faculty

- Think outside the traditional for manuscript ideas:
  - design/protocol papers
  - analyses of baseline data
  - trial management.
- Just because you're not the PI doesn't mean you're not a PI.
- Identify ways to get graduate student and junior faculty involved in DCCs
- Team science is becoming more valuable to institutions

Strategies for Promotion and Advancement for Faculty and Staff

Advice for Staff

- There are always opportunities to be an *expert* in something. CBQM examples:
  - ➢biostats core lead
  - ➢front- and back-end developer leads
  - ➢regulatory lead
  - ➢3rd party app integration expert

- Expertise + personnel oversight = promotion

Involving Students and Trainees in DCCs

Opportunities & Benefits

- Real-world experience with clinical trials
- Ability to collaborate in a multidisciplinary setting
- Authorship on papers
- Leveraging more advanced training/skills

Challenges

- Can be difficult to formalize if the DCC is outside of an academic department
- Natural turnover with graduate students

Key Takeaways

Well-run DCCs are critical to the success of multicenter RCTs

DCC personnel (faculty and staff) need to be supported and retained

DCC leaders need to think outside the box when it comes to career advancement for faculty and staff

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WORKING TOGETHER FOR VALUE AND IMPACT

Chris Lindsell, PhD, FACTS
Vice Dean, Data Science and AI
Duke University SoM

Why do DCCs matter?

- DCCs improve study design quality, data consistency across sites, analytical rigor
- DCCs enable secondary analyses and knowledge dissemination
- DCCs provide independent oversight, methodological innovation

DCCs result in more credible science

DCCs matter

Why do we have so few?

Why do DCCs vary so much?

Why don’t we have training programs?

How do we surface the impact and relevance of DCCs in today’s biomedical science?

The UNICORN Network

Formed via a 2024 national summit of 14 centers, now more than 70 members from 27 institutions and two countries. Targets for action include:

- Workforce gaps
- Leadership pipeline failure
- Regulatory complexity
- External/institutional misalignment
- Lack of standardization

The UNICORN Network Strategy

To support the shift from a loose community to an organization for impact with:

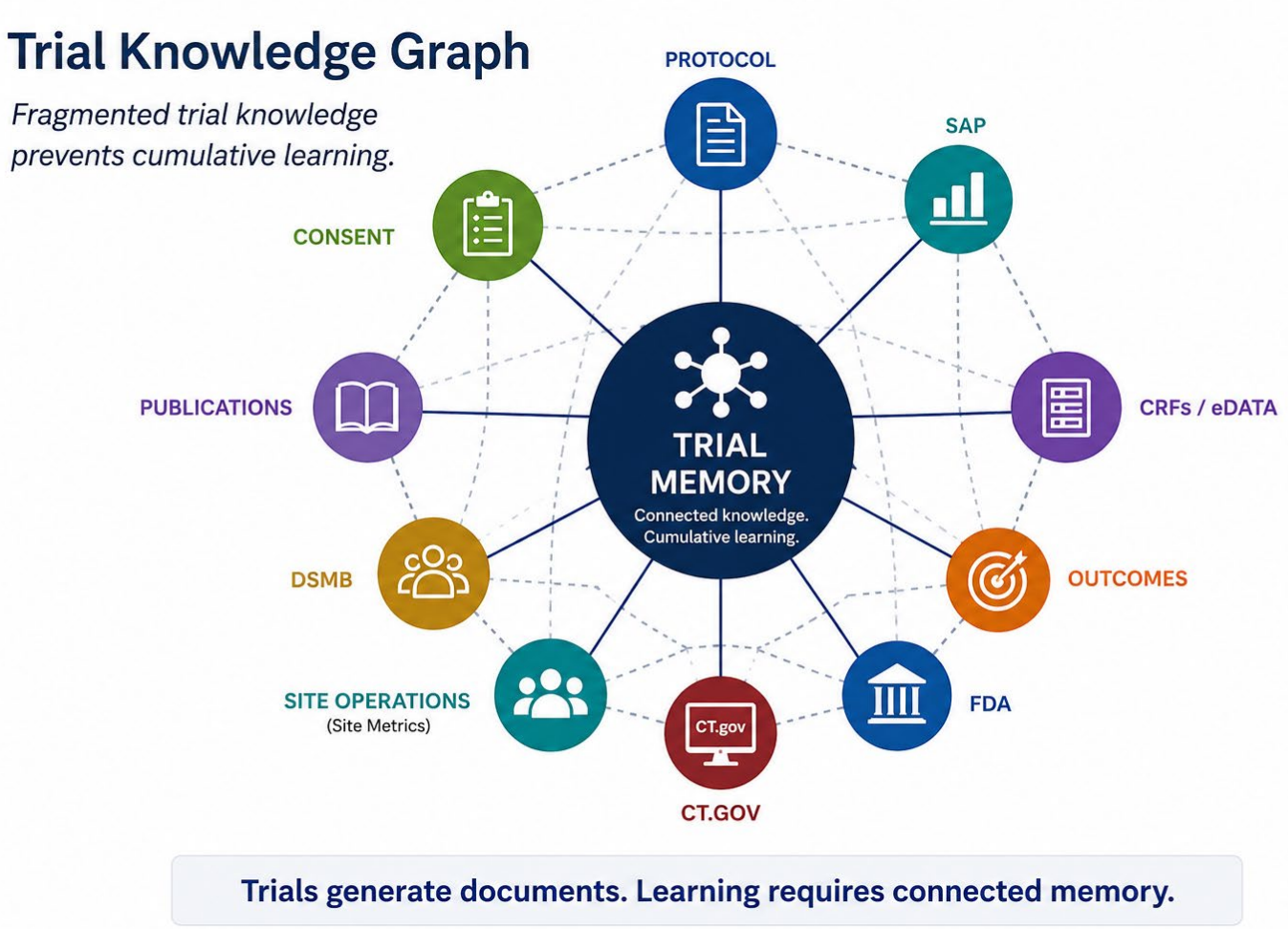
- *Shared infrastructure:* Templates, tools, SOPs
- *Workforce development:* Mentorship + leadership pipeline
- *Standards:* Minimum viable DCC infrastructure
- *Advocacy:* Position DCCs as essential infrastructure

The Future of Data Coordination

- DCCs support both federated and centralized models
- DCCs are critical to support rigor and reproducibility in decentralized trials
- DCCs drive data sharing and open science
- DCCs are integral to successfully enabling trial efficiencies using AI and other enabling technologies

The Future of Data Coordination

DCCs, centered in the UNICORN Network, are establishing a national Learning Research System



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The Future of Data Coordination

Biomedical research is becoming distributed, data intensive, and real time

This cannot function without strong DCC infrastructure

The UNICORN network is the mechanism to make that explicit, scalable, and sustainable

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THE HIDDEN SAUCE: OBSERVATIONS & QUESTIONS

Cathie Spino, ScD
Research Professor of Biostatistics
Director of SABER Center
University of Michigan

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Roles and Responsibilities in Effective DCC Formation and Operations

Soledad Fernandez, PhD

Why would an investigator engage with a DCC?

Core

- Statistics
  - Study design
  - Randomization
  - Final analyses
- Database build & data management, data integration
- DSMB support & reporting, interim analyses

& More…

- Project management
- Clinical monitoring
- Regulatory compliance
- Quality control & assurance
- Software development, websites, IT, security
- Bioinformatics
- Drug supply
- Clinicaltrials.gov (reporting)
- Grant advice & collaboration

Clarity in roles & responsibilities (RACI)

Start-up Activities	DCC	CCC
Project Infrastructure – Organizational structure & management plan; internal website; communication plan	X	
Contracting – Selecting sites; contracts & budgets		X
Regulatory -- IND application submitted to FDA; informed consent form template		X
ClinicalTrials.gov registration; protocol finalized	X	X
DSMB charter, DSMP, scheduling; protocol/ICF sIRB submission	X	
Data Collection & Quality – CRF finalized; database built; randomization schema; clinical monitoring plan, data management plan	X	
Site Activation – Site performance plan; MOP; site training on protocol/science procedures		X
Site training on database/data management procedures; collect site essential documents; provide “green light”	X	

Whole > sum of its parts

- Specialization in clinical trials across therapeutic areas
- Sufficient resources to provide backup
- Cross functional teams in a DCC – e.g., review of CRFs
  - Statisticians from analysis perspective
  - Clinical monitor from concordance with the protocol
  - Project manager from coordinator workflow

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CAREER PATHWAYS INTO DCCS

Kaleab Z. Abebe, PhD

Whole > sum of its parts

- DCC careers as clinical trialists
  - Statistician → specialization in clinical trial methodologies
  - Data manager → Society for Clinical Data Management offers the Certified Clinical Data Manager (CCDM) credential
  - Etc.

- All faculty & staff & students need
  - Clinical research understanding, therapeutic area knowledge
  - Desire to collaborate within DCC and with external collaborators
  - Love the not-one-size-fits-all reality and continuous learning
  - Curiosity

Challenges for career advancement

- For faculty & staff
  - Consider development of promotion pathways on a technical track, not just management (supervisory) track
  - E.g., research professor, research scientist
  - E.g., statistician expert, statistical manager

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WORKING TOGETHER FOR VALUE AND IMPACT

Chris Lindsell, PhD, FACTS

Our value & our impact

- Now, the emphasis is on cross-institutional collaboration among DCCs
- Requires a change in culture –
  - collaboration & not competition among our groups
  - infrastructure support from our institutions
  - funding from sponsors commensurate with the added complexities of modern & future trials

Call for new ideas is not new …

- "Progress on the clinical front has outpaced modernization of *clinical trial designs* used to study novel therapies within possibly heterogeneous – and potentially rare—patient subgroups" [1]
- Statistician Dr. Don Berry called clinical trials the "weakest links in the chain of knowledge for determining therapeutic advances", and noted "it is ironic that we take the same clinical trial approach to evaluate all manner of potentially amazing transformative experimental therapies and **yet we don't experiment with the design of the clinical trial itself**" [2]

[1] Billingham I, et al. Research methods to change clinical practice for patients with rare cancers. Lancet Oncol 2016; 17:e70-e80.
[2] Berry DA. The Brave New World of clinical cancer research: adapative biomarker-driven trials integrating clinical practice with clinical research. Mol Oncol 2015; 9:951-959

But the time remains now … for UNICORN

- Share our experiences, our tools
- Develop guidances & new tools
- Advocate
- SWATs – studies within a trial

- All within a dynamic new world with even more funding challenges, questions about how to wrestle with AI, and (some) existential crises for not just the gen Zs but for all

The hidden sauce

- Having fun and working hard
- Enjoying the company of colleagues
- Working together, passionate about making a healthier world for our loved ones

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Questions

1. What guidance would you give to someone who wants to start a DCC?
2. What is one new idea to improve DCCs?
3. How do DCCs improve rigor and reproducibility?
4. What is your greatest fear for the future of DCCs? Your greatest hope?
5. How do you convince your institution to provide infrastructure?
6. Describe one sure-fire way to hire your replacement as DCC director.
7. What is the right size for a DCC?
8. Why are academic medical center DCCs “so expensive”?
9. What are your thoughts on commercial software vs home-grown systems?

UNICORN Special Interest Group Gathering

- 5:30 PM – 6:30 PM
- Room: Palm 2AB (2nd floor)

Thank you!