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Establishing the UNiversity Data COoRdinating CeNter (UNICORN) Network to Advance Data Coordination in Clinical Research

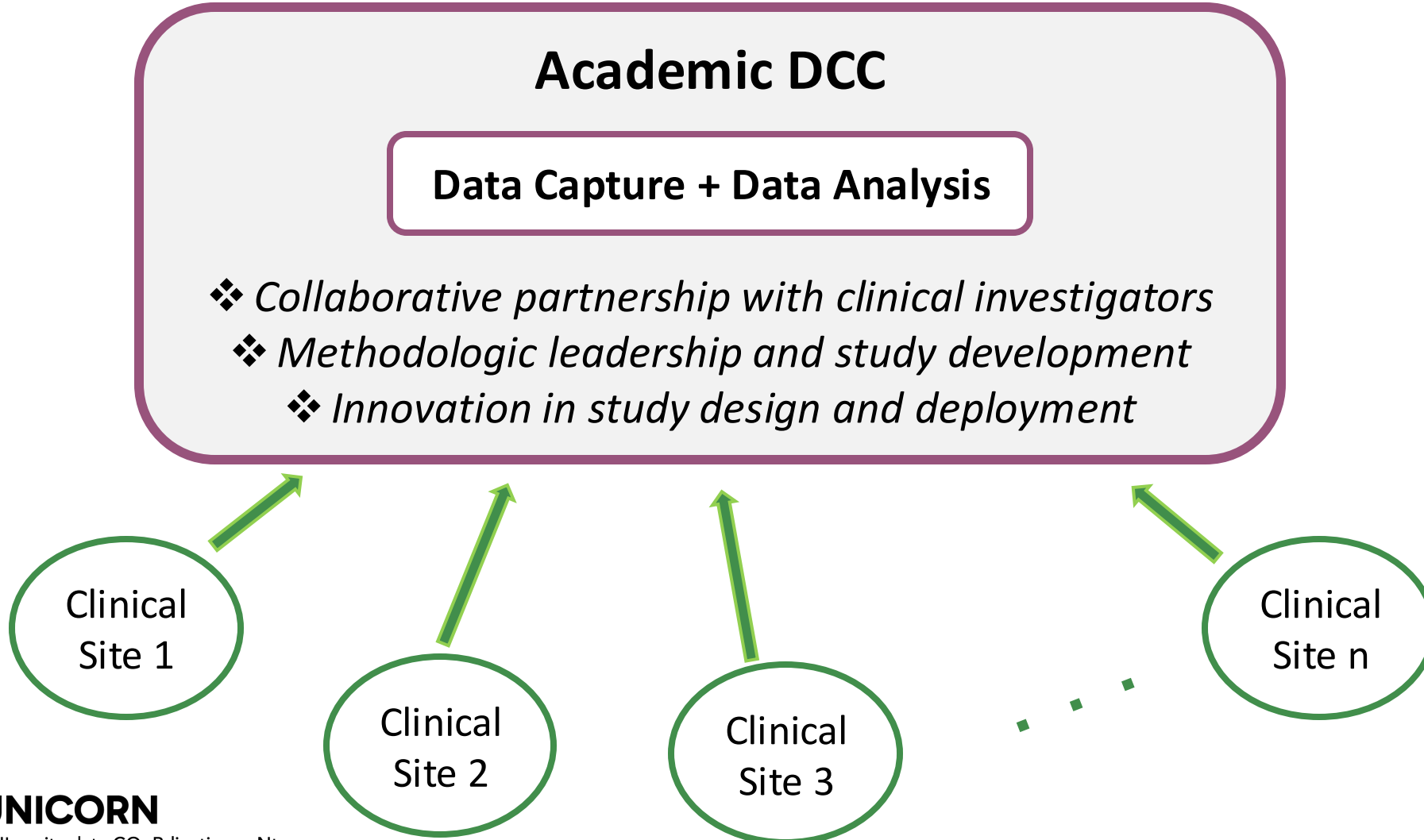
Chair: Denise Scholtens (Northwestern University)

Presenters: Chris Lindsell (Duke University), Catherine Dillion (MUSC), Cristina Murray-Krezan (University of Pittsburgh)

Discussant: Nick Pajewski (Wake Forest University)

What is an Academic Data Coordinating Center?

Multi-Site Clinical Trial



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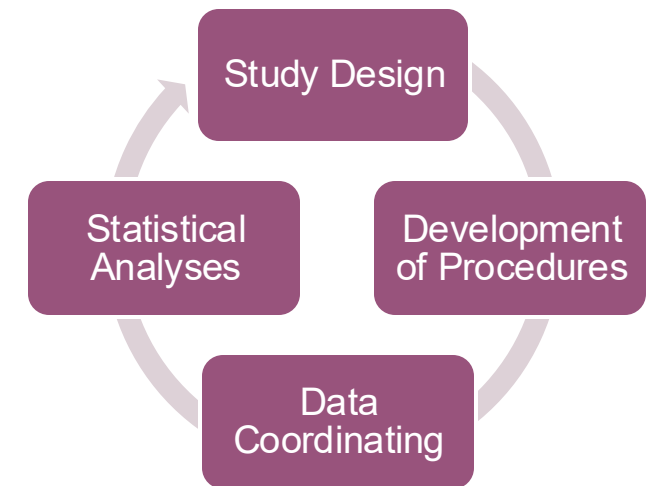
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❖ *Collaborative partnership with clinical investigators*

- *Academic DCCs:*

- Develop executable protocols designed to accomplish clinical scientific goals
- Ensure regulatory compliance of all study procedures at study outset and throughout study conduct
- Partner closely with clinical investigators and contributing sites throughout the study life cycle

Northwestern University Data
Analysis and Coordinating Center
(NUDACC)

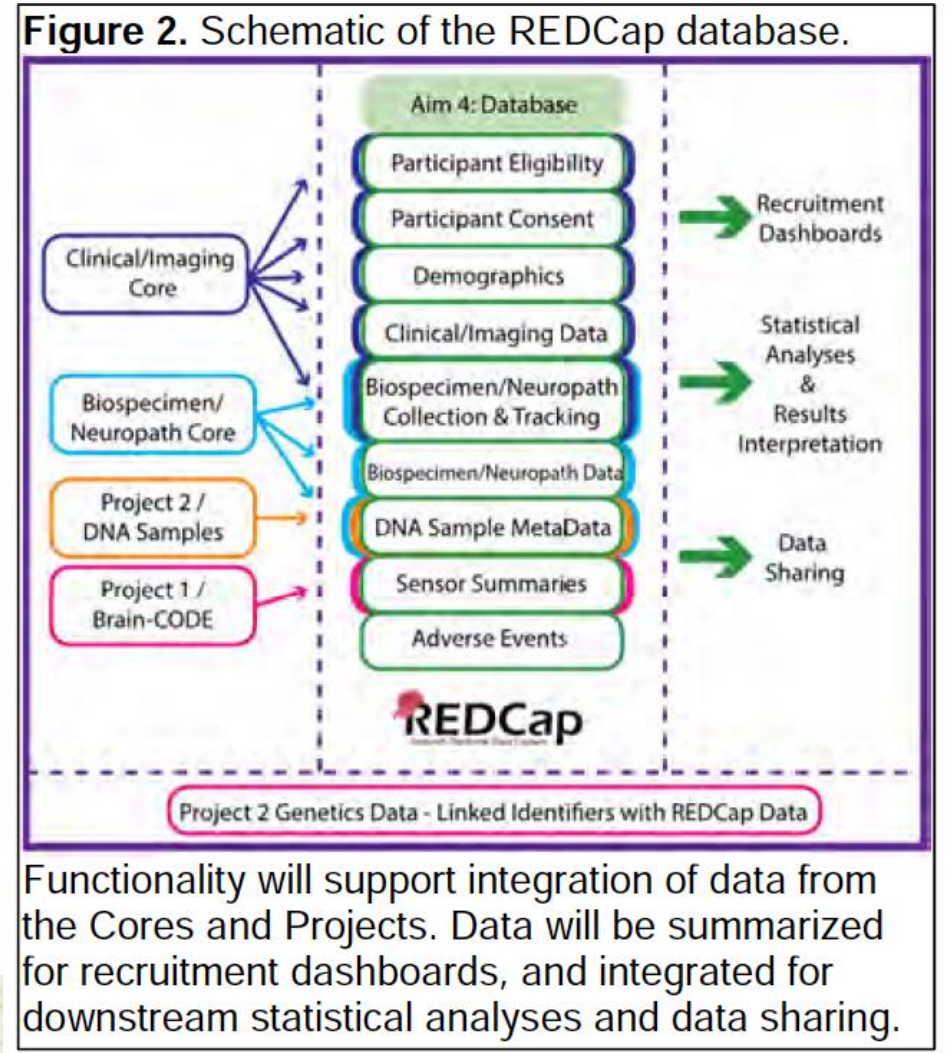


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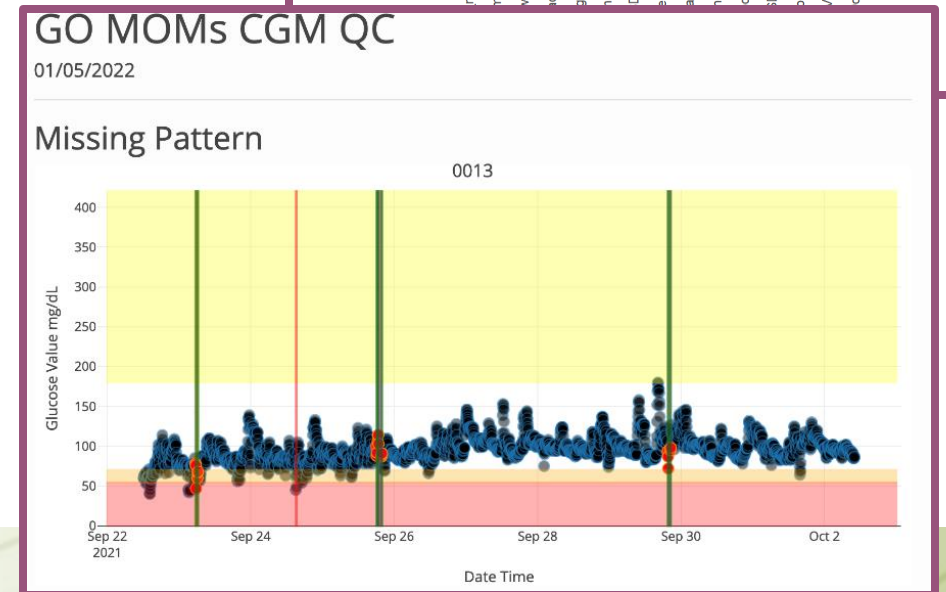
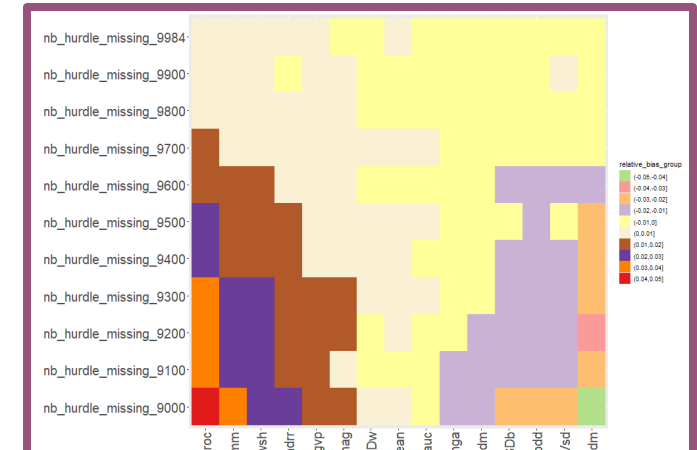
❖ *Methodologic leadership and study development*

- *Academic DCCs:*
 - Unite biostatistics, informatics, and data science methodology experts uniquely suited to help address the clinical question
 - Provide effective, efficient, reproducible, and rigorous data analyses and results interpretation
 - Often in partnership with CCCs, align clinical protocol components with data capture and ensure clarity and accuracy of all study documents and procedures



❖ Innovation in study design and deployment

- Academic DCCs:
 - Leverage a range expertise for developing data capture pipelines that often extend beyond traditional case report form collection
 - Innovate analytic methods for emerging data types



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❖ Innovation in study design and deployment

- *Academic DCCs:*
 - Apply cutting edge study designs for efficiency and accuracy
 - Deploy randomization methods that are often sophisticated and tailored to study design

NUDACC / 2gether_det_msb Public

forked from j3schaue/redcap_det_msb

<> Code Pull requests Actions Projects Security Insights

main Go to file Code

This branch is 1 commit ahead, 8 commits behind j3schaue:main.

j3schaue Updated 2Gether repo and made test run on sec... on May 25, 2022

code	Updated 2Gether repo and made test run on s...	10 months ago
README.md	Updated repo to contain base elements of DET...	10 months ago
index.php	Updated 2Gether repo and made test run on s...	10 months ago

README.md

REDCap Minimal Sufficient Balance Integration

This repository contains base code to link REDCap data entry triggers to algorithms to randomize participants in randomized experiments. The focus is on the Minimal Sufficient Balance (MSB) algorithm.

The code is structured to run on a secure server, with the following scripts managing interactions with REDCap's data entry trigger:

- `index.php` Listens for DET payloads sent to the secure server.
- This script can be edited and tailored to specific REDCap projects, but should contain the REDCap PID and relevant instrument names.



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Next Up!

- Chris Lindsell
 - *Introduction to UNICORN Network*
- Cristina Murray-Krezan
 - *Landscape and Challenges of Academic DCCs*
- Catherine Dillon
 - *Best Practices and Advocacy for Data Coordination*
- Nicholas Pajewski
 - *Discussion*



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CJ Lindsell, PhD

Disclosures

Grants, contracts, DSMBs

- NIH
- Society for Critical Care Medicine
- Cytokinetics
- Novartis
- Biomeme
- Rocket Pharmaceuticals
- Persistence Bio
- VUMC
- Emory University
- Regeneron

Other commitments

- EIC, Journal of Clinical and Translational Science
- External Advisory Boards
- Stock options in Bioscape Digital
- Patents for risk stratification in sepsis and septic shock held by CCHMC



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Disclosures



A very brief history

- Formal DCCs began to emerge in the 1970s
- Funding agencies increasingly emphasize independent DCCs
 - To support informative trial design within the context of implementation
 - To maximize integrity and quality of data essential to the trial
 - To support independent trial oversight
 - To provide independent assessment of the data
- Evolving technology, data systems, and regulatory frameworks are forcing local centralization of DCC activities



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What is an academic DCC?

- Data Coordinating Centers (DCCs) provide collaborative leadership in multi-site clinical research studies
- They offer support with study design and collecting, verifying, storing, and analyzing data, and are essential to the success of large clinical research studies
- Not every DCC operates the same

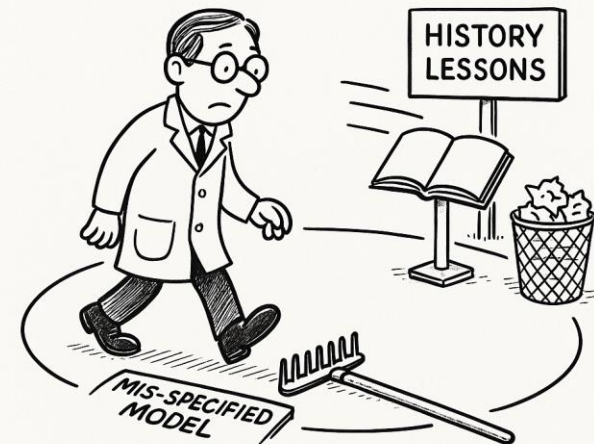


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Why is a network needed

- DCCs have emerged to meet the needs of the clinical research enterprise
- There is no textbook
- Every DCC has developed with its own foci, strengths, and weaknesses
- The academic and scientific contributions of DCCs are not well recognized in academia
- Without learning from one another, we are doomed to repeat our mistakes



2024 Academic DCC Summit

- Informal gathering of representatives from 15 institutions



- Convened to discuss
 - State of data coordination in academic environments
 - Challenges to progress
 - Potential collaborations

Attendees

Abby Smith Northwestern University	Alexis Ogdie University of Pennsylvania	Amy Goodman University of Utah	Barbara Braffett George Washington University
Bryce Rowland University of North Carolina	Catherine Dillon Medical University of South Carolina	Cathie Spino University of Michigan	Chris Coffey University of Iowa
Chris Lindsell Duke University	Christoph Hornik Duke University	Cristina Murray-Krezan University of Pittsburgh	Dandan Liu Vanderbilt University Medical Center
Daniela Sotres-Alvarez University of North Carolina	Denise Scholtens Northwestern University	Dixie Ecklund University of Iowa	Emily Dressler Wake Forest University
Jens Eickhoff University of Wisconsin	Jess Collins Vanderbilt University Med Center	Jody Ciolino Northwestern University	Kaleab Abebe University of Pittsburgh
Kevin Anstrom University of North Carolina	Kevin Weatherwax University of Michigan	Laine Thomas Duke University	Liang Li University of Texas/ MD Anderson
Emine Bayman University of Iowa	Giselle Kolenic University of Michigan	Jack Shostak Duke University	Jamie Dwyer University of Utah
Lisa Wesby University of Pennsylvania	Maria Sanchez University of North Carolina	Matthew Shotwell Vanderbilt University Med Center	Michelle Lancet University of Pittsburgh
Nick Pajewski Wake Forest University	Rebecca Clifton George Washington University	Rex Edwards University of Michigan	Sally Jo Zuspan University of Utah
Shawn Ballard University of Pennsylvania	Valerie Durkalski-Mauldin Medical University of South Carolina	Walter Ambrosius Wake Forest University	



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Commitment

- Form a network that can serve as a professional home for leaders and others engaged in DCCs
 - Focus on academics, recognizing the importance of the external academic context on establishing the discipline of data coordination
 - Conduct a landscape analysis
 - Invite others to the table



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Forming the network

Outreach for members

Word of mouth

Web search (e.g. NIH Reporter)



Charter development

Leadership structure

Committees

Membership



Sustainability

Business model

Professional home



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UNICORN's Founding Principles

Open and
transparent
communication
and decision-
making

Leadership
and guidance
by members

Sharing
of best
practices and
experiences



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Mission

The **UNI**versity data **COoR**dinating ce**N**ters (UNICORN) Network convenes members of academic institutions that lead DCC activities to advance the discipline of data coordination



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Strategies

The UNICORN Network aims to improve the rigor and impact of clinical research using a **collaborative approach**

The UNICORN Network **develops and shares best practices** for establishing and sustaining academic DCCs, conducting DCC activities, and training DCC personnel

The UNICORN Network also **advocates** for best practices of study design, DCC activities, and statistical analysis that will broadly inform the advancement of DCCs involved in clinical research



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Current state

Committees & meetings

Executive
Committee

Steering Committee

Finance committee

Network

Landscape

Initial evaluation
complete

Comprehensive
landscape
assessment in
process

Outreach

Website

Presentations

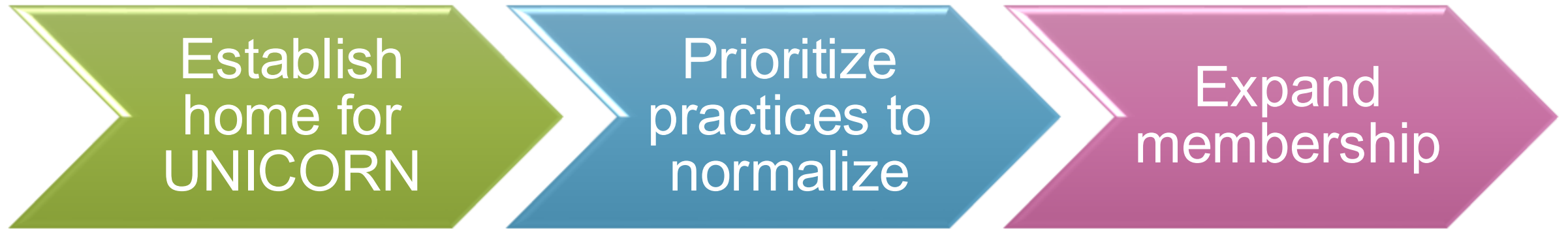
Word of mouth



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Moving forward



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Public launch



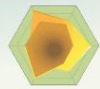
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HOME ABOUT MEETINGS CONTACT US

Want to get involved with UNICORN Network?
Contact us to learn more.

Learn More



Academic Data Coordinating Centers (DCCs) provide collaborative leadership in multi-site clinical research studies. They offer support with study design and collecting, verifying, storing, and analyzing data. DCCs are essential to the success of large clinical research studies. However, not every DCC operates the same. The **UN**iversity data **COoR**dinating **ceN**ters (UNICORN) Network convenes members of academic institutions that lead DCC activities to advance the discipline of data coordination.

THE MISSION

UNICORN Network aims to improve the rigor and impact of clinical research using a collaborative approach. UNICORN Network develops and shares best practices for establishing and sustaining academic DCCs, conducting DCC activities, and training DCC personnel. UNICORN Network also advocates for best practices of study design, DCC activities, and statistical analysis that will broadly inform the advancement of DCCs involved in clinical research.



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Discover the UNICORN Network



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Landscape and Challenges of Academic DCCs

Cristina Murray-Krezan, PhD

Center for Biostatistics and Qualitative Methodology

University of Pittsburgh

Motivation for Survey

- Understand the current landscape of academic DCCs
- Set long-term goals and guide focus for UNICORN



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Survey Design

- Topic items brainstormed at “DCC Summit” (UNICORN kick-off meeting) March 2024
- Team of five drafted questions
- Sent to DCC Summit participants for feedback

34 questions comprised the following topic areas:

- | | |
|----------------------------|---|
| • Organizational structure | • Data collection, management, analytic tools |
| • Institutional support | • Strengths/weaknesses |
| • Project leads | • Strategic and sustainability plans |
| • Types of trials/studies | • Info for UNICORN to disseminate |



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Identification of DCCs



- Personal knowledge
- NIH RePORTER
- Web search in each state



- Had at least one contact email address
- List checked for duplicates



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Survey Creation and Dissemination

- Survey drafted in Qualtrics by UNC
- Received exempt-status IRB approval from UNC May 2, 2024
- Survey sent via email to identified contacts May 13, 2024
- Survey remained open and sent to additional contacts through November 2024
- UNC and Duke: DUA executed late fall 2024



Survey Dissemination and Analysis

- ~50 DCCs identified
 - Some may not meet our current definition of DCC
 - DCC = coordinated group running more than one multicenter trial
- Varied in size, formality, scope
 - Large, multicomponent with dozens of DCCs
 - Small, limited number of components, fewer studies
- Survey sent to 1-2 contacts/DCC

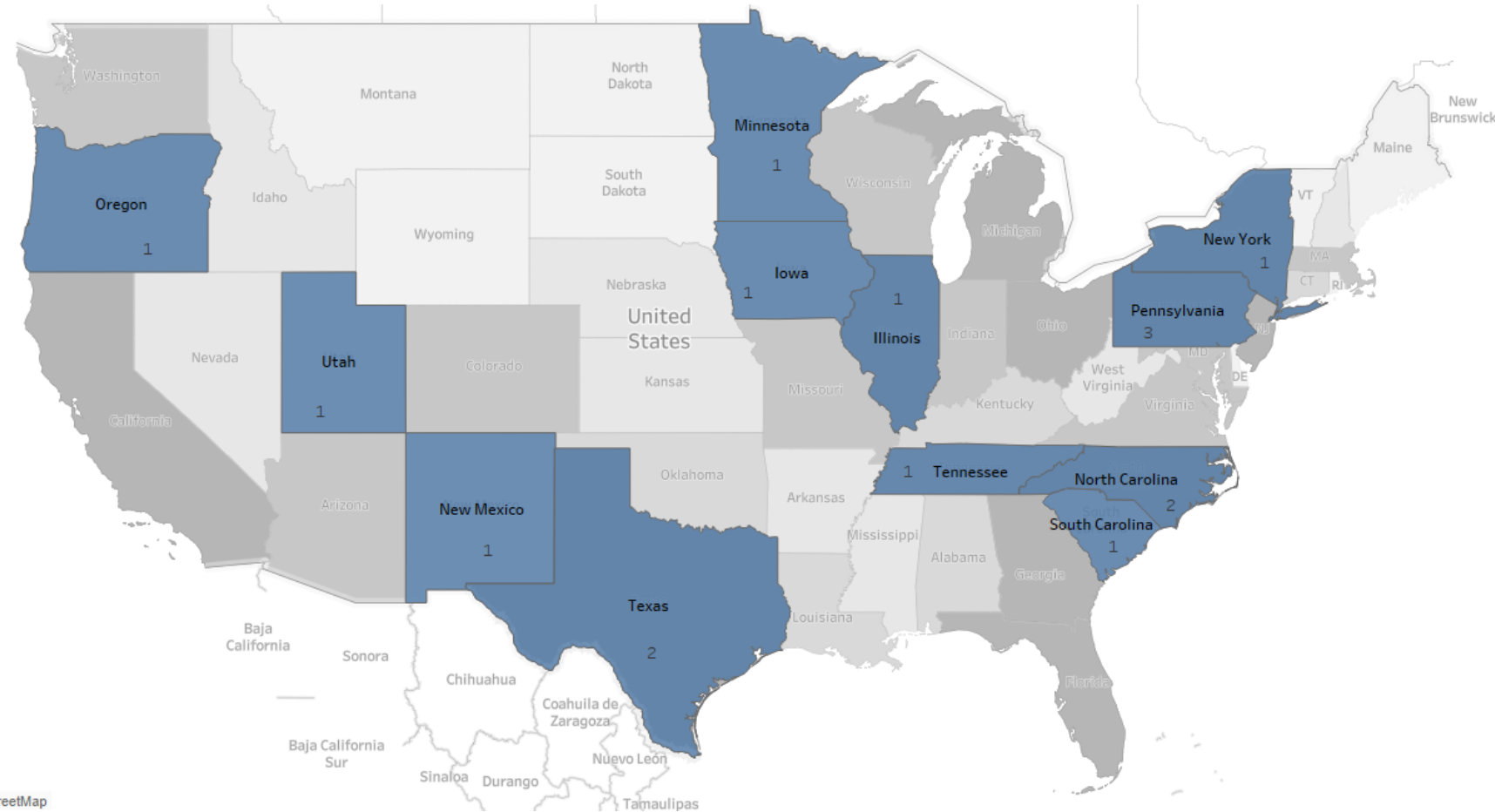
Analysis

- Descriptive statistics calculated by Duke Clinical Research Institute

Results: Who Responded

- 16 DCC respondents included (3 excluded with response rates <20%)

- DCCs housed in:
 - 50% Medicine
 - 25% Public Health
 - 25% Other



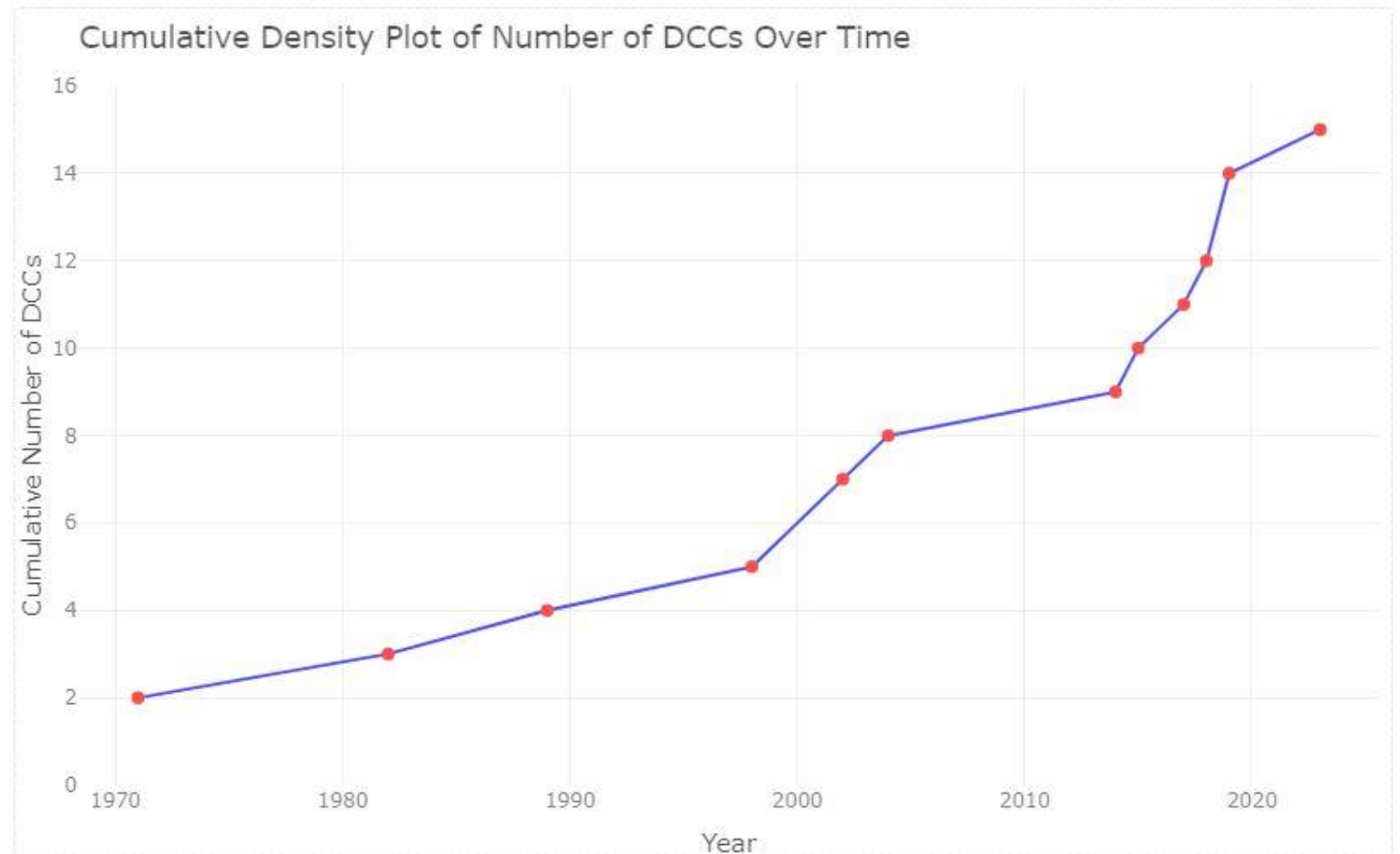
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Results: Age of DCCs

- 2 DCCs founded 1971
- 10 founded \geq 2002



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Results: Composition of DCCs

	# DCCs reporting	Median FTEs	Q1, Q3
Faculty			
Tenured/tenure track	14	1.75	1.00, 3.75
Non-tenure track	12	6.25	1.88, 8.00
Data Managers/Data coordinators	14	5.50	2.44, 12.75
Biostatisticians/Analysts			
MS or BS	15	5.00	1.86, 10.00
PhD	5	1.00	1.00, 2.00
Data scientists	4	1.00	1.00, 1.00
Developers/Programmers	15	4.00	2.25, 6.50
Administrative/Fiscal/Grant support	13	1.00	0.75, 5.00
Project manager/Director	13	3.00	1.00, 7.00



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Results: Types of Trials

	# DCCs reporting	Median # trials/studies	Q1, Q3
Network multisite trials/observational studies	12	5	4, 21
Non-network multisite trials/observational studies	12	6	3, 9
Investigator-initiated single site trials/observational studies	9	3	1, 7
Industry-sponsored multi- or single site trials/observational studies	5	2	2, 2
Surveys , large-scale cross sectional or longitudinal	5	2	1, 2



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Results: Support

Charge model:

- Percent effort only, n = 10
- Hourly rates only, n = 1
- Combination of percent effort and hourly rates, n = 5

Majority of portfolios NIH: median = 80%, [Q1, Q3] = [62.5%, 87.5%]

Half receive a return on indirect dollars, return rate: 2% to 15%

Half or more receive institutional support for

- IT, n = 11
- Space, n = 14
- REDCap or other DM tool, n = 8



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Results: Additional Information

Primary data collection tool:

- REDCap, n = 7
- Proprietary system, n = 6
- Other off-the-shelf product, n = 2

5 respondents said DCC serves as CCC for ≥ 1 study (max = 22)

$\geq 50\%$ conducting trials that...

- ...are pragmatic
- ...include technology (wearables, devices)
- ...develop/maintain cloud-based platform for data repository, sharing, and computing



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Results: Challenges



- Lack of institutional support
 - Reliance on grant funding is a vulnerability
 - Grant funding can be “feast or famine”
- Institutional restrictions result in below-market salaries
 - Difficult to attract new talent
 - Harder to retain talent



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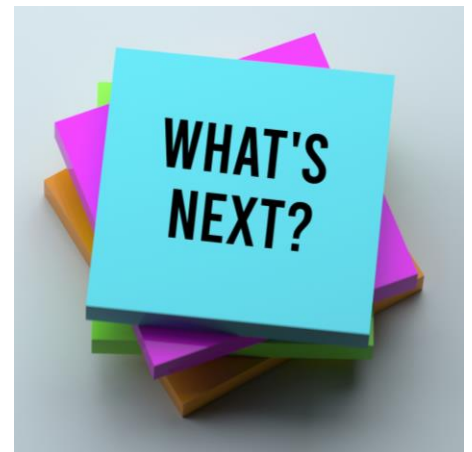
Limitations and Next Steps

Limitations

- Limited number of respondents so far
- Identified DCCs may not all meet UNICORN's definition of a DCC
- Some questions were challenging for centers to answer

Next Steps

- DCC Landscape Survey 2.0:
 - Revised and simplified questions (March-May 2025)
 - Removed questions related to salaries to avoid perception of collusion
 - Now available!
- Developing initial UNICORN manuscript



Conclusion

- Respondent DCCs are fairly mature and well-established
- All look different: size, scope
- No clear set of best practices across the DCCs

By gaining a clearer understanding of our collective identity, the UNICORN Network will empower academic DCCs to address national research needs through the identification of best practices, the establishment of new centers, and the expansion of capabilities.



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Acknowledgements

UNICORN Founding Leadership	DCC Landscape Survey 1.0 Design	DCC Landscape Survey 2.0 Design
Chris Lindsell (Duke University)	Emine Bayman (University of Iowa)	Emine Bayman (University of Iowa)
UNICORN Administrative and Statistical Contributions	Barbara Braffett (George Washington University)	Chris Lindsell (Duke University)
Jacqueline Huvane (Duke University)	Dixie Ecklund (University of Iowa)	Cristina Murray-Krezan (University of Pittsburgh)
Erin Abbenante (Duke University)	Cristina Murray-Krezan (University of Pittsburgh)	
Uchechukwu Ikeaba (Duke University)	Maria Sanchez (University of North Carolina)	



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THANK YOU!

**Please take the
DCC Landscape Survey 2.0**



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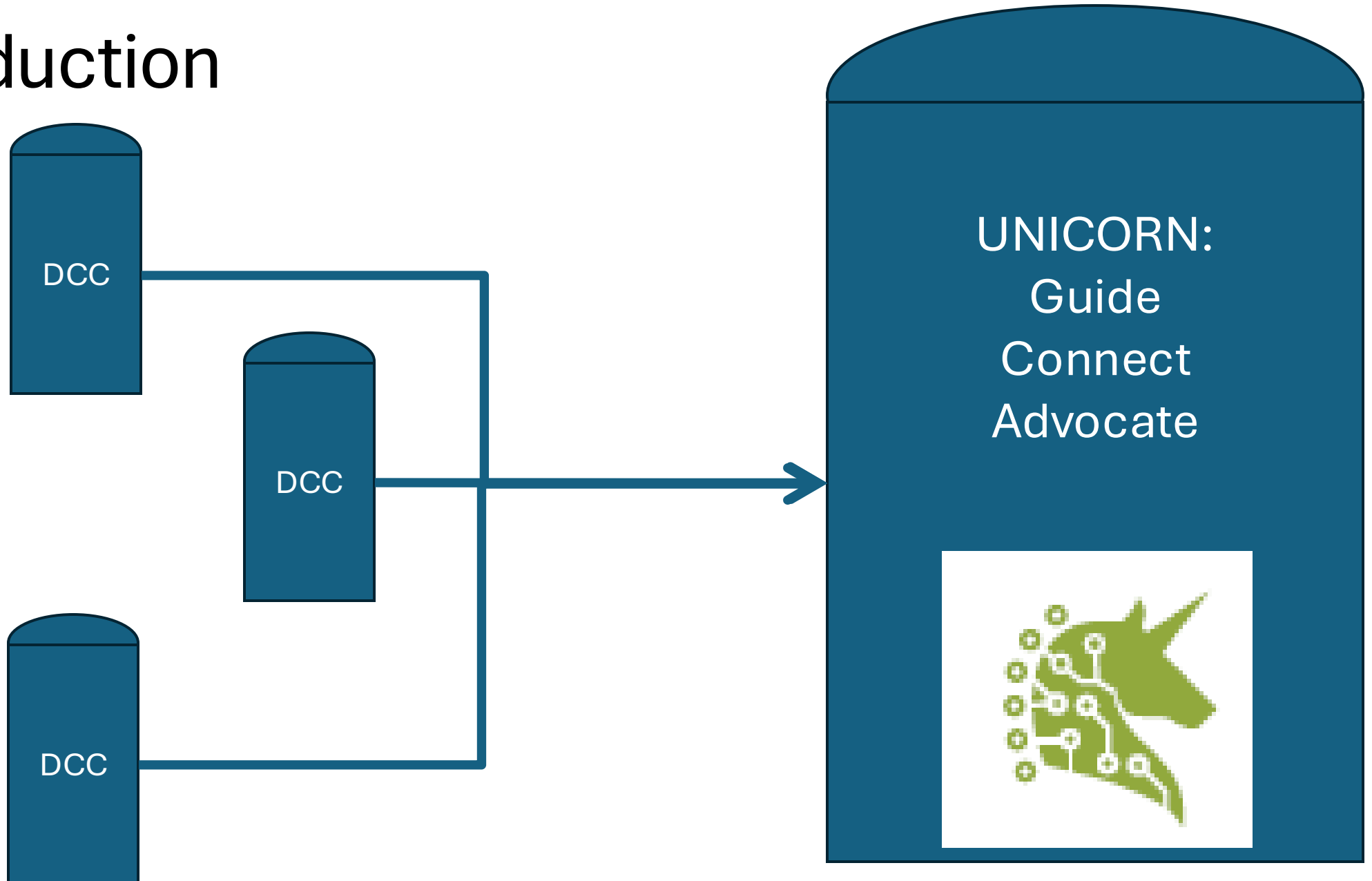
Best Practices and Advocacy for Data Coordination

Society for Clinical Trials 2025

Vancouver, CA

Catherine Dillon

Introduction

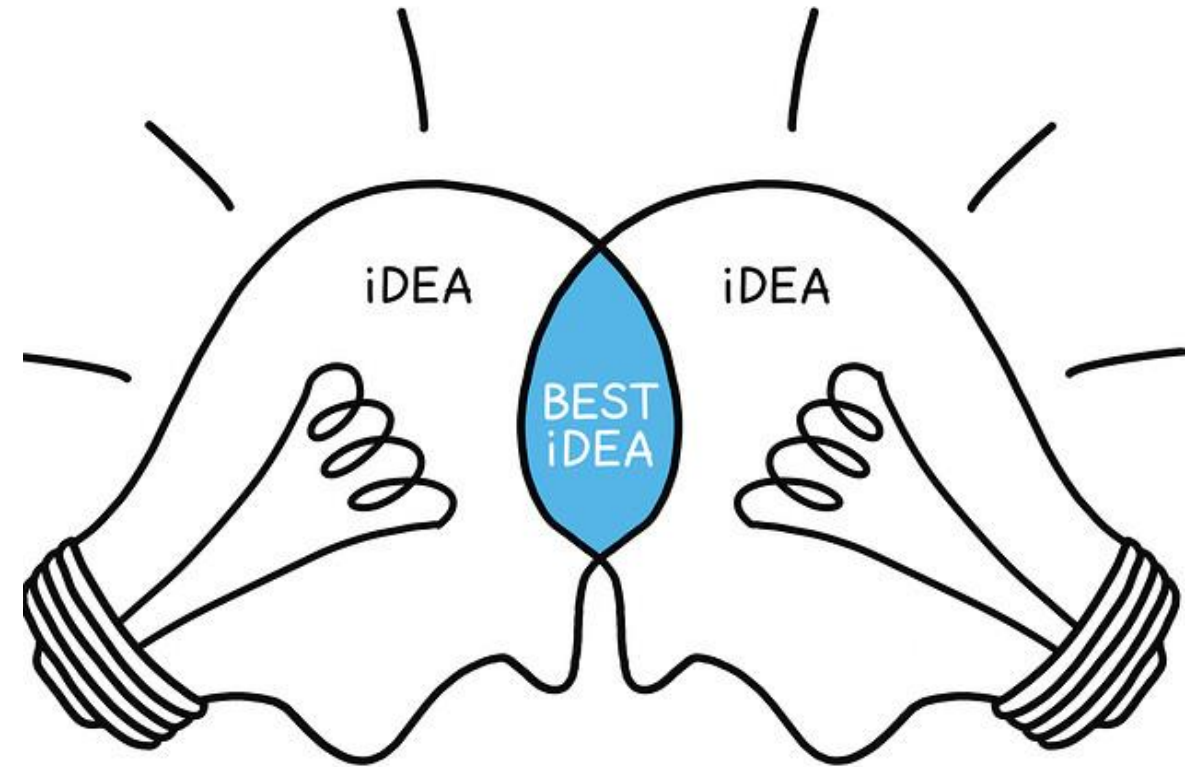


Collaboration

- Non-hierarchical, member led
- Value of informal knowledge

Efforts:

- Sharing practices
- Co-development of tools
- Shared authorship/presentations
- Working groups



Tools for Establishing and Operating DCCs

- SOPs/process guides
- Templates/workflows
- Governance/oversight models
- Platform decision support

www.unicorn-dcc.org



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Best Practices for Establishing and Operating DCCs

- Data Management
- Technology advancements
- Cybersecurity
- Collaboration with CCCs
- DCC evolution



Professional Development

- Identify core competencies
- Develop job descriptions
- Support mentorship
- Promote formal career pathways
- Develop training
- Encourage up-skilling
- Advocate for retention



Advocacy- Championing Value of Academic DCCs

- Raise awareness
- Educate funders, policy makers, inst. leaders
- Articulate value
- Promote funding
- Encourage sustainable infrastructure



Not a CRO, Not a Sponsor—A Community



We're just getting started! Join us!





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Discussion and Questions with Nicholas Pajewski