



**ECHO**

Environmental influences  
on Child Health Outcomes

A program supported by the NIH

**IDEA States Pediatric  
Clinical Trials Network**

# Getting to Know Your Data Management and Informatics Team

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# DCOC

- Operates on a cross-functional team approach
- 12 DCOC Functional Teams
  - Biostatistics
  - Communications
  - Finance & Administration
  - Informatics
  - IRB Administration
  - Participant Safety
  - Professional Development
  - Program & Project Specialists
  - Project Leadership
  - Quality Assurance
  - Site Management
  - Technical Writing





Are we...

...the IT department?

No.

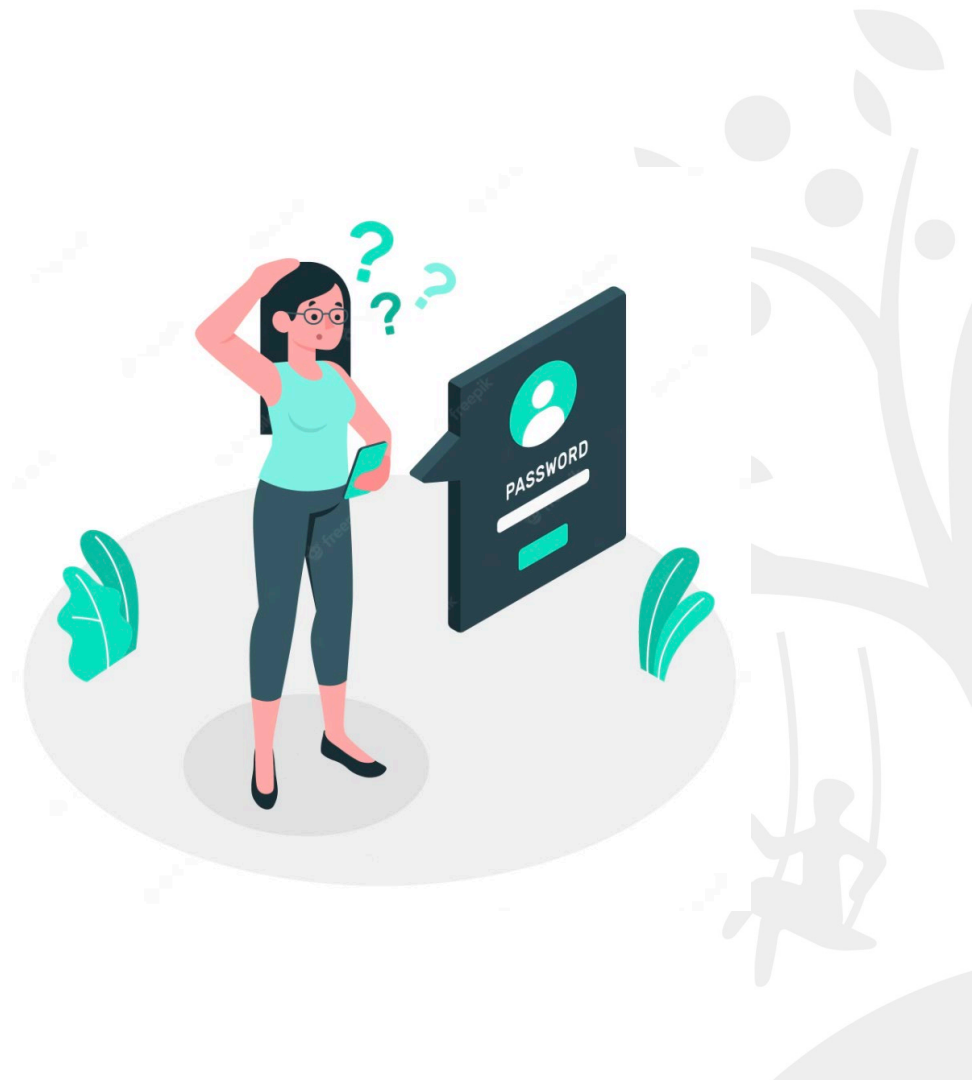


*Chris O'Dowd in the IT Crowd (2006)*

# Are we...

...the people who reset  
your forgotten password?

**It depends.**



# Are we...

...the people who send  
you annoying queries?

**Sometimes.**

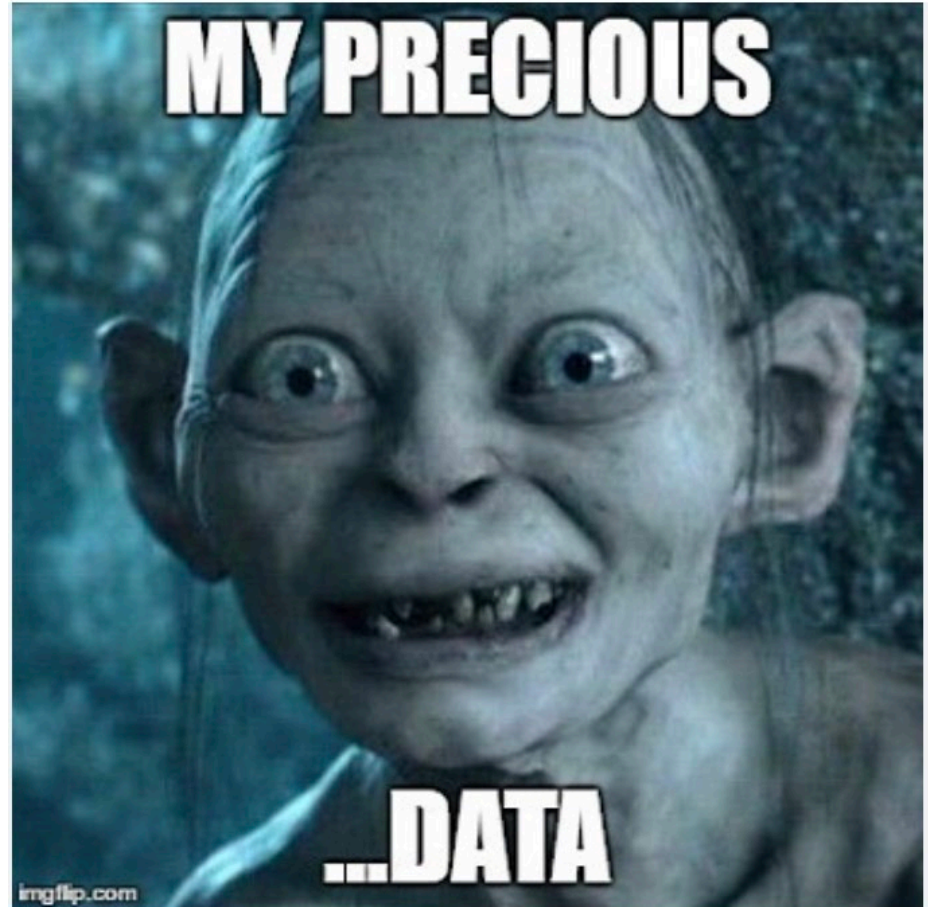


[https://www.youtube.com/watch?v=d16C\\_GrZrbE&t=110s](https://www.youtube.com/watch?v=d16C_GrZrbE&t=110s)

Are we...

...unapologetic data  
nerds?

Of course.



# Are we...

...professionals tasked with collecting the data necessary to answer the scientific questions posed by the clinical trial protocols?

**Yes!**

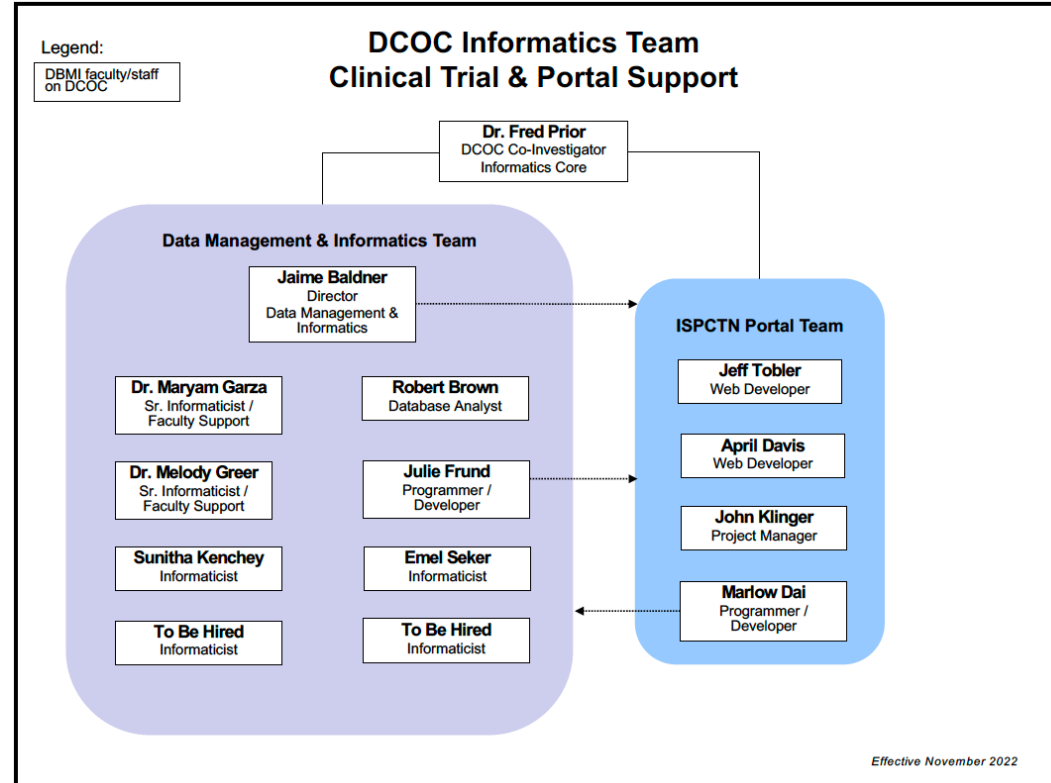




# Meet the Team!

## Data Management & Informatics

- DM+I have roles in front of and behind the scenes
- Org chart highlights team members with whom the Network is most likely to interact
  - Most of the Network have Portal accounts and use the Portal on some frequency
  - Some of the Network directly work on clinical trials

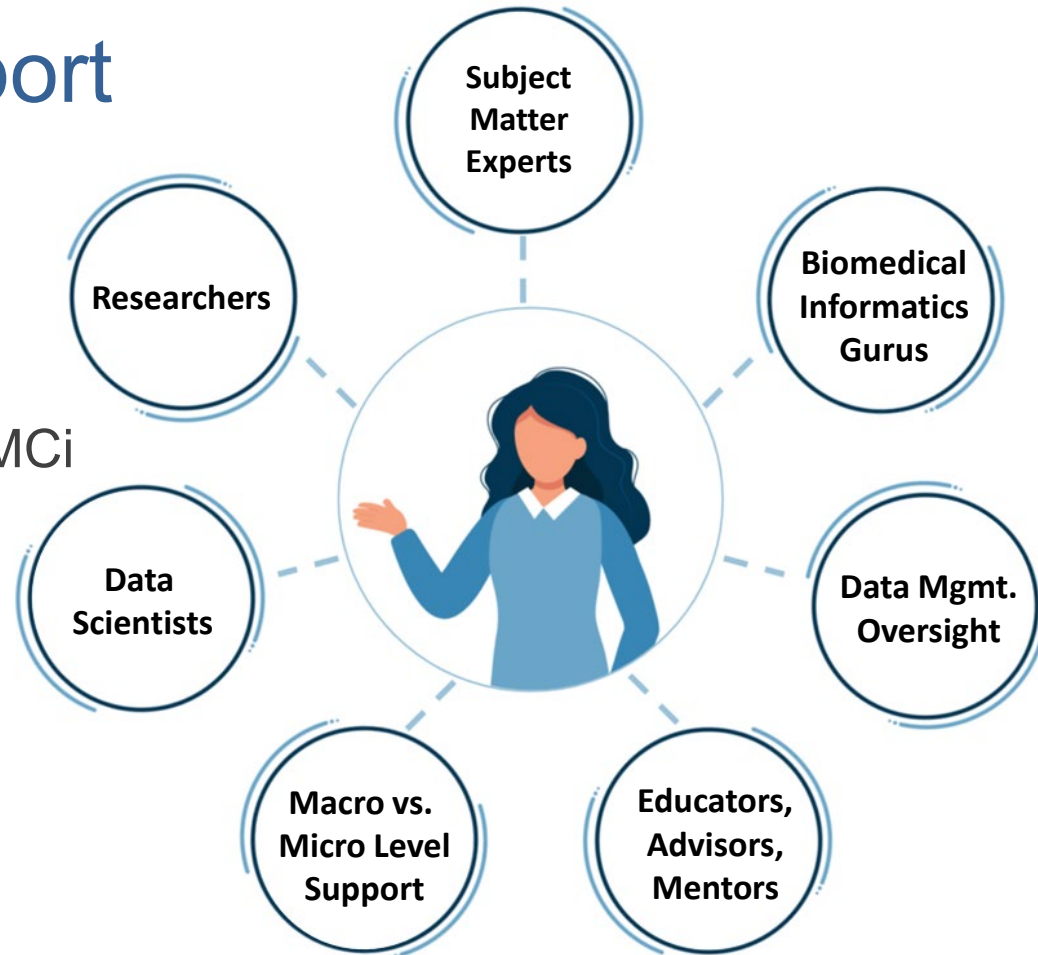


# DCOC Faculty Support

*Data Management & Informatics*

## *Who Are We?*

- Fred Prior, PhD
- Maryam Garza, PhD, MPH, MMCi
- Melody Greer, PhD



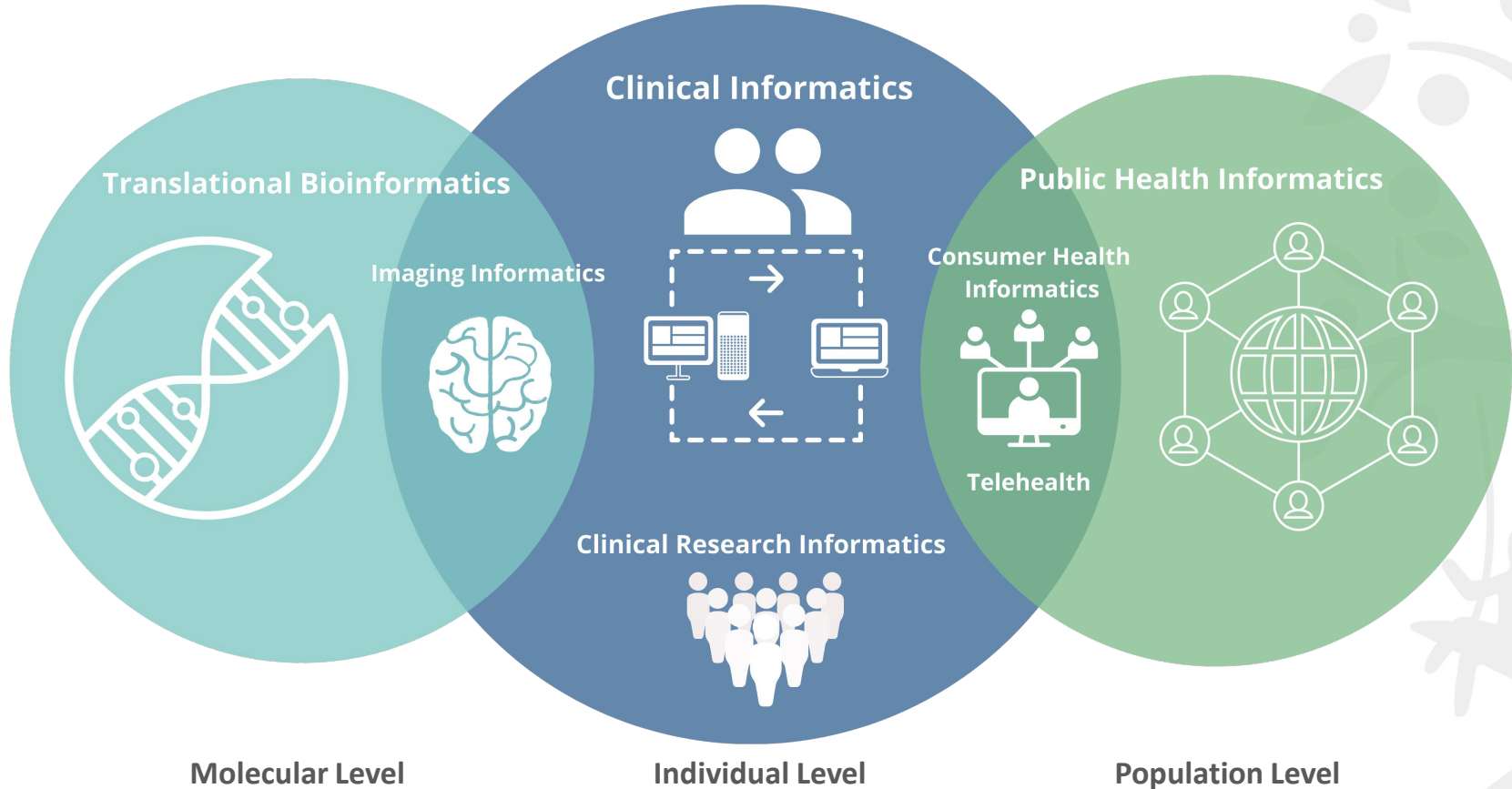
# DCOC Faculty Support

*Data Management & Informatics*

## *What Do We Do?*

- Review & provide feedback to Concept (and other) Proposals
- Offer DM&I thought leadership during Protocol Development
- Provide general oversight of DM&I operations (hands-on, as needed)
- Ensure that we are following best practices (GCDMP) and SOPs
- Collaborate with other Functional Group Leads
- Represent DM&I at the DCOC & ISPCTN leadership level
- Participate in or lead Manuscript Writing

# What is Biomedical Informatics?



# What is Data Management?

**EDC & SYSTEMS  
DEVELOPMENT**

**DATA  
GOVERNANCE**

**DATA  
INTEGRATION**

**DATA  
ARCHITECTURE**

**PROTOCOL  
DEVELOPMENT**

**CROSS-  
COLLABORATION**

**INFRASTRUCTURE  
&  
ARCHITECTURE**

**METADATA  
MANAGEMENT**



**DATA  
MANAGEMENT**

**DATA  
WAREHOUSING**

**DATA  
QUALITY**

**OPERATIONAL  
SUPPORT**

**IDENTIFY  
DATA  
SOURCES**

**DATA  
SHARING**

**DATA  
SECURITY**

**DATA  
STANDARDS**

**BUSINESS  
INTELLIGENCE**

# Quality Management System – SD Focus

## *Software Development Lifecycle (SDLC)*

- Building or selecting software
- Installing software
- Validating the installation
- Maintaining the software
- Backing up / restoring the software
- Changing the software in a controlled manner
- Retiring the software
- Managing user identities in Network systems



# Quality Management System – DM Focus

## *Data Management (DM)*

- Data management planning
- Creating data capture strategies
- Developing case report forms (CRFs)
- Building databases
- User testing
- Acquiring, processing, reporting, extracting, sharing, and archiving data
- Managing user access to data systems



# Data Management & Informatics

**Long Term**

- Contributing to DM&I Components of DCOC QMS
- Reviewing concept proposals & contributing to scientific & DM components of protocols
- Assessing data system needs for CRF & non-CRF data; collaborating with external data providers
- Creating data flow diagrams
- Creating data element spreadsheets
- Representing Informatics on study meetings

- Developing & maintaining ISPCTN Portal
- Processing CRF & vendor data
- Extracting data for analysis
- Writing papers & manuscripts
- \*Publishing data to DASH

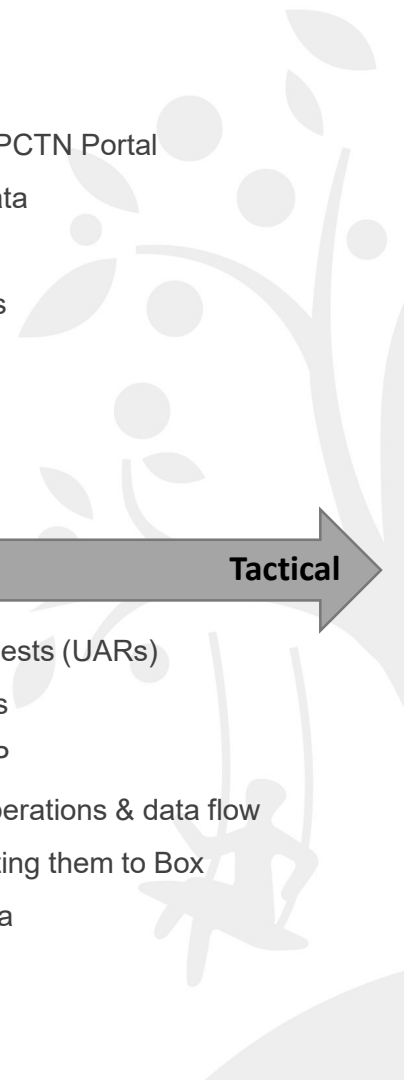
**Strategic**

- Creating user testing plans for EDC systems
- Creating CRF & EDC training materials
- Creating data management plans
- Designing data entry forms
- Designing the reporting suite
- Managing change control projects for Portal & EDC
- Contributing to writing teams

**Tactical**

- Processing user access requests (UARs)
- User Testing of EDC systems
- Contributing to DSMP & MOP
- Creating alerts to facilitate operations & data flow
- Running study reports & posting them to Box
- Storing & archiving study data

**Short Term**





# Wearing ALL the hats

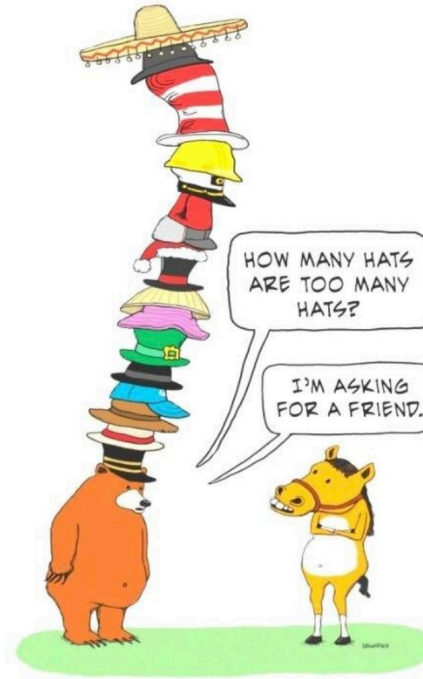


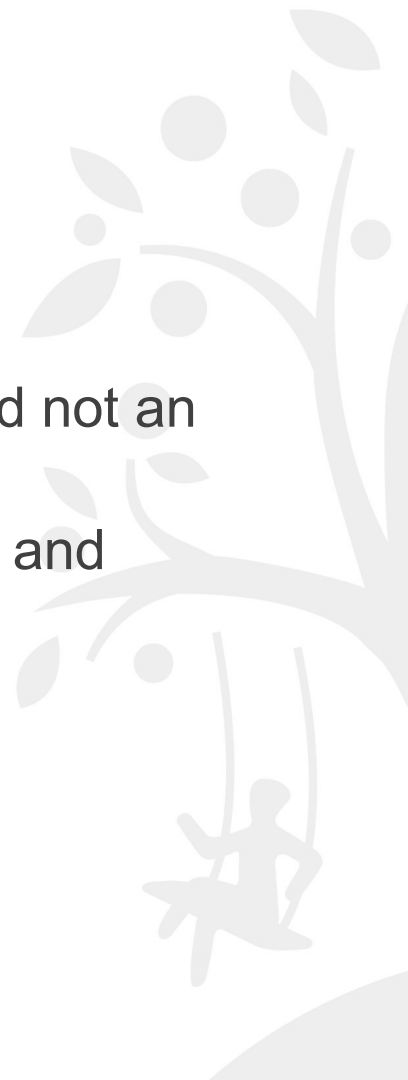
Image credit: [Zazzle.com](https://www.zazzle.com), [Chuck Ink](#)

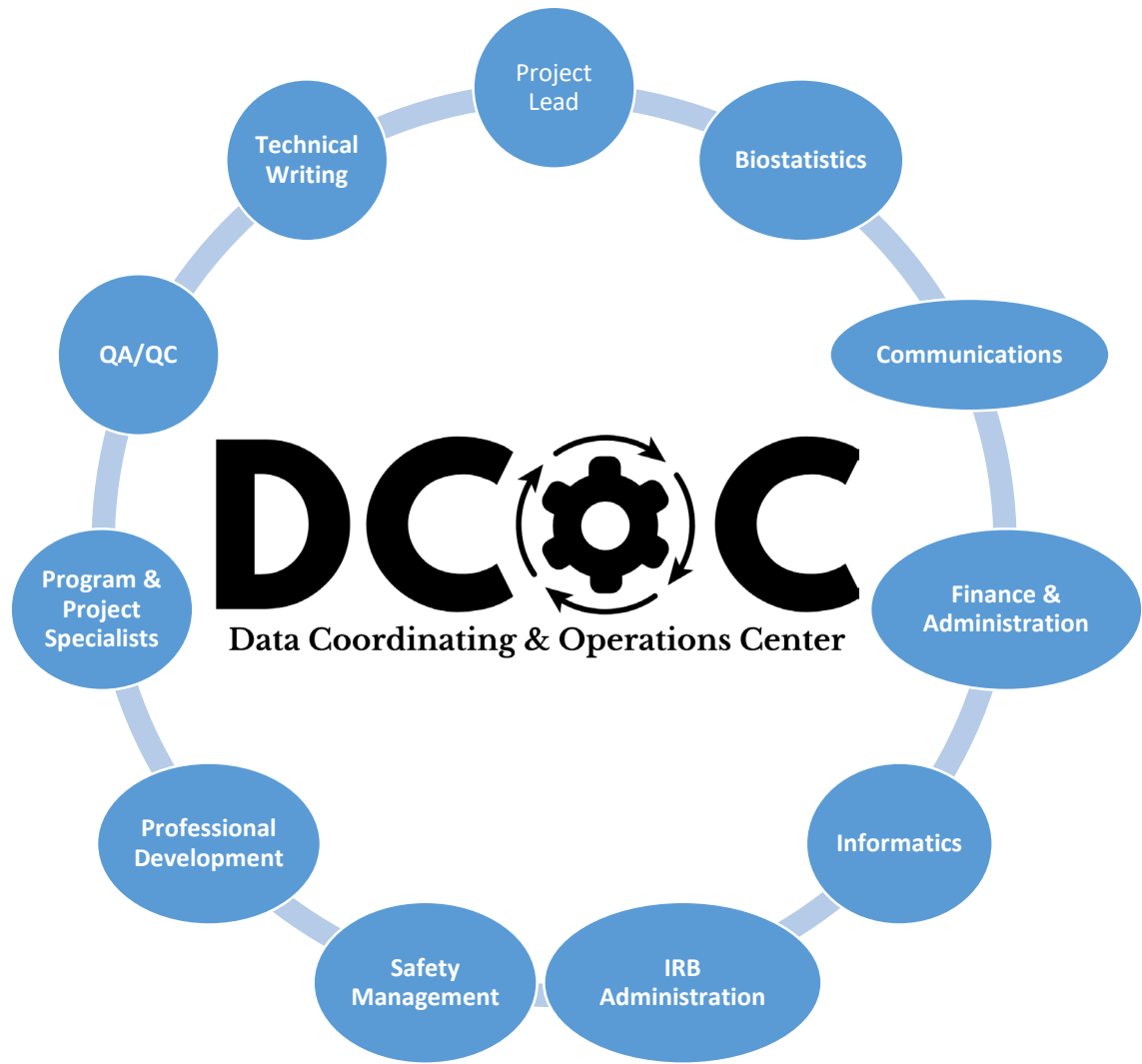


# Let's work together!

- Communication is key
- Data is the Network's currency so should be a priority and not an afterthought
- We are your data team – data capture, integrity, security, and transmission are our focus

*Help us help you!*





Thank you for your time!

What questions do you have for us?

