

# Supporting Open Access for Researchers (SOAR)

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**Duke** Clinical Research Institute

FROM THOUGHT LEADERSHIP  
TO CLINICAL PRACTICE

SOAR

SUPPORTING OPEN ACCESS FOR RESEARCHERS

# Goals and Principles of Open Science at Duke

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- Advance Science
  - Answer new questions
  - Combine data to increase it's power
  - Avoid duplication of effort
  - Foster new connections and collaborations
- Improve Research Integrity
  - Validate original analyses
  - Promote transparency and trustworthiness
- Principles
  - Facilitate appropriate access
  - Ensure appropriate governance
  - Maintain data utility
  - Share results (and data) from secondary analyses
  - Acknowledge and provide academic credit for those who share original data

The open science roadmap was introduced by Adrian Hernandez, MD

<https://medschool.duke.edu/about-us/news-and-communications/med-school-blog/introducing-duke-school-medicine-roadmap-open-science>



# SOAR™ *Supporting Open Access for Researchers!*

... A collaboration between Duke Clinical Research Institute (DCRI), academia, and private industry to share clinical research data and resources for the benefit of public health

## Goals:

- Foster transparency & openness
- Inform & accelerate science by building on prior work & lessons learned

- More Efficient
- More Effective
- More Timely

access to healthcare innovations that improve population health!



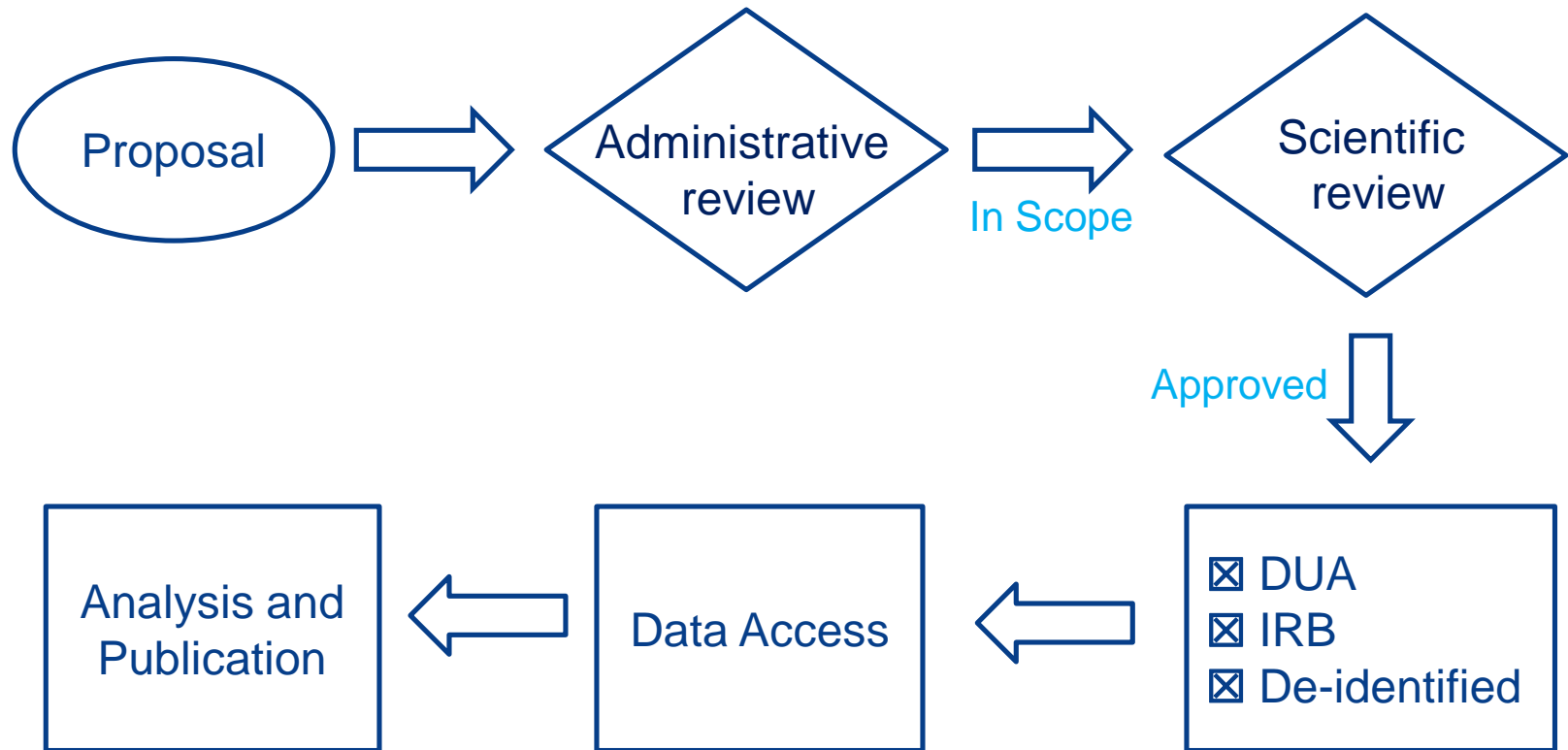
**Target Audience:** Investigators, Data Scientists, Statisticians



.....Through SOAR, DCRI offers access to:

- 1. An Independent Review Committee (IRC) with subject matter experts**
  - a) Duke Clinical Research Institute (DCRI) & Bristol-Myers Squibb (BMS)
    - a) BMS shares its Clinical Trial datasets
    - b) DCRI's academic experts reviews proposals
- 2. DCRI Datasets**
  - a) **Duke Cardiac Catheterization Research Dataset** (DukeCath)  
(de-identified)
  - a) **Duke Cardiac Catheterization Educational Dataset** (DukeCathR)  
(anonymized and modified)
- 3. Other Data Sharing Resources**
  - a) Links to the Aggregate Analysis of ClinicalTrials.gov (AACT) database & dataset
  - b) Links to request datasets shared through other platforms (i.e., NIH/DASH)
  - c) DCRI Dataset Catalog

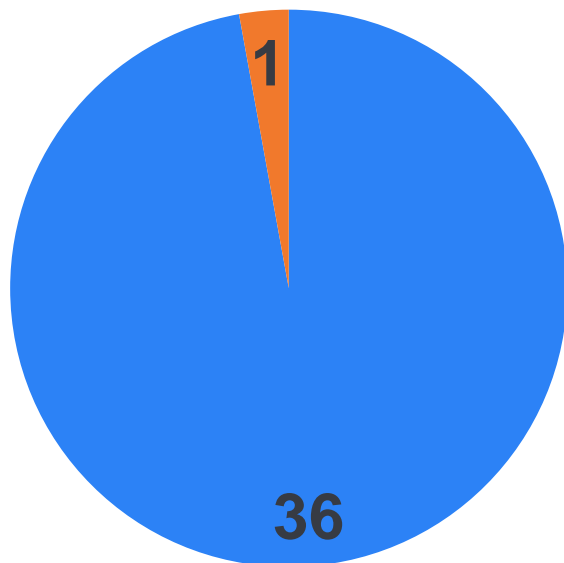




\* Feedback cycle is activated when IRC requests clarification or additional information from researcher

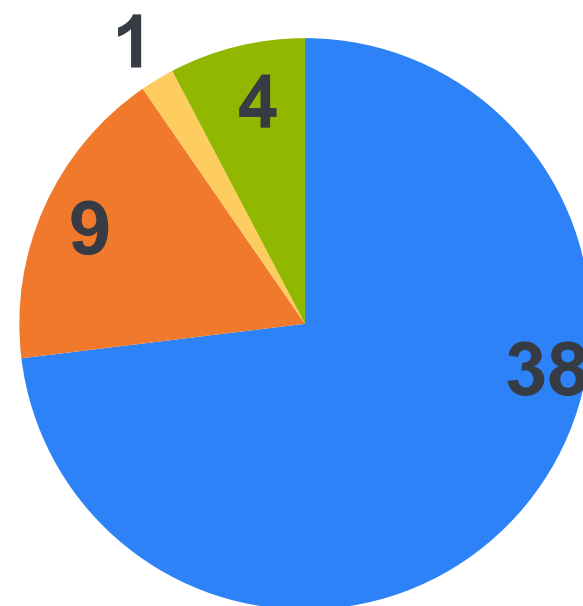
## Reviewed BMS-DCRI Proposals

n = 37



## DukeCath Datasets

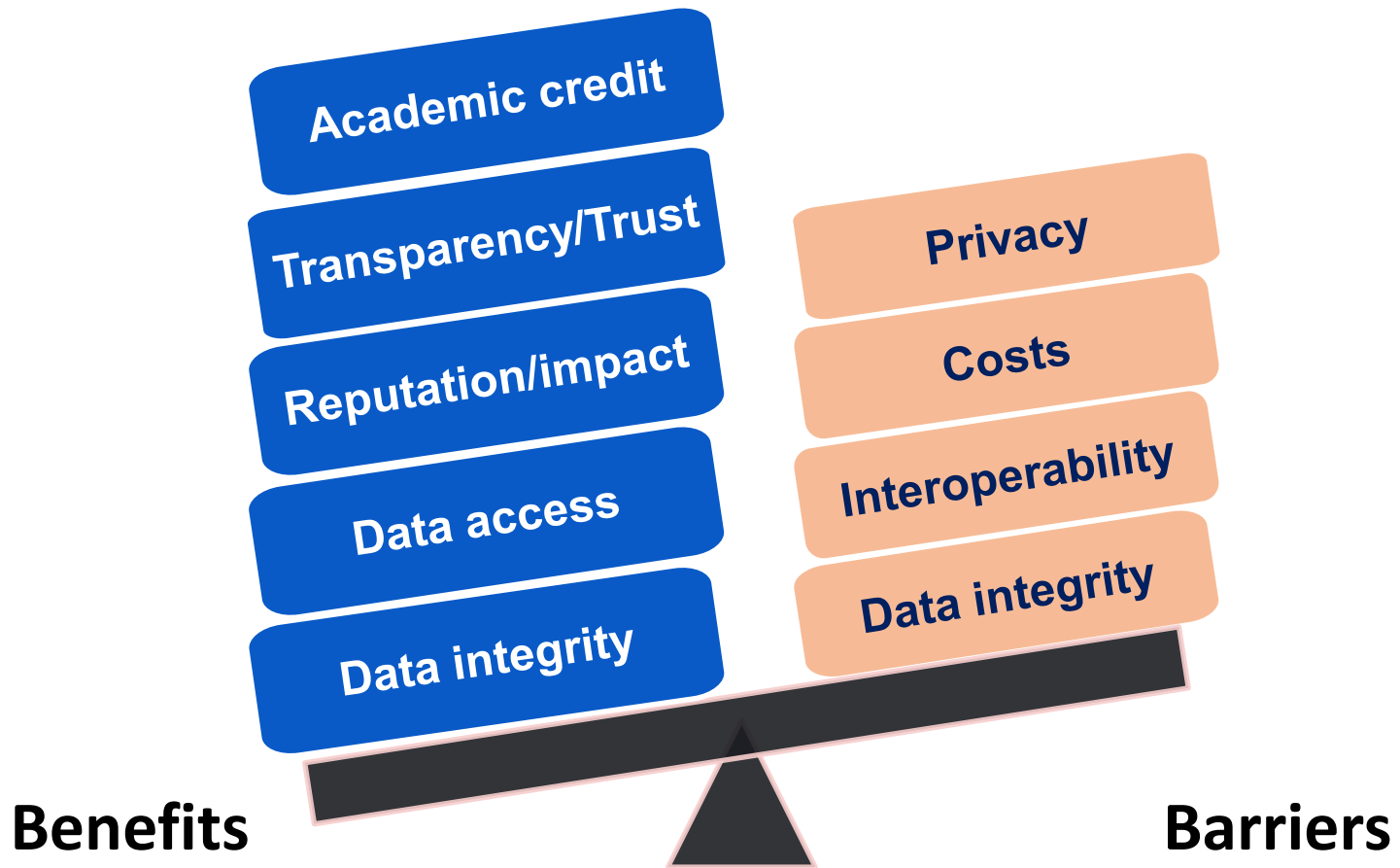
n = 50



■ Academia ■ Industry ■ Non-profit ■ Other

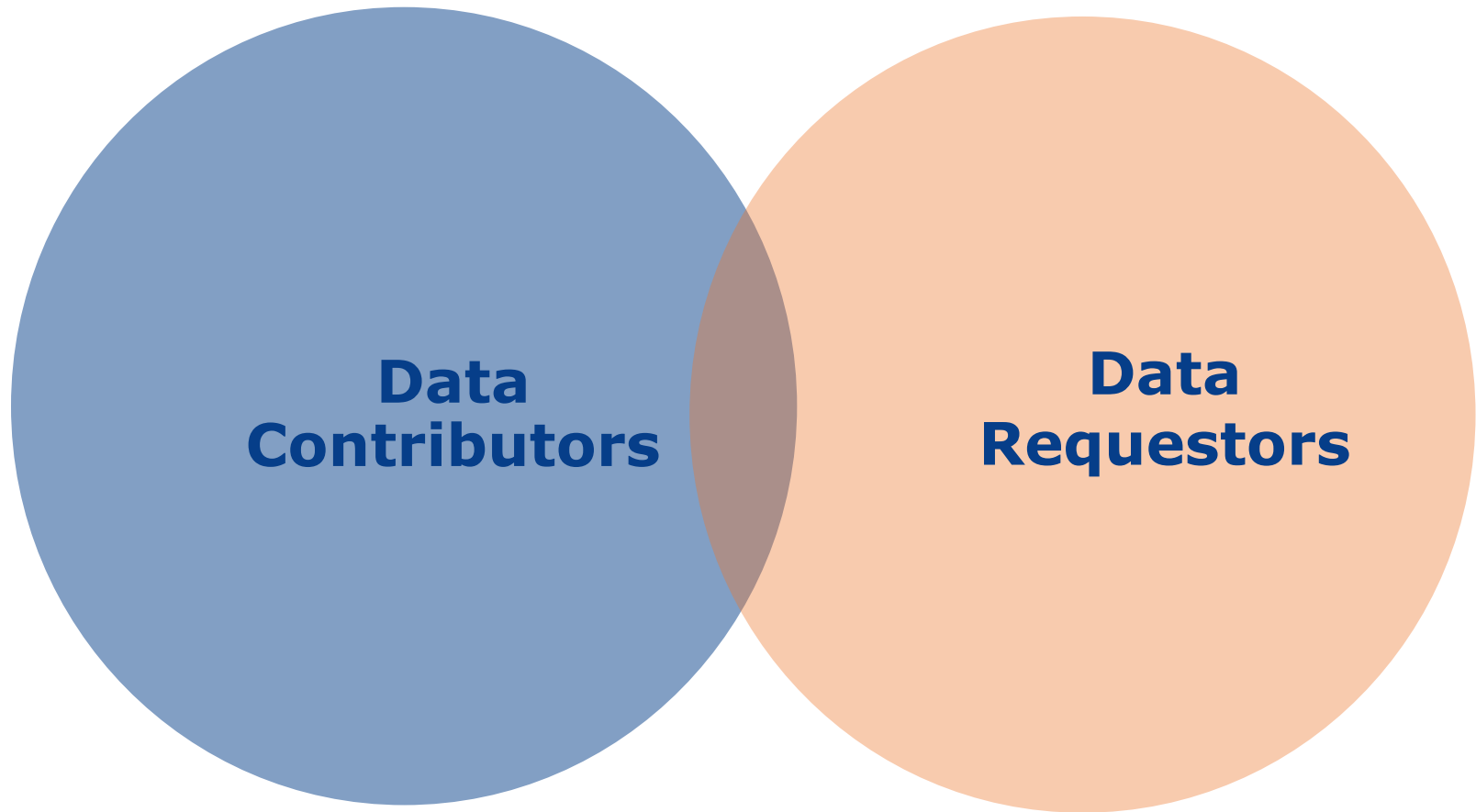
# Benefits & Barriers: Desired Future State

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# Data Sharing: Current State

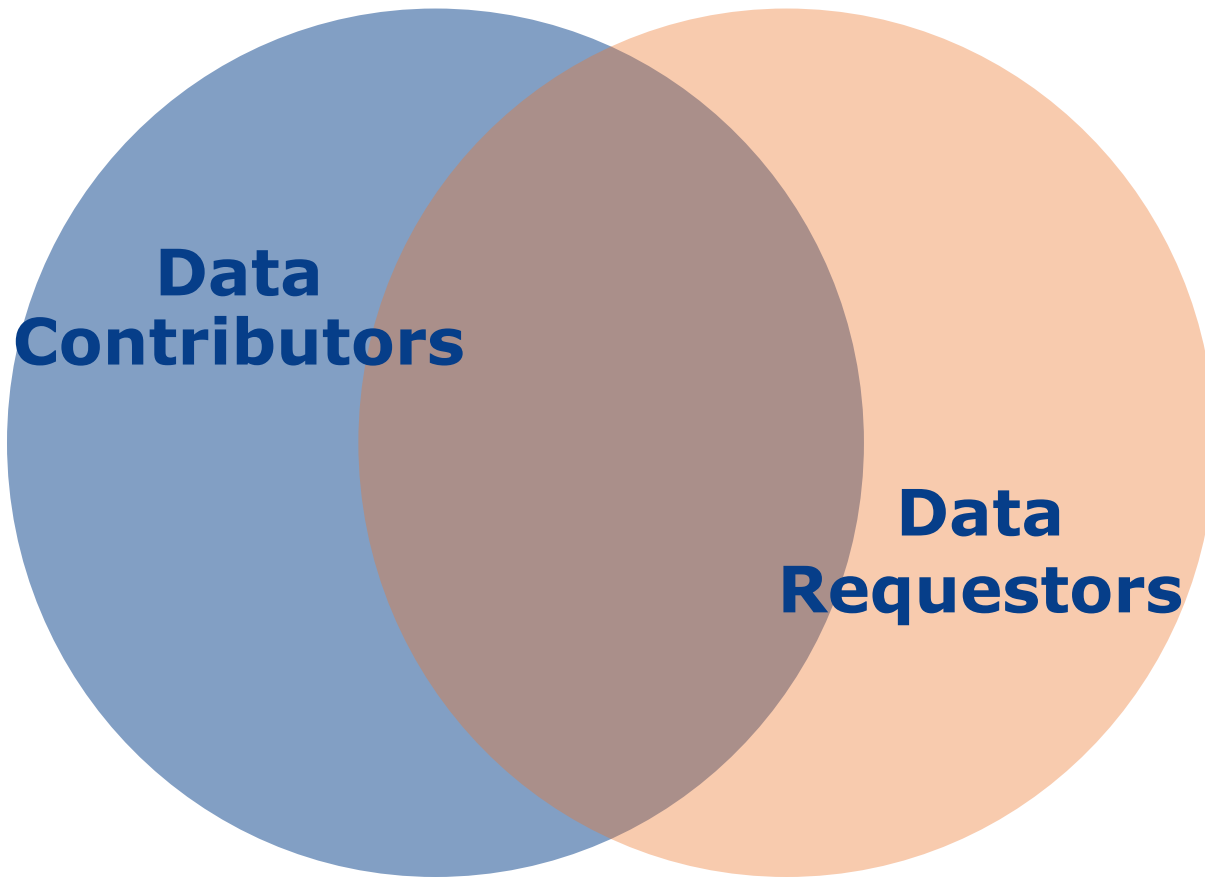
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# Data Sharing: Desired Future State

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# Discussion

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# Extras

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## Disclosure Statement – *Frank W Rockhold, PhD*



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**Consulting, DSMB's and Honoraria:** DCRI COI Disclosure Rockhold



**Boards:** European Medicines Agency Technical Advisory Group, Frontier Science Foundation Board of Directors, DataVant Scientific Advisory Board, Spencer Health Solutions Scientific Advisory Board, Athira Pharma Scientific Advisory Board, Vivli Platform Steering Committee, PI and chair SOAR Review Panel



**Equity Interest:** GlaxoSmithKline, DataVant, Athira, Spencer



# SOAR Organizational Structure

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## SOAR Faculty Leadership

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### Sponsor/Study Team:

Operational Support  
Clinical, Data  
Provisioning,  
Statistical Experts

### Independent Review Committee:

**Duke Faculty**  
+  
**Invited Members**  
Subject Matter Experts  
(Duke and non-Duke)

### SOAR Operations Team:

Project Management  
Communications  
Statistics  
Regulatory  
Contracts  
& more



## Independent Review Committee

- Bristol-Myers Squibb shares its Clinical Trial datasets
- DCRI's academic experts review proposals

## Sharing DCRI Datasets

- DukeCath for research (de-identified)
- DukeCathR for education (anonymized and modified)

## Works in Progress:

- Collaboration with Vivli
- Sharing of additional DCRI-owned datasets
- Links to sites/platforms where DCRI-facilitated datasets are shared (ie NIH DASH)
- DCRI Dataset Catalog
- Extending the independent review committee (IRC) service

# Lessons Learned (so far!)

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- SOAR Organizational Structure - it takes a village
  - Multi-disciplinary resources from sponsor and DCRI
- Collaboration... *Not Competition*
- Not necessarily 'build it and they will come...'
- Transparency is more than the dataset
  - Data dictionaries
  - Contextual documentation
  - Subject matter expertise
  - Includes sharing of the secondary analysis datasets, methods and results





# SOAR Questions

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## Faculty Leadership

- \* Frank Rockhold, PhD
- \* Eric Peterson, MD, MPH
- \* Michael Pencina, PhD
- \* Adrian Hernandez, MD

## Project Leader:

Rebecca Wilgus, RN MSN

**Email:** [data-sharing@dm.duke.edu](mailto:data-sharing@dm.duke.edu)

***Thank you!***



# Benefits & Barriers: Current State

