

PHUSE US Connect 2026  
Data Integrity and Public Trust



# Strategic Approaches to Patient Centricity in Data Science

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Learn more at [www.mrctcenter.org](http://www.mrctcenter.org)



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## About Us

MRCT Center is an applied policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials around the world.

## Our Vision

Improve the integrity, safety, and rigor of clinical trials around the world.

## Our Community

We engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

# Session Overview



Continuing to **build public trust** in clinical research is critical to population health and well-being.

**Data scientists can play a critical role in bridging the gap between researchers and the public.**

Increasing data transparency, can increase the public's research understanding, appreciation, and participation.

**Topics that will be covered in this session include:**

- the role of participant-focused approaches in the data sciences,
- best practices in collaborative study design, and
- organizational change models that prioritize the participant.

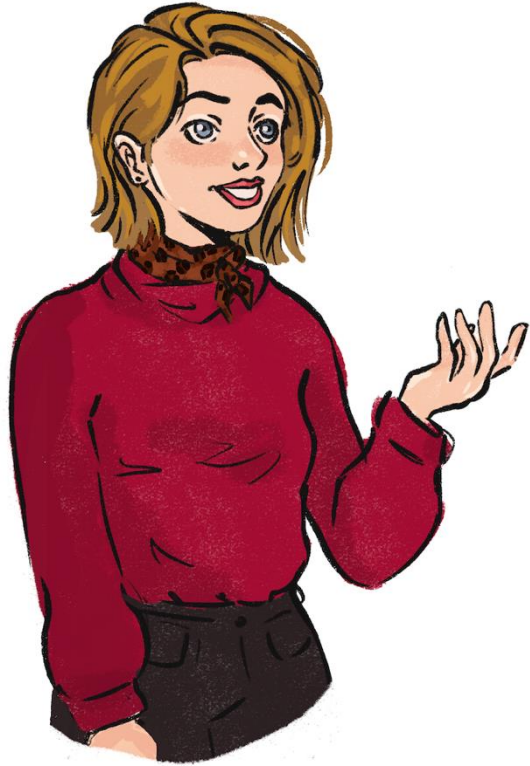
# Session Objectives



By the end of the session, attendees will be able to:

- 1) Describe the **role of patient centrality in data science** (and the role of data scientists, biostatisticians, and data managers in ensuring patient centrality)
- 2) Explain how **patient-centric approaches can support** study teams, research participation, and public trust.
- 3) Identify **patient-centric approaches that can be applied** in clinical research design, conduct, and reporting.

# My Starting Assumptions



- 1) The field of Data Science includes data scientists, biostatisticians, and clinical data managers (CDMs).
- 2) Data scientists, biostatisticians, and CDMs all play critical roles in clinical research (and you have the power to influence clinical research studies)
- 3) Patient centricity can be defined as “putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family”\*

\*Yeoman G, Furlong P, Seres M, Binder H, Chung H, Garzya V, Jones RR. Defining patient centricity with patients for patients and caregivers: a collaborative endeavour. BMJ Innov. 2017 Apr;3(2):76-83. doi: 10.1136/bmjinnov-2016-000157. Epub 2017 Mar 24. PMID: 28890797; PMCID: PMC5468520.

A large, teal-colored speech bubble with a black outline, pointing towards the bottom left. It contains the main text of the slide.

**What does “putting the patient first”  
look like in clinical research?**

# Patient-Centric Approaches Related to Clinical Research Data



**Engage in Collaborative  
Study Design**



**Integrate and Leverage  
Real World Data**



**Apply Health Literacy  
Best Practices**



# Example #1 - Engage in Collaborative Study Design



**Involve patients and care partners in study planning and design, including endpoint selection and review of feasibility from a participant perspective.**

Ask about their needs and desires related to the study and determine whether the study could help address their concerns and is likely to be successful in retaining participants.

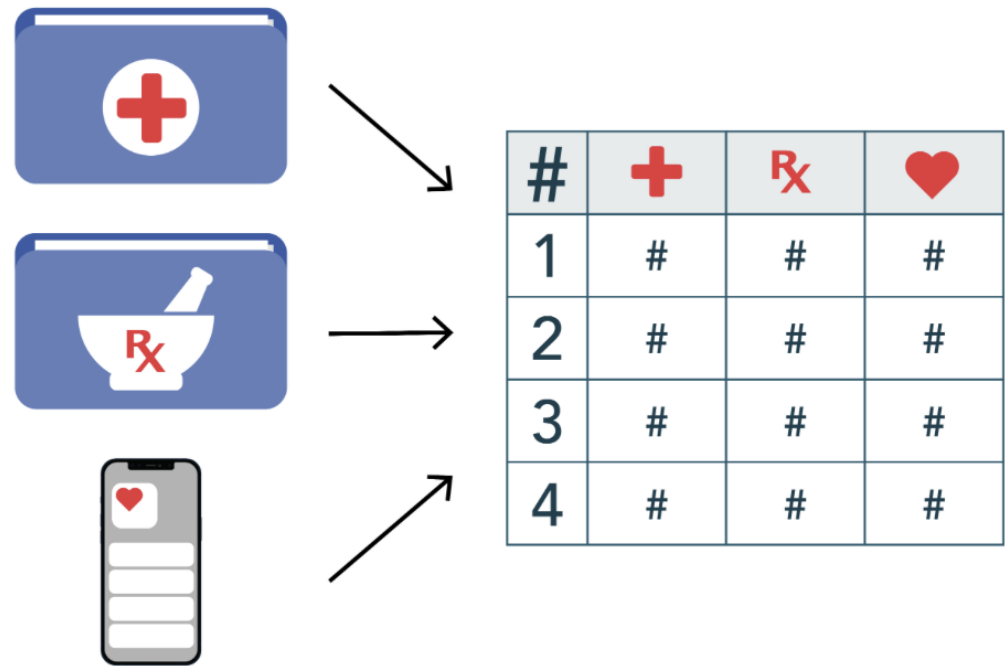
Consider including data elements, like patient experience data, which provide information about how the participants, and others as applicable, are impacted by the disease or condition, the therapy, or the clinical investigation.

**Potential Impact** - supports the selection and efficient collection of data elements that meet the study's scientific goals and provide information that is qualitatively meaningful to participants.

# Example #2 - Integrate and Leverage Real-World Data



In healthcare, there are readily available Real-World Data (RWD) sources like insurance claims, electronic medical records, and pharmacy records.



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RWD can help identify the more practical patient-centric impacts of a particular clinical research study

Using RWD supports broader applicability to the larger impacted patient community.

**Potential Impact:** reduces patient and care partner burden in the study and allows for more nuanced explanations of study outcomes.

# Example #3 - Apply Health Literacy Best Practices



## Personal Health Literacy

## Organizational Health Literacy

The degree to which **individuals** have the ability to **find, understand, and use** information and services to inform health-related **decisions and actions** for themselves and others.

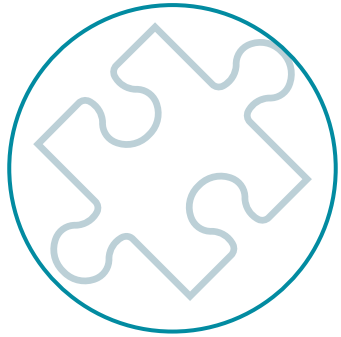
The degree to which **organizations equitably enable individuals** to **find, understand, and use** information and services to inform health-related **decisions and actions** for themselves and others.

<https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/health-literacy-healthy-people-2030>

# Example #3 - Apply Health Literacy Best Practices



## A - Plain Language



**Information that can be understood the first time someone reads or hears it.**

- Useful when communicating numeric information, like risk, randomization, uncertainty, and the meaning of study results
- Helpful to diverse audiences of patients and participants, study teams, health care providers, and even new colleagues in data science, biostatistics, or data management.

## Clinical Research Glossary

### Helping you understand clinical research

The **Clinical Research Glossary** offers easy to understand clinical research definitions.

All definitions are developed by the MRCT Center and a committed team of patient advocates and other professionals in medicine and research. Before definitions are released, they are reviewed by members of the public.

The Clinical Research Glossary started as a pilot project in 2020 and is now a CDISC global standard for clear communication. This means that more and more groups are learning about and using this resource.

Welcome! We hope this resource is helpful to you.

LEARN MORE GET INVOLVED MEET THE TEAM DOWNLOAD

Search

A B C D E F G

**A**

**additive effect** -  
The combined effect when two or more things are used together.

**adherence** -  
Following the study directions and requirements.

**adverse event** -  
Any health problem that happens during the study.

**adverse reaction** -  
A health problem that happens during the study and is reported as possibly caused by the study treatment.

**analyze** -  
To examine study data to answer a question and help reach conclusions.

**adherence** cdisc

Following the study directions and requirements.

**Example of adherence in a sentence**  
Adherence to the study instructions is important so reliable information about the study treatment can be collected.

**More Info**  
Adherence to the study **protocol** helps ensure the **data** from all study **participants** can be evaluated appropriately.  
Reliable research **results** depend on both researchers and **participants** carefully following the **protocol** and study instructions.  
The words "adherence" and "**compliance**" are often used in the same way.

**Other info to think about when joining a study**  
During study visits, someone from the study team may ask about your adherence to the study directions. That could **mean** following the exact directions for taking the **investigational medicine** or writing journal entries at specific time points.  
When you are reading through the **consent form** you may see that it says you could be removed from the study by the **investigator** if you are unable to follow the study procedures.  
You may wish to ask what you should do if you were unable to follow the study directions on a particular day. For example, if you forgot to take the study treatment at the right time.  
If you have a hard time following the **study procedures**, let the study team know so they can help you.

**Related Words**  
**compliance**

**Other Resources**  
**NCI Thesaurus**

If you know of other



[www.mrctcenter.org/glossary](http://www.mrctcenter.org/glossary)

Endorsed by  
CDISC as a  
global data  
standard



**NIH NATIONAL CANCER INSTITUTE EVS Explore**

HOME NCI THESAURUS - VERSION: 26.02D; RELEASE DATE: 2026-02-23 SUBSETS MAPPINGS HIERARCHY DOCUMENTATION HELP

The EVS website hosts biomedical terminologies that NCI does not own or control. Some of these sources may contain gender-related terminology that does not comply with Executive Order 14168

**Adherence ( Code - C25729 )** -- Open in Hierarchy Term Suggestion Form Collapse All Export New Search

All | CDISC-GLOSS | MRCT-Ctr | NCI

|                     |                                           |                        |
|---------------------|-------------------------------------------|------------------------|
| NCI Thesaurus Code: | C25729 (Search for linked caDSR metadata) | Synonyms               |
| Semantic Type(s):   | Functional Concept                        | Other Properties       |
| Preferred Name:     | Adherence                                 | Parent/Child Concepts  |
|                     |                                           | Roles and Associations |

**Definitions ( 3 ) [top]**

| Definition [1]                                                                                                                                                   | Source [1]  | Attribution |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------|
| Following the study directions and requirements. ( <a href="https://mrctcenter.org/glossaryterm/adherence/">https://mrctcenter.org/glossaryterm/adherence/</a> ) | MRCT-Ctr    |             |
| The act of abiding by a stated treatment plan or protocol.                                                                                                       | NCI         |             |
| The act of abiding by a stated treatment plan or protocol. [NCI]                                                                                                 | CDISC-GLOSS |             |

**Synonyms & Abbreviations ( 4 ) [top]**

| Term [1]  | Source [1]  | Term Type [1]    | Code [1] | Subsource Name [1] |
|-----------|-------------|------------------|----------|--------------------|
| adherence | CDISC-GLOSS | PT               |          |                    |
| adherence | MRCT-Ctr    | PT               |          |                    |
| Adherence | NCI         | PT               |          |                    |
| Adherence |             | (Preferred_Name) |          |                    |

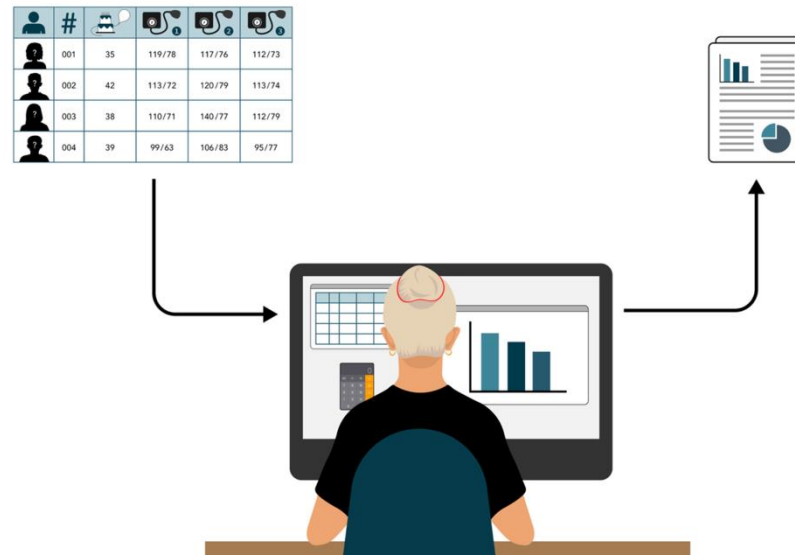
# Example #3 - Apply Health Literacy Best Practices



## B - Data Visualization

**Visual and graphic representation of data through charts, graphs, maps, interactive dashboards, and other visual imagery.\***

- Supports the transformation of data into actionable information and insights.
- Especially helpful in the return of results via Plain Language Summaries, in journal articles, and in considerations around Participant Data Return



\*Digital.gov

# Example #3 - Apply Health Literacy Best Practices



## Potential Impact:



- increased understanding by study teams and participants that can support the conduct of the study, participant retention, and reporting of the clinical trial results.
- stronger understanding of the research and its results amongst participants, which can influence:
  - how they feel about research,
  - what they tell others about their experience,
  - whether they would consider participating in research in the future, and
  - overall trust in the research enterprise.

# Patient-Centric Approaches Related to Clinical Research Data



**Engage in Collaborative  
Study Design**



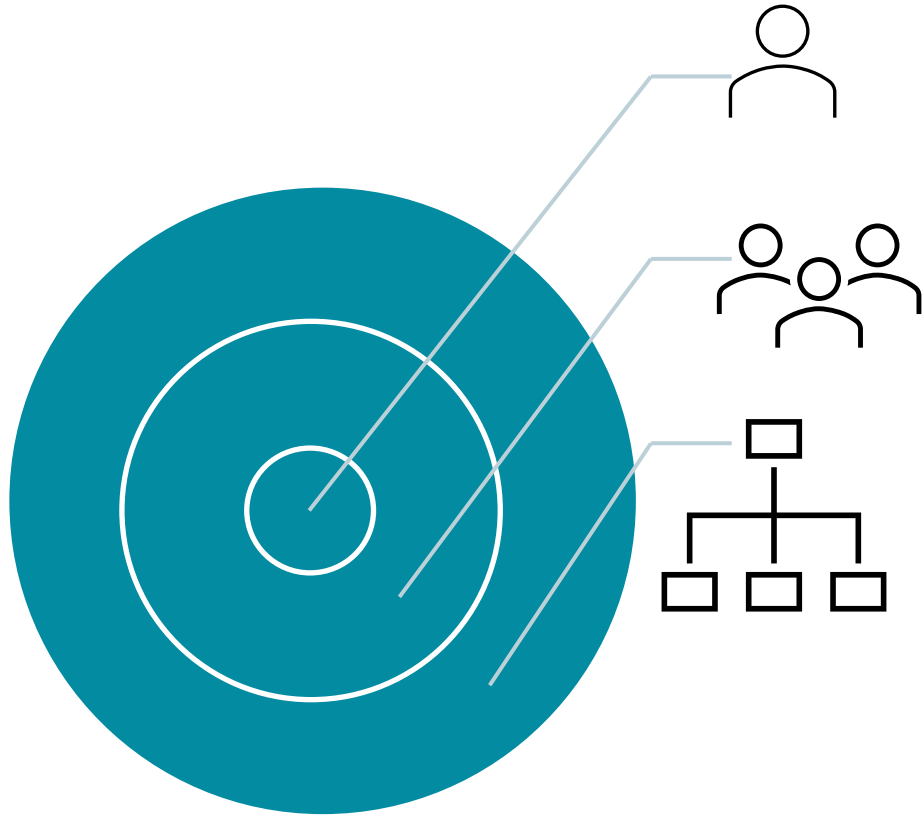
**Integrate and Leverage  
Real World Data**



**Apply Health Literacy  
Best Practices**



# Spheres of Influence and Organizational Change



- 1) Individual** – Be open to continued growth and learning; advocate for bringing patient insights into the study design and the selection of data endpoints that matter clinically; implement health literacy best practices.
- 2) Team** – Share learnings and insights about patient-centric approaches with colleagues; mentor others in the practices you apply and the lessons you learn; commit to making incremental change in your work together.
- 3) Organization** – Lead by example; integrate lessons learned into communications with and for higher-level leadership to gain buy-in; identify allies in senior roles to champion and support your patient-centric efforts.

# Key Takeaways



- There are many approaches to integrating patient centrality into the collection, management, analysis, and reporting of clinical trial data.
- Data scientists, biostatisticians, and clinical data managers all can play a role in clinical research patient centrality by:
  - Staying curious and open to learning more
  - Advocating for patient-centric approaches
  - Involving patients and their care partners in study design, conduct, and reporting
  - Integrating existing data sources into studies
  - Using plain language and data visualization techniques
  - Offering clear communication outputs about the study and its results



Thank you!  
What questions do you have?

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