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MULTI-REGIONAL
CLINICAL TRIALS
THE MRCT CENTER OF
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

phuse

Data Literacy in Clinical Research

Enhancing Trust and Transparency

Thursday April 3, 2025
10 - 11 AM ET

This session is being recorded and will be available on the MRCT Center website

Disclaimer

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We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results, and deliverables.

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Welcome

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Thank you to all who have contributed to this effort!

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About the MRCT Center

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The 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.

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Agenda

- Welcome & Introductions
- Intro to Data Literacy
- Video Development Process
- Infographics Development Process
- Q&A

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Key Topics to be Covered Today

1. **Data Literacy as a Component of Health Literacy**
    - Explore how understanding research data supports informed decision-making and aligns with broader health literacy efforts.
2. **Plain Language and Visual Tools for Data Communication**
    - Learn how the MRCT Center and PHUSE have used plain language and infographics to make clinical research data more accessible.
3. **Empowering Participants with Transparent and Actionable Information**
    - Identify ways to integrate data literacy resources into your clinical research processes to support research trust and engagement.

Why does data literacy matter in the context of patients, participants, and the public?

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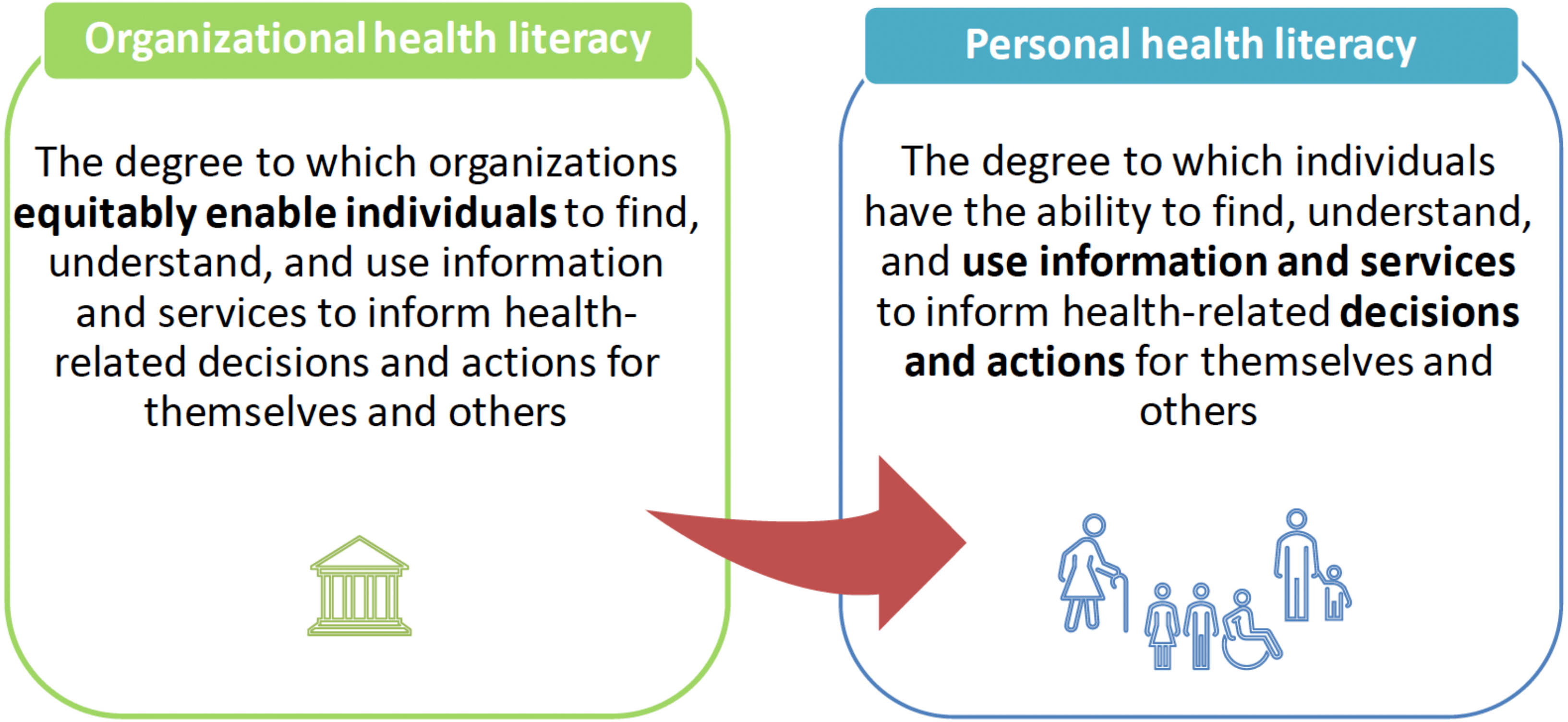
Data Literacy is a part of Health Literacy



Organizational health literacy

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

Personal 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

Similarly, data literacy refers to being able to access and use data in ways that are helpful and meaningful.

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Understanding Clinical Research Data and its Uses

Clinical research relies on the collection of data from human participants.

Communicating clearly about what personal information will be collected from participants, how it will be protected, and in what ways it will be used:

- Fosters transparency
- Lays a foundation of trust
- Supports the informed consent process

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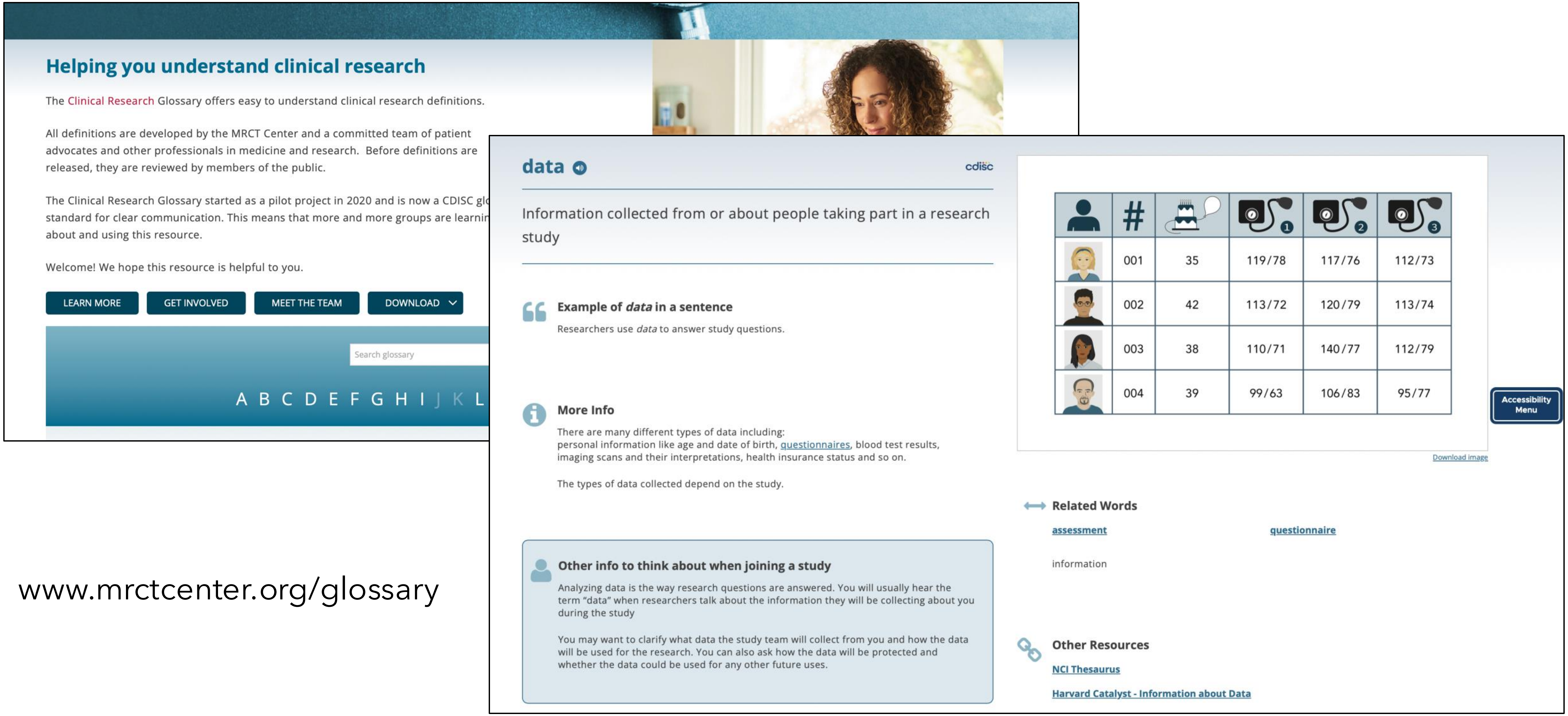
The MRCT Center Clinical Research Glossary



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 gl standard for clear communication. This means that more and more groups are learnin about and using this resource.

Welcome! We hope this resource is helpful to you.

data

Information collected from or about people taking part in a research study

Example of *data* in a sentence

Researchers use *data* to answer study questions.

More Info

There are many different types of data including: personal information like age and date of birth, questionnaires, blood test results, imaging scans and their interpretations, health insurance status and so on.

The types of data collected depend on the study.

Other info to think about when joining a study

Analyzing data is the way research questions are answered. You will usually hear the term "data" when researchers talk about the information they will be collecting about you during the study

You may want to clarify what data the study team will collect from you and how the data will be used for the research. You can also ask how the data will be protected and whether the data could be used for any other future uses.

	#		1	2	3
	001	35	119/78	117/76	112/73
	002	42	113/72	120/79	113/74
	003	38	110/71	140/77	112/79
	004	39	99/63	106/83	95/77

Related Words

assessment

questionnaire

information

Other Resources

NCI Thesaurus

Harvard Catalyst - Information about Data

www.mrctcenter.org/glossary

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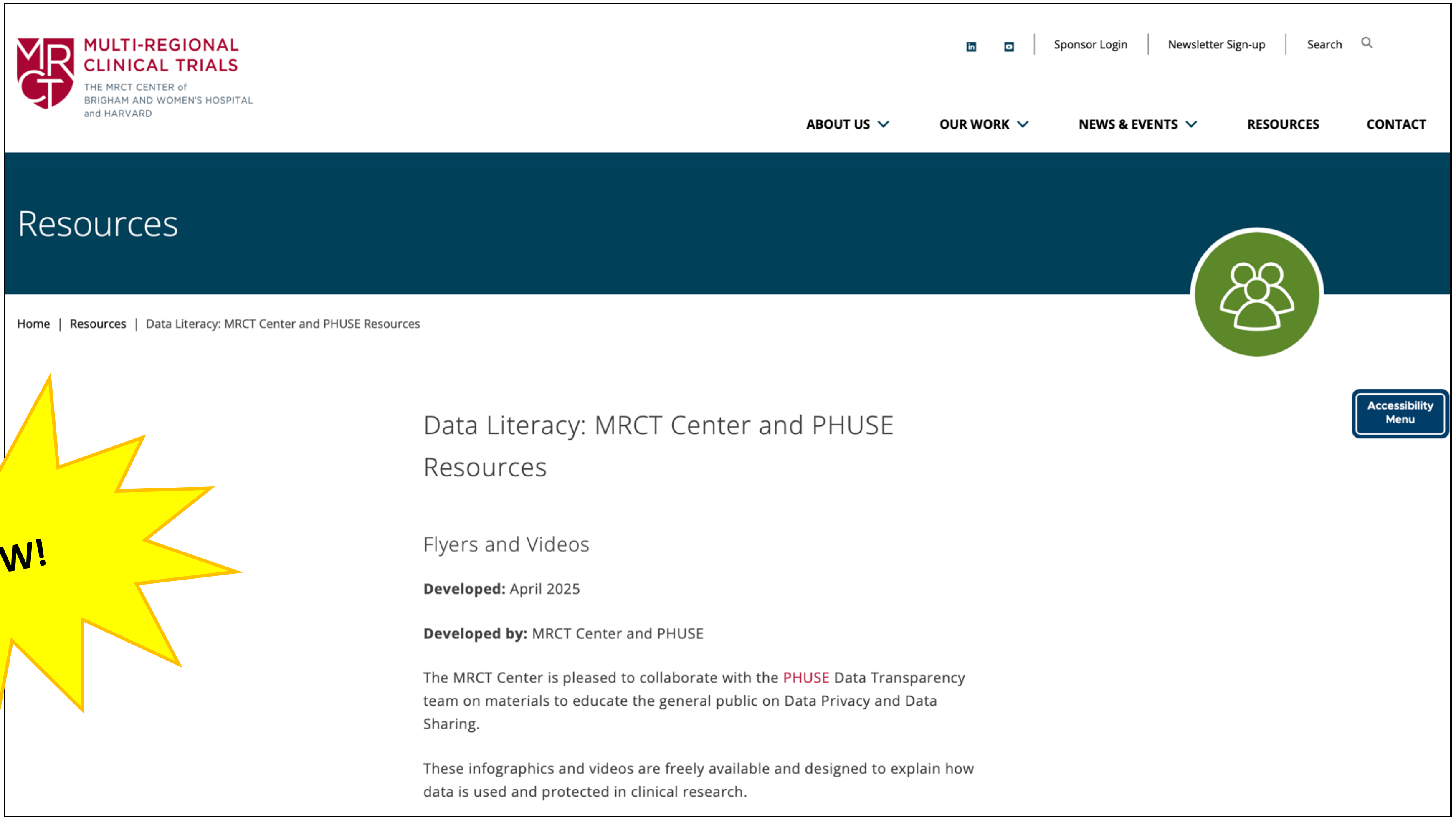
Opportunity to Collaborate on Resources

NEW!



Resources

Home | Resources | Data Literacy: MRCT Center and PHUSE Resources

Data Literacy: MRCT Center and PHUSE Resources

Flyers and Videos

Developed: April 2025

Developed by: MRCT Center and PHUSE

The MRCT Center is pleased to collaborate with the PHUSE Data Transparency team on materials to educate the general public on Data Privacy and Data Sharing.

These infographics and videos are freely available and designed to explain how data is used and protected in clinical research.

https://mrctcenter.org/resource/data-infographics/

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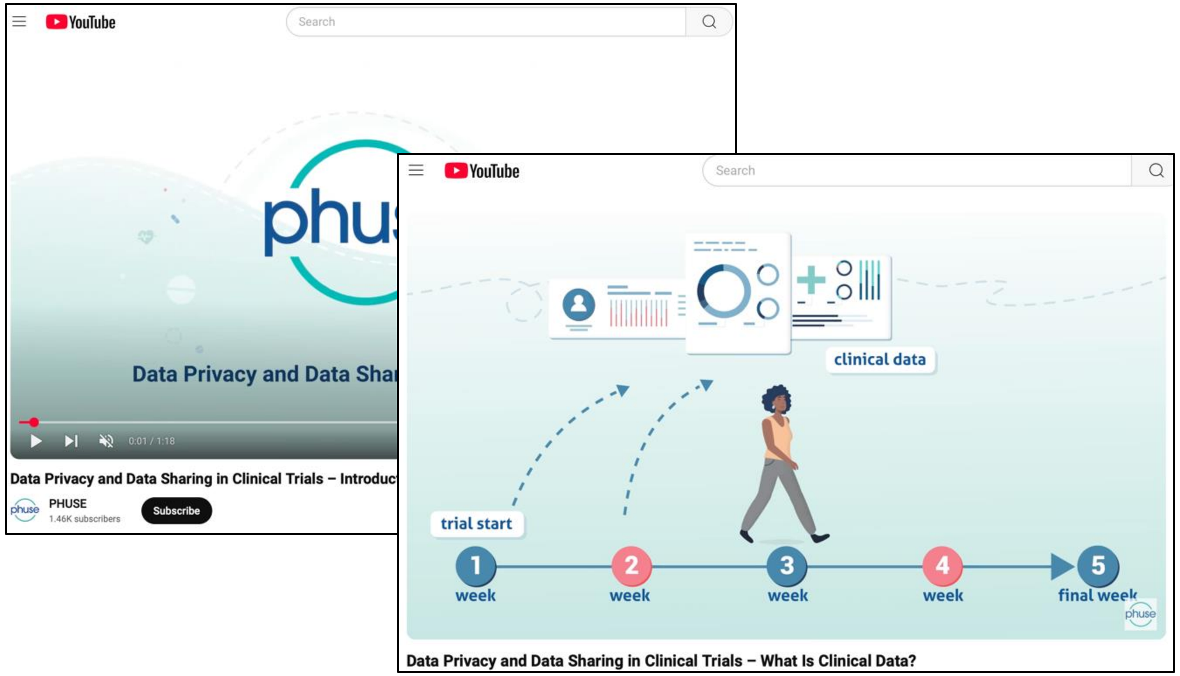
These collaborative resources include:

PHUSE-led videos



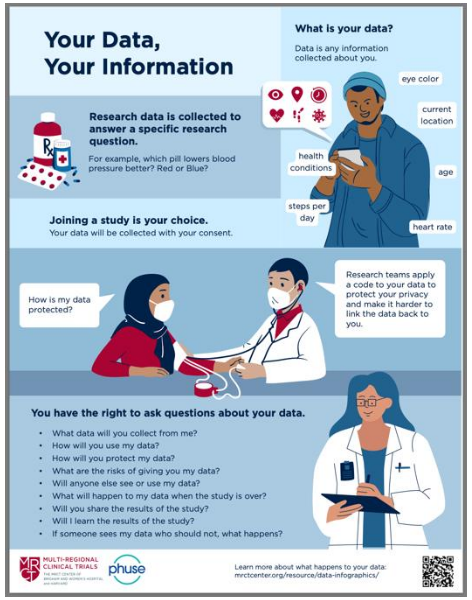
Data Privacy and Data Sharing in Clinical Trials – Introduc

PHUSE
1.46K subscribers

Data Privacy and Data Sharing in Clinical Trials – What Is Clinical Data?

- Data Privacy and Data Sharing in Clinical Trials – Introduction (Video 0)
- Data Privacy and Data Sharing in Clinical Trials – Importance of Clinical Trials (Video 1)
- Data Privacy and Data Sharing in Clinical Trials – What Will I Receive and When Will I Receive It? (Video 2)
- Data Privacy and Data Sharing in Clinical Trials – What Is Clinical Data? (Video 3)
- Video 4: 'Journey of a Data Point' – in progress
- Video 5: 'What is Data Sharing?' – in progress
- Video 6: 'What is Data Privacy?' – in progress

MRCT Center-led infographics



Your Data, Your Information

What is your data?

Data is any information collected about you.

Research data is collected to answer a specific research question.

For example, which pill lowers blood pressure better? Red or Blue?

Joining a study is your choice.
Your data will be collected with your consent.

How is my data protected?

Research teams apply a code to your data to protect your privacy and make it harder to link the data back to you.

You have the right to ask questions about your data.

- What data will you collect from me?
- How will you use my data?
- How will you protect my data?
- What are the risks of giving you my data?
- Will anyone else see or use my data?
- What will happen to my data when the study is over?
- Will you share the results of the study?
- Will I learn the results of the study?
- If someone sees my data who should not, what happens?

Learn more about what happens to your data: mrctcenter.org/resource/data-infographics/

Tus Datos, Tu Información

¿Cuáles son tus datos?

Los datos son cualquier información recopilada sobre usted.

Los datos de investigación se recopilan para responder una pregunta de investigación específica.

Por ejemplo, ¿qué pastilla baja mejor la presión arterial? ¿Rojo o azul?

Unirse a un estudio de investigación es su elección.
Tus datos serán recogidos con tu consentimiento.

¿Cómo se protegen mis datos?

Los equipos de investigación codifican sus datos para proteger su privacidad y dificultar la vinculación de los datos con usted.

Tiene derecho a hacer preguntas sobre los datos de su investigación.

- ¿Qué datos recogerán de mí?
- ¿Cómo protegerán mis datos?
- ¿Cuáles son los riesgos de darte mis datos?
- ¿Alguienmásverá o utilizará mis datos?
- ¿Qué pasará con mis datos cuando finalice el estudio?
- ¿Compartirás los resultados del estudio?
- ¿Me enteraré de losresultados del estudio?
- Si alguien ve mis datos y no debería, ¿qué pasa?

Obtenga más información sobre lo que sucede con sus datos en mrctcenter.org/resource/data-infographics/

English

- **Infographic #1:** 'Your Data, Your Information'
- **Infographic #2:** *'What Happens to Data During a Research Study?'*
- **Infographic #3:** *'What Happens to Data After a Research Study?'*
- **Infographic #4**: '*What is a Data Repository?*'
- **Infographic #5**: '*What Happens to Data if You Leave a Research Study?'*

Spanish

- **Infographic #1:** 'Tus Datos, Tu Información'
- **Infographic #2:** ¿Qué Sucede Con Los Datos Durante un Estudio de Investigación?
- **Infographic #3:** *¿Qué Sucede Con Los Datos Después de un Estudio de Investigación?*
- **Infographic #4**: ¿Qué es un Repositorio de Datos?
- **Infographic #5**: ¿Qué pasa con los datos si te retiras de un studio de Investigación?

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Resources Development

Video Process

This session is being recorded and will be available on the MRCT Center website

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About PHUSE

PHUSE is an **independent, nonprofit organization run by a worldwide team of volunteers** providing the healthcare industry with a premier platform for open-access knowledge sharing of ideas, tools, and standards around data, statistical, and reporting technologies.

We are a **free-to-join global community** of data science professionals who are passionate about our collaborative work and collective purpose to advance clinical information and the future of life sciences.

To fulfil our mission to **share – contribute – advance**, PHUSE has successfully built relationships with regulatory agencies, standards organizations, and industry groups. PHUSE has become the industry voice to regulatory agencies and standards organizations such as the FDA, EMA, and CDISC. We value these relationships and partnerships. Our collaborations have been strengthened through our events and Working Groups.

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Project Scope and Delivery

There is increasing interest by the general public in data privacy and sharing and most publicly available information is targeted toward individuals with training / experience / expertise in these areas

Accessible and understandable content will increase general public knowledge (and accuracy)

This project focuses on creating engaging content on data privacy and data sharing that can be understood and used by the general population (any member of the public regardless of their sector or profession)

Ultimately, this understanding will enable viewers to become more informed, thus helping to have a positive impact on their families and the wider community.

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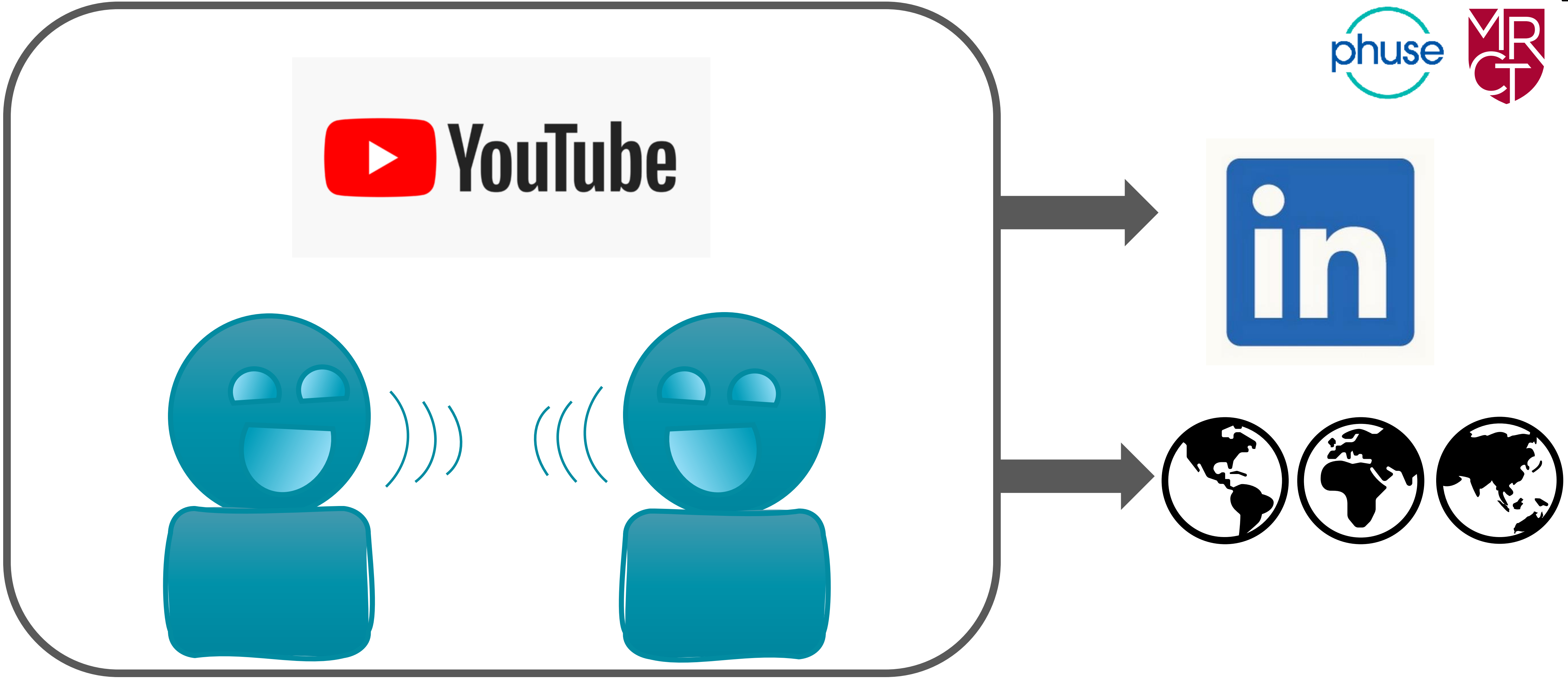

Character 1

Character 2

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Video Topics

Video 0: Introductory video (teaser)

Video 1: Importance of Clinical Trials

Video 2: What Will I Receive and When Will I Receive It?

Video 3: What Is Clinical Data?

Video 4: Journey of a Data Point

Video 5: What Is Data Sharing?

Video 6: What Is Data Privacy?

Data Transparency Working Group's first deliverables aimed at the general population.

Both pilot videos yielded a combined total of 900+ YouTube views during 4-month review window, attracted attention of industry, patient advocacy groups and consortia around the world ☺

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Scriptwriting

The project team started by **brainstorming** ideas alongside **patient advocates' feedback**.

Precise word choice and concise sentences convey complex concepts clearly and technical terminology is explained within the conversation.

- We also repeat the terms "**safe**" and "**effective**" as these underpin the main objectives of clinical trials.

Before sending the proofread script to the videographer, the project team highlighted part of the script for keywords to appear as bold on-screen to **emphasise important words and phrases**, and particular words or phrases for a focus on **tone and empathy**.

A style guide has recently been developed by the project team for future use to act as a useful reference point for reviewers and the audience viewing our suite of educational resources.

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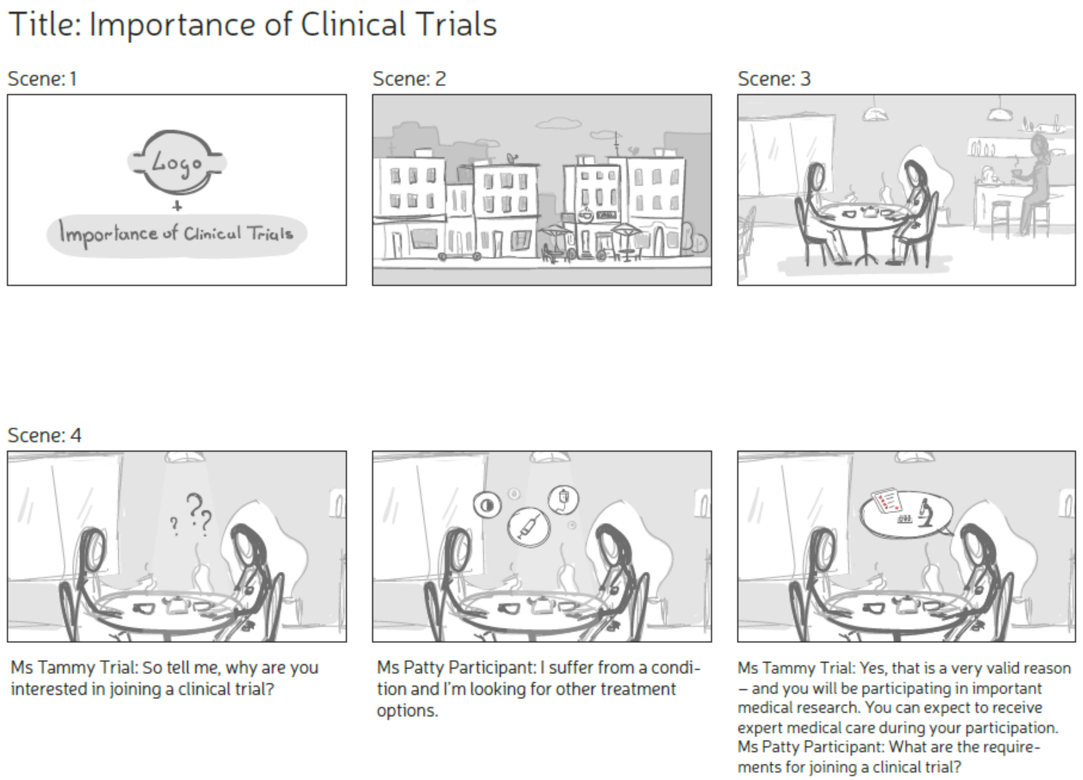
Example: Black and white sketch drawings based on script



Title: Importance of Clinical Trials

Scene: 1

Scene: 2

Scene: 3

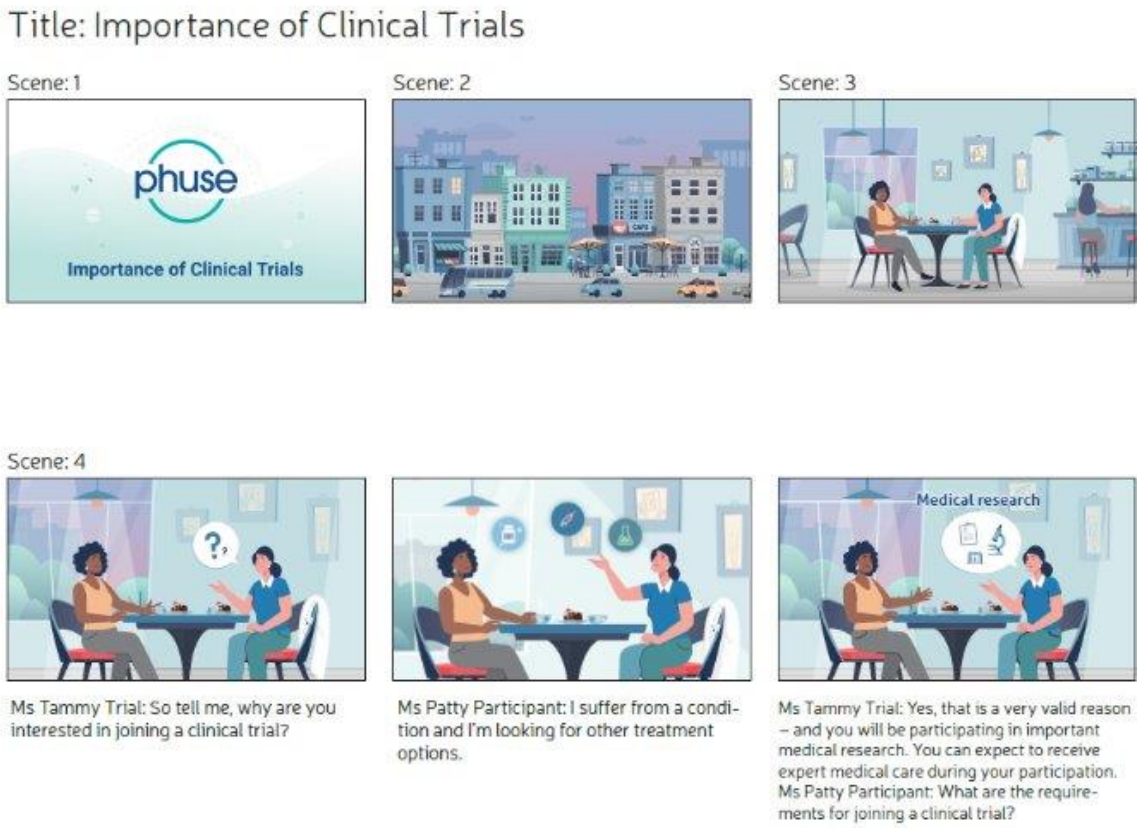
Scene: 4

Ms Tammy Trial: So tell me, why are you interested in joining a clinical trial?

Ms Patty Participant: I suffer from a condition and I'm looking for other treatment options.

Ms Tammy Trial: Yes, that is a very valid reason – and you will be participating in important medical research. You can expect to receive expert medical care during your participation. Ms Patty Participant: What are the requirements for joining a clinical trial?

Example: Colour storyboard



Title: Importance of Clinical Trials

Scene: 1

Scene: 2

Scene: 3

Scene: 4

Ms Tammy Trial: So tell me, why are you interested in joining a clinical trial?

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Ms Tammy Trial: Yes, that is a very valid reason – and you will be participating in important medical research. You can expect to receive expert medical care during your participation. Ms Patty Participant: What are the requirements for joining a clinical trial?

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Video production and process

1) Starting a contract;

2) Send approved (final) script;

3*) Voiceover artist selection;

3.1*) Voiceover creation;

3.2*) Approvement / some fixes to record if needed;

4) Storyboard creation (sketched / drawn scenario based on the script);

4.1) Approval / discussion

5) Animation creation;

6) Discussing edits if required and implementing changes

**can go in parallel with storyboard creation*

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Video formatting and design

First three episodes (Video 0, Video 1, Video 2) – two characters in a coffee shop

Fourth episode (Video 3) – walk outside to the park to continue their conversation

Fifth episode (Video 4) – coffee shop thumbnail image to the side of the screen whilst Tammy Trial walks us through the Journey of a Data Point

Sixth episode (Video 5) – dinner at Tammy's house and introduction of a new character (Nina Neighbour)

Seventh episode (Video 6) *– script planning in progress*

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As an Aside – The use of AI

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We used **Murf AI** for Videos 2 and 3 - a new opportunity to explore AI voiceover software in our project:

Pros

- Reduce costs to **balance content and time length**
- Proposition of AI usage was a matter of economy, **increased flexibility and easy usage**

Cons

- Concerns included the voice sounding **impersonal and robotic**
- Delivery issues (e.g., **lack of pauses, too fast, strange intonations and inflections**)

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Summary of Collaborative Steps

Co-creation in a **multistakeholder group** through **robust review and approval**

- Followed by **user testing and feedback**.

Patients and carer participation in content-creation process

Learning about users' **attitudes and expectations**

An **information-gathering exercise** to collect input on the **distribution and dissemination** of the videos

- Done via an interactive **PHUSE Community Forum,** February 2023
- Event focused on open-ended survey questions distributed by PHUSE.

Feedback from **PAIR Network (Patient Advocates in Research)**

External information-gathering & dissemination

- **DIA Patient Engagement Community**
- **Inspire2Live World Campus Data Group**
- **Inspire2Live Congress**.

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Feedback Process for Videos and Infographics

Feedback collection - open ended questions to stakeholders

Response documentation - depends on complexity and type of deliverable

Video comments captured via email alongside associated timepoints, for sharing with Videographer

Script comments documented on file itself & actioned by Project Lead

Infographic comments maintained in a comments log file

Comments resolution

Comments are reviewed for consistency with style of deliverable

Requests are responded to and actions are outlined (including rationale for actions taken)

After updates are made, deliverable is recirculated with Project Team to confirm action taken

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Educate the General Population on Data Privacy and Data Sharing
Thank you to all our Working Group Project Team ☺ both past and present!

Current Project Members

Alyssa Panton
Barbara E. Bierer
Benjamin Shim
Bhargavi Raghavan
Cheryl Jernigan
Dan Bilodeau
Devi Gurrappadi
Diane Heditsian
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Nicole Hinton
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Parveen Kumar
Pooja Phogat
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Rene Allard
Sanjay Bagani
Shannon Lefaivre
Sharon Niedecken
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Nathalie Sarbanovic (PHUSE Marketing & Comms)
Kayley Stephens (PHUSE Marketing & Comms)

Project Leads

Lucy Marks (PHUSE Senior Project Coordinator)
Devaki Thavarajah (PHUSE DT Working Group Lead)

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Thank you!

Any additional points you would like us to take note of? ☺

If you are interested in participating in this project, please email: workinggroups@phuse.global

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The Global Healthcare Data Science Community

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Resources Development

Infographics Process

This session is being recorded and will be available on the MRCT Center website

Data Literacy Infographics

The PHUSE process already existed.

The MRCT Center joined the workgroup to start working on videos and identified an additional potential modality – the infographic – to support learning across the digital divide.

The infographics have been designed to complement the existing videos.

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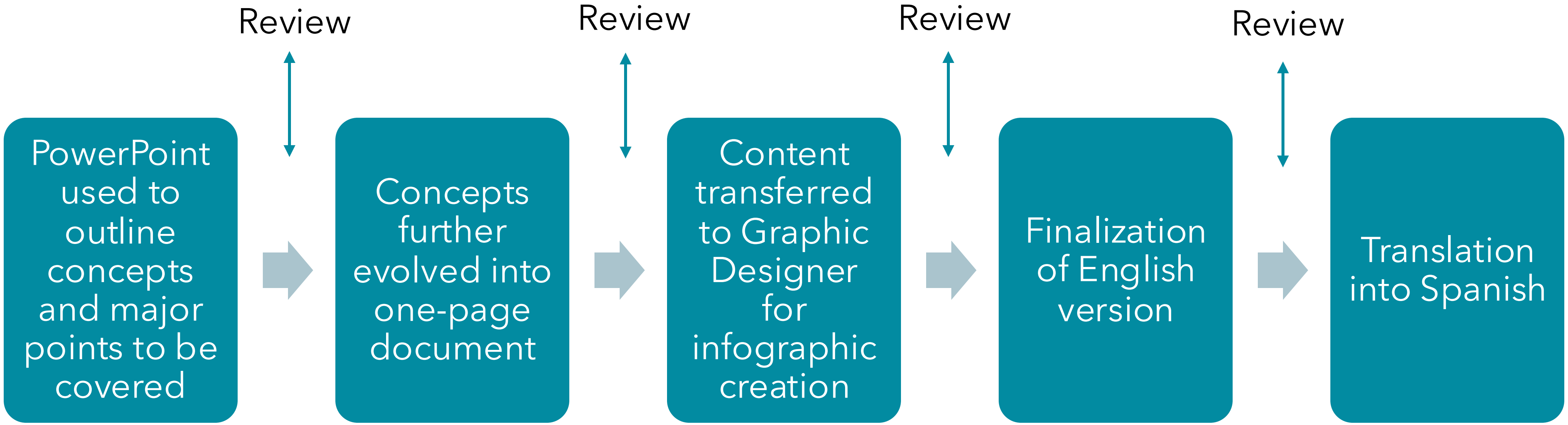
Iterating on the Infographics Content



PowerPoint used to outline concepts and major points to be covered

Review

Concepts further evolved into one-page document

Review

Content transferred to Graphic Designer for infographic creation

Review

Finalization of English version

Review

Translation into Spanish

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Opportunities for Learning

- Technical information harmonization and accuracy – navigating international perspectives.
- Achieving a balance of the “right” amount and depth of information designed for a general audience who may be new to research and the world of research data.
- Workgroup knowledge changing and evolving through the resource creation process..

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Thank you to all who contributed to this project

PHUSE working group, including MRCT Center’s Barbara Bierer and Alyssa Panton

MRCT Center Graphic and Informational Designer, Chloe De Campos

Subject Matter Experts, Małgorzata Sztolsztener and Brandy Hemmer

Spanish Language Translation by Headland’s Alejandro Silva

MRCT Center Team, Nannie Clough, Kristin Bartlett, Kaitlin Hersey, and Kayleigh To

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We invite you to share!

Everything we've shared today is free for you to use.

Bookmark, download, and share these resources!

https://mrctcenter.org/resource/data-infographics/

THANK YOU

You can reach me at sbaedorfkassis@bwh.harvard.edu

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Discussion and Q&A

THANK YOU!