



**Prevent  
Blindness**

Focus on Eye Health  
National Summit

# Eye-conic Approaches to Eye Health

**July 13–14, 2022**

*A Virtual Interactive Event*





# Equitable Practices for Children's Vision Research

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MRCT Center  
Harvard Medical School

# The Multi-Regional Clinical Trials Center (MRCT Center)



## Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

## Our Mission

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



(c) MRCT Center: Do not duplicate

# Importance of diversity and inclusion in clinical research



- Analyses of group differences in outcome among diverse populations can promote identification of underlying biological and socially relevant factors that affect health, but only if data exist.
- Diversity in enrollment seeks fairness in the distribution of direct and long-term benefits of research.
- Diverse representation in clinical trials is not simply a matter of biology, but a matter of health equity and fairness.
- Participation helps build public trust in research and healthcare.

# Diversity is multi-dimensional

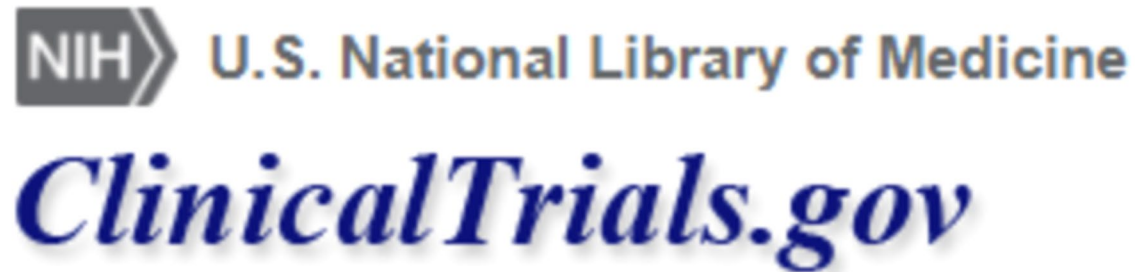
- Race
- Ethnicity
- Sex
- Gender
- Children
- Elderly
- Disabled
- LGBTQIA+ ...



- Each dimension must be considered
- And each person, in their own unique individuality, needs to be considered



# Children with vision disorders in clinical research



205 Studies found for: **Vision Disorders | United States | Child**

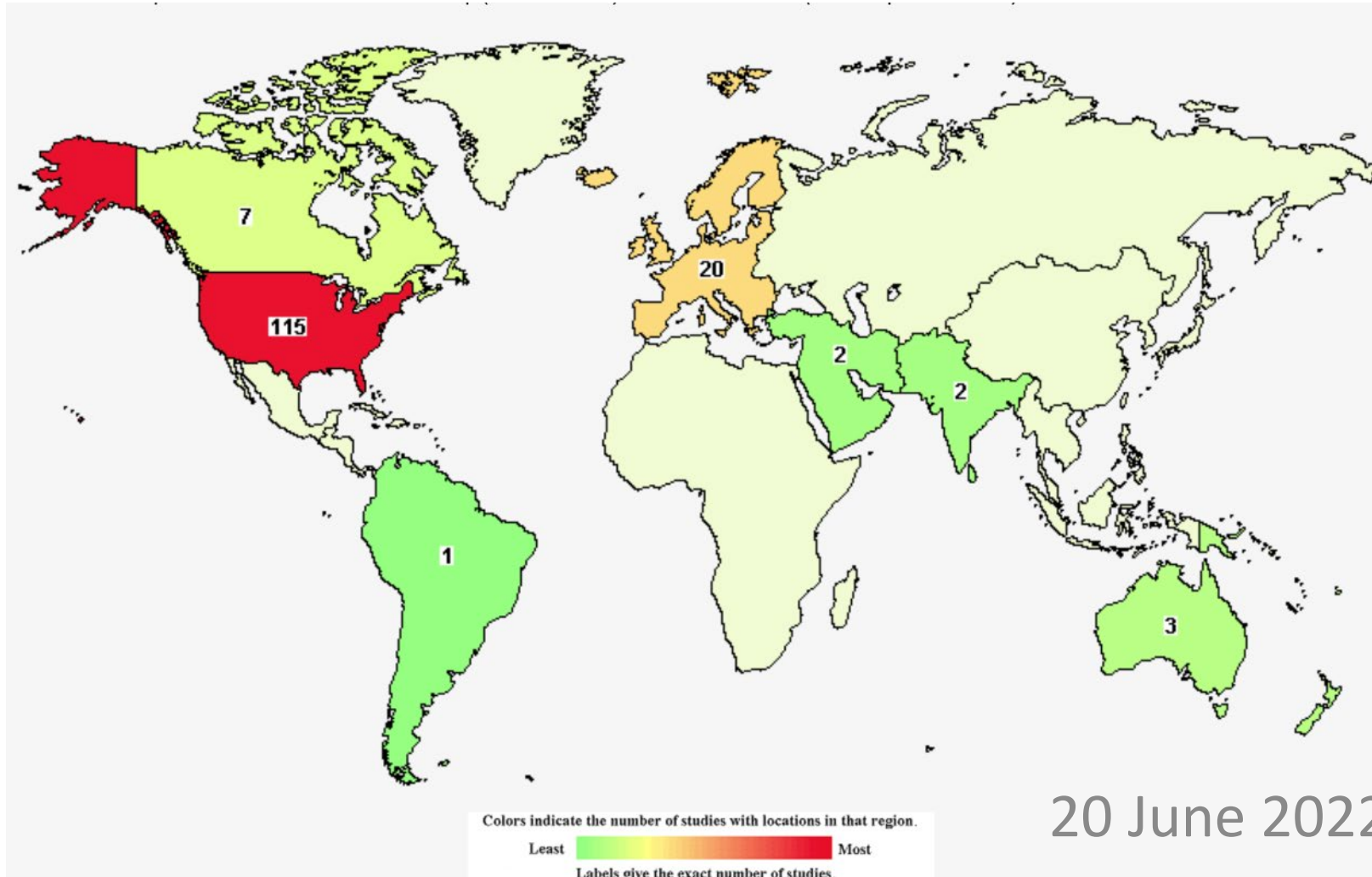
**115** Studies in last 10 years

**71** Studies in last 5 years

**16** Studies with key word “Blindness”



# Studies of children with vision disorders in clinical research



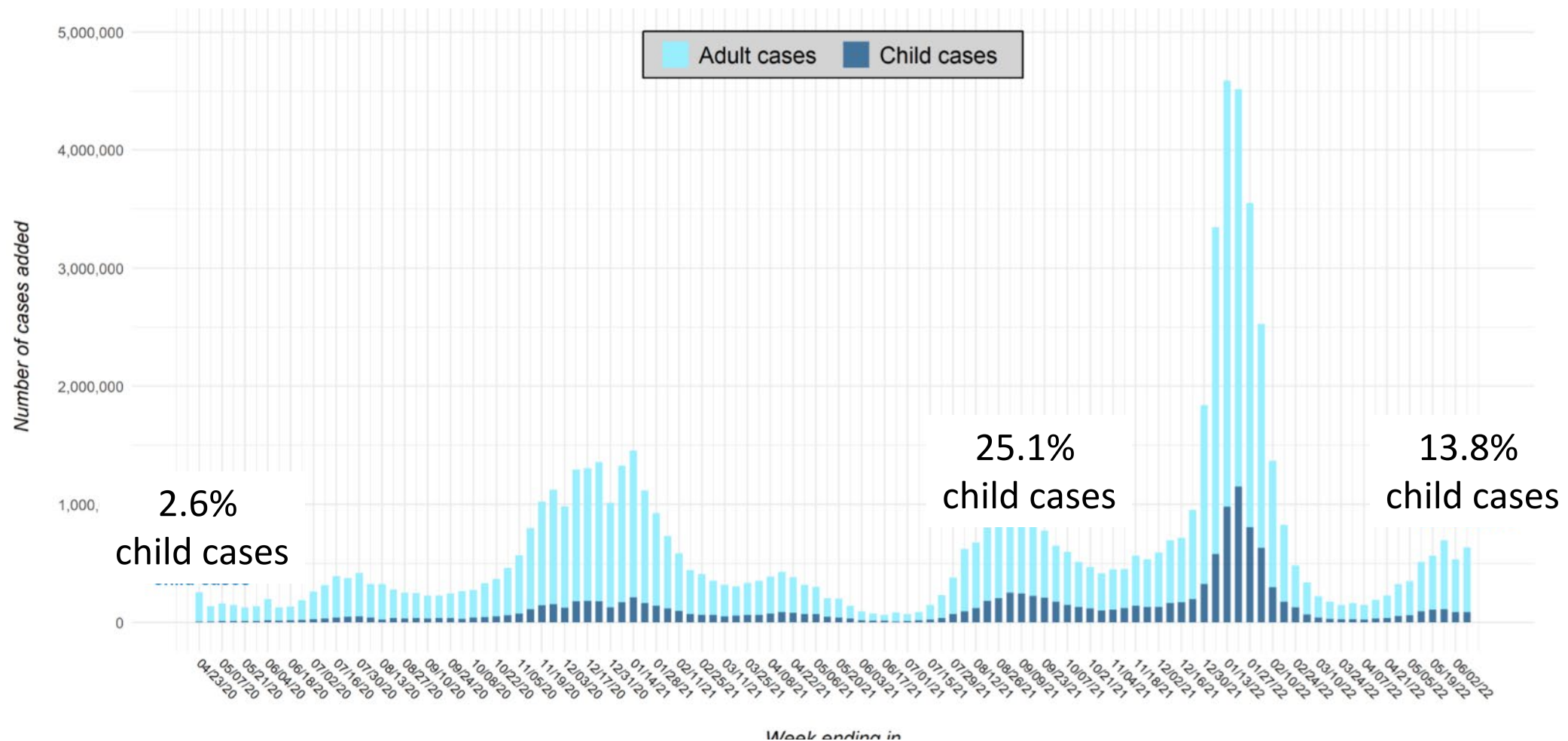
ClinicalTrials.gov  
115 Studies in last 10 years

20 June 2022

# Underappreciated: COVID-19 and pediatrics



## United States: Number of COVID-19 Cases Added in Past Week for Children and Adults\*



[https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%206.9.22%20FINAL.pdf?\\_ga=2.90536857.2014404101.1655747383-1470071932.1648666956](https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%206.9.22%20FINAL.pdf?_ga=2.90536857.2014404101.1655747383-1470071932.1648666956)



# Underappreciated: COVID-19 and pediatrics



**Case Data Available on 6/9/22**

<b>Child population, 2019</b>	<b>Cumulative total cases (all ages)</b>	<b>Cumulative child cases</b>	<b>Cumulative percent children of total cases</b>	<b>Cases per 100,000 children</b>
75,266,842	71,733,195	13,541,153	18.9%	17990.9

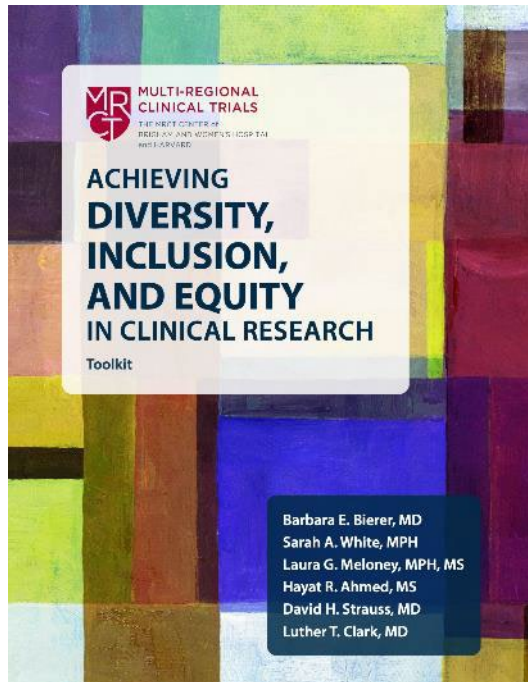
Children deserve to be included in research.


[https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%206.9.22%20FINAL.pdf?\\_ga=2.90536857.2014404101.1655747383-1470071932.1648666956](https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%206.9.22%20FINAL.pdf?_ga=2.90536857.2014404101.1655747383-1470071932.1648666956)

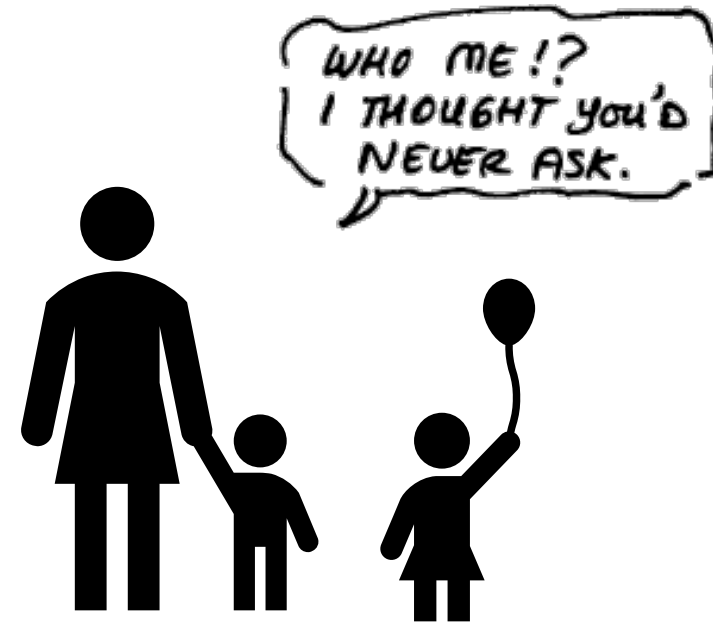
# Access to clinical trials, and to accessible clinical trials



## Achieving Diversity, Inclusion, Equity In Clinical Research



 amazon.com



<https://mrctcenter.org/diversity-in-clinical-trials/>

# Barriers to inclusion at all levels



Sponsors/Institutions/Sites/Regulators



Investigators/Referring Physicians/Staff



Patients/Advocates/Communities



Data Collection/Data Analysis

It can be done

# Patient and community engagement support diverse participation



Form  
Relationships

Patient/community: leaders,  
advisors, and consultants.

Provide Training  
and Support

Research priorities  
and questions

Identify Shared  
Goals

Tailor study design and  
conduct



Trust and trustworthiness

Study  
Question

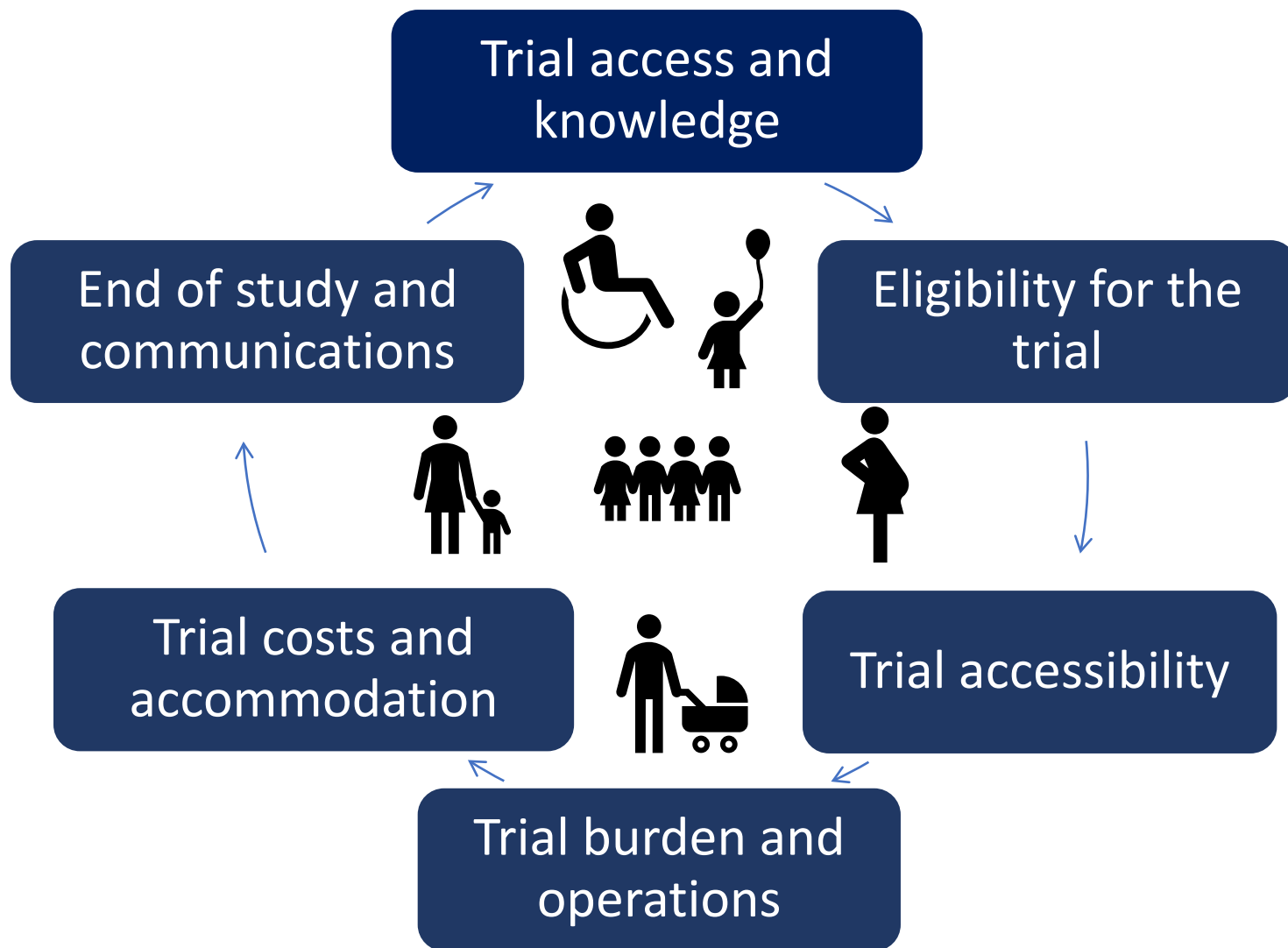
Study Design

Data  
Collection

Analysis  
Interpretation

Dissemination

# Participation in any trial is a journey



- Child
- Parent(s) or Guardian
- Caregiver
- Siblings and family
- Legally authorized representative

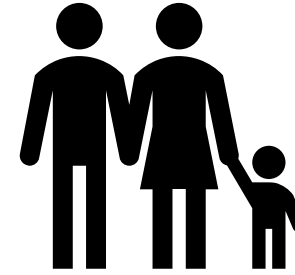


# The challenge of participation



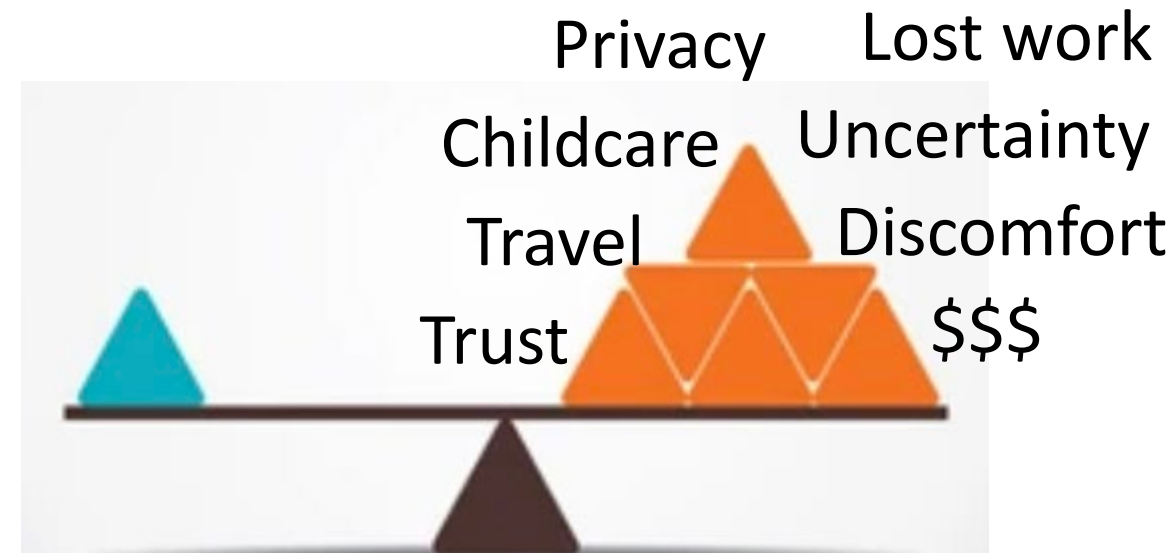
Benefit

Risk



Benefit

Risk



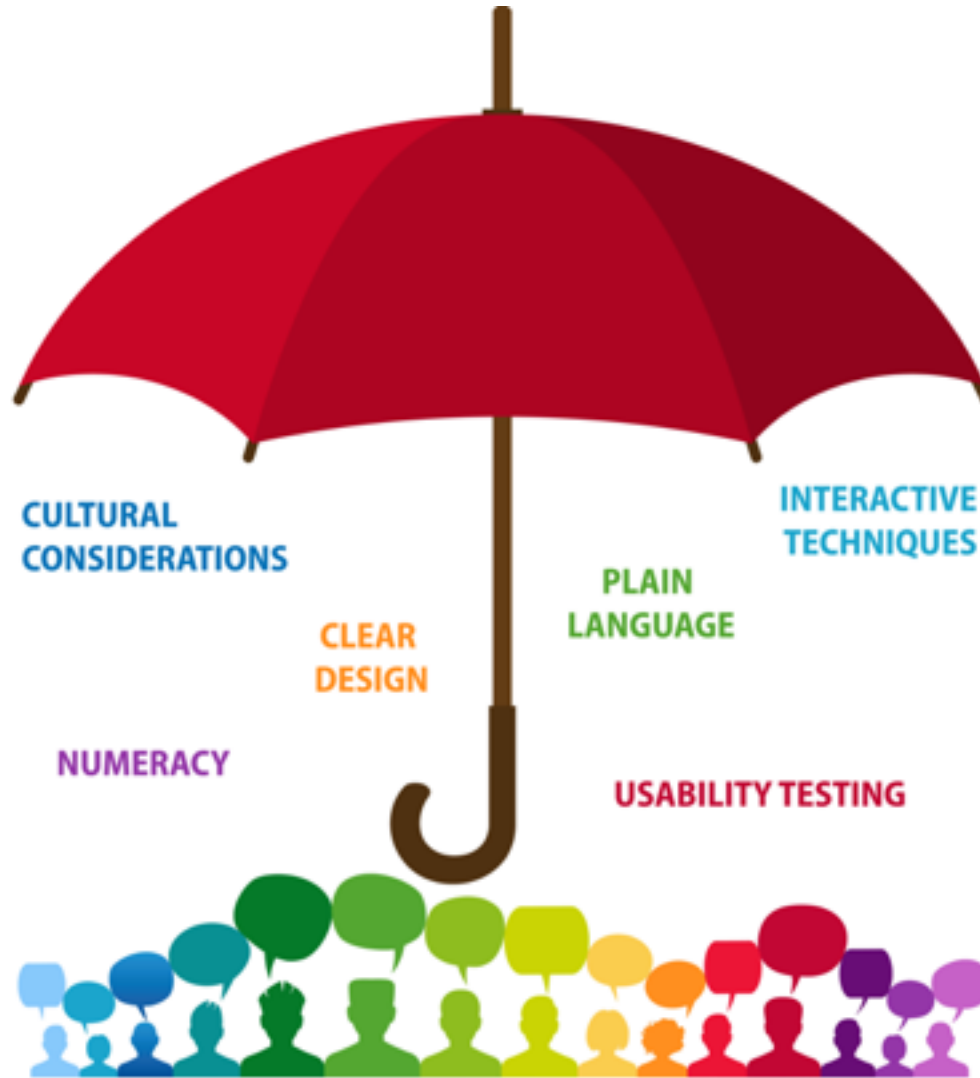
# Clear communication is a shared responsibility



- The listener does not have “poor literacy,” and is not responsible for making sense of the information.
- The communicator is responsible for sharing information that is understandable to the listener.
- The listener should be comfortable communicating any lack of understanding.
- And it is a greater problem for individuals whose preferred language is other than English.

<https://mrctcenter.org/health-literacy/>

# A Broad View of Health Literacy Components



- Plain language
- Numeracy
- Visualization
- Clear design
- Cultural considerations
- Interactive techniques
- Usability testing



# Plain Language Across the Clinical Trial Life Cycle



DISCOVERY

Awareness  
Outreach  
Engagement  
Education



RECRUITMENT

Flyers  
Recruitment  
Adverts



CONSENT

Consent  
Instructions  
Calendars



ON STUDY

Medications  
Adverse Events  
Satisfaction



END OF STUDY

Study results  
Transition to care  
Access  
Follow-up



# Health literacy beyond the ICF

## Injection Guide for Study Drug or Placebo Panel A (Days 1-5) and Panel B (Days 6-10)

### Instructions for Use

#### Study Drug or Placebo Injection

Each vial contains 1 mL of study drug or matching placebo. The volume removed from the vial determines the dose administered. The study staff will tell you how much to inject from each vial.

#### Important Information

- > Refrigerate kit box: Do Not Freeze.
- > Vials should only be used one time.
- > Only uncup the vials that you are preparing to inject.
- > Only inject the volume instructed by study staff. Do not inject the entire contents of either vial.
- > Always use a new site-provided syringe/needle for each injection.

#### Step 1: Prepare Vials

- Remove 2 vials from the kit box and return kit box to the refrigerator.
- Allow vials to come to room temperature for at least 15 minutes.
- Vials should then be inverted a minimum of three times.
- Wash your hands with soap and water.

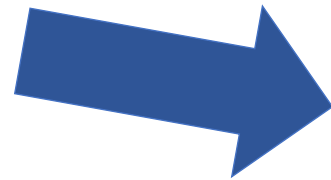
#### Step 2: Prepare Syringe

- Remove the cap from one of the vials and wipe the top of the vial with an alcohol swab.
- Open a new syringe and needle.
- By pulling back on the plunger, draw air into the syringe up to the mark of the volume to be injected and then slowly inject the air into the vial.
- Keep the needle in the vial and turn the vial upside down. Make sure that the needle tip is well below the surface of the liquid in the vial.
- With the tip of the needle in the liquid, pull slowly back on the plunger to get the right volume into the syringe.
- Check the syringe for air bubbles. If there are bubbles, hold both the vial and syringe in one hand, and tap the syringe with your other hand. The bubbles will float to the top. Push the bubbles back into the vial, then pull back to get the right volume of study drug/placebo.

- When there are no bubbles, take the syringe out of the vial. Put the syringe down carefully so the needle does not touch anything.

#### Step 3: Injection

- Clean an injection site that is about 2-3 inches away from your belly button on your abdomen with a new alcohol swab. Let dry thoroughly.
- Hold the syringe in the hand that you will use to inject study drug. Use the other hand to pinch a fold of skin at the cleaned injection site.
- Use the injection technique shown to you by the study staff.
- After the needle is inserted and while pinching the skin, pull the plunger back slightly. If no blood appears, steadily push the plunger all the way down until the study drug is injected. **Note:** If blood enters the syringe, remove the syringe, clean and prepare another spot on your abdomen and using the same syringe/needle, inject the product.
- Leave the syringe in place for about 6 seconds after injecting (the pinch may be released) and remove. After the needle is removed, you can apply light pressure with clean gauze or cotton ball but, do not rub the site.
- Place used syringe/needle (do not re-cap the syringe) in a sharps disposal container provided by site.



## How to give yourself the study medicine

Panel A (Days 1-5) and Panel B (Days 6-10)

### Study medicine

Each bottle holds 1 mL of active drug or placebo.

The study staff will tell you how much medicine to use each time (this is called your dose). Only give yourself the dose the study staff told you. Do not use all the medicine in the bottle.

The study staff will tell you how much to inject from each bottle.

### Important safety information

- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncup the bottles when you use them.

## Steps to give yourself the study medicine

### Get ready

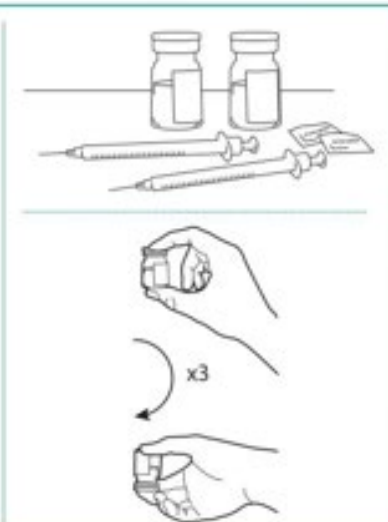
#### 1. Gather your supplies:

- 2 syringes
- 2 bottles of medicine
- 2 alcohol swabs

#### 2. Take out 2 bottles from the kit box and put the kit box back in the refrigerator.

- Let the bottles sit on the counter for at least 15 minutes to get to room temperature.
- Turn the bottles upside down and then right side up at least 3 times.

#### 3. Wash your hands with soap and water.

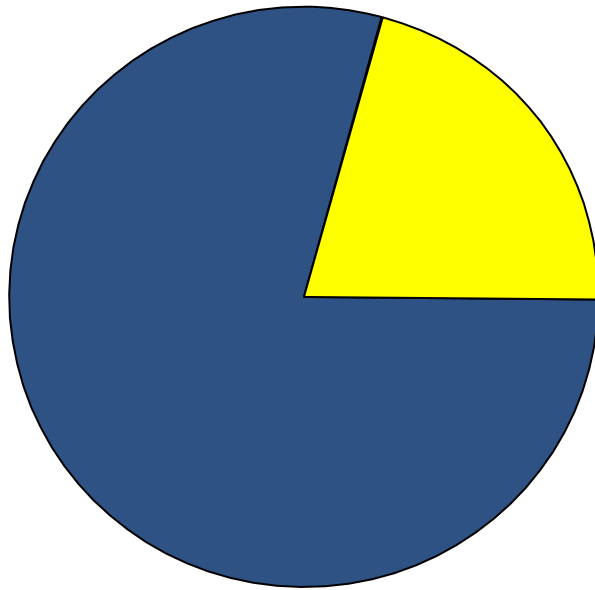


<https://mrctcenter.org/health-literacy/>

**Prevent**

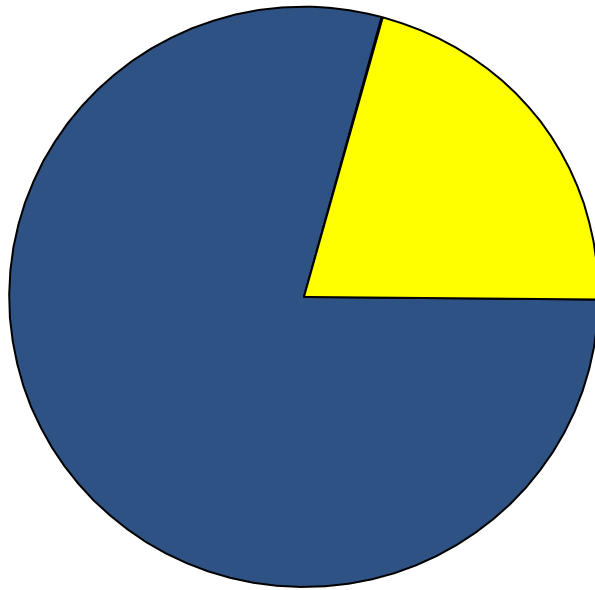


# Numeracy



In 20% (or 1 in 5) of patients, tumors got at least 30% smaller

# Numeracy



In 20% (or 1 in 5) of patients, tumors got at least 30% smaller

In 80% (or 4 in 5) of patients, tumors did not get at least 30% smaller

# Use and Share Plain Language Information



- The **MRCT Center Clinical Research Glossary** provides plain language research information developed by and for participants.
- Now being expanded.

<https://mrctcenter.org/clinical-research-glossary/>

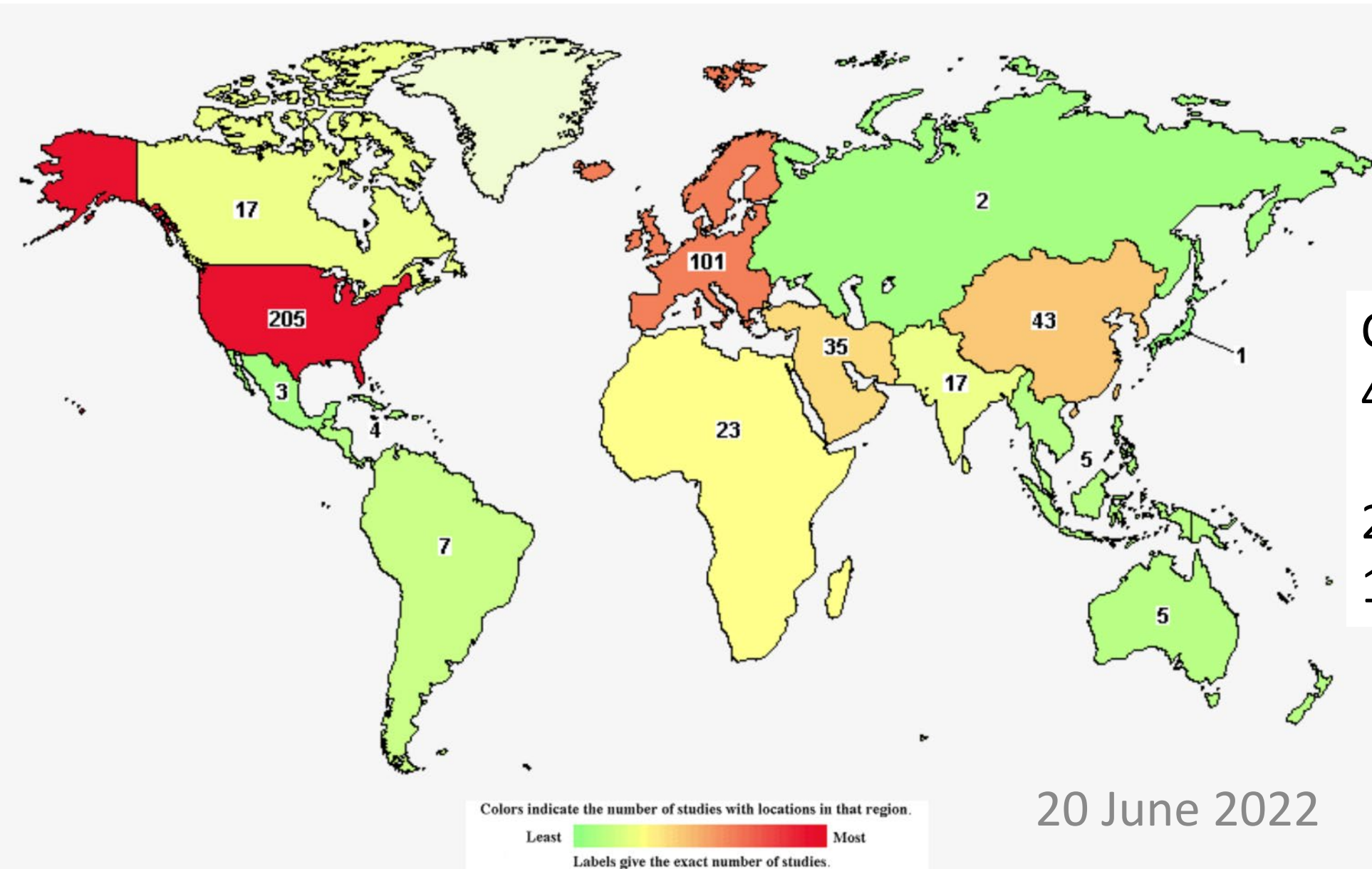


# Promoting Clinical Research in Children

- ❖ The problem: Protection from research, not through research
- ❖ Shift in perspective: Protection by inclusion
- ❖ Global differences, such as:
  - ❖ Laws
  - ❖ Health care available
- ❖ Cultural differences
- ❖ Process differences



# Global map of children with vision disorders in research



ClinicalTrials.gov  
461 Studies

294 Studies in last  
10 years

20 June 2022





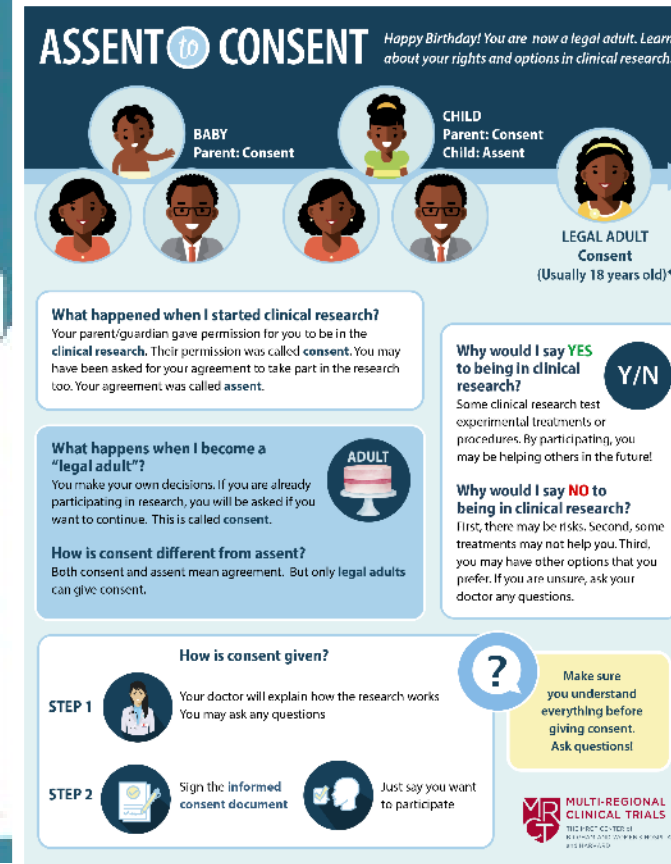
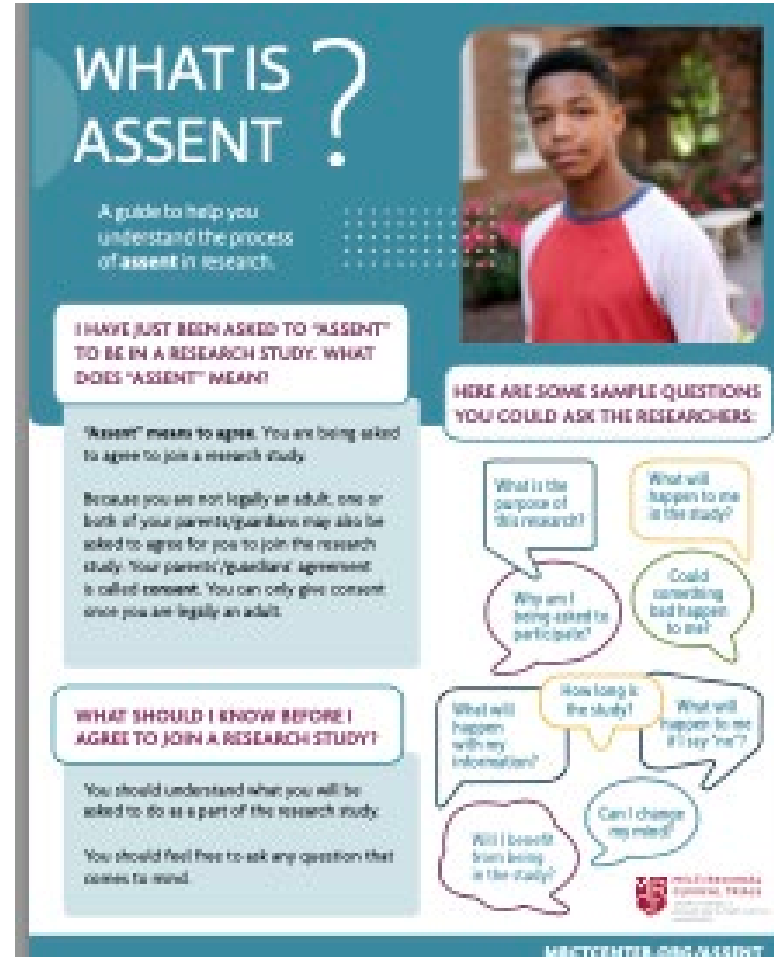


# Promoting Clinical Research in Children

- ❖ Listening to children (and their parents)
  - ❖ How can we do that well?
  - ❖ How do you know if you have spoken to enough children?
  - ❖ Can one child speak for another?
  - ❖ Can anyone speak for “everyone”?
  - ❖ Consider a 7 year old versus a 17 year old.

# Prioritize participant engagement

- Gap in accessible general information about clinical research for children
- All materials were developed by young people and reviewed by young people's advisory groups and international stakeholders.



<https://mrctcenter.org/blog/resources/pediatric-research-informational-materials/>

# Resources for children



## I AM A HEALTHY CHILD: Should I Join a COVID-19 Vaccine Research Study?

Kids who do not have COVID-19 can help researchers learn more about the disease.

**A research study:**

- collects new information about health and disease.
- tries to answer new questions that researchers have.
- researchers have needs volunteers to sign up.

**COVID-19:**

- is a new disease caused by a type of virus called coronavirus.
- may cause some people to have symptoms like cough, fever, weakness, muscle and other pains, and breathing problems.
- can be mild, but it can also make some people very sick.

**What is a vaccine?**

- A vaccine is a form of a virus given to a healthy person, usually through a needle, to teach their body how to recognize and fight the virus.
- People who get a vaccine may be better able to fight the virus in the future.

**Why are there research studies about COVID-19 vaccines right now?**

- Since COVID-19 is a new disease, there is no vaccine yet and new vaccines are being tested.
- Researchers want to learn if a new vaccine is safe and works.

**Why can't I go to school or see friends now?**

- This virus spreads from a sick person to a healthy person very quickly.
- Being too close to your friends can pass the virus around.
- You sit and stand close to your friends when you are at school and when you play.

**Why am I being asked to join a COVID-19 research study?**

- You can help researchers learn about the virus and the disease.
- Being in the study might help other people.
- If the vaccine works, it might help prevent you from getting COVID-19 in the future.

**What else should I know about being in a COVID-19 research study?**

- You can talk to your doctor, your parent, or any adult you trust to help you decide if you want to be in the research study.
- You can change your mind at any time.

**Being in a COVID-19 research study is your choice.**

**More can be learned about COVID-19 if you join a research study.**

Thank you for thinking about joining a COVID-19 research study. Please ask the research team ANY questions you have.

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THE MRCT CENTER AT BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD

**HARVARD CATALYST**  
Harvard Clinical & Translational Science Center

## I AM CHILD WITH COVID-19: Should I Join a COVID-19 Research Study?

Kids who have COVID-19, or might have COVID-19, may be able to join a COVID-19 research study.

**A research study:**

- collects new information about health and disease.
- tries to answer new questions that researchers have.
- needs volunteers to sign up.

**COVID-19:**

- is a new disease caused by a type of virus called coronavirus.
- may cause some people to have symptoms like cough, fever, weakness, muscle and other pains, and breathing problems.
- can be mild, but it can also make some people very sick.

**Why can't I go to school or see friends now?**

- This virus spreads from a sick person to a healthy person very quickly.
- Being close to your friends can pass the virus around.
- You sit and stand close to your friends when you are at school and when you play.

**Why are there research studies about COVID-19 right now?**

COVID-19 is a new virus so it is important to understand more about:

- How the virus spreads.
- Why some people barely get sick and other people get very sick.
- Which treatments work the best.
- How to stop spreading it.

**What else should I know about being in a COVID-19 research study?**

- You can talk to your doctor, your parent, or any adult you trust to help you decide if you want to be in the research study.
- You can change your mind at any time.

**Being in a COVID-19 research study is your choice.**

**More can be learned about COVID-19 if you join a research study.**

**A virus doesn't have legs, so how does it travel?**

There are more adult research studies right now because adults seem to get sicker from COVID-19 than children.

It is very important to conduct studies with children to find treatments and prevention methods that are right for them.

Being in a study might help other people.

Thank you for thinking about joining a COVID-19 research study. Please ask the research team ANY questions you have. We hope you feel better soon.

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## VACCINE RESEARCH: Should I Join a COVID-19 Vaccine Research Study?

People who do not have COVID-19 can help researchers learn more about the disease.

**A research study:**

- collects new information about health and disease.
- tries to answer new questions that researchers have.
- needs volunteers to sign up.

**COVID-19:**

- is a new disease caused by a type of virus called coronavirus.
- may cause some people to have symptoms like cough, fever, weakness, muscle and other pains, and breathing problems.
- can be mild, but it can also make some people very sick, and may lead to death.

**What is a vaccine?**

- A vaccine is a form of a virus given to a healthy person, usually through a needle, to teach their body how to recognize and fight the virus.
- People who get a vaccine may be better able to fight the virus in the future.

**Why are there research studies about COVID-19 vaccines right now?**

- Since COVID-19 is a new disease, there is no vaccine yet and new vaccines are being tested.
- Researchers want to learn if a new vaccine is safe and works.

**What should I ask the research team before joining a COVID-19 research study?**

- Why is the study being done?
- What will happen if I agree to join?
- Could the study help me? Could it help others?
- Could the study cause risks to me?
- Do I have to pay money to be in the study?
- Will I be paid to be in the study?
- How will my personal information be protected?
- How long will the study last?
- Can I leave the study at any time?
- What will happen if I get hurt in the study?
- Who should I call with questions about the study?
- Will I get to see the study results?

**What else should I know about being in a COVID-19 research study?**

- You can talk to people you trust about whether to join the study.
- You can change your mind at any time.

**Being in a COVID-19 vaccine research study is your choice.**

**More can be learned about COVID-19 if you join a research study.**

Thank you for thinking about joining a COVID-19 vaccine research study. Please ask the research team ANY questions you have.

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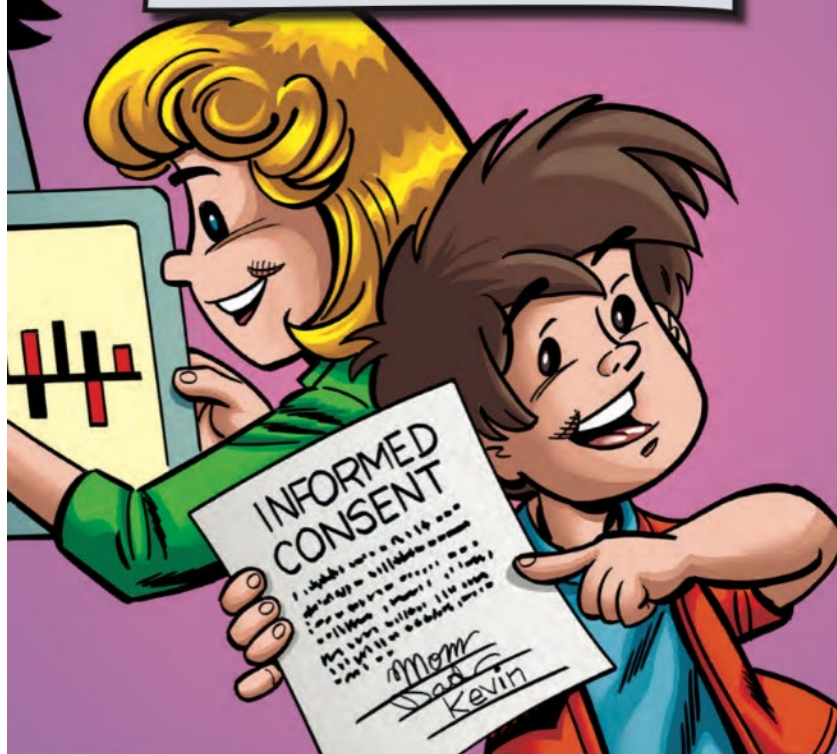
**HARVARD CATALYST**  
Harvard Clinical & Translational Science Center

<https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/>



# SOPHIE'S SCIENCE PROJECT

WHAT IS MEDICAL  
RESEARCH?



## Resources for children

<https://www.youtube.com/watch?v=m8e0z-96QTU&t=6s>

<https://catalyst.harvard.edu/publications-documents/sophies-science-project-what-is-medical-research/?ref=true>

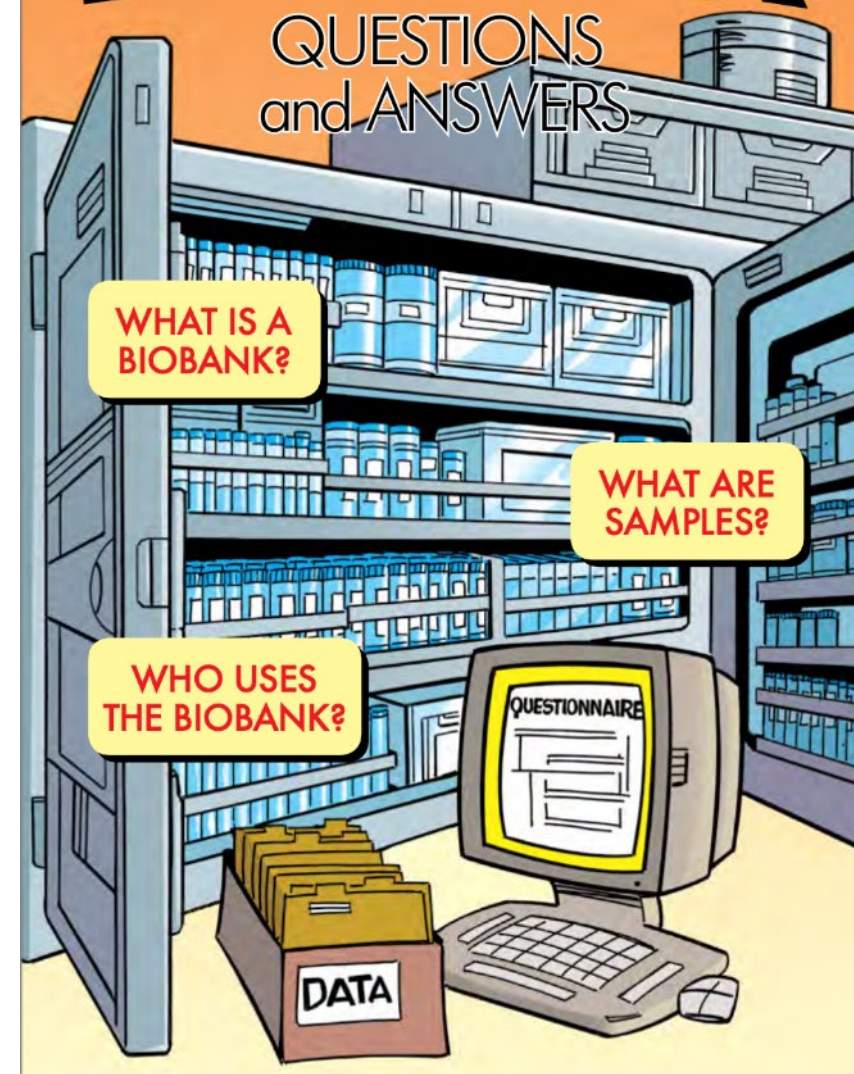
# BIOBANK

QUESTIONS  
and ANSWERS

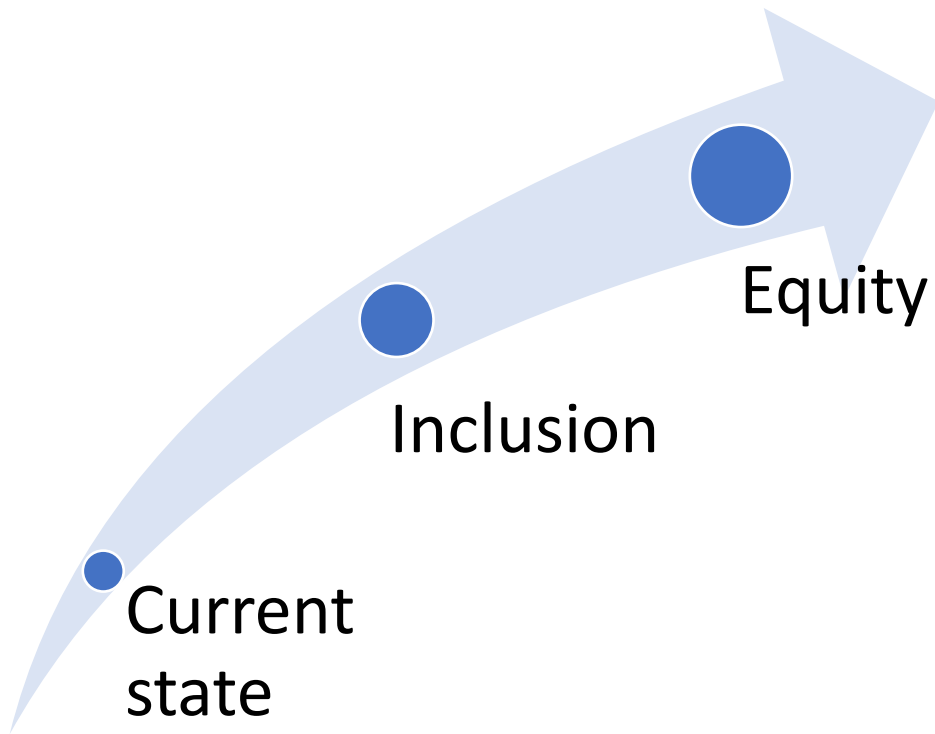
WHAT IS A  
BIOBANK?

WHAT ARE  
SAMPLES?

WHO USES  
THE BIOBANK?



# We are all accountable







# We need your help

- How do we do this work and do it well?
- What is representativeness?
- What are successful strategies?
- How can we work together?



Thank you

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<http://MRCTcenter.org/>