11th Annual

Prevent Blindness

Focus on Eye Health National Summit

Eye-conic Approaches to Eye Health

July 13–14, 2022

A Virtual Interactive Event

Prevent Blindness
Focus on Eye Health National Summit

Equitable Practices for Children's Vision Research

Barbara E. Bierer MD
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.

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

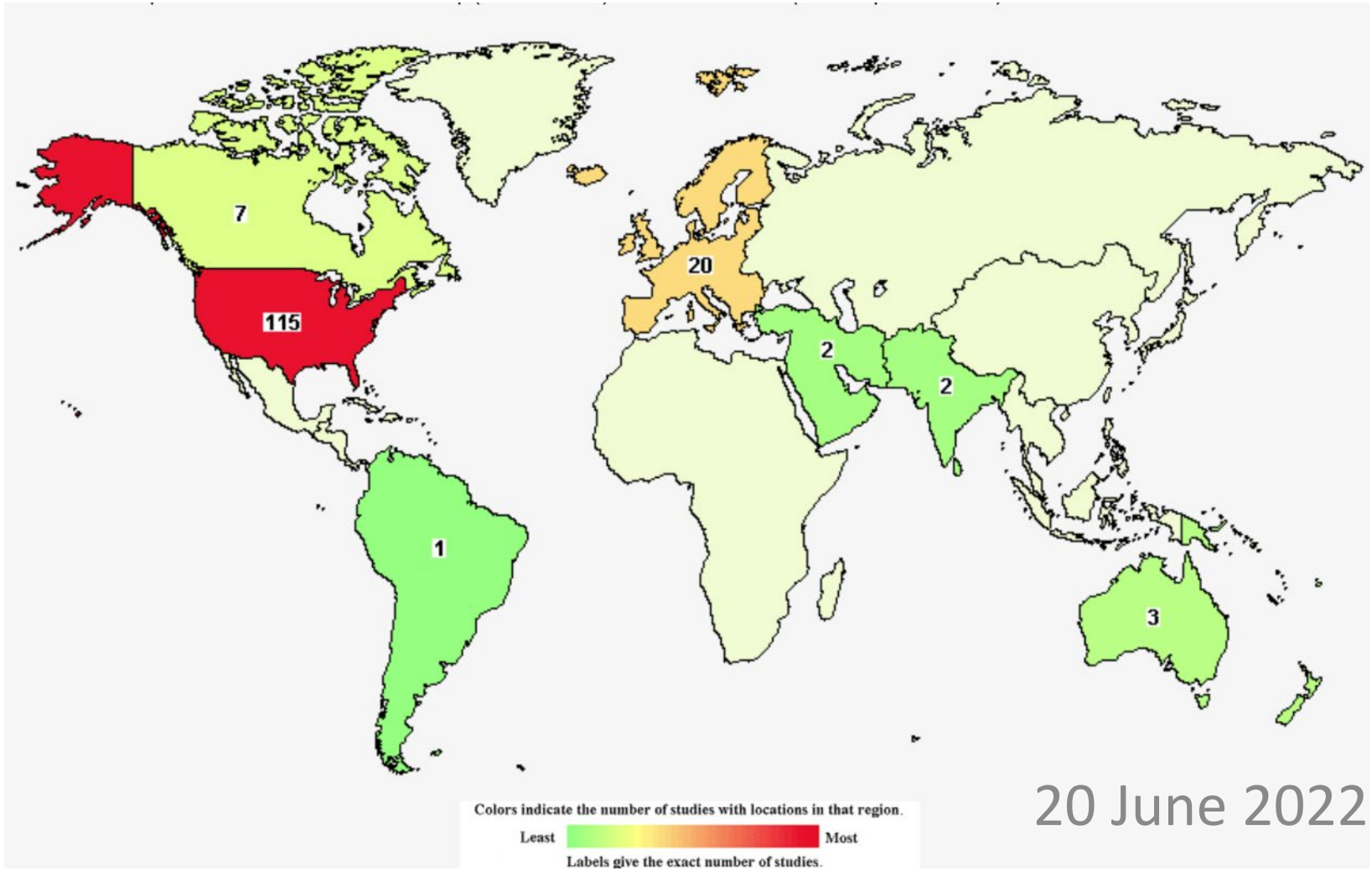
205 Studies found for: **Vision Disorders | United States | Child**

115 Studies in last 10 years

71 Studies in last 5 years

16 Studies with key word “Blindness”

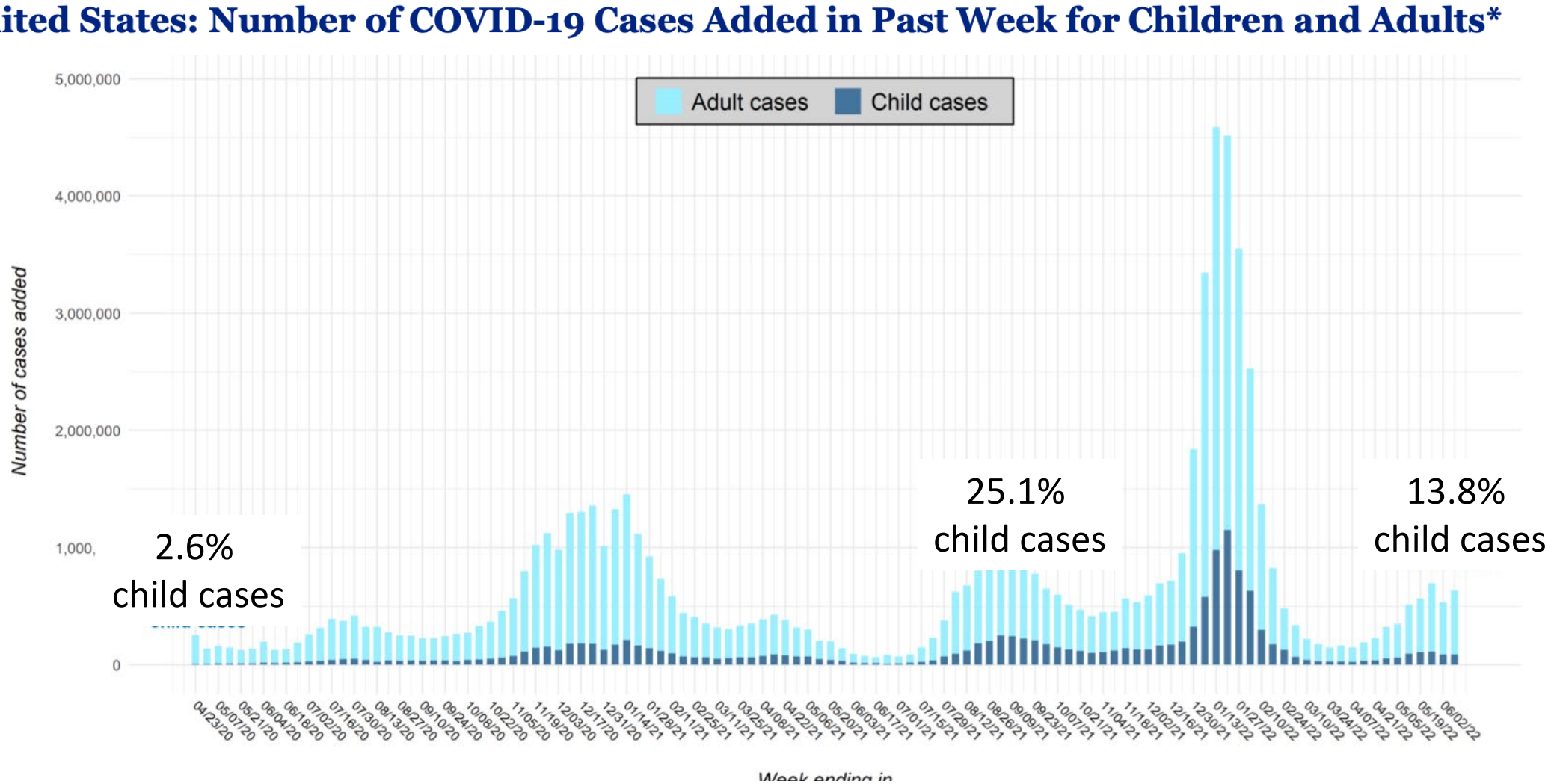
Studies of children with vision disorders in clinical research



20 June 2022

ClinicalTrials.gov
115 Studies in last 10 years

Underappreciated: COVID-19 and pediatrics



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

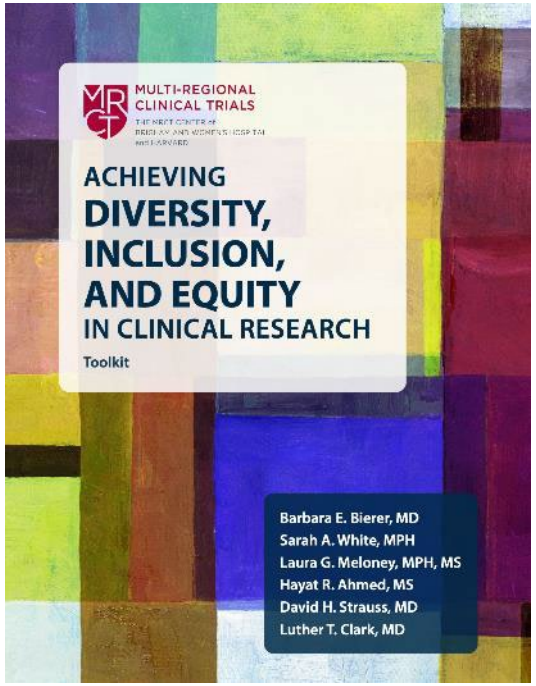
Child population, 2019	Cumulative total cases (all ages)	Cumulative child cases	Cumulative percent children of total cases	Cases per 100,000 children
75,266,842	71,733,195	13,541,153	18.9%	17990.9

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

Access to clinical trials, and to accessible clinical trials

Achieving Diversity, Inclusion, Equity In Clinical Research



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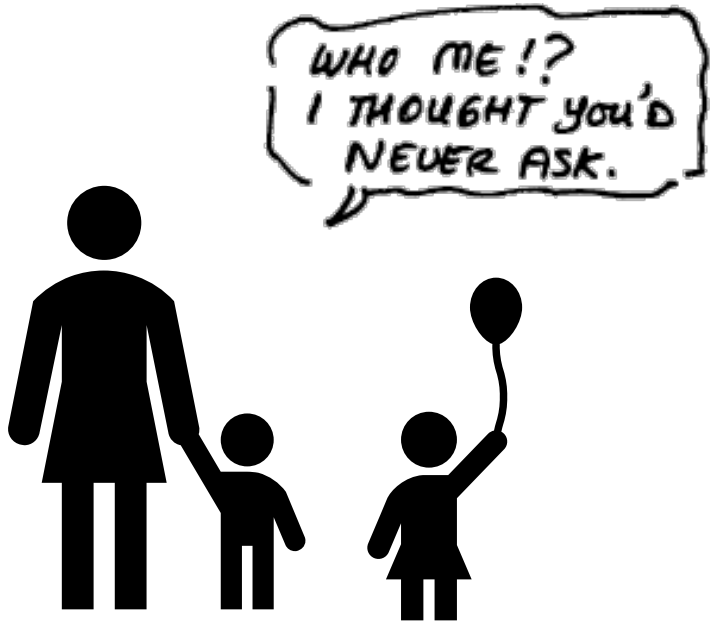


https://mrctcenter.org/diversity-in-clinical-trials/

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

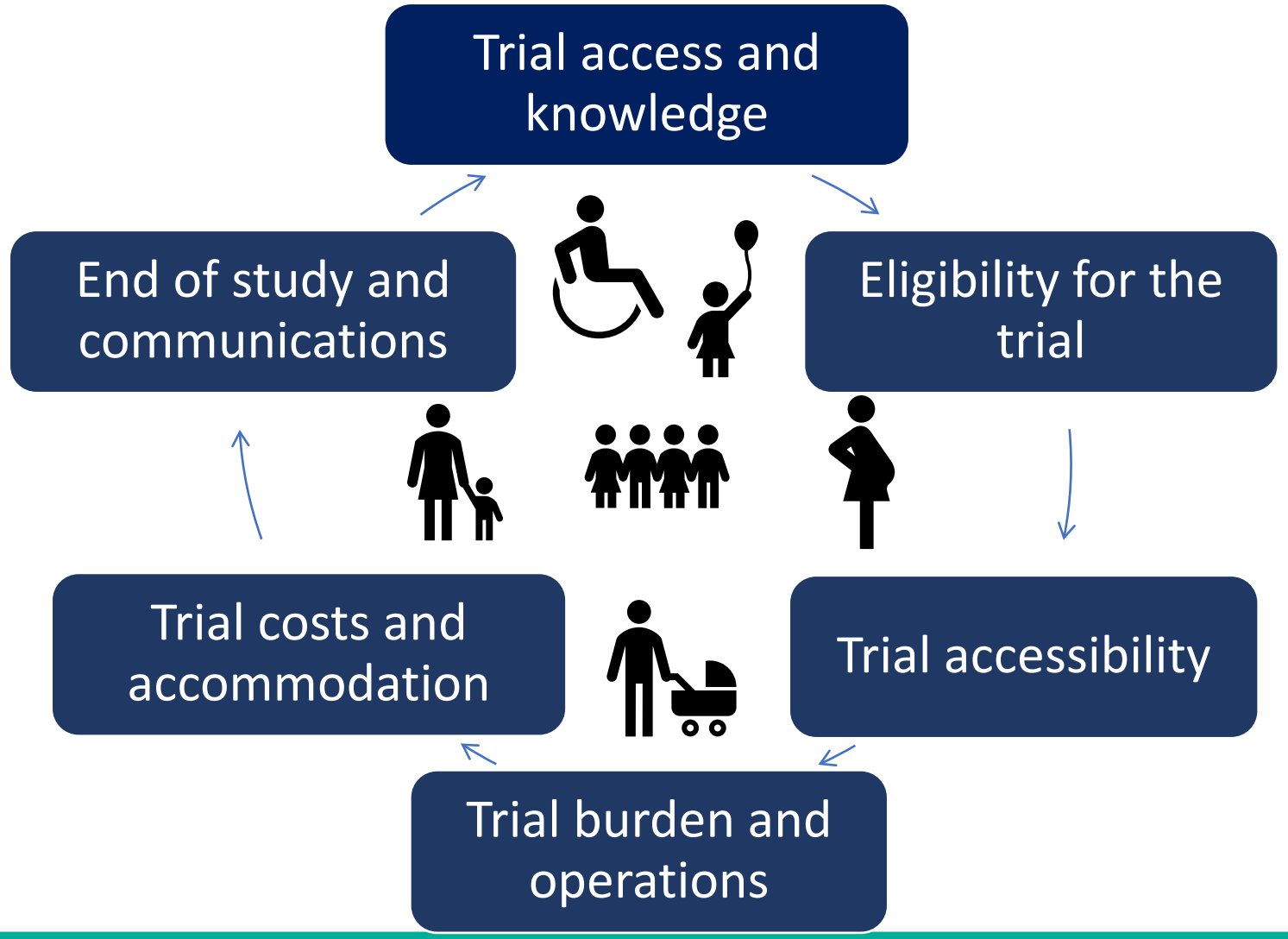
Patient and community engagement support diverse participation

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**

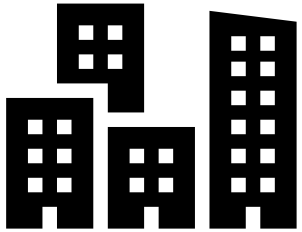
Participation in any trial is a journey



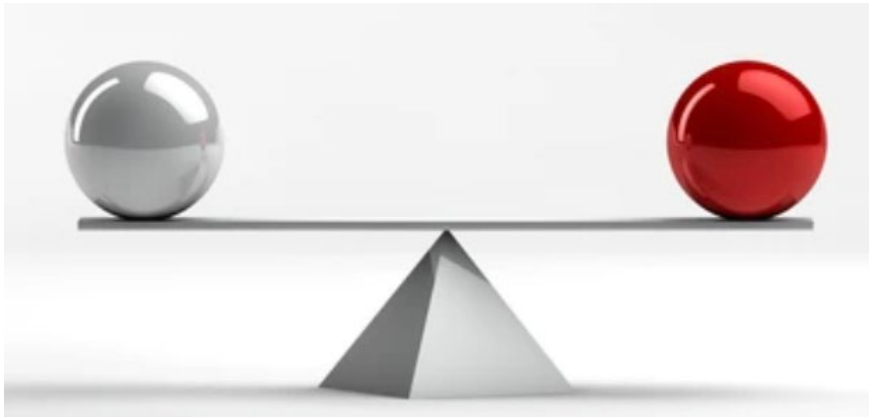
- Child
- Parent(s) or Guardian
- Caregiver
- Siblings and family

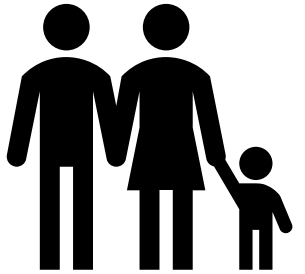
- Legally authorized representative

The challenge of participation



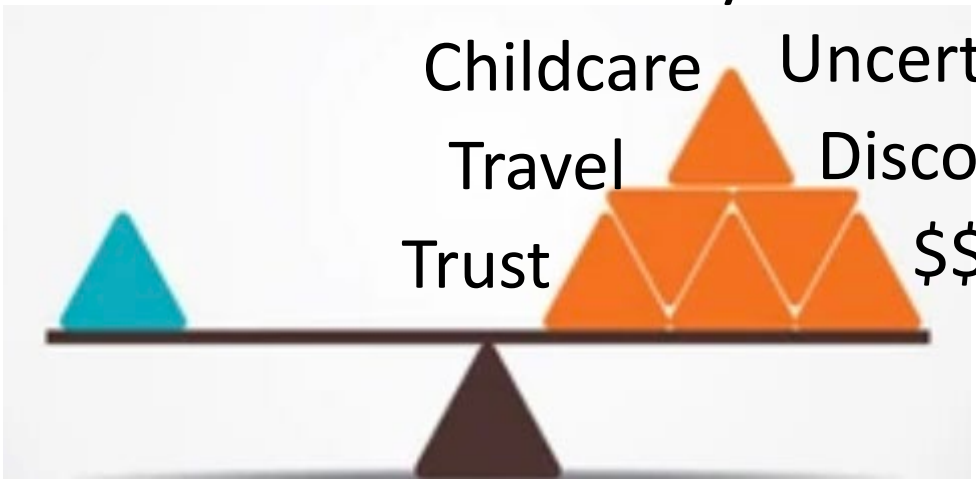
Benefit Risk





Benefit Risk

Privacy
Lost work
Childcare
Uncertainty
Travel
Discomfort
Trust
$$$



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	RECRUITMENT	CONSENT	ON STUDY	END OF STUDY
Awareness	Flyers	Consent	Medications	Study results
Outreach	Recruitment	Instructions	Adverse Events	Transition to care
Engagement	Adverts	Calendars	Satisfaction	Access
Education				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 uncap 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.

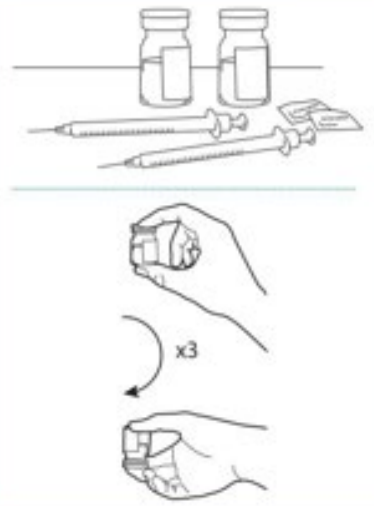
Important safety information

- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncap 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.

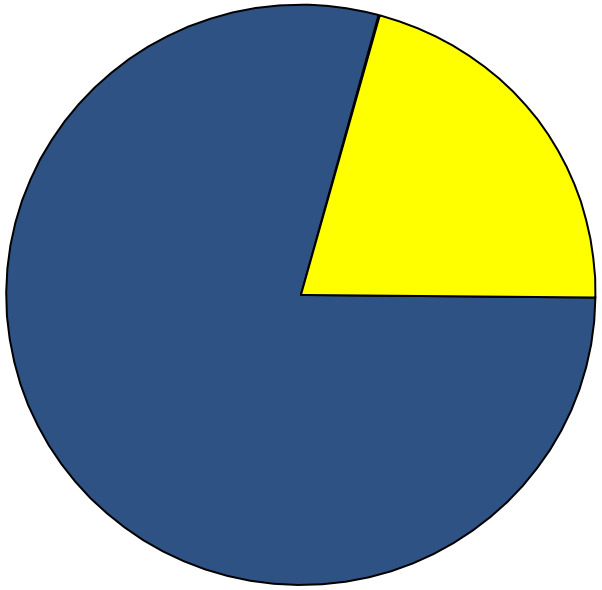


https://mrctcenter.org/health-literacy/

Merck & Co., Inc. example with input from Health Literacy Media

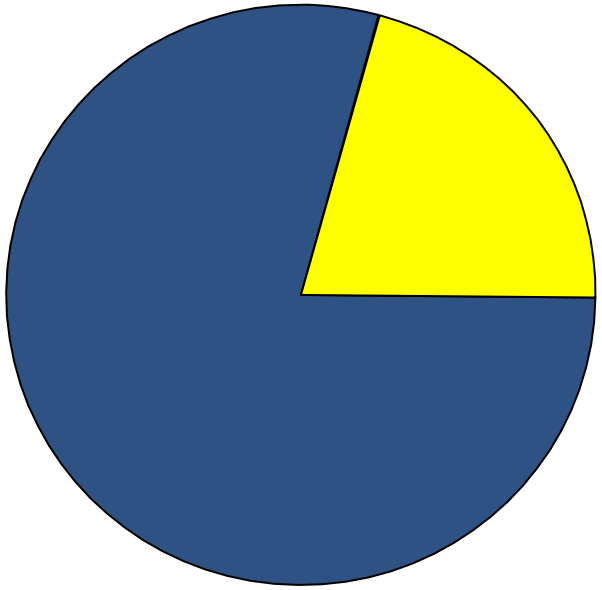
Prevent

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.

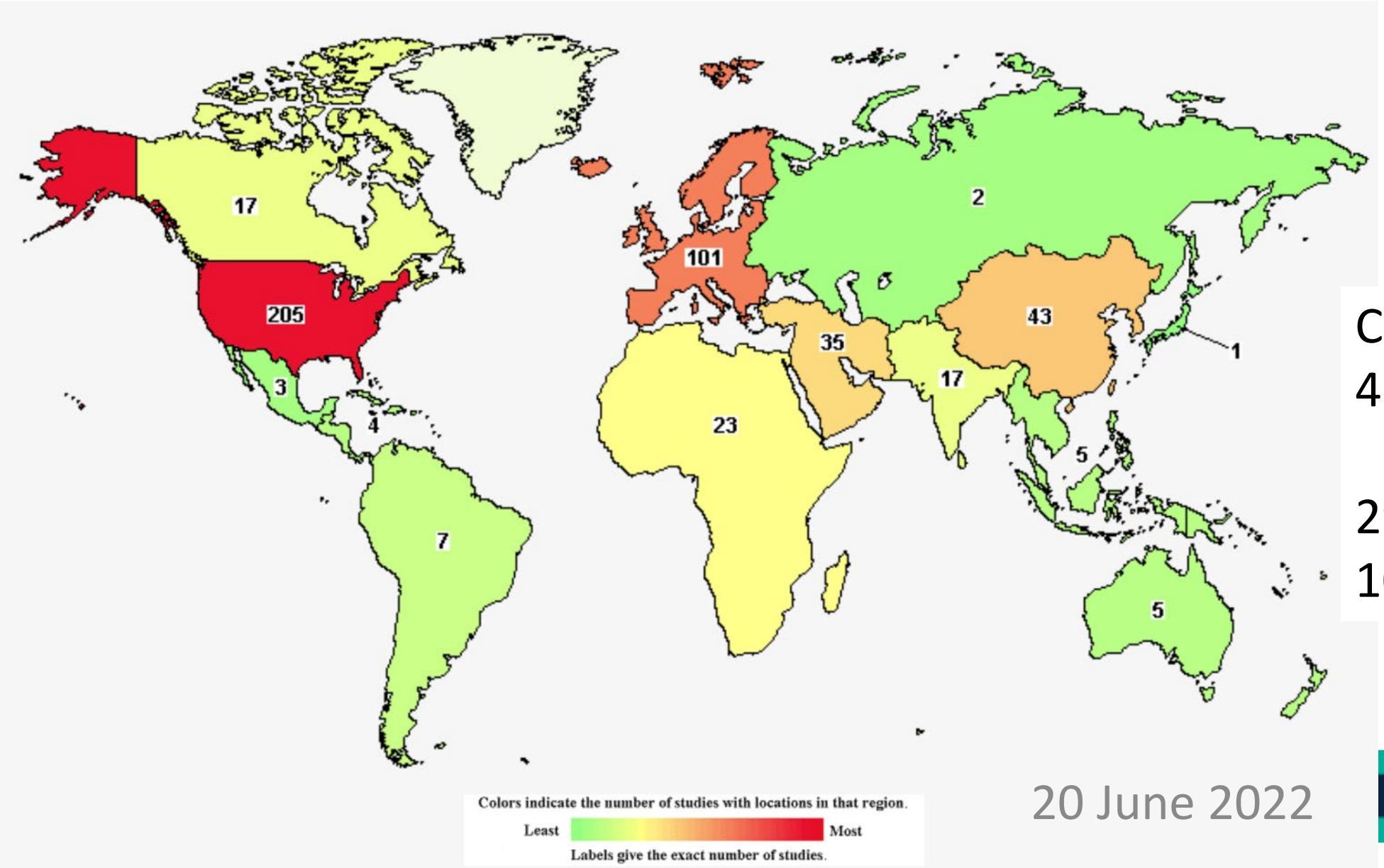
- Now being expanded.

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

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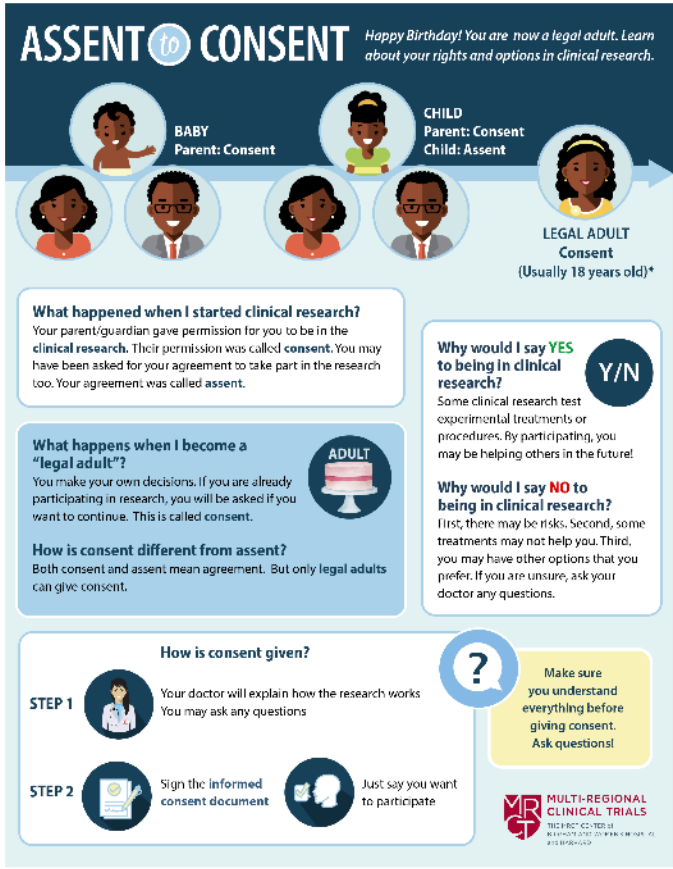
Promoting Clinical Research in Children

- 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.

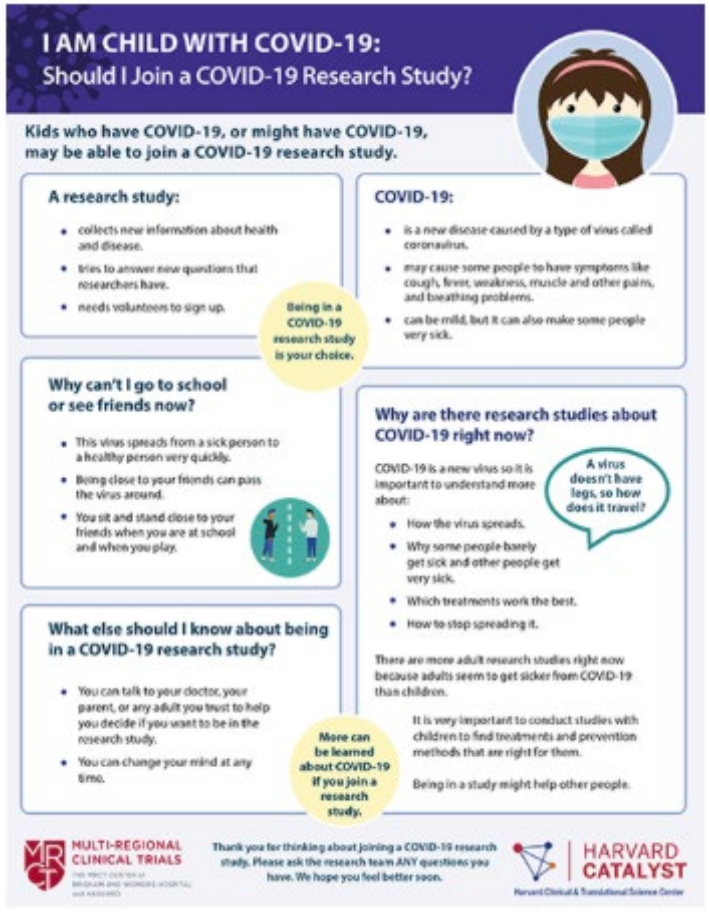
Prioritize participant engagement

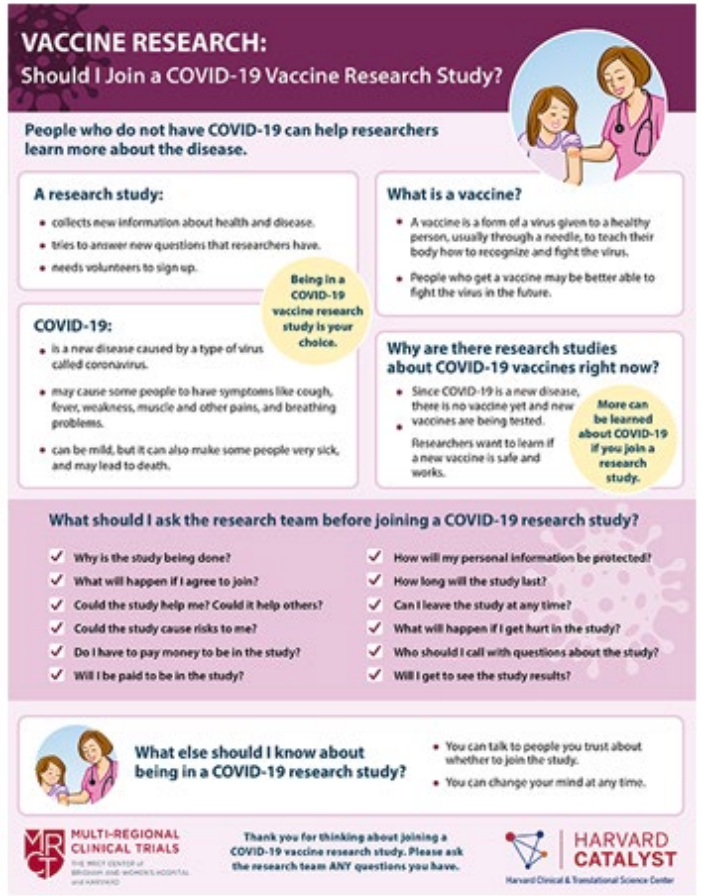
- Gap in accessible general information about clinical research for children
- All materials were developed by young people and reviewed by young people's advisory groups and international stakeholders.



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

Resources for children

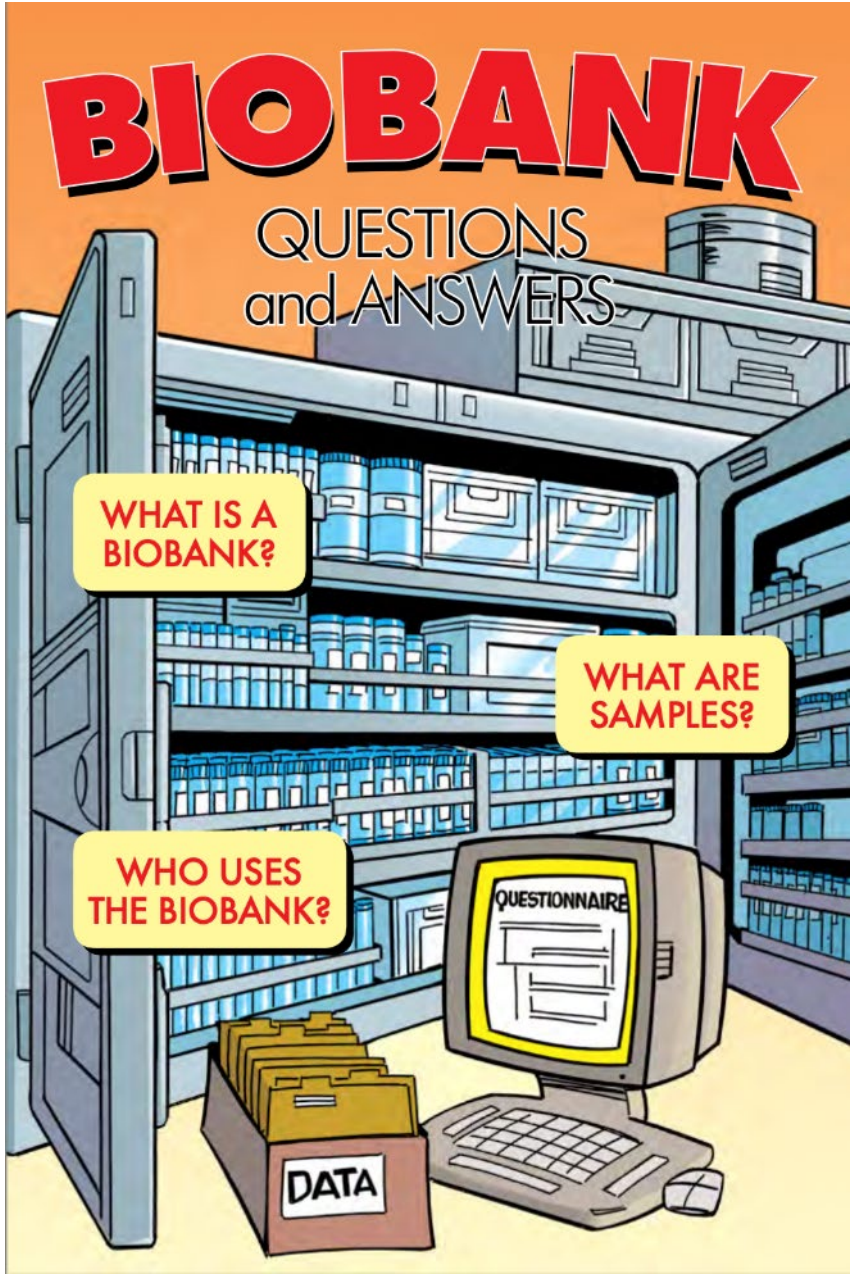




https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/

Focus on Eye Health Summit: Eye-cont

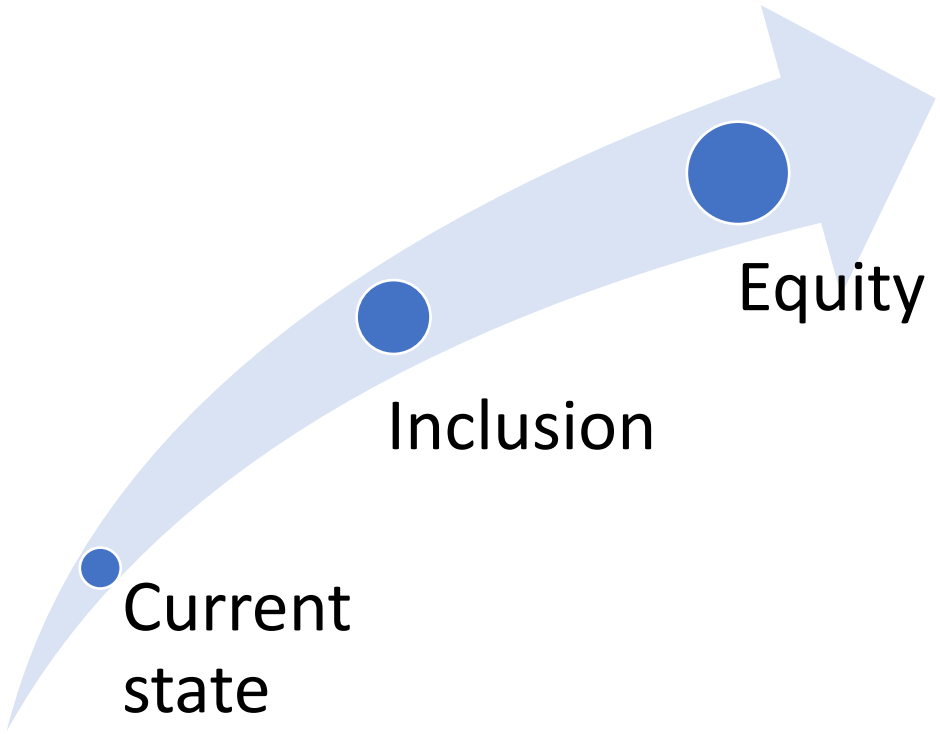
Resources for children



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

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

Barbara E. Bierer, MD

bbierer@bwh.harvard.edu

http://MRCTcenter.org/