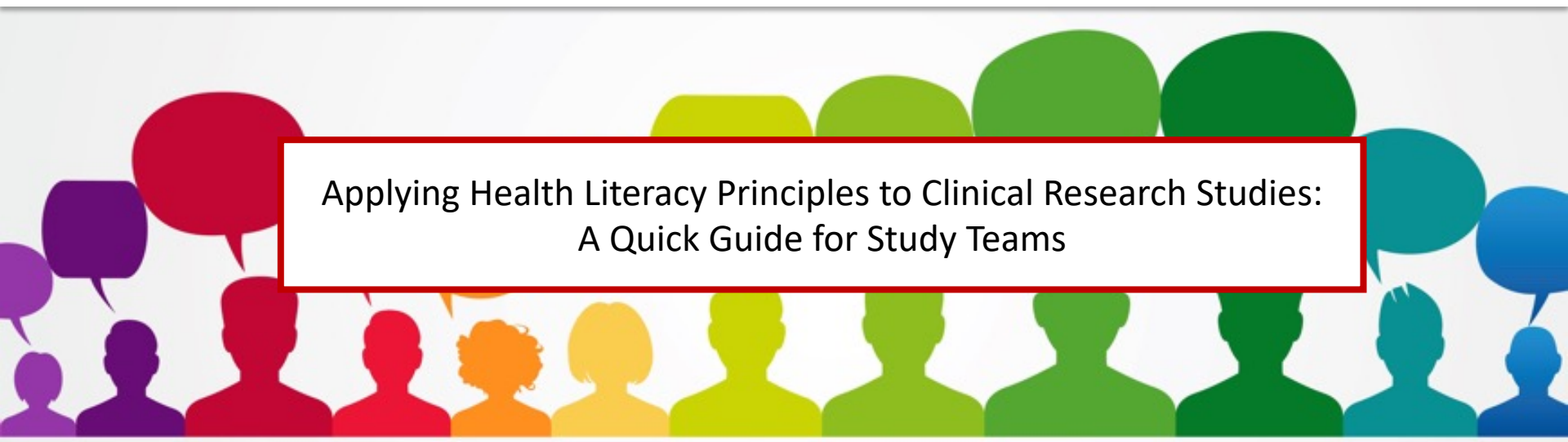




MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

A horizontal row of stylized human silhouettes in various colors (purple, red, orange, yellow, green, blue) with speech bubbles of different shapes and colors above them, representing a diverse group of people.

Applying Health Literacy Principles to Clinical Research Studies: A Quick Guide for Study Teams

Sylvia Baedorf Kassis, MPH
MRCT Center

Disclaimer

- The opinions expressed are those of the author(s) and/or presenter(s) and are not intended to represent the position of Brigham and Women's Hospital or Harvard University.
- The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions, and government entities (see www.MRCTCenter.org) and well as by grants.
- We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center retains responsibility and final control of the content of any products, results, and deliverables.
- I have no personal conflicts of interest relevant to this presentation.

Objectives

- By the end of the session, attendees should be able to:
 - Describe what health literacy is and its relevance to clinical research.
 - Explain how health literacy best principles can be integrated into different phases of the clinical research life cycle.
 - Identify at least one health literacy best practice to integrate into a participant-facing communication.

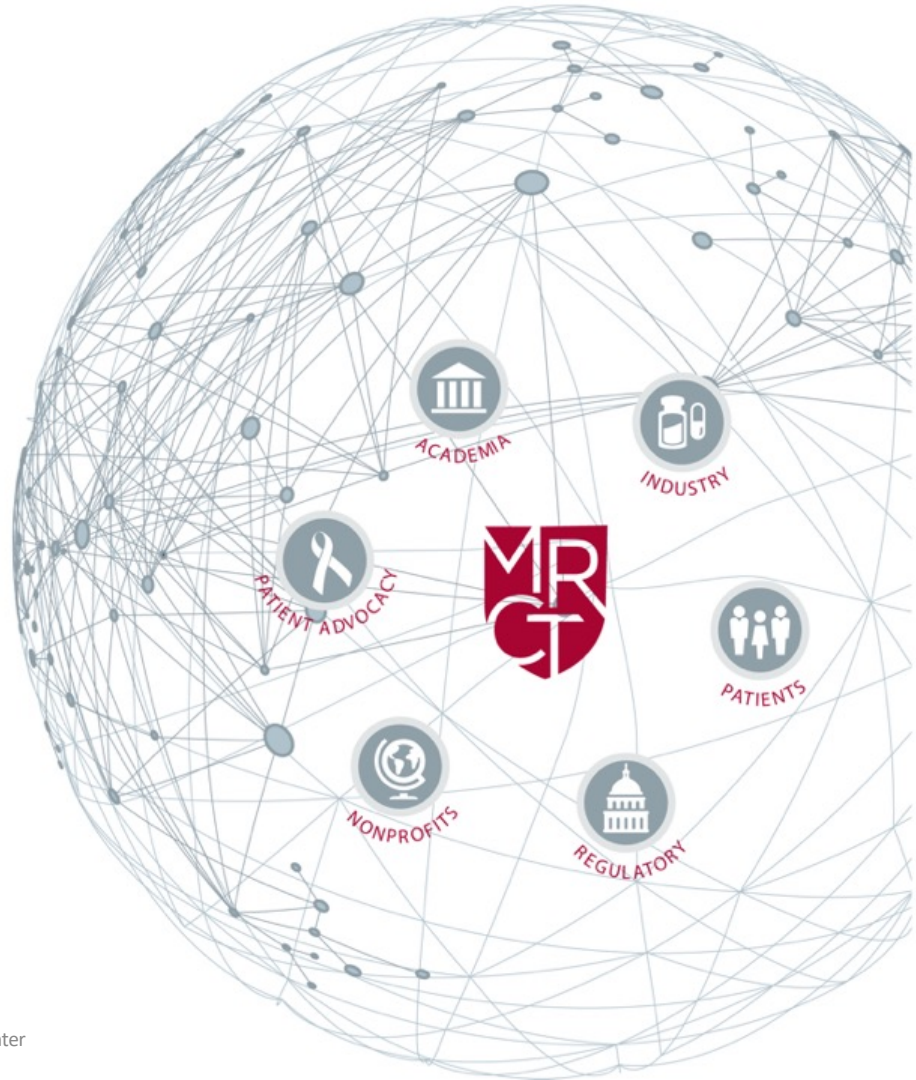
Introduction to the MRCT Center

Our Vision

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

Our Mission

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



MRCT Center's Commitment to Health Literacy

- 2019 - Completed a multi-stakeholder initiative focused on health literacy and launched a publicly available website on Health Literacy in Clinical Research

www.mrctcenter.org/health-literacy

- 2020 – Co-developed COVID-19 pamphlets to support understanding of clinical research (in English & Spanish, for adults and children).

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

- 2021 – launched a patient co-developed Clinical Research Glossary (expansion starts this month!)

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





MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

A horizontal band across the middle of the slide features a row of colorful silhouettes of people's heads and shoulders, transitioning from purple on the left to blue on the right. Above each silhouette is a speech bubble of a matching color. A white rectangular box with a red border is superimposed over the center of this graphic.

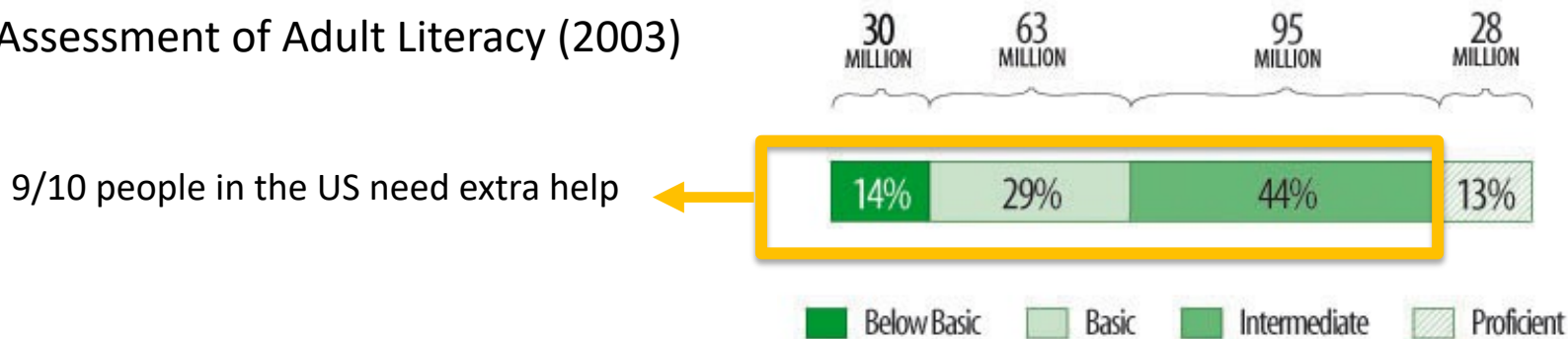
Background

A story about health literacy



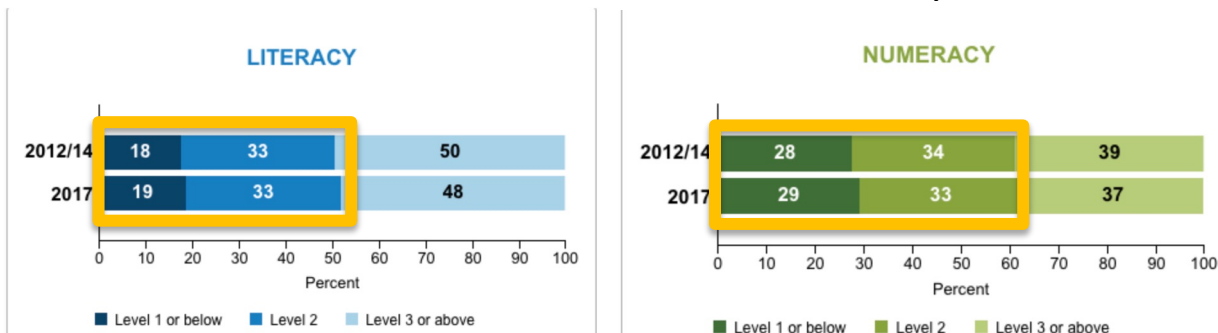
The Challenge of Low Literacy in the US

- National Assessment of Adult Literacy (2003)



From: https://nces.ed.gov/naal/kf_demographics.asp

- Program for the International Assessment of Adult Competencies



From: https://nces.ed.gov/surveys/piaac/current_results.asp

Evolving Definition of Health Literacy

“Health literacy is the degree to which **individuals** have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions.”

Nielsen-Bohman L, Panzer AM, Kindig DA, Editors, Committee on Health Literacy. Health Literacy: A Prescription to End Confusion. Washington, DC: Institute of Medicine. The National Academies Press; 2004.



Personal health literacy is 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.

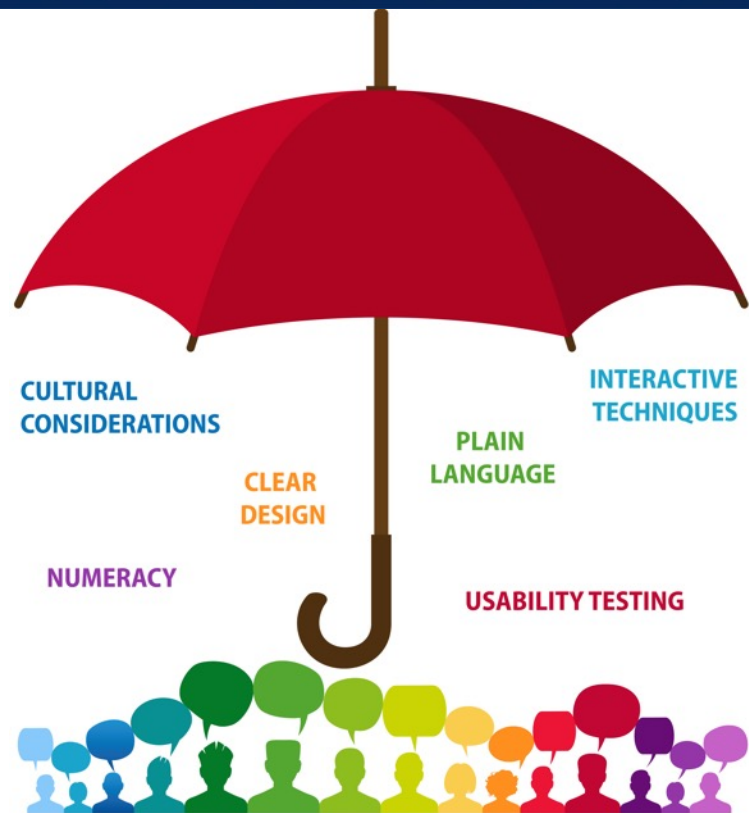
Organizational health literacy is the degree to which **organizations equitably enable individuals** to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

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

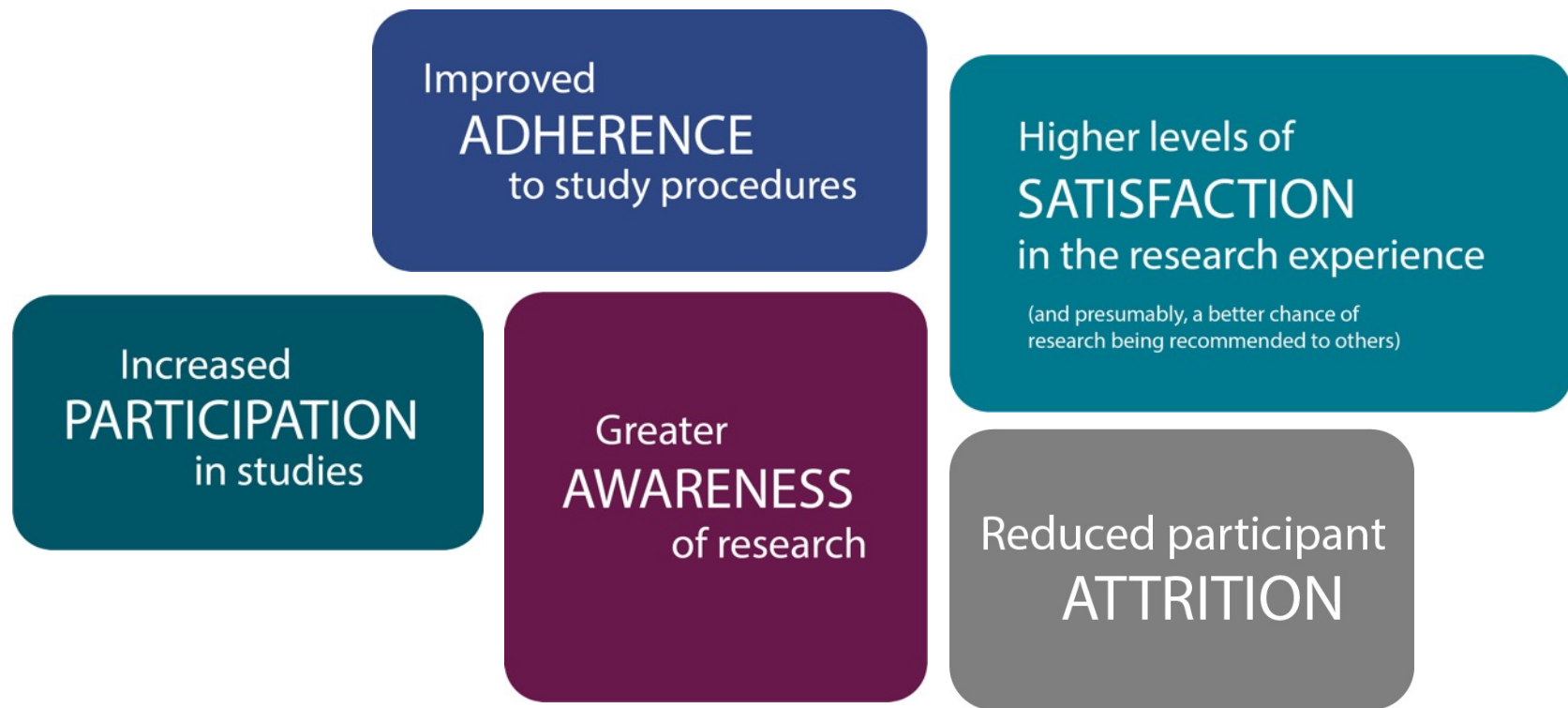
Individual Ability

Communicator's Skill and Responsibility

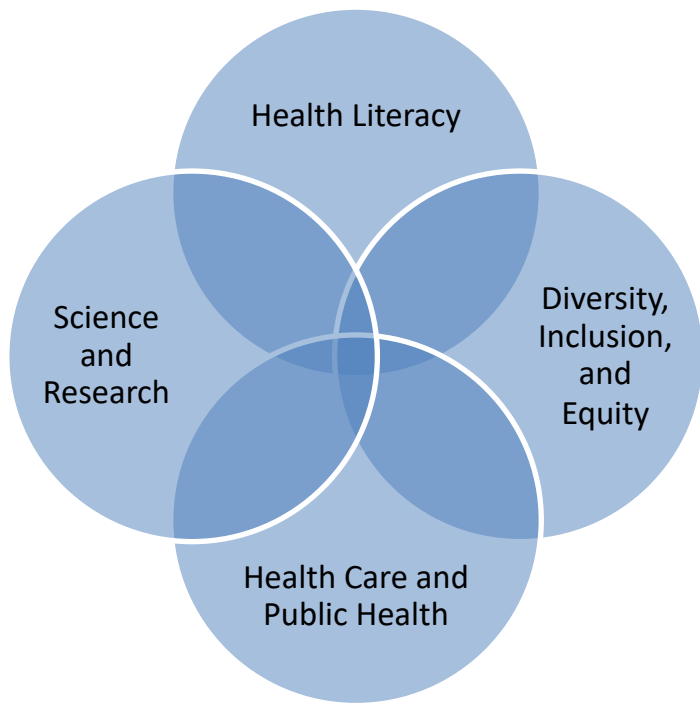
A Broad View of Health Literacy



The Potential of Applying Health Literacy Best Practices



The Bigger Picture of Health Literacy



Health literacy helps fulfill key ethical research principles:

- Respect for Persons
 - A right to understand
- Beneficence
 - An effort to reduce harm
- Justice
 - Equitable access to research



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

A horizontal illustration at the bottom of the slide depicts a diverse group of people. The silhouettes of the individuals are in various colors (purple, red, orange, yellow, green, blue) and are arranged in a line. Above each silhouette is a speech bubble of a corresponding color, creating a rainbow gradient effect from left to right. A white rectangular box with a red border is superimposed over the center of this illustration.

The Clinical Research Life Cycle

The Clinical Trial Life Cycle

Clear communication is essential throughout the participant's clinical research journey.



DISCOVERY



RECRUITMENT



CONSENT



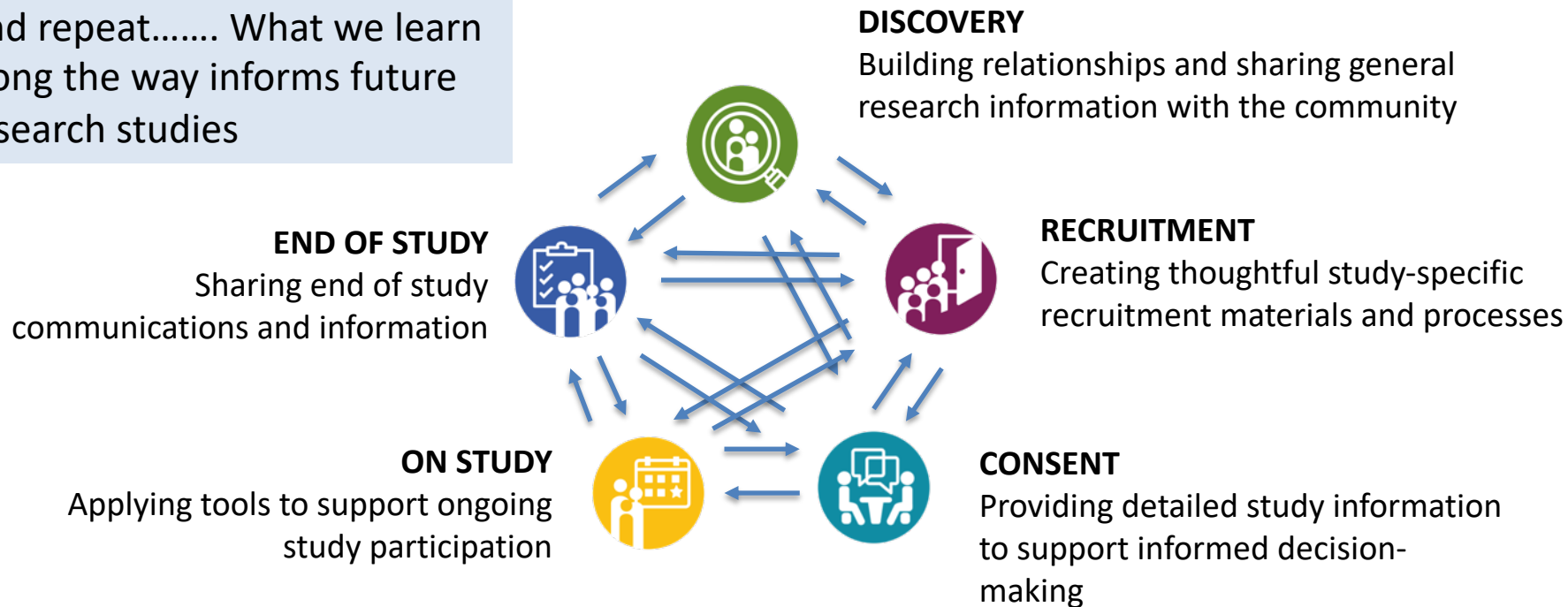
ON STUDY



END OF STUDY

Integrating Health Literacy Principles

And repeat..... What we learn along the way informs future research studies





- General research awareness campaigns
- Outreach and engagement efforts to solicit potential participant input into study design and development

Recruitment



- Advertisements and flyers
 - Print, web-based, e-mail
- Recruitment scripts for study staff
 - Phone or in-person

Consent



- Consent forms
- Consent scripts and guides for study staff
- Study schedules/calendars
- Post-consent study enrollment surveys



- Study medication/intervention instructions
- Study commitment contracts
- Adverse event reporting information
- Participant satisfaction surveys
- Individual study results (as applicable)

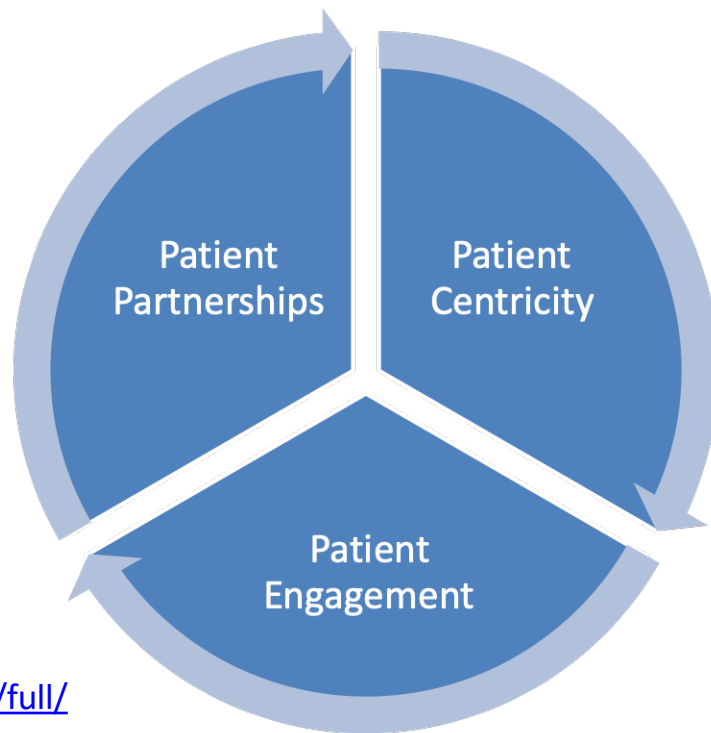
End of Study



- Instructions for coming off the study
- Information on maintaining access to treatment options
- Aggregate (and possibly individual) study results/plain language summaries
- End of study surveys

An Additional Opportunity: Partnering with Patients

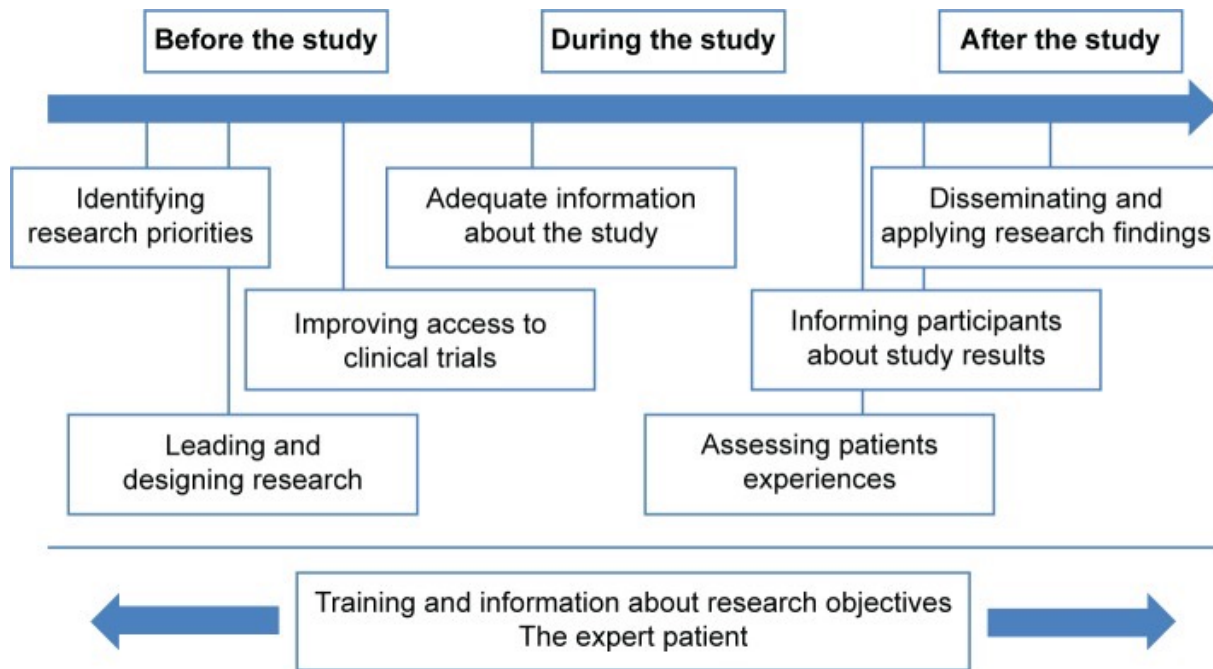
- Lessons learned from healthcare
 - People actively involved in their health and health care tend to have better outcomes.*
 - Patient decision making is *enhanced* by personal experience and *complemented* by scientific knowledge of healthcare professionals.**
 - Recognition of patients as experts fosters collaboration.**



*<https://www.healthaffairs.org/doi/10.1377/hpb20130214.898775/full/>

**<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4391791/>

Integrating Patient and Participant Input Throughout the Study



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4854260/>

Additional Resources



Patient Protocol Engagement Toolkit (P-PET)



Resource Guide
Version 1

<https://www.transceleratebiopharmainc.com/ppet/planning-for-patient-engagement/>



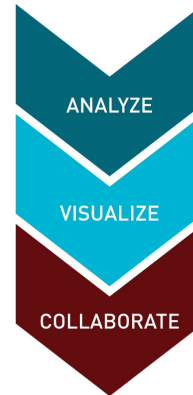
CTTI Prioritization Tool for Sponsors and Patient Groups

OVERVIEW

ANALYZE

VISUALIZE

This tool helps patient groups and clinical research sponsors identify high-value opportunities to work together. Using this tool, you will:



- ▶ Select engagement opportunities that are relevant to the project or collaboration you have in mind.
- ▶ Use our comprehensive list or add your own.
- ▶ Rate the benefits and investments for each opportunity.

- ▶ Review and adjust your analysis within a visual display.
- ▶ Add a partner's analysis for comparison and discussion.

- ▶ Select opportunities to pursue with your partner and get started!

<https://prioritizationtool.ctti-clinicaltrials.org/>



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

A horizontal band of colorful silhouettes representing a diverse group of people. The silhouettes are in various colors including purple, red, orange, yellow, green, and blue. Above each silhouette is a speech bubble of a matching color, creating a visual representation of communication and diversity.

Health Literacy in Clinical Research Examples

Developing Clear Communications*

1. Purpose
2. Audience
3. Process

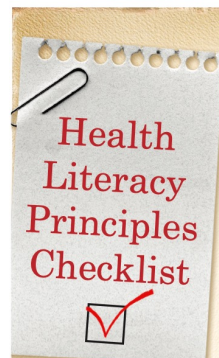


*More about developing consent forms can be found here:

<https://mrctcenter.org/health-literacy/tools/overview/consent-guide/>

"three pillars" by [controlenthused](https://controlenthused.com/) is licensed under [CC BY 2.0](https://creativecommons.org/licenses/by/2.0/)

Helpful resources are available



Health
Literacy
Principles
Checklist

1

PLANNING

- ☐ **Objective**
 - Define the communication objectives.
- ☐ **Target audience**
 - Know audience needs, interests, and behaviors.
 - Identify ways to engage the target audience.
 - Involve the target audience in development and testing.

CONTENT

- ☐ **Purpose**
 - Focus and limit the objectives.
 - State your objectives in the title, cover illustration, and introduction.
- ☐ **Evidence**
 - Ensure content is accurate and evidence-based.
 - State what is known and when relevant, what is not known.
- ☐ **Scope**
 - Limit to essential information. Include the "need to know", but not the "nice to know".
 - Include only information that is relevant and meaningful to the intended audience.
 - Focus on behaviors, skills and instructions.
 - Go beyond the facts to include action-oriented material.
 - Stress, repeat and summarize the main points.
- ☐ **Language and culture**
 - Ensure you have high quality translation and interpretation of content.
- ☐ **Demographics**
 - Ensure content reflects age, education, income, gender, occupation, and residence of intended audience.
- ☐ **Clarity**
 - State the information as clearly and simply as possible.
- ☐ **Tone and appeal**
 - Include positive, truthful and helpful content.
 - Edit content for bias and prejudice.
- ☐ **References**
 - Note key sources.
 - Provide sources for more information.
- ☐ **Date/authorship**
 - Include author(s) and date of publication or revision.

LITERACY DEMANDS


- ☐ **Reading level**
 - Ensure as many people as possible can read and understand the materials.
 - Consider using a readability calculator, but be sure you understand its limitations.
- ☐ **Choice of words**
 - Use common, every-day, specific words that are two syllables or less.
 - Avoid using jargon, abstract words, technical terms, statistics, abbreviations and acronyms.
 - Include the pronunciation of words that may not be familiar.
 - Explain words, expressions, and phrases through simple definitions. Consider using word/picture association or examples.
 - Use positive statements. Limit sentences that begin with "don't" or "never".

Ensure that materials are plain, simple and understood.

The best way to do this is to follow as many of these principles as possible.

2

"Everything should be made as simple as possible, but not simpler."
Albert Einstein



- ☐ **Sentences/paragraphs**
 - Write in a conversational style, using active voice.
 - Use short, simple and direct sentences (8-15 words).
 - Use short paragraphs and avoid large blocks of text.
- ☐ **Use of numbers**
 - Do the math for the reader, do not require addition, subtraction, multiplication or division.
 - Consider using visual presentations of numbers.
 - Use whole numbers when possible (1 in 1,000 instead of 0.001).
 - Express risk information in frequencies (1 out of 10 instead of 10%).

ORGANIZATION

- ☐ **Context**
 - Present context before new information.
- ☐ **Sequence**
 - Present information that is logical and easy to follow.
 - Position important information at the beginning and end for emphasis.
- ☐ **Groupings**
 - Divide information into small, logical sections.
- ☐ **Headings**
 - Use short, simple and explanatory headings to organize.

LAYOUT AND TYPOGRAPHY

- ☐ **Font**
 - Use a clear typeface like Times New Roman or Arial.
 - Use upper and lowercase letters; avoid using all uppercase.
 - Limit the variations of typefaces used.
 - Use a type size that is easy to read and as large as possible (at least 12 point; 14 or 16 point text is preferred).
- ☐ **Headlines and titles**
 - Use headlines and titles to orient and engage the reader.
- ☐ **White space**
 - Provide breaks for the eye with white space.
 - Balance the use of white space with content and graphics.
 - Separate paragraphs and topics by one or two lines.
- ☐ **Justification**
 - Avoid full justification of text; format edges flush left with right ragged instead.
- ☐ **Highlights/cues and color**
 - Use bulleted lists, underlining, and bold for emphasis.
 - Introduce color to highlight, add clarity, differentiate or focus the eye.
 - Use shading, boxes, and arrows to direct attention to key content.

GRAPHICS

- ☐ **Engagement**
 - Use graphics to grab attention.
 - Spotlight the objectives with the cover graphic.
 - Reinforce the objectives with graphics.
 - Choose graphics that are friendly, attractive and recognizable.
- ☐ **Relevancy**
 - Use action oriented graphics.
 - Show key desired behaviors, rather than behaviors to avoid.
 - Choose graphics that reflect the age, gender, ethnic and cultural background of the audience.
 - Design graphics that support and reinforce important points.
- ☐ **Clarity**
 - Use simple design, free from clutter and distractions.
 - Avoid diagrams, graphs, charts and data tables that require multiple steps for use.

Authors: Jacobson, Kara L; Parker, Ruth M. 2014.
Reference: Doak, CC; Doak LG; Root JH. (1995).
Teaching Patients with Low Literacy Skills. 2nd Edition. J.B. Lippincott Company. ©2014

<http://centerforhealthguidance.org/health-literacy-principles-checklist.pdf>

Authors: Jacobson, Kara L; Parker, Ruth M. 2014.
Reference: Doak, CC; Doak LG; Root JH. (1995).
Teaching Patients with Low Literacy Skills. 2nd Edition.
J.B. Lippincott Company.

Health Literacy in Action

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 the 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.

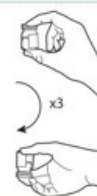
Steps to give yourself the study medicine

Get ready

- Gather your supplies:
 - 2 syringes
 - 2 bottles of medicine
 - 2 alcohol swabs



- 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.



- Wash your hands with soap and water.

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

All text left justified
which is easier to
read.

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.

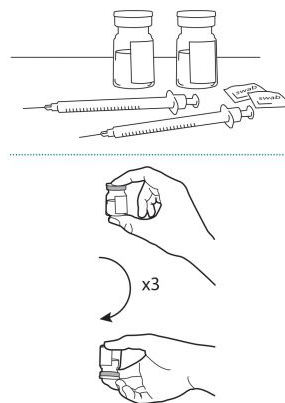
Important safety information

- 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.



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

Information
broken into
chunks that are
easier to read and
manage.

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.

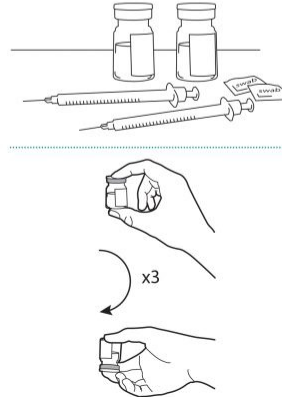
Important safety information

- 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.



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

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.

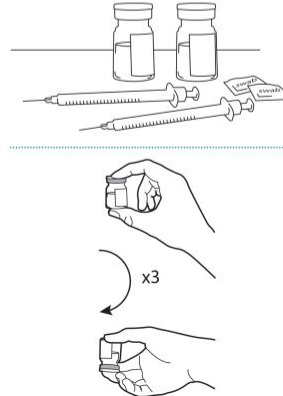
Important safety information

- 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.



Different sections shaded with different colors to break-up content.

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

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.

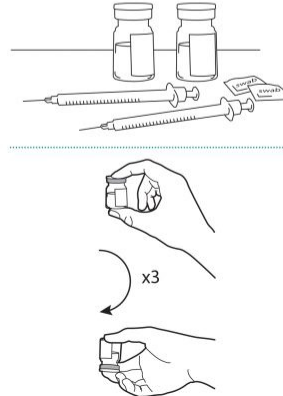
Important safety information

- 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.



Informative headings
that are easy to spot.

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

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.

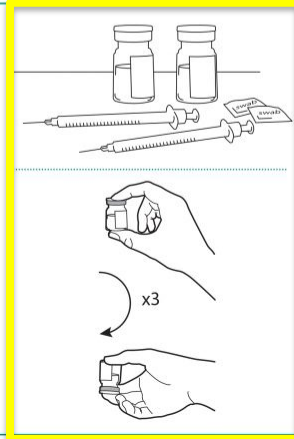
Important safety information

- 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

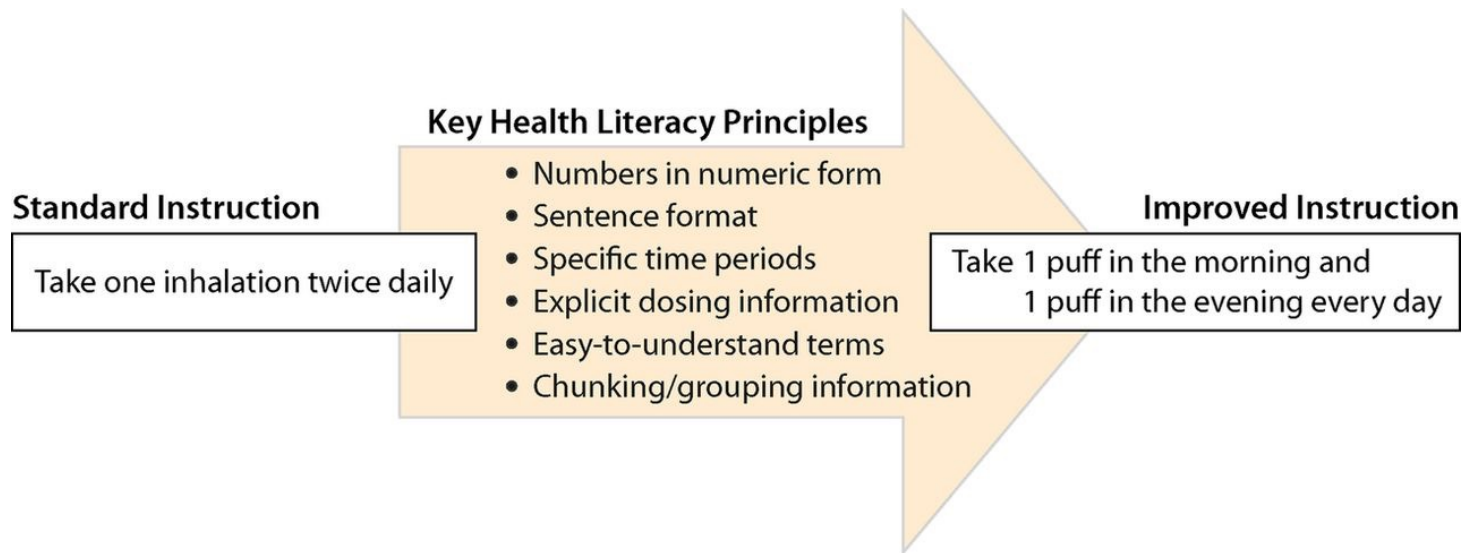
Get ready

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.



Graphics added to make instructions easier to follow.

Health Literacy in Action



<https://bmjopen.bmj.com/content/4/1/e003699>



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

A horizontal band at the bottom of the slide features a row of colorful silhouettes of people's heads and shoulders. Above each silhouette is a speech bubble of a matching color. The colors transition from purple on the left, through red, orange, yellow, green, and finally blue on the right. A white rectangular box with a red border is superimposed over the center of this band.

Key Takeaways

Key Takeaways

- Each of us can play a role in creating more understandable research materials
 - Clear participant-facing communications are essential throughout the clinical research life cycle.
- Consider health literacy best practices in your planning
 - Preparation and planning for clear research communications starts early in the process.
- Engage patients and participants with the lived experience to co-create
 - Including input is an essential part of developing understandable study-related materials.
- Practice makes perfect better.



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Thank you!
Questions?

Clear Communications Benefit Everyone

www.mrctcenter.org/health-literacy

(whether you're 6 or 86!)

