



Thought Starters for Explaining Clinical Trials

This document outlines some key challenges of explaining clinical trials, and provides thought starters to help address them. These thought starters are based on our learnings from building patient communications with patients and cross-disciplinary experts, across disease states.

Other available thought starter topics:

- Biological Processes
- Data
- Health-related Finances
- Risks and Benefits

Resource contents:

- Guidance, standards, and best practices
- Building blocks or assets
- Assessment methods and tools

Applicable to:

- All patient communications
- Specific topics

For more guidance on how to make your explanations more patient friendly, see the *UPL Rules* and the *UPL Style Guide*.



A Starting Point: This tool contains some early work and may change significantly.

Why is it important to understand clinical trials as a concept?

Understanding the concept of clinical trials can help people:

- Recognize the importance of clinical trial research and the role that study participants play in them
- Consider participating in clinical trials with increased knowledge about the process
- Have more meaningful conversations with their healthcare team

What are the key challenges for explaining clinical trials?

- Distilling some of the vast and complex workings of clinical trials to a level that is digestible and useful to the audience
- Identifying the aspects about clinical trial research that are critical to building understanding
- Translating medical research terminology into plain language that can be easily understood

Thought starters for explaining clinical trials

There is no ‘one’ way to explain any given topic. Explanations are uniquely built for the specific audience — like patients from a particular disease state or demographic — and the objectives of the communication. These thought starters are meant to help you craft an explanation that works for your audience. The accompanying examples illustrate how these thought starters have been put into practice in existing UPL patient communications.

Help people understand the purpose and value of clinical trials.

Some people don’t have an understanding of what clinical trials are for, which can lead to skepticism. Help people understand the importance and value of clinical trials by explaining how trials are part of the process of getting health authorities to approve new treatments.

Show people how clinical trials work.

Clinical trials can be complicated operations with many moving parts. Mapping out the fundamental steps of a clinical trial can help people understand how the results can be used by researchers and health authorities.

Acknowledge that people aren’t just a subject or a number — humanize the trial experience and outcome.

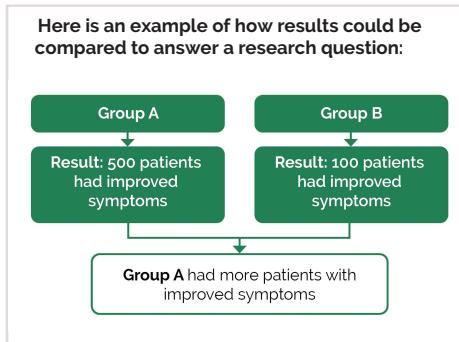
People want to feel like individuals, not just a number in a trial. Some people reacted negatively when explanations were showing ‘them’ as a dot on a timeline. Illustrations of people signal that we think of them as individuals, and not just data points.

Why do people take part in cancer clinical trials?

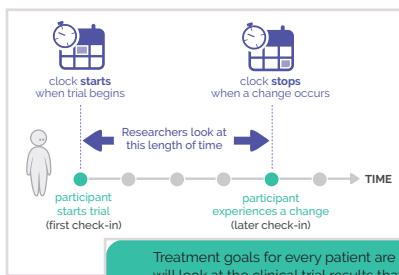
People take part in cancer clinical trials for a variety of reasons that are unique to them. For example, some people may decide to take part for the following reasons:

-  to help researchers better understand cancer, and
-  to help researchers find new treatments for people in the future.

This example explains the role of clinical trials in helping better understand cancer and investigate potential new treatments.



This example describes how clinical trials are set up, and uses a fictional trial to help potential study participants understand how clinical trials yield information about an investigational treatment.



Treatment goals for every patient are unique. Your healthcare team will look at the clinical trial results that are important to your goals. By understanding the different ways the results are measured, you can have a more complete picture of how a treatment may affect you.



Anticipate questions about participation, and be transparent about what is involved.

Deciding to participate in a clinical trial can be a big decision based on a lot of unknowns, and is bound to come with a lot of questions. While it is impossible to answer all questions, provide information that can help people weigh their options and support further discussion with their loved ones and healthcare team.

Who participates in clinical trials?

People of many ages and backgrounds participate. However, there are eligibility requirements for each trial that must be met in order to take part.

Requirements may be based on:

- age
- gender
- type/stage of disease
- previous or current treatments
- other medical conditions



Providing clearer information about eligibility criteria helps people to better understand if they are qualified to participate in a particular trial.

What will be my time commitment in this study?

You will be in this study for up to 2 years and 2 months. The exact time commitment will depend on several factors, like:

- your availability to come for appointments,
- your reaction to the study drug(s), and
- your hospital or clinic's ability to do specific tests and procedures.

The study is divided into 3 separate periods.



Eligibility period (up to 1 month)

During this time, you may have several hospital or clinic visits for a medical history check and lab tests.

Pros

- Close attention from your study team, such as follow-ups regarding your care
- \$0 Access to study-related medical care at no cost
- + Chance to receive treatment that may not be available to the public

Cons

- Potentially greater time commitment as there may be more tests and visits
- Your condition may not improve
- ! You may experience unpleasant, serious, or life-threatening side effects

Providing clearer information about what study participants are committing to allows them to more accurately assess whether they want to participate in a clinical trial.

Providing clearer information about the pros as well as the cons helps improve expectations and reduce potential surprises.

Patient Experience

We are determined to ensure the **voice of our patients** is continuously present - to both inform and inspire - in ways that **help teams across all business units** achieve their goals, meet the needs of our customers, and provide a positive **patient experience**.

Acknowledgment

bridgeable

The UPL and its applications were created with the support of Bridgeable, a service design firm based in Toronto, Canada. Bridgeable has worked with BMS on all elements of the UPL, from overall strategy to creating and applying design capabilities and UPL tools, training BMS employees in UPL, and designing UPL.org. The team includes design strategists, interaction designers, and service designers, plus a team of biomedical communicators who specialize in visually communicating science and medicine.

© 2024 Bristol Myers Squibb Company. Universal Patient Language and the UPL logo are trademarks of Bristol Myers Squibb Company. Bridgeable is a trademark of Cooler Solutions, Inc