Thought Starters
for Explaining Risks and Benefits

This document outlines some key challenges of explaining risks and benefits to patients, 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
- Clinical Trials
- Health-related Finances

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

Resource contents:

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

Applicable to:

- ○ All patient communications
- ☑ Specific topics

! **Ready But Limited:** This tool still has areas for improvement, and more resources will be added over time.

Why is it important for patients to understand risks and benefits?

Understanding risks and benefits can help patients:

- Have appropriate expectations for what they may experience, whether good or bad
- Understand the options they have, and what the implications are for each option
- Weigh what is important to them when making health-related decisions with their healthcare team

What are the key challenges for explaining risks and benefits?

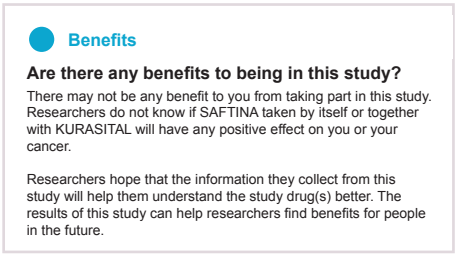
- Staying unbiased while helping patients weigh risks and benefits
- Balancing fear and optimism
- Reducing emotional stress while maintaining clarity about risks and their likelihood
- Communicating risks and benefits in a relatable way, while abiding by laws and regulations (e.g., from the FDA)
- Communicating the role of patients in reporting, preventing, reducing, and managing risks

Thought starters for explaining risks and benefits

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.

Even if there are no known benefits (or risks), be upfront about it and state it explicitly.

There shouldn't be a situation where only risk information is provided, or only benefit information. Knowing that there is no known benefit is still an important piece of information that patients can use to make a decision. Seemingly counterintuitive, this approach demonstrates honesty and adds credibility. Transparency and balance are key.



Benefits

Are there any benefits to being in this study?

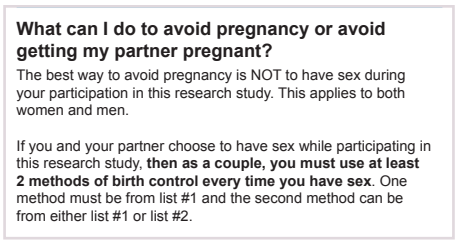
There may not be any benefit to you from taking part in this study. Researchers do not know if SAFTINA taken by itself or together with KURASITAL will have any positive effect on you or your cancer.

Researchers hope that the information they collect from this study will help them understand the study drug(s) better. The results of this study can help researchers find benefits for people in the future.

This example shows one way to be upfront about how there may be no direct benefit for trial participants, but the research may benefit other people in the future.

Describe benefits and risks in practical terms.

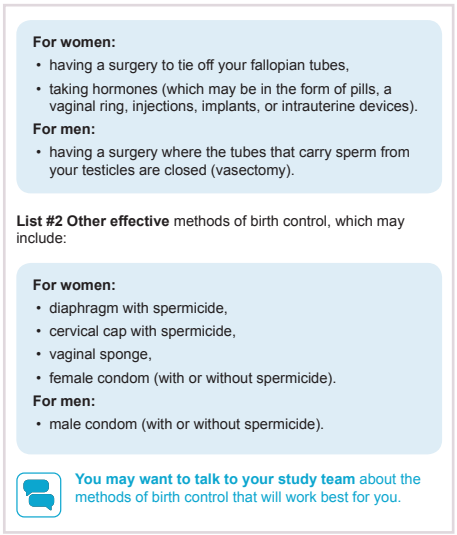
Benefits and risks are easier to grasp and evaluate when put in terms of everyday life (e.g., physical, emotional, job, money, time, travel to hospitals, etc.). When presenting risks, include actionable ways to manage or deal with risks associated with their healthcare options. This approach addresses patients' worries by giving back a sense of control and also helps them understand the implications of their treatment choices and weigh the risks more objectively.



What can I do to avoid pregnancy or avoid getting my partner pregnant?

The best way to avoid pregnancy is NOT to have sex during your participation in this research study. This applies to both women and men.

If you and your partner choose to have sex while participating in this research study, **then as a couple, you must use at least 2 methods of birth control every time you have sex**. One method must be from list #1 and the second method can be from either list #1 or list #2.



For women:

- having a surgery to tie off your fallopian tubes,
- taking hormones (which may be in the form of pills, a vaginal ring, injections, implants, or intrauterine devices).

For men:

- having a surgery where the tubes that carry sperm from your testicles are closed (vasectomy).

List #2 Other effective methods of birth control, which may include:

For women:

- diaphragm with spermicide,
- cervical cap with spermicide,
- vaginal sponge,
- female condom (with or without spermicide).

For men:

- male condom (with or without spermicide).

You may want to talk to your study team about the methods of birth control that will work best for you.

This example provides ways to prevent pregnancy for both women and men, helping patients better assess the risk, its implications, as well as the strategies for managing it.

SAFTINA and KURASITAL are fictional drugs, and do not exist as treatment for any kind of medical condition(s). Any similarity to actual drug development program(s) (past, present, or future) by Bristol Myers Squibb or any other organization is entirely coincidental.

Remind patients to reflect on their own perspectives on the risks and benefits.

Every patient is different, and what one patient deems a risk, may not be a risk to another. While there are objective risks and benefits, some are more dependent on the patient's situation. Enabling patients to think through the more subjective risks and benefits can help them check in with what they value, and temper expectations.

What factors are important for me to consider?

To help you get started, here's a list of factors that you may want to think about as you learn more about a specific clinical trial:

- Will I have a convenient way of getting to the clinic?
- Do I have support or a caregiver to help me through this?
- If I choose to take part in this clinical trial, will that affect my chances of taking part in other clinical trials later on?
- Will I be able to choose which study drug to receive?
- Will I have to take time off work?
- Will I still be able to take part in the activities that are important to me?
- If I move, can I continue the study at another hospital?
- Will I be allowed to get pregnant while on the study?

Consider using the space below to add your own questions.

This list of questions neutrally suggests possible concerns to allow patients to truly reflect on what matters to them.

When presenting multiple options, communicate the risks and benefits in a manner that is easy to compare.

In order to make informed decisions, patients need to get a sense of not just one, but all available options. When risks and benefits are presented in a way that allows for direct comparison, options may become easier to process and weigh.

TABLE #1: Most common side effects were experienced by **5 or more people out of 100**.

● marks a known side effect of the study drug(s).

LOCATION IN THE BODY	SAFTINA	SAFTINA + KURASITAL
HEAD AND NECK		
Dry mouth	●	
Swelling and redness inside mouth		●
Abnormal taste		●
CHEST		
Chest pain	●	
Cough	●	●
Increased heart rate *(may be related to thyroid abnormalities)*	●	●
STOMACH AND PELVIS		
Feeling sick	●	●
Burning feeling while urinating		●
Stomach pain	●	
Diarrhea *(may be related to pancreatic abnormalities)*	●	
GENERAL		
Tiredness	●	●
Chills	●	●
Greater sensitivity to cold *(may be related to thyroid abnormalities)*	●	●
Swelling of feet, legs, arms	●	
Rashes, bruises, sores, ulcers	●	●

This table clearly shows how risks for two study arms compare.

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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.

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.

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