TRUST BUILDER:

SUPPORTING PATIENT CONVERSATIONS ABOUT MISTRUST BELIEFS IN CLINICAL TRIALS

sanofi



Taking a motivational interviewing approach to support positive patient outcomes:

- R ESIST telling them what to do
- U NDERSTAND their motivations
- ISTEN with empathy
- **MPOWER** them

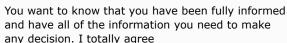
I may not be given all of the information about the study

PERCEPTION

Q

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SUGGESTED RESPONS



- I can understand why this might make you feel nervous about joining the trial. You need to feel that everything you will undergo within the trial will be explained at the beginning
- You can ask any questions and raise your concerns so that we can provide you with the answers you need to make an informed decision. If you have any more questions in the future, just let us know
- Here is the informed consent form, a member of the team will be happy to go through any questions you have. It's your decision to be involved or not and it won't impact on your future medication. You should take all the time you need to evaluate the information

(This trial will not benefit people like me

PERCEPTION

SUGGESTED RESPONSE

You want to be sure that the trial is right for you. I really understand what you are saying

- This trial has been designed for all patients affected by your condition. Your individual concerns are important to us
- Let's discuss what is worrying you and I will give you the information you need to feel that this trial is right for you
- The final decision to participate is always yours.

 Our job is to ensure you have enough information to make an informed decision which you can change at any time

I will sign away my rights during the consent process

PERCEPTION

SUGGESTED RESPONSE

I recognise that you have some concerns about signing the consent form

- It is understandable that you might be worried that you are signing away important rights
- The purpose of the consent process is to inform you about all aspects of the trial. When you sign the form, you only agree to participate. Your signature does not take away any rights. You can remove yourself from the trial at any time. There are strict laws to keep your private information protected
- If you have time, we can go through the form and you can let me know which areas worry you. Your concerns are important to us

I have no idea what's in the medicine. How do I know it has been properly tested?

PERCEPTION

SUGGESTED RESPONSE

You can be reassured about any medication you receive during the trial. The medication has been rigorously tested under the appropriate guidelines

- I understand that you might feel worried.
 Although the drug is still under development, you will be closely monitored at all times. Your health is always a priority
- I can provide you with more information about the trial. This will help you understand what your experience might be within the trial
- Take as much time as you need to come to the decision that's right for you. The choice to participate is always yours

I am afraid I will not be told about all of the risks

PERCEPTION

SUGGESTED RESPONSE

Being sure you understand all of the risks involved is an important part of trial participation

- Your concerns are understandable, I want to re-assure you that trial guidelines are designed around safety
- We see trial participation as a partnership. You will remain fully informed at every stage of the trial and we will make decisions together. If new information comes out, we will tell you as soon as we can. Let's discuss which parts of the trial you are worried about and we can talk through them
- Please be reassured that you will always be asked for your agreement at each stage in the trial

V3 Nov 2022

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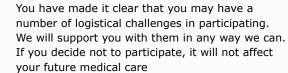
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The staff won't understand the challenges I will face while participating

PERCEPTION

SUGGESTED

I can hear that you feel unsure that you will receive support from the staff during the trial



- I am here to discuss this with you if you have time. Let's work together and identify any additional support you might need
- Once we have identified the challenges and the support we can provide, you can then make an informed decision in your own time. As a starting point do any of these look likely to be an issue?

The costs & insurance implications may not be fully explained (costs of participation)

PERCEPTION

Q

SUGGESTED RESPONSE

If you have financial concerns over participation in the trial it is our role to help you resolve them

- I can hear that you are worried about unseen costs or insurance complications that would be a worry for anyone
 - Let's sit down and try to address them together. As a starting point, which of these are worrying you?
 - ☐ Transport ☐ Work ☐ Childcare ☐ Other Schedule
- Please be reassured that most of the costs are covered in a clinical trial, such as treatments and examinations. All clinical trials have insurance coverage (country specific)

The trial will benefit the pharmaceutical company and not me

PERCEPTION

SUGGESTED RESPONSE

Your concerns about who will benefit from a clinical trial is a valid issue

- You rightly want to know if the people that benefit are the patients who have the same condition as you
- Trials are designed for and with patients. Patients are involved from the beginning. Patients' needs come first. The sole priority is to find ways to improve the treatment of your condition
- The choice to participate is always yours. You should be comfortable the trial has been set-up and designed for all patients living with this disease

Staff will not treat all participants equally

PERCEPTION

RESPONSE

I can hear that it is important for you to be treated fairly and with respect



believe everyone is treated with equal respect

Every participant matters and we have
detailed guidance to ensure these ethics are

at the center of how we treat everyone

Clinical trials should be a place where people



Your participation will help with advancing successful treatment of this condition but your health is always a priority

I am concerned that I will be given a placebo and have wasted my time

PERCEPTION

ESPONSE

I hear that you are concerned about the use of placebo medication in the clinical trial



Understandably you want to know if you might receive the placebo and what that might mean for your condition



In clinical trials, the treatments being investigated are compared with placebo to better evaluate the treatment's effectiveness and is a way for scientists to find new treatment options for patients



Once you have reviewed the information and only when you are ready, you can decide if it's right for you