

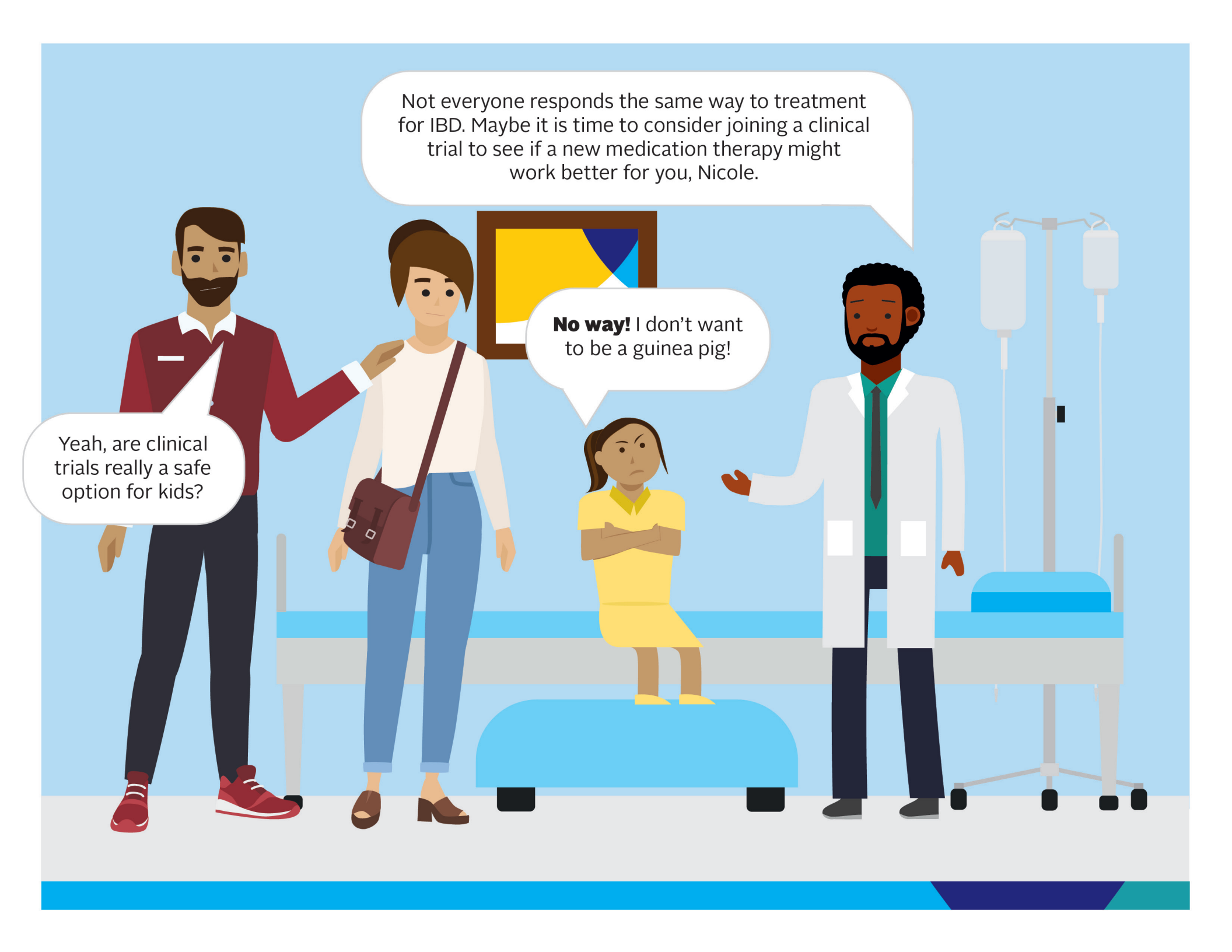
Nicole Learns All About Clinical Trials



You don't look like you feel well, Nicole.

No, I really don't feel well. And I have gotten really good at taking all of my medicine just like you told me to do.

We just don't understand why she still feels so bad most of the time.

An illustration of a doctor's office. A doctor in a white lab coat stands on the right, gesturing towards a woman in a white shirt and blue jeans who is being comforted by a man in a red sweater. A young girl in a yellow dress sits on a blue ottoman in the center, looking angry with her arms crossed. In the background, there is a hospital bed with blue linens and two IV stands with white bags. A framed picture hangs on the wall.

Not everyone responds the same way to treatment for IBD. Maybe it is time to consider joining a clinical trial to see if a new medication therapy might work better for you, Nicole.

No way! I don't want to be a guinea pig!

Yeah, are clinical trials really a safe option for kids?

Clinical trials do have some risks because there are still a lot of unknowns about the medication. But a lot of research is done on the medication before it can even be tested in kids. There are also a lot of rules that studies must follow to limit any harm to the people who are participating in them. If you do decide to join a clinical trial, the research team will explain all of the risks and benefits that are a part of being in their study.





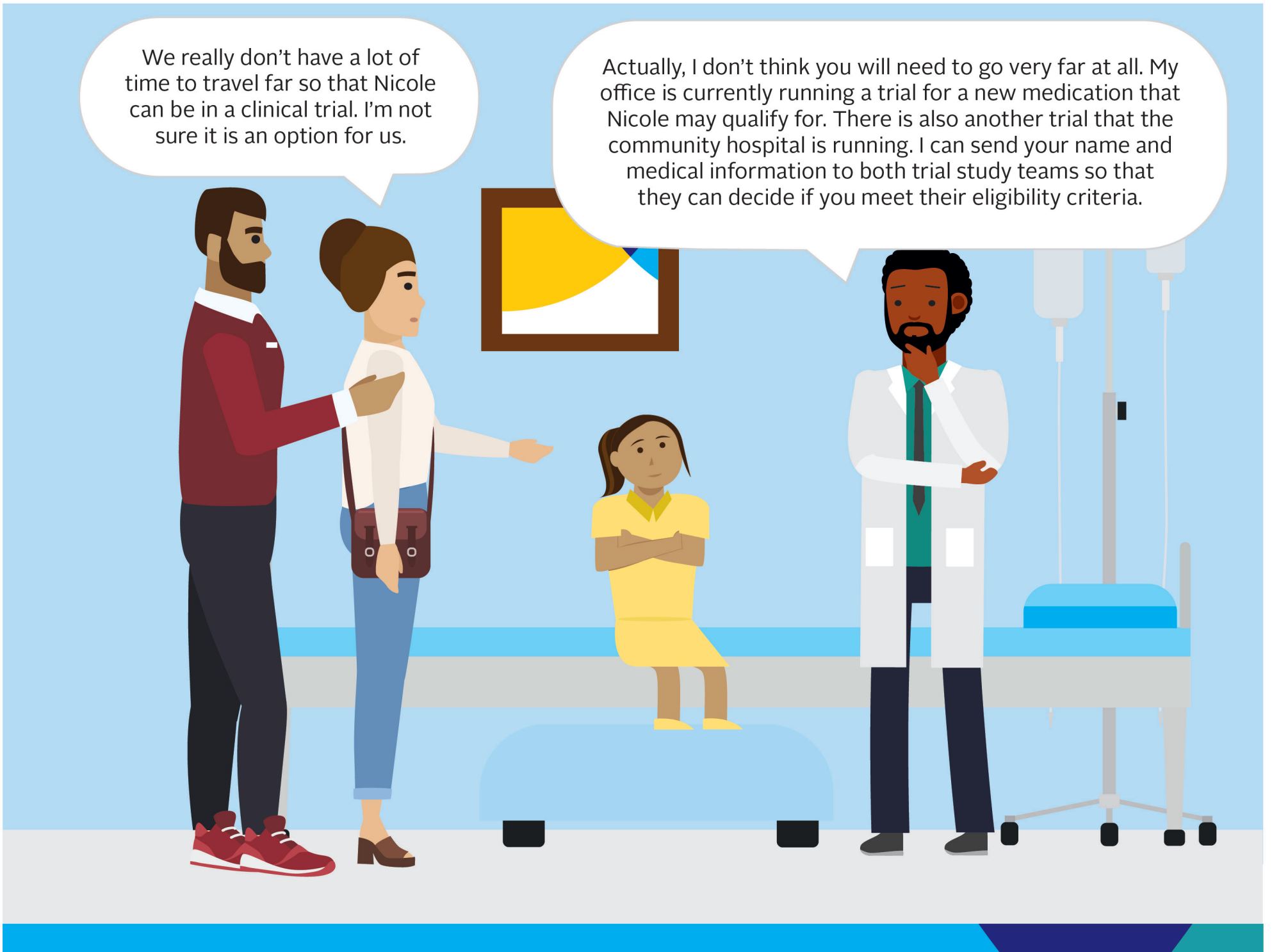
**Patient participation
in clinical trials**

**New treatment
options for patients**

It is important to understand that the only way we find new treatments for Crohn's disease and ulcerative colitis is by having patients participate in clinical trials. And for pediatric patients, clinical trials also help researchers better understand if a medication or therapy that works for adults is also good for kids.

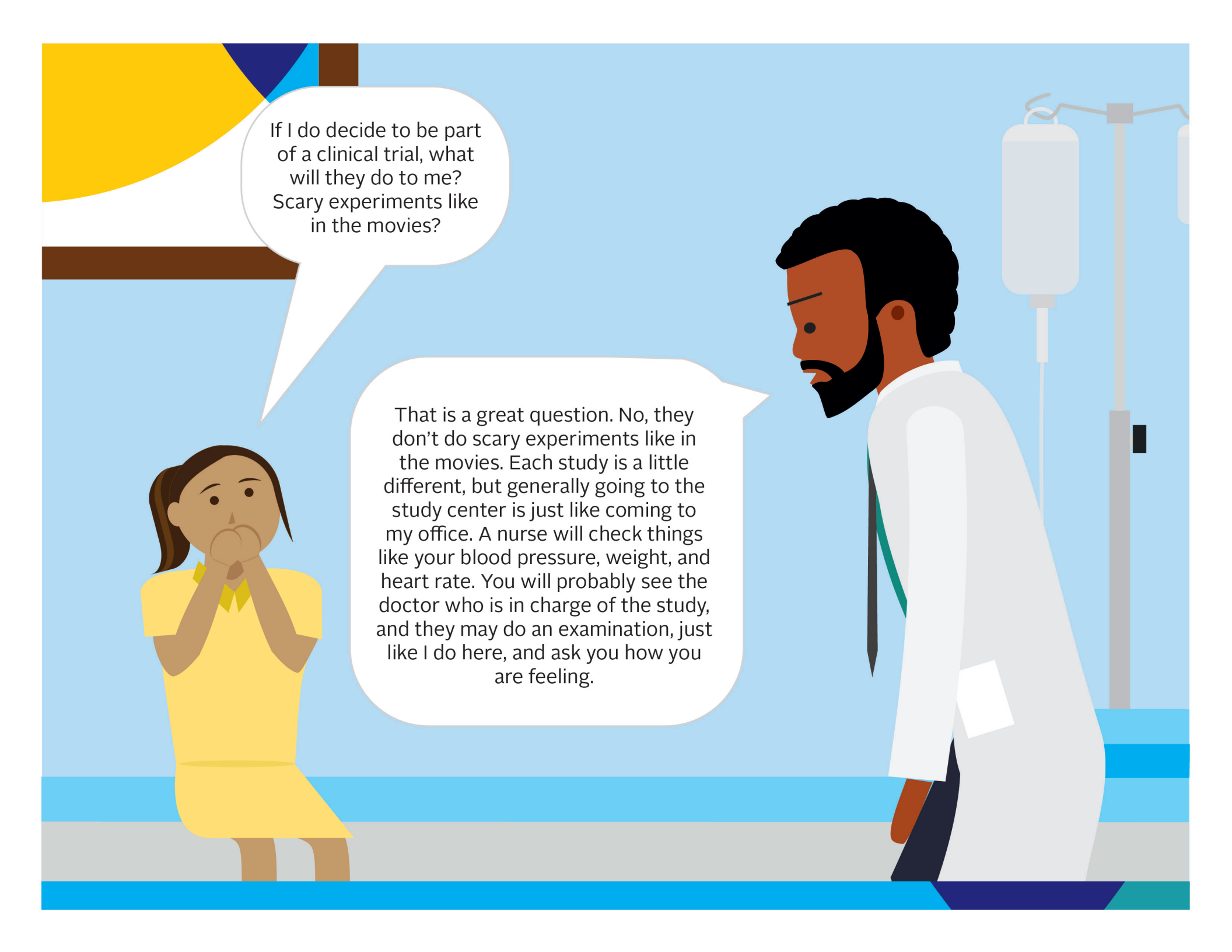
We really don't have a lot of time to travel far so that Nicole can be in a clinical trial. I'm not sure it is an option for us.

Actually, I don't think you will need to go very far at all. My office is currently running a trial for a new medication that Nicole may qualify for. There is also another trial that the community hospital is running. I can send your name and medical information to both trial study teams so that they can decide if you meet their eligibility criteria.



Eligibility criteria is a list of characteristics that patients must have in order to participate in the trial. Criteria, such as age, gender, previously used medications, and IBD symptoms may be considered. The list of characteristics can help researchers to enroll participants, they can expect the clinical trial treatments will be safe and can help them feel better. As a result, the researchers can enroll the appropriate participants in the clinical trial to answer the questions needed concerning the new medication. Someone from the clinical trial study will decide if you meet their eligibility criteria, and then, if you do, they will call you to ask more specific questions.



An illustration of a doctor and a patient in a hospital setting. The doctor, a man with a beard wearing a white lab coat and a tie, is standing on the right. The patient, a woman in a yellow dress, is sitting on the left with her hands clasped in front of her face, looking concerned. In the background, there is a blue wall, a grey floor, and a medical stand with a white bag hanging from it. A speech bubble from the patient asks about scary experiments, and a larger speech bubble from the doctor explains that clinical trials are not like movies and are more like a regular office visit.


If I do decide to be part of a clinical trial, what will they do to me? Scary experiments like in the movies?

That is a great question. No, they don't do scary experiments like in the movies. Each study is a little different, but generally going to the study center is just like coming to my office. A nurse will check things like your blood pressure, weight, and heart rate. You will probably see the doctor who is in charge of the study, and they may do an examination, just like I do here, and ask you how you are feeling.




Daily Diary
Blood Tests
X rays

They may also have you fill out a daily diary at home about how you are feeling, which they will go over with you during each visit. You may take blood tests or x-rays to see how you are responding to the treatment.




I heard some people in clinical trials don't actually get the medication that is being studied. They get a sugar pill instead. Will we know what medication Nicole is getting?



It depends on the trial. In some studies, everyone gets the medication that is being studied. In others, one group gets the medication that is being studied, while the other group gets something called a **placebo**.


A placebo is given the same way as the study medicine but contains no active medication. So for medicines that are pills, the placebo would be a sugar pill. The researchers essentially flip a coin to decide who gets which medication, and in these types of studies, you and your doctor probably won't know what Nicole is getting.



Why would some patients not get the “real” medication?

We know that even without treatment, patients’ symptoms can get better or worse. Some patients will even feel better just by participating in a clinical trial with frequent monitoring. This positive thinking that the medication will help them is called the ‘placebo effect’.

So in some clinical trials, it is important that some patients are assigned to a placebo medication, at least for some period of time, to make sure any positive effects seen are because of the medicine being tested. In some clinical trials, patients given placebos are allowed to change or “cross-over” to the active medicine after a period of time.

An illustration of a woman on the left and a doctor on the right. The woman has short brown hair, is wearing a white long-sleeved shirt and blue jeans, and has a brown messenger bag slung over her shoulder. The doctor has a beard and is wearing a white lab coat over a teal shirt and a dark tie. They are standing in front of a light blue background with a yellow and white striped canopy above them. Two speech bubbles are present: one from the woman and one from the doctor.

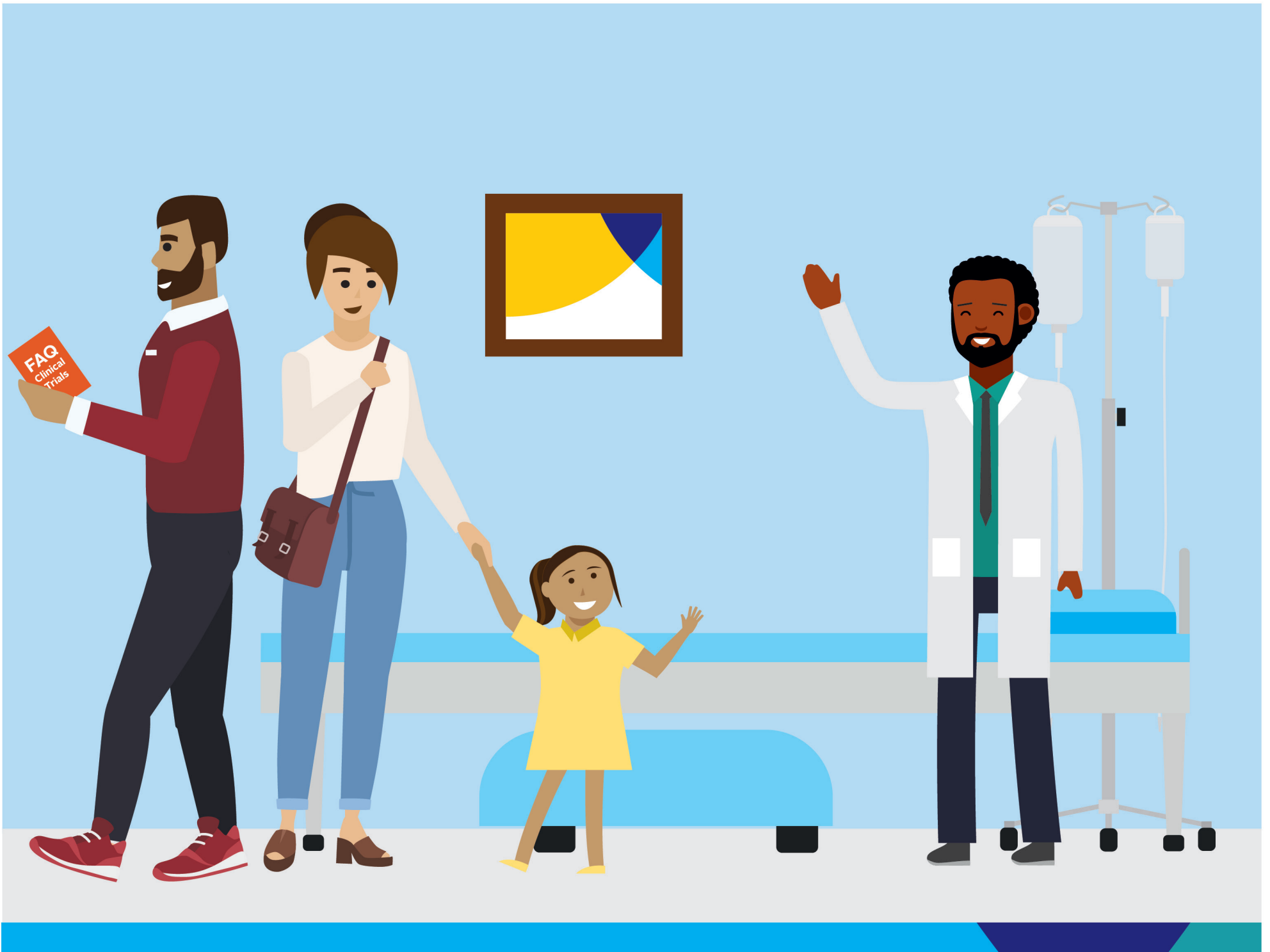
Can we go home and talk about this some more?

Absolutely, there is no hurry to decide. Even once you say you want to be in the study, you will have all the time you need to ask the research team questions and think about whether it is a good idea for Nicole to enroll. Even once you are in the trial, Nicole, you are always allowed to ask questions, and you can even leave the clinical trial for any reason if you don't feel comfortable being in it anymore.

Let me give you a booklet that you can read at home. It may answer any other questions that you have about being in a clinical trial. Once you decide if you want to do it, just call my office and I will submit your name to the different trial teams.



Thank you,
Doctor!





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