

## **This is happening really fast. How do we know it's still safe?**

I can totally understand where those concerns are coming from, because I think what people are hearing is that we're rushing things, or they're hearing that it's happening so much faster than it was before.

I think what it's important to highlight is that the time in which these vaccines have been developed is shorter because of the advances in science, like the level of international co-operation that's happened, and how focused everyone is globally on the development of the vaccine.

An average vaccine submission is hundreds of thousands of pages, and it takes usually around 2,000 person hours to complete the review; there's a team of seven to 12 people with a whole series of different backgrounds. We're still doing that.

One of the things that the interim order process allows us to do is something called a rolling submission. So instead of the company having to wait until all of the studies are done to give us the information, they can actually give us that data as it becomes available.

So it allows our reviewers to start the review, as opposed to having to wait till everything is finished before we start.

## **Who reviews it? Who are these people?**

There's a whole team that reviews it.

We have people like toxicologists that are looking at the laboratory data and the animal data. They focus on any safety issues and making sure that it looks promising in terms of the immunological response. Are the vaccines doing what they're supposed to do?

Then we have the clinical data, which is all the information from the Phase 1, Phase 2, and Phase 3 clinical trials. Those are the trials in humans. We have physicians, infectious disease specialists, microbiologists and immunologists looking at that type of information. They're really looking for any safety issues and figuring out what the best dose would be ... but also at the efficacy, or how well it works.

We also have biostatisticians looking at the statistics and the epidemiology.

Then there's all the information that goes into the manufacturing of the vaccine, and that's a very complicated process. We have people in microbiology that have the expertise to do the assessment of the actual manufacturing part, which is very, very