JEFFREY BUGULISKIS: Welcome to GENCast, a sponsored podcast series brought to you by *Genetic Engineering and Biotechnology News*. I am your host, Jeff Buguliskis.

The coronavirus pandemic, unfortunately, shows little signs of slowing. Still, the resourcefulness and adaptability of scientists and engineers working in the biotechnology industry has many projects moving forward at a rapid pace.

Our previous podcasts have highlighted a couple of common themes, one being the power virtual tools have afforded bioproduction professionals when conducting important trials so as not to delay crucial timelines, and the other being support from the experts at the M Lab Collaboration Centers at Merck, who help provide the solutions that keep it all on track.

In this GENCast, we will hear how Janssen process engineers got the help they needed from the M Labs to conduct the first run of Pmax filter sizing trials virtually. The ingenuity that this collaboration bred will become obvious very quickly.

Let us meet our panelists for today's discussion. Hi, everyone. Can you guys introduce yourself to the *GEN* audience and tell us a little bit more about yourself?

TERRI LOVE: Hi, I am Terri Love. I am an MSAT manager based in Ireland with Merck.

IREOLUWA OLAJITAN: Hi. My name is Ireoluwa Olajitan. I am a process engineer based in Janssen Sciences Ireland in Ringaskiddy, Cork.

BAPTISTE BALBUENA: Hi. I am Baptiste Balbuena. I am a biomanufacturing engineer, and I am working for Merck, and I am based in France.

JEFFREY BUGULISKIS: Great. Thanks very much, guys. Welcome to this GENCast. Let us get to the questions right away, because we know we have a really good discussion here. And Ire, I am going to start off with you. And maybe you could tell the *GEN* audience a little bit more about how this collaboration began.

IREOLUWA OLAJITAN: Yeah, sure. So essentially how this began was we were looking to run a set of filtration trials for one of our drugs here. The drug in question would be a monoclonal antibody, and it would be used to treat adult patients who have multiple myeloma. And the reason we decided to do this was to optimize our centrifugation process. So that is, you know, to optimize flow speeds, your flow rates and your back pressure.

And the reason we decided to conduct the trials -- more specifically, the Pmax trials -- was to be able to see

how well the centrifuge did perform, which would be effectively how well the filter train was sized on the capacity of the filter train.

So now pre-COVID, this trial would have been done by the M Lab team. They would have come inside to conduct the trials. But as a result of the pandemic, the travel and site restrictions had already been put in place, so the team were not able to actually physically come on site.

So essentially, we had to find a way to be able to run these trials with, you know, representative feed material as it would be from the process. And I think one of the early options, which was ruled out quickly enough, was to, you know, ship it offsite or to get it offsite for the trials to be run on. But that was ruled out. So this is where we had to get onto Terri and the M Lab team to see how we would be able to solve this dilemma.

TERRI LOVE: That was a really interesting point you made there, Ire, about the onsite support. Typically, what I would do is go onsite at Janssen, run these filtration trials for the guys there on site. But the request came in very shortly after the lockdown came in Ireland. So, I think the last trials that I had done in Janssen were around the 9th of March, and then lockdown came the week after, and then this request came in from Ire.

So I was sort of thinking, you know, maybe I can go on site, because things were still very uncertain at that point, but realized that we really did have to have a backup plan, because we did not know the way things were going to go.

So that is what got us thinking about, how could we support these trials virtually? So, what do we need to put in place to make this work? Because nobody in Janssen had ever run this type of trial before. They had seen me do it multiple times, but they had not actually taken on the task themselves.

So, then we collaborated really well with Janssen to put a plan together on this and to get some good input into the protocol. So this provided a very good foundation for the process. And then once we started to develop the protocol, we thought about how we could actually support them when they were running the trials.

JEFFREY BUGULISKIS: So, Terri, this sounds like a pretty unique scenario. Maybe you could tell us a little bit more about how you navigated the challenges of conducting a virtual Pmax trial.

TERRI LOVE: Sure, Jeff. We were cooperating closely with Janssen on the protocol, and as we were writing it, realized that it needed to be quite detailed in the way it

was written. So, when I run trials, I am used to running them, whereas somebody running the trials from scratch might not have even seen one of these filters before. So, we had to be very mindful of having really accurate instructions on the flashing and the venting procedures involved with these filters.

And in addition to that, the trials were not really your typical Pmax trial in that normally you would run these trials with a single filter. What Ire wanted to achieve was a scaled-down simulation of what they were doing at process scale. So that meant that we had several filters connected together, several pressure sensors, and we had a data recording system, as well.

So, the protocol needed to be really detailed, but also, we needed to make it a little bit more foolproof in the way the filters were connected together. So that was when I engaged Baptiste in our M Lab because I wanted something that Ire could just plug and play, and he could just get going with the trials.

So Baptiste then took up the project and helped me out in the M Lab because he could physically go to our M Lab in France, whereas I could not physically go to the customer site or to the M Lab at the time.

BAPTISTE BALBUENA: Yes, absolutely, Terri. I think our main aim of our support was to make the trial easy, but due to the current situation, we had to drop some constraints. The first thing that we did was to set up the entire filtration train with the filters and sterilizing-grade filters in our M Lab.

Then we shot a video explaining and showing how to set filter, pressure sensor, how the flushes are set up and equilibrate the filters and so on. It was mainly closed, because the setup used for this particle or trial was not really usual. Several filters we were plugged in in parallel. We had something like seven.

But anyway, the setup was then splitted and sent in Spare Parts. All Spare Parts have been -- in the video we named and identified. I think it allows to facilitate the installation somewhere. In parallel, we also showed to Ire how to record the data with an automated acquisition system with a webcam and with Teams meeting.

But I think that this approach of providing a video and a setup in Spare Parts was not as efficient as in usual support. Use a video in the Spare Part setup, and that training was like following instructions as when you are building a Swedish furniture while following a DIY tutorial on the Internet. In this approach, most of the effort is

by the learner, and it is kind of a one-way approach, I would say.

And then we had the idea about the smart glasses, which had allowed us to be involved within trials. These remote tools allow us to see what the customer is seeing right now, and so we are able to guide him and to share advice in real time.

IRE: Yeah, so, just to build on that, on Terri and Baptiste's point from a Janssen perspective, so when we did get the protocol, which was in itself really detailed and, you know, had all the steps we needed, there was still a learning curve. And this is where the plug-and-play model really came in handy, because if this part already came, all we needed to do was assemble it, attach it to the filters, which also came separately. I also had to attach it to the data collection software, as would normally be done if the M Lab team were doing it.

So, what we did was, those first training sessions, which was done over webcam -- and this is where I essentially used the plug-and-play model, I used the protocol, and I used a video that was sent by Baptiste and Terri to set up the whole filtration system for the trials. And then we conducted a practice run, and this actually yielded encouraging results, because it had showed that we

were actually able to set it up and do a dry run of the trials.

So, then the smart glasses Baptiste mentioned then came after. So, what we did was we conducted a second practice run. And now, the reason we did this is because this is something Janssen would not routinely do. So, we just had to make sure these trials went exactly according to plan.

So what we did was we used the smart glasses connected with my colleagues here in Janssen internally, and was able to set up the system as we did during the practice session, set it up with the filter, set it up with the data collection software, and we were able to go through the process. And this, again, this was a dry run, but it did yield encouraging results. So, we have now done this twice in practice, and we are ready to do this for the actual trials.

Now, for the actual trials, this actually fell out of hours due to the project schedule, so this was Sunday morning at 7 A.M. Irish time. So now this would be out of hours for the M Lab team. So this is where the smart glasses were most efficient, and this is where they really came in handy, as we were able to connect with our colleagues all over the Janssen network, and they were able

to provide, you know, SME support as we were conducting the trials.

They were able to see in real time how the trials were set up, the flush processes, the vend process, and even when we were able to feed with their representative material. They were also able to direct our attention to things that we would not really notice.

That is really an appreciation for my colleagues here in Janssen Cork, who were able to support these trials, because these trials are about, you know, 9 to 10 hours, you know, including your flushing, including your setup, including your takedown. And also to our colleagues over in the states, because, as I mentioned, this was, you know, on a Sunday morning at 7 A.M., so even due to the time difference, they were still able to support us.

JEFFREY BUGULISKIS: So, you are -- I think there is a lot of people in the *GEN* audience who are in a similar situation as you guys are with the pandemic and all. So maybe you could tell us a little bit more about what exactly you learned from this experience.

IREOLUWA OLAJITAN: So, this would have been a very different setting to what we are used to. Like most of our development work in the lab would have been put on hold due

to the pandemic. But then these were trials that really had to go ahead.

So, like normally, all we would be doing, as Terri said, was just to supply feed material and maybe feed utilities and consumables that would have been used in the process from our lab, but now we would be the ones to conduct the trials. We would be the ones to take inline measurements, the titrating, and the volume sampling. And this was all learned, like we eventually got over, because now that we could feel -- was to be confident enough to do these trials.

And actually, to date now, we have done these trials twice, and we have achieved positive outcomes from both. We have been able to properly size a filter train. We have been able to confirm the capacity of our filter train, and we will be very confident in, you know, setting up ourselves, setting up the tubes, setting up the filters and be able to know what we are looking for within the process.

So I feel like -- from a Janssen perspective, anyways -- like with the support we have gotten from the M Lab team and the technology that they would have given to us -- as a result of this support, we would definitely be very confident to run these trials again.

TERRI LOVE: It is great to her that, Ire, that you are confident that you would be able to run these again. As you already mentioned, you know, some of these trials do fall out of hours. So even outside of the pandemic, we were working towards empowering our customers to run their own trials with this remote support. And the pandemic has accelerated the need for that.

And these were probably some of the earlier trials that were done within the scope of the pandemic. So, you know, this was really kind of our starting point into looking at how we can support in a virtual world. And it was really positive from our side, as well, and great to get feedback from Janssen that it was positive from their side, too.

And, you know, it was a great learning experience on both sides. So giving the customer the confidence to run these trials again and helping us grow our virtual tools and our virtual support on our side.

BAPTISTE BALBUENA: Yeah, this experiment was quite interesting for all of us. I think we have experimented a new way to provide our support. At the beginning, I think we were more focused on the training just to be sure that they are comfortable with running the trials. This is a protocol, how to run the deck, et cetera.

And finally, the use of the smart glasses has allowed us to facilitate the whole process, and to bring a kind of digital but still human support. I think the smart glasses avoid the splitting between taking a look at the manual and then come back to the technical part. We are all inside the lab somewhere. This approach is much more inclusive for all of us. Everybody is a part, is included within the trial, and passing all the geographic and physical constraints that we have during the outbreak.

JEFFREY BUGULISKIS: Well, thanks very much, guys, for telling us about this scenario. I think it is really interesting. Again, like I said, I think it is something that the *GEN* audience is aware of, and many of them were actually a part of, as well. So, I think your experiences will be able to help them out a lot. So, we appreciate your time today, and thanks for joining this GENCast.

Thanks for listening to GENCast. For Genetic Engineering and Biotechnology News, I am Jeff Buguliskis.

[END]