

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

For many years, we have heard technology gurus and futurists expound on the merits of a virtual world where technology allows us to do our jobs at a distance with just the touch of the finger. It is hard to imagine that any of these technological prognosticators had a global pandemic in mind when they were envisioning the future, yet here we are, many of us working remotely and in new ways we never imagined, where virtual is the reality.

Pharmaceutical manufacturers have had a particularly difficult time during the COVID-19 crisis, as many of them have not only been called upon to create new drugs and vaccines to combat the SARS-CoV-2 virus, but also have the responsibility to keep up with supply chain of existing therapeutics that are essential to so many other patients.

Getting the much-needed assistance to move manufacturing projects forward, scientists in the biopharmaceutical industry search for creative ways to get the job done. In this GENCast, we will hear how Vuab Pharma, based in the Czech Republic, turned to the experts at the M Lab Collaboration Centers at MilliporeSigma to

assist them in their clinical trial efforts that were under very short timelines.

Due to the COVID-19 travel restrictions, scientists were unable to interact in person, but our podcast panelists will tell us how they were able to work together to solve this challenge through virtual collaboration. Let us meet our guests for today's podcast.

Paul Kaschutnig: My name is Paul Kaschutnig. I am an EMEA process development scientist based in South Germany. In this role, I provide technical support to our clients in Germany and Austria, and I am also part of the M Lab Collaboration Center Network.

Marine Maszelin: Hello, Jeff. I am Marine Maszelin. I am also a senior process development scientist for Europe, Middle East and Africa. I am based in Zurich, and I am covering France, Switzerland and Eastern Europe in that role.

Ondřej Žítek: And my name is Ondřej Žítek. I work as the head of research and development center at Vuab Pharma, and our company is based just outside of the city of Prague in the Czech Republic.

JEFFREY BUGULISKIS: Great. Thank you very much, Paul, Ondřej, Marine. Welcome. Thanks for joining us today. Ondřej, my first question is really going to be for

you, I think, to start off with. How has the COVID-19 pandemic impacting your business? What challenges have you encountered?

ONDŘEJ ŽÍTEK: Well, Jeff, I can talk for our R&D center. So the COVID-19 affected I think most of our projects, and that is mainly because we lacked of the staff, and it was when the government restrictions were on, and most of my colleagues needed to stay home with their kids.

So at that time, we needed to put on hold some of the projects, but then there were some that we really needed to finish, and that was also the case of this story, when we already planned since February the TFF trials on our site, but then we were in the global crisis, and the onsite support was not available. So then it ended up we received the virtual support from Marine and Paul.

PAUL KASCHUTNIG: Yeah, Ondrej, so this case, of course, also contained some significant challenges for us as a supplier. Obviously, due to the COVID-19 pandemic, we were not able to support Ondrej on site. As he just mentioned, there was no face-to-face meeting or onsite technical support possible. And he just brought up the thing that there were some projects, especially this one,

where Vuab Pharma was in need for immediate technical support due to the tight project timelines.

So one of the major challenges, I think, for us was that the scheduled TFF trials, they are usually quite complex. They have many individual steps, and our client, Ondrej, he was not experienced at TFF technology to that point. So therefore, we had to assess some new options to provide the technical support without active being there on site.

MARINE MASZELIN: If I can jump in, as well, I think we had an additional challenge as a supplier. Basically, the support for Vuab Pharma was the first remote support we had in Europe during the pandemic, so we had no internal process to be able to support, so we had to find our own way, and we even did not know how, you know, the quarantine and everything will evolve. So, we have created a whole process to be able to support remotely a customer from the beginning, through the qualification and see to the end of the trials.

JEFFREY BUGULISKIS: So those are some pretty unique, interesting challenges, guys, and thanks for bringing them up. So I guess my next question sort of stems around that. Many companies are taking the opportunity to reinvent the way they work and response to things like global pandemics.

How are you guys adapting to solve the challenges that you just mentioned?

PAUL KASCHUTNIG: Good question, Jeff. So, as mentioned before, the initial plan, the onsite visit, obviously, was not possible. It was also not possible to ship the product to the M Lab, which was also once as a plan B in our minds. So, we ended up with this proposal of virtual technical support.

We brought this up to Vuab Pharma, and gladly they were quite convinced by that idea. So, this, of course, included a lot of pre-work and preparation. So, we shift equipment, we provided a protocol and reviewed that experimental protocol together with Vuab Pharma and staff, so to say.

We also provided TFF tutorial videos via our company YouTube channel in order to provide the client with some concise TFF crash course. Most of the other added steps, which were very important. Marine, maybe you can add something here.

MARINE MASZELIN: Yeah, indeed, I think, as well, we had to think about the digital tools. Even if in our group we are exploring for a long time some digital way to support, it was never so concrete, if I can say. So we had

to identify together with Ondrej the tools that we could use.

So, we went finally for tools such as BlueJeans, a smart phone to be able to see the lab and to be able to discuss. We had also to organize on our supplier side the support. So, what we have decided is to go for two PDS, two process development scientists to provide constantly support and availability to Ondrej. So, I just remind you that it was eight days' trials, so very long and complex.

And to finish, I think we were also able to adapt along the trials and to show a lot of flexibility. So, for example, at the beginning, we did not define any area to share the files, and through the trials, we decided to go through Google Drive to share our different information and to follow together. So definitely, there was a preparation, but also during the trials, we have improved and overcome some challenges.

I do not know, Ondrej, from your side, what you could say, as well, regarding the challenges.

ONDŘEJ ŽÍTEK: Well, I have to say at first that on our side it was more like the whole company-wide effort, and many of our departments were involved. Actually, even prior, the testing itself, we asked our IT guys if they would be able to set up some additional wi-fi hotspots in

the labs in order to improve the wi-fi around. And then during the testing itself, we realized that it was a good idea, because we could easily share the video connection.

Then I also should mention the colleagues from our analytics department. They were quite flexible to form all the analysis during the trials, and that helped us quite significant because within the testing, we needed to choose what direction we should go further. And I should not forget to thank also to my colleagues who were helping to perform the experiments themselves.

And Marine mentioned within a week, I would not say it was anyhow different from onsite trial with some technical support from the M Lab. The only difference was that, instead of every morning meeting in a lab we had together the call, and only I was in the lab, and Marine was in Switzerland, Paul was in Germany. But by the beginning of every day, we just discussed how should we continue on trials what is the plan of the day. And that was it.

Also, what I might mention is on -- maybe Marine said it already -- that during the week, we improved some of the tools that we used for sharing the data, so by the end of the week we did quite a nice way of sharing the data.

JEFFREY BUGULISKIS: Thanks for that, guys. I think the GEN audience would be really interested to know whether

or not you thought this new way of working was a successful alternative to an in-person visit, and whether or not you could conduct this virtual trial again.

MARINE MASZELIN: I am not sure that virtual support will be an alternative to onsite support in the future, because nothing can replace the relationship and the onsite support. Nevertheless, I think it is a very nice tool that we now have into our panel of supports, and that can really have in some situations, such as the one we had.

I think to ensure a successful remote support, you have to really prepare it properly. So the preparation of those trials was very important. So we spent some time with Ondrej to discuss the protocol to share some tutorial video, to share some user guide to allow him to feel comfortable manipulating all the setup.

Also, something else that was really crucial to ensure nice support was the quality of the connectivity. So, the video for the iPhone was really nice, and we had absolutely no issue to see what he was doing and to discuss. And to finish, I think the way to share the data was also something reliable that allowed to be efficient and quick when we had to take some decisions, as well.

PAUL KASCHUTNIG: I fully agree with you, Marine. As Marine said, of course, the virtual support has its

shortcomings. Nevertheless, I think it was the right tool at the right moment, so to say, and we were able to do the job despite travel restrictions, which I think also pleased Vuab Pharma, but Ondrej will maybe mention something in that regard.

But I think it is also important to notice that we also got some important learnings from our side, you know? So, as Marine mentioned earlier, this was one of the first cases in that typical form in all of Europe, and I think we learned as much as Vuab, so to say, throughout the specific case. I hope, Ondrej, you agree with me.

ONDŘEJ ŽÍTEK: Yes, definitely. As Marine said, also, as me as a customer in this case, if I in the future can choose in between the in-person visit or this kind of virtual support, I would definitely go still for in-person visit. It just cannot be replaced. But as we experienced this virtual support, it is definitely a viable alternative in such a difficult time as it was during this COVID-19 crisis.

And from my perspective, I have to say that it was definitely way more time-consuming for me, because, at the beginning, you mentioned that I had no prior experience with TFF, and so I needed to learn quite a lot. But on the

other side, I think I gained also quite a lot of the new experience in this field.

And I have to say that Vuab Pharma was very pleased that you guys provided such nice support even that you can present on your own on our site, and we reached our targets for the experiment. So we were happy.

JEFFREY BUGULISKIS: Thank you very much, guys, Marine, Ondrej, Paul. I really appreciate you guys discussing with us today this really important topic, obviously, in this pandemic situation that we have going on. Virtual tools or knowing that there are virtual tools that can sort of assist the biopharmaceutical industry is a really important aspect for all of us to know. So, we thank you again for joining GENCast and for your time today.

ONDŘEJ ŽÍTEK: Thanks a lot.

MARINE MASZELIN: Thank you.

PAUL KASCHUTNIG: Thank you, Jeff. It was a pleasure.

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

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