Pandemic Sparks Streamlined, Life-Saving Innovation

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“This is one of those stories that shows the power of people coming together. The big takeaway from this is the science, the creativity, the passion of these people coming together and learning and teaching and helping each other. That’s what we need more of right now.” – JJ Snow of the MVM team

Why do stories matter to the innovation process? What values can be instilled in innovators who share stories? How do innovation leaders inspire creators to tell and share their success and failure stories?

We speak with Professor Fernando Ferroni, Dr. Art McDonald, Lieutenant Colonel Jennifer “JJ” Snow, and Professor Cristiano Galbiati about how they teamed up to create MVM – the Mechanical Ventilator Milano (https://mvm.care/) – in response to the COVID-19 crisis. By providing streamlined, collaborative innovation, the MVM team created a cheaper, more COVID-19 focused ventilator that was FDA approved within a historic time frame of six weeks. Learn how they accomplished such a feat with a ventilator that helps COVID-19 patients and hospitals. Listen in as the team shares how they effectively innovated together and their biggest takeaways for the future.

Professor Fernando Ferroni is a professor of Physics at the Gran Sasso Science Institute (GSSI) and former President of the National Institute for Nuclear Physics (INFN). He also served as member of CERN Council and of the Governing Board of Science Europe. He has focused his scientific studies on experimental particle physics, starting his research at CERN. In the early nineties he joined the BABAR collaboration as a visiting scientist at the Stanford Linear Accelerator Centre (SLAC). Since 2004 he has been searching for the neutrino-less double beta decay with an experiment at the underground Gran Sasso Laboratories and he is the author of several hundred articles in scientific journals.

Art McDonald CC, O. Ont, O. N.S., FRS, FRSC, P. Eng, is a native of Sydney, N.S. Canada. He has degrees in physics from Dalhousie University (BSc, MSc) and Caltech (PhD) and fifteen honorary degrees. From 1969-1982 he was a Research Officer at AECL Chalk River Laboratories; 1982-1989, Professor at Princeton University; 1989-2013 Professor at Queen’s University, Kingston, Canada, 2006-2013 Gordon and Patricia Gray Chair in Particle Astrophysics and 2013 became Gray Chair Emeritus. Since 1989 he has been Director of the Sudbury Neutrino Observatory (SNO) Scientific Collaboration. Among many awards, he is a Companion of the Order of Canada, Co-recipient of the 2015 Nobel Prize in Physics and 2007 Benjamin Franklin Medal; the

TRANSCRIPT

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Katie: *[00:00:04]* Welcome to Untold Stories of Innovation, where we amplify untold stories of insight, impact and innovation. Powered by Untold Content. I'm your host, Katie Trauth Taylor.

Katie: *[00:00:19]* We have an incredible team of guests today on the podcast. JJ Snow, who is the chief technology officer of the United States Air Force AFWERX, chief operating officer of the Mentor Project and one of Stonehill Innovations seven design thinking thought leaders to follow on LinkedIn is here with us alongside a team of researchers, Dr. Cristiano Galbiati, a professor of physics at Princeton University. Art McDonald, co recipient of the Nobel Prize in physics in 2015 for the discovery of Neutrino Oscillations, which shows that neutrinos have mass. Author of more than 150 papers in physics and a physicist at Queen's University in Kingston, Canada. And also Fernando Ferroni, professor at Gran Sasso Science Institute and a physicist at the Sapienza University of Rome. Thank you so much to everyone on this call for joining in on the podcast today.

Art McDonald: *[00:01:18]* You're welcome.

JJ Snow: *[00:01:19]* Happy to be here.

2016 Breakthrough Prize in Fundamental Physics and the 2013 Cocconi Prize of the EPS with the SNO Collaboration. He continues to be active in basic research in Neutrinos and Dark Matter at the SNOLAB underground laboratory.

Lt Col Jennifer “JJ” Snow is the AFWERX Innovation Officer for the U.S. Air Force, SAF-A8I, the Pentagon. She serves as the military representative for technology outreach and engagement bridging the gap between government and various technology communities to improve collaboration and communications, identify smart solutions to wicked problems and guide the development of future technology policy to benefit the US Air Force, Department of Defense, Interagency and Allied partners.

Prior to her current assignment, Lt Col Snow was the Donovan Group Innovation Officer for US Special Operations Command and the SOFWERX Innovation Team. She is a Distinguished Graduate of the Naval Postgraduate School. Her work has been presented to members of the National Security Council, the White House and key seniors across the DoD, IC and Interagency to inform and highlight emergent risks and opportunities involving technology and technology influenced environments.

Cristiano Galbiati is Professor of Physics at Princeton University, Princeton, NJ, USA, and Professor of Astroparticle Physics at Gran Sasso Science Institute, L’Aquila, Italy. He is also an APS Fellow and a scientific associate of Istituto Nazionale di Fisica Nucleare, Italy. He focused his research on solar neutrinos and direct dark matter searches at Laboratori Nazionali del Gran Sasso, Italy. He leads The Global Argon Dark Matter Collaboration in the development of its DarkSide-20k dark matter experiment.

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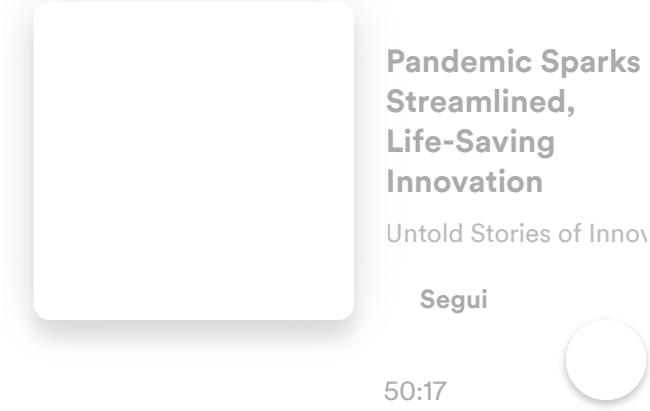

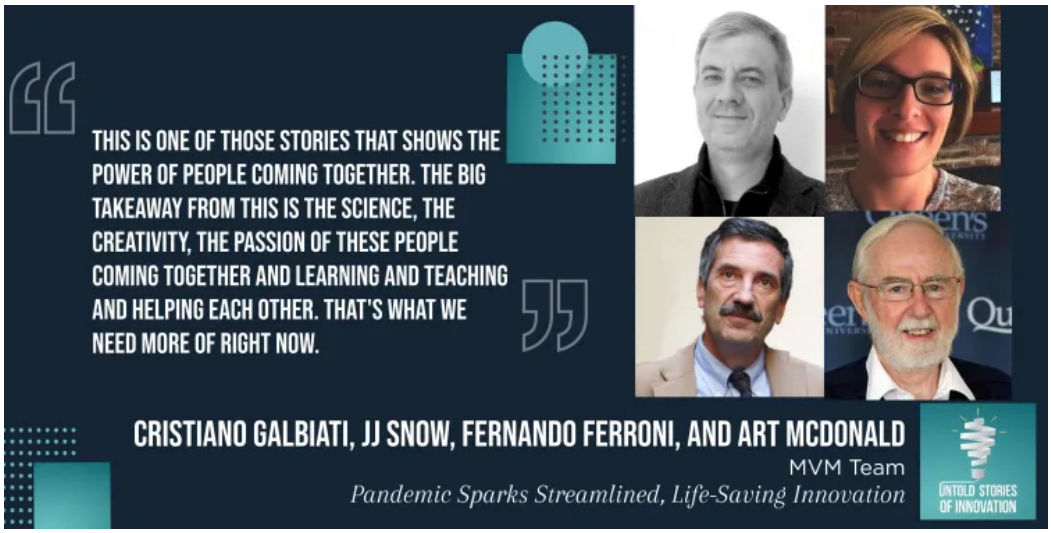

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Katie: *[00:01:20]* JJ, could you kick us off and tell us what brought this incredible team together?

JJ Snow: *[00:01:25]* Well, actually, I kind of found myself reaching out to Cristiano because we were in search of the top ventilator's solutions to help support the response in the US. And the person team came very quickly to the forefront, moving fast and having a fantastic solution. I reached out to him and he responded the same day and we connected. And I've got to tell you, I was really blown away by the level of collaboration that was happening across spaces to make a difference globally and to really reach out and create a product or device that would be relevant and would support everyone worldwide was at the heart of this team and that drew us in very quickly. And we realized that the right people, the right competency and expertise was present and the right passion was there. And that's how this all kicked off.

Katie: *[00:02:21]* Doctor Galbiati, could you explain the inspiration behind the M.V.M the Mechanical Ventilator Milano and its emergence in light of COVID-19?

Cristiano Galbiati: *[00:02:33]* It was a combination of two factors. First of all, the incidental factor that I was in lockdown in Milan at the start of the pandemic. Then I decided to go back to Milan to support my family. The second factor is the fact that we lead – myself and Professor McDonald – a collaboration that has the goal of identifying and discovering dark matter. And it turns out that for this discovery of dark matter, much depends on the ability to carry out to completion very special projects that involve the essentially

technical guises of a very, very significant complexity. So when the lockdown started, I myself, like any one of us, could only think of this pandemic. We were blocked at home and it was a major disruption to our daily activities, including research. And one day I learned that this problem of the ventilator's was very, very significant to the point where all of this but being placed there to staff the hospital in the wards in Lombardy, which was one of the early centers of the Pandemics in the Western world, were being canceled because of the unavailability of [wording unclear]. And that's when I thought we needed to do something. Now, with the Know-How that we have, we are carrying out much more complex projects in different guises. We must put our know-how, the collective Know-How on the collaboration to use to help out in this moment of crisis. These were the two factors enabling the project.

Katie: *[00:04:14]* Are physicists typically innovators and creators of ventilators?

Cristiano Galbiati: *[00:04:21]* I would say not. I would say not, but the physicists are a curious bunch of people. What we do in our departments is a research that we call and identify as curiosity-driven. That we're naturally brought to try and discover things that were not seen before and trying to expand the horizon of our knowledge. And for this reason, I believe that this curiosity-driven research is a land that could set to build a cohort of people that are able to quickly pivot around the needs for research. What we realized simply in these, not thanks to me, but thanks to a bunch of other subjects, including the Professor MacDonald, including Professor Ferroni, who will join us shortly, is the fact that due to this pandemic that was developing, that we really needed to do something different. We needed to put how our daily jobs, our research into dark matter, on hold and to devote the broader Know-How of the collaboration to something that was far more urgent with a much greater impact upon society. We were able to do it quickly because of the leadership that was brought in from several different angles, including the said before, Professor MacDonald, Professor Ferroni firming up director of [wording unclear] in the US. Those really enabled us to be a very, very strong collaboration. And it became a reality thanks to the work class leadership of the U.S. Air Force approach and personnel.

Katie: *[00:06:02]* Before we move more deeply into the process that your team utilized to create this mechanical ventilator within one month, by the way, and already has received FDA approval. It's a truly unprecedented innovation. Can we pause for a second and go back to dark matter? Dr. McDonald, would you mind giving our podcast listeners a quick description of what dark matter is, what the collaboration among this team looked like before the pandemic began?

Art McDonald: *[00:06:35]* If you look out on a starry night, it turns out there's about five times as much mass in the region between the stars as there is in the stars themselves. We know that's the case because of the way in which the stars in our Milky Way Galaxy form their orbits. We don't know what that is. It doesn't fit anything that we have ever seen in our experiments here on Earth. We are attempting to produce such particles. We think they could be making up this mass at our major accelerators on Earth, at CERN [The European Organization for Nuclear Research] in particular. So for the first time since the Big Bang, by having enough energy to do it. But we know that in the Big Bang, there was enough energy to do it and that there are particles, there are particles that are left over. We think from the Big Bang. Our objective is to find very sensitive materials. Put them in a deep underground laboratory where you can get the lowest background from other things because the rock shields out all the cosmic rays that strike. If you are on the surface and we look for very faint signals in large vats of liquid argon, which is particularly ideal for observing when a dark matter particle hits our detector. And we have been collaborating in that way in Italy and in Canada, in the United States and other countries for a number of years. And our major project right now is a 50 ton liquid argon detector in the Gran Sasso Laboratory in Italy. And that is what our international collaboration diverted their activities from in order to do these ventilators.

Katie: *[00:08:27]* Dr. Galbiati, could you explain what aside, of course, from the urgency, the urgent need for ventilators. What was it that made this team decide, you know, let's pivot during this time we think we can make a difference and create something that's really completely different from what our day to day research activities are focused on.

Cristiano Galbiati: *[00:08:49]* I think everyone in the team felt very personally this need of helping out on the pandemics. When we started this enterprise, I remember it very well when I first reached out to a few collaborators. It was the day of March 20. Pandemics had not yet arrived in the US or in other parts of Europe, but it was already trending very strongly in Italy. And every one of the collaborators has strong links to Italy because of the medical operators in Italy, the lab in Italy. And I would say they were all very, very sympathetic from the very beginning to cooperate on a project that could do some good for the ventilators in Italy, in the US and Canada and elsewhere. So everyone was very personally into it for their links to the project. But besides this, there was also something that was so deeply interesting from the standpoint of the technology and the like. Because it is true that in this collaboration, we have some of the best experts in the world of particle physics in the hands of technical guises. Also some people that have a very strong expertise in the controls of equipment with the advanced technologies of computing and the electron controls. And it was also the technological aspects of this challenge, that of fields that are still a variety of collaborators. And I found them also quite challenging and interesting from a technological standpoint to deliver a ventilator that has some characteristics of a truly excellent performance. So it was a combination of personal affection and personal attention to the problem of the pandemic centered care for COVID-19 patients and technological inquiries.

Katie: *[00:10:52]* Dr. Ferroni, you've said that the creation of this ventilator is a demonstration that the particle physics community pays attention to the application of basic research for social needs. Can you tell us a little bit more about, you know, the world of particle physics? Physics is rather complex for the average person to understand, right? It's often quite invisible. And so communicating around it, storytelling around it is critical work. And could you tell us a little bit about how inventions like this helped to bring, you know, the work that you do as physicists into it? A little bit of a deeper understanding for the everyday person?

Fernando Ferroni: *[00:11:37]* Well, as you said, though, particle physics doesn't really excite anybody except those that practice physics. So we are all the same to the art of doing particle physics because we believe in doing

particle physics. So we have a chance to understand more about the natural order of the universe that can go on below that fundamental goal in the universe, which is so beautiful around us. Now we are conscious that many applications that we have developed for studying this particle have already demonstrated their ability in solving critical issues for society. But I think that if I want to go back just because particle physics says it's a [wording unclear] concept, something that you can not see, something that people say about what they are looking at, how they do and the key is, how they do. To understand and study finding it is extremely difficult to measure, but extremely difficult to visualize in a sense extremely difficult to understand the behavior. You need a technology which is the bleeding edge, like you need that technology as you with no something to that. That's beyond what yesterday you were able to do. We can only do that. You cannot buy. You don't go to the shelves of the supermarket or even a very well stocked electronic shop. And you buy the main instrument to me that you have to develop your instrument. So we are constantly fighting for a building object so that yesterday didn't exceed that and allow us to bring a different period of understanding particle physics a bit beyond what was what yesterday. Now it's clear that doing so some of this technology necessarily can be translated into something that's useful to society. I want to be completely frank. It is not our first goal, not that they want a better look. They know that. I immediately think that also now I measure the Fuze particle. That we build a decent machine for making cement. That doesn't work. Right. But you have such an ability and you have such a capital, if you want, of possible new technology. Is that often when you understand that the effect on which which is in need, not medically met is a privileged sector for application of new technology in particle physics. If you think that there is going to be the greatest answer, you think of the electron possible tomography if you need it there, you are not much easier to think so that that is something that we would have found. I mean, all these applications come from particle physics to maybe things. I have to remind you that the first application from particle physics to Edison, [unclear wording] And this was replaced with X-ray just discovered by chance. So this long history now has brought us to think that on this specific issue we do with our laboratories closed, that is because we didn't go in and play with our toys. We found that that was a moment to get out, though, all the things that we had around and make of this problem if possible.

Katie: *[00:15:21]* JJ, when we first reached out to you and we learned about the work that this team was doing with the Mechanical Ventilator Milano, it was probably, right, two weeks maybe into this research initiative. And you said we're working 70 hour weeks. I can't see straight at the moment. I'll get back to you in a little bit when we can come up for air. And I'm so grateful that everyone on this and this team was able to come up for air and talk with us about this discovery. Tell us a little bit more about the process. I am enamored by the amount of passion and commitment that this team demonstrated to making this happen in such a short period of time.

JJ Snow: *[00:16:02]* It was really incredible. I've got to say, you know, we had I think it was close to 400 scientists that were spread out, around 100 different institutions and seven different countries. And everybody was plugging and playing. It actually reminded me of Linux. So the Linux model where everybody was very flat, very streamlined, working around the clock to make the first Linux kernel. They were plugging away. Constant feedback. OK. We need help over here. Who can help out? It was just such an awesome natural partnership. I mean, the people and the countries involved, these are the same partners that we've teamed up with across a variety of challenges in the past. And it just makes sense how we were working around the clock. The part that I work here in the US was with the FDA team, [wording unclear] and her team. And I have to say, I was so blown away because they had hundreds with solutions coming in daily, and yet they dedicated an entire team to work alongside this team and to make sure that we could move it quickly through for FDA approval. And that was accomplished in about six weeks, which is almost unheard of.

Katie: *[00:17:09]* Right.

JJ Snow: *[00:17:10]* And so just watching everybody jump online. We had meetings throughout the day. People were sharing documents and updating documents, everything from the labeling to the testing and the reports and making sure that everything was put together in exactly the right format so that we could keep it moving forward. Just a lot of enthusiasm was inspirational. Everybody wanted to make a difference. And we saw this as being something that was going to help the larger global population, because

this setup is just so smartly done. It's less than 100 components. It's easy to source. It's very low cost, very durable. This is the only ventilator out there that has specialty COVID settings. So we can address those unique respiratory complexities. And here it is ready in a matter of weeks because people were working around the clock to make that difference. Very selfless. So a lot of selflessness is seen in the actions of all of the scientists that came together to make this happen. And they didn't sleep. I remember talking to Art and Cristiano and sometimes it would be the middle of night, you know, either in Canada or over in Italy. And if we had to jump on a call, we did, or it would be the first thing in the morning or late in the afternoon and everybody just let it happen. No excuses. Just pulling together. It was very cool.

(https://untoldcontent.com/datastorytellingtraining/)

Katie: *[00:18:36]* What was compelling you, Art and Christiano and Fernando, what was making you work through the night? Was it the personal, the deep social need to make this happen. And the feeling that it really was right at your fingertips.

Fernando Ferroni: *[00:18:55]* Look, I want to be sincere, extremely frank. I spent many, many nights of my life in front of screens. Screen to fix it with a screwdriver, fixing the problems in the back of that. And then and after all the reward, there was much less than spending a night thinking that you are doing something, that it is really potentially important for somebody. I mean, even if – not only because I mean, after all, are we living in a country so that there are other ways these are. Eventually I think that I can go ventilators you

can find somewhere saying there probably is no just by some silly death. But thinking about what you are doing, it might be beneficial to our country and to people that have more access to facilities that way. [Unclear wording] dispenses I think at that point that you don't you don't think if it's 3am or or 3:00 p.m., it doesn't. It doesn't really matter. You want to go through and get to the project now. OK, thank you very much for this comment.

Katie: *[00:20:10]* Thank you so much.

Fernando Ferroni: *[00:20:12]* It has been great to chat.

Art McDonald: *[00:20:14]* So what I would comment, Cristiano contacted me just three or four days after he started the project. Of course, we've been working closely on the other project. And I immediately contacted the heads of national laboratories in Canada, Triumph and Chalk River and Sudbury, where we do underground science and an institute at our own institution. And there was an immediate response from the heads of the laboratories. But more so when they said we'll devote our teams to doing this on the part of the teams themselves in the sense that they were realizing that they could use skills that they had to make a contribution to this COVID-19 crisis in a situation where they previously had been feeling somewhat helpless, in fact. In a really world affecting situation. And so they really have been in Canada, Italy and the United States. All of the people working on the project have been selfless, as Jen [JJ] said, in their approach to it, and it's entirely nonprofit on the part of all of the institutions. It's a humanitarian effort that is being taken universally to do something to help with the COVID crisis. And that that motivation has led to a very, very welcoming collaboration in terms of who can do this "oh I can" "fine, please do it for us" sort of spirit. And Cristiano's leadership has been essential to all of this. And it's been really a great experience, still is a great experience as we move towards the actual supply for the world, we hope.

Katie: *[00:22:12]* Thank you, Art. Cristiano, could you paint the picture for what this collaboration looked like? I assume with that many different teams having to mobilize toward one problem and deliver one target solution? How did you manage that? Especially as many research labs were closed and people were working from home?

Cristiano Galbiati: *[00:22:34]* That was the easy part, because that's our day job coordinating teams. It comes with the territory. We've been doing it for a number of years. We're doing it. All of us, a lot, from Art and from his common leadership in the last few years of doing the job. So that was the easy part. The one of keeping everyone organized. I will say that keeping everyone motivated, that was not part of the job because everyone was very, very high on the motivation.

Katie: *[00:23:08]* Yes.

Cristiano Galbiati: *[00:23:08]* There were certainly technical difficulties. There were a lot of cultural challenges because no one of us as a physicist, you know what a curiosity driven enterprise ever had to certify a medical product. And now we have come through a process that has led us to build a very significant appreciation for the value that is brought cited by these people, not only building great instruments, able to save lives, but they also are subjected to an extremely rigorous process of certification whose scope and breadth was… I would say impossible for me to imagine before we entered into this enterprise, and it's opening up new horizons, a new perspective also for me as a researcher.

Art McDonald: *[00:24:04]* My wife keeps reminding me I have a doctorate, of course, in physics. And a few honorary degrees. But she keeps telling me, you know, you're not a real doctor. I think we were very conscious of that. And I have to say, we had the same spirit of cooperation from people who were in the medical field, and were experts at this. Cristiano within a week was able to go into a hospital in Monza in the midst of the epidemic and get strong cooperation from doctors and the use of human lung simulators to test the prototypes that have been put together on that sort of timescale. And that continued. We had contributions from Canada, from the US and further in Italy. And that was very important to us because we needed to have that sort of expertise in order to. Well, we knew our own limitations, but this collaboration really is very important to us.

Katie: *[00:25:07]* Yes, absolutely. And I assume that that kind of testing and feedback and collaboration with medical providers and researchers is part of the reason why the FDA process was as rapid as it ended up being. Right?

Art McDonald: *[00:25:22]* I agree.

Katie: *[00:25:23]* Can you tell us, Cristiano, you mentioned the technical challenges. Can you tell us you had really a handful of weeks to make this ventilator happen. Can you walk us through some of the setbacks, some of the successes along that journey? What was the process like?

Cristiano Galbiati: *[00:25:40]* I think it was also a process of discovery and adaptation. We went in with some ideas that were proven right on the part of the general concept of the distribution of drugs in the system, for example. We went in with another few ideas that proved to be naive and delivered. When we first set foot into the hospital in Monza, they told us, "Oh, great job on these pressure limiting valves," so that we've got essentially water corruption. They want the best. We can choose them. You know, you can't have modern models juggling around the college boards where everyone moves around very rapidly and knocks them over. So, yeah, there were clearly a few items on which we were not prepared. And I think it took a lot of flexibility, adaptability, humility in the sense that we were walking into territory that was not ours. And we needed to be ready to change ideas depending on the situation that we found on the field. So there were a lot of adaptations during this process. Clearly, the strongest difficulties came when we came out of the validation of the general concept and to go into the process of guaranteeing that this was not only a tool to play with in an underground laboratory, but needed to be a real product that was fully certified following very rigorous and extremely detailed international standards. This was a completely different game, not one that I personally had never entertained to play with in my professional life before. And I think it was a very gratifying experience and something that certainly strengthens my understanding of physics and also the relationship with technology.

Art McDonald: *[00:27:44]* May I add another thing that was extremely valuable for us from the beginning and continues to be the case?

Katie: *[00:27:51]* Yes, please, Art. Yes.

Art McDonald: *[00:27:52]* Which is the relationship with manufacturers. Because, well, Cristiano had a relationship there in Italy with Elamaster and we developed the relationship. And in Canada with a company that partnered with them, Vexos Canada, which also is involved in the same efforts in the United States. And Elamaster in the United States is involved. But because of very early involvement with manufacturers, we began to learn all of the elements that are necessary to turn an idea into a final manufactured product. Supply chain questions: can you actually get the parts from all around the world that are necessary to do this in a rapid fashion? What about reliability? What about you? You want this to be such that it goes into the hospital and doesn't require service very often. All of the things that we had the advantage of working – in Cristiano's case, directly. He was in the Elemaster facilities in Italy doing this development and we have had a close relationship with our companies: Vexos and JMP here in Canada. And that's helped us a lot in moving this forward in a rapid way, because, for example, it's Elemaster that has the approval of the FDA. That's the way it works. It's the final manufacturer that gets regulatory approval. So that closeness and Cristiano's work with them – Cristiano and his teams – work with them. In addition to the medical was what gave us a real advantage in the speed with which this was done.

Katie: *[00:29:47]* Yes. The other fascinating thing about the design decisions is it's completely open source. Tell us about that decision. That's a brave and important element to how you design the MVM.

Cristiano Galbiati: *[00:30:02]* So the MVM is indeed an open access project. I would classify it really as open access rather than as open source. And there is a fundamental difference between the projects. If you look at the structure of product design, whether it's self-taught or backward, flaws in four different steps. And that is the determination of the problem that you are trying to address and the requirements, the so-called requirements there. Then there is the step of the advanced conceptual design. Then there is the step of the detailed engineering implementation. And finally, this type of certification. The first two steps are the most important one, determining which problem you're trying to solve. Determining in general the requirements and providing the advanced conceptual design. If we were dealing with a pattern, those two

elements would constitute the equivalent of a [unclear wording], OK? So what we decided immediately, and I think it was the right decision, is that we will not [unclear wording] and we will put it in the public domain. These two steps. This was essential because only in this fashion, we could work truly freely with the other researchers and attract the critical mass of people to work on this project. So these are – we are making it open access and accessible to everyone. When it comes to the other two steps, which are detailed engineering and certification, our determination is that it's best to leave these two steps in the hands of the companies. And it cannot be any one company because you're not dealing with a tool that is a toy, OK?

Katie: *[00:31:55]* Yes.

Cristiano Galbiati: *[00:31:55]* You're dealing with a medical device which has the lives of people depending upon it. So these medical devices can only be built by companies that are certified electro medical device builders. The data qualified, according to ISO, nine thousand procedures. And that especially can build safely and can deploy a product that can be certified. So we believe that we have rendered our service to the society, making our research available. What we can not take on as a group of researchers is the liability that comes from being directly responsible for the detailed engineering of the project or for the certification of the project. This is something that has to be borne by companies that are structured to do it. And I guarantee you that in order to arrive at that certification, that you really need a strong backbone in order to deliver that, that you have to match that.

Katie: *[00:33:00]* And that decision to work with companies doesn't necessarily mean that these will be, you know, expensive. Right? One of the major challenges you were trying to solve against is the price of ventilators and the cost of the parts and the supply chain problems around getting those parts. So now with this invention, we're able to see something that is able to be produced by companies worldwide at a lower cost much more quickly with a reliable supply chain, is that correct?

Art McDonald: *[00:33:35]* That's what… you said it!

Cristiano Galbiati: *[00:33:35]* I'll give you one. Absolutely correct. I'll give you one number, OK? The ventilators that were bought in March. The average cost was over thirty five thousand euros.

Katie: *[00:33:49]* Wow.

Cristiano Galbiati: *[00:33:49]* On this basis, the government of Italy is preparing a breathing process for another five thousand units for design. But the budget that has been set aside is equivalent to something like thirty seven thousand five hundred euros per unit. It is a staggering price. The unit MVM will be produced at a very, very limited fraction of this cost. It is not for me because I'm not any companies or representatives to relay – to divulge these numbers. But you've seen a ventilator, subdued, for emergency use, coming reliably below the ten thousand dollar max, even in the U.S. Our unit is designed to be the cheapest of the lot. And at the same time, to be endowed with great advice, the solutions for the care of patients. It is not a genetic ventilator. It is a ventilator that was designed with the director of the doctors and anesthesiologists around the world, but especially those that the wards of Lombardi have seen a number of COVID patients and were able to impress upon us in the very early days of the project, what were the specific needs or requirements for the [unclear word] care of these patients. So the unit was designed exactly around those principles and following those specific guidelines.

Katie: *[00:35:25]* Yes, because certain research (https://jamanetwork.com/journals/jama/fullarticle/2764365) was coming out early in the pandemic to show that intubation could actually cause damage to the lungs. And I believe the statistic is, and we'll try to find the research study and link it in the show notes, but nearly 50 percent of patients who were intubated were not surviving. And there was a suspicion that some ventilators were causing more damage to the lungs. So the MVM actually has programmable settings or unique features that allow for it to meet the unique needs of COVID-19 patients, correct?

Cristiano Galbiati: *[00:36:05]* The statistics that you cite: that is unfortunately correct. People and patients that end up in an intensive care unit. No matter what is a high probability of nothing they can get through. That's a very, very

sad part. That's not withstanding provided intensive fine and best care. The percentage of lethality is very significant. But that said, OK, if you don't provide a ventilator, the fatality rate is much, much higher than that. It's nearly a certainty.

Katie: *[00:36:40]* Exactly. Yes.

Cristiano Galbiati: *[00:36:41]* So a ventilator is a very important tool if you want to save the lives of people that end up in an intensive care unit. That said, the ventilator must be safe. Now, first of all, we must avoid the battle trauma. And now we've had reports of units that have caused the battleground spikes in pressure that have damaged the lung tissue. And the lung is a very, very delicate object. You must have a ventilator that is powerful but is very gentle and kind on the lungs. You must also have units that have very special characteristics because the general anesthesia ventilators are not necessarily built for the care of patients that have the need of being cared for for a long term ARDS – Acute Respiratory Distress Syndrome. Think about the general anesthesia ventilators. These are machines that are built to care for a patient during the few hours of a surgical procedure and then allow for it's awake case or awakening. In our case, you have patients that are sedated for days. For weeks. And when they try to wake up…they've completely lost the ability to be independent in the respiratory act because the muscles of the [unclear wording] and the abdomen, of the diaphragm, are so weakened by these very long sedations. So you need to have a machine that is powerful and that allows for a total weaning of the patients by having a pressure cycle that is very controlled and at the same time is able to respond to the patients need of seeing supported and incipient respiratory act that they are not able to complete a little.

Art McDonald: *[00:38:30]* There's an additional perspective that can be added to that for the longer term, when we have drugs that are able to control or limit the impact of COVID-19. And that is ventilators, for example, in pneumonia cases are often used during the period while they're waiting for the antibiotics to kick in. In order to cure the patient. And so when we have treatments for COVID-19, then we might – we will hope that the combination of a ventilator to keep a person alive when they've reached that very serious

point, combined with therapeutic drugs, can help get that fraction of people who survive to be much greater. So all that Cristiano said, plus, hope for the future makes us feel that ventilators are still very valuable in this way. But of course, we also have a situation where there are large fractions of the world that have not yet had the impact of the full pandemic. And so ventilators are going to be needed very soon and very extensively. And so there is a strong motivation still to have the development of inexpensive and relatively easy to manufacture ventilators across the world.

Katie: *[00:39:55]* Absolutely. Could you share with us – and JJ, perhaps you have insight into this question as well. What's next for MVM? It's gone through FDA clearance at this point where it's approved. What should we expect over the coming weeks and months?

JJ Snow: *[00:40:13]* Well we're – one of the things we started to do was reach out to those areas that really need help the most. For example, we've talked with a number of innovators across Africa right now who are telling us not only do they not have medical facilities, but in many cases they have zero ventilators. We've got 13 different countries right now that have identified that they have no ventilators. They don't have personnel that have trained on them. They may not even have power in specific areas outside of the larger cities to make these work. And so we've been trying to figure out, you know, how can we rapidly produce and get these devices into the hands of the nations that need them most. The same with portions of Southeast Asia, portions of the Middle East and Latin America. A couple of things there that the team was incredibly thoughtful about the design. It's very intuitive to use the manual extremely user-friendly and walks through step by step by step in great detail to the point where when I look through it, I felt as if even without having medical experience, if I was confronted with having to use one of these devices or having to operate one of these devices, that I could follow the manual and do it successfully. And that speaks volumes right there. The training has to be easy. It has to be very clear. And it's got to be something that translates well across languages. And I think the team did an incredible job in capturing that. The other part was, as Art mentioned, talking with a variety of industry partners and figuring out how to leverage existing supply chains, logistics chains to move devices from producers into those consumers

that need them the most. And then the final part, of course, was that low cost and the ease of sparing and the fact that they are very durable, in many of these countries, they don't have a lot of money to spend. So for them, they need a device that's economical. It's got to be easy to use and it's got to be something that they can rapidly acquire, especially as COVID begins to move into some of these other areas, as we start to see those booms really, really take off across the board. I think that team was very thoughtful about all of this. And then the engagement with the industry partners, that was really amazing. Elemaster was fantastic. I was blown away by the level to which they went and did all of the testing to ensure that we had the appropriate certifications and met the right ISO standards to the point where when the emergency use authorization package went forward, many of the tasks that we saw Elemaster complete for the device were at or above what the requirement was. And now moving forward, I'm really excited to see the team working on a permanent FDA approval, which means following COVID-19, these devices will be available for purchase and will be available to continue supporting populations around the globe. If you look at where COVID is today, even with, you know, finding a vaccine and a treatment in the next 18 to 24 months, rolling that out is going to be a process, which means we're going to be dealing with this for the foreseeable future. So we have to have a layered approach to make sure that we've got the right parts and pieces in place to support the global population. This is a global problem. It's a borderless problem. And we have to treat it as such and things like that and all come together around it. Yeah, I think the team was fantastic in that aspect. And we've had so many industry partners come alongside this whole system. Salesforce, Rootstock, [Unclear wording] International, Statler, Vexos, Elemaster… Just amazing. Dedicating their time, opening their platforms for free, helped us to find resources for components that were hard to find. And they didn't have to do any of that. But they did because this is a global problem. But they also acknowledged the fact that they're part of that global community. And that's the part that I walked away from being really inspired by how that's the lesson that came from all of us, was this is how we rapidly address challenges in a crisis, especially a crisis that's impacting everybody. And that was really neat to see.

Katie: *[00:44:44]* Thank you so much, JJ. Could we conclude with sharing the role that you felt story and storytelling played in the creation of this invention? And in the communication of science more broadly as well.

JJ Snow: *[00:44:57]* Oh goodness. This is one of those narratives. It's one of those stories that shows the power of people coming together and not getting stuck on. "No," or "we can't" or "we've never done it this way before." But I think a positive pathway forward. And there wasn't one single person, when we talked to them or called them out of the blue, that said, "no, we can't help." Or "that's never been done before." Everybody said, "how can we help? Let's make this work. Let's figure out how to make this available to everybody." The big takeaway from this is the science, the creativity, the passion of these people coming together and learning and teaching and helping each other. That's what we need more of right now. And that was the part that really got me excited, because this model, this model tends to reignite how we work around the globe, how we reignite our economy, how we come together between nations as partners. There's a really significant lesson to be learned here based on the interactions and the teaming and the fact that we took the red tape. We got rid of the barriers. There were no egos. Nobody cared about who was getting credit. It was just how can we do this for the better of humanity? And what does that look like? And when that happens and you have a team that it doesn't matter, you know, we're just going to get it done. That's when amazing things like this happen. And I was truly humbled and proud to be a small part of this project.

Katie: *[00:46:43]* Art and Cristiano?

Art McDonald: *[00:46:45]* Well, I think the story of COVID-19 has been in everyone's soul, if you like, across the world. And we all feel impacted by it, but also helpless in the face of it. And I think that's the story, if you like, that inspired people to try to make a contribution. It really is a war against something that's invading our humanity. And I think that's the big story that has inspired the small things that we've contributed.

Cristiano Galbiati: *[00:47:27]* For me, getting to stories about research and its cornerstone, which is that openness and transparency and sharing repeat formation. If we win this battle it is because we're each other's wings. Many

mistakes were made in the early days. We've seen what has happened at the origin of the virus. The suppression of the scientist's reports. The lack of sharing of information which has led to a spreading of the disease that was larger than necessary at the point of origin of the disease. This is the wrong way to approach it. What was very heartening when the pandemic got around here in Italy is that when we sounded out to our partners in the U.S. and in Canada, France and Spain and all and many other countries. Everyone felt compelled to work in a very open way without borders at the moment, which borders what, it's between states weren't coming up. The research was truly international, truly open without borders arriving at the speed of light on the fibers of the Internet. Ours is a very small building block in a much more complex story. But if you have to win the coronavirus. Research has to prevail in this fashion.

Katie: *[00:48:53]* Absolutely. Wow. Thank you so much to each of you for being on the podcast, for making time for this. Thank you for your dedication and your creativity, your collaboration. It's truly an inspiring moment for global humanitarian innovation. So, please, if you are listening to this, check out the Mechanical Ventilator Milano, follow its work, see how you might be able to participate and collaborate in helping to advance research against this pandemic. So thank you for listening today. Thank you for being here, everyone.

Art McDonald: *[00:49:32]* Thank you.

Cristiano Galbiati: *[00:49:32]* Thank you.

JJ Snow: *[00:49:33]* Thank you.

Katie: *[00:49:35]* Thanks for listening to this week's episode. Be sure to follow us on social media and add your voice to the conversation. You can find us at @untoldcontent.

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