



Cover Story

Reset 2021

21. Dr Kurt Höller
Major Changes in European Health Innovation

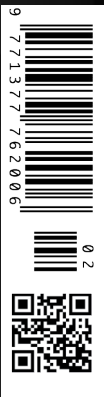
30. Prof Dr Robert Vander Stichele et al.
Ensuring COVID-19 Vaccine Traceability

33. Prof Florencio Travieso
2021 in Healthcare: Snowballing into the Future

37. Prof Massimo De Vittorio
The DEEPER Project: Augmenting the Understanding of Brain Disorders

43. Prof Davide Caramella, Maurizio Mian
Charitable Institutions During the COVID-19 Pandemic: The Pisa Experience

46. Prof Theresa Rohr-Kirchgraber, Kaela Miller
Breast Cancer Screening After Male-to-Female Transition in Transgender Women



Major Changes in European Health Innovation

Author: [Dr Kurt Höller](#) | Director of Business Creation | EIT Health | Munich | Germany

Since the start of the COVID-19 pandemic, the healthcare sector has been changing at an unprecedented pace. Some innovative solutions, which seemed futuristic just recently, are becoming part of the routine and many others are in the pipeline. HealthManagement.org talks to Dr Kurt Höller of EIT Health about the dramatic shifts happening in the field of healthcare innovations in Europe and the priorities and challenges that will be defining the year of 2021 and beyond.

What major changes, both positive and negative, did you see in the European health and care landscape in 2020?

There can be so many answers to that. If you look from a birds-eye perspective, of course, we have all seen that healthcare in general has changed. Everyone had to focus on COVID-19, and it had an impact on routine care, which had been dramatically reduced, including people who could get access to face-to-face care but were hesitant to go to a hospital. That has transformed the whole healthcare landscape at a high level.

Looking at how EIT Health and our partners have been affected, in the first months of the pandemic we were facing some delays with advancing our projects. Clinicians have, rightly, concentrated on treating COVID-19 patients, and getting prepared for the emergency situation. Hospitals are very important partners in our work, but they were understandably dealing with the pressing pandemic situation and did not have the capacity for much else.

In turn, the necessity of doing additional research also got tiered, especially in areas related to COVID-19. There was an interesting situation when, on the one hand, the whole world was looking to see developments in the healthcare area and at the same time there were reductions in research spending. Even in the European Commission, the discussions on the recovery funds versus expenditures on research last autumn were quite intensive. That was one very important question: how much we could focus on clinical research that was not directly related to COVID-19. In the end, however, I think we found a good balance. Over the year, there were moments and months when hardly any collaboration with a medical hospital was possible, and then the overall attention to clinical research, the value of it and everyone on the front line got a major boost. In other words, the research aspect really went up and down, down and up.

The third aspect, especially important in my area where startups are involved, is about the investment that usually goes into new companies: it was not as freely available during the early stages of the pandemic. Many investors held their capital

back for their portfolio companies because they expected those companies might struggle. Especially in the beginning, in March, we saw that there was an absence of large investments into new companies.

Seeing this, we launched the [Start-up Rescue Instrument](#), an initiative for startups to receive up to €500,000 in co-investment from EIT Health, in return for options. With this, we were able to inject some investment into new companies, to give a push into those investment rounds by attracting additional capital. We first developed this concept at EIT Health and then the other eight EIT KICs (knowledge and innovation communities) – joined. Overall, the Commission invested a significant amount of money, €60 million, into the EIT crisis response.

The Rescue Instrument initiative covered two directions. One was the crisis support for startups to get additional investments in their current fundraising rounds. The other one focussed on the development of COVID-19-specific products and services. We got a lot of positive feedback from our investment network for this.

We focussed on promising companies with a value of at least €5 million, that were in the middle of a fundraising round they could not conclude due to the pandemic. We got about 300 interested companies – an unprecedented amount within such a short period of time – and 120 of those applied. Just imagine 120 companies working in the healthcare domain in Europe with a value of more than €5 million that were actively fundraising at that point of time! Eventually, 11 companies were selected, to which we will be contributing up to €500,000 each under the condition that other investors would remain on board and the companies could conclude their investment round. The launch of the instrument also spurred investment from others, one which was concluded in early January, was €15 million. In the end, we decided to step away from this particular company so as not to crowd out the private investors and focus on others who were struggling.

In any case, it was interesting to see how through that trigger we could contribute to supporting innovation in healthcare even amid the crisis. The Commission is perhaps not widely perceived as being fast, but collectively we managed to get €60 million released within a couple of weeks. That was remarkable, I would say.

What were the most important technological advances in healthcare last year?

One aspect was certainly digital health, which made a huge leap in terms of technology but also recognition and adoption. Of course, it was always attractive – and we already had digital health and AI in healthcare as areas of focus within EIT Health, but their importance became abundantly clear to all stakeholders during the crisis. There are several reasons for this. Before the pandemic, the value of digital health was not always fully understood. As an example, digital health solutions such as telemedicine were considered valuable in specific circumstances such as providing access to care for people in rural areas. But we could have never imagined that the general population across Europe would not have access to face-to-face care because clinics were closed. In this new situation, where people have to stay at home and hospitals are open only to emergency care, digital health has gained a completely different dimension. We are seeing many new technologies focussing on digital health and AI activities, both in the crisis response initiative and our innovation projects.

Digital health is certainly here to stay. Interestingly, some countries benefitted from having launched digital health initiatives just before the pandemic. One of them is Germany, which rolled out its Digital Healthcare Act in spring 2020, at exactly the right moment, so, without knowing it upfront, they were very well-prepared.

The interest in companies with digital tools is supported by increasing willingness of investors to invest in digital health, it is being viewed as a growth area that is very resilient. Moreover, local reimbursement is being adapted in line with the needs of the pandemic which is leading to adoption at a much greater speed and without some of the red tape we have seen, which has impeded the speed of uptake of digital solutions. We can certainly see an emergence of a 'new normal' for digital health based on the experiences and progress we have made during the pandemic.

Would you say that regulation lags behind the technological developments in European healthcare?

When the GDPR was introduced, the positive effects for healthcare that could have been considered back then were not fully leveraged. We would have included some regulations on how clinical data can be shared and used, for example, to train algorithms – they have to be trained with a lot of data, which means we need to have those data available. This has not been implemented back then, but I think we will now move into that direction, even if that's an ongoing process. The importance of having the data regulation that is allowing to train digital health technologies is certainly big.

Let's look also at the Medical Device Regulation that is due to come into force this May, after being postponed for a year due to COVID-19. This delay was a very wise decision because even before COVID-19 it would have been difficult for all stakeholders to align within the timelines, and during the pandemic completely impossible. I have a feeling that even by May 2021 not all companies will be fully prepared.

Jumping to a related topic, I would certainly add reimbursement into this consideration.

The reimbursement landscape is totally different to regulation, even though they're so closely related. Reimbursement is extremely fragmented. Take, for example, a small startup in Belgium that has developed an algorithm to identify atrial fibrillation. They have programmed the algorithm, patented it, and even got a CE mark for it. But in order for their solution to actually be bought and used by healthcare providers, they need to apply for reimbursement in each country individually, sometimes it is fragmented even further than country by country, to region by region or hospital by hospital. The point is that there is no way of getting approval for reimbursement in the whole European (or just EU) region. That's a huge disadvantage compared, for example, to the U.S. where, once you get approval, you get reimbursement across all its regions. I think that's still the biggest problem Europe is facing and I hope we can begin work to solve it.

Does this mean that in the health innovation domain the EU is behind other big markets, such as the U.S. or China?

There are, of course, different strengths and weaknesses in every system. In the U.S. healthcare is extremely expensive and not affordable for many people there, but the revenue opportunities for the new companies are pretty good. Earning money in the U.S. seems easier, on the face of it. Again, China has its own specifics. It's very hard to get into the system but once you have access, you can scale immediately because everything is just replicated. I think Europe needs to focus on ensuring broad adoption and uptake of healthcare innovation once it is certified, and for this we need to address our problems with reimbursement.

Nevertheless, I would say that the creativity we have in Europe as well as the willingness to focus on health innovation is high. It's certainly not too easy to enter the market, but if you have the right partners and if you get to the right networks, then your chances for success are high. That's exactly what EIT Health does – making sure startups get access to the right knowledge and expertise, networks and partners.

How would you describe the current role of startups in the European healthcare sector?

They are key drivers of innovation.

This is one of the reasons EIT Health together with the European Investment Fund (EIF) has started its Venture Centre of Excellence ([VCoE](#)), a programme bringing together investors and other key stakeholders from the life sciences and healthcare ecosystems through a custom AI platform.

Personally, I find this new instrument amazing and hope that corporates in Europe would look more into the European innovation landscape.

Our intention with VCoE is exactly that: we want to make sure that European corporates are watching the European innovation ecosystem driven by startups and entrepreneurs. The model is rather simple. EIF provides co-investments to the VCs, we at EIT Health identify corporates and their VC arms to partner up with private VCs that are supported by EIF, and we present a portfolio of vetted startups to these investors. As a first milestone, the European Commission has dedicated €150 million investment in the VCoE.

In January, EIT Health and the European Innovation Council (EIC) signed a Memorandum of Understanding. What are the expectations from this partnership?

At some point, we realised that about 25% of the companies that EIT had supported in one of its major programmes have also been supported by EIC, so there was a huge overlap in terms of having the same companies but providing different tools and instruments, not in terms of doing the same. EIC was supporting them with money and we were offering them education, funding and access to the network. The idea of a pilot emerged around 2019, first with three EIT KICs – EIT Energy, EIT Climate and EIT Digital, with EIT Health – and, eventually, the rest of the KICs – also joining.

It's a huge opportunity. We bring together the methodology of the KICs mainly focussing on networks, access to partners, education, and the funding that is available via both EIC and the EIT. There are three main interests that we want to address. First, we would like some companies that have been supported financially through EIC, to join our EIT Health programmes like [Bridgehead](#) or the [EIT Health Catapult](#) and vice versa, EIT Health-supported startups should have access to EIC programmes. EIC is extremely interested in this, and as soon as we have the confirmation of our proposal, which should happen shortly, the formal partnership can begin and we can take the first companies in.

We still have to address some challenges, like the GDPR, especially if we want to do this on a larger scale and to have joint databases.

Another aspect, which is very important, is to create a fast track between the two institutions. This would mean easier access for those companies that have already been vetted, to EIC resources and vice versa, without the need for them to start from scratch. This dimension is something that we need to build up. We need to bridge the processes in both institutions and to do that, we have to define a good mechanism that is compliant with the GDPR and quality expectations.

What are the priorities for EIT Health for 2021?

I would say the focus for business creation is on having fewer companies but with more tailored support. We want to go back

and concentrate on defining a journey for our companies and initiating more interaction with partners. Right now this interaction is happening at a programme level, but I would like to also see that at an organisation level.

From an innovation perspective, we want to give [more attention](#) to high value care (HVC). Until now we have been focussing on new innovation projects that involve technology and are mostly business-driven. With HVC we want to change the system and have an impact on the way healthcare is delivered, with a focus not only on the service but also on the outcome.

What changes do you expect to see in your area in 2021?

Circling back to the 'new normal', in 2020, we found out that we could still bring forward innovation, support startups and make things happen without travelling 3-4 times a week. Our organisation is built 100% on networking, exchange and trust. It was interesting to see that it also worked online, so we'll definitely be acting and behaving differently, focussing now on both personal and online interaction. Nevertheless, switching to online has worked out only because we have built that trust before, I am absolutely sure of that. Therefore, we will have to have a good balance, at some point being able to meet again but at the same time using online technologies more. That's certainly a huge change for our organisation.

What does it mean for innovation in general? I've heard about billions being paid for companies with the investors having never met any of those people in person. That is something that never could have been anticipated before. In spring 2020, when we first talked about having online investment conferences, many investors insisted that it was essential to meet people in person. So the basic principle is that there will be a long-term change in how we do business, and I believe this will be a positive change. It can make life easier for everyone, and speed things up.

Education, which is a key priority area for EIT Health, has also evolved dramatically, and will continue to do so. The online education that is now possible changes the way skills are provided. So far, for us it was somewhat fragmented, with summer schools and various programmes in the education pillar usually happening separately. However, our mindset is shifting to consider how we can reframe the delivery of education in light of the 'new normal'. It may be that we see a shift in education altogether to 'online first', that's not to say all education will be delivered online, but I think in-person education will become less of a pinnacle for education. This presents a huge benefit and means that access to education can be much broader – from anywhere in the world, across time zones, for example, and it could attract more talent that has previously struggled to access traditional education, such as women with young children.

Conflict of Interest

None. ■