Karin Blumer – Director Global Patient Engagement, Novartis Oncology



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Karin Blumer, director of global patient engagement at Swiss giant Novartis, gives fascinating insights into the global patient advocacy landscape today and how Novartis interacts with it, the work being done on patient engagement and expectation management for the firm's cutting-edge CAR-T therapies, and how a stronger patient voice can converge with scientific development within Big Pharma companies.

What has your career trajectory up to this point been and how would you define the scope of your current role as global director of patient engagement for Novartis' oncology division?

I recently celebrated 20 years at Novartis and I have never regretted joining the private sector. I am deeply grateful for the many opportunities I have been offered to learn and grow. My career path had not been a straight road. After graduating from high school in the late 1980s, I worked as a nurse's assistant in Munich's University hospital. In May I had been a partying 18-year-old, while in June I found myself at the bedside of terminally ill (and dying) AIDS and cancer patients. While I always wanted to become a doctor, in the absence of psychosocial support, this difficult experience led me to become a veterinarian. After graduation I was deeply intrigued by bioethics – driven by my passion for research and the growing debate on gene technology in the 1990s – it was the age

of “Dolly” the sheep! I studied philosophy at a Jesuit University and freelanced in science journalism prior to joining Novartis in a global policy role, later on changing to government affairs and communication.

I have always been attracted by cutting edge science and how it can impact patients and societies. Imagine, today an HIV infection is no longer the death sentence it was back in the 1980s!

Therefore, when Novartis acquired what is now its CAR-T business, I was very happy that I was appointed to lead communication and patient relations for Europe. The launch phase of the first-ever CAR-T therapy for adult lymphoma and paediatric leukaemia patients was for sure the most exciting phase of my career. In 2020, Novartis decided to take a new, truly holistic approach to its patient engagement function. I am proud to now work at the global level for the indications in which we work in CAR-T. In my current role, I am not responsible for CAR-T products per se; instead, we look at patient engagement in the same way that patients do. A patient organization would not have a CAR-T focus for example, but instead would focus on paediatric oncology or lymphomas and seek to shape the environment from the early research phase on until patients have equal access to innovation. Moreover, patients look at how treatment options impact their daily life – and the lives of their caregivers and families.

We now engage with patients across the lifecycle of a product, and across our entire portfolio. For example, were Novartis to in-license or develop a biologic that treats lymphoma, I would work on this as much as I currently work on CAR-T. Working across divisions means not only Novartis’ innovative medicines, but also our biosimilars via Sandoz, meaning that we can take a more holistic perspective in engaging with the patient community.

What is your assessment of the global patient advocacy landscape today and how do you interact with it?

There is a huge diversity of patients, patient groups, and caregivers out there. Our first priority is always the patients who are suffering from a disease and who are touched by our development programs or our products. Patient advocacy groups are the natural place where the interests of these patients are aggregated, analysed, and translated into community positions. For that reason, it is essential that we engage with these groups – local, national, and international. Last – but certainly not least – we also interact with patient-driven foundations which invest in research; a model born in the US, but which now reaches across the world.

My role is global, and I therefore mainly interact with global organisations, but I also work closely with country-focused colleagues to support them in their local and regional interactions.

There are four geographic levels to patient issues. The first is a patient's local treatment and the impact it has on them individually. The second are national-level issues such as pricing and reimbursement decisions and treatment guidelines. Third are regional-level issues such as the EMA's approval processes or research policies in Europe. Fourthly, there are issues of a global scope such as scientific trends and global clinical trials. We interact with patient groups according to these metrics, but the real impact for an individual patient always happens locally. This means that, ultimately, my work is meaningless if it does not support my colleagues working on a national or local level and helping the real patients.

Patients organise themselves differently depending on geography but tend to strive for the same aims. What trends have you witnessed in terms of how patients view CAR-T and other cutting-edge therapies?

We are at a very interesting historical phase for two reasons. Firstly, the digital natives – those who have grown up with self-empowerment and Dr Google – are becoming adults and parents. The generation of non-digitally savvy patients is reaching the end phase of their lives. My generation, now in our 50s, may not be native but we have the internet and digital skills in in our daily toolkit, which is very different from the generation of my parents who are now in their 80s. The inability of patients like my mother to access information autonomously, at least in the developed world, is gradually phasing out.

Secondly, we have had the biggest ever learning and training experience on research and clinical development over the last two years through the global discussion around the development of COVID vaccines. As a positive result of the pandemic, most patients and caregivers – in fact most citizens – now have at least a basic understanding of what drug development and what a clinical trial is.

In addition to this time argument, there is a geographic question about patient empowerment where we still see a very scattered image. In my opinion – one year into my global role – a lot of this has to do with language. The most empowered patients tend to be in countries that are either native English speaking or in those, such as Germany, where school education prioritizes English as foreign language so access to English language content is not difficult.

In countries without high levels of English, not only can patients not access medical information through Google as easily, but they also encounter more challenges in connecting with other patients. The patient empowerment movement has its strong cultural roots in the Anglo-Saxon world.

On a deeper level, another issue may be the paternalistic nature of certain healthcare systems. Within such systems, patients tend not to speak up or challenge their doctors. However, I firmly believe that the maturity of the digitally native generation will challenge this paternalism and encourage greater patient empowerment, no doubt spurred on by the COVID pandemic.

What are the benefits for companies like Novartis of patients becoming more empowered and how can a stronger patient voice converge with scientific development?

It must be remembered that patient empowerment is good for all of us, because all of us could be patients – or caregivers – one day. We know that an empowered patient who really understands what is happening to them will better comply with their treatment. Non-compliance is a big issue in non-oncology indications, but if a patient truly understands what high blood pressure or high cholesterol means, they will be more likely to comply with their prescribed medication. That is good for the patients, first and foremost, but also for their families, the overall healthcare system, and for the science and medicine because it will create robust long-term data and real-world evidence on the efficacy and value of the medicine.

In drug development, we need to become better at making clinical trials that reflect patients' true needs across all aspects. Traditionally, we always focus on the hard medical data, which is where our strength is. However, often a key benefit of a medicine may not be visible at first glance but will have a huge impact on a patient.

For example, in paediatric oncology the difference between a child spending six months in a hospital versus the same child getting treatment in an outpatient setting can make the world of difference. The COVID lockdown experience has shown us all what it means for a child to not be able to go to school or play with their friends for six months. An outpatient treatment option means that paediatric patients can lead a more normal life, even during cancer therapy. That is why we need to get insights from empowered patients who speak up to give us the true picture of what their daily life looks like and how disease and therapy affects it

What are the key concerns in terms of data collection and use that patient groups are bringing up today?

The responsible use of health data is a significant concern. The first type of data is that which comes from clinical trials; this tends to be highly regulated and standardised as it is subject to very intense regulation. The second is the post-market authorization commitments. For example, in CAR-T there is a commitment for 15 years' worth of registry data. This is also highly regulated, with registries such as EBMT hosting the data.

However, these is also an emerging ecosystem of more fluid health data, which is sometimes summarised as real-world evidence data. Here, there are multiple sources with patients tracking their data via apps on their phones and watches.

Also, patient groups increasingly aim to build up international disease specific registries. In some areas, such as paediatric oncology, we are talking about ultra-orphan diseases, meaning that national registries may be too small. Compiling such data sets is a tremendous technical and legal challenge for patient groups – especially smaller ones – given the different data privacy legislations across countries. That is certainly, therefore, an area in which different stakeholders – all of whom understand the value which this data brings – can cooperate more broadly.

The industry does not need to own or manage this data itself – if indeed any external can actor can *own* personal healthcare data – but should help build data repositories that comply to the highest ethical and regulatory standards. These repositories should then be accessible to interested parties – whether academia or industry – to analyse and gain insights from. This space will develop over the coming years with greater standardisation.

CAR-T was first approved by the FDA in 2017 amid a great deal of fanfare and high expectations among patients about its potential. What were your first impressions and what have been the key messages you have had to communicate?

The media coverage of the 2018 approval of CAR-T in Europe was amongst the largest ever, perhaps behind only Viagra and now the COVID vaccines. Almost every tier one outlet covered this approval, which was a good development in as far it raised awareness of some cancer patients' unmet needs. However, in some instances, it also generated expectations that were not put into the correct context. Some haematologic malignancies respond extremely well to CAR-T therapies, and it may in the long run prove to be a definitive treatment option, but some of the media

coverage made it seem as if any cancer was curable with CAR-T. This is a claim that the industry itself did not make and which would have been irresponsible to make.

Personally, I am thrilled by the scientific and medical potential of these therapies. Patients with a life expectancy of just a few weeks can go into full remission and get their lives back; an impact rarely seen in the oncology space. It is therefore an honour and very humbling to be allowed to work on such a class of treatment options. I even received several heart-breaking personal requests from cancer patients whose illness was outside of the scope of CAR-T – such as those with solid tumours – requesting access. This meant that open and honest conversations around managing expectations were desperately needed.

How realistic is it to be able to manage patient expectations around these types of breakthrough therapies?

Unfortunately, with primetime TV news coverage in many countries focusing on sensational stories where a child seemingly doomed to die made a miraculous recovery, it was very difficult to dampen patients' high expectations for CAR-T at the outset of their approval. Fortunately, those days are over to an extent and now – at least in the professional patient advocacy groups – there is a good understanding of the context of CAR-Ts and where they sit in the oncology treatment spectrum. Ongoing dialogue and exchange of views between all stakeholders has certainly contributed to this. What is currently missing, are the deeper discussions that take place at the national or international scientific congresses. Hopefully these can return on a normal level in 2022!

Some patient groups have told us that sponsors often focus too much on the science in their patient group interactions and awareness raising exercises. Is there work to be done to redress this balance?

Patient groups are correct that there is a lot of room for improvement in the way we talk to, and about, patients. This will allow not only our actions, but also our language, to become more patient-centric. We need to speak to patients in a language that is understandable, as far as it complies with laws and regulations, because we must carefully strike a balance between legitimate simplification and accuracy.

Additionally, many of the professional patient organisations nowadays are extremely well versed in the science. When we invite patient organisations to review our clinical trial protocols to ensure that they are sufficiently patient-centric, for example, they understand the science perfectly. However, the ultimate recipient of our messages is not only the patient advocacy groups but the actual patients and we need to become better at communicating with them. Moreover, we need to seek dialogue with the authorities on jointly working on regulations that allow for more patient-centric language.

Again, paediatric oncology is a good example. A child will not understand a 40-page informed consent sheet, but – as we agree that children, depending on their age, should be able to grasp what is happening to them – we need to work with patients and caregivers to develop material that is understandable to children.

Patient groups have also highlighted the CAR-T patient journey as in need of improvement, given existing challenges around time, travel, cost, and emotional strain. How is Novartis working on these issues?

This is a key point. The CAR-T patient treatment journey is much more complex than that of patients who are prescribed a pill by their physician which they then pick up in a pharmacy and take orally. As I mentioned earlier, regulations are set nationally or regionally, but patients are treated locally. We know that the journey can be very smooth for patients who live in densely populated areas with nearby treatment centres. However, for those in rural areas or who need to travel to another country to receive the treatment, the situation is completely different. They may need a radically different support system and may not even speak the local language. We have seen that the treatment comes with a lot of complexity for patients and their caregivers.

This is an ecosystem issue and not something that Novartis can – or should – try to solve alone. However, with our country-based patient engagement colleagues, we can work to understand the key pain points in specific healthcare centres or geographies and how can we collaborate with the ecosystem to find tailored solutions. For example, many hospitals have stem cell coordinators who help patients with stem cell transplants, while others have support organizations for paediatric patients such as Ronald McDonald Houses. Both of these – along with patients and caregivers themselves – are good potential collaborators in the push to find truly patient-centric solutions.

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