

'sphin-X: Because a comm path is simply much bette

Interview: Maro Bader (Roche Pharma, left) and Michael Hübner (Sana Kliniken)

In an interview with 'Monitor Versorgungsforschung', Maro Bader (Excellence Lead Digital Transformation at Roche Pharma) and Michael Hübner (Manager Innovation and Digitalisation, Corporate Development at Sana Kliniken) explain why they founded and joined the sphin-X industry association. Talking to each other, building trust, concluding target-oriented agreements, setting new standards where none yet exist and then: just getting on with it. In this way, sphin-X wants to develop individual use cases as blueprints and thus test reusable building blocks, services and standards of an infrastructure on which many IT projects can be realised more easily.

>> If you enter the term 'One data space for health' into Google, the first two hits are pages from sphin-X (1), followed by a page from the EU Commission on the European Health Data Space Regulation (2). If you search further, you will almost as quickly come across GAIA-X (3). Mr Bader, how does sphin-X differentiate itself from both?

Bader: There are many initiatives and projects that are working towards a similar or the same goal as us, that of a common data space. Many other major industries in Europe and around the world have long been in the process of creating a digital substructure on which all kinds of applications can operate and interact digitally, either individually or with each other.

Hübner: All industries need an interoperable foundation that can be used by everyone, which acts as a kind of blueprint and develops and defines many things: How can such ecosystems be designed and implemented in terms of architecture? How should the rules of the game be formulated? Which building blocks are needed? How is data protection regulated? How about ownership and usage rights? There are initiatives like ours in many sectors that are asking themselves these and similar questions and are gradually starting to implement a shared data space in line with their respective visions.

Bader: If we stay in the healthcare system, it becomes even more detailed, because the aim must be to bring together the healthcare data ecosystems that exist in many places, from outpatient and inpatient primary care, care and rehabilitation to individually collected health data from trackers and mobile phones, for example. In each of these areas, there are in turn several initiatives and activities that attempt to extract their respective data - for example from primary care - for research and secondary utilisation purposes and make it available in a legally compliant, interoperably structured data space.

'The fact is that we are nowhere near where we need to be technologically in order to make meaningful data usable, analyse it, link it in its entirety and longitudinally and then present it in context.'
Michael Hübner, Sana Kliniken

Such as the European Health Data Space Regulation.

Hübner: The EHDS is one of many data spaces. However, there is also the research data centre currently being set up in Germany, as well as various university-based medical networks, the medical informatics initiative and, for example, large hospital chains such as Sana: they are all trying to securely extract their often very large volumes of data for various purposes and make them available for secondary use.

Sounds like a lot of small or large silos with even greater hopes of interoperability.

Bader: What we are aiming for with sphin-X is a larger framework, because healthcare takes place on both sides of and beyond internal sector circles. Our aim is to share all available data from all industrial and institutional players. However, before we can tackle data convergence and interoperability, it is important that we talk to each other in the first place to build trust and mutual understanding. This is extremely important because we will only be able to solve the problems we face together.

Now sphin-X has started as an industry-driven association with the aim of supporting the development of the entire healthcare data ecosystem.

Bader: Wherever we can actively contribute to implementation, we are happy to get involved in order to realise as many different data applications as possible.

How does a hospital group like Sana benefit from this, Mr Hübner?

Hübner: As a large healthcare provider, we produce a lot of different data, but so far we have only actually used around 3 to 5 per cent of this data for healthcare provision and research. So we definitely still have a lot of upside potential. The problem is that our data, like that of most other healthcare providers, is stored in relatively unstructured data silos, which means that it cannot be utilised very well.

A quick question: 3 or even 5 per cent doesn't sound like a lot.

Hübner: Certainly at first glance. However, the fact is that the largest amounts of data in diagnostic imaging are often generated with terabyte-sized amounts of data per patient. It is logical that not every image generated is used for medical care, so a purely quantitative view of the amount of data used is misleading. Nevertheless, the fact is that we are nowhere near where we need to be technologically in order to make meaningful data usable, analyse it, link it in its entirety and longitudinally and then present it in context. We are also making initial attempts to do this with AI-supported big data analytics in order to make our own data usable across systems, harmonised and structured with a sensible data structure and good data quality. However, doing this is very time-consuming. This is precisely where we hope that a partnership-based collaboration will help us to harmonise and bring together the existing data and make it usable in a use case-driven manner - both for primary data use in our healthcare and for secondary data use in research.

In cooperation with the pharmaceutical industry.

Hübner: Of course. We have realised that it can only work together. And that pharmaceutical companies in particular need to research and further develop their products with the help of our data, because we use it every day in patient care. The goal of providing our

patients with better medicine can only be achieved together - data is a means to an end. This is exactly what we want to contribute to. Let's think back to the coronavirus pandemic for a moment: at the time, we had to buy data from Israel because we couldn't or didn't want to make our own data usable.

'It makes more sense to bundle and converge the various efforts, which really affect many players at the same time, and to agree on common paths.'
Maro Bader, Roche Pharma

Bader: It should no longer be the case that data protection, as important as it is, should be prioritised over the value of human life, to put it bluntly and exaggeratedly. For a long time, people have been very dogmatic about data protection and have repeatedly used it to find excuses to construct any theoretical risks with the lowest probability of occurrence in order not to use the available data after all. This is not an argument against data protection as such, which we all take very seriously. However, it is a petition in favour of recognising the use of data as an opportunity to protect human lives, to make them a little more liveable or even to save them. This general cultural rethink in all companies and institutions is very important and is happening right now. Accordingly, we will experience a major change in the coming years.

Although we are currently experiencing counter-movements with the launch of the ePA.

Bader: There will always be guarding and persistence tendencies. After all, medicine is a people business. In the end, decisions are always made by people, often unfortunately based more on eminence than evidence. Nevertheless, I believe that data will help us to make even better informed and, above all, evidence-based decisions in the future. What Mr Hübner has just said about the challenges his company faces with regard to data availability are fundamental tasks that we all have together, whether hospital, health insurance company or industry: we all have exactly the same challenges when it comes to data protection, mentalities and cultures. However, we have come to the conclusion that the previous approaches, in which individual local players attempted to create solutions, are not sustainable enough to achieve the fastest possible scaling. It makes more sense to bundle and converge the various efforts, which really do affect many players at the same time, and to agree on common approaches. At the moment, however, industry at least is not sufficiently involved in this dialogue. As an industry, we cannot make a constructive contribution to agreeing on common standards.

What is the aim of sphin-X?

Hübner: We all want to make a decisive contribution to harmonising these different efforts, which are associated with high investments of capital and human resources.

Bader: That's why we're naturally incredibly pleased that we're cooperating with the Sana clinics and that this is creating a very productive dialogue and a nucleus for using data and conducting research together with as many other partners and clinics as possible.

Hübner: We simply can no longer afford to develop individual projects, technologies and data protection concepts side by side. We will only be able to create interoperability together. For this reason, with sphin-X we will develop individual use cases as blueprints together with all partners and thus test reusable building blocks, services and standards of an infrastructure on which many such projects can be realised more easily.

You are therefore hoping to achieve scaling benefits by optimising processes that will enable you to handle data faster, more securely and better.

Bader: By analogy with our road network. However, the digital data ecosystem does not yet have its own road network with its own rules of the game, commonly accepted road signs, established petrol stations, car parks and rest areas and an MOT that inspects everything that drives on it. Another analogy is the railway network: here, route providers and train manufacturers have agreed on a rail width instead of trying to impose their own. That sounds absurd, but it is the reality in many areas of the healthcare sector. We have therefore set out to scrutinise whether our own approach is the right one or whether a joint approach would not be much better wherever there is no unique selling point or potential for differentiation.

Hübner: We don't really care which standard prevails. It is much more important that there is a standard at all that we can orientate ourselves by. If we can agree on such standards together with many players - from health insurance companies to clinics and industry - then this will automatically contribute to scaling data availability and utilisation.

What happens when EHDS and Gaia-X set such standards?

Bader: Whoever gets there first will probably prevail. Or not.

As we saw in the format war between various competing and co-existing video cassette systems in the 1970s and 1980s. Of VHS, Betamax and Video 2000, only the VHS format prevailed worldwide.

Bader: And it is now so outdated and has been replaced by DVD for over 20 years. It makes far more sense to pull together from the outset and work on jointly accepted standards. We are all endeavouring to act in a very coordinated manner. We are therefore in dialogue with all initiatives in Germany and Europe. For example, we do not develop new standards if there are already international standards that we can adhere to.

Hübner: We are convinced that nobody can afford to work redundantly any more. But the issue is also the necessary speed that we need and want.

In terms of time and speed: The EHDS Regulation (2) came into force in March 2025. By March 2031, primary use should be possible, with which health data (medical images, laboratory results and hospital discharge reports) can be exchanged in all EU member states; from March 2034, third countries and international organisations will also be able to apply to participate in HealthData@EU for secondary use. When do you want to reach your goal with sphin-X?

Bader: We will never really reach our goal. There will always be

continuous further development. However, the first milestone we have set ourselves is that we want to have an infrastructure with technological solutions in place this year, which we can use to demonstrate that it is possible for two legal entities - a hospital group and a pharmaceutical company, for example - to share data.

Hübner: That may sound trivial, but it's not. An incredible number of fundamental things have to be developed for this: starting with legal agreements at different levels, the necessary data models, the basic infrastructure and ending with the data protection concept. sphin-X is the framework that is intended to drive this vision forward, but the implementation always takes place in separate workbench projects. The operation of the infrastructure is also outsourced independently of the association to several separate operating companies. We first had to bring all of this to life in the first year of our existence.

Bader: The second goal over the next few years will be to continuously develop the data infrastructure of the individual solutions so that they can support even more and even more complex use cases.

Until data protection strikes.

Hübner: That's why we are starting pragmatically with less sensitive and less problematic data, with which we can build and test the necessary infrastructure together. Our current focus is on proving that it is even possible to exchange data securely between legal entities in the healthcare sector. We are currently laying the foundations for this. Once this has been achieved, we will venture into more complicated data and scaling.

Bader: I compare it to the aviation industry. Nowadays, you can book a ticket from any Internet café or mobile phone, select the menu, the drink and the seat and then print out the ticket yourself, which can be used anywhere in the world. A generally accepted logic has been developed and implemented for one activity. And everyone can be absolutely sure that the entire process is handled in a legally compliant and data protection-safe manner. The whole thing is a real, functioning data ecosystem that we would like to see in a similar way for health data - always bearing in mind, of course, that health data is highly sensitive data. But so are bank and flight data.

Hübner: It is important for all of us that we take a use case-driven approach. We are not just trying to make as much data as possible available, but only the data that we need to achieve a precisely defined project goal based on an individual application scenario. But: always one thing at a time. Then evaluate, learn and move on to the next one. In the end, there will be so many use cases for which patient-specific data will certainly be needed, but which will then be usable in a form that is absolutely compliant with data protection law.



Maro Bader

is an expert in digital transformation in the healthcare sector in the German policy team of the pharmaceutical company Roche and Chairman of the Board of sphin-X e. V. His focus is on building a networked and interoperable healthcare data ecosystem. With sphin-X, he is making a decisive contribution to the realisation of this goal together with all relevant players from the industry. Maro Bader studied computer science at the Free University of Berlin and has more than 16 years of professional experience at the interface of technology, politics and healthcare.

What does the top management at Sana Kliniken think about this?

Hübner: Our top management generally considers the topic of health data utilisation to be very important. At Sana, by the way, we have a wide range of issues to deal with here, from purchasing and logistics to healthcare and research.

Who came up with the idea for sphin-X?

Bader: It was me three and a half years ago, when I was able to pool the experience from many research collaborations for Roche. These were often very expensive, lengthy individual projects with their own ethics and data protection approvals and very complicated and expensive procedures. At the end of a Gaia-X workshop, which was intended to solve precisely these problems, I asked the question: You've had a data architecture for a long time, why don't you use it in reality? That's when I realised that such institutions are not in a position to take such activities on the road and implement them. I was referred to the Fraunhofer Institute for Software and Systems Engineering ISST and its director, Professor Dr Boris Otto, who wrote the book 'Designing Data Spaces' (4), which is really worth reading. The book is about how stakeholders who do not actually trust each other can nevertheless realise a project together. This basic idea gave rise to sphin-X, the 'secure platformfor health informationeXchange'.

Mr Bader and Mr Hübner thank you for talking to us.. <<

The interview was conducted by editor-in-chief Peter Stegmaier

Links:
1: https://sphin-x.de
2: https://t1p.de/agyzr
3: https://gaia-x-hub.de
4: https://t1p.de/ui8xe



Michael Hübner

has worked in various positions in the healthcare sector for more than 17 years. He has a degree in health economics (M.Sc.). He joined Sana Kliniken AG in November 2021 as a manager in the area of digitalisation. In his role, he manages innovative digitalisation projects throughout the Group and develops strategies and new business areas as part of the digital transformation.
Since November 2024, Hübner has been a board member of the healthcare industry association sphin-x e. V., whose aim is to create a collaborative healthcare data space in Germany. Before joining Sana Kliniken AG, he advised international companies in the healthcare industry for KMPG. Before that, he was an account and project manager for a digital health start-up and led an interdisciplinary team in a consortium project with Charité and the Fraunhofer Institute.

EHDS: 2022 to 2034

>> The EHDS Regulation, as initially proposed by the European Commission in March 2022, was the subject of extensive negotiations before it was adopted by the European Parliament and the Council. It is now being implemented in a phased and structured manner to ensure a smooth transition. On 5 March 2025, the Regulation on the European Health Data Space was published in the Official Journal of the European Union. It entered into force on 26 March 2025, marking the start of the transition phase for its application. The European Health Data Space (EHDS) is one of the cornerstones of the European Health Union and represents the first common EU data space in a specific area resulting from the EU Data Strategy.

Important milestones on the way to full implementation:
- March 2025 : the EHDS Regulation enters into force at the start of the transition period.
- March 2027: Deadline for the adoption of several key implementing acts by the Commission with detailed rules for the operationalisation of the Regulation
- March 2029: The main elements of the EHDS Regulation enter into force, including the exchange of the first set of priority categories of health data (patient summaries, electronic prescriptions/electronic prescriptions) for primary use in all EU Member States. The rules on secondary use will then also apply to most categories of data (e.g. data from electronic health records).
- March 2031: For primary use, the exchange of the second group of priority categories of health data (medical images, laboratory results and hospital discharge reports) should be operational in all EU Member States. The rules on secondary use will then also apply to most categories of data.
- March 2034: Third countries and international organisations can apply to participate in HealthData@EU for secondary use. <<

Link: https://t1p.de/agyzr

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