Regions4PerMed

Personalising Health Industry

D4.3 | KA3 Report | Addendum In-Situ Visit

22-24 September 2022

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825812

Abbreviations

ATMP	Advanced Therapy Medicinal Products
ICCA cell	Chimeric Antigen Receptor T cell
COO	Chief Operating Officer
EKFZ	Else-Kröner-Fresenius Center for Digital Health
EU	European Union
ICCAS	Innovation Center for Computer Assisted Surgery
Fraunhofer IZI	Fraunhofer Institute for Cell Therapy and Immunology
KA	Key Area
KAIT	Knowledge-driven and Artificial Intelligence-based Platform for Therapy Decision Support in Hematology
MS	Multiple Sclerosis
MDR	Medical Device Regulation
IVDR	In-vitro Diagnostic Regulation
PH	Personalised Health
PM	Personalised Medicine
R&D	Research and Development
SME	Small and Medium Enterprises
SPRIND	German Agency for Disruptive Innovation

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1 Aim of in-situ-visit

Regions4PerMed's overall objective is to advance the uptake of personalised medicine (PM) and personalised health (PH) in European regions. To this end, Regions4PerMed has initiated a stakeholder dialogue and engagement process in five thematically focused key areas (KA) to inform relevant regional stakeholders about the opportunities and needs of PM and PH. Each of the five regional partner organisations of Regions4PerMed is responsible for one specific KA, namely: "Big data, electronic health records and health governance", "Health technology in connected and integrated care", "Personalising health industry", "Innovation flow in the healthcare", and "Tackling ethical, economical, legal and social aspects of Personalised Medicine".

The thematic dialogue is organised in a series of interactive events. These consist of a technical conference outlining the most relevant aspects of the respective KA followed by a workshop and co-creation meeting. The latter is intended to discuss and evaluate relevant best practices and stakeholder needs of the respective KA within the European regional context.

In order to provide the Regions4PerMed partners a deeper, more hands-on understanding of the topics discussed, the workshops were planned to be accompanied by an in-situ visit of regionally embedded high-level organisations that are contributing to the field of PM and PH. These present their PM and PH approaches in relation to the respective KA on-site providing the participating partners with a deeper understanding of the KA and also offering an opportunity for an in-depth exchange with regional stakeholders.

Due to the Covid-19 pandemic most of the Regions4PerMed events had to take place in a virtual format, though the initial concept was aiming for in-person interactive events. Due to this, the in-situ visits could in most instances not take place in-person during the above-described events, but had to take place virtually or to be postponed.

Being responsible for KA3, Personalising Health Industry, SMWK also had to take its stakeholder-event-series online, organising a thematic online-conference on October 15th - 16th 2020 and two workshops on April 28th and May 19th 2021, respectively. It was decided by the consortium that the in person in-situ visit would be postponed. Therefore, KA3 in-situ visit was moved to September 22nd and 23rd 2022.

The focus of the KA3-in-situ-visit was put on regional organisations with a high level of relevance for PM and PH in Saxony. With Leipzig and Dresden, Saxony currently has two hots pots for PM and PH, accompanied by some smaller centers of expertise that are present throughout the region and that also contribute to the Saxon PM and PH ecosystem. Both Leipzig and Dresden, are larger cities (500 K+ inhabitants) with internationally acknowledged universities.

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Both enjoy a high visibility and reputation in the medical field, being home to renowned university clinics, other hospitals, polytechnic universities and numerous public and also private research institutes, many of which belonging or being relating in different ways to the broad topic of healthcare. The Saxon PM and PH ecosystem is characterised by a strong academic-scientific base and a growing number of SMEs, and also some representation of large pharma companies, such as a vaccine manufacturing site of GlaxoSmithKline in Dresden. There is a well-developed support infrastructure, consisting of regional networking organisations and incubators.

The in-situ visit was divided between the two cities. In Leipzig the aim was to meet different relevant stakeholders of this ecosystem, such as Biosaxony, which also represented BioCity Campus Leipzig, and the Medical Forge Leipzig, and research institutes such as the Fraunhofer Institute for Cell Therapy and Immunology, and the Leipzig University Innovation Center for Computer Assisted Surgery (ICCAS). In Dresden, the focus was put on an in-depth encounter with the Else-Kröner-Fresenius Center for Digital Health, a University Institute that is funded by a private trust (Else-Kröner-Fresenius Foundation). As the aim was to initiate a dialogue with relevant Saxon PM and PH stakeholders the Networking Dinner on September 22nd was used for a moderated in-depth discussion.

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2 Agenda of In-Situ-Visit

22. September 2022, Leipzig

12:15 a.m.	**Lunch at BioCity Leipzig Bistro**
1:15 p.m.	**Short Tour of BioCity Campus and Medical Forge Leipzig**
2:30 p.m.	**On-site visit Fraunhofer IZI: CAR-T-Cell Production, SaxoCell, Regulation, Translation of Science to Commercial Application**
4:00 p.m.	**On site visit of ICCAS – Innovation Center for Computer Assisted Surgery**
7:00 p.m.	**Networking Dinner, Restaurant "Felix im Lebendigen Haus"** (Consortium Members, Saxon Advisory Board Members, invited guests) **Keynote Lecture of Prof. Thomas Neumuth** **"Transfer Concepts for Personalised Medicine in Light of the Vision of a Center for Medicine Innovation (CMI) in Halle / Leipzig Area"**

23. September 2022, Dresden

10:00 a.m.	**Center for Regenerative Diseases and Therapies (CRTD)** **InnoDays 2022 of Else-Kröner-Fresenius Center for Digital Health (Day 1)**
12:00 a.m.	**Lunch Meeting with pre-scheduled personal interaction opportunity with EKFZ projects** (tbc)
1:30 p.m.	**Afternoon Programme EKFZ / end of in-situ visit for "Friday home-travelers"** Travel home/check-in to Hotel in Dresden for those who can stay until Saturday, 24th
6:30 pm.	**EKFZ InnoNight** **(Evening Event, registration is not included, separate registration by participants is required)**

24. September 2022, Dresden (optional)

10:00 a.m.	**Center for Regenerative Diseases and Therapies (CRTD)** **InnoDays 2022 of Else-Kröner-Fresenius Center for Digital Health, Day 2**
2:45 p.m.	**End of EKFZ-InnoDays 2022**

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3 Summary of the In-Situ-Visit

The aim of the in-situ-visit was to obtain an overview of Saxon institutions, infrastructures, and facilities that are of high relevance for the development of personalised medicine and health. Due to the geographic distance between Leipzig and Dresden, the visit was structured such that the first day was used to gain an insight into institutions of the Saxon Ecosystem that are localised in Leipzig Area, such as BioSaxony, the Medical Forge Leipzig, BioCity Leipzig, Fraunhofer Institute for Cell Therapy and Immunology, and the Innovation Center for Computer Assisted Surgery at Leipzig University. At the end of the first day, the Regions4PerMed Networking dinner took place, during which consortium members could discuss topics of high relevance for Personalised Medicine and Health with invited guests, including the Saxon Advisory Board members of Regions4PerMed. The second day of the in-situ- visit was taken to obtain an in-depth insight into the Else-Kröner-Fresenius Center for Digital Health in Dresden by participating in the InnoDays, the center's annual scientific networking conference that is also used to showcase the center's activities.

In the following section the individual activities are presented in their chronologic order.

a. BioSaxony e.V.

BioSaxony e.V. was introduced to Regions4PerMed by its CEO André Hofmann. The **regional association of the biotechnology, medical technology and health economy sector** within the Free State of Saxony has approx. **140 members** consisting mainly of SMEs, research institutes, and other stakeholders serving and supporting biotechnology and medtech, some also belong to related areas of engineering and material sciences. By bringing biotech and medtech together, BioSaxony creates a supportive environment for industry development. It organises recurring networking events in different locations in Saxony, such as the "Bionection" conference and "BioSaxony on-site"-Meetings. It also hosts a number of working groups for its members on topics such as "stem cell therapies", "implementation of medical care", "law and taxes", and organises training opportunities with third party providers. Recently, BioSaxony has been accredited as an educational service provider, allowing it to directly offer certified educational programmes. The first one is a GMP-operator training programme termed "QualiBioPharma" which addresses the strong regional demand for GMP-trained staff, thus ensuring sufficient supply of qualified human resources within the region. The dialogue with André Hofmann vividly illustrated the importance of this **proactive network and engagement platform for the regional development** of the biotech/medtech industries and also for a personalising health industry. By fostering communication and professional exchange between regional stakeholders, BioSaxony is able to closely monitor its members' needs, to engage in

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and lead collaborative processes, and also to voice policy needs. To develop a personalising health industry supportive ecosystem, such focussed activities are indispensable.

b. Medical Forge Leipzig

Simone Haubner (BioSaxony, COO Medical Forge) introduced the delegation to the Medical Forge Leipzig, a novel project initiated and carried out by BioSaxony in close collaboration with the City of Leipzig. The project supports **new medical technology business establishment in the Leipzig area** by helping start-ups and innovative companies to bring their medical products faster to the German healthcare market. Mostly international participants join a customized full-year programme that addresses specific development needs of young medical technology companies. A **network of hospitals, health insurances** and **experienced industry partners** provide **advice, training, insights, and new project opportunities**. The services have an overall value of up to 210,000 Euro per project, including the use of BioCity Leipzig based **co-working laboratories, offices, and a novel 3D-printing facility**. Participants can participate in workshops and receive consulting and mentoring. While they have to contribute 21,000 Euro of their own capital, they also receive a 25,000 Euro team budget for the program. Up to seven projects per year can join in the Medical Forge. Aside from the direct effect of supporting potential start-up/ SME settlements in the region of Leipzig, the close collaboration between BioSaxony and the participants provides an unique learning opportunity for both, as the participants not only provide information on their needs in respect to the German market, but they can, in the best case, also become links into their originating regional ecosystems.

c. BioCity Campus Leipzig

In his function as CEO of BioSaxony Management GmbH which operates the campus, Andre Hofmann also presented the BioCity Leipzig on which BioSaxony is located. Set up in 2003, the **campus is currently providing 20,000 square meters of rental lab and office space** for biotech and medtech SMEs, as well as six biotech-focused university departments and non-university institutes. The facilities are equipped with cutting-edge technology and fully rented. The BioCity was expanded in 2013 by the **BioCube Leipzig, which is offering an additional 6,400 square meters of S1- and S2**-standard laboratories, office, production, and warehouse spaces. The BioCube serves companies beyond the start-up phase that want to continue growing on campus.

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FIGURE 1: REGIONS4PERMED PROJECT PARTNERS IN FRONT OF A BUILDING OF BIOCITY LEIPZIG

Looking ahead, **the campus will be developed further by three additional construction projects**: "BioSquare Leipzig" will add another 18,500 square meters of medtech facilities for expanding companies and shall take up operations in 2025. Also, in 2025 a novel "Innovation Center" for life-sciences start-ups and SMEs shall be launched. The historic "Halle 12" will serve as a new Life Science Hub offering 10,000 square meters of offices, laboratories, workshop & conference rooms, and communal spaces for networking distributed across four floors. The building will offer cutting-edge equipment combined with spatial flexibility as premises can be adjusted to tenants' needs. In addition, a private investor is preparing the CLL City Lab Leipzig offering another 6,000 square meters of flexibly adjustable office and lab space in close proximity.

The **availability of adequate expansion space is essential** for the development of high-risk and capital intense life sciences SME, and thus also for SMEs active in the field of PM. A lack of sufficient expansion space is a critical growth limiting factor for such companies. **SMEs and especially start-ups frequently lack the resources to finance and administrate such investments on their own**. As a critical locational factor, it can make a regional geographic area particularly supportive and encouraging for start-up companies. This can be a key differentiating factor for companies that are seeking geographical expansion – under the precondition that other critical factors are present, such as a fitting academic and non-academic research-base, access to qualified human resources, existence of an adequate support-network, and access to capital.

The regional health-related innovation system of Saxony, especially at its Leipzig location, is providing a **unique combination of "brains and bricks"**: a strong, vivid academic base, an actively managed regional network with supportive, growth enhancing services such as the Medical Forge, training activities to ensure availability of future staff, as well as a significant

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investment in start-up and expansion space, as outlined for the BioCity Campus Leipzig. Overall, this is an exemplary development of a highly supportive regional ecosystem.

d. Fraunhofer Institute for Cell Therapy and Immunology

The Leipzig-based Fraunhofer Institute for Cell Therapy and Immunology (Fraunhofer IZI) is located in close proximity to the BioCity Campus. It was introduced to Regions4PerMed by Dr. Thomas Tradler (Head of the Executive Department Business Development / Patent Management), Jens Augustin (Head of Press and Public Affairs), and Prof. Ulrike Köhl, its Managing Director. The German **Fraunhofer Society is a leading applied research organization with global impact**, and as such a major player for scientific and technological innovation in Germany. Founded in 1949 it operates76 institutes and research units across Germany with an annual research budget of 2.9 B Euro. Its 30,000+ employees, mostly scientists and engineers, work in a broad spectrum of science and technology. With low public base-financing, Fraunhofer Society is mostly funded by industry collaboration and public grant-based project revenues, amounting to more than 2.5 B Euro annually.

Fraunhofer IZI operates four sites across the eastern part of Germany and has 632 employees in total, of which 430 are based in its Leipzig headquarters. The institute generates **more than 44 M Euro in project revenues annually**, mostly from industry, followed by national and regional government grants and other project revenues. For the Saxon PM and PH ecosystem, Fraunhofer IZI functions as an important innovation engine and translational entity due to its strong industry collaboration base (with +100 industry partners), numerous patent applications, a significant scientific output, and regional spin-out activities.

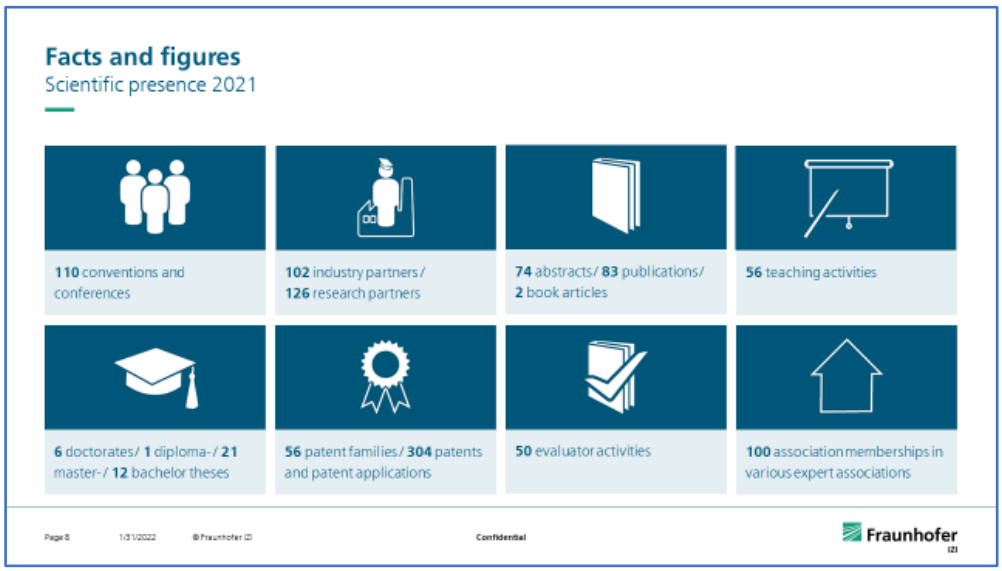

FIGURE 2: OVERVIEW OF THE SCIENTIFIC OUTPUT OF FRAUNHOFER IZI IN 2021

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With its **scientific expertise in immune-oncology and infectious disease pathology**, Fraunhofer IZI operates four business areas: (1) cell and gene therapy, (2) drugs and vaccines, (3) molecular diagnostics and immunodiagnostics, and (4) extracorporeal therapies. As **an active networking nucleus**, Fraunhofer IZI has been critical for the development of the **SaxoCell Cluster** that is supported with 15 M Euro of federal Clusters4Future funding (which may be expanded to 45 M Euro). Within SaxoCell mainly, but not only regional academic and commercial entities collaborate closely on the development and production of so-called living therapies. In addition, Fraunhofer IZI is engaged in several large EU projects advancing topics such as the use of digital avatars to improve **safety of immunomodulatory therapies** (www.imsavar.eu) as part of the Innovative Medicines Initiative, or the **repurposing of drugs** (www.remedi4all.org). Fraunhofer IZI is offering a **unique infrastructure**. Being familiar with the complexity and stringency of GMP operations, its GMP facility can cover medium-size production steps, and allows for incubation of small approaches to first scaling steps.

During the in-situ visit, the Regions4PerMed delegation was shown some of Fraunhofer IZI's **core facilities**, such as the institute's **13 GMP production class B cleanrooms**. The high standards of GMP production were explained, e.g. during GMP classified procedures strict and detailed rules need to be followed and closely documented. All production process steps executed by one person are monitored by a second person which is acting as an observer and record-taker. Especially in high-income countries, such processes become very expensive, which is one of the reasons for the high cost of innovative personalised cell-based therapies. With increasing demand and in an ageing society, access to qualified HR for such tasks becomes increasingly difficult and a reduced availability of adequately trained human resources may become a future bottleneck.

The delegation learned that the lengthy production processes of *autologous* cell-based therapies increases the risk of therapy failure due to rapid patient-deterioration and the poor quality of patient derived samples (as patients have been heavily pre-treated) which reduces obtainable product quality. To overcome such technology-specific disadvantages, **more technological innovation will be needed,** e.g. towards allogenic therapies and especially **a higher degree of automation** may become critical to reduce cost. Fraunhofer IZI is actively engaging in such R&D, e.g. in the context of SaxoCell and significant innovation is foreseen. For Europe to stay competitive, a smart bundling of such innovation efforts and a fitting regulatory setting may be critical.

e. Innovation Center for Computer Assisted Surgery (ICCAS)

The Innovation Center Computer Assisted Surgery (ICCAS) was presented to Regions4PerMed by Prof. Thomas Neumuth (CTO). As an **interdisciplinary research center** of Leipzig University medical faculty, ICCAS is a pioneer in developing computer-aided, integrative technologies and intelligent assistance systems in medicine by combining expert knowledge of clinical and

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economic requirements. The main objective of the center is the improvement of novel therapy products, methods and work processes to increase patient safety through economically sustainable technology. With its scientific staff of 64 and 45 guest researchers, the center had an output of + 50 scientific contributions in 2021 and obtained almost 3 M Euro of external funding.

The center has four main areas of expertise: (1) computer-assisted image guided interventions, (2) model-based medicine and intelligent operating room, (3) intraoperative multimodal imaging, and (4) biomedical data analysis. Several R&D projects were presented during the visit, demonstrating the versatility of the center. With **Multiguard,** a development project for a **multispectral monitoring** system to non-invasively analyse the health status of patients was shown. The delegation also learned about **image-guided surgery**, in which imaging via ultrasound allows a precise monitoring and execution of minimally-invasive procedures such as biopsies, thermal ablation and embolization. A visit to the **intelligent operating room** gave an impression how surgical workflow can be improved by computer-assisted technology, making surgery safer for patients and taking much of the documentation burden from the medical staff by smart assistance systems. In addition, a **digital patient model** was presented that has been developed in the project "Knowledge-driven and Artificial Intelligence-based Platform for Therapy Decision Support in Hematology" (**KAIT**). The aim of this project is to enable **personalized treatment for patients with a group of highly heterogeneous blood disorders**. Finally, the **MOMENTUM** project was presented, in which medical technology is being developed for external care, e.g. at the site of an accident and in the ambulance. For this a 5G-equipped model-ambulance has been taken into operation that can be controlled with the help of innovative virtual reality tools.

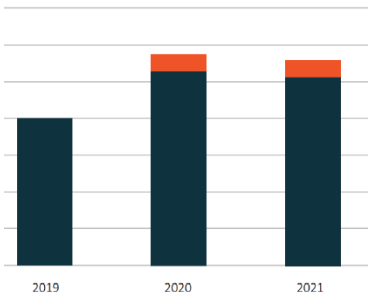

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FIGURE 3: THE DELEGATION OF REGIONS4PERMED VISITING ICCAS: INTELLIGENT OPERATING ROOM (LEFT PICTURE) AND THE NEWLY ACQUIRED 5 G-EQUIPPED MODEL-AMBULANCE THAT CAN BE OPERATED USING VIRTUAL REALITY (RIGHT PICTURE)

During the dialogue with ICCAS representatives, the Regions4PerMed delegation learned that the center's services meet an increasing demand by industry. According to the center, there is a growing trend for industry to outsource research and development activities as industry is suffering from a shortage of qualified staff, especially in the southern part of Germany, where most clients of ICCAS are located. As the center is providing a well-developed unique and interdisciplinary combination of expertise at the intersection of IT, AI, and engineering with a deep understanding of the needs and requirements in the medical field, it is well suited to provide such development services for external partners. ICCAS is therefore a regional player with a growing potential. As it uses its expertise also to train and educate future technicians and scientists, it adds to the future potential of the region, and increases regional visibility by engaging in public relation activities.

f. Regions4PerMed Networking Dinner

The day closed with a Regions4PerMed Networking Dinner at the Restaurant "Felix im Lebendigen Haus" in Leipzig. This provided an opportunity for a focused discussion of the delegation with the regional Advisory Board Members of Regions4PerMed, and regional participants of the "Personalising Health Industry" conference and workshops, as well as two representatives of BioSaxony. To create a supportive atmosphere for the conversation, a separate room was booked. Though it was planned to begin the evening with a presentation on the topic of translation, this had to be skipped due to timing restrictions. Throughout the dinner the conversation was guided by a moderation of the host with an underlying focus on the topic of regional ecosystems for a personalising health industry.

After a short tour-de-table, the conversation quickly turned to the topic of **how to support a PM enhancing regional development**. Based on the perception of the Saxon ecosystem, the need to improve **access to finance** and a lack of **Venture Capital for PM** was discussed as **growth-slowing and -limiting for the translation of PM and PH**, specifically for the development of SME. The high degree of complexity of product development and market regulation in this field make it riskier and more time-consuming than other business areas[1]. The creation of **dedicated regional venture funding for life sciences and medtech start-ups** was suggested as a useful approach to support industry establishment and growth to **attract more external investment**. Also, the adoption of a **dedicated public pre-commercial procurement (PCP) in-**

[1] Has also been discussed during the KA3 conference in October 2020, see KA3 report.

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strument for PM was suggested. Referring to SPRIND, the German Agency for Disruptive Innovation, which has implemented the concept for the national level, PCP was seen as a particularly effective approach to keep innovators and innovation attached to their region of origin[2].

It was noted that regions benefit **from a clear regional strategic focus** in terms of R&D and investment policies as this helps to increase synergies within the region and to gain visibility, if backed by appropriate policies[3]. Participants agreed that **Saxony has developed some particular regional strengths in the life sciences** in the past twenty plus years as a result of its dedicated "Biotechnology Initiative". An outstanding capability was developed in the field of **cell and gene therapies** which led to the creation of **SaxoCell**. With Fraunhofer IZI, Leipzig and Dresden universities serving as nuclei, SaxoCell is successfully **bundling regional competences** through collaboration between regional public and private actors and increasing its visibility.

In this context, **stem cell therapies** were characterized as **one of the most amazing success stories in PM** to date. As these therapies are currently very costly for payers, the latter are not always supportive of this therapeutic approach. The **need to reduce the cost of such therapies** was stressed and will depend on an increasing use of **automation and robotics** (see above). To enable further breakthrough developments in the field of PM and PH, more **interdisciplinary approaches will be needed** that integrate cutting edge knowledge and technology from different areas. Regional **policy instruments to advance and enhance interdisciplinary collaboration** could be an effective tool for this.

The translation of innovative therapies is compounded by **issues of liability** that are currently not sufficiently resolved, particularly in the field of cell therapies. This was seen as critical, indicating a **need for improved regulation**. **Regulation is posing a significant hurdle on many levels**. A **lack of interregional harmonisation within Germany** was described, e.g. virus-specific T-cells are classified as "advanced therapy medicinal product" (ATMP) in northern parts of Germany but as "cell product" in southern Germany (namely Bavaria). Such divergence may seem trivial on paper but can have significant implications for handling (and cost) of respective materials. Another example of regulatory hurdles was seen in contracting for clinical trials of ATMP, which is very slow in Germany in international comparison. According to an attending expert in China it takes about three weeks, in the USA three months, and in Germany three years to contract ATMP related clinical trials. There are also significant **differences within Europe**. Among others, for **Germany** this was attributed to the way how the **regionally based ethics committees** operate, which does not seem to be sufficiently standardized. To counteract, it was suggested to introduce the option for SMEs to buy a **fast-track procedure**, especially for ethics evaluations. Also, other regulatory aspects, such as data privacy issues,

[2] Successful examples of PCP and also of Public Procurement of Innovation (PPI) relating PM have been presented in the context of KA4 conference and workshops, see KA4 report.
[3] This supports approaches such as the European RiS3 concept.

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were perceived as problematic. Great differences across the EU were noted, with **Spain** being exemplified as having **more advanced and ATMP- and clinical research facilitating policies**.

To advance personalisation in the medical field, a **need for more (academic) investigator initiated clinical trials** was seen, especially for niche indications with a limited profit-potential for pharmaceutical companies or for therapeutic adjustments that may reduce corporate profits by improving patient stratification and treatment regimens. As clinical trials are costly, funding mechanisms for academic research frequently are inadequate. From this perspective **funding programmes such as ERA PerMed were perceived as too limited**, as they do not allow for clinical trials. However, **clinical trials are seen as an important bottle neck and translational hurdle for PM,** leading to a "Valley of Death" for such approaches. As personalisation tends to reduce relevant patient populations, trial decentralisation is frequently a resulting side effect. However, decentralised clinical trials tend to be more complex in terms of regulation, coordination and monitoring. To facilitate such trials, a need for more **adequate support structures** was discussed.

Though not a regional topic, the consequences of the introduction of EU **Medical Device Regulation** (MDR; 017/745) was discussed, which is perceived as an **innovation barrier for industry**, especially for SMEs. One of the reasons is a shortcoming of notified bodies in Europe (currently there are 40). For SME, **the cost for regulatory support has doubled** on average, while the speed of certification processes was slowed down. Due to the new regulatory requirements, established niche products are taken from the market as they cannot maintain certification. Also, the introduction of incremental innovation to existing products has become less attractive for manufacturers, due to regulatory hurdles. The situation is perceived as suboptimal across Europe for manufacturers and patients alike.[4]

From a **systemic perspective**, it was noted that **in the EU** much r**egulation is developed on a high level of policy, while interpretation is taking place on lower levels**, potentially leading to a diverse interpretation landscape and **regulatory fragmentation**. For industry, especially for SME, this poses a serious problem as it leads to **regional and national differences across the EU.** This makes **market introduction of regulated products in the EU cumbersom**e, slow, and costly, creating a **barrier for industry development**. In comparison **US regulation and interpretation of regulation** is done on a higher level, creating a **more uniform, consistent and predictable regulatory environment**. According to the participants, regulative shortcomings within the EU are compounded by a perceived **understaffing of regional authorities** in some regions, resulting in **slowed processes and a loss of innovative potential** for the respective regions, but also for the EU as a whole. Regulatory fragmentation favours large companies while posing a disadvantage for SME, as large companies tend to have the capacity and funds to better manage fragmentation.

[4] In Germany, this has led to a **German Federal Council request (445/22)**, spearheaded by Bavaria and Baden-Wurttemberg to address this issue with the EU legislative bodies.

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In the **national German context, a potential duplication of regulatory pathways** and communication channels, as is possible within DiGA regulation, was also questioned. This regulation makes direct agreements with local payers possible, which is perceived to be more straightforward for SME; however, if this approach is taken, all payers need to be approached individually, which increases organisational burden.

Still, the participants perceived an important **innovative opportunity for regions in the medical area**. The concept of a **"medical innovation region"** was discussed that could extend across national boundaries and support intra- and interregional networks. This could include **shared and facilitated** approaches for **handling of data** and data protection and regulation, encompass more **resources for regional authorities** in terms of staffing and competencies, and include **optimization of regulatory processes** on the regional level. Added by more regional venture funding, **the uptake of medical innovations within a region** could be sped-up.

The idea for a dedicated innovation supporting agency, an **"office-of-opportunities" for medical innovation** was outlined, that could act as **a facilitator within a region to advance translational projects**. This could also **support bringing innovation to the periphery** e.g. by developing processes that make specialist services of the centers, such as the molecular tumour board for oncologic indications, accessible to the periphery[5]. With an improved data infrastructure, including the reduction of data silos and a more uniform approach to data management in healthcare, efficiency gains would be possible[6]. A need was seen for an **"enabling mentality"** that focuses on **making things happen**, instead of explaining why they are not possible.

In summary, the **participants of the dinner agreed that PM and PH had made significant progress over the past years**, especially in the field of cell therapies. Future progress will most likely depend on more interdisciplinary approaches, an adequate data infrastructure, innovation facilitating policies, administrations, and funding, areas in which **regions can shape the respective ecosystem by taking supportive actions**. However, further **dedicated efforts are needed on a higher level of policy to reduce regulatory fragmentation within the EU** in order to make market access strategies more predictable and governable, especially for SME.

Efforts to achieve this o need to be carefully crafted in order to not create novel hurdles.

[5] In Northrine-Westphalia, a concept to resolve the differences between healthcare in the centers and the periphery was developed as part of the Innovationsfonds project „TELnet@NRW" (from 2017-2020). This has led to the establishment of a network of a virtual hospital concept (VKH.NRW), in which university hospitals provide support to local and community hospitals, currently covering the field of intensive care and infectious diseases.

[6] In Germany, individual hospitals have different, and generally disintegrated information management systems which is suboptimal for physicians and patients. While electronic health records within different departments of hospitals are standard, these frequently are not integrated across departments; and the data they contain, usually is not accessible to outpatient practicioners.

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g. Else-Kröner-Fresenius Center for Digital Health

On the second day of the in-situ visit, Regions4PerMed made use of the special opportunity of the EKFZ InnoDays 2022 that took place at the Center for Regenerative Therapies TU Dresden (CRTD) on 22nd to 23rd September 2022. The Else Kröner Fresenius Center for Digital Health is a **joint cross-faculty initiative** at the Technische Universität Dresden, and the Carl Gustav Carus University Hospital Dresden along with other partners on the Dresden campus. The Center was founded based on a grant of 40 Mio. Euro for a period of 10 years by the Else-Kröner-Fresenius Foundation. The EKFZ for Digital Health is included in the list of best practices of Best Practices of KA1 and KA3, as it is relevant for both fields. The main focus of the center is to **facilitate and ignite on campus innovation in the field of digital health**.

For this, the EKFZ for Digital Health is following three approaches: (1) innovative project funding, (2) developing talents and professionals, and (3) building a strong on-campus and outward industry network.

The EKFZ InnoDays supported all three purposes. The conference with its integrated exposition included a presentation of 22 ongoing development projects that are being or have been supported by the center with funding. It also included a number of high level and inspiring scientific presentations, which gave the audience new insights into the field and **a glimpse into the future of medical technology and digital healthcare**. In addition, all of the **EKFZ-projects shown in the exhibition were presented orally**. Also, the third purpose of the center to build a strong scientific and industry network for digital health in Dresden and beyond, was served by providing networking pitches which allowed regional organisations and initiatives to present their specific competencies and offerings for the digital health community. Many ties to regional SMEs and international players have been set up and collaborative structures formed, including a participation in the newly formed and federally funded SEMECO cluster to promote AI application in medtech products and regulatory processes. An outline of the programme is provided in Annex B.

With its **flexible funding format**, **proof-of-principle projects on campus can be financed** for up to two years and up to 400 T Euro per project. Project funding can also be used to leverage further funding from other sources. Projects need to address a medical need, integrate “new” talents, which are (clinical and tech) specialists, and integrate an experienced clinician as mentor. They need to be **interdisciplinary** and draw upon expertise that is **beyond state-of-the-art**. Topics are not restricted except for an integration of digital-health concepts. In general, projects are derived from the clinic and maintain integration into the medical context while ongoing, so they can optimally integrate the needs of patients and also of medical practitioners. The center reports that ongoing projects are characterized by **steep learning curves** and a **broad and deep knowledge transfer** between the clinic and the tech-side. During the conference, it was possible to listen to the presentation of the individual projects, and also the

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meet project teams in person, with an opportunity to learn about their motivation and ambitions. In discussions with representatives of different projects, the steep learning curves of the interdisciplinary teams became evident and also, that the route to translation of an innovation is not always straightforward for the participants.

The **keynote-lectures offered complementary knowledge** to the projects. On day one, Prof. Christian Johner, head of the Johner Institute (Konstanz, Germany), summarized the **impact of regulatory requirements on the market access of medical devices**. He noted that regulatory systems for medical devices are currently **diverging globally**. As already outlined above, in Europe, regulation is shaped by the newly introduced EU Medical Device Regulations MDR and by the In-vitro Diagnostic Regulation, IVDR. Especially the MDR regulation is perceived as a problem for industry development. Prof. Johner showed data in support of this, including an assessment of SME showing that a third of SMEs currently feels threatened in their existence by the changed legal environment and more than half of manufacturers expect a negative impact on the market introduction of novel products. One of the reasons is increased cost of certification by Notified Bodies, but also the approval times for Medical Devices in the EU are perceived as threatening, on average being more than twice as long than US approval times (see figure 4). Interestingly EKFZ is also partner in the new **SEMECO consortium**, which is federally funded as part of the Clusters4Future initiative. SEMECO stands for "Secure Medical Microsystems and Communications" and aims to significantly speed up innovation processes for medical devices by introducing AI concepts into their development but also into the regulatory processes.

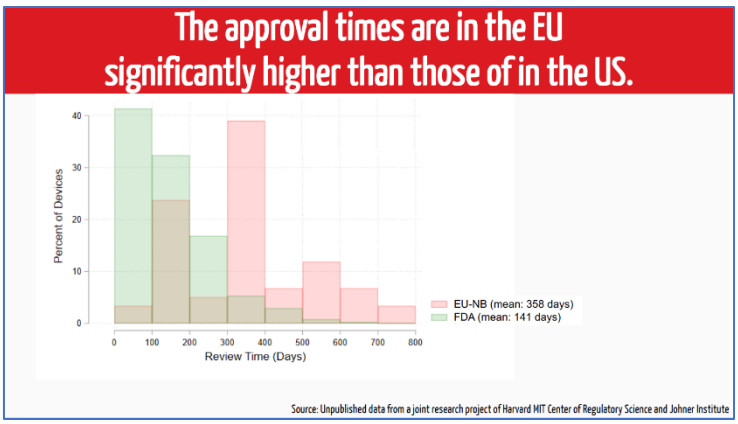

FIGURE 4: CURRENT APPROVAL TIMES FOR MEDICAL DEVICES IN THE EU IN COMPARISON TO US.

In his talk on **Artificial Intelligence in Medicine**, PD Dr. med. Daniel Truhn, senior physician at the University Hospital Aachen, explained why mutual understanding is of enormous importance in the interaction between users and machine learning models. He also stressed the importance of **making AI understandable to humans** with explainable AI as an important tool to overcome the black box effect of some AI. Constantinos Patsakis, associate professor at

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the University of Piraeus, sensitized the audience to the **importance of cybersecurity** in healthcare, stressing the high **vulnerability of such systems** and explaining which information security principles should be applied in practice.

On day two, Prof. Christoph Keplinger, Director of the Max Planck Institute for Intelligent Systems (Stuttgart, Germany), provided an overview of current **development of artificial muscles** and their **applications in robotics**. He presented a new class of self-sensing, high-performance artificial muscles, called hydraulically augmented self-healing electrostatic actuators (HASEL). Prof. Tjalf Ziemssen, head of the Multiple Sclerosis Center at Dresden University Hospital, explained the benefits, challenges and practical aspects that need to be considered when implementing **a digital twin in MS therapy**.

4 Conclusions

The in-situ visit provided a deep insight into the Saxon Ecosystem for Personalising Health Industry. The feedback of the participants (Annex C, feedback questionnaires) was very positive and specifically the networking dinner that was used as a moderated discussion was pointed out as an insightful format. It became evident that the region of Saxony can draw upon some unique areas of scientific excellence and that it is profiting from the introduction of some innovative concepts such as the Medical Forge Leipzig, the Innovation Centre for Computer Assisted Surgery, the SaxoCell Consortium, or the EKFZ for Digital Health and that these efforts are enhanced by a very active networking organisation. Also, it was notable that the existence of and investment in sufficient lab space and dedicated facilities for life sciences SME is a critical building block to support industry development.

In the discussions during the visit, most participants identified the EU MDR regulation as an obstacle for industry development. This regulation is beyond the scope of regions as is true for many other relevant regulations; however in some areas, certain aspects of regulation are implemented regionally. This may to some degree open a sphere of influence within regions which could be utilized to the benefit of the region, e.g. by developing the idea of a medical innovation region. This could be guided and supported by an “office-of-opportunity” that could also support the navigation of regulatory processes. Although only outlined in a rather vague sense, the idea could benefit from further attention. If installed properly and with good linkages to regulatory authorities, an additional and focused innovation enhancing regional agency could become a competitive benefit for further regional development. This could also be expanded cross-regionally. In such a setting, regions could become motors for harmonization of regulation in areas, where fragmentation is harmful for industry development. However, such a regional effort would need sufficient funding.

Also, regions can craft policies to enhance interdisciplinary R&D and collaboration in order to support development of industries that require such interdisciplinary approaches. This can be

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enhanced by participating in EU-wide coordinated and focused funding activities, such as ERA-Nets and European Partnerships. However, as demonstrated in Saxony by the EKFZ for Digital Health, SaxoCell and most likely in the future also by the new SEMECO Cluster, inner-regional interdisciplinary coordination is an essential component and it may create valuable new potential within a region that has the potential to become the engine for new economic development. Therefore, regions are well advised to craft and implement such R&D enhancing programmes that strengthen this approach.

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Annex A Participants In-Situ Visit

Participant	Function	Organisation	Position
Gianni D'Errico	Coordinator of Regions4PerMed	Tuscany Life Sciences Foundation, Italy	International Project Officer & European Affairs International Project Officer & European Affairs
Dr. Eva-Maria Stegemann	Partner of Regions4PerMed	SMWK	Desk Officer, European and International Affairs
Justyna Jureczek	Partner of Regions4PerMed	Wroclaw Medical University, Poland	Clinical Studies Coordinator Wroclaw Medical University Center for Clinical Studies
Dr. Joanna Misztal-Dadacz	Partner of Regions4PerMed	Lower Silesia Marshall Office, Poland	Head of the Public Health Team (Health Department)
Aldona Iwasieczko	Partner of Regions4PerMed	Lower Silesia Marshall Office, Poland	Chief Specialist of the of the Public Health Team (Health Department
Marcello De Amico	Partner of Regions4PerMed	Fondazione Regionale per La Ricerca Biomedica, Italy	Project Manager
Dr. Gretel Wittenburg	Guest of Regions4PerMed	SMWK	Desk Officer, European and International Affairs
Robert Bläsche	Guest of Regions4PerMed	SMWA	Policy Officer, Technology

Additional Guests to the Networking Dinner

Sebastian Alexander, VivoSensMedical AG (Representative of BioSaxony e.V.)

Prof. Martin Bornhäuser, Technische Universität Dresden, (Representative of BioSaxony e.V.)

Prof. Ulrike Köhl, Fraunhofer IZI, Managing Director (Advisory Board Member)

Prof. Thomas Neumuth, ICCAS, Managing Director (Advisory Board Member)

Prof. Uwe Platzbecker, Leipzig University (Presenter at KA3 Workshop)

Oliver Stenzel, Novartis Deutschland GmbH, Head of Public Affairs Pharma (Presenter at KA3 Workshop)

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Annex B Programme of EKFZ InnoDays

EKFZ Digital Health

INNODAYS

Friday, 23rd September 2022

10:00h – 10:15h	**Opening** Andreas Handschuh | Saxon State Secretary for Science Michael Albrecht | CEO of Dresden University Hospital Esther Troost | Dean of TU Dresden Medical Faculty
10:15h – 10:45h	**Keynote: The impact of regulatory requirements on medical devices** Christian Johner | Johner Institut
10:45h – 11:05h	**KIMEDS: AI-assisted certification of medical technology software** Jochen Hampe | Scientific Speaker EKFZ
11:15h – 12:00h	**EKFZ Innovation Teams** ReMoTe CarE | priorICare | iSpine | NGScopes
12:00h – 13:30h	Lunch break & Get together
13:30h – 14:00h	**Keynote: Artificial Intelligence in Medicine - Einstein or E.T.?** Daniel Truhn | University Hospital RWTH Aachen
14:00h – 14:20h	**IntelliLung** Jakob Wittenstein | Clinician Scientist
14:20h – 15:15h	**Network Pitches**
15:15h – 15:45h	Coffee break | sponsored by ZEISS
15:45h – 16:15h	**Keynote: Cybersecurity in healthcare: The landscape and theory vs. practice** Constantinos Patsakis | University of Piraeus
16:15h – 16:35h	**Regulatory Science @ EKFZ**
16:35h – 17:10h	Patientenfunk | PITROS
17:10h – 17:30h	Coffee break | sponsored by ZEISS
17:30h – 18:00h	For EKFZ Members: Mitgliederversammlung **For guests:** IIP Demo Session | lobby and 1st floor
	EKFZ | InnoNight (conference dinner)
18:15h	Bus transfer from CRTD
18:30h	Boarding at Terrassenufer, **pier 5**
19.00h	Departure steamboat LEIPZIG
22:00h	Arrival at Terrassenufer | End of InnoNight

Saturday, 24th September 2022

10:00h – 10:30h	**Keynote: HASEL Artificial Muscles - Versatile High-Performance Actuators for a New Generation of Lifelike Robotic Systems** Christoph Keplinger | Director Max-Planck-Institute for Intelligent Systems
10:30h – 11:15h	**EKFZ Innovation Teams** BrainAce | KTeXpand | OralSens
11.15h - 12:00h	**Network Pitches**
12:00h - 12:45h	Snack break | IIP Demo Session
12:45h – 13:15h	**Keynote: Multiple Sclerosis Management 4.0: MS digital twin** Tjalf Ziemssen | Multiple Sclerosis Centre, University Hospital Dresden
13:15h – 13:35h	**Clinical AI-Team @ EKFZ**
13:45h – 15:00h	**EKFZ Innovation Teams** Enhanced Catheters | AI4PD | D2EAR

Conference language is English. IIP Poster and Demo Sessions during all breaks.

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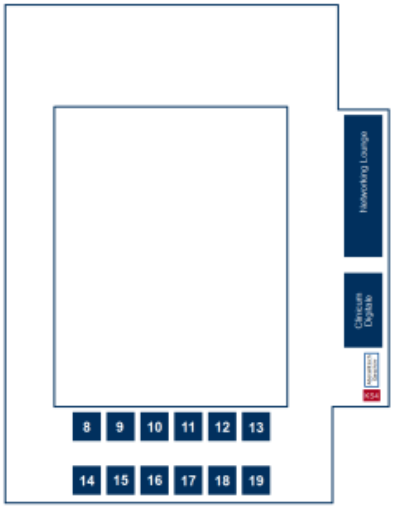
PROJECTS | DEMO SESSIONS

lobby | ground floor

- 3 D2EAR
- 7 Hybrid Echo
- 1 IntelliLung
- 4 NGScopes
- 2 Patientenfunk
- 5 VirChip
- 6 VRAD

first floor

- 14 AI4PD
- 17 CRT
- 12 imPRESSing
- 11 iSpine
- 9 KTeXpand
- 18 MOVERAD
- 19 OES
- 16 OralSens
- 8 PITROS
- 10 priorIcare
- 15 ReMoTe CarE
- 13 TransIC
- Clinicum Digitale
- 10A BrainAce
- ALERT



NETWORK PITCHES

Friday, 23.09.

Time	Pitch
14.20h	Detlef Houdeau Infineon Technologies AG
14.25h	Helena Jambor NCT/UCC
14.30h	Luis Antonio Panes Ruiz TU Dresden
14.35h	Sebastian Wolfram WOLFRAM Designers und Ingenieure
14.40h	Kristin Dittrich Universitätsklinikum Dresden
14.45h	Mirza Mohtashim Alam Institute for Applied Informatics
14.50h	Joerg Schüler Hightech Startbahn GmbH
14.55h	Iris Steinebrunner dresden|exists
15.00h	Lisa-Marie Lüneburg TU Dresden
15.05h	Karsten Wendt TU Dresden

Saturday, 24.09.

Time	Pitch
11.15h	Georg Pöhle Fraunhofer-Institut IFAM
11.20h	Nadine Leistner Mec-ABC GmbH
11.25h	Jakob Schäfer Universitätsklinikum Dresden
11.30h	Ahmad Nimr TU Dresden, Vodafone Chair
11.35h	Mariana Medina Sánchez TU Dresden, Leibniz IFW
11.40h	Timm Zörgiebel qualitype GmbH

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Annex C - Participant Feedback

(based on scanned documents, thus formatting not in all cases optimal)

2.	**Please share your thoughts and insights that you gained for each particular programme part. What did you find particularly interesting and noteworthy?**
	Day Programme 22.9.22
	Was very well planned. Fascinating walk through the Leipzig Biocity and high-end Institutes. We had deep conversations in the group and thrilling discussions on PerMed topics with local researchers and spokespersons of those locations. Very fruitful exchange.
	Networking Dinner 22.9.22
	The evening event was even at the forefront of those intense discussions. It was conducted as a high-level expert interview with direct feedback and input from other supreme participants. This kind of science-business-politics exchange was very welcome to all parties, as it was held very open and appreciative, even at points of conflicting interests. The atmosphere created the opportunity and the security to express controversial opinions and doubts as well as courageous proposals, hopes and visions for the future. Extraordinary fruitful exchange.
	Day Programme 23.9.22 EKFZ InnoDays
	-
3.	**If you compare what you know about your own regional PM innovation ecosystem to the components of the Saxon PM innovation system that were presented to you –are there notable differences in set up and approaches? Please describe.**
4.	**Are there take-home messages / models that you consider transferable and important for other European regions with an interest in Personalised Medicine and Personalised Health? Please put them down in writing**
	You need bricks and brains. If you just have one of the two it will not be sufficient for the region to further develop PerMed products to the market. It takes time to collect experiences with a lot of single cases so thirty years is not very long to draw conclusions from. That means PerMed is a topic like marathon. If you once have started to invested, you should definitely not stop, because the big success and breakthroughs will only come in the long run. In addition, the interpretation of guidelines and regulations should be made as application-oriented as possible, therefore it is necessary to have highly qualified personnel on all sides (science-economy and politics). Without the exchange on eye-level, the imbalance in this triad is disadvantageous for any kind of decision making. A perpetuated handicap for Permed.
5.	**Is there any part of the programme that you found particularly beneficial?**
	The dinner. It was a deep insight into the PerMed brains of Saxony. Thank you so much for sharing knowledge, visions and hesitations openly.
6.	**Please also let me know, what could have been done better?**
	A bit more time to rest, reflect and contemplate between the intensive visiting points.
7.	**Any other comments?**
	Thank you so much for inviting me to the great In-situ-Visit 2022. It was a pleasure being part of the group.

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2. Please share your thoughts and insights that you gained for each particular programme part. What did you find particularly interesting and noteworthy?
Day Programme 22.9.22
From my point of view, I found that all the facilities located in Leipzig and laboratories were very modern. It gave me the idea of realities that produce a lot of innovation and continuous progress.
Networking Dinner 22.9.22
About the dinner, the themes that emerged from both stakeholders (public and private) and the project partners highlighted the importance of dialogue and discussion to address existing/unsolved issues or to gather new ideas for development in research and medical field.
Day Programme 23.9.22 EKFZ InnoDays
The InnoDays, held at the Else Kröner Fresenius Center for Digital Health in Dresden, were an important opportunity to discover new innovations and technologies in the medical and device sector. It also represented an excellent symposium on present/future issues (such as artificial intelligence or Cybersecurity) as well as on laws and regulations in the field of medical devices and in general in the scientific field.
3. If you compare what you know about your own regional PM innovation ecosystem to the components of the Saxon PM innovation system that were presented to you –are there notable differences in set up and approaches? Please describe.
The impression was that the Land of Saxony and the University of Leipzig collaborate in full synergy with the ecosystem of private companies, producing enviable results in terms of research and a positive impact for the citizenship i.e., job opportunities and personal growth of students/researchers and innovation. Considering the differences among regions, it is difficult to make a comparison.
4. Are there take-home messages / models that you consider transferable and important for other European regions with an interest in Personalised Medicine and Personalised Health? Please put them down in writing
N/A
5. Is there any part of the programme that you found particularly beneficial?
The visit to the Innovation Center for Computer-Assisted Surgery (ICCAS) was unique as it was possible to see live demonstrations of truly advanced devices for imaging in surgery.
6. **Please also let me know, what could have been done better?**
N/A
7. Any other comments?
N/A

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2. Please share your thoughts and insights that you gained for each particular programme part. What did you find particularly interesting and noteworthy?
Day Programme 22.9.22
The study visit allowed for the exchange of experience and information on the implementation of the project between members of the consortium and representatives of Fraunhofer IZI, an academic institution - Universität Leipzig, Faculty of Medicine Innovation Center Computer Assisted Surgery (ICCAS). It allowed to learn about the research conducted and developed by the Institute of Cell Therapy and Immunology. Fraunhofer solutions at the intersection of medicine, life sciences and engineering. As part of the meeting, problems in the implementation of innovative solutions for industrial application or their implementation into medical procedure algorithms were identified for the Saxony Region.
Networking Dinner 22.9.22
During the meeting, the concept of transfer was introduced for personalized medicine in the light of the vision of a Medical Innovation Center in the Saxony region. Problems with the implementation of innovative solutions for industrial application or their implementation into medical procedure algorithms were identified for the Saxony Region. Numerous legislative problems were indicated in the context of implementing new technologies in Germany and individual federal states.
Day Programme 23.9.22 EKFZ InnoDays
• The impact of regulatory requirements in the Free Region of Saxony on the implementation of new solutions in personalized medicine in the field of engineering, biotechnology and medical devices. • Solutions and perspectives in the area of software certification for medical technology powered by artificial intelligence, • Possibilities and projects in the field of application of artificial intelligence in medicine, • Considerations in the field of cybersecurity in health care, with particular emphasis on the aspects of the environment, theoretical assumptions in confrontation with the current practice in the Region,
3. If you compare what you know about your own regional PM innovation ecosystem to the components of the Saxon PM innovation system that were presented to you –are there notable differences in set up and approaches? Please describe.
The visit made it possible to clarify the problems and restrictions related to implementation and implementation common to the regions implementing the Regions4PerMed Projectinnovative solutions for industrial application or their implementation into medical procedure algorithms. It contributed to the diagnosis of potential areas of mutual support between regions in the area of implementing innovative scientific solutions. The knowledge necessary to define good practices in the area of proceedings aimed at implementing new solutions in the field of personalized medicine was consolidated. It became the starting point for creating the concept of a planned new project which would be a continuation of the Regions4PerMed. The participants were talking about the role of the Lower Silesia region in coordinating activities under the new program approach, taking into account the scientific, research and implementation potential existing in the region in the field of implementation of innovative solutions for industrial application or their implementation into medical procedure algorithms.

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4. Are there take-home messages / models that you consider transferable and important for other European regions with an interest in Personalised Medicine and Personalised Health? Please put them down in writing
5. Is there any part of the programme that you found particularly beneficial?
6. Please also let me know, what could have been done better?
7. Any other comments?

2. Please share your thoughts and insights that you gained for each particular programme part. What did you find particularly interesting and noteworthy?
Day Programme 22.9.22
Every place we visited in Lepzig was extremely interesting for me. I was impressed the most in the **ICCAS,** especially with biopsy-robots and application for oncological treatment using AI. I was also fascinated with CAR T research and production in **Fraunhofer IZI**. It was great to visit the GMP facility. I find Medical Forge Leipzig extremely interesting idea and I hope such concept become more popular across Europe.
Networking Dinner 22.9.22
It was great idea to book a table in private room where we could freely discuss important and difficult issues, especially according regulatory topics. It was great discussion and I learned a lot during this evening. Great selection of invited guests.
Day Programme 23.9.22 EKFZ InnoDays
The whole idea of InnoDays I find important. It is great opportunity to present current innovations in digital medicine. It was great to see all the projects. The most interesting lecture for me was "Artificial Intelligence in Medicine - Einstein or E.T.?" by Daniel Truhn and the most interesting project for me was IntelliLung presented by Jakob Wittenstein.
3. If you compare what you know about your own regional PM innovation ecosystem to the components of the Saxon PM innovation system that were presented to you –are there notable differences in set up and approaches? Please describe.
The most straightforward observation I have is that the Saxon PM innovation system is well funded however the major drawbacks for its development are regulatory isssues (too complicated bureaucracy) what makes the innovative ideas less competitive and les attractive (because of lost of the time).
4. Are there take-home messages / models that you consider transferable and important for other European regions with an interest in Personalised Medicine and Personalised Health? Please put them down in writing
Other countries should follow the model of investing money from "carbon transformations" into Biotech and Medtech innovations development. Especially how Biocity Leipzig works.
5. Is there any part of the programme that you found particularly beneficial?
Moderated discussion during the Networking Event
6. **Please also let me know, what could have been done better?**
Everything was great.
7. Any other comments?
Thanks a lot for organizing this event ☺

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