Living Labs for Medical Technology

TED

Ш

₩

iil Ш Ш H

=

The Mannheim Model

Authors



Anna Gustedt	MANNHEIM ² Medical Technology Cluster Project Management
Martina Langhals	Medizinische Fakultät Mannheim UNIVERSITÄTSMEDIZIN MANNHEIM UNIVERSitätsklinikum Mannheim Project Management M ² AXI Usability Lab
Preetha Moorthy	Medizinische Fakultät Mannheim UNIVERSITÄTSMEDIZIN MANNHEIM MANNHEIM Head of M ² AXI Usability Lab
Dr. med. Fabian Siegel	Medizinische Fakultät Mannheim der Universität Heidelberg Universitätsklinikum Mannheim Acting Head of the Department of Biomedical Informatics

Authors are listed alphabetically by institution.

Content

Authors	2
Content	4
Preface	5
Starting point	6
Living labs: Definition and classification	8
Living labs for medical technology	9
Overview of existing living labs in medical technology 10	D
The Mannheim Model 13	3
INSPIRE Platform	6
Hybrid-OR	8
Digital patient admission – TEDIAS	D
M ² AXI Usability Lab	2
INSPIRE Living Lab	4
Structured collaboration	7
The benefits of living labs	D
Summary and outlook 36	6
Imprint	7
Literature	8

Preface

The Mannheim living labs are part of a highly innovative and dynamic ecosystem that includes a variety of stakeholders, collectively creating a unique and integrative medical technology landscape of clinics, industry and science. In these living labs, complex medical and regulatory challenges are addressed by companies and startups alike. Collaborative processes and combined expertise help to overcome these challenges. The following chapters present the Mannheim model of living labs, which serves as a beacon in the German-speaking world due to its pioneering structure in the medical technology sector.



© Freepik

Starting point

The medical technology sector is facing a number of challenges that can affect the innovative capacity and growth of young companies in particular.

First and foremost, the European Union's new Medical Device Regulation (MDR)¹ came into force on May 25, 2017, with a transitional period ending on May 26, 2021. The regulation aims to improve the safety and performance of medical devices and to increase consumer confidence in these products. However, the extensive regulation entails many new requirements and procedures - from stricter clinical evaluations to extended post-market surveillance. These additional requirements lead to longer development times, higher costs, and a more complex regulatory environment, which ultimately makes it more difficult to launch products on the market. Smaller companies and startups in particular can be overwhelmed by the new requirements and find it difficult to remain competitive. At the same time, the general shortage of skilled workers is further exacerbating the situation, making it particularly challenging to find and retain qualified personnel to conduct and analyze clinical studies.

Although artificial intelligence (AI) has the potential to revolutionize medical technology and improve patient care, the regulatory framework is often opaque and unpredictable. The **Artificial Intelligence Act (AIA)**², which was negotiated at the EU level and adopted on May 21, 2024, is an important set of regulations intended to guarantee »a balance between innovation and risk protection«³ and thus establish clear rules for the use of AI in medical technology and other areas. However, companies fear overregulation that could hold back innovation².

Currently, there are still barriers to accessing **health data**. In principle, the availability of health data is of crucial importance for the development of innovative medical technologies and the improvement of healthcare. There is vast potential for the effective use and exchange of this data to advance research and develop new medical technologies to improve medical treatments. Unfortunately, healthcare data is often difficult to access due to strict **data protection regulations** and a lack of interoperability between different data sources and systems. Companies often point out that the framework conditions for the use of health data are unclear. There is also public resentment towards the provision of such data, even in a strictly anonymized form. This makes it difficult to combine and analyze different health data, which is slowing down the development and implementation of innovative technologies.

Furthermore, factors such as unclear **reimbursement mechanisms** for the final product and the **lack of investors** influence the industry's ability to innovate. Uncertainty about the insurance companies' assumption of costs for new technologies can deter potential investors and hinder the development of innovative products.

All of these points lead to a lengthy product development time



© Adobe Stock

in medical technology. It typically takes several years from the initial idea to certification, and only then can the company start marketing the product. Consequently, startups, in particular, are dependent on external funding in order to successfully complete the product development process and avoid abandoning it prematurely. The aim should be to shorten this time and support innovative companies during this period with specialized expertise and funding.

Despite these challenges, medical technology is an important driver for improving healthcare and developing new diagnostics and therapies. By overcoming these obstacles, companies can help improve healthcare for patients around the world and have a positive impact on people's health and well-being. The state of Baden-Württemberg, in particular, is striving to become a transregional leader in the field of MedTech. Such efforts are reflected, for example, in the programs of the Forum Gesundheitsstandort Baden-Württemberg⁴ and the state agency BIOPRO⁵. The Mannheim real-world laboratories are making a decisive contribution to this strategic development.

Current challenges

- Medical Device Regulation
- Regulation in the field of Artificial Intelligence
- Availability of health data
- Financing of the company during product development
- Highly regulated product development cycle

Living labs: Definition and classification

Living labs provide the opportunity to test and develop concepts and products in an environment as close to reality as possible. Although this approach has been gaining acceptance in practice across all industries for a number of years, the literature does not provide a consistent definition of the term *»living lab*«. The term *»living lab*« is synonymous with real-world laboratories, although the term *»regulatory sandbox*« is also typically used interchangeably. In the literature, these test spaces of the future are currently viewed from different perspectives such as research-related approaches, business-promoting aspects, legal frameworks, and support options⁶⁻⁹. The state of Baden-Württemberg provides the following definition:

»Living labs as test spaces for innovation and regulation make it possible to test innovative technologies, products, services or approaches under real conditions that are only partially compatible with the existing legal and regulatory framework. They offer the opportunity to bring together society, science, business, and politics to find solutions.«¹⁰

Building on this general definition, which highlights the potential of living labs, it is worth taking a look at the typology developed by the Fraunhofer Institute for Industrial Engineering (IAO), which addresses the different ways in which living labs are designed in practice. In the publication »Innovationsmethode Reallabor« (2023), the authors identify three dimensions that can be used to classify the various real-world laboratory structures: framework conditions, ecosystem and technology. Each dimension includes several design features. The characteristics relevant to this White Paper are the innovation area and the integrated living lab.

»Innovation areas are large-scale infrastructures in which several different living labs can exist simultaneously. They can be living labs themselves and provide the infrastructure for further living labs.« »Integrated living labs are characterized by the fact that existing, complex, self-contained infrastructures are expanded to become a real-world laboratory. Living labs are not built from scratch, but are integrated into existing processes, structures or organizations that were previously largely or completely sealed off from external influences.«⁷

The Mannheim innovation area is located within the ecosystem of the University Hospital Mannheim and offers a well-designed infrastructure with several living labs of varying degrees of integration (see Mannheim model chapter, p. 13). The extent to which the Mannheim model has integrated living labs is explained in more detail in the following chapters. In general, it should be noted that living labs can provide significant benefits in the development and testing of products through collaborative processes. In the field of medical technology, this ideally means that products and ideas can be tested directly in real clinical environments. Researchers and manufacturers receive direct feedback from users, allowing them to improve the effectiveness and userfriendliness of their products and create solutions that are even more customer- or patient-oriented in the future.

Living labs for medical technology

The importance of living labs should not be underestimated, especially in the field of medical technology. This is where innovative ideas are put into practice, and new technologies are tested for their effectiveness and safety. Living labs not only provide a space for companies to apply theoretical concepts, but also allow simulation and research in the real world of patient care. Here, researchers and developers have the opportunity to test their products under real-world conditions at an early stage and optimize them to meet the highest standards of patient care. The early involvement of users makes it possible to gain important insights into the opportunities and risks of a new product at an early stage of development and from different perspectives. Based on the outcomes, innovations can be adapted and further developed into a product-ready feature for approval. This reduces the risk of undesirable developments, directly benefiting medical technology manufacturers, medical personnel, and patients.

As living labs always entail the transfer of research into practice, they can be classified according to their degree of integration into real-world environments. The following chart describes the different levels of integration of MedTech living labs on a scale from »none« to »maximum«.

Integration of MedTech living labs into real environments

Development lab

- Technical infrastructure available
- Processes cannot be mapped under real conditions

Specific living lab

- Technical and medical infrastructure and interfaces in test systems available
- Sub-processes can be simulated under real conditions
- Medical users can be involved

Integrated living lab

- Medical infrastructure and interfaces to production systems available
- Isolated scenario and physical structures in place
- Processes can be mapped under real conditions
- Medical users, hospital IT, administration and patients are involved

Real-world laboratory

- Medical infrastructure and interfaces to production systems available
- Extended scenario and structures
- Processes and logistics can be fully mapped
- Medical users, hospital IT, administration and patients are involved

None

Level of integration

Maximum

Figure 1: Own illustration of the degree of integration of living labs based on the Fraunhofer IAO classification, adapted for MedTech environments.

The **development laboratory**, on the one hand, offers the opportunity to use a technical infrastructure, but without replicating real-life conditions. In the **specific living lab**, on the other

hand, technical and medical infrastructures are available to a certain extent, as are interfaces to test systems. Here, it is possible to simulate selected real-life conditions and to involve medical users (e.g., doctors, nurses, physiotherapists). In some cases, it is not necessary to involve patients directly, as general product properties are tested that do not require a specific indication. Nevertheless, the aim here can also be to replicate real-life conditions in a simulated environment.

Integrated living labs offer an actual medical infrastructure and interfaces to productive systems. Testing is possible in selected scenarios in spatially limited areas. Processes can be mapped in real life and medical users, patients, and hospital staff from various areas (e.g., IT, data protection, logistics, compliance/legal) can be directly involved. Therefore, this test environment is not a simulation, but rather an actual day-to-day reality.

The **real-world laboratory** is the ideal vision of an extensive medical infrastructure that fully outlines processes and logistics. This includes entire departments, clinics, or an entire medical ecosystem, including the integration of general practitioners, referring physicians, and aftercare providers. Compared to a traditional development laboratory with a minimal degree of integration into real environments, integrated real laboratories and real-world laboratories offer various advantages that directly benefit both medical technology companies and patients.

>>

The Mannheim model offers an extensive infrastructure with specific and integrated living labs for testing medical technology innovations in everyday clinical practice. It ensures the direct involvement of employees in development projects and therefore assumes the characteristics of a »real-world laboratory« with a focus on clinical care and healthcare.

Overview of existing MedTech living labs

In 1999, the Massachusetts Institute of Technology (MIT) created one of the first living labs, the PlaceLab, an apartment fully equipped with sensors to study the everyday behavior of people at home⁷. At the beginning of 2000, the Finnish company Nokia brought the concept over to Europe. However, in the USA and Europe, the concept of living labs differs: North American living labs focus strongly on observation and data collection, whereas European living labs prioritize user involvement and a more inclusive approach^{7, 11}. It should also be noted that living labs in the US are often not embedded in stand-alone facilities but in larger innovation areas, such as the research department X¹² of the US holding company Alphabet Inc. (holding company of Google LLC, among others) or the Harvard Innovation Labs¹³. The following table lists a selection of living labs in the European healthcare sector that promise medical technology companies efficient market access with their range of services. All of the living labs listed are institutions with access to medical expertise. Some also offer co-design or co-creation, prototyping, and utilization studies or clinical studies. Many provide support during the development and approval of medical devices and offer training on MDR topics.

The Healthlab NRW¹⁴, the MEDERI Living Lab¹⁵, the Medical Delta Living Lab Geriatric Rehabilitation@Home¹⁸ and the National eHealth Living Lab (NeLL)¹⁹ from Medical Delta focus on innovative digital health applications. Two concepts that are similar to the offer in Mannheim are the Healthcare Living Lab Catalonia (HCLLC)¹⁶ in Barcelona, whose services include co-creation, prototyping, usability studies, clinical validation, and support with funding applications, as well as the Innovation HUB of the AP-HP (Assistance Publique - Hôpitaux de Paris)¹⁷ in Paris.

Overview of Med Tech living labs in the European region

	Components							
	Location in the Hospital*	Consulting**	Available patient data	Usability Studies	Clinical Studies	Prototyping	Co-Design/ Co-Creation	Training
	INSPIRE Platform							
HYBRID-OR	~	~		~		~	~	~
TEDIAS	~	~	~	*	~	~	~	
M ² AXI Usability Lab	~	~	*	*		~	~	*
INSPIRE Living Lab	~	~	~	*	~			
		Liv	ing Labs in th	e European r	egion	U		
AP-HP Innovation HUB (Paris)	~	<		>	*		<	
Healthcare Living Lab Catalonia (Barcelona)		(✔)***		>	~	~	~	
Healthlab NRW ¹⁴ (Düsseldorf)		(🖍)		>			*	>
LallianSe ²⁰ (Paris)	~	<						>
MEDERI Living Lab (Valencia)				(🖍)			*	
Medical Delta Geriatric Rehabilitation@Home (Delft)		~		<	~		~	
Medical Delta Instruments (Delft)	*	~		~	~	~		
National eHealth Living Lab (NeLL) (Delft)		~		~	~			
Medical Delta ResearchOR (Delft)	~	~		*	~			
OpenCare Lab (Straßburg)	(🖍)	(✔)		<			<	

Figure 2: Own illustration for an overview of living labs in Europe.

*With regard to the technical infrastructure, the mapping of real processes, and the involvement of experts and users.

** With regard to product development, approval, and potential funding applications.

*** Partially implemented.

At the AP-HP Innovation HUB, startups can apply for individual support. The projects are then pursued in one of the 38 AP-HP hospitals, where they benefit from an ecosystem of medical personnel, universities, and external stakeholders. The HUB supports the implementation of tools, provision of services, and data structuring, among other things.

In addition, more than 360 researchers from several institutions in the province of South Holland work together on an interdisciplinary basis in the Medical Delta²¹ in Delft. The Medical Delta has 16 interdisciplinary scientific programs and practice-oriented field and real-world laboratories. The medically relevant living labs include the ResearchOR²² at the Reinier de Graaf Hospital in Delft, where a multidisciplinary team operates a special operating room, the Living Lab Geriatric Rehabilitation@Home¹⁸, which investigates e-health applications for elderly rehabilitation patients in various medical facilities, the Living Lab Medical Delta Instruments²³, which develops high-quality prototypes of minimally invasive instruments for clinical pilot trials, and the National eHealth Living Lab (NeLL)¹⁹, which focuses on e-health applications. The Strasbourg-based OpenCare Lab²⁴ also has a special feature. The living lab has a recruitment platform on which registered users (healthcare professionals, patients, caregivers or citizens) are assigned to suitable projects depending on the requirements of the innovation.

Despite the differences in the approaches to living labs in the U.S. and Europe, it is worth taking a closer look across the Atlantic. In Stanford, California, a different strategy has been established to promote innovation in the medical technology sector and make it available to the market more quickly. Stanford Biodesign and its fellowships²⁵ offer various courses for students on a range of topics from product ideas to market launches, as well as a comprehensive training experience in the field of innovative health-care technology. In all fellowships, practical health technology projects are developed and implemented in multidisciplinary teams.

Based on Stanford Biodesign's offering, a number of comparable fellowship programs have been developed in various European countries, all of which pursue a similar goal: to discover unmet clinical needs and adapt them to the market. Particularly noteworthy are the BioInnovative Fellowship at the University of Galway in Ireland²⁶, Oxford Biodesign in England²⁷, the Clinical Innovation Fellowship Program in Sweden²⁸ and dHealth Barcelona in Spain²⁹.

The Netherlands has a unique multi-stakeholder infrastructure: the Health Innovation Netherlands (NI-NL)³⁰, which brings together all key stakeholders (patients, healthcare providers, regulatory authorities, etc.) involved in the use, evaluation, implementation, and expansion of innovations via a »Round Table Service«. The aim is to ensure early involvement of key stakeholders, a faster development process, and better implementation of innovations.

Overall, it can be concluded that there are many different approaches to fostering innovation, and that living labs have proven to be an effective and efficient way to do so, particularly in the medical technology sector. The absence of a uniform definition of the term »living lab« is reflected in the overview presented here; various living labs in Europe feature different components. Mannheim is characterized above all by its comprehensive range of services, in which young medical technology companies in particular can find services tailored to their specific needs in order to accelerate their product development through to market launch.

The Mannheim Model

In the heart of the dynamic Rhine-Neckar region, Mannheim offers an overview of a successful and organically grown ecosystem for innovations in the field of medical technology. Since 2011, the city of Mannheim has resolutely pursued the goal of supporting and promoting the industry in this sector. As a startup city, Mannheim offers an ideal environment for turning ideas into marketable products, particularly due to its strong focus on innovation transfer.

Location and ecosystem

Mannheim is the ideal location for successful developments in medical technology due to a large number of contributors, including the Medical Faculty Mannheim of the Heidelberg University, the University Hospital Mannheim, the Mannheim University of Applied Sciences, the Fraunhofer Institute and an established Medical Technology Cluster connected to over 250 companies in the field. This results in opportunities that can only be exploited through close cooperation and open communication between hospitals, research and companies. The city of Mannheim has succeeded in creating permanent channels and platforms for this exchange: The INSPIRE Platform is an outstanding example of this.

For several decades, clusters and cities in the region have been committed to attracting successful companies in the healthcare industry, encouraging startups and retaining established businesses on-site. This long-standing commitment to the industry has generated a critical mass of companies that provides the region with visibility on the one hand and acts as a magnet for further startups and relocations on the other.

The Rhine-Neckar region is home to a large number of universities, colleges and training centers for medical personnel, where new specialists graduate every semester. Thanks to the many attractive employers and the high quality of life in the region, they tend to stay here and are available as employees and future experts.

The foundation of these efforts, which has grown organically, is the interplay of the region's various focal points. For example, there are clear synergy effects from the strong medical and biological research in Heidelberg and the vibrant innovation and transfer culture in Mannheim. This ensures that the latest research findings are integrated directly into market-ready products and thus become beneficial to patients.

There are a number of support programs in the region to help startups take their first steps. One outstanding example is the »Life Science Accelerator Baden-Württemberg«³¹, which is

managed by the cities of Mannheim and Heidelberg. Here, founders receive guidance and training and are connected with mentors for all crucial matters related to establishing startups in the life sciences sector. In collaboration with the transfer organizations from colleges and universities and the expert network from clusters and clinics, numerous synergy effects are generated.

Living labs play a crucial role, especially in the medical field, where the development process is often lengthy and promising ideas can fail due to insufficient resources. They provide a carefully designed infrastructure and accelerate time to market maturity through direct communication with experts in the early stages of product development. Since 2015, the concept of living labs has been consistently explored and further developed onsite across all industry development projects. **The shared vision** of all stakeholders is to provide a suitable setting for each step of the patient journey by experimenting with and testing new products, from the general practitioner's office and patient admission to the hospital, surgery, rehabilitation, and prevention.

The Mannheim Medical Technology Campus is the central hub between clusters and living labs in the field of medical technology in Mannheim. It brings together innovative concepts and promising ideas to promote the growth and development of the city. Located next to the University Hospital Mannheim, the campus includes two modern startup centers, a conference center and facilities rented by established medtech companies.



UMM Campus	MMT-Campus	Alte Brauerei
University Medical Center Mannheim INSPIRE Platform	3 CUBEX41	Residential and commercial space
1 TEDIAS		Campus MaReCuM
 M²OLIE INSPIRE Living Lab 	5 TPMA 1 6 TPMA 2	Teaching and research campus of Heidelberg University
2 M ² AXI Usability Lab	7 ТРМА З	
Fraunhofer IPAHybrid-OR		

Figure 3: Bird's-eye view of the Mannheim Medical Technology Campus. © City of Mannheim The startup centers CUBEX41 and CUBEX ONE were financed by the city of Mannheim with support from the state of Baden-Württemberg and the European Regional Development Fund (ERDF). The startup centers offer a range of facilities from office and laboratory space to co-working areas and dedicated rooms specifically for startups in their early stages of operation. This enables innovative startups to concentrate their resources on product development. Established companies can rent space directly next to the startup centers within the Mannheim Technology Park, which is a wholly-owned subsidiary of L-Bank. This arrangement allows companies to transition from clinical and research operations and find the appropriate infrastructure needed for each stage of their development.



Figure 4: Business Development Center CUBEX ONE. © Daniel Lukac

The services offered by the business incubators are complemented by an integrated congress center, which hosts industry events from the region and is also available for the tenants to use at a low cost. For example, the Mannheim Medical Technology Cluster's quarterly networking events (known as MedTech Dialogue) take place on the premises, where representatives from companies, research, and clinics meet to discuss current trends and developments. Mannheim's Living Labs are closely integrated into this infrastructure. On the one hand, this is due to their physical proximity: The distance between the core of the campus and the Living Labs is only about a five-minute walk. On the other hand, there is close cooperation: As experts and consultants, the operators of the Living Labs are an important part of the support system for the young medical technology companies and many of the tenants of the startup centers are customers of one or more living labs.

INSPIRE Platform

·>> inspire



Figure 5: The INSPIRE Platform is located at the University Hospital Mannheim campus. © UMM

INSPIRE – the Development and Testing Platform for Digital Health and Medical Devices Mannheim/Rhine-Neckar was cofounded by the Mannheim Medical Technology Cluster and plays a key role in promoting innovation in the healthcare sector in the region. To optimize the companies' access to the clinic, the establishment of this industry-in-clinic platform was necessary. INSPI-RE offers individual support and guidance to the respective living lab offers directly on-site. The platform at the University Hospital Mannheim serves not only as a resource network connecting stakeholders from industry and science. It also serves as the first point of contact, particularly for startups and small to mediumsized enterprises (SMEs). After the establishment of the platform with funding from the state of Baden-Württemberg, INSPIRE has been maintained by its core partners through unfunded, ongoing regular operation since the year 2019. It offers systematic access to knowledge, technology and supply and is dedicated to the mission of initiating and supporting specific entrepreneurial research and development initiatives. Today INSPIRE is supported by six core partners that form the backbone of this platform. The INSPIRE Partners



The low-threshold and structured access to contacts within the clinic particularly enables startups and SMEs to shape transformations in clinical healthcare technologies and maximize their opportunities in the global and scalable growth market. INSPIRE bridges the gap in the innovation process that often arises from prolonged communication channels. The platform considers the individual medical, ethical, regulatory, and healthcare system challenges and provides solutions that can only be achieved through collective expertise.

INSPIRE systematically connects startups, SMEs, corporations, healthcare providers, research institutions, and experts throughout the patient journey, creating a comprehensive approach to address challenges in the healthcare sector. The INSPIRE Platform management team serves as the primary contact for all inquiries from diverse stakeholders including medical technology companies, directing these inquiries to the relevant living labs in Mannheim for further collaboration opportunities. With its core partners and many collaborators, the platform provides a highly competent network that can be consulted during every phase of product development: from preclinical research, ethics applications, funding applications, usability studies to clinical studies – in short, from the idea to practical application.

- Six strong partners from clinics and research
- One-stop store for startups, SMEs, and large companies
- Individual support that starts with the product idea
- Unique infrastructure with specific and integrated living labs
- Systematic knowledge transfer and access to care
- Support with ethics applications and government funding

Hybrid-OR

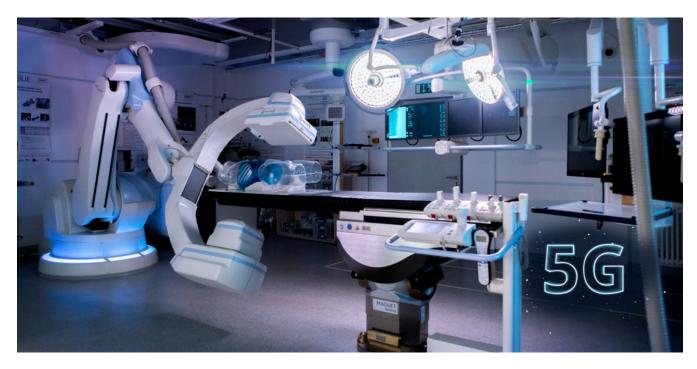


Figure 6: The experimental hybrid OR enables the development, testing, and training of technologies and processes in a simulated operating room. In addition to imaging, connection to a corresponding PACS, functional phantoms, image and sound transmission, and direct access to biolabs, the living lab also offers a modern 5G infrastructure. © Fraunhofer IPA

The operating room (OR) is a central component of hospitals, where a variety of different technologies and requirements intersect and processes are closely interlinked. In terms of technology, this ranges from special illumination and surface characteristics to positioning systems and systems for imaging, ventilation, patient monitoring, and of course, the corresponding interfaces for data exchange. On the procedural side, there is the actual intervention, along with its preparation, follow-up, and support processes as well as detailed documentation of the procedure. This is one of the reasons why operating rooms are comparatively expensive and why they are designed for the maximum possible capacity utilization. Testing new technologies, products and processes during hospital operations is only feasible, if at all, as part of a study or during off-peak times without patient operations. This makes long-term development or the study of individual scenarios that could lead to changes or downtime in the operating room extremely time-consuming and costly. On the other hand, even for developing and testing products with supposedly low degree of complexity, such as positioning aids, it is essential

to consider the interaction of processes and technologies. In this context, the available space, lighting for detecting markings, the influence on imaging, and the workflow from placement to documentation and cleaning are just a few examples. Systems with a higher level of complexity and integration requirements, such as robotic assistance systems, require additional consideration of the interaction at both technical and procedural levels with a large number of other technologies used in clinical applications.

While certain factors can be taken into account during the development process through compliance with standards, theoretical considerations, or the use of technical development laboratories, integration into a comprehensive process requires appropriate consideration in an overall realistic scenario and environment. Delays in such a realistic evaluation, whether due to cost reasons or limited availability, may result in expensive and time-consuming adjustments, or in the failure of technically functional innovations due to a lack of usability.

For this reason, the Fraunhofer Institute for Manufacturing Engineering and Automation IPA operates an experimental hybrid OR as a living lab on the campus of the University Hospital Mannheim. The OR offers application-oriented, preclinical development and testing, ranging from early stage (mock-up) to application training or comparison with established technologies. The design and equipment are modeled on a typical hybrid operating room (imaging, patient positioning, lighting, PACS connection). In addition, a modern network infrastructure (5G campus network), a selection of medical devices (e.g. operating microscope, endoscopy tower, electrosurgical instruments), and various phantoms are available in-house and via external partners. The room is equipped with systems for video and audio transmission to the nearby conference room, as well as for connecting external experts directly to the operating room.

The experimental hybrid OR is part of the Mannheim living lab ecosystem. This means that processes and technologies can also be considered that require, for example, data exchange between the OR and the ward or sample transfer between the OR and the adjacent biolab. The central location on the campus enables both medical experts and equipment from clinical departments to be integrated at short notice. The hybrid OR is often used in connection with joint development and research projects with Fraunhofer IPA. It is also possible to collaborate with other partners through Fraunhofer via the INSPIRE Platform and with technical and administrative support (e.g. radiation protection officers).

Hybrid OR – the specific living lab for testing medical technology developments and processes

- Development, testing, and training of surgical devices, procedures, and assistance systems
- Access to infrastructure and application experts
- Medical devices, tracking, and 5G network structure
- Video recording, streaming, and conference rooms

Digital Patient Admission – TEDIAS

The digital patient journey begins with patient admission. This first contact of the patient with the »hospital« already determines the completeness, structure, and quality of a large amount of data that is recorded. This includes the patient's medical history (anamnesis) and initial vital signs. The patient is informed about the procedure, the risks are explained, and consent for the procedure or, for example, enrollment in a study is obtained. While direct interaction between the doctor and patient remains highly valued, especially when providing information and clarifying questions, the recording of vital data and medical history has a very high potential for digitization and automation. This reduces the effort required to document the data and increases the completeness, availability, and comparability of the data collected.

As a result, there is a wide range of potential digital innovations in this area: from questionnaires to measurement technology, language models, dashboards, and support systems. However, an essential aspect of the development of such solutions is that they are integrated into the overall hospital workflow, allowing them to transfer the data to a common target system, e.g. a hospital information system (HIS). Otherwise, products will become isolated solutions that do not generate any sustainable added value to the workflow and are therefore unlikely to prevail. Furthermore, in the development process, user requirements of the large number of people involved in the process must be taken into account as early as possible. In addition to accessibility and usability for different patient groups, the possibility of cleaning the system using established methods, as well as the form factor, integration into existing processes, data formats, network connections, and interfaces also need to be considered.

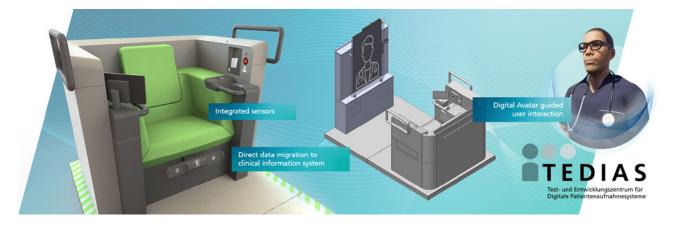


Figure 7: The basic elements of the living lab for digital patient admission (TEDIAS) is a chair into which sensors can be integrated in a modular fashion, and an interaction system supported by an avatar and a chatbot for guidance and data collection using questionnaires. The information collected in the modular workflow is summarized and transferred to the hospital information system in a structured manner.

The Test and Development Center for Digital Patient Admission Systems (TEDIAS) was established as a living lab at the University Hospital Mannheim under the technical direction of Fraunhofer IPA in collaboration with the Heidelberg University and the Medical Technology Cluster of the City of Mannheim to develop and investigate products that support digital patient admission in the early stages of the overall process. This development was funded as part of the Forum Gesundheitsstandort Baden-Württemberg. TEDIAS is integrated into the infrastructure of the University Hospital Mannheim enabling development operations for technical aspects and processes, as well as actual patient operations under the medical supervision of the University Hospital.

The entire digital admission process is mapped in TEDIAS using a

modular control system that allows for the integration and specific orchestration of new elements such as questionnaires, measurement technology, and dashboards. A secure connection to the clinical information system has been established for patient interaction, allowing the data collected to be exchanged automatically once the case number has been matched (e.g. by scanning the patient's wristband).

The patient is guided through a modular process by a customized avatar, a chatbot, and other audiovisual content.

This facilitates the evaluation and integration of new solutions into the overall workflow process.

Through close cooperation with the infrastructure and resource network of the INSPIRE Platform and the planned integration into patient portals, TEDIAS is developing into an integrated living lab. This will enable application-oriented development and testing from admission to intervention and discharge management.

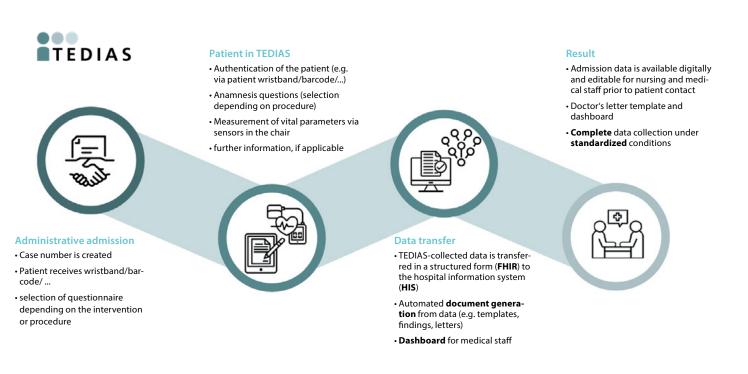


Figure 8: In TEDIAS, the entire workflow can be mapped, from the medical admission to the use of the collected data for the preparation of diagnoses. The living lab is therefore particularly suitable for investigating the patient's and staff's acceptance, but also the technical integration capability of digitalization and automation solutions. © Fraunhofer IPA

TEDIAS – the specific living lab for digital patient admission

- Development and testing of solutions for digital patient admission processes
- Living lab in development and clinical operations
- Automated and digitalized processes
- Patient guidance by an avatar and chatbot
- Structured data storage and integration into the clinical information system
- Integration of solutions into an existing framework of questionnaires, dashboards, and measurement technology

M²AXI Usability Lab

The Mannheim Medical Usability and User Experience Innovations Lab (M²AXI Usability Lab) of the Medical Faculty Mannheim of Heidelberg University is located at the heart of the University Hospital Mannheim. It serves as a central facility for evaluating and improving the user-friendliness of digital products in the medical and health sectors. A key factor of the M²AXI Usability Lab is the direct involvement of key stakeholders in the medical and healthcare sector, including doctors and patients. The central location of the laboratory at the University Hospital Mannheim promotes seamless collaboration and knowledge sharing between research, industry, and application, making it a center for innovation in medical technology. The M²AXI Usability Lab is open to all internal and external institutions, such as startups, companies, and scientific research groups, offering an integrative environment for conducting research and development. Open and inclusive access to the lab ensures that a wide range of stakeholders can use the lab's resources and expertise to drive innovation and transformation in medical device design.

The M²AXI Usability Lab supports designing medical products and software using design methodologies, such as co-creation and co-design in collaboration with the respective stakeholders to meet the needs of end users. The lab plays a large role in the various development phases of medical products and software for the medical and healthcare market, as it offers valuable insights into usability and the effectiveness of the respective design. By conducting usability testing early and often with lowfidelity and/or high-fidelity prototypes, and assessing the impact of individual design changes, developers can iteratively improve their products. This ensures an optimal user experience before market approval and launch.

The M²AXI Usability Lab features a testing room and an observation room similar to an investigation room with a one-way mirror. These are equipped with state-of-the-art technologies, creating a controlled environment for evaluating the usability of digital products in the medical and healthcare fields.



Figure 9:

The M²AXI Usability Lab features a controlled environment for evaluating the usability of digital medical products. © Medical Faculty Mannheim of Heidelberg University



Figure 10:

 $With its observation room and test room, the M^2 AXI Usability Lab offers a professional, controlled experimental setting for conducting studies. \\ @ Medical Faculty Mannheim of Heidelberg University Professional Setting for Conducting Setting Faculty Mannheim of Heidelberg University Professional Setting Faculty Professional Setting$

With the help of modern equipment and advanced instruments, such as eye-tracking devices and biometric sensors, tasks can be individually designed to meet the criteria of usability studies. These tools can collect data from the studies and deliver a detailed analysis of the participants' behavior and physiological responses. This comprehensive approach to early data collection and analysis provides valuable insights into the usability of the product, enabling iterative improvements and optimizations in the product development process. In addition to conducting usability studies, the M²AXI Usability Lab also offers consulting, services in the areas of user research, design control, and interface design and supports the documentation according to IEC 62366-1, and risk management. Further services include workshops that

integrate design thinking methods and user-centered design principles to complement the respective offerings.

The M²AXI Usability Lab is a cornerstone for innovation and transformation in medical and health products. It provides a collaborative environment and state-of-the-art facilities to advance usability and user experience. With its multi-faceted approach to testing, analysis, and consulting, the lab is shaping the future of medical technology and ensuring that products are designed to be intuitive and efficient.

M²AXI Usability Lab – the specific living lab for user experience & usability

- Specification of user requirements
- Expert feedback on medical technology products
- Recruitment of participants for studies
- Formative/summative evaluation for medical technology products
- Design of user interfaces for digital applications
- Consultation on usability documentation [IEC 62366]
- Provision of laboratory and equipment
- Workshops on design thinking and user-centered design

INSPIRE Living Lab



Figure 11: Medical devices, MedTech devices and digital health applications can be tested in the INSPIRE Living Lab at the University Hospital Mannheim in a real-life ward environment. © UMM

The INSPIRE Living Lab is an integrated living lab at the University Hospital Mannheim, where inpatients with surgical focus are treated. Here, medical products and digital health devices can be tested and further developed in real clinical settings, where realtime data can be collected for studies. This modern hospital ward features multiple testing environments with an innovative room design and a high level of technical flexibility and adaptability.

Patients from urology and the orthopedic departments are treated post-surgery in the ward. Startups, SMEs, and businesses can have their products tested by expert groups including doctors, nurses, and patients. In adherence to strict data protection regulations, product testing is also feasible for medical devices that are not yet certified.

Since it is hard to anticipate what kind of future innovations will be tested on the ward tomorrow, the University Hospital Mannheim has implemented a room design for the ward that aims to be as flexible and adaptable as possible. This ward is equipped with 27 modern beds and is designed to be "startup-ready". Removable wall panels, easy access to cable ducts, and extensive access to power and network connections enable the easy installation of sensor technology.

All patient beds are equipped with tablets that provide entertainment and information for patients (e.g. radio, internet, telephone, information about the hospital, etc.) and also allow startups and companies to make their apps available directly at the patient's bedside for testing and receiving direct user feedback. For example, the patient app FLOW from the Munich-based startup Cliniserve is installed on every patient tablet and enables communication between patients and nursing staff. Core principles of the concept of »healing architecture« have been integrated into the design of the ward.

For example, a special lighting system in the patient rooms designed to increase wellbeing, and an open desk environment instead of a closed base as the heart of the ward were considered. These renovation initiatives were made possible through funding from the EFRE (a European regional development fund) and the hospital's own financial resources.



Figures 12, 13, 14 and 15: In the open, modern hospital ward, a wide variety of test scenarios can be implemented in which doctors, nurses and IT can be directly involved. © UMM

Startups, SMEs, and companies interested in collaborating with the INSPIRE Living Lab showcase their innovations in an initial meeting, which can occur online or on-site. It will then be determined whether the INSPIRE Living Lab is the appropriate environment for potential joint projects. The Living Lab is open to startups at all stages of development, so having a prototype is not a requirement. Companies and businesses can receive feedback from the clinic at any time. If there are clinical areas that are more relevant to industry partners than those offered by the Living Lab, the management team will facilitate contact with the INSPIRE Platform to connect the startup or SME with them and find suitable contacts. Before a product or prototype is tested in the Living Lab, all formalities concerning data protection, IT connections, and contractual steps are processed, followed by the active test phase. The INSPIRE Living Lab is an integrated living lab, as it is incorporated into the daily routine of a hospital ward at the University Hospital Mannheim. In this environment, processes are not mimicked or simulated; instead, testing occurs within the actual hospital workflows.

The processes and workflows are based on the standards of medical and nursing care and allow testing under real conditions.

INSPIRE Living Lab - the integrated living lab in the hospital

- Real clinical ward routine
- Integration into actual clinical processes
- Expert feedback
- Modern IT infrastructure with various connection options
- Integration of patients

Structured collaboration

Despite being affiliated with different institutions, the living labs in Mannheim are within walking distance of one another and connected under the umbrella of the INSPIRE Platform. While the INSPIRE Platform management office and the M²AXI Usability Lab are associated with the Mannheim Medical Faculty of Heidelberg University, the INSPIRE Living Lab is directly affiliated with the University Hospital Mannheim. The Hybrid OR and TEDIAS are also situated on the campus of the University Hospital Mannheim, but they are operated by Fraunhofer IPA. Owing to the diverse sponsorships and affiliations, the organizational and conceptual trajectories in the individual testing environments are different. This diversity is precisely the reason each organization addresses product developments at varying degrees of maturity and within distinct contexts and settings and a range of research questions. For this reason, mutual support in collaboration with startups, SMEs, and companies is also feasible among the individual living labs without competition. This enables the exploitation of synergy effects and provides long-term support for startups from one living lab to the next.

Through close collaborations, all stakeholders of the Mannheim model benefit equally from greater publicity, which in turn also increases the awareness of Mannheim as a MedTech hub. The partners meet regularly to plan joint campaigns and stay informed about current developments in the individual living labs. The INSPIRE Platform coordinates external inquiries in order to provide startups and companies with the right contact person within the Mannheim network. On the one hand, this simplifies the startups' search for a suitable cooperation partner, but also guarantees the professionalism of the request vis-à-vis the internal contacts, as the INSPIRE management office already carries out preliminary screenings.



Figure 16: Process from the request to the project consortium on the INSPIRE Platform. Own representation. Figure 16 shows the structured approach within the INSPIRE Platform from the initial inquiry from startups to collaborative projects. Once initial contact is established, the INSPIRE management identifies a suitable core partner from the network. If the core partner and the associated living lab show interest in collaborating, a contact group is created, to handle the detailed project development and the necessary organizational steps. The Mannheim model of living labs facilitates support from product conception to sustainable application in practice through organized collaboration.

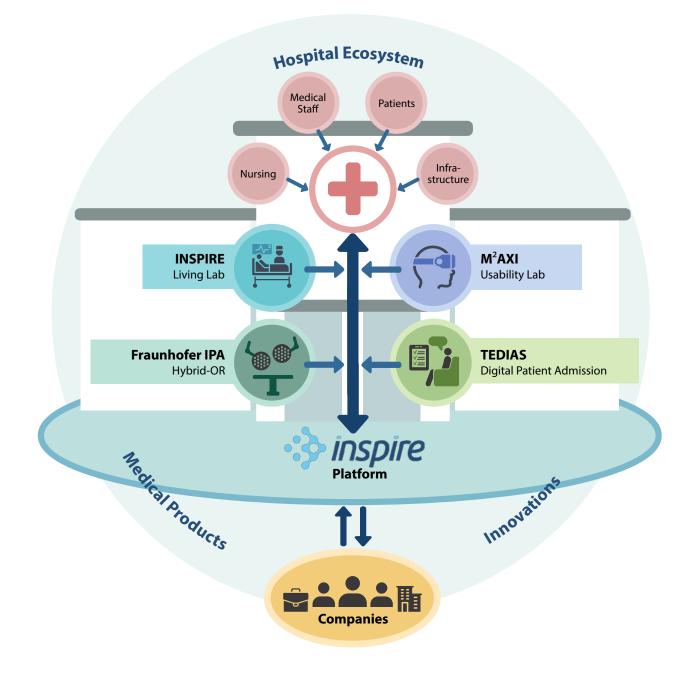


Figure 17: Representation of the Mannheim living labs in the hospital ecosystem. Own representation.

The startup's path with the Living Labs within the product development cycles

The Mannheim model supports startups, SMEs, and companies in the MedTech ecosystem from the initial idea to the finalization of the product. The aim is to engage in early and organized discussions with potential users and customers starting from the initial concept or early stage of development of a potential medical device or digital health application. From the outset, startups can engage and connect with potential customers and users to gather valuable feedback. The specific purpose of a product can be shaped through the involvement of experts along with feedback from users and customers. The development process can be intentionally iterative so that the product can be tailored to medical needs. This approach accelerates product development and subsequent validation. Certification and market launch can therefore be planned and prepared effectively.

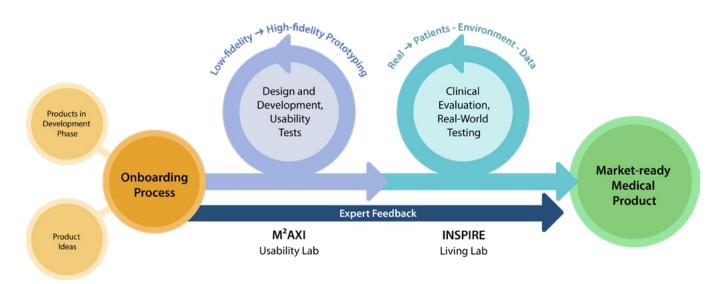


Figure 18: From onboarding to market maturity: the innovation path from the M²AXI Usability Lab via the INSPIRE Living Lab to the medical device.

The Mannheim living labs collaborate closely, providing strong support for startups, SMEs and companies from the initial product idea to certification and market entry. The INSPIRE management office acts as an intermediary between these different phases of product development. For each necessary subsequent step of the development process, it connects the company with other experts from the clinical environment and the extended Mannheim ecosystem.

The benefits of living labs

Benefits for companies	»Living labs improve the innovative strength and competitiveness of companies, as they enable products and workflows to be tested under real-world conditions.«
Benefits for patients	»Living labs improve patient care through participatory approaches that enable custo- mized solutions for complex challenges in the healthcare sector.«
Benefits for the clinic	»Living labs provide medical personnel with a testing environment to explore innovative solutions and optimize existing workflows.«
Benefits for science	»Living labs enrich science by establishing a direct connection between theory and practice and addressing complex healthcare challenges in a real interdisciplinary setting.«
Benefits for the region	»Living labs strengthen and promote the inno- vative capabilities of a specific location.«
Synergies	»The collaboration among living labs enables a comprehensive representation of complex interrelationships. In the Mannheim model, clinical processes can be illustrated with a high degree of realism and accuracy.«
Benefits for society	»Living labs accelerate innovation, promote social participation, and facilitate the transfer of solutions for a sustainable and digital future.«

Thesis 1 – Benefits for companies

»Living labs improve the innovative strength and competitiveness of companies, as they enable products and workflows to be tested under real-world conditions.«

Living labs, due to their proximity to everyday clinical practice, provide companies of all sizes the opportunity to gain practical insights into the performance and marketability of their products and services. This approach reduces the likelihood of adverse developments bypassing end users and ensures co-creation with users, thereby facilitating the identification of early opportunities and risk assessment²¹. The earlier a product is tested, the better, as user-friendliness and expectations can be incorporated iteratively. At the M²AXI Usability Lab at the University Hospital Mannheim, usability studies of products can be conducted during the early stages of development, and at a later stage, they can be tested in clinical practice at the INSPIRE Living Lab. Especially startups benefit from engaging with the livings labs early on.

This interaction allows them to refine their business plans at the outset, allocate resources and finances effectively, and test their innovations at various stages, promoting sustainable development. Compliance with MDR standards mandates the implementation of a quality management system, a structured documentation process, and, above all, clinical studies for conformity. This poses considerable challenges for companies. It is therefore an additional advantage, especially for startups, to address the

regulatory requirements for the approval of their medical device at an early stage.

By involving user groups such as physicians, nurses and patients, product development can be tailored directly to customers. This approach reduces the costs associated with the delayed consideration of usability and user experience studies. Living labs provide companies the opportunity to enhance their innovation processes, more effectively align their product developments with market demands, and consequently remain successful and agile in the long term. This streamlined product development cycle generates competitive advantages, enabling companies to respond more swiftly to market changes.

Another crucial aspect is the collaboration among experts from different disciplines working closely in living labs. Experts from fields such as medicine, engineering and data science bring their unique individual perspectives to create holistic solutions. This interdisciplinary teamwork not only promotes innovation, but also enables more efficient integration of new technologies into clinical practice.

Thesis 2 – Benefits for patients

»Living labs improve patient care through participatory approaches that enable customized solutions for complex challenges in the healthcare sector.«

Engaging particular patient groups ensures that medical products directly meet their needs. Gathering direct feedback fosters active participation in the development process, symbolizing patient empowerment. This involvement positively affects the quality of life and disease management as new ideas are applied alongside direct patient participation. For instance, in the INSPIRE Living Lab, inpatients are directly involved and play a key role in product development. Similarly, the M²AXI Usability Lab enables research studies involving a wide range of patient groups.

As described in thesis 1, living labs facilitate faster product development leading to earlier market launches. This directly benefits affected patient groups and improves their inpatient care or everyday medical routine. Living labs offer benefits not only to patients receiving treatment directly within them but also improve long-term care for broader patient populations in society. For instance, elderly patients often find it difficult to access digital technologies. However, it is precisely this population that can benefit greatly from medical technology tools, as they are more likely to suffer from multimorbidity. The design and development of digital health applications, especially in collaboration with the elderly, can largely help this population group to maintain their independence and manage their daily lives, improving their overall quality of life. The studies conducted in the living labs can focus on these affected groups and incorporate usability considerations from the earliest stages of development.

Thesis 3 – Benefits for the clinic

»Living labs provide medical personnel with a testing environment to explore innovative solutions and optimize existing workflows.«

By collaborating with startups, living labs offer insights into the latest developments in medical technology. By testing and experimenting with a wide range of entrepreneurial solutions to a specific problem, the clinic can identify the best approach and, when applicable, implement it permanently. At the University Hospital Mannheim, a comprehensive plan for a new clinic building is currently underway and insights gained from the INSPIRE Living Lab will directly influence its design. The hardware, software, and processes that have been successfully tested in the Living Lab will be considered from the outset in the planning of spaces, equipment, and usage concepts.

Often, there are numerous possible solutions to a problem. For instance, the INSPIRE Living Lab allows the testing of which options are most suitable for effective use at the University Hospital Mannheim. Moreover, innovative approaches and workflow optimizations can be assessed in the hybrid operating room. In addition to serving as a platform for companies, the hybrid operating room also serves as a training and educational center for healthcare professionals. By practicing in a realistic environment, physicians, nurses and technicians can hone their practical skills and prepare for complex situations. This helps to optimize patient care and improve the quality of medical services.

The inclusion of real patient data establishes a direct connection to clinical practice. Thanks to the establishment of suitable IT infrastructures, living labs can break down data silos and promote data integration. The Data Integration Center (DIZ) at the University Hospital Mannheim provides support for networking and data extraction as needed. By involving multiple providers, certain comparability among individual product groups addressing similar topics is achieved. Furthermore, product-specific studies, as well as meta-analyses and social studies, can also be conducted. Living labs thus create an environment where data from real-world daily operations can be collected in a structured and comparable manner.

The INSPIRE Living Lab demonstrates that an innovative environment fostering employee engagement has a powerful impact, largely increasing workplace appeal. Despite the ongoing nursing shortage, the nursing team for this newly established ward is fully staffed. A considerable number of these new employees actively sought positions in the Living Lab from external sources. A key motivator mentioned was the opportunity to actively engage and contribute to shaping their professional responsibilities and the hospital environment. Additionally, the clinic and its patients gain valuable insights into current trends and advancements in the digital health sector. This not only offers new perspectives for medical personnel, enriching their professional experience, but also allows patients to experience firsthand how cutting-edge developments improve their medical care.

Thesis 4 – Benefits for science

»Living labs enrich science by establishing a direct connection between theory and practice and addressing complex healthcare challenges in a real interdisciplinary setting.«

Living labs provide researchers with the opportunity to conduct studies in real clinical environments, enabling a deeper understanding of complex phenomena and processes. With interdisciplinary collaboration, experts from various fields can exchange ideas and methods, ideally leading to innovative solutions. By testing hypotheses and prototypes in real-world contexts, researchers can assess their feasibility, effectiveness, and scalability, thereby accelerating innovation and technology transfer. In this regard, living labs, such as those in the Mannheim model, enable the testing of solutions to complex problems in realistic conditions.

The inclusion of stakeholders such as local communities, industry partners, and policymakers ensures that the research produces relevant outcomes that address societal needs. This inclusive approach also accounts for the concerns and requirements of the respective target groups. Living labs support the development of medical and healthcare products through scientific research and the sharing of findings in academic publications.

Collaborative exploration of extensive medical technology issues can be facilitated by the coordinated efforts of interconnected living labs. This approach prevents data gaps and enables interdisciplinary investigation of research questions. For instance, in Mannheim, research questions can span from patient admission to the operating room and inpatient settings. The Usability Lab allows selected experts, users, and patients to participate in data collection during all phases of the research project. By bringing together experts across different disciplines, new insights can be gained that contribute to effectively addressing critical health challenges and improving overall healthcare delivery.

Thesis 5 – Benefits for the region

»Living labs strengthen and promote the innovative capabilities of a specific location.«

Living labs, particularly when integrated into a dynamic ecosystem such as Mannheim's, enhance the attractiveness of the area to emerging startups and companies. This is due to multiple factors, including opportunities for product testing, expert feedback, proximity to clinical practice, access to a comprehensive resource network, and modern, state-of-the-art infrastructure.

The location's reputation and appeal are largely enriched when a substantial number of startups and companies have established themselves, particularly when successful transfer projects – especially those supported by living labs – are consistently showcased. This emphasis on transfer has been a hallmark of Mannheim for years, highlightedby the high number of business incubators in the city. Living labs expand, refine, and make this approach even more tangible by adding new components to the model.

The ecosystem created by the living labs establishes a robust network of diverse expert groups centered around transfer and product development. This not only benefits the living labs and startups but also strengthens the entire location by broadening access to expertise and infrastructure.

The Life Science Accelerator Baden-Württemberg, a comprehensive support system, also promotes the establishment of startups and companies in the Mannheim area. They assist startups in addressing various economic challenges by providing a centralized pool of knowledge, workshops, consulting services, and a robust network. Many stakeholders in the region bring decades of experience in the MedTech industry. This expertise benefits the ecosystem, increasing the region's appeal and elevating its prominence on both national and international levels.

Thesis 6 – Synergies

»The collaboration among various living labs enables a comprehensive representation of complex interrelationships. In the Mannheim model, this indicates that clinical processes are illustrated with a highest degree of realism and accuracy possible.«

The Mannheim living labs focus on various stages and aspects of clinical care. By fostering close collaboration through established frameworks, synergy effects can be generated. The collective efforts of these living labs promote knowledge exchange and build expertise, leading to an accelerated innovation process. Through this collaborative work best practices and insights can be shared across the labs, effectively reducing redundancies, speeding up problem-solving, and streamlining development cycles. For startups, the interconnected living labs in the Mannheim model offer numerous advantages. For example, all inquiries from SMEs can be efficiently channeled within the ecosystem, ensuring they are addressed promptly by the appropriate contact. Overall, this approach enables unique support for companies throughout the entire value chain – from the initial idea to the commercialization of the medical product.

In the Mannheim ecosystem, the medical care process can be gradually mapped through living labs, and new living labs can be added as needed. These labs can also benefit from joint public relations efforts, including shared exhibition stands, information events, and workshops. The INSPIRE Platform plays a coordinating role in this process. The Mannheim living labs are currently on their way to becoming a comprehensive real-world laboratory that focuses on clinical and care-related areas. This harmonized infrastructure provides an excellent foundation for regional and even national visibility.

Thesis 7 – Benefits for society

»Living labs accelerate innovation, promote social participation, and facilitate the transfer of solutions for a sustainable and digital future.«

Living labs play a crucial role in society as they offer a space to experiment with and develop groundbreaking innovations. They accelerate transformations in socio-ecological areas, for example, advancing new technologies and concepts in medical care. By implementing and testing these innovations under real-world conditions, it becomes easier to understand their functionalities and their potential contributions to society.

Furthermore, living labs provide the freedom and open space where individuals can learn how to maintain protection and security standards for personal and highly sensitive data in an increasingly digital world. Health data, in particular, requires special protection. By testing technologies and concepts in real environments beforehand, potential risks can be better assessed, and appropriate security measures can be developed.

Moreover, living labs encourage participation and strengthen societal acceptance of innovations by giving the civil society the opportunity to actively engage in the development of new solutions. This approach helps ensure that innovations are more closely aligned with the needs and demands of society – making them more likely to be embraced by users.

Another important contribution of living labs is their ability to facilitate and accelerate the transfer of innovations into practice. By practical testing in real-world environments, it becomes easier and quicker to identify which innovations are already successful and which may still require further development. This allows for more flexible and faster scaling of technologies and concepts, both technologically and socially.

Overall, living labs help strengthen a society's capacity for innovation and accelerate the transition to a more sustainable and digital future. They play a vital role in addressing complex societal challenges and provide space for creative solutions.

>>

Living labs are essential hubs for progress in medicine and medical technology. They allow not only for the development and validation of innovations, but also promote collaboration and the training of specialists. The continued investment in living labs ensures that the future of medical care leads to continuous improvement in patient care through sustainable developments.

Summary and outlook

The Mannheim living labs are part of an excellent network through the INSPIRE Platform and have consolidated their resources in all key stages of medical technology product development – from the inception of an idea to its market readiness. The expertise and areas of application are diverse and offer interested startups and SMEs a wide range of access, resources, and services. To enhance engagement with the various regional stakeholders, the living labs are currently developing a recruitment platform, similar to the one established at the Opencare Lab in Strasbourg²⁴. The platform will eventually allow patients, medical professionals, and interested citizens to seamlessly sign up for tests and studies involving new medical technology products.

In addition, the Mannheim innovation area will be further expanded over the next few years. Although the already well-equipped living labs cover several steps of the patient journey, it remains essential to implement additional real-world laboratories, particularly when the patient journey is complex for certain conditions, such as cancer. Building on the many years of extensive work at the Mannheim Molecular Intervention Environment (M²OLIE)³³ Research Campus, a real-world clinical care laboratory for cancer patients with oligometastases will be established at the University Hospital Mannheim. In the so-called M²OLIE Clinic, complex medical processes will be advanced further and new test settings will be made available in these areas. The aim is also to involve the AI4U³⁴ (»Artificial intelligence for digital personalized mental health promotion«) at the Central Institute of Mental Health (ZI Mannheim) more closely. The living lab investigates digital transformation in the healthcare sector by applying AI methods to digital mobile health (mHealth) training tailored to the individual, the moments, and the contexts in the real world to promote the mental health of adolescents and young adults. The city of Mannheim is also planning to support the establishment of additional living labs that can address scenarios related to prevention and rehabilitation.

The current living labs in Mannheim can pave the way for similar initiatives in other locations and have a progressive effect on the development of the vision and concept. Overall, the expansion of additional living labs is essential in order to tackle the major health challenges of tomorrow. For startups, SMEs, and large companies, this means an even more extensive and individualized

access point for their innovations, ultimately leading to faster innovation cycles.

The educational mission of the Mannheim living labs for society, facilitated by the participation of universities, is set to expand further in the future. By collaboratively organizing and participating in events, such as the »Long Night of Startups and Culture«³⁵, the connection between research, cutting-edge technical innovations, and society at large will be solidified as an essential cornerstone in Mannheim. Through even more intensive participatory processes, the living labs of the future will prove their added value in society.

Imprint

Typesetting and layout: Vanessa Stachel

All rights reserved. © 2024

Literature

1

European Union. New Regulations - European Commission. Published May 27, 2024. Accessed June 7, 2024. https://health.ec.europa.eu/medical-devices-sector/new-regulations_en BVMed-Stellungnahme zum "Artificial Intelligence Act" (AIA) der EU-Kommission: "Überregulierung vermeiden, Datenzugang ermöglichen". 2. BVMed. Accessed May 13, 2024. https://www.bvmed.de/verband/presse/pressemeldungen/bvmed-stellungnahme-zum-artificial-intelligence-act-aia-der-eu-kommissionueberregulierung-vermeiden-datenzugang-ermoeglichen Einheitliche Regeln für Künstliche Intelligenz in der EU. Die Bundesregierung informiert | Startseite. Published May 22, 2024. Accessed June 28, 3. 2024. https://www.bundesregierung.de/breg-de/themen/digitalisierung/kuenstliche-intelligenz/ai-act-2285944 Forum Gesundheitsstandort Baden-Württemberg 4. https://www.forum-gesundheitsstandort-bw.de/ueber-das-forum/ueber-das-forum-gsbw 5. Landesagentur BIOPRO https://www.bio-pro.de/de/biopro VDI/VDE Innovation + Technik GmbH, Deutsche Gesellschaft für Biomedizinische Technik im VDE, IGM Institut Gesundheitsökonomie und 6. Medizinmanagement HN. Studie zur Identifizierung von Innovationshürden in der Medizintechnik. Accessed April 23, 2024. https://www.gesundheitsindustrie-bw.de/application/files/9014/3521/2666/import_06269_de.pdf Anduschus P, Bienzeisler B, Prochazka V. Innovation im Blick Innovationsmethode Reallabor. Accessed April 23, 2024. 7. https://publica-rest.fraunhofer.de/server/api/core/bitstreams/5184aa79-10e2-4fa6-8341-2e178cf46576/content Wanner M, Fischedick M, Liedtke C, Baedeker C. Thesenpapier: Reallabore als forschungsbasiertes Innovations- und Transformationsinstru-8. ment. Published March 15, 2023. Accessed April 23, 2024. https://www.bundestag.de/resource/blob/937516/c25c2242080e70b431da58d349a03df8/A-Drs_20-18-103a-data.pdf 9. BMWK-Bundesministerium für Wirtschaft und Klimaschutz. Grünbuch Reallabore-Konsultation für ein Reallabore-Gesetz und ergänzende Maßnahmen. Accessed April 23, 2024. https://www.bmwk.de/Redaktion/DE/Downloads/G/gruenbuch-reallabore.html 10. Reallabor zu Künstlicher Intelligenz in Gesundheit und Pflege gestartet. Baden-Württemberg.de. Published October 21, 2022. Accessed April 23, 2024. https://www.baden-wuerttemberg.de/de/service/presse/pressemitteilung/pid/ reallabor-zu-kuenstlicher-intelligenz-in-gesundheit-und-pflege-gestartet 11. Ballon P, Schuurman D. Living labs: concepts, tools and cases. info. 2015;17(4). doi:10.1108/info-04-2015-0024 12. X, the moonshot factory. https://x.company/ 13. Harvard Innovation Labs https://innovationlabs.harvard.edu 14. Innovations-Ökosystem - Das Healthlab NRW Lab fördert und entwickelt. https://healthlab.nrw/ 15. MEDERI Living Lab: MEdical Devices Research and Innovation. http://mederi.ai2.upv.es/en.html 16. Healthcare Living Lab Catalonia (HCLLC) https://healthcarelivinglab.cat/ 17. Innovation HUB des AP-HP (Assistance Publique – Hôpitaux de Paris) https://www.aphp.fr/connaitre-lap-hp/recherche-innovation/linnovation-lap-hp 18. Medical Delta Living Lab Geriatric Rehabilitation@Home. https://www.medicaldelta.nl/en/living-labs/medical-delta-living-lab-geriatric-rehabilitation-home National eHealth Living Lab (NeLL). Medical Delta. 19. https://www.medicaldelta.nl/en/living-labs/national-ehealth-living-lab-nell

- 20. LallianSe Life Sciences Integrator | Building the successful environment for healthcare innovations. https://lallianse.com/site/home-en/
- 21. Medical Delta in Delft (Niederlande) https://www.healthinnovation.nl/
- 22. Medical Delta Living Lab ResearchOR. https://www.medicaldelta.nl/en/living-labs/medical-delta-living-lab-researchor
- 23. Medical Delta Instruments. https://www.medicaldelta.nl/en/living-labs/medical-delta-instruments
- 24. OpenCare Lab.
- https://www.opencare-lab.fr/
- 25. Stanford Biodesign und seine Fellowships https://biodesign.stanford.edu/
- 26. BioInnovative Fellowship der University of Galway in Irland https://www.bioinnovate.ie/how-we-do-it/fellowship.html
- 27. Oxford Biodesign in England https://www.oxhealthtechlabs.org/
- 28. Clinical Innovation Fellowship Programm in Schweden
- https://clinicalinnovation.se/about-cif/ 29. dHealth Barcelona in Spanien
 - https://dha.bihealth.org/
- 30. Health Innovation Netherlands (NI-NL) https://www.healthinnovation.nl/
- 31. Life Science Accelerator Baden Württemberg https://www.lifescience-bw.de
- 32. BMWK-Bundesministerium für Wirtschaft und Klimaschutz. Reallabore Testräume für Innovation und Regulierung. Published October 7, 2023. Accessed June 7, 2024.
 - https://www.bmwk.de/Redaktion/DE/Dossier/reallabore-testraeume-fuer-innovation-und-regulierung.html
- 33. Forschungscampus M²OLIE

https://www.m2olie.de

- 34. Reallabor AI4U am Zentralinstitut für Seelische Gesundheit (ZI) Mannheim https://ai4u-training.de/
- 35. Lange Nacht der STARTUPS und KULTUR NEXT MANNHEIM. Accessed April 23, 2024. https://next-mannheim.de/events/lange-nacht-der-startup-und-kultur/

Contacts

Fraunhofer IPA - »Healthcare Technologies and Processes« Theodor-Kutzer-Ufer 1-3 CUBEX41 | Haus 41 68167 Mannheim

INSPIRE Platform

University Medical Center Mannheim Theodor-Kutzer-Ufer 1-3 68167 Mannheim https://www.inspire-mannheim.de/

INSPIRE Living Lab

University Medical Center Mannheim Theodor-Kutzer-Ufer 1-3 68167 Mannheim https://www.livinglab-umm.de/

M²AXI Usability Lab

Department of Biomedical Informatics Medical Faculty Mannheim of Heidelberg University Theodor-Kutzer-Ufer 1-3 68167 Mannheim https://www.umm.uni-heidelberg.de/miism/biomedizinische-informatik/m2axi-usability-labor/

City of Mannheim

Mannheim Medical Technology Cluster CUBEX ONE Franz-Volhard-Straße 5 68167 Mannheim https://medtech-mannheim.de/