

PAPER

Stakeholders of Cardiovascular Innovation Ecosystems in Germany: A First Level Analysis and an Example

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ABSTRACT

This paper aims to provide a first attempt towards analysis innovation ecosystems for cardiovascular pathologies in Germany through the use of a stakeholder model. We present essential stakeholders for the development and deployment of innovations in the field of cardiovascular research and medicine, and the primary functions they fulfill in the context of these innovation ecosystems. The adopted approach consists of the implementation of a multilevel system model for analyzing stakeholders in this particular field. Data acquisition transpired through systematic literature review of multiple articles and studies. Data analysis phases were executed until reaching a point at which the considerable amount of data was discovered, ensuring consistency across various sources. We demonstrate that innovation ecosystems in cardiovascular medicine involve interconnected networks of stakeholders across different fields. Moreover, through an investigation of innovation ecosystems of cardiovascular pathologies particularly in Germany, we present the functions undertaken by each stakeholder, which are essential for the participation in the innovation ecosystems. The findings presented in this paper hold the potential to bring better understanding of cardiovascular pathology innovation ecosystems in Germany. This assertion is substantiated through a comprehensive examination of relevant scientific literature.

KEYWORDS

cardiovascular pathologies, innovation ecosystems, stakeholder analysis

1 INTRODUCTION

Cardiovascular disease takes a central place in German healthcare. It is the most common cause of death in Germany and was responsible for 43.9% of all deaths in women and 36.1% in men in 2012 [1]. Similarly high are the numbers for Europe, accounting for 45% of all deaths [2]. Furthermore, they dramatically impact the health of individuals and, therefore, cause high healthcare costs for the government. Due to steadily increasing incidence of cardiovascular diseases, they have become one of the primary reasons for hospital admissions and readmissions, and in this

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respect, preventing readmission of patients with cardiovascular pathologies is one of the main priorities for clinicians, researchers, and other stakeholders [3].

Cardiovascular diseases have great relevance to modern healthcare in Germany and worldwide because of their prevalence rates. The major factors that influence the manifestation of these diseases, such as obesity, diabetes mellitus and high blood pressure, can be moderated through lifestyle changes, including healthy diet, weight loss and improvement of fitness [4]. Innovations in the sphere of prevention, diagnosis and therapy of cardiovascular pathologies have enabled a substantial reduction in the age-adjusted cardiac mortality rates since the 1950s [5]. These innovations can be directly related to integration of various tools and techniques. Noteworthy examples involve introduction of the intra-aortic balloon pumps introduced by Kantrowitz [6], promotion of defibrillators by Zoll and others [7], development of coronary angiography by Sones [8], advancements of right heart catheterization techniques by Ganz and Swan [9], innovation of percutaneous intervention by Grüntzig [10], and the introduction of transcatheter aortic valve insertion by Cribier [11] among other breakthroughs. The development and integration of these novel tools highlight how the innovation allowed to significantly contribute to the advancement in patient care outcomes [12].

Although these innovations have indeed brought about a revolutionary transformation in cardiovascular clinical practice, barriers continue to exist. The optimal approach to advancement requires the concerted involvement of a diverse array of stakeholders united by a shared vision. It is this aspect that one may expect to be the unique value proposition of the various innovation ecosystems. Bolstering collaborations within the field of cardiovascular therapy is the key, necessitating partnerships spanning technology enterprises, including large, small and medium sized or start-ups, different industrial sectors, academic institutions, and other private actors, with an emphasis on various forms of innovation. The objective lies in establishing connections between patients, clinical researchers and technology developers, in order to push advancements in a field of cardiovascular disease therapy

2 METHODOLOGY

For the conducted literature review stakeholder analysis was used to identify the relevant stakeholders of cardiovascular innovation ecosystems in Germany. The search of relevant literature for this review was performed through the PubMed database (<https://pubmed.ncbi.nlm.nih.gov/>).

The higher order search terms were ‘cardiovascular disease’, ‘innovation’ and ‘stakeholder’. This led to the discovery of a journal article with a headline ‘Innovation in cardiovascular disease in Europe with focus on arrhythmias: current status, opportunities, roadblocks, and the role of multiple stakeholders’ [13].

Based on this article, stakeholder categories of this particular field were identified. Research was identified as the most important part of innovation and the subsequent search through the PubMed database with keywords ‘cardiovascular’, ‘research’ and ‘Germany’ took place. A journal article titled ‘Cardiovascular Research in Germany’ was identified as highly relevant [14]. It helped in getting a more in-depth analysis of the research facilities in Germany such as universities, research institutions and various scientific societies.

The data of specific research institutions, scientific societies and governing bodies was acquired through the annual reports of the respective institutions and for the period between 2013 to 2022, which are publicly accessible on the official websites of each of them, such as the German Research Foundation (DFG.de), the

German Centre for Cardiovascular Research (DZHK.de), the Max Planck Institute for Heart and Lung Research (MPI-HLR.de) and the Institute for Quality and Efficiency in Health Care (IQWiG.de). For the acquisition of data concerning specific investors and private companies, the annual reports of these companies were used.

The specific example of Topaz tricuspid heart valve that we present in Section 5 as an empirical example took place during the investigation of TRiCares as a private company that operates in Germany. Data concerning this innovation has been acquired through the PubMed database, utilizing ‘Topaz’ and ‘transcatheter’ keywords.

3 RESULTS

Innovation in the field of cardiovascular pathologies, same as in other fields, requires a combination of various contributing factors and resources. Innovation ecosystems, defined as complex networks of organizations, individuals, and institutions collaborating to drive innovation, are recognized for their role in initiating advancements across various sectors, including healthcare. Understanding the dynamics of stakeholders within cardiovascular innovation ecosystems is essential to enable effective collaboration and support the rapid translation of research findings into impactful clinical solutions. For Germany, there are several contributing stakeholders deeply interconnected with each other, as illustrated in Figure 1, that can facilitate innovation which we briefly present in the next subsections.

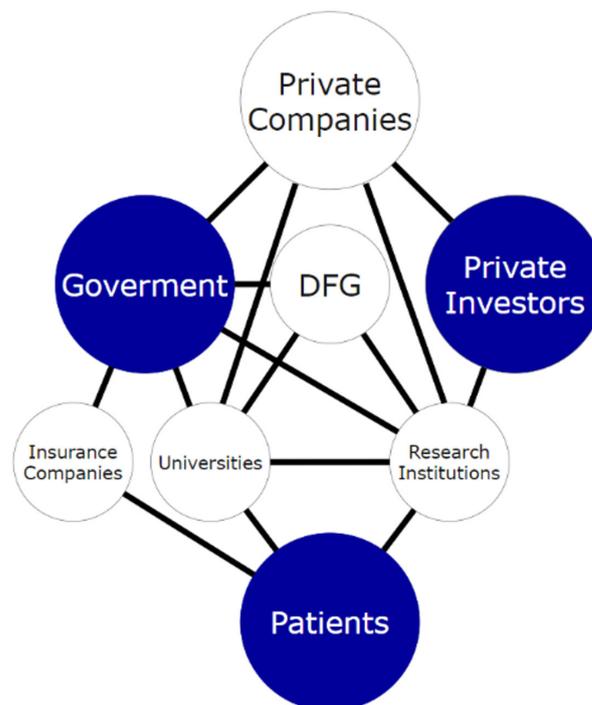


Fig. 1. Contributing stakeholders for the German medical and in particular cardiovascular pathologies ecosystem

3.1 Government

The German government takes up a central place in the cardiovascular innovation ecosystem in Germany. One of the most significant ways the German

government supports cardiovascular innovation is through research funding. The government allocates funds to support research in cardiovascular health through various channels, including federal and state research agencies, as well as collaborative initiatives. Organizations such as the German Research Foundation (DFG) and the German Center for Cardiovascular Research (DZHK), which derive their funding exclusively from the government, distribute considerable resources to support projects in cardiovascular research.

The government plays a crucial role in shaping policies that influence cardiovascular innovation. It can further strengthen primary care to deliver prevention, early diagnosis and management of cardiovascular diseases by introducing innovative elements such as benchmarking and monitoring of patients. Government synchronizes policies with innovation objectives and by that means creates an ecosystem suitable for growth and development of modern cardiovascular technologies [15]. The German government has shown a keen interest in promoting the integration of digital solutions into healthcare delivery. Initiatives like the “Digital Health Applications” program support the development and implementation of digital tools for cardiovascular risk assessment, remote patient monitoring, and telemedicine consultations [16].

The Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) establishes policies to provide guidance at the federal level. It develops laws and provides guidelines for autonomous activities inside the healthcare system. It is responsible for the administration of multiple institutions and other entities that handle diverse challenges faced by German healthcare. One of these institutions is Federal Institute for Drugs and Medical (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). It is responsible for making decisions regarding the approval of innovative medications and medical devices. The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) is tasked with making decisions regarding which medical services will be included in coverage provided by statutory health insurance (Gesetzliche Krankenversicherung, GKV) and the form of this coverage [17].

Quality assessment of health care is another responsibility of the Government. The Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) is responsible for carrying out this function. It is a public entity independent of insurance companies and healthcare providers. IQWiG evaluates advantages and risks associated with new therapies and diagnostic procedures, by collecting and analyzing the available research data about these therapies and procedures. The outcomes of their analysis are then to be taken into account when making a decision regarding health care [17]. For instance, this institution receives all the preoperative, intraoperative and postoperative data about every patient with statutory health insurance undergoing any type of heart valve replacement. Afterwards, this data will be anonymized, carefully examined, and presented annually [18].

Collaboration and partnership between the government and private sector, including medical device companies, is essential to advance cardiovascular innovation. These collaborations *provide a translation of research discoveries into practical applications* ranging from advanced medical devices to new treatment methodologies. The German government encourages such collaborations through initiatives like tax incentives for research and development activities in exchange for novel technologies and knowledge [19]. It supports patient advocacy organizations and, by involving patients in discussions about research priorities and treatment options, ensures that innovative solutions are aligned with patient needs [20].

3.2 Academic and research institutions

Academic and Research Institutions within the cardiovascular innovation ecosystem include a diverse range of organizations dedicated to advancing scientific knowledge, training the next generation of cardiovascular researchers and healthcare professionals, conducting cutting-edge research, exploring innovative technologies, and investigating the molecular and physiological basis of cardiovascular diseases. These institutions include universities and other research institutions.

Universities. Renowned universities with medical and life sciences faculties represent a key stakeholder group in a field of cardiovascular innovation. They contribute to research, education, and collaboration that drive advancements in the field.

Cardiovascular academic medicine in Germany was traditionally separated into clinical cardiology and basic science departments, such as physiology, pharmacology, and pathology. Over the past three decades, this model has experienced gradual evolution [21]. The majority of university cardiology clinics now not only engage in clinical cardiology, but also perform basic science studies. Basic cardiovascular science used to be limited to traditional university departments such as physiology, pharmacology, and pathology. Nowadays there are numerous university chairs (Lehrstühle) dedicated to experimental cardiovascular medicine, operating under diverse titles and designations. Consequently, there is growing pressure to secure competitive external funding to sustain operations and research projects [14].

Research Institutions. Research Institutions are playing a very important role as a stakeholder in cardiovascular innovation ecosystems in Germany. Examples of notable German research organizations are the German Centre for Cardiovascular Research (DZHK), the Max Planck Society, the Leibniz Association, Fraunhofer Society and Helmholtz Centers. These research organizations have their own research institutes dedicated to cardiovascular research [21].

The German Center for Cardiovascular Research (DZHK) consists of a network of 31 notable research institutions allocated across seven partner sites, including centers of the Helmholtz Association, Max Planck and Leibniz Institutes in addition to 14 university hospitals [22]. 90 percent of its funds come from the Federal Government (Bundesrepublik Deutschland) and 10 percent from State Governments (Bundesland) in the regions these institutions are located [23]. The main objective of the DZHK is to encourage comprehensive collaboration between outstanding scientists who specialize in cardiovascular research. These collaborations among scientists in the field of cardiovascular research should enhance the translation between scientific insights and clinical practice and advance the exchange of knowledge [24]. DZHK places a strong emphasis on turning research discoveries into real world benefits through strategic planning and targeted financial support. [25].

The Max Planck Society (MPS) maintains The Max Planck Institute for Heart and Lung Research (MPI-HLR) dedicated to cardiovascular research. It's funded by both the Federal Government and State Governments. About 18 years ago, the MPI-HLR was restructured, gaining its new focus on the cardiovascular and pulmonary systems. Since then, basic cardiopulmonary research has been a dominant theme at the MPI-HLR. This has led to numerous groundbreaking discoveries which had an enormous impact on the research community. Research in MPI-HLR laboratories is mainly funded by the Max Planck Society (MPS), the German Research Foundation (DFG) and the German Center for Cardiovascular Research (DZHK) [26].

3.3 German research foundation

German Research Foundation (DFG) plays a prominent role as a stakeholder, advancing innovation in the field of cardiovascular pathologies in Germany. It is the most important funding organization in Germany. It is governed by scientists, who are nominated by the universities and elected by all active scientists including post-doctoral fellows. It independently selects research projects on a competitive basis and distributes money, which is contributed by the federal state (70%) and the individual states of Germany (30%), that is, tax payers' money. The funding of individual research projects and scientists makes up to 45% of their annual budget. It is the largest research funding program in Germany, accessible to all fields of science [14]. To encourage commitment of universities to a certain field of research, DFG also supports networks of various sizes within universities and groups of universities and other entities. For example, research units support small consortia (around 6–9 projects) and Collaborative Research Centers support larger consortia (around 15–10 projects) [14].

A Research Unit (Forschergruppe, FOR) is formed by a team of researchers collaborating on a research project that goes beyond the funding available for individual grants. These types of projects have a medium-term duration, usually around 6 years, and involve aspects like topic focus, duration, and funding. Clinical Research Units (Klinische Forschungsgruppen, KFO) are specific medium-term research projects that require coordinated efforts because their expected outcomes cannot be achieved through individual grants alone. They offer similar opportunities for disease- or patient-centered clinical research [14].

More extensive networks are sustained by Collaborative Research Centers (Sonderforschungsbereiche, SFB), which operate within the defined structure of a 12-year funding trajectory. Transregional Collaborative Research Centers (Transregio, TRR) constitute networks including up to three universities. Among the existing 268 CRCs, a notable proportion, approximately 2.9%, are concentrated on cardiovascular research. Additionally, cardiovascular scientists are engaged in CRCs that cover a wider scope than just cardiovascular disease and include interdisciplinary collaboration [14].

Clusters of Excellence (Exzellenzcluster, EXC) are specialized research networks composed of universities and research institutions. These were launched in 2019 and aim to spark innovations in German universities. This is meant to be achieved through the funding of project-based research at universities, the improvement of research profiles, and the facilitation of collaborative efforts within the research ecosystem [21].

DFG also provides specialized graduate training initiatives in cardiovascular research or fields closely associated with it. These initiatives, known as Research Training Groups (Graduiertenkollegs, GRK), are instituted within universities and receive backing from the DFG for a period of up to 9 years. Their objective is to furnish doctoral education within a well-defined research framework, coupled with a thoroughly designed training regimen. These programs serve to cultivate early scientific autonomy and encourage independent scholarly pursuits [21].

3.4 Pharmaceutical and medical device companies

Pharmaceutical and medical device companies assume an exceptionally important role in the cardiovascular ecosystem innovation in Germany, as they are not only involved in research, development, and therapies for cardiovascular diseases but are assigned the role of bringing these innovations into practice and, as

a consequence, to the market. Germany is an attractive market for medical device companies involved in cardiovascular technologies. They invest heavily in research and development and collaborate with various research facilities, such as universities and research institutions, to create innovative cardiovascular devices and technologies and to conduct clinical trials to test the safety and efficacy of their devices and to gather data and demonstrate the effectiveness of their products. They continuously innovate to create new and improved cardiovascular devices such as pacemakers, stents, catheters, and imaging equipment. Among these companies, are, for instance, JenaValve Technology with a focus on developing and manufacturing innovative heart valve replacement technologies, such as transcatheter aortic valve replacement (TAVI) [27], Osypka Medical, who specializes in electrophysiology and interventional cardiology products, including catheters and diagnostic tools to diagnose and treat heart rhythm disorders [28], Medtronic, who offers a huge variety of cardiovascular devices, including cardiac rhythm management, structural heart, and coronary and peripheral intervention solutions [29] and numerous others.

The rising prevalence of cardiovascular diseases and a growing preference for minimally invasive medical procedures are influencing the expansion of the market. According to the statistics of the German Heart Surgery Report 2021 [30], there were a total of 161,261 cardiac procedures performed in Germany in year 2021. Among them, 36,714 were heart valve procedures and 19,490 were pacemaker and cardiac implantable electronic device-related procedures. These numbers illustrate how high is the demand for cardiovascular devices in Germany [31].

3.5 Investors

The development of innovative medical technologies requires substantial to not say extreme amounts of financial resources in the form of direct investments. Investors support the research and development of these technologies, which greatly enhance the diagnosis and treatment of cardiovascular diseases. Investors provide essential financial support to startups, research institutions, and healthcare companies working on cardiovascular innovations. They also support various clinical trials by providing seed funding and investments to test the safety and efficacy of new therapies. For example, High-Tech Gründerfonds (HTGF) is one of Germany's largest venture capital firms, focusing on technology startups. They currently invest in healthcare companies working on innovative cardiovascular solutions, such as advanceCOR, a drug-developing biotech company which focuses on a cardiovascular diseases research, and Capical, a world leading company for contact-free ECG-measurement via capacitive electrodes [32], Wellington Partners, who provided financial support to TRiCares during the development of minimally invasive tricuspid heart valve replacement system [33], Sunstone, who supported JenaValve Technology in the development of trilogy heart valve system [34] to name only a few. These examples illustrate the diverse range of investors and organizations involved in cardiovascular innovation in Germany. They provide resources, helping to drive advancements in cardiovascular healthcare into innovative applications and product offerings.

3.6 Insurance companies

Insurance companies have an interest in promoting cardiovascular health to reduce the prevalence of costly claims related to cardiovascular diseases. It lies also in the

sphere of their interests to promote a healthy lifestyle and offer preventive measures, such as regular check-ups, screenings, and wellness programs. They analyze large volumes of wealth to health-related data to identify high-risk groups, to detect potential issues and to develop targeted interventions. Insurance companies provide financial support for cardiovascular innovation through investments, partnerships, and funding mechanisms. They engage patients in their cardiovascular health by providing information about innovative treatments, lifestyle changes, and disease prevention.

Insurance companies seek the balance between the advantages of innovation and economic sustainability. Their priority is to improve procedures, end results and quality of life, but they must at the same time take economics of healthcare sector and operational effectiveness into consideration. It can be complicated to a certain degree to integrate an innovative treatment into standard healthcare because of extended assessment periods and the necessity, sometimes, for regulatory changes related to health insurance. Public health insurance companies in Germany, for example, take part in an innovation fund with an intention to stimulate and accelerate innovations to improve patients' outcomes [13].

3.7 Patients

Patients and their families serve as catalysts for cardiovascular innovation by demanding better treatments, diagnostics, and therapies. Their perspectives, needs, and experiences are central to the development, adoption, and success of innovative cardiovascular technologies and treatments. Patients are essential participants in clinical trials and research studies related to cardiovascular innovation. Their willingness to participate in these trials helps researchers evaluate the safety and efficacy of new treatments and technologies. Their feedback contributes to continuous quality improvement in healthcare institutions and influences healthcare policies and regulations. Patients' input addresses ethical concerns in cardiovascular research and care, such as privacy, consent, and transparency, in sharing medical information, and helps to shape guidelines, reimbursement policies, and regulatory decisions related to cardiovascular therapies.

Patient advocacy groups, such as the German Heart Foundation (Die Deutsche Herzstiftung), play a significant role in representing the interests of cardiovascular patients. These groups collaborate with healthcare professionals, researchers, and other stakeholders to ensure that innovations align with patients' needs and preferences and contribute to better outcomes in cardiovascular care. To further advance medical progress, the German Heart Foundation also actively engages in research funding.

4 AN EMPIRICAL EXAMPLE

The validity of the proposed definition of innovation ecosystems can be illustrated through an empirical case of the development of the Topaz tricuspid heart valve replacement system. In recent years, innovative, minimally invasive transcatheter therapies, such as transcatheter aortic valve implantation (TAVI) and transcatheter mitral valve implantation (TMVI), have induced a revolution in clinical practice, significantly contributing to a better patient treatment and reducing mortality among high-risk patients [35]. Nevertheless, there was no comparable treatment for patients with tricuspid regurgitation. Severe tricuspid regurgitation is a common condition affecting the tricuspid heart valve, often leading to poor outcomes. However, a substantial number

of patients are ineligible for surgery due to the significant surgical risks [36]. The viable surgical procedures such as isolated tricuspid valve repair and tricuspid valve replacement are associated with a hospital mortality as high as 10 and 20% respectively [37]. Because of such high mortality during an open heart surgery, a minimally invasive transcatheter option of tricuspid valve implantation was being developed by TRiCares.

TRiCares is a medical device startup organization that was established in 2013, with its headquarters located in Paris, France, and its operational base situated in Munich, Germany. Its main objective was to help people affected by severe tricuspid regurgitation by introducing a transfemoral tricuspid valve replacement system, replacing an open heart surgery that was associated with high mortality and offering them a better option. The company has garnered support from prominent European investment companies, including Andera Partners, Wellington Partners, BioMedPartners, Credit Mutuel Innovation, GoCapital and Karista [39]. Notably, the first successful implantation occurred at University Hospital Henri Mondor in Créteil, France, on June 7, 2021 and the first successful implantation in Germany took place at University Hospital Mainz, on 8 April 2022 [38]. The first-in-human study [39] started on 15 July 2022 and the primary completion is estimated to be on 15 October 2023. This clinical study is financed by TRiCares and takes place in numerous hospitals in Europe. This case of the development of the minimally invasive Topaz tricuspid heart valve illustrated in Figure 2 shows the interactions of various stakeholders in the field of cardiovascular pathology innovation ecosystems.

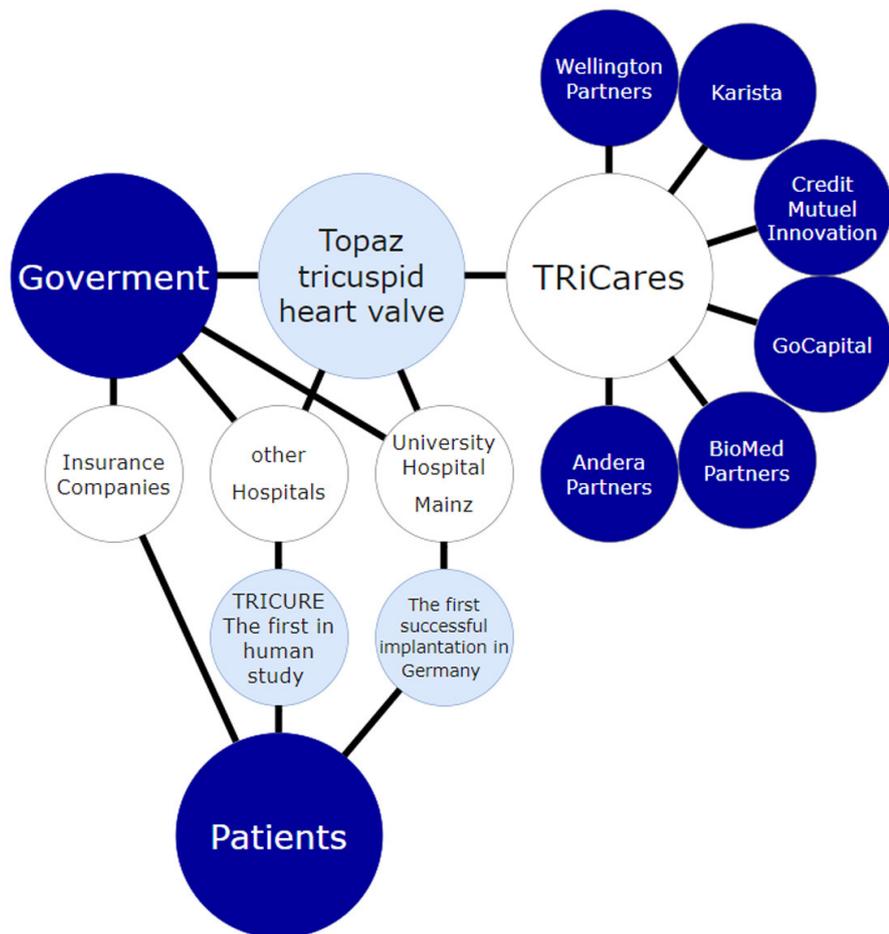


Fig. 2. Ecosystem for the case of the development of the minimally invasive Topaz tricuspid heart valve

5 DISCUSSION AND CONCLUSIONS

As identified in [40], ‘orchestrating scientific work in educational research laboratories is demanding, especially when many interdisciplinary perspectives are involved’. This applies to the case of innovation ecosystems in medicine at large as well as in any specific case of tackling a disease or a pathology. Their role will be dramatically increasing, as a result also of the proliferation of artificial intelligence (AI) in healthcare, and as digital health start-ups are bringing new digital technologies and services to the market, allowing for cost savings and service improvements in the healthcare sector [41]. The importance that these may have on ‘the growth of the respective demand and supply sides’ and the resulting ecosystems has been examined in [42] with the use of a practical example.

The existing literature barely explains the complexity of ecosystems of cardiovascular innovation, regarding the range of stakeholders and their role within the ecosystem. In our report we tried to address this deficiency by means of identifying the relevant and demonstrating the complexity of cardiovascular innovation ecosystems which consist of multiple levels and each level comprises various stakeholders. Additionally, we elaborate the role of each stakeholder in the engagement within the ecosystem and follow the dynamics of cardiovascular research through the analysis of its catalysts. The outcomes reinforce the point of innovation ecosystems continuously advancing, rather than functioning at a certain level of development.

Germany’s cardiovascular innovation ecosystems thrive due to the *active participation and collaboration of a diverse set of stakeholders*. From academic institutions and healthcare providers to government agencies and patient advocacy groups, each plays a unique and critical role in driving forward advancements in cardiovascular care. As innovation continues to evolve in response to the ever-changing landscape of cardiovascular diseases, these stakeholders will remain essential in shaping the future of German healthcare. The development of collaborations between key stakeholders in Germany has undeniably improved interactions within the ecosystem of cardiovascular innovation, supporting a conducive environment for the synergistic evolution of technologies and the equitable exchange of resources.

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