

EUHA INNOVATION

Prescription for Progress: University Hospitals as Innovation Hubs and Drivers of Economic and Societal Development in Europe



Full Title: University Hospitals as Innovation Hubs and Drivers of Economic and Societal Development in Europe

This paper is authored by the EUHA Innovation Network, with contributions from representatives across all EUHA member hospitals. A dedicated writing committee, coordinated by Thomas Gazlig from Charité – Universitätsmedizin Berlin (thomas.gazlig@euhalliance.eu & thomas.gazlig@charite.de), has led its development. Designed as a living document, the paper aims to provide an evolving framework for fostering healthcare innovation within EUHA institutions. It will be updated regularly to reflect new insights and advancements; the current version is from June 2024.

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Introduction

Innovation is vital for the progress of society and a core function of European university hospitals. Innovation facilitates the realisation of personalised, sustainable, and forward-thinking medicine, while also maximising the impact of life science research through efficient knowledge valorisation. It also offers a pathway to tackle present and future workforce challenges, along with barriers that impede healthcare service quality and capacity.

To promote innovation in healthcare, the <u>European Univeresity Hospital Alliance</u> (EUHA) has established its <u>Innovation Network</u>, bringing together innovation leaders from both the clinical and knowledge valorisation sectors within its member hospitals. On behalf of EUHA, the Innovation Network has developed this living document to explore solutions to unlock the potential of innovation for better healthcare and improved patient outcomes, a competitive European economy, and to enhance the sustainability and future readiness of university hospitals and the healthcare system at large.

In this paper, EUHA discusses key factors preventing innovation from thriving in today's organisations. It provides an understanding of the innovation process across the EUHA members and proposes possible solutions for decision-makers to stimulate the innovation ecosystem. The paper starts by setting out the importance of innovation and its essential role within university hospitals. It explores challenges leading to sub-optimal European innovation capacity and recommends actions to strengthen European health innovation. Specifically, how university hospitals can serve as innovation hubs and what actions must be undertaken to strengthen the European innovation ecosystem and to benefit society, patients, and the economy. The paper could also be seen as a repository that maps a broad spectrum of innovation measures from which tailored action could be derived.

We are pleased to present this paper to decision-makers within government at the national and European level, particularly in the fields of life sciences and health, and university hospital management.

Executive Summary

Innovation, as a transformative force, is the cornerstone of driving progress, particularly in the healthcare sector where it directly translates to improved patient outcomes and societal wellbeing. University hospitals stand at the forefront of healthcare transformation, serving as innovation hubs that integrate research, clinical practice, and education. EUHA emphasises the pivotal role university hospitals play in stimulating economy. Healthcare will become a major part of future industry by providing a more efficient and sustainable healthcare and delivering precise patient management that requires fewer workforces. The key drivers of this process lie in the role of university hospitals as innovation hubs, making impact orientation part of the scientific currency and promoting consistent standardisation, such as the future University Hospital Spin-out and Investment Terms Guide based on the recently published University Spin-Out Investment Terms (USIT) Guide. At the same time, it is crucial to reduce administrative burden and allocate sufficient resources to knowledge valorisation.

University hospitals are uniquely positioned to lead healthcare transformation from a patient perspective, valorise knowledge through technology transfer, and optimise organisational processes. However, realising this potential requires a paradigm shift towards impact orientation—a mindset change underpinned by cultural transformation within academic systems that values innovation achievements alongside traditional academic metrics.

To catalyse innovation, EUHA advocates for simplifying and accelerating innovation processes by improving the conditions under which they operate. This involves establishing innovation as a strategic field across university hospitals and fostering an environment conducive to ideation, validation, and value creation—the three phases of the innovation journey.

Key areas of focus include:

• **Mindset Change and Cultural Transformation:** Encouraging a culture that rewards impactoriented activities is essential. This shift necessitates recognising the economic and societal benefits of scientific achievements early on and fostering entrepreneurial attitudes among staff.

- Strategic Emphasis on Innovation: Innovation must be embedded as a core strategic endeavour
 within university hospitals. This includes prioritising research findings that benefit patients and
 society while ensuring fair economic participation for the institutions in case of commercial
 success.
- **Streamlining Innovation Processes:** Simplification and acceleration of administrative processes are crucial for leveraging innovation potential. Standardisation can create transparency, simplify decision-making paths, and enable quicker negotiations based on established standards.

The EUHA paper outlines five fields of action to drive innovation:

- **Ideation**: University hospitals should drive a culture where innovation is an integrated part of healthcare and seen as fundamental for improvement of efficiency and precision, and in addition is valued as an important element of academic achievements. This involves establishing accessible idea offices for staff to share and develop concepts with innovation managers, who can guide promising ideas towards realisation. Emphasising impact orientation in academic evaluations and celebrating successes publicly will encourage a more entrepreneurial mindset, essential for nurturing groundbreaking innovations.
- Validation: Intellectual property (IP) management is critical in the validation phase, ensuring that
 research outcomes are protected and can attract industry investment. Effective IP strategies
 should complement scientific publications, not hinder them. University hospitals need to balance
 open science with securing patients at the right time, providing mandatory training for
 researchers and physicians on IP management, and establishing clear conflict-of-interest policies
 to maintain transparency and trust.
- Value Creation: For innovations to reach their full potential, university hospitals must enable fair
 economic participation and establish structures and programmes to reinvest revenues into
 innovation activities (innovation funds). Transparent startup-friendly models and term sheets will
 accelerate spin-off processes while safeguarding patient interests. A compact set of KPIs should
 be defined to measure innovation performance without adding administrative complexity,
 ensuring a focus on creating tangible societal and economic value.
- Organisational Improvement: Innovation should be part of the core strategy of university
 hospitals, with clear mandates from leadership teams. Simplifying administrative processes and
 adopting digital solutions will enhance operational efficiency. By investing in technology
 transfer offices and fostering an entrepreneurial spirit within the organization, university
 hospitals can become more agile and responsive to the dynamic nature of healthcare innovation.

• **Collaboration & Open Innovation:** Sharing best practices through a centralised repository can optimise patient care across institutions. Establishing effective procurement systems for innovative solutions ensures that resources are allocated efficiently, avoiding redundant development efforts. Collaborations with companies through public-private partnerships are crucial for bringing innovations to market, requiring streamlined legal frameworks at national and European levels to facilitate these joint ventures effectively.

EUHA's vision extends beyond regional confines; **international collaboration is vital for accessing new markets and maintaining competitiveness.** Engaging with private sectors through **public-private partnerships** is also emphasised to drive forward innovative endeavours.

In conclusion, university hospitals have the potential to be powerhouses of innovation that contribute significantly to Europe's economic growth and social advancement. By adopting a culture that embraces risk-taking, prioritises impact orientation while assessing research results, simplifies processes, and fosters collaboration across borders, these institutions can unlock their full potential as catalysts for transformative change in healthcare delivery and medical research.

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Promoting Innovation in University Hospitals

Europe is confronted with significant challenges and innovation is the key to addressing, for example, health crises and fostering future social and economic development. University hospitals, along with their affiliated medical faculties and universities, are hubs of innovation, offering a wide range of healthcare services, conducting fundamental and clinical research, and continuously generating medical knowledge, excellence, and discoveries through their highly skilled professionals. This makes them an ideal place for creating long-term impact on healthcare, society, and economy. Furthermore, university hospitals serve as hubs for educating and training our future professionals. At the same time, university hospitals are confronted with the sense of urgency that society and the healthcare system are experiencing. Widespread workforce shortages, increasing necessity for healthcare transformation, and the acute realisation that health emergency preparedness is necessary, are creating a perfect storm that is imposing significant pressures on the economy and social cohesion, while testing the very fabric of our societies.

Innovation serves as a central pillar for EUHA, strategically and operationally. It offers a pathway to tackle present and future workforce challenges, along with barriers that impede healthcare service quality and capacity. Innovation facilitates the realisation of personalised, sustainable, and forward-thinking medicine, while also maximising the impact of life science research through efficient knowledge valorisation.

What is innovation?

Innovation is defined as something new or substantially different that is implemented to create value, while an invention is the first appearance of a novelty (product, process). Therefore, innovation does not exist if it is not implemented.

The crucial role of innovation in expediting knowledge translation to industry and patients, creating societal impact, and addressing the growing, diverse, and sometimes acute healthcare demands in times such as during the COVID pandemic cannot be underestimated. **University hospitals, which combine research, clinical practice, patient access, and rapid capacity of implementation of solutions, are excellent environments for the fostering of innovation.** By this, they contribute to regional, national, and European economic and societal progress.

Innovation transcends mere healthcare; it encompasses the expansion of the workforce, sustained and continuous investment in university hospital innovation ecosystems and infrastructures, and tax benefits that attract investors, budding enterprises, and top talent. Collaborating with engineering departments, university hospitals serve as powerful catalysts for advancements in medicine, patient care, and health engineering. Take mRNA vaccines, for instance—an innovation originating from academia. While industry scales and distributes these vaccines, it is academia - together with university hospitals - that initially drives impact. This underscores how innovation generates systemic and individual benefits, such as improved patient outcomes, job creation, the development of novel products and services, and increased tax revenues.

Innovation should be an important part of university hospital missions and core strategic endeavours, ensuring research discoveries benefit patients, healthcare systems, and society at large, with a focus on impact by caring and curing. Ideally, this also leads to some monetary gains. For this, it must be ensured that in the event of economic success, the university hospital benefits in a fair and reasonable manner so that the revenues could be re-invested for further development of the innovation infrastructure within the university hospital in order, create a self-sustained cycle.

EUHA views university hospitals as innovation hubs and pivotal drivers of economic and societal advancement in Europe. Such innovation hubs are dynamic environments crafted to promote creativity and breakthroughs. University hospitals possess unique expertise that positions them as ideal nuclei for innovation hubs. They cultivate vibrant environments conducive to spin-offs, crossfertilisation, and the attraction of innovative talent. By prioritising the development of innovation hubs, the EU can **stimulate economic growth and regional development,** leveraging the momentum generated by these hubs to extend beyond healthcare into areas like agricultural sciences. EUHA itself serves as an overarching entity, for example, for exchanging expertise and providing templates and guidelines to **streamline innovation processes.** Overall, a university hospital innovation hub policy could be developed that could be used as a **blueprint** for all European countries.



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Innovation Hub

An innovation hub is a space fostering the convergence of individuals, businesses, and organisations to exchange ideas, collaborate, and pioneer innovative solutions, leveraging its appealing research expertise, infrastructure, and concentration of talent.

However, EUHA's role transcends simply fostering innovation hubs; it also entails bridging European regions for mutual benefit. University hospitals, with their strong networks, exert a significant influence at regional and national levels, spreading innovation beyond their immediate spheres to enrich other regions, universities, and research institutions. Collaboration and cross-pollination are crucial for seizing promising opportunities, underlining the importance of aligning mindset with supporting structures to drive effective innovation.

Innovation hubs bring together diverse stakeholders, offering them physical and digital resources, mentorship, and networking opportunities. These ecosystems facilitate **idea cultivation, prototype development, and collaborative ventures,** often focusing on specific industries or technologies and driving economic growth and technological advancement. The hallmark characteristics of these hubs include openness, flexibility, and a supportive community fostering experimentation and knowledge exchange. **Regulatory considerations,** such as the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), must be navigated carefully to ensure that innovation thrives within these hubs. One potential approach to help develop and strengthening innovation hubs is provided by EUHA with the EUCCAT initiative (European Center for Cell and Gene Cancer Therapy). <u>EUCCAT</u> stimulates the collaboration between established and developing centres for cell and gene therapies.

JOIN4ATMP – fostering novel therapies

JOIN4ATMP is an EU-funded **EUHA-driven** project that aims to develop alternative regulatory environments to help accelerate the development and thus the broad availability of novel therapies - so-called Advanced Therapy Medicinal Products (ATMPs). ATMPs are medicines that are based on genes, tissues, or cells. For example, it is possible to take white blood cells from a person with leukaemia and genetically modify them in the laboratory so that - back in the body - they recognise and destroy the cancer cells.







In addition to the topic of innovation, EUHA is focused on other important issues that are often linked to innovation as part of its strategic agenda: How could we overcome the complex regulatory hurdles that hamper innovation and weaken Europe's position in the competition for clinical trials? How can we overcome the shortage of clinical staff? How do we make the best possible use of artificial intelligence for the benefit of patients? How do we operationalise data use and valorisation within the new European Health Data Space?



Setting up an Innovation Framework

Innovation is a multifaceted and complex endeavour which includes different processes, professionals, actions, and organisational aspects. There are three areas of relevance within university hospitals that influence and reinforce each other:

- Healthcare Transformation
- Knowledge Valorisation
- Organisational improvement

Healthcare Transformation – A Sense of Urgency

Healthcare Transformation involves enhancing the preparedness of clinical services to tackle **future challenges and trends**, such as precision medicine, and to improve patient outcomes. An example of this interconnectedness is seen in the implementation of new diagnostics and treatments within a university hospital setting.

Healthcare, as we know it, must transform, and will transform. An ageing population, more citizens living with multiple chronic diseases, and imminent resource scarcity if we provide our services in the same way that we have in the past, are only a few of the reasons why. The **shortage of clinical staff** presents university hospitals with almost insurmountable challenges. Campaigns to recruit staff from abroad bring short-term solutions at best and at the same time exacerbate the problem in other countries. **Personalisation** of treatments and informed and empowered patients present new challenges and opportunities for healthcare providers. Therefore, **embracing innovation** and undergoing transformation is essential, acknowledging its crucial role in progress. While it is expected that innovation will help, its full impact remains uncertain. For instance, while Artificial Intelligence may prove beneficial in certain domains, it may also introduce challenges in others.

Knowledge Valorisation - Fostering Societal and Economic Impact

Knowledge Valorisation is the process of creating social and economic value from knowledge by transforming data, know-how and research results into tangible products, services, solutions, and evidence-based policies for the betterment of society and economy. This includes technology transfer. Examples of cross-connections include the potential for successful valorisation to improve clinical outcomes, while simultaneously being hindered by overflowing regulatory complexity.

Knowledge valorisation is a key tool for fostering sustainable economic development by creating and managing intellectual property and an environment conducive to converting knowledge into marketable products and services. The translational process is only successfully completed if innovations get effectively implemented into standard patient care. In almost all cases, this requires an industry partner to take over financial investments, secures operational services and scaling, and provide additional expertise to complete the translational process. However, partners are only prepared to invest or join in the codevelopment if existing data is convincing and **intellectual property** (IP) is secured so that a return of investment can be expected. For these reasons, managing IP assets (patents, copyright, designs, knowhow, etc.) is crucial.

Technology Transfer Becomes Knowledge Valorisation

The concept of technology transfer is evolving, giving way to a more holistic understanding known as "knowledge valorisation. This shift arises from the realisation that "technology transfer" does not encapsulate the full spectrum of value throughout the innovation journey. Knowledge valorisation goes beyond. It recognises the intrinsic value of knowledge and how it extends beyond academic boundaries. This value encompasses scientific generation knowledge, technical know-how, intellectual property assets, and financial from revenue derived licensing agreements and industry collaborations.

Open science and intellectual property rights are not contradictory, timing is key. Patents complement and strengthen publications. They are published and are thus part of "Open Science" - and Open Science does not mean that everything is free of charge.

Technology push or co-creation are different approaches to improve healthcare. To facilitate the adoption of solutions, transparent decision-making processes are essential, especially when considering the purchase of innovative solutions, including those stemming from public-private co-creation or collaborations ("outside-in innovation"). In the healthcare sector, it is crucial to evaluate both the ability and willingness to function as buyers in accordance with procurement legislation related to co-creation. Before buying an innovation, university hospitals may have an important role to play to prioritise the technologies with the greatest impact on healthcare: hospital-based-HTA (health technology assessment) is an important tool for decision makers to gather all the evidence available on the technology and to describe all potential impacts; post-market clinical trials or health economic studies are often necessary to complete the available publications; finally, real-world experimentations may be necessary to assess the real impact in a specific setting and the integration in the existing workflow or patient journey.

^{1.} University Startup Basic Outlicensing Template (US-BOLT) – Life Science Term Sheet edition. Accesssed November 21, 2024. https://autm.net/AUTM/media/Surveys-Tools/TTO-and-VC-Early-Stage-Life-Science-Term-Sheet-(11-19-22-launch).pdf

^{2.} TenU. "The USIT Guide: Leading Universities and Investors Launch Set of Recommendations for the Innovation Sector." TenU, May 1, 2024. https://ten-u.org/news/the-usit-quide.

Organisational Improvement - Using the Innovation Potential

Organisational improvement involves comprehensively re-thinking non-clinical administrative and management processes to enhance innovation and effectiveness across the entire university hospital. Key principles include standardsation, process optimisation, and waste avoidance. This innovative approach is crucial for swiftly and sustainably implementing advancements to address quality and capacity concerns, such as those related to workforce challenges.

To leverage the potential benefits of innovation in university hospitals, administrative processes need to be simplified and thus also accelerated. The adoption of new and innovative technologies and processes can **improve efficiency and reduce costs** in administrative and operational functions. **Standardisation** is a crucial step in accelerating innovation processes. It creates transparency for all stakeholders and simplifies processes and decision-making paths.

One example is the startup-friendly combination of moderate shareholder ownership and exclusive licensing standards that guarantee fair and appropriate benefits for all stakeholders. Even if such standards do not cover all eventualities depending on the situation, they always provide or support a basis on which negotiations can be concluded much more quickly. However, these conditions should also be mandatory all employees without exception. Further acceleration can be achieved if **EUHA-proofed** standards were harmonised across Europe's life science and health sector.^{1,2} Nurturing Spin-off processes often leads to their departure from Europe after the initial financial round. Implementing standards and clear rules can persuade venture capitalists to not only invest in European startups but also to support their ongoing development within Europe.

University Hospital USIT Guide

The initiatives led by Ivy League Columbia universities, particularly University, encompassing term sheets and participations, alongside the recently USIT (University released Spin-out Investment Terms) guide by TenU, are internationally recognised best practices. Leveraging this model, a European adaptation of the 100-page university hospital USIT quide could be spearheaded by EUHA for European university hospitals. Establishing common standard will mitigate detrimental intra-European competition for terms, which frequently obstructs implementation efforts.

In this way, resources can be freed up to benefit both knowledge valorisation and healthcare transformation. Like a systematic rubbish disposal, all existing processes must be critically scrutinised and those that do not add value must be, where possible, eliminated or at least simplified. Comprehensive, sustainable, and **process-oriented digitisation** of administrative processes is essential. This digitisation should be coupled with prior process optimisation and the incorporation of data-driven and artificial intelligence methodologies. To create truly digital workflows, investments in both software and hardware are required.

Examples of **obstacles** include public procurement law, EU state aid law or strict budgetary requirements for areas such as personnel, finance or purchasing. Public institutions must adopt a more entrepreneurial mindset. Not every operational decision necessitates approval from a superior or a committee. Both university hospitals and funding agencies have a role to play in this context. On one hand, we require swift decision-making through well-defined structures and responsibilities, and on the other, a reduction in administrative burdens and a greater willingness to experiment is essential.

To successfully implement an innovation framework, EUHA recommends both a cultural and an organisational shift.

Cultural Shift - The Most Fundamental Factor

It is essential that all employees at all levels embrace innovation as a fundamental discipline for challenging the status quo in both clinical and managerial realms. This is crucial for nurturing a **proactive mindset** among those who grapple with these challenges daily. Providing access to and support for a common language, established innovation processes, incentives, and connections with innovation champions or ambassadors can be highly advantageous.

Impact Orientation Does Not Harm Science

Independent, open-ended research is and will be the basis for groundbreaking innovation, but it is crucial to assess all scientific achievements for their potential economic and societal benefit as early as possible. According to the Coalition for Advancing Research Assessment (CoARA), it is important to recognise the contributions that advance knowledge and the (potential) impact of research results. Impact of research results implies effects of a scientific, technological, economic and/or societal nature that may develop in the short, medium, or long-term, and that vary according to disciplines and research types (e.g. basic and frontier research vs. applied research).3 EUHA will establish communication lines with CoARA leaders and aims introduce innovation impact indicators.



^{3.} CoARA. Agreement on Reforming Research Assessment. Accessed November 7, 2024. https://coara.eu/app/uploads/2022/09/2022_07_19_rra_agreement_final.pdf.

Acting More Courageous and Agile

Innovation often requires quick decisions, entrepreneurial attitudes and sometimes embracing risk for success. Nevertheless, the public sector has a historical and valid inclination towards risk aversion. This tendency must be proactively addressed prior to the adoption of innovation strategies. In any scenario, patient safety remains paramount and must never be compromised. Tensions between organisational structures and innovation teams often arise when the established hierarchies and processes clash with the dynamic and experimental nature of innovation initiatives. Balancing the need for stability within an organisation's structure and the flexibility required by innovation teams can be a challenging aspect in fostering a culture of continuous innovation.

Organisational Shift

Mandate

For innovation to thrive in an organisation, it must be supported from the top down with a clear direction. Innovation should always be a strategic decision. This means that the leadership team must prioritise innovation and make it a core part of the university hospital's strategy and operation. Innovation should be given a "seat at the table" as a fourth **strategic field alongside clinical care, research, and education.** This will ensure that innovation is not treated as an afterthought but is integrated into the organisation overall ambitions, objectives, and roadmaps.

Investment

Investing in innovation is crucial to achieve sustained success. However, it is essential to invest in the right way. Ad-hoc investment in individual projects or departments may lead to short-term gains but may not to create long-term value. Innovation should not only be externally financed as this dilutes the purpose to that of the financiers. Instead, investment in innovation should focus on establishing an organisation with innovative competences.

Long-term ambitions

Innovation is all about shaping the future. It requires a commitment to invest in it over time with significant dedicated resources. Innovation cannot fit into a one-year financial plan, it requires long-term ambitions. Furthermore, innovation in healthcare is typically evidence-based and often experiences a longer time-to-market compared to other industries, primarily due to rigorous regulatory demands and multifaceted implementation challenges such as digital integration, legal considerations, and change management.

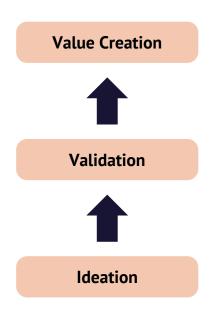
Healthcare and Life Science Innovation Journey

Every innovation journey can be initiated from distinct starting points: **Need-driven, technology-driven, or research-driven innovation** is often differentiated between radical (game-changing) and incremental (improvements). The innovation journey consists of three phases.⁴

In **ideation**, the focus is on creating and conceptualising innovative ideas to address existing healthcare challenges. This stage involves conducting thorough needs assessments, market research, and engaging with healthcare professionals, patients, and stakeholders to identify unmet needs and pain points.

In **validation**, identified ideas and inventions are rigorously tested and validated. This involves for example conducting clinical and feasibility studies, prototyping, and proof-of-concept tests to assess the practicality of the proposed solutions. In the context of stakeholder management, feedback from patients, clinicians, and experts are identified and incorporated into the iterative design process.

In the **value creation** phase, the focus shifts towards scaling and implementing innovations to create a tangible impact in the healthcare ecosystem. This phase involves conducting larger-scale clinical trials and real-world evaluations to demonstrate the efficacy and safety of the solutions. Additionally, strategic partnerships and collaborations are formed to facilitate widespread adoption and integration into healthcare systems.



Throughout the entire innovation journey, it is essential to recognise that potential **revenues** generated from successful innovations could be **reinvested** into further research and development. This cyclical approach ensures a continuous stream of innovative ideas, validation efforts, and impact creation, fuelling a sustainable ecosystem of healthcare innovation and driving progress in the field to benefit patients and society at large. By embracing this reinvestment ethos, innovations can drive transformative advancements and shape the future of healthcare.

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^{4.} Guidance and Impact Tracking System. "GAITHealthcare Innovation Cycle." GAITS. Accessed November 7, 2024. https://www.gaits.org/web/gaits-community/-/1a-healthcare-innovation-cycle.

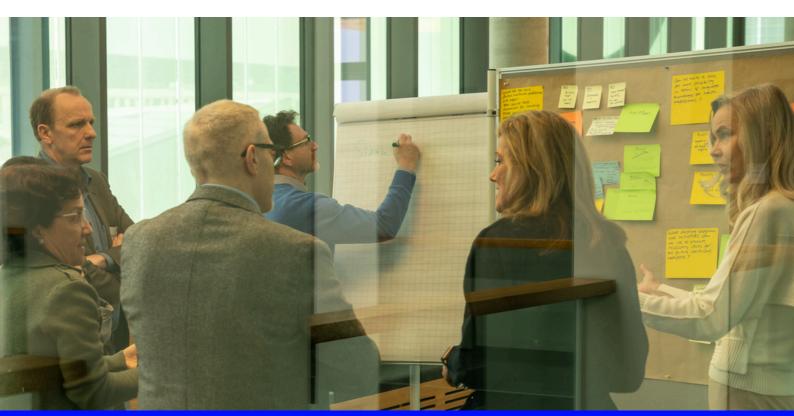
No innovation without collaboration

International collaborations and networks facilitate both insights and access to new markets, ensuring university hospitals stay relevant and competitive. By leveraging the strengths and expertise of their international partners, they can increase their effectiveness and efficiency in bringing research results to the market. Such collaborations should also have the ambition to promote mutual learning and exchange of best practices, while enabling university hospitals to address complex global health challenges, collaboratively.

In addition, international collaborations and networks enhance the global visibility and reputation of university hospitals, opening new avenues for research collaboration and funding opportunities. By building partnerships across borders, they can expand their reach and influence, while creating a more diverse and inclusive ecosystem for innovation and entrepreneurship. **Ultimately, international collaboration is a key enabler of global innovation and contributes to a better society.** EUHA's perspective emphasises the importance of engaging with the private sector to drive innovation. The potential for interaction includes **public-private partnerships, contract research, and collaborations**. In the future, collaboration with investors will also become increasingly crucial. This calls for both a willingness to collaborate and the establishment of clear rules and effective conflict of interest management.

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Fields of Action for Setting up Innovation Frameworks

EUHA has developed exemplary action items in five key areas, each aimed at fostering significant impact in Europe: ideation, validation, impact creation, organisational improvement, and collaboration and open innovation. Each action item is categorised by time perspective—long-term and short-term—and target audience—government or political decision-makers (gov) or university hospital management (UH). These initiatives are designed based on essential framework conditions.

Field of Action 1: Ideation

- Mindset and culture transformation to more impact orientation (long-term, gov/UH).
- Establishing low-threshold, idea offices (short-term, UH).
- Driving cultural change with communication (long-term, UH).
- (1) For innovation to thrive, the culture and mindset must be conducive to disruptive and entrepreneurial thinking. Impact orientation should become a complementary part of the scientific currency. However, with the current emphasis on measuring science only by publication records and third-party funding, exploring new ideas and bringing them to the market plays only a minor role in academia. Cultural transformation will only succeed if it is rewarded by the academic system and supports the career paths of scientists, clinicians, and managers. One way to achieve this is to introduce impact-oriented qualitative, rather than exclusively quantitative criteria in the evaluation of scientific outputs or in recruitment processes for new professorships or decisions on permanent employment of scientific and clinical personnel. EUHA aligns with the CoARA principles and at the same time calls for these to be further developed in the direction of innovation. Together with providing incentives for successful innovation practices, such as financial participation in innovation success, translational career paths, or protected time for development and innovation projects, such initiatives would stimulate an entrepreneurial and innovation-oriented culture.
- (2) University hospitals could provide low-threshold models for open discussion. For example, the establishment of an easily accessible idea office, whether physical or virtual, dedicated to fostering the exchange of ideas among researchers and clinicians in a secure environment. Here, they can openly discuss their early-stage projects, potential inventions, or entrepreneurial concepts with innovation managers. These innovation managers will then identify promising ideas and provide support for their further development. There is a strong need for sustainable investment in such activities and the long-term funding of innovation managers.

(3) External and internal **communication** could address the value that stakeholders in the innovation process (inventors, creators of new teaching materials, company founders, patients, tech transfer managers, etc.) bring to society and the economy, highlighting successes such as licensing of inventions, setting up joint ventures with industry, or creating new startups. In addition to the widespread recognition of the paper of the month, university hospitals could also proclaim an **impact of the month**. Furthermore, institutions could showcase and use the successes of their spin-offs to communicate their value as partners in the transfer process. By creating a "giving back culture", spin-offs are more likely to support their "scientific home", resulting in a "win-win" situation for all involved.

Field of Action 2: Validation

- IP management and publications should go hand in hand (short-term, UH).
- Establishing conflict-of-interest management policy (short-term, UH).
- Setting up early-stage validation programs (long-term, gov/UH).
- (1) With an impact-oriented mindset, there will be a greater awareness to control and manage intellectual property that results from biomedical and clinical research. In drug development, for example, without protected intellectual property, such as patents, there would be no industry investment, no product development, and consequently, no innovation in the standard of patient care. This is why patents and publications must complement each other; they are not mutually exclusive but mutually reinforcing. University hospitals still lose a significant part of their innovation potential due to premature publications. At the same time, the sheer number of patents is clearly not a key performance indicator – patents are just a necessary instrument and it is the implementation of an innovation that counts. Technology transfer offices must function as promotors of innovation and the creation of impact. Sometimes research results might be too protected and are waiting in drawers for years for their best chance, which will probably never come. This hampers innovation. In more technological or MedTech areas, effective IP management may also involve intentionally relinquishing property rights. However, this should be a conscious decision rather than the result of careless actions. University Hospitals should adopt the perspective that publications and intellectual property rights are not mutually exclusive but rather complementary. This responsibility extends to all managers, and fundamental knowledge in this regard should be conveyed through a brief yet mandatory annual training program.

- (2) A conflict-of-interest policy is crucial, especially when it comes to collaboration with industry and the formation of spin-offs and the distinct roles that scientists and physicians then perform (e. g. professor, secondary employment, founder, CEO/CSO). Transparent rules and clear guidelines on what is possible and what is not foster innovation processes. The interests of all parties involved must be considered, as well as the applicable legal and ethical framework. Ideally, such an EUHA conflict-of-interest policy will be driven from the innovation instead of the legal perspective and harmonised on a European level. EUHA could further develop and advocate for these initiatives at the European level, potentially incorporating them into a proposed University hospital USIT guide. Establishing a robust standard at the European level would streamline spin-off formation by providing clear guidelines.
- (3) **University hospitals should set up validation programmes** to support and guide researchers and clinicians on their hopefully successful innovation journey. Networking, co-creation processes, collaboration in public-private partnerships involving individuals from various disciplines, IP protection and management, funding, regulatory compliance, data protection, implementation strategies, integration with existing platforms, and adherence to clinical practices are all complex disciplines. Support structures should be strengthened and continuously developed and professionalised through high level training of and engagement with innovation managers. Furthermore, scientists and clinicians need also to be informed about funding opportunities and patenting requirements. This can be achieved through training and communication by innovation experts and project scouts. Early-stage soft funding, validation and incubator programs are crucial in helping innovators develop their technology and attract external funding.

Field of Action 3: Value Creation

- Enabling fair economic participation and setting up innovation funds (long-term, gov/UH).
- Establishing transparent startup-friendly models and term sheets (short-term, gov/UH).
- Setting up a compact set of established KPIs (short-term, gov/UH).
- (1) For university hospitals, the benefit to society has greater weight than financial profit-seeking. At the same time, **fair and equitable economic participation in commercial success** is based on solidarity and the "polluter pays" principle. The promotion of science and research and the specific academic environment lay the foundations for future economic applications. Financial participation helps to strengthen innovation processes because everyone pulls together and strengthens each other. In the sense of an exploitation cycle, a share of generated revenues should be made available for new transfer projects and thus contribute to increasing future exploitation potential. In the coming years, spurred by EUHA's leadership, university hospitals should establish **standardised criteria at the EU level for licensing intellectual property to industry.**

To provide flexible and sustainable internal financing options for innovation development such revenues should be transferred into university hospital innovation funds that are also available over the course of a year. Since such **innovation funds** can only be realised to a very limited extent within public structures, private structures should be created for this purpose as building blocks of the future innovation ecosystem. An integral component of every innovation hub, exemplified by initiatives like the Leuven Fund, involves navigating regulatory landscapes such as tax exemptions and state aid laws. As part of this broader initiative, efforts should focus on delineating the regulatory and economic frameworks conducive to innovation. Establishing a **Think Tank** dedicated to crafting such a regulatory framework for innovation is imperative.

- (2) Transparent, industry-specific, **startup-friendly standard conditions will accelerate spin-off** processes. It is essential to avoid approaches that merely socialise risks while rewarding private individuals. The combination of **minor dilutable equity participation** (less than 20 %) and **exclusive licensing** is the most common and successful model internationally. Concurrently, for the economic development of startups, liquidity-preserving conditions in the early stages are crucial, as well as appropriately adjusted royalties with deferred payments for exclusive licenses. To safeguard the interests of patients, it must be ensured that licensed assets to companies are further developed by the company and not hindered by a buy-out or will be used only for speculation with technological assets. The efforts of Ivy League universities under the leadership of Columbia University (including term sheets, participations) and the recently published **USIT guide are exemplary in this respect.** These guidelines should be adapted by the EUHA to fulfil the special needs of university hospitals, set up as a standard cookbook, and jointly developed further. To this end, an EU project under EUHA leadership could be set up to bring together the relevant stakeholders and summarise the different ideas in a **university hospital USIT guide.**
- (3) Key performance indicators (KPIs) are important to measure and monitor improvement, performance, and successes of innovation endeavours but must not lead to additional administrative burdens and increased complexity. To achieve this goal, EUHA will define a very simple and limited set of KPIs which should be based on already established criteria of the international organisations such as AUTM and ASTP and allow benchmarking of different university hospitals.

Field of Action 4: Organisational Improvement

- Integrating innovation into corporate strategy and operation (long-term, gov/UH).
- Establishing clear and standardised processes, roadmaps, and access points (long-term, gov/UH).
- Providing sustainable resources for innovation (long-term, gov).

- (1) One crucial step to truly foster innovation is to establish innovation as an overarching, independent strategic and operative field of action and core aspect of the mission of university hospitals alongside research, teaching, and patient care. Greater visibility with your own budgets will create an environment that supports impactful innovation and cultural transformation. Some institutions choose to facilitate the innovation character of an organisation, by making innovation a higher management priority, and even establishing Chief Innovation Officer roles within the top management.
- (2) Innovation is a fast-moving business. To become more innovative, university hospitals must become bolder, less risk averse, more entrepreneurial and not hidden behind superiors or committees for every operational decision. This is a challenge for both university hospitals and their funding bodies. What is needed on the one hand is (1) more delegation of responsibility (dare to make quick decisions), (2) a streamlining of structures (dare to be more linear), and on the other hand (3) a reduction in administrative requirements and (4) a willingness to experiment with clauses that, if proven, (5) should quickly become new standards with legally proofed templates and guidelines. Some of these requirements depend on legal frameworks that can be difficult to circumvent (e. g. personal data protection, public procurement, MDR/IVDR-regulations) but this should not be an obstacle to improving the framework conditions. There is also an urgent need to harmonise nationally differing regulatory requirements so that new medical procedures become genuine innovations quickly and throughout Europe.
- (3) To foster innovation, university hospitals should invest in their technology transfer/innovation offices by providing the necessary resources to support their operations. These offices are responsible for identifying and managing intellectual property, managing relationships with industry partners, and facilitating the commercialisation of research findings through licensing or spin-offs. However, without adequate funding they may struggle to effectively fulfil their mandate. The need for a long-term investment is crucial because innovation is a high-risk business, and it usually takes many years and a multitude of projects to yield significant returns. To achieve this, university hospitals could allocate a regulated percentage of total government and third-party funding to innovation. By sustainable investing in their technology transfer and innovation offices, university hospitals drive innovation, create a culture of entrepreneurship, and contribute to a better and healthier society.

Field of Action 5: Collaborations and Open Innovation

- Setting up a repository to sharing best practices and adopting optimised procedures (short-term, UH).
- Establish innovation procurement systems (short-term, UH).
- Establishing alternative market mechanism for new preventive, affordable, and sustainable medicine (long-term, gov/UH).
- Fostering collaboration with companies (long-term, UH).
- (1) University hospitals are constantly optimising patient care. These are not always made available to others. As a result, many small or even large improvements often quite practical things remain unknown or not widely applied. New ways need to be found to systematically share such innovations. To enhance their operations, it is also important to share best practices and find better ways to learn from each other's expertise to take steps towards continuously improving standards in patient care. One option could be to set up a repository or innovation map managed and driven by EUHA acting as a kind of European Agency for Improving Healthcare. Such an endeavour should be non-profit and financed by all European partners and the European Union.
- (2) An effective innovation procurement system should be set up because it is essential to manage "make or buy" decisions. Every innovation process needs to consistently assess whether viable solutions are already accessible in the market. If such solutions are found, decisions regarding whether to create or purchase them should be made to ensure that valuable resources are not allocated to unnecessary development endeavours. Sometimes, by looking at technologies developed for other purposes and adapting them to the healthcare industry, new ideas spark to patient benefit. Innovation procurement in this context also means acquiring pioneering solutions that may not yet be available in the market or are in early stages of development.
- (3) The search for sustainable and affordable **preventative medicine** and treatments is key in modern healthcare innovation. Yet, the current economic landscape, particularly favoured by venture capitalists, leans toward long-term medication models. This hampers the development of breakthrough permanent medical solutions. Long-term medication offers financial stability to investors due to recurring drug consumption, making it attractive. Consequently, sustainable, and affordable innovations may be neglected due to perceived financial risks. Such innovations may even be shelved by stakeholders vested in the status quo, denying patients curative options. To counter this trend, collaborations between university hospitals and public entities are crucial. University hospitals foster pioneering research and support sustainable and affordable treatments. Government funding and initiatives provide financial incentives for research, ensuring promising solutions are not overlooked. Diversifying market mechanisms can help too. Government policies prioritising sustainable and affordable treatments with streamlined regulations and reimbursement incentives can attract private investment in transformative healthcare solutions. Together with the European Union and its funding bodies, EUHA aims to develop alternative market mechanisms and funding models that prioritise cures over long-term therapies. One approach would be to supplement founder-driven spin-off processes with institutionally driven spin-off processes in which the university hospitals themselves act in the driver-seat.

(4) Entering multi-stakeholder environments characterised by diverse disciplines and perspectives can lead to the emergence of valuable insights, expediting their transition into implementation and impactful outcomes. Innovations are generated through either technology push or co-creation in public-private collaborations. In the realm of fostering innovation, collaboration between university hospitals and established companies through **Public-Private Partnerships (PPPs)** holds paramount significance. The joint development of innovations in such partnerships is instrumental in propelling the innovation process forward. University hospitals, in tandem with regulatory authorities, must strive to streamline and standardise legal frameworks at both European and national levels, thereby expediting collaboration. The European University Hospital Alliance (EUHA) is committed to actively contribute to the development of these standards. By doing so, EUHA aims to facilitate an environment where collaboration with companies evolves into a win-win situation for all parties involved.

About EUHA

The European University Hospital Alliance, founded in 2017, is formed of 10 leading European university hospitals. University hospitals play an essential role in healthcare systems and society, taking care of the most complex patients, performing research, pioneering healthcare and innovation, and training the next generation of healthcare professionals.

