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Preparing Belgium's Healthcare System for Digital Pathology and AI Innovations - A novel funding and reimbursement framework

The BELDIPA initiative

Policy report

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Colophon

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Commissioned by	This report was developed by Inovigate and made possible through funding from Roche Diagnostics, AstraZeneca, Novartis, IBEX and with the support of the Belgian Society of Pathology. It synthesises the findings, analyses and recommendations produced within the BELDIPA project. Inovigate has performed this research and analysis under complete intellectual independence.
Publication date	September 2026
How to refer to this document	INOVIGATE – Maes I., Kok E., Koeken I., Preparing Belgium's Healthcare System for Digital Pathology and AI Innovations - A novel funding and reimbursement framework for innovations - The BELDIPA initiative, 2026

Disclaimer	External experts have contributed via in-depth interviews. Input from these interviews was analysed and discussed in two stakeholder roundtables and resulted in this report. The external experts did not coauthor this report and therefore did not necessarily agree with every element and/or recommendation in this report.

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Executive summary

Belgium is entering a decisive moment in the evolution of diagnostic medicine. Across the world, digital pathology (DP) and artificial intelligence (AI) are reshaping how diseases are diagnosed, how treatment decisions are made, and how healthcare systems organise their diagnostic capacity, forming the foundation of the emerging field of computational pathology. These technologies enable faster and more accurate diagnostics, support personalised medicine, and help address growing diagnostic complexity, increasing demand for expert review and long-term healthcare sustainability. As these technologies mature and **digital pathology becomes the new standard in routine care, clinical trials and research environments**, Belgium must adopt a forward-looking, coherent, and evidence-based funding and reimbursement framework to ensure timely access, equitable adoption, and long-term value creation for patients, healthcare professionals, payers, and society. Despite this global momentum, Belgium does not yet have a coherent, forward-looking and financially sustainable framework to support investment in DP infrastructure and the evaluation, funding and adoption of AI tools or more in general new promising health technologies. **The current reimbursement system is rooted in traditional laboratory practices and nomenclature, and does not provide a mechanism to evaluate, fund or scale digital innovations.** As a result, adoption remains fragmented, laboratories face unequal investment capacity, and the country risks falling behind in both clinical excellence and research competitiveness.

The BELDIPA (Belgian Digital Pathology) **initiative was created to address this gap.** Through an extensive process involving literature review, a national e-survey, in-depth interviews and two multi-stakeholder round tables with representatives from authorities, laboratories, hospitals, academia, industry and patient associations, a shared vision has been developed. This vision forms the basis for a national policy framework that enables the responsible, evidence-based and equitable introduction of DP and AI in Belgium.

The **proposed funding and reimbursement framework** establishes a clear, structured pathway through which **innovations can be assessed, piloted, funded, and scaled**. It is intentionally designed to be **as simple as possible** and can evolve into a **general framework for other med tech and AI applications,** with AI tools for digital pathology as the first use case. It is designed to **complement existing Belgian instruments and related reforms,** rather than replace nomenclature.

The proposed framework is based on five foundational **principles**: (1) a clear separation between infrastructure funding, implementation support and reimbursement of clinical use; (2) independent and evidence-based assessment of clinical value, budget impact and genuine substitution effects; (3) predefined criteria governing pilot testing, scale-up, reassessment, and potential discontinuation; (4) transparent governance with robust conflict-of-interest safeguards; and (5) enforceable requirements for quality, cybersecurity, interoperability, data portability and the prevention of structural vendor lock-in. It provides clarity for laboratories and pathologists regarding implementation requirements, gives companies predictability about evidence expectations for reimbursement, and ensures that payers retain control over budgets and quality.

This report outlines the strategic context and rationale for action, describes the current landscape of DP and AI in Belgium and abroad, identifies the key challenges that hinder adoption, and translates international best practices into lessons for the Belgian context. It then presents a **concrete funding model for the implementation of digital pathology and reimbursement framework for corresponding AI tools, including a six-step evaluation procedure, a horizon-scanning mechanism and a budget-neutral approach grounded in real-world evidence and therapy optimisation**. Finally, the report proposes a **phased implementation roadmap** and a governance structure **to ensure national coordination, standardisation, long-term sustainability** and lay the foundation for a sustainable integration of digital and AI-driven solutions in clinical practice.

Belgium has the opportunity to position itself as a European leader in digital diagnostics. By adopting the funding and reimbursement framework for innovation, the country can ensure equitable access to high-quality pathology services, accelerate personalised medicine, support innovation, and strengthen its **healthcare system for the future**.

1. Context & rationale

1.1. The transformation of pathology

The field of pathology is undergoing a profound digital transformation that is reshaping the foundations of diagnostic medicine. For decades, histopathology has relied on physical slides, microscopes and manual workflows. Although this traditional approach has served clinicians and patients well, it is increasingly reaching its limits. Diagnostic questions are becoming more complex, the demand for subspecialised expertise continues to rise, and the number of available pathologists is insufficient to meet the growing workload. At the same time, clinicians as well as patients expect faster turnaround times, while the volume of biomarker-driven therapies and the role of pathology in clinical trials and personalised medicine continue to expand. From a **patient perspective**, digital pathology and AI can contribute to **faster and more accurate diagnoses**, supported by data and slide image sharing that allows expert collaboration on complex cases, reducing uncertainty and time to treatment. However, patient representatives also highlight the importance of trust, transparency, robust validation and continued human oversight in AI-supported diagnostics, underlining the need for a patient-centred implementation approach.

Digital pathology offers a response to these pressures by converting tissue samples into high-resolution whole-slide images (WSI) that can be viewed, shared and analysed digitally. This shift enables remote consultation, supports more efficient workflows and creates the foundation for advanced computational analysis. As a result, digital pathology is no longer an emerging technology but is rapidly becoming the backbone of modern diagnostic practice.

1.2. The rise of AI in pathology

Artificial intelligence (AI) is accelerating the transformation of pathology by enabling the automated analysis of digital images and streamlined workflow management. AI and machine-learning algorithms (ML) can analyse complex histological data with a level of depth and consistency difficult to achieve manually, detecting subtle patterns, quantifying biomarkers with high precision and integrating multiple features beyond what the human eye can discern. These computer-based tools are specifically designed to support healthcare professionals (HCPs) in making informed clinical decisions by providing timely, evidence-based information at the point of care. Rather than replacing pathologists, AI strengthens their expertise and, in many cases, functions as a digital biomarker by predicting disease progression or therapy response. Together, **digital pathology and AI form a cornerstone of future diagnostic practice**.

Artificial intelligence (AI) algorithms also enable automated analysis of these digital images and streamlined workflow management. These computer-based tools are specifically designed to assist healthcare professionals (HCPs) in making informed clinical decisions by providing timely, evidence-based information at the point of care. The primary objectives are to enhance diagnostic accuracy, patient outcomes and improve the efficiency of healthcare processes.

The range of AI applications in pathology is broad. They support three core areas:

- **Improving workflow efficiency:** AI-supported image analysis and workflow management systems accelerate the processing and review of digital slides, reducing the time required for initial assessment and enabling pathologists to manage larger caseloads without compromising quality. The workflow can also made more efficient by decreasing the need for additional (reimbursed) ancillary techniques such as immunohistochemistry (IHC) or molecular techniques.
- **Enhancing diagnostic accuracy**: AI tools support biomarker quantification and interpretation, highlight regions of interest for pathologist review, perform automated tumour detection and grading, and quantify cellular characteristics such as expression levels of biomarkers. By identifying patterns that may be missed by the human eye or being more accurate in counting numerous cellular elements in one physical slide, these tools improve the precision of diagnoses.
- **Optimizing treatment decisions**: AI-based clinical decision support systems assist in selecting targeted therapies and planning follow-up strategies. Predictive modelling algorithms forecast

treatment responses by analysing comprehensive sets of molecular and morphological features, thereby supporting more personalized and effective treatment planning.

Together, these capabilities enhance diagnostic accuracy, reduce inter-observer variability and support more personalised and data-driven patient care. Overall, digital pathology and AI have a clear potential to enable more accurate analysis of patient data and support healthcare professionals in making evidence-based diagnostic and therapeutic decisions and enable personalised medicine. **These technologies can deliver qualitative and quantitative benefits for patients, healthcare professionals, and society.** Digital pathology is therefore increasingly becoming the standard approach in clinical care, research environments, and clinical trial settings.

1.3. Why Belgium must act now

Belgium faces a convergence of pressures that make timely action essential. There is a current shortage of pathologists, and the workload continues to grow. Subspecialisation and expert knowledge among pathologists are increasingly necessary to maintain diagnostic quality, yet not all centres have access to the required expertise. Meanwhile, AI is advancing rapidly, with several tools already approved by the European Medicines Agency (EMA), and biomarkers are becoming indispensable in oncology and other therapeutic areas.

Despite these developments and existence of broader national initiatives supporting the adoption of AI in Belgium, the adoption of digital pathology (DP) and AI remains fragmented. While AI is attracting considerable attention, its successful implementation depends on the availability of a robust digital pathology infrastructure. Yet limited laboratories have made significant progress, while others lack the resources to invest in the necessary infrastructure. This uneven landscape risks creating disparities in diagnostic quality and access. Budget constraints further complicate the situation, as investments in DP and AI require predictable and value-based funding mechanisms. At the same time, neighbouring countries such as France, the United Kingdom, the Netherlands, regions of Spain, Portugal, Switzerland, Norway and Denmark have already started to create national strategies or frameworks, positioning themselves at the forefront of digital diagnostics.

If Belgium does not act now, it risks falling behind in clinical innovation, research participation and cross-border collaboration. More importantly, patients may face unequal access to high-quality diagnostics, undermining the principles of equity and excellence that underpin the Belgian healthcare system.

1.4. The need for a coordinated national approach

Across interviews, surveys and round-table discussions, stakeholders consistently emphasised the need for a coordinated national approach. They highlighted the importance of establishing a clear funding and reimbursement framework that recognises the specific characteristics of digital and AI-enabled diagnostics. They also stressed the need for a unified national interpretation of regulatory requirements, particularly in relation to GDPR, data sharing and the EU AI Act, and compliance requirements under the EU MDR/IVDR framework.

Standardisation and interoperability emerged as essential prerequisites for successful implementation. Without common technical and procedural standards, laboratories risk developing isolated solutions that cannot be scaled, integrated or remain future proof in an evolving digital healthcare ecosystem. Stakeholders also pointed to the need for centralisation and pooling of expertise, enabling smaller centres to benefit from subspecialised knowledge and shared infrastructure. Evidence generation through pilot projects was identified as a critical step to demonstrate clinical value, support reimbursement decisions and build confidence among clinicians and payers.

Finally, stakeholders agreed that a dedicated governance structure is necessary to coordinate implementation, ensure transparency and maintain alignment across the ecosystem. The BELDIPA

initiative was established to meet these needs and to develop a shared, multi-stakeholder solution that is both ambitious and realistic for the Belgian context.

2. Current landscape of digital pathology and AI

The landscape of digital pathology and AI is evolving rapidly, both internationally and within Belgium. Although the underlying technologies have matured significantly over the past decade, their integration into routine clinical practice remains uneven. Belgium finds itself at a crossroads: the scientific and technological foundations are firmly in place, yet the structural, financial and organisational conditions required for broad adoption are still developing.

Digital pathology has already demonstrated its value in numerous clinical environments. Laboratories that have transitioned to digital workflows report improvements in efficiency, consistency and collaboration. Whole-slide imaging allows pathologists to review cases remotely, consult subspecialists more easily and integrate digital tools into their daily practice. These capabilities are particularly relevant in a healthcare system where expertise is distributed across multiple centres and where timely access to specialised knowledge is essential for high-quality care.

AI tools are beginning to complement these digital workflows. Several algorithms have received regulatory approval in Europe and are being used to support tasks such as tumour detection, grading and biomarker quantification. In research settings, AI is already embedded in biomarker discovery, clinical trial stratification and exploratory analyses. The potential for AI to serve as a digital biomarker, offering predictions about disease progression or treatment response, is increasingly recognised and is expected to play a growing role in precision oncology.

Despite these advances, Belgium's adoption of DP and AI remains fragmented. Some laboratories have invested in scanners, storage infrastructure and digital workflows, while others continue to rely entirely on traditional methods. This uneven progress reflects differences in financial capacity, institutional priorities and local interpretations of regulatory requirements. It also highlights the absence of a national framework that provides guidance, predictability and incentives for adoption.

The **Belgian Society of Pathology (BSP)** has taken important steps to promote standardisation and interoperability, recognising that a coordinated approach is essential for the long-term success of digital pathology. However, **without a national funding of digital pathology infrastructure and reimbursement mechanism for AI tools, laboratories face significant barriers to primary investments**. The cost of scanners, storage, software licences and workflow redesign is substantial, and the return on investment is difficult to realise at the level of individual laboratories. As a result, the benefits of DP and AI, including improved diagnostic quality, faster turnaround times and more efficient use of therapies, remain unevenly distributed across the country.

Other countries already demonstrate that a **coordinated national approach** is both feasible and beneficial. France has developed a multi-year national roadmap for digital pathology, Denmark has integrated DP and AI into its regulatory and reimbursement structures, the United Kingdom and the Netherlands have implemented nationwide digital pathology networks, and several countries such as the UK have established clear evaluation pathways for AI tools.
These initiatives demonstrate that large-scale implementation is feasible and that national coordination can accelerate progress while ensuring quality and equity. Belgium's current position underscores the urgency of developing a coherent national strategy that aligns clinical, regulatory, financial and organisational dimensions. Without similar action, Belgium risks losing ground in clinical innovation, research collaboration and healthcare quality.

The current landscape therefore presents both a challenge and an opportunity. Belgium has a strong foundation of clinical expertise, a vibrant research ecosystem and a tradition of high-quality healthcare. **By building on these strengths and addressing the structural barriers that hinder adoption, the country can position itself as a leader in digital diagnostics and ensure that patients across all regions benefit from the most advanced diagnostic tools available.**

3. Challenges and barriers to adoption

The introduction of digital pathology and AI in Belgium is hindered by a set of interconnected challenges that span clinical, financial, regulatory and organisational domains. These challenges were identified through literature review, a national e-survey and extensive interviews with pathologists, laboratory directors, hospital leaders, industry representatives, patient representatives, regulators and payers. Together, they paint a clear picture of the obstacles that must be addressed to enable broad and sustainable adoption.

3.1. Funding and reimbursement

The most frequently cited barrier is the lack of an appropriate funding and reimbursement mechanism. The current nomenclature system and reforms do not recognise the costs associated with digital pathology or AI tools. Laboratories must therefore finance scanners, storage infrastructure, software licences and workflow redesign entirely from their own budgets. These investments are substantial, and the return on investment is difficult to achieve at the level of individual laboratories, particularly smaller centres.

Without a national framework, the adoption of digital pathology remains highly dependent on financial capacity, local institutional decisions and the willingness of hospitals to invest in digital transformations. As a result, adoption across Belgium remains uneven, creating disparities in access to modern diagnostic capabilities and limiting the ability to realise the full benefits of digital pathology on a national level. Given that digital pathology constitutes the foundational infrastructure upon which AI applications depend, dedicated funding and implementation support for digital pathology investments are essential prerequisites for broader AI adoption. While digital pathology requires upfront investments in scanners, storage infrastructure, software and workflow transformation, AI-enabled applications require complementary evaluation and reimbursement mechanisms that reflect their clinical, operational and therapeutic value. Stakeholders also expressed concern that the absence of a structured funding model could lead to uncontrolled budget growth if AI tools were to be reimbursed without clear evidence requirements or budget safeguards. A predictable, value-based and budget-controlled mechanism is therefore essential.

3.2. Clinical value and evidence generation

Although the clinical potential of DP and AI is widely acknowledged, stakeholders noted that the evidence base in Belgium remains limited and heterogeneous. Demonstrating improvements in patient outcomes, diagnostic accuracy or workflow efficiency requires access to real-world data and coordinated pilot projects. Without such evidence, payers are reluctant to support reimbursement, and laboratories face uncertainty about the long-term sustainability of their investments.

Stakeholders also highlighted the need for a clear methodology to assess the clinical value of AI tools. The diversity of applications, ranging from workflow triage to predictive modelling, makes it challenging to define uniform evaluation criteria. A structured approach to evidence generation, supported by national pilots, is therefore critical.

3.3. Regulatory uncertainty

Regulatory complexity is another major barrier. Laboratories and companies face uncertainty about how GDPR, the EU AI Act and EU MDR/IVDR framework apply to digital pathology and AI tools. Data protection officers (DPOs) often interpret regulations differently, leading to inconsistent practices across institutions. Questions about data sharing, anonymisation, model training and medical liability further complicate implementation.

While guidance on in-house medical software regulation and legislation exists, stakeholders emphasised the need for further national interpretation guidance that clarifies how DP and AI can be

implemented in a compliant manner. Without such guidance, laboratories risk delays, inconsistent practices and missed opportunities for collaboration.

3.4. Business and organizational challenges

The transition to digital pathology requires significant organisational change. Laboratories must redesign workflows, invest in training, ensure interoperability between existing and new systems and bear the administrative and resource-related costs for local clinical validation. Many laboratories lack the specialised skills needed to select, implement and maintain digital and AI tools. Pre-analytical variability, such as differences in staining protocols, antibodies and scanners, further complicates standardisation.

Stakeholders also noted that each laboratory currently develops its own solutions, leading to fragmentation and inefficiency. These challenges underscore the need for system-level standardisation, coordinated procurement, and comprehensive support for organisational change. A more centralised and standardised approach would enable economies of scale, improve return on investment and support national quality benchmarking.

4. International best practices

Across Europe and beyond, several countries have already taken significant steps to integrate digital pathology and AI into their healthcare systems. Their experiences offer valuable insights for Belgium, demonstrating not only the feasibility of large-scale implementation but also the importance of national coordination, clear governance and structured funding mechanisms. While each country operates within its own regulatory and organisational context, common themes emerge that can inform Belgium's approach.

The United Kingdom has been one of the early movers in digital pathology, supported by substantial government investment and a clear national strategy. The country has implemented large-scale digital pathology networks that connect multiple hospitals, enabling remote consultation, subspecialty access and shared quality standards. These networks have shown that centralisation and interoperability can significantly improve diagnostic efficiency and consistency. The UK experience also highlights the importance of national guidance on data governance and the integration of AI tools into clinical workflows.

The Netherlands provides another compelling example through its PALGA system, a nationwide pathology registry that has been operational for decades. PALGA enables structured data exchange between all pathology laboratories in the country, supporting diagnostic processes, quality monitoring, cancer registration and research. Its success demonstrates the value of a centralised infrastructure that ensures standardisation and facilitates collaboration. More recently, the Netherlands has expanded its digital pathology capabilities, building on this strong foundation to support personalised medicine and cross-border research initiatives.

France has taken a strategic, multi-year approach by developing a national roadmap for digital pathology. This roadmap includes clear objectives for infrastructure development, standardisation, regulatory alignment and reimbursement. France has also introduced funding mechanisms to support the transition to digital workflows, recognising that upfront investment is essential to achieve long-term benefits. The French model underscores the importance of aligning policy, financing and clinical practice within a coherent national framework.

Denmark has integrated digital pathology and AI into its broader digital health strategy. The country has established clear regulatory guidance for AI algorithms, ensuring compliance with EU medical device regulations while enabling innovation. Denmark's approach demonstrates that regulatory clarity can accelerate adoption by reducing uncertainty for laboratories and companies. It also shows that national coordination can support consistent implementation across regions, even in a decentralised healthcare system.

Switzerland has invested in a national digital pathology infrastructure to support personalised medicine and cross-institutional research. This infrastructure enables secure data sharing, standardised workflows and collaboration between academic centres. Switzerland's experience highlights the importance of interoperability and the potential for digital pathology to strengthen research capacity and innovation.

Germany has taken steps to address regulatory and data protection challenges, including the development of a national anonymisation tool for whole-slide images. This tool ensures GDPR compliance while preserving the utility of data for research and AI model development. Germany's approach illustrates how targeted regulatory solutions can remove barriers to data sharing and support the development of AI tools.

Across these countries, several common lessons emerge. National coordination is essential to avoid fragmentation and ensure equitable access to digital pathology. Standardisation of workflows, data formats and quality processes enables interoperability and supports collaboration. Clear regulatory guidance reduces uncertainty and accelerates adoption. Evidence generation through pilot projects helps demonstrate clinical value and supports reimbursement decisions. Finally, dedicated funding mechanisms are necessary to support the substantial upfront investments required for digital

transformation.

These international experiences show that Belgium is not starting from scratch. Belgium has already recognised the broader AI transition through national policy initiatives that support responsible development and adoption of AI. Building on these foundations and these proven international models, Belgium can design a framework that is both ambitious and realistic, ensuring that digital pathology and AI become integral components of a modern, high-quality and sustainable healthcare system.

Challenges	Funding and reimbursement	Clinical value	Regulation	Business and organisational
Best practices	• Denmark provides a reimbursement framework; however it still depends on local authorities and case-by-case evaluations • France has developed a multi-year national roadmap for digital pathologies, which includes the topic of reimbursement • The UK and the Netherlands have rolled-out digital pathology nation-wide • Sweden is developing guidelines and protocols to regulate and facilitate the adoption of digital pathology through the KVAST[1] coding system • The US has established a reimbursement task force to develop reimbursement models for digital pathology	• Cost-effectiveness is important to demonstrate the added value of digital pathology and AI. International studies suggest potential efficiency gains and broader healthcare system benefits, although the magnitude and distribution of these benefits depend strongly on the healthcare setting, organisational model and reimbursement structure. • The Digital Pathology Association (DPA) in the US has created an ROI calculator to assess the cost-effectiveness of digital pathology adoption	• In Denmark, AI algorithms and it's the implementation follow EU MDR regulations • Health Canada focusses on post-market surveillance of AI tools • A digital pathology task force in France has developed a national roadmap for further implementation of AI and clinical decision support systems (CDSS) based on a regulatory framework with clear definitions • In Germany, a code for an anonymization tool of WSI ensures GDPR compliance while keeping the data usable for research and AI development	• In several countries, streamlined workflows and standards are implemented that make collaborations between institutions possible • Digital pathology will result in time savings, with the potential of reducing workload up to 50% • The Netherlands' PALGA network serves as a national pathology registry enabling standardised data exchange and interoperability across laboratories
Take-away for Belgium and the BELDIPA initiative	Setting up a task force to create a nation-wide reimbursement framework, similar to several other countries	By implementing digital pathology nationwide, both pathologists, patients and payers can benefit from the many qualitative and quantitative advantages.	A regulatory framework with clear definitions can be developed based on the French taskforce model	Efforts are underway by The Belgian Society of Pathology to improve interoperability, standardisation and streamlined workflows across digital pathology systems and laboratories.

[1] KVAST: Swedish Quality & Standardisation Committee

5. BELDIPA Approach & methodology

The BELDIPA initiative was designed from the onset as a collaborative, evidence-driven effort to develop a national framework for digital pathology and AI in Belgium. Recognising that no single stakeholder group could address the challenges alone, the project brought together representatives from across the healthcare ecosystem to build a shared understanding of the issues and co-create practical solutions. The methodology combined structured research, broad stakeholder engagement and iterative refinement, ensuring that the final recommendations reflect both international best practices and the realities of the Belgian healthcare system.

The process began with an extensive review of scientific literature, policy documents and international case studies. This research provided a comprehensive overview of the global evolution of digital pathology and AI, highlighting the technological advances, regulatory developments and implementation strategies adopted in other countries. It also helped identify the initial set of challenges that Belgium would need to address, ranging from funding and reimbursement barriers to regulatory uncertainty and organisational constraints.

To validate and enrich these findings, BELDIPA conducted a national e-survey targeting pathologists, laboratory directors and other healthcare professionals. The survey captured insights into current practices, perceived barriers, expectations for digital transformation and readiness for AI adoption. The responses confirmed that while enthusiasm for digital pathology and AI is high, significant structural obstacles prevent widespread implementation. The survey also revealed substantial variation in digital maturity across laboratories, underscoring the need for a coordinated national approach.

Building on these insights, the project team conducted a series of in-depth interviews with key stakeholders, including representatives from federal authorities, Sciensano, health insurance funds, pathologists, hospitals, industry, academic institutions and professional associations (BSP, pharma.be, BeMedTech). These interviews provided a nuanced understanding of stakeholder perspectives, priorities and concerns. They also offered concrete suggestions for potential solutions, including the need for a structured reimbursement pathway, national regulatory guidance, standardisation efforts and pilot projects to generate real-world evidence.

The findings from the interviews were synthesised into a preliminary framework proposal, which served as the basis for the first multi-stakeholder round table. This meeting brought together thirty participants from across the ecosystem to discuss the challenges, validate the proposed direction and identify areas requiring further refinement. The discussions highlighted the importance of budget control, evidence-based decision-making and the need to align the framework with existing Belgian instruments. Participants also emphasised the necessity of centralisation and pooling of expertise, to ensure equitable access and efficient use of resources.

Following the first round table, the project team refined the proposed framework and developed a detailed set of recommendations. These were presented at a second round table, where stakeholders reviewed the refined framework and the **implementation roadmap** and discussed the practical steps required to operationalise the framework. The meeting confirmed **broad support for the proposed approach** and provided valuable input on governance, regulatory interpretation and the design of pilot projects.

Throughout the process, BELDIPA maintained a strong focus on co-creation and transparency. Each stage of the methodology was designed to ensure that the final framework would be both technically sound and broadly supported. The iterative nature of the approach allowed stakeholders to shape the recommendations, ensuring that they are realistic, aligned with Belgian healthcare structures and capable of delivering meaningful impact.

The result of this methodology is a comprehensive, multi-stakeholder policy framework that addresses the full spectrum of challenges associated with digital pathology and AI. It provides a clear

pathway for evaluation, funding and implementation, supported by a **phased roadmap and a governance model** that ensures long-term coordination. By grounding the framework in evidence and stakeholder consensus, BELDIPA has created a **foundation for sustainable digital transformation** in Belgian pathology.

6. Proposed funding and reimbursement framework

The introduction of digital pathology and AI into the Belgian healthcare system requires a **funding and reimbursement framework that is both forward-looking and firmly grounded in the realities of clinical practice, budgetary constraints and regulatory expectations**. Throughout the BELDIPA process, stakeholders consistently emphasised that the absence of such a framework is one of the most significant barriers to adoption. Laboratories cannot be expected to make substantial investments in scanners, storage, software licences and workflow redesign without clarity on how these costs will be recognised and supported. At the same time, payers require mechanisms that ensure budget control, evidence-based decision-making and alignment with broader healthcare priorities, including the evolving healthcare financing landscape.

The proposed framework responds to these needs by **offering a structured, predictable and value-driven approach to funding and reimbursement**. A fundamental principle of the framework is the distinction between digital pathology and AI-enabled applications. Digital pathology constitutes the foundational infrastructure required to modernise pathology workflows and therefore requires dedicated investment and implementation support, while AI applications build upon this digital foundation and require separate evaluation and reimbursement pathways when they demonstrate clinical, operational or therapeutic value. It is designed to complement existing Belgian instruments rather than replace them, ensuring continuity with the current system while creating a **dedicated pathway for digital and AI-enabled innovations**. In this sense, the proposed framework complements the current reimbursement nomenclature (reform) but does not replace it; instead, it fills a critical gap by providing a mechanism tailored to the specific characteristics of innovations, such as AI. A forward-looking funding & reimbursement solution is needed for these innovations to avoid delays in access and adoption. The proposed framework is designed to be as simple as possible and could **become a general framework for clinical decision support tools and other (medtech) innovations, with digital pathology as a first use case.**

6.1. Funding and reimbursement architecture

Structural reimbursement conditions

To ensure sustainable adoption and equitable access to digital pathology and AI, several **structural conditions** must be met:

As a first step, **scaling and centralisation** are important enablers of the digital transition in pathology, allowing laboratories to share resources, expertise and infrastructure investments. They should be organised through population-based diagnostic networks rather than purely geographic boundaries. Dedicated diagnostic hubs, like those used for next-generation sequencing (NGS), can concentrate expertise, optimise resources, and support consistent quality across regions. For digital pathology, such centralisation should be even more feasible to implement than for NGS, as it does not require the physical transport of samples but relies primarily on robust digital infrastructure for image sharing and analysis. The objective is to centralise expertise, infrastructure and quality assurance, while maintaining broad participation of laboratories and avoiding excessive concentration of market power and access to diagnostic services. Safeguarding equitable access, transparency and balanced participation across the network is essential.

Second, **accreditation and clear recognition criteria** are essential to enable collaboration between laboratories and ensure that participating centres meet uniform standards of quality and competence.

Third, a **shared digital image repository** should be established at the diagnostic hub level, allowing multiple laboratories to access and contribute to a common data environment. This shared infrastructure promotes collaboration, specialisation, and efficient use of digital resources.

Finally, **standardized structured reporting (SSR)**, through initiatives such as BELSYROPA (by BSP) (Belgian Synoptic Reporting), must guarantee standardised, high-quality data that can be seamlessly

exchanged between laboratories. This ensures interoperability, transparency, and continuous improvement in diagnostic accuracy.

Together, these conditions create a coherent foundation for funding and reimbursement, fostering collaboration, scalability, and data-driven quality improvement across the Belgian diagnostic landscape.

A phased, evidence-based reimbursement adoption

At its core, the framework is built around the principle of **controlled, phased adoption**. Rather than granting immediate structural reimbursement for all AI tools, the model introduces a **stepwise process in which innovations are evaluated, based on evidence**. This approach ensures that only AI-tools demonstrating clear clinical value, workflow efficiency or therapeutic optimisation progress to broader reimbursement. It also allows payers to **maintain oversight of budget impact**, while laboratories gain the predictability needed to plan investments.

The proposed funding model combines **public-private partnership (PPP) for initial infrastructure investment in digital pathology with a hybrid reimbursement model for AI-tools, based on a temporary innovation-enhancing payment and a consecutive permanent reimbursement,** based on proven value.

Upfront capital funding for digital pathology, such as hardware (scanners, storage) and software (Image Management System for digital whole slide viewing, workflow management, integration with the laboratory information system) **and collaborative network development** should be structured as a PPP, combining public and private financing. Public funding opportunities exist within EU grant programmes, ongoing data-capability initiatives and other subsidies. Private funding contributions may come from AI tool companies, medtech companies, pharmaceutical companies, and other stakeholders with interest in advancing digital pathology and AI.

For potential reimbursement of AI, the framework begins with a **structured evaluation phase**, during which developers submit evidence on the clinical performance, safety and intended use of their tools. This evaluation is not limited to traditional clinical endpoints but also considers workflow improvements, diagnostic consistency and the potential for more precise therapy selection. By broadening the scope of value assessment, the framework recognises the multifaceted benefits of digital pathology and AI.

Following evaluation, selected AI-tools enter an optional **pilot phase**. These pilots are conducted in representative laboratory settings that have digital workflows and are designed to generate real-world evidence on clinical value, operational impact, cost-effectiveness and integration into routine practice. Beyond demonstrating added value, pilot projects provide an opportunity to evaluate interoperability with existing systems, identify implementation challenges and assess the broader impact on the healthcare system. This includes monitoring potential unintended consequences such as excessive volume growth, disproportionate concentration of services or expertise, and inequities in access. By generating practical evidence under real-world conditions, the pilot phase supports informed reimbursement decisions and enables refinement of both the technology and the framework.

If the pilot results demonstrate clear value and meet predefined criteria relating to clinical value, feasibility and operational performance, the AI-tool progresses to a **temporary reimbursement phase** (Article 56 temporary conventions). This phase allows for broader use while maintaining budgetary safeguards and ongoing data collection. Temporary reimbursement ensures that innovations can be adopted without delay, while still requiring continued evidence generation to support long-term decisions. In addition to clinical outcomes, this phase enables the assessment of budget impact, healthcare system consequences and the extent to which a tool substitutes existing activities, procedures or costs. Evidence generated during this phase should be evaluated through the established assessment and reimbursement pathway to support objective and evidence-based reimbursement decisions.

The final step in the framework is **structural reimbursement**. Only AI-tools that demonstrate sustained clinical value, cost-effectiveness and alignment with national healthcare priorities progress to this stage. Structural, technological neutral reimbursement provides long-term stability for laboratories and developers, ensuring that proven innovations become part of routine clinical practice. It also reinforces the principle that reimbursement must be earned through evidence, not assumed based on technological novelty. Where evidence generated during temporary reimbursement demonstrates measurable efficiencies, healthcare system benefits or cost savings, these findings may support the reallocation of resources towards long-term structural reimbursement. Structural reimbursement should remain subject to periodic review and may be adapted or discontinued if the expected value is no longer demonstrated. Structural reimbursement of AI-tools could be either nomenclature-based funding (cfr. for a medical device) or bundled payments.

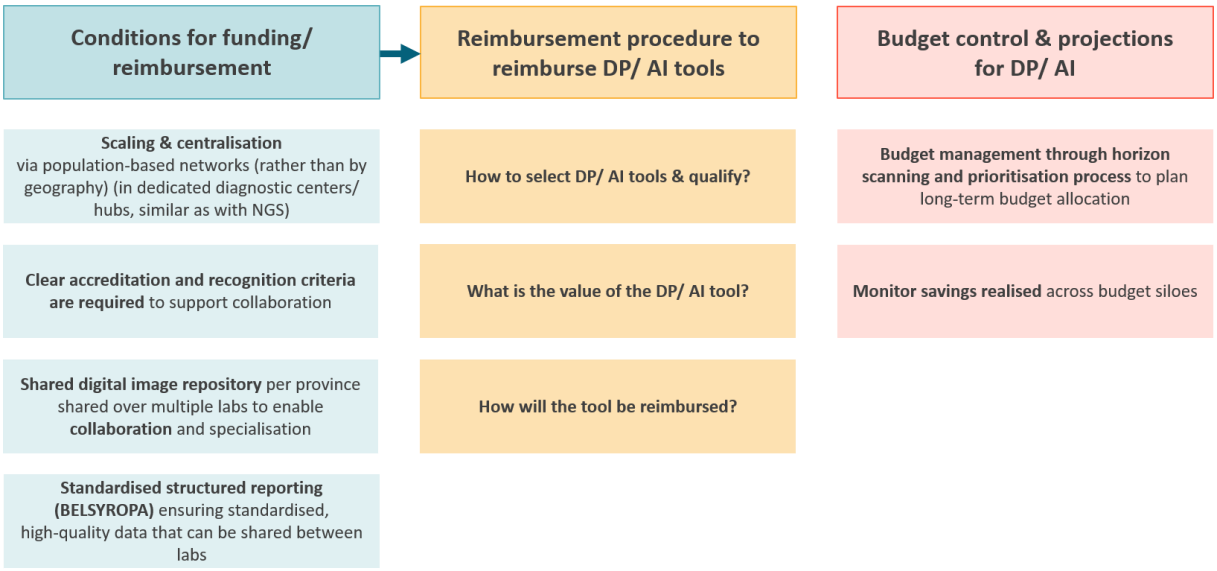
Nomenclature updates can follow international precedent by either adapting existing pathology codes to differentiate digital image analysis (for example, with higher payment for digital images versus glass slides, as implemented in Norway), or by introducing a new dedicated reimbursement code for digital pathology services (as implemented in Switzerland). This nomenclature component provides a sustainable, accessible baseline for core digital pathology services. As digital pathology primarily represents an infrastructure and workflow transformation rather than a distinct medical act, nomenclature updates alone are unlikely to provide a complete solution for supporting the digital transition of pathology laboratories.

Bundled payment mechanisms should be established initially through Article 56 temporary conventions, with duration sufficient to enable pilot projects to generate rigorous evidence of clinical value and healthcare system savings. If pilot evaluation confirms anticipated benefits, digital pathology and AI tools reimbursement transitions to **permanent Article 22 conventions**, providing long-term funding stability.

A balanced and future-oriented framework

Within these bundled payment arrangements, pathologists retain professional responsibility for selecting the most appropriate diagnostic techniques for individual cases, ensuring that clinical judgment remains central to diagnostic decision-making. This professional autonomy is essential for maintaining diagnostic quality and allows pathologists to adapt technique selection based on case-specific requirements and evolving clinical evidence.

Throughout all phases, the **framework incorporates mechanisms for budget control**. These include predefined spending limits, value-based criteria and the use of savings generated through more precise therapy selection to offset the costs of digital and AI tools. By linking reimbursement to demonstrated value, the framework ensures that innovation does not lead to uncontrolled budget growth but instead contributes to a more efficient and sustainable healthcare system.



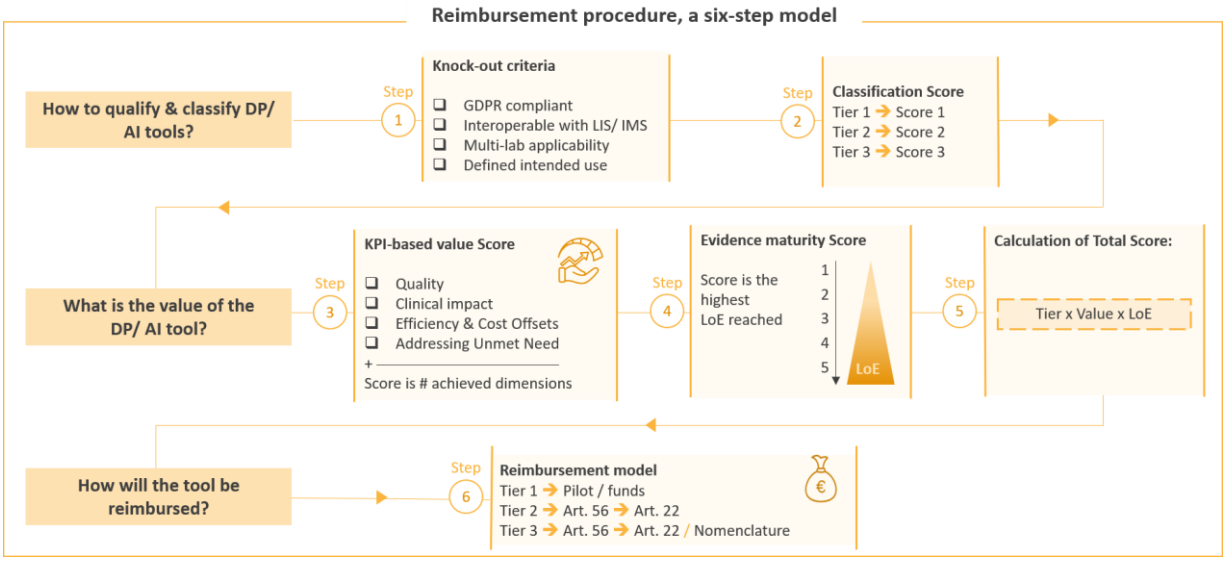
The proposed funding and reimbursement framework for AI tools for digital pathology therefore provides a balanced, pragmatic and future-oriented solution. It supports laboratories in making the transition to digital pathology, offers developers a clear and predictable pathway, and gives payers the tools they need to manage budgets responsibly. Most importantly, it ensures that patients across Belgium benefit from high-quality, timely and personalised diagnostic care.

6.2. Reimbursement procedure: a comprehensive six-step model

To ensure that AI tools for digital pathology are introduced into the Belgian healthcare system in a responsible, evidence-based and financially sustainable manner, the funding and reimbursement framework proposes a structured six-step reimbursement procedure. This model creates a clear pathway from early evaluation to structural reimbursement, allowing innovations to be assessed and adopted in a controlled and transparent way. It balances the need for timely access to new technologies with the requirement for robust evidence and budgetary oversight, ensuring that only tools that demonstrate real value progress to long-term funding.

The reimbursement of AI tools for digital pathology requires a structured, transparent and evidence-driven process that reflects both the complexity of these technologies and the need for financial stewardship within the Belgian healthcare system. The framework therefore proposes a six-step reimbursement model that guides each tool from initial qualification to a final reimbursement decision. This model ensures that only tools that meet minimum regulatory and system-readiness criteria enter the evaluation pathway, that their value is assessed in a consistent and objective manner, and that reimbursement decisions are aligned with the level of evidence, clinical relevance and system impact of each tool.

The six steps form a coherent sequence: qualification, classification, value assessment, evidence scoring, tier-weighted valuation and reimbursement decision. Together, they create a predictable and scalable mechanism that supports innovation while safeguarding quality and budget control.



Step 1 – Intake and minimum qualification

The process begins with a strict intake phase in which each AI tool must demonstrate that it meets a set of **minimal, non-negotiable criteria. These "knock-out" criteria** ensure that only tools that are legally compliant, technically interoperable and operationally feasible enter the reimbursement pathway. A tool must be GDPR-compliant, ensuring that patient data are processed in accordance with European data protection standards. It must be interoperable with laboratory information systems (LIS) and image management systems (IMS), enabling seamless integration into existing workflows using the appropriate (inter)national data standards. Data portability across systems and multiple laboratories is necessary, avoiding vendor-locked or single-site solutions that cannot scale nationally. Finally, the tool must have a clearly defined intended use, specifying its clinical purpose, operational scope and expected impact. Notably, after reimbursement approval cybersecurity requirements must be met to ensure the confidentiality, integrity and availability of patient data and digital infrastructure.

Tools that do not meet these criteria are excluded from further evaluation. Those that do qualify proceed to the next step.

An exception exists for companion diagnostics, where interoperability may not be technically feasible due to the validated "closed combination" of stainer, scanner and algorithm. In such cases, the intended use and regulatory validation define the boundaries of acceptable non-interoperability.

Vendor labelling plays a critical role here: once a vendor labels its system as compliant with a specific interoperability standard, laboratories can require this as part of accreditation or procurement, effectively making interoperability a market-driven obligation.

Step 2 – Classification by intended use and risk (tiering)

Once a tool has passed the qualification stage, it is **classified according to its intended use and associated level of clinical and system risk**. This **tiering system** is central to the framework, as it determines the level of evidence required, the evaluation pathway and the reimbursement instrument that may ultimately apply.

The classification is based on function rather than vendor, ensuring neutrality and consistency. Tools are grouped into three tiers:

- Tier 1 includes workflow and efficiency tools that support operational processes but do not influence clinical decision-making. These tools carry low risk and typically include quality control applications, case routing systems and workload optimisation algorithms.
- Tier 2 encompasses clinical decision support tools that assist pathologists in interpretation but do not independently determine diagnoses or therapy choices. These tools carry moderate risk and include triage systems or second-reader algorithms.
- Tier 3 includes diagnostic or therapy-decisive tools, such as biomarker quantification algorithms, grading tools or AI systems that function similarly to companion diagnostics.

Moreover, Tier 2 tools should be strongly aligned with the requirements of CE-IVDR and MDR, ensuring compliance with regulatory standards. As part of the CE-IVDR requirements, individual laboratories will also have to verify the tool in their own setting. Tier 3 tools carry high risk and require full compliance with CE-IVDR or MDR regulations, as they directly influence patient outcomes.

Tier	Intended use	Risk	Typical tools
Tier 1	Workflow & efficiency	Low	QC, case routing, workload optimisation
Tier 2	Clinical decision support	Moderate	Triage, second reader
Tier 3	Diagnostic/ therapy-decisive	High	Biomarker quantification, grading, CDx-like AI

This tiering system prevents unnecessary burdens on low-risk tools while ensuring that high-risk tools undergo rigorous evaluation. It also aligns the reimbursement pathway with the clinical relevance and potential impact of each tool.

Scoring could be done by existing bodies for Tier 2–3 tools, such as ComPerMed (Commission for Personalised Medicine) and the CDx (Companion Diagnostic) Platform. For Tier 1 efficiency tools and in-house developed tools, a dedicated team of pathologists (e.g. from the BELDIPA community, BSP) can evaluate the scoring of Tier 1 efficiency tools.

Step 3 – KPI-based value assessment

After classification, each tool undergoes a structured value assessment **based on a standardised set of key performance indicators** (KPIs). This step evaluates whether the tool delivers meaningful value to the healthcare system and provides a transparent basis for comparing diverse tools.

The KPI framework covers four value dimensions:
- The first dimension, quality, assesses improvements in reliability, reproducibility, structured reporting completeness and reductions in diagnostic errors or rework.
- The second dimension, clinical impact, evaluates whether the tool enhances diagnostic accuracy, is pharmacopredictive, shortens time-to-treatment or improves patient stratification.
- The third dimension, efficiency and cost offsets, examines time savings, reductions in unnecessary tests and the expected return on investment.
- The fourth dimension, addressing unmet need, and incorporates societal considerations (in line with evolving EU guidelines)

Each tool is scored according to the number of dimensions it meaningfully addresses. There is no hierarchy among the dimensions; instead, the breadth of value determines the score. This approach ensures that tools with diverse strengths can be compared fairly and that value is assessed holistically rather than narrowly.

Step 4 – Evidence maturity scoring (level of evidence)

The fourth step evaluates the **maturity of the evidence supporting the tool**. The LoE framework comprises five progressive levels, each with defined requirements. Evidence is scored on a **graded scale from Level of Evidence (LoE) 1 to 5**.

- LoE 1 reflects technical feasibility, demonstrating that the tool functions as intended.
- LoE 2 requires external analytical validation, confirming performance across independent datasets.
- LoE 3 involves retrospective and/or prospective real-world clinical validation, showing that the tool performs reliably (intraclass correlation coefficient of 0.75 or higher (Koo and Li,2016)) in routine practice.
- LoE 4 requires evidence of clinical utility, demonstrating prospective impact on patient care.
- LoE 5 represents the highest level of evidence, including health-economic and system-level analyses.

Tools are scored based on the highest level of evidence they achieve; achievement of lower levels provides a foundation for progression to higher levels of evidence.

The evidence maturity score provides a clear view of the tool's readiness, identifies gaps and guides decisions on whether additional evidence is required before reimbursement can be considered.

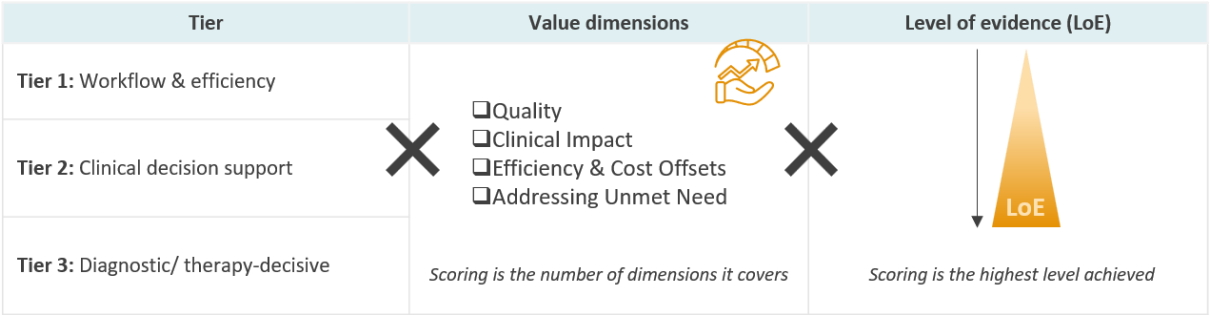
Level	Type of evidence	
1	Technical feasibility	Level 1 evidence establishes that a digital pathology or AI tool is technically sound and capable of functioning as designed This level includes: • Algorithm description, architecture, and training data overview • Basic performance metrics on internal test sets • No external validation *Typical output*: accuracy, sensitivity, specificity, and area under the curve (AUC)
2	Analytical validation:	Level 2 evidence demonstrates that a tool performs reliably beyond its training environment. Achieving Level 2 requires: • Performance on external datasets from at least one independent institution • Robustness testing: staining variability, scanner variability, artefacts • Reproducibility and repeatability *Goal*: demonstrate that the model works beyond its training environment.
3	Real-world clinical validation	Level 3 evidence establishes that a digital pathology or AI tool is clinically valid and effective in real-world diagnostic settings. This level requires: • Real world clinical datasets (preferably Belgian or international real-world evidence when comparable systems) • Comparison with pathologist performance • Inter observer variability analysis • Workflow integration studies *Goal*: show clinical relevance and reliability in intended-use conditions. Systematic reviews emphasize the need for

		stronger diagnostic accuracy evidence before clinical introduction.
4	Clinical utility (prospective impact)	Level 4 evidence demonstrates that a digital pathology or AI tool improves diagnostic or clinical practice in real-world conditions. Achieving Level 4 requires: • Prospective studies or pragmatic trials. Often missing: Very few digital pathology AI tools have prospective utility studies. • Impact on diagnostic accuracy, turnaround time, workload, triage efficiency • Evidence that AI improves patient outcomes or system performance
5	Health-economic & system-level evidence	Level 5 evidence establishes that digital pathology and AI tools deliver measurable healthcare system benefits and represent cost-effective investments. This level encompasses: • Cost-effectiveness vs. standard workflow • (long term) budget impact • Impact on workforce, quality assurance, and scalability • Alignment with HTA requirements (EUnetHTA, etc.) Note: all tools that obtained a positive full HTA assessment reach level 5

Step 5 – Tier-weighted value calculation

The fifth step integrates the results of the previous steps into a single **tier-weighted value score**. This score reflects the overall relevance of the tool for public reimbursement by combining its tier classification, value score and evidence maturity. Each tool receives a score based on its tier, value dimension, and LoE (with the condition they meet the knockout criteria).

The formula multiplies the tier score (1, 2 or 3) by the number of value dimensions achieved and by the highest LoE reached, resulting in an **overall assessment score.**



Example:
Tier 2 tool, reaching 3 value dimensions (Quality, Clinical impact and Efficiency) with LoE 4 → Score = 2 x 3 × 4 = 24

This calculation creates a transparent and comparable ranking across tools. It also establishes minimum score thresholds for each tier. Tools that fall below the minimum threshold are not eligible for reimbursement and must generate additional evidence. Tools that exceed the threshold may proceed to reimbursement consideration, with higher scores enabling faster progression to permanent reimbursement and higher reimbursement amounts.

The tier-weighted value score therefore serves as the **central decision metric**, ensuring that reimbursement decisions are consistent, evidence-based and aligned with system priorities.

Flexible threshold application:
Not all criteria must be fully satisfied for an application to qualify for eventual reimbursement. Instead, the framework establishes a minimum aggregate threshold score or evidence standard. This flexibility enables consideration of promising technologies and applications even if they do not excel across every value dimension, while maintaining overall quality standards through the minimum threshold requirement.

Priority application areas:
Certain disease areas and clinical contexts offer particular promise for early implementation and demonstrate strong alignment with Belgium's healthcare priorities. Rare disease applications, particularly in nephrology, represent high-priority opportunities. It offers strong potential as it already benefits from an existing registry system. Moreover, new therapeutic advances increasingly target rare diseases and require specialised pathological assessment for diagnosis, treatment selection, and treatment monitoring.

Step 6 – Reimbursement decision

The final step determines the **appropriate reimbursement instrument** based on the tool's tier and tier-weighted value score. Each tier corresponds to a specific reimbursement pathway:

- Tier 1 tools, which focus on workflow and efficiency, are supported through **upfront investment** mechanisms such as innovation funds, digitisation grants or pilot funding. These tools follow a "test and learn" approach, enabling laboratories to adopt them without long-term financial commitments.
- Tier 2 tools, which provide clinical decision support, are reimbursed through **time-limited Article 56 conventions**. These conventions include budget caps, KPI-based continuation criteria and the possibility to transition to structural reimbursement under Article 22 once sufficient evidence has been generated.
- Tier 3 tools, which are diagnostic or therapy-decisive, follow a pathway like companion diagnostics. They may receive **temporary reimbursement under Article 56 and become eligible for structural reimbursement following a positive HTA assessment. Tools that have already undergone and successfully completed a full HTA may be granted structural reimbursement immediately.** Structural reimbursement is achieved through inclusion in the **nomenclature**, either via new codes or adaptations of existing ones or in a **bundled payment under Article 22 or in case of a companion diagnostic under Article 33Ter**.

	Tier 1	Tier 2	Tier 3
Overview	Tier 1 tools optimize lab operations by supporting workflow and quality control without impacting diagnostic decisions.	Tier 2 tools assist pathologists with suggestions like region highlighting and case triage, influencing but not autonomously diagnosing.	Tier 3 tools directly impact patient management through biomarker quantification and grading, requiring rigorous validation.
Typical digital pathology or AI use case	• Quality control checks • Case routing/ slide pre-screening support • Workload optimisation	• ROI highlighting • Case prioritisation or triage suggestions support • Second-reader support	• Biomarker quantification (expression levels) • Tumor grading/ scoring • AI linked to therapy choices (CDx-like)
Level of Evidence	Usability, organisational impact, safety mitigations, basic performance.	External validation, effect on diagnostic decisions, failure modes.	Robust clinical validation, generalisability across labs, and economic impact.
Level of Evidence requirement	• Assess organisational value • Safety & feasibility	Demonstrate added clinical value • Show impact on decision-making • Define KPI obligations	• Full HTA incl. economic impact • Value-for-money decision
Primary Belgian reimbursement route	These tools typically receive low reimbursement, as they improve efficiency without significantly impacting diagnostic outcomes. Alternative funding mechanisms include: • Upfront investments via innovation or digitisation funds • Pilot funding (e.g. NIHDI pilot projects) • Public-private partnerships (PPPs) Funding sources to support implementation: National innovation and digitisation funds • EU grant programmes and data capability initiatives	Bundled conditional payment via convention: • Temporary reimbursement through an Article 56 convention (2 - 5 years), supported by evidence generation of value and savings in the healthcare system. This is a time-limited reimbursement art 56 innovation with controlled spend, via pseudo codes (could be based on specific pseudo-nomenclature codes, to allow NIHDI to know exactly how often these tools are used and funded, for which indication and at what stage of the condition) Coverage with evidence development:	Tools with proven clinical and budget impact (full HTA scrutiny) receive: Structural reimbursement integrated into existing regular reimbursement codes: • Adapting existing codes to include digitisation (as done in Norway, e.g. a higher payment for a digital image, instead of a glass slide) • Introducing a new dedicated code (as implemented in Switzerland) Structural reimbursement in bundled payment (depending on the evidence score/ HTA): • Adjusted in point/ level value as evidence and workload evolve, via the German-inspired point-based reimbursement, which supports adaptive reimbursement, allowing

	• Private contributions from industry (e.g. AI and pharma companies) These mechanisms enable a one-off upfront investment to support digitisation and collaboration under defined conditions.	• Conditional reimbursement while generating real-world evidence • Transition to structural funding (Art. 22) if evaluation is positive Key design principles: • Time-limited convention (Art. 56) • KPI-based continuation or discontinuation • Gradual transition from temporary to structural funding based on level of evidence	updates as LoE and performance evolve in learning health system A clear role and responsibility for pathologists in selecting the most appropriate techniques within bundled payments.
Decision logic	"Let's test & learn"	• Time limited reimbursement • Budget caps	• Structural reimbursement after full HTA • Otherwise time-limited reimbursement
Budget control logic	• Limited scope • Time-bound funding • No automatic structural impact	• Controlled uptake via convention • Evidence-linked continuation o Continuation only if KPIs met o Budget exposure capped	• Budget impact assessed ex-ante • Post-launch monitoring & reassessment
Belgian precedents and examples	Telemonitoring pilots (early phase, administrative digital tools, historically funded via pilots, innovation budgets, conventions, no immediate structural nomenclature change).	Telemonitoring conventions, clinical decision support tools: does not replace clinician judgement: Belgium already uses conditional reimbursement via conventions. Continuation depends on KPIs & outcomes.	Companion diagnostics (CDx), medical imaging diagnostics, tool directly impacts treatment selection & budget. Requires full HTA + economic evaluation. Leads to structural reimbursement/ nomenclature embedding.

This proposed hybrid reimbursement mechanism is a workable, transparent and scalable model that safeguards innovation, is clinically relevant and keeps budgetary control.

The **reimbursement decision is dynamic**. As tools generate additional evidence, their reimbursement status may evolve from temporary to permanent. Conversely, tools that fail to demonstrate sustained value may be withdrawn.

By progressively linking funding to evidence generation and real-world performance, the framework ensures that **reimbursement decisions evolve in line with accumulated evidence, knowledge and societal value**.

Throughout all six steps, the model incorporates mechanisms for transparency, accountability and budget control. Decisions at each stage are based on predefined criteria, and progression is contingent on the demonstration of value. This ensures that the pathway remains predictable for developers, fair for laboratories and sustainable for payers. It also reinforces the principle that reimbursement is not automatic but earned through evidence and performance.

The six-step reimbursement procedure therefore provides Belgium with a robust and future-proof mechanism for integrating digital pathology and AI into its healthcare system. It supports innovation while safeguarding quality and financial sustainability, ensuring that patients benefit from the most advanced diagnostic tools available.

HTA framework adapted to digital pathology AI tools

Determining the value of AI tools requires a comprehensive, systematic assessment. A Health Technology Assessment (HTA) can provide the methodological framework for this value determination. Belgium should adapt established HTA approaches to the specific characteristics of AI tools or directly implement EU developed frameworks, ensuring that reimbursement decisions are grounded in rigorous value assessment.

The HTA framework for digital pathology AI tools should be built on five core assessment domains, applicable across all technologies:

- Clinical value: assessment of whether the tool improves diagnostic accuracy, consistency, and precision compared to standard practice
- Safety and reliability: evaluation of potential risks, adverse events, and failure modes
- Organisational input: examination of how the tool affects laboratory workflow, staffing requirements, turnaround times, and quality assurance processes
- Economic value and budget impact: assessment of the economic consequences of implementing and operating the tool, including cost effectiveness and budget impact through improved diagnostic outcomes, laboratory efficiency, and healthcare system savings
- Ethical and legal aspects: assessment of ethical considerations including accountability for AI-supported decisions, fairness and potential bias in algorithmic decision-making, and legal compliance with data protection and medical device regulations

Beyond these core HTA domains, AI tools require assessment of factors specific to machine learning technologies:

- Data representativeness
- Training and validation of data quality
- Bias in algorithm development and generalisability
- Clinical risk of false negatives and positives
- Safety evaluation
- AI lifecycle focus.

Belgium should align its assessment approach with established international HTA frameworks and standards, such as the AI-HTA Framework (Di Bidino et al., 2024), AQuAS HTA Agency Catalonia AI Assessment Guide and the European EdiHTA Initiative. Standards and guidance from NICE, the WHO and FDA also need to be considered.

ComPerMed and CDx platform advisory bodies

Belgium already possesses established advisory bodies with expertise and governance structures suitable for evaluating new technologies: ComPerMed (responsible for scientific advisory on personalised medicine applications within Article 56 conventions) and the CDx (Companion Diagnostics) platform (responsible for the evaluation of combined drug-diagnostic reimbursement requests under Article 33ter) (Delnord et al.,2022). Rather than creating parallel advisory structures, the recommended framework extends these existing bodies to incorporate digital pathology and AI tools within their respective remits. The governance of molecular and companion diagnostic testing operates through these two complementary frameworks that together ensure scientific rigor, clinical relevance, and reimbursement alignment. Nevertheless, the evaluation, monitoring and reassessment of digital pathology and AI tools will require dedicated expertise (through pathologists) and operational capacity to ensure timely, high-quality and evidence-based decision-making.

Under Article 56, the Convention for Personalised Medicine (**ComPerMed**) acts as the national advisory body. It develops clinical and technical guidelines and advises the NIHDI on which biomarker tests and algorithms should be reimbursed. Its remit includes assessing the value of molecular tests in oncology and identifying genes that warrant analysis through next-generation sequencing (NGS). The Convention's structure reflects its broad stakeholder base: a Management Board of 23 members representing NIHDI, the CDx platform, cancer foundations, oncology colleges, BELAC, FPS Public Health, KCE, and FAMHP, supported by a Scientific Board of 143 experts spanning clinicians, IT specialists, pathologists, and bioinformaticians. The Secretariat, hosted by Sciensano, ensures coordination and continuity.

Complementing this, Article 33ter establishes the **CDx Platform** for companion diagnostics, a permanent working group within NIHDI supporting two committees: the Medicines Reimbursement Committee (CTG) and the Technical Medical Council (TGR), which oversees test nomenclature. This platform evaluates clinical evidence from submitted dossiers, reviews good clinical practice, and assesses the feasibility and cost of performing tests in Belgium. The platform includes representatives from laboratories (pathologists, clinical and molecular biologists, geneticists), treating physicians, insurance institutions, and scientific bodies such as Sciensano and KCE.

This dual structure ensures that Belgium's approach to personalised medicine remains both evidence-based and operationally feasible—bridging innovation with sustainable healthcare policy.

Together, these mechanisms form a coherent and complementary system: ComPerMed would continue evaluating AI tools for digital pathology proposed for temporary Article 56 conventions, while the CDx platform would assess AI tools proposed for permanent nomenclature integration under Article 33ter.

- ComPerMed provides scientific and policy advice on the value of molecular tests and could also be expanded with AI tools.
- CDx Platform translates that advice into nomenclature and reimbursement proposals. Similar it could also advice for AI tools.

This integration builds on proven advisory mechanisms while avoiding duplication and administrative complexity.

Within the framework, stakeholders consistently emphasize the need for transparency and communication from the advisory bodies: ComPerMed and the CDx Platform. While these structures already provide a foundation for scientific and reimbursement guidance, their processes remain largely opaque to external actors. To ensure trust, efficiency, and inclusiveness, stakeholders call for clearer communication on five essential dimensions.

- First, the agenda and timing of discussions should be made publicly available, ideally through an accessible online platform. This would allow laboratories, clinicians, and industry partners to anticipate topics and contribute relevant evidence in a timely manner. Today, the dossiers under evaluation are communicated by mail to the labs on the mailing list and also posted on the RIZIV website (https://www.riziv.fgov.be/nl/professionals/verzorgingsinstellingen-en-

diensten/laboratoria/gepersonaliseerde-geneeskunde-en-companion-diagnostics-lopende-dossiers). Decisions and summary reports are also accessible at the RIZIV site (https://www.riziv.fgov.be/nl/webtoepassingen/geneesmiddelen-terugbetaling-ministeriele-beslissingen-en-ctg-beoordelingsrapporten).

- Second, the requirements for file submission, including format, content, and procedural steps—should be explicitly defined and communicated. Instructions are posted on the RIZIV website (https://www.riziv.fgov.be/nl/professionals/verzorgingsinstellingen-en-diensten/laboratoria/terugbetaling-van-gepersonaliseerde-geneesmiddelen-en-companion-diagnostics and https://www.riziv.fgov.be/nl/thema-s/verzorging-kosten-en-terugbetaling/wat-het-ziekenfonds-terugbetaalt/geneesmiddelen/farmaceutische-industrie#richtlijnen-voor-het-indienen-van-ctgdossiers). Transparent submission criteria would help applicants prepare complete dossiers and reduce administrative delays.

- Third, clear timelines for approval are necessary.

- Fourth, extension of the advisory bodies to include an industry observer representative, through BeMedTech. This industry observer would not have voting rights but will support balanced governance reflective of the diverse stakeholder interests, similar to the mHealth procedure.

- Finally, there is a strong demand for clarity on the rationale behind decisions and recommendations. Understanding how evidence and stakeholder input are weighed would enhance confidence in the system and foster alignment between scientific innovation and reimbursement policy.

In short, extending ComPerMed and the CDx Platform to include AI tools for digital pathology will only be effective if accompanied by a culture of openness and structured communication. Transparency on agendas, submission pathways and timelines, and decision logic is not merely procedural, it is fundamental to enabling innovation to translate into equitable, evidence-based clinical practice in Belgium.

Reimbursement decisions should be informed by an independent assessment of:
- clinical benefit and diagnostic performance;
- expected and observed budget impact;
- healthcare system efficiency gains;
- potential substitution of existing diagnostic procedures, tests or resources.

Assessments should be performed using transparent and predefined evaluation criteria proportionate to the risk, intended use and maturity of the technology.

Online register for digital pathology AI tools

Evidence in the AI market for digital pathology is often sparse, incomplete, or inconsistent, with limited independent validation directly compromising HTA confidence and reimbursement decision-making. To further support transparency and evidence-based decision-making, Belgium should set-up an **online public register providing accessible information on AI tools** and supporting evaluation by laboratories, healthcare systems, and payers. The register would serve as a centralised, authoritative resource documenting regulatory approvals, clinical validation, and published evidence, enabling informed procurement and reimbursement decisions. It would make clear where robust validation exists and where evidence gaps remain. This transparency supports **realistic expectations regarding tool maturity and evidence quality**. Rather than forcing decision-makers to conduct independent literature searches with uncertain completeness, the register centralises publicly available evidence in a structured, accessible format.

For each registered AI tool, the register would provide publicly available information including regulatory approvals and certifications (such as CE-MDR/IVDR status and relevant quality standards), intended clinical use and approved diagnostic indications, and links to published validation studies documenting analytical and clinical performance.

Because many AI tools evolve substantially through model updates, algorithm refinements, and expanded applications, the register must incorporate a **lifecycle approach aligned with Software as a Medical Device (SaMD) clinical evaluation concept**. Rather than treating tools as static once approved, the register should document both pre-deployment evidence and post-deployment monitoring data, reflecting the reality that AI tools require continuous evaluation as they evolve. This lifecycle perspective enables ongoing assessment of tool performance in real-world conditions, supports the responsible scaling and expansion of AI tools in clinical settings, and documents the accumulation of evidence as tools mature over time. The register therefore serves as a living document, regularly updated as new scientific evidence becomes available and as tools evolve.

The register could be **hosted and maintained by Sciensano**, mirroring the successful governance model of existing registries such as the clinically validated PCR and HPV tests registry. Sciensano already maintains robust registries of validated molecular diagnostic tests and has demonstrated expertise in registry management, evidence curation, and regular updating as new scientific evidence emerges.

What will be the reimbursement level?

Belgium can draw inspiration from Germany's structured point-based reimbursement model (Einheitlicher Bewertungsmaßstab, EBM) to determine reimbursement levels for tools. This approach offers a transparent and flexible mechanism that directly links reimbursement to demonstrated clinical value and system-level impact.

The German model is built on a straightforward but powerful formula:

$$\text{Reimbursement amount} = \text{Points} \times \text{Value} \times \text{Factor}$$

- **Points** represent the tool's contribution score, reflecting elements such as data complexity, disease complexity, clinical-question complexity, and the degree of AI involvement.
- **Value** is the monetary amount assigned per point, aligned with national reimbursement coefficients.
- **Factor** is an optional multiplier that adjusts for diagnostic difficulty, required physician oversight, or other clinical-complexity considerations.

In the Belgian adaptation, the **overall assessment score, or points**, for a digital pathology AI tool is derived from three components: the **tier score** (1, 2, or 3), the **number of KPI-based value dimensions achieved**, and the **highest Level of Evidence** (LoE) reached. This composite score reflects the magnitude of clinical and economic benefit the tool delivers.

This composite score is then multiplied by a **healthcare-system value multiplier** (value). This value multiplier might be yearly determined based on the available budget for digital pathology AI tools.

An additional optional **factor** may be applied to account for diagnostic difficulty, increased physician involvement, or other relevant complexity parameters.

This structure ensures that reimbursement is directly proportional to the tool's proven value, while maintaining transparency, predictability, and alignment with broader health-system priorities. This point-based approach aligns reimbursement with clinical value and diagnostic complexity rather than volume of use, enables integration into existing coding systems without administrative disruption, facilitates adaptive reimbursement that evolves as evidence develops, and provides transparent, auditable payment decisions. The tiered structure encourages meaningful clinical use while discouraging low-value applications. It also facilitates scalability and cross-system adoption, as points can be converted across reimbursement contexts (existing nomenclature).

This approach ensures that reimbursement decisions balance evidence quality with practical healthcare system impact: tools demonstrating both strong evidence and substantial healthcare value receive higher scores and are prioritised for reimbursement approval, while tools with weaker

evidence or limited healthcare impact proceed through conditional reimbursement pathways requiring continued evidence generation.

How the whole process could work together

The procedure begins with an **initial submission phase**, during which developers present a comprehensive dossier describing the tool's intended use, clinical performance, regulatory status and technical requirements. This submission marks the formal entry point into the procedure and ensures that all relevant information is available for assessment. It also provides clarity for developers, who gain a predictable and standardised process for introducing their innovations into the Belgian system.

Once the submission is complete, the tool enters a **structured evaluation phase**. During this stage, experts assess the clinical relevance, safety and potential impact of the tool. The evaluation goes beyond traditional clinical endpoints and considers the broader value of digital pathology AI tools, including improvements in diagnostic consistency, workflow efficiency and therapy optimisation. This holistic approach reflects the multifaceted nature of digital innovations and ensures that the assessment captures their full potential contribution to patient care.

If the evaluation confirms that the tool has meaningful potential, it progresses to a **pilot phase**. These pilots are conducted in selected laboratories that represent the diversity of the Belgian healthcare landscape. The objective is to generate real-world evidence on how the tool performs in practice, how it integrates into existing workflows and what impact it has on diagnostic processes and clinical decision-making. The pilot phase is essential for validating the tool's added value under real conditions and for identifying any operational or organisational challenges that may need to be addressed before broader adoption.

Following successful pilots, the tool may be granted **temporary reimbursement**. This phase allows for wider use across the country while maintaining a controlled environment in which data collection continues. Temporary reimbursement ensures that patients and clinicians can benefit from promising innovations without delay, while still requiring ongoing evidence generation to support long-term decisions. It also provides payers with the opportunity to monitor budget impact and verify that the tool delivers the expected value.

If the accumulated evidence demonstrates sustained clinical benefit, operational feasibility and cost-effectiveness, the tool becomes eligible for **structural reimbursement**. This final stage integrates the tool into routine clinical practice and provides long-term financial stability for laboratories and developers. Structural reimbursement is granted only when the tool has proven its value across multiple dimensions, ensuring that the healthcare system invests in technologies that genuinely improve patient outcomes and system efficiency. This could also entail the integration in the official Belgian nomenclature only for AI tools that have demonstrated sustained value. Structural reimbursement is granted only when long-term evidence confirms that a tool contributes meaningfully to patient outcomes, system efficiency or therapeutic precision. This ensures that the healthcare system invests in technologies that deliver measurable and lasting benefits.

How the whole process could work together:

Can we afford it?

Intake & horizon scanning
based on supply-driven market scans as well as on demand, such as patient & societal needs (e.g. KCE NEED framework)

- Intended use & setting
- Horizon scan to anticipate budget pressure
- Prioritisation
- Expected budget impact
- Early dialogue with NIHDI / RIZIV

Post-reimbursement monitoring payer reassurance)

- KPI follow-up & RWE
- Budget impact monitoring & control
- Trigger for re-assessment / withdrawal

What evidence do we require before paying?

How to qualify & classify DP/ AI tools ?

Step 1: Intake & minimum qualification / knock-out criteria
Before any reimbursement discussion, a DP/ AI tool must meet qualification criteria

Tools meeting these criteria can enter formal evaluation / are eligible for evaluation → proceed

Step 2: Classification by intended use & risk / Tiering
What level of risk and system impact are we dealing with?
The tool is classified by function, not by vendor.

Tier	Intended use	Risk
Tier 1	Workflow & efficiency	Low
Tier 2	Clinical decision support	Moderate
Tier 3	Diagnostic/ therapy-decisive	High

(This prevents over-burdening with full HTA for low-risk tools)

What is the value of the DP/ AI tool?

Step 3: KPI –based value assessment (value for money)
Does this tool deliver value for the healthcare system?

Each tool is assessed using a standardised KPI framework across four value dimensions:

- ❑ Quality
- ❑ Clinical Impact
- ❑ Efficiency & Cost Offsets
- ❑ Addressing Unmet Need

Resulting in a transparent, comparable value profile per tool

Step 4: Evidence maturity scoring/ using Level of Evidence (LoE)
Evidence is scored on a graded scale:

Providing clear view on evidence maturity, gaps and next steps

Step 5: Tier-Weighted Value Calculation
How relevant is this tool for public reimbursement?
To reflect system relevance, the LoE score is weighted by tier and by value dimensions reached

This creates a transparent, comparable value ranking across tools to support reimbursement decisions and prioritisation

How do we pay for it

How will the tool be reimbursed?

Step 6: Reimbursement Decision Linked to the value of the tool
Based on the tool's classification (tier) and scoring, the appropriate reimbursement model can is determined (ranging from temporary to permanent reimbursement).

As more evidence is gathered, the reimbursement model may change over time.
Only when conducting an HTA (maximum LoE 5) the tool may obtain permanent reimbursement

6.3. Budget control and horizon scanning

A sustainable integration of digital pathology and AI into the Belgian healthcare system requires a combination of infrastructure funding, implementation support and a clear reimbursement pathway for AI tools. Investment in digital pathology infrastructure, including hardware and software components, is a prerequisite for the adoption of AI-enabled applications. At the same time, **robust mechanisms to ensure budgetary predictability and long-term financial stewardship are required**. Throughout the BELDIPA consultations, payers and policymakers emphasised that innovation can only be supported if it is accompanied by transparent, controlled and evidence-based financial management. The proposed framework therefore incorporates two essential components: budget control and horizon scanning. Together, these elements ensure that the adoption of DP and AI remains aligned with national healthcare priorities, available resources and evolving technological developments.

Budget control is embedded throughout the reimbursement pathway. Rather than granting immediate structural reimbursement, the framework introduces a phased approach in which financial exposure is carefully managed depending on the overall assessment score, or points. During the pilot phase, investments are limited and targeted, allowing payers to assess the real-world impact of a tool before committing to broader funding. Temporary reimbursement provides an intermediate step in which usage expands but remains subject to predefined conditions, ongoing data collection and periodic review. Only when a tool has a high overall assessment score or has demonstrated sustained clinical value and cost-effectiveness it progresses to structural reimbursement, ensuring that long-term funding is reserved for technologies that deliver measurable benefits.
This approach also allows for the use of value-based funding principles. Digital pathology and AI have the potential to generate savings through more precise therapy selection, reduced diagnostic errors, improved workflow efficiency and shorter turnaround times. These savings can be reinvested to support the adoption of new tools, creating a self-reinforcing cycle in which innovation contributes to financial sustainability rather than undermining it. By linking reimbursement to demonstrated value, the framework ensures that investments in DP and AI strengthen the healthcare system, while discouraging unnecessary volume growth and additional strain on budgets.

Horizon scanning complements budget control by providing a forward-looking mechanism to anticipate emerging technologies, upcoming regulatory changes and potential shifts in clinical practice. Digital pathology and AI are rapidly evolving fields, with new tools, biomarkers and analytical methods entering the market at an accelerating pace. Without a structured process to monitor these developments, Belgium risks being unprepared for future innovations or facing sudden budgetary pressures as new tools seek reimbursement. The horizon-scanning function systematically reviews the pipeline of digital and AI-enabled diagnostic tools, assesses their potential impact and identifies those that meet Belgium's health objectives and unmet needs and may require evaluation or pilot testing in the near future. Horizon scanning and market forecasting of digital pathology and AI solutions provide essential insight into the tools expected to enter the Belgian healthcare market. Additionally, it could be closely linked to the proposed national AI register and may build on existing expertise and capabilities within Sciensano, particularly in relation to data governance, evidence monitoring and technology landscape assessments.

By systematically monitoring emerging technologies, policymakers and payers can anticipate future reimbursement requests and better understand the likely budgetary impact of these innovations. This intelligence supports **improved prioritization and long-term budget management** by identifying which solutions are most likely to be eligible for reimbursement in Belgium. As a result, budget allocations can be planned proactively rather than reactively, enhancing financial predictability and sustainability. Importantly, this approach ensures that healthcare expenditure remains controlled by focusing reimbursement on tools that demonstrate clear added value and true innovation, rather than incremental or low-value solutions.

This proactive approach, in which **NIHDI acts as a buyer instead of a payer**, enables policymakers to anticipate financial needs, plan for infrastructure requirements and align regulatory guidance with technological trends. It also provides laboratories and developers with greater predictability, as they

gain insight into the types of innovations that are likely to be prioritised for evaluation and reimbursement.

Importantly, horizon scanning is not limited to technological developments. It also considers broader trends in personalised medicine, clinical research, regulatory frameworks and international policy. For example, the increasing use of AI-supported biomarkers in oncology trials, the emergence of adaptive clinical pathways and the evolution of the EU AI Act all have implications for the future of digital pathology in Belgium (Deman et al., 2026). By integrating these insights into **strategic planning**, the healthcare system can remain agile and responsive, ensuring that policy keeps pace with scientific progress.

Together, structured budget control and horizon scanning form the financial and strategic backbone of the proposed framework to **guide reimbursement decisions** for AI tools. The framework is designed to balance innovation with affordability and consists of the following elements:

- **Alignment of healthcare expenditure with economic growth**, applying an overall expenditure growth rate (x%) that reflects macroeconomic constraints.
- **Differentiated growth allowance for "truly innovative" tools**, defined by high levels of evidence (LoE) and positive health technology assessment (HTA) outcomes, allowing targeted investment where clinical value is clearly demonstrated.
- **Risk-sharing and accountability mechanisms** to manage budget overshoots, such as outcome-based agreements or expenditure caps shared between payers and manufacturers.
- **Horizon scanning combined with financial assessment of unmet medical needs**, enabling the early identification of high-performance tools with the greatest potential health impact. A comprehensive mapping of currently available AI and digital pathology tools, complemented by horizon scanning of solutions in development, provides a clear overview of technologies that may seek reimbursement in the near to medium term. This overview forms the basis for structured selection and prioritization. Using a KPI-based selection framework, only the most promising tools are selected for formal reimbursement evaluation. Technologies that do not meet predefined thresholds are excluded from reimbursement consideration, ensuring efficient use of public funds.
- **Budget predictability** through strategic budgeting and proactive resource planning, supported by the horizon scanning, also clarifying the payer's willingness-to-pay and supporting the formulation of policy objectives for investments.

They ensure that innovation is introduced responsibly, that investments are aligned with evidence and national priorities, and that Belgium remains prepared for the next generation of digital diagnostic tools. By embedding these mechanisms into the reimbursement pathway, the framework supports a **sustainable, forward-looking and value-driven approach to digital transformation**.

7. Benefits for all stakeholders

The proposed funding and reimbursement framework for digital pathology and AI delivers tangible benefits for all key stakeholders, while remaining fully compatible with the structure and principles of the Belgian healthcare system.

For pathologists and laboratories, the framework supports the safe, effective, and clinically responsible adoption of AI. By emphasising workflow integration, diagnostic safety, and real-world usability, it ensures that new tools enhance rather than disrupt clinical practice. The phased approach and clear evidence requirements build confidence in clinical decision-making while avoiding unnecessary administrative burden. The model also strengthens financial predictability for laboratories, enabling a clearer return on investment.

For patients, the framework ultimately aims to improve quality, accessibility, and equity of diagnostic care across Belgium, regardless of geographic location, by facilitating collaboration between laboratories and pooling of expertise. By enabling structured and evidence-based adoption of digital pathology and AI, patients benefit from more accurate, faster and consistent diagnoses, reducing uncertainty and time-to-treatment. Improved diagnostic precision supports better treatment selection, enabling more personalised and effective care pathways.

For companies, the framework provides transparency and predictability regarding evidence expectations at each stage of adoption. Clear criteria for levels of evidence, performance thresholds, and progression pathways reduce uncertainty for developers and investors. This enables more targeted innovation aligned with clinical needs, payer expectations, and health-system priorities.

For the payer (NIHDI), the framework ensures budgetary control and predictability. It enables innovation without defaulting to automatic or premature structural reimbursement, making the financial impact of digital pathology and AI both manageable and governable. Importantly, the model builds on existing Belgian instruments, avoiding the need for new legislation. The Tier 2 reimbursement pathway allows NIHDI to actively support innovation through controlled, temporary funding while maintaining strict budget discipline. This tier provides early access, avoids premature changes to the nomenclature, and still requires robust clinical and economic evidence, fully consistent with established Belgian practice, where conventions serve as a bridge between pilots and permanent reimbursement.
The proposed six-step procedure further reduces workload and administrative effort by offering a transparent, standardised evaluation process. Much of this assessment could be automated, lowering the operational burden for both NIHDI and applicants.

Overall, the framework is well aligned with the Belgian context and builds on mechanisms already in use, such as telemonitoring and next-generation sequencing conventions, innovation pilots, and the gradual integration of validated technologies into the reimbursement nomenclature.

8. Implementation roadmap

Timely action is required for Belgium to maintain its position as an innovation leader, as other countries have already started similar initiatives

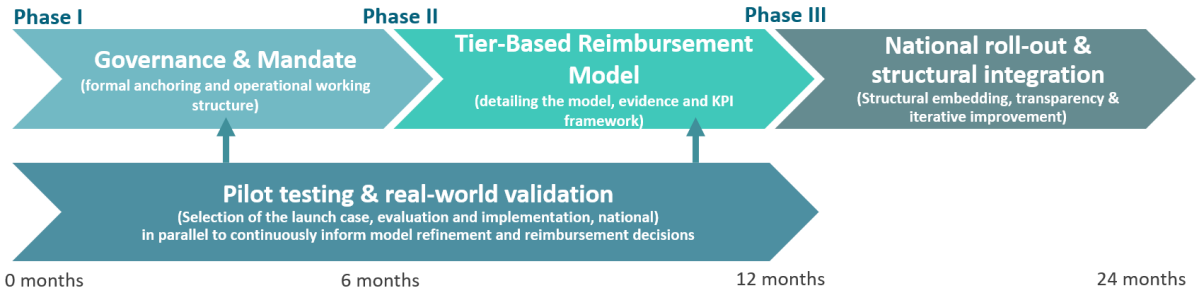
The successful integration of the proposed funding and reimbursement framework for digital pathology and AI into the Belgian healthcare system requires a **phased and carefully coordinated implementation strategy** approach to translate policy design into national implementation. The BELDIPA roadmap provides a structured approach that guides the transition **from initial preparation to nationwide adoption**. The objective of the implementation roadmap is to introduce the proposed funding and reimbursement framework in a manner that enables structured and scalable deployment across Belgium, balances innovation with demonstrated clinical value and budgetary sustainability, and establishes a learning reimbursement system grounded in a "learn-and-adapt" principle.

Each phase builds on the previous one, ensuring that regulatory clarity, evidence generation, infrastructure development and governance structures evolve in a coherent and mutually reinforcing manner. This phased approach allows Belgium to move forward with ambition while maintaining control over quality, budget and operational feasibility.

Implementation is guided by a set of **core principles**. First, the framework is introduced in a phased and conditional manner, allowing gradual uptake while managing uncertainty and financial risk. Second, a strong institutional mandate is essential, with NIHDI playing a central role in governance, coordination, and decision-making. Third, robust multi-stakeholder governance is required to align clinical, technical, regulatory, and financial perspectives. Finally, continuous dialogue with all stakeholders is maintained throughout the implementation process to ensure transparency, trust, and adaptability.

8.1. Implementation phases

The implementation consists of three phases and one parallel track.



Phase I – Governance & mandate

The first phase focuses on establishing the foundational conditions necessary for the responsible introduction of digital pathology and AI. This includes clarifying the regulatory landscape, particularly in relation to GDPR, the EU AI Act and medical device regulations. Stakeholders repeatedly emphasised that regulatory uncertainty is one of the most significant barriers to adoption. Therefore, Phase I prioritises the development of national interpretation guidance that provides laboratories, developers and data protection officers with clear, consistent and practical instructions on how to implement DP and AI in a compliant manner.

In parallel, this phase involves defining the governance structure that will oversee the implementation of the funding and reimbursement framework. This includes establishing roles and

responsibilities, decision-making processes and mechanisms for stakeholder engagement. The governance structure must be sufficiently robust to coordinate national efforts while remaining flexible enough to adapt to technological and regulatory developments. The establishment of the governance structure should include the formal designation of implementation responsibilities, project ownership and programme management capacity.

Timeline	0-6 months	
Scope	I.II Formal anchoring of BELDIPA • Set-up the BELDIPA Steering Committee (with one representative per stakeholder group) • Secure an institutional mandate with NIHDI • Formalise BELDIPA as national coordination platform • Define governance processes on decision-making and escalation rules • Supported by external professional coordination and guidance • Explore European funding opportunities (e.g. Cancer Image Europe and AI factory Antenna)	I.II Operational working structure • Set up 3 permanent action groups 1. Tier-based reimbursement & coding 2. KPI & evidence framework 3. Governance & transparency • Appoint a lead for each action group. • Define scope, deliverables, and reporting lines.
Stakeholders	NIHDI & FPS Public Health (FOD), FAMHP, BSP, Hospitals, companies	
Outcome	A nationally recognised governance is created with a formal mandate, clear decision-making rules, defined responsibilities, appointed leads, and aligned milestones to ensure coordinated progress. Financial planning should include not only investments in infrastructure and innovation, but also resources to support implementation activities, including programme and project management.	

Phase II – Tier-based reimbursement model

Once the regulatory and governance foundations are in place, the roadmap moves into a phase dedicated to detailing the tier-based reimbursement model and the Evidence and KPI frameworks.

Timeline	6 – 12 months	
Scope	II. I Tier-based reimbursement model • Finalise the three-tier reimbursement model • Align with existing Belgian nomenclature principles (and ongoing reforms)	II.II Evidence and KPI framework • Approve a fit-for-purpose LoE ladder (incl. RWE, international clinical data, …etc.) • Classification: Differentiate requirements for efficiency-focused AI tools, clinically impactful AI & companion diagnostics
Stakeholders	BELDIPA working groups, NIHDI, BSP, companies	

Outcome	Reimbursement model, flexible for the scope of the tool, including clear KPI and evidence requirements

Parallel phase – Pilot testing & real-world validation

Parallel to phase I and II the **test cases** (to test the model) will be used. Based on practical cases the tier-based model and evidence and KPI frameworks can be developed and tested on their practical feasibility at the same time.

Timeline	0 – 12 months, in parallel with the other phases	
Scope	I. Selection and launch of test cases (to test the model based on the learn & adapt – principle) • Select 3- 5 test DP/ AI use cases across different tiers • Test cases may include new cases or real-world implementation of tools with existing international clinical and economic evidence	II. Evaluation & Implementation • Evaluation (based on clearly defined success criteria) • Publish a national policy report with recommendations and lessons learned • Define annual evaluation milestones • Enable automatic transition to structural implementation when predefined success criteria are met
Stakeholders	BELDIPA steerco, NIHDI, FAMHP, BSP, companies, Sciensano	
Outcome	Selection & launch of first test cases Evaluated framework	

Preparing and launching pilot projects

These pilots are essential for generating real-world evidence on the clinical value, operational impact and cost-effectiveness of digital pathology and AI tools. They also provide an opportunity to test interoperability, assess workflow integration and identify practical challenges that may arise during implementation.

Pilot sites are selected to reflect the diversity of the Belgian healthcare landscape, ensuring that the evidence generated is representative and applicable across regions and laboratory types. During this phase, detailed protocols are developed, data collection frameworks are established, and training is provided to participating laboratories. The objective is to create a controlled environment in which innovations can be evaluated rigorously and transparently.

Following successful pilot evaluations, the roadmap transitions to a phase of controlled adoption. Tools that demonstrate clear value progress to temporary reimbursement, allowing them to be used more broadly while maintaining budgetary safeguards and ongoing evidence collection. This phase is critical for balancing timely access to innovation with financial responsibility.

Temporary reimbursement provides laboratories with the confidence to invest in digital workflows, knowing that the tools they adopt have been validated in real-world settings. At the same time, it allows players to monitor budget impact and verify that the expected benefits, such as improved diagnostic accuracy, workflow efficiency or therapy optimisation, are being realised. This phase also supports the gradual scaling of infrastructure, training and standardisation efforts across the country.

Phase III - National rollout and structural integration

The final phase of the roadmap focuses on the structural embedding the BELDIPA procedures within standard NIHDI processes, after early communication and participation of the authorities in the detailing process in the previous phase.

During this phase, national standards for interoperability, data exchange and workflow integration are fully implemented. Centralised or networked infrastructures may be expanded to support cross-institutional collaboration, quality benchmarking and research. The governance structure continues to play a central role, ensuring that implementation remains aligned with national priorities and that emerging challenges are addressed proactively. The national DP and AI register should be set-up and operational at that time.

Phase III also marks the transition from project-based implementation to long-term operational sustainability. Digital pathology and AI become embedded in routine clinical practice, supported by stable funding mechanisms, standardised processes and ongoing quality monitoring. The horizon-scanning function ensures that the system remains prepared for future innovations, while continuous evaluation allows for iterative improvements.

Timeline	12 - 24 months	

Scope	**III.I Structural embedding**
	• Embed BELDIPA procedures within standard NIHDI processes, after early communication and participation of authorities
	• Integrate DP/ AI reimbursement codes into the official Belgian nomenclature
		III. II Transparency & iterative improvement
		• Establish a national DP/ AI register.
		• Organise annual reviews of:
		  • Tier definitions
		  • KPI frameworks
		  • Reimbursement levels

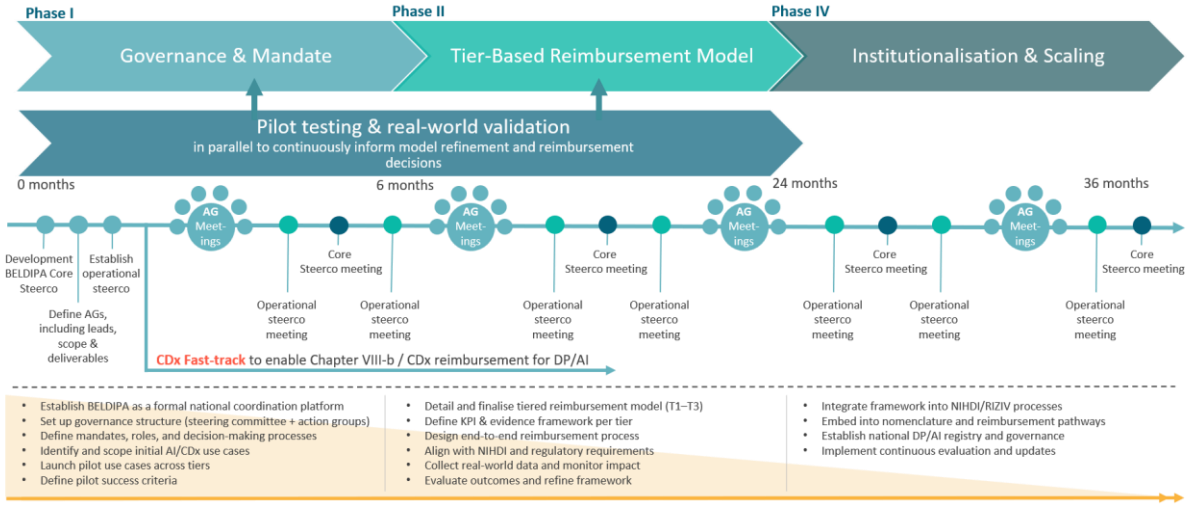
Stakeholders	BELDIPA steerco, NIHDI, Sciensano, BSP, companies	
Outcome	Framework embedded in NIHDI processes, supported by a national register and annual performance reviews	

8.2. Implementation governance model

A successful national transition to digital pathology and AI requires more than a reimbursement pathway and a phased implementation plan. It demands a governance model capable of coordinating stakeholders, ensuring regulatory compliance, safeguarding quality and guiding long-term strategic development. Throughout the implementation process, stakeholders consistently emphasised that governance is the backbone of sustainable digital transformation. Without a clear structure, implementation risks becoming fragmented, inconsistent and vulnerable to delays or misalignment between institutions.

The proposed governance model is designed to provide coherence, transparency and continuity. It establishes a **central coordinating steering committee** responsible for overseeing the implementation of the funding and reimbursement framework, ensuring that decisions are evidence-based and aligned with national healthcare priorities. This steerco acts as the anchor point for all activities related to digital pathology and AI, bridging the perspectives of authorities, laboratories, clinicians, industry, regulators and patient representatives.

To ensure trust, legitimacy and broad stakeholder support, the governance structure should be built on clear governance principles. Representation within the steering committee should remain balanced across public authorities, payer, healthcare providers, patient representatives, academia and industry. Relevant interests should be disclosed transparently, and appropriate conflict-of-interest management procedures should be established to **safeguard independent and evidence-based decision-making.** These measures help ensure that decisions remain aligned with patient needs, healthcare system priorities and broader societal interests.



Finally, the phased implementation roadmap, supported by a **steerco-led and action group-driven governance structure**, with representatives of all involved stakeholder groups, ensures ongoing stakeholder engagement. Digital pathology and AI affect a wide range of actors, each with unique perspectives and responsibilities. Each **action group** will consist of contributing team of experts and stakeholders working on the action, based on an action charter per action group and led by an **action group lead and co-lead**, with the objective of detailing the solutions for implementation.

The operational steerco will consist of the action group leads and will discuss action status and interdependencies between the action groups to avoid overlaps and gaps.

The national coordination platform provides a platform for continuous dialogue, ensuring that decisions are informed by clinical realities, operational constraints and patient needs. This inclusive approach strengthens trust, fosters alignment and supports the long-term sustainability of the funding and reimbursement framework.

In addition to strategic governance and stakeholder representation, successful implementation will require dedicated operational coordination. A project owner, supported by professional project management, should be appointed to oversee the implementation of the roadmap, coordinate stakeholders, monitor progress, prepare decision-making and ensure continuity between governance meetings. Adequate resources should be allocated to support this operational function.

A core function of the governance structure is to provide regulatory clarity. Digital pathology and AI operate at the intersection of multiple regulatory domains, including GDPR, medical device legislation and the EU AI Act. Laboratories and developers need consistent, authoritative guidance to navigate these requirements. Therefore, the initial steerco should transition to a **national coordination platform** that plays a central role in developing national interpretation guidelines, harmonising practices across institutions and ensuring that compliance does not become a barrier to innovation.

Quality assurance is another essential pillar of the national coordination platform. As digital workflows and AI tools become integrated into routine practice, maintaining high standards of diagnostic accuracy, data integrity and interoperability becomes increasingly important. The

governance structure oversees the development of national standards for image quality, data formats, workflow integration and validation procedures. It also supports the creation of benchmarking mechanisms that allow laboratories to compare performance, identify areas for improvement and ensure consistent quality across the country.

The national coordination platform also facilitates coordination between laboratories. Digital pathology and AI thrive in environments where data can be shared securely, expertise can be pooled and workflows can be harmonised. The governance body promotes collaboration by supporting networked infrastructures, encouraging shared procurement strategies and enabling cross-institutional training programmes. This collaborative approach ensures that smaller laboratories benefit from the same level of expertise and technological capability as larger centres, promoting equity and efficiency.

Another key responsibility of the governance structure is to oversee evidence generation and evaluation. As new tools enter the reimbursement pathway, the national coordination platform ensures that pilot projects are conducted rigorously, that data collection is standardised and that results are analysed transparently. It also plays a role in determining whether tools have met the criteria for progression to temporary or structural reimbursement. By centralising these functions, the national coordination platform ensures consistency, fairness and accountability in decision-making.

The national coordination platform also integrates the horizon-scanning function, enabling Belgium to anticipate emerging technologies, regulatory developments and shifts in clinical practice. This forward-looking capability ensures that the healthcare system remains agile and prepared for future innovations. It also supports strategic planning by identifying areas where infrastructure investment, training or regulatory adaptation may be required.

In essence, the proposed governance model provides the structural foundation for Belgium's digital pathology and AI ecosystem. It ensures that implementation is coordinated, evidence-based and aligned with national priorities. By establishing clear roles, transparent processes and mechanisms for collaboration, the governance structure enables Belgium to move confidently toward a modern, high-quality and future-proof diagnostic landscape.

9. Conclusion

Belgium stands at a pivotal moment in the evolution of diagnostic medicine. The rapid advancement of digital pathology and artificial intelligence is reshaping the global healthcare landscape, offering unprecedented opportunities to enhance diagnostic accuracy, accelerate clinical workflows, extent clinical expertise and support the expansion of personalised medicine. These technologies are no longer experimental or optional; they are **becoming essential components of modern healthcare systems**. For Belgium to maintain its longstanding commitment to high-quality, equitable and innovative care, a coordinated national strategy is both timely and necessary.

The BELDIPA initiative has demonstrated that the challenges associated with med tech innovations, such as digital pathology and AI are multifaceted, spanning financial, regulatory, clinical and organisational domains. Yet it has also shown that these challenges are surmountable when stakeholders work together toward a shared vision. Through extensive research, broad stakeholder engagement and iterative refinement, BELDIPA has developed a **comprehensive framework** that **addresses the full spectrum of barriers to adoption**. This framework provides Belgium with a clear, evidence-based and future-oriented **pathway for integrating digital pathology and AI into routine clinical practice**.

Central to this framework is the recognition that innovation must be introduced responsibly. The proposed funding and reimbursement model ensures that digital pathology and AI tools are evaluated rigorously, piloted in real-world settings and adopted only when they demonstrate clear clinical value and cost-effectiveness. By embedding budget control and horizon scanning into the reimbursement pathway, the framework **safeguards financial sustainability while enabling timely access to promising innovations**.

The **phased implementation roadmap** further ensures that adoption proceeds in a structured and coordinated manner, supported by regulatory clarity, standardisation and continuous evidence generation.

Equally important is the **governance model**, which provides the structural foundation for long-term success. By establishing a **central coordinating body** with clear responsibilities for regulatory guidance, quality assurance, evidence evaluation, project implementation and stakeholder engagement, Belgium can ensure that digital pathology and AI are implemented consistently and transparently across the country. This governance structure also positions Belgium to anticipate future developments, adapt to evolving technologies and maintain alignment with European and international standards.

The transition to digital pathology and AI is not merely a technological upgrade; it represents a fundamental transformation of diagnostic practice. It requires investment, collaboration and a willingness to rethink traditional workflows. But the benefits: improved diagnostic accuracy, faster turnaround times, more precise therapy selection and enhanced research capacity, are substantial and far-reaching. By embracing this transformation, Belgium can strengthen its healthcare system, support its clinicians and ensure that patients across all regions receive the highest standard of care.

The funding and reimbursement framework offers a realistic and actionable blueprint for achieving this vision. It reflects the **collective expertise and commitment of stakeholders** across the healthcare ecosystem and provides the tools needed to navigate the complexities of **digital transformation of anatomic pathology**. With decisive action and sustained collaboration, Belgium can position itself as a leader in digital diagnostics and ensure that its healthcare system remains resilient, innovative and **prepared for the future.**

10. List of abbreviations

Abbreviation	Definition
AG	Action Group
AI	Artificial Intelligence
AQuAS	Agency for Health Quality and Assessment of Catalonia
AUC	Area Under the Curve
BELDIPA	Belgian Digital Pathology
BSP	Belgian Society of Pathology
CE-IVDR	CE-marking under the European In Vitro Diagnostic Regulation
CDSS	Clinical Decision support systems
CDx	Companion Diagnostic
ComPerMed	Commission for Personalised Medicine
DP	Digital Pathology
DPA	Digital Pathology Association
DPO	Data Protection Officer
EBM	Einheitlicher Bewertungsmaßstab (German Uniform Value Scale reimbursement system)
EdiHTA	European Digital Health Technology Assessment framework
EUnetHTA	European Network for Health Technology Assessment
FDA	Food and Drug administration
FOD	Federale Overheidsdienst Volksgezondheid
FPS	Federal Public Service
GDPR	General Data Protection Regulation
HCP	Healthcare Professional
HTA	Health Technology Assessment

IMS	Image Management System
KCE	Belgian Health Care Knowledge Centre (Federaal Kenniscentrum voor de Gezondheidszorg)
KPI	Key Performance Indicator
LIS	Laboratory Information System
LoE	Level of Evidence
MDR	Medical Devices Regulation
ML	Machine Learning
NEED	New Evidence Evaluation and Development framework
NGS	Next-generation sequencing
NICE	National Institute for Health and Care Excellence
NIHDI	National Institute for Health and Disability Insurance (RIZIV)
PPP	Public-private partnership
QC	Quality Control
RIZIV	Rijksinstituut voor Ziekte- en Invaliditeitsverzekering (NIHDI)
RWE	Real-World Evidence
SaMD	Software as Medical Device
WHO	World Health Organization
WSI	Whole Slide Imaging

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