AI-enabled Health Innovation and IP

From idea to impact

ITU

World Health Organization

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

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Introduction

Launched in 2023, the Global Initiative on AI for Health (GI-AI4H) brings together three leading United Nations organizations with distinct but complementary expertise in artificial intelligence (AI). The International Telecommunication Union (ITU) drives global standards and connectivity for AI-enabled technologies. The World Health Organization (WHO) provides authoritative guidance on the safe and ethical use of AI in health systems, grounded in its Global Strategy on Digital Health 2020–2025 (extended to 2027) and its AI Ethics & Governance Guidance (2021). The World Intellectual Property Organization (WIPO) serves as the leading international forum on the intersection of AI and intellectual property (IP). Since 2019, WIPO has worked with its member states and stakeholders to support understanding of IP as a catalyst for AI-driven innovation.

Health innovation increasingly applies AI.[1] Given the opportunities and risks to public health caused by this rapid expansion, the IP Working Group of the GI-AI4H identified a need for practical tools for innovators and policymakers. These should guide the responsible integration of AI into health care, while supporting well-designed IP strategies that safeguard innovation and investment and help to extend AI-enabled innovations to patients in all settings. This publication provides a resource to support that process.

By raising awareness and providing information, ITU, WHO and WIPO are committed to the role of IP in continuing to support breakthrough innovations that improve lives everywhere. A broad range of stakeholders, including national governments, regional organizations, health funders, research institutions, industry and civil society organizations also share an interest in this mission. As AI advances and interest in it grows, global cooperation among relevant stakeholders will be essential. Where AI-enabled health innovation flourishes, patients and populations will benefit.

What is ahead in this publication?

ITU, WHO and WIPO jointly developed this publication under the GI-AI4H. The chapters address key themes emerging in AI-enabled health care: IP considerations, including regulatory pathways; commercialization approaches; and health data governance and standards. While each topic is relevant on its own, the three are also interdependent, in considering the development and deployment of AI-enabled health innovations.[2] Taken together, the three

1 *Getting the Innovation Ecosystem Ready for AI: An IP Policy Toolkit* (WIPO, 2024), notes the exponential evolution of AI technologies and some uses in health care. The *WIPO Patent Landscape Report on Generative AI* (2024) sets out specific trends in applying generative AI to the life sciences. While there is no international definition of AI, and a synthesis of its multiple uses for health is outside the scope of this document, WHO has provided an overview of some applications for health care, research and drug development, health systems management and planning, and public health, including surveillance. Some specific examples include remote diagnostic tools, predictive analytics in patient care and intelligent hospital logistics. Further discussion can be found in *WHO Guidance on Ethics and Governance of Artificial Intelligence for Health* (2021).

2 For the purposes of this publication, AI-enabled innovations may include inter alia innovations made possible, enhanced, or accelerated through the application of AI.

chapters provide guidance for innovators in AI-enabled health care, including inventors, entrepreneurs, businesses of all shapes and sizes, universities and research institutions.[3]

Specifically the publication may help to navigate the many decisions required to turn ideas into impact. Considering some aspects of existing legal and other frameworks, it focuses on how to use IP to protect and promote new or improved health care solutions that use AI to address global health challenges, while remaining commercially viable and globally scalable.

Beyond examining relevant topics, this publication provide a range of company case studies from around the world.[4] Each case study has been distilled into key lessons that may be useful for innovators.

The case studies focus on IP and commercialization strategies for AI-enabled health innovation across medical devices, diagnostics, digital health technologies, and related applications. While case studies span various health innovation contexts including pharmaceutical applications to illustrate diverse IP approaches, this publication does not intend to address pharmaceutical regulatory frameworks, drug manufacturing processes, clinical trial requirements for therapeutic products, or pharmaceutical policy matters.

Who should keep reading?

The publication is meant to inform AI-enabled health innovators across the broader health care ecosystem including those who assist them, such as policymakers and regulators, health system implementers, and investment and partnership decision-makers. Practical guidance on using the IP framework to turn ideas into reality helps to advance both innovation and global health impacts.

Key lessons

A mixed IP modality is universal

Innovators deploying effective IP strategies to protect and promote their AI-enabled innovations, which are AI-powered healthcare technologies, employ multiple forms of IP protection simultaneously. Patents may cover a wide range of inventions, including core technical methods such as federated learning, image guidance, reinforcement learning and knowledge graphs. Trade secrets may protect data sets and operational know-how. Copyright may safeguard software implementation, while strategic open-source contributions may build ecosystem trust. No company presented as a case study relied solely on one particular type of IP protection such as patents – different IP rights often have roles to play.

Regulatory clearances enhance enterprise and transactional value

Regulatory authorization emerges as a decisive value inflection point rather than a downstream compliance exercise. Innovators that progress beyond research validation to secure formal regulatory clearances demonstrated materially stronger acquisition outcomes, partnership depth and market credibility compared to peers operating solely at the research or pilot stage.

Regulatory clearance performs several distinct but complementary functions in the AI-enabled health innovation value chain:

3 For the purposes of this publication, AI-enabled innovators may include inter alia innovators making use of AI in the process of innovation and inventors of AI tools.

4 While every effort has been made to ensure accuracy, company information may change after publication. Patent status, regulatory approvals, funding amounts, partnerships and company ownership may have changed since data collection in December 2025. Case studies are presented for educational purposes only to illustrate IP strategies and principles in AI-health innovation. Readers should verify current information through company websites and official databases, and conduct independent research before engaging with any company. Information is provided "as is" without warranty of any kind. No representations are made regarding accuracy, completeness or fitness for any particular purpose. These case studies have been developed using information in the public domain.

- **Risk reduction for acquirers and partners:** Formal authorization by regulators, such as the United States Food and Drug Administration (FDA), the State Council of China National Medical Products Administration (NMPA), the European Medicines Agency (EMA) or European Union (EU) bodies that issue certificates of Conformité Européenne (CE), provide independent verification of safety, performance and clinical relevance. This substantially reduces technical, clinical and liability risks for strategic buyers and enterprise partners, accelerating diligence timelines and increasing the willingness to transact.
- **Conversion of technical assets into commercial products:** Regulatory approval transforms certain types of AI models from experimental tools into deployable medical products with defined intended uses, labeling and post-market obligations. This transition enables scalable revenue models, reimbursement discussions and global distribution, which are key drivers of valuation alongside IP.
- **Strategic leverage in transactions:** In acquisition contexts, cleared products can be immediately integrated into the acquirer's portfolio. For companies that desire to enter into partnerships, regulatory status enables deeper, longer-term collaborations with hospitals, governments and multinational device manufacturers.

The case studies in this guide demonstrate that regulatory clearance operates as a multiplier of underlying IP assets. For example, patents and trade secrets establish technical differentiation, but regulatory validation converts those assets into realizable enterprise value. In many jurisdictions, regulatory approval is also a prerequisite for the lawful commercialization, distribution, and deployment of regulated healthcare products. For innovators in AI-enabled health innovation, early and deliberate investment in a regulatory strategy significantly increases the probability of successful exits, durable partnerships and sustainable commercialization, particularly alongside IP portfolio development. While enterprise value is key and critically important, innovation also creates significant value for broader public health. Benefits extend beyond commercial returns.

Geographic diversity opens opportunities

AI-enabled health innovation is not limited to traditional biotech hubs. Successful companies using AI in health innovation operate across Europe, Africa, Western Asia, Southern Asia and the Americas. The approach to IP in low- and middle-income countries, including to support equity and access, involves multiple factors, such as differences in digital infrastructure, data availability and technical capabilities. Different stakeholders may prioritize various aspects, from incentivizing innovation to enabling technology diffusion across markets with varying characteristics and capabilities, including through public-private partnerships.

Partnership models vary by technology class and buyer economics

Partnership structures are not uniform; they diverge systematically based on technology type, buyer incentives and regulatory posture. Drug discovery and biological AI platforms primarily operate in business-to-business research and development (R&D) markets. As a result, these platforms favor long-term, milestone-based research collaborations, often spanning 5 to 15 years and structured around shared discovery pipelines, co-development, option-to-license arrangements and downstream royalty participation. This partnership orientation reflects the underlying economics of pharmaceutical R&D, that is, long timelines for development and market approval procedures, and significant technical and clinical risks.

Medical device-oriented AI companies operate in a fundamentally different environment. Their primary customers are hospitals, health systems and imaging networks, where procurement decisions hinge on regulatory clearance, workflow integration, reimbursement potential and immediate clinical utility. Accordingly, these companies prioritize:

- **Early regulatory approval** (FDA, CE, NMPA) to unlock hospital procurement and enterprise sales
- **Offering products or services** (e.g., software as a service, per study pricing and device-embedded software) rather than bespoke research collaborations to grow faster and more profitably
- **Commercial partnerships or acquisitions** with incumbent medical device manufacturers (e.g., ultrasound, imaging, and picture archiving and communication system vendors) seeking to enhance existing product lines

The future demands collaboration

Looking forward, the rapid advancement of generative AI, multimodal models and federated learning will continue to raise questions relevant to IP frameworks, which has always been the case when new technologies emerge. Policymakers, innovators and regulators must work collaboratively so that IP systems continue to support AI-enabled health innovation. The case studies presented in the following chapters demonstrate that health care using AI requires more than technical innovation alone. It calls for strategic IP management, regulatory foresight, collaborative partnerships and a commitment to ethical, patient-centered innovation. As the field evolves, lessons from early pioneers will inform the next generation of innovators in AI-enabled health care worldwide.

1 IP considerations supporting health impacts across the AI-enabled innovation life cycle

Key takeaways

- Depending on the health innovation and jurisdiction, innovators in AI-enabled health care should consider a combination of IP protection mechanisms. They should evaluate strategic decisions to manage their IP.
- Different innovation decisions are required at each development stage, from ideation through global deployment.
- Innovation in health care calls for careful consideration of regulatory and compliance issues as well as clinical and safety considerations.

1.1 The foundations of AI-enabled health innovation

Jurisdictions recognize and understand the use of AI in health care through regulatory and legal frameworks. These vary across jurisdictions and may impact innovation strategies, including protection by IP. Health data governance and standards (see Chapter 3) and regulatory pathways[1] are primary gateways for the definition of AI in health care. Topics including clinical integration, evidence standards and liability frameworks are also relevant. While AI-enabled health innovation can emerge across diverse geographies and innovation ecosystems, differences in regulatory and legal frameworks across jurisdictions may still influence where companies choose to develop and commercialize products, how they design validation studies, and which IP protections they prioritize across markets.

1.2 IP protection mechanisms for AI-enabled health innovation

AI-enabled health innovation typically requires considering the relevance of a combination of IP protection mechanisms as well as IP licensing models that may be used strategically to protect IP rights. Some IP rights relevant to AI-enabled health innovation include patents, trade secrets and copyright. Decisions on IP rights are not static. IP protection must be assessed throughout the innovation life cycle (see Section 1.4).

Patent rights are territorial in nature. Patents are granted based on an application by national or regional offices for inventions, such as products or processes, in all fields of technology. In order to obtain a patent, an invention must fall under the category of patentable subject matter, and meet the patentability criteria. As far as subject matter eligibility is concerned, the definition of an invention and permitted policy choices may exclude some creations from patentability, namely: scientific theories, aesthetic works, mathematical methods, plant or animal varieties, discoveries of natural substances, business methods, methods for medical treatment and computer programs, which are not patentable in some jurisdictions. The substantive criteria of novelty and inventive step require the invention to be a globally new technical solution to a problem that can be applied in industry, which is non-obvious for a person skilled in the art.

1 WHO (2023). Regulatory Considerations on Artificial Intelligence for Health. Available at https://www.who.int/publications/i/item/9789240078871.

After successful registration, with associated costs, the patent owner secures exclusionary rights for a certain term, allowing the inventor to stop others from using, making or selling the invention without permission. A patent is granted for a limited period, usually not exceeding 20 years from filing the application. In return, the patent applicant must disclose the invention in the application, with such disclosure being published in the patent documents. Once the period of protection terminates, the invention becomes part of the public domain; anyone can commercially exploit it.

For AI-enabled health innovations, patents may protect technical solutions – such as model architectures; training pipelines; data-processing methods; medical devices, including sensors; and algorithms, encompassing those for drug design – as long as the claimed invention meets applicable patentability requirements (see Table 1). When seeking patent protection for an invention which discloses nucleotide or amino acid information, all applicants must file what is known as a sequence listing, compliant with WIPO Standard ST.26.[2] Since this requirement came into force on July 1, 2022, AI algorithms now have easier access to this data due to the nature of the structured format. WIPO produces a software for applicants to generate these sequence listings compliant with WIPO ST.26 called WIPO Sequence, which is freely available on their website.[3]

For AI-enabled health innovators, understanding comparative legal IP landscapes across jurisdictions is critical for both innovation strategy and market entry. Subject matter eligibility rules differ among countries; an AI-enabled invention that is patent-eligible in jurisdictions such as Japan or the Republic of Korea may require different claim drafting to satisfy patent eligibility requirements in the United States or before the European Patent Office. While an extensive analysis of the approach to subject matter eligibility for AI inventions is outside the scope of this chapter,[4] it may be worth noting approaches in some jurisdictions and the possible relevance for AI-enabled health innovations.

2 WIPO Standard ST.26: https://www.wipo.int/documents/d/standards/docs-en-03-26-01.pdf
3 WIPO Sequence: https://www.wipo.int/en/web/standards/sequence/index
4 While the intersection of AI and inventorship may have legal implications for innovators in AI-enabled health care, a detailed discussion of this issue goes beyond this publication. The WIPO Standing Committee on the Law of Patents has considered the issue of AI and inventorship. A compilation of approaches can be found in a 2023 document prepared by the committee's secretariat, *Artificial Intelligence (AI) and Inventorship (SCP/35/7)*. Where AI systems contribute to inventions, inventorship rules in many jurisdictions still require a human inventor. This may create complexities for patent portfolios built on AI-assisted discovery and should be considered when pursuing patent validity across jurisdictions.

Table 1 Health innovations and subject matter eligibility of AI inventions across jurisdictions

Jurisdiction	Standard/framework	Key requirements and considerations for AI health inventions
United States	Alice/Mayo test (35 US §101); USPTO examination	Claims to certain types of subject matter, such as mathematical formulas and algorithms must demonstrate a practical application beyond mere data processing. Successful strategies include tying AI methods to specific technical improvements (e.g., faster image reconstruction, reduced radiation dose), claiming integrated systems with sensors, devices, or clinical workflows, and emphasizing how the AI model solves a concrete technical problem in healthcare delivery.
European Union / EPO	"Technical effect" requirement	AI inventions must provide a technical effect beyond normal computer processing. In healthcare, this is often met when the invention improves diagnostic accuracy, optimizes treatment plans, or enhances medical device performance. Claims should clearly articulate the technical contribution. EPO examination guidelines may also require specific disclosure of training data surrounding algorithms used by an AI invention.
United Kingdom	EPO-aligned approach (Emotional Perception AI Ltd v Comptroller-General [2026] UKSC 3)	Artificial neural networks (ANNs) may be deemed computer programs but are not excluded for that reason, since an ANN can only be implemented on computer hardware, ensuring technical character is present. Non-technical features are then "cleaned" from the invention for the purposes of the inventive step analysis.
Canada	Purposive construction	Essential claim elements must have physicality rather than constituting merely abstract algorithms.
Japan	"Laws of nature" requirement	AI/ML methods must demonstrate "utilization of laws of nature" rather than purely mathematical operations.
China	CNIPA Patent Examination Guidelines (amended 2020)	Increasing receptivity to software-implemented medical AI patents, particularly for diagnostic imaging, treatment planning, and clinical decision support. AI methods producing technical effects in specific technical fields qualify as patentable.
Republic of Korea	KIPO; National AI Strategy (2019)	Numerous patents granted for health AI, including medical diagnostics (ECG analysis, medical imaging interpretation), personalized treatment recommendations, and patient monitoring systems. The 2019 National AI Strategy prioritizes healthcare AI, creating supportive patent examination practices for medical AI innovation.
India	Technical advancement requirement	AI/ML inventions must demonstrate technical advancement beyond computer programming, with patents obtainable by emphasizing technical improvements in medical imaging processing.
Singapore	EPO-aligned approach	Requires demonstration of a "technical contribution."

In cases where a patent examination is a requirement to grant a patent, some patent offices provide more detailed guidance on the treatment of inventions using AI and machine learning (ML) in their patent examination guidelines.[5] The boundaries between eligible subject matter and excluded mathematical methods remain dynamic, particularly in EU law, and continue to evolve across jurisdictions through patent office guidance and case law.

5 See the European Patent Office's (EPO) Examination Guideline 3.3.1 on artificial intelligence and machine learning, which provides guidance on the patentability of inventions using AI and ML. The Japan Patent Office's Examination Handbook for Patent and Utility Model (2019 revision) provides AI-specific guidance under computer software-related inventions. The China National Intellectual Property (CNIPA) Administration Guidelines (2020 amendment) clarify that pure mathematical algorithms are not patentable, but AI methods producing "technical effects" in specific technical fields qualify, and examiners apply a "technical problem, technical means, technical effect" framework. The Korean Intellectual Property Office Examination Guide in the Artificial Intelligence Field (2020) ties the patentability of AI inventions to a creation of technical ideas utilizing a law of nature. The Swiss Federal Institute of Intellectual Property's Guidelines for Examination of Computer Related Inventions (2021 update) indicate that AI/ML with technical applications in health care are patentable if they demonstrate technical advancement beyond computer programming. Indian health start-ups using AI (e.g., Qure.ai) have obtained patents by emphasizing technical improvements in medical imaging processing and diagnostic output generation. The Intellectal Property Office of Singapore's Examination Guidelines (updated 2019) have a section on computer-implemented inventions.

Trade secrets protect confidential information that has commercial value stemming from its confidentiality against unauthorized access, disclosure or use in a manner contrary to honest commercial practices (i.e. misappropriation) provided that reasonable steps have been taken to keep their secrecy. There is no registration process for trade secrets, and protection lasts as long as the information remains secret. Protection varies by jurisdiction – some protect trade secrets through dedicated statutes, while others rely on a combination of statute and case law, or primarily on common law principles such as breach of confidence. Successful approaches to trade secret protection may rely on clear written policies, strict access controls, physical and technical security measures, training, non-disclosure agreements (NDAs) and incident protocols. Trade secrets in AI-enabled health innovation may include large proprietary data sets, model weights, feature engineering methods, operational procedures and evaluation harnesses. The use of trade secret protection for AI-enabled health innovation algorithms involves navigating expectations around transparency, including explainability standards for clinical decision-making, auditability mechanisms for quality assurance and regulatory disclosure obligations for safety monitoring. However, regulatory expectations increasingly extend beyond explainability alone to include technical documentation, quality management, human oversight, traceability, and lifecycle monitoring, while preserving the protection of legitimate trade secrets.

Copyright protects eligible works of authorship, including original literary and artistic works, which cover an enormous range of items, including books, journals, music, paintings, sculpture and films as well as computer programs, compilations of data,[6] maps, technical drawings and more. Copyright is granted automatically by the creation of the work as long as it is fixed in a tangible medium, with no requirement for registration or other formalities. It provides authors with economic and moral rights, allowing them to derive economic benefit from the use of their works and to protect the integrity of their works. The copyright term of protection as a minimum standard normally lasts for the life of the author plus 50 years after the author's death. In certain jurisdictions, however, it can last longer or vary based on the type of work protected. Copyright works relevant to AI-enabled health innovation may include code, compilations, model cards, documentation and curated content.

Copyright may also be used to protect a database that meets relevant requirements, including displaying originality (the amount can vary by jurisdiction) in the selection or arrangement of its contents. In some jurisdictions, for databases meeting the relevant threshold, database rights may apply adjacent to the copyright protection. For example, sui generis database rights (a specialized protection for specific subject matter not covered by traditional IP laws) may protect against the extraction and reutilization of substantial parts of the database without permission. Sui generis database rights only exist in certain jurisdictions (principally the EU and UK).They are not international rights.

1.3 IP licensing mechanisms for AI-enabled health innovation

The IP framework creates the legal foundation for the control and use of protected innovations and creations. Within this framework, some approaches may allow permissions and uses depending on the choice of the owner of the IP, including the innovator or creator. These approaches may comprise assignment (the exercise of rights enabled through the permanent transfer of IP ownership) or licensing (the exercise of rights contractually enabled without the transfer of IP ownership). Deliberate and strategic licensing choices, along the spectrum from narrow to permissive, can complement proprietary assets and standards of participation (see Box 1).

Ultimately, AI-enabled health innovation that achieves the objectives of the IP owner may depend on a multidimensional approach. This requires strategic decisions about what to patent, what to keep secret, when to use open source and when to participate in standards. Licensing as a relevant access model has a significant role in the management and use of IP rights to deliver the specific objectives of rights holders. This may encompass for example, protection and control, collaboration and partnership, the leveraging of a strategic advantage to maximize commercial opportunity and/or support for access models (see chapter 2). Licensing approaches

6 Copyright will not protect individual data points, just as it does not cover facts or ideas, but it can cover the ways in which they are expressed. Compilations of data, such as databases or spreadsheets, are subject to copyright.

may differ according to the IP right, that is, the copyright or patent. Moreover, the role of IP rights in supporting access to technologies and their management will be impacted by other relevant factors, such as the disease burden, the size of the company, regulatory considerations, production sites, manufacturing skills and capacity, the expertise of the licensee and the nature of the product.

WHO's *Regulatory Considerations on Artificial Intelligence for Health* [7] provides a framework for how regulatory pathways, safety standards and post-market surveillance obligations interact with the IP life cycle for AI-enabled health tools. This entails considerations that are especially relevant for innovators seeking deployment across diverse health systems, including in low- and middle-income countries. Innovators may wish to consult this guidance alongside their IP strategy as regulatory and IP decisions are most effective when developed in parallel, rather than sequentially.

Box 1 A spectrum of IP licensing approaches

IP licensing approaches relevant to AI-enabled health innovations exist on a spectrum, from permissive to restrictive, reflecting the diverse strategies that innovators employ to balance openness, collaboration and business sustainability. Exclusive voluntary licensing (a license granted to one party by the IP owner to permit particular uses of the IP-protected work) and non-exclusive voluntary licensing (a license granted by the IP owner to permit particular uses of the IP-protected work by multiple parties simultaneously) are two approaches. Open-source licensing is another way to license.

Open-source licensing approaches are numerous. They may apply to copyright-protected works, including software. Open-source licensing approaches may contribute to rapid iteration and trust within the IP framework. The Open-Source Initiative maintains criteria for licenses to be considered truly "open-source," including the freedom to use them for any purpose, access to source materials and the ability to create derivatives. In recent years, however, some AI developers have adopted source available or restricted licenses that allow inspection but impose limitations, such as restricting commercial use, competing services or use by certain entities. These licenses represent a middle ground between proprietary and open approaches.

1.4 The innovation journey: A life cycle IP matrix

AI-enabled health innovation follows a clear journey from the earliest spark of an idea to potentially large-scale, global deployment. At each stage, innovators face different decisions that shape not only the technology but also its long-term integration into health systems. These decisions are shaped by regulatory and compliance issues as well as clinical and safety considerations. Early choices around IP can lay the groundwork for later success.

This chapter introduces the **innovation life cycle IP matrix**, designed to help innovators in AI-enabled health care to manage IP strategically, from concept through commercial scale-up. Each phase of development presents distinct opportunities, risks and requirements across six dimensions: patents, trade secrets, copyright and data protection with due regard to sui generis database rights, open-source, regulatory and standards considerations, and contracts. While these dimensions apply across technology sectors broadly, by mapping them to the product life cycle, AI-enabled health innovators can anticipate challenges, avoid common pitfalls and unlock the full value of their IP. This, in turn, supports access to and the availability of technologies. Areas that may be particularly relevant for AI-enabled health innovation include trade secrets and regulatory and standards issues. While the matrix largely focuses on predictive AI, the rapid advancement of generative AI and multimodal models may require additional considerations, including the copyright implications of generated outputs.

7 Available at https://www.who.int/publications/i/item/9789240078871

The innovation life cycle IP matrix in Table 2 serves as a quick reference tool, distilling actionable steps for each stage, from ideation through health system integration. It supports AI-enabled health innovators to better identify, protect, manage and leverage their assets according to their objectives. It is not a substitute for legal advice, but it can enable more effective, informed conversations with IP advisors, helping innovators to translate strategic IP planning into successful, scalable health care solutions. To use this innovation life cycle IP matrix:

1. Identify your current life cycle stage
2. Review all columns for that stage
3. Identify relevant IP actions and find more detail in section 1.5 of this publication

Table 2 Innovation life cycle IP matrix

	IP Considerations					
Lifecycle stage	**Patents**	**Trade Secrets**	**Copyright and data**	**Licensing approaches including open-source**	**Regulatory and standards**	**Contracts**
Ideation	Invention disclosures and early filing thresholds	Access controls and NDAs	Ownership clarity	Posture and policy	Identify and review	Background and foreground IP definitions
Training	Method/ system patent claims for training pipelines	Secure data, weights and logs	IP rights related to data including datasets and associated license management	License hygiene	Data transfer compliance	Data-use agreements
Validation	Refining patent claims via technical effect	Protection of evaluation harnesses	Documentation and model cards protection	Selective releases on non-core tools as open source	Clinical evidence protocols appropriately aligned with regulations and standards, including subgroup performance reporting that addresses algorithmic bias obligations	Agreements on trial data rights
Approval	Align patent claims with intended use	Protection of operational know-how	Labeling and IFU protection	OSS compliance with device distribution	Conformance / benchmarks for standards requirements: AI-specific vigilance reporting, performance drift thresholds, and real-world performance reporting	Field-of-use restrictions and contractual updates
Deployment and post-market monitoring	Continuation filings	Operations runbooks; SRE secrets	Manuals, user interfaces	Governance tooling	Post-market monitoring obligations for regulations and standards	Standard Licensing Agreements and safety provisions in contracts
Scale-up and strategic partnerships	Patents Portfolio Expansion including through WIPO PCT	Protection in joint ventures, etc.	Knowledge transfer plans	Select license models to achieve objectives	Where relevant consider FRAND, for example, for interoperability standards (HL7, FHIR, DICOM, WHO SMART Guidelines)	Assignment and other relevant considerations

Note: This Innovation life cycle IP matrix provides general guidance for innovators in AI-enabled health. It should not be construed as legal advice. IP laws, enforcement environments, regulatory requirements and best practices vary significantly by jurisdiction, technology type, business model and health system context. There may be substantial differences across countries. Approaches by innovators may need to differ according to the country context and relevant legal frameworks. The checklist is intended as an educational tool to help innovators identify relevant IP considerations. It is a starting point, not a substitute for reflection, conversation and/or consultation with qualified legal and regulatory advisors. Compliance requirements with other laws or regulations may not be captured in this table; however, some relevant data governance and privacy regulations can be found in chapter 3 of this publication. Where relevant, WHO's publication *Regulatory Considerations on Artificial Intelligence for Health* provides complementary guidance, particularly for innovators navigating diverse health system environments.

1.5 Details of the innovation life cycle IP matrix

Stage A: Ideation and concept development

Innovation begins with ideation, but this early stage is also where many IP missteps may occur. Capturing ideas promptly and accurately, clarifying ownership and making early strategic IP decisions establish the foundation for the rest of the innovation life cycle.

Invention disclosure form: An invention disclosure form is a confidential document that captures a technical innovation before a patent application is filed, given that patent filing may be premature at the ideation and concept development stage. The form is an important procedural step in internal decision-making. While this information may not be readily available, it may broadly describe the following aspects:

- **The invention itself**, including its general technical field, the problem it addresses, and a clear explanation of how it works at a technical level, including its key features and distinguishing aspects, without limiting the description to a single implementation.
- **The novelty and technical contribution**, describing what is new relative to existing solutions, why prior approaches are insufficient and what technical effects or improvements the invention achieves.
- **The state of the art**, including what was known or used before the invention, relevant publications or patents if known, and how the invention differs from or improves upon those references.
- **The development context**, such as how and when the invention was conceived and developed, what stage it has reached and what work has already been carried out versus what remains to be done.
- **The people involved**, identifying who contributed to the invention, the nature of their contributions and any information necessary to later determine inventorship or authorship.
- **Disclosures and confidentiality**, including whether the invention has been disclosed or shared in any form (e.g., publications, presentations, demonstrations, etc.), whether such disclosures were confidential and whether any further disclosures are planned.
- **Funding and third-party involvement**, covering whether the work was supported by external funding, carried out under collaboration agreements or relied on third-party materials, data, software or ideas that could affect ownership or freedom to operate.
- **Software- or data-related aspects (where relevant)**, such as the role of code, models, data sets, tools or external components, and any licensing or access conditions that might be relevant to protection or exploitation.
- **Potential applications and use**, describing how the invention could be used in practice, what kinds of products, services or processes it might enable, and in which fields.
- **Commercial and strategic considerations**, at a high level, including why the invention may be valuable, how it compares to existing solutions in the market and what kinds of exploitation pathways (e.g., licensing, spin-out, collaboration or publication) might be used to further develop the invention.
- **Any constraints or risks**, such as prior disclosures, contractual obligations, co-ownership issues or dependencies that could affect patentability, ownership or commercialization.

Access controls and NDAs for trade secrets: From the ideation phase, confidential information must be secured even if it may not necessarily qualify as a trade secret. Access should be limited, on a need-to-know basis, with secure storage in encrypted, password-protected repositories, logging of access events or breaches and periodic audits of permissions. Any external parties should sign robust NDAs before receiving confidential information. These agreements should define confidential information broadly enough to cover complex assets such as models or data sets, specify exclusions, set confidentiality periods (typically two to five years, or indefinitely for trade secrets), detail obligations upon termination (including material return or destruction) and outline remedies for a breach (injunctive relief or damages).

Ownership clarity of IP, including data: Employment, consultant and contractor agreements should address the ownership of work-related IP in accordance with the applicable jurisdiction. This may be achieved either through explicit assignment and work-for-hire clauses, where required by local law, or by referencing statutory provisions governing service inventions and employee inventions, where such legislation exists.

In research collaborations, IP terms should be negotiated upfront, including background IP brought into the collaboration, such as preexisting code, data and patents, and the handling of joint ownership or licensing rights.

Licensing approach: Deciding early on an IP licensing strategy is critical, as it dictates how you engage stakeholders and position yourself in the market. For example, full proprietary protection may be used for commercial medical device companies, keeping code and models confidential. The selective open-source release of non-core components may attract community input while safeguarding competitive advantages. Policies should be documented, and all team members trained on compliance, including to avoid improper code integration from incompatible licenses.

Regulatory and standards planning: Even at the ideation stage, regulatory pathways must be identified. Clarify whether the product will be classified as a regulated medical device and determine its risk classification. Identify relevant pathways, such as predicate devices for clearance, applicable quality and safety standards (e.g., International Organization for Standardization (ISO) 13485 Quality Management System for Medical Devices) and data privacy and protection laws. In some instances, regulatory pathway selection at the ideation stage is also influenced by whether the product will be classified under EU Medical Device Regulation/ In Vitro Diagnostic Medical Device Regulation, the EU AI Act or both. These classifications may diverge, requiring parallel compliance tracks.

Background IP definition in contracts: Background IP exists before or outside a collaboration. It is brought into a project by the parties and may include preexisting patents, trade secrets, code or data owned by each party before collaboration begins. Foreground IP may include new IP generated during a collaboration or project. In collaborations, it is important to precisely distinguish between the two. The rights to use each should be defined, including ownership structures, licensing conditions and publication policies, including review and approval requirements.

Stage B: Data strategy and model training

During the training stage, data governance and trade secret protection become paramount. This is where the AI model is developed and the most valuable IP assets, such as data sets and trained model weights, are typically created.

Method/system patent claims for training pipelines: Novel aspects of model training, such as unique architectures, targeted data augmentation techniques, active learning methods, approaches to preserving privacy or optimized hardware and software integration, may be patentable. Giving due regard to relevant subject matter eligibility criteria, consider whether it may be helpful for claims to emphasize practical technical implementation rather than abstract concepts.

Securing data, weights and logs as trade secrets: Training data sets and model weights should be stored securely, using encryption and strict access controls. Logs of training runs containing hyperparameters and performance metrics should remain confidential. Version control systems should be private repositories and secured with multifactor authentication. NDAs should be executed with vendors and cloud providers, and contracts should ensure that data use is confined to agreed purposes.

Manage data sets as appropriate and license tracking: It is important to maintain provenance for every data set, track license terms and keep records on informed consent for patient data. Document de-identification methods and ensure compliance with relevant data privacy regulations. Execute agreements with data providers covering usage rights, retention and disposal.

Open-source and license management: Track and audit all open-source software (OSS) dependencies, verify compatibility with commercial goals, identify any licensed data that could create obligations to make relevant code open source, ensure attributions are properly maintained and conduct quarterly license audits as new dependencies are added.

Data transfer compliance with relevant regulations and standards: Cross-border data movement must align with local regulations, using contractual clauses, agreements or localization measures as required, and ensuring encryption in all transfers and storage.

Contracts and data use agreements: For each data source or service provider, define restrictions, allowed derivative works, publication rights, retention terms, breach obligations and compliance requirements, including with other applicable laws, particularly on data protection and data privacy (see chapter 3) and other underlying IP rights. For cloud service agreements, negotiate terms for protecting data security and confidentiality and prohibiting secondary data use. Include provisions requiring immediate notifications of any data breach or unauthorized access.

Stage C: Validation and evidence generation

Validation demonstrates that an AI model performs as intended in real-world conditions. This stage generates critical evidence for regulatory submissions, publications and commercial negotiations.

Refining patent claims based on technical effect: Validation data may allow the narrowing of patent claims to specify measurable performance improvements, clinical benefits or hardware integration advantages, and to add new claims through the continuation of application filings.

Protecting evaluation harnesses as trade secrets: These may include test set curation, evaluation metrics, validation protocols, negative results, internal records of failed experiments and model limitations, and post hoc analyses.

Copyright and data protection for model cards and documentation: Detailed technical documentation should be created, including reports, user manuals, training materials and summaries. These will be protected by copyright and may support both regulatory submissions and operational needs.

Open-source strategic release of non-core tools: Releasing generic evaluation frameworks, visualization utilities or benchmarking tools may build trust, while keeping core assets proprietary.

Clinical evidence protocols aligned with regulatory and standards expectations and guidelines: Validation protocols should align with regulatory expectations, follow standard reporting guidelines and include comparator studies against standard care. Where applicable, validation should also comprise subgroup performance reporting across relevant demographic groups (such as age, sex and ancestry) to address algorithmic bias and fairness obligations under emerging AI-health regulations.

Contracts and clinical trial data rights: Agreements with validation partners should clarify ownership, publication rights, regulatory use, future uses (including derivative works) and the confidentiality of trial data.

Stage D: Regulatory approval and market access

Regulatory approval is a critical milestone that reduces risk for commercial deployment of the technology. The alignment of an IP strategy and regulatory submissions will ensure consistency and enforceability. To note, regulatory authorization does not validate IP ownership or the freedom to operate. Regulatory clearance enables commercial deployment but is independent of IP ownership validation.

Patent claims aligned with intended use: Claims must match the approved clinical application, with continuation filings expanded as new indications gain approval.

Operational deployment as trade secrets: Integration procedures, monitoring protocols, incident handling and customer support processes should be protected as trade secrets, given that they involve significant operational know-how.

Copyright in labeling and instructions for use: Regulatory-compliant labeling, instructions for use (IFU), information to use with patients such as simplified explanations where applicable, marketing content and translations for international markets should be treated as copyright works.

Open-source compliance in distributed products: Ensure that any open-source components in the device meet license obligations, including source code provision, license notices and modification documentation.

Demonstrating conformance with standards requirements: Demonstrate compliance and conformance with relevant standards, including those relevant to quality management or interoperability, and maintain proof of compliance.

Field-of-use restrictions and updated rights in contracts: Structure customer agreements to manage IP and regulatory obligations, including by limiting customer use to approved indications, retaining rights to update software, meeting regulatory compliance obligations, applying data for improvement and termination rights.

Stage E: Deployment and post-market monitoring

Once IP is deployed, ongoing management, regulatory compliance and operational security are essential. Post-market surveillance generates real-world evidence and may identify new IP opportunities.

Filing a patent for continuous learning innovations: Continuation filings can protect methods for model updates, new clinical indications identified in real-world use and integration advances.

Protecting operational runbooks and monitoring procedures as trade secrets: Deployment playbooks, monitoring dashboards, incident protocols, scaling methods and disaster recovery plans should be confidential as they are valuable trade secrets.

User materials and user interface designs protected as copyright: Updated manuals, guides, videos, visual designs and integration documentation should be protected as copyright.

Community governance through open-source tools: Consider open sourcing certain monitoring, explainability, performance or audit tools to strengthen ecosystem engagement, as an option.

Monitoring obligations for regulations and standards: Many regulators require post-market surveillance for AI devices, including performance tracking, vigilance reporting and periodic safety updates. AI systems may also be subject to AI-specific obligations, such as monitoring for performance drift, defining retraining triggers and providing real-world performance reporting.

Service-level agreements and safety provisions in contracts: Customer agreements should set performance benchmarks, grant rights to deploy urgent safety updates, allocate obligations if model performance falls below specified thresholds and enable the use of deployment data for safety monitoring.

Licensing and Deployment Strategies: During deployment and post-market monitoring, innovators may implement licensing and distribution strategies aligned with the innovator or organization's objectives. Licensing terms should also address software updates, post-market monitoring obligations, data governance and ongoing regulatory compliance.

Stage F: Scaling up and strategic partnerships

At the scale-up stage, strategic decisions about licensing, partnerships and potential exit strategies become central. An IP strategy may help to balance proprietary protection with ecosystem collaboration.

Patents portfolio expansion: Develop a diverse patent portfolio through divisional filings and continuations; foreign filings, including by pursuing the WIPO Patent Cooperation Treaty's national phase entry in key markets; portfolio reviews and freedom-to-operate analyses.

Protection of trade secrets in joint ventures or other strategic partnerships: Implement information firewalls, escrow arrangements and strict terms when working with partners, especially to safeguard crown jewel trade secrets such as proprietary data sets, unique model architectures, algorithms for data preprocessing, augmentation or feature engineering and methods for addressing AI-specific challenges.

Knowledge transfer plans for copyright works: In scaling or acquisitions, plan for knowledge transfer, including documentation, the development of training programs, the negotiation of source code rights, the clarification of data rights (which may go beyond copyight) and the definition of support obligations. Knowledge transfer may also require consideration of relevant licensing approaches including whether additional licenses are required.

Bilateral Licensing Models: To facilitate targeted commercialization and technology deployment, consider structuring negotiated bilateral licensing agreements with clearly defined rights, territories, fields of use and revenue-sharing mechanisms tailored to each partner. Revenue models should reflect the scope and exclusivity of the license, while bilateral arrangements can support strategic partnerships, market expansion, local adaptation and long-term collaboration.

Open-source and dual licensing models: To balance open collaboration with commercial revenue, consider releasing a core version under an open-source license while offering premium features commercially, backed by contributor agreements. The revenue models should reflect the licensing approach. Open-source versions can be used to build community, drive adoption and create network effects.

Standards participation: Where technology becomes essential to a standard, assess and manage licensing commitments while retaining exclusivity where possible. Join standards bodies (ISO, International Electrotechnical Commission, Institute of Electrical and Electronics Engineers (IEEE) and Health Level Seven (HL7)) to influence standard development, identify which patents may be essential to implementing a standard, declare the willingness to license essential patents on RAND or FRAND terms, retain full exclusivity on non-essential patents and trade secrets, and negotiate royalty rates that balance access with fair compensation.

Exit readiness through contractual assignment : Ensure complete IP assignment to the company, resolve encumbrances that could complicate a transaction, obtain confirmatory assignments from all inventors and contributors, prepare standard agreement templates for efficient negotiation, and maintain organized IP due diligence materials. Separate licensing and deployment strategies, including tiered pricing, licensing approaches, local patent filing, and voluntary technology transfer, may also be considered when expanding into low- and middle-income countries.

Case study: Caption Health – AI-guided ultrasound acquisition

Caption Health, founded in 2013 in California, pioneered AI-driven real-time guidance for ultrasound image acquisition. It has addressed a critical bottleneck in diagnostic imaging: the shortage of trained sonographers and technical expertise to capture high-quality images. Its flagship software, Caption AI, uses computer vision and deep-learning algorithms to analyze live ultrasound video streams in real time, evaluating the probe angle, cardiac chamber visualization and image clarity. It guides clinicians through voice prompts and visual overlays to optimize positioning, effectively transferring expert sonographic knowledge to the point of care and enabling non-specialist clinicians to capture diagnostic-quality cardiac images.

Caption Health's IP strategy combined patents, trade secrets and copyright protection. Its core United States patent (US 11,844,654 B2, "Ultrasound guidance dynamic progression method") covers methods for dynamically guiding ultrasound workflows, real-time feedback presentation, adaptive sequence management and the integration of guidance logic with ultrasound diagnostic systems. Notably, the claim structure emphasizes practical guidance and system orchestration rather than abstract neural network structures, tying protection to specific types of technical implementation and thereby supporting enforceability under United States patent eligibility standards. Alongside this, the company's most competitively sensitive assets, including proprietary training data sets comprising thousands of expert annotated cardiac ultrasound studies, model weights optimized for real-time clinical inference and annotation methodologies developed with sonographer input, were maintained as trade secrets. The software, user interface designs and technical documentation were protected by copyright.

In 2020, Caption Guidance received FDA marketing authorization via the De Novo pathway, establishing a new Class II device category that subsequently served as a predicate for 510(k) clearance (K200755). This authorization required a demonstration of safety and effectiveness, clinical validation of image quality, human factors testing with nonexpert operators, software verification and cybersecurity risk management. The regulatory clearance proved strategically transformative: it validated clinical utility, created a reusable regulatory predicate for future submissions and materially increased the company's acquisition value. In February 2023, GE HealthCare acquired Caption Health, integrating Caption AI into its Vscan and LOGIQ ultrasound systems and leveraging GE's global distribution network and regulatory expertise to scale up internationally. This outcome illustrates how regulatory clearance can serve as a value multiplier on underlying IP assets.

Key lessons for innovators

- Regulatory clearance often significantly enhances acquisition value. FDA 510(k) clearance de-risks the technology for potential acquirers and demonstrates clinical validation.
- A combination of patent and trade secret protection is powerful. Patents provide defensive protection and licensing leverage, while trade secrets protect the core competitive assets (such as data sets, models and clinical know-how).
- Strategic positioning supports acquisition. Caption Health built exactly what a large medical device company would want to acquire – validated technology with regulatory approval, strong IP and a clear path to integration.
- A focus on clinical workflow integration adds value. Rather than building a standalone product, Caption Health designed for integration with existing ultrasound equipment, making adoption frictionless.

Sources: GE HealthCare acquisition announcement (February 2023); FDA 510(k) database (radiological acquisition and/or optimization guidance system clearance under K200755 and subsequent clearance for cardiac guidance clearance under K243065); United States Patent and Trade Office (USPTO) patent database (US 11,844,654 B2); Caption Health archived press materials.

Case study: Deep Genomics – AI-driven RNA therapeutics

Deep Genomics, founded in 2015 and headquartered in Toronto, Canada, applies AI to the design and development of genetic medicines. Its proprietary platform analyses large genomic data sets to predict how genetic mutations affect cellular processes and to identify RNA-based therapies for rare genetic diseases, including Wilson's disease and beta thalassemia. The process enables the design of oligonucleotide therapeutics that modulate RNA splicing and gene expression in a more systematic way than traditional trial-and-error drug discovery approaches.

The company's IP strategy combines a robust patent portfolio with extensive trade secret protection. Patents issued by the United States, including US 11,887,696 B2, US 11,636,920 B2 and US 11,568,960 B2, cover machine-learning systems for classifying and interpreting genetic variants, training convolutional neural networks on biological sequence data and scoring variant impacts on molecular phenotypes. Spanning patent classifications across genetic engineering, therapeutic preparations and bioinformatics, these patents are framed around systems and methods applied to real biological sequence data rather than abstract algorithms, strengthening their commercial enforceability. Complementing this patent portfolio, the company's most valuable asset is its proprietary database of genomic variant effects. It built this through years of curation and experimental validation and protected it as a trade secret, alongside neural network architectures, oligonucleotide design algorithms and experimental validation protocols.

Deep Genomics has raised over USD 180 million in private venture capital from investors including SoftBank Vision Fund 2, and has advanced several RNA-based drug candidates into preclinical and clinical testing. The company has benefited significantly from Toronto's world-class AI research ecosystem, drawing on the University of Toronto, the Vector Institute and a deep pool of AI and genomics talent produced through strong academic and government-supported programs. It has also accessed federal R&D tax credits and orphan drug incentives from the province of Ontario to help conserve capital during the early stages of commercialization.

Key lessons for innovators

- Building a strategic patent portfolio provides broad protection and a competitive advantage: Deep Genomics filed foundational patents on RNA-targeting methods before clinical validation. Patent filing (preclinical data) can be advantageous when technology is novel and competitors are emerging.
- De-risking through partnerships before major fundraising is critical. The SoftBank Vision Fund 2 investment (USD 180 million) was predicated on showing proof-of-concept pharma collaborations.
- Geography matters for accessing specialized talent and government incentives. Toronto's AI talent pool (such as the Vector Institute and the University of Toronto) provided technical talent, while Canadian orphan drug incentives and R&D tax credits reduced early-stage risk.
- United States market validation is essential. Despite its origin in Canada, Deep Genomics prioritized United States patent protection and FDA orphan drug designations, recognizing access to this market as critical for exit valuation and pharma partnerships.

Sources: Deep Genomics company website and press releases; USPTO patent database (US 11,887,696 B2, US 11,636,920 B2, US 11,568,960 B2); venture capital databases; Nature Biotechnology coverage.

Case study: InstaDeep – reinforcement learning for biotechnologies

InstaDeep was founded in 2014 with roots in Tunis and headquarters in London. It specializes in decision-making AI systems using advanced machine learning techniques, particularly reinforcement learning. The company gained international recognition for applying AI to drug discovery, vaccine design and protein structure prediction, with its work on COVID-19 variant tracking bringing it to global prominence. Its platform combines reinforcement learning with domain-specific biological knowledge to explore vast chemical and biological design spaces through iterative optimization. This approach is particularly well suited to problems where the optimal solution must be discovered rather than learned from labeled data.

InstaDeep's IP strategy balances patents, trade secrets and strategic open-source contributions. As a co-assignee with BioNTech SE, the company holds United States patent application 20250292868A1, covering machine learning systems for multimodal biological sequence analysis that integrate sequence representations with natural language interfaces. Rather than claiming reinforcement learning algorithms in the abstract, the patent is framed around practical system architectures, including biological sequence encoding, multimodal input handling, flexible inference pipelines and human-in-the-loop interaction models. This approach provides commercially meaningful coverage while mitigating subject matter eligibility risks. Core competitive assets, including proprietary data sets combining computational predictions with experimental validation data, optimized model architectures and reward-shaping techniques, are maintained as trade secrets. Contributions to open-source reinforcement learning frameworks focus on general-purpose tools rather than domain-specific implementation, building ecosystem credibility without exposing proprietary biotech capabilities.

InstaDeep's Tunisian origins are significant, demonstrating that world-class AI innovation can emerge from markets outside traditional biotech hubs when supported by strong science, technology, engineering and mathematics education; multilingual talent; government support for tech entrepreneurship and well-developed diaspora networks. In January 2023, BioNTech acquired InstaDeep for a reported GBP 362 million upfront, one of the largest AI-biotech deals in Europe. This enabled BioNTech to integrate reinforcement learning capabilities into mRNA vaccine design, enhance computational immunology and accelerate personalized cancer therapy development. InstaDeep's investors gained substantial returns and access to resources to scale up globally.

Key lessons for innovators

- Companies in low- and middle-income countries can compete globally. Tunisia's tech ecosystem produced a company that attracted a major pharmaceutical acquirer, demonstrating that geographic origin is not destiny.
- Reinforcement learning offers unique value in biopharmaceuticals. The ability to explore design spaces and optimize complex objectives aligns well with drug discovery challenges.
- Strategic partnerships accelerate growth. InstaDeep's early collaborations with pharmaceutical companies validated its technology and created acquisition interest.

Sources: BioNTech acquisition announcement (January 2023); STAT News interview with BioNTech CEO Ugur Sahin (January 2023); USPTO patent database (US 20250292868A1); InstaDeep company history and press materials.

Case study: Infervision – AI radiology at a global scale

Infervision, founded in 2015 and headquartered in China, develops AI-enabled medical imaging software with flagship products focused on lung nodule detection from chest computed tomography (CT) scans and stroke triage workflows. Its commercial positioning emphasizes workflow-integrated decision support for radiologists alongside an expanding global regulatory footprint.

Infervision's IP strategy combines patent protection in key commercial markets with confidential know-how for proprietary training data and rapid iteration capabilities. Despite its origins in China, the company has pursued United States patent protection, recognizing that it provides global validation and supports commercial positioning for international partnerships. Its portfolio includes both narrow, application-specific patents (such as US 10,937,157 B2, covering convolutional neural network integration with CT image preprocessing pipelines for pulmonary nodule detection) and broader platform-level patents (such as US 11,200,982 B2, covering medical data analysis methods driven by machine learning and applicable across imaging modalities). This dual approach creates defensive coverage that protects current products while preserving the freedom to expand into new clinical indications. Alongside its patent portfolio, the company likely maintains confidential treatment of curated CT imaging data sets, neural network architectures, training protocols and operational processes, enabling rapid model updates and hospital integration.

Infervision has secured regulatory clearances in both China and the United States, strengthening its position across key markets. In the United States, it obtained FDA 510(k) clearance for its InferRead Lung CT AI system in 2020 (K192880), followed by a second clearance in 2025 (K240554) for an enhanced version with expanded nodule characterization capabilities. In China, it received NMPA Class III approval in 2022 for its InferRead CT Stroke solution. While these clearances do not provide statutory exclusivity in the manner of pharmaceutical data protection, they create meaningful first-mover advantages through established clinical evidence and predicate device status that later entrants must meet or exceed through their own validation processes.

Key lessons for innovators

- A dual market regulatory strategy can reduce single-market dependence and strengthen international commercialization pathways. Infervision's approach entailed dual-track regulatory strategy – pursuing both FDA clearances (market credibility in the United States) and NMPA approvals (domestic market protection). This approach is particularly relevant for companies that are based in markets with evolving regulatory frameworks and are seeking to establish a global presence.
- Benchmarking tools may support understanding of the regulatory landscape. For innovators targeting markets beyond China, the United States and the European Union, where national regulatory authorities may lack AI-specific frameworks, WHO's Global Benchmarking Tool[8] for regulatory system maturity offers a practical reference. It helps in understanding the regulatory landscape and engaging constructively with national authorities with varying levels of capacity. The tool assesses national regulatory systems across six functions, including market authorization, post-market surveillance and laboratory access, providing innovators with a structured basis for evaluating the regulatory environment in target markets.

Sources: FDA access data; global.infervision.com; bioworld.com; USPTO Patent Database.

8 Available at https://www.who.int/tools/global-benchmarking-tools.

2 Commercialization pathways: Approaches to innovation and access

Key takeaways

- Licensing can be structured across different application areas, enabling multiple partnerships simultaneously.
- Field-of-use licensing by geography or market segment can simultaneously serve public health goals in resource-constrained settings and commercial objectives in high-income markets.
- Access to AI-enabled health innovations may be supported by IP strategies that take into account different models, for example, access models, including differential pricing commitments.
- Dual strategies of licensing to others while developing internal products may provide more stability than single-approach models.
- Cloud-based delivery approaches protect core technology while enabling broad deployment to health systems.

Emerging patterns in IP licensing strategies demonstrate how AI-enabled health innovators can support pathways that promote commercial viability and public health objectives.

2.1 Field-of-use licensing and parallel partnerships

A key lesson from AI-enabled health innovators is that licensing can be structured across different application areas or geographical territories, enabling multiple partnerships to operate simultaneously without conflict. This approach, known as field-of-use licensing, allows a patent holder to license the same underlying technology for different purposes, for example, licensing diagnostic AI algorithms separately for infectious disease detection, cancer screening and cardiovascular assessment.

By segmenting rights according to a therapeutic area, geography or market segment (such as high-income or low- and middle-income countries), innovators can partner with multiple organizations that are best positioned to serve different populations or address different health challenges. This maximizes both the reach of the technology and its impact, while generating diversified revenue streams that support continued R&D. From a global health perspective, the ability of innovators to structure licensing differently for diverse populations and markets is a significant tool. Field-of-use licensing enables tailored partnerships with local manufacturers or distributors in resource-constrained settings, facilitating technology transfer and capacity-building while preserving commercial opportunities in other markets.

2.2 Out-licensing and internal development

Strategies that combine out-licensing to external partners with internal product development may achieve broader health and commercial objectives than a single approach to licensing. Out-licensing may be necessary when the licensor lacks the resources to continue downstream development of IP, as this provides a pathway to valorizing it.

Companies that rely solely on internal commercialization may lack the resources or market access to achieve broad global impact. A flexible approach allowing both out-licensing and internal development allows innovators to maintain direct engagement with product development in selected markets, while leveraging partners' expertise, infrastructure and local knowledge in others. For technologies addressing global health challenges, dual strategies enable companies to pursue market commercialization that generates revenue to drive forward operations while simultaneously partnering with public health organizations or generic manufacturers for deployment in low-resource settings.

2.3 Cloud-based delivery as an access enabler

Innovative deployment models, particularly cloud-based or software-as-a-service architectures, demonstrate how technology companies can protect core IP while enabling broad deployment to health systems with varying technical capacities. By hosting AI algorithms, databases or analytical tools centrally and providing access through secure interfaces, innovators retain control over proprietary models and training data (often protected as trade secrets) while making functionality available to end users. This approach reduces barriers to adoption (as health facilities need not invest in specialized hardware or maintain complex software), while enabling continuous updates, quality monitoring and standardized performance across diverse settings.

From an access perspective, cloud-based delivery facilitates differential pricing commitments. Resource-constrained health systems pay reduced fees or access services through subsidized programs, while the same technology generates commercial revenue in higher-income markets. This model exemplifies how technical architecture choices intersect with IP strategy to advance both sustainability and access objectives. Yet cloud delivery also raises considerations around data sovereignty, cross border data flows, internet connectivity requirements and long-term service continuity as well as the environmental impacts of data servers. These issues could be managed and may require deliberate design choices, including offline-capable architectures, local data-hosting options and transparent service continuity commitments so that cloud-based models facilitate access.

2.4 Access models, including licensing

Access models may involve licensing agreements to support feasible real-world availability and benefits from innovations, in a manner that remains commercially efficient and sensitive to the conditions for downstream development and does not compromise safety, quality and efficacy. Access models include licensing on voluntary and mutually agreed terms, and allows adaptation to patient needs and the demands and unique attributes of a jurisdiction.

Access models may also include differential pricing commitments requiring lower prices in low- and middle-income countries, humanitarian provisions allowing royalty-free use in specified contexts, sublicensing rights that may support local production, technology transfer and capacity-building obligations, and transparency, all with the aim to improve access to medical countermeasures. Factors that may limit commitments to access models include limited facilities, size of market and innovator and expertise, which may impact downstream production and distribution.

For health technologies using AI, access models may mean structuring licenses to enable the adaptation of algorithms for local disease patterns, sharing training methodologies while protecting proprietary data sets or providing preferential licensing terms for public health applications. It may also encompass commitments to share model performance data across diverse population groups, ensure algorithmic non-discrimination, and support the local capacity to audit and validate AI tools. In addition to bilateral licensing, WHO and WIPO support IP licensing mechanisms, such as the Medicines Patent Pool (MPP), an independent public health organization founded by UNITAID, highlighting a balanced approach to the management of IP. The MPP enables patent holders to voluntarily license IP to enable the generic production of medical technologies, including in resource-limited settings.

These examples show how licensing approaches may embrace diversification and attention to social impact. For health technologies using AI, which often involve multiple layers of IP (such as algorithms, training data, software implementations and user interfaces), licensing structures can unbundle these elements, offering different terms for various components or use cases. By deploying IP strategically, in ways that advance both innovator and global health objectives, commercialization pathways can be closely intertwined with the goal of improved health outcomes for all.

Case study: Qure.ai – AI for diagnostic imaging in underserved markets

Qure.ai, founded in 2016 in India, develops deep-learning algorithms for medical imaging and diagnostics. It has a particular focus on addressing health care gaps in low- and middle-income countries, where radiologist shortages and clinical backlogs limit access to timely diagnostic care. Its flagship product, qXR, detects abnormalities in chest X-rays, including tuberculosis (TB), lung nodules and pneumonia, while its expanding portfolio covers the AI-assisted interpretation of head CT scans for stroke triage, guidance for placing breathing tubes and other emergency care applications. The company's tools have been deployed in over 90 countries across Africa, the Americas, Asia and Europe, serving approximately 15 million patients annually. TB screening alone analyses up to 10 million chest X-rays per year.

Qure.ai's competitive position rests primarily on regulatory clearances, proprietary training data sets and algorithmic implementations developed specifically for resource-constrained settings, rather than on a prominent patent portfolio. Its most strategically valuable confidential assets are likely its curated imaging data sets, drawn from diverse patient populations underrepresented in Western training data; technical implementations addressing challenges common in low- and middle-income countries, such as low-quality equipment and high TB prevalence; and operational expertise in integrating AI tools into resource-limited clinical workflows and mobile screening programs.

In low- and middle-income countries, regulatory clearances from recognized authorities provide the independent clinical validation that health ministries and international procurement bodies require to justify deployment at a national scale. For its chest X-ray TB solution for use without a human reader, Qure.ai had secured 18 FDA 510(k) clearances as of late 2024, Class IIb CE Mark certification under the EU Medical Device Regulation and WHO policy recognition of its chest X-ray TB solution following independent evaluation demonstrating that it met WHO performance standards for tuberculosis screening. The company has raised approximately USD 125 million from investors, including Peak XV Partners, Novo Holdings and Lightspeed India Partners, as well as a USD 8 million grant from the Gates Foundation, supporting continued expansion across high-, middle- and low-income country markets.

Key lessons for innovators

- Leveraging local health care needs and vast imaging data sets can provide an advantage. Health-tech innovators in low- and middle-income countries can deliver globally relevant diagnostic AI solutions, achieve iterative regulatory clearances across multiple jurisdictions and secure funding from strategic global investors.
- Regulatory validation (FDA, CE mark) combined with WHO normative guidance provides market credibility.
- Public health partnerships enable large-scale validation and deployment that would be costly for commercial-only strategies.
- The role of mixed funding points to sources outside private venture capital. These include public health program partnerships, national government procurement and multilateral and bilateral health funding.

Sources: Qure.ai corporate materials; FDA and CE regulatory records; Reuters; Economic Times/ ETHealthWorld; Frost & Sullivan interview; Time Magazine.

Case study: BenevolentAI – knowledge graphs for drug discovery

BenevolentAI is a UK-based AI company that applies machine learning and large-scale biomedical knowledge graphs to drug discovery and target identification. It integrates structured biological data, scientific literature and experimental evidence to uncover previously unrecognized disease mechanisms and therapeutic targets. Since 2019, the company has collaborated with AstraZeneca across multiple disease areas, including chronic kidney disease, idiopathic pulmonary fibrosis, systemic lupus erythematosus and heart failure. It has identified novel targets that have progressed into AstraZeneca's research portfolio and demonstrated the commercial viability of AI-enabled target discovery when incorporated into established pharmaceutical pipelines.

BenevolentAI's IP strategy combines patents protecting core platform methods with trade secret protection for its most competitively sensitive assets. Representative patent filings, including WO 2024236317A1 and US 20250022615A1, describe systems for identifying and ranking therapeutic targets by integrating machine learning inference with the structured querying of biomedical knowledge graphs. Claims are framed around applied, system-level implementation, rather than abstract algorithms. This satisfies the technical requirements of the EPO and the inventive concept requirements of the Alice/Mayo framework in the United States. It also provides protection against design-arounds by competitors using different machine learning models within similar knowledge graph architectures.

To complement these patents, the company maintains its most valuable assets as trade secrets, including a proprietary biomedical knowledge graph drawing on over 40 million scientific papers, curated training data sets recording drug target trial outcomes, trained model weights and target prioritization scoring functions. This patents-for-methods and trade-secrets-for-data approach reflects a deliberate recognition that methods are at risk of reverse engineering through publications. Data curation and model training are substantially harder to replicate.

BenevolentAI was listed on Euronext Amsterdam in April 2022 through a special purpose acquisition corporation merger valued at approximately USD 2 billion. Its collaboration agreement with AstraZeneca is structured to allow each party to retain background IP while jointly owning novel targets identified through the collaboration. AstraZeneca holds exclusive licensing rights in agreed therapeutic areas; BenevolentAI retains platform rights for use in other partnerships, generating revenue through a combination of research funding, milestone payments and downstream royalties.

Key lessons for innovators

- A strategic IP allocation can maximize protection without disclosing core competitive advantages. BenevolentAI illustrates the value of deliberately deciding which innovations to patent and which to keep confidential. Patents cover novel computational methods, system integration and algorithmic innovations that competitors could replicate. Trade secrets protect training data, knowledge graph content and model weights, and target prioritization heuristics that cannot be reverse engineered.
- Partnership IP structuring can support field-of-use exclusivity. In its deal with AstraZeneca, BenevolentAI granted exclusive rights in specific therapeutic areas (chronic kidney disease, idiopathic pulmonary fibrosis, systemic lupus erythematosus and heart failure) while retaining platform rights for other indications. This enables multiple disease-specific partnerships using the same technology, increasing platform value. For AI–pharma collaborations, therapeutic area exclusivity is preferable to platform-wide exclusivity, as it supports diversified revenue streams.
- Drafting claims that emphasize architectures, data structure integration and technical improvements strengthens long-term enforceability. BenevolentAI's patents focus on integrated system architectures combining knowledge graphs and machine learning. This strategy has been effective in systems in the United Kingdom/EPO and United States that allow functional claims with structural support. Such claims are broader, more defensible against design-arounds and more likely to survive eligibility challenges than narrow algorithmic claims.
- A hybrid business model combining a platform and pipeline diversifies revenue and reduces reliance on any single source. The company mitigates risk by pairing platform licensing, exemplified by AstraZeneca's access to its AI system, with internal drug development

programs, such as BEN-2293 and BEN-8744.
- Regulatory exclusivities complement IP. BenevolentAI's clinical candidates will gain regulatory data exclusivity in addition to patent protection. Combining composition-of-matter, method-of-use and formulation patents with regulatory exclusivities can extend effective market protection to 20 to 25 years, from initial discovery through generic entry.

Sources: BenevolentAI corporate website (benevolent.com); USPTO and WIPO patent databases (US 20250022615A1, WO 2024236317A1); special purpose acquisition company merger documents (Odyssey Acquisition S.A., April 2022); FierceBiotech (2021), Alice Corp. v. CLS Bank, 573 U.S. 208 (2014).

Case study: CytoReason – computational immunology

CytoReason, founded in 2016 and headquartered in Tel Aviv, applies machine learning to large-scale, harmonized, multiomics data sets to reconstruct cell-level representations of immune-mediated disease. Its computational disease models, sometimes described as digital twins, generate interpretable immune cell interaction maps and disease state models. Pharmaceutical partners use these to support target discovery, indication selection, patient stratification and the prediction of clinical responses across immunology and inflammation-driven conditions.

The company's IP strategy combines patent assets with extensive trade secret protection. Its long-term competitive advantage derives primarily from the scale, quality and continuous refinement of its proprietary biological data sets and disease models rather than its patent portfolio alone. CytoReason operates a cloud-based business-to-business platform through which pharma partners submit analytical queries via API and receive outputs such as target recommendations and biomarker candidates. Underlying data sets and model architectures remain confidential and protected from reverse engineering. This architecture is reinforced by contractual provisions granting partners exclusive rights to specific targets or biomarkers within defined therapeutic areas. CytoReason retains ownership of the core platform and the freedom to collaborate with other partners across different disease domains, enabling multiple simultaneous partnerships without conflict.

CytoReason has established a strong portfolio of pharmaceutical partnerships, reflecting the commercial traction of this model. Its collaboration with Pfizer, expanded in 2022, has a total potential value exceeding USD 110 million and includes an equity investment. The company has also announced collaborations with Sanofi, Ferring Pharmaceuticals, Merck KGaA and other biopharmaceutical organizations, applying its disease models across immunology, inflammation, oncology and reproductive health programs.

Key lessons for innovators

- A business-to-business pharma platform model offers an alternative to clinical deployment. Health companies using AI can build sustainable businesses by licensing to pharma R&D teams rather than deploying clinical decision support tools.
- Trade secrets provide protection that is superior to patents for data-driven platform where a competitive advantage derives from accumulated data assets rather than novel algorithms.
- Field-of-use exclusivity enables multi-partner models. CytoReason partners with multiple competing pharma companies simultaneously by granting each partner exclusive rights in specific therapeutic areas while retaining platform ownership.
- A cloud platform architecture protects trade secrets. CytoReason's API-based platform delivers analytical outputs without exposing underlying data or models, enabling monetization while maintaining trade secret protection. This contrasts with on-premise deployments where customers could reverse engineer proprietary methods.

Sources: CytoReason.com; Pfizer.com; GlobeNewswire; Reuters.

3 Health data governance and standards

Key takeaways

- Health data receive special legal protection as long as they are not anonymized, requiring distinct strategies beyond general AI approaches.
- Techniques to preserve privacy, such as federated learning, can become competitive advantages, while enabling collaboration.
- Data governance strategies must consider both regulatory compliance and health system interoperability requirements. The latter may require consideration of coordinated IP, technical and policy approaches, as appropriate.
- Sharing cross-border health data calls for coordinated legal, technical and policy approaches.
- The adoption and use of technical standards enables ecosystem growth while preserving competitive differentiation.
- Public health partnerships can accelerate validation and deployment while creating sustainable impact.
- Health data governance frameworks vary significantly. Innovators targeting deployment in low- and middle-income countries may benefit from engaging early with local data protection authorities and community stakeholders.

3.1 Data rights and privacy frameworks

Data rights and privacy regulation are important considerations to support AI-enabled health innovation, shaping not only legal compliance but also IP strategy, the freedom to operate and commercial scalability. Unlike patents, data sets are generally not protectable as such, although some jurisdictions have specific protections that may apply. Value is preserved through a combination of regulatory compliance, contracts, trade secret protection and database rights, where available. The interaction between data protection and IP strategies is relevant in considering AI-enabled health innovation, particularly where data governance may affect the long-term exploitation of AI models trained on health data. This chapter outlines some selected data governance frameworks that may be relevant for innovation and IP strategies. Emerging tools, including the European Health Data Space, may have a bearing on this discussion in the future.

3.1.1 European Union: General Data Protection Regulation

The 2016 General Data Protection Regulation (GDPR), effective as of May 2018 establishes one of the world's most stringent regimes for processing personal health data. The material scope of the regulation is set out under Article 2(1). Further definitions of personal data are in Article 4(1) and Recital 26. Provisions apply to personal data, meaning information relating to an identified or identifiable natural person and will only apply if data are not anonymized. In the case of anonymization, health data do not fall under the GDPR. If the GDPR does apply, developers must identify and document a lawful basis for processing, under Article 6, as well as, where health or other sensitive data are involved, a condition permitting the processing of special categories of personal data under Article 9. Depending on the context, these may include Article 6(1)(a) and explicit consent under Article 9(2)(a); public interest in public health under Article 9(2)(i); or

scientific research exemptions under Article 9(2)(j). In addition, controllers must implement data protection by design and by default (Article 25) and, where processing is likely to result in high risk to individuals' rights and freedoms,conduct data protection impact assessments (Article 35).

Other GDPR provisions that may be relevant to AI-enabled health innovation include:

- Special category data (Article 9): Health data receive heightened protection requiring explicit consent or specific exemptions. AI training on health data must satisfy both general lawfulness (Article 6) and special category conditions (Article 9).
- Genetic data (Article 9(1)): These data are explicitly listed among the special categories of personal data, alongside health data and other sensitive information, as categories considered specifically sensitive and subject to stricter data processing requirements.
- Automated decision-making (Article 22): Individuals may not be subject to decisions made exclusively by automated processing where such decisions have legal consequences or similarly significant effects. In healthcare systems, this may apply in particular to determinations related to medical diagnoses or treatments. Health systems using AI must incorporate human oversight or obtain explicit consent.
- Transparency requirements (derived from Articles 13, 14 and 16 as well as Recital 71): Data subjects have the right to obtain meaningful information about the logic involved in automated processing. This may impact AI model opacity and confidential business information or trade secret protection.
- Data portability (Article 20): In certain circumstances individuals can request their data in machine-readable format, potentially requiring AI developers to provide patient-level data even when aggregated for model training.
- Right to erasure (Article 17): Data subjects have the right to have their personal data deleted where certain conditions are met. This can create tensions, especially where data sets are valuable assets. While IP rights may protect the structure or compilation of a data set (e.g., database rights), they do not override data protection rights. In practice, this means that AI developers and data holders must design systems that allow for compliance with erasure requests, even if this is technically complex or economically inconvenient. This right is not absolute, however, and may be limited by competing interests, such as legal obligations or public interest (Article 17(3)).

3.1.2 European Union: Data Governance Act

The 2022 European Union Data Governance Act (DGA), effective as of September 2023, complements the GDPR by creating structured mechanisms for lawful data sharing, including:

- Data intermediaries (Articles 10–12): Trusted entities that facilitate data-sharing between data holders and data users without accessing the data themselves. Data intermediaries must maintain neutrality and cannot use shared data for their own purposes.
- Data altruism organizations (Articles 16–24): Not-for-profit entities that collect data based on consent or permission to make it available for objectives of general interest (e.g., health research, public health or official statistics). Registered data altruism organizations receive a European Union-recognized label.
- Public sector data reuse frameworks (Articles 3–9): Conditions for the reuse of certain categories of public sector health data that are protected for reasons such as commercial confidentiality, statistical confidentiality, intellectual property rights, or personal data protection. This may be relevant for health-related public-sector datasets (e.g., hospital records, disease registries or health surveys). Access remains subject to applicable EU and national rules, as well as technical, organizational, confidentiality, and privacy-preserving safeguards.

Importantly, the DGA does not create new IP rights in data; instead, it clarifies how existing rights (database rights, trade secrets, confidential information) may be exercised in data-sharing environments. Article 5(10) explicitly states that reuse of protected data shall be without prejudice to IP rights, and that data intermediaries must respect trade secret protection for commercially sensitive information shared through their platforms.

3.1.4 United States: Health Insurance Portability and Accountability Act

In the United States, the 1996 Health Insurance Portability and Accountability Act (HIPAA) governs the use of protected health information by health care entities and their business associates, including AI developers. They are required to enter into business associate agreements; implement administrative, technical and physical safeguards; and follow prescribed de-identification protocols via either the safe harbor or expert determination methods (45 CFR § 164.514(a)–(b)). HIPAA compliance has direct implications for AI development, since data sets that are inadequately de-identified may retroactively become protected health information subject to breach notification requirements. This may undermine trade secret protections and trigger regulatory penalties. Several states, including California, Washington and Nevada, have enacted health privacy laws exceeding HIPAA requirements. AI-enabled health companies operating in the United States must comply with the most stringent applicable standard at both the federal and state levels.

3.1.5. Canada: Personal Information Protection and Electronic Documents Act

Canada's 2000 Personal Information Protection and Electronic Documents Act, amended in 2015, establishes a consent-based framework for private-sector data processing. Bill C-27 (the Digital Charter Implementation Act, introduced in 2022 but no longer under consideration) would have launched the Consumer Privacy Protection Act and the Artificial Intelligence and Data Act, with enhanced requirements for AI transparency, algorithmic impact assessments and automated decision-making disclosures. The federal Government is considering new privacy reforms and AI regulation. The Office of the Privacy Commissioner has issued guidance on AI and data analytics (2021), emphasizing transparency obligations when using health data for machine learning.

3.1.6 Japan: Act on the Protection of Personal Information

Japan's 2003 Act on the Protection of Personal Information, with a major revision in 2017 and a further amendment in 2020, effective as of 2022, permits the processing of anonymized information and pseudonymized information with specific safeguards. The 2020 amendments introduced explicit provisions for cross-border data transfers and created a new category of "pseudonymous information" that enables broader research use while maintaining privacy protections. That said, the Act requires consent for processing, cross-geographic transfer and third-party receipt of personal information. Many forms of consent may be required. AI-enabled health innovators will have to determine how to manage these requirements. Japan's Personal Information Protection Commission has issued guidance on AI and automated profiling (2021).

3.1.7 India: Digital Personal Data Protection Act

India's Digital Personal Data Protection Act, enacted in August 2023, introduces consent-centric data governance modeled partially on GDPR principles but with differences (e.g., no data localization requirements and streamlined compliance for start-ups). The Act requires "verifiable consent" for data processing. It grants access, correction and erasure rights to individuals. Sectoral rules for health data processing were under consultation as of early 2026, with implementation rules expected to specify additional safeguards for sensitive personal data, including health information and genetic data. The Data Protection Board of India is being established to enforce the Act.

3.1.8 Brazil: Lei Geral de Proteção de Dados (General Data Protection Law)

The 2018 Lei Geral de Proteção de Dados (General Data Protection Law), effective as of 2020, establishes comprehensive data protection requirements closely aligned with GDPR principles, including lawful bases for processing, data subject rights (access, correction, deletion and portability), data protection impact assessments and accountability requirements. Brazil's National Data Protection Authority has issued guidance on health data processing (2021) and AI systems (2023). The law requires explicit consent for processing sensitive personal data, including health information, with provisions for research exceptions under ethical oversight.

3.1.9 China: Personal Information Protection Law and Data Security Law

China's data governance framework for AI-health innovation is governed by two laws enacted in 2021.

The Personal Information Protection Law establishes comprehensive requirements for the processing of personal information, including health data, with obligations closely paralleling those of the GDPR in structure but with distinct Chinese characteristics. Health information is classified as sensitive personal data under the law, requiring separate and explicit consent for processing. The cross-border transfer of personal data requires either a security assessment administered by the Cyberspace Administration of China, certification by an accredited institution or execution of standard contractual clauses issued by the Cyberspace Administration. These provisions create significant compliance infrastructure requirements for international AI-health collaborations involving Chinese patient data.

The Data Security Law introduces a national data classification system based on the importance of data to national security and public interest, with health data potentially qualifying as "important data" subject to heightened protection and mandatory security assessments before a cross-border transfer. For AI health innovators, these frameworks create meaningful data localization pressures. Training data sets derived from Chinese health institutions may be subject to restrictions that preclude transfers to overseas model development environments, making federated learning architectures particularly relevant in the Chinese market.

3.1.10 Australia: Privacy Act and My Health Records Act

Australia's privacy framework for health data operates across two instruments. The Privacy Act 1988, incorporating the Australian Privacy Principles (APPs), establishes baseline requirements for handling personal information, including health records. APP 11 imposes specific security obligations and APP 8 governs cross-border disclosure. Health information receives heightened protection as a sensitive information category. The My Health Records Act 2012 establishes a distinct national framework for the digital health record system. It imposes strict limitations on the secondary use of records for purposes including AI training, requiring specific legislative authorization for research use. Australia's Privacy Act is currently undergoing significant reform. A 2023 review proposed strengthening individual rights, introducing a direct right of action and expanding the definition of personal information in ways that would affect AI training data practices. AI-enabled health innovators targeting the Australian market should monitor reform developments closely.

3.1.11 Singapore: Personal Data Protection Act

Singapore's 2012 Personal Data Protection Act provides a mature and frequently updated framework for personal data governance. In 2020, amendments introduced mandatory data breach notifications, enhanced accountability obligations, and, importantly for AI and health contexts, new provisions on deemed consent through legitimate interests. The last element provides a lawful basis for data processing, where the individual would reasonably expect use and it does not adversely affect them. The act's research exception permits the processing of personal data without consent for research purposes, where results are not published in individually identifiable form. This is relevant to AI model training on health data sets. Singapore's Personal Data Advisory Committee has issued specific guidance on AI governance through the Model AI Governance Framework (2020, updated). It addresses data quality, algorithmic transparency and human oversight in AI systems, making it one of the more developed non-EU frameworks for AI-specific data governance in the health context.

3.1.12 African regional frameworks

National data protection laws across Africa reflect principles established by the GDPR and included in the 1995 EU Data Protection Directive. The latter, which precedes the GDPR, includes data subject rights and the recognition of special categories of data and adequacy determination. The African Union adopted the Convention on Cyber Security and Personal Data Protection (Malabo Convention, 2014), which establishes GDPR-aligned principles, including

lawfulness, purpose limitation, data minimization and accountability. As of 2026, 14 African Union member states had ratified the Convention.

National implementation shows strong convergence with GDPR standards. South Africa's 2013 Protection of Personal Information Act became fully effective in 2021. It closely mirrors the GDPR structure with special protections for health data and the creation of an information regulator. Kenya's 2019 Data Protection Act establishes data subject rights, requires impact assessments for high-risk processing and restricts international data transfers to countries with inadequate protection, mirroring GDPR's adequacy requirements. Nigeria's 2019 Data Protection Regulation introduced GDPR-aligned principles, later strengthened through the 2023 Nigeria Data Protection Act, which created the Nigeria Data Protection Commission with powers similar to EU supervisory authorities. Rwanda's Law No. 058/2021 established heightened protections for health data, mandatory breach notifications and cross-border transfer restrictions.

3.2 Standards and interoperability

Standardization inside Standard Development Organizations (SDOs) and Standard Essential Patents (SEPs) have played central roles in the information and communication technology sector, where interoperability is critical for widespread adoption (see: Box 2 Experiences with SEPs).

Box 2 Experiences with SEPs

SEPs protect inventions that are used when implementing technical standards. The IPR policies of SDOs usually set forth requirements that such patents are declared and their holders undertake to license them either royalty free or on FRAND terms. In the health technologies sector, FRAND licensing typically applies to interoperability standards such as DICOM for medical imaging, HL7/FHIR for health data exchange, and communication protocols for connected medical devices. FRAND undertakings are not characteristic to pharmaceutical products, as drug patents are not subject to technical standardization requirements. The WIPO report on *Valuation Methods in Licensing Standard Essential Patents*[1] offers a practical reference on the economic methods used to assess FRAND licensing terms in the field of SEPs.

To balance incentivizing participation in developing standards and broad implementation, and to mitigate possible competition law concerns, SDO IPR policies generally include requirements to disclose potential SEPs and offer licenses on fair, reasonable, and non-discriminatory (FRAND) terms. ITU's Common Patent Policy for ITU-T/ITU-R/ISO/IEC and the European Telecommunications Standards Institute (ETSI) IP policy illustrate this approach.[2]

In the health sector, however, exclusivity strategies may reflect a range of specific considerations, including market positioning and regulatory requirements . Accordingly, FRAND licensing will not be equally relevant across all AI-enabled health technologies. Its role is most likely to arise in relation to standardized technical specifications and interoperability-enabling interfaces – such as data formats and communication protocols – rather than safety critical clinical decision logic or proprietary algorithmic architectures that form the competitive core of medical AI products. The latter are not necessarily the kinds of interfaces or specifications that a standard requires all implementers to use.

1 https://www.wipo.int/web-publications/frand-economics-valuation-methods-in-licensing-standard-essential-patents/en/index.html

2 Examples of different IP policies are available at https://www.wipo.int/en/web/patents/topics/sep.

Case study: Owkin – federated learning for drug discovery

Owkin, a start-up founded in 2016 in France and the United States, specializes in applying AI and federated learning to medical research, enabling multiple institutions to collaborate on AI model training without sharing raw patient data. Its federated learning platform distributes model training across participating hospitals, research centers and pharmaceutical companies. Each site trains a local model on its own data and shares only model updates with a central aggregator, which combines them into a global model for further refinement. This approach to preserving privacy addresses one of the fundamental challenges in health care AI: training robust models on large, diverse data sets while respecting patient privacy and institutional data governance requirements.

Owkin's IP strategy combines patents, trade secrets and selective open-source contributions. Its core European patent application (EP 4256758A1) covers the administration and orchestration of federated learning networks. It protects key architectural elements, including distributed training protocols, secure aggregation mechanisms, privacy-preserving safeguards and techniques for managing data heterogeneity across participating institutions. By grounding claims in system-level architecture and concrete technical solutions, rather than abstract algorithmic concepts, the patent establishes a defensible position targeting the practical implementation challenges of federated learning in health care environments.

In tandem, the company maintains trade secrets covering proprietary data sets, model architectures, training procedures optimized for federated settings and operational deployment configurations. It also contributes selectively to open-source federated learning frameworks to build research community credibility without exposing production implementation or clinical validation methods.

Owkin has established significant pharmaceutical partnerships that demonstrate the commercial viability of its platform. In 2021, Sanofi made a USD 180 million equity investment to collaborate on oncology drug discovery and patient stratification, representing one of the largest AI–pharma collaborations in Europe. Additional partnerships with Bristol Myers Squibb and Johnson & Johnson cover immunology, oncology and surgical outcomes prediction. As of March 2025, Owkin has raised over USD 304 million in total funding and achieved unicorn status with a valuation exceeding USD 1 billion.

Key lessons for innovators

- Federated learning addresses a critical market need. It enables AI training on distributed health care data without centralization, thereby respecting privacy regulations and institutional autonomy.
- A mixed IP strategy is essential. Patents protect the core technical architecture, trade secrets safeguard operational know-how and partnerships, and selective open-source contributions build ecosystem trust.
- Strategic partnerships with and investment by pharmaceutical companies, provide both funding and access to real-world clinical data, regulatory expertise and commercialization pathways.
- European data governance frameworks (i.e., GDPR and DGA) can be a competitive advantage when properly navigated. They enable compliant multi-institutional collaborations that would be difficult to replicate in less regulated environments.

Sources: Owkin company website (owkin.com); Sanofi press releases (2021, 2024); Reuters reporting on Sanofi investment; Forbes interviews with Thomas Clozel; EPO (EP 4256758A1).

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