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Unlocking the potential of socially responsible licensing of medical innovations

Guidance brief to improve access to publicly funded medical innovations

wemos

Make health justice happen

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Guidance brief to improve access to publicly funded medical innovations

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Index

Executive summary

Access to medicines remains one of the greatest challenges to health equity, particularly in lower- and middle-income countries, where high prices and limited availability continue to deny millions the benefits of medical innovation. When public funds underpin pharmaceutical research and development, governments have a responsibility to ensure that the resulting knowledge, technologies and medicines serve the public interest, making strong governance, transparency and public accountability not optional, but essential.

Public funding key to medical innovation

Public financing plays a central role in advancing medical innovation and in governing the translation of publicly funded research and development into tangible public benefit. Public universities, university medical centres and research institutes conduct much of the early-stage research and innovation that can lead to medicines, diagnostics, treatments and other health technologies.[1] This research is supported by national governments, the European Union and other public funders,[2] while private companies may subsequently take innovations through clinical development, manufacturing and commercialization.

Shaped by commercial considerations

Public funding therefore creates not only innovation but also leverage to ensure this innovation primarily serves the public interest. Yet public investment does not automatically ensure that resulting health technologies are affordable, available or accessible. Once publicly supported knowledge and intellectual property are transferred to private developers, decisions about development, pricing, production and market availability can increasingly be shaped by commercial considerations. It has been found that the expected financial return on a medical innovation ultimately determines whether it is further developed up to launch.[3]

Protecting the public interest

There are two opportunities to protect the public interest along this pathway. First, public funders can attach access and public benefit conditions to research funding agreements. Second, public research institutions can incorporate public interest conditions when licensing technologies to commercial developers. This is where socially responsible licensing (SRL) applies. These mechanisms operate at different stages but can complement one another.

SRL is an approach to licensing that incorporates public interest considerations alongside commercial objectives. In medical innovation, this can include provisions relating to affordability, availability, non-exclusive licensing, geographic access, continued development, research use, transparency and monitoring. Rather than treating technology transfer solely as a mechanism for commercialization or financial return, SRL recognizes licensing as an opportunity to influence how innovations ultimately reach patients.

1 Mwoka, M. (2024). Funding for equitable infectious disease research and development. In A. Stewart Ibarra & A. D. LaBeaud (Eds.), *Transforming global health partnerships* (pp. 320-321). Springer. doi.org/10.1007/978-3-031-53793-6_22.

2 European Commission. (2025, August). *EC presents proposal for next Framework Programme*. European Research Area. european-research-area.ec.europa.eu/news/ec-presents-proposal-next-framework-programme.

3 SiRM, L.E.K. Consulting, & RAND Europe. (2022). *The financial ecosystem of pharmaceutical R&D: An evidence base to inform further dialogue* (p. 3). www.sirm.nl/docs/The-financial-ecosystem-of-pharmaceutical-RD_2022-06-21-193729_afll.pdf?v=1675090798.

Socially responsible licensing in practice

Practical approaches already exist worldwide. The University Medical Centres Netherlands (UMCNL) Socially Responsible Licensing Toolkit provides principles for incorporating societal considerations into academic licensing. The Medicines Patent Pool's Affordable Access Plan requires licensees to consider how affordable access in lower- and middle-income countries will be achieved. Universities and public research institutions have also developed access policies, model clauses and licensing practices.

These experiences show that SRL does not require choosing between commercialization and public benefit. Conditions can be tailored to the technology, development pathway and markets involved, protecting access where barriers are greatest while preserving commercial opportunities.

However, implementation remains uneven. Key barriers include limited evidence on SRL's impact, concerns about licensing revenues and private sector partnerships, fragmented institutional approaches, and limited awareness and capacity among technology transfer offices (TTOs).

Voluntary principles also need to be translated into clear contractual commitments, monitoring and accountability.

Recommendations to unlock the potential of SRL

This guidance brief calls for SRL to become a more systematic part of medical innovation policy and practice. Funders, policymakers, universities and TTOs each have a role in using the leverage created by public investment to ensure that publicly supported innovation delivers public health benefit, including for populations in lower- and middle-income countries.

Recommendations per stakeholder:

National governments	**Enable and incentivize:** create the necessary policy environment, funding incentives, common principles and public infrastructure.
Public health institutions and funders	**Require and finance:** incorporate SRL expectations into funding, finance evidence generation and training, and monitor implementation.
Public research institutes, universities and TTOs	**Implement:** integrate SRL into institutional licensing strategies, build staff capacity, negotiate appropriate conditions and document outcomes.
Private sector	**Engage and demonstrate feasibility:** participate constructively in negotiations, provide evidence on commercial feasibility and share successful implementation experiences.
Civil society organizations	**Advocate, monitor and amplify:** raise awareness of SRL, represent access considerations, monitor outcomes and disseminate successful practices and demand accountability and reporting.
Multi-stakeholder platforms	**Coordinate and learn:** facilitate dialogue, exchange experiences and continuously improve SRL approaches.

Public money, private products: how medical innovation gets funded and licensed

The public funding landscape for medical innovation

Public universities, university medical centres and publicly owned and funded research institutes play a central role in biomedical innovation ecosystems. A substantial share of the foundational research underpinning medicines, vaccines, diagnostics and other health technologies originates in these public institutions. This research is supported by national and international public funding mechanisms, including national governments, EU Horizon grants and international partnerships.

Public investment is a significant source of funding for biomedical research and development (R&D). In 2020, 26% of pharmaceutical R&D investment, representing approximately 75 billion USD, came from the public sector and not-for-profit organizations.[4] In the Netherlands, public university medical centres (UMCs) received 1.85 billion euros in public funding for medical research in 2021, with government grants accounting for approximately 73% of UMC research and education income.[5] The European Union is also a major funder of early-stage biomedical research, including through the EU Horizon Europe and the forthcoming Framework Programme for Research and Innovation (FP10) which has allocated 175 billion euros for projects from 2028 until 2034 across areas including health, biotechnology, agriculture and bioeconomy.[6]

Together, these figures illustrate the scale of public investment underpinning medical innovation and the corresponding opportunity for public funders and institutions to ensure that publicly supported research delivers public benefit. Public funding is particularly important for high-risk, early-stage research and health needs that may attract limited private investment, including neglected and infectious diseases and diseases disproportionately affecting lower- and middle-income countries and disease burdens[7] that may be less attractive to private sector investment because of limited commercial returns.[8] This gives public funders and research institutions an

4 SiRM, L.E.K. Consulting, & RAND Europe. (2022). *The financial ecosystem of pharmaceutical R&D: An evidence base to inform further dialogue* (p. 14). www.sirm.nl/docs/The-financial-ecosystem-of-pharmaceutical-RD_2022-06-21-193729_afll.pdf?v=1675090798.

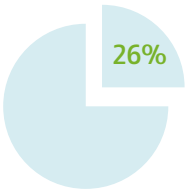
5 Rathenau Instituut. (n.d.). *Inkomsten, onderzoek en zorg van de universitair medische centra* [Factsheet]. www.rathenau.nl/nl/wetenschap-cijfers/geld/inkomsten-uitgaven-van-universiteiten-umcs-en-hogescholen/inkomsten-onderzoek-en-zorg-van-de-universitair-medische-centra.

6 European Commission, Directorate-General for Research and Innovation. (2025). *Europe's budget – Horizon Europe* (2028-2034). Publications Office of the European Union. data.europa.eu/doi/10.2777/8979807.

7 Røttingen, J. A., Chamas, C., Goyal, L. C., Harb, H., Lagrada, L., & Mayosi, B. M. (2012). Securing the public good of health research and development for developing countries. *Bulletin of the World Health Organization*, 90(5), 398-400. doi.org/10.2471/BLT.12.105460.

8 Mwoka, M. (2024). Funding for equitable infectious disease research and development. In A. Stewart Ibarra & A. D. LaBeaud (Eds.), Transforming global health partnerships (pp. 320-321). Springer. doi.org/10.1007/978-3-031-53793-6_22.

Public investments in medical innovation



Percentage of global pharmaceutical R&D investments in 2020 from public and not-for-profit sources, equalling about 75 billion USD.

Public funding for medical research received by Dutch UMCs in 2021. Government grants made up about 73% of their research and education income.

Budget proposed for the EU Framework Programme for Research and Innovation (FP10, 2028-2034), including health, biotechnology and bioeconomy.

important role not only in financing innovation, but also in directing research towards broader public health needs. With these statistics in mind, it becomes essential that SRL practices become part of consistent governance frameworks of funders and research institutions regarding medical innovation.

From research to commercialization

When promising discoveries emerge, universities commonly seek intellectual property protection through patents.[9] University and research centre technology transfer offices (TTOs) or knowledge transfer offices (KTOs) play a key role in managing these assets and facilitating their transition from academic research into products that can ultimately reach patients.[10] They also manage the patent applications and licensing of academic technologies to industrial partners.[11]

Discoveries, such as novel molecules, are often licensed at an early stage.[12] Universities and public research institutions mainly conduct basic biomedical research and their innovative findings are usually in preclinical and animal studies stages, not including interventions with human subjects. The path to a finished commercial product will involve several stages of clinical trials, from T1 to T4. First translating to humans, usually healthy volunteers (T1), then to patients (T2), then into practice through concrete prescription doses and plans (T3) and finally into the community by creating health benefits at a larger scale (T4).[13] Medical innovations at universities and public research institutes are thereby licensed before a finished product has been developed and while their efficacy and commercial potential remain uncertain. Private sector partners may then provide the investment and expertise

9 Miteu, G. D. (2024). Patenting: The Bayh-Dole Act and its transformative impact on science innovation and commercialization. Annals of Medicine and Surgery, 86(6), 3192-3195. doi.org/10.1097/MS9.0000000000002047.

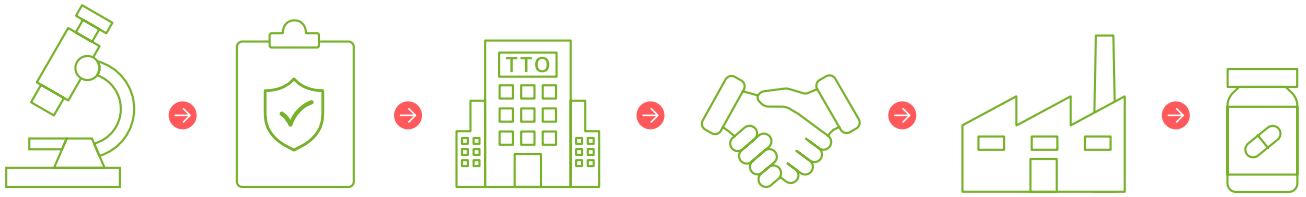
10 Mancha, R., Hallam, C., & Wurth, B. (2016). Licensing for good: Social responsibility in the university industry technology transfer process. 2016 Portland International Conference on Management of Engineering and Technology (PICMET), 307-313. doi.org/10.1109/PICMET.2016.7806747.

11 Rosenberg, N., Stolwijk, N. N., Berg, S. van den, Heus, J. J., Wel, V. van der, Gelder, T. van, & Hollak, C. E. M. (2023). Development of medicines for rare diseases and inborn errors of metabolism: Toward novel public–private partnerships. *Journal of Inherited Metabolic Disease* (p. 3). doi.org/10.1002/jimd.12605.

12 Mwoka, M. (2024). Funding for equitable infectious disease research and development. In A. Stewart Ibarra & A. D. LaBeaud (Eds.), *Transforming global health partnerships* (p. 322). Springer. doi.org/10.1007/978-3-031-53793-6_22.

13 Coller, B. S. (2025). Embedding a commitment to equitable global access into basic and early-phase translational research. *Journal of Clinical and Translational Science*, 9(1), Article e88. doi.org/10.1017/cts.2024.691.

From discovery to patients: the innovation pathway



Publicly funded universities and research institutes identify new knowledge and health innovations.

Universities can seek patent protection for promising innovations.

TTOs manage IP rights, file patents and license technologies to industrial partners.

Innovations are often licensed early, when efficacy is still uncertain and before a final product exists.

Industrial partners invest and advance the development through clinical trials, regulatory approval and manufacturing.

If successful, products are commercialized and brought to the market.

required to advance these innovations through later stages of development, clinical trials and commercialization.[14] In return, universities and research institutes receive a monetary return in the form of royalties, milestone payments, or shares in spin-off companies.[15]

Patent management shapes future innovation

Patent management is more than simply obtaining intellectual property protection. Universities and research institutions make strategic decisions about what to patent, where to seek protection, how broadly to define patent rights, whether to maintain patents over time and how those rights are subsequently made available to others.[16] These choices can affect not only the commercialization of the original innovation, but also whether other researchers and developers can build on it. Broad or unnecessarily restrictive patent protection, combined with exclusive licensing or limited rights for further research, can create barriers to follow-on research and innovation. Conversely, proportionate patenting, research-use rights, non-exclusive licensing and appropriate access to knowledge and technologies can help enable further development. For example, Drugs for Neglected Diseases initiative (DNDi) is a product development partnership that strategically uses patent and licensing of their innovations to "secure non-exclusive, permanent, irrevocable rights to the drugs it jointly develops with its partners for neglected diseases, with the aim of making them accessible to all patients and ensuring all knowledge generated through the R&D process is publicly shared".[17]

14 OECD. (2025). *Health at a glance 2025: OECD indicators* (p. 216). OECD Publishing. doi.org/10.1787/8f9e3f98-en.

15 Rosenberg, N., Stolwijk, N. N., Berg, S. van den, Heus, J. J., Wel, V. van der, Gelder, T. van, & Hollak, C. E. M. (2023). Development of medicines for rare diseases and inborn errors of metabolism: Toward novel public–private partnerships. *Journal of Inherited Metabolic Disease* (p. 3). doi.org/10.1002/jimd.12605.

16 Wild, C., Sehic, O., Schmidt, L., & Fabian, D. (2025). Public contributions to R&D of medical innovations: A framework for analysis (p. 7). *Health Policy*, *152*, Article 105235. doi.org/10.1016/j.healthpol.2024.105235.

17 Drugs for Neglected Diseases initiative. (n.d.). Pro-access policies. dndi.org/advocacy/pro-access-policies-intellectual-property-licensing/.

SRL should therefore consider not only access to the final medical product, but also how patent management and licensing arrangements affect the wider innovation ecosystem and opportunities for future research and development.

Licensing is a public interest decision

Licensing agreements between TTOs and private sector partners determine the conditions under which companies may use academic intellectual property. They can govern issues such as exclusivity rights, geographic scope, development obligations, royalties and milestone payments, sublicensing, research use and the conditions for commercialization. These choices can influence whether a technology is developed, who can use or manufacture it, where it becomes available and whether others can build on it. Public research institutions therefore occupy a unique position at the intersection of public interest and commercialization. Universities are recognized to have three missions: the first being teaching, the second being research, and the third one being the economic and social mission of the university and its contribution to communities.[18] Through their "third mission", universities are expected to ensure that research generates societal value, while bringing discoveries to patients often requires private sector investment and expertise.[19] Once a publicly supported technology is transferred to a private company, decisions regarding pricing, production, availability and distribution will be made based on commercial considerations.[20]

This raises a fundamental question: how can public investment translate into public returns for public health, including in lower- and middle-income countries?

Patent management and licensing are important instruments of public interest decision making and are directly linked to the governance responsibilities of public authorities. The choices made by universities and TTOs can influence whether publicly supported innovations are developed and ultimately reach patients, while also determining the extent to which future research and innovation remain possible. Socially responsible licensing (SRL) provides principles for ensuring that these decisions consider public health and societal objectives alongside legitimate commercial interests.

18 Compagnucci, L., & Spigarelli, F. (2020). The third mission of the university: A systematic literature review on potentials and constraints. *Technological Forecasting and Social Change*, *161*, 120284. doi.org/10.1016/j.techfore.2020.120284.

19 Compagnucci, L., & Spigarelli, F. (2020). The third mission of the university: A systematic literature review on potentials and constraints. *Technological Forecasting and Social Change*, *161*, 120284. doi.org/10.1016/j.techfore.2020.120284.

20 SiRM, L.E.K. Consulting, & RAND Europe. (2022). *The financial ecosystem of pharmaceutical R&D: An evidence base to inform further dialogue* (p. 3). www.sirm.nl/docs/The-financial-ecosystem-of-pharmaceutical-RD_2022-06-21-193729_afll.pdf?v=1675090798.

Scope, application and benefits of socially responsible licensing

Public funding alone does not determine what happens to an innovation once it moves from a public research institution into commercial development. Decisions made during technology transfer and licensing can influence whether an innovation is further developed, where it is made available, who can manufacture it, whether other researchers can build on it and ultimately, whether patients can access it.

There are two distinct points in the innovation pathway at which public interest conditions can be introduced.

1. **At the funding stage**, governments, the European Commission, philanthropic organizations and other public funders can attach access conditions to research funding agreements. These conditions can establish expectations for how resulting knowledge, intellectual property and technologies should later be managed, including requirements concerning affordability, patent management, research use or licensing practices.

2. **At the licensing stage**, a public research institution or its Technology Transfer Office (TTO) can incorporate public interest conditions directly into an agreement with a private developer. This is the point at which SRL applies.

Funding conditions and SRL are therefore distinct instruments. Access conditions operate through the terms attached to public funding, whilst SRL operates through the terms of a licensing agreement. They do not depend on one another but are complementary. Using access conditions in funding with SRL can help safeguard public benefit from the beginning of research through commercial development. Both tools rely on similar approaches and can cover similar types of contractual clauses and ultimately seek to ensure that publicly funded medical innovations respond to public health needs.

What is SRL?

SRL is an approach to licensing publicly generated innovations that incorporate public interest considerations alongside commercial objectives. It aims to ensure that licensing arrangements contribute to broader societal goals and do not unnecessarily restrict access, further development or research. A commonly used definition describes SRL as "the practice of licensing products in a way that is considerate to global needs. It promotes access to innovation for those who need it, whether for health, broadly defined, or further research and innovation".[21]

21 Guebert, J. M., & Bubela, T. (2014). Implementing socially responsible licensing for global health: Beyond neglected diseases. *Science Translational Medicine*, *6*(260), Article 260cm11. doi.org/10.1126/scitranslmed.3009422.

SRL can be applied across different areas of research and innovation, including agriculture, energy and technology. This guidance brief focuses on its application to medical innovation and access to health technologies, particularly in lower- and middle-income countries.

In this context, SRL seeks to ensure that agreements between public research institutions and commercial developers take account of issues such as affordability, availability, continued development, transparency, further research and equitable access.

Why is SRL needed?

Significant public investment in research does not automatically translate into affordable or widely accessible products. Once publicly supported technologies enter commercial development, decisions about pricing, production, registration, geographic availability and further licensing may be primarily influenced by commercial incentives.[22]

This is especially important where the populations most in need of an innovation do not represent the most commercially attractive markets. Medical products relevant to lower- and middle-income countries may face weaker incentives for registration, production or distribution, while exclusive licensing arrangements may limit the number of manufacturers able to produce a technology.

In high-income countries, SRL is also of great importance, as the high prices of medical products put increasing financial pressure on the healthcare systems and insurers that reimburse these costs. The more high-priced – or overpriced – medical products enter the market and get reimbursed, the more they contribute to displacing other essential forms of medical care.

Licensing agreements are therefore not merely technical contracts. They are a point at which public institutions can influence the future development, use and valorization of publicly generated innovation and the underlying patents.

Incorporating access considerations before commercialization takes place, can help avoid situations in which products remain unaffordable, are not registered in priority countries, are insufficiently supplied, or are not developed further at all.

When, where and how to incorporate SRL principles?

SRL principles can be integrated at the earliest possible stage, which is funding. National and international funders can attach conditions in funding contracts that guide the way a future innovation can be licensed to a developer, such as royalty free use for research and intellectual property policies. National legislation, guidelines and integrated toolkits play a large role in this scenario.

Secondly, SRL practices can be set out in internal guidelines of public research institutions even without national legislation mandating this. Research institutions will then negotiate with private parties on a case-by-case basis as part of the individual licensing agreement. Access conditions in funding and SRL practices are crucial in shaping the R&D process and policies from the outset, ensuring greater alignment with global health priorities and patient needs.[23]

Public interest considerations should be introduced as early as possible in the innovation pathway. Public funders can establish expectations through funding agreements before intellectual property is generated. Public research institutions can then translate these expectations into

22 Brightlands Maastricht Health Campus. (2025, January 30). *European interest in socially responsible valorisation.* www.brightlands.com/en/maastricht-health-campus/nieuws/european-interest-socially-responsible-valorisation.

23 Rius Sanjuan, J., Crockett, R., Reid, J., & Chikwanha, I. (2024). *Planning for access during research and development* (p. 16). Uniting Efforts for Innovation, Access and Delivery.

Guiding questions for applying SRL

Before licensing a medical innovation, institutions can ask:

1. **Who is expected to need this innovation?** Which populations, countries or health systems are likely to depend on it?
2. **What could prevent access?** Potential barriers may include high prices, limited manufacturing, lack of registration, exclusive rights, insufficient supply or discontinued development.
3. **Is an exclusive license necessary?** Is exclusivity crucial for the developer or the chance of the innovation being pursued? If so, can it be limited by geography, field of use, duration or sublicensing requirements?
4. **How will affordability and availability be pursued?** Should the licensee be required to develop an access plan, register in priority countries or meet supply commitments?
5. **How will access be sustainable over time?** Is there a plan to maintain the product, update it, and provide technical support over time? Do licensing terms allow additional manufacturers or alternative suppliers if the original licensee cannot meet demand?
6. **What happens if development stops?** Can rights revert to the public institution or be licensed to another developer?
7. **Will further research remain possible?** Are appropriate research-use rights, data access or knowledge sharing provisions protected?
8. **How will implementation be monitored?** What information must the licensee report, who reviews compliance and what remedies apply if commitments are not fulfilled?

institutional licensing policies. TTOs can assess access considerations when negotiating individual agreements with commercial partners. Introducing these considerations early is particularly important because it becomes more difficult to renegotiate access arrangements once exclusive commercial rights have already been granted or substantial investment decisions have been made.[24]

Institutions need flexibility to adapt licensing conditions to different technologies, institutional priorities, partners and development pathways. This flexibility supports public institutions in systematically asking what public interest risks may arise and use the leverage available to them to address those risks in the license.
The absence of a single, universal definition of SRL reflects both its flexibility and its challenges. Flexibility can create uncertainty and fragmented implementation, as evidence of successful SRL practices and challenges are not always easily identified as such. Wider uptake therefore requires a common baseline of public interest principles, accompanied by practical guidance, model clauses, institutional policies and mechanisms for monitoring outcomes.

What can SRL achieve?

SRL provides public research institutions with a practical means of retaining public interest considerations when technologies move into private development. It can help ensure that public investment produces not only scientific and commercial value, but also measurable

24 Global Healthcare Innovation Alliance Accelerator. (n.d.). *Equitable access plans*. MAPGuide. ghiaa.org/mapguide-home/access-plans/.

public health benefits. SRL is not a single standard license. The aim is not to apply every condition to every license. Rather, the relevant parties should assess the likely access risks surrounding a technology and use proportionate provisions to address them.[25]

SRL can support policymakers in creating funding frameworks that benefit public health. Universities and TTOs can develop and use these frameworks to ensure their innovation is licensed in a way that aligns with their public social objectives and reaches patients. Civil society organizations can use national and institutional SRL guidelines to assess how public resources and funding is truly benefitting public health needs.

Public interest objective	Possible licensing approaches
Affordability Refers to the maximum price at which a final product may be offered for sale, reflective of the lowest, sustainable, competitive price level	Affordable access plans, differentiated royalty arrangements, royalty-free or reduced-royalty provisions in defined circumstances
Availability The physical presence, distribution and supply of required pharmaceutical products at a distribution point, such as a pharmacy or clinic, at the time they are needed	Obligations to register, supply or make the product available in priority countries or populations
Competition and production The existence of more than one developer or manufacturer that compete for quality, market, supply and price	Non-exclusive licensing or sublicensing provisions that allow additional manufacturers to produce the technology
Geographic access The physical presence of the product in specific regions and its affordability and availability	Differentiated licensing conditions for lower-income markets or countries with high disease burdens
Continued development The innovation is actively assessed in clinical trials and adapted to commercialization for patient access	Development milestones and obligations to actively develop and commercialize the technology within an agreed timeframe
Clinical research responsibilities Responsibility to conduct ethical and sound clinical trials and to grant host countries and participants access.	Commitments regarding post-trial access and appropriate access for research participants and affected populations and host countries.
Preventing shelving The innovation is used for further research or actively developed into a final medical product	Rights for the public institution to regain or relicense rights if development is discontinued
Further research and innovation The innovation remains available for further research, whilst being commercially developed in parallel	Research-use rights and provisions allowing access to relevant intellectual property, data or knowledge for follow-on research
Transparency, accountability and enforcement Parties agree on responsibilities to report on follow through of SRL agreements from the license	Periodical reporting requirements, monitoring provisions and clearly defined responsibilities for implementation

25 Rius Sanjuan, J., Crockett, R., Reid, J., & Chikwanha, I. (2024). *Planning for access during research and development* (p. 20). Uniting Efforts for Innovation, Access and Delivery.

Why it matters: what happens without SRL

The need for SRL has been highlighted by cases where publicly supported innovations were commercialized without sufficient consideration of affordability and equitable access. These examples demonstrate that the terms and conditions attached to licensing agreements can significantly influence whether publicly funded discoveries ultimately translate into accessible health technologies.

HIV treatment: Stavudine (d4T)

In the early 1990s, researchers at Yale University patented the use of stavudine for HIV treatment. Yale subsequently granted an exclusive license to Bristol-Myers Squibb (BMS), which marketed the medicine under the brand name Zerit.[26]

Due to patent protection and exclusive licensing arrangements, BMS maintained market control in several countries, limiting the availability of generic alternatives.[27] Zerit was sold at approximately USD 1,000 to1,600 per patient per year in high-income markets, while generic manufacturers, including producers in India, could manufacture the medicine at substantially lower costs, around USD 30 to USD 50 per patient per year. The price difference between the branded product and potential generic versions highlighted the consequences of licensing decisions.[28]

Activists and expert organizations argued that publicly supported research should contribute to broader access to essential medicines. Following years of public pressure and court cases, BMS withdrew enforcement of its patent rights in sub-Saharan Africa, enabling wider availability of generic production and substantially reducing prices in affected countries.[29]

The stavudine case illustrates how licensing agreements can influence access outcomes long after the initial scientific discovery has taken place. It also demonstrates how access provisions included at the licensing stage could prevent barriers from emerging later in the product development pathway.

The Plasterk-Amsterdam UMC patent dispute: governance of publicly funded innovation

A more recent example from the Netherlands concerns a dispute surrounding patent ownership on a cancer immunotherapy, developed by Ronald Plasterk, a Dutch scientist and former politician, and Jan Koster, researcher at Amsterdam University Medical Centre (Amsterdam UMC). Plasterk patented the innovation under his own name, with no reference to Koster or

26 Rosenthal, J., Shapiro, I., & Elias, J. (2017, February 24). *Zerit* (Yale SOM Case 17-011). Yale School of Management. cases.som.yale.edu/zerit/access.

27 MSF Access. (2011). *Untangling the web of antiretroviral price reductions* (14th ed.). msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW14_ENG_2011_FINAL2.pdf.

28 UAEM. (n.d.). *UAEM case study.* chapterhandbook.wordpress.com/wp-content/uploads/2020/01/uaem-case-study.pdf.

29 MSF Access. (2011). *Untangling the web of antiretroviral price reductions* (14th ed., p. 45). msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW14_ENG_2011_FINAL2.pdf.

Amsterdam UMC.[30] Plasterk later founded the biotechnology company Frame Therapeutics, based on research connected to these patents. The company was subsequently acquired by CureVac for approximately 32 million euros. Amsterdam UMC took Plasterk to court, claiming significant inventive contribution and funding of the innovation, which should give rise to patent co-ownership and a claim on financial benefits of the sale.[31]

Unfortunately, CureVac halted clinical trials of the method due to the ensuing legal dispute. CureVac was later bought by BioNTech, who shelved the innovation and the immunotherapy never reached patients.[32]

This case highlights broader questions about the governance of publicly supported innovation. Academic research is frequently collaborative, involving multiple researchers, institutions and sources of public funding. When discoveries move from universities into private companies, questions arise about how recognition, ownership and financial benefits should be distributed.

The challenge for public research institutions lies in ensuring that commercialization pathways maintain accountability for innovations that originate within publicly funded systems. SRL provides one approach for addressing these challenges by encouraging institutions to consider public benefit not only during research and discovery, but also when negotiating the terms under which innovations are transferred to private partners.

30 Brouwers, L., & Haan, B. (2024, March 22). Hoe Ronald Plasterk miljonair werd – en de universiteit had het nakijken [How Ronald Plasterk became a millionaire – and the university was left with nothing]. *NRC.* www.nrc.nl/nieuws/2024/03/22/hoe-ronald-plasterk-miljonair-werd-en-de-universiteit-had-het-nakijken-a4193871.

31 NOS Nieuws. (2025, January 26). Amsterdam UMC daagt Plasterk voor de rechter om patentenkwestie. nos.nl/artikel/2553357-amsterdam-umc-daagt-plasterk-voor-de-rechter-om-patentenkwestie.

32 Brouwers, L., & Haan, B. (2024, March 22). Hoe Ronald Plasterk miljonair werd – en de universiteit had het nakijken [How Ronald Plasterk became a millionaire – and the university was left with nothing]. *NRC.* www.nrc.nl/nieuws/2024/03/22/hoe-ronald-plasterk-miljonair-werd-en-de-universiteit-had-het-nakijken-a4193871.

Why SRL matters for lower- and middle-income countries

The potential impact of SRL is particularly relevant for lower- and middle-income countries, where access barriers to health technologies are often greatest. Licensing decisions made early in the innovation pathway can have lasting implications for whether products are affordable, available and adaptable to different health system contexts.

Importantly, SRL does not necessarily conflict with commercial incentives. Access provisions can be designed to protect commercial opportunities in high-income markets while improving availability of products in lower- and middle-income countries. For example, geographically targeted access provisions, non-exclusive licensing arrangements or reduced royalty approaches can enable broader access without eliminating opportunities for commercialization.

For companies, commitments to access for lower- and middle-income countries does not need to interfere with core commercial markets. For universities and research institutions, they provide a mechanism to ensure that publicly funded innovations contribute to global health objectives. SRL can also help reduce inefficiencies within innovation systems. When publicly funded technologies remain inaccessible, are not developed further, or are duplicated through parallel research efforts, public resources may not generate their full potential value. Ensuring that medical innovations are available for further development and use, can help reduce research waste and maximize societal returns.

For lower- and middle-income countries, SRL provides an opportunity to ensure that access considerations are incorporated from the early stage of product development and technology transfer. Rather than addressing affordability and availability barriers after commercialization, SRL enables institutions to anticipate access needs and incorporate equitable access considerations throughout the innovation pathway.

Ultimately, SRL represents an approach to aligning public investment, innovation incentives and global health needs. By integrating access considerations into licensing decisions, universities and publicly funded research institutions can help ensure that scientific advances translate into meaningful and equitable health benefits for the populations they are intended to serve.

SRL in practice: existing models and initiatives

In the context of health research and innovation, several institutions have developed practical frameworks and tools to support universities and TTOs in integrating social considerations into licensing processes. These initiatives aim to move SRL from a broad principle towards concrete contractual practices and create a level playing field for actors in the area of medical innovation.

SRL therefore represents a broader shift in how technology transfer is understood. Rather than viewing licensing solely as a means of generating financial returns or facilitating commercialization, SRL recognizes licensing as an opportunity to shape how innovations are developed, accessed and ultimately reach society.

UMCNL Socially Responsible Licensing Toolkit

The **University Medical Centre Netherlands** (UMCNL) represents all Dutch medical university centres, and has developed the Socially Responsible Licensing Toolkit in 2019.[33] The toolkit provides a practical framework for Dutch academic institutions seeking to incorporate societal considerations into licensing agreements. It was developed to support negotiations between university medical centres and industry partners by providing common principles and concrete building blocks. The toolkit recognizes that licensing agreements frequently contain elements relating to intellectual property rights, development responsibilities and commercial arrangements. The SRL toolkit adds additional considerations to ensure that innovations contribute to societal and public health benefits. According to UMCNL, "The core objective remains to prevent publicly financed research contributing to an extremely high cost of care and other socially undesirable developments."[34]

The toolkit aims to provide guidance in negotiations, an overview of possible aspects and clauses to consider, and model language that TTOs can use in their contracts.

The ten principles cover a wide range of socially responsible elements, starting with the requirement for societal and economic development (principle 1) and retaining the right to use results for research and education (principle 2). Principles 3 and 4 require alignment of objectives of the licensed innovation, such as development of the knowledge and non-conflicting goals of contractual partners. These principles seek to safeguard that the innovation will ambitiously developed, instead of being shelved in order to eliminate a potentially competing medicine.[35] Principles 5 and 6 seek to ensure involvement of affected and concerned parties

33 Netherlands Federation of University Medical Centres (UMC NL). (2020, August). *Socially responsible licensing toolkit for knowledge institutions for a smooth and rapid conversion of academic knowledge into valuable products and services.* www.umcnl.nl/app/uploads/2025/09/Factsheet-Toolkit-Socially-Responsible-Licensing-2020.pdf.

34 Netherlands Federation of University Medical Centres (UMC NL). (2019, June). *Ten principles for socially responsible licensing.* www.umcnl.nl/app/uploads/2025/09/Ten-Principles-for-Socially-Responsible-Licensing-2019.pdf.

35 Brightlands Maastricht Health Campus. (2025, January 30). *European interest in socially responsible valorisation.* www.brightlands.com/en/maastricht-health-campus/nieuws/european-interest-socially-responsible-valorisation.

and protection of indigenous knowledge and inventions. Principles 7 and 8 seek to balance commercial interests with the societal mandate of academic institutions. Principles 9 and 10 seek to safeguard market access and development of the innovation and licensing strategies that do not endanger accessibility.
Importantly, the toolkit is not a legally binding framework. Instead, it provides flexible guidance that institutions can adapt depending on the technology, market context and development pathway. Licensing agreements are usually negotiated at an early stage of research and development, often before a final product is developed, requiring institutions to balance long term societal objectives with the realities of innovation and commercial investment.

The toolkit demonstrates that SRL does not require universities to choose between commercialization and public benefits. Instead, it provides a structured approach for integrating both objectives into licensing decisions.

Since 2019, the SRL toolkit has been applied sporadically by different UMCs in the Netherlands. The Erasmus UMC in Rotterdam and Amsterdam UMC have been most active in integrating some of the SRL principles in their licenses. Leiden UMC and Groningen UMC have also familiarized themselves with the toolkit and are working on integrating it into their standard practices.

Currently, the UMCNL and Ministry of Health, Welfare and Sport; and Foreign Affairs of the Netherlands are increasing their attention towards this toolkit and supporting a more comprehensive and harmonized integration of the principles and the toolkit as a whole at UMC level.

Medicines Patent Pool Affordable Access Plan

The Medicines Patent Pool (MPP) Affordable Access Plan (AAP)[36] provides another practical example of how access considerations can be embedded into licensing agreements.

The MPP, developed an Affordable Access Plan in order to address a recurring challenge in medical innovation: affordability considerations are often addressed only after a product has reached the market and by this stage, options for influencing access are usually limited.

The AAP approach introduces affordability planning at an earlier stage of technology transfer. The AAP framework requires licensees to submit an Affordable Access Plan outlining how they intend to support affordable access to the medical innovation in lower- and middle-income countries.

The plan requires licensees to consider:
- → strategies for ensuring affordable access in lower- and middle-income countries;
- → timelines for implementation;
- → countries where the product will not be commercialized and why;
- → approaches for making the product available to populations who may otherwise face access barriers (nationally, regionally, internationally).

The AAP approach maintains flexibility by allowing different technologies and partnerships to develop context specific access strategies. At the same time, it ensures that access considerations are addressed when universities and developers have the largest opportunity to influence future availability.[37]

36 Medicines Patent Pool. (n.d.). *The affordable access plan provision* [One-pager]. medicinespatentpool.org/uploads/2024/09/MPP_Affordable-Access-Plan-One-Pager.pdf.

37 Medicines Patent Pool. (n.d.). *The affordable access plan provision* [One-pager]. medicinespatentpool.org/uploads/2024/09/MPP_Affordable-Access-Plan-One-Pager.pdf.

The AAP provisions have been adopted by the University of California Los Angeles (UCLA) Technology Development Group, and have since been adopted by a range of other universities, including University of Berkely California[38] and Columbia University Technology Ventures.[39]

Other SRL practices worldwide

Other public institutions have started to explore similar approaches regarding the development of an access plan.

The **European Union** has increased its interest and work on SRL significantly over the last years, recognizing SRL as a tool to increase societal value creation from research and innovation".[40] The European Commission is exploring ways to encourage the use of SRL practices by European universities and public research organizations. The EU increasingly seeks to ensure that technological advancements align with societal values, contribute to the public good through openness, collaboration and social innovation. To this end, the EU has published The Guiding Principles for Knowledge Valorisation in 2022.[41] It has also worked on a Code of Practice on the management of intellectual assets,[42] which aims to increase the use of research results and accelerate the uptake of innovative technologies and establish equitable and ethically responsible access to intellectual assets and management strategies that support open science and innovation, also linked to the Mutual Learning Exercise on Knowledge Valorisation,[43] which engaged 18 countries. In addition, the European Union's **IMPACT3-IP** initiative aims to develop practical tools and training approaches for more sustainable intellectual property licensing. It focuses on increasing societal impact, improving access to technologies and addressing complex licensing arrangements involving multiple partners.[44]

Universities and research institutions in Europe and the United States have explored Affordable Access Plan approaches and related licensing practices, and student led movements contribute to continued advocacy for SRL adoption. The **University of California, Berkeley** (UC Berkeley), was one of the pioneers in institutionalizing SRL. UC Berkeley developed its Socially Responsible Licensing Program (SRLP) in 2003.[45] The initial idea was to change the traditional university technology transfer model: instead of measuring a license primarily by how much royalty income it

38 University of California, Berkeley, Intellectual Property & Industry Research Alliances. (n.d.). *Standard agreements: Sample agreements for licensing intellectual property and establishing startup companies* (sects. 4.9, 8.1). ipira.berkeley.edu/industry/standard-agreements.

39 Medicines Patent Pool. (n.d.). *Upstream access.* medicinespatentpool.org/what-we-do/upstream-access.

40 European Commission, Directorate-General for Research and Innovation. (n.d.). *Socially responsible licensing: A tool to increase societal value creation from R&I.* research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/eu-valorisation-policy/knowledge-valorisation-platform/thematic-focus/socially-responsible-licensing-tool-increase-societal-value-creation-ri_en.

41 Council Recommendation (EU) 2022/2415 of 2 December 2022 on the guiding principles for knowledge valorisation, ST/14448/2022/INIT, 2022 O.J. (L 317) 141–148. http://data.europa.eu/eli/reco/2022/2415/oj.

42 Commission Recommendation (EU) 2023/499 of 1 March 2023 on a Code of Practice on the management of intellectual assets for knowledge valorisation in the European Research Area, C/2023/1321, 2023 O.J. (L 69) 75–84. http://data.europa.eu/eli/reco/2023/499/oj.

43 European Commission, Directorate-General for Research and Innovation. (n.d.). *Socially responsible licensing: A tool to increase societal value creation from R&I.* research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/eu-valorisation-policy/knowledge-valorisation-platform/thematic-focus/socially-responsible-licensing-tool-increase-societal-value-creation-ri_en.

44 IMPACT3T-IP. (n.d.). *The new toolbox for sustainable IP licensing.* www.impac3tip.eu/.

45 Mimura, C. (2007). Technology licensing for the benefit of the developing world: UC Berkeley's Socially Responsible Licensing Program. *Industry and Higher Education, 21*(4), 295-301. eric.ed.gov/?q=Startups+AND+types&pg=3&id=EJ772569.

generates, UC Berkeley would also consider social impact, affordability, accessibility and benefits to underserved populations. As a follow-up, in 2023, UC Berkeley, Universities Allied for Essential Medicines (UAEM) and the MPP released a new license template incorporating **Affordable Access Plan provisions**.[46] The template requires eventual licensees of health technologies to develop an actionable plan for access in lower- and middle-income countries and for addressing inequities in the US.[47]

In addition, the **TenU initiative** spanning across ten leading university technology transfer offices (TTOs) was launched in 2020.48 Participating universities are Columbia University, Massachusetts Institute of Technology, Stanford University in the US, as well as United Kingdom based University of Cambridge, University of Edinburgh, Imperial College London, University College London, University of Oxford, and University of Manchester and KU Leuven (Catholic University Leuven) in Belgium. TenU creates a peer learning network among some of the world's most experienced TTOs and attempts to identify practices that produce better commercialization and societal outcomes.[49]

The **National Institute of Health (NIH)** in the US has developed an Intramural Research Program Access Planning Policy that aims to expand equitable patient access to products that emerge from NIH's own patent licenses.[50] Organizations applying to NIH for certain commercial patent licenses are required to submit Access Plans to NIH outlining steps they intend to take to promote patient access to those licensed products. Section IV of the guidelines stipulates that access plans shall include a brief description of the licensed products, the anticipated patient population, other products, tools, facilities, or unique resources that would be necessary for use of the products and strategies to promote patient access across criteria of affordability, availability, acceptability, and sustainability, to the extent such access can be advanced on terms that are commercially reasonable.

Across **Chile** and **Latin America**, TTOs are coordinating approaches towards SRL. The Chilean Congress has passed a Technology and Knowledge Transfer Bill in June 2026 (Ley de Transferencia de Tecnología y Conocimiento). The new law encourages the implementation and incentivization for research institutions to adopt SRL of technologies developed with public fund contributions.[51] A complementary regulation shall be established by the President, supported by the Ministries of Sciences and Economy, to support practical implementation of the SRL agreements or other equivalent legal instruments. Such instruments will take on conditions that prioritize social commitment equity and public responsibility, thereby promoting equitable access to and ethical use of such innovations.[52]

46 UAEM. (2023, April 25). *UC Berkeley releases new affordable access plan.* www.uaem.org/news/berkeley-aap; University of California, Berkeley, Intellectual Property & Industry Research Alliances. (2023, April). Latest IPIRA Socially Responsible Licensing Program news. ipira.berkeley.edu/node/850.

47 University of California, Berkeley, Intellectual Property & Industry Research Alliances. (n.d.). *Socially responsible licensing.* ipira.berkeley.edu/about/socially-responsible-licensing.

48 TEN-U. (n.d.). *Home page.* www.ten-u.org/.

49 TEN-U. (n.d.). *About.* www.ten-u.org/about.

50 National Institutes of Health. (2025, July 24). *NIH Intramural Research Program access planning policy* (NOT-OD-25-136). U.S. Department of Health and Human Services. grants.nih.gov/grants/guide/notice-files/NOT-OD-25-136.html.

51 Medicines Law & Policy. (2026, June 26). *Chile's Technology and Knowledge Transfer Bill passes Congress with important commitments on socially responsible licensing, transparency.* medicineslawandpolicy.org/2026/06/chiles-technology-and-knowledge-transfer-bill-passes-congress-with-important-commitments-on-socially-responsible-licensing-transparency/.

52 Article 5f of Ley de Transferencia de Tecnología y Conocimiento , Senado de la República de Chile. (2026, May 14). Article 5f of *Ley de Transferencia de Tecnología y Conocimiento*: A tercer trámite proyecto que regula la transferencia tecnológica. www.senado.cl/comunicaciones/noticias/tercer-tramite-proyecto-que-regula-la-transferencia-tecnologica.

A strong supporter and advocate for SRL is the **Universities Alliance for Essential Medicines** (UAEM). UAEM is a student movement originating in 2001 during the Stavudine case at Yale University.[53] Since then, UAEM has student chapters around the world and is supporting universities, funders and the Medicines Patent Pool with their expertise, developing SRL frameworks and guidelines with UC Berkeley, UCLA, Oxford and Cambridge University and played a key role in the formulation of the UMCNL toolkit. Moreover, UAEM monitors licensing contracts by universities worldwide, drawing attention to practices that may undermine equitable access to medicines and applying public pressure where appropriate. During the Covid-19 pandemic, for example, UAEM was involved in advocacy surrounding the Oxford-AstraZeneca licensing agreement. More recently, it has drawn attention to the Amsterdam UMC licensing arrangements in the context of the Plasterk controversy (see page 14).

UAEM has launched the **Global Access Licensing Framework** (GALF) in 2010 which outlines principles that should guide university licensing.[54]

In 2020, UAEM developed the Affordable Access Plan (AAP) Provision at UCLA. It is language that can be incorporated into a licensing agreement, requiring any company licensing the university innovation to submit a plan for making the product affordable and accessible to underserved populations globally. In 2020, UAEM published the Equitable Technology Access Framework (ETAF),[55] which outlines goals and principles for licensing and technology transfer for publicly funded research. ETAF is UAEM's key policy framework used to evaluate university licensing.
At **global policy level**, article 9.5 of the World Health Organization Pandemic Agreement is the first international legal agreement integrating access planning as a WHO Member State obligation. It commits countries to develop policies on attaching public interest conditions to R&D funding.[56]

These initiatives demonstrate growing recognition that technology transfer is not merely a financial or legal process, but also a mechanism through which institutions can shape the accessibility and societal impact of innovation.

53 Universities Alliance for Essential Medicines (UAEM), About Us, www.uaem.org/mvv.

54 Universities Allied for Essential Medicines. (2020, July). *Equitable technology access framework (ETAF)*. static1.squarespace.com/static/63f6e61bbffee85fcaeea17a/t/6430385d1bd23e3dd3765b93/1680881757715/UAEM_Equitable_Technology_Access_Framework.pdf.

55 Universities Allied for Essential Medicines. (2020, July). *Equitable technology access framework (ETAF)*. static1.squarespace.com/static/63f6e61bbffee85fcaeea17a/t/6430385d1bd23e3dd3765b93/1680881757715/UAEM_Equitable_Technology_Access_Framework.pdf.

56 World Health Organization. (2025). Article 9.5 of *WHO pandemic agreement* (WHA78.X). www.who.int/health-topics/who-pandemic-agreement.

Barriers and enablers for successful SRL implementation

Despite growing interest in SRL, several barriers continue to limit its effective implementation and impact. Key challenges include gaps in evidence, concerns about potential trade-offs with commercialization, fragmented approaches across institutions, limited oversight of the end-to-end process, and capacity and awareness gaps among TTOs.

Successful implementation of SRL requires more than individual licensing clauses. It requires institutional commitment and alignment, more transparency, evidence gathering, practical tools and mechanisms to evaluate impact.

Barriers	Enablers and remedies
Lack of evidence There is insufficient empirical research and monitoring of implementation of SRL to demonstrate consistent SRL's impact on: → access to medicines, particularly in lower- and middle-income countries; → pricing outcomes; → financial returns to universities.	**Evidence generation** Robust data on SRL outcomes, especially regarding access, affordability, and financial returns, allowing decision makers to rely on evidence, rather than assumptions.
Perceived conflict with commercialization A dominant concern is that SRL conditions may: → discourage private sector partners; → reduce licensing revenue; → slow down product development.	**Transparency** Clear information on licensing terms and their real world impact: → builds trust and reduces uncertainty; → creates evidence of successful cases; → helps counter concerns about potential revenue loss. **Demonstrating mutual benefits of SRL to:** → enhance institutional reputation and wider societal impact of research; → make a positive contribution to long term innovation ecosystems and policies that govern them.
Capacity and awareness gaps Many TTOs lack: → training on SRL tools; → awareness of existing frameworks; → practical guidance for monitoring and implementation.	**Institutional alignment and capacity building** Universities need to: → strengthen awareness and education among TTO staff; → embed SRL into university policies, incentives, and TTO workflows; → ensure that SRL is not treated as an optional add-on but rather as standard practice.
Fragmented approaches Different institutions apply SRL inconsistently, leading to: → confusion among stakeholders; → reduced scalability; → limited collective impact; → lack of overview of the whole process.	**Flexible tools and terms** SRL must strike a balance between: → standardization: providing clear, easy to use templates; → flexibility: allowing adaptation to different technologies, contexts, markets, and partners.
Relying on voluntary mechanisms and institutional guidelines → Institutional guidelines on SRL are not always legally binding or enforceable. → Contractual commitments are legally binding but lack a solid accountability and enforcement mechanism.	Clear agreements on responsibilities for **monitoring, evaluating and enforcing** SRL.

Conclusion

Socially responsible licensing (SRL) is increasingly recognized as a practical approach to ensuring that publicly supported medical innovation generates meaningful public-health and societal benefits. The evidence and examples presented in this guidance brief demonstrate that public investment not only contributes to medical innovation and creates leverage to influence how resulting knowledge, technologies and medicines are developed, licensed and ultimately brought to patients, and not only shaped by expected financial returns.

SRL is not a barrier to commercialization but a means of ensuring that commercialization is compatible with broader public-health objectives. Access provisions can be negotiated and tailored to the characteristics of an innovation, its development pathway and the markets in which it is expected to be used. Geographic access provisions and affordability clauses should be considered as an integral component of responsible licensing and commercialization across high-, middle- and low-income countries.

Practical approaches and tools for implementing SRL already exist and demonstrate that public interest considerations can be incorporated into funding and licensing decisions. The MPP AAP framework, UMCNL SRL toolkit and the guiding questions for SRL included in this guidance brief support public research institutions and TTOs in translating broad SRL principles into concrete licensing decisions, including by considering access, affordability, patent management, licensing conditions, development obligations, monitoring and accountability. SRL frameworks should remain sufficiently flexible to reflect the development stage, characteristics and anticipated use of each innovation. SRL is most effective when complemented by appropriate access conditions in public funding agreements, responsible patent management, and transparency and accountability among all contractual parties.

Publicly funded medical innovation carries an expectation that the resulting knowledge and technologies will contribute to public health. The task for policymakers, funders, universities and TTOs is therefore to use the leverage created by public investment more deliberately. By embedding SRL principles into funding and licensing decisions, SRL can contribute to a medical innovation system in which public investment is more consistently translated into public benefit. Moving from principles to implementation will require political commitment, institutional leadership, dedicated resources and collaboration across sectors, building on existing tools and emerging practices.

National governments should establish enabling policy frameworks and incentives for socially responsible management of publicly funded research. Public funders should integrate SRL and access expectations into funding agreements, while supporting evidence generation, capacity building and monitoring. Universities and TTOs should embed SRL in institutional licensing strategies and ensure that staff have the mandate and expertise to negotiate appropriate conditions. Private-sector developers should engage constructively in negotiations and contribute evidence on commercial feasibility and implementation. Civil society organizations should advocate for strong public-interest conditions, monitor outcomes and demand transparency and accountability. Multi-stakeholder platforms can support coordination, knowledge-sharing and learning across these actors.

Making SRL part of standard medical innovation practice can help ensure that public investment translates into innovations that deliver meaningful health benefits for all.

Policy recommendations

National governments	**Enable and incentivize:** create the necessary policy environment, funding incentives, common principles and public infrastructure.
Public health institutions and funders	**Require and finance:** incorporate SRL expectations into funding, finance evidence generation and training and monitor implementation.
Public research institutes, universities and TTOs	**Implement:** integrate SRL into institutional licensing strategies, build staff capacity, negotiate appropriate conditions and document outcomes.
Private sector	**Engage and demonstrate feasibility:** participate constructively in negotiations, provide evidence on commercial feasibility and share successful implementation experiences.
Civil society organizations	**Advocate, monitor, and amplify:** raise awareness of SRL, represent access considerations, monitor outcomes and disseminat e successful practices and demand accountability and reporting.
Multi-stakeholder platforms	**Coordinate and learn:** facilitate dialogue, exchange experiences and continuously improve SRL approaches.

Support and incentivize SRL adoption

Supporting SRL implementation and application requires active engagement from policymakers, funders and institutional leaders.

Governments and funding bodies can play a decisive role by integrating SRL principles into research funding requirements and evaluation criteria. By doing so, they create stronger incentives for universities to adopt SRL as part of their standard practices rather than treating it as an optional or secondary consideration. Recognition mechanisms, such as awards or benchmarking systems, can further reinforce this shift by highlighting institutions that successfully implement SRL.

Governments and funders should also provide funding to conduct monitoring activities, evaluating the progress on SRL adoption and its impact regarding access to medical innovations. National governments should create an enabling policy environment for SRL by incorporating SRL principles into public research and innovation policies, funding frameworks and, where appropriate, evaluation criteria for publicly funded research. They can also establish recognition or incentive mechanisms, such as awards, benchmarking initiatives or preferential consideration in relevant funding schemes, to encourage institutions to develop effective SRL practices. National governments must see SRL attached to public funding as a key mechanism for maintaining leverage and governance over the public benefit generated by that funding.

Public health institutions and funders can have an particularly direct influence by incorporating appropriate SRL expectations into funding agreements, calls for proposals and project evaluation criteria. Rather than requiring a single licensing model, funders could require applicants to demonstrate how access considerations will be addressed and allow the specific conditions to be tailored to the innovation, target population and market context.

Universities and TTOs should translate these expectations into institutional policies and operational processes. SRL should be incorporated into licensing strategies from an early stage rather than introduced only when an agreement is being negotiated.

Generate and disseminate evidence

Generating stronger evidence on the impact of SRL is essential for addressing uncertainty about its feasibility and effectiveness.

Governments and public funders are well placed to finance independent research on how different SRL approaches affect access, pricing, availability, commercialization and financial returns. This could include longitudinal studies, comparative analyses and evaluations of specific licensing practices.

Universities and TTOs can contribute by systematically documenting and publicly sharing licensing decisions, access conditions, implementation experiences and outcomes.

Private sector companies can contribute relevant evidence on commercial feasibility and implementation, subject to legitimate confidentiality constraints.

Civil society organizations (CSOs) and independent researchers can complement these efforts by examining outcomes from an access and public interest perspective.

Public institutions or funders could establish shared platforms or databases for documenting SRL approaches and outcomes. Such infrastructure would allow stakeholders to learn from previous negotiations, identify emerging good practices and build a stronger empirical basis for future SRL decisions.

Increase visibility of successful implementation

Increasing the visibility of SRL implementation and its positive outcomes is equally important. Many of the concerns surrounding SRL stem from a lack of awareness of existing success stories.

Funders, universities and TTOs should systematically document and communicate successful cases, including examples where SRL has supported access while enabling technology transfer, investment or commercial development. By actively showcasing examples where SRL has enabled both access and successful commercialization, stakeholders can challenge prevailing narratives about trade-offs. Greater visibility also encourages peer learning, as institutions can draw inspiration from the experiences of others and adapt proven approaches to their own contexts.

Governments and public institutions can further support this through public case study repositories, awards, benchmarking exercises and knowledge sharing platforms.

CSOs can play an important complementary role by amplifying successful examples and translating technical licensing experiences into accessible evidence of public health impact.

Private sector companies can also contribute by sharing cases demonstrating how access conditions have been implemented without undermining commercial viability.

Importantly, visibility efforts should not focus only on exceptional success stories. Documenting both successful and challenging implementations would provide a more credible evidence base and help stakeholders understand which conditions work in which circumstances.

Strengthen SRL awareness and training among TTO professionals

Universities and TTOs are the primary implementers of SRL, making their capacity particularly important. Strengthening awareness and education among TTO staff is another critical step. Training programmes should focus not only on the technical aspects of SRL, such as drafting clauses and negotiating agreements, but also on its strategic relevance and potential impact. Building this capacity requires dedicated resources and collaboration with organizations with expertise in SRL. Over time, greater familiarity and confidence among TTO professionals can support more consistent, informed and effective implementation of SRL across institutions.

Universities should ensure that SRL expertise is embedded within routine TTO capacity building rather than dependent on individual staff members.

Funders and public institutions can support this by financing professional development programmes, developing practical guidance and making training resources widely available.

Governments could support national or regional training initiatives for TTOs.

Promote standardized yet flexible approaches

Promoting a standardized yet flexible approach to SRL is key to ensuring wider adoption and scalability. Developing a common definition and set of core principles of SRL would help align stakeholders, established shared expectations and reduce uncertainty. However, standardization should not result in rigid or one-size-fits-all licensing requirements. Standardized toolkits and model clauses should be designed to allow adaptation to different technologies, markets and institutional contexts. Striking this balance between consistency and flexibility can facilitate broader adoption while preserving the ability to respond to specific challenges, opportunities and local circumstances.

International and national public institutions, together with funders and relevant expert organizations, could develop common principles, model clauses, guidance and decision making tools. These should establish a common baseline while explicitly allowing conditions to be adapted to the characteristics of each innovation, disease area, target population, market and commercialization pathway.

Create mechanisms for dialogue and coordination

SRL implementation often involves actors with different objectives, incentives and information.

Governments and public institutions could facilitate structured dialogue between universities, TTOs, funders, industry and CSOs to develop shared expectations and identify practical barriers to implementation. Regular multi-stakeholder forums, consultation processes or communities of practice could provide a space to exchange experiences and refine SRL approaches over time.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