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Authors	Silvie Daniels (ILI), Anna Colom (The Data Tank), Soujanya Mantravadi						
	(UCAM/IIPM), Natalia Mejía Pardo (The Data Tank), Bruna Pausic (RISE),						
	Marta Poblet (The Data Tank), Jörg Scherer (EURICE), Frank Tietze						
	(UCAM/IIPM), Bruno Vandermeulen (ILI), Ivana Vuka (RISE), Cemresu						
	Yücebalkan (EURICE), Johan Moyersoen (ILI)						

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R: Document, report (excluding the periodic and final reports)

DEM: Demonstrator, pilot, prototype, plan designs

DEC: Websites, patents filing, press & media actions, videos, etc.

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Executive summary

This white paper develops a comprehensive and evidence-based foundation to advance the framework of Impact Licensing (IL) as a systemic response to persistent shortcomings in technology transfer to underserved markets. Traditional licensing often prioritizes economic returns while neglecting societal needs, creating barriers to the equitable diffusion of critical technologies. IL introduces a purpose-driven, contractually binding framework that aligns the interests of technology holders with societal and environmental objectives. At its core lie the I.M.P.A.C.T. principles—Intentionality, Measurability, Participation, Additionality, Comprehensiveness, and Total Return on Assets—which together establish a comprehensive foundation for socially responsible technology transfer. The conceptual foundations of IL draw on multiple global discourses:

- Sustainable Development: IL emphasizes knowledge transfer as a multidimensional process involving skills, training, and institutional capacity, not just intellectual property. Unlike top-down models, IL relies on voluntary partnerships targeted at social impact.
- **Global Health**: Persistent inequalities in health technology access highlight the tension between innovation incentives and affordability. IL addresses this by embedding affordability as a contractual obligation as a part of the "Additionality" principle.
- **Socially Responsible Licensing (SRL)**: Building on SRL, with a focus on university technology transfer, IL scales beyond universities to systematically balance commercial viability with societal benefit.
- Open, Frugal, and Democratized Innovation: IL incentivizes adaptation of innovative technologies
 and their further development for affordability and accessibility, ensuring knowledge sharing
 between licensees and licensors.
- **Shared Value**: IL embeds shared value principles into binding agreements, proving that commercial advantage and societal benefit can be mutually reinforcing.
- **Impact Investment**: IL adapts principles of intentionality, measurability, and additionality to make licensing contracts both socially impactful and investable.

To operationalise these principles, the white paper introduces the Impact Licensing Ecosystem Model, a European-pioneered framework for scaling purpose-driven technology transfer. The model brings together three mutually reinforcing pillars. An International Network of Clearing Houses provides brokerage, harmonization of standards, capacity building, and stewardship of data. An Impact Venture Builder, known as the Impact Licensing Studio, delivers technical expertise, sustainable financial models, and partnerships to ensure successful implementation in local contexts. At the system level, the Impact Licensing Institute acts as the global reference body, responsible for standards, certification, oversight, and governance, with a mission to democratize access to innovation and safeguard accountability, transparency, and sustainability. Supporting these pillars is a Global Partnership Network that collaborates with international organisations such as the United Nations Technology Bank to integrate demand-side needs, expand capacity building, and provide technical assistance. Together, these components form a coordinated pathway to move innovations from research to societal value, particularly in underserved markets.

The ecosystem model was further enhanced after conducting a **needs assessment with stakeholders**³, which confirmed the importance of brokerage mechanisms, sustainable financing, technical expertise, and strong

³ Detailed analyses are presented at the White Paper "Needs assessment for the Impact Licensing concept: Voices from stakeholders for policy and implementation" available at https://impactlicensing.eu/resources







partnerships. Experimental improvement has demonstrated conceptual clarity and feasibility, though scaling the model depends on embedding IL into both institutional practices and policy frameworks. The future of IL will require a dual-track approach that combines bottom-up adoption by organisations willing to integrate IL into their practices with top-down policy support, particularly through the next EU Framework Programme (FP10), to institutionalize the model at scale.





List of abbreviations

ASEAN – Association of Southeast Asian Nations

CTCN - Climate Technology Centre and Network

DNDi - Drugs for Neglected Diseases initiative

EC – European Commission

EU – European Union

EVPA – European Venture Philanthropy Association (now Impact Europe)

GDPR – General Data Protection Regulation

GIE – Global Innovation Exchange

GIIN - Global Impact Investing Network

GSG – Global Steering Group for Impact Investment

GATT – General Agreement on Tariffs and Trade

IMM – Impact Measurement and Management

IoT – Internet of Things

ILA - Impact Licensing Agreement

ILI - Impact Licensing Initiative

IL - Impact Licensing

IP – Intellectual Property

IRIS+ – Impact Reporting and Investment Standards+

LMICs - Low- and Middle-Income Countries

MICs - Middle-Income Countries

RDI – Research, Development, and Innovation

SDGs - Sustainable Development Goals

SEFORÏS – Social Enterprises as Force for Inclusive and Innovative Societies

SMEs – Small and Medium-sized Enterprises

SRL - Socially Responsible Licensing

TFM – Technology Facilitation Mechanism

TRIPS - Trade-Related Aspects of Intellectual Property Rights







TT – Technology Transfer

TTOs – Technology Transfer Offices

UN – United Nations

UNCTAD – United Nations Conference on Trade and Development

UNIDO – United Nations Industrial Development Organization

WIPO – World Intellectual Property Organization

WTO – World Trade Organization





White Paper Objectives

This white paper has been developed to provide a comprehensive and evidence-based foundation for advancing the framework of Impact Licensing. It first introduces the concept of Impact Licensing (Chapter 1) and subsequently elucidates the conceptual (research based) roots that underpin the principles and operational logic of Impact Licensing (Chapter 2), situating the approach within broader discourses on technology transfer, equitable access, and impact-oriented innovation. Systemic barriers persist that repeatedly undermine the practical impact of technology transfer. Impact Licensing seeks to address these persistent barriers by operationalizing an equitable licensing framework. This framework emphasizes voluntary, contractual arrangements designed to align the incentives of technology holders with social and developmental objectives, while also creating the necessary conditions for sustainable technology transfer.

The resulting Impact Licensing Ecosystem Model (Chapter 3) was designed as a systemic response to these persistent shortcomings in technology transfer mechanisms, particularly the lack of widespread adoption and sustainable diffusion of innovations addressing societal challenges. Building on this foundation, the white paper reports on the systematic needs assessment undertaken to critically examine the current configuration of the Impact Licensing Ecosystem Model and presents the empirical validation of its structural configuration (Chapter 4), including the delineation of functional roles and organisational responsibilities of complementary actors as well as the operationalization of Impact Licensing support tools. The white paper concludes with providing an evidence-based framework to guide the progressive development of the ecosystem (chapter 5), ensuring its alignment with the needs identified through stakeholder consultation and survey data.

Through these objectives, the white paper aims to establish a coherent and scalable reference framework for impact licensing that strengthens the legitimacy, transparency, and impact potential of the global Impact Licensing Ecosystem Model, thereby contributing to the achievement of the United Nations Sustainable Development Goals (SDGs) and the European Union's mission-oriented innovation agenda.

1 Introduction to Impact Licensing

The Competence Centre on Technology Transfer⁴ refers to Technology Transfer (TT) as the process through which innovations developed in research and development are translated into practical applications capable of generating both societal and economic benefits. A persistent economic tension arises in TT between societal valorisation—the creation of public, social, or environmental value—and economic valorisation—the generation of financial returns for technology owners and licensees (Corsi et al., 2020; Gerli et al., 2021; Miller et al., 2021; Miller et al., 2018). From the perspective of the technology owner, which may include universities, research institutions, or private innovators, economic valorisation emphasizes the maximization of revenue through licensing, commercialisation, and intellectual property (IP) exploitation. Licensing technologies and intellectual assets to high-value commercial markets ensures cost recovery, profit generation, and the funding of future research. However, such market-driven approaches may conflict with societal valorisation objectives, which often require making technologies accessible at reduced cost or for use in underserved populations where willingness or ability to pay is low. Consequently, technology owners face an economic

⁴ https://knowledge4policy.ec.europa.eu/technology-transfer/what-technology-transfer_en_







trade-off: allocating IP for societal benefit may reduce short-term revenue or cannibalize profitable markets, challenging traditional financial metrics of technology transfer offices.

From the perspective of licensees, which may include commercial firms, non-profits, or social enterprises, similar economic tensions emerge. Licensees are tasked with covering production, distribution, and operational costs while maintaining financial sustainability. Deploying a technology in underserved contexts to meet societal needs may necessitate offering lower prices, investing in training and capacity-building, or adapting technologies to local conditions. These measures increase operational costs and may reduce profitability, potentially disincentivizing engagement in socially oriented deployments unless accompanied by subsidies, incentives, or favourable licensing arrangements. Licensees must therefore balance financial sustainability with mission-driven objectives, seeking strategies that enable impact without undermining business viability.

Central to effective TT is the concept of access, which encompasses the ability of intended beneficiaries (i.e. licensees) to obtain, utilize, and benefit from new technologies. Access can be understood through three interrelated dimensions: **affordability, inclusivity, and equity**, irrespective of whether the technology is deployed in home markets or the Global South.

Affordable access refers to the capacity of individuals, organisations, or communities to acquire and utilize a technology at a cost commensurate with their financial resources. This is particularly critical in sectors such as healthcare, renewable energy, and agriculture, where high costs may preclude low-income populations from benefiting from essential innovations. Strategies to enhance affordability include tiered pricing, targeted subsidies, and public-private partnerships (Adefolaju et al., 2024; Oldfield et al., 2025; Simoens et al., 2022; Vogler et al., 2017).

Inclusive access emphasizes the participation of diverse groups by removing barriers arising from gender, geography, disability, or social marginalization. Beyond affordability, inclusivity ensures that technologies are usable, accessible, and relevant, such as to historically underserved populations. Collaborative initiatives with local communities, non-profits, and small enterprises can support inclusive uptake, ensuring broad dissemination of innovations. For instance, training programs that enable women farmers to adopt climate-smart agricultural technologies illustrate how inclusive approaches can enhance social impact (Adefolaju et al., 2024; Patel et al., 2024).

Equitable access addresses fairness in the distribution of technological benefits, recognising that identical provision does not necessarily produce just outcomes. Equitable approaches account for systemic inequalities and may include tailored deployment strategies, preferential licensing, or capacity-building efforts for disadvantaged populations. By addressing structural disadvantages, equitable access ensures that technological benefits are distributed according to need rather than market potential. For example, deploying advanced diagnostic technologies to rural clinics in regions with historically poor healthcare infrastructure exemplifies the impact of equity-focused strategies (Patel et al., 2024).

A critical consideration in TT is its **responsiveness to societal unmet needs**, defined as gaps between existing societal demands and available technological or service solutions. Such needs manifest across healthcare, energy, agriculture, environmental sustainability, and education, and are often characterized by limited access, inadequate affordability, or insufficient contextual relevance. Examples include the lack of affordable vaccines in low-income regions (Russell et al., 2024; Wouters et al., 2021), insufficient access to clean water





(Fotio & Nguea, 2022), or the absence of renewable energy solutions for off-grid communities (Ventriglio et al., 2021). Examples in developed regions include the growing prevalence of unmet mental health needs (Mori et al., 2024), persistent energy poverty among vulnerable households (Ozdemir & Koukoufikis, 2024), the shortage of affordable and accessible housing (Hick et al., 2025), or the widening digital divide that limits equal participation in education and the labour market (Rydzewski, 2025). Effective TT requires careful assessment of societal priorities, demographic vulnerabilities, and systemic inequities to ensure that innovations address these unmet needs.

This dual perspective underscores the **structural challenge in aligning societal and economic valorisation**: technology owners aim to maximize returns on IP, while licensees must ensure operational and financial feasibility. **Mechanisms such as impact licensing are designed specifically to mediate this tension**. By structuring conditional rights that enable affordable, equitable, and measurable societal deployment without threatening profitable markets, impact licensing provides an economic framework that allows both technology owners and licensees to achieve their objectives while addressing societal unmet needs.

Impact Licensing (IL), proposed by Vandermeulen, Moyersoen et al., offers a structured approach to bridging TT with societal unmet needs. IL is defined as: "Impact Licensing is a time-bound, purpose-driven framework in which a technology or intellectual property owner grants conditional rights at affordable terms to deploy innovations—whether technologies, products, or services—in ways that generate measurable societal or environmental value and address societal needs" (EC, 2020).

IL functions as a hybrid IP model, linking licensing to explicit social or environmental objectives, targeting underserved contexts without cannibalizing existing commercial markets, and embedding accountability through measurable impact metrics. Beyond transferring IP, IL provides know-how, tools, and resources necessary for sustainable adoption, encourages reciprocal innovation feedback, and engages all relevant stakeholders through inclusive governance. In addition, the integration of data stewardship provisions within impact licensing can significantly enhance innovation outcomes. Impact licenses can embed stewardship mechanisms (e.g. data collaboratives, data trusts, etc.) to ensure responsible data governance while maximizing societal value creation. Stewardship models can also establish protocols for data access rights, use and reuse, privacy protections, and benefit-sharing among technology owners, licensees, beneficiary communities, and regulatory bodies. This becomes especially relevant as data-driven technologies (e.g. IoT, AI systems, etc.) often require continuous access to training datasets, real-time data feeds, and digital infrastructure to deliver their intended value, which in turn may require specific data licensing considerations involving all relevant stakeholders.

The IL framework is operationalized through the **I.M.P.A.C.T.** principles, which provide a comprehensive foundation for socially responsible technology transfer:

- 1. **Intentionality**: Licensing agreements are purposefully designed to address clearly defined societal or environmental challenges, obligating licensees to deploy technologies in alignment with sustainable practices and ethical standards, with explicit measurable outcomes.
- 2. **Measurability**: Clear indicators assess the contribution of the technology to intended outcomes. Continuous monitoring, third-party verification, and transparency mechanisms ensure accountability and enable learning from impact results.





- 3. **Participation**: Inclusive engagement of all stakeholders—licensors, licensees, communities, funders, and regulators—is embedded throughout design, implementation, and oversight. Participatory mechanisms include co-development rights, shared governance, dispute-resolution boards, and grievance procedures
- 4. **Additionality**: IL ensures that technologies target additional markets, geographies, or beneficiaries without threatening existing commercial revenue streams, promoting inclusive access.
- 5. **Completeness**: Agreements provide comprehensive access to technical, operational, and market information, alongside ongoing support for innovation and capacity-building, ensuring sustainable adoption.
- 6. **Total Return on Assets (TROA)**: IL enhances value for technology holders by increasing utilization, enabling market entry, fostering open and frugal innovation, and generating additional IP. This aligns with ESG priorities, attracts impact investors, and strengthens stakeholder engagement.

By explicitly linking TT to societal unmet needs and operationalizing these principles, impact licensing ensures that technologies are deployed responsibly, sustainably, and equitably. Integrating affordability, inclusivity, and equity within the IL framework allows both licensors and licensees to achieve societal impact alongside commercial sustainability, transforming TT into a mechanism for broad social, economic, and environmental development.

2 The conceptual roots underpinning the foundations of Impact Licensing

Impact licensing has emerged as a strategic framework for aligning technology transfer with explicitly defined societal and economic objectives. Rather than treating technology transfer as a purely transactional exchange, **impact licensing intentionally directs the dissemination of technology toward outcomes such as improved public health, environmental sustainability, and inclusive economic development**. As illustrated in Figure 1, the concept builds upon a long and diverse tradition of efforts to embed societal value within the practice of technology transfer.

This development must also be situated within the broader context of the profound technological transformations of the past three decades.

Innovation has shifted from predominantly mechanical and analogue systems to digital, data-intensive, and platform-based technologies encompassing software, biotechnology, advanced materials, and renewable energy (Kowalkowski et al., 2023). The rapid rise of digitization, cloud computing, and artificial intelligence has accelerated the global flow of knowledge and intellectual property, significantly diminishing barriers once imposed by geography and infrastructure (Abid et al., 2025).

Simultaneously, **technology transfer** itself has evolved from a primarily patent-licensing, transaction-driven activity into a strategic and collaborative paradigm underpinned by open innovation and multi-institutional research partnerships (Abid et al., 2025). Modern technology transfer offices increasingly engage in codevelopment, knowledge exchange, and capacity building—practices that respond to the increasing complexity of technologies integrating biological, digital, and mechanical components.





As a result, technology transfer can no longer be understood as the simple transfer of a discrete product or patent. It now represents the orchestration of interconnected and evolving knowledge ecosystems. Digital platforms, open-access repositories, datasets and global collaborative networks have become central mechanisms for maximizing impact, enabling technology transfer to balance commercial priorities with technical, social, and ethical imperatives. Within this environment, impact licensing offers therefore a framework to structure impact licenses but also an Impact License Innovation Ecosystem (see chapter 3) to ensure that technology transfer remains agile, inclusive, and responsive to the multidimensional nature of contemporary innovation systems.

International Institutions / Beneficiaries 1. Sustainable international development NGO's Enabling Impact organizations Global Health **Impact** Licensing Investors Foundations 5. Socially Shared value responsible licensing Democratizing (open) Private sector Universities Innovation agencies

The Conceptual Roots of Impact Licensing

Figure 1: schematic representation of the conceptual roots of Impact Licensing

2.1 Sustainable international development

A foundational origin of Impact Licensing (IL) lies in the broader practice of technology transfer within the context of international development. Efforts to link technology transfer with development emerged in the post—World War II period, when initiatives such as the United Nations Technical Assistance Program (1949) and the Colombo Plan (1950) emphasized knowledge-sharing as a critical driver of economic recovery and industrial growth (Blackton, 1951; Owen, 1950). These programmes recognized that the diffusion of technical knowledge, alongside equipment and infrastructure, was essential for rebuilding economies and fostering sustainable industrialization (Maskus, 2024). Technology comprises both physical and informational dimensions; it includes the hardware of machines, tools, and processes, as well as the software of knowledge, experience, and organisational routines (Abd Wahab et al., 2012). Technology transfer therefore extends beyond the transactional transfer of artifacts or intellectual property, involving the deliberate movement







of knowledge, skills, and capabilities across contexts, supported by training, institutional guidance, and adaptive learning, thereby enabling local innovation rather than mere replication. This principle is reflected in the "I.M.P.A.C.T" framework of IL, particularly the principle of completeness, which encourages licensors to provide comprehensive contextual information on technology use, manufacturing, and training, thereby reducing the transaction costs of technology transfer.

The decolonization era of the 1960s and the rise of the "Global South" and "Low- and Middle-Income Countries" generated demands for a more equitable international economic order. The Group of 77 (G77), established in 1964 as a coalition of developing countries within the United Nations, emerged as a central political actor advocating for technology transfer, equitable trade terms, and strengthened industrial capacity in LMICs (Williams, 1987). Concurrently, the creation of the United Nations Conference on Trade and Development (UNCTAD) in 1964 provided a permanent platform to translate these demands into policy, enabling developing countries to promote trade, investment, and technology flows aligned with their developmental objectives. Early UNCTAD analyses emphasized that without institutional and policy frameworks capable of supporting absorptive capacity and local adaptation, access to technology alone would not yield sustainable development outcomes (UNCTAD, 1985).

Global trade governance evolved alongside these institutional developments. The General Agreement on Tariffs and Trade (GATT), subsequently succeeded by the World Trade Organization (WTO) in 1995, introduced the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), establishing minimum IP standards while including provisions such as Article 66.2, which obligates developed countries to facilitate technology transfer to least-developed countries (Maskus, 2000). Despite these formal commitments, implementation has often been weak, enforcement limited, and developmental impact constrained. In response, the <u>United Nations Technology Bank for Least Developed Countries</u> (UNTBLDC) was established in 2018 to provide LMICs with coordinated access to scientific knowledge, technology resources, and capacity-building programmes, particularly in areas aligned with the United Nations Sustainable Development Goals (SDGs).

Despite decades of institutional efforts, legal frameworks, and international cooperation, systemic barriers persist that repeatedly undermine the practical impact of technology transfer (Pohlmann et al., 2024):

- 1. **Limited absorptive capacity** in recipient markets, shortages of skills, infrastructure, and institutional support—often prevents effective uptake and adaptation of technologies.
- 2. **Power asymmetries** between technology holders (typically in high-income countries) and users (often in LMICs) or high-income and low-income markets, shape negotiations, with licensing terms reflecting unequal bargaining positions rather than developmental needs.
- 3. **Market and commercial risks** discourage firms from offering access on affordable or concessional terms when demand or profitability is uncertain.
- 4. **Policy and regulatory incoherence** across trade, IP, and development agendas create fragmented governance environments that delay or dilute implementation.
- 5. **Resistance from technology holders**—whether due to IP concerns, competitive advantage, or reputational risks—limits participation in voluntary or socially oriented.

Impact Licensing seeks to address these persistent barriers by operationalizing an equitable licensing framework that emphasizes voluntary, contractual arrangements designed to align the incentives of technology holders with social and developmental objectives but as well to establish a supporting for







sustainable technology transfer. In this context, IL has developed a strategic collaboration agreement with the UNTBLDC, aiming to operationalize equitable access and strengthen the absorptive capacity of least-developed countries (see inserted text box pg. 28).

Unlike conventional technology transfer, which often relies on top-down mandates or formal IP obligations, IL leverages voluntary partnerships in which engagement terms are explicitly negotiated to maximize social impact, including the diffusion of both tangible technologies and tacit knowledge critical for local innovation. The effectiveness of IL, however, is contingent upon a supportive ecosystem and institutional context. Consequently, IL should be understood not as a standalone mechanism but as part of a broader strategy integrating capacity-building, policy coherence, and incentives for technology holders, reinforcing that equitable licensing can only be fully realized within a favourable developmental and institutional framework.

2.2 Global Health

Global access to essential medicines and health technologies, and the imperative of affordability, form an additional conceptual foundation of Impact Licensing (IL). The right to health, as enshrined in international human rights law, presupposes equitable access to life-saving interventions (Gostin & Friedman, 2024). Yet, significant disparities persist, particularly in low- and middle-income countries (LMICs), where elevated prices, limited manufacturing capacity, and fragile supply chains compromise public health outcomes (Wirtz, 2015). Intellectual property rights (IPRs) and data access rights create temporary monopolies that may restrict competition and inflate costs, producing a structural tension between incentivizing innovation and ensuring affordability (Kapczynski et al., 2005; Ravinetto et al., 2024).

The global intellectual property regime, shaped by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, establishes minimum patent standards but also incorporates public health safeguards, including compulsory licensing, parallel importation, and extended transition periods for least-developed countries (Correa, 2000; Thambisetty, 2019). In practice, however, the use of TRIPS flexibilities has often been constrained by political pressure, technical barriers, and limited domestic production capacity (Kapczynski & Syed, 2012). Voluntary licensing has thus emerged as a complementary, market-oriented approach, allowing patent holders to authorize generic manufacturing and distribution, thereby facilitating affordable access to medicines, vaccines, and diagnostics (Garagancea, 2021; Morin et al., 2022; Nobre, 2023).

International NGOs and philanthropic actors are central to this effort. The Medicines Patent Pool (MPP), supported by UNITAID, has negotiated licenses for HIV, Hepatitis C, Tuberculosis, and COVID-19 technologies. The Drugs for Neglected Diseases initiative (DNDi) and the Foundation for Innovative New Diagnostics (FIND) incorporate access provisions early in the research and development process and promote technology transfer to LMICs. PATH and Medicines for Malaria Ventures (MMV) employ market-shaping strategies to ensure affordability and sustainability. Major philanthropic foundations, such as the Bill & Melinda Gates Foundation and Wellcome Trust, provide catalytic funding, risk-sharing, and strategic direction to lower prices and scale production. Collectively, these initiatives extend and operationalize TRIPS flexibilities, embedding affordability, geographic inclusion, and capacity-building into licensing frameworks.





Within its IMPACT framework and inspired by the practice of global health NGOs in affordable access, IL explicitly integrates affordable access as a core component of "Additionality," requiring that licenses deliver social benefits in addition to what market forces would provide. Drawing on Penchansky and Thomas's (1981) conceptual model, IL frames affordability as a key dimension of health care access, alongside availability, accessibility, and acceptability.

The COVID-19 pandemic renewed global attention to strengthening local manufacturing capacity in LMICs, both to reduce dependency on global supply chains and to build resilience for future health crises. Key initiatives include the WHO-led mRNA technology transfer hub in South Africa (Kolawole et al., 2025), vaccine manufacturing projects in Rwanda and Senegal (Biontech, 2021; MAlfoundation, 2022), and India's expansion of biologics production through public—private partnerships (Uppal et al., 2022). It's framework directly addresses these needs by incorporating provisions for technology transfer, local production, and assembly across health-related and other technologies. Nonetheless, IL is particularly suited to less complex technologies, as the licensing of medicines and vaccines often requires more specialized, highly regulated arrangements that may extend beyond the scope of IL's general model.

2.3 Socially responsible licensing

Socially Responsible Licensing (SRL) represents a key intellectual and operational antecedent to Impact Licensing (IL). Conceptually, SRL emerged as a normative responsibility of universities, designed to ensure that research and innovation deliver not only economic value but also social benefit, reflecting the broader societal obligations traditionally associated with higher education institutions (Guebert & Bubela, 2014; Mimura, 2007; Mimura et al., 2011). Rather than treating technology transfer purely as a revenue-maximization activity, SRL positions universities as stewards of public knowledge, accountable for ensuring that innovations derived from their research address pressing global health, social, and environmental challenges.

SRL is a values-driven framework that translates the university's social mission into licensing practices, embedding ethical responsibility into the management of intellectual property. Operationally, it incorporates social criteria—such as global access and equitable pricing—into technology transfer agreements, balancing economic incentives with public benefit. IL builds upon SRL by operationalizing these principles in a systematic and scalable way, extending their application beyond the confines of individual universities and balancing societal impact with commercial viability. SRL primarily reflects the perspective of the university as licensor, focusing on maximizing public benefit from publicly funded research. IL complements this approach by actively mediating between the interests of licensors and licensees, facilitating agreements that align ethical objectives with practical considerations of commercial feasibility.

An article "Sharing Value for Impact in Technology Transfer" written by Koenraad Debackere from KU Leuven and published in the <u>European IP Helpdesk Bulletin – Societal Value Creation</u> illustrates how technologies can address critical social and environmental challenges while still generating economic returns through commercial deployment, viewed from a university perspective, he provides insights into the history and activities of <u>KU Leuven Research and Development (LRD)</u>, one of Europe's pioneering academic technology transfer offices. Since its establishment in 1972, LRD has made the translation of scientific results into





meaningful outcomes a defining feature of its work, collaborating each year with hundreds of companies and non-profit organisations at both national and international levels.

SRL typically functions at the level of individual universities or research institutions, guiding internal IP management and licensing practices, often constrained by institutional resources and partnerships. IL extends the principles of SRL to broader contexts, including industry, government, and non-governmental organisations, creating frameworks for societal impact across sectors.

Universities have historically been central drivers of SRL, given their tripartite mission of knowledge creation, education, and societal service. A notable example is the University of California, Berkeley, where the Office of Intellectual Property & Industry Research Alliances (IPIRA) launched the Socially Responsible Licensing Program (SRLP) in 2003. Led by Eva Harris, SRLP sought to ensure that Berkeley's biomedical and public health innovations were accessible to developing nations and underserved populations (Mimura, 2007). Key objectives included:

- Ensuring accessibility of health technologies in low- and middle-income countries (LMICs), reflecting IL's principles of accessibility and affordability.
- Enhancing societal impact and public value of university-generated innovations, aligning with IL's emphasis on sustainability.
- Sharing revenues or other benefits with collaborators and resource providers, fostering transparency and equitable partnerships.
- Crediting contributions of partners, emphasizing multi-stakeholder engagement.
- Attracting external investment to sustain socially impactful research, supporting long-term capacity building.

Subsequent studies illustrate how SRL principles have been operationalized. Heaton et al. highlight Berkeley's use of royalty-free terms, nonassertion of IP, and tiered pricing to optimize public benefit (Heaton et al., 2020). Guebert & Bubela advocate extending SRL beyond neglected diseases to ensure affordability and sustainable global access to medicines (Guebert & Bubela, 2014). Rosenberg et al. show the importance of public–private partnerships for socially responsible pricing, data-sharing, and rapid patient access (Rosenberg et al., 2023). Building on the National Institutes of Health–Moderna COVID-19 collaboration, (Sandrik et al., 2025) propose incorporating global access provisions and affordable pricing, which directly align with IL principles .

Philanthropic organisations—including the <u>Bill and Melinda Gates Foundation</u>, the <u>Rockefeller Foundation</u>, and the <u>Wellcome Trust</u>—have been instrumental in funding SRL-aligned projects, supporting model agreements, and de-risking the inclusion of global access provisions in university—industry partnerships (Kapczynski et al., 2005). Policy frameworks, such as Bayh—Dole-era technology transfer regulations, provide tools like non-exclusive licensing, tiered pricing, and march-in rights to ensure that socially relevant innovations reach underserved populations (Ouellette & Sampat, 2024). Research also highlights challenges and opportunities, including anti-shelving clauses, enhanced academic partnerships, and governance structures that facilitate SRL implementation (Bubela et al., 2020; KNAW, 2021).





Interest in SRL is growing internationally, with initiatives in Europe such as the Netherlands' "Knowledge Transfer for Society" program and the UK's TenU Global Access Principles demonstrating how IL can scale SRL principles to broader contexts. These programs operationalize inclusive, equitable, and sustainable access to technologies beyond individual universities. Despite these advances, SRL remains conceptually and operationally evolving. Persistent gaps include standardisation, measurement of long-term societal impact, and incentives for private-sector uptake. IL addresses these gaps by extending SRL's reach beyond universities, operationalizing it in a balanced and practical manner that integrates both licensor and licensee perspectives while incorporating frameworks for measurable societal impact.

2.4 Open Innovation, Democratizing Innovation, and Frugal Innovation Paradigms

The evolving landscape of intellectual property (IP) management has witnessed the emergence of impact licensing as a significant innovation. Traditionally, IP rights have been designed to incentivize innovation by granting creators exclusive control over the commercialisation of their inventions (Arrow, 1962; Hall & Ziedonis, 2001). However, such exclusivity, while promoting investment, can also act as a barrier to knowledge diffusion and equitable access, particularly in sectors critical to social welfare, such as health, education, and environmental technology (Boldrin & Levine, 2008; Heller & Eisenberg, 1998). The rise of open innovation and democratizing innovation paradigms has challenged these traditional models by emphasizing collaboration, knowledge sharing, and broader participation in innovation processes (Chesbrough, 2003; von Hippel, 2005). Closely related practices such as Creative Commons licensing and the open science movement further advance this agenda by making research outputs, data, and educational resources freely accessible for reuse and adaptation, thus lowering barriers to participation and accelerating discovery (Suber, 2012; Willinsky, 2006). Impact licensing, situated within this context, redefines the relationship between IP and societal benefit by embedding social, environmental, or developmental goals directly into licensing agreements.

Patents, copyrights, trademarks, and trade secrets remain the cornerstones of IP protection, but their exclusive nature can hinder follow-on innovation—creating a "tragedy of the anticommons" (Heller & Eisenberg, 1998). In sectors where timely access is critical—such as pharmaceuticals or renewable energy—restricted access can have substantial societal costs (Moon et al., 2012). While licensing has traditionally maximized financial returns through royalties (Lerner & Tirole, 2003), new models increasingly seek to balance IP protection with openness and social responsibility (Trout & Kleinman, 2020).

Open innovation, popularized by Chesbrough, stresses the value of external and internal knowledge flows for advancing technology and business models (Chesbrough, 2003, 2024; Henkel, 2006; West et al., 2014). The European Union has actively promoted this approach through programmes such as Horizon 2020 and Horizon Europe, which mandate open access to publications, encourage cross-sector collaboration, and promote open data for public benefit. These frameworks operationalize principles of **open science**⁵, fostering collaborative R&D, open access publishing, and knowledge transfer across academia, industry, and civil society—aligning closely with IL's emphasis on broad participation and diffusion.

⁵ European Commission, Open Science Policy: https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/our-digital-future/open-science en







Democratizing innovation extends this by empowering users and communities to adapt technologies to their own needs (Benkler, 2006; von Hippel, 2005). Similarly, **frugal innovation** focuses on affordable, resource-efficient solutions tailored to low-resource settings (Prabhu et al., 2012; Zeschky et al., 2014; Tiwari & Herstatt 2012). **IL supports these approaches by incentivizing licensees to adapt and improve technologies for accessibility and affordability, often requiring that improvements and performance data be shared back with the technology owner. This feedback loop enhances iterative improvement and ensures socially beneficial deployment.**

Impact licensing therefore represents a hybrid model: it retains innovation incentives while embedding equity, accessibility, and sustainability into IP agreements. Some frameworks, such as green technology licenses, mandate deployment in climate-vulnerable regions or require local capacity-building (Gallagher et al., 2011). By enabling universities, NGOs, social enterprises, and communities to adapt intellectual assets for local contexts—and by drawing on principles from Creative Commons and open science—IL accelerates innovation diffusion and strengthens the societal impact of technology.

2.5 Shared value

The concept of shared value, first articulated by Porter and Kramer (2011), provides a powerful conceptual lens for understanding the normative underpinnings of Impact Licensing (IL). Shared value reframes the relationship between business and society by asserting that firms can simultaneously enhance their competitiveness and address pressing social challenges. Rather than treating corporate social responsibility as an external obligation or cost, the shared value framework positions social engagement as integral to a company's long-term economic success. This notion is operationalized through three primary strategies: reconceiving products and markets, redefining productivity in the value chain, and enabling local cluster development (Porter & Kramer, 2011).

Impact Licensing extends this logic into the governance of intellectual assets, embedding shared value principles into legally enforceable agreements. At its core, IL seeks to reconcile the tension between the economic interest of IP holders—recouping R&D investments, maintaining innovation incentives—and the societal interest in equitable, affordable, and timely access to critical technologies. By structuring licenses that include provisions for affordability, geographic inclusion, and technology transfer, IL creates mechanisms through which private innovation contributes to public welfare while still generating sustainable economic returns for innovators. The shared value premise, that competitive advantage and social benefit are mutually reinforcing rather than mutually exclusive (Crane et al., 2014; Porter & Kramer, 2011), is reflected in this balance approach.

Crucially, the shared value framework enables proactive engagement with the private sector, including both large R&D-driven multinational companies and small- and medium-sized enterprises (SMEs). For large firms, IL offers a structured pathway to expand market reach, derisk investments in emerging markets, and demonstrate commitment to ESG objectives. For SMEs, which often face resource constraints, IL can lower barriers to entry by providing access to IP under socially responsible terms, stimulating innovation ecosystems and local entrepreneurship. This proactive interaction strengthens trust between public, philanthropic, and private actors and facilitates co-creation of solutions that align commercial success with public value.

IL operationalizes shared value by shifting from purely transactional licensing models—focused on royalty maximization—to relational and developmental models that establishes a basis for inclusive innovation.





Royalty-free or tiered pricing arrangements align commercial terms with public health priorities, particularly in low- and middle-income countries (Moon et al., 2012). Technology transfer clauses not only expand production capacity but also stimulate local economic activity and skills development, generating positive externalities consistent with shared value's emphasis on local cluster development (Porter & Kramer, 2011).

Importantly, IL contributes to a broader institutional shift toward blended value creation. As Emerson (2003) noted, blended value creation integrates economic, social, and environmental outcomes rather than separating them. This is particularly salient in sectors such as health, agriculture, and climate technology, where the social payoff of innovation is significant and where market failures often impede access for vulnerable populations (Gallagher et al., 2011; Wirtz et al., 2016). By embedding enforceable access provisions in licensing contracts, IL reduces reliance on voluntary corporate philanthropy and ad hoc access initiatives, thereby institutionalizing shared value within the knowledge valorisation system.

Academic critiques of shared value have noted its tendency to understate structural power imbalances and the potential for trade-offs between profit maximization and social objectives (Crane et al., 2014). IL addresses these concerns by specifying ex ante commitments in license terms, making social outcomes a legally binding part of the innovation dissemination process rather than a discretionary by-product. This contractualization of shared value ensures that public welfare objectives are not subordinated to short-term market considerations.

In sum, shared value serves as a foundational root of Impact Licensing, offering the normative and strategic justification for its balanced approach. By integrating economic incentives with societal goals—and enabling structured, proactive engagement with both large corporations and SMEs—IL exemplifies how shared value can be institutionalized in IP governance. This creates a framework where innovation diffusion, affordability, and capacity-building are not externalities but central components of the innovation ecosystem, advancing both firm-level competitiveness and global public welfare.

2.6 Impact investment

The roots of impact investing—and by extension, IL—lie in the broader evolution from social entrepreneurship to financing models that align financial returns with measurable social and environmental outcomes. In "The Meaning of Social Entrepreneurship", Dees (2018) defines social entrepreneurs as "change agents in the social sector" who combine mission-driven orientation with pragmatic business methods to deliver sustainable and systemic improvements for underserved populations. Unlike traditional philanthropy, which often relied on grants and donations, social entrepreneurship introduced the idea that market-based mechanisms could be harnessed to address development challenges, thereby blurring the boundaries between public, private, and non-profit sectors (Dees, 2008).

Throughout the 2010s, the European Union began formally recognizing this hybrid model through initiatives such as the Social Business Initiative and SEFORÏS⁶ (Stephan & Folmer, 2017) which documented the role of social enterprises in institutional change, inclusive innovation, and the diffusion of socially oriented business models. These efforts highlighted a growing consensus: systemic social challenges—from healthcare access to climate adaptation—required financing approaches that went beyond traditional corporate social responsibility or one-off donor funding.

⁶ EU-funded project: https://cordis.europa.eu/project/id/613500







It was in this context that impact investing emerged as a distinct movement, offering capital explicitly designed to achieve both financial returns and measurable social or environmental benefits. Popularized at the 2007 Rockefeller Foundation Bellagio Summit and later defined by the Global Impact Investing Network (GIIN, 2020), impact investing refers to "investments made with the intention to generate positive, measurable social and environmental impact alongside a financial return." This marks a conceptual shift from merely "doing no harm" towards proactively embedding intentionality, measurability, and accountability into financing decisions.

Subsequent frameworks have strengthened this orientation. The Impact Management Project introduced five dimensions of impact—what, who, how much, contribution, and risk—while tools such as IRIS+ standardized reporting metrics for social and environmental outcomes (GIIN, 2020). In parallel, European actors like Impact Europe (formerly EVPA) emphasizes additionality (ensuring investments achieve outcomes beyond business-as-usual scenarios), intentionality (a deliberate focus on positive impact), and risk tolerance (supporting early-stage or underserved markets) as foundations of financing social innovation (EVPA, 2018).

Together, these developments formalized what is now known as Impact Measurement and Management, integrating accountability for social and environmental results into the core of investment practice. For IL, this evolution matters because it provides both the conceptual and operational basis for embedding measurable impact directly into licensing contracts. By linking capital allocation, contractual design, and developmental objectives, impact investing frameworks offer the tools to overcome two recurring technology transfer barriers: the lack of sustainable financing mechanisms and the absence of standardized metrics for assessing long-term social value.

Building on this, three principles drawn from impact investing appear to be particularly important for licensing contracts. *Intentionality* requires that objectives and causal pathways for social or environmental outcomes be clearly defined upfront, ensuring alignment between the technology, its targeted markets, and inclusion rules (Born & Brest, 2013). *Additionality* demands that interventions create value that would not occur otherwise, operationalized through clauses on access thresholds, price or volume commitments, or crisistriggered provisions for rapid deployment (Busch et al., 2025). *Measurability* calls for the use of credible, standardized metrics and independent verification, embedding IRIS+-aligned indicators, third-party audits, and public reporting cadences directly into the licensing terms (GIIN, 2020).

In the IL framework, these principles inform not only contract design—for example, by linking impact conditions, KPIs, and monitoring obligations to access provisions—but also the financing architecture that makes such contracts investable. Instruments such as blended finance facilities, outcome-linked royalties or milestones, and portfolio-level risk-sharing mechanisms housed in "clearing houses" allow licensees and investors to share both financial risk and impact accountability.

While standardisation and data-sharing remain uneven across sectors, IL proposes common templates and governance processes to reduce transaction costs and enable scalability. Together, these elements connect mission-driven licensing clauses with results-based financing and transparent measurement, ensuring that impact objectives are embedded rather than assumed in technology transfer agreements.

Responding to calls from the Stanford Social Innovation Review to avoid "scaling without system change" and reinforced by EU policy shifts such as Horizon Europe's mission-driven Research & Innovation agenda, IL presents a unified model for ethical, inclusive, and measurable technology dissemination. In the next section,







we explore the IL ecosystem model in detail, describing its key components, stakeholders, and operational logic.

To conclude with, this chapter was set out to identify and explain the **conceptual roots that underpin the principles** and operational logic of Impact Licensing through the six concepts of Sustainable International Development, Global Health, Socially Responsible Licensing, Democratic Innovation, Shared Value and Impact Investment. The following table schematically captures the alignment between the governing principles of these six pillars and the ILI I.M.P.A.C.T principles.

	Intentionality	Measurability	Participation	Additionality	Completeness	Total Return on Assets
International	(X)				X	
development						
Global Health	(X)			Х		
SRL	(X)			Х		
Democratizing			Х			
innovation						
Shared value	Х	(X)				Х
Impact	Х	Х		Х		
investment						

Table 1: Alignment between governing principles of International Development, Global Health, Socially Responsible Licensing, Democratic innovation, Shared Value, Impact Investment and the ILI I.M.P.A.C.T principles

3 The Impact Licensing Ecosystem Model

Similar to the concept of **impact licensing** being developed in response to the persistent shortcomings of conventional technology transfer and the limited uptake of innovation in settings with societal unmet needs (e.g. low- and middle-income countries, post-conflict regions, refugee communities, or vulnerable households and unequal labour markets in developed countries), the **Impact Licensing Ecosystem Model was designed to enable a systemic response to the persistent shortcomings** in technology transfer mechanisms, particularly the lack of widespread adoption and sustainable diffusion of innovations addressing societal challenges.

The Impact Licensing Ecosystem Model is a European -pioneered ecosystem to scale purpose-driven technology transfer, built around three mutually reinforcing pillars: an International Network of Clearing Houses (see 4.1), an Impact Venture Builder (see 4.2) to accelerate technology transfer and a centralized Impact Licensing Institute (see 4.4). It represents a coordinated framework of complementary actors, each performing an enabling role across the pathway from screening and selecting key enabling technologies to ensuring their effective translation into societal value for underserved markets. The functioning of the three complementary actors are supported by a Global Partnership Network (see 4.3). It can be conceptualized as a systemic configuration of interrelated entities, providing a structured framework to align technological innovation, licensing, and technology transfer mechanisms with the goal of contributing to the United Nations Sustainable Development Goals.





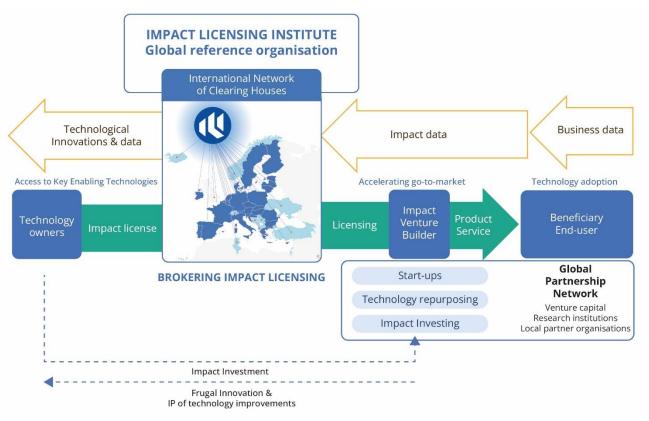


Figure 2: the Impact Licensing Ecosystem Model

Clearing houses act as independent intermediary hubs embedded across regions and technology domains. Their role is to identify promising technologies, screen them for societal applications, and broker impact licensing agreements between technology holders—such as universities, research centres, and R&D-driven companies—and licensees operating in societal markets. Functioning as neutral brokers, clearing houses ensure that agreements are transparent, balanced, and aligned with the UN Sustainable Development Goals. They reconcile the economic interests of IP holders with broader public value, enabling innovations to reach underserved or mission-critical markets in a scalable and responsible way.

These clearing houses collaborate closely with impact venture builders, in particular the **Impact Licensing Studio (ILS)**, which transforms licensed technologies into investable, impact-driven ventures. ILS follows a structured process: validating market demand and adapting technologies with international partners; designing go-to-market strategies with local companies; recruiting and coaching entrepreneurial teams; and finally setting up ventures with robust financial models to attract investment. This approach ensures that technologies are not only transferred but effectively deployed through viable, scalable businesses.

At the system level, the **Impact Licensing Institute** serves as the global reference body for impact licensing. It establishes global standard-setting, provides certification, and executes oversight authority for impact licensing agreements and the network of accredited clearing houses to guarantee consistency, transparency, and measurable impact. The Institute's mission is to facilitate access to technological innovations that address societal unmet needs and contribute to the UN SDGs. It also acts as the custodian of governance, methodologies, and infrastructure that make the ecosystem coherent and scalable.

By combining the localized brokerage role of clearing houses with the venture-building capacity of the ILS and the standard-setting authority of the Institute, ILI is creating a comprehensive European ecosystem for socially







responsible licensing. This model ensures that intellectual property is managed not only as an economic asset but also as a driver of urgent, ethical, and sustainable societal transformation.

The Impact Licensing Ecosystem Model does not exist in isolation but is **embedded within a broader outer ecosystem that both shapes and interacts with its functioning**. This outer ecosystem comprises institutional, regulatory, and policy environments that forms Global Partnership Network and set the enabling conditions for impact licensing practices, including intellectual property regimes, international trade frameworks, public funding schemes, and sector-specific governance structures. The IL ecosystem, therefore, requires engagement with **international organisations that shape global IP and data policy** such as the <u>World Intellectual Property Organization (WIPO)</u>, the <u>European Patent Office (EPO)</u>, and the <u>European Union Intellectual Property Office (EUIPO)</u>, each playing a central role in advancing innovation, sustainability, and fair access.

Through initiatives such as <u>WIPO GREEN</u>, which facilitates green technology transfer, and <u>PAT-INFORMED</u>, that improves access to patent information on medicines, **WIPO** directly supports progress towards the UN SDGs. Similarly, **EUIPO**, as the authority responsible for the registration of EU trademarks and designs, has a crucial role through its involvement in international cooperation projects such as <u>AL-INVEST Verde IPR</u> and <u>AFRIPI</u>, which strengthen IP systems and foster sustainable growth in partner regions.

The **EPO** also plays an essential role through its patent system and innovation support activities. The Office promotes technologies that foster sustainability, energy efficiency, and climate resilience by ensuring timely and effective patent protection. By facilitating access to knowledge, strengthening patent quality, and promoting sustainable innovation, the EPO aligns its activities with the objectives of the EU Green Deal⁷ (climate neutrality, green growth, and digital transition) and the broader framework of the UN SDGs.

These major organisations integrate sustainability principles into their strategies, aligning their work with the objectives of the EU Green Deal and the UN SDGs. Their combined efforts highlight the importance of international collaboration in ensuring that IP systems not only protect innovation but also drive global sustainability and inclusive growth which are fully in line with the IL ecosystem objectives.

Furthermore, the IL ecosystem has been designed to also interact with emerging regulatory frameworks, particularly those in the EU focusing on innovation, data sharing and digital markets. Key legislation includes the future European Innovation Act⁸ (a key milestone of the EU Startup and Scaleup Strategy⁹), the recently applicable Data Act¹⁰, which provides users greater control and access over data generated by connected devices and mandates data sharing in public emergencies, the European Data Governance Act¹¹ (DGA), which

¹¹ European Commission (2022). European Data Governance Act, available at https://digital-strategy.ec.europa.eu/en/policies/data-governance-act





⁷ European Commission (2019). The European Green Deal, available at https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

⁸ European Commission (2025). The European Commission plans to adopt the European Innovation Act in 2026, available at https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/european-innovation-act_en

⁹ European Commission (2025). EU Startup and Scaleup Strategy, available at https://research-and-innovation/jobs-and-economy/eu-startup-and-scaleup-strategy en

¹⁰ European Commission (2025). Data Act Explained, available at https://digital-strategy.ec.europa.eu/en/factpages/data-act-explained



establishes frameworks for data altruism (data shared for the public good) and regulates data intermediaries, the General Data Protection Regulation¹² (GDPR) and other sector-specific regulations within the broader European Digital Strategy, like the European Health Data Space¹³ (EHDS), relevant to how health data can be accessed and licensed for research and societal benefit.

The interaction between the Impact Licensing Ecosystem Model and its surrounding ecosystem is therefore **bidirectional**: while the Impact Licensing Ecosystem Model operationalizes impact-oriented technology transfer mechanisms, it is simultaneously influenced by and operates within the institutional and regulatory frameworks in which it is situated. Recognizing and analysing this interdependence is critical to ensure alignment, legitimacy, and scalability, thereby reinforcing the ecosystem model's potential to deliver systemic and sustainable societal impact.

4 Needs-based Validation of the Impact Licensing Ecosystem Model

In order to experimentally validate the Impact Licensing Ecosystem Model (Chapter 3) with key stakeholders, a systematic needs assessment was undertaken to i) **critically examine** the configuration of the current ILI ecosystem model, ii) **empirically validate** its structural configuration—including the functional roles and organisational responsibilities of the complementary actors and the impact licensing support tools developed —and iii) to **guide its progressive development** in line with the needs identified through the survey.

To capture a **comprehensive range of stakeholder perspectives**, a mixed-methods approach was employed. First, four online focus group workshops were organised with stakeholders representing three thematic domains—Data, Impact Investment, and Health—followed by a validation workshop aimed at refining and verifying the preliminary findings. These workshops yielded in-depth qualitative insights into stakeholder needs, challenges, and expectations. Second, an online survey was subsequently disseminated to a broader cohort of stakeholders to validate and extend these insights. The survey targeted three stakeholder groups identified as critical to the IL ecosystem: **technology holders** (e.g., universities, academic research institutions or private/public sector companies), **intermediaries** (including Tech Transfer Offices (TTOs), patent law firms, licensing intermediaries, and policy institutions), and **technology users** (e.g., SMEs, startups, NGOs, and public health organisations). These complementary methods provided a robust empirical basis for triangulating stakeholder perspectives and advancing the refinement of the IL ecosystem model (A detailed description of survey and workshop methodology, results and limitations of the assessment can be found in the additional White Paper published "Needs assessment for the Impact Licensing concept: Voices from stakeholders for policy and implementation" 14.

In the next sections, the **results from the needs assessment** have been grouped to align with the structural configuration of the IL ecosystem network, whereby each section first describes the needs identified by the stakeholders in the focus groups and surveys (see text boxes), followed by an in-depth description of how these needs are addressed by the actors in the IL Ecosystem Model and its support structures.

¹⁴ White Paper on "Needs assessment for the Impact Licensing concept: Voices from stakeholders for policy and implementation", available at https://impactlicensing.eu/resources





¹² European Commission (2016). Legal Framework of EU Data Protection, available at https://commission.europa.eu/law/law-topic/data-protection/legal-framework-eu-data-protection_en_

¹³ European Commission (2025). European Health Data Space Regulation, available at https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds en



4.1 Needs assessment validation on the functional roles and organisational responsibilities of Clearing Houses

<u>Needs assessment results:</u> Technology owners acknowledged that they frequently lack the entrepreneurial capacity, specialized tools, and administrative resources to navigate impact licensing independently, expressing the **need for facilitation**, emphasizing that Clearing Houses could play a pivotal role by combining legal, technical, and matchmaking support, and **building trusted communities of practice** around licensing services. Intermediaries consistently emphasized and acknowledged the **prioritization of standardisation and active brokerage** as an important role for Clearing Houses.

Furthermore, Intermediary stakeholders emphasized that the role of Clearing Houses must extend beyond brokerage, with expectations that they actively enable adoption by facilitating **matchmaking** and embedding **monitoring frameworks**. Rather than attempting to cover all UN SDGs, clearing houses should **prioritize high-impact technology domains** and provide institutional support.

Also, Technology owners emphasized the need for ensuring integrity, compliance and financial backing to protect them. **Supporting licensing strategies** such as dual licensing approaches emphasize the role of universities capable of prioritizing societal impact. **Collaborations with data intermediaries** should be established to integrate responsible AI and data governance models into IL frameworks.

Finally, technology users identified **capacity building & knowledge transfer**, such as training, tools, and skill development programs essential in supporting the commercialisation and implementation of licensed technologies, as well as the facilitation of partnerships to ensure long-term success through effective knowledge transfer.

Central to the Impact Licensing Ecosystem Model is the establishment of a **Network of Clearing Houses**. The systematic needs assessment provides robust and evidence-based justification for the establishment of this Network of Clearing Houses as an institutional mechanism to facilitate active brokerage and matchmaking, advance and harmonize standardisation processes, strengthen licensing strategies, ensure the integration of data stewardship principles and support capacity building and knowledge transfer. The design of the Network of Clearing Houses reflects a stakeholder-driven approach and aligns with European policy objectives for transparent, efficient, and impact-oriented technology transfer and data governance frameworks.

The proposed **Network architecture for the Clearing Houses aligns with the needs identified**, embedding facilitation and standardisation as cross-cutting requirements in the execution of both the general and domain-specific **roles and responsibilities attributed to Clearing Houses**:

Neutral Intermediary to facilitate active brokerage – The Clearing House operates as an impartial actor, ensuring the balance between commercial objectives and societal impact. This role is vital in mitigating potential conflicts of interest and ensuring that licensing agreements prioritize public welfare alongside economic viability. The Clearing House coordinates with relevant stakeholders—including IP holders, local enterprises, civil society organisations, funders, and regulatory authorities—to promote sustainable and inclusive technology transfer.





Transparency and Accountability – Uphold transparency, accountability, and equitable access as guiding principles in all operational activities. By maintaining independent oversight, the clearing house ensures transparency in the negotiation and enforcement of licensing agreements, thus preventing exploitation and safeguarding against -misuse of the technology. This oversight mechanism also facilitates accountability among all involved parties, particularly in monitoring compliance with agreed-upon terms.

Standardised Licensing Frameworks – In co-creation with the whole network, the Clearing House develops uniform licensing models that align with ethical standards and impact-driven goals. This approach ensures that technology transfer and intellectual property sharing are conducted transparently and consistently, promoting wider access to innovations for social good. The Clearing House shall implement robust systems for monitoring, evaluation, and impact measurement to assess the effectiveness, ethical integrity, and developmental contribution of repurposed technologies.

Alignment with the UN SDGs – The Clearing House ensures that negotiated licensing agreements align with the <u>United Nations Sustainable Development Goals</u> particularly those related to poverty reduction, health, education, clean energy, and innovation. By facilitating technology access in underserved markets, it helps contribute to inclusive, sustainable, and impactful development.

The Clearing House Network is setup to maintain or coordinate ancillary functions such as capacity-building support, and regulatory guidance, as may be deemed necessary to fulfil its purpose and sustain long-term impact. The **prioritization of high-impact technology domains** is assessed through a technology screening process for the identification, ethical screening, and assessment of Key Enabling Technologies developed by companies, universities, and research institutions, within the respective scope and mandate of the entity. Technologies are prioritized that demonstrate scalability, affordability, and applicability to underserved markets.

The Clearing House develops uniform licensing models and **supports licensing strategies** through the Impact License Builder that align with ethical standards and impact-driven goals. This ensures that technology transfer and intellectual property sharing are conducted transparently and consistently, promoting wider access to innovations for social good. The clearing house ensures that negotiated licensing agreements align with the United Nations Sustainable Development Goals particularly those related to poverty reduction, health, education, clean energy, and innovation. By facilitating technology access in underserved markets, it helps contribute to inclusive, sustainable, and impactful development.

Facilitation of and standardisation of licensing is supported by the development of a set of tools and templates that will be made available by the Impact Licensing Institute to Clearing Houses to ensure consistency, transparency, and compliance with established evaluation standards. The Clearing House negotiates and facilitates negotiations between technology owners and potential licensees; drafting, coordinating, and finalizing impact licensing pre-agreements which define the terms for sustainable deployment and ethical commercialisation. They identify, vet, and broker licensing deals with implementing organisations in societal markets and delegate technology transfer responsibilities to an impact venture builder.

Clearing Houses monitor implementation and manage compliance of licensed technologies to ensure adherence to agreed terms; collect and analyse data on technology usage and societal outcomes; and prepare and submit periodic impact reports, summarizing results and alignment with UN SDG targets. Clearing Houses support capacity building and knowledge transfer for technology deployment by coordinating multi-stakeholder engagement and co-design processes with local partners and beneficiaries;





supporting operational deployment, including training, logistics, maintenance planning, and localisation; and monitoring impact and adoption through structured frameworks for evaluation and learning, by following the Monitoring, Evaluation, and Learning (MEL) approach.

Clearing Houses host a **Data Collaborative**, facilitating the sharing of data, ensuring legal and ethical compliance and ensuring that data sharing follows privacy laws, consent rules, and IP rights, offer technical services such as secured data storage, anonymization, encryption, or API access, buildings trust and credibility by acting as a neutral and trusted third party, certifying data quality, provenance, or compliance, and support innovation by reducing friction in accessing and using data.

Clearing Houses also have a specific function in relation to **Data Stewardship** and the **Data Act.** Data stewardship plays a crucial role in maximizing the societal value of data by ensuring it is managed, shared, and re-used responsibly. Through clear principles of quality, ethics, and accountability, data stewardship fosters trust and enables data to be used in ways that benefit the public good. Moreover, it also creates synergies between stakeholders in the ILI ecosystem by facilitating collaboration and access to data through the data collaboratives, unlocking new opportunities for innovation and shared impact. Regulatory compliance for data collaboratives notably includes the provisions of the GDPR, but also relevant legislation such as the 2023 Data Act. As of 12th of September 2025, the Data Act requires IoT manufacturers to make data available to users and authorised third parties. This creates a mandatory regime that may interact with impact licensing approaches.

The delineation of the **operational scope of each Clearing House** will not be determined by geographic boundaries but will instead be guided by the principle of 'smart specialisation'. This strategic approach ensures that Clearing Houses focus on screening, evaluating, and supporting technologies that align with regionally defined innovation priorities and strengths, as identified in local or national innovation strategies and smart specialisation frameworks. By aligning the scope of work with thematic or sectoral expertise embedded in innovation hubs and regional clusters, Clearing Houses are better positioned to leverage existing knowledge ecosystems, institutional capabilities, and market readiness. This approach promotes efficiency, avoids redundancy, and fosters complementary roles within the network. It also encourages the development of high-quality, context-relevant pipelines of technology for impact, aligned with the UN SDGs. As a result, this market segmentation strategy supports a more coherent and differentiated service offering across the network, enabling each Clearing House to become a centre of excellence within its designated field of specialization.

Clearing Houses act as **neutral intermediaries**; i.e., they operate as an impartial actor, ensuring the balance between commercial objectives and societal impact. This role is vital in **mitigating potential conflicts** of interest and ensuring that licensing agreements prioritize public welfare alongside economic viability. By maintaining independent oversight, the clearing house ensures transparency in the negotiation and enforcement of licensing agreements, thus preventing exploitation and safeguarding against -misuse of the technology. This oversight mechanism also facilitates accountability among all involved parties, particularly in monitoring compliance with agreed-upon terms.

4.2 Needs assessment validation on the functional roles and organisational responsibilities of the Impact Venture Builder





<u>Needs assessment results</u>: Technology users indicate that access to patented technologies must be paired with **expertise support** in terms of **technical know-how, expertise, and financial backing** to ensure successful implementation. Grants and **investment partnerships** should be established to help startups and local enterprises integrate new technologies.

Technology owners emphasized in the focus groups the need for **Financially sustainable models**, such as results-based financing, that should be developed to support technology deployment in low-income regions and rendering it essential for long-term participation. Also, the need for market viability and clearly **defining market value** through cost assessments could facilitate the adoption of e.g. universal healthcare

Also, technology users indicate they would benefit from increased empowerment to **replicate and adapt technologies** for their local markets, fostering long-term sustainability and building local market ecosystems.

Clearing Houses or licensees interact with the **Impact Venture Builder (The Impact Licensing Studio)** upon acquisitioning of an impact license for Key Enabling Technologies (KETs). The Impact Licensing Studio (ILS) is a venture studio dedicated to developing asset-driven technology companies that create measurable impact toward the United Nations Sustainable Development Goals (SDGs). ILS builds scalable, investable businesses by integrating high-potential technologies with sustainable financial models. ILS operates in an agile investment model where it initiates venture programmes with the purpose to develop 6-8 venture spin outs within the programmes. Each programme has its own investment capital raise and focus.

The Impact Venture Builder facilitates the technical repurposing or modification, and localisation of existing technologies for specific societal applications; referring to the process of **adapting a technology** to fit the specific needs, conditions, cultures, infrastructure, and regulatory environments of a particular country, region, or community, thereby empowering technology users and fostering long-term sustainability. The strategic adaptation and localization of selected technologies in collaboration with implementation partners, focusses on addressing the needs of low- and middle-income countries and other underserved populations.

The ILS operates with a dual mission: generating substantial social or environmental impact while delivering strong financial returns for its investors. The foundation of each venture is built around KETs licensed from R&D-driven companies and research centres, primarily in Europe and beyond. The venture builder operates with **fund-like structures to provide capital** for its core operations. Investors in each program fund the activities to develop that program's cohort of technologies from licensing through ventures at seed stage. The primary use of investment capital in ILS is to develop marketable products and services, establish go-to-market strategies, and support the creation of strong entrepreneurial leadership for each venture within each programme. By focusing on both impact-licensed technologies and a finance-first approach, ILS creates a framework that ensures both profitability and positive social impact.

The text box below presents an illustrative example of IKIC (I Keep It Cool), a venture initiated under the ILS.





IKIC Passive Cold Chain Technology for first and last mile health and agri-food logistics

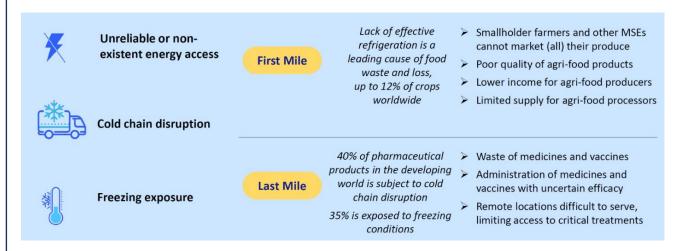
IKIC Impact Ventures (IKIC) is a Belgian company incubated by the Impact License Studio, addressing **cold chain issues in the agri-food and health sectors**, especially in remote areas without reliable electricity. It has licensed and developed a number of advanced technologies for **positive societal impact** to address cold chain and temperature-controlled logistics challenges in LMICs. IKIC's solutions are modular, robust, environmentally friendly and specifically designed to **integrate with existing supply chain**.

Partnership Network and market opportunities in Sub-Sahara Africa

With its current portfolio of market-ready products, IKIC seeks to explore market opportunities in partnership with local actors. Target go-to-market partners include public and private actors operating at national or regional level in primary health care, agriculture, livestock and rural economic development, or more specifically in first and last mile logistics and cold chain solutions in remote areas. Local agri-food, dairy and health equipment suppliers and entrepreneurs could be considered as potential local distribution or franchise partners.

Initial market entry may require export support or local grants from donor agencies, national or regional development banks, investment authorities, impact investors or philanthropic foundations to facilitate real-world demonstration projects, risk mitigation for end users and innovative 'green leasing' financing models. If successful, IKIC plans to scale up with local assembly and production, creating local employment and capacity building, reducing costs and enhancing ownership.

Challenges



The IKIC technology is based on patented advanced eutectic plate technology, also known as **thermostatic batteries (TSB)**. These are stainless steel encased containers filled with a phase-change refrigerant material designed to optimise conductivity and thermal stability. The TSB can be modularised to maintain different long-term cold chain durations, ranging from 48 hours to 14 days, complemented by algorithm-based IoT tools for cold chain assurance prediction and monitoring. The TSBs are recharged in solar-powered freezers of various sizes, ranging from chest freezers to container reefers.





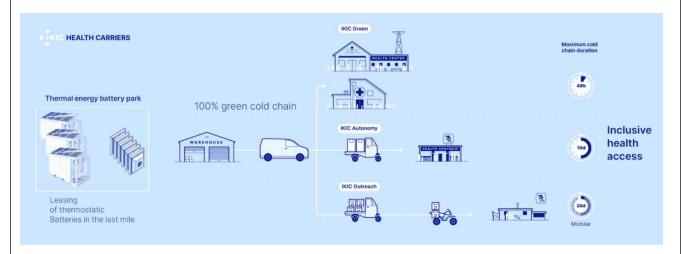
Agri-Food Solutions:

- Milk Link: Cools fresh raw milk from 37°C to below 4°C, providing 24-hour cold storage and transport using modular thermostatic batteries and insulating covers.
- FreshCarrier: Keeps fruits, vegetables, and herbs cool for up to 48 hours during transport from farm to distribution centres.

These solutions can increase smallholder farmers' incomes by up to 50% by improving crop quality and market access, even in remote areas without reliable electricity. Farmer associations, cooperatives, and agrifood processors benefit from a more reliable supply of high-quality produce. Consumers also enjoy better access to nutritious food with lower health risks.

Solutions in Health Logistics

 Green, Outreach, and Autonomy Health Carriers: Ensure vaccines, medicines, and other temperaturesensitive products reach their destinations intact through integrated monitoring of cold chain duration and other vital statistics. These carriers, monitored by IoT tools, support cold chains from 48 hours to 21 days, reducing waste from disposable ice packs and damaged goods.



Cooling-as-a-Service

IKIC cold chain solutions can be arranged in a **hub-and-spoke model** with a **central solar charging hub** and various cold chain services to serve remote areas. These hubs, managed by village-level entrepreneurs and SMEs, provide cold chain services for both public and private sectors in health, agriculture, and food processing.

For more information: IKIC.cool







4.3 Needs assessment validation on the importance of a Global Partnership Network

<u>Needs assessment results</u>: Bridging the gaps in Impact Licensing through raising awareness of IL in accelerators, business schools, and social enterprise networks, as well as **fostering entrepreneurial leadership** to drive adoption beyond traditional licensing frameworks.

Demand-side requirements should be pro-actively assessed, particularly for SMEs and under-resourced organisations, and technology needs assessments for entities that may not fully understand their own technological gaps should be facilitated.

Facilitating **stronger partnerships** with local businesses, governments, and institutions can help overcome operational and legal challenges and ensure long-term success.

Capacity building & knowledge transfer in terms of training, tools, and skill development programs should be made available to support the commercialisation and implementation of licensed technologies, as well as hands-on enablement such as pilot projects, technical assistance, and early/blended finance to prove feasibility and de-risk adoption in local contexts.

The Global Partnership Network established by the Impact Venture Builder and the Clearing Houses constitutes a multi-stakeholder collaboration framework in which universities, research institutions, local governments, ministries, non-governmental organisations, and private enterprises interact as complementary actors. Within this network, the venture builder orchestrates technology transfer processes, including the contextual adaptation and repurposing of technologies to address locally identified needs and conditions. Through co-creation with local stakeholders, the venture builder mobilizes financial resources, enhances legitimacy, and ensures alignment with regulatory and policy environments. Moreover, the network collectively contributes to the development of a context-sensitive go-to-market strategy, thereby facilitating sustainable commercialisation pathways and long-term societal impact.

Capacity building within the partnership network is operationalized as a continuous and multi-dimensional process aimed at strengthening the absorptive, adaptive, and innovative capacities of local stakeholders. This involves targeted training programs, knowledge exchange mechanisms, and co-design workshops that enable universities, research institutions, and local organisations to internalize transferred technologies and repurpose them effectively for local use cases. Local governments and ministries are engaged through policy dialogues and institutional learning platforms to reinforce governance structures and regulatory readiness. In parallel, entrepreneurs, NGOs, and private sector actors receive tailored support to enhance business development skills and market navigation capabilities. By embedding these activities into the venture builder framework, capacity building ensures not only the sustainability of technology adoption but also the creation of resilient local ecosystems capable of driving long-term societal and economic impact.

The text box below provides an **example of the United Nations Technology Bank and the Impact Licensing Initiative's partnership network and capacity building activities** operating at the intersection of supply-and demand-driven needs.







The United Nations Technology Bank for the Least Developed Countries (UN Technology Bank) is mandated to **strengthen the science**, technology and innovation (STI) capacities of the Least Developed Countries (LDCs). Its core objectives include **supporting the development** and implementation of national and regional STI strategies; **fostering partnerships** among public entities, the private sector and other stakeholders; and **facilitating access to and effective use appropriate technologies while respecting intellectual property rights.** By enhancing national and regional capacities, the UN **Technology Bank** aims to enable transformative change and sustainable development in LDCs.

As part of its work, the UN Technology Bank conducts **Technology Needs Assessments (TNAs)** to identify core development challenges and recommend practical technology-based solutions. In LDCs, these assessments are critical for fast-tracking urgent development using science, technology and innovation. In the long term, they assist countries to develop the technological and innovative capabilities to achieve growth, promote structural transformation and reach the Sustainable Development Goals (SDGs). To further these efforts, the **Impact Licensing Initiative (ILI)** has established a strategic collaboration agreement with the UN Technology Bank aiming to operationalize equitable access and strengthen the absorptive capacity of LDCs, aligning with UN Technology Bank's core mandate.

Against this backdrop, **UN Technology Bank** together with the **ILI, European and Tanzanian research institutions**, **Tanzanian government agencies** and **international funding agencies** developed the **first targeted follow-up to the TNA recommendations**, designed to test-drive the recommended preservation technologies in real-world Tanzanian conditions. It will apply a phased, evidence-based approach to evaluate their feasibility and performance, while building national capacity for future scale-up. Specifically, the pilot responds to the challenges identified in United Republic of Tanzania (URT)'s fisheries policy frameworks—including the Fisheries Acts (2003 Mainland, 2020 Zanzibar), National Blue Economy Policy (2024), and both Mainland and Zanzibar Fisheries Master Plans—which all call for expanded access to sustainable, innovative technology and strengthened public-private partnerships.

The project will also serve as a testbed for **private sector engagement**. By generating actionable data on cost, usability, and shelf-life improvement, it aims to lower barriers for future investment in preservation technologies, supporting the creation of market-driven solutions and scalable models. Its outcomes will feed directly into national dialogue on cold chain modernization, helping Tanzanian authorities and private actors co-design the next generation of infrastructure upgrades.

The project aims to introduce and adapt three key technologies—ozonated water, slush ice, and thermostatic batteries—to improve fish preservation and cold chain reliability in these low resourced settings with focus on small scale fishing. By focusing on different fish types and vessel categories, and by emphasizing the active role of women as boat owners and processors, the work addresses both technical and social dimensions of sustainable fisheries development. The approach combines port-based interventions, vessel-level innovations, and solutions for transport and processing, with the aim of creating increased quality preservation along the entire value chain.

Beyond **technology development**, the project will **build capacity** across the sector, with a strong emphasis on **women's participation** and **leadership**. **Economic analysis** will capture both costs and benefits along the value chain, while scientific analysis, monitoring and evaluation will ensure measurable impact, replicability, and opportunities for scaling. Together, these efforts will deliver resilient, inclusive, and energy-efficient cold chain solutions that **improve livelihoods**, enhance **food safety**, and support **sustainable growth** of especially the **small-scale fisheries**. The overall ambition – if the pilot test is successful – is to showcase to the private sector how such models can be leveraged through an **impact licensing approach**, promoting investment and adoption of resilient, inclusive, and energy-efficient cold chain solutions in URT. The approach is deliberately **scalable to other LDCs and neighboring countries** facing similar cold chain, value addition, and climate resilience challenges.





4.4 Needs assessment validation on the importance of Decision Support Tools and Standardisation in Impact Licensing Processes

<u>Needs assessment results</u>: Technology owners cited the absence of **standardized templates** as a major constraint. Clearing houses should provide **decision-support tools**.

This statement was reinforced by intermediary stakeholders indicating that **streamlining and simplifying licensing and technology transfer workflows**, and reducing the administrative burden, as well as standardized templates and **predefined licensing processes** could help lower legal costs, accelerate adoption and make IL more accessible to a broader range of users. A structured, step-by-step approach should be implemented to reduce licensing timelines. Intermediary stakeholders also emphasized that the role of Clearing Houses must extend beyond brokerage, with expectations that they actively enable adoption by providing ready-to-use templates.

Technology users endorsed the **lowering of barriers for adoption** and simplifying licensing processes by using standardized templates and predefined steps to make them accessible for technology users, particularly in the case of startups and small businesses.

Last, respondents indicated that strategies must be in place **to address demand surges** and ensure fair distribution of technologies to technology users across different regions and sectors.

At the system level, the Impact Licensing Institute (ILI) will be setup to function as the central reference authority for the global impact licensing ecosystem. It assumes responsibility for the development and enforcement of internationally recognized standards, the design and administration of certification schemes, and the exercise of oversight functions across impact licensing agreements and the affiliated network of accredited Clearing Houses. These mechanisms ensure procedural consistency, institutional transparency, and the generation of verifiable and measurable societal impact. A core function of the Institute is to advance standardisation as a prerequisite for interoperability, comparability, and the scalability of licensing practices across sectors and geographies. In this capacity, the Institute not only harmonizes methodologies but also integrates evidence-based decision support tools that guide stakeholders in the negotiation, implementation, and evaluation of impact licensing agreements. The Institute's overarching mission is to democratize access to technological innovations that directly respond to unmet societal needs while advancing progress towards the United Nations Sustainable Development Goals (SDGs). In addition, the Institute operates as the custodian of the ecosystem's governance architecture, methodological frameworks, and digital infrastructures, thereby safeguarding accountability, transparency, and long-term sustainability. Through this system-level role, the Institute underpins the legitimacy, coherence, and effectiveness of the global impact licensing model.

In support of the ecosystem network of clearing houses and the impact licensing acquisition process, a suite of purpose-designed **decision support tools** have been developed specifically to support the continued operationalization of impact licensing, lower adoption barriers, streamline licensing processes and provide ready-to-use templates: 1) a technology screening instrument, 2) an impact license quality label, 3) the establishment of an IP pool for emergency and disaster relief and 4) an Impact License Builder.

First, the **technology screening instrument** guides users in a four-step process to explore the societal value creation potential of a technology or product. It provides a structured approach to align technological innovations with societal needs, ensuring effective deployment and creating societal value, resulting in two





key documents able to streamline the drafting of Impact License Agreements and the technology repurposing process.

Second, the **Impact License Quality Label** provides a certification and the assurance that the impact license is ethically sound, legally secure, and socially impactful. When using the Impact License Builder, an automatic scoring and report is generated, informing the user of the potential of the Impact License for acquiring the quality label.

Third, the needs assessment also identified that strategies must be in place to address demand surges. An **IP** pool for emergency and disaster relief is being set-up to enable innovation and critical technology access for humanitarian aid and for recovery ex-post a crisis on a voluntary and consensual basis. The IP Pool enables non-exclusive and pre-agreed access to innovative technologies that support disaster preparedness, response, and recovery on basis of the legal humanitarian aid principles. It enables technologies to be effectively matched with regional humanitarian needs. To avoid non-appropriate use of the technologies, humanitarian core principles¹⁵ (a. Humanity, b. Neutrality, c. Impartiality, and d. independence) are incorporated as enforceable clauses in the licensing agreement. It offers incentives for voluntary private sector participation, such as certification, increased market access, opportunities for frugal innovation and access to impact investment. Additionally, the pool fosters innovation partnerships and supports local adaptation of technologies for disaster relief. The initiative's goal is to create a more resilient global disaster response system, ensuring that critical technologies are always available to mitigate the impact of future humanitarian crises.

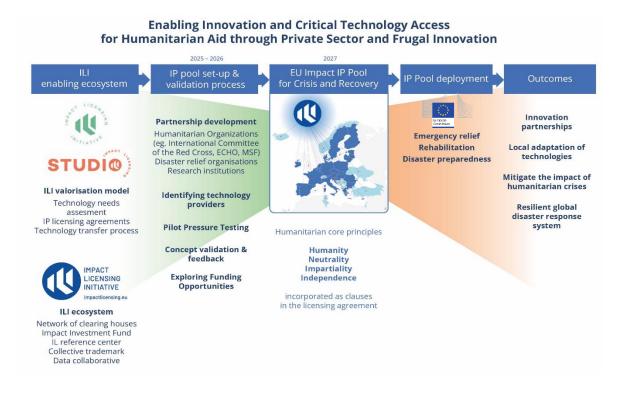


Figure 3: IP pool for emergency and disaster relief

¹⁵ Humanitarian principles are endorsed by 2 UN General Assembly resolutions (<u>46/182</u> and <u>58/114</u>). At EU level, the humanitarian principles are enshrined in the <u>European Consensus on Humanitarian Aid</u>, signed in December 2007 by the Council of the EU, the European Parliament and the European Commission.







For the fourth instrument, the Impact License Builder, a set of specific needs were identified regarding risk management, accessibility, patent enforcement and IP leakage of impact licenses. They are addressed indepth in the separate chapter below.

4.5 Needs assessment validation on Risk Management, Accessibility and Patent Enforcement in Impact Licensing Agreements (ILAs)

<u>Needs assessment results</u>: Technology users emphasize the need for **reducing the complexity of IP agreements** and for enabling easier and more **cost-effective adoption** and stressed that that valuable know-how is often not patented, identifying the need to **account for trade secrets and tacit knowledge** in ILAs, not only patents.

A clear need was identified for technology holders to account for IP & risk management, whereby structured ILAs should address secondary and tertiary additional uses to extend market reach and prevent unauthorized applications. It was suggested that ILAs should be designed to balance patent enforcement with accessibility across diverse markets. Also, sector-specific IP frameworks and enforcement strategies could mitigate risks associated with unlicensed technology usage. Technology owners raised concerns over IP leakage—especially in low- and middle-income countries (LMICs). Intermediaries backed this up by expressing that universities and research institutions often hesitate to license technologies to startups, charities, or organisations in the Global South due to risk concerns.

At the same time, concerns over IP leakage from technology owners were complemented with the need to **ensure fair & equitable access**, in which licensing frameworks should prevent technology users from exclusion based on financial or geographic limitations, ensuring equitable access for all.

In the survey, intermediaries further emphasized that Clearing houses require strong financial backing from aligned financial institutions to **underwrite risks and indemnify** technology holders and, depending on the risk tolerance and business model, they may act as either an intermediary or a direct licensee.

Technology owners also advocated for **flexible licensing models** that allow for iterative "pivoting" of technology applications, allowing for the potential to reorient a product or service to serve a different market, application, or user need than originally intended.

The **Impact License Builder** addresses the need identified here above: it is a structured digital tool designed to support clearing houses in designing Impact Licensing Agreements that enable responsible technology diffusion, promote measurable societal outcomes **and reduce complexity** of drafting IP agreements.

The Impact License Builder is a software employing a hierarchical decision structure supporting customization and allowing users to select specific legal clauses, incorporate sustainability commitments or ethical standards, choose the level of enforceability and create legally secure pre-agreements. The level of enforceability can be selected for all criteria relating to the six principles of the I.M.P.A.C.T framework (Intentionality, Measurability, Participation, Additionality, Comprehensiveness and Total Return on Assets), based on the preferences of Licensor and licensees. It also automatically assesses the quality of the license as input for the Impact License Quality Label.

Inherently built into the Impact License Builder is the inclusion of tangible and intangible assets. Early identification of both tangible and intangible IP assets is supported by through the technology screening





instrument. Tangible assets include i) Patents & Patent Applications including all granted patents and pending applications and Identify geographical protection coverage, ii) Trademarks & Branding Elements identify registered and unregistered trademarks, logos, and brand assets, iii) Copyrights & Software such as proprietary algorithms, databases, and software tools, iv) Technical Designs & Prototypes e.g. blueprints, technical drawings, and product models and v) Registered Industrial Designs. Of equal importance is the identification of intangible assets such as i) Trade Secrets & Confidential Know-how, ii) Technical Data & Experimentation Records e.g. unpublished research findings, test data, and proprietary methodologies, iii) Process Innovation & Manufacturing Techniques, iv) Partnerships & Collaborative Agreements such as joint ventures, co-development agreements, supply contracts and licensing arrangements and v) Employee & Institutional Knowledge.

The agreement includes preferential terms that grants certain **exclusive access rights to the market**, ensuring prioritized opportunities for the licensee, while providing a graded clause structure to choose the level of enforceability. The enforceable clause includes that "the license can be concluded for the maximum term of protection of the intellectual property rights and with a minimum of twenty (20) years as of the Effective Date of the Agreement", moving down to ladder of enforceability to "This license remains exclusive as long as Licensee has demonstrated good faith efforts to work the licensed technology according to impact licensing principles in the licensed Territory" and "This license will become non-exclusive if Licensee does not reach one or more of the agreed Milestones and can be terminated if Licensee does not respect one or more of the impact licensing principles set out in this Agreement".

To ensure **fair, inclusive and equitable access and adoption** of the technology, the ILA includes a suite of measures designed to accelerate and facilitate access to the target societal market. First, the incorporation of a price reduction applied on the eligibility criteria will increase access to the licensed technology in the social market. This can be incentivized through reduced royalty payments or no payments to the licensor, which leads to greater engagement from the licensee. The implementation of non-discriminatory royalties between the various local manufacturers and licensees, provides an equal price setting and reduces animosity between the stakeholders. Second, the licensee develops an access plan containing a strategy regarding use, distributions and implementations to increase access. The licensor may involve a neutral third party with the necessary expertise to evaluate or assist in drafting the access plan. Third, the license stipulates the active fostering of local adoption, local production and local innovation. Non-compliance, such as blocking local adaptations, is a breach and may lead to partial revocation or local sublicensing. Fourth, the license sets out affordability thresholds. Exceeding price limits without justification may trigger financial penalties or market access reviews. The license obliges the licensee to meet cultural acceptability standards. Fifth, the agreement includes binding provisions for handling new intellectual property created through implementation, with shared access or notification clauses.

The need to provide for **Indemnification of technology holders** can be avoided by the inclusion of specific clauses in the licensing agreement. For example, specifying Good Manufacturing Practices (GMP) as a set of quality assurance guidelines that ensure products are consistently produced and controlled according to quality standards, or products are used properly, thereby guaranteeing their safety, quality and efficacy. Additionally, a clause could be included that specifies the avoidance of any negative reputation effect by e.g. specifying the conditions for when the name of the technology holder can be used.

Lastly, the need for **affordable costs** to obtain and maintain IP protection in some LMIC's is important. The filing and renewal fees are proportionally much higher than in Europe and are increasing regularly. For instance, the fees charged by ARIPO for application filings, excess claims, substantive examinations and annual





maintenance have been substantially increased in March 2025, some of which even with even more than 50%.

5 Progressive development of the Impact Licensing Ecosystem model: next steps

The development of the Impact Licensing (IL) ecosystem model has reached a stage where conceptual clarity and initial validation have been achieved. Stakeholders broadly support the model but emphasize that **scaling requires institutional adoption**: trusted organisations must adopt and embed IL in ways that combine clear frameworks with proportionate flexibility. As respondents noted:

"Legal, regulatory and financial support is essential... Ideally, these complexities are reduced by common frameworks." and "...this may be over-regulated to the point where opportunities for impact and value are reduced."

Despite the progress made in conceptualising and operationalising impact licensing, a range of **systemic hurdles continues to persist**. These barriers are embedded across legal, institutional, and market structures, and they constrain the scalability, replicability, and sustainability of impact-oriented licensing frameworks. Addressing these challenges is essential to enable impact licensing to realise its full potential as a mechanism for aligning technology transfer with societal needs and the Sustainable Development Goals.

Challenges encountered are i) the limited absorptive capacity in recipient countries—shortages of skills, infrastructure, and institutional support—often prevents effective uptake and adaptation of technologies, ii) power asymmetries between technology holders (typically in high-income countries) and users (often in LMICs) shape negotiations, with licensing terms reflecting unequal bargaining positions rather than developmental needs, iii) market and commercial risks discouraging firms from offering access on affordable or concessional terms when demand or profitability is uncertain, iv) policy and regulatory incoherence across trade, IP, and development agendas creates fragmented governance environments that delay or dilute implementation and iv) resistance from technology holders—whether due to IP concerns, competitive advantage, or reputational risks—limits participation in voluntary or socially oriented.

The central challenge to the mainstreaming of impact licensing lies in the institutional and legal environments in which these models operate. In the European Union, competition law poses a significant obstacle. The lack of legal tolerance for differentiated licensing practices aimed at equitable access creates uncertainty for organisations wishing to deploy impact licensing at scale. Without a more flexible interpretation that explicitly recognizes and accommodates these approaches, actors remain cautious, wary of regulatory pushback or accusations of market distortion. In low- and middle-income countries (LMICs), the barriers take a different form but are equally constraining. Fragile institutions and underdeveloped intellectual property (IP) frameworks limit the enforceability and credibility of licensing arrangements. Weak regulatory capacity, inconsistent application of IP laws, and limited institutional support undermine trust and sustainability, forcing impact licensing to rely instead on soft IP mechanisms.

The **progressive strengthening of the IL Ecosystem Model** therefore means strengthening the key components of the IL Innovation Ecosystem itself, in line with the evidence from the needs assessment presented in Chapter 4.

Clearing houses as operational intermediaries: Stakeholders agreed that clearing houses should do
more than brokering. They should provide ready-to-use templates, standardised yet proportionate







workflows, liability and insurance mechanisms, and active facilitation. Next steps would include piloting role variants (pure intermediary, agent-of-record) and testing how they perform across sectors such as health or climate.

- Impact venture builder and partnership networks: Need assessment results indicate support for
 confirmed that technology adaptation, localised deployment, and entrepreneurial leadership are
 indispensable. The venture builder model and its networks should therefore be expanded to support
 contextual adaptation, provide technical and business development support, and connect
 technologies with investable ventures.
- Data collaboratives and stewardship: Respondents stressed that legal and regulatory complexity
 must be reduced through common frameworks, but without over-engineering. The focus should be
 on responsible stewardship (GDPR, Data Act), lightweight governance, and trusted mechanisms for
 data sharing that support IL agreements.
- **Finance and support tools:** Financial sustainability was raised across all groups. To that end, blended finance facilities should be integrated, with outcome-linked clauses, and risk-sharing mechanisms. Support tools such as the Impact License Builder, quality labels, and an IP pool for emergencies should be iteratively tested in practice to lower transaction costs and create confidence for licensors and licensees alike.

Priority pilot domains: Health and humanitarian organisations, such as ministries or NGOs, emerged as natural testing grounds for the model, given their mandates to widen access to essential technologies. Embedding IL into their procurement and deployment practices would demonstrate legitimacy and real-world value.

These pathways are not yet institutionalised; they remain **work in progress**. To move forward, they will require iterative testing with sectoral pilots and close dialogue with both technology holders and societal users. At the same time, Impact Licensing Initiative (ILI) has provided **policy recommendations for the next EU Framework Programme (FP10)** in the same direction. Instruments such as a European network of clearing houses, a humanitarian IP pool, and a global taskforce on societal valorisation mirror the adoption needs identified through the evidence presented here.

The progressive development of the IL ecosystem will therefore rest on a dual track: **bottom-up adoption** by institutions willing to integrate IL into their core practices, and **top-down policy support** (as set out in our FP10 recommendations) that embeds IL in European research and innovation frameworks. The alignment of these two tracks will determine whether the model can move from promising pilot to a recognised, scalable pathway for societal impact.

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