STARS EU

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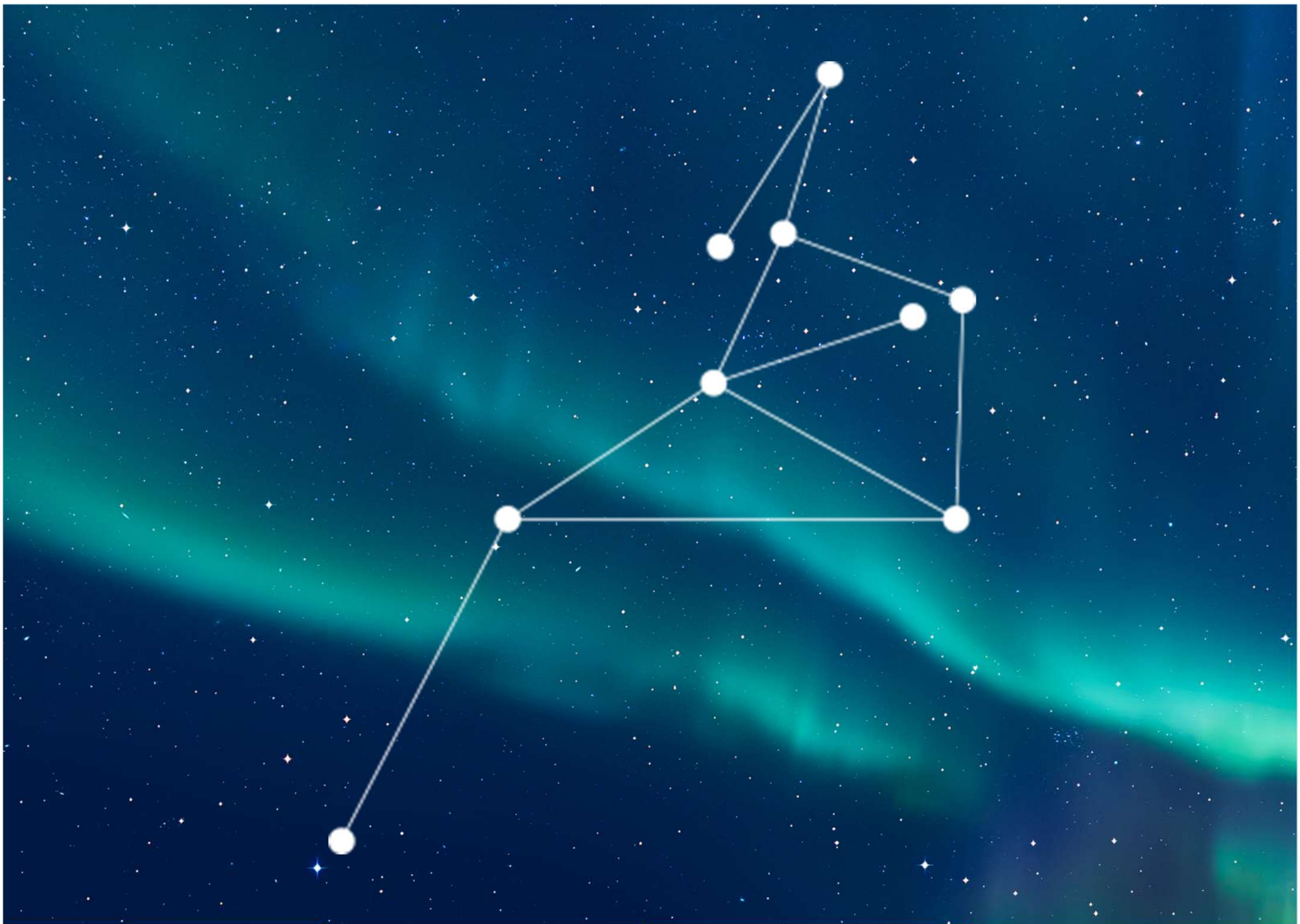
STARS EU Technology Transfer Guide



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Preface

In essence, this **STARS EU Technology Transfer Guide**, by explicitly integrating the challenges identified in Draghi's report *"The Future of European Competitiveness"* with the solutions offered by the Open Innovation paradigm, provides a strategic and practical resource. It aims to empower our universities and their partners to navigate the complexities of technology transfer, accelerate commercialization, strengthen collaborative networks, manage intellectual property effectively (see STARS EU IPR Guide), and ultimately contribute to a more innovative, competitive, and prosperous Europe (Figure P.1). This is a crucial step in transforming Europe's R&D potential into tangible economic growth and societal welfare.

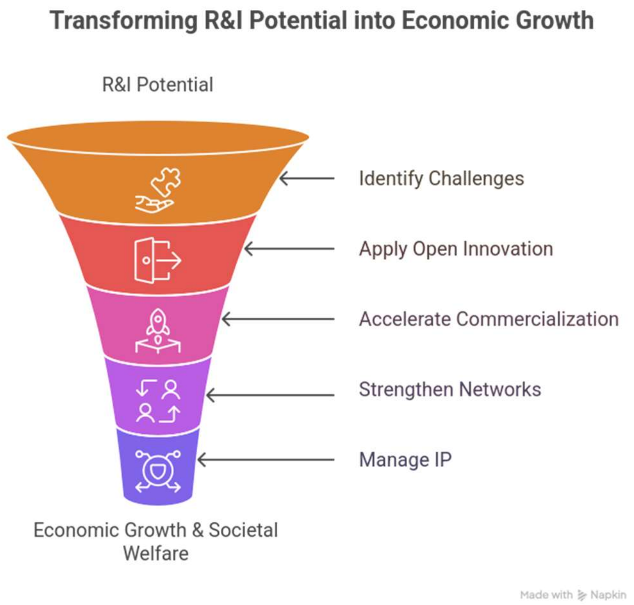

Figure P.1: Transforming R&D into Economic Growth

This guide provides a comprehensive framework for the **commercialization of Research and Development (R&D) results,** particularly focusing on the journey from an innovative idea to its market application. It outlines essential steps and considerations for researchers, innovators, and commercializing entities, such as universities and research institutes.

The document emphasizes the critical need to assess the **market potential of R&D outcomes** from the earliest stages of a project. This involves detailed analysis of the existing state-of-the-art, competitive landscapes, and customer needs to ensure that an innovation genuinely addresses an unmet market demand. Without a concrete market application, an idea remains just that—an idea, not an innovation.

The guide details various **paths for commercialization**, including the assignment of intellectual property rights, licensing agreements, and the creation of spin-off or spin-out companies. It stresses the importance of effective **Intellectual Property (IP) management** and contractual agreements to protect rights and define relationships between parties.

A significant focus is placed on **Science-to-Business (S2B) partnerships**, highlighting that successful implementation of R&D results often requires the active participation of an industrial partner, as research teams typically lack the capacity for production, certification, marketing, and distribution. The guide covers how to identify potential partners, types of collaborations (like strategic alliances and joint ventures), and key considerations for successful partnerships.

Furthermore, the document provides insights into the **management of research and implementation projects**, introducing the concept of Technology Readiness Levels (TRLs) to assess a technology's maturity from basic research to operational implementation. It also goes into crucial aspects like risk management throughout the project lifecycle and the importance of continuous engagement with the business community before, during, and after a project. The ultimate aim is to equip stakeholders with the knowledge and tools necessary to **effectively translate scientific and technological advancements into valuable market-ready solutions (Figure P.2)**

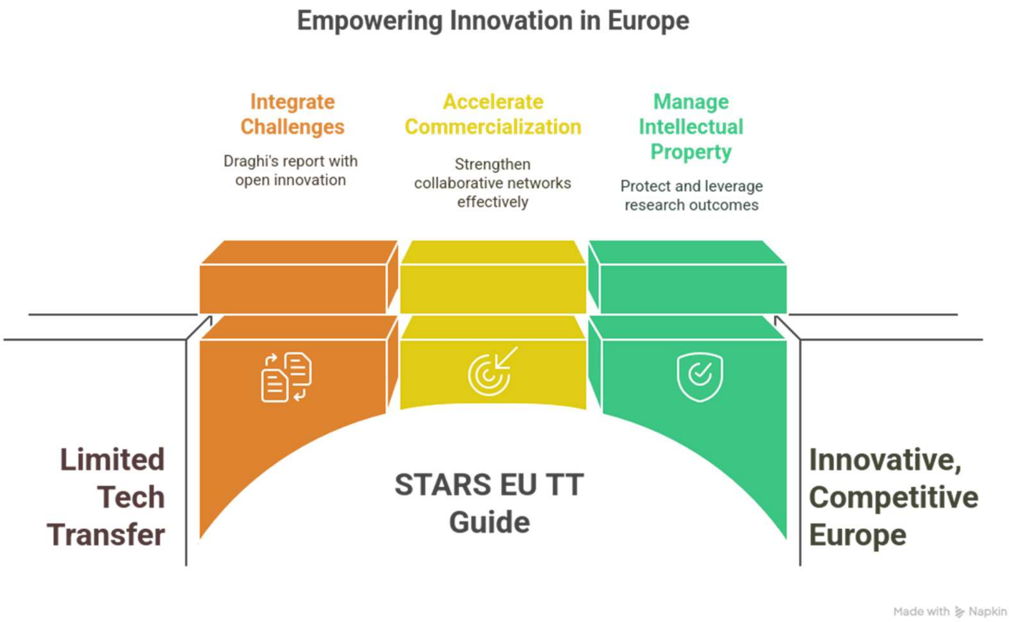

Figure P.2: Empowering Innovation in Europe

This guide aims to provide a solid basis for joint technology transfer to market between STARS EU partners. In this way, the aim is to improve the local situation of each partner, in terms of potential transfer limited by regional isolation, leading to a scenario of improvement of the technological offer based on synergies and joint research (projects, joint PhD,...). This will allow STARS EU partners to collaborate in improving Europe's competitiveness and innovation.

Executive summary

The STARS EU TT Guide is designed to **foster European competitiveness through Open Innovation**, specifically by empowering universities and their partners to navigate technology transfer, accelerate commercialization, and strengthen collaborative networks. It addresses critical challenges highlighted in Draghi's report *"The Future of European Competitiveness"*, aiming to transform Europe's R&D potential into tangible economic growth and societal welfare.

Chapter 0: Technology Transfer within STARS EU: Fostering European Competitiveness through Open Innovation. This introductory chapter establishes the strategic imperative for enhancing Europe's global competitiveness, deeply informed by **Draghi's report** and firmly rooted in the principles of **Open Innovation**. Draghi's analysis reveals Europe's persistent **innovation and commercialization gaps**, characterized by a static industrial structure, less R&I investment compared to global competitors, and a failure to commercially exploit much of the knowledge generated by universities. Key barriers include fragmented public R&I support, weak innovation-to-commercialization pipelines, an incomplete Single Market, onerous regulatory burdens, and insufficient investment in state-of-the-art infrastructure. The report proposes reforms to R&I programs, strengthening academic excellence and commercialization pathways, improving financing, and boosting digital infrastructure.

The **Open Innovation (OI) model**, introduced by Henry Chesbrough, is presented as a transformative theoretical framework, challenging the traditional "Closed Innovation" paradigm by advocating for the **leveraging of both internal and external ideas and pathways to market**. OI processes are categorized into three archetypes: **Outside-in** (integrating external knowledge), **Inside-out** (externalizing internal IP), and **Coupled** (joint innovation and commercialization efforts with partners). In the university context (University Open Innovation – UOI), OI is strategic for generating interdisciplinary solutions and is facilitated by digital transformation. Its success hinges on factors like fostering an innovative culture, effective knowledge management, robust infrastructure, strategic alliances, protection and social diffusion of intellectual property (IP), and the innovation capabilities of the academic community. Different **collaborative flows** between universities and their ecosystems (Inside, Outside, Mixed, Hybrid) define the level of social participation and knowledge exchange. The STARS EU TT Guide serves as a practical implementation of Draghi's vision, operationalizing OI principles by focusing on **bridging the commercialization gap** through various strategies, **addressing fragmentation through collaborative networks** (especially Science-to-Business partnerships), **leveraging universities as entrepreneurial actors**, and ensuring **strategic management of Intellectual Property (IP)**. A key dimension is **market-oriented R&D** and the use of **Technology Readiness Levels (TRLs)** to align research with market demands.

Chapter 1: Market Potential of R&D. This chapter underscores the **critical need to assess the market potential of R&D outcomes from the earliest stages of a project**, asserting that "Without a concrete market application, an idea remains merely an idea, not an innovation". It provides foundational analytical tools for researchers and commercializing entities to proactively orient R&D towards market and societal needs.

Key aspects include:

- **State-of-the-Art (SOTA) Analysis**: Essential for R&D project planning, SOTA research involves a detailed analysis of existing solutions from patent literature, scientific publications, and practical applications. Its objectives are to identify existing solutions, determine research direction, protect inventors from repeating known solutions, and identify the latest trends. In commercialization, it helps to plan new product development and minimize litigation risks from existing exclusive rights.

- **Innovativeness of Project Results**: Defined as "preparing and initiating the production of new or improved materials, products, equipment, services, processes or methods intended for market use or practical application." Innovation is a key factor for business development and a strategic objective for the European Union. The chapter distinguishes between **radical innovations** (redefining markets) and **incremental innovations** (improvements to existing products). It categorizes innovation into **Product, Process, organizational, Marketing, and Social innovation**. The uniqueness and novelty of project results, aligning with market demand, are crucial for successful commercialization.

- **Competitive Analysis**: An essential step to evaluate market potential, as a new product must significantly differ from existing ones to succeed. The analysis considers various competitive factors, including **price, function (substitutes), geographical distribution, organizational structure (e.g., networks), warranty and after-sales service, and environmental impact/sustainability**.

- **Customer Market Analysis and Defining the Target Segment**: It is crucial to identify the target audience early in the concept development phase. This involves understanding customer needs, preferences, and segmenting them based on various purchase criteria (e.g., price, quality, availability). Defining and quantifying the target segment is vital for forecasting sales and pricing.

- **Market Restrictions – Admission to Trading**: This section outlines the formal requirements for market entry, primarily **certification** (evaluating product characteristics against technical and legal requirements) and the **declaration of conformity** (mandatory legal assessment of essential requirements). It highlights stringent restrictions in specific industries like medical devices (MDR Directive), veterinary medical products (Regulation (EU) 2019/6), cosmetics (GMP), and chemicals (REACH directive).

Chapter 2: Commercialization of the Research Results. This pivotal chapter provides a comprehensive framework for **translating innovative Research and Development (R&D) outcomes into tangible economic value**, emphasizing the need for a concrete market application for an idea to truly become an innovation. It highlights the critical importance of effective Intellectual Property (IP) management and well-defined contractual agreements to protect rights and establish clear relationships.

The chapter systematically breaks down commercialization into two main forms:

- **Direct Commercialization**: This involves the **licensing or sale of intellectual property rights (IPRs) or related know-how to third parties**. A key method within direct commercialization is the **assignment of rights**, where a rights holder (e.g., a university) transfers all its rights to the R&D results to a buyer, making the buyer the sole owner. Advantages for the assignor include immediate financial benefits and relief from IP management, while the disadvantage is losing all future commercial rights. For the assignee, advantages include full control and no royalties, but they bear the burden of IP management and a substantial upfront payment. Another crucial direct commercialization pathway is a **license agreement**, a contract allowing other entities (licensees) to use the R&D results. Licenses vary in scope and exclusivity, including **full, restricted, exclusive, non-exclusive, implied, and sub-licenses**. Remuneration typically involves **royalties**, which can be an initial fee, periodic payments, percentage-based, per-unit, or minimum fees. The **Technology Readiness Level (TRL)** significantly influences royalty setting, with higher TRLs commanding higher values. The chapter details the obligations of both Licensor and licensee, and conditions for license termination.

- **Indirect Commercialization**: This primarily involves the **establishment of new ventures, such as spin-off and spin-out companies,** to exploit R&D results or related know-how, often through Special Purpose Vehicles (SPVs). **Spin-offs** are companies created by academic staff/students, dependent on the parent institution and using its IP typically via licensing or in-kind contribution. **Spin-outs** are completely independent entities formed to commercialize specific IP. While offering advantages like focused development, attracting investors, and flexibility, running a spin-off demands significant business skills and commitment from researchers beyond their scientific expertise. **Creator's remuneration** from royalties is discussed, highlighting that national laws often dictate the share inventors receive after the university recoups its IP protection and commercialization costs.

The STARS EU alliance, through its design, aims to significantly improve R&D commercialization by building a **broader, more diverse innovation ecosystem**, enhancing **industry-academia linkages**, streamlining **IP management**, and fostering a **culture of entrepreneurship and innovation**.

Chapter 3: Science-to-Business (S2B) Partnership. This chapter emphasizes that **successful implementation of R&D results from a university fundamentally requires collaboration with an industrial partner**, as universities typically lack the extensive resources needed for scaling, production, certification, marketing, and distribution. This collaborative necessity aligns with the "Coupled Process" of the Open Innovation model.

Key elements for fostering these vital partnerships include:

- **SWOT Analysis**: A universal tool for assessing a project's market potential and viability, helping to identify **Strengths, Weaknesses, Opportunities, and Threats** to inform strategic planning for commercialization.
- **Commercialization Strategies with Business Partners**: The guide stresses the importance of introducing market factors to research projects from their inception, ensuring that research topics originate from identified market needs. Identifying potential partners involves targeting companies with necessary financial resources, infrastructure, and industry knowledge. The choice between partnering with small businesses (good for local markets, simple products) or large enterprises (suitable for large-volume production, highly innovative solutions) depends on the project's nature. Common **S2B cooperation models** include **Strategic Alliances, Joint Ventures, and Licensing**. The guide outlines key considerations for successful partnerships: **clear objectives, mutual benefit, trust, transparency, robust legal agreements, resource commitment, and effective risk management**, along with the need for regular evaluation.
- The **University Broker's Role in S2B Interaction**: This specialization acts as a crucial intermediary between scientists and industry. Brokers combine diverse knowledge (research, market, technical, economic, legal, sociological) to "translate" scientific language into market terms, consult on potential applications, and facilitate partner identification.
- **Valuation of Intellectual Property (IP)**: IP, as a result of R&D, has economic value, and its valuation is critical for transactions like licensing or sales. IP value depends on factors such as **market maturity (TRL), market potential, novelty, uniqueness, and accessibility (patent protection)**. Various methods are discussed: **Cost method** (calculating the cost of a similar IP asset, often setting a minimum price for universities), **Market method** (comparing with similar assets for which prices were paid), and **Income method** (valuing based on expected economic income, adjusted to present value, including the **Discounted Cash Flow (DCF) method**). Practical usage involves comparing results from different methods and using the calculated value to propose a price during negotiations, always aiming for the market price and not below cost.
- **Constructing a Technological Offer**: This is a structured proposal outlining project results and their advantages. The proposal is for potential investors or manufacturers. It should be adapted to its audience and include administrative/legal information, a brief non-technical description of the technology/invention, its goal, verification indicators, market information (SOTA,

competition), unique advantages, the **TRL level**, and proposed pricing, while carefully avoiding disclosure of confidential information early on.

- **Negotiations**: This requires careful planning, including **understanding the value proposition**, thorough **research of the potential partner**, setting **realistic goals and priorities**, preparing a clear **proposal and negotiation strategy**, and conducting the negotiation with a focus on **open communication, collaboration, and win-win solutions**. Finalizing the agreement involves clear documentation of rights, responsibilities, and financial arrangements.

Chapter 4: Management of Research and Implementation Projects. This concluding chapter provides practical tools and insights for effectively managing R&D endeavors from initial conception through to successful market application, directly supporting Europe's competitiveness and innovation goals.

Central to this chapter is the concept of **Technology Readiness Levels (TRLs)**, a nine-level scale (TRL 1-9) used to assess a technology's maturity from basic research (TRL 1) to full operational implementation (TRL 9). TRLs are grouped into basic research (TRL 1), industrial research (TRL 2-6), and development (TRL 7-9) phases. Each TRL represents specific progress in validation and integration. The importance of TRLs is manifold: they are instrumental for **risk identification and mitigation**, crucial for **budget planning** and strategic resource allocation, serve as a **roadmap for project management**, guide **strategic planning** of technology development, inform **investment decisions** by indicating technology maturity, aid in **compliance assessment** with funding guidelines, and provide a **common language for communication** among diverse stakeholders. Challenges in applying TRLs include a lack of universal definitions, subjectivity, interpretation differences, complexity, and resource intensity, while good practices involve adapting to industry specifics and integrating with project management methodologies.

The chapter further explores:

- **The Research Hypothesis, Project Results, and Current State-of-the-Art**: This section details formulating a clear, testable research hypothesis grounded in existing knowledge and market needs. It outlines stages of a research agenda, assessing innovation, benchmarking against competing solutions, and leveraging various scientific and patent databases for state-of-the-art analysis.
- **Working with the Business Community before, during, and after the Project**:
  - **Before**: Emphasizes that research topics should originate from identified market needs, requiring early discussions with industry partners to create a "synergy effect". Signing a confidentiality agreement is advised.
  - **During**: Focuses on maintaining transparent communication, promptly sharing test results with business partners, and adjusting the research agenda based on market changes. Successful commercialization at this stage depends on a competent team, thorough market analysis, stable funding, proving project credibility, and effective communication and sales strategies.
  - **After**: Stresses the need for continuous monitoring of market reactions to the launched product for subsequent modifications and improvements.
- **Technical Cost of Products Manufacturing (TCPM)**: Defined as the total cost of producing a product, including direct and indirect costs. TCPM is vital for evaluating production efficiency, setting competitive pricing, planning production, and making informed financial decisions. It comprises material, labor, machinery, energy, and production overhead costs. The guide details various calculation methods (commissioning, process, unit costing) and the role of optimization tools like Lean Manufacturing (Kaizen, 5S, JIT, SMED, Kanban) in reducing costs

and increasing efficiency. Examples illustrate how TCPM changes (decreases per unit) as TRL increases due to scaling.

- **Project Risk Management**: This involves systematically identifying, analyzing, monitoring, and controlling risks throughout the project lifecycle. Key risk management strategies include **avoidance, mitigation, transfer, and acceptance**. The guide analyzes how risks evolve at different project stages (inception, planning, implementation, closure) and discusses key aspects for effectiveness such as stakeholder engagement, accuracy of analysis, and flexibility. Various tools and techniques are presented, including **SWOT analysis, Risk Matrix, Root cause analysis, Ishikawa diagram, Scenario analysis, Monte Carlo method, and Brainstorming**. Challenges and barriers to effective risk management are identified, such as incomplete identification, lack of stakeholder involvement, and resistance to change. Modern trends include the integration of **Agile methodologies**, continuous improvement philosophies, automation, real-time monitoring, and addressing reputational and sustainability risks. R&D projects inherently carry high risks, both internal and external, introduced and imposed, across micro, medium, and global levels, which must be carefully managed for successful commercialization.

Chapter 0 - Technology Transfer within STARS EU: Fostering European Competitiveness through Open Innovation

As the STARS EU Alliance, a partnership of nine European universities committed to the European Universities Strategy, we recognize the critical imperative to enhance Europe's global competitiveness. This **Technology Transfer (TT) Guide** serves as a foundational document, designed to equip our partners with the knowledge, strategies, and tools necessary to effectively translate research and development (R&D) outcomes into tangible societal and economic value. Our approach is deeply informed by recent analyses of European competitiveness, particularly the insights from **Draghi's report** *"The Future of European Competitiveness"*, and is firmly rooted in the principles of **Open Innovation** as a transformative theoretical framework. This guide aims to bridge the persistent innovation and commercialization gaps identified at the European level, leveraging the collective strengths of our alliance to drive regional dynamism and foster a more competitive and resilient Europe.

0.1 The Imperative for Enhanced Competitiveness: Insights from Draghi's Report

Europe currently faces a **critical juncture** in its economic trajectory, characterized by slowing growth and a widening productivity gap with major global competitors, notably the United States and China. Draghi's report *"The Future of European Competitiveness"* meticulously outlines the structural challenges impeding Europe's ability to maintain and enhance its global position, emphasizing that these issues necessitate a profound shift in strategic focus.

One of the most pressing concerns highlighted is **Europe's innovation gap**. The report points to a **static industrial structure**, where few new companies emerge to disrupt existing industries or create new growth engines. This contrasts sharply with the US, where all six companies valued over EUR 1 trillion in the past fifty years were established from scratch during that period, while Europe lacks any company over EUR 100 billion founded in the last fifty years. This **lack of dynamism** is self-fulfilling, as European companies, often specialized in mature technologies with limited breakthrough potential, consequently invest less in research and innovation (R&I). In 2021, EU companies spent approximately EUR 270 billion less on R&I compared to their US counterparts, a gap primarily driven by higher investment rates in the US tech sector. For instance, while automotive companies have consistently dominated the top 3 R&I spenders in Europe for twenty years, the US top 3 shifted from autos and pharma in the early 2000s to entirely tech companies in the 2020s, indicating a redirection of resources towards sectors with high productivity growth potential.

The core issue is not a deficit of ideas or talent; Europe boasts many talented researchers and entrepreneurs, evidenced by a strong position in fundamental research and patenting (17% of global patent applications in 2021, compared to 21% for the US and 25% for China). However, the innovation process is **blocked at the commercialization stage**. Much of the knowledge generated by European researchers, particularly by universities and research institutions, remains commercially unexploited, with only about one-third of patented inventions being commercially utilized. This failure is partly attributed to researchers in Europe being less integrated into "innovation clusters"—networks comprising universities, start-ups, large companies, and venture capitalists (VCs)—which are crucial for successful commercialization in high-tech sectors. Europe lacks any innovation clusters among the global top 10, whereas the US has four and China has three.

Draghi's report meticulously dissects several **key barriers to innovation in Europe**:

- **Inefficient Public R&I Support and Fragmented Financing**: Public R&I spending in the EU, though similar in share of GDP to the US, is largely carried out at the national level, with only one-tenth occurring at the EU level. This fragmentation prevents the necessary scale for investments in high-risk, breakthrough technologies. Existing EU programs, such as Horizon Europe, are criticized for being spread across too many fields, being excessively complex and bureaucratic, and insufficiently focused on disruptive innovation. For example, the European Innovation Council's (EIC) Pathfinder instrument, designed for radically new technologies at low readiness levels, has a budget significantly smaller than its US counterparts like DARPA.

- **Weak Pipeline from Innovation to Commercialization**: Beyond the lack of integration into innovation clusters, bureaucratic barriers within universities and research institutions impede the effective management of intellectual property rights (IPRs) with researchers. The high application costs and lack of uniform protection for IPRs further deter young companies from leveraging the Single Market.

- **Fragmented Single Market Hindering Scale-Up**: The EU's incomplete and fragmented Single Market, especially in areas crucial for innovative companies, offers weaker growth prospects and requires less financing. This leads many high-growth potential EU companies to seek financing from US VCs and to scale up in the US market, which is perceived as more rewarding due to its wider market reach and faster profitability. Between 2008 and 2021, nearly 30% of "unicorns" founded in Europe relocated their headquarters abroad, predominantly to the US. This fragmentation also causes EU companies to "stay small," as they face high costs of adhering to heterogeneous national regulations and tax compliance, leading to proportionally fewer small and medium-sized companies compared to the US.

- **Onerous Regulatory Barriers**: The EU's regulatory landscape, with over 100 tech-focused laws and more than 270 regulators across Member States, imposes significant compliance costs, particularly on SMEs. A precautionary approach, dictating specific business practices *ex ante*, and fragmentation in implementation (e.g., "gold plating" of EU legislation by national authorities) deter digital companies from operating across the EU. This creates a disadvantage for EU companies, as only larger, often non-EU-based, companies can bear these costs.

- **Lack of Investment in State-of-the-Art Infrastructure**: Developing AI models and maintaining data centers require massive computing power, leading to a global "AI chip race" where smaller, less-funded EU companies struggle. Furthermore, the EU lags in fibre and 5G deployment, facing estimated investment needs of around EUR 200 billion for full coverage, but per capita investment is significantly lower than other major economies due to a fragmented market structure (e.g., 34 mobile network operator groups in the EU versus a handful in the US or China).

To address these profound challenges, Draghi's report lays out a comprehensive **programme to tackle the innovation deficit**. Key recommendations include (Figure 0.1):

- **Reforming EU R&I Programmes**: Refocusing programs like Horizon Europe on a smaller number of commonly agreed priorities, allocating an increased share of the budget towards disruptive innovation, and reforming the EIC into a genuine "ARPA-type agency" that supports high-risk, breakthrough projects. This also entails streamlining application processes and doubling the budget to EUR 200 billion over seven years, conditional on reforms.

- **Strengthening Academic Excellence and Commercialization**: Doubling support for fundamental research through the European Research Council (ERC) and introducing an excellence-based "ERC for Institutions" program. To attract and retain top academic talent, a new "EU Chair" position is proposed, supported by a new EU framework for private funding to enable competitive compensation policies. Crucially, the report recommends measures to make it easier for "inventors to become investors," including a **new blueprint for fair and transparent royalty sharing** in universities and research institutions, adopting the **Unitary Patent** in all EU Member States for uniform IP protection, and introducing an **EU-wide legal statute** ("Innovative European Company") for innovative start-ups to facilitate growth across the Single Market.

- **Improving the Financing Environment**: Expanding incentives for "angel" investors and seed capital, assessing changes to capital requirements for institutional investment in innovative companies, increasing the budget and reforming the mandate of the European Investment Fund (EIF) and EIB Group to support higher-risk, larger-volume ventures and "crowd-in" private investors.

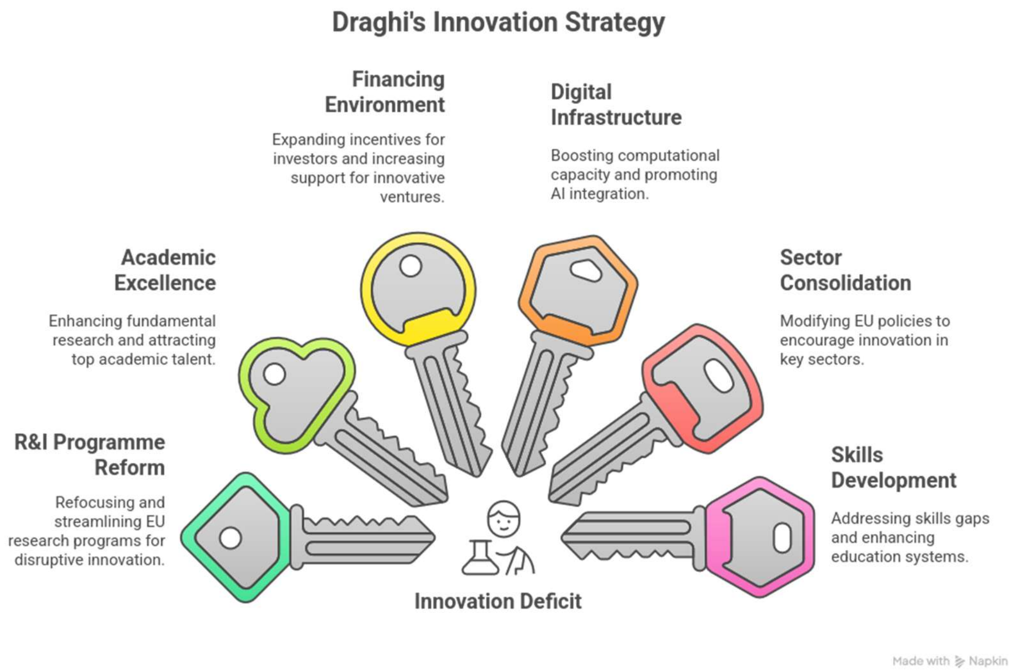

Figure 0.1: Draghi's Innovation Strategy

- **Boosting Digital Infrastructure and AI Integration**: Significantly increasing computational capacity dedicated to AI model training in high-performance computing (HPC) centers and expanding Euro-HPC to additional cloud and storage capabilities. A "federated AI model" based on public-private cooperation is proposed, allowing public sector "computing capital" to be provided to innovative SMEs in exchange for financial returns (e.g., equity options, royalties). The EU should also promote cross-industry coordination and data sharing (e.g., through an "AI Vertical Priorities Plan") to accelerate AI integration, encouraging data contribution by multiple EU companies within sectors under open-source frameworks and safeguarded from antitrust enforcement.

- **Facilitating Consolidation and R&I in Key Sectors**: Modifying the EU's stance towards scale and consolidation in telecoms by defining markets at the EU level and increasing the weight of innovation and investment commitments in merger rules. In pharma, proposals include accelerating the digitization of health systems (European Health Data Space - EHDS) to enable data access for AI development, scaling up genome sequencing, and refocusing EU funding on world-class innovation hubs for advanced therapy medicinal products.

- **Addressing Skills Gaps**: Enhancing the use of skills intelligence, making education and training systems more responsive to changing skill needs, introducing a common system of certification, and redesigning EU programs for education and skills. Specific interventions are recommended for acute shortages in technical and STEM skills, including a new Tech Skills Acquisition Programme to attract talent from outside the EU.

For STARS EU, these findings underscore our mission. As a European Universities Alliance, we are uniquely positioned to address these challenges head-on. By fostering collaboration, streamlining technology transfer, and embracing an open innovation mindset, we can contribute significantly to closing Europe's innovation gap, enhancing its productivity, and strengthening its overall competitiveness. This TT Guide is our concrete commitment to this endeavor, providing the actionable framework for our alliance to become an active part of European innovation.

0.2 Open Innovation: A Theoretical Framework for Technology Transfer

The **Open Innovation (OI)** model, primarily defined by Henry Chesbrough [*Open Innovation: The New Imperative for Creating and Profiting from Technology. HBS Press. 2003.*], represents a fundamental shift from the traditional "Closed Innovation" paradigm, offering a robust theoretical framework for our TT Guide. Historically, innovation was conceived as an outcome of deliberate actions within a single firm, emphasizing self-reliance and control over all aspects of R&D—the "if you want something done right, you've got to do it yourself" mindset. In this **Closed Innovation** model, firms believe they must generate their own ideas, develop them internally, and manage their intellectual property (IP) rigorously to prevent competitors from profiting from their efforts.

However, OI challenges this view by asserting that successful innovation requires leveraging both **internal and external ideas and pathways to market**. It facilitates innovation by blending endogenous and exogenous knowledge, creating a dynamic flow between an organization and its ecosystem. This organizational openness necessitates productive interactions with other entities, such as universities, research centers, suppliers, and customers, to accelerate the assimilation, transformation, and application of knowledge. OI also recognizes that intellectual property, rather than merely being protected, should be viewed as a **tradable good**, where organizations can profit from others' use of their IP and acquire external IP to advance their own business models.

The evolution of innovation models has moved beyond a linear progression (invention, innovation, diffusion) to more complex, cooperative frameworks. The "Triple Helix" concept, for instance, expanded the understanding of innovation by incorporating the interplay of universities, industry, and government. This framework transformed the university's role from a mere knowledge generator to an "Entrepreneurial University," deeply involved in socio-economic development and raising regional knowledge bases and innovation capacities through collaborations and openness to external processes. Subsequent expansions to "Quadruple and Quintuple Helix" models further integrate civil society and natural environments as critical innovation drivers, stressing the importance of third parties and societal engagement.

OI processes are typically characterized by three core archetypes (Figure 0.2):

1. **The Outside-in Process**: This involves enriching a company's internal knowledge base and innovative capacity by integrating external sources. Key external contributors include suppliers,

customers, commercial research institutions, and partners from other industries. This process emphasizes the importance of new forms of customer integration, such as crowd-sourcing or customer community integration, and highlights the role of innovation networks and intermediaries.

2. **The Inside-out Process**: This archetype focuses on externalizing internal ideas and intellectual property (IP) to the market. This can involve selling or licensing technologies that are not aligned with the firm's core business model but hold commercial value for others.
3. **The Coupled Process**: This represents a combination of the outside-in and inside-out processes, entailing joint innovation and commercialization efforts with complementary partners. It signifies a bidirectional flow of knowledge and collaboration, where organizations co-create ideas and bring them to market together.

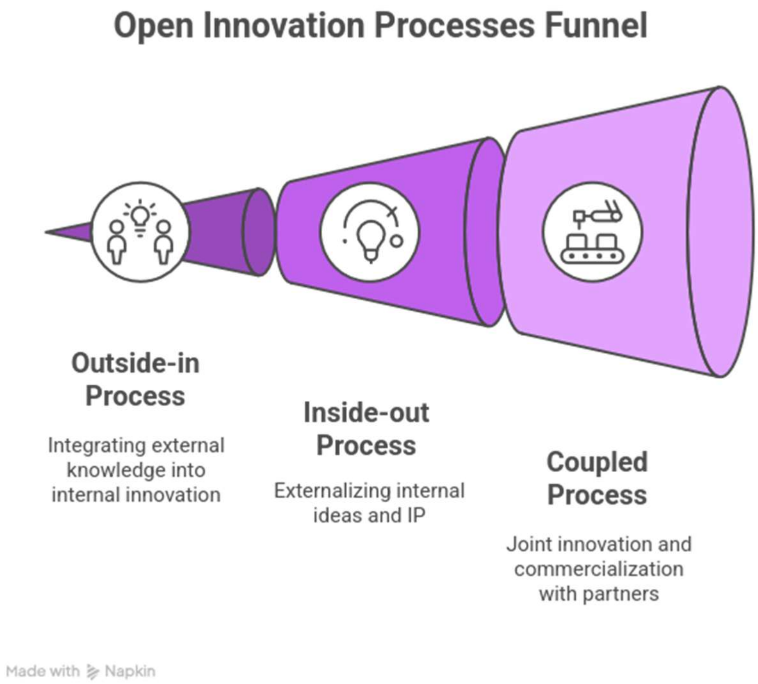

Figure 0.2: Open Innovation Processes Funnel

Open Innovation in the University Context

The principles of Open Innovation are particularly relevant for universities, leading to the concept of **University Open Innovation (UOI)**. Universities are recognized as primary actors in the innovation ecosystem, capable of energizing local ecosystems and driving societal transformation by producing new knowledge flows that have multidimensional and multi-temporal impacts. The linkage between universities and other ecosystem actors has seen a strong upward trend towards an open innovation model over the past three decades.

UOI is strategic for generating interdisciplinary solutions to complex problems in social, public, and productive sectors. It is significantly facilitated by **digital transformation**, which intensifies research, shortens innovation cycles, and optimizes resources by providing easier access to external knowledge generators. The success of UOI hinges on several key factors:

- **Soft and Hard Inputs**: This includes fostering an innovative culture, effective knowledge management, and robust technological infrastructure. The sources note that university structures often feature diverse technological, scientific, social science, and sustainable labs, equipped with both physical and virtual networks for knowledge creation and transfer, collaborative tools, and high telecommunications technology.
- **Support Processes**: These encompass research management, developing relational capital, and forming strategic alliances. The main strategy for UOI is to serve as a flexible, effective, and responsible interface within the ecosystem, focusing on functional connections to solve complex issues and foster institutional capabilities like autonomy and collaboration.
- **Tangible and Intangible Results**: The outcomes of UOI include research results, technological services, and intellectual property. The protection and social diffusion of intellectual property are highlighted as critical, involving strategies like copyrights, patents, utility models, and open source. IP management is considered an essential strategy for sustainable university linkage.
- **Profile of the Academic Community**: The innovation capabilities, institutional and social capital, and knowledge capital of academics are crucial. Academics' expertise and networks enable them to identify potential knowledge supplies and demand opportunities, and their individual attitudes and motivations significantly influence the linking process. This academic community acts as a **mediator variable** in the open innovation process.
- **Collaborative Flows**: UOI involves various types of knowledge flows between the university and the ecosystem (Figure 0.3):
    - **Inside flow**: Academic communities utilize existing knowledge from the environment but do not co-create it with external organizations, resulting in low social participation from the university. The knowledge flow is from outside-in.

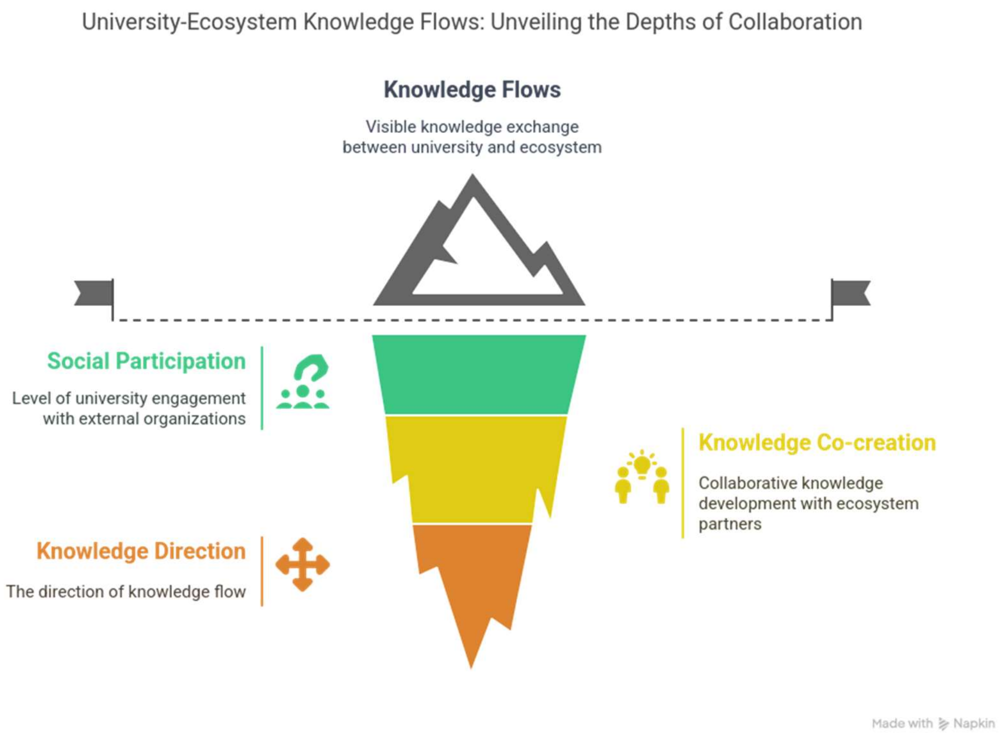

Figure 0.3: University-Ecosystem Knowledge

- **Outside flow**: Academic communities supply knowledge to the ecosystem without co-creation, leading to a medium level of social participation. The knowledge flow is inside-out.
- **Mixed flow**: Academic communities both use and share knowledge with the ecosystem, involving medium-high social participation and bidirectional knowledge flow.
- **Hybrid flow**: Academic communities actively use, share, and co-create knowledge with the ecosystem, demonstrating a high level of social participation and multidirectional, bidirectional knowledge flow.

- **Institutional Policy**: This factor significantly facilitates or inhibits open innovation and the level of university-business linkage. It defines public resources allocated to OI, stimulates academics to strengthen relational capital, and shapes the university's organizational structure to support innovation. For example, Latin American universities, despite continuous efforts, have shown insufficient results in systematic linkages, often due to low demand for scientific and technological knowledge from local productive sectors, leading to a "supply-side" OI model. This emphasizes the need for operational innovation policies that strengthen ecosystem interaction and foster trust and credibility.

The benefits of adopting an OI approach for technology transfer are manifold. It accelerates innovation processes by fostering the exchange and mixing of knowledge. It strengthens relational activities, leading to more alliances and effective knowledge transfer. By engaging with diverse external partners, universities and companies can accelerate learning curves and achieve competitive advantages. Moreover, OI helps overcome resource limitations, particularly for Small and Medium-sized Enterprises (SMEs) and even individuals, who can access a global pool of experts and ideas. From the outset, OI encourages involvement of external partners to ensure market application and commercialization, transitioning ideas into concrete products.

Figure 0.4: Achieving European Competitiveness

0.3 Bridging the Gap: Integrating Draghi's Vision with Open Innovation in the STARS EU TT Guide

The **STARS EU Technology Transfer Guide** could be considered as a practical implementation of the strategic imperatives outlined in Draghi's report, underpinned by the robust theoretical framework of Open Innovation. Our guide directly addresses the critical weaknesses identified in European competitiveness by leveraging the collaborative, outward-looking principles of OI.

Our design flows in a conceptual pathway with the following dimensions (Figure 0.4):

1. Bridging the Commercialization Gap: Draghi's report underscores Europe's failure to translate fundamental research into commercial success, with only a third of patented university inventions being exploited commercially. The Open Innovation (OI) model, through its **Inside-out** and **Coupled processes**, explicitly focuses on selling or licensing ideas and IP to the market, and on joint innovation and commercialization with partners. Our TT Guide operationalizes this by detailing **commercialization strategies with business partners**. It outlines mechanisms such as **direct commercialization** (selling R&D results or granting licenses) and **indirect commercialization** (creating start-ups like spin-offs and spin-outs through special purpose vehicles – SPVs) (Chapter 2 – sec. 2.1). This directly supports the report's call for making it easier for "inventors to become investors" through fair royalty sharing and uniform IP protection via the Unitary Patent. The guide also explains different **types of licenses** (exclusive, restricted, non-exclusive, implied) and how to determine **remuneration/royalties** based on factors like Technology Readiness Level (TRL) and market potential (Chapter 2 – sec. 2.4). By detailing these pathways, the guide provides clear mechanisms to convert academic breakthroughs into marketable products and services, fostering the much-needed industrial dynamism in Europe.

2. Addressing Fragmentation through Collaborative Networks: Draghi's report highlights the detrimental effects of the fragmented Single Market and R&I spending, leading to a lack of scale and hindering innovative companies from growing. The OI model inherently emphasizes the power of **interorganizational and intraorganizational networks**, recognizing that firms are embedded in broader ecosystems. It stresses the importance of engaging a variety of external actors—from suppliers and customers to other industries and research institutions—to enrich the internal knowledge base. Our TT Guide, therefore, places significant emphasis on **identifying potential partners** and building robust S2B (Science-to-Business) partnerships. It explicitly states that "the implementation of the result of research and development results from a university must take place in collaboration with an industrial partner," as universities typically lack the resources to scale up and produce commercial products. The guide outlines different partnership models like **Joint Ventures** and **Licensing**, and crucial considerations for successful commercial partnerships, such as clear objectives, mutual benefit, trust, transparency, legal agreements, resource commitment, and risk management (Chapter 3 – sec. 3.2). By fostering such networked collaborations, the guide helps overcome the limitations of national fragmentation, creating larger pools of resources and expertise that mimic the continent-wide scale seen in the United States.

3. Leveraging Universities as Entrepreneurial Actors: Both Draghi's report and the OI framework underscore the central role of universities as knowledge generators and entrepreneurial entities within the innovation ecosystem. Our TT Guide operationalizes the university's "third mission" by focusing on **working with the business community before, during, and after the project**. It emphasizes that research topics should originate from identified **market needs**, urging researchers to discuss the practical usefulness of their work with companies to create a "synergy effect". The guide advocates for establishing clear commercialization strategies from the initial project phase and adapting them to evolving market conditions. It acknowledges the challenges in university-industry collaboration but stresses the mutual need for contacts and shared goals, as "scientists need inspiration from industry and industry needs innovation to survive and thrive" (Chapter 4). The guide also outlines the **university broker's role in S2B interaction**, facilitating the search for business partners and helping scientists present their inventions clearly and concisely (Chapter 3 – sec. 3.3). This direct engagement transforms universities from "ivory towers to knowledge brokers," a key trend identified in the evolution of OI practices.

4. Strategic Management of Intellectual Property (IP): Draghi's report implicitly points to IP challenges in Europe by recommending policies for fair royalty sharing and uniform patent protection. The OI model regards IP not merely as something to protect but as a **tradable good** from

which to profit. Our TT Guide provides extensive detail on the **management of intellectual property**. It covers the **valuation of IP assets** and addresses **ownership of IPRs**, noting that while rights typically belong to the author, they may be assigned to the employer (e.g., university) under certain circumstances.

The guide elaborates on the **assignment of rights** (full transfer of property rights to a buyer) and various **licensing agreements** (exclusive, restricted, non-exclusive, implied). It also highlights the importance of **confidentiality clauses** and provisions for **further cooperation** in technology development. By providing clear guidelines on IP management, the guide directly addresses a critical barrier to commercialization identified in Draghi's report, enabling universities to effectively leverage their research outputs and attract private investment (Chapter 3 – sec. 3.4).

5. Market-Oriented R&D and Technology Readiness Levels (TRL): To counter Europe's concentration on mature technologies and lack of investment in disruptive innovation, our TT Guide emphasizes starting R&D projects with a clear market focus. The guide begins by detailing the importance of a **State-of-the-Art analysis** to identify existing solutions, determine research direction, and identify latest trends, which is crucial for securing R&D results and planning commercialization. It introduces the concept of **Innovativeness** as preparing and initiating production of new or improved solutions for market use, emphasizing that "Without a concrete market application, we are not talking about innovation, just an idea". A **Competitive Analysis** is deemed essential to evaluate market potential, ensuring new products significantly differ from existing ones (Chapter 1). Central to this market orientation is the use of **Technology Readiness Levels (TRL)**. The guide explains the **nine-level TRL scale**, from basic research (TRL 1) to operational implementation (TRL 9), and its importance for investment decisions, compliance assessment, and communication among stakeholders (Chapter 4). It also discusses **challenges and practices** in TRL application, such as adapting to industry specifics and addressing qualitative assessment issues. By integrating TRLs, the guide provides a common language for assessing technological maturity, facilitating better alignment between university research and industry needs, and directing investment towards technologies with higher commercialization potential, thereby contributing to Europe's goal of leading in new technologies and integrating AI into existing industries.

To conclude this Chapter, the following table summarizes this correlation between the challenges raised by Draghi's report and the solutions provided by our guide, measuring the strength of the STARS EU alliance and the capacity of its partners.

Proposal for a Policy-to-Practice Table: Draghi's Vision and STARS EU TT Implementation

Draghi's Policy Challenge / Recommendation	Corresponding STARS EU TT Guide Objective / Strategy	STARS EU TT Guide Practical Action / Mechanism
Europe's Failure to Commercialize Research. Only about one-third of patented inventions registered by European universities are commercially exploited. *Recommendation:* New blueprint for **fair and transparent royalty sharing** for inventors.	**Bridging the Commercialization Gap & Strategic IP Management:** Leveraging Inside-out and Coupled OI processes to license or sell IP.	Implementing **Direct Commercialization** pathways, detailing the **assignment of rights** (sale) or **licensing agreements**. Determining **creator's remuneration** based on royalties after the university recoups costs. Defining **remuneration/ royalties** based on factors like the value of the IP and **Technology Readiness Level (TRL)**
Fragmentation of the Single Market and R&I Spending. Hindering innovative companies from scaling up; lack of innovation "clusters".	**Addressing Fragmentation through Collaborative Networks.** Emphasizing interorganizational networks and the Coupled OI Process.	Establishing and managing **Science-to-Business (S2B) Partnerships**. Outlining types of cooperation, such as **Strategic Alliances** and **Joint Ventures**. Identifying partners who possess the necessary **financial resources and infrastructure** for scaling, production, certification, marketing, and distribution, which universities typically lack
Static Industrial Structure / Lack of Market-Oriented R&D. EU companies invest less in R&I compared to US counterparts; failure to accelerate innovation in new technologies.	**Market-Oriented R&D and Technology Readiness Levels (TRL):** Ensuring research is proactive and aligns with market needs, asserting that "Without a concrete market application, an idea remains merely an idea, not an innovation".	Conducting a **State-of-the-Art (SOTA) Analysis** to determine research direction, identify existing solutions, and plan commercialization. Employing **Competitive Analysis** to ensure the new product significantly differs from existing ones. Using the **9-level TRL scale** (TRL 1-9) as a tool for project management, guiding investment decisions, and assessing compliance.

Weak Pipeline from Innovation to Commercialization. Bureaucratic barriers within universities impede effective IP management; difficulty for "inventors to become investors".	**Leveraging Universities as Entrepreneurial Actors.** Operationalizing the university's "third mission" and fostering entrepreneurship.	Supporting **Indirect Commercialization** via the establishment of new ventures like **spin-off and spin-out companies**. Defining the **university broker's role** as a crucial intermediary to "translate" scientific language into market terms and facilitate partner search. Emphasizing continuous **engagement with the business community** before, during, and after the project to ensure topics originate from identified market needs.
Need for Strategic Investment and Risk Management. EU programs are excessively complex and bureaucratic; high risks associated with breakthrough technologies require robust planning.	**Strategic Management of IP and Project Management.** Providing tools to assess viability, secure funding, and mitigate high inherent R&D risks.	Performing **SWOT analysis** on project results to assess market potential and viability. Calculating the **Technical Cost of Products Manufacturing (TCPM)** to evaluate production efficiency and plan pricing policy. Implementing comprehensive **Project Risk Management** (identification, analysis, response planning, monitoring) for high-risk R&D endeavors.

Chapter 1 - Market Potential of R&D

The STARS EU Technology Transfer (TT) Guide is designed to address critical challenges facing European competitiveness, particularly the persistent innovation and commercialization gaps identified in Draghi's report. Chapter 0 establishes this imperative, highlighting that despite Europe's strong position in fundamental research and patenting, much of the knowledge generated, especially by universities, remains commercially unexploited.

Building directly on this strategic foundation this chapter is pivotal as it lays out the essential groundwork for transforming innovative ideas into tangible economic value. It addresses the critical need to assess the market potential of R&D outcomes from the earliest stages of a project. The sources emphasize that without a concrete market application, an idea remains merely an idea, not an innovation. This chapter operationalizes the "Market-Oriented R&D" dimension of achieving European competitiveness, ensuring that research aligns with market needs to enhance technology readiness.

In essence, this Chapter 1 provides the foundational analytical tools and insights necessary for researchers, innovators, and commercializing entities to proactively orient their R&D towards market needs, mitigate risks, and ultimately contribute to transforming Europe's R&D potential into tangible economic growth and societal welfare. It directly supports Draghi's vision by ensuring that the innovations developed are not just ideas, but market-ready solutions poised for successful commercialization within a competitive European landscape.

We resume this chapter in this graphic (Figure 1.1) which we develop deeply in the follwing sections.

Figure 1.1: Analytical tools and insights necessary to proactively orient R&D towards market needs

1.1 State-of-the-Art

When planning a Research and Development (R&D) project, it is extremely important to review the current State-of-the-Art in the research area. **Researchers have to check whether there are already existing solutions that could be an obstacle to the implementation of future R&D results.** This will allow them to effectively secure future R&D results and plan an appropriate commercialization strategy.

The objectives of the state-of-the-art analysis are:

- Identify existing solutions in a given technology area;
- Determine the direction of research;
- Protect the inventor from repeating known and protected solutions;
- identify the latest trends.

According to the European Patent Convention (art.54), **the State-of-the-Art includes everything made available to the public through written or oral descriptions, use, exhibition or any other form of disclosure before the date of filing of the European patent application or the priority date, if claimed**.

In the marketplace, the State-of-the-Art is a somewhat broader concept. It refers to all currently manufactured devices, applied patented and unpatented methods, solutions, ongoing research and development, as well as publications in the field.

State-of-the-Art research, i.e., research into the patent environment of a particular technology or industry, is part of basic patent research. It involves a detailed analysis of existing solutions in a given field, known from patent literature, scientific publications, articles and practical applications. The aim is to determine the state of development of a particular technology and identify existing solutions.

In commercialization processes, the state-of-the-art analysis is also a tool for planning the development of a new product/technology, especially for projects whose success is based on an innovative solution.

The State-of-the-Art and freedom to operate analyses support the market development decision process. They help determine whether there are similar or identical solutions that have been filed for protection or for which exclusive rights have already been granted in the country and/or abroad. Such analyses minimize the risk of lawsuits by holders of existing exclusive rights and help avoid the potential litigation costs and damages.

In preparing a patent application, a patent purity examination and a patentability examination are also carried out. Patent purity examination aims to determine whether a product, technology or service infringes on the intellectual property rights of others. In other words, it assesses whether you can freely market your product without the risk of being sued for patent infringement. Patentability examination is a process that aims to assess whether an invention meets the legal requirements for patent protection, meaning it is novel and non-obvious.

The tools used for all these searches must be done in patent databases and search engines. Here follow the main ones at European and Worldwide level:

- ESPACENET database of the European Patent Office (EPO) - https://worldwide.espacenet.com/
- Databases by European countries - https://www.epo.org/en/searching-for-patents/technical/espacenet/national
- PATENTSCOPE database of the World Intellectual Property organization (WIPO) - https://www.wipo.int/patentscope/en/

1.2 Innovativeness of the project results

Innovativeness involves preparing and initiating the production of new or improved materials, products, equipment, services, processes or methods intended for market use or practical application. Innovation is sometimes defined as "a creative activity that begins with the perception of an opportunity, a need to be met or a problem to be solved". The process comes to an end when a decision is made to implement a specific idea, selected from many considered, and to proceed with its implementation. **Without a concrete market application, we are not talking about innovation, just an idea. Innovation occurs when the result of this activity is brought to market.**

Innovation in research and in economic and social life is a key factor in business development and improving the quality of life of citizens. It is one of the strategic objectives of the European Union. **Innovation is essential for the long-term success of an organization.** Examples include the development of new products or services introducing new business models or achieving a competitive advantage through innovative solutions, leading to growth and entrepreneurship and a sustainable market position.

The Oslo Manual 2018 defines innovation as: *"A new or improved product or process (or a combination of both) that is significantly different from previous products or processes".*

A distinction should be made between the degree of innovation:

- **Radical innovations:** Innovations that redefine markets and lead to the complete replacement of previously used solutions and technologies.
- **Incremental innovations:** Improvements to existing products or processes.

This means that not only new products or processes are considered innovations, but also those solutions that bring significant improvements. These improvements must provide new functionalities or features that are relevant to the end user and provide specific benefits.

Innovation can also be considered in terms of scale of impact, whether on an individual/enterprise, national or global scale.

1.2.1 Categories of innovation

Innovation can be categorized in many ways, depending on the focus (e.g., degree of change, what is being innovated, etc.). Here are some common and widely recognized categories:

1. Product innovation: any type of change that improves a product already manufactured by a company or initiates the production of another innovative product.

Example: E-book reader - the introduction of the e-book reader has revolutionised the way books are read. Now one small device can hold several books.

<u>2. Process (technological) innovation:</u> a change in the methods used by a company to provide services or manufacture products.

<u>Example:</u> An example of process innovation could be the introduction of new holiday booking software in a travel agency, the use of barcodes to track the flow of goods, or the use of GPS tracking devices to manage a fleet of vehicles. Another example would be the use of machinery to make butter.

<u>3. organizational innovation:</u> is the introduction of a new method of organizing the way a company conducts its business.

<u>Example:</u> Reorganizing departments in a company to streamline a core process, creating new teams, implementing new management methods, the automation of information flows (using tablets to fill in documents in a production environment so that the area manager has real-time data).

<u>4. Marketing innovation:</u> involves the use of a new method of promotion that involves significant changes to a product's appearance, packaging, advertising or business model.

<u>Example:</u> Hiring celebrities (actors/singers) to promote new products or placing new products in films/series/television clips.

<u>5. Social innovation:</u> is an innovative activity whose primary and intended effect is to meet a real social need or address a real problem.

<u>Example:</u> Projects that use technology to bring health or education services to rural or marginalized communities (e.g. telemedicine or mobile applications for disease monitoring, Learning Management Systems for adults)

Innovation in each category can take different forms. It can also be understood differently depending on the field of knowledge to which it relates and the object of research and purpose it serves. The European Union's innovation-oriented economic policy has defined regional innovation strategies in individual member states. These are based on the identification of economic priorities in the field of R&D&I and the concentration of investments in areas that ensure an increase in the added value of the economy and its competitiveness in foreign markets.

An important role in such strategies is played at regional level with Research and Innovation Smart Specialisation Strategy (RIS3). They should contribute to the transformation of the national economy through modernization, structural transformation, differentiation of products and services and the creation of innovative socio-economic solutions. They also support the transition to an economy that efficiently uses resources, including natural resources.

The main condition for the development of intelligent specializations is to use the potential of each region by optimally matching the directions of scientific development and education to its social and economic specifics. The European Universities Alliance STARS EU is exceptionally well-positioned to help its partner regions achieve their intelligent specialization objectives by leveraging its transnational, collaborative, and interdisciplinary

The innovativeness of the outcome of a specific project lies in the fact that the developed product/technology should have unique features that are unknown or almost absent in the market. The innovative result of the project is expressed in the novelty of the features of the product we want to launch on the market. We should not forget that the novelty of the project results, in line with the expectations of the recipients, is one of the main factors determining the qualification of our product as a response to market demand, i.e., a necessary condition for successful commercialization.

Research and research-implementation projects and business activities aimed at introducing innovative solutions to the market, in accordance with the directions set by the National Intelligent Specializations, receive financial support from the European Union within the framework of the EU budget and NextGenerationEU .

1.3 Competitive analysis

Competition is defined as the phenomenon where market participants pursue their interests by offering more favourable conditions than others, such as better prices, quality, delivery terms and other features that influence the decision to do business. Colloquially, we refer to all companies operating within a particular industry and the services and products they offer as competitors.

A competitive analysis is an essential step in evaluating the market potential of the outcomes of a research and implementation project. If the project's result is identical in terms of manufacturing costs, operating costs, features, durability,etc.,to existing products or services, implementation will be very challenging or even impossible. Generally, a new product can only be successfully launched if it significantly differs from competing products in these aspects.

Developing a new product or service necessitates an analysis of the competition it will face. The market does not operate in a vacuum; there is always some level of competition.

1.3.1 Levels of competition

1. One of the fundamental criteria for comparison is **price**. The price range of products is linked to the purchasing power of the customer segment that the product is intended to reach. If buyers cannot afford a particular product, they will substitute it with a more affordable alternative. Therefore, the pricing policy of competitors should be thoroughly analyzed before launching a product and monitored continuously while the product is on sale. Changes in competitors' prices can weaken our offer (if they decrease) or strengthen our decrease position x (if the prices of the competition increase).
2. It is common for competing products from different suppliers to be available in the market at similar prices levels. This is due to the need to maintain the quality expected by the customers, which is related to the production costs of a product with the desired characteristics. The lack of product differentiation leads to similar pricing. Competition then takes place through branding. Division by product brand refers to companies that produce very similar products, differing mainly in name. It is a strategy focused on shelf competition, where different brands try to attract customer attention by offering similar products. Brands compete mainly by reducing production and distribution costs, resulting in different levels of profit.
3. The second basic criterion of competitiveness is **function**. Competing products can be identified by the function for which that they are designed or the function they actually perform. Products or technologies should not be excluded from the competitive analysis due to different design or origins. Products with different physical features may successfully perform the same or similar functions and therefore constitute a competitive offering. In this case, they are substitutes or replacements.
4. Competition can also affect the market through its **geographical distribution**. Producers tend to have a strong position in regions where their production facilities and main distribution networks are located, as they have better access to consumers without incurring high storage and logistics costs. When planning to enter a particular market, therefore, geography, logistics bases, and transport availability must also be taken into account.

5. **The way competition is organised** also impacts consumer choice. Companies that are members of producer or supplier organizations have a greater market impact, by offering a wider range of products. It is difficult to compete with a single product when competitors offer a range of similar solutions. Individual suppliers are usually unable to compete with networks.

6. An important competitive factor is **the level of warranty and after-sales service.** Consumers are more likely to choose products from companies that offer extended warranties and the ease and speed with which the product can be repaired or returned. The proximity of the service centre to the customer is an important purchase criterion.

7. An increasingly important factor is **the environmental impact** of a product, its sustainability. This is a criterion often used in companies' marketing campaigns and cannot be overlooked when analyzing the competition. The circular economy is becoming an increasingly important factor here with its consequences as to product life cycle.

Competition in the market usually takes place at all these levels simultaneously. Buyers who cannot afford higher-end products will choose lower quality products or substitutes, deliberately foregoing certain features. The **quality/price ratio** becomes the main criterion for purchasing one product over another. Brand loyalty, ease of purchase and after-sales service are also important selection criteria. However, a relatively small number of customers choose products based on environmental characteristics.

When analyzing the competition, all these factors must be considered to determine where we can compete effectively and where our position is too weak to enter and sustain a market presence with a new product.

1.4 Customer market analysis

When designing an innovation, it is crucial to identify the target audience as early as the concept development phase.

An analysis of the customer market helps us understand what is most important to the target group when choosing a particular service or product, and what influences their choice of a specific supplier or service provider. A potential customer should feel a significant need that is not being met by any solution on the market and have a strong desire to fulfil that need. **The ideal innovation is 'tailor-made' for the customer's needs.**

The first step is to define whose needs our product can satisfy in the broadest sense, i.e., who has an unmet need. We then divide them into groups based on different purchase decision criteria, such as:

- Price
- Quality
- Appearance
- Availability
- Purpose
- Range of functions
- Safety of use
- Possible restrictions (physical, formal)
- Ease of use
- Product life cycle (single/multiple use)
- Warranty and repair conditions

- Ease of replacement
- Disposal conditions (payment for used product)

It's important to note that while customer groups may share common decision-making criteria, the weight of each criterion will vary among groups. When analyzing buyers, we should understand not only their preferences, but also their numbers. The number of buyers willing to buy our product will determine the size of the market, i.e., ultimately the volume of sales. For example, customers may have a strong need for a solution with a long-life cycle, but the requirement for higher quality materials increases the product's price. Some customers may not afford the higher-priced product and opt for a cheaper disposable version to meet their immediate need.

The product technologist must decide whether to design a reusable, higher-priced product or a disposable, lower-priced one based on customer market analysis. A small number of buyers willing to pay more for better quality versus a large number of buyers needing an immediate, affordable solution will influence the decision. Conversely, if most buyers expect high quality and are willing to pay for it, the product has higher sales potential.

1.5 Defining the target segment

Following our analysis of the potential market, we must decide on our primary target customer group. If multiple groups are identified, we need to prioritize the one to target initially. Although the product may have broad appeal across different consumer segments, our marketing strategy should first concentrate on a single, primary audience.

This chosen segment is the group most likely to use it, i.e., those with the strongest motivation to buy. For this group, our product must be both attractive, i.e., meet a pressing need, and accessible, i.e., within the budget that this type of audience usually has. Correctly defining the target audience segment is crucial for commercializing the project results. If sales fail, it may be necessary to redesign the product for other audiences. Therefore, we should first look for the most determined consumer and define the target customer precisely.

Criteria for defining the target segment can be:

- gender
- age
- place of residence
- occupation
- social status
- income
- marital status (family or single)
- leisure activities (hobbies)
- typical habits of a certain group

The target segment should also be quantified using statistics, demographics, social reports, market reports, etc, Determining the size of the group is important for forecasting sales and pricing the product.

Example: If market a cosmetic for the face exposed to urban smog, we might filter as follows:

- Gender: female (more sensitive skin group)

- Age: 40 - 55 years old (more likely to notice aging signs and be motivated to buy)
- Where they live: large cities (higher air pollution)
- Social status: working women (less time for personal care)
- Income: middle-income consumers using chain drugstores

While there will be a group of consumers outside the selected segment who will use the product, the main promotional campaigns should target the defined segment.

1.6 Market restrictions - admission to trading

Once we have defined our target segment, identified our competitors, and determined the products we will be competing against, we need to identify the formal requirements necessary to market our product.

- **Certification:** Any product launched on the market undergo a process of evaluating its characteristics and verifying that it meets the technical and legal requirements of the target market. This confirmation is obtained through external review, assessment or audit. Depending on the industry and the intended use of the product, certification may cover one or more characteristics and may be issued by different bodies. The main purpose of certification is to ensure the quality and safety of products.

- **Declaration of conformity:** The assessment of conformity with essential requirements is a mandatory legal action. The legislation of the relevant country clearly defines how this assessment should be carried out and confirmed. Depending on the legislation, it can be conducted either by the manufacturer or with the voluntary or mandatory involvement of a third party -(usually a Notified Body). Certification is always an evaluation of the conformity of the subject with a reference document conducted by an independent third party. Certification can be mandatory (required by law) or voluntary (chosen by the manufacturer).

  Conformity assessment always results in a declaration of conformity with the essential requirements. Certification ends with the issuance of a certificate. The certificate is not a declaration of conformity, but it can serve as the basis for the manufacturer to make such a declaration.

  When designing the features of a new product, we need to determine which features will be assessed in the conformity assessment process and incorporate them into our product accordingly. If our product is subject to certification requirements, we must also consider the features required by the Notifying Body.

  Typically, conformity assessment and certification are based on documents prepared by the manufacturer. Therefore, before placing a product on the market, we should carefully consider what documents will be required for the declaration of conformity and product certification and prepare them accordingly.

  In the case of marketing a product resulting from research in a scientific unit, it is the manufacturer's responsibility to obtain a conformity assessment and product certification. However, this does not relieve the research team of the obligation to identify the product characteristics to be assessed in these processes, as these characteristics must be integrated into the product during the laboratory testing stage and refined during the stage of increasing the product's readiness for implementation.

Each industry has typical market constraints. Just to give some examples, here it follows some of the most restricted ones:

- The most stringent restrictions apply to medical devices. Depending on their intended use, they are divided into classes related to the safety of their use and their potential effect on the patient's body. Each medical device must undergo a certification process specific to its class. Certification can only be successful if the tests show that the product meets all safety standards and has proven specific therapeutic properties. The requirements for medical devices are contained in the MDR Directive or Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
- Products used for the treatment of animals are subject to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medical products. Products used in cosmetics, on the other hand, are subject to Good Manufacturing Practices (GMP). GMP principles apply to all personnel involved in the production of the cosmetic, as well as to the premises and equipment of the production facility. GMP also places requirements on the raw materials used in production, the packaging in which the products are placed, and the way in which the cosmetics are stored and transported. Cosmetic products placed on the market must have a safety report and be notified to the CPNP (Cosmetic Products Notification Portal), a portal run by the European Commission.
- To market a new chemical compound, we must comply with the REACH directive, i.e., Regulation No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals and establishing a European Chemicals Agency: Registration, Evaluation, Authorisation and Restriction of Chemicals. The legislation applies to all chemical substances, not only those used in industrial processes, but also those used in everyday life, such as cleaning products, paints, clothing and household goods.

Chapter 2 - Commercialization of the Research Results

This chapter serves as a pivotal component of the STARS EU Technology Transfer (TT) Guide, providing a detailed framework for translating innovative Research and Development (R&D) outcomes into tangible economic value. The guide emphasizes that for an idea to become an innovation, it must have a concrete market application. This chapter outlines the essential steps and considerations for researchers, innovators, and commercializing entities, such as universities and research institutes, in navigating the journey from an innovative idea to its successful market application. It highlights the critical need for effective Intellectual Property (IP) management and well-defined contractual agreements to protect rights and establish clear relationships among all involved parties. The strategies detailed within this chapter directly support the broader objective of transforming Europe's R&D potential into economic growth and societal welfare by bridging the commercialization gap identified in key reports like Draghi's.

The chapter systematically breaks down the complex process of commercialization into various approaches, offering in-depth insights into both direct and indirect methods, the legal aspects of rights transfer, the intricacies of licensing, and the role of creator-entrepreneurs in launching new ventures.

The first introductory section **lays the groundwork by defining commercialization of R&D results**, explaining it as the transformation of these results into marketable products, technologies, services, or solutions that can generate profit. Section 2.2, building on the concept of direct commercialization, focuses specifically on the **assignment of rights**, which is defined as the process where a rights holder (e.g., a university or research unit) **transfers all its rights to the R&D results to a buyer**, making the buyer the sole owner. Concise Section 2.3 provides a direct comparison of the benefits and drawbacks associated with the assignment of intellectual property rights, examined from the perspectives of both the assignor (seller) and the assignee (buyer). Following, Section 2.4 presents **licensing as another crucial direct commercialization pathway**, defining a license as a contract that allows other entities (licensees) to use the R&D results developed by the commercializing entity (licensor). Finally, Section 2.5 explores the concept of the **creator-entrepreneur and indirect commercialization**, primarily through the establishment of new ventures such as spin-off and spin-out companies.

2.1 Direct and indirect commercialization

Commercialization of R&D results encompasses a broad range of activities, including the licensing or sale of intellectual property rights, the development of new products, and the establishment of new businesses (start-ups) or expansion of existing ones. The sources underscore that for innovations and research results to yield their full benefits, their access must be regulated, primarily through intellectual property rights (IPRs) or confidentiality agreements (know-how). Consequently, legal protection of innovations is deemed crucial for successful commercialization. This section highlights the necessity for commercializing entities to verify their legal entitlement to the results, whether through proprietary rights or rights of use, and to diligently maintain the secrecy of know-how if it is not protected by exclusive rights. It then categorizes commercialization into two main forms: **direct commercialization** (involving the sale or licensing of scientific activity results or related know-how to third parties) and **indirect commercialization** (involving subscription to or acquisition of shares in companies, such as spin-offs or spin-outs, created to exploit these results).

2.1.1 Commercialization of R&D results within STARS EU

Commercialization of R&D results involves transforming R&D results into marketable products, technologies, services or solutions that generate profits. This process includes all activities aimed at applying research results into business practices, such as licensing, selling intellectual property rights, creating new products, establishing start-ups or expanding existing businesses.

Commercialization of scientific research and development results refers to any activity aimed at using and making available the R&D results in such a way as to generate financial benefits on a market basis. An important aspect of commercialization is the collaboration between research organizations and enterprises, which maximizes the potential of science and innovation.

STARS EU, by its very design and stated objectives, **is uniquely positioned to significantly improve the commercialization of R&D results from its partner universities.**

Here's a reasoning of how (Figure 2.1):

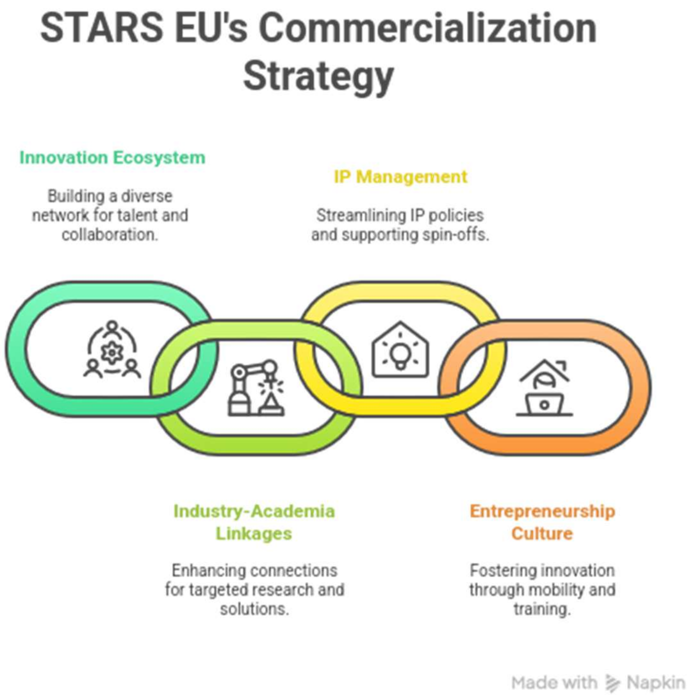

Figure 2.1: STARS EU's Commercialization Strategy

1. Building a Broader, More Diverse Innovation Ecosystem:

- **Expanded Talent Pool and Expertise:** Instead of nine individual university ecosystems, STARS EU creates a larger, interconnected network. This means a wider range of researchers, disciplines, and specialized knowledge is accessible. When seeking to commercialize an R&D result, a company or start-up within one region can potentially tap into expertise or complementary technologies from across the entire alliance.
- **Cross-Regional Collaboration Opportunities:** The alliance fosters collaboration not just among academics but also with regional stakeholders. This facilitates the "entrepreneurial discovery process" on a larger scale. A research breakthrough from one university might find its perfect commercial application in an industry cluster within another STARS EU partner region, due to their specific economic or social needs.
- **Shared Best Practices in Commercialization:** Universities within the alliance, even if they have varying levels of experience in technology transfer and commercialization, can learn from each other. STARS EU can serve as a platform for sharing successful strategies, models, and

intellectual property (IP) management practices, improving the overall commercialization maturity across the network.

2. Enhancing Industry-Academia Linkages:

- **One-Stop Shop for Industry:** For companies looking for R&D partners or innovative solutions, STARS EU can become a more visible and accessible point of contact than individual universities. A company can approach the alliance with a challenge, and the alliance can then identify the most relevant research groups or technologies across its nine members.
- **Targeted Thematic Interest Groups (TIGs):** STARS EU's focus on TIGs (e.g., Circular Economy, Digital Transition, Energy Transition, Sustainable Industry, Entrepreneurship and Innovation, Living Spaces, Arts and Creative Industries, Inclusion and Social Justice and Healthy Ageing) directly aligns with key industrial and societal challenges. This thematic focus allows for more targeted collaboration with industries operating in these sectors, facilitating the development of R&D results that have clear market relevance.
- **Challenge-Based and Applied Research:** The emphasis on challenge-based education and research within STARS EU naturally steers R&D towards addressing real-world problems. This increases the likelihood that research outputs will have practical applications and commercial potential, as they are developed with end-user needs in mind.
- **Joint Research Projects with Industry Involvement:** The alliance can actively promote and facilitate joint research projects involving academic researchers from multiple STARS EU universities and industrial partners from their respective regions. This co-creation process from the outset increases the chances of developing commercially viable solutions.

3. Streamlining Intellectual Property (IP) Management and Spin-off Creation:

- **Harmonized IP Policies (potential):** While challenging due to national legal frameworks, STARS EU could work towards developing common principles or best practices for IP management across its members. This would make it easier for companies to license technologies or for researchers to form spin-offs with cross-border implications.
- **Support for Spin-offs and Start-ups:** The STARS EU Konwledge & Technonology Transfer Office, in particular, can offer targeted support for researchers aiming to commercialize their findings through spin-off companies. This can include business development training, access to mentorship, incubation facilities (potentially shared across regions), and investor networks.
- **Access to Regional Funding and Investor Networks:** By connecting the innovation ecosystems of nine regions, STARS EU can facilitate access to a wider range of regional funding opportunities, venture capital, and angel investor networks, which are crucial for scaling up R&D results into successful businesses.

4. Fostering a Culture of Entrepreneurship and Innovation:

- **Student and Staff Mobility:** Enabling students, researchers, and faculty to move between partner universities exposes them to different regional innovation cultures and market needs. This broadens their perspectives and enhances their entrepreneurial mindset, making them more aware of commercial opportunities for their research.
- **Interdisciplinary and Cross-Sectoral Learning:** The alliance promotes interdisciplinary learning, which is crucial for innovation. By bringing together diverse academic fields, it can lead to novel solutions that combine scientific breakthroughs with market insights, increasing their commercialization potential.

- **Training and Mentorship:** STARS EU can develop joint training programs on commercialization, entrepreneurship, and technology transfer for its students and researchers, equipping them with the necessary skills to translate their research into marketable products or services.

In conclusion, **STARS EU's strength lies in its ability to multiply the resources, networks, and opportunities available for R&D commercialization beyond what any single university or region could achieve alone.** By fostering deeper collaboration, aligning research with market needs, and building a more interconnected innovation ecosystem, it directly contributes to generating financial benefits from scientific advancements across its partner regions.

2.1.2 What can be commercialized?

Generally, commercialization is a broad concept that encompasses various activities aimed at offering goods or services on the market to generate revenue. When referring to commercialization in the strict sense, the focus is on innovations or research results. Commercialization in this narrower sense involves developing a product or service based on research outcomes.

It must be noted that generally available knowledge or results cannot be commercialized (in a strict sense) as such. If an invention is not patented and can be freely used by any entity, a business will not be able to build a competitive advantage solely based on that invention. **The full benefits of innovations and research results can only be realized when access to such results is regulated, either through confidentiality agreements (know-how) or more importantly, through intellectual property rights. Therefore, the legal protection of innovations or research results is crucial for successful commercialization.**

Concerning Intellectual Property Rights (IPR), we refer our reader to the ***STARS EU IPR Guide*** for all detailed information related to this topic. To resume here, as a first step, before entering negotiations with a potential partner, it is essential to verify the legal status of the results. The transferor must be legally entitled to dispose of the results. Similarly, in the case of know-how, the commercialization entity must ensure that all individuals involved in its development are bound by confidentiality obligations. Therefore, it is important to establish and implement appropriate procedures for results handling and IPR and know-how management within such entities. Additionally, before entering into any contract, due diligence must be conducted.

The first condition that must be met for successful commercialization: the commercialization entity must be the owner of the property rights in the commercialized result/solution. Indeed, an entity may commercialize results to which it holds rights, either proprietary rights (as the owner) or rights to use the results to an extent that enables commercialization (e.g., through a license granting the right to sublicense). If the results are not protected under intellectual property rights, their value depends on their confidential nature. Therefore, the commercialization entity must act diligently to maintain their secrecy, as the commercialization potential depends on keeping them confidential.

Commercialization takes different forms depending on whether it is pursued by higher education institutions or business entities. Typically, commercialization conducted by HEIs is by national laws concerning the higher education system.

2.1.3 Ways of Gaining Ownership Over the Results

The methods for obtaining ownership of results depend on the type of intellectual property rights protecting them. The rules may differ depending on whether the result constitutes a patentable invention or a work protected by copyright. Furthermore, the type of contract binding the creator and the entity plays a crucial role, as the rules differ between employment contracts and commission contracts. It is vital to have the necessary agreements in place, clearly defined employment duties, and appropriate clauses included in commission or collaboration agreements. **General requirements for such contracts should be provided within the internal procedures concerning IPR management.**

It is important to emphasize that **moral rights** are non-transferable and therefore remain with the author or inventor. This is because moral rights shall be independent from the **economic rights** and shall remain with the author even after the transfer of the economic rights. Economic rights, however, may be transferred. The default rules governing the ownership of intellectual property rights in the context of employment or commission primarily depend on national law. Generally, the default rules on the ownership of the IPR apply automatically. However, the parties in most cases can modify the default rules by including relevant provisions in their agreement.

A general overview, at EU level, of default principles regarding the ownership of IPR is presented below. If, under the applicable law, the economic rights to research outcomes do not automatically belong to the commercializing entity, it must acquire those rights through an appropriate agreement.

At EU level: In general, the entitlement of an employer or commissioner to intellectual property rights developed under a relevant contract remains within the competence of national law. For example, the EPC states that if the inventor is an employee, the right to a European patent shall be determined in accordance with the law of the State in which the employee is mainly employed.

In the case of designs (*Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs*) and Community designs (C*ouncil Regulation (EC) No 6/2002 of 12 December 2001 on Community designs*), a general rule applies: if a design is developed by an employee in the execution of his duties or following the instructions given by his employer, the right to the design shall vest in the employer, unless otherwise agreed or specified under national law.

On the other hand, the rules determining the **right holder** to a computer program are harmonized by Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs. If a computer program is created by an employee in the execution of his duties or following the instructions given by his employer, the employer exclusively shall be entitled to exercise all economic rights in the program so created, unless otherwise provided by contract.

2.1.4 Paths for commercialization of R&D results

Commercialization can be undertaken by both the academic and industrial sectors. In the case of enterprises, commercialization primarily focuses on gaining financial benefits from their intellectual assets. This can be achieved by directly implementing R&D results into the business operations or by licensing or selling intellectual assets to other entities. There are **two main categories of commercialization: direct and indirect**.

These concepts are associated with both higher education institutions and business entities; however, the rules applicable to each sector differ (Figure 2.2):

- **Direct commercialization** is carried out directly by the university or other entity (for example enterprise) involving the sale of the results of scientific activities or related know-how, or granting their use to third parties through licenses, leases, or rental agreements
- **Indirect commercialization** is carried out by the special purpose vehicle involving subscribing to or acquiring shares in companies or subscription warrants giving the right to subscribe to or acquire shares in companies in order to exploit or prepare the exploitation of the results of scientific activity or the know-how related to those results.

Indirect commercialization is the creation of **start-ups (spin-off, spin-out)**. For example, employees of a university or research institute may create companies (start-ups) that use the research results to bring innovative products or services to the market. Start-ups use solutions developed at universities or research institutes, usually under license agreements.

Figure 2.2: Paths to commercialization

As explained above, solutions created by employees within their employment duties are the property of the employer (university or research institute). Therefore, the start-up must buy or license these solutions from the university, or the university may make an in-kind contribution of research results to a start-up (through a special purpose vehicle (SPV)) in exchange for equity in the start-up.

Any R&D results produced as a product of a joint collaboration of STARS EU partners will benefit from the accumulated experience of all partners, the established communication channels for experience sharing and, most importantly, the possibility of expanding the target markets of that collaboration.

2.2 Assignment of rights to the results: Direct Commercialization

This section offers a detailed examination of one crucial method for bringing Research and Development (R&D) outcomes to market, direct commercialization, becoming a core component of Chapter 2.

2.2.1 What is the result of R&D work?

The result of R&D work is the outcome of a research project carried out in a university, an enterprise or a research unit; this outcome can be intellectual property or know-how. The result of R&D work can be any result (tangible and intangible) product generated by the project, but **not all results may be suitable for commercialization.**

This full transfer of property rights to exploit the results commercially, allows the buyer to freely use the R&D results, including implementing the results in the market, modifying them, or granting licenses to other entities. The assignor (for example a university) loses the right to dispose of the solution, but usually can continue further research and development.

The sale of rights to R&D results may include the transfer of copyright, industrial property rights (such as patent applications, patents, utility models), and other forms of intellectual property to the buyer. From the buyer's perspective, purchasing the rights to R&D results allows for the full exploitation of their commercial potential.

A special case is the transfer of know-how: Know-how is technical or non-technical knowledge (commercial, administrative, organizational, financial) useful for conducting a particular type of business. Know-how is protected by keeping this knowledge secret and is not protected by an exclusive right. Its value derives from the limited accessibility of the knowledge. Therefore, it cannot be sold (in the strict sense) but can only be authorized for use in business activities through a know-how agreement.

2.2.2 Terms and conditions of contracts for the transfer of rights to R&D results

The formalization of an R&D results commercialization agreement is a complex process, requiring technical expertise and legal advice. Researchers do not have this training (nor should they), and the centres that own the results that must have the resources to deal with it. Mistakes at this stage can be catastrophic for all parties involved, with a high impact for universities in terms of reputation and researcher confidence that can affect future projects.

The contract for the transfer of rights to R&D results must clearly define the scope of the rights transferred to the buyer and the obligations of both parties. Here are the key issues we may pay special attention to in a transfer contract::

- **Form of the agreement:** Under national laws, it may be required that an assignment of intellectual property rights (e.g., industrial property rights, copyright, plant variety rights) be in written form to be valid. Such a requirement is typically imposed by the applicable national law governing the specific category of intellectual property rights.
- **Representations of the parties:** The representations of the parties' section in an assignment agreement usually includes key statements and guarantees made by the parties. The assignor may declare that they have full legal authority to transfer the R&D results, that the results are original, and that they do not infringe the rights of third parties. If an application for granting a right has been filed, the assignor may declare that the application has been duly submitted and is pending before the relevant patent office. The assignee may affirm that they have conducted their due diligence on the transferred right and accept its current status. In the case of an application for a right, the assignee may confirm that they are aware of the uncertainty regarding the granting of the right.
- **Subject matter of the contract:** The precise definition of the subject matter of the contract is very important. The contract must precisely define the research results being transferred. If research results are protected under intellectual property rights, the transfer of rights should be explicitly stated in the agreement. It is worth emphasizing that transferring tangible goods, such as a work or a prototype, does not include the transfer of intellectual property rights, such as copyright or the right to obtain a patent.

  If the subject of the contract is an industrial property right application or an already granted right, the relevant application documents should be annexed to the contract. In the case of industrial property rights, the assignment concerns the entire right within the relevant territory where the right is granted. This contrasts with a license, which may allow the use of the right in a limited way, for example, within a specified territory (region), or within a particular sector.

  Regarding copyright, each economic right to a work may be transferred separately. In some countries, a transfer agreement must specify each economic right individually for the transfer to be valid. Moreover, each right may be transferred within a specified territory, for a specific application, or within a particular sector.
- **Remuneration:**
  - ***Lump sum fee*** - In most cases, the sale of rights to R&D results involves a one-off payment of a fixed amount. The fee depends on the potential market value of the results, the cost of the research, and the chances of commercialization.

- *Staged or additional payments* - in some cases a staged price is set or the buyer may commit to additional payments based on the success of commercializing the results.

• **Indication of the moment of transfer of the R&D results:** The moment of the transfer of rights may be specified in the agreement. For example, from the seller's perspective, it may be convenient to stipulate that the transfer of rights occurs at the moment when the full remuneration for the transfer is credited to their bank account. On the other hand, the assignee would prefer that the transfer of rights occurs at the moment of signing the contract.

• **Creators' rights:** Creators of R&D results (e.g. an inventor or an author), such as scientists who have contributed to the invention, retain their moral rights. This means that they have the right to be named as the creator of the invention or work, even if they transfer the ownership of rights to another party. An obligation to respect such rights may be included in the agreement, which may also specify the manner of their implementation (in a manner formally accepted by the creator). While moral rights are not transferable, they may be subject to certain obligations.

For example, the right of first communication to the public may be addressed in the agreement through a relevant statement by the author, agreeing that the assignee may choose the timing and circumstances of such communication. Another example may be the obligation to refrain from exercising moral rights related to supervision over the work. Moral rights are not harmonized at the EU level; both examples provided are based on the Polish legal framework.

• **Possibility of using the subject matter of the assigned rights by the assignor:** The contract usually provides for the transfer of full economic rights to the R&D results to the assignee (buyer), meaning the assignor does not retain any rights to exploit the results commercially. If the assignor wishes to use the work or invention to which the rights have been assigned, they must be authorized by the new owner of those rights. This is usually done through a so-called back license. As a consequence, the IPRs are transferred to the acquirer, and the acquirer grants a license to use those rights to some extent to the seller. For example, a small enterprise may transfer a patent to another entity while still produce and sell goods incorporating a patented invention in the current scale and territory.

It must be underlined that **most national laws allow the use of protected intellectual property for purposes not related to commercial exploitation.** This possibility arises from the scope of protection granted to a given type of IP. For example, depending on national law, a patent usually grants an exclusive right to commercially or professionally use an invention, while copyright provides a monopoly over specific activities such as reproduction, distribution, and communication to the public. Therefore, activities not covered by these exclusive rights are generally permitted.

Moreover, each legal system expressly defines exceptions and limitations to intellectual property rights, such as: private or non-commercial use; experimental use or scientific research; exhaustion of rights; fair use in copyright.

As a result, a given work or invention may be used based on a specific exception provided by law. For example, a patented invention may generally be used for research and experimental purposes without requiring authorization. However, a university or research institution may additionally include provisions in the contract allowing further use of the solution for scientific or teaching purposes.

• **Maintenance of protection:** The contract may include provisions for further patenting of the invention or maintaining its protection. The assignee steps into the seller's shoes and assumes the obligations related to the procedure for granting the intellectual property right and its maintenance. The buyer is required to pay for relevant fees and other costs associated with intellectual property protection.

- **Infringement clauses:** The contract may outline actions to be taken if third parties infringe on the rights to the assigned IP. The buyer may be required to take legal action to protect its rights and the seller may be required to cooperate in such situations.
- **Maintaining confidentiality:** A contract for the transfer of rights to R&D results often includes confidentiality clauses regarding the technology and information relating to the invention, especially in situations where the sale involves results that have not yet been patented.
- **Further development of the technology - research cooperation:** In some cases, agreements may provide for further cooperation between the parties in the development of the technology. Typically, the implementation of the technology will require implementation assistance from the inventors, which may involve research or consulting cooperation.
- **Penalties and termination clauses:** Penalties for breach of contract: The contract may provide for financial or other penalties in the event of a breach of contract, if one of the parties fails to meet its obligations (e.g. deadlines for providing additional documentation, confidentiality).
- **Rescission of the contract:** The assignment is a transfer agreement with a permanent effect. Unlike licenses, the termination of an assignment is possible only in rare cases, as governed by national laws. However, the agreement may include provisions specifying the conditions under which the contract may be "cancelled", such as failure to pay the contractual remuneration. Any such possibility should be linked to a clause defining the moment of the transfer of rights.

- **Change in the relevant register:** In the case of registered rights (e.g., patents, design rights), it may be necessary under national laws to record a change in the relevant rights register for the agreement to be effective against third parties (not involved in the assignment). Notification to the registry is usually made by the assignee, as disclosing information about the new rights holder in the register serves their interest.

Here we resume all these terms and conditions in Figure 2.3.

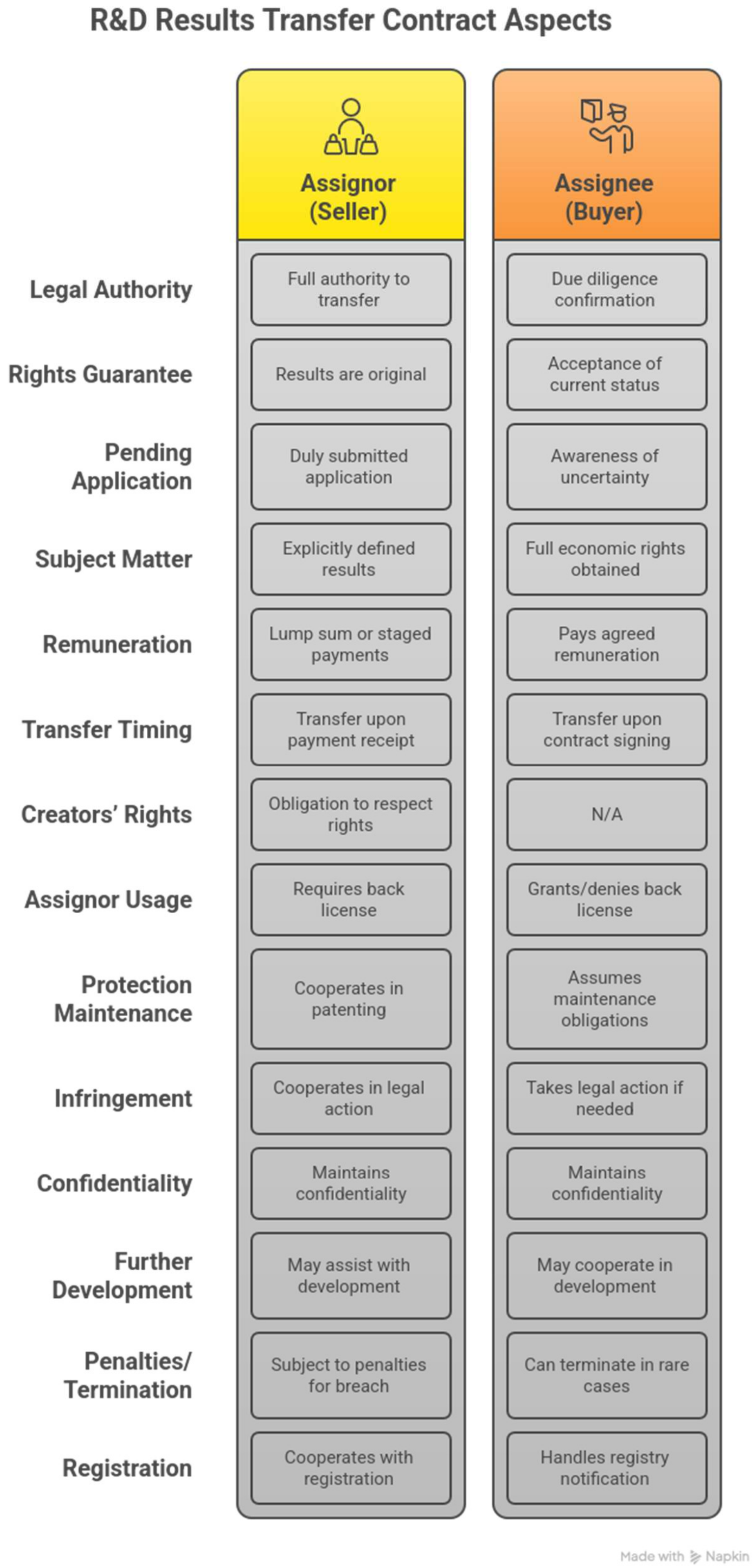

Figure 2.3: Terms and conditions

2.3 Advantages and disadvantages of an assignment

Just selection of the main advantages and disadvantages on any direct commercialization process. This list appears always in any negotiation to complete the costs.

Assignor (seller)	Assignee (buyer)
The seller receives the full payment upfront, providing immediate financial benefits.	The buyer obtains all rights related to the IP, allowing full control over it, including modifications, sales, or licensing.
The seller is relieved of the responsibility of managing intellectual property rights and maintaining legal protection.	If the IP generates high future revenues, the buyer does not have to pay royalties to the seller.
The original owner loses all rights to the IP, which could be disadvantageous if the IP proves to be highly profitable in the future.	An IP transfer agreement usually requires a one-time, often substantial payment, which must be proportionate to the potential value of the IP.
The transaction is typically irreversible, meaning the seller cannot reclaim rights even if business circumstances change.	The buyer must manage intellectual property, including maintaining legal protection (e.g., renewing patents or trademarks).

2.4 License agreement in direct commercialization

This is a critical issue in direct commecialization, everything disussed is converted in a fact by the licence agreement. We again submit the reader to our STARS EU IPR Guide, but for completenessof this STARS EU TT Guide, here are the fundamentals of this topic. Again, recall that all these procedures must be done by technical staff and legal assistants.

2.4.1 What is a License?

A license is a contract that allows others to use the results of R&D developed by the commercializing entity (e.g., a university or research institute). Under the license, the entrepreneur gains the right to manufacture and market products based on the licensed solution. In this way, the rights holder shares the risks and benefits of exploiting the results with one or more licensees. A license agreement is concluded for a specified period of time.

The results of research and development (R&D) are often protected by intellectual property rights such as patents, utility models or copyrights. To enable their use in business practice, licenses may be granted to allow others to use these results under certain conditions. There are several types of licenses, varying in the scope of rights and conditions of use.

2.4.2 License types

We consider six types, but keep in mind that new technologies or markets can generate hybrid types or new ones.

• **Full license:** A full license means that the licensee has the right to use the licensed solution to the same extent as the Licensor (owner). A full license means that the licensee is granted the right to use the invention, technology or R&D results to the full extent provided for in the legal protection (e.g. in a patent or copyright). In practice, the licensee can use the invention to the same extent as the owner (Licensor) and the Licensor does not restrict this use.

Example: The university grants the company the right to fully exploit the invention in production, sales and further development, covering all economic sectors and markets.

• **Restricted (incomplete) License:** A restricted license limits the extent of the licensee's right to use the technology in relation to the Licensor's rights. The license agreement specifies the areas of restriction. Restrictions may relate to subject matter, time or territory. A restricted license may provide that the invention may only be used in a particular industry (e.g. medicine), for a specific activity (e.g. solely for production, excluding the right to trade the products) or in a particular territory (e.g. Europe). The period of use may also be limited, e.g. to a few years.

Example: The company receives a license to use the technology only in a specific sector, such as medical device manufacturing, for a period of 10 years.

• **Exclusive license:** An exclusive license gives the licensee the exclusive right to use the invention or R&D results to a certain extent. This means that the Licensor is not allowed to license the same invention to others or to use the invention itself within the agreed scope. The licensee becomes the only entity that can use the invention in a particular field (e.g. geographical area) or industry. By granting an exclusive license, the Licensor loses the right to further exploit the invention within the specified scope.

Example: The university grants the company an exclusive license to use the technology to produce the new material exclusively for the construction industry in Europe. The university may not license the same invention to other companies or use it itself in this field (e.g., provide services based on the licensed patent).

• **Non-exclusive license:** A non-exclusive license is a license that allows the licensee to use the invention, but at the same time allows the Licensor to license others and to use the invention itself. A non-exclusive license does not give the licensee a monopoly on the use of the invention. This means that the Licensor can continue to use the invention himself and license others.

Example: The university grants non-exclusive licenses to several companies to use the invention in the same regions or sectors, while continuing to provide services based on the licensed patent itself.

• **Implied license:** A license that arises from the conduct of the parties rather than from a formal contract. The possibility of granting an implied license must be based on national law. This is a situation where the licensing party implies that the licensee has the right to use the invention even though no formal license agreement has been signed. For example, if national law recognizes the concept of an implied license, such a license might be granted when a university conduct research under an R&D contract. In the absence of other provisions in the contract, the client may receive an implied license to use the results of the R&D covered by the contract. It should be noted that the client does not become the owner of these results, but only has the right to use them in its business.

An implied license may arise, for example, from a long-standing collaboration between the parties where one party provides the technology and the other uses it, although there is no formal agreement.

• **Sub-license:** A license granted by a licensee to a third party to use an invention or technology on the basis of the main (primary) license obtained. Sub-licenses may only be granted if the primary license provides for this possibility. The scope of the sublicense is restricted by the scope of the primary license.

A licensee who has obtained an exclusive or non-exclusive license may grant sub-licenses to others if authorised to do so by the Licensor. In a sublicense contract, the licensee of the primary license assumes the role of a Licensor. A sub-license is usually subject to the same restrictions as the main license.

Example: A company that holds a license to a patented technology sublicenses it to another company so that it can manufacture products based on that technology in a region that it does not directly affect.

2.4.3 Specific cases of licenses

Beyond the type of exclusivity, licensing agreements can be shaped by various factors and specific circumstances (Contextual Factors Influencing Agreements):

- **Trial license:** A trial license gives the user the right to temporarily test or use the results of the R&D work (e.g. software, technological prototype, tool). It is intended to enable a potential licensee to assess the functionality, usefulness or effectiveness of the invention or software to the full extend before deciding whether to purchase or fully license it. It is usually of limited duration and may also be limited in scope. Under a test license, the licensee may not commercially exploit or profit from the technology.

- **Demo license:** A demonstration license is a license granted to demonstrate the capabilities of a technology or product in a limited or specially prepared version for demonstration purposes. Its purpose is to demonstrate the capabilities of the technology to potential customers, investors, or partners without granting full access to the technology or the ability to implement it. This is typically a license used for marketing purposes, e.g. at trade shows, exhibitions or customer presentations. In the case of R&D work, a demonstration license may show the capabilities of an invention, but without full functionality and without access to the source code.
- **Conditional license:** A conditional license is a license granted subject to certain conditions. As a consequence of fulfilling the condition, the agreement may come into effect (condition precedent) or, alternatively, may result in the termination of the agreement (condition subsequent). For example, a license may be granted subject to the successful completion of tests, the obtaining of relevant certificates or the achievement of certain commercial results. Another example would be a license conditional on subsequent development or implementation work.

2.4.4 Terms and conditions of license contracts

As with any legal procedure, terms and conditions of contracts are relevant. Here are the basic points on this issue (Figure 2.4):

- **Representations of the parties:** The representations of the parties section in a license agreement, as in the case of an assignment, includes key statements and guarantees made by the parties. The Licensor should declare that they have full legal authority to license the R&D results and that executing the agreement does not infringe on the rights of third parties. The licensee may affirm that they have conducted their due diligence on the licensed right and accept its current status.
- **Subject matter of the license:** As with assignments, the precise definition of the subject matter in a license agreement is crucial. The licensed rights must be clearly identified. For instance, if the right to a patent application is the subject matter of the license, details such as the application number, filing date, and the relevant patent office should be specified, and the application should be annexed to the agreement. Similarly, if the subject matter of the license is know-how, a detailed description of the confidential information should be included as an annex to the agreement.

- **Scope and duration of the license:** As explained above, a license may be limited in various ways, making it essential to define the scope of the license with precision. The agreement should specify the territory, exclusivity, duration, and other limiting factors, such as the designated sector or specific activities (e.g., production, marketing, or distribution of products). In the case of industrial property rights (such as a patent), unlike in the case of an assignment, a license can be limited to very specific activities.

  A license cannot be granted for a period exceeding the duration of the underlying intellectual property right (e.g., after a patent has expired). However, certain obligations may extend beyond this period, such as the exploitation of know-how that complements the core patent license or the provision of services accompanying the license. In such cases, it is crucial to clearly define the remuneration for each component of the license separately to ensure transparency and proper allocation of payments.

The agreement should explicitly specify the type of license granted, for example, an exclusive license, a sole license, or a non-exclusive license. The type of license granted may be deduced from the terms of the agreement; however, it is always better to state it explicitly to avoid any doubts.

A license is a fixed-term contract whose duration is limited to the duration of the licensed right (for example, a patent or copyright). If the licensed right expires, the agreement loses its subject matter and terminates. However, license agreements may include certain clauses that remain in effect beyond the expiration of the right, such as confidentiality, or reporting.

It is also possible for a license to partially expire. For example, if several patents are licensed and one of them expires, the license may still remain valid for the other patents. Similarly, if a license covers both a patent and know-how, the license may expire for the patent while remaining valid for the know-how.

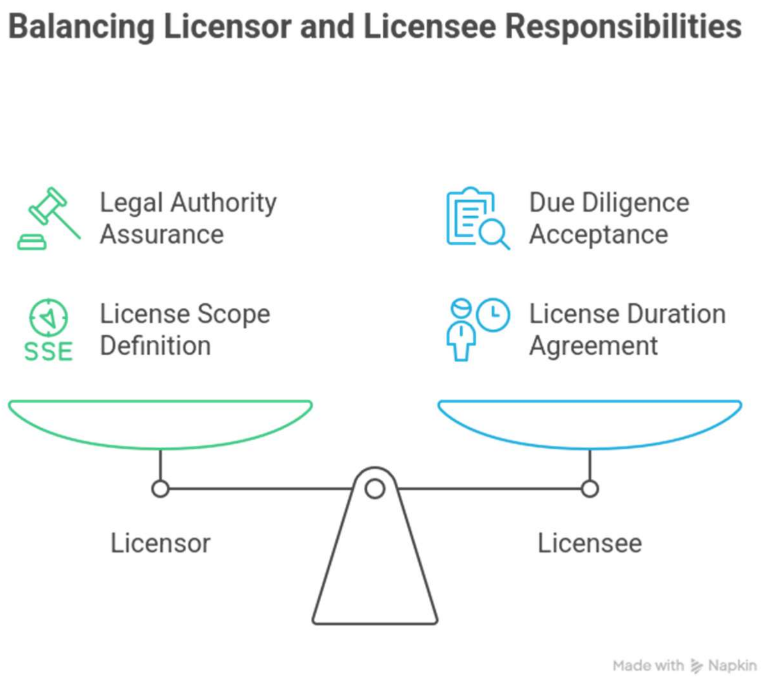

Figure 2.4: Terms and conditions of license contracts

2.4.5 Remuneration: Types of royalties

Royalties in license contracts are one of the key elements that determine the terms of use of the technology by external parties. Setting these royalties is a complex process that depends on several factors, such as the commercialization potential of the R&D results, their uniqueness or breakthrough nature, and how they can be used by the licensee. The license agreement should precisely specify the method for calculating royalties, payment deadlines, and any reporting requirements the licensee must fulfill to ensure transparency regarding the contractual remuneration.

Here is an overview of the types and principles of royalty setting:

- **Initial fee:** This is a one-off fee (lump sum) paid at the start of the license agreement (initial down payment). It usually represents compensation for the transfer of the right to use the invention. Determined on the basis of the market value of the invention, the expected profits and the research and development costs incurred by the Licensor.
- **Periodic payments:** Regular payments, which may be based on specific dates (e.g. annual fees) or on the achievement of specific milestones in the development or commercialization of the invention. They work well for long-term projects where the invention requires further development or adaptation before full commercialization. Usually, recurring payments are structured as percentage-based royalties or per-unit fees; however, it is rare for parties to agree on recurring lump sum payments.
- **Percentage-based royalties:** A fee calculated on the basis of a percentage of sales of products or services using the licensed invention. Most commonly used in agreements where the licensee makes and sells products using the invention. It can be set as a percentage of net sales (e.g. 5% of net sales). Typically ranges from 1% to 10%, but can be higher for very innovative and unique technologies; the level of royalties depends on the industry in which the technology is used.
- **Per-unit royalties:** Per-unit payments are fixed amounts paid by a licensee to a Licensor for each defined quantity (unit) of products (or services) that are produced, marketed, or sold, or otherwise used, as defined in the agreement.
- **Minimum fees:** Minimum amounts that the licensee must pay regardless of the amount of actual sales. They protect the Licensor from a situation where the invention generates no revenue. They provide the university with a minimum return on its research investment, even if commercialization is slower than expected. Their value depends on the market value of the invention and the expected revenues of the licensee.
- **Fees for sub-licenses:** If the license permits the licensee to grant sublicenses, the parties should clearly define the terms under which a sublicense may be granted, particularly the conditions regarding royalties owed to the primary Licensor as a result of the sublicense. These royalties ensure that the original Licensor receives a share of the revenue generated from the sublicenses. The amount typically depends on the terms set forth in the primary license agreement and the anticipated revenues from the sublicense. Such fees may be defined as a fixed amount, a percentage of the revenue generated by the sublicensee (royalty-based), or a combination of both.

The first step in determining royalties is to value the technology. There are a number of factors to consider when setting fees:

- **Technology Readiness Level** (TRL) - the higher the TRL, the higher the value of the license;
- **Competitiveness and uniqueness of the invention** - the more unique and difficult to substitute, the higher the market value;
- **Potential market** - licenses for inventions that are likely to be widely used in a large market will have higher fees;

- **Risk sharing** - Universities sometimes use flexible royalty models that depend on the success of commercialization. For example, they may charge lower initial fees and higher fees if the licensee achieves high sales returns;
- **Research and development costs -** fees should be set at a level that allows the university to recover at least some of the costs associated with developing the invention. This includes both direct research costs and the cost of legal protection;
- **Innovation-related clauses** - some agreements may include clauses for further development of the invention or joint research with the licensee, which may affect the fee structure.

Fees may vary depending on license type:

- **Exclusive license:** usually involves higher fees because the licensee has the exclusive right to use the licensed R&D result.
- **Non-exclusive license**: If the license is granted to several parties, the fees may be lower because the invention is available to a wider group of companies.
- **License term:** long-term licenses may have lower annual fees but higher one-off fees.

In summary, setting royalties is a complex process that requires a thorough understanding of both the potential of the technology and the financial capacity of the licensee, as well as a flexible approach to negotiation that takes into account the interests of both the university and the commercializing companies.

2.4.6 Obligations of the Licensor and the licensee

The license agreement should clearly define the obligations of both parties. The Licensor is typically obligated to:

- provide the licensee with the necessary documentation to implement the licensed technology,
- maintain the legal protection of the licensed technology (e.g., by paying patent maintenance fees),
- defend the licensed IPR against third-party infringements and validity challenges (e.g., in cases where a third party files for patent invalidation).

The Licensor may provide additional services, such as assistance with the implementation of the technology, conducting additional tests, or offering consulting services. Any of these activities may affect the contractual remuneration.

The licensee, on the other hand, generally commits to:

- take the necessary steps to successfully commercialize the licensed technology,
- maintain transparent financial records and grant the Licensor access to those records when required,
- use the licensed IPR strictly in accordance with the provisions of the license and avoid exceeding its authorized scope,
- inform the Licensor of any detected infringements of the licensed IPR.

If the parties decide to grant the licensee the right to conclude further licenses with third parties (sublicensing), the agreement must include clauses explicitly stating this right. In such a case, the royalties derived from sublicensing should be defined, and relevant reporting clauses should be included.

The license agreement may also impose additional conditions or restrictions on sublicensing. For instance, the license agreement may limit sublicensing to specific geographical regions or impose quality control standards on sublicensees to ensure compliance with the original license agreement.

The agreement may include provisions for penalties in the event of a breach of contract. Such penalties serve as an additional sanction to encourage the parties to fully comply with the terms of the agreement. For instance, the parties may agree that the Licensor will be entitled to a penalty if the licensee fails to take all the necessary steps (as defined in the contract) to implement the technology.

2.4.7 License termination

National laws may impose restrictions on the termination of fixed-term contracts, such as a license agreement. Typically, both parties are entitled to terminate the agreement under certain circumstances provided by law, such as a breach of contract by the other party.

The license agreement should clearly define the conditions for its termination and outline the resulting consequences. Termination generally requires an official notice. The contract should specify a notice period, meaning that the license will terminate after a defined period of time following the delivery of the termination notice to the other party. Contractual provisions may also allow for termination throughout the license's duration without the need to meet specific conditions. Conversely, the ability to terminate may be subject to limitations. For instance, the parties may agree that the Licensor may terminate the agreement if the licensee fails to bring a product implementing the licensed invention to market.

2.4.8 Advantages and disadvantages of licensing

Licensor	Licensee
Stable licensing income.	Access to innovative technologies without the need to develop them in-house, reduction of costs.
Strengthened relationships with industry, market expansion – allows the Licensor to enter new markets.	Reducing time to market.
Increased scientific visibility and potential research partnerships.	Formalities regarding the maintenance of IP protection burden the Licensor.
The Licensor retains IPR and, depending on the type of license, may continue using the licensed IP in its own business or even license it to multiple entities.	No need to pay remuneration equal to the value of IP upfront.
Contract management, ongoing compliance monitoring, enforcement, etc.	Usually, there is a possibility to terminate the agreement if the license is not profitable or no longer needed.
	Higher risk due to dependence on the Licensor, who remains the owner of the IP.

2.5 Creator and entrepreneur: indirect commercialization

A common practice among universities and growing companies seeking new revenue streams and market opportunities is the creation of **spin-offs**. This solution has many advantages, as smaller units, separated from the organizational structure of the main business unit, can focus on specialised areas of activity or actively acquire new customers. This model is often used to implement research and development, innovative solutions, new products or services.

Historically, spin-offs have been for decades the Holy Grail of universities. Universities spin-offs are the maximum goal of their Third Mission (Transference), since generate revenues, create jobs, attract talent and promote economic diversification on regions of influence, by development of knowledge-based business. We present its definition in a highlight framework:

> *Generally a **spin-off** is a company that is separated from a parent organization (company, university, research center,...) in connection with its research and development. Such an entity has a certain degree of autonomy and the parent company must agree to its creation. The new entity is often legally and economically separate from the parent company.*

This model also works well in the public sector. However, in order to avoid financial and economic risks, universities or research institutes carry out this task through special purpose vehicles (SPVs), i.e., separate entities set up by the research unit to carry out **indirect commercialization.** Thanks to this procedure, the university or research unit is not burdened with the financial and economic risk associated with the development and implementation of innovative solutions.

As we discussed earlier, **indirect commercialization** involves acquiring shares or subscription warrants in companies. This is done with the aim of implementing, or preparing to implement, the results of scientific research or related know-how through these companies.

For these aims, it is useful to create a Special Purpose Vehicle (SPV) (or Special Purpose Entity (SPE))[1], a limited liability company or limited partnership established for a specific, narrow or temporary purpose and to exclude financial, special tax or regulatory risks. The main purpose of the SPV is to create and acquire shares in spin-off companies created to exploit R&D results or know-how developed at the university or in scientific and research units.

2.5.1 Firms creation from universities

In the core of STARS EU aims, entrepreneur initiatives from research results are of special interest, align with mission and vision of generation the major regional impact.

There are two types of businesses from universities and research institutes. Both types of companies provide an excellent opportunity for the successful implementation of innovative technologies developed by scientific researchers. They differ in the degree of linkage between the company and the university.

[1] Regulation (EU) No 549/2013 of the European Parliament and of the Council of 21 May 2013 on the European system of national and regional accounts in the European Union Place of publication: (OJ EU L 174, 26.06.2013, p. 1, as amended).

Choose the appropriate commercialization strategy for your technology.

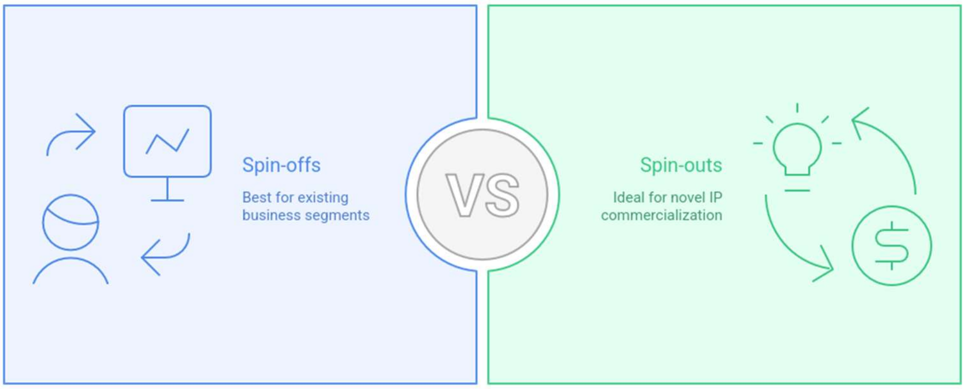

Figure 2.5: Spin-off vs Spin-out

The first type is a **spin-off** company, which is organizationally, formally, or legally dependent on the parent company:

> *A **spin-off** is a company created by at least one academic staff member, doctoral candidate or student for the purpose of commercializing and implementing technologies developed at the higher education institution and which is dependent on the parent company in organizational, formal legal, financial or infrastructural terms. A company set up in this way may use the intellectual property of the higher education institution on the basis of a relevant licensing agreement, a sales agreement or an in-kind contribution to the company*

The second type is a **spin-out** company, which is completely independent of the parent company.

> ***A spin-out** is a company set up by at least one university employee, postgraduate or student to commercialise and implement the university's intellectual property independently of the parent company. Although a spin-out usually has no personal or capital links with the university, cooperation between them is usually established on market terms. It may use the university's intellectual property on the basis of a licensing or sales agreement.*

Both types of enterprise are created by researchers in order to commercialise an invention or technology developed in the research unit.

With the help of these companies, the university research unit can commercialise the results of its research and thus attract new investors. Such a company uses the intellectual property of the parent company based on a separate agreement that defines the principle of use of the intellectual property. This may be a licensing agreement, a sales agreement or, in the case of a spin-off company, the university/research unit may contribute this property in kind to the company.

The choice of the appropriate business model is entirely individual and depends on market, capital and human factors. We study in detail each type.

2.5.2 Spin-off company

It is important to remember that the process of creating a spin-off requires a great deal of effort. First of all, it is necessary to identify the strategic objectives of the company, develop a business plan for the company, and identify sources of funding until revenues are generated from the implementation. In most cases, the spin-off will be a public or private limited company.

The creation of an academic spin-off company by a scientist or a team of scientists, working on a topic in which they have strong expertise, is a proposal that often appears in commercialization strategies and funding programmes for innovation projects (at regional, national and European level). This model of commercialization has a number of advantages, but it can also be challenging.

Many of the companies created by scientists do not succeed in the market, or face various difficulties, but this is not different with any other area of business. Any entrepreneur projects need many requirements and an opportunity window (related with product, market, customers, etc) to success.

In such an entrepreneurial projects (usually also called start-ups), the originator/researcher always has the main substantive role, but is often required to have the business skills necessary to manage and develop the company properly. At the beginning it counts with the help of its own home university, but once it is created, the founders have to address the trip alone.

Advantages of the spin-off company as a commercialization vehicle:

- Easy to open and close;
- Focus on a single research theme and the resulting product;
- The high level of expertise of the team facilitates a flexible approach to the product and its adaptation to market trends;
- Ability to apply for funding for product development through start-up support programmes offered by external institutions;
- Simple business funding model;
- Ability to attract investors who are not interested in investing capital in universities. Spin-offs are easily supported by so-called business angels, in contrast to R&D work carried out directly by universities;
- Possibility to sell the company to an investor or another entrepreneur.

Disadvantages of the spin-off as a commercialization vehicle:

- The need to manage not only the ongoing project but also the company as a whole;
- The need to obtain funding;
- Difficulties in maintaining a positive cash flow (as with any other business);
- The need to meet public and legal obligations specific to the given business;
- When a spin-off company employs staff, it must comply with all employer obligations and labor law requirements, which constitutes an additional burden.

Spin-offs change the life of researchers: not everybody is ready

Running a spin-off company requires much more work and time than developing a new technology or product. Often, after setting up a spin-off company, researchers find that they are no longer able to devote themselves fully to their chosen research topic because running the company involves solving problems that they do not encounter in their work at the university or research centre.

In addition to day-to-day organizational matters, they have to keep the company's accounts in accordance with the accounting laws, prepare periodic financial statements, pay public and legal obligations such as social security contributions and taxes, monitor and service the market of suppliers, distributors and customers, manage production, carry out marketing, formulate a correct pricing policy, provide warranty and after-sales service.

The number and variety of management processes required depend on the size and nature of the business. The founding scientist of the spin-off, who is a specialist in their field, usually does not have sufficient management skills to carry out all these tasks alone. It is usually necessary to bring in several additional people with skills in different management areas. If these people are hired on the basis of an employment relationship, the management of the company has an additional, very important function - that of the employer.

As an employer, the academic spin-off must implement a human resources and payroll policy that complies with the regulations, e.g. pay salaries regularly, at the agreed time and in the agreed amount, along with taxes and social security contributions, if applicable, and ensure employees' rights. In addition to these activities, there is the process of fine-tuning the product and bringing it to market, as well as monitoring and responding to audience behaviour.

Before setting up a spin-off company, the researcher should make a thorough analysis of all the pros and cons, to ensure the decision does not become too much of a physical and emotional burden. Here, universities' training programms help researchers (especially for young ones) to understand and think about the spin-off process. Thus, the construction of a leadership and mindset is a longer process which facilitates the spin-off creation and success.

Business areas recommended for commercialization through a spin-off company:

- When there is a need to attract an investor to increase the technological readiness of a product, e.g. when companies providing funding for pre-implementation work require a start-up to be established with their participation, with the intention of selling their shares after a period when the technology has reached TRL 9;
- When applying for funding for an R&D project to further develop a product, e.g. when a business partner for implementation cannot be found;
- For niche activities where it is difficult to find a business partner with expertise;
- For products of common use that do not require sophisticated methods and tools to produce, so-called low-investment products;
- When we offer a service that is very innovative but requires much more intellectual investment than fixed assets and real estate;
- When the service or product is aimed at a closed, defined audience;
- When the service has outsourcing characteristics.

Commercialization through a spin-off company is not recommended for sophisticated products and technologies:

- Significant financial outlay without the possibility of attracting an investor;
- Extensive infrastructure;
- Extensive human resources;
- Ownership of production lines;
- Audits and costly certifications.

In summary, spin-offs are small companies with up to 10 employees. They are mainly active in high technology areas such as pharmaceuticals, medicine, microbiology, chemistry and biotechnology. Most spin-offs are created in the United Kingdom, Finland and the United States. These micro-enterprises are most often associated with academia, but are also created by research and development institutions and private companies.

2.5.3 Spin-out company

A **spin-out** refers to the creation of a new, independent company that is formed to commercialize precise intellectual property (IP), research, or technology developed within a larger organization, such as a university, research institution, or even a corporate spin-off. The key is that this new company is built specifically around that innovation, whereas the spin-off is usually created around an expertise and know-how (from researchers) and several technologies combined.

In the literature discussing the concepts of spin-offs and spin-outs, it is possible to find a situation where these definitions are often used interchangeably as synonyms or the exact opposite. This is likely due to the fact that both are companies whose purpose is to exploit the intellectual property of the parent organization.

In summary, the choice of the most appropriate form of spin-off depends on the degree of dependence that the founder-creator wishes to have on the parent organization. However, it is clear that both types of companies can be used successfully to commercialise research and scientific and development work.

While there can be overlap in usage, especially when a corporate R&D lab creates a new company around its IP (which some might call a "corporate spin-out"), the clearest distinction lies in the **origin and purpose**: spin-offs are about carving out existing parts of a business, while spin-outs are about creating new ventures specifically to exploit novel intellectual property.

2.5.4 Creator's remuneration

The remuneration of researchers from royalties generated by licensing their R&D results is a complex but crucial aspect of university intellectual property (IP) policies. It aims to incentivize innovation, recognize the contributions of inventors, and encourage the transfer of knowledge from academia to the marketplace.

If the rights to research outputs do not belong to the authors or inventors and are commercialized by another entity, such as an employer or commissioner, the authors may still be entitled to additional remuneration. This possibility is regulated by national laws and may be contingent on the success of the commercialization. The default rules regarding the remuneration of inventors or authors are determined by national law. Some of these default provisions can be modified through contractual agreements. However, each national legal system may include mandatory provisions (ius cogens) that cannot be altered or overridden by the contracting parties.

Once a technology developed at a university is successfully licensed to a company and generates revenue (e.g., upfront fees, milestone payments, or running royalties based on sales), the university's IP office (often called a Technology Transfer Office or TTO) collects these funds. The distribution usually follows a hierarchical model:

- **Recoupment of Costs:** The first portion of the revenue is typically used to **reimburse the university for its direct costs** associated with protecting and commercializing the IP. This includes:
  - Patent filing and maintenance fees (which can be substantial).
  - Legal expenses related to licensing negotiations.
  - Costs incurred by the TTO in marketing and managing the IP.
  - Sometimes, even a portion of the indirect costs of research are factored in.
- **University Share:** After costs are recouped, a significant percentage of the remaining "net revenue" is retained by the university. This share helps support the TTO's operations, fund further research, provide general institutional support, and sometimes directly benefit the departments or schools involved in the research.

- **Inventor Share (Researcher Remuneration):** The remaining portion is then distributed to the inventor(s) and their associated departments/schools. This is the direct financial remuneration for the researchers.

Chapter 3 – Science-to-Business (S2B) partnership

Science-to-Business partnership is fundamental to achieving the guide's central aim: **transforming Research and Development (R&D) potential into tangible economic growth and societal welfare**. Building upon the critical insights from Draghi's report, which highlights Europe's persistent innovation and commercialization gaps, and integrating the transformative principles of Open Innovation, this chapter provides a comprehensive framework for **establishing and managing collaborations between scientific institutions and businesses**.

The chapter's core premise is that the **successful implementation of R&D results from a university must take place in collaboration with an industrial partner**. Universities and research institutes typically lack the extensive resources and infrastructure necessary for scaling up, producing commercial products, managing certification, marketing, and distribution. Therefore, the industrial partner acts as a crucial intermediary, bridging the gap between scientific innovation and market application. This collaborative necessity aligns perfectly with the "Coupled Process" of the Open Innovation model, which emphasizes joint innovation and commercialization efforts with complementary partners, signifying a bidirectional flow of knowledge and collaboration. This focus helps overcome the fragmentation identified as a barrier to European competitiveness.

To equip stakeholders for these vital partnerships, Chapter 3 details essential analytical tools and strategic approaches. It introduces the **SWOT Analysis (Strengths, Weaknesses, Opportunities, Threats)** as a universal tool for assessing a project's market potential and viability, aiding in strategic planning for commercialization. Another critical aspect covered is the **Valuation of Intellectual Property (IP)**, explaining how to determine the monetary value of R&D outcomes for transactions like licensing or sales. This section discusses various methods, including cost, market, income, and Discounted Cash Flow (DCF) approaches, emphasizing IP's importance in commercialization strategies.

The chapter further explores diverse **commercialization strategies with business partners**, detailing various types of business partnerships common in Science-to-Business (S2B) cooperation, such as **Strategic Alliances, Joint Ventures, and Licensing**. It elaborates on key considerations for successful commercial partnerships, including **clear objectives, mutual benefit, trust and transparency, robust legal agreements, resource commitment, and effective risk management**.

A significant focus is placed on the **university broker's role in S2B interaction**, acting as an intermediary and interpreter between scientists and industry. This role helps identify market needs, find partners, and translate scientific language into market-oriented terms. The guide stresses the importance of **introducing market factors to research projects from the earliest stages**, advocating for research topics to originate from identified market needs and for scientists to engage with companies to ensure practical usefulness. Finally, it provides guidance on **constructing a technological offer** and **negotiating S2B partnership agreements**, ensuring proposals are well-defined and negotiations are strategic and mutually beneficial.

In essence, Chapter 3 serves as a practical guide for **transforming academic research into valuable market-ready solutions** by fostering robust collaborations, strategically managing intellectual property, and ensuring a market-oriented approach from inception to commercialization.

3.1 SWOT analysis of the project result

To effectively implement the project results, we must look at them as a product that is intended to respond to a specific market need and compete in the existing marketplace. One of the universal tools that allows you to assess the market potential of a product is SWOT Analysis (Figure 3.1).

Figure 3.1: SWOT diagram (https://en.wikipedia.org/wiki/SWOT_analysis)

SWOT analysis helps focus on project strengths, minimize risks and identify project gaps, enabling proactive strategy planning. However, interpreting the results can present challenges. For instance, addressing uncertain or ambiguous factors and prioritizing issues may lead to a lengthy and disorganized list of elements.

To avoid confusion in interpreting the SWOT analysis results, categorize the identified factors based on their impact on the commercialization of the project. Concentrate on those elements that will have the greatest impact on the success of the project.

How to use the result of SWOT in further planning the marketing strategy:

- **Building on Strengths:** Identify and reinforce strengths of your product.
- **Addressing Weaknesses:** Acknowledge your product's weaknesses and seek ways for improvement.
- **Seizing Opportunities:** Capitalize on favorable conditions in the business environment and on the market.
- **Mitigating Threats:** Anticipate and counteract potential external threats.

Remember that your product must possess strong advantages to compete effectively in the market. While it's important to recognize weaknesses, the primary focus should be on enhancing strengths.

The insights gained from the SWOT analysis will deepen your understanding of your product and the environment in which you will commercialize it, aiding in the search for partners to implement your idea.

Example: *SWOT analysis of Electric Vehicles*

Strengths:	**Weaknesses:**
• Latest technology, still under development • High energy efficiency • Low running costs • Total power available regardless of engine speed • High ride comfort • Low noise • Zero emissions	• Higher production costs compared to internal combustion engines • Limited range on a single charge • Long charging time • Limited battery life • Lack of noise while driving poses a danger to pedestrians
Opportunities:	**Threats:**
• Tax relief on purchase • Electric mobility subsidies • Possibility to use bus lanes • Product under development, constantly improving: longer range, faster charging • Expansion of charging infrastructure provides opportunity to reach new customer segments • Growing environmental awareness • Rising fuel prices driving demand	• Many types of chargers • Lack of charging points • Lack of co-operation between manufacturers • Dependence on battery power • Uncertain price and availability of raw materials • Uncertainty of operational safety

As illustrated, some strengths can also be perceived as weaknesses. For example, the lack of noise of electric vehicles is a comfort for the driver but poses a risk to pedestrians. To mitigate this, electric cars are equipped with a system that generates engine noise to avoid accidents with pedestrians.

Threats can also be turned into opportunities; the lack of charging points is a challenge, but the ongoing development of charging infrastructure in many countries is an opportunity to increase sales in the future.

3.2 Commercialization strategies with business partners

This section underscores that **successful implementation of R&D results from a university requires collaboration with an industrial partner**. Universities typically lack the resources for scaling, production, certification, marketing, and distribution. This section details how to identify potential partners and explores various partnership types common in Science-to-Business (S2B) cooperation, such as **Strategic Alliances, Joint Ventures, and Licensing**. It emphasizes key considerations for successful collaborations, aligning with the "Coupled Process" of Open Innovation.

When and how to introduce market factors to the research project? Introducing market elements to the project should begin the moment when the idea for the invention arises in the scientist's mind. As the definition of the invention's features progresses, it should be accompanied by an improvement in the needs it aims to satisfy. The creator shapes the product's characteristics based on their identification of the specific needs that the product must address.

The commercialization strategy for the invention should be established at the initial stage of the project and adapted to the evolving characteristics of the invention or market conditions

If during the project development, which extends beyond the conceptual phase, it becomes impossible to outline of the commercialization strategy, it is likely that the project will not be suitable for implementation.

3.2.1 Identifying Potential Partners

The implementation of the result of research and development results from a university must take place in collaboration with an industrial partner. Universities and research institutes typically lack the resources and infrastructure to scale up and produce commercial products. In a partnership, universities and research institutes act as the system provider - originating the idea, while the industrial partner, often a production facility, serves as the system user, responsible for bringing the project results to fruition. **Members of the research team must be aware that no implementation will take place in the laboratory and that the participation of an industrial partner in the process is essential.**

The project plan must include space, tasks and the associated budget for the industrial partner. This partner need not be the final recipient of the project result. In most cases, they often serve as the intermediary between the technology provider and the end user, assuming responsibilities related to production, product certification, marketing, and distribution. These are tasks that cannot be performed by the research team due to a lack of physical capacity but are necessary to bring the product to market. Potential commercialization partners should be companies within the relevant industry that possess the necessary financial resources and infrastructure. It is vital that these partners have a solid understanding of the industry and the needs of the target audience.

The industry serves as an excellent barometer for assessing the market value of innovations, as companies have an intimate knowledge of end-user requirements, as the products and services they bring to market must be competitive. Additionally, industry players can help to minimize the risks associated with a new product or market segment.

Meetings with potential partners should be targeted at segments of the industry where we have innovation to offer, where we feel confident, and where we have the ability to conduct in-depth research into a new product.

Business discussions should be concise and focused; companies typically have a need for innovation, and while they may possess the necessary infrastructure, they often lack ideas. In meetings, it is important to present ideas clearly and succinctly, avoiding the disclosure confidential information in the early stages of discussions.

The innovator should stay informed about developments in their industry and reach out to multiple companies when seeking implementation partners. They should meet regularly with representatives of the companies that can provide valuable insights into their plans and needs.

3.2.2 How to effectively search for business partners

Usually, every company has the need for innovations. The scientist and broker must stay updated on the news in the industry in which they operate. The broker should reach out to multiple companies, meet their representatives and discuss their development plans.

Meetings should be focused on the segments where we have inventions to offer, as companies prefer not to waste time discussing irrelevant topics. It is advisable to invite scientists to such meetings to present their invention – clearly and concisely.

Never send a patent description to the company!

When it is more profitable to establish cooperation with a small business and when with a large one?

Some inventions are better suited for development in the start-up phase, others require established companies firmly embedded in the industry. The decision on which development strategy to implement is always unique and requires thorough analysis. A small entrepreneur can be an excellent partner for projects implemented on local markets. This is particularly true when introducing innovations does not require an extensive marketing campaign and when the sale of a product or service does not necessitate distribution channels.

A large enterprise should be chosen as a partner for inventions entering large-volume production, where it is necessary to have a technological line, warehouses and logistics.

A large enterprise is also a suitable partner for highly innovative solutions requiring high expenditure on implementation. However, large companies typically require that innovations align perfectly with their development strategy. In general, large companies do not invest in technologies or products with poorly defined scopeσ of application and/or that do not meet market targets.

When to look for cooperation on the domestic market and when on an international scale?

Local Market

- Products and technologies having several substitutes;
- Regional usage of product;
- Lack of recognized international competition;
- Domestic Intellectual Property protection only.

International Market

- International protection of Intellectual Property Products and technologies with unique features that are difficult to replicate; main production and distribution chains located abroad;
- Implementation strategies focus on other markets.

Long-term S2B relationship:

- Maintain contact with company representatives;
- Stay informed about organizational changes within the company;
- Follow the strategic development of your partners;
- Inform them when new opportunities arise at the university Invite them to the seminars organized by the university, local authorities etc.;
- Ensure that the meetings and conferences you invite them to offer valuable insights for the industrial partner;
- Receive regular feedback from your partner and work on influencing the scientists.

3.2.3 Types of Business Partnerships used in S2B cooperation

The main objective of an S2B partnership is to streamline production processes, improve product functionality, or implement new solutions, so it is important to define the partnership model appropriately to achieve the objective as effectively as possible.

The following cooperation models are the most common (Figure 3.1):

- **Strategic Alliances:** Businesses with complementary skills or resources team up to pursue a common goal. This model often involves knowledge sharing and technology transfer.
- **Joint Ventures:** Two or more companies create a separate entity to achieve a specific goal, such as entering a new market or developing a new product. All partners share risks and rewards.
- **Licensing:** A business grants another the right to use its intellectual property in exchange for royalties. This model is common in industries like technology and entertainment.

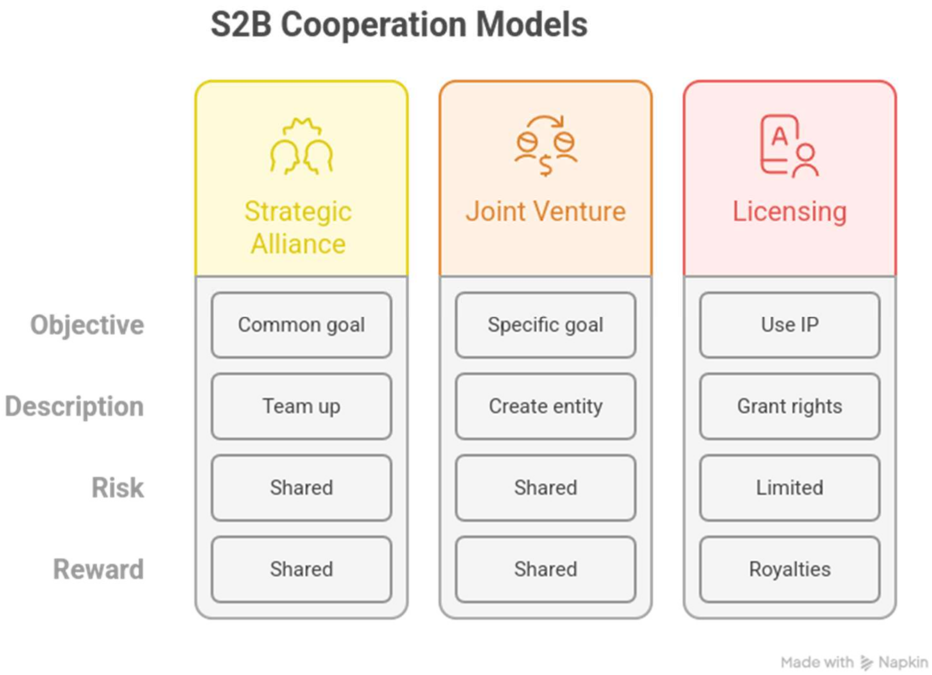

Figure 3.1: S2B Cooperation Models

Examples:

1. A computer program to help manage an industrial plant in real time, based on continuous measurements of technological parameters. In principle, once such a product has been tested and the data from the specific equipment (obtained from the end user) has been fed into the algorithms, it does not need to be scaled up and can be sold as a ready-to-use product.

   However, deploying such software requires appropriate hardware, operational knowledge and the tools and skills to maintain, update and troubleshoot the software. Therefore, the optimal business partner for the implementation of such software will not be the end user - the owner of the plant/algorithmic production line, as his competence relates to the product coming off the line.

The plant owner needs to use the services of a company that provides the software, guarantees its correct functioning, and provides full after-sales support. Such a service cannot be provided by the university where the software was developed. The implementing partner will therefore be an IT company that can offer the software on the basis of purchasing a license from the university, or even purchasing the right to use the software without time, application or territorial restrictions.

This company can benefit from the university's technical support in the event of problems with the software or the need to adapt further functions, but the end-user (production line) support itself will not be a burden on the university's staff wishing to carry out new research. The business partner is the bridge between the system provider and the system user.

2. Another example of an S2B partnership is a joint application for an externally funded research and deployment project. Here, the type of relationship between the university and the company is usually determined by the conditions of the competition. In most cases it is a consortium partnership, i.e., all partners are jointly and severally liable for the results of the project, which is treated as a joint venture.

   In some competitions, the partnership involves the university commissioning research work to develop an innovation by a company, which then implements this innovation in its business practice.

3.2.4 Matters needing attention in commercial partnerships

Any business action requires precise procedures to ensure the success (Figure 3.2):

1. **Clear Objectives:** Partners must define and align their goals and expectations before entering the partnership. This ensures that both parties are working towards the same outcomes.
2. **Mutual Benefit:** A successful partnership should result in mutual benefits for all parties involved. Imbalances in benefits can lead to conflicts and the eventual breakdown of the partnership.
3. **Trust and Transparency:** Open communication and transparency are crucial. Partners should share information and insights to build trust and ensure that everyone is on the same page.
4. **Legal Agreements:** Draft legally binding agreements that outline each partner's responsibilities, contributions, profit-sharing arrangements, dispute resolution mechanisms, and exit strategies.
5. **Resource Commitment:** Partners must commit the necessary resources, including time, capital, and expertise, to the partnership's success.
6. **Risk Management:** Identify potential risks and develop strategies to mitigate them. This could involve contingency plans for unforeseen challenges.
7. **Regular Evaluation:** Regularly assess the partnership's performance against set objectives. Adjustments can be made as needed to ensure alignment with changing market conditions.

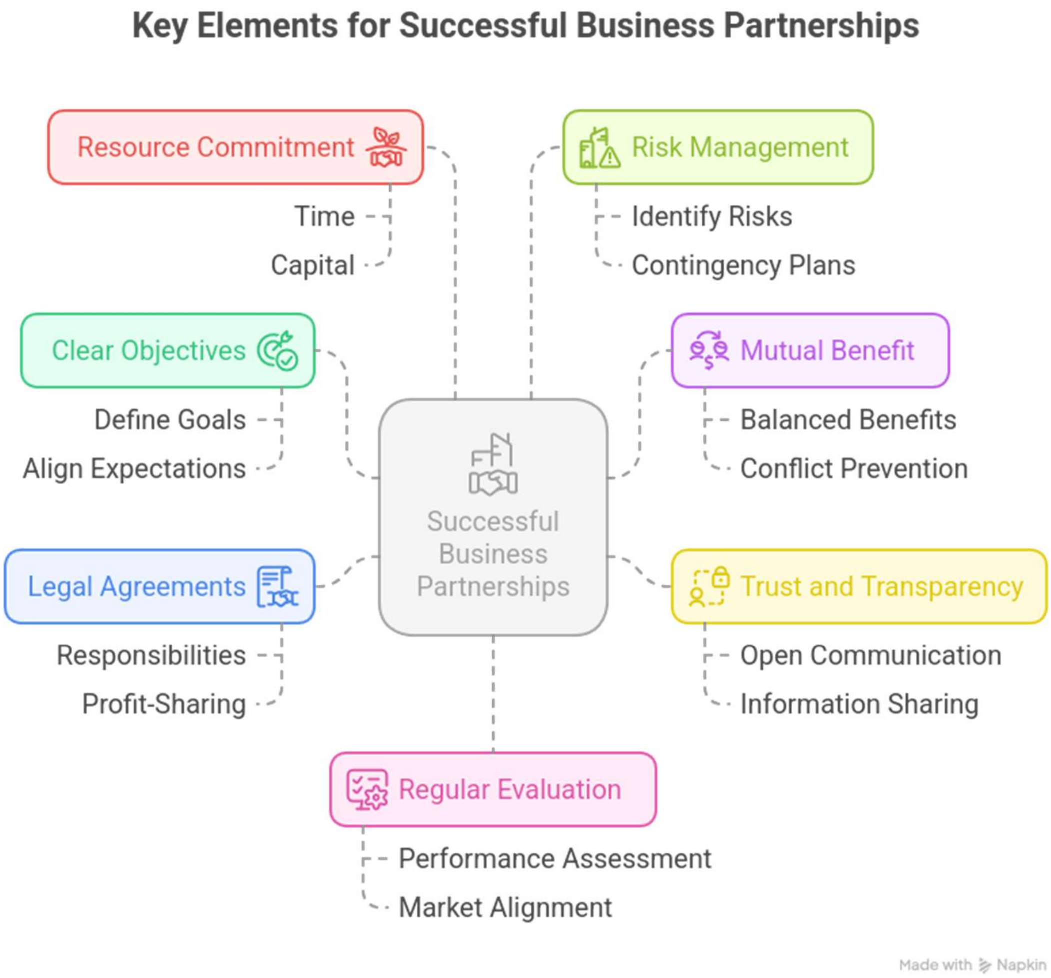

Figure 3.2: Key elements for successful business partnerships

After negotiating the terms and conditions of the partnership, the next step is to draft and review the partnership agreement or contract. It is essential to ensure that the document is clear, concise, accurate, and comprehensive, reflecting the mutual understanding and agreement of both parties. Consulting with legal and financial advisors is crucial to ensure the document complies with relevant laws and regulations. Careful review is necessary to identify any errors or inconsistencies and to request clarifications or revisions if needed. Once both parties are satisfied with the document, the partnership agreement or contract is signed and finalized, following proper procedures and formalities. This may involve using electronic signatures, witnesses, or notaries. Keeping a copy of the document for records and sharing it with relevant stakeholders marks the official start of the partnership and the beginning of the implementation phase.

3.2.5 Launch and manage the partnership

The mutual benefits of S2B partnerships are the basis for success; for this aim, effective communication and collaboration with your partner are paramount at this stage.

Execution of the partnership plan should adhere to the agreed deliverables, milestones, and metrics. It is crucial to monitor and measure the performance and results of the partnership continually. Providing feedback and support to your partner is essential for the partnership's success. Celebrating successes, addressing challenges, and resolving any arising issues or conflicts are vital tasks. Regular review and evaluation of the partnership should be conducted to identify areas for improvement and growth.

How the industry can help the scientist?

Industrial activity is an excellent market barometer. The application value of the invention shall be not based on intuitions, but on facts. Industry has experience in how a given product or service sells itself on the market. Very often the perception of the demand for a given product feature by a scientist and entrepreneur differs dramatically; thus the entrepreneur knows how to target the product so that it can be sold. Moreover, the industry helps to define the risks associated with an innovative project.

How the scientist can help the industry?

For the company, that lacks well-equipped laboratories and high-qualified team of research teams, universities serve as their R&D centers, assisting in the development and testing of inventions before the scaling process. Strategic partnerships in applying for joint R&D projects can also provide the financial resources to conduct the research.

For companies with their own R&D center and staff, universities can furnish auxiliary expertise in specific issues, being the objective for long term university research programs that companies may not have the time or access to pursue.

What the industry expects from scientists?

Businesses place a high value on time; **time is money.** The industry focuses on rapid product sales, while scientists often engage in lengthy and detailed work on inventions.

The industry expects scientists to align with market recommendations regarding product orientation. They also anticipate that scientists will be ready to collaborate on implementation and demonstrate determination in their efforts.

Moreover, the industry is generally **risk-averse**. They expect cooperating scientists to actively work on minimizing the risks associated with introducing innovations to the market.

What elements of the research project make it attractive for the entrepreneur?:

- The invention is in line with current needs signaled by users.
- The invention gives the opportunity to gain a competitive advantage for the entrepreneur.
- The project is at the stage of development enabling pre-implementation and implementation work.
- The project is well-defined and intelligibly described.
- The project is correctly conducted, with a clear schedule and marked milestones.
- The project is regularly consulted with the implementing company to potential changes in requirements.

What barriers of cooperation between industry and science can be seen by entrepreneurs?:

- Lack of scientists' confidence in the industry and vice versa;
- Sometimes, scientists speak disparagingly of industry, considering the pursuit of profit as questionable;
- Researchers are too attached to their ideas to bend to market requirements;
- The scientific projects are often on significantly low market readiness and the scientist is not willing to develop it;
- The time between capital investment on the development of the invention and its market implementation is crucial;

- Pre-implementation and implementation work must be faster than the changes in market demand for a given product feature.

3.2.6 University broker's role in S2B interaction

A **technology broker (innovation broker)** is a specialization that has emerged in the last decade as a result of the global development strategy's focus on bringing innovative solutions to the market. In practice, **the broker has to combine knowledge and experience from various fields.** They should understand the specifics of research work, be familiar with the principles of market operation, and have technical, economic, legal and sociological knowledge. Strong communication and negotiation skills are also important in the broker's role.

Regarding performance:

- The broker works on the development of the invention together with a scientist.
- The broker acts as an intermediary and interpreter between the scientist and the industry.
- Through contact with many entrepreneurs, the broker finds industry partners to recognize the sought after product features.
- The broker "translates" the content of the invention from scientific language to the language of the market
- They consult potential applications with current market demand

3.3 Valuation of intellectual property

The result of a research and development project is intellectual property (IP), which has an economic value. IP valuation is the process of determining the monetary value of these assets. It is critical for transactions that involve sharing IP with another party, such as licensing, selling, or entering into collaboration agreements. Understanding the value of intellectual property (IP) assets is essential for all parties involved in the process.

The value of IP depends on many factors and changes over time. The main factors affecting the market value of the result are:

- **Degree of market maturity.** The value of the IP increases as the marketability of the result increases. (TRL level of readiness for implementation).
- **Market potential.** The higher the market potential of an outcome, the higher its value.
- **Novelty.** The value decreases with the time between the development of the outcome and its implementation. It may be that the intellectual property has no value after a few or several years.
- **Uniqueness.** Weak and limited competition increases the value of the result.
- **Accessibility.** Limiting accessibility through patent protection increases the value of the result.

3.3.1 Methods for valuing IP assets

1. **Cost method:** The cost method establishes the value of an IP asset by calculating the cost of a similar or exact IP asset. This method is useful when the IP asset can be easily reproduced, and when the economic benefits of the asset cannot be accurately quantified. Cost method is most commonly used to calculate the minimum price that the university shall obtain as a reward by selling rights to the project outcome, because it assumes that the price set is to reimburse the costs incurred by the research entity in developing the result.

2. **Market method:** The market method values IP assets by comparing them with similar assets for which actual prices have been paid under comparable circumstances. This method is straightforward and based on market information, making it useful for establishing approximate values for determining royalty rates, tax, and inputs for the income method.
3. **Income method:** The income method is the most commonly used method for IP valuation, however is not the most accurate for the valuation of results from R&D. It values the IP asset based on the economic income it is expected to generate, adjusted to its present-day value. This method is suitable for IP assets with positive cash flows, whose future cash flows can be estimated reliably, and for which a proxy for risk can be used to obtain discount rates.
4. **IP valuation by DCF method**
    - **Conducting an IP audit:** By conducting an IP audit, businesses can ensure that their IP assets are properly valued and protected, making them more attractive for potential partnerships, investments, or other transactions. This process includes:
        - Identifying and cataloging IP assets
        - Reviewing legal documentation
        - Assessing the strength and enforceability of IP rights
        - Evaluating the competitive landscape
        - Identifying any potential infringement risks

      The Discounted Cash Flow (DCF) method is a popular valuation technique used to estimate the value of an investment based on its expected future cash flows.
    - **Key concepts:** Discounted cash flow (DCF) analysis estimates the present value of expected future cash flows using a discount rate. It helps determine whether an investment opportunity is worthwhile by comparing the DCF value with the current cost of the investment.
    - **Projecting Cash Flow:** To conduct a DCF analysis, investors must estimate the future cash flows of the investment, equipment, or other assets. These cash flows are then discounted back to the present day using a projected discount rate.
    - **Determination of Remaining Economic or Useful Life (RUL) of the IP asset:** The time value of money assumes that a dollar received today is worth more than a dollar received in the future because it can be invested. Hence, DCF analysis is used to estimate the money an investor would receive from an investment, adjusted for the time value of money.
    - **Risk Consideration and Discount Rate Determination:** The discount rate used in DCF analysis is crucial and varies depending on the project or investment under consideration. Factors such as the company's risk profile and the conditions of the capital markets affect the discount rate chosen. If the investor cannot estimate future cash flows accurately or the project is complex, DCF may not be the best valuation method.

Example of DCF: Your company wants to launch a project with a weighted average cost of capital of 5%.

The initial investment is €11 million, and the project will last for five years, with the following estimated cash flows per year:

Year	Cash Flow
1	1 M
2	2 M
3	3 M

4	4 M
5	5 M

Using the DCF formula, the calculated discounted cash flows for the project are determined, and the net present value (NPV) is calculated. If the NPV is positive, the project may generate a return higher than the initial cost and could be considered worthwhile.

Advantages and Disadvantages of DCF:

Advantages:	Disadvantages:
• DCF analysis provides an idea of whether a proposed investment is worthwhile. • It can be applied to a variety of investments and capital projects. • Projections can be tweaked to provide different results for various scenarios, allowing users to account for different projections.	• DCF relies on estimates, not actual figures, and the result is also an estimate. • Future cash flows rely on various factors that cannot be quantified exactly, such as market demand, economic conditions, and competition. • DCF should not be relied on exclusively, and other valuation methods and known factors should be considered.

How Do You Calculate DCF?

Calculating DCF involves three basic steps:

1. Forecast the expected cash flows from the investment.
2. Select a discount rate, typically based on the cost of financing the investment or the opportunity cost presented by alternative investments.
3. Discount the forecasted cash flows back to the present day.

3.3.2 Practical usage of calculated value of IP

It is best to evaluate the project results using two separate methods and compare the outcomes. If the results are inconsistent, it likely indicates that incorrect assumptions were made. Verify your assumptions and perform the calculations again.

The calculated price should be included in the offer we make to the potential recipient. In the offer, we propose a price slightly higher than the calculated one, leaving a margin for negotiations.

The general rule is that IP shall not be sold below its cost value, in order to reimburse the expenses incurred in developing the product. Sales price shall be the market price. It means that the actual IP value is as much as the buyer is willing to pay for it. With many potential buyers, the value of the IP may increase. This value is always negotiated with the potential buyer and the right to the result should be sold to the highest bidder.

3.4 Constructing a technological offer

A technological offer is a structured proposal that outlines the main features of the project's result and its advantages. The proposal is the document that initiates the process of negotiation with potential investors/manufacturers/users.

The offer may be intended for inclusion:

- on the website
- in the conference directory
- as so-called White Paper for the professional seminar
- to be sent to a potential investor

The proposal should vary according to its final destination. The first three types of offers are general information about the technology, a brief description of the technology or invention in non-technical language, listing the functions to be achieved, possible areas of application of the technology/product.

An offer to a specific investor should be much more thoughtful and provide details without revealing the essence of the solution. It is essential to issue a proposal before signing a confidentiality agreement.

In this type of proposal, we shall include following:

1. **Administrative and legal information**

The offer includes administrative and legal information for a potential investor:

- The entity submitting the proposal (University, TTC).
- Name and title of the scientist, author of the invention.
- The department, institute in which they work.

2. **Subject of the proposal**

- Brief description of the technology or invention in non-technical language.
- A scientific hypothesis and a rational basis for research in the direction of this technology / product.
- The function to be achieved and possible fields of application for the technology / product.

3. **Principle of operation**

- A simplified description of the principle of operation.
- **Warning:** This description should not contain any confidential or protected information, even if the patent is granted, and cannot be a description of a patent application.

4. **The Goal of invention**

- The main focus in preparing the proposal is to clearly inform what this technology/product can do, but not how it is made.

5. **Verification indicators**

- The main indicator that the technology / product fulfills its function.
- Data confirming the effectiveness of the product technology.
- Test results - preferably based on applicable standards.
- Other indicators proposed by the scientist.
- Coefficients should be quantitative and qualitative.

6. **Market information**

- The State-of-the-Art.
- current competitive products / substitutes used in the market.
- Brief description of the competition.

7. **Advantages given by technology/product**

   - Unique features that contribute to sales success: the so-called "WOW" factor.
   - Comparison to currently used products
   - If we make the proposal is for a specific company, we could refer to this company's actual products.

8. **TRL level of invention**

In the case of a technology / product that is not ready for sale, and we are looking for a partner for the B & R project for pre-implementation work, we must provide:

   - TRL readiness level with justification.
   - What work / actions should be taken to prepare the technology / product for implementation on the market and the sales process.

9. **Optional: action plan for market implementation**

In the case of a technology / product at a very low TRL level, there is a high probability that we will not be able to describe all 10 features, because we simply do not have the knowledge yet, e.g. data confirming effectiveness. In this case, these issues should be listed in the action plan.

10. **Intellectual Property Rights**

We should inform the party receiving the proposal about who holds the actual Property Rights and who will negotiate on behalf of the university

11. **Proposed price**
   - The price for the purchase of the rights to the patent or license
   - An Invitation to negotiate
   - an invitation to conduct joint research on the technology/product
   - Details of the person for further contact

12. **Proposal validity Period**

The Proposal should be valid for at least one month but no longer than 6 months from the date of submission. After this period, the proposal may need to be renewed, and the price recalculated.

3.5 Negotiations

Negotiating a successful Science-to-Business (S2B) partnership agreement requires careful planning and consideration (Figure 3.3)

Understanding the Value Proposition

Before entering into negotiations, having a clear idea of what can be offered to the potential partner and what can be expected from them in return is crucial. The value proposition should be based on strengths, capabilities, and competitive advantages, as well as the partner's goals, challenges, and preferences.

In S2B partnerships, the value proposition typically revolves around the unique benefits and solutions that the research institution or university can provide to the industry partner. This could include access to cutting-edge research, specialized knowledge, intellectual property, or innovative technologies. Understanding the specific needs and objectives of the industry partner is essential for tailoring the value proposition to their requirements.

Researching the Potential Partner

Understanding the potential industry partner is crucial before negotiation. Research their background, culture, reputation, financial situation, market position, and objectives. Identify their needs, interests, concerns, and expectations from the partnership.

In S2B partnerships, thorough research of the industry partner is essential to ensure alignment between the research institution's capabilities and the partner's requirements. This includes understanding the partner's market position, competitive landscape, ongoing projects, and areas of strategic focus. Additionally, research should encompass the partner's technological needs, innovation goals, and potential areas for collaboration.

Setting Goals and Priorities

Define goals and priorities for the negotiation. Ensure they are realistic, measurable, and specific, aligned with the value proposition and the partner's needs.

In S2B partnerships, setting clear and achievable goals is essential for ensuring that the partnership delivers tangible benefits for both parties. These goals may include objectives such as technology transfer, joint research projects, product development, or commercialization of intellectual property. Priorities should be established based on the strategic importance of each aspect of the partnership agreement, such as research scope, duration, responsibilities, risks, benefits, and costs.

Preparing the Proposal and Strategy

Based on goals and priorities, prepare the proposal and negotiation strategy. Outline the main features and benefits of the partnership agreement, as well as the expected contributions and obligations of each partner.

In S2B partnerships, the proposal should clearly articulate the value proposition, outlining the specific benefits and opportunities for the industry partner. This may include details about access to research facilities, expertise of research staff, intellectual property rights, and potential commercialization opportunities. The negotiation strategy should focus on building trust, fostering collaboration, and ensuring that the partnership agreement is mutually beneficial for both parties.

Conducting the Negotiation

Follow best practices during the negotiation to achieve a positive outcome. Establish a friendly and respectful tone, actively listen to the partner's feedback, and present the proposal confidently and compellingly.

During S2B partnership negotiations, it is essential

to maintain open communication and collaboration between the research institution and the industry partner. This involves active listening, understanding the partner's needs and concerns, and addressing any questions or objections they may have. The negotiation process should focus on finding common ground, exploring win-win solutions, and building a strong foundation for future collaboration.

Finalizing the Agreement

After reaching an agreement, finalize and formalize the partnership agreement. Review and summarize the main points and terms, document the agreement in writing, and have it signed by both parties.

In S2B partnerships, the finalization of the agreement marks the beginning of a collaborative relationship between the research institution and the industry partner. The agreement should clearly outline the rights, responsibilities, and expectations of both parties, including details of research collaboration, intellectual property rights, commercialization strategies, and financial arrangements. Once the agreement is signed, both parties should work together to ensure its successful implementation and ongoing management.

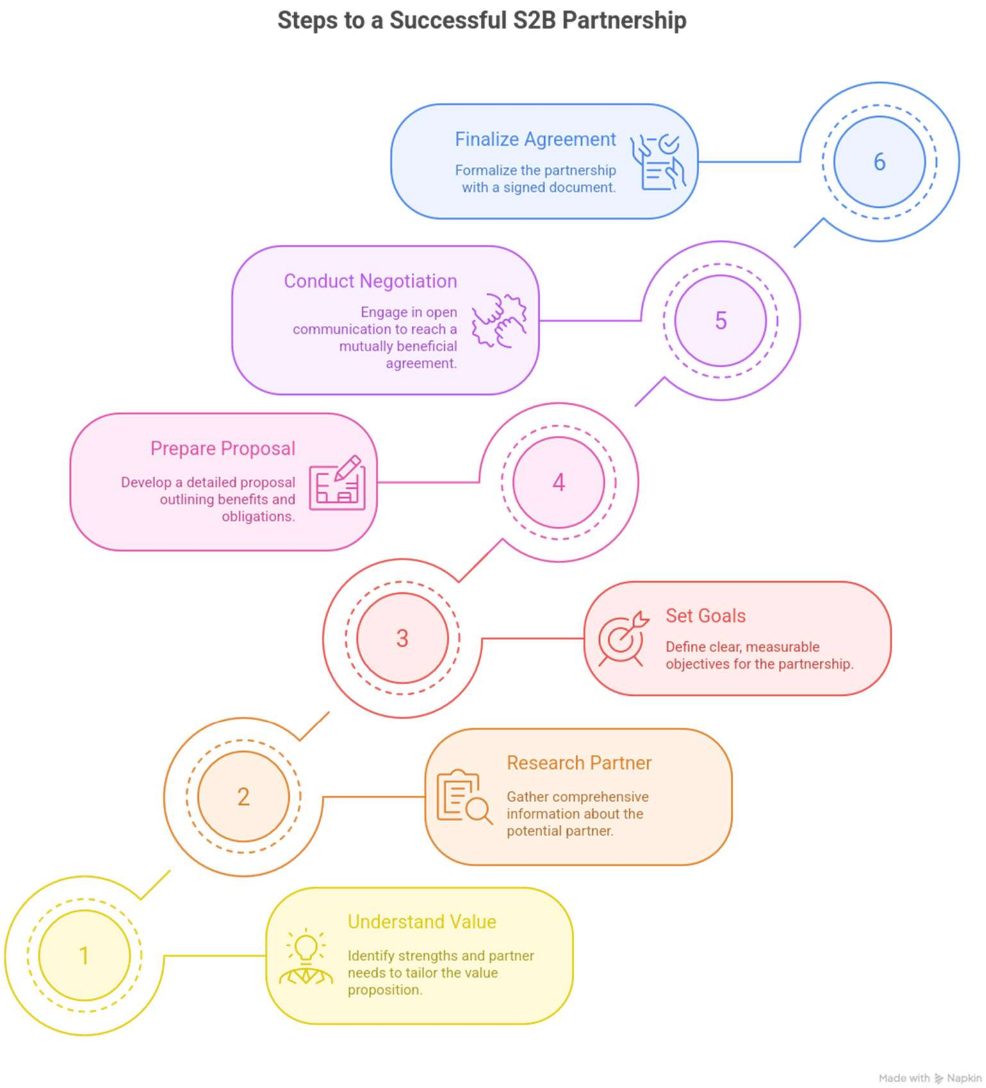

Figure 3.2: Negotiation for a successful Science-to-Business (S2B) partnership

Chapter 4 – Management of research and implementation projects

This final chapter is fundamental to the guide's core objective, **transforming Research and Development (R&D) potential into tangible economic growth and societal welfare**. As you will check, it provides practical tools and insights for effectively managing R&D endeavors from initial conception through to successful market application.

A cornerstone of this chapter is the concept of **Technology Readiness Levels (TRLs)**. The TRL methodology employs a nine-level scale to **assess a technology's maturity**, from basic research (TRL 1) to full operational implementation (TRL 9).

Later, we strongly emphasize **continuous engagement with the business community**. This collaboration is essential as universities typically lack the resources for scaling, production, and market activities. The guide outlines how to work with industry partners before, during, and after a project, from defining market needs to monitoring post-launch product reactions.

Another critical element is the **Technical Cost of Products Manufacturing (TCPM), which** is vital for **evaluating production efficiency, setting competitive pricing strategies, and making informed financial and production planning decisions**. It also discusses various calculation methods and the role of optimization tools like Lean Manufacturing.

Finally, Chapter 4 provides extensive guidance on **Project Risk Management**, acknowledging the inherent high risks in R&D projects, particularly in achieving research objectives and meeting market expectations.

In summary, Chapter 4 provides a comprehensive framework to ensure that scientific advancements are not only robust in their research but also **strategically aligned with market demands, financially viable, and managed effectively against inherent risks**, thereby directly supporting Europe's competitiveness and innovation goals.

4.1 Technology Readiness Levels (TRL)

Technology Readiness Levels (TRL) is a methodology used to assess the maturity of a technology throughout its development stages, from early conceptual research to operational implementation. The TRL scale has nine levels, with TRL 1 representing the lowest level of technology readiness and TRL 9 the highest. The TRL levels help determine how much work has been done and what remains to be done to bring our idea to market.

The TRL scale can be broken down into (Figure 4.1):

1. Basic research, which includes level 1
2. Industrial research, which covers levels 2-6
3. Development, which covers levels 7-9

Technology Readiness Level 1

This is the lowest level. Creative thought is defined, the concept of which is not ready. Technology is in the theoretical stage. At this stage, new phenomena and properties are discovered through basic scientific research. The technology is not tested in any practical application. Also, solutions that could be protected by law are not created at this stage.

Example: Inventing a material with interesting properties without specifying where this material could be used.

In the field of health (medicine, pharmacy, nutrition, food for special nutritional conditions, dietary supplements): Identification of the opportunity (examples: atopic dermatitis, cancer, gastroesophageal reflux, Alzheimer's and others).

For the healthcare sector: Identify the pathology for which you want to develop a drug, food for special nutritional conditions, a food supplement or a medical device.

Establish the state of knowledge regarding treatments for the respective pathology, using scientific databases (for example, PubMed, Web of Science), and intellectual property/patent or patent application databases - WIPO, Epicene, OSIM, Patent Google, USPTO, PQAI and others). Studies of pathogenesis and pathophysiology related to humans and laboratory animals.

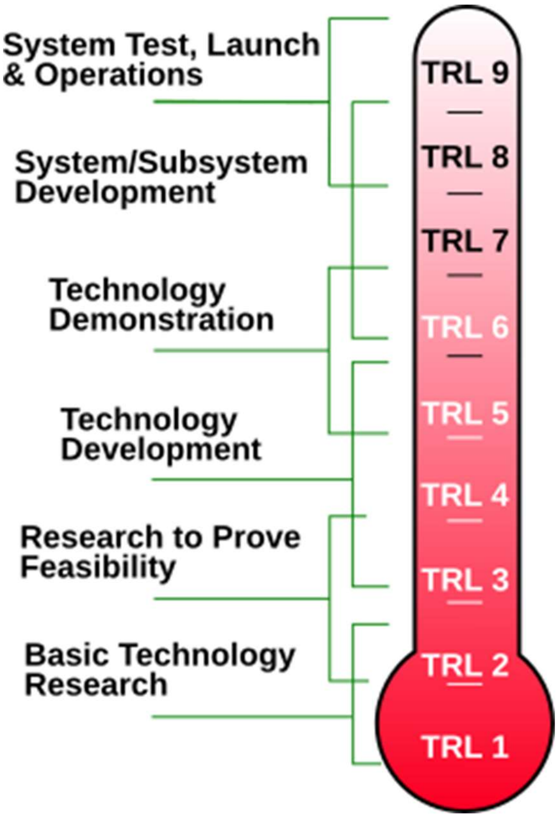

Figure 4-1: NASA TRL by Hari Seldon - Own work, CC BY-SA 4.0, https://commons.wikimedia.org/w/index.php?curid=148410150

Technology Readiness Level 2

The concept is based on a specific application. However, no tests have been carried out to confirm the assumptions made, so the concept remains abstract.

- Examples for preclinical studies: animals on which other similar research studies have been carried out (rodents, dogs, cats and others): species, line/breed, age, sex, number of animals, number of batches and number of animals per batch, the method of inducing the pathology, the period of treatment or nutritional intervention, the monitored biomarkers, the mechanism of action of the medicine or food, whether the animals had adverse reactions or not, the microclimate conditions of the biobased/experimental research station where the animals were raised.
- For the development of medicines, foods or dietary supplements, the concept is formulated (examples: ointment, capsule, tablet, jelly, biscuits, drink or others) and the technology is analyzed in comparison with other technologies on the market identified in

Technology Readiness Level 3

Experimental work is intended to verify that the concept works as expected. Components of the technology are validated, but there is no strong attempt to integrate the components into a complete system. Modeling and simulation may be used to complement physical experiments.

The concept is based on a specific application. However, no tests have been carried out to confirm the assumptions made, so the concept remains abstract.

Example: Checking the processing properties of whether the material can be used to make a bicycle tire

For the health field (medicine, pharmacy, nutrition): identification and preliminary characterization of the objective (medicine, food for special nutritional conditions, dietary supplement). For example, if the objective is an ointment, the preliminary characterization may be of the type whether it will be hydrophilic or hydrophobic, or if it is a food, it may be of the type whether the food will be liquid, powder, jelly, biscuits, chocolate or another type of food. In the case of food supplements, the preliminary characterization may be of the type of whether it will be a tablet, capsule, syrup, jelly or other type. For all the previous examples, the preliminary characterization may also be whether they will be heat-treated or not, whether they will require special storage conditions such as refrigeration, shelf life to determine the type of preservative needed or the possibility of vacuuming to avoid refrigeration or freezing storage, so as to reduce the carbon footprint. Sustainability can be another preliminary feature of the product, especially in the case of certain food supplements and foods for special nutritional conditions.

The results of the laboratory research support the concept/innovation/objective established in TRL 1. Preliminary efficacy is demonstrated in vitro and/or in vivo, according to the national and European legislative regulations in force. For example, in the case of preliminary verification in vivo, on laboratory animals. The favorable opinion of the Ethics Committee and the Authorization from the Veterinary Sanitary Directorate must be obtained. Following these in vitro and/or in vivo verifications, the first preliminary results emerge which represent the first proofs of the concept/innovation.

Technology Readiness Level 4

Components and their integration have been verified under laboratory conditions in a controlled environment, extending the scope of testing from the TRL3 level.

Example: Testing key material performance characteristics under different environmental conditions relevant to consumers, such as cyclists.

For the health field (medicine, pharmacy, nutrition): Optimization of the drug, food or dietary supplement and in vivo demonstration of activity and efficacy: development of the preclinical study to test critical aspects such as acute toxicity, pharmacodynamics and pharmacokinetics, demonstration of in vivo activity and potential efficacy consistent with the intended use of the product (i.e. dose, duration, route of administration of the drug or dietary supplement or food as e.g. oral or enteral), establishing parameters and markers that will also be used in the clinical evaluation of the efficacy of the drug/food for special nutritional conditions/food supplement.

In TRL 3 and TRL 4, both pharmacovigilance and nutrivigilance can be monitored (of the drug, food or dietary supplement), especially if adverse reactions occur or the developed product interacts with certain drugs/foods that may negatively affect drug clearance and thus may lead to a decrease in the effectiveness of allopathic treatment and the quality of life of patients and their families, respectively in hospitalizations with the implicit increase in health system costs.

From a manufacturing perspective, it is recommended to produce a certain amount of laboratory scale (i.e., non-GMP (Good Manufacturing Practice)) of the proposed bulk and formulated product and store it under various conditions, such as normal, refrigerated conditions, freezing, or very close to heat sources. This type of storage can be very useful if patients/clients do not respect the storage conditions mentioned on the label in the case of foods for special nutritional conditions and certain food supplements, or in the package leaflet and/or the summary of a drug. This way the researcher/inventor can know what the cause is and whether the complaint is well-founded or not.

Technology Readiness Level 5

The technology is integrated, meaning core components have been combined with the actual supporting components in a simulated environment that closely resembles real-world conditions.

Example: The manufactured tire prototype connected to the rim is prepared for initial performance tests under realistic laboratory conditions.

For the healthcare sector (medicine, pharmacy, nutrition): Advanced characterization of the developed product (drug, food for special nutritional conditions or dietary supplement) and initiation of the development of the Good Manufacturing Practices (GMP) process.

Continuation of non-GMP in vivo studies and development of animal models and tests (genetic analyses, tests on reproductive function, or other analyses may be included).

In this stage, a scalable and reproducible manufacturing process adapted to GMP is developed. For food and food supplements, it is recommended to develop a HACCP (Hazard analysis and critical point) plan to identify and analyze possible food safety hazards and for which measures must be implemented in the manufacturing process to prevent them. Examples of stages where preventive measures must be implemented: receipt of raw materials, dosing of food additives, pasteurization, sterilization, baking, storage, transportation of finished products or other stages, depending on the product developed.

Also at this stage, the development of animal models for efficacy and dose variation studies continues. It is very important to know what happens at higher doses and what adverse reactions may occur. It is recommended to establish protective correlations and/or markers for efficacy for use in future GMP studies on animal models and identify the minimum effective dose to facilitate the determination of the "humanized" dose once clinical data are obtained.

Performing analyses by analytical methods for product characterization and release, including assessments of potency, purity, identity, strength, sterility and quality, as appropriate. Demonstration of acceptable absorption, distribution, metabolism and elimination characteristics and/or immune responses in non-GMP animal studies, for medicinal products in particular. These tests are also necessary if the inventor or assignee wishes to submit the file to a national or European authority (e.g., EFSA or EMA) for approval for manufacturing and/or marketing in the European Union, where EFSA represents the European Food Safety Authority and EMA is the European Medicines Agency.

Industrial production: the development of processes for small-scale production, according to GMP, is initiated. At this stage, it is important to consider the minimum capacity of the leading/main equipment/machinery in the production line and its type, to ensure that the quality of the developed product is not negatively affected. The minimum capacity of the leading machine is important for establishing the quantities of raw and auxiliary materials needed, for establishing the number of packaging and labels needed, and more.

Technology Readiness Level 6

This stage marks the conclusion of industrial research, featuring a more advanced prototype than that at TRL 5, tested under simulated operational conditions. The prototypes at this level are closer to the final production version.

Example: Bicycle tires are mounted and tested on a simulated road using specialized equipment or platforms.

For the healthcare sector (medicine, pharmacy, nutrition): GMP pilot batch production, submission of dossiers to local or national authorities and phase 1 clinical trials. Manufacture of GMP-compliant pilot batches. Preparation and submission of the newly developed and reviewed product dossier to local/national/European authorities and conduct of monocentric or multicentric phase 1 clinical trials.

Animal models: Further development of animal models through toxicology, pharmacology, and immunogenicity studies.

Tests: Establishment of tests for production quality control and immunogenicity, if applicable.

Manufacturing: Manufacturing, releasing and performing stability testing of bulk and formulated products in accordance with GMP in support of clinical trials.

Target product profile (drug, food for special nutritional conditions or dietary supplement): Updating the target product profile, as appropriate.

Devices: Prototype system/device demonstrated in an operating environment. Clinical testing may be required to demonstrate safety. Depending on the classification of the device, pre-market approval or pre-market notification may apply.

The product (drug/food for special nutritional conditions, dietary supplement) meets industry expectations. Determination of the safety and pharmacokinetics of the clinically tested developed product. It meets the requirements of external stakeholders.

Technology Readiness Level 7

This stage marks the beginning of development, where the prototype is tested under full operating conditions.

Example: A tire fitted to a bicycle is tested on a real road.

For the healthcare sector (medicine, pharmacy, nutrition): Scale up, initiate GMP process validation, and phase 2 clinical trials.

Perform animal efficacy studies, as appropriate. Perform phase 2 clinical trials.

Animal models: Refine the development of animal models in preparation for animal efficacy studies.

Testing: Validate tests for production quality control and immunogenicity, as appropriate.

Manufacturing: Scale up and validate the manufacturing process according to good manufacturing practices (GMP and HACCP for foods or food supplement) at a scale compatible with the legal or other requirements of the economic operator. Initiate stability studies of the product in a formulation, dosage form and container in accordance with the target product profile. Initiate validation of the manufacturing process and production of a pilot batch/lot.

Target product profile: Update the description of the target product (drug, food for special nutritional status, food supplement, medical device), as appropriate.

Devices: Conducting clinical safety and efficacy studies using fully integrated prototype version of the developed product or medical device in an operating environment. Data evaluated to support further development. Final product design is validated and final prototype and/or device for commercial use is produced and tested.

Technology Readiness Level 8

At this level the technology is mature and complete. It has been tested in the intended environment confirming its usability under the conditions assumed at TRL 2 and has the necessary market approvals with the most relevant constraints. At this stage, the prototype demonstration is completed, a pilot batch is produced, and technical and service documentation is created.

Example: confirmation, e.g., declaration of conformity assessment, that the tire is marketable. A statistical pilot batch has been tested by consumers.

For the health field (medicine, pharmacy, nutrition): Completion of GMP validation, HACCP plan and pilot batch production, essential animal efficacy studies or clinical trials and preparation of documents for approval or manufacturing and marketing license to local or national authorities.

Complete stability studies in support of the label expiry date (examples of physic-chemical, microbiological or other type of analyses).

In the case of medical devices, before commercialization, the documents must be sent to the national authorities in order to receive the favorable opinion/approval.

Technology Readiness Level 9

The technology is ready for commercialization and has reached its final form. It can be implemented in industry and mass production.

Example: A tire has been analyzed for life cycle assessment and is safe to use. A marketing campaign is initiated.

For the health field (medicine, pharmacy, nutrition): Post-license and post-approval activities - The actual application of the technology in its final form, under operational mission conditions and the launch of the product on the market.

In this stage, the products are marketed, and studies and post-marketing surveillance are carried out, including in the fields of pharmacovigilance for the pharmaceutical field (drugs) and nutrivigilance (food supplements and foods for special nutritional states).

The customer/economic agent controls the technology.

4.2 The importance of the TRLs

TRL technology readiness levels play an important role across various sectors of the economy, and they are a crucial framework for assessing the maturity of a technology and its readiness for practical application. They provide a standardized metric that facilitates communication, risk management, and decision-making across various sectors. Here's a detailed look at the key roles TRLs play:

Risk Identification and Mitigation: TRLs are instrumental in identifying and mitigating potential risks associated with technology development. By assessing the technology's maturity level, stakeholders can pinpoint areas of uncertainty and potential failure. For instance, a technology at TRL 3 (experimental proof of concept) carries significantly higher risks than one at TRL 7 (system prototype demonstration in an operational environment). This understanding allows for proactive risk management strategies, such as:

- **Early-stage risk mitigation:** Identifying fundamental scientific or engineering challenges early in the development process.
- **Resource allocation:** Directing resources towards addressing the most critical risks based on the TRL assessment.
- **Contingency planning:** Developing backup plans and alternative approaches to mitigate potential failures.

By systematically evaluating risks at each TRL, organizations can make informed decisions about whether to proceed with further development, modify the technology, or abandon the project altogether.

Budget Planning: Effective budget planning is essential for successful technology development, and TRLs provide a valuable tool for allocating resources strategically. By understanding the technology's TRL, organizations can better target resources where they are most needed. This includes:

- **Prioritizing funding:** Allocating more resources to technologies with higher TRLs that are closer to commercialization.
- **Optimizing resource allocation:** Identifying areas where additional investment is needed to advance the technology to the next TRL.

- **Phased funding:** Implementing a phased funding approach, where funding is released incrementally as the technology progresses through the TRLs.

By aligning budget allocations with the TRL assessment, organizations can ensure that resources are used efficiently and effectively, maximizing the chances of successful technology development.

Project Management: TRLs serve as a roadmap for project management, providing clarity on the R&D pathway and enabling the setting of clear objectives and milestones. The TRL levels assigned to specific tasks in the research agenda clarify the R&D pathway, allowing clear objectives and milestones to be set and progress to be monitored. This includes:

- **Defining project scope:** Establishing clear boundaries for the project based on the target TRL.
- **Setting milestones:** Defining specific, measurable, achievable, relevant, and time-bound (SMART) milestones for each TRL.
- **Tracking progress:** Monitoring progress against the milestones and identifying any deviations from the planned trajectory.
- **Resource allocation:** Allocating resources to specific tasks based on their TRL and importance to the overall project.

By integrating TRLs into project management, organizations can ensure that projects stay on track, resources are used efficiently, and objectives are achieved.

Strategic Planning: TRLs are essential for long-term strategic planning of technology development strategies to maintain market advantage or increase competitiveness. By understanding the TRLs of their technologies, organizations can:

- **Identify strategic gaps:** Identifying areas where technology development is lagging behind competitors.
- **Prioritize investments:** Focusing investments on technologies that have the greatest potential to create a competitive advantage.
- **Develop technology roadmaps:** Creating long-term plans for technology development, outlining the steps needed to advance technologies through the TRLs.
- **Assess market readiness:** Determining when a technology is ready for commercialization based on its TRL.

By incorporating TRLs into strategic planning, organizations can make informed decisions about technology development, ensuring that they remain competitive in the long term.

Investment Decisions: A defined TRL indicates the maturity of the technology, enabling investors to make informed financial decisions. Investors use TRLs to assess the risk and potential return of technology investments. A higher TRL indicates a lower risk and a higher potential return, while a lower TRL indicates a higher risk and a lower potential return. This includes:

- **Due diligence:** Conducting thorough due diligence on the technology's TRL to assess its maturity and potential for success.
- **Valuation:** Determining the value of the technology based on its TRL and potential market impact.
- **Investment structuring:** Structuring investments to align with the technology's TRL and risk profile.

- **Monitoring progress:** Monitoring the technology's progress through the TRLs to ensure that it is meeting expectations.

By using TRLs to inform investment decisions, investors can reduce their risk and increase their chances of success.

Compliance Assessment: TRLs help assess compliance with project funding competition guidelines. Many funding agencies use TRLs as a criterion for evaluating project proposals. By defining the TRL of the proposed technology, applicants can demonstrate that their project is aligned with the funding agency's goals and priorities. This includes:

- **Eligibility:** Determining whether the project is eligible for funding based on the funding agency's TRL requirements.
- **Proposal evaluation:** Assessing the project's technical feasibility and potential for success based on its TRL.
- **Reporting:** Reporting on the project's progress through the TRLs to demonstrate compliance with the funding agency's requirements.

By using TRLs to assess compliance with funding guidelines, funding agencies can ensure that their resources are used effectively and that projects are aligned with their strategic goals.

Communication: TRLs provide a common language among different communities and stakeholders, increasing the likelihood of successful technology transfer and implementation. This includes:

- **Facilitating collaboration:** Enabling researchers, engineers, investors, and policymakers to communicate effectively about technology development.
- **Promoting technology transfer:** Facilitating the transfer of technology from research labs to commercial applications.
- **Enhancing public understanding:** Improving public understanding of technology development and its potential benefits.

By providing a common language for technology development, TRLs can help to bridge the gap between different communities and stakeholders, fostering collaboration and accelerating innovation.

In conclusion, Technology Readiness Levels (TRLs) are an indispensable tool for managing technology development across various sectors. Their ability to facilitate risk identification, budget planning, project management, strategic planning, investment decisions, compliance assessment, and communication makes them essential for driving innovation and ensuring the successful transfer of technology from research to practical application.

The following graphic resumes this section (Figure 4.2):

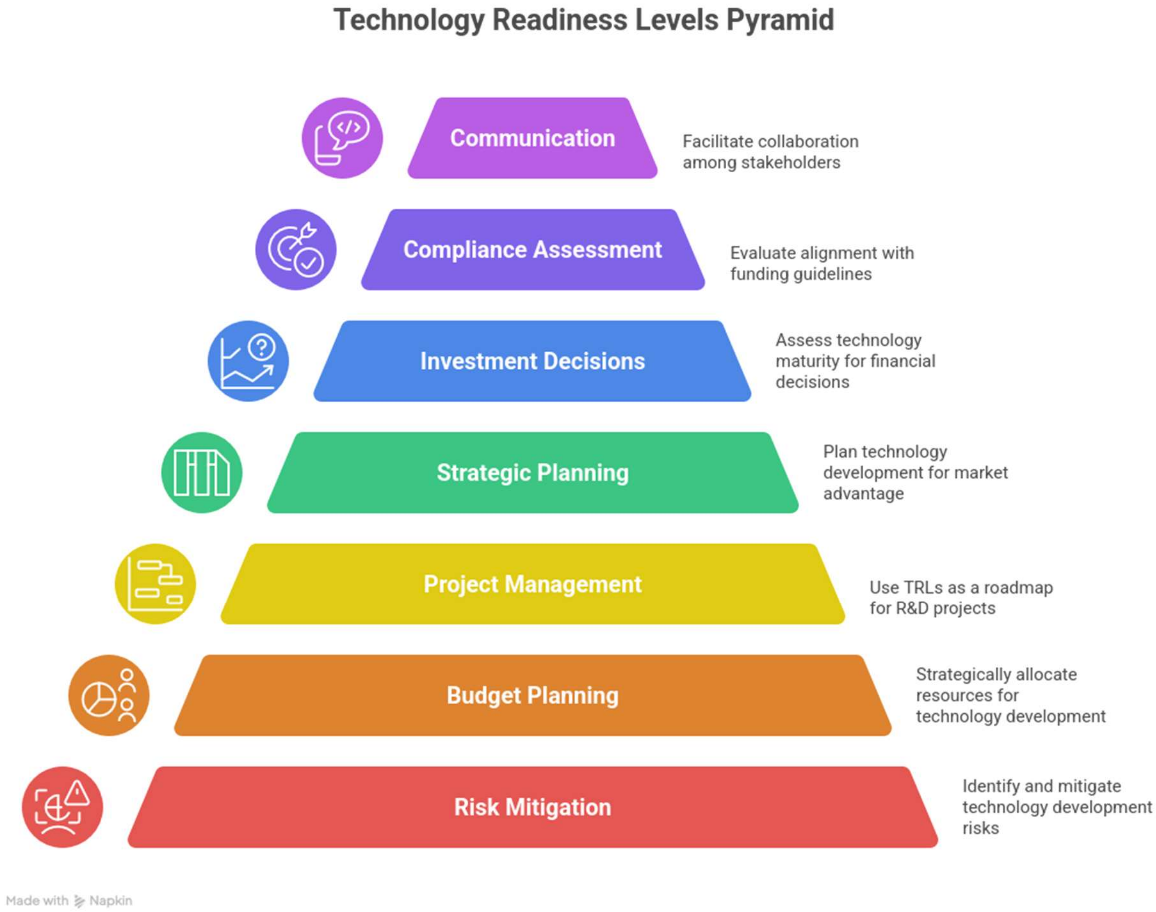

Figure 4.2: Key roles of TRLs

4.3 Challenges and practices

This section focuses on the challenges and practices encountered when applying Technology Readiness Levels (TRLs). Key challenges discussed include the lack of universal definitions, the inherent subjectivity in qualitative assessments, variations in expert interpretation, and the complexity of integrating TRLs with broader project management or market contexts. The section also addresses issues like resource intensity, time consumption, and the struggle of TRLs to keep pace with rapidly changing technological conditions.

Adaptation to industry specifics: TRLs were originally developed for the aerospace sector, which can make them difficult to apply directly to other sectors such as medicine, IT or energy**.** Each industry has its own unique requirements and characteristics. It is therefore important to adapt the definitions and interpretations of the different TRL levels to the specific industry and market constraints. The introduction of sectoral or even company-specific guidelines for the interpretation of TRLs can help to standardize technology assessment within an industry.

Lack of universal definitions: Each industry may have different interpretations of TRL levels, leading to discrepancies in the assessment of technology maturity. This variability can hinder cross-sector comparisons and collaborations. To reduce the subjectivity of the assessment, it is important to develop clear and detailed information for each TRL level.

Qualitative assessment: Although presented as an objective tool, TRLs often rely on qualitative assessments by experts. The subjectivity of these assessments can lead to inaccuracies in determining the true maturity of a technology, especially in complex and interdisciplinary projects.

Differences in interpretation: Variations in expert interpretation of TRL levels can lead to ambiguous results, potentially resulting in suboptimal decisions regarding technology development. Regular consultation with industry and technology experts during the TRL assessment helps to minimize these differences in assessment.

Complexity of the technology: Assessing Complex technologies that integrate many different components or require integration into large systems may be difficult to assess clearly using TRLs. The framework may not fully account for all development aspects, such as technology integration or adaptation to market changes. Integrating TRLs with project management methodologies such as Agile, Lean, PRINCE2 or Six Sigma can improve consistency of effort. However, this can be challenging, especially in large organizations with extensive management structures.

Lack of market context: TRLs focus on technological aspects often overlooking market, regulatory, or business readiness, which can be critical in certain sectors. A technology may be mature (high TRL) but not ready for the market due to the lack of an appropriate business or regulatory environment.

Alignment with corporate strategy: TRLs may not be easily integrated into an organization's internal decision-making processes, which can lead to friction between different departments (e.g., R&D vs. management) based on differing interpretations of TRL levels.

Resource requirements: Implementing TRLs in an organization can require significant resources, both human and financial. Establishing and maintaining an accurate TRL assessment system tailored to the specifics of the organization can be costly, especially for small and medium-sized enterprises.

Time consuming: The process of accurately assessing TRLs, especially for complex projects, can be time consuming, potentially lengthening decision -processes and delaying technology development- especially problematic in fast-paced markets.

Changing technology conditions: In rapidly evolving sectors, such as IT or biotechnology, the pace of change is very fast. The static nature of the TRL scale may struggle to keep pace with dynamic requirements and technological advances, necessitating constant updating.

Evolving standards and regulations: As technologies mature, industry standards and regulations change. TRLs do not always reflect these changes, impacting the accuracy of technology readiness assessments.

Evolving methodologies: As technologies advance and industries transform, the TRL scale needs to be updated or adapted to remain useful and relevant. Failure to evolve in this way can diminish its values as an assessment tool.

Cultural and regional differences: In an international context, it may face challenges due to cultural, legal and regulatory differences. This can complicate global projects where different regions may approach technology assessment differently.

Project life cycle: TRLs can serve as milestones throughout the project lifecycle, facilitating better monitoring of progress and decision-making based on objective indicators.

Risk mapping: Integrating TRLs with risk management. By determining the level of TRLs organizations can identify potential risks associated with further technology development and allow for early countermeasures.

Document the process: It is important to thoroughly document the TRL assessment process so that all decisions are transparent and can be reviewed if necessary. This builds trust between teams and stakeholders.

Reporting and monitoring: Regular reporting on progress against the TRL helps to keep all stakeholders informed and enables a swift response to any delays or problems.

Technology portfolio management: In organizations developing multiple technologies simultaneously, TRLs can help manage a portfolio of technologies, helping to allocate resources to the highest priority or potential projects.

Feedback loop: Establishing mechanisms to gather feedback from TRL users in an organization or industry can help identify areas for improvement, enhancing the overall effectiveness of the TRL framework.

4.4 The research hypothesis, the results of the project and the current State-of-the-Art

This section details the foundational elements of R&D projects. It focuses on defining a clear, testable research hypothesis grounded in existing knowledge and market needs. The section emphasizes assessing the innovativeness of project results by comparing them with current solutions and market potential. It also outlines the stages of a research agenda, relevant databases for state-of-the-art analysis, and provides examples of good practice. Ultimately, this section guides researchers to ensure their work is scientifically sound, market-oriented, and poised for successful commercialization.

4.4.1 Description of the research hypothesis

This subsection focuses on **formulating a clear and testable research hypothesis** for an R&D project. This hypothesis is crucial as it **defines the project's purpose**, aiming to address specific questions or solve particular problems. It must be grounded in existing scientific literature* to identify knowledge gaps or unmet needs. The subsection emphasizes that the **hypothesis should be concrete and testable**, clearly stating its variables, and it connects this to an analysis of the State-of-the-Art and competing products to show how the proposed study improves on existing solutions.

Rationale

- Purpose: The hypothesis should clearly state what the research project aims to achieve, addressing specific questions or solving specific problems.
- Evidence-based: The hypothesis should be grounded in existing scientific literature and research identifying gaps or inconsistencies in knowledge that the project aims to address.

Content

- Concreteness: A clearly stated hypothesis that can be tested experimentally.
- Testability: Must be confirmed or rejected on the basis of the data collected.
- Variability: A clear statement of the independent and dependent variables.

State-of-the-Art

- Conduct a literature review to identify current trends, available technologies, current research and findings.
- Indicate how the hypothesis addresses unmet needs or gaps in knowledge.

Comparison with competing products or services

- Competitor analysis: Review existing products/services, noting their benefits and limitations.
- Identify how the proposed study has the potential to improve on existing solutions.

4.4.2 Stages of the research agenda

Here we outline the **structured approach to conducting R&D projects**. It breaks down the research process into key phases to ensure systematic execution and monitoring.

Planning

- Determine the methodology: choice of research methods (experimental, observational, simulation).
- Preparation of the work plan and resources, including the technology, equipment and personnel required.
- Breakdown of work by TRL level
- Carrying out the research
- Use standard scientific methods (e.g., experiments, statistical analysis) to test the hypothesis.
- Monitor progress and document results at each stage.

4.4.3 Innovation

Defining the research hypothesis and conducting the research systematically and scientifically ensures that the hypothesis can be reliably tested and that innovations with market potential can be identified.

- **Novelty assessment:** Does the project bring new knowledge, technology or methods that have not been used before?
- **Market potential:** Does the project offer solutions that have the potential to significantly impact the market by improving efficiency, cost or accessibility?
- **Social or economic impact:** Can the research contribute to the development of new standards, regulations or practices?
- **Basis for comparison**
    - Identifying comparison criteria: Determining which features, characteristics and benefits are key to evaluating a product or service. Examples include performance, cost, durability, ease of use, energy efficiency, uptime, safety, etc.
    - Competitor Assessment: Performing an analysis of available competing solutions, considering their strengths and weaknesses.
- **How to benchmark**
    - Benchmarking: Gathering data on current solutions, for example through literature reviews, market research, user testing or technical analysis.
    - SWOT analysis: Identifying the strengths and weaknesses of the new solution in relation to the competition (market opportunities and threats).
- **What to compare**

- Technical parameters: such as performance, response time, efficiency, robustness, etc.
- Functionality: innovative features and benefits offered by the product/service.
- Cost: cost of manufacture, cost of ownership and end user price.
- Safety and compliance: health, environmental and regulatory aspects.

Parameterization of the comparison

- Quantitative metrics: Evaluation of measurable metrics such as speed of operation, energy consumption, product lifetime, etc.
- Qualitative metrics: Qualitative evaluation including user experience, ease of use, user satisfaction.

How to make a comparison

- Define specific criteria for the comparison and weight them according to their importance.
- Collect data from existing studies, reports and market data.
- Carry out comparison tests in real conditions or simulations.
- Use multi-criteria analysis tools (e.g., AHP multi-criteria analysis) to evaluate and compare potential benefits and features.

How to carry out the analysis

- Literature review: Identify recent publications, scientific articles, reports, patents and standards related to the research area. Determine which research is considered seminal or key.
- Trend analysis: Examine current research directions and technologies being developed by competitors.
- Identify knowledge gaps: Identifying which aspects of the topic have not yet been researched or are poorly understood.

What to look out for

- Credibility of sources: Use of peer-reviewed articles, recognized journals, industry reports.
- Timeliness of information: Focus on the latest data and trends to ensure the hypothesis aligns with current knowledge.

Best practice

- Structured analysis: Organize the literature review around key themes or research questions.
- Accurate documentation: Record all relevant sources to support claims.
- Critical appraisal: Evaluate the quality of research, methods and findings to avoid basing a hypothesis on flawed or weak foundations.

What to avoid

- Over-reliance on a single source: Use a wide range of sources to get a more complete picture.
- Outdated research: Avoid relying on older publications that may be out of date.
- Unclear or unverified sources: Rejecting material from uncertain or unverified sources.

A sound analysis of the current state of knowledge is key to understanding how a hypothesis fits into the existing research landscape and its chances of implementation.

4.4.4 Databases used in R&D

To analyses the current state of knowledge in relation to the research hypothesis, it is useful to use the following databases:

- Google Scholar - a broad database of scientific articles from a variety of disciplines.
- ScienceDirect - access to peer-reviewed scientific articles and journals.
- IEEE Xplore - a key database for technology and engineering, including automotive composites.
- Web of Science - a comprehensive source of citations and scientific articles
- Patents: Google Patents or European Patent Office (EPO) - allow you to search for existing patents and patent applications.

4.4.5 Example of analysis and good practice

Subject: Development of an innovative lightweight, durable composite material for automotive applications.

- **Literature review:** Review of articles on lightweight composites (e.g., CFRP - Carbon Fiber Reinforced Polymer) used in the automotive industry in databases such as IEEE Xplore and ScienceDirect.
- **Patent analysis:** Search for existing patents on automotive composites on Google Patents or EPO.
- **Technology benchmarking:** Assess the performance of current composites (e.g., tensile strength, weight, manufacturing cost) and compare with proposed innovations.
- **Innovation assessment:** Identify innovative features (e.g., improved strength, lower production cost, corrosion resistance) compared to current solutions.
    - This analysis determines whether the innovative composite product adds value to the market and has the potential to replace existing technologies.
    - How to verify innovative features
        - Determine the parameter of the feature that demonstrates innovation
        - Define the baseline and/or competitive value of this feature
        - Define the innovative value of that feature
- **Review industry standards:** Review current standards and requirements for automotive composites (e.g., ISO, ASTM) to understand the characteristics new materials must meet.
- **Market trends Analysis:** Monitor market reports and industry research (e.g., McKinsey, Deloitte) to understand the demand for lightweight automotive materials and future developments.
- **Consult with experts:** consult with industry experts to gain practical insights into innovation potential, technical challenges and market implementation opportunities.
- **Identify research gaps:** Focus on areas where there is a lack of research or conflicting data, indicating opportunities for a new product.
- **Good practice**

  - **Take a systematic approach:** Conduct the analysis according to key themes such as materials, production methods, applications and cost effectiveness.
  - **Transparency:** Document the sources and methods of analysis to ensure the reliability of the results.
  - **Critical thinking:** Evaluate not only the results of the study, but also the methods and context in which they were conducted.
- **Pitfalls to avoid**
  - **Overlooking recent research:** Outdated data can lead to incorrect conclusions.
  - **Focusing too much on one technology:** Losing sight of the broader market and technology context can limit the innovation perspective.
  - **Ignoring the market perspective:** Limiting the analysis to technical aspects without understanding market needs and trends.

By applying the above steps and good practices, a state-of-the-art analysis can be effectively carried out in the context of R&D work, allowing a better understanding of the feasibility and innovativeness of projects.

4.5 Working with the business community Before, During and After the project

4.5.1 Before

A research topic to be developed for implementation should have its genesis in the identification of a market need for the solution to be developed. Before starting the project, current market trends and consumer needs should be verified so that the result can be commercialized. A partner for the identification of market needs is industry. They have extensive and specialized knowledge of their area of activity and experience of operating in the sector. A researcher who selects a research topic on the basis of an analysis of scientific literature should discuss the practical usefulness of this topic with companies operating in the relevant field. Interaction and exchange of experience in a field in which both parties are specialists - the researcher from the point of view of scientific achievement and the entrepreneur from the point of view of serving the market - creates a synergy effect characterized by the accuracy of the diagnosis and the effectiveness of the solution developed.

Innovative ideas in business are the basis for gaining a position on the market and beating the competition. Novelty attracts the interest of customers, provides an opportunity to dynamically mark one's presence in the industry, and allows one to develop solutions that outperform competitive offers.

Introducing market elements into a project should start as soon as the idea germinates in the mind of the initiator. As the definition of innovation crystallizes, there should be a better definition of the need that the project outcome is intended to satisfy.

The way to market an innovation should be defined in the initial phase of the project and adapted to changing market needs and expectations.

If we do not know how to define the main points of the implementation strategy in the initial phase of the project, beyond the concept phase, it is most likely that our project will not be suitable for implementation.

Although research teams complain about the difficulties of contacting entrepreneurs, and entrepreneurs often report negative experiences of collaborating with universities and research institutes, both sides should strive for mutual contacts, exchange of experiences and agreement on common goals, as scientists need inspiration from industry and industry needs innovation to survive and thrive in a competitive market.

Before discussing the details of the research programmed and the requirements of the selected market segment, it is good practice to first sign a confidentiality agreement between the research unit and the company, which will protect the confidential information exchanged and provide a safeguard against potential misuse.

Once agreement has been reached on the topic and purpose of the research, a decision is made to jointly implement the project. Projects may be carried out with the help of public funding sources available at regional, national and international level, or with own funds. While the use of state aid tends to be governed by rather rigid stipulations in the model agreements signed by the beneficiaries prior to the application, R&D projects financed from own resources of research units and enterprises are characterized by a high degree of freedom in the design of mutual relations and obligations.

4.5.2 During

The developed agreement is recorded in the form of a commercialization strategy. The strategy covers the range of activities from inception to completion of the project.

When developing a commercialization strategy, the following should be considered:

- the timing and territorial scope of intellectual property protection
- the benefits and risks of publication by the R&D partners
- the changing State-of-the-Art
- trends in customer preferences
- the business environment
- the state of the law; expected changes

Once a project has been completed, it is very difficult to develop an effective strategy for commercializing its results if market aspects have not been taken into account during the project.

Important steps after the decision to jointly implement a project

- Determine whether the project will make use of the parties' existing knowledge and achievements - so-called background IP, possibly proprietary know-how;
- Clearly define the tasks to be performed by the project participants;
- Determine how ownership of IP developed in the project will be shared;
- Determine who will be able to use the project results and to what extent;
- Determine whether rights to IP will be transferred at the end of the project.

Transparent and complete communication should be maintained by both parties throughout the project. The results of the tests should be communicated to the business partner as soon as possible in order to check whether the results obtained satisfy the parameters expected by the market. Any discrepancy between the desired results and those obtained should be analyzed and, if necessary, modify the characteristics of the target product according to public acceptance - e.g., by changing some of the functions and scope of the product. Obviously, the research agenda should be adjusted as the market changes. The research team should make both parties aware that any deviation from the planned results may lead to a significant change in the commercialization potential of the project outcome, which may prevent the entrepreneur from bringing the product to market.

Both parties should follow a pre-agreed commercialization strategy that systematizes subsequent tasks, also allowing for necessary changes. Successful commercialization of research results and project implementation are impossible without the active participation of the research team -as a substantial partner- and the company- which takes the market risk.

<u>Successful marketing of an idea requires six well-planned steps:</u>

1. **Building a competent team**

   Commercialization is a complex activity that must encompass all aspects of the project. A successful launch requires a team of specialists from various disciplines. It's not enough to have people who excel in creating innovative product or service concepts; effective innovation also requires reliable subject matter partners, especially at the beginning of the process, as well as people with full business competencies, including marketing, sales, finance, production and logistics.

   An industry partner involved in the project can be a substantive partner in this respect.

2. **Market analysis and differentiation**

   Market analysis, particularly a thorough analysis of the competition, is essential for a precise definition of the offer.

   If the idea is to be innovative, it must stand out and not be easily replicated by others. This involves a complex process of designing unique, measurable, credible and providing tangible value to the target audience. The entire communication and brand strategy will be built around them. This stage is the responsibility of the research team, but it must incorporate suggestions from the business/industry partner.

3. **Analysis of examples**

   It's beneficial to build on the successes of predecessors rather than starting from scratch. Analyzing examples of successful implementations and drawing conclusions can make the job easier. Most successful projects have been commercialized by well-rounded teams with commercial, business and investor experience. Solid sources of marketing experience allow for the development of an in-depth understanding of the needs targeted by the end product, and studying the stories of successful start-ups is a must.

4. **Stable funding (e.g., through KIS)**

   In the early stages of commercializing an idea, a stable budget is crucial. Until the process has been completed and stabilized, the venture must have a financial guarantee.

   Capital must be provided for the creation of the prototype, for its first successful sale and launch, and for further development. There must be no sudden shortage of funds until a stable income is generated.

   The budget for the whole venture must be carefully planned.

   It is advisable to divide it into successive phases and to have a contingency budget to be used only in exceptional situations.

5. **Proving the credibility of the project**

   Proving the project's credibility to business partners and the market is a critical step in marketing the project outcome, thus building the first RTB (Reason To Believe).

   RTB is a supporting argument in commercial discussions.

   If compelling competitive differentiators have been successfully combined and the value of the innovative solution effectively presented, the next step can be taken. The success of this step depends on the synergy between the business partner and the research team.

6. **Communication and sales at scale**

   Turning the first victory into a mass success requires highly developed marketing and sales skills. Production capacity must also be maintained to keep pace with rapidly growing sales and increasingly demanding customer service.

   Sudden success can exceed expectations and create new needs for which the entrepreneur may not be prepared. In this final stage, the synergy of all the company's skills, which begin to interact effectively, in parallel and in the long term, becomes crucial.

   The success of the commercialization phase depends mainly on the skills and determination of the entrepreneur.

4.5.3 After

The end of a project should not mark the end of collaboration between stakeholders. The launched product will require modifications, improvements and adaptations to the changing needs of the audience. Partners in the commercialization process should monitor market reactions to the launched product, both positive and negative. Positive feedback may lead to the development of a better version of the product, which will increase market share and thus revenues.

Negative feedback should prompt the improvement of the criticized features, as passivity from the producer and originator could halt sales and cause losses.

4.6 Technical Cost of Products Manufacturing (TCPM)

The Technical Cost of Products Manufacturing (TCPM) is the total cost of producing a product, encompassing all costs associated with the production process. This includes both direct and indirect costs. The calculation of the PTOM allows the company to evaluate the efficiency of the production process, make decisions on the profitability of production, plan the pricing policy, develop sales strategy, and manage current resources more efficiently.

4.6.1 Use in production planning and management

The Technical cost of products manufacturing (TCPM) is critical at several stages of production planning and management:

- **Production planning** - at this stage TCPM helps to assess the costs associated with different production options and to select the most cost-effective solutions.
- **Budgeting and cost control** - knowledge of TCPM enables accurate budgeting, cost control and identification of areas where savings can be made.
- **Pricing policy** - based on the TCPM, the company can set prices for its products, considering both costs and the planned profit margin.
- **Profitability analysis** – TCPM is used to analyses the profitability of producing specific products or product lines.

4.6.2 Components and stages of the TCPM calculation

TCPM consists of several basic elements (Figure 4.3):

- **Material costs** - the cost of raw materials, semi-finished products and other materials directly consumed in the production process.
- **Labor costs** - wages and salaries of employees directly involved in production, including non-wage costs (e.g., insurance, social benefits).
- **Machinery costs and depreciation** - costs associated with the operation and maintenance of machinery and depreciation of production equipment.
- **Energy costs** - the cost of the energy required to operate machinery and lighting in the production process.
- **Production overheads** - other costs associated with maintaining production, such as building maintenance, stock management, etc.

Steps in calculating the TCPM:

- **Data collection**
    - Identify and collect all direct costs associated with production, such as material costs, employee wages, machine depreciation, etc.
    - Include indirect costs such as energy costs, maintenance costs of the production facility, management costs.
- **Cost per unit calculation**

  Allocate the collected costs to individual stages of production or to production units, depending on the chosen calculation method (order-based, process-based, unit-based).

- **Analysis of the results**
    - Compare the calculated technical costs of manufacturing products with sales prices and budgeted costs.
    - Assessing whether the current cost structure is optimal and identifying potential areas for improvement
- **Implementation of optimization strategies**

  Based on the analysis of the **TCPM**, decisions are made to implement changes in production processes, renegotiate contracts with suppliers or introduce new technologies to reduce costs.

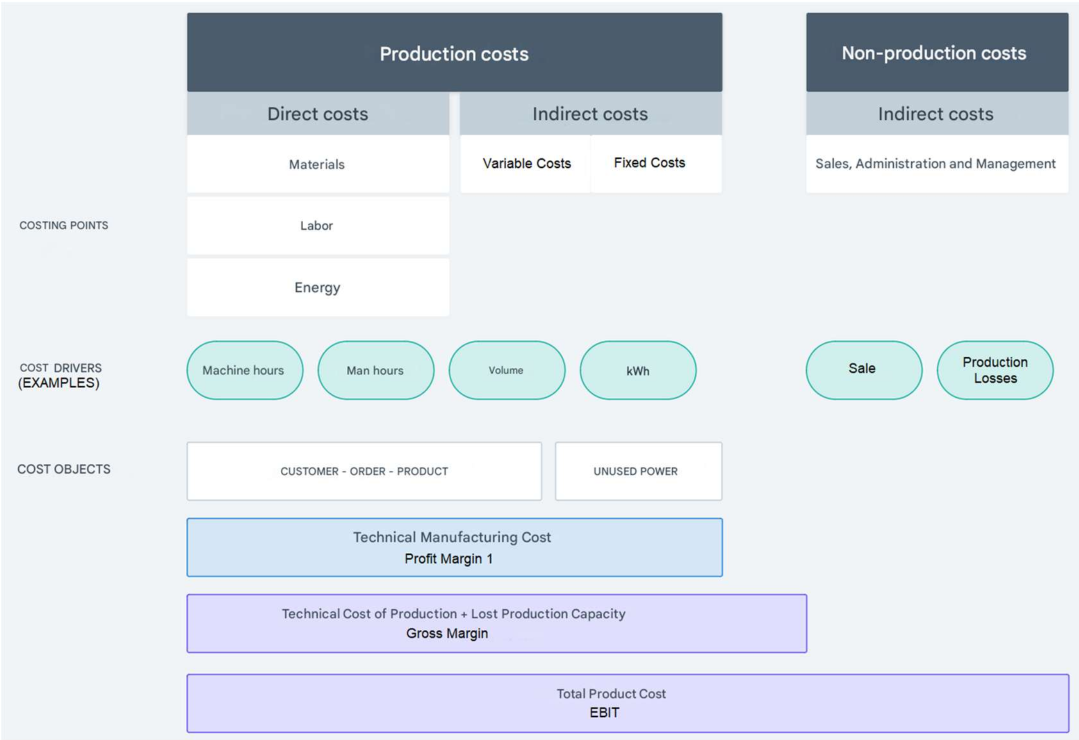

Figure 4.3: TCPM scheme

4.6.3 Methods for calculating the TCPM

Now we proceed by examples to complete a TCPM.

1- **Commissioning calculation method** - costs are allocated to a specific production order to determine the exact cost of producing a particular product.

This method is mainly used in one-off or small batch production, where each product or series of products is treated as a separate production order. Costs are allocated directly to a specific order.

General formula: **TCPM = MC + LC + MWC + MOC**

Where:

- TCPM – **technical cost of products manufacturing**
- MC – material costs (raw materials, direct materials)
- LC – labor costs (salaries, insurance and benefits for production workers)
- MWC – machinery wear costs (depreciation, repair and maintenance costs)
- MOC – manufacturing overheads (fixed overheads per order)

Example of the calculation of the TPCM using the order method: Assume that the cost of materials is MC is 10,000€, labor costs LC are 5,000€, machinery wear costs MWC are 2,000€, and manufacturing overheads MOC are 3,000€.

TCPM = 10,000 + 5,000 + 2,000 + 3,000 = 20,000

2- **Process costing method -** costs are allocated to individual production processes, which is effective in mass production where it is difficult to allocate costs to individual units of a product.

A method mainly used in mass production where the production process is repetitive, and costs are allocated to individual process steps and then divided by the number of units produced.

General formula: $\mathbf{TCPM = \sum(KM_i+KL_i+KZ_i+KO_i)/LPU}$

Where:

- MC_i – material costs at the i-th stage of the process.
- LC_i - labor costs at the i-th stage of the process.
- MWC_i – machine wear and tear costs at the i-th stage of the process.
- MOC_i– manufacturing overheads at the i-th stage of the process.
- NPU – number of produced units.

Example of calculating TCPM using the process method:

Let's assume there are three stages in the production process:

- Stage 1: MC_1 = 3,000 €, LC_1 = 1,500 €, MWC_1 = 500 €, MOC_1 = 700 €.
- Stage 2: MC_2 = 2,000 €, LC_2 = 1,000 €, MWC_2 = 300 €, MOC_2 = 400 €.
- Stage 3: MC_3 = 4,000 €, LC_3 = 2,500 €, MWC_3 = 700 €, MOC_3 = 900 €

Total for stages:

$$\sum(MC_i + LC_i + MWC_i + MOC_i) = 3{,}000\text{ €} +1{,}500\text{ €} +500\text{ €} +700\text{ €} +2{,}000\text{ €} +1{,}000\text{ €} + +300\text{ €} +400\text{ €} +4{,}000\text{ €} +2{,}500\text{ €} +700\text{ €} +900\text{ €} = 17{,}500\text{ €}$$

If the number of units produced is 500 then:

TCPM = 17,500 €/500 = 35 € per unit

3- **Unit costing method** - the cost of each unit of product is calculated by dividing the total cost by the number of units produced.

General formula: **Unit TCPM = Total costs / Number of units**

Example of calculating unit TCPM**:** If total production costs are 100,000 € and 10,000 units of the product are produced, then unit TCPM = 100,000 € / 10,000 = 10 € per unit

Tools to support the calculation of the technical cost of products manufacturing:

- **Production Management Software**

Today's companies often use sophisticated ERP (Enterprise Resource Planning) software to manage production costs, including TCPM. This software automates data collection, costing and reporting to enable ongoing cost control and rapid decision making.

- **Scenario Analysis**

Companies can use scenario analysis to predict how changes in material or labor costs, or changes in production scale, will affect TCPM and profitability. This enables them to prepare for different market situations and changes in demand.

- **Benchmarking**

Comparing TCPM with similar costs at competitors (benchmarking) is useful in assessing whether a company is cost-competitive. If a company has higher manufacturing costs than its competitors, this may indicate a need to optimize production processes.

4.6.4 Meaning of the technical cost of products manufacturing

Knowledge of the technical cost of products manufacturing is crucial to the management of a manufacturing company:

- **Increase efficiency** by identifying costs that can be reduced without compromising product quality.
- **Optimize processes** through TCPM analysis, more efficient production processes can be implemented.
  - **Optimize production costs**: Accurate calculation of TCPM allows companies to identify the elements of the production process that generate the highest costs. This makes it possible to implement optimization measures such as:
    - **Switching raw material suppliers**: The analysis of material costs (MC) can lead to the renegotiation of contracts with suppliers or the search for cheaper raw materials of similar quality.
    - **Production automation:** High labor costs (LC) can lead to investment in automation or robotics of processes, reducing labor costs in the long term.
  - **Production planning:** TCPM is fundamental to the preparation of production schedules and financial plans. Knowing exactly what it costs to produce a certain number of units of a product allows for more efficient production planning. The company can assess in advance which orders are more profitable and what quantities are worth producing in order to maximize profit.
  - **Financial control and budgeting:** TCPM is a key indicator in the preparation of annual and quarterly budgets. By comparing actual production costs with budgeted assumptions, cost efficiency can be monitored on an ongoing basis and any necessary adjustments made. Regular

monitoring of TCPM enables deviations from planned costs to be identified, which in turn enables a rapid response, e.g., by introducing savings or changes to the production process.

- **Product pricing and pricing strategy**: Knowing an accurate TCPM is essential for product sales pricing. The price of a product must cover the cost of production and ensure a profit.
- **Applying Lean Manufacturing tools** to minimize the technical cost of products manufacturing
  - **Kaizen** a philosophy of continuous improvement that encourages employees at all levels to look for ways to improve production processes.
    - ✓ Impact on TCPM: Continuous process improvement, even by small steps, can lead to significant savings across production. Eliminating unnecessary steps and improving the efficiency of machinery reduces variable costs and also has the effect of reducing fixed costs in the long term.
  - **5S (Sort, set in order, Shine, Standardize, Sustain**), a workplace organization system that aims to create a clean, tidy and safe working environment
    - ✓ Impact on technical cost of products manufacturing: Improved work organization and increased operational efficiency result in reduced waste of time and resources, thereby reducing direct and indirect costs associated with production
  - **Just-In-Time (JIT)**, a manufacturing strategy that delivers materials and raw materials exactly when they are needed in the production process, minimizing inventory.
    - ✓ Impact on technical cost of products manufacturing: Reducing inventory reduces storage costs and the risk of waste, which in turn reduces material costs. In addition, more efficient management of raw materials can reduce the need for overtime and improve the use of production resources.
  - **SMED (Single Minute Exchange of Die),** a technique aimed at reducing machine changeover times (production configuration changes) to single digits, i.e., less than 10 minutes
    - ✓ Impact on technical cost of products manufacturing: Reducing changeover times allows faster production changeovers and less downtime, resulting in better utilization of machines and labor. This in turn reduces the variable costs associated with downtime and unproductive energy consumption.
  - **Kanban**, a production management system based on visual signals that indicate when to start a new production batch or material delivery.
    - ✓ Impact on technical cost of products manufacturing: Improved synchronization of production and material deliveries minimizes overproduction and reduces costs associated with storing and handling excess raw materials.

- **To maintain competitiveness,** awareness of actual costs allows competitive pricing of products on the market.
  - **Set minimum selling prices** that cover production costs and make a profit.
  - **Develop a rebate policy**, knowing to what level the price can be reduced so that the company continues to make a profit.
  - **Segmenting the market** by offering products with different levels of quality and price to reach a wider range of customers.
- **Assessing Profitability and Viability.** The technical cost of products manufacturing enables companies to assess the profitability not only of individual products, but also of entire production lines or business units. Based on TCPM and margin analysis, decisions can be made to continue, restructure or close unprofitable production lines.
  - **The break-even point** is the level of production at which total costs (both fixed and variable) are covered by sales and profit is zero. Knowing this point is crucial because it allows a company to determine the minimum number of units it must produce and sell to avoid losses.

- **Break-even point formula**: Break-even point (in units) = Fixed costs/(Unit price - Unit variable cost)

  Example: If fixed costs are 100,000 €, the unit selling price is 50 € and the variable cost per unit is 30 €, the break-even point in units is:

  Break-even point = 100,000€/(50€ - 30€) = 5,000 units

  This means that the company must sell at least 5,000 units of the product to cover all costs.

- **Investment decisions**, when planning to invest in new technology, production lines or machinery, an analysis of TCPM can estimate the costs associated with production on the new equipment. TCPM can also be used to assess the return on investment (ROI), which is crucial when making capital allocation decisions.

4.6.5 Example of the TCPM calculation in an R&D project

Project assumptions: The project concerns the development of a new composite material to be used in aircraft construction. Costs will vary according to the TRL level. Assume that a unit (piece) of material is a certain amount of pilot production (e.g., 1 m² of composite).

Core costs:

- material costs (MC) - the cost of raw materials and consumables required to produce a unit of composite material.
- labor costs (LC) - the cost of the research team, engineers, technicians, etc.
- machinery wear costs (MWC) - costs associated with the purchase, hire or depreciation of equipment.
- overheads (OC) - other costs associated with the project, e.g., logistics, administration, testing.

Calculation of the technical cost of products manufacturing at different TRL levels

TRL level 1-3 (conceptual and fundamental research phase): At TRL level 1-3, the project is in the conceptual and basic research phase. At this stage, costs are mainly related to laboratory studies, simulations and small-scale experiments.

Assumptions:

- Number of units produced (pieces of material) = 10 pcs.
- MC (cost of materials) = 5,000 PLN
- LC (labor costs of the research team) = 50,000 PLN
- MWC (equipment and depreciation costs) = 10,000
- MOC (overhead costs) = 5,000
- Calculation:
  - ✓ Total TCPM =MC+LC+ MWC +OC
- Total TCPM =5,000+50,000+10,000+5,000=70,000
- Cost per material unit (piece):
  - ✓ Unit TCPM = Total TCPM /Number of units
  - ✓ Unit TCPM = 70,000/10=7,000 PLN/unit.

Justification of TCPM at TRL 1-3: High labor cost (LC) in relation to total cost as the project is focused on research and experimentation. Unit costs are high due to the small scale of production and the high proportion of fixed costs.

TRL 4-6 (Development, test and validation phase): At TRL 4-6 the project enters the prototype development and testing phase. As the number of units produced increases, the cost of materials and testing increases, but the cost per unit may decrease due to the higher number of units produced.

Assumptions:

- Number of units produced (pieces of material) = 100 pcs.
- MC (cost of materials) = 40,000
- LC (labor costs of the research team) = 100,000
- MWC (equipment and depreciation costs) = 200,000
- MOC (overhead costs) = 15,000
- Calculation:
  - ✓ Total TCPM =MC+LC+ MWC +OC
  - ✓ Total TCPM =40,000+100,000+20,000+15,000=175,000
- Cost per material unit (piece):
  - ✓ Unit TCPM = Total TCPM /Number of units
  - ✓ Unit TCPM = 175,000/100=1,750 /unit.

Justification for TCPM at TRL 4-6: Lower unit costs compared to TRL 1-3 as costs are spread over a larger number of units. A Larger proportion of material (MC) and labor (LC) costs resulting from prototype production and testing. Increased overhead costs (OC) associated with validation.

TRL 7-9 (demonstration, certification and deployment phase): At TRL 7-9, the technology is close to commercialization. Pilot production costs are increasing due to preparations for mass production, but unit costs may decrease due to further scale-up.

Assumptions:

- Number of units produced (pieces of material) = 1000 pcs.
- MC (cost of materials) = 200,000
- LC (labor costs of the research team) = 300,000
- MWC (equipment and depreciation costs) = 150,000
- OC (overhead costs) = 100,000
- Calculation:
  - ✓ Total TCPM =MC+LC+ MWC +OC
  - ✓ Total TCPM =200,000+300,000+150,000+100,000=750,000
- Cost per material unit (piece):
  - ✓ Unit TCPM = Total TCPM /Number of units
  - ✓ Unit TCPM = 750,000/1,000 = 750 /unit.

Justification for TCPM at TRL 7-9: Unit costs are significantly lower due to large scale production and more efficient distribution of fixed costs (MWC and MOC). High material (MC) and labor (LC) costs, but their impact on the unit cost is reduced by mass production. Significant production equipment costs (MWC) are amortized over a larger number of units, reducing the unit cost.

Summary of TCPM differences by TRL level:

- **TRL 1-3:** High unit costs (PLN 7,000/unit) due to small scale of production, high proportion of labor costs (LC) and depreciation of research equipment (MWC).
- **TRL 4-6:** Lower unit costs (PLN 1,750/unit) due to higher production volumes and more efficient cost allocation.
- **TRL 7-9:** Lowest unit cost (PLN 750/unit) achieved through large-scale pilot production, allowing fixed and variable costs to be spread over a larger number of units.

4.7 Project Risk Management

Project Risk Management is the process of systematically identifying, analyzing, monitoring and controlling risks that may affect the achievement of project objectives. It is a key element of project management as it helps minimize uncertainty, improve decision-making and increase the chances of achieving the intended results.

The risk management process consists of several steps (Figure 4.4):

- **Risk identification**, identifying all the potential risks that may affect the project. These risks can have various sources, including technical, operational, financial, schedule, resource, regulatory, etc.
- **Risk analysis**, assesses the likelihood and potential impact of each risk to identify which risks are most critical to the project.
- **Risk response planning,** developing risk management strategies to minimize or eliminate the negative impact of risks on the project. This includes both preventive actions and response plans when risks occur.
- **Risk monitoring and control**, regularly tracking and evaluating risks and the effectiveness of the management strategies implemented. Adjustments and new countermeasures are implemented as necessary.
- **Communication and documentation**, informing stakeholders of identified risks, management strategies and the current status of risks. It is also important to fully document the risk management process.

Figure 4.4: Risk Management

4.7.1 Risk Management Strategies

Now we details various **approaches to minimize or eliminate the negative impact of identified risks** within a project. The section provides practical methods for project managers to strategically handle uncertainties throughout the project lifecycle (Figure 4.5).

- **Risk avoidance**, taking steps to remove risk from a project altogether. For example, changing the scope of the project or using proven technologies rather than experimental ones.
- **Risk mitigation**, reducing the likelihood of a risk occurring or its impact on the project. Examples include additional quality testing, backup resources, or changing the schedule.
- **Risk transfer**, the transfer of risk to an external party, for example through insurance or contracting with a supplier to take responsibility for certain risks.
- **Risk acceptance**, the deliberate acceptance of a risk, usually when its potential impact is low and the cost of avoiding or reducing it would be too high. As part of this strategy, a contingency plan is put in place in case the risk materializes.

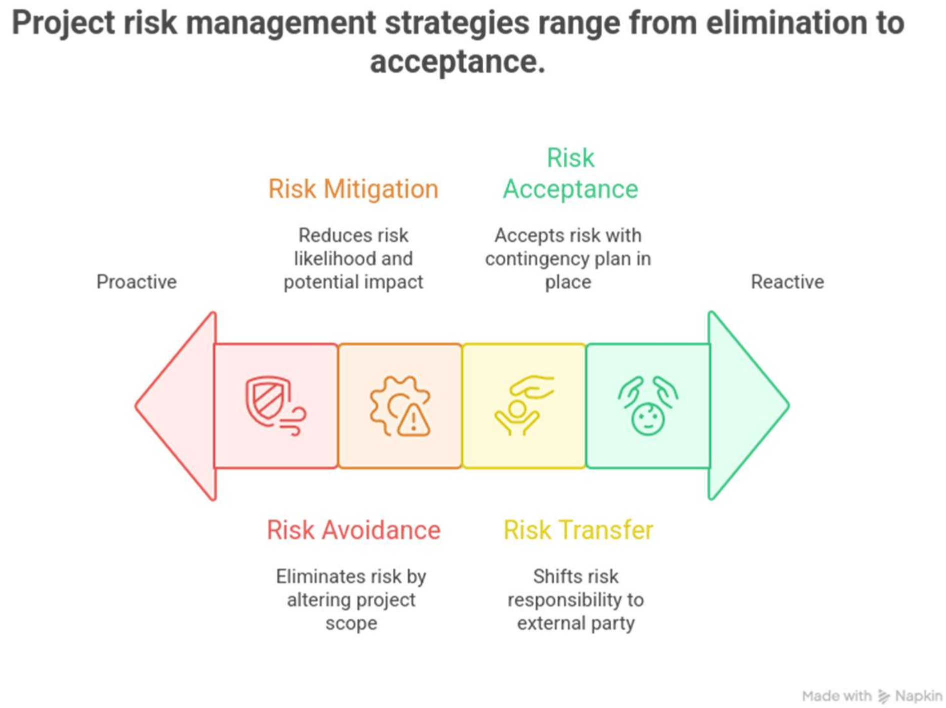

Figure 4.5: Risk Management Strategies

4.7.2 Risk analysis at different stages of the project

Here we study how **risks evolve and are managed across the project lifecycle**. It categorizes risks by **project stage**: inception, planning, implementation, and closure. For each phase, it identifies common risks, such as strategic risk at inception or technical risk during implementation, and provides **strategies for their minimization**. This systematic approach ensures that project managers can proactively identify and address uncertainties from beginning to end, enhancing the likelihood of project success (Figure 4.6).

- **Inception stage**
  - Strategic risk, misjudging the viability of the project, poorly defined objectives or lack of support from key stakeholders;
  - Minimization, involvement of stakeholders in the decision-making process, thorough SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis, preparation of a business plan.
- **Planning stage**
  - Timing risks, underestimating the time needed to complete tasks, dependence on external suppliers;
  - Minimization, use of schedule management techniques such as Gantt chart, critical path analysis and preparation of time buffers;
  - Financial risk, underestimation of costs, exchange rate fluctuations, lack of liquidity;
  - Minimization, regular budget reviews, building a financial reserve, strict management of project changes.
- **Implementation phase**
  - Technical risks, technology implementation problems, hardware failures, system incompatibilities;
  - Minimization, testing, selection of proven technology solutions, strict quality control;

- Operational risks, resource availability problems, staff turnover, lack of team skills.
- Minimize, train, hire experts, maintain back-up resources.

- **Closure phase**
  - Compliance risk, failure to comply with all formal requirements, misreporting.

Figure 4.6: Risk Management

4.7.3 Key aspects of risk management

Effective risk management is based on the following activities:

- Identifying and describing risks
- Assessing the severity and likelihood of occurrence
- Value of the risk - in terms of the potential loss that may be incurred
- Planning actions to avoid the risk
- Contingency plan - if the risk does occur

The following considerations influence the effectiveness of risk management

- **Stakeholder engagement**, regularly updating stakeholders and involving key stakeholders in the risk management process is crucial for ensuring their support and understanding of risks.
- **Accuracy and completeness of risk analysis**, accurate identification and assessment of risks enable effective risk management. Underestimating risks can lead to serious problems later in the project.
- **Flexibility in management**, the ability to adapt risk management strategies in response to changing project conditions is key. constant monitoring and willingness to modify risk management plans is essential.
- **Organizational culture**, risk management is more effective in organizations with culture of open reporting and rapid response to risks.

4.7.4 Risk management tools and techniques

To effectively manage risks in a project, professionals use a variety of tools and techniques to help identify, analyses and monitor risks, such as:

- **SWOT analysis**, this tool assesses the strengths and weaknesses of the project and identifies external opportunities and threats. SWOT is particularly useful at the project initiation and planning stages, as it helps to understand the context in which the project operates.
- **The Risk Matrix**, is a visual tool that helps to classify risks based on two criteria: probability of occurrence and impact on the project. Risks are classified as low, medium or high, making it easier to priorities countermeasures.
- **Root cause analysis**, a technique used to identify the root causes of risks. By understanding the root cause of the problem, actions can be taken to eliminate or reduce the risk.
- **Ishikawa diagram (fishbone diagram),** a tool used to identify and analyses the causes of problems. It is particularly useful when analyzing technical risks where various factors can influence the final outcome.
- **Scenario analysis**, a technique that involves imagining different possible scenarios of how events might unfold and assessing how each scenario might affect the project. This helps to prepare appropriate countermeasure strategies should any of these scenarios materialize.
- **Monte Carlo method**, an advanced simulation technique used to assess risk in projects. It allows the modelling of uncertainty in a project by generating multiple random scenarios and assessing how these variables could affect the project schedule or budget.
- **Brainstorming**, a group idea generation technique that helps to identify potential risks. It is valuable at an early stage when the project team is considering together what risks might occur and how to deal with them.
- **Risk Audit:** Regular risk reviews and audits are essential to assess the effectiveness of risk management and to identify new risks that may have arisen during the project.

Risks have different effects on the project. Their severity needs to be assessed and the impact they may have on the course of the project and its outcomes needs to be evaluated.

Risk analysis is best presented in the form of a risk matrix (Figure 4.7):

	Impact				
Likelihood	Negligible	Minor	Moderate	Significant	Severe
Very Likely	Low Med	Medium	Med High	High	High
Likely	Low	Low Med	Medium	Med High	High
Possible	Low	Low Med	Medium	Med High	Med High
Unlikely	Low	Low Med	Low Med	Medium	Med High
Very Unlikely	Low	Low Med	Low Med	Medium	Med High

Risk Colors				
1	2	3	4	5
2	3	4	5	5
1	2	3	4	5
1	2	3	4	4
1	2	2	3	4
1	2	2	3	4

Figure 4.7: Risk matrix

We rank the risks on the chart as follows:

- On the X-axis, we mark the impact of the risk on the course and outcome of the project: from a risk of zero, the impact of the risk increases as the value of X increases.

- On the Y-axis, we mark the probability of a risk occurring, which increases as the value of Y increases.
- Risks with low impact and low probability are colored green, risks with medium impact and medium probability are colored light green, risks with medium impact and medium probability are colored yellow, risks with medium impact and medium probability are colored orange and risks with high impact and high probability are colored red.
- We monitor the risks at regular intervals and produce successive versions of the risk matrix showing their evolution over time.
- As the project progresses, we may find that some risks change category or disappear, but new risks may also emerge.

4.7.5 Challenges and barriers

Despite the many tools and techniques available to project managers, risk management is not without its challenges. In real projects, there can be a variety of barriers to effective risk management, such as

- **Incomplete risk identification**, in some projects not all risks are identified at an early stage. This may be due to the inexperience of the team, the complexity of the project, or an overly optimistic approach to planning. As a result, unforeseen risks may materialize and affect the project in ways that could have been avoided.
- **Lack of Stakeholder Involvement,** if stakeholders are not actively involved in the risk management process, some key risks may not be adequately identified or managed. Stakeholders may have a unique perspective on potential risks that the project team may overlook.
- **Resistance to change** Many organizations resist implementing changes necessary to manage risk. This resistance may stem from a lack of understanding of the benefits of risk management, fear of additional costs or lack of resources. As a result, the organization may be exposed to risks that could be minimized or avoided.
- **Failure to communicate** Effective communication is key to risk management but can be difficult to maintain in practice. Lack of clear communication between the project team, stakeholders and management can lead to misunderstandings and incomplete implementation of risk management plans.
- **Lack of resources**, often project teams do not have sufficient resources (time, money, people) to manage risks effectively. This can lead to risks being overlooked or inadequately addressed, increasing the likelihood of problems.
- **Deferring risks to the future,** sometimes risks are identified but mitigation is deferred in the hope that the risk will not occur, or its impact will be minimal. This type of approach can be very risky, especially in long-term projects where impacts can be cumulative.

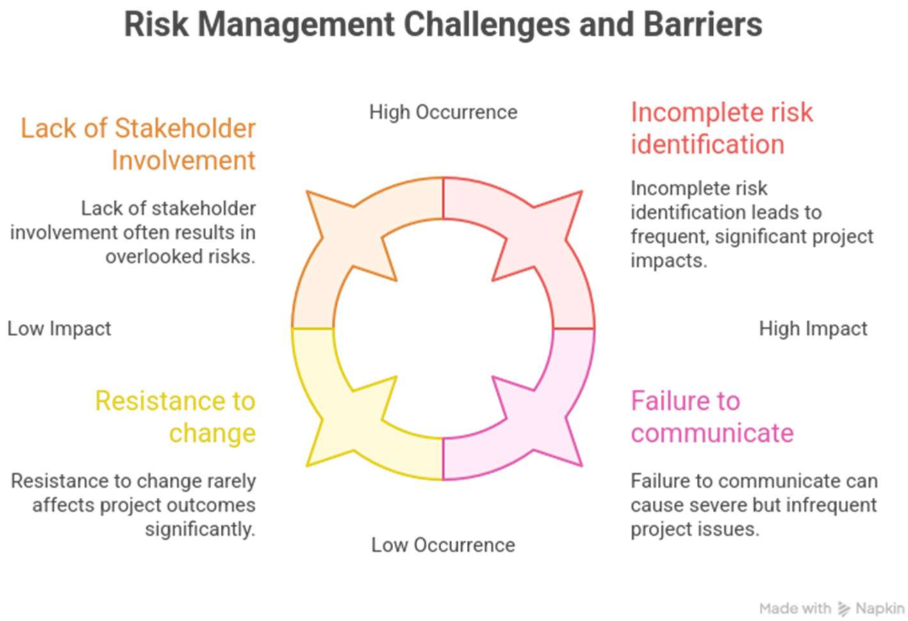

Figure 4.8: Risk Management Challenges and Barriers

4.7.6 Risk management, selected methods and trends

This section explores various **tools and evolving approaches for effective project risk management**.

- **Agile** - With the rise in popularity of agile methodologies in recent years, the approach to risk management has evolved. In traditional projects, risk management is often seen as a separate phase, whereas in an agile environment it is an ongoing process and integrated into the day-to-day practices of the team.
- **An iterative approach to risk,** in Agile methodologies risks are identified and managed at each stage of the project, allowing rapid response to changing conditions and rapid adjustment of plans. Each iteration (e.g., a sprint in Scrum) ends with a retrospective, where the team analyses what went well and what might pose a risk in future phases.
- **With an agile structure**, agile teams can quickly adjust their actions in response to emerging risks. Instead of long-term risk management plans, Agile teams often use short-term strategies that can be quickly changed as needed.
- **Working closely with stakeholders**, Agile places a strong emphasis on continuous communication with stakeholders. Through regular meetings (e.g., daily stand-ups, sprint reviews), stakeholders are kept informed of progress and risks, enabling faster decision-making and minimizing risk.
  One of the key elements of Agile is the **early delivery** of working parts of the product. This allows project assumptions to be quickly tested, risks to be identified and necessary changes to be implemented at an early stage, minimizing the risk of the entire project failing.
- **Continuous Improvement -** One of the key aspects of modern risk management is its integration with the philosophy of continuous improvement. This approach views risk management not as a one-off activity, but as an iterative process that is constantly evolving.
- **Retrospectives** allow teams to reflect on the risk management process and identify areas for improvement. This allows teams adapt their risk management strategies to the reality of the project.

- **Learning from mistakes**, as part of the continuous improvement philosophy, failures and mistakes are treated as valuable lessons to help the team manage risk better in the future. It is important that these lessons are formally documented and implemented in future projects.
- **Knowledge management,** organizations that manage knowledge effectively are better able to identify and manage risk. Creating knowledge repositories where risk cases and their management are documented is key to continuous improvement.
- **Trends** - Project risk management is evolving in response to changing market, technological and social conditions. Here are some of the trends shaping the future of risk management:
  - **Risk management automation:** More and more organizations are using advanced analytical tools and artificial intelligence (AI)-based systems to identify and analyses risks. These tools can predict potential risks based on analysis of historical data and current trends, enabling faster and more accurate responses to risks.
  - **Real-Time Risk Monitoring**: With the development of technology and digital tools, it is becoming possible to monitor risks in real time. This allows organizations to keep abreast of changing conditions and respond quickly to potential risks.
  - **Reputational Risk Management**: In the age of social media and instant information sharing, reputational risk has become one of the most important risks for organizations. Managing risks in this area requires special attention and advanced communication management strategies.
  - **Risk management in the context of sustainability**, more and more organizations are integrating risk management with sustainability goals. This involves analyzing the risks associated with the environmental, social and economic impacts of the business and seeking to minimize negative impacts in these areas.

4.7.7 Typical risks of research and implementation projects

Research projects are high-risk projects because there is no certainty that the research hypothesis will be confirmed and the intended effects will be achieved before the research is completed. In research and implementation projects, the risk of achieving the research objectives is compounded by the risk of meeting market expectations, which is essential for successful commercialization.

Risks typical of R&D projects can be divided into internal and external risks, introduced risks and imposed risks.

- Internal risks arise from the nature of the project and the organization of the work.
- External risks result from the actions of other stakeholders on the course of the project.
- Introduced risks stem from inadequate knowledge or failure to carry out part of the work.
- Imposed risks - are project conditions that are beyond our control.

From the project environment perspective, these risks can be divided into micro risks, medium risks, and global risks. At university level, microrisks are the most common and we detail this type:

Micro-level risks - usually arise from the project organization and are mostly internal risks.

The main micro-level risks are:

- Risks associated with the departure of key personnel,
- Risk of making wrong assumptions,
- Organizational risks,
- Risk of poorly defined schedule,
- Cost risk (spending too much),
- Operational risk (we may not deliver the process),

- Risk of not making the installation efficient.

We minimize **the risk of understaffing or lack of experience in the research team** by clearly defining the tasks to be performed and recruiting capable individuals. If we do not have project staff with the skills best suited to the project, we minimize this risk by seeking external advice where necessary.

Here follows a basic classification of risks on the research project:

- **External risk:** The selected contractor cannot complete part of the work on time. We minimize this risk by having a back-up contractor to whom we can assign that part of the project if necessary.
- **Introduced risk:** Insufficient estimated budget to complete the study. We minimize this risk by including a financial contingency reserve.
- **Imposed risk:** short timescale for research can be managed by careful planning and strict adherence to the timetable. Negotiating with the project's funder may also be an option.
- **Intermediate scale risks** usually relate to the market aspects of the project.

Once the research phase of an R&D project has been completed, the risks associated with conducting the research will cease to exist, but there are still risks associated with bringing the research results to market, i.e., commercialization.

<u>Risks typical of the commercialization process:</u>

- **Intrinsic risks** are the risk of not achieving the effectiveness of the technology/product. We minimize this risk by assessing the results of intermediate research stages in terms of their marketability and meeting the expectations of future customers. If the results of the research do not satisfy us, we try to change the research agenda to look for other characteristics of the product under development that may be a distinguishing feature of its suitability for the function for which we want to allocate it. It is important that this modified feature/function is still desired by the market.
- **External risks** are barriers to entry. There may be a change in entry criteria because there has been a change in consumer awareness, their preferences or economic conditions have changed, or a competing product has entered the market in the meantime to meet their needs. This risk is always present in the process of bringing an innovation to market. The only effective way to minimize this risk is to use an agile management approach, where we try to deliver finished project components (e.g., research results) as quickly as possible to test their usefulness in the consumer decision-making process, and to react quickly and flexibly when changes in trends are identified.
- **Introduced risks** are related to the marketization of the project outcome, such as inappropriate pricing of the marketed product. This includes both too low and too high an input price. Setting the price too low may result in not achieving economic objectives, while setting it too high may create an economic barrier. This risk is often due to inadequate market understanding and business model development.

  In general, this type of risk (introduced risk) in commercialization is almost always due to an inadequate understanding of the current market offer and consumer purchasing capabilities and/or an inaccurate development of the venture's business model.
- **Imposed risk** - in the commercialization process this may take the form of the need for certifications and approvals, which may require additional specialized and expensive testing. In some cases, such as commercializing an innovation in the form of a medical

device or pharmaceutical molecule, biocompatibility testing or clinical trials may be required. As it cannot be assumed that these tests will be successful, the decision to market a medical device involves accepting the risk, imposed by the regulatory authority, of not meeting the conditions required for the use of these products.

We point out that careful identification of the customer's current market offers and buying power, and the development of an appropriate business model for the venture, are two of the most difficult steps in the whole commercialization process to achieve and should therefore be given particular attention when bringing an innovation to market.

We minimize this risk by ensuring that

- the product has a clear competitive advantage
- the new product is introduced before competitors introduce similar products
- the company anticipates possible reactions from competitors
- the new product provides an opportunity to create barriers for competitors
- monitor competitors' reactions and take appropriate countermeasures if necessary
- the consequences of being a leader or a follower are anticipated.

Macro risk is a global risk. An example of this is international competition in the speed and efficiency of research carried out simultaneously by several research centers on the same or a very similar topic. The first to complete the research and successfully commercialize the result is likely to become the market leader, while the research investment of the other research centers may never be recouped. Fortunately, risks at the global level rarely affect the current research agendas of universities and institutes at the national level.

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