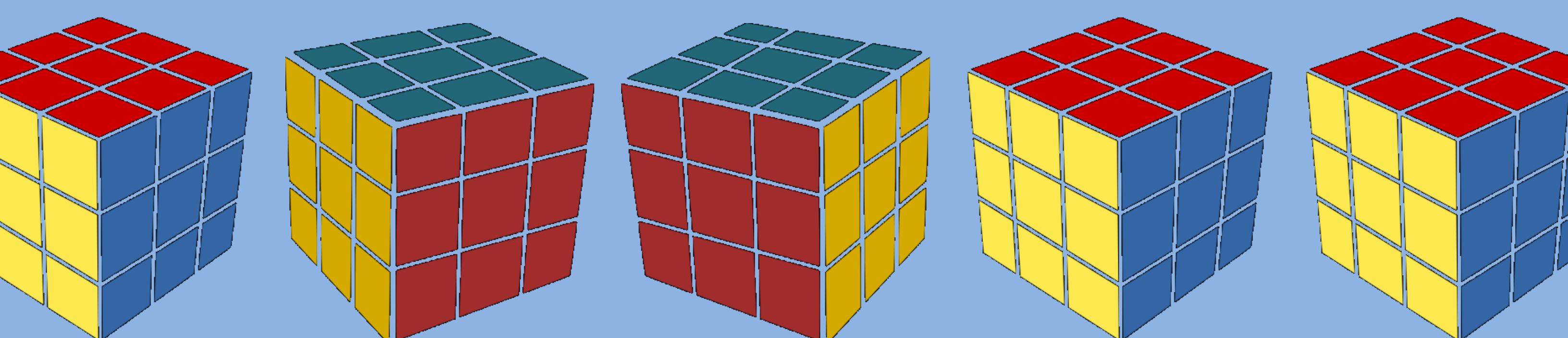
TARGET

SEVENTH FRAMEWORK PROGRAMME

Targeted R&D Policy



Promoting Biotechnology: A Generalized Toolkit for Policymakers

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1. Introduction to TARGET

Policymakers have increasingly taken it upon themselves to introduce policies promoting the economy's ability to host science-based industry. Science-based sectors are emphasised as sources of economic growth and as potential market-arenas for the enhancement of the national or regional economy's competitiveness. Some policies are responses to market failures, plugging gaps in the resources available to firms or the science base while not necessarily seeking to change the systemic structures within which these firms operate. As more research on science-based sectors and innovation has been conducted, and as experience in the business and policy areas has accumulated, arguments for more systemic approaches to policy have increased.

The TARGET approach presented here will help policymakers form a strategic roadmap and determine feasible interventions that lead to a functioning biotechnology system of innovation within a country or region. The goal of the toolkit is not to present a single recipe of specific policies for success; as will be noted later on, the variety of cases and their development mean that no single path to a functionally biotechnology sector can be realistically described.

The TARGET approach takes the biotechnology system of innovation as the "unit of analysis." By taking such a unit of analysis, the approach can account for the different structures which form a part of the system and affect its actions, as well as take into account external influences, while not losing sight of the sectoral innovation system as the whole unit. Alternatively, what the TARGET approach does offer is a way for policymakers to work through this complexity and come up with a tailored, context specific strategy based on realistic assessments of their country or region's resources and capacities.

The TARGET approach is based on an evolutionary theory of innovation which sees different sectors as going through a life cycle of development. At different stages of a sector's progress, the ground work for development to the next stage is laid and the specifics of this groundwork will influence how the subsequent stage is realized. When describing the different Phases of evolution, Sector Drivers will be discussed which are key to moving the sector through the phases to maturity. The drivers described as necessary to take into consideration for assessment purposes and policy action fall under science, training, commercial capacity/experience, finance and human resources. They also include "other institutions" which would include IP, a working health delivery system and different regulatory systems which can affect the costs of the biotech sector (e.g. drug regulation, tax regime). These categories of drivers will be used when discussing the phases of evolution, however the individual drivers and their values/qualities will change phase by phase; these changes should be reflected in policy interventions implemented to reach policy goals.

2. The Structure of TARGET Approach

The TARGET toolkit is meant to provide policymakers with a systemic way of addressing the challenge of supporting a biotechnology sector. Working in a volatile global environment, policymakers are faced with conditions of high uncertainty. Within this context, it becomes very challenging to assess the effect of policy measures on different parts of the innovation system; thus, a systemic way of addressing this issue becomes highly relevant. The biotechnology sector is dynamically changing both in terms of the way we understand scientific and technologic developments and in terms of how policymakers are supporting the emergence of the sector.

The main objective of the TARGET approach it to provide policymakers with a conceptual framework that will be productive for policymaking and policy implementation. By analytically breaking the policy challenge into different elements it becomes easier to understand what has to be addressed and how. The three elements of TARGET Approach are: 1) Industry Life-Cycle; 2) Sector Drivers; and 3) Policy Dimensions.

Element 1: The Industry Life-Cycle

The Industry Life-Cycle, presented in Chapter 3, deals with the development of the biotechnology sector itself. Based on an evolutionary perspective, the TARGET approach recognizes that different industries progress through a cycle of development which is uniquely characteristic to them. In the case of biotechnology, three phases of development have been recognized to date: Background Phase, Pre-Emergence Phase and Emergence Phase. Chapter 3 details each phase's properties in terms of the biotechnology sector. Different phases call for different policy measures and its imperative that policymakers identify what phase they are about to interact with. For instance, at the Background Phase there would likely be little specific expertise in biotechnology within public or private R&D, thus the implementation of a grand VC program would not be the best entry-point for policy as there would be few opportunities present in the investment pipeline. **Thus, the very first element of**

The Structure of the Toolkit

Element 1: Industry Life-Cycle

Answers the Question:
Where are we?

Element 2: Sector Drivers

Answers the Question:
What do we need to move forward?

Element 3: Policy Dimensions

Answers the Question:
How to approach what we need?

the TARGET approach deals with the identification of the current phase of the sector in terms of the Industry's Life-Cycle. This is done through the Sector Drivers. Once the phase has been recognize, all stakeholders can focus on advancing the sector to the next cycle.

Element 2: The Sector Drivers

The Sector Drivers, detailed in Chapter 4, are the 'engines' which move the sector from one phase of the Life-Cycle to the next one. Studying different case studies around the world, we have identified the following Drivers: Science, Training, Commercial, Financial, Human Resources and Other Institutions. Chapter 4 details each Driver at length and its features at every phase of the Life-Cycle. Using the example mentioned above, at the Background Phase there are no specific capabilities in biotechnology, but there are established R&D capabilities in general. Therefore, the Science Driver will look differently at this phase in comparison to the Pre-Emergence Phase, in which specialization in biotechnology begins. **Understanding which of the Drivers is lagging behind helps policymakers determine what the best entry-point is in terms of policy measures.** For example, if all Drivers are at the Pre-Emergence Phase, but the Finance Driver is lagging, then starting with financial support may be the appropriated course of action. Thus, assessing how the country/region is doing in terms of each of the drivers allows for policy coordination and clarification of the policy challenge. Once the Drivers have been mapped, the Policy Dimensions will help to address the specific Drivers requiring attention.

Element 3: The Policy Dimensions

The Policy Dimensions, detailed in Chapter 5, deal with the different decisions that must be taken at any point of the policy process. These dimensions describe how to approach a Driver. Some Policy Dimensions, such as the decision on the Vision and Realistic Sectoral Assessment, must be present during the entire policy process (and will be termed *strategic decisions*), while others, such as the decision on Entry-Points, change with every policy modification (and will thus be termed *tactical*

> TARGET offers conceptual tools that make the challenge of supporting a biotechnology sector easier and clearer. Due to the complex nature of the challenge, we do not offer one-size policy schemes but rather focus on the different elements which policymakers must take into consideration while formulating their own particular schemes. The following chapters will provide useful information and productive tools.

decisions). Supporting a biotechnology sector takes time and the policy process will go through different stages. **At each stage there will be a need to define the relevant Policy Dimensions and to make the relevant decisions.** For instance, the entry-point for the first policy scheme will be different from the scheme in the second stage of policy, which might take place some five years after the first. Thus, Chapter 5 addresses the issue of actual policy implementation and provides a framework for formulating concrete policy programs by listing all areas which require attention.

3. The Industry Life-Cycle

The TARGET approach is based on an evolutionary theory of innovation, The Industry Life Cycle. At every stage of the sector's progress, the ground work for development to the next stage is laid, and the specifics of this groundwork will influence how that subsequent stage is realized.

A biotechnology system is seen by the Industrial Life Cycle Approach as a dynamic, constantly evolving set of structures affected by:

- Spontaneous interactions between agents of knowledge creation and agents of commercialization.
- The geographic context.
- The historical context, including industrial and social history.
- The influence of the political system and agents purposely using policy mechanisms to grow the economy and exploit the opportunities presented by new knowledge and technology.

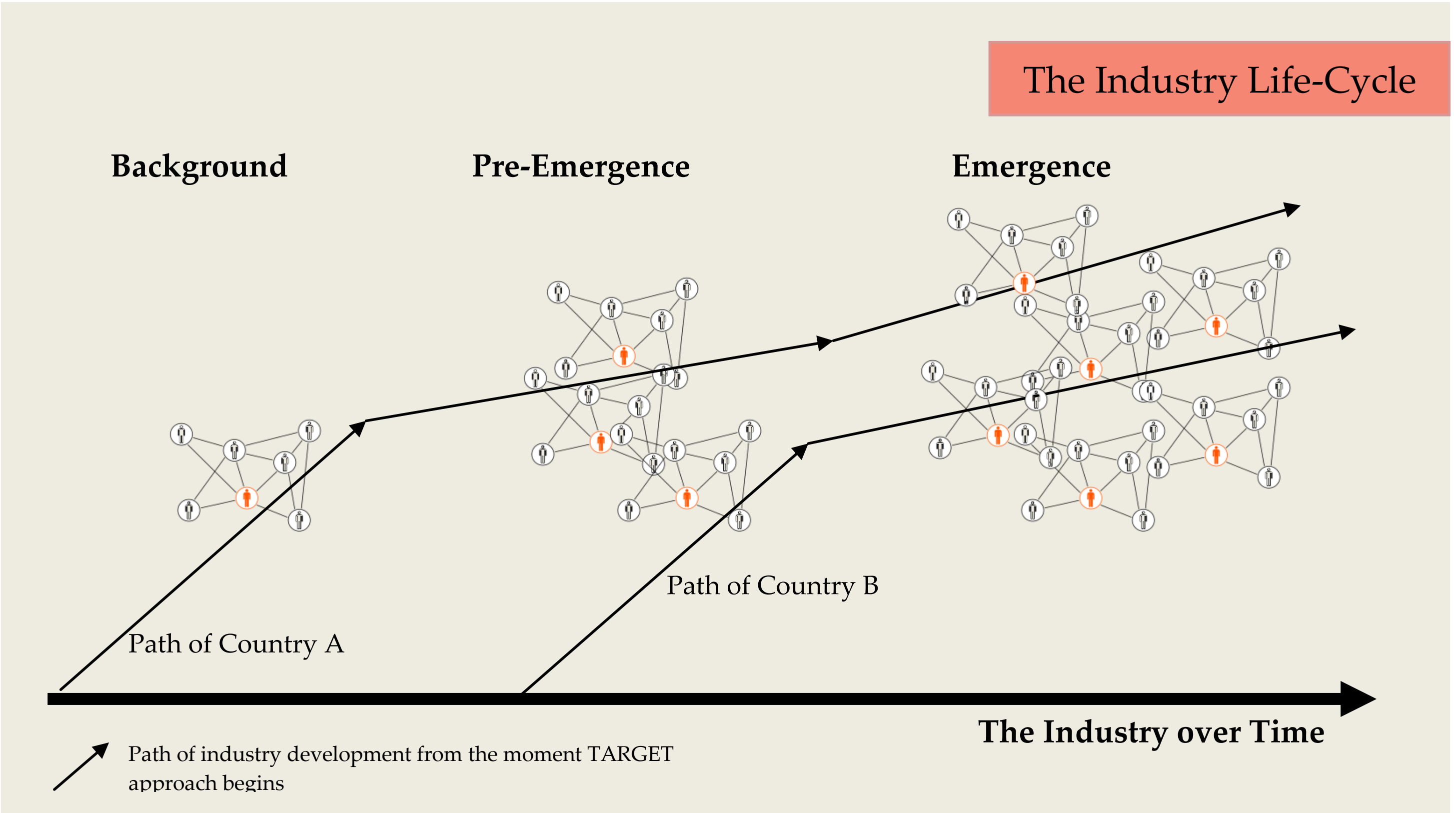
Using this approach allows policymakers to see not only how policies may have an impact on a current area of the economy, but also how it may impact events or conditions in the future, thus, it contributes to any long-term industry-building goals.

A realistic assessment of commitment is crucial, since the development of a biotechnology sector requires long timelines of more than 20 years.

The industry Life Cycle Approach, which sees different sectors as going through a life cycle of development, breaks down an industry's levels of development and maturity into three phases:

The Background Phase is the phase before the sector actually appears. **In the background phase there is as yet no biotechnology sector per se**; rather the initial seed conditions are present or being formed. At this stage there would be very little commercial activity or experience with the sector, though transferable knowledge, experience and institutional settings should be present in order to begin transitioning to the next phase. Furthermore, while actors may have rudimentary awareness of the potential for the creation of a biotechnology sector and how the current conditions encourage the emergence of the sector, there is as yet no consistent, organized interaction between actors in this regard.

The Pre-Emergence Phase is the phase in which initial activities of the sector appear. **The pre-emergence phase shows the beginning of a biotechnology sector, though its main feature is that the activities are not yet self-sustaining or institutionalized**; rather, the activities suggest



some specialization in the R&D sector, strong science, the development of entrepreneurial action and some initial commercial activity and investment. These activities involve some implicit exploration of the different market possibilities that the nascent sector may move towards. Actors in this phase begin showing an awareness of the sector, and interactions between actors are increasing.

The Emergence Phase is the phase before the sector becomes standardized. **The emergence phase shows the sector beginning to achieve critical mass**. Commercial exchanges begin to lose their one-off, tentative nature. Whereas in the Pre-emergence phase transactions between actors may have been exploratory or ad hoc, in the emergence phase these transactions have become more regular. Of course, activity may still be exploratory and structures may be adjusted to facilitate what is still a new market with high levels of uncertainty, but biotechnology (or its sub-sectors) does not have to "prove itself" as a commercial activity or source of investment and public policy.

An Important Note on the Idiosyncratic Nature of the Biotechnology Life-Cycle:

The path which a country/region takes towards the Emergence Phase will be idiosyncratic and contingent on the country/region's specific historical development. For example, illustrated in the above diagram, a country which begins the TARGET approach in the Background Phase (Country A) will advance differently than a country which begins in the Pre-Emergence Phase (Country B).

Previous interventions in the innovation system have created various path dependencies and trajectories that will influence both future policy as well as the development of the sector. This also shows the significance of proper assessment as to the position of the country/region. Different policy schemes will be needed for different starting points, and policymakers should be careful when comparing local progress to that made in other places, as the idiosyncratic nature of the Life Cycle means that there is no one development path to expect and imitate.

Brief Examples of the Co-evolution of the Sector Drivers

In the Israeli case, co-evolution is most clearly seen in the development of venture capital (VC) alongside the information technology sector and their later implications for the biotechnology sector. Venture capital promotion was instituted twice, with the first program (Inbal) failing in the sense that its value generated remained low. Additionally, it suffered from bureaucratic problems. The program did, however, stimulate learning in the private sector and the public sector which led to a more successful VC program under Yozma. The evolution of policy knowledge, along with the evolution of private sector experience in entrepreneurial activity, led to success the second time around. This success was also dependent on circumstances such as a high influx of skilled immigrants, and a military R&D background which provided technology to be exploited. A venture capital industry then helped to facilitate early development of the biotechnology sector, demonstrating a further link between system components.

A second clear example of co-evolution is presented in the case of Scotland and the generation of new firms in biotechnology. Academic excellence provided the source for new firm development in Scotland which continued to develop with the recognition of star scientists in the Scottish R&D system. Firms were created out of this mostly using public venture and angel money, as well as other public supports for creating new firms. Eventually, a set of Scottish companies were able to attract funding from outside of Scotland for large valuations not possible with local investors. The success of these firms, and the creation of other life science based firms in Scotland, meant that policy efforts turned away from firm creation and began focusing on firm growth. Unfortunately, a number of Scottish firms failed. With fewer firms being created, investors from abroad had no reason to stay in Scotland. In this sense, academic, financial, and policy drivers were evolving simultaneously and impacting one another. Moreover, Scotland's sector evolution was impacted by the continuing development of the Cambridge and South East England biotechnology sectors. With these sectors continuing to grow and produce new firms, a slow downturn in Scotland provided little incentive for investors from London to look for Scottish opportunities despite past promise. This experience has also meant that entrepreneurial activity in Scotland has shifted away from drug discover to lower risk endeavors.

4. The Sector Drivers

The Industrial Life Cycle Approach combined with the sector drivers provides a holistic perspective of the biotechnology sector, which assists in understanding how each of the drivers are tied together and co-evolve over time.

The Sector Drivers are the 'engines' which move the sector from one phase of the Life-Cycle to the next one. The drivers presented in this toolkit are those which have been determined as important throughout the different phases of the life cycle: Science, Training, Commercial, Financial, Human Resources and Other Institutions. The drivers are described at each evolutionary phase to help policymakers evaluate what phase each of their own country/region's Sector Drivers is located. Mapping each of the Sector Drivers and realizing its position on the Life-Cycle is essential for the policy program to address the real needs of the country/region.

Sector Drivers at the Background Phase

Science A strong basic R&D system either public or private exists, though in most cases this will be in public institutions such as universities. This need not be in specific biotechnology areas at this stage. A scientific research base is necessary to create both absorptive capacity in R&D structures and the necessary science which would lead down a path of specialization in biotechnology or other techno-innovation paths which may appear. A funding base for R&D should also be present, preferably organized around competition to ensure that the best projects and scientists are supported and retained in the system.

Training A system of training producing skilled personnel in the sciences exists in order for the local system to maintain its R&D capacities or for utilizing science produced in the system further down the value chain.

Commercial Experience of public and private sector use of science produced by the abovementioned R&D system is a necessary background condition, demonstrating a local path for technological uptake by consumers. Additionally, industrial capacity in manufacturing, and preferably in higher value-added activities, such as product development or quality control is a good background condition as it shows experience in quality manufacturing, the presence of a

> An interesting example is Ireland, which has been attempting to build its life sciences industry based on its quality manufacturing experience and facilities, with science and training catching up to these features.

skilled workforce and management and the existence of firms which would act as either the developers of new technologies or partners/suppliers for new ventures. The Commercial driver should also include experience in transnational economic relations and collaborations, particularly as industries such as biotechnology will not be contained in one economy in the sense of knowledge creation, investment, and sales.

Financial Financial structures should be present for the transfer of capital towards new ventures or established ventures looking to take on new risk, and for investors to realize returns. This does not need to include a fully functioning venture capital market at this stage; however, the institutional structures, laws and regulations should be present to facilitate the creation of such a market if necessary.

> For example, Scotland's start-up finance was mostly centred on angel investors and public sources of support, later attracting venture capital. Sweden, on the other hand, moved forward with established public investors such as Industrifonden, direct and indirect support from established parent firms, as well as the publicly funded creation of a local VC market.

> Excellent science in conjunction with financial support for R&D and the availability of VC funds are the basic elements in the development of a biotech sector.
>
> When excellent science is not well established and there is no biotech industry in place at early stages of a biotechnology sector's development, policies targeting finance and the establishment of start-ups as an entry-point, are questionable.

Human Resources A labour market should be present which allows for the movement of skilled personnel, their attraction and retention.

Other Institutions Clarity in regulatory systems such as Intellectual Property regulations, or regulations which may impact health products should be present. Lack of clarity in these areas creates disincentives for potential investors and potential entrepreneurs, particularly in high risk sectors. Related to the abovementioned public and private use of science, a working system of health care (public or private) should be a basic background condition as it provides a system of hospitals that offer a domestic market, and potentially further R&D capacity including clinical trials. Finally, a political system with a history of cooperation is useful as this will lower the risk of erratic policy changes which affects the economic arena in which entrepreneurs and investors find themselves in.

Sector Drivers at the Pre-Emergence Phase

Science Public and private R&D sources at this stage begin specializing in biotechnology, with both basic and applied science being produced by the R&D system, particularly with an eye towards eventual commercial use. A pool of scientists in the different disciplines which make up biotechnology are present in the economy and star scientists are being recognized both locally and abroad for the work they do in the sector.

Training Graduates and new researchers in the biotechnology sector are increasing, supplying the scientific, technical and support skills necessary for both research and industry.

Commercial Closely tied to the scientific system, methods of technology transfer are generally developed more fully during this phase, facilitating the use of new knowledge by industry. Entrepreneurial activity has begun in earnest during this phase, either through the development of start-ups or spin-offs, directly from academia or from already existing firms and industry. Furthermore, key individuals with experience in the sector or who have been successful and can "reinvest" their knowledge in the sector, should become visible during this period; from these individuals the first set of serial entrepreneurs may emerge to further the sector's commercial development. Large pharmaceutical firms or other large firms in the biotechnology sector should also begin to settle in the local economy at this stage, recognizing the value of local inputs and adding a further source of attraction to other potential investors. Finally, related service and support providers should begin to appear at this stage alongside the increasing number of biotechnology firms.

Financial Finance for start-ups should not only have begun to appear by this phase but have begun to be institutionalized in some form; examples can be the formation of public venture capital schemes, more organized angel activity, or increasing private venture capital investment.

Human Resources The provision of skilled workers continues, with an increase in those with business skills, in addition to maintaining the system's R&D skills.

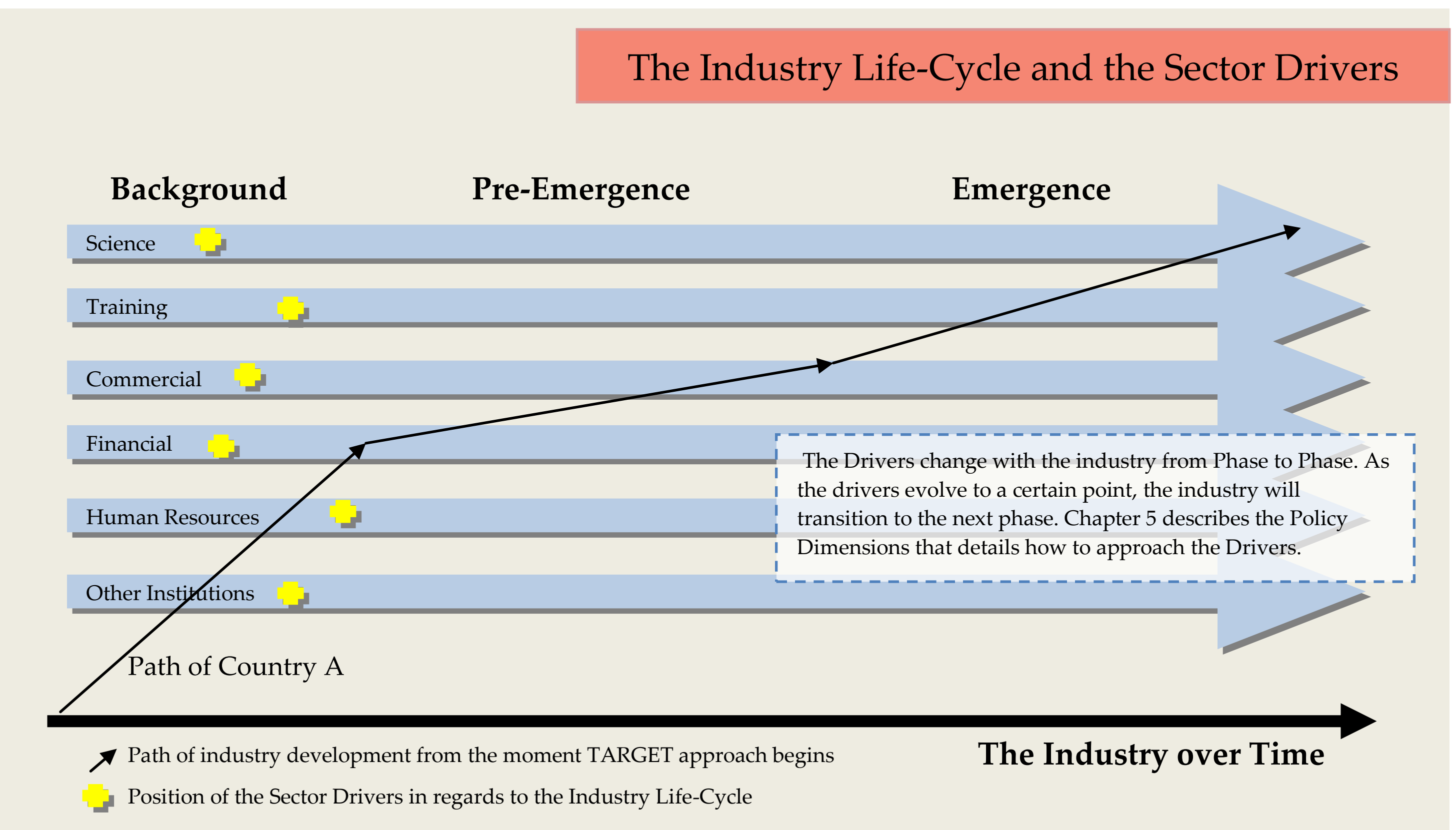
Other Institutions Trial infrastructure for new health related products will likely begin to appear at this stage. Also, while key individuals will have begun to appear in the commercial world, key individuals or champions may also appear in other areas such as the policy realm; policy support (direct or indirect) and recognition of the sector should be well-established by this phase.

Sector Drivers at the Emergence Phase

Science The science driver at the Emergence Phase is an extension of the previous phase's conditions. R&D work expands, and star scientists continue to garner recognition. Furthermore, more top quality researchers are attracted to the locality to participate in research.

Training Extension of the Pre-Emergence phase: A system of training producing skilled personnel in the science exists in order for the local system to maintain its R&D capacities or for utilizing the science produced in the system further down the value chain.

Commercial A pipeline of products is apparent and moving through the research and, more importantly, the development processes are on their way to market. Dependence on one or two products is lessened, and more companies are becoming multi-product/service providers. The emerging market for biotechnology products is gaining some stability and will not collapse with the failure of some of the companies involved, or some of the products failing to pass through different development hurdles. Manufacturing in the biotechnology sector is expanded and may involve a separation from commercial R&D entities. Links between firms at this stage become more stabilized in the sense of collaboration as well as supply relationships, and there is a growing recognition of the



local sector as a "unit" to which actors belong. Start-ups and spin-offs will continue to be created, and serial entrepreneurs should have appeared by this stage.

Financial The locality's attraction to investors becomes more established, no longer based on one-off opportunities or pleasant surprises. Start-ups and spin-offs continue to receive funding, and growth capital becomes available as well.

The existence of top quality scientific research is a key precondition for the development of the biotechnology sector. However, there have been relatively successful biotechnology firms based on less-than-revolutionary science, which highlight the importance of industry applicable science.

Simply building up the science base for the sake of having the best science may not lead to biotechnology success – the science must be applicable to industry and commercializable.

Human Resources There should be a higher amount of employment "churn", with skilled labour moving between companies, coming into the local economy as well as moving to other established biotechnology sectors abroad – tacit knowledge exchange and experience will increase in the system in this manner.

Other Institutions Some elements of public support may begin to be phased out, however new policies or concerns may emerge such as how to retain local ventures, and how to increase access to foreign markets.

Sector Drivers in each Phase of the Industry Life-Cycle; Part 1

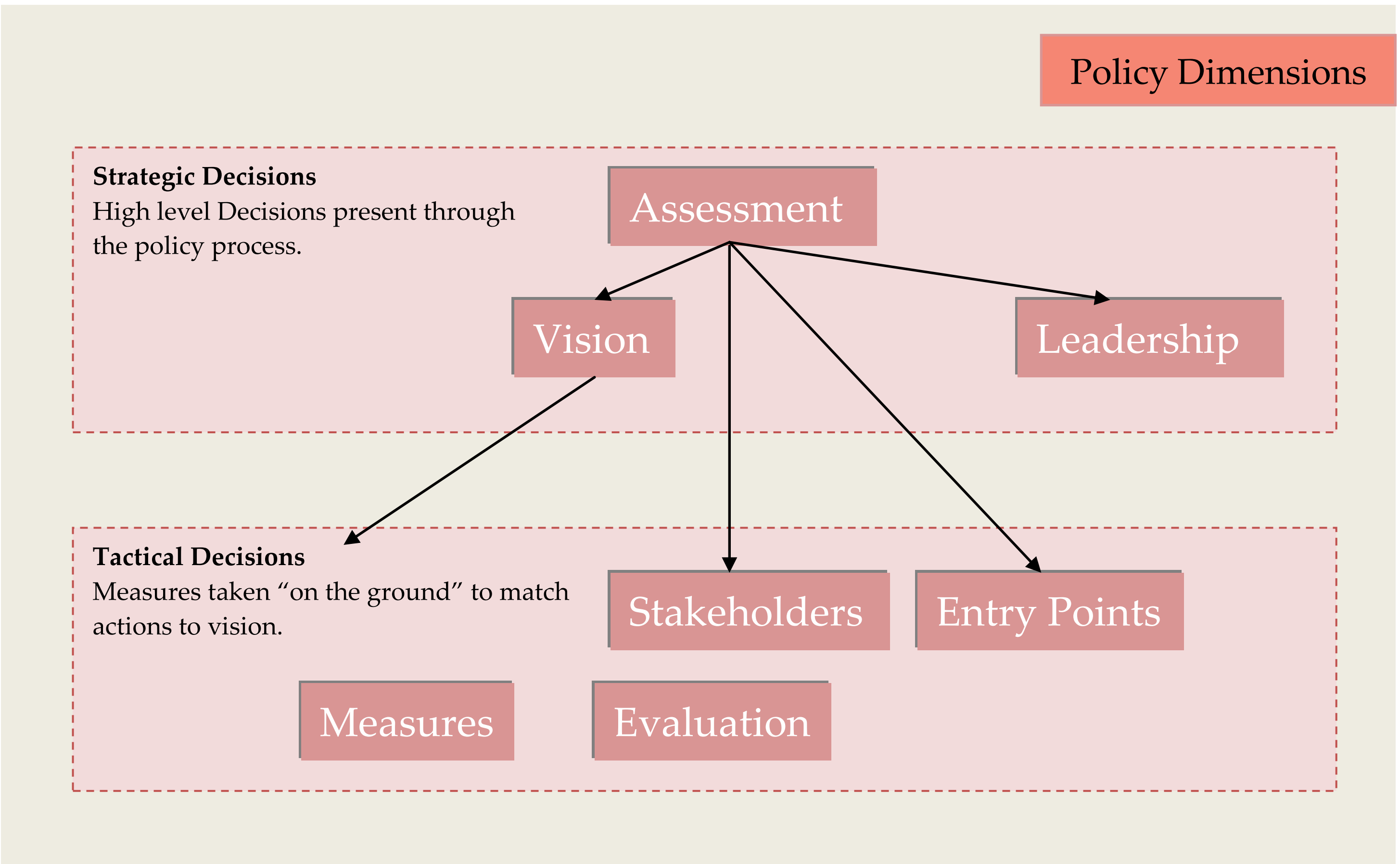
	Background Phase	Pre-Emergence Phase	Emergence Phase
Science	A strong basic R&D system (mostly in academia), not specifically in biotechnology.	Public and private R&D sources begin specializing in biotechnology, with both basic and applied science being produced by the R&D system, particularly with an eye towards eventual commercial use.	R&D work expands and star scientists continue to garner recognition. Top quality researchers are attracted to the locality to participate in research.
Training	A system of training skilled scientific personnel is present.	Graduates and new researchers in the biotechnology sector are increasing.	Extension of the Pre-Emergence phase.
Commercial	Experience of public and private sector use of science produced by the R&D system. Industrial capacity in manufacturing, and preferably in higher value-added activities. Experience in transnational economic relations and collaborations.	Entrepreneurial activity. Key individuals with experience in the sector or who have been successful and can "reinvest" their knowledge in the sector become visible. Large pharmaceutical firms or other large firms in the biotechnology sector begin to settle in the local economy. Related service and support providers begin to appear.	A pipeline of products is apparent and the development processes are on their way to market. More companies are becoming multi-product/service providers. Links between firms become more stabilized. Start-ups and spin-offs will continue to be created, and serial entrepreneurs are appearing at this stage.

Sector Drivers in each Phase of the Industry Life-Cycle; Part 2

	Background Phase	Pre-Emergence Phase	Emergence Phase
Financial	No fully functioning venture capital market. Financial structures are present for the transfer of capital. Institutional structures, laws and regulations existing.	A Finance for start-ups is institutionalized in some form: the formation of public venture capital schemes or increasing private venture capital investment	The locality's attraction to investors becomes more established Start-ups and spin-offs continue to receive funding and growth capital becomes available.
Human Resources	A labour market which allows for the movement of skilled personnel, their attraction and retention.	The provision of skilled workers continues, with an increase in those with business skills	Higher amount of employment "churn". Skilled labour moving between companies. Tacit knowledge exchange and experience.
Other Institutions	Clarity in regulatory systems. A working system of health care. A political system with a history of cooperation.	Trial infrastructure for new health related. Key individuals or champions appearing in the political or policy realm. Policy support and recognition of the sector.	Some elements of public support may begin to be phased out. New policies emerge such as how to retain local ventures.

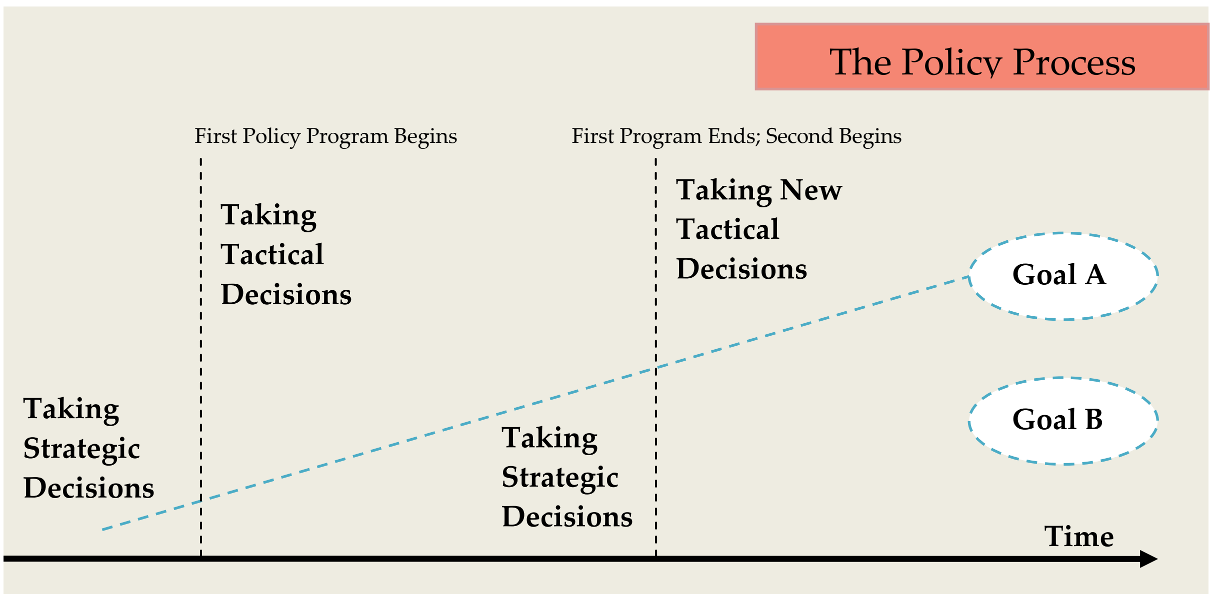
5. The Policy Dimensions

With a basic understanding of the Industry Life-Cycle and the Sector Drivers which move the biotechnology sector from one phase to the next, **policymakers are subsequently provided with a description of eight policy dimensions.** These policy dimensions are seen as key decisions points for policymakers and can be divided into **strategic and tactical decisions**.



The first four dimensions are strategic because they establish the call to pursue a biotechnology sector actively and the broad vision that efforts will work towards achieving. Once these high level decisions are made, the specific steps needed to fulfil them will have to be carried out, i.e. the tactical decisions and steps. The strategic level aspects may be determined by politicians, ministers, leaders of industry, or high ranking and influential civil servants who can influence government beyond specific policies. The tactical decisions discussed will likely be carried out by policymakers "on the ground," trying to match their actions to the vision they have been charged with working towards.

The following Diagram illustrates the policy process in terms of the different Policy Dimensions. As seen, the Strategic decisions are taken at the very beginning of policy implementation and shape the path of advancement towards the policy goal. There are different possible goals for a biotechnology sector and the Strategic decisions will determine which goal is being targeted. Once the Strategic decisions have been made, implementation begins and tactical decisions are taken. New tactical decisions are taken for each policy program. As time progresses the sector itself changes and the tactical decisions must be changed appropriately. For instance, if the country/region works under a 5-year policy program, when the first ends and a new one begins – there will be a need to revise the previous tactical decisions according to the new situation (a mechanism of on-going assessment during this period of time, not just at the end, would also be recommended). It is important to note that Strategic decisions might also need revision, especially if assessment suggests that the targeted goal might not be feasible at the moment. This will be clarified below.



Strategic Policy Dimensions

1. Realistic Sector Assessment

- **<u>A review process</u>:** Before deciding to carry out policy intervention with a functioning biotechnology sector as its goal, it is crucial that an objective assessment be carried out to establish at what phase the sector and national/regional economy is in. Using the Industry Life-cycle approach, part of the Realistic Sector Assessment must be an analysis of the Sector Drivers already existing in the economy and which could play a role in the emergence of the sector. The assessment process is given primary importance here in that it sets the targeting process on the right track. The assessment is a comprehensive review process which concerns any possible component of the sectoral system of innovation.

- **<u>Sector Drivers</u>:** The assessment should consider the Sector Drivers detailed in chapter 4: the science base (bio and medical), institutional and political framework already existing (e.g. support for targeting, tech transfer capacity), innovation policy budget, entrepreneurial capacity, industrial and public health infrastructure, small business finance, and regulation (i.e. IP, ethical approach to things like stem cells and risk-related factors especially in relation to clinical trials). The assessment process should include an assessment of global trends and competition in order to identify opportunities and competitors.

- **<u>The Capability to secure a long-term commitment</u>:** When going through the assessment, one political issue which must be determined concerns the capability to secure a long-term commitment; this is vital in the biotechnology sector, where knowledge translation and product/service development takes 10-20 years, requires major capital investments (often beyond the capacity of many countries/regions) and involves very high rate of failure. Also, concerning the science base assessment – a variety of different measures can be used, such as publications, citations, movement of skilled people, etc.; **but it is not only quantitative measures which are important, but also qualitative dimensions** such as the divisions between public and private science, the presence of networks and communication between them and the structure of the public science base. Furthermore, the assessment should consider both absolute and relative measures.

- **<u>The assessment's outcome</u>:** The outcome of this process should lead the country/region to decide:

    - Do we want to consider targeting biotechnology?

      Policymakers must take into consideration that the assessment may result in the conclusion that acting on developing a biotechnology sector may not be the best route for their particular country/region. However, if the decision is made that intervention should be pursued regardless, actors must seek to first establish pre-conditions, namely to create the missing Sector Drivers. As a result, the process will be longer and, while it may not require more buy-in from different stakeholders, will require more patience and a longer-term view by those actors pursuing the strategy.

    - What should the exact goal be? (see next point)

→ ***See the list of questions which policymakers can use as a guide to their initial assessment at annex 1.***

2. VISION

-**Definition and profile:** A decision to target a particular sector or industry requires a definition of that sector and some profile of how the sector will look after the policy is implemented.

-**Conceptualization of the policy process:** Furthermore, the conceptualization of a policy program must be multidimensional and systemic in terms of how different components in the economy influence the targeted sector, stakeholder incentives, and the potential systemic changes or adjustments needed. This conceptualization is necessary regardless of the type of interventions that may or may not take place, as it provides a long-term vision that allows for flexibility; it would allow for later interventions to be designed as necessary in a way that would not block or misalign earlier stage interventions.

-Alternative goals: The vision must address the different possibilities and capabilities of the country/region and to designate a Goal for the process. There are various forms a Biotechnology sector might take and policymakers need to take into consideration different possible goals. Alternate goals should be considered if system assessments indicate extreme difficulty in achieving a fully functioning sector, or if unintended developments arise in the life cycle requiring a change in vision.

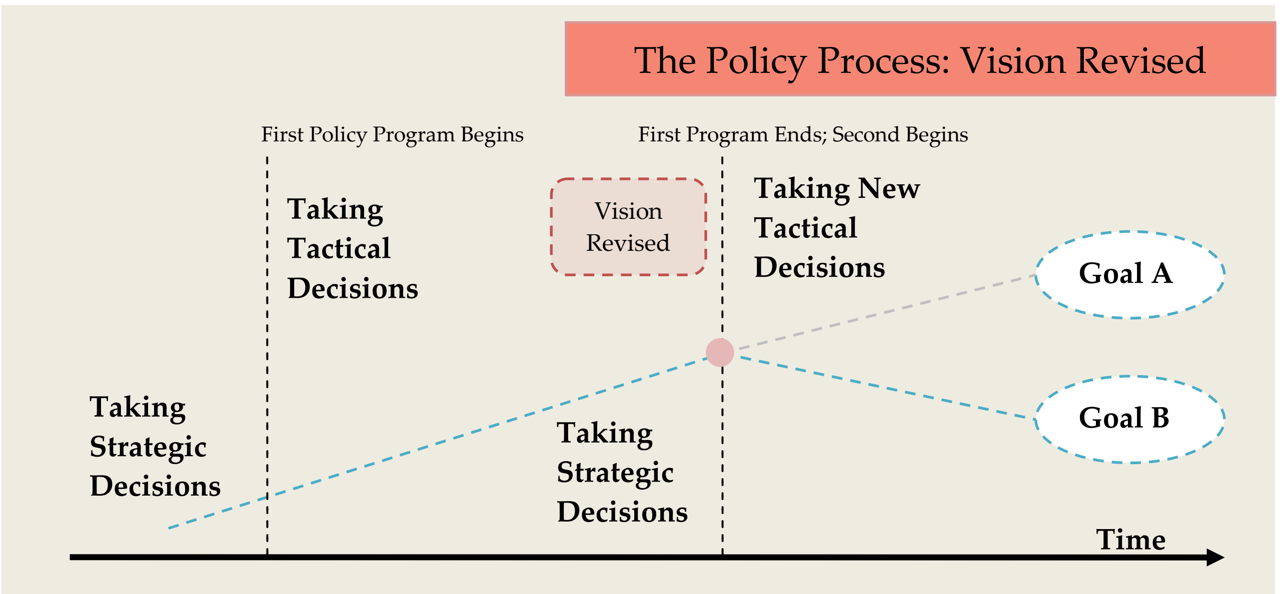
The vision should reflect not only decision-makers' "ambition to bio" but also the reality of cases assessment which delineate key capabilities of the country or region.

One of the key lessons derived from our case studies is that achieving a functioning life science cluster with any degree of critical mass will require a minimum of 20 years investment and reinvestment. It may therefore be necessary to aim for more modest goals. Such endpoints are not less valuable in that they may provide a more realistic option for return on investment, and may also lead to new potential pathways in the future.

- Full Bio cluster
- Niche Bio Cluster
- SME Generator
- Bio Supply or Service (participation in single part of value chain)
- Partner Technology (not bio, focus on a different but potentially collaborative technology)

-Broader Objectives: Just as important is the need to understand how targeting a sector forms part of broader objectives for the national or regional economy. Without this vision of its part in the broader economy, such a policy process runs the risk of being seen as a short-term fad or policy whim and would not be given the long-term resources required. Too often, high level policymakers decide to pursue their "ambition to bio," aiming for a world class, competitive, fully innovation cluster without properly understanding the timelines and resources needed.

-**Regular system re-assessments**: This is where frequent assessments become vital. In order to realize if a Goal is feasible, policymakers need to assess their progress on an on-going basis, especially when switching between policy programs. Thus, regular system re-assessments (along with policy evolution) are important features of the Target process, along with subsequent opportunities to adjust the Goals.



3. Leadership

-**Kicking-off the Target effort:** To begin the process, entrepreneurial actors are needed to kick-off the Targeted effort, regardless of whether they are involved in the management of the subsequent process. Such a decision could be taken by any entity or body that has official recognition such as a ministry, committee or even a private body that represents the field.

-Strong Unity: What is important, and creates a major challenge in achieving a coherent targeted strategy and establishing a roadmap, is the acceptance of a common mission or overarching goals by a multitude of parties. On the government/political side this means acceptance from multiple political parties, as well as other influential ministries and agencies active in the economy, but it should also include acceptance from private and third column stakeholders (e.g. universities and research institutes) in order to better facilitate coordination and less interference during the operation of the strategy itself. A minimal condition should be strong unity in either the public or private sector in this regard if not both. The condition of unity in one or both of the public and private sector should be an early part, if not precede, the early pre-implementation analysis described above.

4. A Coordinating Body

-The Coordination body's general role: A Coordinating Body is here described as an organization (or consortium) charged with carrying out the Target strategy and delivering or advising on different policy measures necessary to achieve the Goals. As such, it involves decisions at the strategic and tactical level in terms of how to construct the Coordinating Body in terms of its institutional structure, but also in terms of how the knowledge creation, experience and data it gathers feeds back into strategic outlook and tactical policy construction. The Coordinating Body should be able to translate this information into a roadmap and to create the drive for such a roadmap to be implemented. Additionally, the Coordinating Body should be responsible for monitoring progress, ensuring on-going learning, enabling feedback from different stakeholders and constructing policy that will deal with any blank spots in the roadmap as information becomes available. Because of the undefined nature of some of the new technology markets and business plans, ideally a Coordinating Body could engage in a conscious consideration of sector context, strength and a creative process of projecting possible paths that are realistically obtainable in the economy. From that analysis, the Coordinating Body can then help to guide the next step of strategy.

> The Coordinating Body has to be able to ask the hard questions and make the difficult decisions which may not necessarily appeal to short term political interests. Without this ability, the difficulty of actively pursuing a biotechnology sector is increased.

-The Coordinating Body's structure: The Coordinating Body should be created as part of the strategy, if there is no already existing organization which can be designated as the Coordinating Body. The Coordinating Body could take several forms of organization. It can be based on existing private/public/governmental bodies or it can be formed especially to fulfill this task. It can be based on a formal secretariat or it can be in the form of advisory committee. Whatever form the Coordinating Body will take it must consist of people being able to collect and assess information which is generated by different stakeholders or being generated by experts. Ideally, the Coordinating Body should benefit from having the necessary political will (and financial support) to operationalize the strategy.

-**Division between the strategic and operative levels:** The Coordinating Body should be divided strategically and operationally, with one body or division working to determine strategic level directions and another to operationalize and deliver programs. This separation can be done by either having an umbrella organization operating alongside other organizations (e.g. Ireland with Forfas and EI, IDA, SFI) or one organization which is internally divided (Scottish Enterprise). The separation of these functions requires a crucial linking mechanism in order to keep a very effective feedback and evaluative loop. Having said that, the benefit of separating the functions allows for the strategic level body to maintain the strategic objectives but absorb the environmental changes and new information in order to adjust details of the roadmap to better reach the end vision or result.

-Operational Role: The operational role of the Coordinating Body will depend on the pre-conditions already present and whether or not market failures will be additional to structural corrections that must be addressed. An important role is that despite the business/academic/research culture in the location, the Coordinating Body must seek to build and strengthen networks between stakeholders as part of its program executions, not simply to provide funding or incubation services, or other direct activities. Including network building activity would help to create opportunities for private actors to take on more responsibility or, at the very least, allow for Coordinating Body programs to have more deliverable impact through indirect spillovers.

Tactical Policy Dimensions

1. Identification of Stakeholders

While discussed at a strategic level regarding consensus for the policy process, it is important to re-state the need to identify as many stakeholders in academia, the public sector and private sector who currently, or might in the future, contribute to innovation in the sector selected, as well as any institutions which may have an indirect impact on the sector (e.g. groups which may influence ethical considerations in scientific development but are not involved in research or commercial development). This is particularly important as the most successful systems of innovation are those which demonstrate high levels of coordination between stakeholders, and take advantage of the systemic nature of innovation and technological development. This is important not only for strategy buy-in, but also to determine which policy measures should be aimed at, who they may impact, and how stakeholders may be added, disappear, or change over the course of the strategy.

2. Identification of Entry-points

Entry points for any policies or interventions in attempts to develop an industry must be defined, and there must be minimal conditions present for action at an entry-point to be effective. The entry-points are the particular areas that policy will be implemented to enact direct change or amplification of activity. Realistic chances of influence must be assessed, both in the specific entry-point and the overall system – for example, it would be pointless to select venture capital creation as an entry point if there is no knowledge available from which to create start-ups.

The decision of how to choose the particular entry-points must also consider whether the correct entry-points are those "low-hanging fruit", or those which may be more difficult but have a longer-term positive influence on the innovation system. On the one hand, while a longer term vision is encouraged for a targeted approach, the long-term planning of resources and time commitment create challenges for policymakers. Short-term goals may be an easy success, but may not be best for the system. However, a different consideration may be that low-hanging fruit can create further buy-in from stakeholders and therefore allow for more long-term commitment. Practical versus theoretical consideration must therefore be considered and policymakers should develop this awareness.

3. Design and Execution of Measures

The point above regarding effective policies at specific entry-points is important to the design of measures take to reach the selected goals. It is also important to keep in mind the stakeholders who may be involved both as providers and as 'clients' of the measures. It is recommendable to engage private sector stakeholders in the design and delivery of a measure, both because it enhances coordination and because it would help to create a realistic delivery time. For example, a measure designed to correct the funding gap for start-up firms would be hampered significantly if it was characterized by slow decision and delivery times; start-up firms would likely avoid such measures due to the resources required to fill out the necessary paper work, plus the prospect of missing market windows. On the other hand, radical systemic changes may require entrepreneurial solo action by public or private actors (e.g. an economic development agency, or a consortium of private sector actors) if potential partners are too risk-averse to cooperate. Regardless, to determine each possibility, stakeholder communication is necessary.

Proper budgeting is also important to ensure effective implementation of a Target Strategy. The main concerns regarding budgeting are the difficulty to predict how much may be needed once a measure is launched, and whether or not the budget will be maintained in the long-term or potentially be cut.

4. Appropriate Evaluation

An important but potentially overlooked part of a Target Strategy is the development of appropriate evaluation mechanisms. Evaluation is important because it allows for feedback to policymakers

> In Lithuania, the Innovation Strategy stated that a full set of European Innovation Indicators that would be used to determine the strategy's progress. While this may be useful, relying arbitrarily on this set of indicators would be problematic as the indicators were not selected based on their appropriateness for the Lithuanian setting, and therefore would not help to provide the specific feedback necessary for policymakers at the stage of development the economy is in.
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> In Scotland, the evaluation mechanisms for innovation were altered from quantitative measures (of how many firms were created, money invested, etc.) to mechanisms which sought to determine how policies increase national gross added value. Changing evaluation mechanisms to judge the effectiveness of policies that were not planned with such mechanisms in mind meant that some policies may have been cancelled prematurely.

regarding policy effectiveness. More importantly, however, evaluation mechanisms should also provide feedback regarding the overall state of the industry as this would allow policymakers to maintain a systemic view of what is happening, and adjust the overall Target process rather than simply adjusting some specific policies. Therefore, what is necessary is a system of policy evaluation and system (re-)assessment. While advanced evaluation mechanisms should be utilized, the evaluation of policies should rest both on indicators but also on a clear view of what the goal or intention the policy set rested on, whether the indicators appropriately capture that, and whether these goals or intentions are still valid.

The TARGET approach presented here will help policymakers form a strategic roadmap and determine feasible interventions that lead to a functioning biotechnology system of innovation within a country or region. The goal of the toolkit is not to present a single recipe of specific policies for success; as will be noted later on, the variety of cases and their development mean that no single path to a functionally biotechnology sector can be realistically described.