# DESIGNING A TECHNOLOGY AND INNOVATION PLATFORM FOR ONCOLOGICAL DRUGS: AN INTEGRATED FORESIGHT FRAMEWORK

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## ABSTRACT

Technology platforms have been conceptualized as the result of the exploitation and reutilization of knowledge and experience accumulated by the institutions and firms in a sector, generating, with that, new knowledge and distinctive technological competences that can be shared by product families, applications and future businesses. This paper aims to present an integrated foresight framework customized for designing a technology and innovation platform and defining a strategic R,D&I Agenda for oncological drugs in Brazil. This framework encompassed: (i) development of technological roadmaps, looking for technological and market bottlenecks and opportunities for this segment in the period of 2013 to 2030; (ii) identification of local distinctive competences concerning four categories of oncological drugs – chemotherapy; hormone therapy; immunotherapy; and argeted therapies; (iii) establishment of strategic R,D&I portfolios for each category, considering local distinctive competences versus strategic importance for the Brazilian health system; and (iv) strategic roadmapping for designing the technology innovation platform for oncological drugs, considering three distinct time horizons. From this experience, one can conclude that: (i) the integrated foresight framework was demonstrated to be effective for designing a technology and innovation platform for oncological drugs in Brazil; (ii) the most promising local opportunities for cooperative R,D&I projects in this pharmaceutical segment could be identified; and (iii) it was possible to establish conditions for replication of this foresight framework at sectorial level for other drugs segments.

**Key words:** Integrated foresight framework; technology platforms; distinctive competences; oncological drugs.

## INTRODUCTION

The technology platform concept, adopted in Europe and other regions, including Latin America, is aimed at the identification and proposal of valid approaches to deal with the main economic, technological and social challenges based on future cooperative R,D&I projects. To succeed, it is necessary to engage stakeholders through the formation of effective public-private partnerships, in order to establish and implement R,D&I Agendas.

By way of illustration, we can cite the technological platform for drugs titled "The Innovative Medicines Initiative (IMI): Strategic Research Agenda", published by the European Commission in 2005 (European Commission, 2005). According to European Commission (2005),

> "the development of a new drug is long, resource intensive and complex. The overall cost is variously estimated at between $400 and $900 million (US) for the period 1994-2000. The possibility of failure to reach the market is high and the project may fail for many reasons at many points in its evolution. The greatest need for the pharmaceutical industry is to detect the possibility of failure at the earliest stage as possible, and it is in this context that advances in basic biomedical science within the European research community could make the greatest contribution" (European Commission, 2005: 10).

In this case, the main bottlenecks of the research, development and innovation (R,D&I) process concerning strategic drugs were initially identified, as represented in Figure 1. From that diagnosis, recommendations were formulated on how to address these bottlenecks, using a pre-competitive approach supported by technological distinctive competences accumulated in Europe. Specific recommendations resulted from interviews with various stakeholders during the period of 2004-2005.

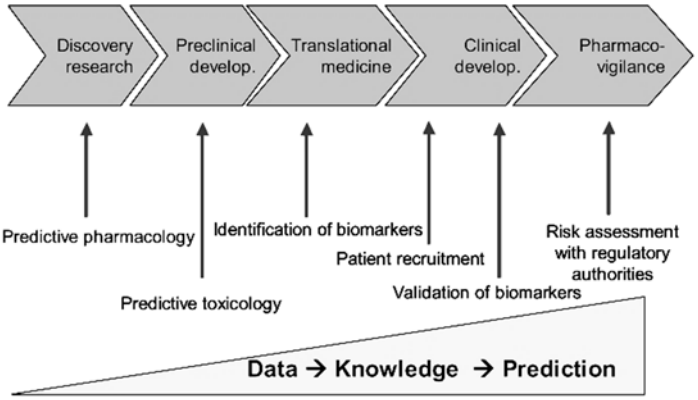


*Figure 1: The Pharmaceutical R,D&I Process and Key Bottlenecks, Source: European Commission (2005)*

In the case of Brazilian adoption of strategic technology platforms within its Health System, the main critical issue refers to the large gap between the level of accumulated scientific capacity and the existing innovation capabilities of the productive base of this system. In addition, given the low intensity of the innovative efforts of companies, universities and technology centers have focused their R&D activities on basic or applied research and failed to advance to subsequent stages of the R&D process towards product and process innovations and production at industrial scale (Paim et al., 2011).

In this context, the creation of technology and innovation platforms for drugs through cooperation with companies and other agents in the National System of Science, Technology and Innovation (NSSTI) emerges as an alternative to deal with the critical issues and key bottlenecks in the R,D&I process of strategic drugs identified in previous local studies (CGEE, 2013).

The design of a technology and innovation platform for strategic drugs required a systemic and integrated approach for analyzing the respective drugs supply chains. Also, it benefitted from the inclusion of perceptions and perspectives of the various stakeholders that should be involved in future developments according to the platform concept. In addition, the choice of methodological approach should consider the strategic dimensions of the R,D&I process, as follows: (i) human resources, with particular emphasis on identifying distinctive competencies at country level; (ii)

infrastructure associated to the whole process, from applied research to manufacturing and commercialization stages; (iii) investments and financial mechanisms required; (iv) regulatory issues; (v) ability to articulate R&D cooperation and partnerships; and (vi) intellectual property and technology transfer issues.

Finally, by adopting the conceptual approach of technology and innovation platforms, the relationships that should occur between different NSSTI agents were emphasized, in a form analogous to usual models that have been applied in business partnerships.

This paper aims to present an integrated foresight framework customized for designing a technology and innovation platform and defining a strategic R,D&I Agenda for oncological drugs in Brazil. This framework combines well-known technological foresight approaches with the resource-based view of distinctive technological competences, and also emphasizes the importance of the active participation of all relevant stakeholders (industry, government, academia, clinicians, regulatory and ethics specialists).

## THEORETICAL BACKGROUND

In this section, we discuss the theoretical bases concerning two main themes: (i) technological and innovation platforms supported by distinctive competences; and (ii) technology foresight as instrument for the governance of technology and innovation platforms.

### Technological and Innovation Platforms supported by Distinctive Competences

Technology and innovation platforms have been conceptualized as the result of the exploitation and reutilization of knowledge and experience accumulated by the institutions and firms in a sector, generating, with that, new knowledge and distinctive technological competencies that can be shared by product families, applications and future businesses (European Commission, 2004; Forfás, 2005; Nasiriyar, 2010; and Nasiriyar *et al*., 2010).

Figure 2 shows a schematic representation of a technological and innovation platform.

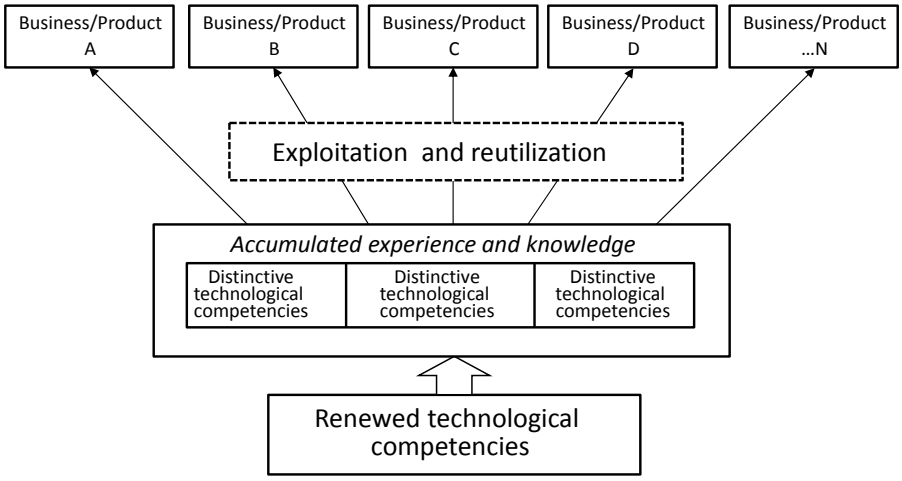


*Figure 2: Schematic Representation of a Technological and Innovation Platform, Source: Nasiriyar, 2010*

In order to exploit and reutilize accumulated experience and knowledge, participants of a technological platform must: (i) have previous experience and knowledge regarding the technologies

considered; (ii) be capable to introduce changes in their development, through analyses and reconfiguration of the technologies developed; and (iii) be capable of renovating themselves by developing new markets and businesses and also by introducing high impact technological changes.

The conceptual approach of distinctive competences has been disseminated since the early 1980s through the writings of Snow and Hrebiniak (1980); Hitt and Ireland (1985); Hofer and Schendel (1978); Itami and Roehl (1987); Hayes, Wheelright and Clark (1988); Prahalad and Hamel (1990); and Pavitt (1991). It stems from a theoretical stream in the field of strategic management known as resource-based view or RBV (Penrose, 1959; Wernerfelt, 1984; Barney, 1991; and Peteraf, 1993).

In the early 1990s, Prahalad and Hamel (1990) and Pavitt (1991) reinforced the importance of integration and coordination of internal strategic capabilities and technologies for creating competitive advantages and diversifying businesses. According to Prahalad and Hamel (1990), distinctive or core competences represent "the collective learning in the organization, especially how to coordinate diverse production skills and integrate multiple streams of technologies" (p. 82).

Rumelt (1994, p. xv-xvi) characterizes distinctive competences into four aspects: (i) 'corporate span': core competencies span business and products; (ii) 'temporal dominance': products are temporary expressions of competences, once competences are stable and evolve more slowly than products do; (iii) 'learning by doing': competences are developed through continuous practice; and (iv) 'competitive locus': product-market competition is usually the superficial expression of a deeper competition over competences.

For the purpose of designing a technology and innovation platform for strategic drugs in Brazil, distinctive competences are defined as an integrated set of skills and technologies of a given organization (or organizations in co-operation), which are unique strategic resources that can be shared by product families, applications and future businesses. From the perspective of a technology and innovation platform, distinctive competences of different agents should be combined through cooperative R,D&I efforts.

**Technology Foresight as Instrument for the Governance of Technology and Innovation Platforms**

The second part of the theoretical background refers to technology foresight, focusing on its role as instrument for the governance of a given technology and innovation platform.

According to a recent literature review on this subject,

> "the concept of technology foresight took off in the 1990s, as European, and then other, countries sought new policy tools to deal with problems in their science, technology and innovation systems. Large-scale exercises drew in numerous stakeholders as sources of knowledge and influence, and the prominence of these exercises led to 'foresight' being used much more widely to describe futures activities of many kinds" (Miles, 2010, p. 1448).

Technology foresight has been defined as a structured approach for setting priorities for science and technology (S&T) resource allocation (Keenan et al., 2003), but also as a dialogue process that support Martin and Irvine's five Cs, as follows: (i) concentration on the long term horizons, (ii) improved coordination among the stakeholders' visions, intentions, and actions, (iii) consensus on research areas that seem particularly promising, (iv) more intensive communication, and (v) commitment to the implementation of S,T&I policies (Martin and Irvine, 1989).

The contributions of Georghiou et al. (2008); Keenan and Popper (2007); Miles (2010); Kuosa (2012); Phaal et al. (2001; 2004); and Voros (2001; 2003; 2005) proved to be of great value to the development of an integrated foresight framework customized for designing a technology platform for oncological drugs in Brazil. This framework combined a well-known technology foresight tool - technological roadmapping - with the concept of technological platforms and distinctive technological competences.

Although much of the foresight literature has been concerned with the shaping of S,T&I policies, foresight is here defined "as a purposefully organized process bringing together expectations of diverse actors about a technology, to formulate strategic views about the future that take into account broad social and economic developments" (Webster, 2002). For purposes of building an integrated foresight framework for designing a technology and innovation platform, the conceptual model developed by Voros (2001; 2003; 2005) was adapted. The aim of Voros' model is to show that the activity of foresight precedes and subsidizes strategic decision making ('what needs to be done?') and the formulation of the strategy ('what will be done?' and 'how to do it?'). The model structure comprises four phases: (i) inputs; (ii) foresight; (iii) outputs; and (iv) strategy formulation. The sequential structure proposed by the author aims to add value to information obtained at the initial stage, transforming them into knowledge and, subsequently, in strategy.

Assuming that technology foresight activities search for a shared vision of the most important demands and promising fields of research in the future in order to establish priorities, it's role is reinforced here as an instrument for the governance of a given technology and innovation platform. As a matter of fact, technology foresight activities enhance engagement of diverse stakeholders around the problematics of an uncertain future and its complexity constraints, as well as issues such as life quality and society improvement.

**METHODOLOGY**

The methodology encompasses methods and tools, which can be classified into participative and applied research. An integrated foresight framework was conceptualized on the basis of a previous literature review and validated in workshops by a group of more than 60 representatives of local stakeholders.

Figure 3 provides an overview of this framework, which was developed for designing a technology and innovation platform for a target drugs segment. The methodology comprised four modules:

- Module 1: Definition of technological foresight objectives and choice of the target drugs segment;
- Module 2: Definition of technological foresight scope, i.e. definition of technological topics to be assessed in each category of the target drugs segment, based on a detailed analysis of previous studies on this segment, and also on expert opinions;
- Module 3: Technological foresight *per se*, supported by selected tools – technological roadmapping, R,D&I portfolio analysis; and strategic roadmapping;
- Module 4: Establishing R,D&I Agenda for the target drugs segment, encompassing six dimensions: human resources; infrastructure; investments; regulatory aspects; cooperation and partnerships; and intellectual property and technology transfer.

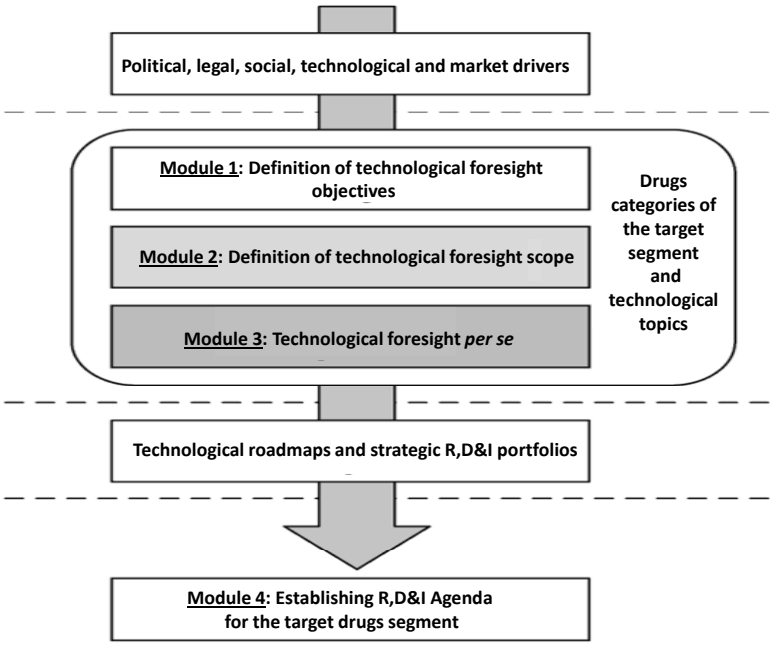


*Figure 3: An Integrated Foresight Framework for Designing a Technology and Innovation Platform, Source: Adapted from Voros (2003)*

The activities concerning each module are described in full alignment with the institutional context of the target drugs segment.

**Module 1: Definition of Technological Foresight Objectives and Choice of the Target Segment**

An assertive definition of technological foresight objectives is of great importance in determining the scope of TF activities themselves and also in establishing guidelines and assumptions for the subsequent strategic analysis to be conducted throughout the TF activities in Module 3. These activities should be guided by a broad understanding of the institutional context of target drugs segments, namely regulatory, ethical, social, technological, and market drivers, besides critical uncertainties around the future development of the technology and innovation platforms preliminarily considered.

In this module, the target segment of strategic drugs that should be the object of TF activities should be selected based on criteria previously defined by representatives of all stakeholders involved.

**Module 2: Definition of Technological Foresight Scope**

Fundamental to the success of this Module is the definition of a set of economic, social and environmental criteria for the selection of associated topics to each drugs category. From this perspective, the definition of TF scope must necessarily consider current typologies of drugs belonging to the target segment, i.e., drugs categories by therapeutic class, by technological route; or by other criteria deemed more appropriate.

For each drug category, one should select a preliminary set of technological topics associated with the strategic demands of the National Health System (current and future demands). It begins with the institutional mobilization of all stakeholders around the strategic demands, in order to:

- identify and analyze sectorial and market studies (outlook and also prospective scenarios) related to strategic demands;
- carry out a survey and analysis of scientific literature and patents on a global and local level for each strategic demand and their technological topics;
- identify technology trends and strategic moves of the actors of the NSSTI and the industry, based on sectorial and market studies, semi-structured interviews or on another research methods.

**Module 3: Technological Foresight *per se***

Module 3, along with Module 4, constitute the heart of the framework customized for designing a technology and innovation platform and defining a strategic R,D&I Agenda for oncological drugs in Brazil. In this Module, the combination of technological roadmapping tools (Phaal *et al*., 2001; 2004), strategic R,D&I portfolio analysis (Martino, 1995; Cooper *et al*., 1999); and strategic roadmapping (Camarinha-Matos and Afsarmanesh, 2004; Millett, 2006), is strongly recommended. Besides the mentioned TF tools, it is also recommended to combine two or more TF techniques, as, for example, Delphi technique associated with technological roadmapping; and evaluation of the environmental and economic impacts of the technologies that will be developed or adapted combined with strategic roadmapping.

During the participatory activities of technological roadmapping, it is important to note the foresight abilities required for the construction of the upper stages of the respective technological roadmaps (Hogon, 2006; Phaal et al, 2001; 2004). They refer to marketing and manufacturing foresight. For more effective results, it is recommended to invite representatives from companies and also other stakeholders in the NSSCTI to participate in the TF workshops.

Table 1 presents the conceptual grid suggested for technological roadmapping concerning a target drugs segment in three time-horizons.

*Table 1: Conceptual Grid for Technological Roadmapping Concerning a Target Drugs Segment*

| Stage | Category [title] | | |
|---|---|---|---|
| | Short-term foresight | Medium-term foresight | Long-term foresight |
| **Marketing and sales** | Marketing and sales capacity on a large scale in the time horizon considered. Applied to both Active Pharmaceutical Ingredients (APIs) and drugs. | | |
| **Drug and API production** | Production in large scale in the time-horizon considered. Applied to both Active Pharmaceutical Ingredients (APIs) and drugs. | | |
| **Bioequivalence and Pharmaceutical Equivalence** | Ability to conduct bioequivalence and pharmaceutical equivalence tests. Two products are pharmaceutically equivalents, if they have the same amount of the same active substance in the same pharmaceutical form, if they have identical or comparable standards, and if they are indicated for administration in the same way. Bioequivalence consists of the pharmaceutical equivalence demonstration between products presented under the same pharmaceutical form, containing identical qualitative and quantitative composition of active(s) principle(s), and having comparable bioavailability when it's studied under a same experimental drawing. Applied only to drugs. | | |

| Stage | Category [title] | | |
|---|---|---|---|
| | Short-term foresight | Medium-term foresight | Long-term foresight |
| **Phase III** | Ability to conduct clinical tests of Phase III (expected duration of 36 months). The new drug should be administered in double blind tests on two large samples of patients with the target disease. Long-term toxicity tests are performed in parallel. Applied only to new drugs. | | |
| **Phase II** | Ability to conduct clinical trials of Phase II (expected duration of 24,3 months). The new drug should be administered to a few patients with the target disease. Applied only to new drugs. | | |
| **Phase I** | Ability to conduct clinical trials of Phase I (expected duration of 15, 5 months). The new drug should be administered to a small number of healthy volunteers, with different dosages, to test absorption, metabolism and toxicity. Applied to new drugs. | | |
| **Development** | Ability to generate results on a pilot scale in the time horizon considered. After synthesis and purification of a candidate to medicine (generic or new), preclinical tests are performed. Applied to both Active Pharmaceutical Ingredients (APIs) and drugs. | | |
| **Applied Research** | Ability to generate results from applied research to the time horizon considered. It refers to both Active Pharmaceutical Ingredients (APIs) and drugs. | | |

During the TF workshops, the various stakeholders should identify their legitimate interests in future research and development initiatives (positioning future initiatives in the lower layers of the roadmap template, according to Figure 3) and pointing out their strategic demands (in the upper layers of the roadmap – 'production, marketing and sales'). All these prospective activities should be carried out in total alignment with the industrial and S,T&I public policies.

Figure 4 schematically represents a technological roadmap for a specific drug category pertaining to the target segment (Brazilian or global level). As it can be observed in Figure 4, technological topics of a given drug category must be positioned according to their stage within the R,D&I cycle and also to the different time horizons (if short, medium or long-term foresight). Each drug category should have a corresponding technological roadmap. Subsequently, a comprehensive roadmap concerning all strategic demands (identified in individual roadmaps) should be consolidated under a systemic perspective.

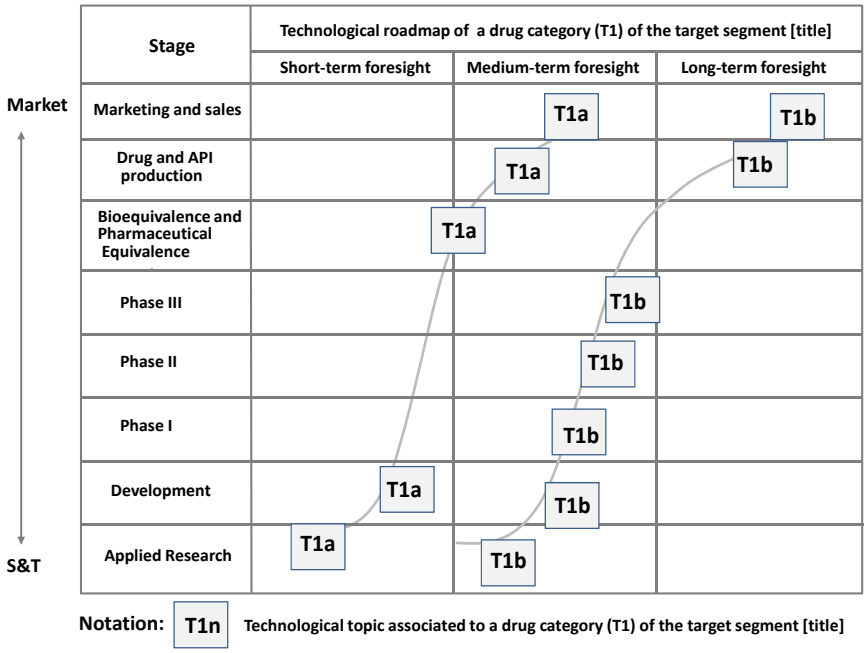


*Figure 4: Technological Roadmap of a Drug Category (T1) of the Target Segment: Three Time Horizons*

The technological topics (T1a … T1n) positioning, as indicated by alphanumeric references in Figure 4, together with their technological and market trajectories, should be collectively discussed during the TF exercises, considering the expected evolution through the time horizon considered.

The TF exercises also include the analysis of R&D and industrial bottlenecks, technological gaps, and market opportunities based on the results of the technological roadmapping and, particularly, on the stakeholders perceptions and interests. In relation to these 'warning issues', necessary support actions should be addressed for implementation, in order to reach the collective long-term vision (as represented through the trajectories of the technological topics being analyzed).

Additionally, in each technological roadmap and for each technology topic trajectory (when applicable), the points where a decision should be made in relation to the 'warning issues' should be highlighted with different colors associated to the dimensions used in the strategic analysis, as follows: (i) human resources (orange); (ii) infrastructure (blue); (iii) investments (pink); (iv) regulatory issues (green); (v) cooperation and partnerships (yellow); (vi) intellectual property and technology transfer (red).

Table 2 contains descriptions of the above mentioned dimensions, as well as the conceptualization of 'strategic orientation for R,D&I' efforts, considering potential market opportunities.

*Table 2: Dimensions Concerning Strategic Analysis for Formulating a R,D&I Agenda for Drugs of the Target Segment*

| Dimension | Description |
|---|---|
| **Strategic orientation for R,D&I efforts, considering market aspects** | Strategic guidelines related to topics of the technological roadmaps of drug categories of the target segment, which indicate: (i) opportunities and bottlenecks associated with technological trajectories of the topics of a given drug category; (ii) recommendations for technological cooperation, internal development or acquisition, depending on the degree of technological |

| | |
|---|---|
| | maturity of the topics and the degree of internal competence in each of the stages of technological roadmaps; and (iii) opportunities for effective insertion of innovations into national and international markets , to consolidate the supply chain of the target drug segment. Power of institutional buying and other marketing aspects, besides expiration date of drug patents, are also taken into account. |
| **Human resources** | Incentive to the development and training of strategic human resources for the covered technical areas and disciplines associated to the target segment, from the perspective of consolidating distinctive competencies that will support the technology platform of the target drugs segment in the country. |
| **Infrastructure** | Consolidation and expansion of the physical infrastructure of public and private institutions, which have the mission of developing of R,D&I focused on the target drugs segment. This dimension also includes the creation of favorable environments for greater interaction between the business community and the S&T centers and for emergence of new technology-based companies. |
| **Investments** | Financial support mechanisms in order to: (i) provide adequate funding sources, including those of non-refundable nature, as well as strengthening of risk capital contribution to the creation of new companies or platforms of innovative companies; (ii) evaluate the use of tax relief instruments for industrial modernization, innovation and export s. |
| **Regulatory aspects** | Legislation and regulatory framework improvement and their direct impacts on the development of technology and innovation platform for the target drugs segment. |
| **Cooperation and partnerships** | Ability to generate knowledge and promote innovation through cooperation and partnerships. This dimension includes: (i) skills to identify potential partners, to explore and use the collaborative relationships between organizations; (ii) technological cooperation network, comprising cooperation between intra and inter-institutional researchers participating in the technology and innovation platform for the target drugs segment. |
| **Intellectual property and technology transfer** | Legal and contractual mechanisms to be adopted by platform agents for protecting and transferring the knowledge new technologies to market. |

The strategic R,D&I portfolios, in turn, should be analysed for each category of drugs, by plotting the technological topics in focus, according to two axes, as follows:

- Strategic importance for the country, resulting from the assessment of the technological topics by the following criteria (defined in Module 2):
    - Strategic demands of the National Health System associated to drugs supply;
    - Market opportunities and potential increasing of Brazilian competitiveness (including issues regarding patent expiration dates and local production of generics);
    - Ability to generate incremental or radical innovations aiming at domestic production;
    - Previous experience, accumulated knowledge and distinctive technological competence associated to each technological topic;
    - Contribution to the reduction of Brazilian trade deficit as related to strategic drugs, by

import substitution or increase in exports;

- Existence of local initiatives aimed at a group or subgroup of the "List of Strategic Drugs" established by the Brazilian Ministry of Health;
- Level of effort required for the whole trajectory of each technological topic, as indicated in the respective technological roadmaps.

The graphical representation of a strategic R,D&I portfolio concerning one of the drugs categories (T1, in this didactic example) is shown in Figure 5.

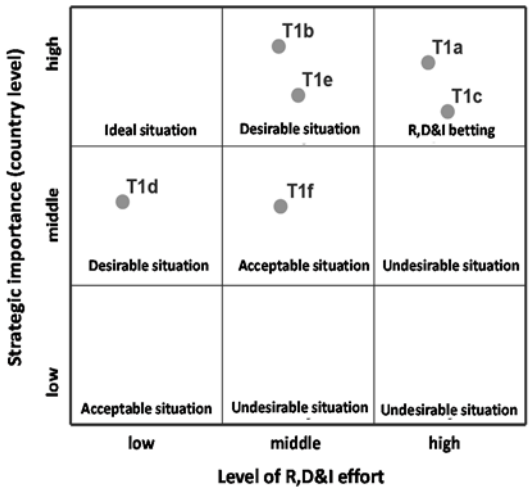


*Figure 5: Graphical Representation of a Strategic R,D&I Portfolio Concerning One of the Drugs Categories (T1) of the Target Segment*

At the end of technological roadmapping and the strategic R,D&I portfolio analysis focusing on the selected drugs categories, it is necessary to consolidate the results under a systemic perspective, reducing bias, reworks and undesirable overlays. Adjustments in individual roadmaps and portfolios may occur at that time. The inclusion of new technological topics, resulting from the convergence of different views, could also occur. So, the final results constitute the basis for the formulation of a R,D&I agenda, which is considered the central point of the technology and innovation platform for the target drugs segment.

Finally, it is important to mention that a special coordinated effort should be made in order to guarantee that stakeholders be involved in all TF steps of Module 3, assuring that government, business, public and private labs, academy and other agents could present their visions in a harmonious and complementary way.

**Module 4 – Establishing R,D&I Agenda**

The tool of choice suggested for formulating the R,D&I agenda associated with the target segment is the strategic roadmapping technique (Camarinha-Matos and Afsarmanesh, 2004; Millett, 2006), as illustrated in Figure 5.

The conceptual approach to be adopted during the construction of the strategic roadmap of the technology and innovation platform includes the formulation of a 'long-term vision', and also the definition of the guidelines and actions required to strengthen the strategic positioning of the country on the target drugs segment.

The ultimate purpose of a technology and innovation platform is to develop a R,D&I long-term vision for the target drugs segment. It is recommended that, initially, strategic goals by category of drugs be set. Then follows the creation of strategic roadmaps corresponding to the same categories, as shown in Figure 6 .

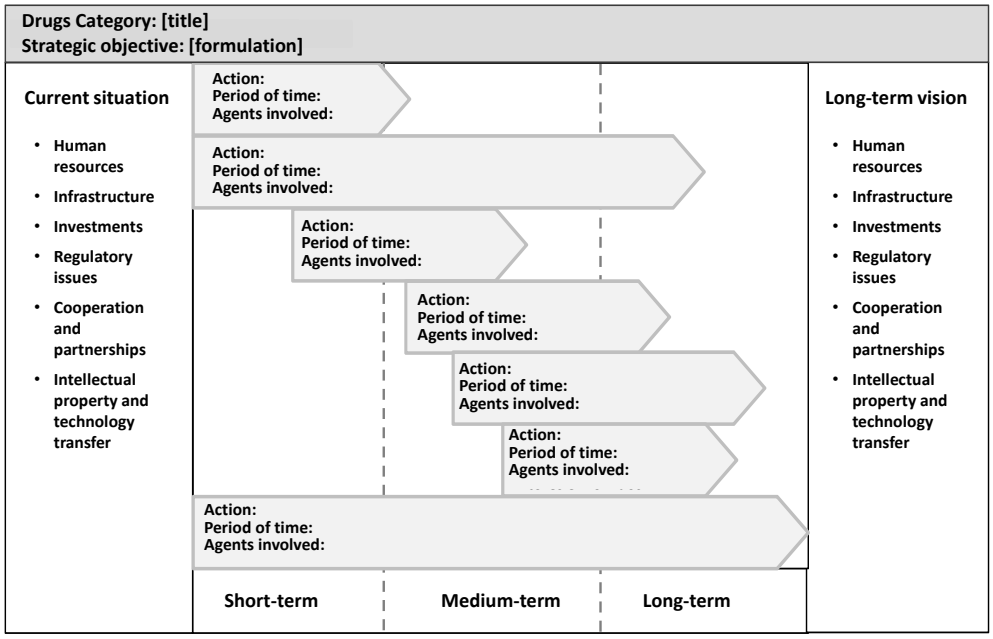


*Figure 6: Strategic Roadmap Schema for Structuring a Technology and Innovation Platform for the Target Drugs Segment*

Aiming at building the strategic roadmap for developing a technology and innovation platform for the target drugs segment, we define long-term vision as a clear description of strategic intentions of the agents involved in a particular period of time, represented by the statement of the country's strategic positioning for the future of the drug segment in focus, within that time horizon. It should represent the expectations and the legitimate interests of the diverse stakeholders involved (government, business, academia and others) for the future development of the drugs segment.

The long-term vision should also be aligned to the technological roadmaps and strategic R,D&I portfolios of the respective drugs categories. These roadmaps and portfolios are, therefore, the starting points and a robust basis not only for the statement of the long-term vision, but also for the formulation of a strategic roadmap associated with the development of a technology and innovation platform for the target drugs segment.

In Module 4, a final document - bringing together the results of all four modules - sets out the strategic R,D&I Agenda for the target drugs segment in Brazil. Distinctive local competences and bottlenecks in the biomedical R&D process should be identified and reported. Also, recommendations on how to enhance competences and to unblock these bottlenecks should be formulated based on pre-competitive and cooperative approaches. It is suggested that the recommendations are organized around the six dimensions described in Table 2: (i) human resources; (ii) infrastructure; (iii) investments; (iv) regulatory issues; (v) cooperation and partnerships; and (vi) intellectual property and technology transfer. By way of illustration and focusing on oncological drugs segment, this final document should be structured as follows:

- An introductory section, highlighting the strategic importance of creating technology and innovation platforms for the country, particularly those addressed to fulfill strategic demands of the National Health System. It should include a brief overview of global and Brazilian outlooks for the drug segments associated to these demands;
- A second section, describing the integrated foresight framework customized for designing a technology and innovation platform for oncological drugs in Brazil;
- A third section, defining strategic drivers of a technology and innovation platform for oncological drugs, i.e., long-term vision and strategic objectives associated to four oncological drugs categories – chemotherapy, hormone therapy, immunotherapy, and targeted therapies;
- A section about the platform governance system, with a set of general guidelines for the operation and management of the platform and description of the governance structure itself and respective responsibilities of the agents involved;
- A section bringing together the technological roadmaps, with identification of bottlenecks and strategic opportunities for the country, and also their corresponding R,D&I portfolios - all concerned with the four mentioned oncological drugs categories (totaling four roadmaps and four R,D&I portfolios);
- A section presenting the "R,D&I Agenda for Oncological Drugs in Brazil: 2013-2030", based on technological platform conceptualization with support of TF tools.
- Finally, a conclusions section, with lessons-learned, good practices and general recommendations for the implementation of the R,D&I Agenda.

**RESULTS AND DISCUSSION**

The main results can be summarized as follows: (i) technological foresight objectives and choice of the target drugs segment; (ii) technological foresight scope; (iii) technological foresight results related to the four categories of oncological drugs; and (iv) R,D&I Agenda for oncological drugs in Brazil, based on the technological platform conceptualization.

**Technological foresight objectives and choice of the target drugs segment**

For the definition of TF objectives and the choice of the target drugs segment for designing a technology and innovation platform, one first workshop was carried out with the participation of 30 representatives of local stakeholders, with a predominance of industry representatives.

The segment of choice was oncological drugs, according to the criteria mentioned in last paragraphs of the description of Module 3 ('Methodology' Section).

The technological foresight objectives were defined as follows:

- To develop technological roadmaps and R,D&I portfolios concerned with four oncological drugs categories in Brazil, from the perspective of identifying technological and market bottlenecks and opportunities for the country in the period of 2013 – 2030;
- To build the basis for defining a R,D&I Agenda for Oncological Drugs in Brazil, based on the concept of technology platform and covering a range of short, medium and long term

associated to six dimensions: (i) human resources; (ii) infrastructure; (iii) investments; (iv) regulatory issues; (v) cooperation and partnerships; and (vi) intellectual property and technology transfer.

**Technological foresight scope**

For the definition of the TF scope and the development of TF activities *per se,* a second workshop mobilizing 60 stakeholders took place in Brasilia, on 20-21 June 2013. In this occasion, an outlook of the international market of oncological drugs was presented, based on a recent study published by Visiongain, covering the period 2013-2023 (Visiongain, 2013). This outlook provided all attendees a broad understanding of strategic moves of international players, and the economic and market importance of the main oncological drugs, with their respective patent expiration dates.

Then, four working groups were organized by oncological drugs category to initiate the TF activities. The typology defined by Visiongain (2013), which consists of four categories - chemotherapy; hormone therapy; immunotherapy; and targeted therapies - was adopted for purposes of TF activities. For each category, the respective working group defined technological topics, coming up with a total of 50 drugs, as shown in Table 3.

*Table 3: Definition of Technological Forecasting Scope*

| Oncological drug category | Number of technological topics |
|---|---|
| **Chemotherapy** | 7 |
| **Hormone therapy** | 9 |
| **Immunotherapy** | 12 |
| **Targeted therapies** | 22 |
| **Total** | 50 |

By way of illustration, Table 4 presents the 12 topics selected within the category 'Immunotherapy', with a brief description of each topic, patent expiration dates, and the respective stage of technological maturity (world and Brazil). According to Roussel (1984), each new technology is exposed to a certain maturation sequence during its developmental and applied life cycle. He describes four sequential stages of technological maturity, namely the embryonic, growth, mature and aging stages.

*Table 4: Technological Topics Associated to 'Immunotherapy' Category*

| Ref. | Topic | Description | Technological maturity [world] | Technological maturity [Brazil] |
|---|---|---|---|---|
| **T3a** | Trastuzumab | Monoclonal antibody that interferes with the HER2/neu receptor. Its main use is to treat certain breast cancers. The primary patent on Herceptin expired on July 28, 2014 in Europe. | Mature | Embryonic |
| **T3b** | Infliximab | Chimeric monoclonal antibody against tumor necrosis factor alpha (TNF-α) used to treat autoimmune diseases. Remicade's patent protection is until February 2015 across all | Mature | Embryonic |

| Ref. | Topic | Description | Technological maturity [world] | Technological maturity [Brazil] |
|---|---|---|---|---|
| | | currently approved indications, adult and pediatric. The patent was originally expired in Europe in 2014. | | |
| **T3c** | Rituximab | Chimeric monoclonal antibody against the protein CD20, which is primarily found on the surface of immune system B cells. The U.S. patent was issued in 1998 and will expire in 2015. | Mature | Embryonic |
| **T3d** | Cetuximab | Chimeric (mouse/human) monoclonal antibody given by intravenous infusion that is distributed under the trade name Erbitux. Patent will expire in 2018. | Growth | Embryonic |
| **T3e** | Adalimumab | TNF inhibiting anti-inflammatory drug manufactured by AbbVie. It is the world's largest-selling drug. Humira with lose its U. S. patent protection at the end of 2016. | Mature | Embryonic |
| **T3f** | Denosumab | Fully human monoclonal antibody for the treatment of osteoporosis, treatment-induced bone loss, bone metastases, multiple myeloma, and giant cell tumour of bone. Patent will expire in 2016. | Growth | Embryonic |
| **T3g** | Lenalidomide | Derivative of thalidomide, it was initially intended as a treatment for multiple myeloma. Trade name: Revlimid. Patent for Revlimid (US 5,635,517) expires in October 2019. Two method of use patents (7,189,740 and 7,968,569), which expire in 2023, may become the battle ground for extending exclusivity for Revlimid beyond 2019. | Growth | Embryonic |
| **T3h** | Bevacizumab | It is a recombinant humanized monoclonal antibody that blocks angiogenesis by inhibiting vascular endothelial growth factor A. Trade name: Avastin. Patent expiration on hold until 2019 in the U.S. and 2022 in Europe. | Growth | Embryonic |
| **T3i** | Ipilimumab | It is a monoclonal antibody developed that works to activate the immune system by targeting CTLA-4, a protein receptor that down regulates the immune system. Patent covering ipilimumab, which expires in the US in 2016 and Medarex composition of matter patent will expire in 2020. | Growth | Embryonic |
| **T3j** | Pertuzumab | Monoclonal antibody marketed by | Growth | Embryonic |

| Ref. | Topic | Description | Technological maturity [world] | Technological maturity [Brazil] |
|---|---|---|---|---|
| | | Genentech for the treatment of HER2-positive breast cancer, in combination with Trastuzumab and Docetaxel. Patent will expire in 2025. | | |
| **T3k** | Gardasil® | Recombinant human papillomavirus vaccine [types 6, 11, 16, 18]. Gardasil's patent expires in 2015 and an extension application may possibly reach 2020. | Growth | Embryonic |
| **T3l** | Cervarix® | Recombinant bivalent vaccine containing human papilloma virus HPV-16 and HPV-18 virus-like particles (VLP) with AS-04 adjuvant. It prevents cervical cancer and precancerous lesions associated with human papillomavirus (HPV). Cervarix is protected by US patent which expires in 2026 and European patent which expires in 2019. | Growth | Embryonic |

The alphanumeric references in the first column of Table 2 were adopted throughout the technological roadmapping and analysis of the strategic R,D&I portfolio associated with 'Immunotherapy' category. Similar contents were generated for all topics associated to the other categories of oncological drugs.

**Technological Foresight Results Related to Four Categories of Oncological Drugs**

The collective construction of four technological roadmaps associated to the four oncological categories (Table 3) took into account basic information about 50 selected drugs, namely: (i) active pharmaceutical ingredient (API); (ii) trade name; (iii) producers; (iv) competing drugs, when information was available; (v) CAS number; (vi) priority number of the first patent; (vii) expiring patent dates; (viii) countries, where occurred the first application; (ix) deposit number in Brazil, if any; and (x) the drug formula.

For purposes of building technological roadmaps concerning the 50 focused drugs, the TF tool proposed by Phaal et al. (2001; 2004) was adopted. According to the conceptual grid for technological roadmapping presented in Table 1, the time horizons considered were 2013-2016 (short-term); 2017-2023 (medium-term); and 2024-2030 (long-term).

In summary, during the second workshop, four technology roadmaps – corresponding to the categories of Table 3 - were generated collectively, and bottlenecks, technological gaps and R,D&I could be identified by the companies and NSSTI agents who participated in this event.

**The R,D&I Agenda for Oncological Drugs in Brazil, based on Technological Platform Conceptualization**

The "R,D&I Agenda for Oncological Drugs in Brazil" was also defined during the second workshop, with the support of strategic roadmapping technique (Camarinha-Matos and Afsarmanesh, 2004; Millett, 2006). On this occasion, four working groups identified technological gaps between the 'current situation' and the 'long-term vision' and strategic opportunities for the country concerning the four oncological drugs categories.

The identification of gaps, bottlenecks and strategic opportunities allowed the formulation of a set of strategic initiatives, objectively addressing the weaknesses identified and exploiting the R,D&I opportunities. The time horizons of the strategic roadmap were the same set for technological roadmaps, i.e.: 2013-2016 (short-term); 2017-2023 (medium-term); and 2024-2030 (long-term).

Based on the results of a well-structured technological forecasting process, and according to the proposed schema represented in Figure 5, the 50 technological topics considered strategic for the country were classified into four situations, as follows: (i) 'R, D&I betting', referring to drugs that were classified as being of high importance and whose development requires high level of effort. In most cases, they are at an embryonic stage of technological maturity (world state-of-the-art); (ii) 'ideal situation', when the topics are of high strategic importance for the country and its development requires little effort; (iii) 'desirable situation', when the topics are of high strategic importance and its development requires an average effort; and, finally, (iv) 'acceptable situations', as shown in Figure 5.

*Table 5: Strategic Orientation for R,D&I Efforts Concerning Selected Oncological Drugs: 2013-2030*

| Category | R,D&I betting | Ideal situation | Desirable situation | Acceptable situation | Total |
|---|---|---|---|---|---|
| **Chemotherapy** | 1 | 2 | 4 | 0 | **7** |
| **Hormone therapy** | 3 | 5 | 1 | 0 | **9** |
| **Immunotherapy** | 7 | 0 | 4 | 1 | **12** |
| **Targeted therapies** | | 1 | 21 | 0 | **22** |
| **Total** | **11** | **8** | **30** | **1** | **50** |

As mentioned before, a set of recommendations and support actions relating to R,D&I bottlenecks and opportunities was formulated, looking at the six dimensions, as defined in Table 2. With the contribution of all stakeholders who participated in the TF workshops in 2013, the "R,D&I Agenda for Oncological Drugs in Brazil: 2013-2030" was consolidated.

**FINAL REMARKS**

This article summarized the main results of a research project titled "Technology Platforms for Drugs: Articulation between industry and the National System of Science, Technology and Innovation (NSSTI)", showing that its objectives were fully achieved. Based on the results of two workshops coordinated by CGEE (Center for Strategic Studies and Management) aiming at a collective

construction of a technology platform, it was possible to offer alternatives and establish conditions for replication of the integrated foresight framework here presented into a sectorial scale.

This framework encompassed: (i) the development of technological roadmaps, looking for technological and market opportunities and bottlenecks for the period 2013-2030; (ii) identification of local distinctive competences concerning four categories of oncological drugs – chemotherapy; hormone therapy; immunotherapy; and targeted therapies; (iii) development of R,D&I portfolios for each group, considering local distinctive competences versus strategic importance for the country; (iv) development of a strategic roadmapping for designing the technological platform for oncological drugs as a whole.

Essentially, from this experience it is possible to conclude that: (i) the integrated foresight framework was demonstrated to be effective for designing a technology and innovation platform for oncological drugs in Brazil; (ii) the most promising local opportunities for cooperative R,D&I projects in this pharmaceutical segment could be identified; and (iii) it was possible to establish conditions for replication of this foresight framework at sectorial level for other pharmaceutical drugs segments.

For the purpose of replication of the foresight framework in other segments of Brazilian Health system, it is recommended:

- Environmental scanning of the target drug segments (social, technological, economic, environmental, and political issues);
- Systematic survey and preliminary analysis of the scientific literature and patents, at the global and national levels, related to drugs in each target segment;
- Identification of technological routes associated to the target drugs, as well as technological bottlenecks and opportunities for cooperative R&D addressed to their development and local production;
- Mapping of technological distinctive competences (experts and research groups at country level) for each of the target drug segments considered for replication;
- Monitoring of technology trends and strategic moves of the industrial actors at country and global level;
- Mobilization and commitment of respective members of the governance system of future technology platforms, since the beginning of replication processes;
- Promotion of engagement of stakeholders in the design of future technology and innovation platforms, particularly the participation of companies and actors of NSSTI, active in the targeted segments;
- Follow-up of the first structural and mobilization actions of the R,D&I Agenda, aiming at improving the conception and design of the next technology and innovation platforms within the Brazilian Health System.

Finally, it is worth noting that the results here presented are very promising, when one think about the replication of the TF framework to other segments of the Brazilian Health System. However, these results should be treated as a first approximation to the intended design for future technology

and innovation platforms concerning other drug segments. The institutional learning from the implementation of this first technology and innovation platform should significantly contribute to the consolidation of the TF model here presented.

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