

# Productive Development Partnerships: a strategic monitoring proposal

## *Parcerias para o Desenvolvimento Produtivo: uma proposta de monitoramento estratégico*

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**ABSTRACT** It is an experience report on the methodological construction of a strategic monitoring proposal from the Productive Development Partnerships (PDP), which comprises all of the process of establishing partnerships phases and provides elements for structuring a program of evaluating the initiative in order to verify the performance of the partnerships and their impact, bringing together the economic and social aspects. Such proposal integrates methodological procedures with different metrics and information sources (documentary analysis, logic models, inquiry with the actors involved in PDP and multiple case studies) with qualitative and quantitative approaches from a perspective of collective construction. The presented experience, yet to be validated by Unified Health System's (SUS) governance, aims to offer a business oriented infrastructure intelligence that allows the conversion of data and information into useful knowledge for action, contributing to the success of the initiative, and, thus, to the strengthening of the Economic Industrial Health Complex and the increase of public production of medicines for the SUS.

**KEYWORDS** Public-private sector partnerships. Technology transfer. Program evaluation.

**RESUMO** Trata-se de relato de experiência da construção metodológica de uma proposta de monitoramento estratégico das Parcerias para o Desenvolvimento Produtivo (PDP) que compreende todas as fases do processo de estabelecimento das parcerias e fornece elementos para estruturação de um programa de avaliação da iniciativa a fim de verificar o desempenho das parcerias e o seu impacto, congregando os aspectos econômico e social. Tal proposta integra procedimentos metodológicos com diferentes métricas e fontes de informação (análise documental, modelos lógicos, inquérito com os atores envolvidos com as PDP e estudo de casos múltiplos) com abordagens quali e quantitativa em uma perspectiva de construção coletiva. A experiência apresentada, a ser validada pela governança do Sistema Único de Saúde (SUS), objetiva oferecer uma infraestrutura de inteligência de negócios que permita a transformação de dados e informações em conhecimento útil para a ação, contribuindo para o sucesso da iniciativa e, assim, com o fortalecimento do Complexo Econômico Industrial da Saúde e o incremento da produção pública de medicamentos para o SUS.

**PALAVRAS-CHAVE** Parcerias público-privadas. Transferência de tecnologia. Avaliação de programas e projetos de saúde.

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## Introduction

Strategic monitoring is based on the search for knowledge through the recording, analysis and interpretation of the implementation of public policies reality, in order to produce timely information for decision-making by governance<sup>1</sup>. Although it is essential for all initiatives, programs and policies of the Public Administration, monitoring and evaluation are recent practices in many countries<sup>2</sup> and are not institutionalized in most Brazilian government agencies. However, they have increasingly aroused the interest of the public sector, government and academia to promote effectiveness, efficiency, performance and accountability in public management<sup>3,4</sup>.

For Productive Development Partnerships (PDP), this scenario is no different. Although the Ministry of Health (MH) has indicators in many programs<sup>5</sup> and an information and communication technology platform for monitoring<sup>6</sup>, these do not include the PDP initiative. Strategic monitoring of the initiative is also not institutionalized by governance, lacking a business intelligence infrastructure that enables the transformation of data and information into useful knowledge for action.

The launch of the PDP occurred in 2009 through the inter-governmental interinstitutional articulation<sup>7</sup> as one of the first initiatives coordinated by the Industrial Complex and Innovation in Health Department (Deciis) of the Secretariat of Science, Technology and Strategic Inputs (SCTIE) of the MH.

Initially referred to as Productive Development Agreements, the PDP reflect the new position of the Brazilian State as a promoter of economic and social development, coming with the fourth Administration Reform, the Managerial Reform of the Brazilian State. Advocating the transfer of technology and knowledge developed in the private sector to the public sector, the PDP are shown as means to reverse the backwardness of national technological and productive industrial development in the health sector

and the high dependence on imports of medicines, drugs and equipment<sup>8</sup>, reflections of the economy's opening of the neoliberalism in the 1990s. Associated with this, they aim to expand the access of the population to strategic products for the Unified Health System (SUS) and promote better resource management in the acquisition of these products – medicines, vaccines and equipment<sup>8</sup>.

The construction and improvement of the PDP occurred as they were implemented, based on the results arising from the strategies discussed at the National Conference on Science, Technology and Innovation in Health to consolidate the national production base and with the Executive Group of the Health Industrial Complex (Gecis) holding a central role in the construction and development of the initiative.

The revision of the PDP regulatory mark in 2014 brought new actors to the process<sup>9</sup>, providing greater transparency and robustness, and consolidated instruments for the management monitoring of partnerships<sup>10</sup>. The technical monitoring of technological and productive activities, technology transfer and the development of capacities of the public producer to the new technological level, under the PDP, is foreseen in the new regulatory framework, being the responsibility of the MH, with the participation of the National Health Surveillance Agency (Anvisa), through the performance of the Technical and Regulatory Committees (TRC), and based on specific instruments and methodologies<sup>11</sup>. Different government agencies and institutions also make up the Technical Evaluation Committee (TEC) and the Deliberative Committee (DC), which are responsible for evaluating new proposals and requests for changes to ongoing projects<sup>11</sup>.

The existing management monitoring tools in the government sector are focused on monitoring each PDP project or the set of projects by public producer and private entity for the purpose of verifying and controlling the transfer, absorption and internalization of technology<sup>10-12</sup>.

Despite being a relatively recent strategy, with little more than nine years of implementation, the current stage of the initiative already does not require evaluative methods to analyze its scope and the necessary adjustment and control points<sup>13</sup>.

Measures to change this paradigm in public administration have been formulated, such as publications published nationally by the Institute for Applied Economic Research (Ipea)<sup>1,14</sup> and international guides for conducting evaluative studies<sup>15,16</sup>.

This paper presents a methodological proposal developed for strategic monitoring of PDP. This proposal comprises all phases of the partnership establishment process (Phase I – PDP project proposal, Phase II – PDP project, Phase III – PDP and Phase IV – technology internalization) and provides elements for structuring a program of evaluation of the initiative to verify the performance of the partnerships and their impact, bringing together the economic and social aspects. It is a management model for policy that allows SUS governance to ‘think’, ‘decide’ and ‘act’ as recommended by Matus<sup>17</sup>.

As part of the public policy cycle<sup>18</sup>, strategic monitoring of PDP can contribute to the effectiveness of the initiative by assisting in recognizing the challenges for effective implementation of PDP in Brazil and in finding strategies for addressing them through ongoing monitoring of the environment. Such challenges include, among others, factors associated with the technology

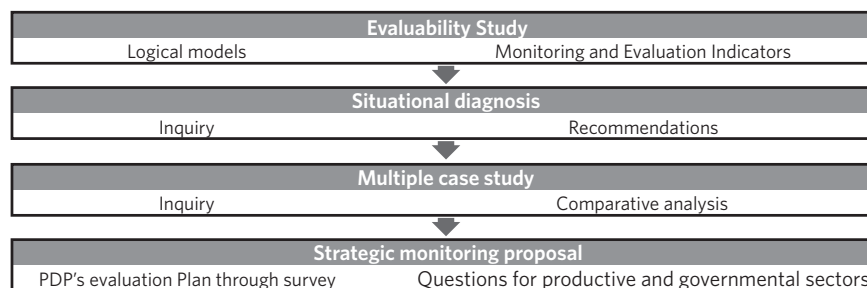
absorption process characterized by difficulties in meeting PDP schedules and technology internalization<sup>12</sup>; the adhesion of the productive sector to the demands of SUS reflected in the reduced presentation of proposals for the production of orphan diseases and Neglected Diseases (ND) due to the great competitiveness in proposals of high cost and biological products<sup>19</sup>; the characteristics of health production<sup>20</sup>; the undersized structure of public agencies for the execution and monitoring of the initiative<sup>12,20,21</sup>; the limitations of public producers regarding the development of technical skills, management capacity and investments<sup>8,12,21</sup>; the economic risks<sup>12</sup> and the political disputes and contingencies so striking in an agenda of technology transfer and fostering innovation based on the purchasing power of the health sector<sup>13</sup>.

## Material and methods

The protocol of this research was approved by the Research Ethics Committee of Fiocruz Brasília in the Brazil Platform system according to Opinion n° 1.549.078, of 05/17/2016.

The triangulation of methods was used, involving four stages: evaluability study through document analysis, situational diagnosis of the initiative, multiple case study and elaboration of a proposal for strategic monitoring of the PDP<sup>22</sup>. The first three stages provided baseline elements for the final proposal (*figure 1*).

Figure 1. Methodological route for the construction of the proposal for strategic monitoring of the PDP



Source: Own elaboration (2017).

In the evaluability study of the PDP, the following steps were performed: collection and analysis of normative documents and published literature, assembly and validation of logical models, vulnerability analysis and construction of monitoring and evaluation indicators. The methodology used by the Ministry of Planning, Budget and Management presented by Ipea<sup>14</sup> was adapted to elaborate three models: a) explanation of the problem that PDP seek to face; b) basic references of PDP; and c) structuring of PDP to achieve results. The built models were presented to managers and researchers with experience in the PDP theme, who discussed the adequacy and the relevant inclusions.

In the situational diagnosis, a survey was conducted with the application of electronic questionnaires prepared in FormSUS to actors involved with PDP signed since 2009 and in force in 2016, followed by qualitative and quantitative analysis<sup>22</sup>. The questionnaires were elaborated from the PDP theory organized by the logical models. A 51% response rate was obtained with the participation of 41 of the 81 guest actors members of the TEC, DC, TRC and public institutions and private companies participating in the PDP, with 17 respondents from the 18 managers and technicians of participating public producers of the PDP of medicines implemented from 2009 to 2016 invited; 10 of the 34 managers and technicians from private entities participating in the drug PDP implemented from 2009 to 2016; and 14 of the 29 members of the TEC, DC and TRC organs and secretariats in 2016 – Health Care Secretariat (SAS), Health Surveillance Secretariat (SVS), Executive Secretariat (ES) and SCTIE of the MH; Ministry of Industry, Foreign Trade and Services (MDIC); Ministry of Science, Technology, Innovations and Communications (MCTIC); National Bank for Economic and Social Development (BNDES); Finep Funding Authority for Studies and Projects; and Anvisa.

In the multiple cases study, documentary and literature research, and data from the

situational diagnosis inquiry were used, followed by quantitative and content analysis. The method proposed by Yin<sup>23</sup> was used, involving: a) development of a theory; b) case selection; c) planning; d) data collection and analysis of selected cases; e) preparation of reports of individual cases; and f) comparative analysis between the cases and of these with the elaborated theory.

The results of these first three steps were presented in scientific articles<sup>19,24,25</sup>. The last stage involved the articulation of the results obtained in the previous three stages, in which a strategic monitoring proposal was conceived in a PDP business intelligence system, containing a PDP evaluation plan.

The proposition of the monitoring instruments was structured according to the Innovation Octagon<sup>26</sup> dimensions – strategy, relationship, culture, people, structure, processes, funding and leadership – assuming that PDP are an innovative initiative in federal public management<sup>27</sup>.

## Results and discussions

### International Public-Private Partnerships versus Partnerships for Productive Development

Public-private partnerships have been explored as a mechanism for mobilizing additional resources for health activities, notably in low and middle-income countries<sup>28</sup>. Internationally, partnerships are identified in the health sector that focus on research and development of new technologies, medicines and other products for ND<sup>29,30</sup>. There are also economic and technology transfer agreements signed between some of the countries of the global South in order to enhance research and innovation, the exchange of economic, personal and scientific resources for the growth of countries and the expansion of the productive capacity of local laboratories<sup>31</sup>.

In Brazil, PDP are one of the initiatives in this field, but they differ, in a positive way from international partnerships. While Product Development Partnerships are one-off initiatives by some institutions and entities in a narrow scope of products and resources, PDP involve a large number of actors in the production and government sectors articulated in an expanded socio-technical network<sup>9</sup> for high impact interventions in the Health Economic-Industrial Complex (Ceis) regarding the productive, technological and innovation capacities, as well as in the generation of jobs and income in the Country. In the productive sector, there are 61 involved entities, public and private; and in the government sector, there are nine organs and secretariats that make up the 18 TRC, the TEC and the DC<sup>9</sup>.

PDPs involve the transfer of technology from strategic products already launched in the market to train public producers in new health technology platforms for SUS. In this sense, they also differ from international initiatives that are associated, for the most part, with research and development of new innovative products. Further strategic and structuring effects are pursued through the PDP with the focus on the total manufacturing of the technology by the public producer regardless of the transferring private partner and the pharmaceutical input active by the national pharmachemical, and, subsequently, in the innovation of processes and products from new technological systems.

### **Productive Development Partnerships: a brief contextualization**

The inclusion of the PDP in the political agenda occurred in a favorable environment in the political arena, provided by political bases led by different fronts that came to recognize the potential of productive development of Ceis in the economic and social perspectives to expand access to priority health technologies for the Country<sup>32</sup>.

The establishment of this initiative was initially based on the Innovation Law which allowed preferential treatment in the acquisition of goods and services by the public authorities to companies that invest in technology research and development in the Country<sup>33</sup> and the encouragement by the three spheres of government and the promotion agencies, the formation of strategic alliances focused on research and development activities aimed at generating innovative products, processes and services and the transfer and diffusion of technology<sup>34</sup>.

A major factor that enabled the PDP was the restructuring of the Pharmaceutical Assistance Program that centralized the acquisition of higher unit cost medicines by the MH<sup>35</sup>, which enabled the wider use of state purchasing power for technological health development<sup>36</sup>. In this sense, the alterations of article 24, items XXV, XXXI and XXXII of the Bidding Law were important to enable PDP<sup>33</sup> by including the exemption from public bids for product acquisition when there is technology transfer of strategic products to SUS, introducing the use of State purchasing power as real factor of development and incentive to technological production in Brazil<sup>37</sup>.

The first specific regulatory framework of the PDP was published in 2012 through Ordinance n° 837/MH, three years after the signing of the first partnerships. This Ordinance, then, brought the norms of an earlier practice, in order to favor the establishment of PDP<sup>33</sup>.

Two years later, due to the need to improve the regulatory mark, Ordinance n° 2.531/2014/MH was published, which repealed the previous Ordinance, redefined the guidelines and criteria for the preparation of the list of strategic products for SUS and the establishment of PDP<sup>11</sup>. From this new regulatory mark, the PDP were consolidated as instruments for the promotion, incentive and development of Ceis and the

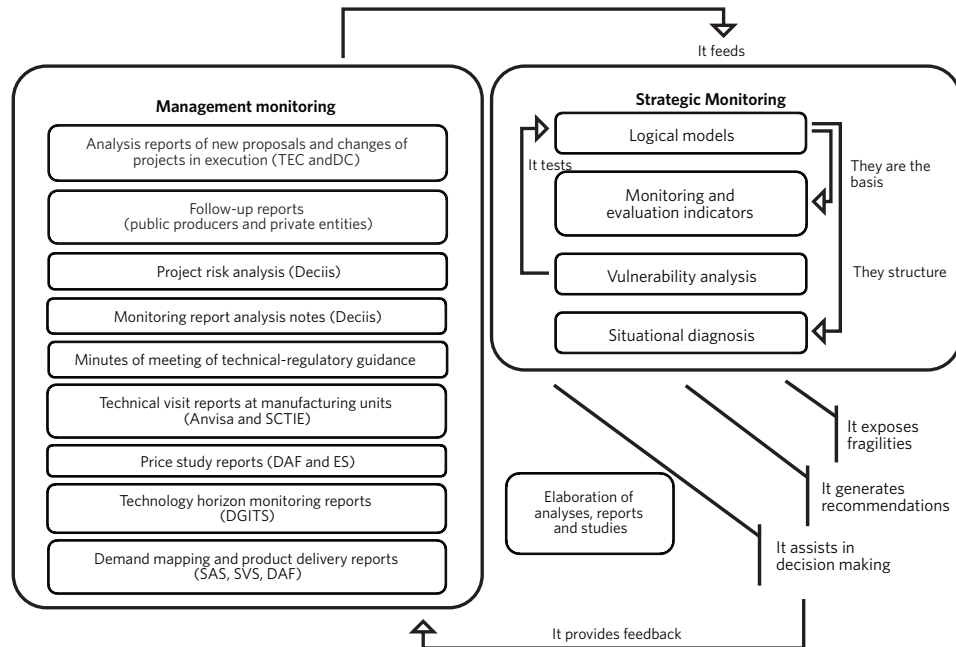
improvement of partnership management by the federal government<sup>10,37</sup>.

The revision of this regulatory framework resulted from the need, among others, to provide more transparency and security to the process of establishing PDP as recommended in audits of the Federal Audit Court (TCU) and the Comptroller General of the Union (CGU) following complaints and investigations that were associated with the PDP during its implementation, such as Operation Car Wash. These instances also recognized the importance of PDP monitoring given the proportion of projects under execution (81 PDP in force in 2016<sup>9</sup>), the volume of public resources involved and the great relevance of the initiative.

### Business intelligence system of Productive Development Partnerships

The monitoring proposal involves two components that make up the business intelligence system of the PDP: managerial and strategic. *Figure 2* shows the systematized graphic representation, where much of the managerial component prioritizes the contractual instruments of partnerships and feeds the strategic component. It is structured in four subcomponents: logical models; monitoring and evaluation indicators, based on the models; vulnerability analysis that tests the models; and, finally, situational diagnosis of performance evaluation, structured by the models, to feed back the management monitoring component.

Figure 2. Proposal for strategic monitoring to be articulated to management monitoring: business intelligence system of PDP



Source: Own elaboration (2017).



A feedback flow between the components is observed, compounding a business intelligence system for monitoring PDP, predicting the utilization of data and information obtained from different sources and qualitative and quantitative approaches.

## Management monitoring

In managerial monitoring, most instruments and documents were established by the MH and the evaluation bodies, which were: a) reports on the analysis of new proposals and changes to projects under execution prepared by the TEC and the DC; b) monitoring reports sent every four months by public producers in conjunction with private entities; c) project risk analysis; d) technical notes for analysis of follow-up reports made by Decis/MH; e) minutes of the meeting of technical-regulatory orientation of the TRC; and f) reports of technical visits to the manufacturing units of public producers and private entities, elaborated by Anvisa and Decis<sup>10-12</sup>. For some of these instruments, alteration needs were indicated by the actors interviewed in this study as will be presented in the following situational diagnosis.

These tools allow the management of PDP when verifying the advances in the technology transfer steps, compliance with regulatory and health requirements and the fulfillment of the schedules of product delivery to MH. Thus, they provide information on the feasibility or not of the scope of the internalization of technology by public laboratories throughout the project, serving as basis for decision-making on the restructuring of projects that are unsuitable or for the extinction of projects that are not viable for further development.

To complement this monitoring, other instruments are proposed such as: a) reports of price studies of the products under PDP to be prepared by the Department of Pharmaceutical Assistance and Strategic Inputs (DAF) and ES/MH; b) monitoring reports of the technological horizon to be constructed with the support of the Department of Management

and Incorporation of Health Technologies (DGITS)/MH and the Brazilian Health Technology Assessment Network (Rebrats); and c) demand mapping and product delivery reports for joint elaboration of the DAF and SAS/MH or SVS/MH, depending on the type of product being transferred from technology.

The search for economicity, advantage and economic sustainability of SUS is among the objectives of the PDP, having as its guideline the gradual reduction of prices of the partnership's product object. Since, throughout the projects, such prices may vary, price studies may provide important elements for monitoring and for the negotiation of MH with producers.

The monitoring of the technological horizon can help in the previous stages of building the list of strategic products for SUS, mapping future technologies in a prospective view, as well as, throughout the instituted projects, analyzing if the time already spent and if delays would make PDP unfeasible given the longevity of the technology.

The mapping of demands and deliveries, in turn, will provide producers with predictability of the required quantity of the product in the period, allowing them to adequately qualify for SUS care. In addition, it will indicate to the MH the need to seek other suppliers in advance if PDP producers are unable to meet all demand.

## Strategic monitoring

In strategic monitoring, data and information come from the application of management monitoring tools implemented by the multiple actors involved in the management of PDP and own instruments developed for situational diagnosis. The four subcomponents are detailed below.

Three logical models were designed and organized the PDP theory, composing an evaluability study, to demonstrate that the PDP initiative was able to be evaluated<sup>23</sup>. The first refers to the explanation of the problem 'difficulties in guaranteeing access

to strategic technologies in SUS'. The causes of this problem, their descriptors, consequences and their interrelationships were explained<sup>23</sup>.

The second contains the basic PDP references and explained how the initiative is structured to solve the problem. In addition to the problem and its descriptors, the general and specific objectives of the PDP, target audience and beneficiaries<sup>23</sup> were presented.

The third model demonstrated the structuring of PDP to achieve results and helped in understanding how to make the initiative work<sup>23</sup>. The actions, their products, results and effects have been defined in that model, with an indication of the size and stages of the PDP establishment process to which they correspond, and whether they relate to budgetary or non-budgetary resources. This latter model was tested by the second component of strategic monitoring (vulnerability analysis) and founded the creation of the third component (product indicators and results)<sup>23</sup>.

The vulnerability analysis matrix presented conditions of invalidation of the PDP structural model in order to identify eventual weaknesses in the initiative structure and allow control actions to be taken<sup>23</sup>.

The indicators suggested for monitoring and evaluation comprise two groups: product indicators and result indicators. The product indicators are: approval rate of PDP proposals, technology competitiveness rate, effectiveness of project actions, optimization of project actions, proportion of public producers with Good Manufacturing Practice and Quality Control Certificate (CBPF) in force, application of health purchasing power in PDP, and proportion of projects completed under the PDP<sup>23</sup>. Such indicators focus on the verification of the execution of technology transfer projects, regarding the measure of expected product generation (as the actions performed have generated expected products), such as drug registration, national production of active pharmaceutical ingredient, factory suitability, product manufacturing (formulation, filling and packaging, in reverse logic), drug supply, among others<sup>23</sup>. The focus

of these indicators is on the implementation of the PDP, in order to analyze whether they are being performed satisfactorily.

Proposed outcome indicators are: public producer accession index for PDP, private entities adherence to PDP, economy of the MH with PDP, evolution of drug supply, coverage of the National List of Essential Medicines (Rename) by product list strategies, rejection rate of strategic products for SUS, and evolution of access to medicines<sup>23</sup>. These indicators focus on the results achieved with the implementation of the PDP from the intended objectives, ranging from verification of fostering scientific and technological development by indirect indicator, to the analysis of evolution of access to medicines subject to PDP.

The business intelligence system incorporates as the fourth component of the strategic monitoring a diagnostic evaluation of the PDP performance through survey, whose questions must be answered by the productive sector and the government sector. The aim is to integrate the dimensions of the Innovation Octagon<sup>26</sup>, in order to better manage the outcome of the PDP.

The purpose of this diagnosis is to generate periodic information on the macro performance of the initiative in the perception of the actors involved with the governance of the PDP. The evaluative method of this diagnosis is exploratory research through an inquiry, with annual periodicity and total duration of about three months.

The methodological route for the application and analysis of this diagnosis comprises: a) construction of the FormSus questionnaire, based on the questions in *charts 1* and *2*, and sent by the evaluator to key actors in the productive and government sectors; b) response of respondents with grade assignment from 1 to 9 for each statement according to their assessment, with response time of one month; c) analysis of the data by the evaluator in the next two months, involving, calculation of the weighted average of the three questions of each dimension and construction of graphs; and d) publication of findings and recommendations.



Chart 1. Performance evaluation questions of the PDP for private entities and public producers involved in partnerships

Nº	Question	Dimension
1	Our PDP and new proposals are aligned with the needs of the Unified Health System.	Strategy
2	There are specific projects for the PDP with defined managers, as well as their responsibilities.	Structure
3	We provide time, staff, financial and non-financial resources for the implementation and monitoring of the PDP.	Culture
4	The objectives and importance of the PDP are understood and recognized by everyone within the organization.	People
5	We have a suitable structure for the execution of the PDP, with appropriate tools for project management and monitoring.	Estrutura
6	Our organization presents a clear focus for the type of technologies (to be) developed or technological platforms and has clear criteria for choosing the products to be the object of PDP and partners.	Strategy
7	Our organization understands that the PDP involve technological risk projects and manage them in the search for new solutions.	Culture
8	The actions and activities of the PDP are outlined and have a defined coordination.	Estrutura
9	The leaders of the organization have clarity about the concept and importance of PDP.	Leadership
10	We have sources of resources for investments in PDP projects, either through the partnership itself or through other projects.	Funding
11	We use project management tools to conduct the PDP.	Process
12	PDP products and outcomes are assessed according to performance measures that take into account existing risks and uncertainties.	Funding
13	The performance of the areas involved with the PDP is evaluated with specific metrics related to their performance in the PDP management process.	Leadership
14	The knowledge and tools required for the entire process of technology transfer within the PDP are known to everyone involved within the organization.	People
15	We use our networks of researchers, suppliers, customers and companies in the productive sector to generate and refine new ideas, improve PDP and facilitate the process of technology internalization.	Relationship
16	Leaderships devote time and attention to monitoring PDP projects.	Leadership
17	There are themes, objectives and targets defined for PDP projects.	Strategy
18	We systematically assess the results of the PDP initiatives.	Process
19	We are deeply aware of the needs of our customers, society and the Unified Health System.	Relationship
20	We have a structured process for managing technology transfers and monitoring PDP.	Process
21	We have a systematic process for monitoring new market and technological trends.	Relationship
22	We use communication mechanisms to promote PDP within and outside the organization.	Culture
23	Our team presents high diversity of knowledge and training in technology transfer projects.	People
24	We seek financial resources for PDP and innovation in different sources, such as notices, government bodies and partners.	Funding

Source: Own elaboration (2016) from Scherer and Carlomagno model adaptations<sup>26</sup>.

Chart 2. Questions for evaluating the performance of PDP to actors of the government sector involved in partnerships

Nº	Question	Dimension
1	The products defined as strategic are aligned with the needs of the Unified Health System and technological trends.	Strategy
2	There are specific administrative processes for the PDP with defined technicians, as well as their responsibilities.	Structure
3	We provide time, staff, financial and non-financial resources for the evaluation and monitoring of the PDP.	Culture
4	The objectives and importance of the PDP are understood and recognized by all within the institution.	People
5	We have a suitable structure for the management, monitoring and evaluation of the PDP, with appropriate instruments for this.	Structure
6	There are clear criteria for defining the technologies or technological platforms to be subject of PDP and for the selection of proposals.	Strategy
7	Our institution understands that PDP involves technological risk projects and guides producers to search for new solutions.	Culture
8	The actions and activities for the evaluation and monitoring of the PDP are delineated and have a defined coordination.	Structure
9	The leaders of the institution have clarity about the concept and importance of PDP.	Leadership
10	We have sources of resources for acquiring PDP products and/or for carrying out monitoring and evaluation activities.	Funding
11	We use project management tools to monitor and evaluate PDP.	Process
12	PDP products and outcomes are assessed according to performance measures that take into account existing risks and uncertainties.	Funding
13	The performance of the sectors involved with the PDP is evaluated with specific metrics related to their performance in the process of monitoring and evaluation of the PDP.	Leadership
14	All those involved within the institution have mastery over the knowledge and tools necessary for the process of monitoring and evaluation of the PDP.	People
15	We use our networks of researchers, suppliers, public producers and companies in the productive sector to generate and refine new ideas, improve the PDP initiative and facilitate the process of internalization of technology by public producers.	Relationship
16	Leaders devote time and attention to monitoring PDP projects.	Leadership
17	There are themes, objectives and targets defined for PDP projects.	Strategy
18	We systematically assess the results of the PDP initiatives.	Process
19	We know deeply the needs of the productive sector, society and the Unified Health System.	Relationship
20	We have a structured process for monitoring and evaluating PDP.	Process
21	We have a systematic process for monitoring new market and technological trends.	Relationship
22	We use communication mechanisms to promote PDP inside and outside the institution.	Culture
23	Our team presents high diversity of knowledge and training in technology transfer projects.	People
24	We provide financial resources for the PDP, through the purchase of products or financing of projects, and for other innovation projects by notices and programs.	Funding

Source: Own elaboration (2016) from Scherer and Carlomagno model adaptations<sup>26</sup>.

The questions included in the diagnosis are reflexively based both on the results of this research and on the model proposed by Scherer and Carlomagno<sup>26</sup>. It is understood that the application of these issues for strategic monitoring can be carried out by the PDP participants themselves, from the productive and government sectors, so as to reflect on the performance of each institution in the initiative. Furthermore, it is important that this proposed governance instrument be operationalized by a local government agency or an independent audit in order to impartially verify the performance of the strategy. Thus, there is the independence of the public manager who coordinates the PDP in the strategy evaluation, which becomes relevant in order to enhance the process.

The results of the situational diagnosis performed can be added to the monitoring

and evaluation indicators applied for collective improvement construction to all those involved with the PDP. It is proposed that such activity be carried out within two months of the release of the results of the diagnosis at a meeting for this purpose.

### Experience report of methodological application

The first application of the inquiry in 2016 allowed a situational diagnosis of the performance of PDP implementation between 2009 and 2016, from the perspective of the actors involved<sup>25</sup>. It was performed through validated and expanded structured questionnaires, differentiated from those proposed in this article<sup>22</sup>. The summary of the results of this diagnosis according to each dimension of the Innovation Octagon is presented in *chart 3*.

Chart 3. Situational diagnosis of the performance evaluation of the PDP from the perspective of the actors involved, by dimension of the Innovation Octagon, 2016

Dimension	Situational diagnosis
Strategy	<p>A. Of those interviewed, 52.6% believe that the regulatory mark of PDP helps in the achievement of results;</p> <p>B. Positive and negative aspects of the regulatory framework were presented;</p> <p>C. Of those interviewed, 63% indicated suggestions for adjustments to the regulatory mark of the PDP, among them: increase the institutionality of the initiative with the publication of a law or decree on the PDP; improve predictability on the issue of prices; include criteria for health technology evaluation to define the list of products strategic for SUS; and define regulations for the implementation of PDP by public producers;</p> <p>D. Of the respondents of the producing entities, 88% had prospects of presenting proposals for PDP of drugs for chronic non-communicable diseases; 87% for other diseases; and 67% for neglected diseases.</p>
Leadership	<p>A. The respondents of the producing entities considered that the degree of involvement of high management in PDP is high (average of 4.5 in a range of 1 to 5).</p> <p>B. The government sector interviewees did not agree that the degree of involvement of senior management in the PDP was adequate for the implementation of the partnerships (Level of agreement of - 9.1%).</p>
Funding	<p>A. Of those interviewed, 50% considered that investments for the execution of PDP are paid off with the supply of products and 50% believe that an additional resource source is needed, being the most cited resource projects with BNDES;</p> <p>B. The participation of the PDPs in the total revenues of the entities was evaluated as below 50% in 62% of the entities, and as above 70% in 38% of the entities.</p>
Culture	<p>A. The degree of recognition of PDPs as a strategic priority from the perspective of the respondents of the producing entities was 4,3, which indicates a high degree; and the government sector was 3,6 (medium degree);</p> <p>B. The degree of intragovernmental articulation to achieve the PDP objectives was assessed as 3,3 (medium degree);</p>

Chart 3. (cont.)

Culture	<p>C. The willingness to take risks in ventures was assessed by the actors of the producing entities at 3,3 (medium degree)</p> <p>D. The degree of risk-taking in dealing with intersectoral conflicts was considered 3,4 by actors of the government sector (medium degree).</p>
Structure	<p>A. Of the respondents, 68.2% indicated that their producing entities need to purchase equipment; 54.5%, build; 45.5%, enlarge; 31.8%, reform; and 22.7% do not need adjustments</p> <p>B. The adequacy of the PDP monitoring framework (resources and instruments) was considered 100% by private entities; 67% by public producers and 29% by the government sector;</p> <p>C. Most respondents indicated that the detailing of technical visits and the frequency of meetings of the TRC, TEC and CD reports and visits to institutions should be increased; the frequency of follow-up reports should be reduced.</p>
People	<p>A. The respondents of the producing entities presented a need to increase the human resources framework for project management, research and development, quality assurance, quality control and production.</p> <p>B. Of the respondents of the producing entities, 47.6% reported that their team needed training, with 28.6% having experience in technology transfer projects, and 19.0%, not</p> <p>C. Government sector respondents stated the need to increase staffing for monitoring PDP.</p> <p>D. Of the government sector respondents, 78.5% indicated that their team needed training, and 71.4% reported having experience in technology transfer projects, and 7.1%, not</p>
Relationship	<p>A. The respondents reported having positive results generated from the interactions between the institutions, but indicated that networking in PDP has been little verified.</p> <p>B. Suggestions for improvement were presented for the interactions between the government sector and between these and the producer entities</p>
Process	<p>A. The adequacy level of the transfer methodology was rated at 92.0%.</p> <p>B. All stages of the establishment process of the PDP were considered critical, and in ascending order: phase II, phase I, phases III and IV</p> <p>C. The most critical activities in each phase were considered: phase IV - effective public production (indicated by 63% of respondents), phase III - factory suitability (34%), phase II - regulatory steps (35%), phase I - partner search/selection (26%) and executive project design (26%).</p> <p>D. Of the respondents of the producing entities, 80.9% indicated having specific team in the units for project management and monitoring.</p> <p>E. Suggestions for improvement at all stages of the process were presented.</p>

Source: Own elaboration from the survey (2016).

By the situational diagnosis, as presented in *chart 3*, it was possible to recognize facts and problems that can generate an action plan by the governance of the PDP to improve the initiative. There are also recommendations from the investigation which need to be analyzed, particularly with regard to increasing the institutionality of the initiative and improving predictability on the issue of prices.

The other way to learn from the experience in this research was performed by the study of multiple cases, which allowed to understand the differences between drugs for ND and for

Chronic Non-Communicable Diseases (NCDs) in terms of impact on the process of establishing partnerships and provided elements for the assertion that the therapeutic class and the economic and social aspects involved interfere with the implementation of the PDP projects<sup>19</sup>.

With the inquiry questions, in this other study<sup>19</sup>, the facilitating elements for both types of partnerships were mapped out, namely: the commitment to purchase the product during the PDP, the projected investments for the project, the team capacity and the time of the project. The hindering elements were also

identified by the authors and differed between: a) common elements: resources for building the manufacturing unit and for training, uncertainties regarding the conduct of the policy; b) elements with the greatest impact on PDP of drugs for DCNT: productive platform, intellectual property and technology incorporation; c) elements with the greatest impact on PDP of drugs for ND: supply value and manufacturing cost, clinical studies and regulatory requirements; and d) elements with an impact exclusively on PDP of drugs for ND: variation in demand, technology obsolescence and difficulty in selecting private partners<sup>19</sup>. The analysis of these factors allows governance to evaluate how to maintain and succeed in each type of PDP project.

The study also mapped<sup>25</sup> assisting measures for the implementation of PDP of drugs for ND: linking high-value products with low added value, presentation of projects by technology platform, fulfillment of responsibilities, assessment of technology horizon, implementation of monitoring policies, differentiated pricing for ND drugs associated with investments and implementation of new strategies such as research, development and innovation PDP<sup>19</sup>.

As evidenced in the practical application of the elements of the PDP strategic monitoring proposal, this monitoring exposes weaknesses, generates recommendations and provides elements for the improvement of public policies.

## Final considerations

PDP are characterized by the complexity of high technology risk projects, the large volume of resources involved and the involvement of multiple actors and interests. They, therefore, align the public and collective logic of well-being and social inclusion with the private and individual market logic in so far as gains are verified for all those involved in the PDP – the Brazilian State, in the figure of the MH and public producers, absorbing and having mastery over technology; the private sector,

supplying the product on a large scale and, therefore, promoting the development of the national industry; and the society that has ensured the supply of SUS<sup>33</sup>.

For such logics to be truly compatible and these gains to be equitable, during the technology transfer process of current projects, it is up to SUS governance to resolve the bottlenecks that involve such an initiative in different fields. To this end, PDP monitoring is a fundamental requirement for SUS governance so that resources and efforts are concentrated on what really needs to be improved or adjusted.

The presented proposal brings together, in a business intelligence system, management and strategic monitoring of PDP and diagnosis of performance evaluation from the perspective of key actors, productive sector, executor of PDP, and government sector, responsible for sustaining the initiative.

Based on references applied to public policies<sup>1,14,17</sup>, the presented proposal articulates three main attribute groups of a business intelligence system: a) informative and formative, represented by the logical models and product and result indicators, which produce dense and thorough knowledge of the reality and implementation of daily management of PDP; b) analytical and evaluative, represented by the diagnosis and performance evaluation, involving a dynamic, systemic and multidisciplinary verification of the implementation of the partnerships; and c) prospective and corrective, represented by the relationship between the situational diagnosis structured in the dimensions of the Innovation Octagon and case studies, as it generates harmonized information and useful indicators for improving the initiative<sup>1</sup>.

The first application of this tool was through the study of multiple cases and situational diagnosis previously published<sup>19,25</sup>.

The classification of PDP projects as secret by the Access to Information Law is identified as limitations of this work, and it is not possible to make more in-depth evaluations on the projects; the professional performance



of the first author in SCTIE/MS, not having the desired distance in scientific studies of the research object; and the rate of participation achieved in the investigation should take into account the institutional political moment in which the period of performance of the work took place. However, these limitations do not invalidate the results found, and it is up to the next researchers to test or minimize the possible biases in new studies.

The implementation of this proposal can benefit from the improvement and integration of existing information and communication systems in MH. As an example, the Support System for PDP, launched in 2017 for project submission, could include the proposed analysis and monitoring modules and be integrated into the Strategic Management Support Room (Sage) and e-CAR Strategic Planning. Such integration may promote greater process transparency, control and social participation, and greater efficiency in management processes. Given the scope of the strategy, the migration of the system, which currently uses a private domain to house the platform (<http://www.parceriaspdp.com.br>), into a public domain of the federal government, is urgent<sup>22</sup>.

It is important to consider that the indicators are not limited to the proposed ones and that the built models should not be understood solely in a cartesian way, considering the multiple variables that make up the execution of the PDP, such as the economic, macropolitical, sanitary and regulatory context and the elements of the technology itself as an object of

the transfer<sup>22</sup>. As Portes<sup>38</sup> points out, in a real context, the scopes and schedules of technology transfer projects are modified in function of these variables in case of inefficiency or inefficiency of stages of the production process or the adequacy of infrastructure. Thus, SUS governance should be aware of these variables and have flexibility to understand the peculiarities of each process<sup>22</sup>.

The monitoring proposal can be applied to PDP based on the culture of transparency and accountability in public administration<sup>39</sup>. By proposing a theoretical and instrumental mechanism of strategic monitoring, it is possible to analyze the management and implementation of technology transfer projects in public producers and their results in the economy for the MH, in national technological development and in the public production network, reducing the vulnerability of SUS to the international market and its impact on the trade balance, and the production, supply and access of the population to strategic products for SUS.

## Collaborators

Silva GO (0000-0003-1809-3789)\* contributed to the research data collection, analyzed and interpreted the data and wrote the manuscript. Elias FTS (0000-0002-7142-6266)\* contributed to the collection, analysis and interpretation of the research data and revised the manuscript. ■

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