

# How has the future investment program stimulated research and innovation in health?

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### **THERAPIES**

## **HEADING: Giens Workshops 2021/Translational research**

How has the future investment program stimulated research and innovation in health?\*

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#### Summary

Ten years after the launch of the Future Investment Program (Programme d'Investissement d'Avenir, PIA) and the implementation of these tools, one of Giens' roundtable workshops wanted to further explore the impact of PIA on health research and innovation with the aim of preparing action reports (bibliometrics, valuation, reputation) based on 2019 findings and the history of PIA deployment in relation to the healthcare sector; to analyze the development of the industrial sector vis-a-vis the PIA actions and to examine how the specific actions and the healthcare sector in general were able to duly articulate themselves, or, take form, given existing structures or organizations and contribute to site policies through Idex/Isite. Five success keys have been identified, which should serve as a strategic compass for future action plans to develop health innovation: Full trust governance between the project manager and the institution, driven by project objectives; An increased role of universities in the steering of PIA objects, joining together in a federation, in a site policy for the Hospital University Centres and Public Scientific and Technological Establishments; A simplification of public/private partnership schemes, in the nature of the Assessment and Action Plans, and in the responsiveness of the institutions; help with the development of local ecosystems, the fostering and support of young researchers; early crossfertilization between the academic and industrial worlds.

#### **KEYWORDS**

Programme for the Investment in the Future; University Hospital Institute; Calls for Assistance and Action plans; University Hospital Research; University Hospital Institute; Cohort, General Secretariat for Investment

#### Abbreviations

AAP: call for projects (appels à projets)
ANR: National Research Agency (Agence régionale pour la recherche)
EQUIPEX: Equipment of Excellence
ICAN: Institute of Cardiometabolism and Nutrition
ICM: Paris Brain Institute
IDEX: academic sites of excellence
IMI: Innovative Medicine Initiative
LABEX : laboratoires d'excellence" (Laboratories of Excellence)

LIRYC: Electrophysiology and Heart Modeling Institute RHU: university hospital research

#### Introduction

The Future Investments Programme was launched around ten years ago, following the "Invest in the future" report on strategic investment and national borrowing priorities, led by Alain Juppé and Michel Rocard [1]. One of the actions identified in this report was to accelerate the development of life sciences, which can have a significant impact on the health of our fellow citizens. There were two specific actions highlighted: (i) the creation of University Hospital Institute care platforms, research and teaching platforms, organized around a coherent scientific project and site; (ii) the financing of cohorts over a long-time period. The healthcare sector was also concerned with the establishment of academic sites of excellence (Idex), the designation of "laboratoires d'excellence" (Laboratories of Excellence [Labex]) and, too, of "équipements d'excellence" (Equipment of Excellence [Equipex]), as well as support for the creation of innovative SMEs (start-ups). In the course of the plan, calls for university hospital research ("RHU") projects appeared in 2015, which were in 2021, in their fifth edition.

In 2019, the Barbizet report [2] presented the first lessons learned from the Programme for the Investment in the Future, ten years after its launch. For the healthcare sector, the results have been contrasted. The health-biotech actions have been deemed to be of medium-level performance, whilst the University Hospital Institutes offer a lesser performance. The specific cohorts are not discussed in this report. On the other hand, the performance of Idex and Labex is considered high, however, this absent specific analysis of coordination with the healthcare sector. Beyond these general findings, it has been important in Giens meetings to be able to further explore the impact analysis of the Future Investments Programme as to health research and innovation..

#### Methodology

In the course of 6 two-hour meetings via video conference, we collected input and feedback from participants involved in PIA projects, in the capacity of managers or partners, or who had to interact with PIA projects from their institutional in respect of their entrepreneurial role/post and we have established work objectives that enabled a collective review and reflection.

The objectives were: (i) to prepare an actions report (bibliometrics, valuation, notoriety) based on 2019 findings and the history of PIA deployment in relation to the healthcare sector; (ii) to analyse the development of the industrial sector in respect of PIA actions; (iii) to examine how specific actions and the healthcare sector in general may have been able to organise themselves as per existing structures or organisms (University Hospital Centre, University, Inserm, Public scientific and technological establishment), or, contributed to site policies via Idex/Isite.

This has led us to a final deliverable in the form of a strategic compass that could be useful in informing public policies during PIA 4, highlighting the keys to success. Indeed, the health crisis that we are currently experiencing has revealed, or confirmed, weaker areas in the healthcare sector, both in the public and private dimensions, offering perhaps clues as to choices to be made in respect of priority areas to support and methodological or organizational approaches.

#### PIA health objectives inventory

Health represents one of the main sectors benefiting from PIA: during the first 3 components of PIA, it benefited from a total of €5.4 billion in the form of 27 devices supporting 350 operations. This article will focus solely on objects funded by health care actions: University Hospital Institute, University Hospital Research, Cohorts.

The most representative purpose of PIA, the University Hospital Institute's call for projects (*appel à projets*, "AAP") was launched by PIA 1 in 2010. It elicited 19 applications and following a particularly selective procedure, an international jury selected 6 projects:

- LIRYC (Electrophysiology and Heart Modeling Institute), Bordeaux, France
- ICAN (Institute of Cardiometabolism and Nutrition), Paris, France
- ICM (Paris Brain Institute), Paris, France
- Imagine, Paris, France
- IHU de Strasbourg (Institute of Image-Guided Surgery in Strasbourg), Strasbourg, France
- Méditerranée Infection (Méditerranée Infection Foundation), Marseille, France

These first 6 University Hospital Institutes were allocated the financial contribution of  $\notin$ 350M over 10 years. A second call for projects selected, in September 2018, a seventh University Hospital Institute, Insight, Foresight – Paris ( $\notin$ 50 million over 10 years). It is therefore a total of  $\notin$ 400M that has been disbursed over 10 years, as invested by the PIA to the University Hospital

Institutes, to which it would be advisable to add €50M in respect of the B-University Hospital Institutes (1<sup>er</sup> and 2<sup>nd</sup> Assistance and Action plan) and an additional €74M which was granted for the period 2020-2025 following the final selection process by the jury.

Representing a strong health-related feature of the PIA, the first 6 University Hospital Institutes were assessed at mid-term, as well as at the end of the initial 10 years following funding by the international juries. These assessments are important steps as they measure progress in the implementation of selected projects and also identify issues to be resolved. The recommendations of the jury are followed by the University Hospital Institute Action Steering Committee, who is authorised to make sometimes drastic decisions to ensure implementation. This was particularly the case for one University Hospital Institute whose grant payments were frozen for a long time, until important corrective actions were implemented.

The first part of the PIA also led to a call for projects dedicated to specific cohorts. The launch of this Assistance and Action plan was based on the observation of the shortfall in longterm, competitive, funding necessary to create and implement cohort studies that, by definition, are long-term programmes. Testament to the importance of cohorts in the future vision of health PIA, the Assistance and Action plan Cohorts was the second health action initiated by the PIA and led to the selection, by an international jury, of 10 cohort projects, out of a total of 44 that wer reviewed, and which received funding in the amount of €66M over 10 years. To these first 10 disease-focused cohorts, 4 general population cohorts were added, selected as part of the Research Infrastructure Assistance and Action plan, with the Cohort allocation not allowing for the financing of the high costs of the general population cohorts. The only cohort concerning the general population, CONSTANCES, has, for example, benefited from the allocation of more than €35M. As with any healthy PIA object, these cohorts were evaluated mid-term, resulting in budget changes or redeployments, as well as the actual discontinuation of one of them. An evaluation performed at the end of the initial 10 year-funding period was also conducted by an international jury whereby 11 cohorts (of the 14 total Assistance and Action plans combined) were extended until 2025 and obtained additional funding in the amount of €26 million, even though as per the terms of the PIA, autonomous functioning is indeed provided for.

Finally, in 2014, the launch of the Assistance and Action plan, University Hospital Research served to complement the health-related PIA actions. The purpose of the Assistance and Action plan, University Hospital Research, can be summarized in the following way: it introduces innovations from French University Hospital teams to the clinic, to patients. As such, this is an Assistance and Action plan aimed at ambitious translational research projects. Indeed, it allows a public-private consortium to be granted in the amount of 4 - 10M€ of public aid over the period of 5 years. If projects are to be led by university hospital teams, the University Hospital Research Programme also aims to fully include partners bringing expertise (clinical, regulatory, industrial development, etc.) as to yield the necessary fundamentals enabling these innovations to become healthcare products benefiting both patients and practitioners, whilst ultimately operating independently. An allocation of €200 million was originally planned for two waves of APA. A global jury reflecting the translational ambition of this PAA (academic, clinician and industrial) selected only 4 out of 25 projects filed in the first wave, demonstrating the need to support the hospital-university community in ownership of this new PAA with different expectations than the usual outlets. The strength is to see that the UHR APA has finally settled in the French landscape. 5 waves have been launched, selecting 56 projects to receive support in the amount of approximately €446M.

#### The keys to governance success

The objects of the health sector PIA, like with others, must be project-oriented and project-specific. There should be no new institutional structures introduced, so as not to create new & unwieldy frameworks that could only serve to undermine the given project by generating unnecessary snags and obstacles within existing institutions. It should be noted, however, that for the University Health Institutes, the reasoning was reversed: new structures with a specific budget and a separate status. On the other hand, institutions must, for their part, admit that the processing of these projects, which are inherently time-limited, requires celerity and simplicity.

The first step for institutions is to recognize the legitimacy of these projects, which are the result of a competitive process. However, to support this legitimacy, it is essential that institutions are themselves heavily involved, upstream, in the formation of these projects, which must, as such, be integrated into a general strategy.

One possible cause of failure is that institutions consider these projects as objects/projects other than an overall strategy, but, on the other hand, scientific and technical leaders accept involvement in the form of guardianships, dedicated to strategic definition and project management.

Schematically, two governance models can be discerned. The first is direct management by an institution, the second is steering by a specific structure with a legal personality. The first solution has the advantage of anchoring the management of the given PIA project at the institutional level, however, with a risk of less agility. This model is thus feasible when it comes to a targeted project (University Research Hospital or Labex-type programme), involving a limited number of players. However, for larger projects (University Hospital Institute-type), the recommendation is to preferably use a specific structure as the foundation.

However, in the second-named configuration, it is imperative to ensure a strong commitment from the public institutional founders, who must enjoy their given rights, whilst also assuming duties.

- The rights are those of an unwavering involvement in the strategy and operation of the project, which cannot follow solely from the will of the management team, given the nature of the projects, which, in large part, are intended to strengthen hospital-university interactions writ large, in respect of a dual perspective of economic valuation plus social transfer.

- The duty, or duties, involves doing everything possible to facilitate the actual deployment of the project. One example, in this context, is that the provision of staff should no longer be considered a taboo topic, even though we know that this is what makes life easier for these types of projects.

Contrariwise, the scientific and technical manager and the management team supporting her must have at their disposal continually updated awareness and knowledge of their work with institutions. This explains that the team can be renewed according to the advice of the respective Foundation's board of directors, if the objectives set out under the strategic contract are not met, or if the actions taken deviate from them. Indeed, it is about building trust and a sense of teamwork through regular work within the framework of a steering/managing committee, since strategic discussions cannot be limited to two annual board meetings.

One possible action to anchor such good practice principles is through training. First, there is training for future managers to be considered. Being a manager is not a matter of improvisation. Such training could be a requirement prior to receiving funding.

The training of administrators is just as essential, since part of being a good administrator is continued learning. Experience is important but a director must know his/her role, his/her mission, rights, duties, applicable legal framework and other legal concepts related to his/her assignment (e.g. affectio societatis). As with for managers, administrator training sessions that could be made a requirement for future PIA funding. The role of qualified persons in the board of directors is essential. Indeed, these individuals must bring their respective skills and experience to the table, in order to achieve the institution/foundation's missions, and can also sometimes play the role of mediator within the administrative framework, always promoting, as such, the best interest of the institution. They must therefore be completely independent of stakeholders, especially founders. This which is indeed enshrined in the jurisprudence of the Council of State. Paradoxically, although the General Secretariat for Investment serves as the guarantor vis-a-vis Parliament and the given controlling body, as to the proper use of financial resources, the Secretariat has never held an automatic place on the administrative boards assigned the "projects/programmes" of the PIA. This position deserves review in light of some challenges encountered in implementing complex projects. Additionally, it could also be interesting to have one to two annual follow-up meetings with representatives of the General Secretariat for Investment, the French National Research Agency (ANR) and ministries, as was done for Idex/Isite, offering an important opportunity for the financing State to evaluate the progress of projects.

All of these issues of governance of PIA programmes arise because they are merely symptomatic of the overly complex French research system, which is probably even more acute for the healthcare sector, as the number of players involved there is very significant.

This is in addition to the revolution of translational research that is presently extending into health data and that effectively calls for serious, co-ordinated administration and the responsibility of each actor, namely: hospitals to receive and treat patients, universities to receive and train students, whilst promoting research; and research organizations to guide and administer research whilst funding or co-financing teams. This revolution requires rethinking collaborations, and the integration of all components/actors in order to effectively support, offer training in, and innovate Healthcare in France.

The State, through the Idex/Isite process, has wished to promote academic championships, the champions of which can go on to take their place in the international competition. At many of university academic sites, health is one of the leading areas of excellence. It would therefore be coherent to offer these public institutions strategic leadership, by strongly integrating the University Health Centres, as per the Nantes I-Site model, and, in agreement with the Public scientific and technological establishment, to support certain local strategies based on their national strategic axes.

This would facilitate real-world site policies, with confident and assumed leadership offered by universities.

#### PIA objectives, site policy stakeholders

The PIA objectives and projects were sometimes considered as NPIVOs, which were imposed on institutions, perhaps because of a lack of upstream strategic work. In fact, in order to succeed and be fully productive, PIA objectives and projects need to be born and integrated into the given site policy, again requiring co-ordination between carriers/providers and institutions. There are two situations.

The first is a juxtaposition of PIA objectives and projects without a strong integration between them. The absence of a thematic framework does not mean that a strategy in and of itself becomes impossible, since indeed, other tools, such as research training structuring tools ("SFRI programme"), make it possible to create thematic academic research schools specialised in the field of healthcare, with a strong interdisciplinary offering, allowing for high-level training.

The second situation is where there is better strategic alignment, as illustrated by the case of Lille. At this site, the healthcare theme is dedicated to precision medicine, with a concomitant decline in diabetes that brings together a Labex, a genomic Equipex, a national center for precision medicine (from the IHU2 PAA) and a University Research Hospital, on the hepatic consequences of type 2 diabetes.

The creation of Investigational Public Institutions, supported by an Idex or I-Site, also promotes a better health-world interfacing policy in collaboration with other areas. This is particularly the case with engineering, thanks to the combination of universities and engineering schools, which promote these interactions. This is particularly the case in Nantes, Nancy or Lille where projects to optimise diagnostic technologies, medical devices or innovative treatments are being rolled out between faculties and engineering schools. This was also modelled in the creation of the University of Strasbourg and the formation of an image-guided University Hospital Institute combining a robotic research lab from an internal university school with that University Hospital Institute. The identification and structuring of several sites in France, with a level of excellence in health and scientific differentiation, now promotes better development of public/private partnerships.

#### **Public/private partnerships**

For industrial actors, it appears that the PIA has accelerated innovation in France, whether through the support of technological development at academic laboratories or giving more international visibility to medical and scientific centres of excellence, by promoting innovation projects (University Hospital Research, PSPC). The PIA project expertise, entrusted to international judging committees, has made it possible to substantiate these points of specialisation, by means of a process of the international qualification of teams, the promotion of centres of excellence to promote the contracting of partnerships with national as well as international companies. It is the prior-defined valuation policy that has increased innovation capability & value of this innovation, as well as its attractiveness for international researchers. The PIA tools could also help to increase the emergence of young talent.

However, many subjects remain open to improvement in order to promote better interaction between academic and private actors and to strengthen the ability to build partnerships, such as the financing of mixed university/industry undertakings. In this context, the degree dedicated to healthcare entrepreneurship established in Lille, or the bio-business administration master offered at the University of Paris [3] can be cited.

Whilst we can certainly congratulate ourselves on building a credible ecosystem for innovation in France through the PIA, as well as one for tomorrow through the France 2030 plan, and its healthcare component, obstacles and lack of knowledge of the tools remain, as shown by the survey that was carried out with participant companies that attended a roundtable. This survey, carried out using a low degree of sampling, illustrates some trends. It was observed that 75% of the private actors who responded are aware of PIA objectives and projects, mainly thanks to the competing departments and units, which seem to play a critical role in supporting companies in the development of their respective innovations. The PSPCs and SATTs are the most well-known tools, even though the awareness of University Research Hospitals is lower. This is certainly due to the fact that the PSPCs are carried out by private actors whilst the University Research Hospitals are carried by academic actors. A majority of the industrial actors surveyed also believes that the PIA had a beneficial impact on the development of innovation and employment in France, whilst not having directly benefited from it. Indeed, many private actors continue to favour two-party partnerships, whilst possibly engaging one or two third parties, which is basically less complex to create. As such, these PIA frameworks have made the territories and teams of excellence easier to define, based on business strategies, with whom to develop close links in order to build ambitious partnerships. In this respect, the PIA was a true catalyst for the structuring of health innovation

(University Hospital Institute, Labex, Equipex, National research infrastructure, cohorts...). The questionnaire developed by the roundtable could be used by the SGPI to follow-up, every two years, on the industrial sector's implementation of tools in the healthcare sector.

These interim results reflect the need to better clarify the given tool, which is built, or developed, gradually, but, too, that the manufacturing actors have probably not yet been sufficiently involved, or even in some cases offering resistance or skepticism due to the administrative complexity. This is the case for the delays in the drawing up of tender files, investigations, the implementation of contracts, sometimes with delay or blockages in the evaluation services examining the institutions, which are poorly equipped in terms of necessary responsiveness with regard to the level of international competition.

The tools must also be evaluated: the roundtable felt that the PSPC (multiple appendices, lack of financial confidence, between 18 and 24 months) was still too complex, making the University Research Hospital more attractive.

A unique and single tool, which can be used by either an academic actor or by a manufacturer, could be proposed, based on feedback from these two previous tools. Long-term support, involving long-term investments possibly through dedicated incubators, also appears necessary in order to see joint laboratory-type mixed teams emerge, and for the success of start-ups whose creation should not be the only marker of success. The implementation of large-scale strategic initiatives in France, allocating more resources, would certainly provide more of an impact and visibility internationally, compared to the same investment amounts distributed across multiple projects.

Nonetheless, in the final analysis, the critical question is the early involvement of healthcare manufacturers in the innovative processes of academic structures. To that end, the model that should be referenced is that of the Innovative Medicine Initiative (IMI), that combines and coordinates, starting from the conceptual stage, the academic world, as well as the industrial one, in fomenting pre-competitive research. Future academic innovation hubs should foster this upstream work, which offers a dual advantage: (i) contribute to the increased thematic differentiation of sites, leverages the strength of local ecosystems; (ii) more quickly integrates aspects of value into academic work whilst sharing, with manufacturers new concepts gleaned from more fundamental/thematic-based research. It is this cross-fertilization that can effectively promote innovation, provided that it represents a simplification of administrative circuits tying back to one and the same operator, whilst incorporating the necessary integration of the fundamental research that the European Research Council has demonstrated is a major source of innovation; too, the existence of a strong ethical charter to ensure quality research and its compliance with the sustainable development objectives laid down by the United Nations. The emergence of a new innovation agency during a sudden health crisis will not escape the need for its integration into a complex national research landscape.

#### Conclusion

At the end of the roundtable discussion, five specific keys to success have been identified, to serve as a strategic compass for future action plans to develop health innovation:

- ✓ Governance must be driven by specific project objectives, with a driving role taken on by institutions, plus an unwavering trust enjoyed between these and the given scientific and technical manager
- ✓ An increased role of universities in the steering of PIA objectives and projects, consolidating on one and the same site policy that of University Hospital Centres and the Public scientific and technological establishment.
- ✓ The simplification of public/private partnership schemes, in the nature of Assistance and Action plans and, especially, in the responsiveness of institutions
- ✓ Support for the development of local ecosystems, fostering the emergence of young researchers whilst promoting the long-term support of start-ups (Incubators, nurseries?)
- ✓ Early cross-fertilization between the academic world and industry, allowing for the sharing of results from pre-competitive research.

#### **Disclosure of interest**

Authors have no competing interest to declare

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