



## Interdisciplinary Objects 2021

### Application Form

#### Part 1: Project profile

Project title (in French): **PARIS Saclay foRmation rEcherche & hôpital, construire l'interface entre l'écosystème « technologie pour la santé » et les hôpitaux de Paris-Saclay**

Acronym (in French): **Hub PASREL**

Project title (in English): **PASREL, bridging the "technology for health" ecosystem and the Paris-Saclay hospitals**

Acronym (in English): **PASREL Hub**

#### Description of the team making the project proposal:

Surname	Name	Email	Current position	Role and responsibilities within the project
Lebon	Vincent	vincent.lebon@universite-paris-saclay.fr	Hospital and university professor (UPSaclay)	in charge of the "technologies for biomedical research" axe of the project
Baudouin-Cornu	Peggy	peggy.baudouin@cea.fr	project manager (CEA <sup>1</sup> )	in charge of the "technologies for organizational innovations" axe
Guettier	Catherine	catherine.guettier@aphp.fr	Hospital and university professor (UPSaclay)	in charge of the Smart Imaging part (combination of IA and imaging)
Lewin	Maité	maite.lewin@aphp.fr	Hospital and university professor (UPSaclay)	in charge of the Smart Imaging part (combination of IA and imaging)

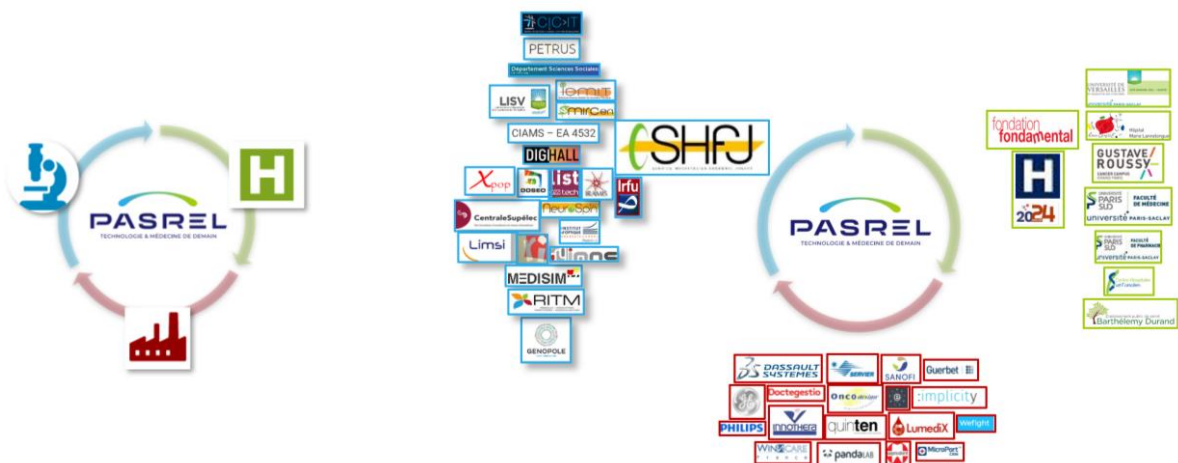
<sup>1</sup> CEA, Commissariat à l'Énergie Atomique et aux Énergies Alternatives

Executive Summary in French (max 1 page):

Le Hub PASREL vise à fédérer les laboratoires de Paris-Saclay, qui développent des technologies pour la santé, et à les accompagner pour leur transfert clinique. Grâce à sa gouvernance, qui impliquera des chercheurs de l'Université Paris-Saclay ainsi que des personnels hospitaliers et industriels, le Hub PASREL favorisera l'acculturation entre les différents acteurs de la communauté de l'innovation en santé et portera une réflexion sur les métiers de demain dans ce domaine. Son programme scientifique, fruit de plus de deux ans de dialogue étroit avec les établissements de santé, les chercheurs universitaires et l'industrie, s'articule autour de 2 axes : les technologies pour la recherche médicale (y compris la combinaison de l'imagerie et de l'intelligence artificielle) et les technologies pour l'innovation organisationnelle en santé.

En s'appuyant sur six *graduate schools* piliers (deux dans le domaine de la santé, deux dans le domaine des technologies et deux dans le domaine des sciences humaines et sociales), le hub PASREL a pour objectif de structurer le réseau des laboratoires de recherche en technologies pour la santé de Paris-Saclay, de les connecter à des équipes d'établissements hospitaliers de Paris-Saclay, de faire émerger des projets pilotes et d'assurer leur transfert clinique. Le hub PASREL permettra un transfert à la clinique rapide et l'évaluation en conditions réelles des développements technologiques. Il tirera pleinement parti des compétences existantes au sein de l'Université Paris-Saclay pour proposer un accompagnement adapté aux spécificités de technologies de santé.

D'ici 2025, le bâtiment PASREL sera construit sur la même parcelle immobilière que le futur Hôpital de Paris-Saclay. Il abritera notamment une unité de recherche en imagerie biomédicale déjà constituée (UMR BioMaps) ainsi que des plateformes ouvertes d'imagerie et, à leur demande, pourra accueillir des équipes académiques et industrielles qui voudront développer leurs innovations au plus près des soignants et des patients de l'hôpital. La mise en œuvre du programme scientifique du hub PASREL dès 2020 fera de cet ensemble un démonstrateur de « l'hôpital du futur » où seront testées les innovations issues des laboratoires avant d'être diffusées à l'ensemble des établissements hospitaliers de Paris-Saclay.



*Left: PASREL aims at connecting academic research, industrial research and hospitals. Right: first actors involved in the PASREL Hub project*

### Executive Summary in English (max 1 page):

The PASREL Hub aims at federating the laboratories of Paris-Saclay, which develop technologies for health and accompanying them for their clinical transfer. Thanks to its governance, which will involve researchers from Paris-Saclay University as well as physicians from Paris-Saclay hospital and industrial staff members, the PASREL Hub will promote the acculturation between the various stakeholders of the health innovation community and will address tomorrow's careers in this field. Its scientific program, the fruit of more than two years of close dialogue with healthcare institutions, academic researchers and industry, is articulated around 2 axes: technologies for medical research (including the combination of imaging and artificial intelligence) and technologies for organizational innovation in healthcare.

Backed by six pillar graduate schools (two in the field of healthcare, two in the field of technology and two in the field of human and social sciences), the PASREL Hub will establish a structured network of academic laboratories involved in healthcare technologies in Paris-Saclay, to connect them to hospitals and industrial companies, to generate pilot projects and to enable their evaluation in real conditions, thus accelerating their clinical transfer. It will take full advantage of the existing skills within the Paris-Saclay University to offer a coaching adapted to the specificities of health technologies.

By 2025, the PASREL building will be built on the same plot of land as the future Paris-Saclay hospital. It will house, among other things, an already established biomedical imaging research unit (BioMaps) as well as open imaging platforms and, at their request, will be able to accommodate academic and industrial teams who want to develop their innovations as close as possible to the hospital's caregivers and patients. Thanks to the deployment of the PASREL Hub's scientific program as early as 2021, this facility will become a demonstrator of the "hospital of the future", where innovations from the laboratories will be tested before being distributed to all the hospitals in Paris-Saclay.

### Graduate Schools involved in the project

GS BioSphERa	<input type="checkbox"/>	GS Geosciences, Climate, Environment and Planets	<input type="checkbox"/>	<b>GS Health and Drug Sciences</b>	<input checked="" type="checkbox"/>
GS Chemistry	<input type="checkbox"/>	GS Cultural and Heritage Science	<input type="checkbox"/>	GS Public Health	<input type="checkbox"/>
<b>GS Computer Science</b>	<input checked="" type="checkbox"/>	<b>GS Life Sciences and Health</b>	<input checked="" type="checkbox"/>	<b>GS Engineering and Systems Sciences</b>	<input checked="" type="checkbox"/>
GS Law	<input type="checkbox"/>	GS Mathematics	<input type="checkbox"/>	<b>GS Sociology and Political Science</b>	<input checked="" type="checkbox"/>
<b>GS Economics &amp; Management</b>	<input checked="" type="checkbox"/>	GS Occupations in Research and Higher Education	<input type="checkbox"/>	GS Sport, Movement, Human factors	<input type="checkbox"/>
GS Education, Teaching, Training	<input type="checkbox"/>	GS Physics	<input type="checkbox"/>	The Institute of Light Sciences	<input type="checkbox"/>

## Part 2: General framework of the project

### 2.1 Description of the scientific, technical or societal issues addressed (5 pages max)

*You should describe here the context and scope of the project in the three areas: research, training, innovation. The local, national and international positioning should be presented. Describe the "academic" challenges as well as the possible interactions with the socio-economic environment. Describe the expected impact and the goals at 3 and 5 years.*

#### **Building on the strengths of the Paris-Saclay territory to bring 4P medicine to patients**

4P medicine is based on a multifactorial approach that considers all of the patient's biological, environmental and behavioral variables. It results from the massive integration of technological innovation and requires, in parallel, organizational innovations. This dual idea is the core of the "Ma Santé 2022" plan presented in September 2018 by the French Ministry of Solidarity and Health and the French Ministry of Higher Education, Research and Innovation.

To succeed in this integration, it is essential to interface and coordinate different disciplines (medicine, pharmacy, physics, chemistry, engineering sciences...), different partners (national, European, academic, SMEs, large companies...) and different ecosystems (research, care, industry), as close as possible to healthcare professionals and patients. **This is the main objective of the PASREL hub: to initiate and structure collaborations between hospitals, academic research and industry in order to encourage the development and validation of innovations in full compliance with clinical issues and hospital needs.**

The creation of the Hub benefits from two concomitant events. First, the creation and structuring of the Paris-Saclay University, which offers an exceptional multidisciplinary environment. Among the expertise that are developed in the Paris-Saclay's laboratories, we have pinpointed the following as particularly relevant for our project: **medical imaging, robotics, -omics, microfluidic devices, connected objects and artificial intelligence.** The second event is the building of a new hospital on the Plateau de Saclay. This hospital is the result of the merger and relocation of the Orsay, Longjumeau and Juvisy hospitals (the three of them constitute the GHNE, *Groupe Hospitalier Nord-Essonne*). This real estate project obtained the necessary financial and political support by highlighting its privileged relationship with the CEA Saclay (part of Paris-Saclay University) through its Service Hospitalier Frédéric Joliot (SHFJ), and by claiming an increased connection with the research laboratories of Paris-Saclay. In addition, the health crisis linked to covid-19 has highlighted the importance of connecting research and healthcare players to accelerate the development of health technologies. This crisis has also underlined the importance of organizational reflections and innovations to allow the reception of patients in the best conditions, even in degraded situations.

In the long term, thanks to strong interactions between researchers, industrials, physicians, nursing staff and patients, the PASREL Hub will improve access to personalized medicine for the 500,000 patients of Paris-Saclay, as well as more adapted and more humanized care paths.

The PASREL Hub will thus be a strong element of attractiveness of the region for industrials, researchers and students. Public events such as seminars, open houses and science forums on health technologies will be organized to encourage dialogue with the public.

#### **Research and Innovation**

The scientific project carried by the PASREL Hub is based on two axes: **1) technologies for medical research and 2) technologies for organizational innovation in health.** Discussions with laboratories in Paris-Saclay have revealed the significant strengths of both communities, as well as a real potential for synergy between them. Indeed, some technological building blocks developed for medical research

can easily be adapted for organizational research and conversely. For example, an AI algorithm analyzing medical images to identify biomarkers relies on the same technological building blocks as an algorithm analyzing patient data to automatically produce a hospitalization report. Similarly, an exoskeleton accompanying functional rehabilitation of upper limbs shares the same technologies as an exoskeleton assisting hospital staff in handling patients. The presence of two technological goals, which is a trademark of our project, will allow to federate a large research community and to impulse multiple synergies.

The axis of **technologies for medical research** is at the crossroads of two fields of competence: *i.* technologies developed in the laboratories of Paris-Saclay University and *ii.* Biomedical research developed in hospitals. The objective is to develop cutting-edge technologies to revisit medical knowledge and practices. The PASREL Hub will fulfill a scientific animation function aiming at networking research communities. It will act as a hub by bringing together research laboratories around projects defined in consultation with the faculties of Medicine and Pharmacy, industrials and the Medicen Paris Region competitiveness cluster. The PASREL Hub will enable technological developments to be evaluated in real-life conditions to promote rapid transfer to the clinic. It will take full advantage of existing skills within Paris-Saclay University to provide support and training. Among the flagship technologies developed in Paris-Saclay, *in vivo* imaging offers unique tools for medical research. In recent years, Paris-Saclay teams have enabled the emergence of highly innovative medical imaging approaches. Examples include the high magnetic field MRI techniques developed at NeuroSpin and the radioisotope imaging techniques developed at BioMaps/SHFJ (see §2.2 above). Important work is underway to transfer these technologies to the hospital in the framework of clinical research protocols. These techniques have relevant applications in infectiology and internal medicine (imaging of viral reservoirs in HIV by radiolabeling of antiretroviral drugs), in pharmacology (study of SLCO/OATP drug transporters by <sup>11</sup>C-glyburide PET), in neurology (study of the variability of response to psychotropic drugs by functional PET-MRI with <sup>11</sup>C-buprenorphine, PET-MRI imaging of drug-resistant epilepsy by <sup>18</sup>F-DPA-714 neuroinflammation imaging), in psychiatry (molecular imaging of drug-resistant depression) or in rehabilitation (study of post-stroke neuronal plasticity by functional and structural MRI). The PASREL Hub project integrates the interdisciplinary project Smart Imaging, which aims to apply the methods of artificial intelligence both to medical imaging and histological imaging. By promoting collaboration between imaging physicians, data scientists and AI researchers and by relying on medical databases already constituted, the Smart Imaging component of PASREL Hub aims at producing algorithms with diagnostic, prognostic and predictive value resulting from artificial intelligence. These algorithms, developed in the key fields of activity of the hospitals of Paris-Saclay, will be transferred to industrials in order to implement them in the routine imaging workflow.

Discussions initiated in recent months have already identified promising prospects involving other technologies such as -omics, robotics or computer science. Of note is the emergence of ambitious projects combining -omic analysis, neuroimaging and AI for personalized medicine in psychiatry. These projects are supported by the ADAPT University Hospital Federation, which brings together the players in psychiatric research and care in Paris-Saclay. The dynamics of this project illustrate the relevance of PASREL Hub's technological positioning: psychiatry's recent interest in Paris-Saclay is mainly due to the technological expertise present there, which will make it possible to revisit the underlying mechanisms of mental illness. Continued reflection with the medical faculties and teams of the future Paris-Saclay hospital is one of the challenges of the PASREL Hub. The objective is to develop high-potential collaborative projects in these areas during the period 2020-2024, projects that will take off when the hospital opens in 2024. Other federative projects are under discussion, concerning the combination of robotics and high field MRI for the study of neuroplasticity.

The axis of **technologies for organizational innovation in health** aims at improving the efficiency of care by automating tasks performed by caregivers, optimizing the "patient pathway" and strengthening patient follow-up and the link between personal physicians and hospital carers. Organizational innovations can only be developed by stakeholders who have both an excellent knowledge of applicable technologies and a strong knowledge of the healthcare system and its capacity to integrate innovative technologies. Organizational health research is an emerging and poorly structured field, both in Paris-Saclay and nationally. The opening of the Paris-Saclay hospital is a unique opportunity to federate the researchers already working in this field and to unleash the considerable potential of this research. This axis will rely on technological building blocks common to those identified for the "medical research" axis, in particular artificial intelligence and robotics. Of note, although they will be involved in both axes, for instance to work on the dissemination of technological innovations in health, we will heavily rely on colleagues of the humanities and social science to address this axe. Indeed, organizational innovation more specifically raises questions such as the adaptation to change of the various actors, the evolution of professions and their interactions, the involvement of the patient in their care, the evolution of economic models, etc.

### **Training**

Training will have a dual role in the PASREL Hub: 1) to train students at the interface of technology and medicine in order to meet the growing demand of academic and industrial laboratories and 2) to contribute to the dissemination of technological innovations tested and validated in the hospital, in line with the strategy developed by IRCAD, in Strasbourg.

To be sure to participate in the implementation of relevant training, both initial and life-long, the project will rely on its governance (see below) to maintain a regular dialogue with both industry and teacher-researchers of the university, in order to define expectations, needs and anticipate as much as possible the "jobs of tomorrow".

#### *Training at the interface of technology and medicine*

Courses at the technology/medicine interface will be offered for both initial and life-long education. These courses will be given by the teacher-researchers of the partner laboratories, strongly involved in the teaching of medical physics in Paris-Saclay. A global reflection will be undertaken to decompartmentalize the teaching of "medical physics" and to replace it with teaching of "medical technology" integrating, in addition to physics, engineering sciences and chemistry. Proposals will be developed within the framework of initial training (master's degree, doctoral courses). Particular attention will be paid to coherence with existing training courses, especially those offered to engineers by the IFSBM. In addition, continuing education programs will be offered to physicians in order to raise their awareness of the leading health technologies available in Paris-Saclay laboratories. Reciprocally, engineering students could be trained in Paris-Saclay hospitals in order to develop technologies adapted to the expectations of the medical communities.

#### *Life-long training in health innovations*

There is a need for appropriate training throughout the development of innovative health technologies: during clinical validation to train users in the correct procedures, when they are put on the market and then during their follow-up. Depending on the situation, the PASREL hub will provide training in the use of technological innovations developed as part of its own projects, as part of its support services or as part of specific partnerships with similar structures of other regions like Innov'Pôle Santé in Toulouse. This training offer will be made in partnership with the GHNE network and may involve its staff, particularly when it comes to training in organizational innovations developed

with it. In this way, GHNE will share its expertise with other health establishments in the region and become the "demonstrator" of hospital innovation in Paris-Saclay.

### **Local, national and international positioning**

#### *Local positioning*

PASREL Hub will connect the technological research laboratories, which are mainly located around Saclay, to the university hospitals located further to the east (Kremlin-Bicêtre, Paul Brousse, Antoine Béclère) and to the west (Versailles Saint-Quentin) of the University's vast territory. PASREL's networking and connection actions will address the geographic distance between the technological laboratories and the university hospitals. General hospitals such as the GHNE, located in Saclay, will also be partners of the PASREL Hub. Although these hospitals do not have the resources to conduct ambitious biomedical research projects, their small size gives them a certain agility to rapidly test organizational innovations. PASREL is thus carrying out a FabLab network project, under the leadership of the Hephaïstos FabLab in Kremlin-Bicêtre: a GHNE FabLab could enable the rapid evaluation of innovations which could, in a second phase, be transferred to the Paris-Saclay university hospitals.

Focused on the issue of clinical transfer, PASREL Hub is positioned in a complementary way to other interdisciplinary projects and will be able to accompany in further steps their emerging projects. Thus, we have agreed to hold joint meetings with ISIT (research on drugs and therapeutic innovation) and iNanoterad (Nanotechnologies and Radiation based Therapies). On training issues, we will work closely with the interdisciplinary program AVERROES, which aims to develop dual medicine/science training. Representatives of these candidate interdisciplinary objects will be invited to our annual general meeting and we will share with them project committees (see below), seminars or webinars. Finally, we will also be able to share with them our ideas on the "professions of tomorrow" within our training committees (see below) so as not to overburden the industrial partners who will accompany us in this reflection. Discussions are also underway with the "augmented operating room" innovation chair (BOPA chair). A first joint action is the organization, at the beginning of the next school year, of a visit/conference around the iMiGINE prototype (the world's first prototype for automated and miniaturized production of radiopharmaceuticals as close to the patient as possible, designed in partnership with the industrialist PMB and installed at the SHFJ) and around the BOPA Chair for students in the HSB ("Healthcare and Biomedical Services") major at CentraleSupélec.

Regarding the industrial transfer and the help to VSE/SME, exchanges took place with several incubators (Incuballiance, Incubateur et Accélérateur X-Tech and X-Up) and the SATT Paris-Saclay but no concrete action has been launched yet. Because of its links with the CEA, the PASREL Hub is also connected to the Hub4Aim network (mainly located in Grenoble) and will be able, if relevant, to transfer to it the technological, regulatory and industrialization support of start-up projects in the field of medical devices. Finally, PASREL regularly exchanges with the Medicen Paris-Region competitiveness cluster that labelled a first declination of PASREL, the "PASREL-Imagerie" project, allowing it to obtain a "Sésame Filières PIA3" financing from the Paris Region. The involvement and the support of the Medicen Paris-Region competitiveness cluster in the project confirm the need of health innovation SMEs for a validation structure in real conditions.

It should be noted that the real estate project PASREL was the subject of a request for CPER financing (State-Region Plan Contract) carried by the Paris-Saclay University. It appeared then that it was important for PASREL and the other projects supported by the university that could seem similar, for example the project "Virtual Hospital" of Prof. Djillali Annane and the simulation center LabForSIMS of the Faculty of Medicine of Paris-Saclay, to carefully explain their respective positioning and their

complementarities. A schedule of quarterly meetings between the three structures is being finalized for this purpose. These meetings will most likely lead to joint actions.

### *National and international positioning*

The PASREL Hub is a local project whose objective is to bring together Paris-Saclay researchers, manufacturers and health care institutions to develop technological innovations that meet clearly identified needs in health care ("medical pull"). The approach consisting in backing a research structure with a hospital to develop research as close as possible to the needs is a fundamental trend in France and abroad. A benchmarking study on research structures combining care/academic research/industrial research was carried out in early 2019, integrating the University Hospital Institutes (IHU) and the French CIC-IT network, as well as some international structures (WYSS Institute in Boston, Bio-X Clark Center in Stanford). This study highlighted the importance of acculturation and valorization, for which the PASREL Hub will rely on existing structures, such as the SATT Paris-Saclay.

PASREL was conceived to limit as much as possible redundancies and to offer a good complementarity with already existing local structures, for example with IHUs. Thus, discussions with representatives of several IHUs during the project set-up have allowed us to refine our positioning (focus on technologies and not on families of pathologies, the pathologies of interest for the biomedical research axis being defined in close collaboration with the medical faculties). The capacity of PASREL to facilitate access to the laboratories of Paris-Saclay University was of particular interest to them. PASREL is also connected with other structures giving the same importance to acculturation and co-construction in the development of technologies for health: we regularly exchange with Innov'Pôle Santé in Toulouse to share our good practices.

Finally, the approach of being attentive to the needs of future users of health technologies (patients, caregivers and/or carers), of encouraging acculturation and networking, and of testing innovations in real-life conditions, in this case in hospitals, places the PASREL Hub project in the line of living labs. As the CEA is a participant and, since the end of 2020, a member of the Board of Directors of the Forum of Living-Labs in Health and Autonomy (LLSA), the PASREL Hub is well connected to their activity. In particular, one of the co-initiators of PASREL Hub participates in their "ORG" working group on the organizational impacts of health technologies.

## **2.2 Describe the added value of the project (1 page max)**

*You should present here why and how your project will increase the visibility and the research, training and innovation missions of Université Paris-Saclay and its structuring effect.*

### **Structuring leading research communities towards precision medicine**

Paris-Saclay offers an exceptional environment for training, research and innovation in the field of health technologies: the Paris-Saclay area alone concentrates about 20% of French public research in health technologies<sup>2</sup>. By structuring this vast community and connecting it to care and industrial research, the PASREL Hub will increase the visibility and scientific productivity of the Paris-Saclay University. PASREL will make Paris-Saclay a major player in the "medicine of the future", also called "precision medicine", which replaces the current approach with a multifactorial approach that, beyond the pathology, considers all the biological, environmental and behavioral variables of the patient<sup>3</sup>.

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<sup>2</sup> Alliance Aviesan, document stratégique Décembre 2011

<sup>3</sup> « 5 propositions pour la médecine du futur, un enjeu pour la France », report submitted to the French government, coordinated by André Syrota and Olivier Charmeil, 2016



PASREL will help integrating technological and organizational innovations in medicine, bringing a major contribution to the development of precision medicine.

### **Capitalizing on the successful experience of medical imaging in Saclay**

In 1958, the CEA decided to place one of its research units in the Orsay hospital in order to promote the use of artificial radioactivity in health applications. This is the origin of the only hospital service of the CEA, the SHFJ. Since its creation, it has been a leader in the development and transfer, both clinical and industrial, of innovations in medical imaging. Most recently, the SHFJ participated in the development of iMiGiNE, the first prototype for automated manufacturing of radiopharmaceuticals "on demand" for medical imaging<sup>4</sup>. The PASREL Hub will build on the successful experience of SHFJ in the field of medical imaging and extend it to the development of health technologies. Following this model, it will allow acculturation between the different communities and the development of this research activity by privileging the "medical-pull" approach over the "techno-push" approach. It fills a gap in the development process of health technologies, between the very first proof of concept in the laboratory and the transfer to more downstream structures such as the SATTs or, in the case of medical devices, the Hub4Aim network. In this way, the PASREL Hub will ensure that the upstream phases of health technology development are perfectly aligned with the downstream phases, thereby saving precious time for project developers and, ultimately, for patients.

### **Responding to pressing demands**

Without waiting for the "Interdisciplinary Object" label, the structuration of research communities has begun, under the impulse of the numerous research teams of the University that expressed their interest for the PASREL project<sup>5</sup>. Networking has begun in the form of acculturation seminars organized between the engineering and social science laboratories and the health establishments of Paris-Saclay (3 seminars organized in 2020 and 2021). Two concrete projects have already emerged from this approach (one in AI for the patient pathway and one on sensors for critical care). The working groups set up on targeted themes are continuing their work. Since then, the PASREL team is regularly solicited by technological research laboratories seeking to connect to hospital services or by medical practitioners looking for specific technological solutions.

In addition to the demand expressed by academic teams, PASREL will meet the expectations of industrial partners. The Paris-Saclay region hosts major industrial clusters bringing together leaders in pharmaceuticals, medical engineering, biotechnologies and digital technology. Industrial partners also want to be connected to technological research and health establishments in Paris-Saclay. A project to open up Paris-Saclay's health technological platforms to pharmaceutical and medical imaging industries was recently initiated by PASREL<sup>6</sup>.

One of the challenges of the "PASREL Hub" IO is to ensure the sustainability of these projects.

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<sup>4</sup> The first two syringes of this first compact and fully automated prototype combining all the components of the radiopharmaceutical manufacturing chain were produced at the end of 2020 at SHFJ. Thanks to their very good knowledge of the hospital environment and the regulatory constraints specific to radiopharmaceuticals, the SHFJ staff was able to accompany and advise PMB, the manufacturer, in this adventure.

<sup>5</sup> More than 100 research teams of the University have expressed their interest for the PASREL project (by filling in an online form and participating to dedicated webinars)

<sup>6</sup> Project « PASREL-imagerie » funded by BPIfrance and Paris-Region in April 2021

## 2.3 Organisation of the project and its interactions (when applicable) with other objects (2 pages max)

*Describe here the organisation of the object, placing it within its environment (e.g. LABEX, DIM, EUR, Graduate Schools, other interdisciplinary objects, etc.). Describe the proposed governance.*

### **Proposed governance and organisation**

The governance of the PASREL Hub will be central in the realization of its missions on the three pillars of interdisciplinary objects that are research, innovation and training. It will aim at promoting acculturation between the different communities and the expression of needs regarding technological innovations in health, the implementation of specific training and access to technological resources and expertise. The governance proposed below will be refined during its implementation to ensure optimal efficiency without unnecessarily burdening the already very busy schedules of the experts and partners involved.

The **steering committee** will supervise the functioning of the interdisciplinary object by assessing its past activities, by validating the objectives for the following year and by sharing with it the information and contacts it has available to enlighten its understanding of the health innovation ecosystem and help it in its missions. It will decide which events will be organized during the year, either on the proposal of the training committee or the project committee, or on its own initiative. Finally, the steering committee will address the integration of patients or patient associations in the governance of the PASREL Hub and will have the opportunity to adjust the governance to make it more efficient. The steering committee will meet at least once a year and can organize exceptional meetings if needed. The steering committee will be made at least of the PASREL Hub initiators, the project manager, representatives of the national research organizations, representatives of the 6 pillar graduate schools, representatives of the schools of medicine, pharmacy and sciences, and representatives of the project committee and the training committee (see below).

The **training committee** will be responsible for proposing training courses that are consistent with the existing offer. It will be in charge of mapping and monitoring existing training in the field of health technologies and their transfer, paying particular attention to training in regulatory aspects, which is becoming increasingly critical with the implementation of the new European regulations (MD and IVDMD). The committee will participate in the development of training courses at the interface between technology and medicine, will think about the professions of tomorrow and will propose to the steering committee the organization of events related to training. It will meet at least twice a year, more if necessary, for example when it is working on the implementation of new training courses or when organizing an event. The training committee will include at least representatives of the master's programs and the Doctoral Schools involved. It should either include industrialists, or organize exchanges with them to be sure to listen to their expectations.

To encourage research and innovation, the PASREL Hub will support projects that may, if necessary, benefit from seed funding for collaboration (maximum 15 k€). The conditions to benefit from this seed funding will be specified by the steering committee. For example, funding conditions could include the obligation for the project to involve at least one team affiliated to the Economics, Management and Sociology graduate schools. The support of the selected projects, whether funded or not, will be done by a specific project committee (see below).

The **project committee** will be responsible for the scientific animation as well as the selection and support of emerging projects supported by the hub. It will decide on the allocation of seed funding based on the recommendations of the project unit (see below) and will advise project leaders. This committee will include the PASREL Hub project manager, representatives of the hospital, scientists,

legal experts and clinicians, in order to provide comprehensive support for projects. The technology transfer offices of the various institutions involved will also be represented on this research committee to secure intellectual property from the start. Depending on the project, the committee may invite experts. It will thus seek to represent all facets of project development in health technologies: technical aspects, medical needs, ethical aspects, etc. As much as possible, and taking care to respect the confidentiality of the presented projects, manufacturers or representatives of competitive clusters may be invited. The project committee will have to make project leaders aware of the various technical, regulatory, clinical, etc. stages of health technology development, and may use tools such as Aviesan’s BMK Tools and ParcoursDM for this purpose. He will share his address book with them to enable them to interact with the most relevant contacts at the development stage of their project. When the time comes, he can also advise them on their market study. The project committee will meet once a month, its composition being refined in regard to the nature of the projects considered during this monthly meeting.



It is the **project unit** that will make the first selection of projects to be supported. This unit, composed of the project manager and supported by the co-founders of the PASREL Hub, will be the first contact of the project leaders who will be able to contact it throughout the year. The project unit will decide whether or not the project can be presented to the project committee and whether it meets the criteria for applying for seed funding. The project unit will be responsible for organizing the schedule of monthly meetings of the project committee by gathering projects of the same nature and inviting the appropriate experts to the corresponding project committee’s meeting. If necessary, depending on the funds of the PASREL Hub and the needs of the project leaders, the project unit will make a proposal for a seed fund budget. If the project is too far upstream to be presented to the project committee, the project unit will explain the reasons to the project leader and will propose actions to be taken before applying again for project support. The project unit may organize calls for expressions of interest to identify projects to be supported.

Once a year, the PASREL Hub will hold its **general assembly**. This important event will gather the members of all the above committees, including the experts invited from time to time, and will be an additional opportunity to promote acculturation between the different communities. During this general meeting, the project manager will present a progress report of the accompanied projects (taking into account confidentiality constraints) in order to make them known to the ecosystem and to identify ways to improve the support. A representative of the training committee will present the mapping of existing training courses and the reflection carried out on the "missing training courses" and/or the "professions of tomorrow". Activities (round tables, presentations, interactive surveys, etc.) will help define the expectations of healthcare institutions, both in terms of training and innovation, as well as the expectations of manufacturers in terms of initial and ongoing training and their vision of the professions of tomorrow. This general meeting will be widely open, including to patients and patient associations.

### **Interactions with the participating graduate schools**

In addition to their involvement in the above committees, preliminary discussions with the graduate schools that will be involved in this project of interdisciplinary objects have highlighted the following possible interactions:

**Life Science and health:** the PASREL Hub may offer training courses in masters programs to promote acculturation between communities (biologists, bioinformaticians...) and offer sabbatical years between M1 and M2. It should be noted that two of the initiators of the PASREL Hub are delegated directors of this GS (delegated director "interactions with the hospital" and delegated director "partnership-transfer-innovation").

**Health and Drug Sciences:** this GS is particularly interested in projects involving biomarker research and the development of targeted therapies. They would also be interested in training courses regarding the development of medical devices. It should be noted that strong links are already planned with the ISIT interdisciplinary object project, which is close to this GS (see above).

**Computer Science:** the interdisciplinary object could connect computer science researchers to health institutions (doctors or hospital directors) and their databases. Training courses on artificial intelligence for medical students could be organized with the help of this GS.

**Engineering and Systems Sciences:** the Hub could allow (i) researchers working on engineering technologies linked to health such as medical image processing, robotics, microfluidic devices, connected objects, biomechanics to do clinical research, and (ii) engineering researchers working on medical task automation as well as medical operation management to capture patient data and experiment organizational innovations at hospital scale.

**Sociology and political science:** GS researchers could intervene on subjects such as the place of the patient in the hospital, the sociology of work and change management. Project leaders are increasingly expected to assess the organizational impact of their health innovations ([https://www.has-sante.fr/jcms/c\\_2902770/fr/cartographie-des-impacts-organisationnels-pour-l-evaluation-des-technologies-de-sante](https://www.has-sante.fr/jcms/c_2902770/fr/cartographie-des-impacts-organisationnels-pour-l-evaluation-des-technologies-de-sante)): researchers of the GS could collaborate with them on this aspect. The projects accompanied by the PASREL Hub could also be a field of study for the GS, for example to analyze how new objects are produced and implemented in a hospital environment.

**Economics and management:** This GS brings together economists in the field of health economics and in the field of health management. They propose that these two types of profiles be represented in the different committees. Concerning the projects that will be accompanied by the PASREL Hub, they propose to intervene in two ways: either in the framework of an observation project (the coaching of the PASREL Hub would become a subject of study), or in an intervention framework, by collaborating with the project leaders. Some GS researchers have also expressed interest in accessing the GHNE and other partner hospitals via the Hub to conduct quantitative and qualitative surveys.

**Public health:** The involvement of this GS in the PASREL Hub is still to be defined since it has not been identified among the 6 proposed pillar GS. However, many interactions are possible. For example, the GS offers two masters in ethics in which are addressed the issues of research ethics and ethics of care, two subjects of interest for people developing innovations in health. Among the research axes of this GS are also the issues of acceptability and of the diffusion of innovations beyond the economic aspect. These issues are of great interest when developing technological innovations in health. The GS will designate an interlocutor to carry on the discussions with us.

### Part 3: Description of the methodology of reflection on “the jobs of tomorrow” (1 page max)

*Describe here how the project will advise and propose, along with the Undergraduate University School, the Undergraduate College and the Graduate Schools, appropriate interdisciplinary courses or other initiatives within the scope of the project to prepare students for future job opportunities. This includes opening new fields for PhD thesis.*

In the medium term, the development of relevant technological innovations in health care will require training researchers at the interface of engineering and health care professions, which today remain largely compartmentalized. In addition, technological innovations will change professional practices and lead to new jobs, such as data scientists who are appearing in hospitals. The question of "jobs of tomorrow" is therefore central to the PASREL Hub. We propose to approach the question of "jobs of tomorrow" according to the following methodology.

#### **1<sup>st</sup> phase: inventory of the existing situation and international comparison:**

- Inventory of training courses at the technology/medicine interface in Paris-Saclay
- Survey of expectations from the 3 ecosystems concerned: academic research, healthcare, industrial research
- Benchmark of training at the interface in France and Europe

#### **2<sup>nd</sup> phase: elaboration of training proposals allowing the acculturation and the acquisition of skills at the technology/medicine interface:**

- Consultation with the Undergraduate University School, the Undergraduate College and the Graduate Schools.
- Consultation with researchers and healthcare professionals on continuing education programs such as the University Diploma or Inter-University Diploma on Technologies for Medicine.
- Consultation with industrial partners in the health sector who will be asked about their expectations in terms of new skills and know-how.

### Part 4: Project viability plan (2 pages max)

*Interdisciplinary Objects are not intended to be fully supported by Université Paris-Saclay. It is therefore necessary to prepare a viability plan beyond the first 5 years.*

PASREL will build on the dynamics of the creation of Paris-Saclay University to connect the academic, industrial and healthcare research communities across the University's territory. However, the strategies implemented to connect these 3 ecosystems will have to be constantly renewed in order to adapt to the rapid evolution of technologies, knowledge and medical practices. PASREL will therefore have to be a long-term program and benefit from funding relays beyond the next 5 years.

Financial leverage effects are expected from both research and healthcare funding windows. Following discussions held in recent months with research laboratories and health institutions, a project for a University Hospital Federation<sup>7</sup> at the technology/psychiatry interface was selected in 2020 (FHU ADAPT). In addition, we have obtained seed funding from the CEA for a project on AI-based semantic analysis of hospital information systems. For this project, we are also in discussion with the Agence Régionale de Santé for co-financing. Another leverage effect could be the involvement of national research organizations alongside the University: INSERM, which shares the observation that organizational research is insufficiently structured in France, intends to invest in this field of research in Paris-Saclay in the forthcoming years.

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<sup>7</sup> FHU2019 call by AP-HP, Inserm and Paris-Region Universities

Industrial funding is another lever for PASREL. The relevant industrial sectors are mainly the drug sector, the instrumentation/medical device sector and the digital sector. Contacts with many industrialists in these three domains have been established over the past 18 months, confirming their interest in PASREL, which is seen as an early testing ground for diagnostic, therapeutic and organizational innovations. In the field of medical imaging, an ambitious program to open up CEA-Paris-Saclay's medical imaging research platforms to industry has just been financed by Paris-Region and bpifrance (public investment bank). This program, which involves four CEA/Paris-Saclay University research laboratories, aims to increase partnerships with industrial companies in the drug and medical instrumentation sectors.

## Part 5: Budget request and its justification (2 pages max)

*As per the viability plan described above, you should detail here the proposed budget request (salaries, research expenses, network expenses, operational budget...) for the project.*

The PASREL Hub is not intended to fund research projects, but to enable the development of projects at the interface of technology and medicine and to accompany these projects. The required budget aims at continuing the actions initiated in the last few years towards academic research communities, hospitals and health industry. The financial support will make it possible to organize the scientific networking, to initiate research projects and to accompany the projects. The total annual budget requested for the PASREL Hub is 160k€.

### Budget requested for scientific networking (70k€/year)

The PASREL Hub involves scientific and medical communities that are relatively dispersed, both thematically and geographically. For the past 2 years, the PASREL Hub's leaders have crisscrossed the Paris-Saclay region to structure these communities. In total, more than 100 meetings have been organized with teacher-researchers, lab directors, faculty directors, heads of research organizations, physicians, hospital directors, innovation directors, etc.... This heavy work will have to be continued with the same intensity, in order (i) to encourage the emergence of innovative projects and (ii) to create a pool of experts to assist project leaders in every aspect of the development and integration of technological innovations in healthcare. The current project leaders will not be able to maintain this effort over the long term without strong support from the University. This implies the recruitment of a full-time project manager in order to coordinate the scientific networking. The annual cost is estimated at 70k€ (50k€ salary + 20k€ operating expenses). His/her main missions will be the following:

- to lead the project unit (see above) that will be the first contact of the project leaders applying for support; the project manager will be responsible for organizing the schedule of monthly meetings of the project committee by gathering projects of the same nature and inviting the appropriate experts to the corresponding project committee's meeting.
- to organize the governance of the PASREL Hub in conjunction with the graduate schools according to the scheme proposed above,
- to coordinate acculturation seminars and assess whether projects emerging from these seminars are eligible to support,
- to develop networking actions towards academic, industrial, regulatory... stakeholders in order to pinpoint the right experts for the Project Committee,
- to perform the reporting of the PASREL Hub's activities using the following indicators: number of projects submitted to the Project Unit, number of projects supported, diversity of supported projects, number and variety of experts in the Project Committee, number of students potentially involved in the training projects, number of participants in the General Assembly.

### Budget requested for seed funding (90k€/year)

In order to promote research and innovation, the PASREL Hub will offer seed funding for highly interdisciplinary projects at the technology/medicine interface, involving at least 2 different graduate schools. The conditions to benefit from this seed funding will be specified by the steering committee. For each project, funding will include:

- Support for one Master2 scholarship: 4k€/student,
- Support for operating costs/small equipment: 5k€/project.

Up to 10 projects will be supported each year (i.e 90k€/year). This funding will allow to start upstream research prior to the identification of an industrial partner willing to commit to downstream PhD program (CIFRE funding).