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La science pour la santé
From science to health

Inserm's position

Towards the tenth European Framework Programme for Research and Innovation (FP10)

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Key messages for the next Framework Programme (2028-2035):

- Significantly increase the share of funding dedicated to Research and Innovation; ensure a balance between anticipation and flexibility in strategic programming to adapt to new health crises and the scientific advances.
- Health must be a priority in European funding for research and innovation.
  - Increase funding for transnational European clinical trials, which are essential for health innovation. Facilitate the regulatory process.
- Simplified European research funding, for greater clarity and efficiency.

Structure

  - Keep a 3-pillars structure, but within these pillars simplify and restructure a financing system deemed too complex.
  - Pillar 2: increase readability and propose calls with broad thematic spectrums and low TRL.

Instruments

To be maintained and strengthened:

  - ERC and Marie-Sklodowska Curie Actions (MSCA) have proven their added value – to be strengthened.
  - Partnerships to coordinate European and national policies: e.g. the Innovative Health Initiative (IHI) must be continued, but in a transparent co-construction approach between industry and academic teams.
  - The European Innovation Council (EIC) must propose simplified calls for tenders, which should be fairly open and with increased success rates.
  - Research infrastructures: assess their added value compared to local infrastructures, then facilitate the use of the most relevant ones in research projects.

To be repositioned:

  - The Cancer Mission: it is a good integrator between research and public health activities (DG RTD/DG SANTE) which needs to be made more cross-functional by considering the FP and the health program (EU4Health currently).

To be reviewed:

  - European Institute of Innovation (EIT): for the moment it is not satisfactory; the projects are very complex to manage, and the academic actors do not find their way around.
- An open funding system for upstream research while preserving our sovereignty.
  - Continue to offer funding opportunities open to countries outside Europe for upstream research, but strengthen sovereignty and strategic autonomy in terms of innovation and exploitation of the results, for greater returns on investment within the European Union. Maintaining excellence as the primary evaluation criterion.
- Simplification.
  - Simplify submission and management procedures, to reduce the administrative burden, reduce delays and guarantee a maximum of R&I time for participants; provide unit costs for all types of expenditures.
  - Ensure that lump sum procedures do not increase managerial work during preparation and then in the monitoring projects.
- Other points to bear in mind.
  - Mastering the future biotechnologies of tomorrow, having innovative health companies and encouraging the repatriation of medicine production lines in Europe, to have a sovereign healthcare industry.
  - Ensure the integrity, reproducibility, interoperability and durable storage of the research data. Promote the sharing, open access and transparent publication of research results. Establish common European guidelines for the management and long-term availability of research data and source codes to foster collaboration and data reuse.

Significant funding for European research and innovation is essential to remain globally competitive

Significant **EU funding for research and innovation** is **an essential investment for Europe's future**, which will have major economic and strategic benefits. The time for research is not the time for politics (the work on messenger RNAs at the origin of Covid vaccines started 20 years ago). The budget of the 10th Framework Programme for Research and Innovation (FPRI) for the period 2028-2035 should therefore be significantly increased to **exceed 10% of the EU budget**. This funding effort is needed to **ensure** Europe's sovereignty and **independence** in a landscape of global competition **in strategic sectors**, **including health,** which is doubly strategic (internal strategic dimension, because health is a major concern for European citizens, and external strategic dimension, because access to medicines and advanced therapies is a matter of sovereignty). As healthcare represents a major global economic market, innovation in this area will lead to the creation of skilled jobs. If efforts are not coordinated at a European scale, but fragmented at the level of each country, this will inevitably lead to a regression in the face of global competition and the high levels of investment in research and innovation of some countries, such as the United States or China. The European socio-economic model involves high labour costs, so Europe cannot compete on mass production and has no choice but to bet on innovation to remain a leader in high-tech industry and preserve the standard of living of its citizens. This requires an ever-increasing structuring of research and collaboration of talents within the European area.

To develop our research, we need funding instruments that are on the one hand individual and on the other hand collaborative. Competitive individual European funding force you to get out of a national community and allow you to confront to the best in research in a particular field at the European level. This contributes to **increase the skill of research teams**. Collaborative European funding, on the other hand, promote the creation of thematic structuring networks that **broaden the spectrum of skills of national teams** with high-level international collaborators, **to set up research programmes that a country could not do alone**. The diversity of research issues in Europe and the multitude of approaches enrich research within each country and bring synergy.

European calls for proposal that bring together academic and industrial laboratories, are also particularly important to **increase the competitiveness of our companies,** ensure the **commercial exploitation of innovations resulting from European research** and maintain our **strategic autonomy** in the event of an emergency, such as health crisis.

FP10 is intended to help countries/regions to define **strong strategic areas of specialisation** at the territorial level. With the new multiannual financial framework, there is a need for better coordination between FP10 funding and other sources of European funds such as the European Structural and Investment Funds (ESIF) which must act in synergy. For example, it is necessary to continue to **develop the labelling (seal of excellence) of projects that are well rated** at the FPRI level, but not financed due to lack of budget, so that they find alternative funding at a national/regional level through the ESIF or some associative funding, if the themes are in line with the priorities of the territories.

Years of industrial delocalization have caused a loss of sovereignty. Part of our research and innovation projects should therefore **finance collaborative work between academics and industry**, with incentive budgets to encourage them to repatriate their research and production activities to Europe.

Health must be a priority in the European funding for research and innovation

As demonstrated by the COVID crisis, **health** must be **a priority in the European funding** for research and innovation because it is an issue that goes far beyond national borders.

EU funding will address **the many common challenges** that Europeans will face: an **ageing** population, **non-communicable diseases** (metabolic diseases, cancers, immune diseases, cardiovascular diseases and respiratory diseases), **mental health**, **pandemics**, **antimicrobial resistance** and **environmental health**. Inserm believes that certain clinical trials, cohort studies for prevention (exposure to pollution, effects of stress, sustainable diet) or research on the efficiency of healthcare systems, should also benefit from additional subsidies from the European Commission's Directorate-General for Health and Food Safety (DG Health) via the successor programme of EU4health. This requires greater European and national coordination.

European funding is used to set up research programmes that cannot be carried out by a single country. For example, for the study of rare diseases, this is essential to **build larger cohorts**. With the advent of precision medicine, it is important to cover the diversity of genetics, epigenetics and continental lifestyles, to offer everyone the most suitable care. In other cases, it offers the possibility of **replicating results** obtained in one country as well as in other regions of Europe, to then implement new common therapeutic solutions. It also allows each **country/region** to **specialize in certain areas while covering all health issues at the European level** and having access to all the cutting-edge technologies to offer innovative care solutions. This, however, requires amplifying the work to harmonize data and make them interoperable.

We are convinced that **Europe must master the biotechnologies** of tomorrow **and have innovative companies** to implement them, to have a sovereign pharmaceutical industry (vaccines, antibiotics, biomedicines, etc.) capable of providing fair access to healthcare for all our citizens and being resilient to face future health crises.

In a world where our democratic systems are sometimes threatened, **European research must be brought closer to its citizens** so that they understand that Europe contributes to protect their health through answers validated by science. Most European citizens remain unaware of the centrally funded research by the Commission and its executive agencies. Therefore, the Commission must **better communicate on the academic and industrial successes made possible by European funding** to promote the importance of Europe to the lay public. Since the Commission monitors projects during their development, and proposes the following programmes, it has the necessary material and the legitimacy to carry out this narrative. To bring researchers closer to citizens, there is also a need for more networks structuring projects between researchers and associations, with truly shared governance in a **participatory and transdisciplinary research** approach. This requires sufficient time between the publication of the calls and the submission of applications to allow the consolidation of strong interdisciplinary consortia, the widespread inclusion of association representatives in project evaluation committees, and in the definition of cross-cutting health research priorities.

Simplified European research funding, for greater clarity and efficiency

In the 10th FP, Inserm recommends maintaining **a 3-pillars structure. However**, within these pillars, it is necessary to **simplify and restructure a funding system considered way too complex**, and where it is often difficult to find one's way around the numerous calls. There are currently too many tools, and the complementarity between the instruments is not sufficiently visible, so mergers need to be carried out. While pillar 1 tools are generally popular among researchers, this is not the case for tools under the other pillars. It is therefore necessary to continue the presentation of these tools while simplifying them and clarifying the wording of the calls for projects. The **European research funding system** needs to become **more understandable** and accessible to newcomers. There is a need to better demonstrate the complementarity between the different instruments, and to help researchers move from one stage to the other in a pipeline from research to innovation. Unless there is a major change, the names of the instruments between Horizon Europe and FP10 should be kept as much as possible, to make the programs easier to understand.

In Horizon Europe, there is **not enough funding for basic research** outside the European Research Council (ERC). To remedy this, if ERC blank calls must continue to be mainly monobeneficiary (it should be noted that Inserm researchers particularly appreciate Synergy calls), it is necessary to create a place in **pillar 2** for **very open collaborative calls at low TRL** aimed at supporting competitive projects **for consortia of reasonable size** (e.g. 5 to 10 partners). Inserm proposes that this could be done in the form of calls for projects with broad, flexible thematic spectrums, in line with the health priorities that will have been identified in the strategic programming of the future framework program. In this context, it is also necessary to avoid financing overly large consortia that often lose efficiency.

For **research projects**, the **excellence** and originality of the project **must remain the main evaluation criteria,** in addition to impact and implementation. Inserm does not endorse the introduction of other restrictive criteria (geographical distribution, involvement of SMEs, gender balance, etc.). Inserm supports the initiative to **reduce the importance of CVs in evaluation**, but points out that it is important to be able to describe the models, lineages, cohorts or very specific instruments that a research team owns, to guarantee the success of a project. For **projects that are more innovation-oriented**, in addition to **excellence, impact should be assessed, while remaining realistic** and not encouraging teams to oversell their projects. Feasibility indexes should be put in place, and one of the evaluation criteria could be the achievement of objectives set in previous projects.

Pillar 1: Excellent Science

Pillar 1 is the one that **gives the most satisfaction** and that the scientific community recognises and cites the most easily. Inserm believes that 25% of the funding for the 10th FPRI should be devoted to it.

Inserm is calling for the **ERC to be maintained, as an attractive and excellent instrument**. However, we propose several improvements to the system. To maintain an evaluation system based on excellence but to increase the success rate towards 15%, **we recommend that the overall ERC budget be increased** accordingly. In addition, we suggest that the amount of financing be revised upwards in view of the inflation of recent years.

It would be interesting to strengthen promotional actions for *advanced grants*, for which the number of applications remains limited, recalling that it is more the quality and originality of the project that will be evaluated, than the prestige of the holder's CV. While Inserm is fully satisfied with the

introduction of auditions for all types of ERC funding, we regret to see that a limited number of candidates are invited to the oral exams in the *starting, consolidator and advanced* categories. Finally, to facilitate the work of the support functions, we are asking for a better spread of the dates for the submission of the various calls for tenders over the year.

Inserm is asking that the **Marie-Sklodowska Curie Actions** (MSCA) **be maintained** as they are now. The MSCAs must **focus on training and attracting the talent** of tomorrow for brain-gain and, to a lesser extent offer training actions for people already in place. When researchers go for training in the rest of the world, strong measures must be maintained to encourage their return to Europe, to avoid the brain drain. Specific training actions for people from widening countries and countries of the South need to be strengthened to enable these scientific communities to improve their skills. We are pleased that maternity leaves are now covered and would like to see family allowances considered as well. It is good to have homogenized all the doctoral networks to 540 people/month and to have extended the possibility of recruiting *joint-doctoral networks* to 4 years. The re-submission restrictions for *post-doctoral fellowships* make sense in view of the large number of submissions. We **appreciate the lump sum financing** which makes **administrative management simple** and consider the funding levels to be attractive. For the *MSCA and citizens* tool, which brings the lay public closer to science, we propose to **encourage the promotion of major scientific advances made possible thanks to European funding**, so that citizens better understand the importance of supporting research at the European level. This involves presenting very concrete successes that speak to the lay public, because they have an impact on their daily lives.

Comments on Infrastructure are set out below.

Pillar 2: Global challenges and European Industrial Competitiveness

The **organisation of Pillar 2 into thematic clusters allows for good readability,** and it is important to **maintain a strong health cluster** in view of the challenge it represents for European citizens. Within the health cluster, current **destinations should be replaced by** the following **7 thematic health priorities** for greater efficiency and comprehensibility:

- diseases linked to the ageing of the population,
- non-communicable diseases (metabolic diseases, cancers, immune diseases, cardiovascular diseases, hepatogastric diseases, osteoarticular diseases and respiratory diseases),
- brain health,
- pandemics and antimicrobial resistance,
- rare diseases,
- environmental health,
- technologies at the service of health.

It is appropriate for the EU to establish strategic axes and objectives for each thematic priority, but Inserm wishes to find in pillar 2 collaborative calls for proposals that are very open to the thematic health priorities addressing the common challenges Europe will face, and to possibly leave room for what is not covered by national priorities. Such *bottom-up* funding for upstream research (TRL 1 to 4) in pillar 2, should represent 20% of the 10th FPRI funding. In the next FPRI, more funding is needed for research in pathophysiology, to deepen our knowledge of disease mechanisms, a prerequisite for developing innovative prevention, diagnosis and treatment strategies. It is therefore necessary to **reintroduce the funding of fundamental research actions.** In fact, after an ERC, there is usually still a lot of prospecting to be carried out before the research turns into innovation.

Inserm believes that a **steering committee** should be set up **for each cluster** to **analyse the coherence of the programme** regarding the EU's objectives, the priorities of the Member States and the expectations of the citizens. The mission of these steering committees would be to establish joint calls for tenders with other clusters (Digital and Artificial Intelligence cluster, for example) or other DGs (DG Connect, DG Health) to address major societal challenges, while avoiding redundancies between funding tools. Each cluster, depending on its level of transversality, would be set a target for joint calls for tenders to create synergy, increase interdisciplinary work and enhance the overall coherence of the programme. For the whole program to work smoothly, there is also a need for more feedback on project evaluations from the executive agencies to the programming agencies and steering committees.

We are convinced that co-financed partnerships must continue, but their number needs to be mastered, and they should be included for the health cluster, in one of the health priorities as much as possible. Two partnerships per health priority seems to be an appropriate number. Partnerships with delegation of programming to national agencies must **promote strategic alignment between European and national policies**, and benefit from significant funding over a long period, such as 7 years, **with the aim of making significant progress** for the benefit of European society **in their fields**. Inserm would like to see certain partnerships link up with national initiatives to promote better coordination of policies at the European level. Partnerships are particularly well suited to work on rare diseases or to provide solutions to major problems that transcend national borders such as epidemics, or to issues requiring large cohorts. We also believe that, when structured networks bring added value to research teams or citizens, they should be able to apply for calls for tenders to be sustainable.

Without an automatic follow-up, Europe must provide long-term support to the unifying initiatives that work best.

Given that **Missions** cover a wide range of fields not always related to research, they **could play the role of conductor, with the authority to influence the existing instruments** in the various DGs in order to make coordinated progress on a given issue. Therefore, Inserm is wondering whether their place is within the 10th PCRI, or rather in a broader supervisory body. The institute managed the coordination and support action (CSA) UNCAN.EU which issued, among other recommendations, to launch a future call with '*use-cases*'. One of the calls that appears in the work programme takes up this point, but it seems too broad to us. Even if the Missions calls encompass a broad vision, the research projects must remain of an acceptable size to be effective. The integration of the results of various projects must then be carried out by Programme Managers as at the European Innovation Council (EIC). These people, because of their skills, are able to initiate joint meetings, push the reflections, and propose the next steps. Alternatively, the coordination of results could involve the launch, in a second phase of a CSA for scientific project leaders.

The ***Innovative Health Initiative (IHI)*** **institutional partnership must be pursued in a** transparent **co-construction approach**, as interactions with industrial partners are currently very difficult, especially for one-stage calls. To bring together the private and academic sectors on low-TRL research projects, our proposal is to launch **calls for expressions of interest** at the request of industrialists able to provide 45% of the co-financing of the project budget, followed by a **connection with academics, to then authorize the submission of collaborative projects evaluated independently**. These two-stage calls of the IHI partnership should be part of the 7 health priorities identified to maintain good readability and coherence. In addition to this, the IHI could propose a call for tenders for 'European joint laboratories' between academics and industry.

The Global Health European and Developing Countries Clinical Trials Partnership (**GH EDCTP**), the main partnership between EU Member States and low- and middle-income countries, **should be continued**. It makes it possible to mobilise particularly substantial funding for European research teams working in partnership with teams in sub-Saharan Africa. The 11th EDCTP Forum held in November 2023 highlighted the involvement of European and African partners such as the Africa CDC. In the FP10, the links between the GH EDCTP Partnership and other co-funded partnerships implementing clinical trials need to be continued and strengthened.

Pillar 3: Innovative Europe

Inserm calls for **the continuation and improvement of the European Innovation Council (EIC).** For instance, the EIC could propose the deployment of tools, such as living labs to evaluate feedback from first users of a solution. On the other hand, it is recommended to **reconsider the positioning of the European Institute of Innovation (EIT),** whose project set-up and management are complex, and currently unsatisfactory according to various sources. Therefore, we propose to merge EIT with the EIC.

The EIC must continue to fund disruptive innovation with its *Pathfinder* programme. The *Transition* and *Accelerator* programmes must be more open to support high-quality research with industrial purposes. The **success rate of the Pathfinder program is too low**. A success rate of at least 15% is recommended by allocating more budget to this instrument. The *Transition* programme should not be

restricted to projects already supported by European funding. Additionally, it must also support more validation of therapeutic targets because this is a prerequisite now demanded by manufacturers before any investment in a health project. Beyond that, for a better readability of the PCRI, it is necessary to homogenize and simplify the rules between the different programs. For example, why not offer the same grant amount between the *Pathfinder open* and the *Pathfinder challenges*. Finally, while the themes of the *Pathfinder challenges* calls for tenders were quite broad at the beginning of the Horizon Europe programme, they are now increasingly specific. Inserm would like the EIC to offer more open calls.

The EIC *Accelerator* could be a 2-stage support system in articulation with the national/regional relays (BPI in France...). The first stage would aim to support the development of the product on a small scale and the other stage would aim to scale up production, which remains a major challenge for young innovative European companies. As part of this scheme, the European Innovation Ecosystems (**EEI**) programme in partnership with the EIC **will ensure that regions develop coherent and complementary specialisation ecosystems to promote** the implementation and **growth of industrial treasures in Europe**.

Horizontal pillar

In the FP10, it is necessary to maintain a widening programme promoting access to excellence for Europe's enlargement and outermost regions in the transversal axis, to help them join some FP10 projects already funded, provided that they bring added value to those projects.

Research infrastructures should also be included in the cross-cutting axis to promote synergies between pillars. **Little is known about** the activity and service provided to the community by the **research infrastructures** labelled in the roadmap of the European Strategy Forum on Research Infrastructures (ESFRI). The **evaluation of European infrastructures** in bio-health **highlights minimal benefits**, with a very large majority of teams never mentioning significant contributions to strategic projects. As most research infrastructures are now mature, it is necessary to **analyse the support they provide to research projects** to verify that they meet a still proven need. A revised ESFRI model should focus on **improving the most widely used equipment** in major health research sites to maximize our investments. Challenges also remain, for distributed infrastructures excluded from the scope of the European Research Infrastructure Consortium (ERIC), creating difficulties in terms of staff allocation and funding. The analysis of funding instruments also raises concerns. We therefore need to **rethink our approach to maximize the impact of our research infrastructures** while ensuring the wise use of resources. It is crucial to further **encourage the use of infrastructure in research projects** to bring them closer to researchers, while limiting these European infrastructures to what cannot be achieved nationally. To achieve this, a significant part of the infrastructures' budget must come from their involvement in FP10 research projects. The development of new infrastructures will occur in a very targeted manner to meet emerging needs. For example, an infrastructure for validating biomarkers for personalised medicine and prevention would provide added value at European level. There is also a need to strengthen the infrastructures for storing and processing data in health biology. It is therefore important to continue to allocate specific funds to support the **modernisation and expansion** of IT research-dedicated infrastructure accessible via the *cloud*, with a focus on strategic areas such as healthcare, life sciences and emerging technologies. To this end, financial incentives should be

established to encourage research organisations to invest in improving their infrastructure and making it more accessible to European researchers.

The main **objective of the Joint Research Centre** (JRC) for the biomedical field **should be to improve the reproducibility, interoperability and sustainability of health research data** by being placed in the transversal axis. The JRC could fund and participate in multi-center pre-clinical trials as well as the establishment of standardised study designs. We propose that it contributes through specific calls for proposals to develop standards to increase reproducibility, improve interoperability and ensure the sustainability of research data. This, in turn, could lead to the establishment of common European guidelines for the management of research data, including the creation of data management plans (DMPs), to ensure their integrity, security and long-term availability, as well as source codes. The JRC should also develop training and awareness-raising programmes for researchers, health professionals and policymakers on best practices in data management, research ethics and responsible innovation.

The long-term storage of data from European projects is a major challenge for the future. The Commission has taken up the issue of health data, but much remains to be done for research data, the quantity of which is growing very rapidly. Research organisations should be financially encouraged to develop interoperable research cloud infrastructures, making it possible to offer at the European level a federation of high added-value services based on the contribution of artificial intelligence (AI) and big DATA. Europe supports the European Open Science Cloud (EOSC) infrastructure project, but its work is not very pragmatic. Directives with clear and concrete objectives should be promulgated in the European programme.

It is also important to allocate specific funds to support the **fostering of the skill of health research teams on AI, particularly in deep learning and big data, and to develop dedicated European competence clusters. For translational research, efforts need to be devoted to explainable AI** (XAI; an AI system over which it is possible for humans to maintain intellectual oversight). To train AI models, for example in the field of cancer, some international consortia are making available matched data used mainly for training models in a research setting, such as the Cancer Genome Atlas (TCGA), the International Cancer Genome Consortium (ICGC), the European Genome-Phenome Archive (EGA) and the Molecular Taxonomy of Breast Cancer International Consortium (METABRIC). This is insufficient in view of the volume of data required and the multitude of issues that models will have to address on well-calibrated data.

Organizing the **collection of multimodal and multi-scale information** to have large matched datasets **is a major challenge**, and already a project initiated by several state institutions that the next **PCRI should promote**.

Tomorrow's health challenges and the obstacles to be overcome for competitive research for health

Climate change, changing lifestyles, ageing populations and associated diseases will place an increasing burden on our health care systems. It is therefore necessary to prevent today to treat effectively and quickly tomorrow. This requires the identification of a growing number of biomarkers, and the development of personalized and precision regenerative medicine. Biomedical research will develop very rapidly in the coming years with the rise of AI, new high-throughput analysis techniques, advances in imaging and targeted vectorization. Multidisciplinarity will be important to remove technological

barriers. Even if certain health issues such as antibiotic resistance, metabolic diseases or neurodegenerative diseases are foreseeable, we must also have the capacity to meet other challenges, as yet unidentified, and that will arise during the course of the program. The **10th FPRI must** therefore strike a **balance between predictability and flexibility to adapt** and publish calls for projects quickly in the event of a new **health crisis** or according to the **progress of discoveries**. Inserm is calling for the 10th PCRI to continue to fund research using animals, while encouraging the use of alternative methods where possible.

For **European clinical trials**, even if there is the Clinical Trials Information System (CTIS) which makes things easier, **Inserm is asking for simplification and standardization procedures** at the regulatory and administrative level, which remain, particularly for start-ups, a real obstacle to development. This requires, for example, facilitating procedures for long-term cohort studies in the general population, which are essential for identifying risk or protective factors. For greater efficiency, it must also be easier to reuse health data and biological samples for another study, if patient consent is obtained.

For the smooth running of projects, the project officers in charge of monitoring the programmes must be better chosen, to be able to fully understand the issues of biomedical research and facilitate the progress of the projects. Apart from the technical aspects, the financing of clinical trials remains very complicated for European projects with, when they exist, often insufficient funds. The ideal situation would be to allocate the entire budget to the recipient partner of the funding (sponsor), who would be responsible for redistributing it to the other recruiting centres or contract research organisations (CRO) involved in the form of subcontractors, as each site has its own business model and costs vary greatly depending on the country.

An open funding system for upstream research while preserving our sovereignty

The 10th FPRI should offer funding opportunities **open** to countries outside Europe **for upstream research, but** more **focused on European interests when it finances innovation and the exploitation of research results**, for greater industrial returns. For upstream research, we need to be pragmatic and develop collaborations with countries that have a high standard of research, that share the same values as us, that offer well-defined reciprocal funding agreements and with which we have historical links. **In terms of innovation**, Inserm recommends **promoting industrial and commercial exploitation in Europe of the research work funded by the PCRI,** to preserve our sovereignty and keep the innovative companies that are inventing the world of tomorrow. We are convinced that Europe must remain open to the countries of the South with which we already have links, to enable them to increase their level of health research and prosper economically.

Administrative aspects

Inserm is calling for the **simplification of** the submission and management **procedures** in FP10 to lighten the administrative burden and provide greater readability.

The project financial management system generates too much administration to the detriment of research resources. At first glance, the lump sum system currently being tested, seems simpler and more attractive for researchers, but it is of great concern to support functions, for whom management based on real costs remains more appropriate. Indeed, there is every reason to **fear that *lump sums* will generate a considerable increase in managerial work** at the time of set-up and then in the follow-up of projects, which will have to be passed on. There is also a fear that the financial package will become a major factor in the evaluation of projects at the expense of the quality of science. Inserm also does not want project leaders to have to validate their partners' expenses. We believe that it is up to the funder to do so. In addition, reports are often turning into audits. To avoid this, it is necessary for project managers to be better trained in research professions. These project managers must also have sufficient time and be stabilized in their functions, to properly monitor the projects, and support the most successful ones towards financing that will make it possible to sustain certain consortia. To simplify and standardise procedures, the **Commission should propose** or validate **models of unit costs of expenditure a priori**, to simplify financial management and the risk of problems in the event of an audit. Lump sum grants, as is the case with MSCA funding, are very suitable for us. If the Commission decides to generalise lump sums, this will require more time for the projects to be put together. More generally, it is requested that the calls for projects be opened much further upstream with a more linear distribution of the number of calls proposed over the years in each area and to **give priority to calls in 2 stages.**

It is good to limit the maximum number of pages for the scientific part (part B), but more flexibility in the number of pages in the administrative part (part A) is needed for the description of the partners, because on large consortia this sometimes requires several teams to be grouped together to respect the space allotted. Nevertheless, Inserm wants science to remain the key element of the projects.

Non-directed overheads at a rate of 25% for academic co-funded projects are currently suitable for Inserm. On the other hand, this rate appears to be insufficient if the committee generalises lump sums and if it is desired to involve SMEs in subjects for which they would not otherwise have co-financing.

Relations between FP10 and HERA

The European Health Emergency Preparedness and Response (HERA), was created by the European Commission following the Covid crisis on the model of the American BARDA to anticipate threats and potential health crises. HERA was set up as the new Directorate-General of the European Commission on September 16th, 2021, to fill a gap in the EU's response and preparedness to health emergencies.

Inserm believes that if HERA must be able to coordinate the different aspects of health emergencies from preparedness to implementation, and if HERA must also be able to ensure that companies take ownership of technologies or that supply chains exist, it must invest in research in non-crisis periods to ensure that the various scientific options to solve a new crisis are present Europe. To succeed in this point, it is necessary for research to be present at a high level in the governance of HERA. To this end, representation by the Ministry of Research is important but other major players in the field (such as the ANRS-MIE or the pandemic prepardness partnership) should also be present in governance bodies. In addition, it is important for HERA to have its own budget in the future, which is not currently the case. But with the aim of simplification and overall cohesion, the research part of this budget must be placed within FP10 to maintain a one-stop shop and uniform rules for participation and management.