



Call for the Public-Private Partnerships Innovation Subsidy Scheme

1. Summary

The Dutch Ministry of Economic Affairs and Climate Policy stimulates public-private partnerships (PPP) via the PPP-Programs 2025 for Research and Innovation made available by the Top Sector Life Sciences & Health (LSH) and managed by the communication portal <u>Health~Holland</u>. With these programs, consortiums of researchers and companies are encouraged to invest in joint research and development.

<u>The IMPACT PPP Program</u>, a result of the long-standing collaboration between Erasmus MC and UMCG, aims to support collaborations with private partners. The program falls under the framework of the <u>PPP Allowance Regulation</u> of the Dutch Ministry of Economic Affairs and Climate Policy and the National Regulation Economic Affairs Subsidies (Ch. 3 Innovation and Entrepreneurship, Title 3.2 PPP-allowance and innovation).

IMPACT Program description.

The IMPACT program aims to advance machine perfusion technologies for organ preservation, assessment, and repair. By collaborating with top institutions and private partners, it drives innovative solutions to improve organ viability, enhance regeneration, and reduce immunogenicity, strengthening the Netherlands' position as a global leader in transplantation.

Focus Areas of the IMPACT Program

The IMPACT Program will concentrate on four key areas of transplantation:

- Heart transplantation
- Lung transplantation
- Liver transplantation
- Kidney transplantation

With an emphasis on applied research, IMPACT supports the development of technologies with practical applications in industrial research, through collaborative projects between healthcare institutes and industry partners.

Contact: impactprogram@umcg.nl

2. Call requirements

- The research fits within the social theme 'Health & Care', the Central mission and one of the five focused missions, as described in the <u>Knowledge and Innovation Agenda (KIA) 2024-2027</u> of Top Sector LSH. (see Appendix 1).
- The research aligns with at least one of the abovementioned Program themes.
- The project consists of industrial research, experimental development, or a combination thereof (TRL 5 7).
- The project has a maximum duration of 4 years.
- Effective collaboration takes place.¹ The project is executed at joint efforts, costs and risks all consortium partners contribute to the project substantially.
- A collaboration agreement using the template approved by Health~Holland should be signed by the start of the project.
- At least one program partner (i.e. UMCG and/or ErasmusMC) must be part of the project consortium. Priority, in terms of scoring during the evaluation, will be given to projects involving both program partners. Particular attention will be given to projects arising from existing or previous collaborations, emphasizing the added value of extending those partnerships.
- The maximum PPS allowance for a single project is EUR 400,000. All consortium partners should make an in-kind contribution. This means, for example, but not limited to, all consortium partners must incur payroll costs and that

¹ Definition of 'effective collaboration' according to the <u>Framework for State aid for research and development and</u> <u>innovation</u>: 'effective collaboration' means collaboration between at least two independent parties to exchange knowledge or technology, or to achieve a common objective based on the division of labor where the parties jointly define the scope of the collaborative project, contribute to its implementation and share its risks, as well as its results. One or several parties may bear the full costs of the project and thus relieve other parties of its financial risks. Contract research and provision of research services are not considered forms of collaboration.





these costs are visible in the budget form. For projects involving large enterprises (RVO definition), a minimum of 20% cash contribution is required.

- Additional evaluation points will be awarded to projects collaborating with Dutch SMEs and/or strategically important partners (e.g., patient associations, NGOs, non-profit entities, end-users).
- Signed 'Verklaring geen onderneming in moeilijkheden' for every SME that applies for PPP Subsidy. Template to be downloaded from <u>RVO Verklaring Geen Onderneming in Moeilijkheden</u>

3. Financial terms.

Health~Holland encourages consortia to jointly design the activities and budget within the project, with both research organisation(s) and companies contributing equal content to the project. In addition, Dutch SMEs are given the opportunity to apply for PPP subsidy for their R&D activities.

A project can consist of a combination of two types of research: industrial and experimental (See Appendix 3 for definitions). Different funding rules apply: Table 1A shows the maximum amount of funding eligible to the project per type of research at partner level, and Table 1B presents the minimal contribution required per partner to the project.

Financial conditions

- The maximum PPS allowance for a single project is EUR 400,000.
- Research organisation may finance a maximum of 70% of their costs (e.g. personnel, consumables and the use of equipment etc.) with PPP subsidy in the case of fundamental/industrial research and a maximum of 60% of their costs in the case of experimental development.
- Dutch SMEs may finance a maximum of 60% of their costs (e.g. personnel, consumables and the use of equipment etc.) with PPP subsidy in the case of fundamental/industrial research and a maximum of 40% of their costs in the case of experimental development.
- All consortium partners should at least incur payroll costs.
- All consortium partners should make an in-kind contribution.
- A company that receives PPP subsidy **cannot** contribute in-cash to the project.
- The research organisation must contribute at least 10% of the total project costs.
- Depending on the type of research the enterprise(s) must contribute at least 15% to 30% of the total project costs. For projects involving large enterprises (RVO definition), a minimum of 20% cash contribution is required.
- The budgeted, subsidised costs are directly related to the **R&D activities**, and do not include non-eligible costs. (See Appendix 3)

| Max % PPP subsidy based on eligible | Industrial research | Experimental development | |
|-------------------------------------|---------------------|--------------------------|--|
| costs partner | | | |
| Research organization | 70% | 60% | |
| Dutch SME | 60% | 40% | |
| Large enterprises, non-Dutch SME, | 0% | 0% | |
| Dutch and non-Dutch other parties | | | |

Table 1.A: Funding by type of research at partner level

The percentages listed in Table 1.A are percentages taken over the total costs of the organization in question.

| Table 1. | B: Minima | contrib | utions at | project | level | |
|----------|-----------|---------|-----------|---------|-------|--|
| | | | _ | | | |

| Minimal contribution based on total | Industrial research | Experimental development | | |
|--|---------------------|--------------------------|--|--|
| project cost | | | | |
| Research organization(s) | min. 10% | min. 10% | | |
| For-profit and not-for-profit enterprise(s) | min. 15% | min. 30% | | |

The percentages listed in Table 1.B are percentages taken over total project costs.

Instructions Budget Form

A specific budget form is mandatory to use within the IMPACT Program. The budget form uses multiple built-in functions and redirects. Therefore, it is important to follow the instructions included (see the "Instructies" tab of the budget form). Please consult with the department financial officer for guidance on how to complete the budget. Given the financial conditions presented above, project budgets may not be finalized without additional negotiations among project





partners. A Business Developer of the Innovation Center and ErasmusMC Technology Transfer Office will be available to support the development of the proposal and the negotiations with the partners, when necessary.

4. Application procedure

The application procedure is set out in one phase. It is mandatory to use the application template forms provided by the PPP team. All templates are available for download at the IMPACT website: <u>The IMPACT PPP Program</u>.

| Phase | Timeline | Description |
|---|----------------------------|---|
| Contact and intake | Open, anytime | Contact impactprogram@umcg.nl to receive information, have an intake meeting to discuss your idea and receive the application documents. |
| Open Call for applications phase | 01/06 – 01/10 | If the project idea fits, the applicant is invited to apply. The applicant must fill out and submit the <u>application</u> and the <u>budge</u> t forms, as well as indicate the <u>status of contractual discussions</u> with the company. Complete application can be submitted at any time before 01/10/2025. |
| Evaluation and decision on the submitted applications | | The IMPACT Evaluation Committee will review the applications based on eligibility Call criteria (see Appendix 2). The IMPCT Front Office communicates the decision to the applicant. |
| | 01/12/2025 – 01/05/2026 | Parties are committed to start the project and all application documents are finalized. Ideally, the project collaboration agreement should be signed by 01/05/2026. |

5. Evaluation criteria.

Eligibility of application

Upon receipt of the application and budget forms, each will be screened for eligibility by the IMPACT Front Office within five working days. This eligibility check will verify the completeness of the dossier and the fitness to the general administrative requirements set out in this IMPACT Program Call. If the application is incomplete, the consortium will be given one opportunity to make the necessary adjustments and provide the requested information.

Evaluation of the application.

Eligible applications will be assessed by the IMPACT Evaluation Committee (7 people), which is composed by: representatives from the UMCG Innovation Center (2), Erasmus MC TTO (2), External Experts (2), and a patient representative. The detailed description of the evaluation committee, time of evaluation and notes of the process will be accounted in the evaluation checklist, which can be made available to the applicant, upon request. Applications will be assessed for content and quality of the research on the basis of the evaluation criteria layout in Appendix 2.

Monitoring of awarded proposals.

The IMPACT Program is required to report once a year to Health-Holland. The Program Coordinator will get in contact to enquire about:

- The status of the project (project development and any important updates)
- Deliverables to declare (monitoring of results, publications, patent or spin-off potential)
- Please note that the Ministry of Economics (RVO) may audit your project for further controls. In that case, the coordinator will get in contact with additional questions.

End of the project / Final reporting.

At project termination, a report with an outline of the project results and the complete (audited) financial overview should be provided to Health~Holland for the final review. The definitive amount of PPP subsidy allocated to the project will be recalculated based on the final financial report.





Information available in the appendixes.

- Appendix 1: Definitions Social theme, Missions and documents to consult.
- Appendix 2: Evaluation criteria.
- Appendix 3: Information on type of research, TRL levels, Publications, Open access, Data management, FAIR principles, User participation, HI-NL Round table service.
- Appendix 4: Examples of ineligible costs and third party costs.

Appendix 1: Definitions Social theme, Missions and documents to consult.

Social theme 'Health & Care'

In the spring of 2019, the Ministry of Health, Welfare and Sport (VWS) established five missions for the social theme Health & Care. One central mission and four focused missions. The central mission focuses on living in good health longer, while reducing health disparities between people of high and low socioeconomic status. The other four missions contribute to this central mission through changes in the living environment, providing more care in the right place and better prospects for people with chronic diseases and dementia. The missions have a time horizon extending to 2040. In the fall of 2023, a fifth focused mission was added aimed at societally disruptive health threats. The Knowledge and Innovation Agenda 2024-2027 (KIA) describes the ambitions and goals on the health and care missions within the field of public-private partnerships. As lead party, the Top Sector LSH has prepared this KIA together with many public and private stakeholders. The process involves building on a powerful ecosystem of public-private partnerships that has been established in recent years. A large number of these stakeholders have committed themselves to the objectives of the KIA by means of in mind, in kind and in cash contributions to the Knowledge and Innovation Covenant (KIC).

Missions of the Top Sector LSH

- <u>Central Mission</u>: By 2040, all people in the Netherlands will live at least five years longer in good health, while the health inequalities between the lowest and highest socio-economic groups will have decreased by 30%.
- <u>Mission I</u>: By 2040, the burden of disease resulting from an unhealthy lifestyle and living environment will have decreased by 30%.
- <u>Mission II</u>: By 2030, the extent of care provided to people within their own living environment will be 50% more than today or such care will be provided 50% more frequently than at present.
- <u>Mission III</u>: By 2030, the proportion of people with a chronic disease or lifelong disability who can play an active role in society according to their wishes and capabilities will have increased by 25%.
- <u>Mission IV</u>: By 2030, quality of life for people with dementia will have improved by 25%.
- <u>Mission V</u>: By 2035, the population is better protected from socially disruptive health threats.

Guidance documents

- Missions Health & Care document 2024-2027: <u>Missies Gezondheid & Zorg 2024 2027 (health-holland.com)</u>
- Health~Holland publication on Health & Care 2030: <u>Van toekomstbeelden naar toekomstgerichte actie voor</u> noodzakelijke impact | Health~Holland (health-holland.com)
- Knowledge and Innovation Agenda 2024-2027: <u>Kennis- en Innovatieagenda Gezondheid & Zorg 2024-2027</u> (fliphtml5.com)
- Knowledge and Innovation Convenant 2024-2027 <u>Knowledge and Innovation Covenant 2024-2027</u> <u>Covenant</u>
 <u>Rijksoverheid.nl</u>
- HI-NL Round table service, provided by Health~Holland: <u>About | Health Innovation Netherlands</u>





Appendix 2: Evaluation criteria.

Evaluation Criteria:

- The project aligns well with the Knowledge and Innovation Agenda 2024-2027 of the Top Sector Life Sciences & Health and herewith the contributions to the missions are well substantiated.
- Administrative and registration information is complete.
- The project's time schedule is realistic.
- The research is well described, aligned with the IMPACT Program themes and the goals of the project are clear.
- The intended methods, with respect to feasibility, have been properly chosen and substantiated.
- The project is innovative and provides new scientific insights.
- The project meets societal needs, and the societal importance is well substantiated.
- The economic impact and importance of the project is well described and this impact is of value to the (northern) Netherlands.
- The economic added value of the project for each consortium partner is well substantiated.
- The consortium has the appropriate expertise, network, manpower, facilities and resources to ensure a successful outcome of the project. The different roles of the consortium partners are complementary and well defined and effective collaboration takes place.
- If applicable, the number of subjects and/or laboratory animals are realistic and adequate.
- The work plan is worked out in sufficient detail, including timeline, milestones and deliverables. The work packages are clearly linked and well aligned with each other.
- The risks of the project have been properly assessed and adequate consideration has been given to how these risks will be dealt with.
- Data are properly handled within the project.





Appendix 3: Information on type of research, TRL levels, Publications, Open access, Data management, FAIR principles, User participation, HI-NL Round table service and examples of ineligible costs

Definitions of type of research

Fundamental research means experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any direct commercial application or use in view.

Industrial research means the planned research or critical investigation aimed at the acquisition of new knowledge and skills for developing new products, processes or services or for bringing about a significant improvement in existing products, processes or services. It comprises the creation of components parts of complex systems, and may include the construction of prototypes in a laboratory environment or in an environment with simulated interfaces to existing systems as well as of pilot lines, when necessary for the industrial research and notably for generic technology validation.

Experimental development means acquiring, combining, shaping and using existing scientific, technological, business and other relevant knowledge and skills with the aim of developing new or improved products, processes or services. This may also include, for example, activities aiming at the conceptual definition, planning and documentation of new products, processes or services. Experimental development may comprise prototyping, demonstrating, piloting, testing and validation of new or improved products, processes or services in environments representative of real life operating conditions where the primary objective is to make further technical improvements on products, processes or services that are not substantially set. This may include the development of a commercially usable prototype or pilot which is necessarily the final commercial product and which is too expensive to produce for it to be used only for demonstration and validation purposes. Experimental development does not include routine or periodic changes made to existing products, processes, services and other operations in progress, even if those changes may represent improvements.

Please note that in case of drug development, pre-clinical research in animals falls within the research category 'industrial research'. In principle, the clinical phases 1 and 2 fall within the research category 'experimental development'. Phase 3 clinical trials (and beyond) are seen as competitive development and fall outside the scope of the PPP Subsidy Regulation.

| TRL | Definition | Type of research |
|-------|---|--------------------------|
| TRL 1 | Basic principles observed | Fundamental |
| TRL 2 | Technology concept formulated | Fundamental |
| TRL 3 | Experimental proof of concept | Fundamental |
| TRL 4 | Technology validated in lab | Fundamental |
| TRL 5 | Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies) | Industrial |
| TRL 6 | Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies) | Industrial |
| TRL 7 | System prototype demonstration in operational environment | Industrial/ Experimental |
| TRL 8 | System complete and qualified | Experimental |
| TRL 9 | Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space) | Experimental |

Technology Readiness Levels

Publication requirements.

It is mandatory to acknowledge the PPP IMPACT program and Health Holland in all external communication about the project. For all publications (i.e. papers, webpages, posters, presentations, reports.). During the course of the project, it is recommended that in every publication or deliverable that comes from an activity which is partly financed by the PPP subsidy, the following words (or similar) should be mentioned: "The collaboration project is financed by Ministry of





Economic Affairs and Climate Policy by means of the PPP subsidy made available by the Top Sector Life Sciences and Health to stimulate public-private partnerships."

Open access.

In accordance with the Health~Holland and the UMCG guidelines, the research results that are (partially) funded with PPP subsidy should be freely accessible worldwide. All scientific publications of research funded by PPP subsidy should therefore immediately (at the time of publication) be freely accessible worldwide (open access).

FAIR principles.

Data should be stored according to the FAIR principles: findable, accessible, interoperable and reusable. This means that the data generated in the projects can be found, understood and used by both humans and machines.

Data Management Plan.

Applicants should answer a number of questions on Data Management in the application form. Once a project is awarded, applicants need to prepare a data management plan. This is a mandatory requirement for the project. The respective Research Institution's approved Data Management Plan template can be used for this purpose.

Patient/end-user participation & Inclusivity

Inclusivity entails paying attention to diversity and differentiation of the target groups concerned, including characteristics as sex, age, socio-economic status (SES), level of education, migration, cultural background, and sexual orientation, to the extent these are relevant for the theme of the project.

The applicant will be asked to provide a description of plans and activities on how the project takes into account relevant differences between people and how citizens in their role as patients, end users, clients, and/or loved ones are involved in the design, execution, and dissemination/implementation of the project.

Innovation guidance - HI-NL Round table service

Health~Holland provides guidance for innovation trajectories and MDR/IVDR certification through the HI-NL Round Table Services. The applicant will be asked to answer questions about this trajectory and whether the consortium plans to engage with the provided services during the course of the project.

Examples of ineligible costs

The following are examples of ineligible costs. Therefore, these costs should not be entered on the budget form.

- Applying for and maintaining patents (costs for patents purchased on arm's length terms from or licensed from outside sources are eligible);
- Auditor's statement;
- Benchfee (note: costs for consumables are eligible);
- Travel within the Netherlands;
- Support staff, not directly related to the R&D activities, such as: project controller, business developer, administrative officer;
- Preparation of a business case;
- Costs related to implementation of the developed innovation;
- Carrying out effectiveness studies (Health Technology Assessment, HTA);
- Non-scientific dissemination. However, scientific dissemination, including attending a scientific congress or publishing a scientific article, is eligible;
- Project management tasks, not directly related to the specific R&D activities, such as: escalation to a steering committee, preparing a risk management model, preparing reports to meet funding obligations, administrative accountability. Project management tasks that do relate directly to the R&D activities (e.g., discussions with staff, analyzing technical risks, preparing research reports, preparing specifications) are eligible.