

TKI Life Sciences & Health

TKI LSH Pilot Call for public-private partnerships in 2024

Call for applications for PPP Innovation subsidy at the Top Sector Life Sciences & Health

NOTE: This call is for the Pilot Call only with a deadline of October 1, 2024.

1. Summary

The Top Sector Life Sciences & Health (LSH) promotes innovative research by (financially) supporting public-private partnerships (PPPs) in the LSH sector. With this Pilot Call, research organizations and companies are encouraged to collectively invest in research & development (R&D) with the aim of developing sustainable innovative products and services within the LSH sector. The Top Consortium Knowledge and Innovation (TKI) office is the executive body of the Top Sector LSH and can financially support a collaborative project by awarding PPP Subsidy.

As of 2024, the 'PPP Research and Innovation regulation' will change into the 'PPP Innovation Subsidy Regulation'¹. Among other things, this amended regulation includes new funding conditions. In this Pilot Call the Top Sector LSH will provide €7.5 million in PPP Subsidy in 2024 to enable parties to gain experience with the structure of the new regulation and the associated financial conditions.

Key requirements:

- The research fits within the central mission and one of the five focused missions that contribute to the central mission as described in the <u>Knowledge and Innovation Agenda (KIA) 2024-2027</u> of Top Sector LSH.
- The consortium consists of at least one for-profit enterprise and one research organization.
- The project is executed at joint cost and risk and all consortium partners contribute to the project substantially.
- The project consists of fundamental research, industrial research or experimental development, or a combination thereof.
- The main applicant is based in the Netherlands, and the project has a maximum duration of 4 years.

The deadline is <u>October 1, 2024 CET 17:00</u> at which time new applications will be reviewed and considered. Allocation will be based on the following criteria and the corresponding sections of the application form:

- Appropriateness within the PPP Innovation Regulation;
- Scientific quality (section B);
- Impact and relevance (section C);
- Feasibility (sections B and D);
- Appropriateness within the missions of VWS (section E);
- Reduction of health disparities (section E);
- Involvement of end users (section E);
- Added value to the strategy of the Top Sector LSH (section C and E);

In addition, leading up to the deadlines, consortia may request a personal meeting with a Health~Holland representative in order to solve consortium or application specific questions. These requests can be made up to three weeks prior to the respective deadline by sending an email to tki@health-holland.com. Please include: "Request Pilot Call application advice" in the subject line.

¹ https://www.rvo.nl/subsidies-financiering/pps-innovatie



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2. Background Information

2.1 Background Top Sector LSH

In 2011, the Dutch Cabinet at the time reformed business policy by launching the top sectors policy. The success of the top sector policy led the Rutte III administration to decide that the top sectors should act as a "tool" in the mission-driven top sector and innovation policy. Herein, four societal themes are defined, and consideration is given to key technologies and key methodologies, and societal earning potential. One of the societal themes is "Health & Care".

Top Sector LSH promotes and facilitates public-private partnerships. The interdisciplinary collaboration from top scientific expertise is, after all, essential to achieve socially relevant and economically efficient innovations. To promote (new) PPPs in 2024 through the new PPP Innovation Regulation, the Pilot Call was created. This call is executed by the Top Consortium Knowledge and Innovation (TKI) of the Top Sector LSH: TKI-LSH. TKI-LSH is registered at the Chamber of Commerce under the name 'Stichting LSH-TKI', but is better known as Health~Holland (branding name)

In the Pilot Call, companies and recognized research organizations are invited to jointly invest in R&D for evidence-based innovative products and services. In addition, the Pilot Call offers other parties, such as health funds and health insurers, the opportunity to co-invest and innovate.

The aforementioned arrangement falls within the framework of the PPP Innovation Regulation of the Ministry of Economic Affairs and Climate.

2.2 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).

2.3 Key enabling technologies and key enabling methodologies

In addition to the four societal themes, the Dutch government also focuses on key enabling technologies (KETs), for future economic opportunities. In addition, the Top Sectors are encouraged to make targeted technological contributions to solving societal challenges. The Top Sectors together with the ministries and knowledge institutions are realizing these efforts through the Knowledge and Innovation Agenda Key Technologies (KIA-ST). The research agenda Key Enabling Methodologies (KEM) is part of the KIA-ST. It sets out a broad interpretation of the concept of key methodologies (KEMs) and presents the most relevant categories of KEMs for mission-driven innovation. The KEMs constitute the new toolbox needed for the creation of societal innovation in the form of models, strategies, processes, and tools. More information can be found on the KEM website and for further questions regarding the deployment of and research on KEMs, please contact CLICKNL: kems@clicknl.nl.



3. Terms and conditions

3.1 Terms and conditions for the collaborative project

The application must meet a number of conditions. Important aspects in this regard are:

- The main applicant is based in the Netherlands.
- The consortium consists of at least one for-profit enterprise and one research organization². Foreign for-profit enterprises and research organizations are encouraged to participate in the consortium; as long as the results of the research project benefit the Dutch knowledge infrastructure and economy.
- Effective collaboration takes place³. This means, among other things, that the project is carried out at joint cost and risk and that all consortium partners make a substantive contribution to the project.
- The project consists of fundamental research, industrial research or experimental development, or a combination thereof⁴. A description of the three types of research is described in Appendix D of the application form.
- The research fits within the social theme 'Health & Care', the central mission and at least one of the five focused missions that contribute to the central mission of this theme, as concretized in the KIA 2024-2027 Health and Care, and the objectives of the regulation.
- The research is of high scientific quality.
- The project deliverables are innovative products and services that add social and economic value.
- All consortium partners should make an in kind contribution. This means, for example, that <u>all</u> <u>consortium partners must incur payroll costs</u> and that these costs are visible in the budget form (Excel).
- In addition to the aforementioned in kind contribution, it is possible to contribute in cash. If an enterprise contributes in cash, it is required to be an in cash contribution owed to the research organization in the Netherlands (and not to the project concerned).
- Consortium partners may not hire or compensate each other for services or products within the project.
 Consequently, consortium partners may not invoice each other. Third parties may be hired for services; they are not consortium partners.
- In principle, it is up to the enterprise(s) how they finance their own contribution. However, we strongly advise against creative constructions; improper use of PPP subsidy by consortia must be prevented at all times, e.g. using PPP subsidy and making an in cash contribution by the same party.
- If the consortium has received or will receive other public grants for the submitted project, for example from NWO, ZonMw, TNO, TTW or Health~Holland, the regulation regarding cumulation of different grants applies⁵.
- The project starts no later than May 1, 2025
- The project has a maximum duration of 4 years.

² Definition of research organization according to the <u>Framework for State aid for research and development and innovation</u>: 'research organization' means an entity (such as universities or research institutes, technology transfer agencies, innovation

intermediaries, research-oriented physical or virtual collaborative entities), irrespective of its legal status (organized under public or private law) or way of financing, whose primary goal is to independently conduct fundamental research, industrial research or experimental development or to widely disseminate the results of such activities by way of teaching, publication or knowledge transfer. Where such entity also pursues economic activities, the financing, the costs and the revenues of those economic activities must be accounted for separately. Undertakings that can exert a decisive influence upon such an entity, for example in the quality of shareholders or members, may not enjoy a preferential access to the results generated by it.

³ Definition of 'effective collaboration' according to the <u>Framework for State aid for research and development and 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.

⁴ In case of drug development, pre-clinical research in animals falls within the research category 'industrial research'. In principle, 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.

⁵ The accumulation provisions are stated in Section 2, article 6, of the <u>Framework Decision National Grants of the Ministry of Economic Affairs</u>. The support limits with respect to the acquisition of PPP Subsidy are stated in article 3.2.5 of the <u>Regulation National Grants of the Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture, Nature and Food Quality.</u>



 Pilot call specific versions of the application form, budget form and consortium agreement have been used, provided through the TKI or PPP contact within your organization. Outdated or other versions of these documents will not be accepted.

3.2 Consortium composition

PPP subsidy applicants compose a consortium in which research organizations and for-profit enterprises, and preferably also relevant public organizations, while retaining their own identity and responsibility, jointly realize a project based on a clear and optimal division of tasks and risks. All consortium partners make an equitable financial and substantive contribution to the project. The consortium will provide a project coordinator (also main applicant), who will be Health~Holland's contact person throughout the entire project. The main applicant can be either a research organization or a for-profit enterprise. Any other party within the consortium is a coapplicant. The regulation is open to co-applicants from the Netherlands and abroad, both research organizations, for-profit enterprises and other private or public parties, as long as the research contributes to the Dutch knowledge infrastructure. It's possible that multiple companies, research organizations and additional parties may be affiliated with the consortium.

3.3 Intellectual property policy

The consortium must reach agreements on the intellectual property (IP) related to the products and services developed in the project. These agreements are recorded in the consortium agreement. A 'first option right' is among the possibilities. Agreements on IP follow the <u>Framework Regulation on State Aid for Research, Development and Innovation</u> (specifically article 2.2.2.) and the PPP Innovation Regulation (<u>Staatscourant October 20, 2023, 28651</u>). These state, amongst other matters, that enterprises and other private partners that participate in the project may acquire the IP from the research organization for a market-based fee (minus the amount already invested by them) and that results from which no intellectual property rights can be derived may be widely disseminated. The model consortium agreement for the Pilot Call has been made available through the TKI or PPP contact within your organization.

Note: Use of the model consortium agreement made available for the Pilot Call is mandatory. Any modifications in the model must be immediately recognizable to Health~Holland.

3.4 What amount of funding can be applied for?

Note: A PPP Subsidy or TKI contact person within your organization should always be contacted first. If the contact details of this person are unknown to you, please contact Health~Holland as soon as possible.

Within this call, funding (PPP subsidy) may be applied for by parties that have built up and deployed PPP allowance on the basis of the "grondslag" in recent years. The parties are divided into three groups, based on each party's average generated PPP allowance from the "grondslag" 2020, 2021 and 2022. For each group, a maximum amount of PPP subsidy has been determined that can be applied for by each party in this group. Please contact your PPP subsidy or TKI contact for the amount of PPP subsidy available to your organization.

Research organizations, such as universities, UMCs, universities of applied sciences, TO2s, KNAW institutes and other organizations that meet the definition of research organization, may fund up to 70% of their **own costs** with PPP subsidy in the case of fundamental and industrial research. Research organizations may fund up to 60% of their **own costs** with PPP subsidy in the case of experimental development. Dutch SMEs (for-profit and not-for-profit enterprises⁷) may fund up to 60% of their **own costs** using PPP subsidy to conduct fundamental and industrial research. Dutch SMEs may finance up to 40% of their **own costs** with PPP subsidy to conduct experimental development.

Table 1.A shows these maximums in more detail. A project can consist of a combination of the three types of research. Health~Holland encourages consortia to jointly organize the activities and budget within the project, with both research organizations and enterprises contributing equally in terms of content to the project. In addition, Dutch SMEs are given an equal opportunity to apply for PPP funding for their R&D activities.

⁶ All eligible costs incurred by that particular partner, except any in-cash contributions.

⁷ Each unit, irrespective of its legal form or manner of funding, that carries out an economic activity. See Appendix A: Definition of enterprise in the application form.



Large enterprises (Dutch and foreign), foreign SMEs and Dutch and foreign other parties are not permitted to apply for PPP subsidy; the expenses they incur should be equal to the in-kind contribution they provide.

Table 1.B shows the minimum percentage of the **total project costs** that must be contributed by the research organization(s) and enterprise(s) in the project. Section 5.1 provides two calculation examples applying the funding requirements to two different types of consortia.

Table 1.A: Funding by type of research

Partner level

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

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

Table 1.B: Minimal contributions

Project level

Minimal contribution based on total project cost	Fundamental and industrial research	Experimental development	
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.

3.5 Calculating project costs

Eligible costs

Only those costs that are directly related to the R&D activities within the project (eligible costs) can be entered on the budget form. Examples include: scientific staff, technicians, support staff, consumables and the use of equipment specifically required for the project (depreciation system). Historical cost should be used when entering the cost of consumables. Entering commercial rates is not permitted. For an explanation of the (calculation of) eligible costs see the Commission Regulation (EU) No. 651/2014 of June 17, 2014, Article 25 and the Framework Decision National EZK and LNV Grants, Chapter 4, Article 10-14.

Parties that do not use PPP subsidy are not required to use one of the payroll costing systems prescribed by the <u>Framework Decision on National EZK and LNV Grants</u>. These parties may also use their own hourly rate. A condition is that the calculation of the costs takes place on the basis of a customary and verifiable method and is based on business principles and standards that are considered acceptable in society and that the participants in a collaborative project apply systematically. On the budget form, these parties should choose "fixed hourly rate" and adjust the standard hourly rate of EUR 60 to an hourly rate that is customary and verifiable for them.

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);
- Overhead;
- 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.

Costs attributable to third parties.

If some of the activities are subcontracted, those costs due to third parties can be allocated to the project and entered on the budget form. Care should be taken to ensure that the costs due to third parties are in proportion to the rest of the budget. Should this cost category be particularly high, this could influence and become part of the evaluation committee's assessment.

Instructions Budget Form

A specific budget form will be used within this Pilot Call. The budget form uses multiple built-in functions and redirects. Therefore, it is important to follow the instructions of the budget form (see the "Instructies" tab of the budget form).

3.6 Data management

Open access

Health~Holland believes that research results that are (partially) funded with PPP subsidy (public funds) 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). Via the website http://www.openaccess.nl/nl/node/644 you can check whether your organization has made agreements with traditional publishers regarding open access. Among other things, this website provides an overview of over 8,000 journals in which corresponding authors from Dutch universities and UMCs can publish in open access for free or at a discount. Costs associated with open access publishing fall under eligible project costs.

FAIR

Health~Holland encourages optimal use of research data and therefore requires this data to be stored according to the <u>FAIR principles</u>: 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. The process of making data FAIR is explained by the GoFAIR foundation in the <u>three-point FAIRification framework</u>. Health~Holland plans to expand its policy regarding FAIR data management in the future and will increasingly monitor the FAIRness of data.

Data management plan

Health~Holland also wants to raise awareness among researchers about the importance of responsible data management. Applicants should therefore answer a number of questions on data management under sections B.13 and B.14 of the application form. After final approval of an application, applicants need to prepare a data management plan, using Health~Holland's template. Approval of the data management plan by Health~Holland is a condition for the provision of PPP subsidy.

3.7 Evaluation of health and care innovations.

This option only applies if it is likely that the consortium will apply for CE-marking for the innovation <u>during or</u> within two years of the project period.



HI-NL

The number of health and healthcare innovations is growing by the day. These range from implants and high-tech diagnostic and prognostic machines to biomarker assays, AI algorithms, medical apps and wearables for self and home management. While the evaluation methods, introduction, implementation and reimbursement of drugs are clearly defined and regulated, this is not the case for non-medicinal (medtech) innovations. Health~Holland considers it essential to analyze impact and opportunities for implementation of medtech innovations at an early stage, as early as the R&D phase. Health~Holland therefore works closely with the Health Innovation Netherlands (HI-NL). HI-NL brings together all relevant parties at the earliest possible stage who have a vital role to play in the medtech development, evaluation, use, scale-up, decision-making and reimbursement process to help innovators on their way to success. These meetings are called "roundtables".

Innovation guidance from HI-NL

The aim of a HI-NL roundtable is to get an overall picture of how an innovation will fit into the healthcare or prevention landscape and to analyze what is needed to do so as early as possible. During the roundtable, the relevant parties involved will discuss the following aspects, among others:

- The value of the innovation from the perspective of each relevant party, including the innovator, given
 the intended claims, target population, healthcare market, integration into the current healthcare
 context and guidelines, the research needed for and evidence on the impact of the innovation, and
 identifying potential barriers and solutions to them;
- The evidence needed to achieve the next innovation development steps, including CE-marking;
- Exploring potential barriers and facilitators for implementation.

At the conclusion of the roundtable, HI-NL delivers a comprehensive and concrete advisory report, an "innovation guide," and a follow-up phone call is scheduled. The innovation guide contains consensus advice from all relevant parties. In addition, this document contains an overview of the main steps an innovator should take to successfully evaluate, scale up and implement the innovation in its intended (healthcare) context. The innovation guide is a confidential document and the property of the innovator.

Which steps should the consortium take?

Should a consortium wish to learn more about HI-NL and the HI-NL Roundtable service and consider making this part of the application, the consortium can contact <u>HI-NL</u> no later than three weeks before the Pilot Call deadline. HI-NL will then analyze whether a round table and innovation guide can be of value to the innovator with its innovation. If after contacting HI-NL it appears that developing an innovation guide would be of added value, this can be indicated on the application form (section E.6 *Innovation guidance*). In addition, an earmarked budget of €33,275 (including VAT) may be included on the budget form by the project coordinator for the preparation of the innovation guide. This amount can be included under the heading 'third party costs' stating 'development of innovation guide by HI-NL'. The costs of developing an innovation guide can be financed by PPP subsidy.

Only after the application for PPP subsidy is (conditionally) granted will the consortium be asked to elaborate the plans regarding the development of the innovation guide in the application. The details of this will be included in the award letter, which the project coordinator will receive within 10 weeks of the Pilot Call deadline.

HI-NL contact person

The HI-NL contact person can be reached at the following email address: info@healthinnovation.nl. More information about HI-NL can be found at www.healthinnovation.nl.

3.8 End user participation

Health~Holland encourages equitable collaboration with end users, such as citizens in their roles as patients, clients, end users and relatives. Therefore, it is important that equitable co-creation takes place during the project. Optimal co-creation occurs when a safe collaboration with the end user is achieved in which they are able to contribute to the project in an open, vulnerable, creative and solution-oriented manner. In doing so, researchers must be able to apply participation methods that establish this equitable and safe collaboration. To encourage equitable collaboration with end-users, specific questions regarding end-user participation are included in the application form (Section E.3 *Inclusivity and end-user participation*). Within the Pilot Call, it is



permitted to hire an external center of expertise on citizen participation in their role as patients, end-users, clients and/or relatives. These costs, within the duration of the project, are eligible and fundable by PPP subsidy.

3.9 Impact on health disparities

Despite the collective efforts in the field of Health and Care on the part of government, business and knowledge institutions, people with low income and low education (primary education + pre-vocational secondary education) spend 15 years less in good health than people with a college or university education and a high income. In addition, the difference in life expectancy between these groups is 7 years. The central mission of the social theme Health and Care is consequently that "by 2040 all Dutch people should live in good health for an additional five years and the health differences between the lowest and highest socio-economic groups must be reduced by 30%.

It is important to focus research and innovation efforts on specifically what makes innovations effective for people in vulnerable situations and with health impairments. In this respect, it is essential to involve the experiences and/or knowledge of people with lower socioeconomic status in projects from the start. A solid base of scientific and practical knowledge is available on what is needed for a successful strategy in addressing health disparities. Accordingly, within the Pilot Call, it is permitted to hire an external center of expertise in the area of reducing health disparities. These costs are, within the duration of the project, eligible and fundable with PPP subsidy.



4. Procedure

4.1 Application procedure

4.1.1 Application submission - deadline October 1, 2024, CET 17:00

Only PPP subsidy applications submitted using the TKI-LSH Pilot Call application form will be considered. This form can be obtained through your organization's PPP subsidy or TKI contact or on our <u>website</u>. In addition to completing the application form, the project coordinator should include at least the following attachments:

Please note that outdated versions of the documents below will not be considered.

- Specified Budget. Template to be downloaded from our website.
- Letters of commitment confirming per participant the commitment of co-financing and the amount of the in-kind and/or in-cash contribution by the parties, signed by an authorized person. The main applicant/project coordinator is not required to provide a letter of commitment. Letters of intent will not be accepted. The letter of commitment template to be used is available for download on our website.
- Consortium Agreement. This should be an unsigned draft version, a blank format is not sufficient. The consortium is required to use the model consortium agreement made available by Health~Holland⁸. This is available for download on our website. Only non-essential changes and modifications that do not conflict with the Framework should be made to this model. When in doubt about changes, the consortium should consult an expert: e.g. the technology transfer office (TTO) of the research organization or a lawyer. If the project is awarded the signed consortium agreement should be submitted as soon as possible, but no later than February 1, 2025.
- A statement must be sent with the application indicating that the PPP subsidy contact person or other authorized person may apply for the reserved PPP subsidy for this project.

4.1.2 Eligibility of application.

Upon receipt of the application, it will be reviewed for eligibility by Health~Holland within two working days. This eligibility check will verify that the application meets the prerequisites according to Appendix H of the application form.

If the application is incomplete, the consortium will be given one working day to make the necessary adjustments and provide the requested information. If the application proves ineligible, this will be communicated to the applicants within two working days.

4.1.3 Evaluation of PPP subsidy applications

Eligible applications will be assessed by Health~Holland in accordance with the conditions as stated in *Chapter 3*. *Terms and conditions*. Applications that meet these conditions will, in addition, be assessed for content by an expert and independent evaluation committee. The evaluation committee may, if desired, engage one or more independent referees. Both the evaluation committee members and referees must sign a confidentiality agreement before they are allowed to evaluate a PPP subsidy application.

The evaluation committee will advise the Board of Health~Holland on the appropriateness of the application within the PPP-Innovation regulation. The application will be assessed on appropriateness within the PPP-Innovation regulation, scientific quality, impact and relevance, feasibility and added value to the strategy of the Top Sector LSH and the societal challenge 'Health and Care', with each criterion being weighed proportionately in the assessment. Only the most relevant and most promising applications will be awarded. Health~Holland aims to award at least 66% of the submitted applications.

The board will ultimately decide whether or not to award the application and the amount of PPP subsidy for the collaborative project in question. The applicant will receive the decision by letter no later than ten weeks after the Pilot Call deadline.

⁸ Please contact Health~Holland when an existing consortium agreement is already in place



NOTE: When both necessary and desirable, applicants may request Health~Holland to sign a non-disclosure agreement.

4.1.4. Content criteria

The evaluation committee evaluates project applications on the content criteria listed below. The content criteria are divided into criteria on scientific quality, impact and relevance and feasibility.

1. Scientific quality criteria

- a) The research is well described, and the goals of the project are clear;
- b) 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.
- c) It is clear when the project can be labeled "successful" and what criteria are used to do so.
- d) The planned activities to further develop, disseminate and implement the results from the proposed research (TRL9) are well thought out and described for the partners.
- e) If applicable, the number of subjects and/or laboratory animals are realistic and adequate.
- f) Data are properly handled within the project. Where possible, data is reused and new data is made reusable at the end of the project.

2. Impact and relevance criteria

- a) The project is innovative and provides new scientific insights.
- b) The project meets societal needs, and the societal importance is well substantiated.
- c) The economic impact and importance of the project is well described and this impact is of value to the Netherlands.
- d) The economic impact of the project for each consortium partner is well substantiated.
- e) 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.
- f) Sufficient and proper attention has been paid to reducing health disparities as part of the central mission of VWS.
- g) Patients and/or end-users are sufficiently involved in the project and possible inclusion in any follow-up projects is also considered.

3. Feasibility criteria

- a) 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.
- b) The risks of the project have been properly assessed and adequate consideration has been given to how these risks will be dealt with.
- c) The intended methods, with respect to feasibility, have been properly chosen and substantiated;
- d) The project's time schedule is realistic;
- e) The project's budget is realistic (including number of man-hours per organization, realistic costs of materials and equipment and realistic "costs due to third parties").

4.2 Award procedure, monitoring and payments

- 4.2.1. After a PPP subsidy application has been awarded.
 - The project coordinator/main applicant must deliver an <u>unsigned</u> final consortium agreement agreed upon by all partners to Health~Holland for review no later than <u>January 20, 2025</u>.
 - After Health~Holland approves the consortium agreement, the consortium will be given two weeks to have it signed by all partners.
 - When the consortium agreement is fully signed and approved, Health~Holland drafts an implementation agreement (PPP Subsidy Agreement). The PPP Subsidy Agreement is a contract between Health~Holland and all consortium partners that defines, among other things, the rights and obligations as well as (financial) contributions of the various partners. This agreement is drawn up by Health~Holland and must be signed by all partners within four weeks.



- Together with the signed version of the PPP Subsidy Agreement a data management plan must be submitted. Health~Holland will review the data management plan as quickly as possible.
- Health~Holland publishes information of all awarded projects on the projects page of its website (http://www.health-holland.com/project). Together with the signed version of the PPP Subsidy Agreement, a completed project profile of the project according to Health~Holland's format must also be submitted.

Once Health~Holland has received and approved the signed PPP Subsidy Agreement, data management plan and project profile for the Health~Holland projects page, the first installment of PPP subsidy will be paid. The subsequent payments will be made annually upon receipt and approval of a progress report. Disbursements will be made to the institution where the project coordinator is employed; the project coordinator is responsible for any further financial distribution to the other consortium partners as well as the collective accountability for the utilization of the funding.

4.2.2. During the course of the project

- During the entire project period, a record of each employee's working hours should be kept.
- It is expected that RVO will request progress information of all ongoing PPP subsidy projects every calendar year. For this purpose, the project coordinator will receive an Excel form "request for information about project efforts" at the beginning of each calendar year. The primary purpose of this request is to inform the House of Representatives and the general public annually about the progress of the top sector policy within the area the TKIs are responsible for. This form will be completed in advance by Health~Holland and must be checked and completed by the consortium (costs realized over the previous calendar year). This may be subject to change.
- Within six weeks after each project year, the project coordinator needs to submit a progress report. The format for this will be provided by Health~Holland. If the project has a duration of less than 18 months, only a final report is required.
- The consortium is required to arrange a steering committee meeting each year. The project coordinator is required to notify Health~Holland of these meetings in order for a Health~Holland delegate to attend the meetings. The steering committee meetings halfway through and at the end of the project will in principle likewise be attended by a delegate of the evaluation committee and should be linked to a progress or final report.

4.2.3. After the end date of a project

Within eight weeks after the end date of the project, the project coordinator must submit the following documents to Health~Holland:

- A final report (the format of this will be provided by Health~Holland).
- If a consortium partner has used no PPP subsidy or less than EUR 125,000 PPP subsidy, a board statement must be submitted regarding the total project costs of that consortium partner.
- If a consortium partner has used EUR 125,000 or more of PPP subsidy, an auditor's statement must be submitted regarding the total project costs of that consortium partner.
- An updated project profile including the results of the completed project.

The final PPP subsidy payment will take place when the aforementioned documents are received and approved by Health~Holland9.

⁹ Please note that de documents required for the final report may be subject to change depending on any new requirements of RVO



4.3 Intended timeline

Announcement Pilot Call	4 January 2024
Deadline	1 October 2024 at 17:00 (CET)
Eligibility check	Within 2 working days of receipt of application
Assessment by LSH Evaluation Committee.	±5 weeks after deadline
Decision Board of Health~Holland	±8-9 weeks after deadline
Award or rejection letter	±10 weeks after deadline
Submit final unsigned Consortium Agreement.	No later than 20 January 2025
Submit signed Consortium Agreement.	No later than 3 February 2025 (after approval final version by Health~Holland)
Submit signed version PPP Subsidy Agreement	Within 4 weeks of receipt PPP Subsidy Agreement.

Please note that this schedule may be subject to change.



5. More information

5.1 Calculation examples

<u>Calculation example 1 - Research organization and Dutch SME.</u>

The calculation example assumes a project consisting entirely of industrial research.

Consortium partners	Costs
Research organization X	€ 600.000
Dutch SME Y	€ 400.000
Total	€ 1.000.000

Consortium partners	Max. % PPP subsidy	Max. € PPP subsidy
Research organization X	70%	€ 420.000
Dutch SME Y	60%	€ 240.000
Total	66%	€ 660.000

^{*}Percentage of PPP subsidy is calculated over the total cost of the partner in question.

Minimal required contributions	% of total cost*	Minimal contribution (€)	
Research organization(s)	10%	€ 100.000	
Enterprises (for-profit and non-profit).	15%	€ 150.000	
Open amount to be freely funded based on cost and minimum required contribution	=€1.000.000 (cost) - €660.000 (max. PPP subsidy) - €250.000 (min. contributions)	€ 90.000	

^{*} Percentages for minimal required contributions are calculated over the total cost of the project.

Funding per partner

Consortium partners	Total cost	In kind	In cash	PPP subsidy
Research organization X	€ 600.000	€ 180.000	€0	€ 420.000
Dutch SME Y	€ 400.000	€ 160.000	€0	€ 240.000
Total	€ 1.000.000	€ 340.000	€0	€ 660.000

In this example, the open fundable amount of €90,000 is divided between the research organization and the SME, with both parties using their maximum allowable amount of PPP subsidy.

Calculation example 2 - Consortium consisting of four parties

The calculation example assumes a project consisting entirely of industrial research.

Total	€ 1.000.000		
Hospital A	€ 100.000		
Large enterprise Z	€ 250.000		
Dutch SME Y	€ 150.000		
Research organization X	€ 500.000		
Consortium partners	Cost		
The calculation example assumes a project consisting entirity of madathan research			

Consortium partners	Max. % PPP subsidy	Max. € PPP subsidy
Research organization X	70%	€ 350.000
Dutch SME Y	60%	€ 90.000
Large enterprise Z	0%	€0
Hospital A	0%	€0
Total	44%	€ 440.000

^{*}Percentage of PPP subsidy is calculated over the total cost of the partner in question.



Minimal required contributions	% of total cost*	Minimal contribution (€)	
Research organization(s)	10%	€ 100.000	
Enterprises (for-profit and non-profit).	15%	€ 150.000	
Open amount to be freely funded based on cost and minimum required contribution	=€1.000.000 (cost) - €440.000 (max. PPP-subsidy) - €250.000 (min. contribution)	€ 310.000	

^{*}Percentage of PPP subsidy is calculated over the total costs of the project.

Funding per partner

3				
Partijen	Total cost	In kind	In cash	PPP subsidy
Research organization X	€ 500.000	€ 125.000	(€ 25.000)*	€ 350.000
Dutch SME Y	€ 150.000	€ 60.000	€0	€ 90.000
Large enterprise Z	€ 250.000	€ 250.000	€ 50.000	€0
Hospital A	€ 100.000	€ 75.000	(€ 25.000)*	€0
Total	€ 1.000.000	€ 510.000	€ 50.000	€ 440.000

^{*}The numbers in parentheses mean that these partners receive and use the private cash to cover part of their costs. In this case, the in cash contribution from the Large Enterprise is divided between Research Organization X and Hospital A.



5.2 Downloads

Documents to be completed, found at: https://www.health-holland.com/en/pilot-call-2024

- Word-version of the Pilot Call application form Health~Holland
- Budgetform PPP-subsidy Health~Holland
- Model consortium agreement PPP subsidy Standard
- Model consortium agreement PPP subsidy Clinical studies
- Template Letter of Commitment Dutch
- Template Letter of Commitment English

Documents to consult:

- Mission document 2024-2027
- Knowledge and Innovation Agenda 2024-2027
- Knowledge and Innovation Convenant 2024-2027

Relevant laws and regulations:

- Definitions research and development from the EU Support Framework
- Framework for State aid for research and development and innovation
- Regulation National Grants of the Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture,
 Nature and Food Quality
- Framework Decision National Grants of Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture, Nature and Food Quality
- PPP-Innovation Regulation Government Gazette 20 October 2023
- Commision Regulation (EU) nr. 651/2014 of 17 June 2014

5.3 Questions

For questions regarding the Pilot call please contact tki@health-holland.com

5.4 Submission

Applications must be submitted to Health~Holland via tki@health-holland.com.