TKI Life Sciences & Health SME Call 2024

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

1. Summary

The Top Sector Life Sciences & Health (LSH) encourages innovative research by (financially) supporting publicprivate partnerships (PPP) in the life sciences & health sector. This scheme encourages for-profit enterprises and research organizations to jointly invest in research and development (R&D) with the aim of developing sustainable innovative products and services within the LSH sector for the purpose of generating economic revenues. The Top Consortium Knowledge and Innovation (TKI) office is the operating body of the Top Sector LSH and can financially support a collaborative project by awarding PPP Subsidy.

Within the mission-driven top sector and innovation policy, the Top Sector LSH focuses, with the public-private partnerships, on the social theme Health & Care (MT G&Z). The <u>Knowledge and Innovation Agenda (KIA) 2024-2027</u> Health & Care describes the ambitions within the MT G&Z and the corresponding strategy to realize these ambitions. One of these strategies concerns the engagement and stimulation of SMEs. In the recent Parliamentary Letter Innovation and Impact from the Ministry of Economic Affairs and Climate and the Ministry of Education, Culture and Science, these ambitions are explicitly highlighted and will be continued in 2024-2027. To realize this strategy, this new call has been launched. With this call, the Top Sector LSH hopes to meet the wishes and needs of SMEs.

In 2024, the Top Sector LSH has reserved €5 million in PPP Subsidy for the SME call. Of this sum, €3.3 million is available for SMEs. Through this new call, SMEs can receive subsidies under certain conditions to fund one existing or new R&D FTE working on an industrial public-private partnership project.

Terms and conditions

Each application must meet at least the following terms and conditions:

- The research contributes to the realization of the missions and the strategy set out for this purpose in the <u>Knowledge and Innovation Agenda (KIA) 2024-2027</u> of the Top Sector LSH substantially;
- The research is of high quality;
- The consortium consists of at least one for-profit enterprise and one research organization;
- The project covers only industrial research;
- The project is carried out for joint account and risk and all consortium partners contribute content to the project;
- The main applicant is a SME and is based in the Netherlands;
- A maximum of one application per lead applicant. If multiple applications are submitted, only the first one will be taken into consideration.
- SME's whose applications were successful in the previous round are excluded from participating in this call.
- The project lasts a maximum of 2 years;
- Per project year, SMEs may claim a maximum of €150.000 PPP Subsidy;
- Per project, research organizations may claim a maximum of €150.000 PPP Subsidy;
- The PPP Subsidy is used to fund one existing or new R&D FTE, corresponding to 1720 hours.



The application process is composed of the following three steps:

- Step 1: Submit a letter of intent (available February 1, 2024, CET 12:00, application closes after the limit is reached)
- Step 2: Recommendation to submit full application (no later than 5 workdays after submission of intent letter)
- Step 3: Submit full application (deadline April 9, 2024, 17:00 CET)

Granting will take place based on appropriateness within the requirements of this call and the PPP Subsidy regulation, feasibility, scientific quality, and economic and societal impact (including added value to the strategy of the Top Sector LSH and the societal challenge 'Health & Care' and connection to key technologies and use of key methodologies).

2. Background information

2.1 Background Top Sector LSH

In 2011, the administration at the time reformed business policy by launching the top sector 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 cooperation. 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 Scheme, the Pilot Call was created. This subsidy call is executed by the Top Consortium Knowledge and Innovation (TKI) of the Top Sector LSH: TKI-LSH. The TKI-LSH is registered at the Chamber of Commerce under the name LSH-TKI Foundation, but is better known as Health~Holland (branding name)

In the Pilot Call, companies and recognized research organizations are invited to co-invest in R&D for evidencebased 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 Scheme of the Ministry of Economic Affairs and Climate.

2.2 Social theme 'Health & Care'

In spring 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, 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 quartermaster, 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 in mind, in kind and in cash in the Knowledge and Innovation Covenant (KIC).

2.3 SME

The PPP allowance is largely granted to knowledge institutions working on fundamental projects in cooperation with enterprises. The knowledge institute is often leading in initiating these research projects with PPP allowance. This ensures that research funded with PPP allowance is often fundamental in nature and focused



on knowledge development rather than knowledge application. Most of the PPP allowance flowed back to the knowledge organizations, reinforcing the investment focus on fundamental research.

In contrast, innovative SMEs have a greater need for research closer to the market that supports them in marketing their product or service. The current design of the scheme leaves the further development of innovations by SMEs at a less optimal pace than possible. This leads to fewer potential products and services that, in addition, are also less likely to reach the patient or consumer.

The Top Sector LSH is striving for the PPP scheme to better connect with innovative SMEs. This is only possible if the scheme offers clear value to these entrepreneurs; there must be incentive for SMEs. This means that the entrepreneur must be in the lead in determining the direction of research and that research should focus on industrial research rather than fundamental research.

Therefore, within this new call, under defined conditions, an SME can receive funding to hire one existing or new R&D FTE on a public-private collaborative project conducting industrial research. With the SME call, we increase the R&D capacity of SMEs, giving them more manpower and resources to turn knowledge and innovations into products or services faster and more effectively. As the Netherlands' total R&D spending needs to increase to 3% of gross domestic product (GDP), without decreasing the private share, this call contributes to this aim.¹

The Netherlands is highly skilled at generating new knowledge, but lags behind in the step toward valorization²,³. To bridge this gap, the knowledge of valorization among academic researchers must be increased. One way to achieve this is to train these academic researchers within a business, so-called industrial PhDs or Postdocs. In this call, medium-sized companies are challenged to hire a PhD or Postdoc researcher.

2.3 Key enabling technologies and key enabling methodologies

In addition to the four societal themes, the Cabinet is committed to key enabling technologies (KETs), for future economic opportunities. In addition, the top sectors are encouraged to make targeted technological contributions to solve 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.

¹ Kamerbrief innovatie en impact van de Ministers van Economische Zaken en Klimaat en Onderwijs, Cultuur en Wetenschap van 11 november 2022, p.6

² Kamerbrief innovatie en impact van de Ministers van Economische Zaken en Klimaat en Onderwijs, Cultuur en Wetenschap van 11 november 2022, p.24

³ European Commission (2021): European Innovation Scoreboard 2021.



3. Terms and Conditions

3.1 Terms and conditions for the collaborative project.

The application must meet several terms and conditions. Important issues here include:

- The project consists of industrial research⁴. A description of this type of research is available at point 5.1 Downloads;
- The research is of a high scientific quality and the innovative products and services are of social and economic added value as deliverables;
- The research fits within the societal theme 'Health & Care', the central mission and one of the supporting missions, as outlined in the <u>mission document 2024-2027</u> and the <u>Knowledge and Innovation</u> <u>Agenda 2024-2027</u>, and the objectives of the regulation.⁵
- The consortium consists of at least one for-profit company and one research organization. Foreign
 companies 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.
- The main applicant is an SME and is based in the Netherlands;
- Effective collaboration takes place⁶. This means, for example, that the project is realised at joint cost and risk and all consortium partners make a substantive contribution to the project.
- All consortium partners should contribute in kind. This means that all consortium partners must incur salary costs 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 a company
 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 in question).
- 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.
- If the consortium has or shall receive other public funding for the project submitted, for example from NWO, ZonMw, TNO, TTW or Health~Holland, the regulation concerning accumulation of different grants is applicable⁷.
- In principle, it is up to the company or companies themselves how they finance their own contribution. However, we strongly advise against creative constructions; improper use of PPP subsidy by consortia must be prevented;
- The project starts no later than January 1, 2025;
- The project has a maximum duration of 2 years.
- The SMEs may claim a maximum of €150.000 PPP Subsidy per project year.
- The research organizations may claim a maximum PPP Innovation Subsidy of €150.000 per project.
- A maximum of one application per lead applicant.
- SME's whose applications were honored in the previous round are excluded from participating in this round.
- The PPP Subsidy is used to fund one existing or new R&D FTE. At least 1720 hours of labor costs per year should be incurred for the SME.

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 KIA and KIC 2024-2027 will be published at the end of 2023. When they are available, they will be added to this document. Until then, the mission document can be used as a guide to the ambitions and goals within the Societal Theme Health & Care. ⁶ 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 labour 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.

⁷ The accumulation provisions are stated in Section 2, article 6 of the <u>Framework Decision National Grants of the Ministry of</u> <u>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</u> <u>National Grants of the Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture, Nature and Food Quality</u>.



3.2 Evaluation of health and care innovations

This option is only applicable if the innovation falls under the MDR/IVDR and it is likely that the innovator/consortium will apply for CE marking in the future or already has CE marking.

Collaboration Health~Holland and Health Innovation Netherlands

Health~Holland believes it is vital to analyse the actual impact and possibilities for implementation of innovations at an early stage, i.e. while these are still in the R&D phase. Performing such an analysis for MedTech innovations is complex and involves many stakeholders. Therefore, Health~Holland collaborates with <u>Health Innovation Netherlands</u> (HI-NL). HI-NL is a multidisciplinary infrastructure initiated by several prominent parties in the healthcare field, including The National Health Care Institute, The Netherlands Federation of University Medical Centres, Health~Holland, and The Ministry of Health, Welfare and Sport. Through its activities, HI-NL facilitates an early, targeted, tailor-made dialogue between innovators and all relevant stakeholders in the healthcare system, supporting and directing the development, evaluation, implementation, upscaling and reimbursement of promising and sustainable (health)care innovations for patients and citizens.

Insight into the innovation development path

The Round Table service is one of HI-NL's activities and provides innovators with expert support and multistakeholder advice about the development path of their specific innovation, tailored to the innovation type and development phase. The aim is to give innovators insight as early as possible into how their innovation will fit into the healthcare or prevention landscape and to provide them with concrete next steps for the further development path of their innovation. The HI-NL Round Table service consists of three consecutive tailor-made phases:

- The intake, in which the fit, scope, direction and timing of the Round Table service is discussed. For scope and direction, examples are (not exhaustive): the intended claims, the target population, the strength of the current evidence and the required evidence, the comparison with the current standard in healthcare, the application and integration in the current healthcare context, CE, reimbursement, implementation and upscaling.
- Extensive **scoping & synthesis** of the innovation and its targeted context and setting by a team of health(care) innovation experts (a so-called case team) in collaboration with the innovator.
- The Round Table session with all relevant stakeholders (e.g. patient, medical specialist, health insurer, CE expert, policy makers etc.). In this phase, all relevant stakeholders in the healthcare domain that may play a role in the specific innovation are selected and brought together in the Round Table session to provide innovators with consensus advice about their innovation and necessary follow-up steps. The gathered knowledge from the scoping & synthesis phase together with the multistakeholder advice is then compiled into a final comprehensive Innovation Guide and delivered to the innovator. The Innovation Guide is discussed through a close-out call and is a confidential document and the property of the innovator.

Which steps should the consortium undertake?

If the consortium is interested in learning more about HI-NL and the HI-NL Round Table service and is considering including it as part of the project application, the consortium can contact <u>HI-NL</u> no later than three weeks before the closing of the SME Call deadline on April 9, 2024. An intake interview will then be scheduled, in which HI-NL will explain the Round Table service in more detail and how it could serve the innovation/project. Before the intake takes place, the consortium is requested to complete the <u>intake form</u>, so that HI-NL will get insight into the current status of the innovation and its development (also in the context of the SME call project application) and questions / desired topics. If, after contact with HI-NL, it appears that a Round Table service is of added value, this may be indicated on the SME call application form (section *E.5. Innovation guidance*). In addition, the project coordinator may include an earmarked budget of \in 33.275 (incl. VAT), covering the costs of the entire HI-NL Round Table service, on the budget as part of the total requested PPP Subsidy. This amount can be included under the heading "costs owed to third parties" together with the specification "HI-NL Round Table Service".

The evaluation committee will independently assess whether the HI-NL Round Table service will be of value to the success of the application. After the application for PPP funding has been (conditionally) awarded the consortium will be asked to elaborate on the plans related to the HI-NL Round Table service in the application.



The details of this elaboration will be included in the award letter, which the project coordinator will receive within 10 weeks of the closing of the SME Call deadline.

Contact person HI-NL

HI-NL can be reached via the following e-mail address: <u>info@healthinnovation.nl</u>. More information about HI-NL can be found at <u>www.healthinnovation.nl</u>.

3.3 Consortium composition

PPP Subsidy applicants compose a consortium in which research organizations and companies, 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/pensperson (also main applicant), who will be Health~Holland's contact person throughout the entire project. The lead applicant can be either a research organization or a for-profit company. Any other party within the consortium is a co-applicant. The scheme is open to co-applicants from the Netherlands and abroad, both research organizations, for-profit companies or other private or public parties, as long as the research contributes to the Dutch knowledge infrastructure. Multiple companies, research organizations and additional parties may be affiliated with the consortium.

3.4 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 for State aid for research and development and innovation</u> (specifically article 2.2.2.) and the PPP Innovation Regulation (<u>Government Gazette October 20, 2023, 28651</u>). These state, amongst other matters, that participating companies and other private partners may take over the IP from the research organization for a market-based fee (less 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 SME Call has been made available through the TKI or PPP contact within your organization.

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

3.5 What amount of PPP Subsidy may be applied for?

For each project year Dutch SME(s) can apply for a maximum of ≤ 150.000 , while research organizations can apply for a maximum of ≤ 150.000 per project. The SMEs may fund a maximum of 60% of their incurred costs. The research organization may fund a maximum of 70% of their incurred cost.⁸

In addition, there are minimum contribution requirements at the project level. SMEs must contribute at least 15% of the total costs on a project level in kind. For research organizations, the minimum is 10% on project level. All percentages are shown in Table 2.

A budget of \in 5 million is available for this call. A total of \in 300.000 of PPP-Subsidy is available for the SME based on a 2-year project. For the research organizations, the available PPP-Subsidy per project is \in 150.000. A calculation example is shown in Table 3.

⁸ All eligible costs incurred by the relevant partner, except for any in-cash contributions.



Table 2: Funding by research type and minimum contributions

Conditions	Max. PPP-Subsidy based on eligible costs per partner	Minimum contribution based on total project cost
Research organization(s)	max. 70%	min. 10%
For-profit and non-profit enterprise(s)	max. 60%	min. 15%

Table 3: Calculation example

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Calculation	Amount	Remarks
Cost SME	€500.000	
Cost research organization	€250.000	
Total cost	€750.000	
In kind contribution SME	€200.000	Difference between eligible cost and PPP
		grant received (at least 15% of total
		project costs)
In kind contribution research organizations	€100.000	Difference between eligible cost and PPP
		grant received (at least 10% of total
		project costs)
PPS-Subsidy SME	€300.000	Max. €150.000 per project year (max. 60%
		of eligible cost)
PPS-Subsidy research organizations	€150.000	Max. €150.000 per project (max. 70% of
		eligible cost)
Total funding	€750.000	

3.6 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 recording the cost of consumables. The recording of commercial rates is not permitted. For an explanation of the (calculation of) eligible costs see the <u>Commission Regulation (EU) No. 651/2014 of June 17, 2014, Article 25</u> and the <u>Framework Decision National EZK and LNV Grants, Chapter 4, Article 10-14</u>.

Parties that do not use PPP Subsidy are not required to use one of the payroll costing systems prescribed by the Framework Decision on National EEZK and LNV Grants. 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 cooperation project apply systematically. 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 on the budget form.

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);
- Auditing;
- Benchfee (note that material costs are eligible);
- Domestic travel;



- Support staff, not directly related to the substantive R&D activities, such as: project controller, business developer, administrative assistant;
- Preparation of a business case;
- Costs related to implementation of the developed innovation;
- Carrying out effectiveness research (Health Technology Assessment, HTA);
- Overhead;
- Non-scientific dissemination, including marketing cost. However, scientific dissemination, including attending a scientific congress or publishing a scientific article, is eligible;
- Project management tasks, not directly related to the substantive R&D activities, such as: escalation to a steering committee, preparing a risk management model, preparing reports to meet grant obligations, administrative accountability. Project management tasks that do relate directly to substantive R&D activities (e.g., discussions with staff, analyzing technical risks, preparing substantive reports, preparing specifications) are eligible.

Expenses 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. If this cost is particularly high, this may have an impact and be included in the evaluation committee's assessment.

3.7 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 wants this data to be stored according to the <u>FAIR- principes</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 three-point FAIRification framework. 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 should 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.



4. Procedure

4.1 Pre-proposal application process

4.1.1 Intent letter submission – start February 1, 12:00 CET

A letter of intent must be submitted in the first phase of the call. Only intent letters submitted on the accompanying form (*Intentieverklaring MKB Call 2024*) will be considered. The intent letter form will be available on our <u>website</u> February 1, 2024, 12:00 CET. No other attachments besides the completed letter of intent form are required for submission.

4.1.2 Admissibility of intent letter

Upon receipt of the preliminary notification, Health~Holland will assess the application's eligibility within two working days. This eligibility check will ensure that the application meets the following conditions:

- The application does not meet the requirements for a collaborative project (section 3.1);
- The research does not meet the conditions of industrial research as defined in: <u>'Definities Onderzoek & ontwikkeling uit het EU Steunkader</u>;
- The consortium applied for other grants, resulting in overlapping activities covered by multiple grants (subsidy stacking);
- There are substantial variances in the projected budget that conflicts with the terms and conditions of the call.

For the letter of intent, Health~Holland will use a first come, first serve procedure. After the eligibility check, the applicant will receive the message whether a developed application may be submitted. When the applicant receives this message, Health~Holland expects the consortium to submit a detailed application. Should it turn out that it is not possible to write an application before April 9, the applicant must notify Health~Holland by February 21 at the latest. If no application is submitted before the April 9 deadline, the lead applicant will be excluded from submitting an application in the next two SME Call rounds.

Health~Holland intends to have a total of 30 consortia to submit a developed application, for an available budget of €5 million. Once the limit of 30 letters of intent is reached, the next 10 submitters will be put on the reserve list. Should a consortium be unable to apply by April 9, the next on the reserve list will be approached to write a detailed application.

4.2 Application process full application

4.2.1 Submission full application - deadline April 9, 2024, CET 17:00

Only applications for PPP Subsidy submitted using the TKI-LSH SME application form will be considered. This form will be available on our <u>website</u> after the granting of the full applications at the latest. In addition to completing the application form, the project coordinator should include at least the following attachments:

- Specified Budget using the budget form template available on our <u>website;</u>
- Letters of commitment stating the commitment of co-financing and the amount of the in cash/in kind contribution of each party involved. The main applicant does not need to provide a letter of commitment. Letters of intent will not be accepted. A template letter of commitment will be available on our <u>website</u>;
- Consortium Agreement. If a signed version is not yet available, a draft version should be provided. Using the model consortium agreement made available by Health~Holland is mandatory within this call and can be downloaded from our <u>website</u>. In addition, when drafting a draft consortium agreement, it is recommended to use an expert: the technology transfer office (TTO) or a lawyer. The signed consortium agreement should be submitted as soon as possible but no later than 18 weeks after the deadline of the full application.



4.2.2 Admissibility of full application

Upon receiving the application, it will be checked for admissibility by Health~Holland within two working days. This admissibility check will verify that the application meets the call terms and conditions.

If the application is not yet admissible, the consortium will be given one working day to make the necessary amendments and provide the requested information. If the application proves inadmissible, this will be communicated to the applicants within two working days.

4.2.3 Assessment of detailed applications

Admissible full applications will be assessed by Health~Holland against the terms and conditions as stated in point 3. *Conditions*. Proposals that meet the call conditions will be evaluated by an expert and independent evaluation committee. The evaluation committee may, if desired, engage an independent referee. Both the evaluation committee members and referees must sign a confidentiality agreement before they are allowed to evaluate PPP grant applications.

The evaluation committee advises the board on the appropriateness of the application within the PPP Subsidy scheme and the call. The application is assessed on relevance, quality, and feasibility, as described in section 4.3 *Content criteria*. The application will be assessed on all criteria, with each component being weighed proportionally in the assessment. Only the most relevant and most promising applications will be selected. Health~Holland strives to grant at least 11 full proposal.

The board will ultimately decide whether or not to grant the application and the amount of the PPP Subsidy for the collaborative project in question. The applicant will receive the verdict by letter no later than twelve weeks after the deadline.

For an overview of the timeline of the SME call, see section 4.5 Intended timeline.

4.3 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 plan of action 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 risks of the project have been properly assessed and adequate consideration has been given to how these risks will be dealt with;
 - e) The planned activities to further develop, disseminate and implement the results from the proposed research are well thought out and described for the partners.
- 2) Relevance and impact
 - a) The project meets societal needs and is well justified in the project;
 - b) The project is innovative and provides new insights that lead to significant improvements in a product or service (TRL 4-6);
 - c) The economic impact is well described for the entire project, supported in part by a cost-effectiveness analysis and competitive analysis;
 - d) Future goals for further business development during and after the project are defined, supported by a business case;
 - e) Planned activities to further develop introduce the innovation to the market have been described and supported by a financial projection including an estimated launch date and estimated revenue.



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 the collaboration is equitable.
- b) The intended methods, with respect to feasibility, have been properly chosen and substantiated;
- c) The project's time schedule is realistic;
- d) 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").

4.4 Allocating procedure, monitoring and payments.

After a PPP Subsidy grant application is granted:

- No later than 16 weeks after the corresponding deadline date, the project coordinator must deliver an unsigned final consortium agreement agreed upon by all partners to Health~Holland for review;
- After approval of the consortium agreement by Health~Holland, the consortium will have 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/obligations and 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 provided. Health~Holland reviews the plan as soon as possible;
- Health~Holland publishes on the projects page of its website (www.health-holland.com/project) information of all honored projects. Along with the signed version of the PPP Subsidy Agreement, an accessible summary of the project should be provided.

Once Health~Holland has received and approved the signed PPP Subsidy Agreement, data management plan and project profile for the benefit of the Health~Holland projects page, the first installment of PPP Subsidy will be paid. The remaining disbursements 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 financial breakdown to the other consortium partners and collective accountability for the utilization of finances.

During the course of the project

- During the entire project period, time records must be kept for each employee.
- 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 deployment project" 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 regarding the part carried out by the TKIs. 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/pennor should provide a progress report. The format for this will be provided by Health~Holland. If the project lasts 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 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.



After the end date of a project

Within eight weeks after the end date of the project, the project coordinator/pender 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, a management statement must be provided regarding the total project costs of that consortium partner.
- If a consortium partner has used EUR 125,000 or more in PPP Subsidy, an audit opinion must be issued 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 be issued when the aforementioned documents are received and approved by Health~Holland.

4.5 Intended timeline

Publication SME-call	January 9, 2024
Start submission intent letter	February 1, 2024, 12:00 CET
Eligibility check intent letter	Within 2 working days of receipt of the intent letter
Preliminary advice intent letter	±1 week after submitting intent letter
Deadline full application	April 9, 2024, 17:00 CET
Eligibility check full application	Within 2 working days of receipt of application
	documents
Assessment by Evaluation committe	±7 weeks after full application deadline
Verdict board	±9 weeks after full application deadline
Award or rejection letter	±13 weeks after full application deadline
Submission of final unsigned consortium agreement	Within 16 weeks after full application deadline
Submission of signed consortium agreement	Within 2 weeks of approval of the unsigned
	Consortium Agreement
Submission of signed PPP Subsidy Agreement	Within 4 weeks of receiving the PPP Subsidy
	Agreement

Please note that this schedule may be subject to change.



5. More Information

5.1 Downloads

Documents to be consulted:

- Missiedocument 2024-2027
- Kennis- en Innovatieagenda 2024-2027
- Kennis- en Innovatieconvenant 2024-2027

5.2 Questions

For questions about the PPP Subsidy scheme, please send an e-mail to tki@health-holland.com.

For any questions relating to this specific call, please contact: Sten Heck (<u>heck@health-holland.com</u>) or Jochem Christiaansen (<u>christiaansen@health-holland.com</u>)

5.3 Submission

The application process is composed of the following three steps:

- Step 1: submit a letter of intent (available February 1, 2024, CET 12:00, application closes after the limit is reached)
- Step 2: Recommendation to submit full application (no later than 5 workdays after submission of intent letter)
- Step 3: Submit full application (deadline April 9, 2024, 17:00 CET)

The application, both for the intent letter and the full application, can be submitted by email to Health~Holland at tki@health-holland.com, with "**Submission project SME call**" in the title.