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

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 SME 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.

In this SME Call the Top Sector LSH will provide around €8 million in PPP Subsidy in 2025, divided over two rounds of €4 million, to enable the SME to fund one existing or new R&D FTE working on an industrial public private partnership project.

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 Knowledge and Innovation Agenda (KIA) 2024-2027 of Top Sector LSH.
- The research fits within one of the Growth Markets and/or one of the key technologies within the National Technology Strategy (NTS).
- 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 covers industrial research (TRL 4 to 6).
- The main applicant is an SME based in the Netherlands.
- The project lasts a maximum of 2 years.
- SMEs may apply in total a maximum of €150,000 PPP subsidy per project year;
- Research organisations may apply a total maximum of €150,000 per project;
- The PPP subsidy is used to fund one existing or new R&D FTE per year (1 FTE equals 1650 hours). The remaining grant may be used for other eligible costs (including materials, other personnel, etc.)

For Round 1 of the SME Call 2025, the pre-application form can be submitted from **30 October 2024, 12:00 CET until 2 December 2024, 12:00 CET**. Only pre-applications that fully meet the SME Call selection criteria will be invited to submit a full application.

The deadline for the full application is **February 11, 2025 CET 17:00** after 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 (section D);
- Appropriateness within the missions of VWS (section E);
- Appropriateness within the National Technology Strategy and/or Growth Markets (section E);

More information about Round 2 of the SME Call 2025 is expected to be published Q1 2025.

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 one week prior to both deadlines by sending an email to tki@health-holland.com. Please include: "*Request SME Call application advice - <name main applicant>*" in the subject line.

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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. 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).

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

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)[1] 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 Growth Markets

At the end of 2023, Dialogic and SEO mapped the promising growth markets for the Netherlands on behalf of the Ministry of Economic Affairs[2]. To give the Netherlands an innovative, sustainable and strong economy, the Ministry of Economic Affairs believes it is important to invest in growth markets where there are the greatest opportunities in the future to strengthen Dutch earning capacity and where the Netherlands is good at. Within the LSH sector, 'medical technology' and 'innovative and high-quality molecules in the biotech sector' are described as promising growth markets.

2.4 National Technology Strategy (NTS) and key enabling methodologies

The National Technology Strategy (Ministry of Economic Affairs, 2024) defines building blocks for a strategic technology policy in the form of ten priority key technologies where the Dutch knowledge field and business can make a positive impact and which are essential for the future. For almost all of these key technologies, application in the medical world plays an important role to further develop and market the technologies. The most telling examples for the LSH sector are the key technologies: 'Biomolecular and cell technologies', 'Imaging technologies' and 'Artificial Intelligence and Data Science'.

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

[1] https://www.health-holland.com/publications/useful-documents/kia
[2] https://www.rijksoverheid.nl/documenten/rapporten/2023/12/05/dialogic-seo-groeimarkten-voor-nederland

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.

2.5 SME

In previous years the PPP Subsidy (formerly 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 previous design of the subsidy scheme leaves the further development of innovations by SMEs at a less optimal pace than possible.

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.[3]

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

3. Terms and conditions

3.1 Terms and conditions for the collaborative project

The application must meet the conditions of the call. Important aspects in this regard are:

- The main applicant is an SME based in the Netherlands.
- The main applicant and other Dutch SMEs applying for PPP funding are no *Enterprises in Difficulty* (Onderneming in Moeilijkheden).
- The consortium consists of at least one for-profit enterprise and one research organization[4]. 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 place[5]. 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 fully of industrial research and meets TRL levels 4 to 6[6]. A more detailed explanation of industrial research including examples are described in Appendix A.
- 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 project aligns well with one or more of the defined Growth Markets and/or the project aligns well with one or more of the 10 priority key technologies from the National Technology Strategy.
    - Specific Growth Markets of focus are:
        - Medical Technology
        - Innovative and high-performance molecules in the Biotech sector
    - Specific Key Technologies of focus are:
        - Biomolecular and cell technologies
        - Imaging technologies
        - Artificial Intelligence and data science
- The research is of high scientific quality.
- All consortium partners should make an *in kind* contribution. This means, for example, that all consortium partners must incur payroll costs and an *in kind* contribution and that these costs and contributions are visible in the budget form (Excel).
- In addition to the aforementioned *in kind* contribution, it is possible to contribute *in cash*. An *in-cash* contribution from one party should be used within the project to cover costs of another partner. The consortium should jointly decide whose costs the relevant *in-cash* contribution will be used for.
- 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.
- The project starts no earlier than July 1, 2025 and no later than November 1, 2025.
- The project has a maximum duration of 2 years.
- SMEs may apply for a total maximum of €150,000 PPP subsidy per project year.
- Research organizations may use a total maximum of €150,000 PPP subsidy.
- The SME is involved in only one project application within this call.
- A minimum of 1650 hours of labour costs should be incurred per project year by the company (e.g. for a 1.5-year project, the company should therefore incur a minimum of 2475 hours of labour costs).

[4] Definition of research organization according to the Framework for State aid for research and development and innovation (Chapter 1.3, article 16.f)

[5] Definition of 'effective collaboration' according to the Framework for State aid for research and development and innovation (Chapter 1.3, article 16.f)

[6] In the case of clinical drug research, preclinical research in animals is included in industrial research. The clinical phases 1 to 2 fall under experimental development. Phase 3 (and beyond) clinical studies are regarded as competitive development and therefore fall outside the framework of the PPP Innovation Regulation

- The subsidy used by SMEs must be used to cover the wage costs of 1 R&D FTE. The remaining subsidy may be used for other eligible costs (e.g. materials or more personnel).
- It is mandatory to use SME call specific versions of the application form, budget form and consortium agreement, provided by the TKI or PPP contact within your organization. Outdated or other versions of these documents will not be accepted.

The main applicant is excluded from participation in this TKI-LSH SME Call if one of the following situations applies:

- An application in previous TKI-LSH SME Call rounds has been granted and this project has not yet been completed.
  - The applicant may submit a preapplication when the previous awarded SME-Call project has been fully completed and the final report including financial documents has been approved by Health~Holland.
- The application has been rejected by the evaluation committee within the 2024 TKI-LSH SME Call.
  - The applicant may participate in the next round. In Q1 of 2025, more information will become available about Round 2 of the SME Call 2025.
- The project of the main applicant has already been rejected twice within previous SME Call rounds on substantive grounds by the evaluation committee: this application is completely excluded from participation. It is, however, permitted for the main applicant to submit a new project on a different topic. If this applies to your consortium, please contact us as soon as possible at tki@health-holland.com.

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 must be an SME based in the Netherlands**.** Any other party within the consortium is a co-applicant. 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 Framework for State Aid for Research, Development and Innovation (specifically article 2.2.2.) and the PPP Innovation Regulation (Staatscourant October 20, 2023, 28651). 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 SME Call has been made available through the TKI or PPP contact within your organization. If your consortium uses previously made intellectual property agreements, e.g. through a licence agreement, you should contact Health~Holland as soon as possible before submitting the fully developed application.

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

3.4 What is the amount of funding that can be applied for?

Within this call, funding (PPP subsidy) can be applied by Dutch SME's and research organisations**.**

Dutch SMEs (for-profit and not-for-profit enterprises) may fund up to 60% of their **own costs**[7] using PPP subsidy. 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.

Foreign university medical centers and recognized universities may, in consultation with Health~Holland, participate as research organizations. These research organizations may fund up to the same percentages of their own costs with PPP subsidy as Dutch research organizations, with a maximum of €120.000,- PPP subsidy per foreign research organization. Large companies (Dutch and foreign), foreign SMEs, Enterprises in Difficulty (Onderneming in Moeilijkheden / OIM) and Dutch and foreign other parties may not use PPP subsidies; the costs they incur should be equal to the in kind contribution they make.

If the research organisation is based abroad and/or does not fall into the categories mentioned above, please contact Health~Holland directly at tki@health-holland.com to check whether the partner can classify as a research organisation.

In addition, the project should also meet minimum contributions at project level. Companies must contribute at least 15% of the **total project costs** in kind. For research organisations, this is at least 10% of the total **project costs**. Table 1 shows all percentages in a convenient manner.

Table 1: Maximum funding and minimum contribution

Conditions	Max % of PPP Subsidy based on the amount of eligible costs per partner	Minimum contribution based on the total project cost
Research organization	Max. 70%	Min. 10%
Dutch SME	Max. 60%	Min. 15%

1) Enterprises in difficulty (OIM) and foreign companies are not allowed not use PPP subsidy.

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 use PPP subsidy are obliged to use one of the payroll costing systems prescribed by the Framework Decision on National EZK and LNV Grants. Parties that do not use PPP subsidy are not required to use one of the payroll costing systems prescribed by Framework Decision on National EZK 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 collaborative project apply systematically. On the budget form, these parties should choose "fixed hourly rate" and adjust the standard hourly rate of €60 to an hourly rate that is customary and verifiable for them.

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

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;
- Research aimed at establishing the business case. These include:
    - Competition analyses;
    - Market research;
    - Comparison studies with product of competition or 'gold standard';
    - Satisfaction studies;
    - Cost-effectiveness analyses;
- 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 SME 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 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. 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 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 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, 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 Health Innovation Netherlands (HI-NL). HI-NL is a multidisciplinary infrastructure initiated by several prominent parties, 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, tailor-made dialogue (Animation) between innovators/entrepreneurs 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 HI-NL innovation procedure provides innovators/entrepreneurs 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/entrepreneurs 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 innovation procedure consists of four consecutive tailor-made phases:

- **The intake**, in which the fit, scope, direction and timing of the HI-NL innovation procedure 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. This phase requires about 4 meetings (over a period of 8 weeks) between the case team and the innovator, which may also require some preparation time from the innovator/entrepreneur.
- A **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.
- Innovation guide; 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 innovation procedure and is considering including it as part of the project application, the consortium can contact HI-NL no later than three weeks before the closing of the Call deadline. An intake interview will then be scheduled, in which HI-NL will explain the innovation procedure in more detail and how it could serve the innovation/project. Before the intake takes place, the consortium is requested to complete the intake form, so that HI-NL will get insight into the

current status of the innovation and its development (also in the context of the project application) and questions / desired topics. If, after contact with HI-NL, it appears that a HI-NL innovation procedure is of added value, this may be indicated on the SME call application form (section *E.3*. *Innovation guidance*). In addition, the project coordinator may include an earmarked budget of € 33.275 (incl. VAT), covering the costs of the entire HI-NL innovation procedure, 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 Innovation procedure”.

The evaluation committee will independently assess whether the HI-NL innovation procedure 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 Innovation procedure in the application. The details of this elaboration will be included in the award letter.

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

4. Procedure

4.1 Preapplication procedure

4.1.1 Preapplication submission - submission deadline from 30 October 2024, 12:00 CET to 2 December 2024, 12:00 CET

A preapplication is mandatory for this SME call. Only pre-applications using the TKI-LSH SME Call 2025 pre-application form will be considered. This form is available through our website. It is not possible to submit a full application without a preapplication. In addition to a fully completed pre-application form, the project coordinator should include the following attachments:

- A signed '*Verklaring geen onderneming in moeilijkheden'* for all SMEs applying for PPP subsidy within the project. The declaration can be found here and on our website.
- A confirmation of SME status for all SMEs within the project: fill in the SME self-assessment questionnaire for this purpose. The result of the questionnaire should be submitted together with the preapplication.

The pre-application will be assessed by Health~Holland for completeness and appropriateness within the SME call. Please note: Due to the high interest in this call, Health~Holland will strictly enforce the criteria below. This means that there will be no possibility to address omissions for the preapplication.

The pre-application will be assessed on the following selection criteria:

- The pre-application is complete and filled in correctly;
- The maximum word count per question may not be exceeded;
- The main applicant is an SME based in the Netherlands;
- The main applicant and other Dutch SMEs using PPP subsidy are not Enterprises in Difficulty (Onderneming in Moeilijkheden / OIM);
- All Dutch SMEs have demonstrated SME status by completing and submitting the 'SME self-assessment questionnaire';
- The consortium consists of at least one for-profit Dutch SME and one research organisation;
- The project includes industrial research and meets TRL levels 4 to 6. Further details on industrial research including examples are described in Appendix A;
- The project mainly contributes to achieving the central mission and at least one of the five specific missions within the social theme 'Health & Care', as described in the KIA 2024-2027 Health and Care;
- The project aligns with at least one of the Growth Markets and/or one key technologies within the National Technology Strategy (NTS);
- All consortium partners should contribute in kind. This means, among other things, that all consortium partners in any case incur wage costs and make an in-kind contribution and that these costs and contribution are also visible on the pre-application form;
- The consortium is not using financially creative constructions; improper use of PPP subsidy by consortia is not allowed (this includes using PPP subsidy and making an in-kind contribution by the same party);
- No other public grant, e.g. from NWO, ZonMw, TNO, SIA or Health~Holland, has been applied for, awarded or received for the activities within this project.
- The project starts no earlier than 1 July 2025 and no later than 1 November 2025.
- The project lasts a maximum of 2 years.
- SMEs may use a total maximum of €150,000 in PPP subsidy per project year.
- Research organisations may use a total maximum of €150,000 in PPP subsidy.
- A Dutch SME is involved in only one application within this call.
- Per project year, at least 1650 hours of labour costs must be incurred by the company (e.g. for a 1.5-year project, the company must therefore incur at least 2475 hours of labour costs).
- Versions of the pre-application form specifically for this SME Call have been used. Outdated or other versions will not be accepted;
- The expected budget included in the preapplication conflicts with the funding conditions as described in Table 1 under article 3.4;

- The preapplication form has been signed by all consortium partners by an authorized person within the organization;
- The activities and costs of the project are eligible within the PPP Innovation Regulation.

Health~Holland aims to inform the applicant regarding the outcome for submitting a full application within two weeks after the pre-application deadline.

If your preapplication is rejected based on completeness and appropriateness of this SME call, the consortium will receive a message explaining why the project does not meet the conditions. The consortium will then have the opportunity to make these adjustments and submit a new preapplication in the next round of the SME call. The submission opportunity for Round 2 is scheduled for mid-May 2025. More information will be published in Q1 2025.

4.2 Full application procedure

4.2.1 Submission of full application - deadline 11 February 2025, CET 17:00
Only applications using the TKI-LSH SME Call 2025 application form will be considered. This form can be obtained via our website. In addition to filling in the application form, the project coordinator/partner should send 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~Holland[8]. 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 **4 weeks after the award date**.

If the consortium has made previous agreements regarding IP rights, for example by means of a licence agreement, this should be reported to Health~Holland no later than 3 weeks before the deadline of February 11, in order to receive advice on how these existing agreements can possibly be used within this project. When submitting the application, the consortium should also send these existing agreement(s) along with the draft consortium agreement.

4.2.2 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 G 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.

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

4.2.3 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 and feasibility, with each criterion being weighed proportionately in the assessment. Only the most relevant and most promising applications will be awarded. For Round 1 of the TKI-LSH SME Call, around €4 million in PPP Subsidy is available.

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 13 weeks after the call deadline.

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

4.2.4. 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 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;
      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").

4.2.5. Decision of (conditional) granting or rejection

Around 13 weeks after the deadline, the consortium will receive a letter containing the decision from the board of Stichting LSH-TKI. In this, the consortium may receive the following options:

- Conditional granting of your PPP subsidy application
    - The board conditionally grants your application. In the letter, the consortium will receive comments from the evaluation committee, which should be addressed by means of a rebuttal. These rebuttals serve to strengthen the granted application. In addition, the consortium will also receive comments from the Health~Holland office regarding the conditions of the call.
- Additional information required for your PPP subsidy application
    - The evaluation committee requires additional information to assess your application. The board will honour your application if the questions and comments of the evaluation committee are satisfactorily addressed. The questions and comments should be explained through a rebuttal and adjustments in the application form. Please note: if the points and questions of the evaluation committee are not addressed to the satisfaction of the evaluation committee and the board, the board will reject your application. There will be no opportunity for further clarification thereafter.
- Rejection of your PPP subsidy application
    - The board will reject your application. In the letter, the consortium will receive comments on which the rejection is based.
    - With a rejection, the main applicant is excluded from participation in the next round of the TKI-LSH SME Call. However, the lead applicant may submit a preapplication in the Round 1 of SME Call 2026 if necessary.

4.3 Award procedure, monitoring and payments

4.2.1. *After a PPP subsidy application has been awarded*.

- The project coordinator/main applicant must deliver an unsigned final consortium agreement agreed upon by all partners to Health~Holland for review no later than **16 weeks after the submission deadline**
- 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. 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 and in the end a final 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 €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 €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~Holland[9].

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

4.4 Intended timeline

Round 1

Announcement SME Call	October 17, 2024
Submission option for the preapplication	October 30 2024, 12:00 CET until December 2 2024, 12:00 CET
Decision preapplication	±2 weeks after the submission deadline of the preapplication
Deadline full application	February 11 2025, 17:00 CET
Eligibility check	Within 2 working days of receipt of application
Assessment by LSH Evaluation Committee.	±7 weeks after deadline
Decision Board of Health~Holland	±9 weeks after deadline
Award or rejection letter	±13 weeks after deadline
Submit final unsigned Consortium Agreement.	±16 weeks after deadline
Submit signed Consortium Agreement.	Within two weeks after approval of the 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.

Round 2 of the SME Call 2025 will start around mid-May 2025 with the possibility of submitting the pre-application. The target timeline for Round 2 is expected to be published by the end of Q1 2025.

5. More information

5.1 Calculation examples

Calculation example 1 - Research organization and Dutch SME.

Consortium partners	Costs
Research organization X	€ 200.000
Dutch SME Y	€ 500.000
Total	**€ 700.000**

Consortium partners	Max. % PPP subsidy	Max. € PPP subsidy
Research organization X	70%	€ 140.000
Dutch SME Y	60%	€ 300.000
Total		**€ 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%	€ 70.000
Enterprises (for-profit and non-profit).	15%	€ 105.000
Open amount to be freely funded based on cost and minimum required contribution	***=€700.000 (cost) - €440.000 (max. PPP subsidy) - €175.000 (min. contributions)***	**€ 85.000**

*** 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	€ 200.000	€ 70.000	€ 0	€ 130.000
Dutch SME Y	€ 500.000	€ 200.000	€ 0	€ 300.000
Total	**€ 700.000**	**€ 270.000**	**€ 0**	**€ 430.000**

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 – Multiple research organizations, one Dutch SME and one SME abroad

Consortium partners	Costs
Research organization X	€ 80.000
Research organization Y	€ 60.000
Dutch SME	€ 300.000
Non-Dutch SME	€ 150.000
Totaal	**€ 590.000**

Consortium partners	Max. % PPP subsidy	Max. € PPP subsidy
Research organization X	70%	€ 56.000
Research organization Y	70%	€ 42.000
Dutch SME	60%	€ 180.000
Non-Dutch SME	0%	€ 0
Total		**€ 368.000**

**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%	€ 59.000
Enterprises (for-profit and non-profit).	15%	€ 88.500
Open amount to be freely funded based on cost and minimum required contribution	***=€590.000 (costs) - €368.000 (max. PPP subsidy) - €147.500 (min. contributions)***	**€ 74.500**

*** 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	€ 80.000	€ 35.000	€ 0	€ 55.000***
Research organization Y	€ 60.000	€ 24.000	€ 0	€ 36.000***
Dutch SME	€300.000	€120.000	€ 0	€ 180.000
Non-Dutch SME	€ 150.000	€ 150.000	€ 0	€ 0
Total	**€ 590.000**	**€ 239.000**	**€ 0**	**€ 261.000**

**** The PPP subsidy for the research organizations is lower in order to meet the minimum in-kind contribution of 10% (= €59.000)*

5.2 Downloads

All template documents on our website: https://www.health-holland.com/funding-opportunities/mkb-call

Documents necessary for pre-application:
- TKI-LSH MKB Call pre-application form
- RVO: verklaring geen onderneming in moeilijkheden
- SME self-assessment questionnaire

Documents necessary for full application:
- TKI-LSH MKB Call application form
- TKI-LSH MKB Call Budget form
- Model consortium agreement PPP Subsidy – Standard
- Model consortium agreement PPP Subsidy – Clinical study
- 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 SME call please contact tki@health-holland.com

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

Appendix A: Tools for identification types of research

Within the PPP Innovation Regulation, industrial research is defined as follows:

'Het planmatig of kritisch onderzoek dat is gericht op het opdoen van nieuwe kennis en vaardigheden met het oog op de ontwikkeling van nieuwe producten, procedés of diensten, of om bestaande producten, procedés of diensten aanmerkelijk te verbeteren.
Het omvat de creatie van onderdelen voor complexe systemen en kan ook de bouw omvatten van prototypes in een laboratoriumomgeving en/of in een omgeving met gesimuleerde interfaces voor bestaande systemen, alsmede pilotlijnen, wanneer dat nodig is voor het industriële onderzoek en met name voor de validering van generieke technologie.'

Health~Holland provides more guidance below to help you assess whether your research falls within the definition of industrial research, that makes your project eligible for PPP funding within the SME Call. **Please note: the guidelines below are provided as support. Each application will be assessed separately whether the project and activities meet the framework of industrial research.**

If, based on reading the guidelines below, your consortium has specific questions regarding the determination of the type of research of certain work packages within your project, please contact Health~Holland as soon as possible at tki@health-holland.com. Please keep the following in mind with this mail:

- Please mention in the email header: *Advice SME Call - <name company main applicant>.*
- An explanation of the work package(s) about which there is doubt in the classification. It is not possible to have your entire application assessed by research type.
- Health~Holland will provide you with advice on what to consider. This advice is not a final assessment, and no rights can be derived from it.

Industrial research vs Technology Readiness Levels:
Industrial research is aimed at acquiring new knowledge for the purpose of developing an innovation. With this, this type of research falls under the development phase and is thus generally defined under TRL levels 4, 5 and 6. The definitions for all TRL levels can be found on the RVO website.

Guidelines:

Based on the above information and the definitions given on the RVO website, the following principles should be used:

- The research aims to use the new knowledge to further develop the product/service/process.
- You have carried out the initial *proof-of-concept*: the concept has been validated so that you can work towards a first prototype. If so, the project meets at least TRL4, making it eligible for subsidy within the SME Call.
- Demonstration of prototypes in operational environments are defined as experimental development and thus fall outside the SME Call framework. Here, Phase 1 clinical research can be used as a guideline.

In addition, below are some guidelines and examples specifically related to a particular sector:

Biotech:
- In vitro *proof-of-concept* is classified as fundamental research (TRL3).
- Preclinical studies in vivo/animal models fall under the definition of industrial research.
- Phase I clinical studies are assessed as experimental development (TRL7).

Drug development / pharma:
- *Drug discovery* and *development* have a different route to prototyping which differs significantly from the classic *proof-of-concept*. *Target Discovery* and *Hit Identification* are classified as research within TRL 2 and 3, putting them outside the framework of industrial research. *Hit-to-Lead conversion, Lead Optimisation* and further preclinical research up to the start of Phase I clinical trials are classified as industrial research within TRL 4 to 6.

Digital Health, mainly AI-related applications:

- AI applications do not follow the standard development procedure compared to other applications within the LSH sector.
    - *Proof-of-principle* and system development without a direct applicability is classified as TRL 2 and 3.
    - Only when applicability-driven development is carried out is it considered TRL4 and falls within the frameworks of industrial research.
        - Developing and testing the *framework computational model*, where the model does not yet have a specific task and/or application falls outside the frameworks of industrial research.
        - Example: cancer screening using an AI-assisted system is considered industrial research when the development is towards a specific application (e.g. colon cancer stage screening: stages 0 - 3)
    - TRL 4 to 6 includes further development of the (*machine learning*) technology into a product form, including application development.
    - We assess integration of the product into existing systems as the start of the demonstration phase (TRL7), with which this development no longer meets the conditions of the SME Call.