

TKI Life Sciences & Health

TKI LSH Match Program for public-private partnerships in MARCH 2024

Call for applications for PPP Allowance for Research and Innovation at the Top Sector Life Sciences & Health

DISCLAIMER: This call applies only to the Match Call deadline of March 2024.¹ Therefore, these terms and conditions only apply to the March 2024 deadline. This is based on the *Grondslag* 2022 (program year 2023).

1. Summary

The Top Sector Life Sciences & Health (LSH) encourages innovative research by (financially) supporting public-private partnerships (PPP) in the life sciences & health sector. With this Match Regulation, for-profit enterprises and research organisations are encouraged to jointly invest in research and development (R&D) with the aim of developing sustainable and innovative products and services within the LSH sector. 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 the PPP Allowance. To be eligible for PPP Allowance, an application should be submitted through our application procedure. More information can be found on our website. Applications may be submitted in March 2024 and will be assessed by an independent and expert evaluation committee. Subsequentially, the evaluation committee advises the LSH-TKI Foundation Board, which decides whether an application is awarded or rejected.

Each application must satisfy at least the following criteria:

- The research fits within the <u>Knowledge and Innovation Agenda 2024-2027</u> (KIA) of the Top Sector LSH, the central mission and one of the supporting missions of the societal theme Health & Care as outlined in the <u>Mission Document 2024-2027</u>, LSH and is of high quality.
- The consortium consists of at least one for-profit enterprise and at least one research organisation. The project will be realised at joint cost and risk and all consortium partners will make a substantive contribution to the project.
- The project consists of fundamental research, industrial research, experimental development, or a combination thereof.
- The main applicant is based in the Netherlands, and the project has a maximum duration of 4 years.

The deadline is <u>Tuesday March 12, 2024 CET 17.00</u>, when newly submitted applications will be reviewed and processed. Allocation will be based on the availability of PPP allowance and the following criteria and sections of the application form:

- Appropriateness within the PPP allowance program;
- Scientific quality (section B);
- Impact and relevance (section C);
- Feasibility (section D);
- Involvement of end users (section E);
- Reduction of health disparities (section E);
- Fit within the VWS missions (section E);
- Need for HI-NL Round Table Service (section E);
- Added value to the strategy of the Top Sector (section E, F);
- Connection to key technologies and use of key methodologies (section F).

If your application is rejected with a positive advice to resubmit, you may submit your revised application before the deadline on <u>Tuesday October 1, 2024 CET 17:00</u>. NOTE: This deadline is only open for previously submitted applications from Match Call March with a positive advice to resubmit.

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¹ If your application is rejected with a positive advice to resubmit, you may submit your revised application before the deadline of October 2024. These resubmissions will be subject to these terms and conditions.



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



2. Background information

2.1 Background Top Sector LSH

In 2011, the Dutch Cabinet reformed the national business policy by introducing the top sectors policy. The success of the top sector policy has led to the decision by the current Dutch government (Rutte III) that the top sectors should serve as the "means" in the mission-driven top sectors and innovation policy. In this, four societal themes are defined, and key technologies, key methodologies and the public earning capacity are taken into account. One of these societal themes is 'Health & Care'.

2.2 Societal theme 'Health & Care'

In the spring of 2019, the Ministry of Health, Welfare and Sport drew up five missions for the societal theme Health & Care: one central mission and four supporting missions that aid in reaching the goal of the central mission. The central mission focuses on living in good health longer, while reducing health inequalities between the lowest and highest socioeconomic groups. The four submissions contribute to the central mission through changes to the living environment, providing more care at the right place and better perspectives for people with chronic illnesses and dementia. The missions should be accomplished by 2040. In the fall of 2023, a fifth supporting mission focused on socially disruptive health threats was included. The mission document 2024-2027 describes the medium-term focus for these missions.

The Knowledge and Innovation Agenda 2024-2027 (KIA) describes the ambitions and aims of the health and care missions within the field of public-private partnerships. As the lead party, Top Sector LSH has drawn up the KIA together with many public and private stakeholders. This was accomplished by expanding a powerful ecosystem of public-private partnerships that was realised in recent years. A large number of these stakeholders have committed themselves to the objectives described in the KIA by means of in mind, in kind and cash contributions to the Knowledge and Innovation Covenant (KIC).

Note: The KIC 2024-2027 will be published at the end of 2023. When the KIC is available, it will be added to this document.

2.3 Key Enabling Technologies and Key Enabling Methodologies

Besides the four societal themes, the Dutch government also focuses on key enabling technologies (KETs) for future economic opportunities. Furthermore, the Top Sectors are encouraged to make targeted technological contributions to solving societal challenges. The key enabling technologies formulated have a broad application area and exert a large influence on innovations in various sectors. They will radically change the way we live, learn, innovate, work and produce, and will offer opportunities to solve problems in society. With the Knowledge and Innovation Agenda Key Enabling Technologies (KIA-ST) the Top Sectors give tangible form to this in collaboration with the government ministries and knowledge institutions.

The research agenda Key Enabling Methodologies is part of the KIA-ST. The focus is on a broad definition of the term key enabling methodologies (KEMs) and the most relevant categories of KEMs for mission-driven innovation are presented. KEMs are methods, models, strategies and processes, in other words instruments, needed for realising social and societal innovation. By deploying KEMS in the right manner, the solutions developed will lead to the desired impact. KEM categories relevant for the societal theme Health & Care, have been included in the application form (section *F.4 Key Enabling Methodologies*). Aside from the deployment of KEMs to better tackle social and societal transitions, methods will be refined and further developed by investigating their effectiveness. To put research in the area of KEMs on the agenda and further encourage their development and employment, the KEM agenda describes which methods are available, what the current scientific state of affairs is and which research questions still need to be answered.

More information can be found on the <u>KEM website</u>. For further questions concerning the deployment of and research into KEMs, please contact CLICKNL: <u>kems@clicknl.nl</u>



2.4 Background TKI-LSH Match Program

The Top Sector LSH encourages and facilitates public-private partnerships. Interdisciplinary collaboration from the perspective of top scientific expertise is vital for realising societally relevant and economically efficient innovations. To encourage (new) PPPs, the TKI-LSH Match Program was established. The program is realised by the Top Consortium Knowledge & Innovation (TKI) of the Top Sector LSH: TKI-LSH. The TKI-LSH is registered with the Chamber of Commerce under the name LSH-TKI Foundation, but is better known as health~Holland (brand name).

The TKI-LSH Match Program invites for-profit enterprises and recognised research organisations to jointly invest in research and development (R&D) for the benefit of evidence-based innovative products and services. In addition, the program offers other parties, such as health funds and health insurance providers, the opportunity to become involved in the public private partnerships.

The PPP allowance Program falls within the framework of the PPP Allowance Regulation of the Dutch Ministry of Economic Affairs and Climate Policy.



3. Conditions

3.1 Conditions for the project

The application should satisfy several conditions. Important aspects in this regard are:

- The project consists of fundamental research, industrial research or experimental development, or a combination thereof². A description of the three types of research is provided in appendix D of the application form 2023.
- The research fits within the societal theme 'Health & Care', the central mission and one of the supporting missions, as outlined in the mission document 2024-2027 and the Knowledge and Innovation Agenda 2024-2027, and the objectives of the regulation.³
- The research is of qualitatively high level and the innovative products and services are deliverables that have an added societal and economic value.
- The consortium consists of at least one for-profit enterprise and at least one research organisation⁴. Foreign for-profit enterprises and research organisations 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 based in the Netherlands.
- Effective collaboration takes place⁵. 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.
- The cash contribution of the enterprises must be due to a Dutch research organisation (and not to the project concerned).
- Besides a possible cash contribution, all consortium partners should make an in kind contribution. This
 means that all consortium partners incur payroll costs. These costs must appear on the budget form
 (Excel).
- Consortium partners may not hire or compensate each other for services or products within the project. Therefore, consortium partners may not send invoices to each other. Third parties may be hired for services; they are not consortium partners.
- In principle, enterprises decide how they fund their own contribution. However, coming up with creative constructions to do so is strongly advised against; improper use of PPP allowance by consortia should be prevented at all times.
- 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 applicable⁶.
- The project must start after the Match Call deadline and before or at the following dates:

² 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 Allowance Regulation.

³ 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.

⁴ Definition of research organisation according to the <u>Framework for State aid for research and development and innovation</u>: 'research organisation' means an entity (such as universities or research institutes, technology transfer agencies, innovation

^{&#}x27;research organisation' means an entity (such as universities or research institutes, technology transfer agencies, innovation intermediaries, research-oriented physical or virtual collaborative entities), irrespective of its legal status (organised under public or private law) or way of financing, whose primary goal is to independently conduct fundamental research, industrial research or experimental development or to widely disseminate the results of such activities by way of teaching, publication or knowledge transfer. Where such entity also pursues economic activities, the financing, the costs and the revenues of those economic activities must be accounted for separately. Undertakings that can exert a decisive influence upon such an entity, for example in the quality of shareholders or members, may not enjoy a preferential access to the results generated by it.

⁵ Definition of 'effective collaboration' according to the Framework for State aid for research and development and innovation: '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.

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



- o Final start date for Match Call round March 2024: September 1, 2024.
- o Final start date for Match Call round October 2024 (open for resubmissions only): April 1, 2025.
- The maximum project duration depends on submission time:
 - o Match Call round March: maximum 4 years (48 months).
 - Match Call round October: maximum 3 years (36 months, open for resubmissions only).

In consideration of a possible resubmission in October, after rejection in the March round, we recommend a duration of 3 years (36 months) for both deadlines.

- In all cases, the consortium should contact the PPP Allowance or TKI contact person within their own organisation well before the application is to be submitted. If you do not know the contact details of this person, please contact Health~Holland as soon as possible.
- The most recent versions of the application form, budget form and consortium agreement, available on our website, were used in the proposal. Outdated versions of these documents will not be accepted.

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 Health Innovation Netherlands (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 Match Call deadline. 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 Match 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 Match call application form (section *E.5. 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 Round Table service, on the budget as part of the total requested PPP allowance. 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 Match Call deadline.

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.

3.3 End user participation

Health~Holland encourages equitable collaboration with end users, such as citizens in their role as patients, end users, clients and/or next of kin. It is therefore important that equitable co-creation takes place during the project. Optimal co-creation occurs when a safe collaboration is realised with the end user, meaning that end users can contribute to the project in an open, vulnerable, creative and solution-focused manner. In addition, researchers must be able to apply participation methods that bring about this equitable and safe collaboration. To encourage equitable collaboration with end users, questions about their participation have been included in the application form (section *E.4 Vision on patient/end-user participation*).

Support and supervision

Within the Match Call, it is both permitted and recommended to recruit an external expertise centre in the area of participation of citizens in their role as patients, end users, clients and/or next of kin. For the duration of the project, these costs are eligible for funding and may be funded using PPP Allowance.

3.4 Impact on health disparities

Despite the collective efforts in the field of Health and Care by government, business and knowledge institutions, people with a low income and low education (primary education + pre-vocational secondary education) live 15 years less in good health than people with a college or university education and a high income. In addition, the difference in life expectancy is 7 years.

The central mission of the Health and Care social theme is that "by 2040, all Dutch people should live in good health at least five years longer and the health gap between the lowest and highest socio-economic groups should have decreased by 30%. Health~Holland, together with its many collaborative partners, aims to realise the VWS central mission of the societal theme Health & Care in all of its activities and, in doing so, to reduce health disparities. In order to realise the central mission, it is vital to be aware that health is never a stand-alone issue. Instead, it is the consequence of the conditions in which a person grows up, lives and works. It is a complex societal problem that requires a broad and domain-overarching approach. In adopting this approach, it is important to focus on what makes research and innovations effective for people in vulnerable situations and with a health disadvantage. Therefore, the experiences and/or knowledge of people with a lower socioeconomic status must be incorporated from the start of all projects.

Currently, a strong foundation of scientific and practical knowledge on what is required for a successful strategy in tackling health inequalities is already available. Health~Holland aims to encourage the implementation of this available knowledge in Match Call projects and, therefore, encourages recruiting external expertise in the area



of health disparities. This will ensure that consortia can make use of the best available knowledge and expertise in this area and can implement this in their project. The central question of this approach should always be: what is needed to enable research and innovations to connect with the demand and context of everybody and, in particular, people with a lower socioeconomic status? To assess whether projects sufficiently focus on inclusivity and take the central mission into account, a core set of "Key Principles" for reducing health disparities has been put together and included in the application form (section *E.1B Inclusion of the Key Principles for reducing health disparities*). Accordingly, this core set is also an instrument for monitoring and evaluating how health disparities are addressed during the project.

Support and supervision

Within the Match Call, it is both permitted and recommended to recruit external expertise in the area of reducing health disparities. For the duration of the project, these costs are eligible for and may be funded using PPP allowance.

Questions regarding recruitment of external expertise may be submitted to Health~Holland through: tki@health-holland.com

3.5 Consortium composition

PPP Allowance applicants put together a consortium in which research organisations and for-profit enterprises, which retain their own identity and responsibility, jointly realise a project based on a clear and optimal division of tasks and risks. All parties make a financial and substantive contribution to the project. The consortium provides a project coordinator (also principal applicant) who will be the point of contact for Health~Holland throughout the entire procedure. Other parties within the consortium are co-applicants. The PPP Allowance program is open to Dutch and foreign co-applicants, both research organisations, for-profit enterprises and other private or public parties, as long as the research contributes to the Dutch knowledge infrastructure.

3.6 Intellectual Property Policy

The consortium must establish agreements about the intellectual property (IP) related to the knowledge and products that will be developed in the project. These agreements are recorded in the consortium agreement. Among these options is the so called 'first option right'. Agreements about IP are in accordance with the Framework for State aid for research and development and innovation (specifically Article 2.2.2.) and the PPP Allowance Regulation (Regulation National Grants of the Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture, Nature and Food Quality). This states the for-profit enterprises and other private parties that participate in the project may acquire the IP from the research organisation against a remuneration (minus the already invested amount). In addition, it states that the results for which no intellectual property rights can be derived may be widely disseminated. A template consortium agreement is available on our website.

Note: each year an updated version of the model consortium agreement will be published on the Health~Holland website. Make sure you always download the most recent version. It is mandatory to use this template consortium agreement. Any modifications in the model must be directly recognisable for Health~Holland.

3.7 What amount can be applied for?

Note: A PPP Allowance or TKI contact person within your own organisation should always be contacted first. If you do not know the contact details of this person, please contact Health~Holland as soon as possible.

Within the Match Regulation, PPP Allowance can only be applied for based on Grondslag 2022. <u>PPP Allowance from grondslag 2022</u> (basic entitlement 2022)

Condition:

If the applicants have generated PPP Allowance in 2023 from the TKI-LSH grondslag 2022 (basic entitlement 2022), this PPP Allowance may be used to co-fund a collaborative project. To accomplish this, a PPP Allowance application should be submitted no later than the first deadline of this Match Call program. For grondslag 2022, this means the application should be submitted no later than March 12,



- <u>2024</u>. The Match Call deadline October, 1 2024 is open only to applications rejected with a positive recommendation to resubmission at the March 12, 2024 deadline.
- If funding is requested from the temporarily reserved PPP Allowance generated from the contributions of private partners to research (Dutch term: *grondslag* 2022) of a research organisation or enterprise, a declaration should be submitted with the proposal. In this declaration, the PPP Allowance contact person or another authorised person indicates that (a specified part of) the PPP Allowance may be used for this project.

Realisation:

• Of the total eligible project costs, a maximum of 75% of the PPP Allowance may be used for fundamental research, a maximum of 50% for industrial research and a maximum of 25% for experimental development. These maximum amounts are restated in Table 1 (p. 9). Additionally, this table shows the minimum percentage a research organisation must contribute and the minimum percentage that enterprises must contribute to a project. In the case of industrial research and experimental development, the columns do not add up to 100%, but to 80% and 90%, respectively. In these cases, parties are free to decide how to obtain the rest of the project funding required. In Table 1, a distinction is made between SMEs and large enterprises. A combination of the three types of research is possible. If you do not know whether you have generated PPP Allowance as the principal applicant (or as one of the co-applicants), please contact Health~Holland.

Table 1: Funding per type of research

Type of research	Fundamental research	Industrial research	Experimental development
Maximum % PPP Allowance to be deployed	75%	50%	25%
Research organisation(s)	min. 10%	min. 10%	min. 10%
For-profit and non-profit enterprise(s)	min. 15%	min. 30%	min. 45%
- Large** - SME***	- min. 2/3 rd in cash* - may be fully in kind	- min. 2/3 rd in cash* - may be fully in kind	- min. 2/3 rd in cash* - may be fully in kind

The percentages in the table are the percentages regarding the total project financing.

3.8 Determining the total project costs

Eligible costs

The project costs that can be incurred (eligible costs) must be directly related to the R&D activities. Examples of this are: scientific personnel, technicians, supporting staff, consumables and the use of equipment specifically required for the project (depreciation system). When entering costs for consumables, the historical cost price should be used. Commercial rates may not be entered. For a more detailed explanation of (the calculation of) eligible costs, please refer to the Commission Regulation (EU) No 651/2014 of 17 June 2014, article 25 and the Framework Decision National Grants of the Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture, Nature and Food Quality Chapter 4, articles 10-14. PPP Allowance can only be used to cover part of the eligible costs (table 1).

Parties that do not make use of PPP Allowance are not required to make use of one of the salary costs systems described in the Framework Decision National Grants of the Ministry of Agriculture, Nature and Food Quality. These parties may also use their own hourly rate. However, this is under the condition that the calculation of the hourly rate is based on a standard and controllable method and on commercial principles and standards that are considered to be acceptable in society. Additionally, the participants should systematically apply these in a collaborative project. On the budget form, these parties

^{*} At least 2/3 of the required minimum contribution of a large enterprise must consist of a cash contribution. This minimum contribution depends on the type of research and is based on their total project contribution.

^{**}The contribution of a large non-profit enterprise may be fully in kind. However, a cash contribution is encouraged.

^{***} May be fully in kind. However, a cash contribution is encouraged.



should choose 'fixed hourly rate' and change the standard hourly rate of 60 euros per hour to the hourly rate they usually apply and is verifiable.

Examples of ineligible costs

An overview of costs that are ineligible is given below. These costs may not be entered on the budget form.

- Patent applications and costs for retaining a patent (patents purchased at arm's length conditions or for which external parties grant a licence are eligible for funding);
- Auditor's statement;
- Bench fee (Note: costs for consumables are eligible);
- Travel within the Netherlands;
- Supporting personnel who are not directly involved in the R&D activities, such as a project auditor, business developer, administrative employee;
- Drawing up a business case;
- Costs related to implementation of the developed innovation;
- Conducting effectiveness studies (Health Technology Assessment, HTA);
- Overhead;
- Non-Scientific Dissemination. However, scientific dissemination, including attending a scientific conference or publishing a scientific article, is eligible;
- Project management tasks that are not directly related to the specific R&D activities, such as: escalating to a steering group, drawing up a risk management model, drawing up reports to satisfy funding requirements, administrative accountability. Project management tasks that are directly related to the R&D activities (e.g. discussions with employees, analysing technical risks, drawing up research reports, drawing up specifications) are eligible for funding.

Costs owed to third parties

If some of the activities are outsourced, then the costs payable to third parties for this can be assigned to the project and entered on the budget form. It should be ensured that the costs payable to third parties are in proportion to the rest of the budget. Should this cost category be very high, this could influence and become part of the assessment of the evaluation committee.

3.9 Use of PPP Allowance

Research organisations, such as universities, university medical centres, universities of applied sciences, TO2 institutes, KNAW institutes and other organisations that satisfy the definition of a research organisation may use PPP Allowance. Dutch SMEs (for-profit en non-profit enterprises ⁷) may use PPP Allowance to a limited extent. In case of fundamental or industrial research, a maximum of 50% of the in kind incurred costs may be funded using PPP Allowance. In case of experimental development, a maximum of 25% of the in kind incurred costs may be funded using PPP Allowance. Large enterprises, foreign SMEs and other Dutch and foreign "other" parties may not receive PPP Allowance; the costs they incur should be the same as the in kind contribution that they provide.

3.10 Data Management

Open access

Health~Holland believes that research results that are fully or partly funded with PPP Allowance (public funds) must be made freely accessible worldwide. All scientific publications emerging from research that is funded through awards from the Match Call should therefore be made freely accessible worldwide (open access) at the moment of publication. Via the website http://www.openaccess.nl/nl/node/644, you can check whether your organisation has made agreements with traditional publishers concerning open access. This website provides, amongst other things, an overview of more than 8000 journals in which corresponding authors from Dutch universities and university medical centres can publish in open access form free of charge or for a discounted price. Costs that are associated with open access publication fall under the eligible project costs.

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



FAIR

Health~Holland encourages the optimal use of research data and therefore requires this data to be stored according to the <u>FAIR principles</u>: findable, accessible, interoperable and reusable. That means that the data generated in projects can be found, understood and used by both humans as well as machines. The process of making data FAIR is specified by the GoFAIR foundation in the <u>three point FAIRification-framework</u>. Health~Holland plans to expand its policy regarding FAIR data management in the future and will increasingly monitor the FAIRness of data.

Data management plan

Health~Holland wants to increase researchers' awareness about the importance of responsible data management. Therefore, the applicant should answer the questions about data management in sections B.13 and B14 of the application form. The applicants only need to draw up a data management plan if an application is granted funding. Approval of the data management plan by Health~Holland is a condition for the disbursement of PPP Allowance.



4. Procedure

4.1 Application procedure

Only PPP-allowance applications using the most recent version of the TKI-LSH application form will be considered. The latest version of this form can be found on our <u>website</u>. In addition to the completed application form, the project coordinator must also include at least the following documents:

- Specified budget. The budget form is available for download from our website.
- Letters of commitment in which a pledge of co-funding and the size of the cash/in kind contribution is stated. The contribution by the parties is confirmed per participant (if this is not stated in the consortium agreement). The main applicant does not need to upload a letter of commitment. A template letter of commitment can be downloaded from our website. Letters of intent will not be accepted.
- Consortium agreement. This should be an unsigned concept version; an empty format is not sufficient. It is mandatory to use the template consortium agreement available on our website. Non-essential amendments and amendments that are not in conflict with the official Framework for State aid can be made to the template. In case there is any doubt regarding amendments, the research organization should call in an expert: a technology transfer office (TTO) or lawyer. The signed consortium agreement should be sent as soon as possible, but no later than 16 weeks after the submission date of the relevant Match Call.
- A statement should also be sent in which the PPP Allowance contact person or another authorised person states that (a specified part of the) reserved PPP allowance may be used for this project.
- If applicable: a PDF file with tables and figures.

Once the application has been received, Health~Holland will check its eligibility within two working days. During this eligibility check, an assessment will be made about whether the application satisfies the call conditions in accordance with Appendix I of the application form.

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

4.2 Evaluation of PPP Allowance applications

PPP Allowance applications are assessed by Health~Holland against the conditions as stated under Chapter 3. Applications that satisfy these conditions will also be assessed by an expert and independent evaluation committee. The evaluation committee may make use of an independent referee, if desired. Both the evaluation committee members and the referees must first sign a confidentiality agreement before they evaluate a PPP Allowance application.

The evaluation committee will issue an advice about the compliance to the PPP Allowance Program, relevance (including the added value to the strategy of the Top Sector LSH and the societal challenge 'Health and Care' and the connection with the Key Enabling Technologies or use of Key Enabling Methodologies), scientific quality, impact and feasibility to the LSH-TKI Foundation Board. The Board will ultimately decide whether to award PPP Allowance and which amount of PPP Allowance will be awarded for the project. The applicants will be informed of the decision by means of a letter sent no later than ten weeks after the closing of the relevant deadline.

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

4.3 Award procedure, monitoring and payments

After a PPP Allowance application has been awarded

 Within 14 weeks after the closing of the relevant deadline, the project coordinator/official secretary should submit <u>an unsigned</u> final consortium agreement approved by all partners to Health~Holland for assessment.

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



- After Health~Holland has approved the consortium agreement, the consortium has two weeks to ensure that all partners have signed the agreement.
- Once the consortium agreement is signed and approved, Health~Holland will draw up a PPP Allowance Agreement. The PPP Allowance Agreement is a contract between Health~Holland and all consortium partners that states, amongst other things, the rights and obligations as well as (financial) contributions of the various partners. This agreement will be drawn up by Health~Holland and should be signed by all partners within a period of four weeks.
- A data management plan should be submitted together with the signed version of the PPP Allowance Agreement. Health~Holland will assess the plan as quickly as possible.
- Health~Holland will publish information about all projects awarded funding on the project page of its website (http://www.health-holland.com/project). A layman's summary of the project should be submitted together with the signed version of the PPP Allowance Agreement.

Once Health~Holland has received and approved the signed PPP Allowance Agreement, the data management plan and the summary for the Health~Holland projects page, the first advance of the PPP Allowance will be disbursed. Subsequential payments will take place on an annual basis after a progress report has been received and approved. The disbursements will be made to the institution where the project coordinator is employed; the project coordinator is responsible for any further distribution of the funding to other consortium partners as well as the collective accountability for how the funding is used.

During the course of a project

- During the project, a record of each employee's working hours should be kept.
- At the start of each calendar year, the project coordinator will receive an Excel form entitled "request for information about project efforts". The primary purpose of this request for information is the annual round of informing the Dutch House of Representatives and a broad public about the progress of the top sectors policy within the area that the TKIs are responsible for. This form will be completed in advance by Health~Holland and only needs to be checked and supplemented (costs incurred over the previous calendar year).
- Within six weeks after the end of each project year, the project coordinator needs to submit a progress report. The template for this will be provided by Health~Holland. If the project has a duration of less than 18 months, then only a final report will be required.
- The consortium must hold a steering group meeting every six months. The project coordinator must inform Health~Holland about these meetings so it can be attended by a representative from Health~Holland. The midterm and final steering group meeting will also be attended by a representative of the evaluation committee. These two steering groups should also be linked to a progress report or the final report.

After project end date

Within 8 weeks after the end date of the project, the project coordinator should submit the following documents to Health~Holland:

- A final report (for which the template will be supplied by Health~Holland).
- If a consortium partner has used equal to or less than 125,000 euros of PPP Allowance a board statement should be submitted concerning the total project costs of that consortium partner.
- If a consortium partner has used 125,000 euros or more of PPP Allowance, an auditor's statement should be submitted concerning the total project costs of that consortium partner.

The final PPP Allowance payment will take place once the documents stated have been received and approved by Health~Holland.



4.4 Intended timetable

Announcement regulation Health~Holland	November 7, 2023	
Deadlines	Tuesday 12 March 2024 at 5:00 PM (CET)	
	Tuesday 1 October 2024 at 5:00 PM (CET) (only for resubmissions)	
Eligibility check	Within 2 workdays upon receipt of the proposal	
Assessment by LSH Evaluation Committee	±5 weeks after deadline	
Decision Board	±8-9 weeks after deadline	
Awarding or rejection letter	±10 weeks after deadline	
Submit final unsigned consortium agreement	Within 14 weeks after Match Call deadline	
Submit signed consortium agreement	Within 2 weeks upon approval of the unsigned consortium agreement	
Submit signed PPP Allowance Agreement	Within 4 weeks upon receipt of the PPP Allowance	
	Agreement	

Please note: this timetable is subject to change.



Further information

5.1 Downloads

Documents to be completed

- Word version of the application form Health~Holland
- Budget form Health~Holland
- Model consortium agreement
- Letter of commitment template English
- Letter of commitment template Dutch

Documents to consult

- Mission Document 2024-2027
- Knowledge and Innovation Agenda 2024-2027
- Knowledge and Innovation Covenant 2024-2027⁹

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 the Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture, Nature and Food Quality
- TKI Allowance Regulation Government Gazette 2012
- TKI Allowance Regulation Government Gazette 2016
- TKI Allowance Regulation Government Gazette 2022
- Commission Regulation (EU) No 651/2014 of 17 June 2014

5.2 Contact

For questions about the Match Call Regulation, please send an email to tki@health-holland.com or contact us by phoning +31 70 205 1400.

5.3 Submission

The application can be submitted by email to Health~Holland via tki@health-holland.com.

⁹ 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.