

### TKI Life Sciences & Health

TKI LSH Match Program for public-private partnerships in 2023

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

#### 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: <a href="https://www.health-holland.com/funding-opportunities/tki-match">https://www.health-holland.com/funding-opportunities/tki-match</a>. Applications may be submitted two times per year 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 Knowledge and Innovation Agenda 2020-2023 (KIA) of the Top Sector LSH and is of high quality.
- The consortium consists of at least one for-profit enterprise and at least one research organisation.
- The project consists of fundamental research, industrial research or experimental development, or a combination thereof.
- The project will be realised at joint cost and risk and all consortium partners will make a substantive contribution to the project.
- The main applicant is based in the Netherlands.
- The project has a maximum duration of 4 years.

There are two deadlines (<u>8 March and 4 October 2023 CET 17.00</u>) where 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);
- Added value to the strategy of the Top Sector (section E, F);
- Fit within the VWS missions (section F);
- Connection to key technologies and use of key methodologies (section F).

In 2023, the focus on the fit of projects within the central mission and four dedicated missions of the Ministry of Health, Welfare and Sport (VWS) will be sharpened. In January 2023, an online information session will be held on the different missions and their future perspectives. More information about this meeting will be posted on our website. website.

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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 <a href="mailto:tki@health-holland.com">tki@health-holland.com</a>. 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.

#### 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. The Knowledge and Innovation Agenda (KIA) 2020-2023 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 <u>Knowledge and Innovation Covenant 2020-2023</u>.

#### 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.7 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 <a href="https://example.com/Health~Holland">Health~Holland</a> (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. Additional background information can be found on our website. Additionally, background documents, such as the Knowledge and Innovation Agenda 2020-2023 and the Knowledge and Innovation Covenant 2020-2023 of the Top Sector LSH are available.

#### 2.5 Research domain of the regulation

Project proposals must fit within the <u>Knowledge and Innovation Agenda 2020-2023</u> of the Top Sector LSH and the central mission and four submissions are described in this strategic document. The <u>Knowledge and Innovation Agenda 2020-2023</u> and the missions provide the framework for the LSH research program of the projects eligible in the Match Program.



#### 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 thereof¹. 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', as outlined in the Knowledge and Innovation Agenda 2020-2023, and the objectives of the regulation.
- 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 organisation<sup>2</sup>. 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 place<sup>3</sup>. 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 <u>all consortium partners incur payroll costs</u>. These costs must appear on the budget form
  (Excel).
- Consortium partners may not send each other invoices for project related costs.
- 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 applicable<sup>4</sup>
- The starting date of the project is after the Match Call deadline.
- The project must start within six months after the awarding letter was received.
- The project may have a maximum duration of 4 years.
- 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.

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> 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 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.

<sup>&</sup>lt;sup>3</sup> 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.

<sup>&</sup>lt;sup>4</sup> 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 3.2.8 of the <u>Regulation National Grants of the Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture, Nature and Food Quality.</u>



• 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 is only applicable if the consortium is likely to apply for CE marking for the innovation <u>during the project</u> period or within two years after this.

#### HI-NL

The number of health and care innovations is constantly increasing. These innovations vary from implants and high-tech diagnostic and prognostic machines to biomarker assays, AI-algorithms, medical apps and wearables for self- and home management. The evaluation methods, introduction, implementation and reimbursement of medicines are clearly described and regulated. However, this is not the case for non-medicinal (medtech) innovations. 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. Therefore, Health~Holland collaborates with Health Innovation Netherlands (HI-NL). HI-NL brings together all relevant parties, at the earliest possible stage, that play a crucial role in the medtech development, evaluation, use, scale-up, decision-making and reimbursement process to help innovators on their road to success. Such meetings are called roundtable meetings.

#### Innovation guidance by HI-NL

The aim of a HI-NL roundtable is to draw up an overall picture at an early stage of how an innovation will fit in the healthcare and prevention landscape and to analyse what is needed to bring an innovation to the market. During the roundtable, the relevant parties discuss the following aspects:

- The value of the innovation from the perspective of each relevant party, including the innovator, given the intended claims, target group, healthcare market, integration in the current care context and guidelines, the necessary research for and evidence about the impact of the innovation, and the identification of possible obstacles and their solutions;
- The necessary evidence for achieving the next innovation development step, including CE marking;
- The exploration of possible obstacles and facilitators for implementation.

After the roundtable, HI-NL issues a comprehensive and concrete advisory report, the innovation guide, and a follow-up telephone consultation is planned. The innovation guide contains a consensus opinion from the panel of all relevant parties. In addition, this document provides an overview of the most important steps that an innovator must take to successfully evaluate, scale-up and implement the innovation in the intended (health) context. The innovation guide is a confidential document and the property of the innovator.

#### Which steps should the consortium undertake?

If the consortium aims to develop an innovation within the submitted project, for which it is likely that CE marking will be applied for during the duration of the project, or within two years after the project period, the consortium may contact HI-NL no later than three weeks before the closing of the Match Call deadline. HI-NL will subsequently analyze whether a round table and innovation guide may offer added value to the innovator and its new product. If, after contacting HI-NL, it appears that the development of an innovation guide would be of added value, this may be indicated on the application form (section 29. Innovation guidance). In addition, the project coordinator may include an earmarked budget of € 33.275 (incl. VAT) on the budget form for the drawing up the innovation guide. This amount can be included under the heading "costs owed to third parties" together with the specification "development innovation guide by HI-NL". The costs for the development of an innovation guide can be funded using PPP allowance.

After the application for PPP funding has been (conditionally) awarded the consortium will be asked to elaborate on the plans related to the development of the innovation guide 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

The contact person at HI-NL can be reached via the following e-mail address: info@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.1 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.3 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 $^{\sim}$ Holland through:  $\underline{tki@health-holland.com}$ 



#### 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 co-applicants from Dutch and foreign 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 (Dutch Government Gazette of <u>4 September 2012</u> and <u>18 November 2016</u>). 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.

There are two options to apply for the PPP Allowance within the Match Regulation<sup>5</sup>:

## <u>Option 1: PPP Allowance from grondslag 2021/2022</u> (basic entitlement 2021/2022) Condition:

- If the applicants have generated PPP Allowance in 2021 from the TKI-LSH *grondslag 2021* (basic entitlement 2021), 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 2023, this means the application should be submitted no later than 8 March. Any PPP allowance generated from the TKI-LSH *grondslag 2022* should be utilised at the deadline of 4 October 2023.
- If funding is requested from the temporarily reserved PPP Allowance via *Option 1* (generated from the contributions of private partners to research (Dutch term: *grondslag*) 2021/2022) 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 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

<sup>&</sup>lt;sup>5</sup> An introduction movie about the Health~Holland's application procedure can be viewed through the following link: https://www.youtube.com/watch?v=5uzzAa0ygq8.



not know whether you have generated PPP Allowance as the principal applicant (or as one of the coapplicants), please contact Health~Holland.

Option 2: PPP Allowance based on cash contributions of for-profit enterprises per individual collaborative project. If the applicants have not generated sufficient- or any PPP Allowance from the grondslag 2021/2022 (basic entitlement 2021/2022) to co-fund a collaborative project, but the for-profit enterprises do make a considerable cash contribution<sup>6</sup>, PPP Allowance may still be applied for. The PPP Allowance applied for may, in principle, be up to 30% of the total cash contributions of the for-profit enterprises to the project and up to €1 million in PPP allowance per project. The LSH-TKI Foundation Board has the right to deviate from this. In addition, the conditions as stated in Table 1 apply here.

In addition, combining options 1 and 2 is possible as well. Please contact Health~Holland for any further inquiries on these possibilities.

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) - Large** - SME***	min. 15% - min. 2/3 <sup>rd</sup> in cash* - may be fully in kind	min. 30% - min. 2/3 <sup>rd</sup> in cash* - may be fully in kind	min. 45% - min. 2/3 <sup>rd</sup> 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, 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 <u>Framework Decision National Grants of the Ministry of Economic Affairs</u>. 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 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.

<sup>\*</sup> 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.

<sup>\*\*</sup>The contribution of a large non-profit enterprise may be fully in kind. However, a cash contribution is encouraged.

<sup>\*\*\*</sup> May be fully in kind. However, a cash contribution is encouraged.

<sup>&</sup>lt;sup>6</sup> Furthermore, the consortium must be able to demonstrate a private cash contribution of at least 10,000 euros per annum for each project.



- 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 <sup>7</sup>) 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 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 <a href="http://www.openaccess.nl/nl/node/644">http://www.openaccess.nl/nl/node/644</a> 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.

#### 3.11 Data management

Health~Holland encourages the optimal use of research data and therefore wants this data to be stored according to the FAIR principles<sup>8</sup>: findable, accessible, interoperable and reusable. Furthermore, 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.

<sup>&</sup>lt;sup>7</sup> 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.

<sup>8</sup> https://www.dtls.nl/fair-data/fair-data/



#### 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. If a signed consortium agreement is not yet available, then a concept version needs to be provided. It is mandatory to use the template consortium agreement available on our website<sup>9</sup>. 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.
- If a claim is made to the temporarily reserved PPP Allowance through Option 1 as described in paragraph 3.7 (generated from the *grondslag 2021/2022* (basic entitlement 2021/2022)) of a research organisation or enterprise, 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. In 2023, the evaluation committee will be advised by independent experts on the adequacy of applications within the five VWS missions. 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.

<sup>&</sup>lt;sup>9</sup> Please contact Health~Holland when an existing consortium agreement is already in place



#### 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 an unsigned final consortium agreement approved by all partners to Health~Holland for assessment.
- 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 (<a href="http://www.health-holland.com/project">http://www.health-holland.com/project</a>). 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 more than 125,000 euros 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	29 November 2023	
Match Call webinar	Announced in January 2023	
Deadlines	8 March and 4 October 2023 at 5:00 PM (CET)	
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

- Knowledge and Innovation Agenda 2020-2023
- Knowledge and Innovation Covenant Top Sector LSH 2020-2023

#### 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
- 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 <a href="mailto:tki@health-holland.com">tki@health-holland.com</a> 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.