TKI Life Sciences & Health

HHINT Kickstarter for public-private partnership in 2021

Call for applications for the Health~Holland International Kickstarter for public-private partnerships for the Top Sector Life Sciences & Health

1. Background and objective of the programme

The Dutch have a long tradition of investing in international cooperation. Investing in an international network can provide a significant acceleration of research and development (R&D). Sharing knowledge between international partners helps to better identify the end users and supports valorisation and export. In addition, international cooperation may be the first step for foreign organisations to invest and settle in the Netherlands. Therefore, internationalisation is one of the focus points of Top Sector Life Sciences & Health (LSH).

The Top Sector LSH wants to stimulate international, public-private partnerships (PPP). Current financial instruments for early partnerships between the Netherlands and non-European countries are limited. To facilitate the first steps to R&D cooperation worldwide, the Top Sector LSH established the programme 'Health~Holland International (HHINT) Kickstarter for public-private partnership'. This programme is realised by the executive office of the Top Sector LSH. It is also known as the LSH-TKI Foundation (brand name: Health~Holland).

With the HHINT Kickstarter, for profit enterprises and recognised research organisations are invited to apply for financial support (PPP Allowance) to get off to a flying start to establish a long lasting foreign public-private partnership in R&D. This PPP Allowance serves as a first driver in international R&D cooperation between the parties. At least one of the consortium partners must be situated in the Netherlands and at least one in a foreign country. The programme falls within the framework of the PPP Allowance Regulation of the Dutch Ministry of Economic Affairs and Climate Policy. Additional information can be found on our website.

The proposed projects must fit within the Knowledge and Innovation Agenda 2020-2023 of the Top Sector LSH. The central mission and four missions are described in this strategic document. The Knowledge and Innovation Agenda 2020-2023 and the missions provide the framework for the research programme of the projects in the HHINT Kickstarter programme.

2. Conditions

2.1 Conditions for the project

The application should satisfy at least the following conditions:

- The project covers fundamental research, industrial research or experimental development, or a combination thereof[1]. A description of the three types of research is provided on our website.
- The project fits within the societal challenge 'Health & Care', as outlined in the Knowledge and Innovation Agenda 2020-2023, and the objectives of the regulation
- The consortium consists of at least one for profit enterprise and at least one research organisation[2]. One of the consortium partners must be a foreign research organisation/for profit enterprise.
- The project contributes to the central mission and to at least one of the four missions of the societal challenge 'Health & Care', as outlined in the Knowledge and Innovation Agenda 2020-2023.
- The consortium partners use an 'input-activities-output-outcome-impact approach' (impact pathway[3]) to increase the societal impact of the project.
- The main applicant is located in the Netherlands.
- Effective collaboration[4] takes place. This means, for example, that the project is realised at joint cost and risk and that all consortium partners make a substantive contribution to the project.
- It is the first time that the parties are jointly realising an R&D project. The PPP Allowance therefore serves as a first driver in international R&D cooperation between the parties.
- To promote sustainable collaboration, consortium partners are willing and able to show significant efforts to strengthen the relationship between the partners during and after the project period.
- The results of the project will benefit the Dutch knowledge infrastructure and economy.
- After the end of the project, the parties have the intention to continue the cooperation or to invest in the Netherlands.
- The knowledge that will be developed by the consortium will be accessible to all participating parties.
- Besides a possible cash[5] contribution, all consortium partners should make an in-kind contribution. This means that at least all consortium partners incur payroll costs. These costs must also be visible on the budget form (Excel).

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[1] In case of drug development, pre-clinical research in animals falls within the research category 'industrial research'. The 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.

[2] Definition of research organisation according to the Framework for State aid for research and development and innovation: '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.

[3] https://www.nwo.nl/impact-plan-benadering.

[4] 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.

[5] The cash contribution of the private partners must be due to a Dutch research organisation (and not to the project).

- Consortium partners may not send any invoices to each other for the project submitted.
- The consortium has not received any other grants for the current project.
- In principle, it is for the enterprises to decide how they fund their own contribution. However, coming up with creative constructions to do this is strongly advised against; improper use of PPP allowance the consortium should be prevented.
- The project may have a maximum duration of 18 months.
- The amount of PPP Allowance that can be applied for is between €50,000 and €120,000 per project.
- The PPP Allowance covers 25% (experimental development) to 50% (fundamental/industrial research) of the total eligible project costs[6].
- Dutch SMEs and other Dutch private parties may use PPP Allowance to a limited extent (see paragraph 2.5 for more details). A maximum of 50% of the PPP Allowance can be used to cover the costs of Dutch SMEs and other Dutch private parties. There are no restrictions on the use of PPP Allowance by Dutch and foreign research organisations.
- The starting date of the project is after the date of submission to Health-Holland.
- The project must start within six months after the awarding letter was received.

2.2 Evaluation of health and care innovations

This condition is only necessary if the consortium is likely to apply for CE marking for the innovation during the project period or within two years after this.

HI-NL

The number of health and care innovations is constantly increasing. These innovations vary from high-tech machines to medical apps and wearables for self- and joint management. The evaluation methods, introduction, implementation and reimbursement of medicines are clearly described and regulated, but that is not the case for non-medicinal 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. Health-Holland therefore works together with the Health Innovation Netherlands (HI-NL). At an early stage, HI-NL brings together the relevant parties[7] that play a crucial role in the development, evaluation, use, decision-making and reimbursement processes, so that innovators are facilitated on their road to success. Such a meeting is called a roundtable.

Innovation guidance by HI-NL

The aim of a roundtable is to obtain an overall picture of how an innovation will fit in the healthcare landscape and to analyse what is needed for this. During the roundtable, the relevant parties discuss the following aspects:

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

After the roundtable, HI-NL issues a report, an “innovation guide”, and a follow-up telephone consultation is planned. The innovation guide contains a consensus opinion from the panel of relevant parties. In addition, this document provides an overview of the most important steps that

[6] See Chapter 3, article 3.2.5, part 1b of Regulation National Grants of the Ministry of Economic Affairs and Climate Policy and Ministry of Agriculture, Nature and Food Quality for rules regarding the total amount of support allowed per beneficiary participant in a project.
[7] Such as National Health Care Institute, Dutch Healthcare Authority, health insurers, health economists, legislators, patients, end users and professional associations.

an innovator must take to successfully implement the innovation. The innovation guide is a confidential document and the property of the innovator.

Which steps should the consortium undertake?
If, with the application submitted, the consortium develops an innovation for which it is likely that CE marking will be applied for during the project period, or within two years after the project period, then the consortium should contact HI-NL 3 weeks prior to the submission of the application. HI-NL will subsequently analyse whether an innovation guide should be developed during the project period. If after contact with HI-NL the development of an innovation guide proves to be recommended, then this should be stated on the application form (part 30). In addition, the project coordinator should include an earmarked budget of € 24.200 (incl. VAT) on the budget form for the drawing up of the innovation guide. This amount can be included under the heading "costs third parties", together with the specification "development innovation guide by HI-NL". The costs for the development of an innovation guide can be funded with a PPP allowance.

Only after the application for a PPP allowance has (conditionally) been awarded funding does the consortium have to elaborate the plans in the application with respect to the development of the innovation guide. The details about this are included in the award letter.

Contact person HI-NL
The contact person at HI-NL can be reached via the following e-mail address: info@healthinnovation.nl.

2.3 Impact Pathway

Society is faced with increasingly complex challenges and issues for which solutions must be found. New knowledge and insights from scientific research can make an important contribution to solutions for these challenges. The chance of social impact is increased by involving stakeholders who may use the knowledge from research and by jointly drawing up an Impact Plan with them on how the desired social impact can be achieved. The Impact Plan approach consists of an integrated strategy in which productive interactions are promoted through the use of a Theory of Change and Impact Pathways. As part of the PPP allowance application process, the consortium will have to draw up an Impact Plan in the first month of the project period.

More concrete information about drawing up an Impact Plan will follow after conditional funding of the project application. Through the following website some background information is already provided.

2.4 Consortium composition

The 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 main applicant) who will be the point of contact for Health~Holland throughout the entire procedure. Each of the other parties within the consortium is a co-applicant.

2.5 Intellectual Property Policy

The consortium must make 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. A 'first option right' is one of the options. 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 4 September 2012 and 18 November 2016). This states that 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) and that the results for which no intellectual property rights can be derived may be widely disseminated. A model consortium agreement is available on our website.

Note: We would strongly appreciate it, if consortia would make use of this model consortium agreement. Any modifications must be recognisable for Health-Holland.

2.6 Calculation of the project costs

Eligible costs
The project costs that can be incurred (eligible costs) must be directly related to the R&D activities. Examples 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 Ministry of Agriculture, Nature and Food Quality, Chapter 4, articles 10-14. The PPP Allowance can only be used to cover part of the eligible costs.

Parties that make no 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 Economic Affairs and Ministry of Agriculture, Nature and Food Quality. These parties may also use their own hourly rate. However, a condition for this is 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 and that the participants systematically apply 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 an hourly rate that they usually apply and that is verifiable.

Examples of ineligible costs
An overview of costs that are ineligible is given below. Therefore, 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;
- Travel within the Netherlands (costs for travel to the Netherlands are eligible for funding);
- 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;
- Overheads;
- 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.

2.7 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 (no restrictions).

Dutch SMEs and other Dutch private parties may use PPP Allowance to a limited extent. In case of fundamental/industrial research, a maximum of 50% of the in-kind costs they incur may be funded with PPP Allowance. In case of experimental development, a maximum of 25% of the in-kind costs they incur may be funded with PPP Allowance.

Large enterprises, foreign SMEs and other foreign private parties may not use PPP Allowance; the costs they incur should be the same as the in-kind contribution that they provide.

2.8 Open access

Health~Holland believes that research results which 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 on the basis of awards from the HHINT Kickstarter 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.

2.9 Data management

Health~Holland encourages the optimal use of research data and therefore wants this data to be stored according to the FAIR principle[8]: 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 in Section 18 of the application form some questions about data management. The applicants only need to draw up a data management plan if an application is awarded funding. The approval of the data management plan by Health~Holland is a condition for the disbursement of the PPP Allowance.

[8] https://www.dtls.nl/fair-data/fair-data/

3. Procedure

3.1 Application procedure

Only applications for PPP Allowance that have been completed on the HHINT Kickstarter application form will be eligible for consideration. This form is available on our website. The project coordinator should send at least the following attachments with the application form:

- Specified budget. This is available for download from our website.
- Letters of commitment in which the pledge of the 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). Only the main applicant does not need to upload a letter of commitment. A letter of commitment template 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 at least a concept version needs to be provided. We would appreciate it if you would use the model consortium agreement that is available on our website. A research organisation should use the services of an expert (technology transfer office (TTO) or a lawyer) to draw up the consortium agreement. The signed consortium agreement should be sent as soon as possible, but no later than 16 weeks after the submission date.

3.2 Evaluation of PPP Allowance applications

A PPP Allowance application is assessed by Health-Holland against the conditions as stated under Section 2. Applications that satisfy these conditions will also be assessed by an independent advisory panel consisting of experts in the field of international R&D. The advisory panel will score the applications on the following aspects:

- relevance (including the added value to the strategy of the Top Sector LSH and the societal challenge 'Health and Care');
- scientific quality of the project;
- feasibility of the project;
- quality of the consortium;
- potential to establish a long lasting foreign public-private partnership in R&D;
- potential to provide a basis for future valorisation and research funding.

The advisory panel members will send their review to Health-Holland. Health-Holland's evaluation committee will issue an advice to the LSH-TKI Foundation Board. Both the advisory panel members and Health-Holland's evaluation committee must first sign a confidentiality agreement before they may assess a PPP Allowance application. The Board will eventually decide whether to **conditionally** award a PPP Allowance to an application and what the size of the PPP Allowance for the project concerned will be. The applicant will be informed of the decision by means of a letter sent no later than twelve weeks after the submission deadline.

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

3.3 Award procedure, monitoring and payments

After a PPP Allowance application has been awarded

- Within 16 weeks after the submission date, the project coordinator should submit a consortium agreement that has been signed by all partners.
- Once the consortium agreement is 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 supplied together with the signed version of the PPP Allowance Agreement. Health~Holland will assess the plan as quickly as possible.
- An impact plan should be drawn up during the first month of the project period.
- Health~Holland will publish information about all projects awarded funding on the project page of its website (http://www.health-holland.com/project). A broadly understandable 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 can be disbursed. The final payment will take place after a final report has been received and approved. The disbursements will be made to the institution where the project coordinator works; 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).
- The consortium must hold a steering group meeting every six months. The project coordinator must inform Health~Holland about this, so that a representative from Health~Holland can attend the meetings.

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). After recipient of the final report, a meeting will be scheduled between the consortium and a representative of Health~Holland to discuss the continuation of the collaboration and potential other funding options. During this meeting, the impact plan will also be discussed and adjusted where necessary.
- A board statement must be provided by all consortium partners that have made an in-kind contribution to the project.
- A Chamber of Commerce extract from each Dutch consortium partner showing that the person who signed the board statement is authorized to sign. In some cases, an additional mandate document needs to be submitted.

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

4. Further information

4.1 Available budget

For the HHINT Kickstarter programme 2021 the total available amount of PPP Allowance is €600,000.

4.2 Submission

Applications can be submitted on a continuous basis from 13 August to 1 December 2021 CET 17.00 via tki@health-holland.com. Applications will be evaluated and awarded based on the 'first come, first served' principle.

4.3 Downloads

Documents to be completed

- Application form HHINT Kickstarter
- Budget form TKI-LSH
- Model consortium agreement (standard)
- Model consortium agreement (clinical studies)
- Letter of commitment template

Information

- Knowledge and Innovation Agenda 2020-2023
- Knowledge and Innovation Covenant Top Sector LSH 2020-2023
- Impact Pathway Approach

Laws and regulations

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

4.4 Contact

For questions about the HHINT Kickstarter programme, please send an email to tki@health-holland.com.