

TKI Life Sciences & Health

TKI LSH Match Regulation for public-private partnerships in 2019

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 a PPP Allowance, an application should be submitted via our online application procedure. More information can be found on our website <http://www.health-holland.com/calls/tki-match>. All applications will be collected two times per year and assessed by an independent and expert evaluation committee. The LSH-TKI Foundation Board decides whether to award an application.

Each application must satisfy at least the following criteria:

- The research fits within the [Knowledge and Innovation Agenda 2018-2021](#) of the Top Sector LSH and is of a high quality.
- The consortium consists of at least one for-profit enterprise and at least one research organisation.
- The project covers 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 located in the Netherlands.
- The project has a duration of a maximum of 4 years.

There are two deadlines (7 March and 9 October 2019) at which point newly received applications will be assessed and processed. Funds will be allocated on the basis of the availability of the PPP Allowance, compliance to the PPP Allowance Regulation, relevance (including the added value to the strategy of the Top Sector LSH and the societal challenge 'Health and Care'), application's scientific quality and feasibility.

2. Background information

2.1 Background Top Sector LSH

In 2011, the Dutch Cabinet reformed the business policy by introducing the top sectors policy. The success of the top sectors policy has led to the current Dutch Cabinet (Rutte III) deciding to use the top sectors as a vehicle for tackling eight societal challenges. One of these societal challenges is 'Health and Care'. The Top Sector LSH has been asked to take the lead with respect to tackling this societal challenge. The [Knowledge and Innovation Agenda \(KIA\) 2018-2021](#) describes the ambitions of the coalition led by the Top Sector LSH in the area of 'Health and Care' for the period 2018-2021. In addition, by means of the [Knowledge and Innovation Contract \(KIC\) 2018-2019](#), the coalition has made agreements about the implementation and collective deployment of the ambitions described in the KIA.

2.2 Background TKI-LSH Match Regulation

The Top Sector LSH encourages 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 Regulation has been established. This regulation 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).

With the TKI-LSH Match Regulation, for-profit enterprises and recognised research organisations are invited to jointly invest in research and development (R&D) for the benefit of evidence-based innovative products and services. In addition, the regulation offers other parties, such as health funds and health insurers, the opportunity to become involved as well.

The regulation 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](#). Background documents, such as the [Knowledge and Innovation Agenda 2018-2021](#) and the [Innovation Contract 2018-2019](#) of the Top Sector LSH, are also available.

2.3 Objectives of the regulation

Besides encouraging new PPPs, the regulation also aims to tackle the theme of cost management in healthcare and to contribute to the ambitions of the Top Sector LSH through R&D. These ambitions entail:

- To become one of the top-3 international LSH sectors by 2030 and to be active in Global Health initiatives in developing countries.
- To compete and collaborate from a solid, future-proof, data- and research infrastructure for health, healthcare and related research.
- To support and facilitate operational public-private partnerships.
- To facilitate start-up companies to scale up and even become global players.
- To support the affordability of healthcare and delivery of healthcare solutions.
- To support the creation and implementation of alternative business models for existing and innovative pharmaceuticals, medical technology and healthcare services.
- To contribute to increasing the work productivity in healthcare.

In realising the aforementioned ambitions, the highest ethical and moral standards will be adhered to and due consideration will always be given to minorities, inequalities, privacy, safety and human- and animal welfare.

2.4 Research domain of the regulation

The proposed projects must fit within [the Knowledge and Innovation Agenda 2018-2021](#) of the Top Sector LSH. Ten LSH roadmaps are described in this strategic document (p. 18). The [Knowledge and Innovation Agenda 2018-2021](#) and the roadmaps provide the framework for the LSH research programme of the projects currently in the Match Regulation.

3. Conditions

3.1 Conditions for the project

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

- The project covers fundamental research, industrial research or experimental development, or a combination thereof¹. A description of the three types of research is provided on our [website](#).
- The research fits within the societal challenge ‘Health & Care’, as outlined in the [Knowledge and Innovation Agenda 2018-2021](#), and the objectives of the regulation.
- The research is of a 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 organisation². Foreign for-profit enterprises and research organisations are also 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 located in the Netherlands.
- Effective collaboration takes place³. 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.
- Besides a possible cash⁴ contribution, all consortium partners should make an in-kind contribution. This means that all consortium partners incur payroll costs, for example.
- The enterprises and other private parties may not send any invoices to the research organisations for the project submitted.
- If the consortium has or shall receive other public funding for the project submitted, for example from NWO, ZonMw, TNO, TTW or Health-Holland, then the regulation concerning the accumulation of different grants is applicable⁵.
- The starting date of the project is after the date of the next deadline for this Match Regulation.
- The project may have a maximum duration of four years.
- The project must start within six months after the awarding letter was received.

¹ In case of drug development, pre-clinical research in animals falls within the research category ‘industrial research’. In principle, 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 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.

⁴ The cash contribution of the enterprises and other private parties must be due to a Dutch research organisations (and not to the project).

⁵ The accumulation provisions are stated in Section 2, article 6, of the [Framework Decision National Grants of the Ministry of Economic Affairs](#). The support limits with respect to the acquisition of PPP Allowance are stated in article 3.2.8 of the [Regulation National Grants of the Ministry of Economic Affairs](#).

3.2 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 principal 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. The regulation 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.

3.3 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 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.

3.4 How much can be applied for?

There are two options to apply for the PPP Allowance within the Match Regulation⁶:

Option 1: PPP Allowance from grondslag 2017 (basic entitlement 2017)

Condition:

- If the applicants have generated PPP Allowance in 2018 from the TKI-LSH *grondslag 2017* (basic entitlement 2017), then this PPP Allowance may be used to co-fund a collaborative project. For this, a PPP Allowance application should be submitted no later than the first deadline of this Match Regulation. For 2019, this may be no later than 7 March.

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 stated again in Table 1 (p. 6). Additionally, this table shows which minimum percentage a research organisation must contribute and the minimum percentage that a for-profit enterprise must contribute. In the case of industrial research and experimental development, the columns do not add up to 100% but to 90% and 80% 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 drawn 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.

⁶ An introduction movie about the Health-Holland's application procedure can be viewed through the following link: <https://www.youtube.com/watch?v=5uzzAaOygg8>.

Option 2: PPP Allowance based on cash contribution of for-profit enterprises per individual collaborative project

If the applicants have not generated sufficient or any PPP Allowance from the *grondslag 2017* (basic entitlement 2017) to co-fund a collaborative project but the for-profit enterprises do make a considerable cash contribution⁷, then a PPP Allowance may still be applied for. The PPP Allowance applied for may, in principle, be 30% of the total cash contributions of the for-profit enterprises to the project. The LSH-TKI Foundation Board has the right to deviate from this. The conditions as stated in Table 1 also apply here.

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 enterprise(s)	min. 15%	min. 30%	min. 45%
- Large	- min. 2/3 rd in cash*	- min. 2/3 rd in cash*	- min. 2/3 rd in cash*
- SME**	- may be fully in kind	- may be fully in kind	- may be fully in kind

* 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.

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

3.5 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](#), 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](#). 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.

⁷ Furthermore, the consortium must be able to demonstrate a private cash contribution of at least 10,000 euros per annum for each project.

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;
- 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.

3.6 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 and other Dutch private parties may use PPP Allowance to a limited extent; 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.

3.7 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 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.

3.8 Data management

Health-Holland encourages the optimal use of research data and therefore wants this data to be stored according to the FAIR principle⁸: 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 15 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/>

4. Procedure

4.1 Application procedure

Only applications for PPP Allowance that are submitted via our online application procedure will be considered. Besides completing the digital application form, the project coordinator/official secretary must upload at least the following annexes:

- 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 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 of the relevant Match Call.
- If a claim is made to the temporarily reserved PPP Allowance (generated from the *grondslag 2017* (basic entitlement 2017)) of a research organisation or enterprise, then a statement should also be sent in which the PPP Allowance contact person or another authorised person states that (part of the) reserved PPP Allowance may be used for this project.
- If applicable: a PDF-document with tables and figures.

4.2 Evaluation of PPP Allowance applications

A PPP Allowance application is 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 so desired. Both the evaluation committee members and the referees must first sign a confidentiality agreement before they may assess a PPP Allowance application.

The evaluation committee will issue an advice about the compliance to the PPP Allowance Regulation, relevance (including the added value to the strategy of the Top Sector LSH and the societal challenge 'Health and Care'), scientific quality and feasibility to the LSH-TKI Foundation Board. The Board will eventually decide whether to 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 ten weeks after 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 16 weeks after the date of the deadline concerned, 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.
- 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 other 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 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).
- 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 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).
- If a consortium partner has not used or has used less than 125,000 euros of PPP Allowance, then 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 in PPP Allowance, then 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	11 January 2019
Deadlines	7 March and 9 October 2019 at 5:00 PM (CET)
Assessment by LSH Evaluation Committee	±5 weeks after deadline
Decision Board	±7 weeks after deadline
Awarding or rejection letter	±10 weeks after deadline

Please note: this timetable is subject to change.

Further information

5.1 Downloads

Documents to be completed

- [Budget form Health-Holland](#)
- [Model consortium agreement](#)
- [Letter of commitment template](#)

Documents to consult

- [Word version of application form Health-Holland](#)
- [Knowledge and Innovation Agenda 2018-2021](#)
- [Innovation Contract Top Sector LSH 2018-2019](#)

Laws and regulations

- [Commission Regulation \(EU\) No 651/2014 of 17 June 2014](#)
- [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](#)
- [Framework Decision National Grants of the Ministry of Economic Affairs](#)
- [TKI Allowance Regulation Government Gazette 2012](#)
- [TKI Allowance Regulation Government Gazette 2016](#)

5.2 Questions

For questions about the Match Call Regulation, please send an email to tki@health-holland.com or contact us by phoning +31 70 349 5145.

5.3 Submission

You can submit your application through the Health-Holland online application system which can be consulted via the website: <http://www.health-holland.com/calls/tki-match>. The digital application form will be made available no later than two weeks before the deadline concerned. A Word version of the application form can be downloaded for reference purposes from our [website](#) as soon as the call is published.