

Overview Requirements LSH PPP Allowance TKI Programme 2022

Top Sector Life Sciences & Health (LSH) supports innovative research and development by public-private partnerships (PPPs) of the Dutch LSH sector. The Top Sector brings together stakeholders in a shared, consolidated innovation infrastructure. By means of PPP Allowance, the Top Sector provides a financial instrument to help consortia consisting of research organisations, knowledge institutes, companies, and health foundations to realise their innovative ideas.

By identifying contributions of private partners in PPPs in the LSH sector, the Top Consortia for Knowledge and Innovation's (TKI) office of the Top Sector can apply for PPP Allowance at the Netherlands Enterprise Agency and Ministry of Economic Affairs and Climate Policy. The Dutch Top Sector Life Sciences and Health ('*Topconsortium voor Kennis en Innovatie*' or '*TKI Life Sciences and Health*') is represented by Stichting Life Sciences Health – TKI (also acting under its trade name Health~Holland).

The Stichting Life Sciences Health (LSH)-TKI has set the public-private partnerships (PPP, 2021 program) allowance reserved for the Lung Foundation at an amount of maximal € 383.700.

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 thereof (see Appendix 1 for a description of the three types of research).
 - 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 organization. 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 place¹. This means, for example, that the project is realised at joint cost and risk and all consortium partners make a substantive contribution to the project.
 - The cash contribution of the enterprises must be due to a Dutch research organisation (and not to the project concerned).
 - Besides a possible cash contribution, all consortium partners should make an in kind contribution. This means that all consortium partners incur payroll costs. These costs must appear on the budget form (Excel).
 - Consortium partners may not send any invoices to the research organisations for project related costs.
 - 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.
1. Effective collaboration: collaboration between at least two independent parties to exchange knowledge or technology or to achieve a common objective based on a division of labor, whereby the parties jointly determine the scope of the collaborative project, contribute to its implementation, and share the risk and its results. One or more parties can bear the full costs of the project and thus relieve the other parties from the financial risks associated with the project. Contract research and the provision of research services are not considered forms of cooperation.

- 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.
- The project must start within six months after the awarding letter was received.

Contribution of private partners

The Longfonds must use the PPP allowance to finance R&D projects involving actual collaboration¹ between at least one knowledge institution and a company. 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 (Appendix 2). Additionally, this table shows the minimum percentage a research organisation must contribute and the minimum percentage that a for-profit enterprise must contribute to a project. A combination of the three types of research is possible. A more detailed description of the different types of research can be found in Appendix 1.

The total public and private contribution to a project depends on the type of research and should be, respectively, 10% and 15% of the total project costs. The private contribution of companies in a project should at least be 15% of the eligible costs of a project. In Table 1, a distinction is made between SMEs and large enterprises. A further explanation and co-financing guideline can be found in Appendix 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 Longfonds throughout the entire procedure. Other parties within the consortium are co-applicants. 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.

Participation end user

Health~Holland encourages equal collaboration with the end users, such as citizens in their role as patients, end users, clients and/or next of kin. It is therefore important that equal co-creation takes place during the project. Optimal co-creation occurs when a safe collaboration is realised with the end user, which means that the end user 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 equal and safe collaboration. To encourage equal collaboration with end users, specific questions about their participation have been included in the application form (section 17: Patient/end user participation).

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. 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 [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). In addition, it states that the results for which no intellectual property rights can be derived may be widely disseminated.

Data management

Stichting LSH-TKI stimulates optimal use of research data and therefore requires that the data is stored according to the FAIR principle: findable (findable), accessible (accessible), interoperable (interoperable) and reusable (reusable). In addition, Stichting LSH-TKI would like to increase awareness among researchers about the importance of responsible data management. Before the start of the projects for which the PPP allowance is used, the parties involved must draft a data management plan indicating how the research data will be stored according to the FAIR principle. More information about the FAIR principle can be found on the website from the Dutch Tech Center for Life Sciences (DTL): <https://www.dtls.nl/fair-data/>.

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 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. 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, 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.

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 (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;

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. If this cost category is very high, this could influence and become part of the assessment of the evaluation committee.

Period of deployment PPP allowance

The period in which the PPP allowance must be used for the 2021 program year runs until the 26th of October 2027. This deadline is a strict deadline.

Assessment of projects

Longfonds must assess the scientific quality of the projects for which the PPP allowance will be deployed. Longfonds will check with the Stichting LSH-TKI whether the requirements for the deployment of the PPP allowance are met.

Open access

The Stichting TKI-LSH requires that research results that are (partially) funded by PPP allowance should be freely accessible worldwide. All scientific publications emerging from research that is funded through a PPP award should therefore be made freely accessible worldwide (open access) at the moment of publication.

Appendix 1

- Kennis- en Innovatieagenda 2020-2023 Topsector LSH:
[Van toekomstbeelden naar toekomstgerichte actie voor noodzakelijke impact | Health~Holland \(health-holland.com\)](#)
- Regeling nationale EZK- en LNV-subsidies:
<https://wetten.overheid.nl/BWBR003547/2021-11-02>
- Kaderbesluit nationale EZ-subsidies:
<https://wetten.overheid.nl/BWBR0024796/2021-03-09>
Kaderregeling betreffende staatssteun voor onderzoek, ontwikkeling en innovatie (2014/C198/01): [Mededeling van de Commissie — Kaderregeling betreffende staatssteun voor onderzoek, ontwikkeling en innovatie \(europa.eu\)](#)

Definitions of the three types of research

Fundamental research means experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any direct commercial application or use in view.

Industrial research means the planned research or critical investigation aimed at the acquisition of new knowledge and skills for developing new products, processes or services or for bringing about a significant improvement in existing products, processes or services. It comprises the creation of components parts of complex systems, and may include the construction of prototypes in a laboratory environment or in an environment with simulated interfaces to existing systems as well as of pilot lines, when necessary for the industrial research and notably for generic technology validation.

Experimental development means acquiring, combining, shaping and using existing scientific, technological, business and other relevant knowledge and skills with the aim of developing new or improved products, processes or services. This may also include, for example, activities aiming at the conceptual definition, planning and documentation of new products, processes or services. Experimental development may comprise prototyping, demonstrating, piloting, testing and validation of new or improved products, processes or services in environments representative of real life operating conditions where the primary objective is to make further technical improvements on products, processes or services that are not substantially set. This may include the development of a commercially usable prototype or pilot which is necessarily the final commercial product and which is too expensive to produce for it to be used only for demonstration and validation purposes. Experimental development does not include routine or periodic changes made to existing products, production lines, manufacturing processes, services and other operations in progress, even if those changes may represent improvements.

Appendix 2: Funding per type of research

Table 1: Funding per type of research	Fundamental research	Industrial research	Experimental development
Type of research			
Maximum % PPP Allowance to be deployed	75%	50%	25%
Research organisation(s)	min. 10%	min. 10%	min. 10%
For-profit and non-profit enterprise(s)	min. 15%	min. 15%	min. 15%
- 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 from a large company 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 a full in-kind contribution, but a cash contribution is encouraged.