**Application Form – TKI LSH**

***Subsidieoproep: Veelbelovende Innovatieve Therapieën voor Dementie***



|  |
| --- |
| **A. Registration** |

**1A. Project title:**

**1B. Project acronym (if applicable):**

**2. Contact details of main applicant (project coordinator)**

*If applicable, list all co-applicants from an organisation under the same consortium partner in the designated table.*

|  |  |
| --- | --- |
| **Consortium partner 1** | |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Male/female/other |  |
| Position |  |
| Address for correspondence |  |
| Telephone |  |
| E-mail: |  |
| Type of organisation  (for enterprise definition see Appendix A) | For profit enterprise |
| SME (MKB)   * Type of SME   (for SME definition see Appendix B) | Yes à  Micro  Small  Medium  No  NA |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |

|  |  |
| --- | --- |
| **Co-applicants from the same organisation as consortium partner 1** | |
| Department | Name of contact person, title(s) |
|  |  |

**3. List of consortium partners (co-applicants)[[1]](#footnote-2)**

|  |  |
| --- | --- |
| **Consortium partner 2** | |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Address for correspondence |  |
| E-mail: |  |
| Type of organisation  (for enterprise definition see Appendix A) | Research organisation  For profit enterprise  Non-for-profit enterprise  Health fund  Other, namely: |
| SME (MKB)   * Type of SME   (for SME definition see Appendix B) | Yes à  Micro  Small  Medium  No  NA |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |

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| **Co-applicants from the same organisation as consortium partner 2** | |
| Department | Name of contact person, title(s) |
|  |  |

|  |  |
| --- | --- |
| **Consortium partner 3** | |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Address for correspondence |  |
| E-mail: |  |
| Type of organisation  (for enterprise definition see Appendix A) | Research organisation  For profit enterprise  Non-for-profit enterprise  Health fund  Other, namely: |
| SME (MKB)   * Type of SME   (for SME definition see Appendix B) | Yes à  Micro  Small  Medium  No  NA |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |

|  |  |
| --- | --- |
| **Co-applicants from the same organisation as consortium partner 3** | |
| Department | Name of contact person, title(s) |
|  |  |

Etc.

**4. Potential conflict of interest**

*Please specify if there are any potential conflict of interests for individual scientists or any of the consortium partner organisations. See Appendix C for more information on conflict of interest. If there is a potential conflict of interest please also indicate how the consortium will manage such conflict.*

**5. Consortium agreement and IP**

1. *Describe the current intellectual property property (IP) rights for this research), indicate which of the applicants is the owner, and provide evidence to support ownership.* 
   * + *Documents can be submitted separate as annex 9. If applicable, please include the corresponding hyperlinks to the Netherlands Patent Office register.*
     + *Describe if you have you performed a prior art search with your Technology Transfer Officer (TTO) or other organisation. Any relevant IP publications, if available, can be listed under section 4.11 Literature and references.*
2. *Regarding the IP generated by the project, the mandatory consortium agreement template can be downloaded from our* [*website*](https://www.health-holland.com/pilot-call-2024)*. Describe any amendments the consortium has made. In addition, describe the reasoning behind these amendments.*

*Note: The deadline for the signed consortium agreement is 12 February 2025.*

**6. Start date (dd-mm-yyyy):**

*Note: Final start date: 1 March 2025.*

**7. End date (dd-mm-yyyy):**

**8. Duration of the project (max. 36 months):**

|  |
| --- |
| 1. **Project overview** |

**Fill in the word count:**

**9A. Project summary (max. 300 words)**

*Describe the background, objective, design, and relevance of the project.*

**9B. Public summary in Dutch**

**Fill in the word count:**

**(max. 300 words, in lay language)**

*Describe the background, objective, design, and relevance of the project.*

**Fill in the word count:**

**9C. Impact summary (max. 300 words)**

*Describe the expected short- and long-term societal impact (1), economic impact (2) and scientific impact (3) of the project.*

**9D. Keywords (max. 5)**

**Fill in the word count:**

**9E. Type of dementia (max. 100 words)**

*Indicate which type of dementia the project focuses on:*

* + *Alzheimer's disease (AD)*
  + *Vascular dementia*
  + *Frontotemporal dementia (FTD)*
  + *Lewy body dementia (LBD)*
  + *other, specify..*

**10. Research category (see Appendix D)**

1. *Please indicate per work package the budget.*

|  |  |
| --- | --- |
| **WP** | % of total budget (WP budget/total budget \* 100%) |
|
| 1 | … % |
| 2 | … % |
| Etc. | … % |

1. *Please provide an explanation that the project and the work packages consist of industrial research.*

|  |
| --- |
| **B. Project description** |

**Fill in the word count:**

**1. Background and Relevance (max. 600 words)**

*Describe the project background and topic. Include citations and list the relevant references under question B.8 “References”. Clearly describe how the intended project aligns with the purpose of the grant call: accelerated realisation of therapies for people with dementia. Describe and substantiate the commercial premise of the project and how this contributes to the accelerated realisation of the therapy.*

**2. State-of-the-art and innovative potential (max 500 words)**

**Fill in the word count:**

*Describe the current state-of-the-art in the field. Please describe and substantiate the relevance of the project with respect to the innovative potential of the therapy: Consider to what extent the intended target or mechanism of action is novel compared to therapies currently in the development pipeline (in phase II studies or higher). This could be a novel application of an existing drug as well.*

**3. Objective and hypothesis (max 300 words)**

**Fill in the word count:**

*Describe the objective of the project. Clearly state the hypothesis that follows.*

Objective of the project:

Hypothesis of the project:

**4. Outline per work package****(max. 2500 words in total)**

**Fill in the word count:**

1. *Outline the work plan per work package (if more than one). Include a table or scheme, that describes the following (at a minimum): aim, time schedule, milestones and deliverables. Indicate the role and responsibilities of the applicants in the activities.*
2. *Describe the coherence between the work packages (if more than one). Include a figure to clarify the coherence.*
3. *List the total number of milestones and deliverables of the (total) project by checking the correct box. In addition, provide a table or scheme of the time schedule of the listed milestones and deliverables in each work package.*

Number of milestones:  
1 2 3 4 5 6 7 8 9 10 More, namely:  
  
Number of deliverables:  
1 2 3 4 5 6 7 8 9 10 More, namely:

Time schedule:

**5. Success criteria**

1. *Describe the criteria that are utilized to determine success, the criteria should be written according to the SMART-principles (Specific, Measurable, Achievable, Realistic, and Timely) whenever possible, for:*

* *Each individual work package (if more than one)*
* *The overall project*

1. *Describe the go/no-go criteria for each of the above-described work packages*

**6. Risks & Mitigation strategies**

*Fill in the table below. Describe all risks (scientific, operational etc.) relating to the execution of the project, and for each individual WP/deliverable. Describe the mitigation strategy already incorporated in the strategy of execution or the proposed strategy adaptations once risks are encountered.*

|  |  |
| --- | --- |
| **Risk** | **Mitigation strategy** |
|  |  |
|  |  |
|  |  |
|  | Etc. |

**7. Dissemination (max. 300 words)**

**Fill in the word count:**

*Describe the activities each consortium partner plans to engage in order to promote the dissemination and implementation (including potential exploitation) of the results. This should not be limited to scientific dissemination. Include, a justification for the chosen approach for each individual consortium partner[[2]](#footnote-3).*

**8. References**

*List all authors of a reference when there are six or less; when there are seven or more authors, list the first three, then 'et al'. Avoid using the words 'in press' and ‘submitted’ in references if possible.*

|  |
| --- |
| 1. **Human subjects, laboratory animals, biological hazards** |

**9. Will the project involve experiments with patient material?**

|  |  |
| --- | --- |
| *Patient material* | **Answer** |
| 1. Use of healthy volunteers. If yes, please provide a power calculation under this table. | Yes  No |
| 1. Use of patients? | Yes  No |
| 1. Number of healthy volunteers. |  |
| 1. Number of patients. |  |
| 1. Is ethical approval from a commission needed regarding experimental subjects? | Yes  No  N/A |
| 1. If ‘d’ is answered with ‘yes’: Do you already have ethical approval from a commission to perform the study? | Yes  No  N/A  Requested |

*Include a power calculation to justify the number of people necessary for the project:*

**10. Animal experiments**

|  |  |
| --- | --- |
| *Animal experiments* | **Answer** |
| 1. Use of laboratory animals. If yes, please fill out question 11. | Yes  No |
| 1. Number of animals needed for the total project. |  |
| 1. Is ethical approval from a commission needed regarding experimental subjects? | Yes  No  N/A |
| 1. If ‘e’ is answered with ‘yes’: do you already have ethical approval from a commission to perform the study? | Yes  No  N/A  Requested |

**11. Specification and justification of animal experiments**

1. *Describe the kind of animals (species, modifications, etc.) used in the project.*
2. *Describe the nature of the animal interventions within the project.*
3. *Indicate if alternative methods (besides experimental animals) have been considered. In addition, describe whether and which experts have been consulted and whether a systematic review has been performed?*
4. *What are the reasons that this project cannot be performed without experimental animals (replacement)?*
5. *What are the reasons that this project cannot be performed with fewer animals (reduction) or with less distress and discomfort for the animals (refinement)? Include a power calculation to justify the number of animals necessary for the project.*
6. *What are the reasons that this project cannot be performed with a lower species of animals?*

**12. Biological risks**

|  |  |
| --- | --- |
| *Biological risks* | **Answer** |
| 1. Use of recombinant DNA? | Yes  No |
| 1. If ‘a’ is answered with ‘yes’: provide class of recombinant DNA |  |
| 1. Use of radiation (wave and/or particle)? | Yes  No |
| 1. Use of radioactive isotopes? | Yes  No |
| 1. Use of pathogenic micro-organisms? | Yes  No |
| 1. Are required grants, permits and facilities available? | Yes  No  N/A |

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| **B. Data management** |

**All data management should comply with the FAIR principles: Findable, Accessible, Interoperable, and Reusable.[[3]](#footnote-4) Applicants need to draw up a data management plan if their application is granted. The approval of the data management plan by Health~Holland is a condition for the disbursement of the PPP Subsidy.**

**13. Use of pre-existing research data**

*Is it possible to answer the research question(s) using existing data and a pre-existing research methodology? If not, or only partially, please explain the added value of the new data and/or methodology to existing datasets.*

**14. Reuse of collected data**

*Please elaborate whether data will be collected or generated that is suitable for reuse by other parties. If not, explain why the project will not result in reusable data, or data that cannot be stored, or data that is not relevant for reuse for other reasons (please explain the reasoning).*

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| 1. **Impact** |

**Fill in the word count:**

**1. Scientific impact (max. 200 words)**

*Describe the impact the project will have on the scientific field. In addition, describe how the project may benefit further research and other research groups within the field.*

**2. Societal impact (max. 200 words)**

**Fill in the word count:**

*Describe the expected impact the project will have on society and the LSH sector in particular. Please include a description of the current societal problem the project (with additional follow-up projects) is aiming to solve.*

**3. Economic impact**

1. *Describe impact the project will have on the Dutch economy (e.g., the size of the market, amount of FTE generated etc.) (1). Include a cost-effectiveness analysis or value-based-reasoning analysis to support your claims (2). In addition, include a description of how the consortium fits into the current competitive environment (3). (max. 250 words)*

**Fill in the word count:**

1. *Describe the expected economic impact the project will have on each individual private party (e.g., projected launch date, projected revenues, projected costs), and public/other party where relevant, involved. (max. 200 words per private party)*

**Fill in the word count:**

**4. Current and expected TRL-levels**

*Indicate the current (1) and expected (2) Technology Readiness Level (TRL; see Appendix E) of the project (level of development/readiness to go to the market), and for each TRL why this is applicable for the project.*

* 1. *Current TRL:*

TRL 1 TRL 2 TRL 3 TRL 4 TRL 5

TRL 6 TRL 7 TRL 8 TRL 9

**Fill in the word count:**

* 1. *Description of current TRL (max. 150 words):*
  2. *Expected TRL:*

TRL 1 TRL 2 TRL 3 TRL 4 TRL 5

TRL 6 TRL 7 TRL 8 TRL 9

* 1. *Description of expected TRL (max. 150 words):*

**Fill in the word count:**

**Fill in the word count:**

**5. Market introduction, reaching TRL 9 (max. 300 words)**

*Describe who (1) and what (2) is needed to introduce the innovation into the market/clinic (TRL 9). If no additional parties (3) are needed to introduce the innovation to the market/clinic, describe how the consortium is planning on accomplishing this on their own and how they comply with the ten principles for* [*Socially Responsible Licensing*](https://www.nfu.nl/sites/default/files/2020-08/19.4511_Ten_principles_for_Socially_Responsible_Licensing_v19-12-2019.pdf)*. Also indicate how collaborating and possibly third parties will comply with the ten principles.*

* *Indicate that you have a clear business plan. The business plan can be uploaded with the application as a separate document, annex 8.*
* *Indicate that a clear business structure has been established to support the business plan and benefit therapy development.*

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| 1. **Collaboration (max. 600 words)** |

**1. Benefits of individual consortium partners to the project**

*Describe how and why each individual consortium partner and its applicants add value to the project. Include a description of why the consortium partners are better equipped to execute the project than other, similar parties.*

**2. Benefits of the project to consortium partners**

*Describe how each of the individual consortium partner benefits from participating in this project (1). In addition, describe how the project fits into the strategic mission of each individual consortium partner (2).*

**3. Responsibilities of consortium partners and collaboration activities**

*Describe the responsibilities of each individual consortium partner within the project. In addition, describe how the consortium plans to collaborate (communication, sharing results, progress meetings, etc.)*

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| 1. **Budget specification** |

**Fill in the Health~Holland budget form. Use the version of the budget form specific for this Call (2024). Other versions of the budget form will not be accepted.**

**4. Deployment of PPP Subsidy**

*Indicate for each consortium partner (1) their total costs; (2) the amount of PPP subsidy that they will use; (3) the percentage of costs that will be financed using the PPP subsidy; (4) the amount of (private) cash that they will use and (5) the activities that will be financed using the PPP subsidy.*

*Notes:*

* *Total costs include all the costs made by the partner, including the costs covered by the in kind contribution, PPP subsidy or in cash contributions to be received from another party. Own in cash contributions to the project are not included as a cost.*
* *Each consortium partner must incur payroll costs (in kind) as part of the collaboration.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Partner** | **Total Costs** | **PPP Subsidy** | **% PPP Subsidy** | **Used cash** | **Activities** |
| ***Name Consortium Partner 1*** |  |  |  |  |  |
| ***Name Consortium Partner 2*** |  |  |  |  |  |
| ***Name Consortium Partner 3*** |  |  |  |  |  |
| **Etc.** |  |  |  |  |  |
| **Total sum\*** |  |  |  |  |  |

**\****Make sure that the above table is in accordance with the budget form, including the total sum of costs and the total sum of PPP.*

**5. Budget specification**

*Please provide a justification and specification of the costs in the budgetform per work package or deliverable. Only referring to the budget form is not sufficient.*

**6. Have the consortium partners requested/received any additional grants for this project or overlapping activities?**

**Yes** **No**

*If yes, please specify grant supplier(s), grant name(s), total amount requested/received per grant (in €) and status (applied/granted) in the TKI-LSH budget form.*

|  |
| --- |
| 1. **KIA, VWS Missions** |

**Fill in the word count:**

**1. VWS missions: central mission (max. 250 words)**

*Describe how the project contributes to the Central Mission of the Ministry of Health, Welfare and Sport (VWS) (below) according to the SMART principles. Consult, reference and use at least one of the aspects described in the* [*Theory of Change*](https://online.fliphtml5.com/gedjp/iwgv/#p=36) *of the central mission. Include a description on how the project outcome, including the outcome of eventual follow-up projects, aids in reducing health disparities between people with high SES and low SES (1), use the* [*Key Principles to reduce health disparities*](https://www.pharos.nl/gezondheidsverschillen-duurzaam-aanpakken/) *in your answer. In addition, include a description on how, at the end of the project, the concrete contribution to the mission can be measured/evaluated.*

***Central Mission:*** *By 2040, all people in the Netherlands will live at least five years longer in good health, while the health disparities between the lowest and highest socio-economic groups will have decreased by 30%.*

*Argumentation (max. 250 words):*

**2. VWS missions: mission I – mission V**

**Fill in the word count:**

**(max. 300 words)**

*Describe how the project contributes to one or more of the underlying missions of the Mission of the Ministry of Health, Welfare and Sport (VWS) (below) according to the SMART principles. In addition, if the project contributes to more than one mission, indicate which of the missions the project mainly contributes to (select one).*

*Consult, reference and use at least one of the aspects described the* [*Theory of Change*](https://online.fliphtml5.com/gedjp/iwgv/#p=42)*of the missions. In addition, include a description of how, at the end of the project, the concrete contribution to the mission can be measured/evaluated.*

***Mission I:*** *By 2040, the burden of disease resulting from an unhealthy lifestyle and living environment will have decreased by 30%.*

***Mission II:*** *By 2030, the extent of care provided to people within their own living environment (rather than in health-care institutions) will be 50% more than today or such care will be provided 50% more frequently than at present.*

***Mission III:*** *By 2030, the proportion of people with a chronic disease or lifelong disability who can play an active role in society according to their wishes and capabilities will have increased by 25%.*

***Mission IV:*** *By 2030, quality of life for people with dementia will have improved by 25%.*

***Mission V:*** *By 2035, the population is better protected from socially disruptive health threats.*

Principal mission the project contributes to (select one):

Mission I

Mission II

Mission III

Mission IV

Mission V

Secondary mission the project contributes to (if applicable):

Mission I

Mission II

Mission III

Mission IV

Mission V

Not applicable

*Argumentation:*

|  |
| --- |
| **E. Patient/end-user participation & Inclusivity** |

**3. Inclusivity and end-user participation**

*Inclusivity entails paying attention to diversity and differentiation of the target groups concerned, including characteristics as sex, age, socio-economic status (SES), level of education, migration, cultural background, and sexual orientation, to the extent these are relevant for the theme of the project.*

* 1. *Please describe to what extent the (health) problem affects men, women and/or other relevant subgroups (max. 300 words). Describe and substantiate how the project takes into account relevant differences between people (e.g. according to sex and/or gender) in the design, execution, analyses conclusions and publication of your research. If there are no relevant differences, substantiate this*

**Fill in the word count:**

* 1. *Please describe how citizens in their role as patients, end users, clients, and/or loved ones are involved in the design, execution, and dissemination/implementation of the project (max. 300 words).*

**Fill in the word count:**

|  |
| --- |
| 1. **Evaluation of health and care innovations** |

**4. Innovation guidance – HI-NL Round Table Service**

*Before answering the questions below, please read section 4.8 of the call.*

|  |  |
| --- | --- |
|  | **Answer** |
| 1. In general, is your innovation in scope of the HI-NL Round Table service? I.e. is it a MedTech innovation, falling under the MDR / IVDR? | Yes  No |
| If no, please explain why: | |
| 1. Did the consortium partners contact HI-NL no later than three weeks before the deadline of the Match Call, and has an intake meeting taken place? | Yes, continue to c  No |
| If no, please explain why: | |
| 1. Is the HI-NL Round Table service of added value for your consortium and project that you are applying for?   *If ‘c’ is answered with ‘yes’: The consortium can choose to enter an amount of 33,275 euros in the budget form under the heading 'costs due to third parties'.* | Yes, continue to d  No |
| 1. What is/are your main question(s) and/or challenges to be addressed by the HI-NL Round Table service? (Multiple boxes can be checked) | Claims and target population  Required (clinical) evidence  Path for CE-marking  Comparison with the current standard of care  Application and integration of innovation in the Dutch healthcare system  Reimbursement of innovation  Strategy for adoption by the market  Scale-up of your innovation  Other, namely: |

|  |
| --- |
| **F. KET’s and KEM’s** |

**1. Key Enabling Technologies (KET’s)**

1. *Indicate on which of the* [*Key Enabling Technologies*](https://www.kia-st.nl/_asset/_public/KIA-ST/Bijlagen/TNO-NWO-Herijking-Sleuteltechnologieen-apr-2023.pdf) *the project applies to*

|  |  |
| --- | --- |
| **Key Enabling Technologies** | **yes/no** |
| Advanced materials | Yes  No |
| Chemical technologies | Yes  No |
| Digital and information technologies | Yes  No |
| Engineering and fabrication technologies | Yes  No |
| Life science and biotechnologies | Yes  No |
| Quantum technologies | Yes  No |
| Nanotechnology | Yes  No |
| Photonics and optical technologies | Yes  No |
| Not applicable | Yes  No |

1. *Name the applicable underlying* [*subcategories*](https://www.nwo.nl/sleuteltechnologieen) *of the Key Enabling Technologies the project applies to.*

**2. Key Enabling Methodologies**

1. *Indicate which of the* [*Key Enabling Methodologies*](https://kems.nl/kem-categorieen/) *the project applies to*.

|  |  |
| --- | --- |
| **Key Enabling Methodologies** | **yes/no** |
| 1. Vision and imagination | Yes  No |
| 1. Participation and co-creation | Yes  No |
| 1. Behaviour and empowerment | Yes  No |
| 1. Experimental environments | Yes  No |
| 1. Value creation and upscaling | Yes  No |
| 1. Institutional change | Yes  No |
| 1. System change | Yes  No |
| 1. Monitoring and effect measurement | Yes  No |
| 1. Not applicable | Yes  No |

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| --- |
| **G. Statement by project coordinator** |

When submitting your application, please do not forget to upload the required budget form file (Excel), letter(s) of commitment, (concept) consortium agreement and other necessary documents such as a statement from the organisation’s TKI contact person.

Please tick the boxes where applicable:

By submitting this form, I declare that I have completed this form truthfully and I declare that I have informed the correct official(s) of my employing organisation of this submission.

I hereby declare that the obligatory letter(s) of commitment of the other consortium partner(s) has/have been uploaded separately.

I hereby declare that the application is checked according to **Appendix H**.

I hereby give Health~Holland permission to share this application, its submitted annexes and the advice regarding this project from the ZonMw evaluation committee, with Alzheimer Nederland, for possible funding of this project. Alzheimer Nederland will treat the documents of this application confidentially.

Name:

Place:

Date:

Please note: Information provided in relation to this application will be treated confidentially by Health~Holland and ZonMw. Health~Holland has to share this application with ZonMw for the purpose of the assessment procedure. Health~Holland has to inform the Netherlands Enterprise Agency (RVO.nl) on the participants of the project and the in cash and in kind contribution of the consortium partners, in order to claim the requested PPP Subsidy. RVO.nl will also treat this information confidentially. Upon granting, the project coordinator will receive a request to provide a project profile, including a summary of the project and other basic project details (see Appendix F) that will be published on the Health~Holland [website](https://www.health-holland.com/project) and for other communication purposes. Other content of the project will not be communicated beyond Health~Holland.

Main applicants must submit this TKI-LSH PPP Subsidy application form by e-mail to

[tki@health-holland.com](mailto:tki@health-holland.com). For any questions regarding submission, please send an e-mail to [tki@health-holland.com](mailto:tki@health-holland.com) or call +31 (0)70 205 14 00.

Attachments to be uploaded:

* TKI-LSH *Promising Innovative Therapies for Dementia*l budget form.
* Letters of commitment of **all** parties involved, each stating the parties’ in kind and in cash contribution (seperately) to the project. Only the main applicant does not need to upload a letter of commitment. See Appendix G for a template of a letter of commitment.
* Signed copy of the consortium agreement and IP settlements agreed upon in this project. If a signed consortium agreement is not yet available, a concept agreement must be submitted. The signed consortium agreement should be delivered no later than February 12th 2025.
* Additional attachments as listed under section 5.5. of the call:
  + Summary for experience experts
  + Gantt chart project
  + Ancillary activities project group
  + EU SME Self Assessment Wizard
  + Business plan
  + Proof of intellectual property

**Appendix A: Definition of enterprise**

*English*

According to established case law from the European Court of Justice, an enterprise is any unit that carries out economic activity irrespective of its legal status and manner of funding.

In this regard, the following points are important:

* The legal status (e.g. a private company or a foundation) of the entity is not important;
* A for-profit status is not required, competition on the market is sufficient (economic activities). This means that the entity participates in economic dealings and that there is business funding. Business funding means that the funding cannot consist entirely of grants, gifts and endowments. A turnover needs to be made and there has to be income from economic activity;
* An entity that carries out both economic and non-economic activities will only be designated as an enterprise with respect to the economic activities;
* The European Court of Justice has further determined that entities that (legally or de facto) fall under the authority of the same main entity should be viewed as a single enterprise;
* Having a Dutch ANBI or charitable status (serving the common interest, no profit-making status, 90% rule) means that such an entity with ANBI status cannot also be an enterprise. That is because an entity with ANBI status enjoys fiscal advantages that a business does not enjoy.

With respect to economic activity, the following aspects are, amongst others, considered in line with the Dutch Tax and Customs Administration:

* Registration with the Dutch Chamber of Commerce (KvK);
* Having a Dutch VAT (BTW) number and/or corporate income tax (VPB) number;
* Goods and/or services are delivered;
* The remuneration received for these is more than symbolic;
* The entity participates in the economic arena and enjoys income from this.

*Nederlands*

Volgens vaste rechtspraak van het Europees Hof van Justitie is een onderneming elke eenheid die een economische activiteit uitvoert ongeacht haar rechtsvorm en wijze van financiering.

Hierbij zijn de navolgende punten van belang:

* De juridische status (b.v. BV of een stichting) van de eenheid is niet van belang;
* Er is géén winstoogmerk vereist, concurrentie op de markt is voldoende (economische activiteiten). Dit houdt in dat er wordt deelgenomen aan economisch verkeer en er ondernemingsfinanciering plaatsvindt. Ondernemingsfinanciering betekent dat de financiering niet volledig kan bestaan uit subsidies, giften en schenkingen. Er zal omzet en inkomsten uit economische activiteit moeten plaatsvinden;
* Een eenheid die zowel economische als niet economische activiteiten verricht, wordt alleen met betrekking tot de economische activiteiten aangemerkt als onderneming;
* Het EU Hof van Justitie heeft verder bepaald dat entiteiten die (juridisch of feitelijk) onder de zeggenschap staan van dezelfde entiteit, als één onderneming dienen te worden beschouwd.
* Het hebben van een ANBI-status (algemeen belang dienen, geen winstoogmerk, 90% regel) sluit uit dat een entiteit met ANBI-status ook een onderneming is. Een entiteit met ANBI-status geniet namelijk fiscale voordelen welke een onderneming niet heeft.

Bij economische activiteit wordt, in lijn met de Belastingdienst, onder andere gekeken naar:

* Inschrijving KVK;
* Het hebben van een BTW-nummer en/of VPB-nummer;
* Er worden goederen en/of diensten geleverd;
* Hier staat een meer dan symbolische vergoeding tegenover;
* Men neemt deel aan het economisch verkeer en daar komen inkomsten uit.

**Appendix B: European Commission Recommendation 2003/361/EC regarding SME definition**

1. **Micro-enterprises** are defined as enterpris­es that employ fewer than 10 persons and whose annual turnover or annual balance sheet total does not exceed EUR 2 million.
2. **Small enterprises** are defined as enterpris­es that employ fewer than 50 persons and whose annual turnover or annual balance sheet total does not exceed EUR 10 million.
4. **Medium-sized enterprises** are defined as enterprises that employ fewer than 250 per­sons and either have an annual turnover that does not exceed EUR 50 million, or an annual balance sheet not exceeding EUR 43 million.

For more details ‘The revised User Guide to the SME definition’ can be downloaded [here](https://ec.europa.eu/docsroom/documents/42921).

Or use the European [SME Wizard](https://ec.europa.eu/growth/tools-databases/SME-Wizard/smeq.do;SME_SESSION_ID=O7sad7FQJ5Yv57HLXygn8qU6Ru3fbfplFT6I0g0MuPKEcCyss4su!-1930018156?execution=e1s1)*.*

**Appendix C: Conflict of Interest**

*This Appendix is also available in Dutch and can be requested by sending an email to* [*tki@health-holland.com*](mailto:tki@health-holland.com)

According to Articles 28.d and 29.c of the Framework, applicable to the PPP Subsidy regulation, research organisations are to receive a remuneration equivalent to the market price for the intellectual property rights arising from their activities during the course of a project. The absence or inadequacy of agreements pertaining to a remuneration based on the market price, leads to the indirect granting of state aid to the participating private parties.

‘A remuneration equivalent to the market price’ creates a best-effort obligation between the parties involved. It means that the research organization and the participating private parties must make an effort to negotiate this remuneration on so-called ‘arm’s length’ terms. Arm’s length conditions mean that the terms of the remuneration do not deviate from those which would be agreed upon in a private setting, between independent parties. Any transaction resulting from an open, transparent and non-discriminatory procedure will be deemed to comply with the arm’s length procedure.

Every project has the potential for a conflict of interest between the research organization and one or more private companies. A conflict of interest can exist on a personal level or on an organizational level. The presence of a conflict of interest means that the arm’s length conditions are potentially not met. Promptly upon identification of an objective conflict of interest, the consortium and Health~Holland should be notified. A pertinent example is when the director of a participating company, also has an employment relationship with the participating research organization.

Potential COI kan arise in multiple ways, including but not limited to:

*Individual potential COI*

* Does the Principal Investigator in the Project have any financial interest in (one of) the industrial participant(s)? If so, how many shares, options and/or other financial benefits do you (or your relatives) have rights to?
* Does any other Institutional investigator involved in the Project have any financial interest in the industrial particpant(s)? If so, how many shares, options and/or benefits do you (or your relatives) have rights to?

Examples of financial interest may be: the PI or its direct family member have shares, options and/or other participation in any of the Industrial participant(s); the PI receive benefits from patent applications licensed to the Industrial participant(s) or is an inventor listed in any patent application licensed or filed by the industrial participant(s) directly or indirectly related to the subject matter of the Project application.

* In the last 12 months, did any commercial entity or any of the entities that are participating in the Project paid for or reimbursed you (or your employer) for consulting services, salaries or otherwise? If, so does such payments exceed €10.000 per year? If so, will the company benefit from the outcome of the Project?

*Institutional potential CoI*

To the best of your or your Consortium Partners’ knowledge

* Are any of the Consortium Partners in the Project affiliated or associated with another Consortium Partner in the Project? If so, how?
* Does any Consortium Partner have directly or indirectly any shares, options and/or any other participation in another Consortium Partners despite of not being an affiliated entity? If so, how many shares, options and/or participations?
* Or, if the financial interest as stated in the two points above does not apply, would a Consortium Partner exercise any control on any of the other Consortium Partners’ decision making? If so, how?
* In the last 12 months, did any commercial entity or any of the entities that would be a Private partner in the Project paid for or reimbursed any sponsored research or services to the Research Organization(s) to the same research group(s) involved in the Project? If, so does such payments exceed €10.000 per year? If so, will the company benefit from outcome of the Project?

Health~Holland will not subjectively assess the conflict of interest. Health~Holland will assess whether the performance of the consortium will be hindered or compromised by the existence of such potential conflict of interest. Health~Holland will therefore require full transparency if and when an objective conflict of interest arises or is likely to arise. ‘Objective’ means that potentially, a conflict of interest can occur, regardless of whether a party or person can derive any benefit or disadvantage from it.

It is up to the parties concerned – and in particular the directors of the participating companies – to recognize, interpret and report such an objective conflict of interest. This obligation to report may already exist at the time of the Match Call application being made. And thus, a notification should be made upon submission of the Match Call application.

Such a notification must be accompanied by the response to the following questions:

* What are the motivations to indicate the presence of a conflict of interest?
* Has the director concerned weighed up the interests?
* Has the potential conflict of interest been adequately addressed?
* Is there a transparent procedure in place to ensure that the director can abstain from involvement in certain decisions (which may involve a conflict of interest)?
* How are the arm’s length conditions adequately met?
* Has the director provided for the involvement of other researchers who can make these decisions without bias?
* Can the director involve his or her fellow director(s) in the decision-making process and is it possible in the management relationship for the director concerned to abstain from taking management decisions (four eyes principle)?

The duty to provide adequate answers to the above questions rests exclusively with the consortium parties involved. This means that the consortium parties involved have the duty to assess whether and to what extent the potential conflicting of interest has been adequately addressed and whether they are satisfied with the precautionary measures that the director(s) concerned have taken.

If, as a result of a conflict of interest, situations occur that violate the arm’s length conditions, the (consortium) parties involved are liable for the resulting damage. Such damage may include the consequences of establishing that indirect state aid has been granted to one or more participating undertakings.

For the sake of completeness, Health~Holland recommends involving legal support from the consortium partners, preferably from the research organization, in order to adequately address a potential conflict of interest.

**Appendix D: Definitions of the three types of research[[4]](#footnote-5)**

**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 E: Technology Readiness Levels**

|  |  |
| --- | --- |
| **TRL** | **Definition** |
| TRL 1 | Basic principles observed |
| TRL 2 | Technology concept formulated |
| TRL 3 | Experimental proof of concept |
| TRL 4 | Technology validated in lab |
| TRL 5 | Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies) |
| TRL 6 | Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies) |
| TRL 7 | System prototype demonstration in operational environment |
| TRL 8 | System complete and qualified |
| TRL 9 | Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space) |

**Appendix F: Project page content for Health~Holland website**

**Health~Holland Project Page**

|  |
| --- |
|  |

**An overview of all public private projects and partnerships supported by the Top Sector Life Sciences & Health**

**The Top Sector Life Sciences & Health (LHS) wants to illustrate all its currently accepted and ongoing public private projects and partnerships to our international audience throughout the world. Therefore, the Health~Holland website will be complemented by the new Health~Holland** [**project page**](https://www.health-holland.com/project)**. This page will provide an overview of all the projects and partnerships hosted in the Top Sector LSH from the start of the top sector approach. To successfully launch our new project and partnership webpage, we ask you to provide us with a correct, clear, and legible content on your public private partnership’s project (all in British English).**

**Project page content**

Health~Holland wants to collect content on your public private partnership’s project. Can you provide us with the following aspects on your partnership/project:

1. **Project number**

HH-PPS-…….

1. **Clear popular title**

This title (max. 10 words) appears above the project. No use of abbreviations.

1. **Clear scientific title**

No use of abbreviations and the title must be understandable for the lay public. In addition, the project acronym can be mentioned.

1. **One liner**

The one liner (max. 15 words) includes a short summary of your project, acts as a trigger to read more or describes the relevance of the project.

1. **Short summary of the project**

A short summary of two sentences (max. 50 words) that includes a brief explanation of the project. This summary will be visible on the project page and helps the reader to decide whether to continue reading about the project. The text has to be both informative and excitatory to continue reading. Please do not use jargon or abbreviations that the lay public may not understand.

1. **Public summary**

The public summary consists of 250 to max. 300 words. The summary is intended for a broad audience with a secondary education language level. In short, the public summary describes the who, what, where, when, why and how of the project. Focus on the core message of the project instead of elaborating on explanations and background information.   
  
Health~Holland would like you to follow these guidelines:

* First paragraph: short summary of the whole project (see point 4) with a highlight on the (newly) established public private partnership.
* Second paragraph: introduction on the societal/economic impact and relevance of the health/disease/vital functioning/etc. and why innovation is necessary. Make use of numbers, statistics, or rankings to illustrate the relevance of the project to the lay public.
* Third paragraph: explanation of the project’s approach and conceptualisation, and how this innovative solution will contribute to the previously described societal challenge(s).
* Fourth paragraph: description of deliverables and, if the project is finished, an illustration of the (end)results.

1. **Keywords**

Define a maximum of five clear keywords.

1. **Consortium partners**

Indicate all partners that contribute and send us the original logos of their organisation/company.

1. **Start date of the project**
2. **End date (intended) of the project**
3. **Project duration**
4. **Image (free of copyright)**

The image will be used to illustrate the project, this can include a picture of the laboratory, consortium partners, target audience, product, innovation, building, university, or ambience of the project. It is important that the image is free of copyright so Health~Holland is able to use it in their communication channels.

1. **Link**

If possible a link to a webpage with more information.

**Project page filters**

Health~Holland makes use of several filters to facilitate the search of projects. Can you select filters that address your public private partnership’s project:

1. **Objective:** prevention, cure or care (select one)
2. **Kind of research:** fundamental, industrial or experimental development
3. **Missions of the Top Sector LSH:** 
   1. Central Mission: By 2040, all people in the Netherlands will live at least five years longer in good health, while the health inequalities between the lowest and highest socio-economic groups will have decreased by 30%.
   2. Mission I: By 2040, the burden of disease resulting from an unhealthy lifestyle and living environment will have decreased by 30%.
   3. Mission II: By 2030, the extent of care provided to people within their own living environment will be 50% more than today or such care will be provided 50% more frequently than at present.
   4. Mission III: By 2030, the proportion of people with a chronic disease or lifelong disability who can play an active role in society according to their wishes and capabilities will have increased by 25%.
   5. Mission IV: By 2030, quality of life for people with dementia will have improved by 25%.
   6. Mission V: By 2035, the population is better protected from socially disruptive health threats.
4. **Major TKI-LSH roadmap of project:** (select one)
   1. molecular diagnostics
   2. imaging & image-guided therapies
   3. homecare & self-management
   4. regenerative medicine
   5. pharmacotherapy
   6. one health
   7. specialized nutrition, health & disease
   8. health technology assessment & quality of life
   9. enabling technologies & infrastructure
   10. global health, emerging diseases in emerging markets
5. **Minor TKI-LSH roadmap of project:** (select one)
   1. molecular diagnostics
   2. imaging & image-guided therapies
   3. homecare & self-management
   4. regenerative medicine
   5. pharmacotherapy
   6. one health
   7. specialized nutrition, health & disease
   8. health technology assessment & quality of life
   9. enabling technologies & infrastructure
   10. global health, emerging diseases in emerging markets
6. **Key Enabling Technologies of project:** (select one)
   1. Advanced materials
   2. Chemical technologies
   3. Digital technologies
   4. Engineering and fabrication technologies
   5. Life science technologies
   6. Quantum technologies
   7. Nanotechnologies
   8. Photonics and light technologies
   9. Not applicable
7. **Operating in:** bio(pharma), medical technology or healthcare (select one)
8. **Technology readiness level (TRL) of project:** select the current and predicted TRL (see attachment A)

Current TRL: -1- -2- -3- -4- -5- -6- -7- -8- -9-

Predicted TRL: -1- -2- -3- -4- -5- -6- -7- -8- -9-

**Comments**

If you have any comments or questions, please note here.

**Editorial rights**

Health~Holland will perform a check on the submitted text prior to publication. If we have any questions regarding the provided content, we will contact you before we publish the content of the project. For more information, please contact [communication@health-holland.com](mailto:communication@health-holland.com).

**Appendix G: Template Letter of Commitment**

***LETTER OF COMMITMENT***

*for the*

***[name of] PROJECT***

Dear [main applicants’ duly authorised representative],

I, [first name and family name], in my capacity of [position in the organisation (has to be a duly authorised person)] at [name legal entity] hereby confirm that [legal entity] is committed to contribute to the [project name] project, on the condition that Stichting LSH-TKI grants the PPP Subsidy as applied for by the main applicant, [first name and family name], [position] at [name research organisation].

[Name legal entity] is aware that it is mandatory for the consortium to use the most recent updated version of the model consortium agreement of Health~Holland. [Name legal entity] is aware that only minimal non-essential changes to this template are permitted and agrees to the content of the model consortium agreement regarding Foreground and intellectual property.

[Name legal entity] will contribute € [•] in cash towards the project costs in accordance with the budget in the project proposal and budget form.

[Name legal entity] will provide an in-kind contribution of [description of the contribution], representing a monetary value of € [•] and further detailed in the project proposal and budget form.

Yours sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name:

Position:

Date:

**Appendix H: Checklist application form**

The consortium must consist of at least one for-profit enterprise and one research organization.

The main applicant is a for-profit enterprise located in the Netherlands.

The project meets the requirement for the maximum project duration (36 months).

The starting date is set after the deadline of the call between and march 1st 2025.

The chamber of commerce number or equivalent is listed for all consortium partners.

Effective collaboration takes place. This means, for example, that the project is realised at joint cost and risk.

The project consists of industrial research.

All consortium partners at least incur payroll costs.

All consortium partners make an *in kind* contribution.

Research organisations may finance a maximum of 70% of their costs (e.g. man hours, consumables and the use of equipment etc.) with PPP subsidy in case of industrial research.

Foreign research organisations may use a maximum of €124.999,- PPP subsidy.

Dutch SMEs may finance a maximum of 60% of their costs (e.g. man hours, consumables and the use of equipment etc.) with PPP subsidy in the case of industrial research.

The research organisation(s) must contribute at least 10% of the total project costs.

The enterprise(s) must contribute at least 15% of the total project costs.

The consortium is aware that in case the project is awarded the PPP Subsidy, the consortium agreement should be completed (after approval of the final version by Health~Holland) and signed by February 12th 2025.

The budgeted costs are directly related to the R&D activities, and do not include non-eligible costs, for example: bench fee costs, travel within the Netherlands, supporting/project management tasks that are not directly related to the project’s R&D activities.

All questions on the application form are answered.

The right versions of the application form, budget form and consortium agreement specific to this have been used.

All required Annexes are submitted:

The budgetform is submitted.

All parties, with the exception of the main applicant, must submit a letter of commitment using the template provided by Health~Holland; a letter of intent is not sufficient.

The consortium must submit an (unsigned) draft consortium agreement using the mandatory Health~Holland template; a blank format is not sufficient.

The summary for experience experts is submitted.

The Gantt chart is submitted

An overview of ancillary activities is submitted.

For enteprises the EU SME Self Assessment Wizard form is submitted.

The business plan is submitted.

The proof for intellectual property of the main applicant is submitted.

1. In case of a potential conflict of interest (at a personal or organizational level), please disclose the situation following Appendix C under question 4. [↑](#footnote-ref-2)
2. Note: non-scientific dissemination costs are not eligible for funding withing the PPP Subsidy program, therefore, costs relating to this dissemination may not be incurred on the official budget form. [↑](#footnote-ref-3)
3. For more information please consult: <https://www.dtls.nl/fair-data/fair-data/> [↑](#footnote-ref-4)
4. 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 Subsidy Regulation. [↑](#footnote-ref-5)