

**Application Form**

**FORESIGHT PPP Program 2025**



**Instructions:**

For the pre-application, please fill the sections highlighted in [**green**] where the instruction [**Fill here**] is displayed. You can use the “**Checklist Pre-application Form**” below as reference for the sections to ensure all necessary sections for the pre-application phase have been completed.Please also consult the appendixes for additional definitions on **A)** Type of enterprise; **B)** Type of SME; **C)** Conflict of interest; **D)** Definitions Type of research and the Technology Readiness Levels.

The sub-sections that are not highlighted in green, will be required to be filled out if your pre-proposal is positively evaluated to proceed to the second stage. We advise you have a look at these points as well, in order to get acquainted with the type of additional information required for the full proposal stage.

**In order to fit with the aims of the Foresight program, please review the list of focus points and eligibility criteria listed in page 2.**

If you have any question on this document, please contact: foresight@umcg.nl

**Checklist PRE-APPLICATION FORM**

|  |
| --- |
| **Sections that should be filled in pre-application phase**  |
| A. Registration |
| 1A. Project title: |
| 1B. Project acronym (if applicable) |
| 2. Contact details of main applicant (project coordinator)  |
| Co-applicants from the same organisation as consortium partner 1 |
| List of consortium partners (co-applicants)1 |
| 4. Potential conflict of interest  |
| 5. Consortium agreement and IP  |
| 6. Start date (dd-mm-yyyy):  |
|  7. End date (dd-mm-yyyy):  |
| 8. Duration of the project (max. 48 months):  |
| A. Project overview |
| 9A. Project summary (max. 300 words) |
| 9C. Impact summary (max. 300 words) |
| 10B. Provide an explanation for the research type(s) chosen. Use the phrasing provided in the definition of the three types of research (see Appendix D).  |
| B. Project description |
| 1. Background (max. 350 words)  |
| 2. State-of-the-art (max 250 words)  |
| 3. Objective and hypothesis (max 200 words)  |
| B.Human subjects, laboratory animals, biological hazards |
| 9. Will the project involve experiments with patient material?  |
| 10. Animal experiments  |
| 12. Biological risks |
| C.Impact |
| 1. Scientific impact (max. 200 words)   |
| 2. Societal impact (max. 200 words)  |
| 3. Economic impact  |
| 4. Current and expected TRL-levels  |
| D. Feasibility - Collaboration |
| 1. Benefits of individual consortium partners to the project  |
| 2. Benefits of the project to consortium partners   |
| 3. Responsibilities of consortium partners and collaboration activities  |
| 3A. Project alignment to FORESIGHT strategy. |

**Criteria and points specific to the FORESIGHT program**

One month after the TEAMS presentations, "pre-proposals" can be submitted with a FORESIGHT pre-proposal template. In addition to FORESIGHT-specific items, the pre-proposal also contains all requirements from the standard TKI-LSH template. This includes the project design, contributions from the project consortium and how the grant will be spent. When preparing the pre-proposals, applicants must contact 1) members of the assessment committee for feasibility assessment, they can also receive advice and coaching and 2) the relevant TTO staff and local financial advisors for the assessment of the public-private partnership and the budget. TTO employees of the institution of the team member involved in the project supports in the negotiations with private partners for the project proposal.

A checklist is used to check whether the pre-proposal meets the requirements of both TKI-LSH (including financial and structural requirements), and FORESIGHT criteria.

Admissible pre-proposals and full project proposals will be assessed and scored with a checklist. The template contains all questions to assess whether you have met TKI-LSH eligibility requirements, including financial requirements.

**General Health Holland requirements for PPPs**

* The research fits within the social theme 'Health & Care,' the Central Mission, and one of the five focused Missions, as described in the [Knowledge and Innovation Agenda (KIA) 2024-2027](https://www.health-holland.com/en/publications/useful-documents/kia) of Top Sector LSH. (see Appendix 1).
* The consortium must consist of at least one research organization and a private partner.
* The project has a maximum duration of 4 years.
* The project consists of industrial research, experimental development, or a combination thereof (TRL 4 – 7). Projects at lower TRL levels (TRL<4, fundamental research) can apply but have a lower chance of being awarded.
* Effective collaboration takes place. The project is executed with joint efforts, costs, and risks - all consortium partners contribute substantially.
* All consortium partners should make an in-kind contribution. This means, for example, but not limited to, all consortium partners must incur payroll costs and that these costs are visible in the budget form.
* A collaboration agreement using the template approved by Health~Holland and the consortium partners should be signed by the start of the project.

**FORESIGHT specific criteria/advices**

* A link with a member of the FORESIGHT core module or disease area teams and at least a private and a public partner.
* Collaboration with companies in the Netherlands or internationally, SMEs, and public partners, such as healthcare providers, patients, and insurers.
* The project should be carried out within the FORESIGHT Innovation and Service Center.
* Contribution to FORESIGHT objectives and appropriate output. We aim to have most of awarded project proposals with TRL ≥4. Technology readiness level: The Development phase (TRL 4, 5, 6), The Demonstration phase (TRL 7 & 8)
* An innovative public-private R&D project in drug development or choice with molecular imaging in one of the four disease areas, using one or more modules.
* Duration preferably 3 to a maximum of 4 years.
* Dissemination to the scientific community and the wider public.
* Social impact well substantiated.
* Economic impact well substantiated.
* Good quality, partly in view of feasibility and mitigation plan.
* Maximum project budget of ~€1,500,000, of which €750,000 is a subsidy, 50% contribution by public-private parties, of which cash contribution is at least 10% for large companies.
* Collaborations with Dutch SMEs are encouraged.

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

**1A. Project title**:

***[Fill here]***

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

***[Fill here]***

**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 *[Fill the table below]*** |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Male/female/other |  |
| Position |  |
| Address for correspondence |  |
| Telephone |  |
| E-mail: |  |
| Type of organisation  | [ ]  Research organisation |
| 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 *[Fill the table below]*** |
| 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 2** |
| Department | Name of contact person, title(s) |
|  |  |

|  |
| --- |
| **Consortium partner 3 *[Delete this table if not applicable]*** |
| 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) |
|  |  |

**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. Please note that at the full proposal stage you will be asked to sign a statement deaclaring you have completed the form truthfully.*

***[Fill here or mark as not applicable]***

**5. Consortium agreement and IP**

*The mandatory consortium agreement template is available on demand. A limited number of amendments can be made to the template and need to be submitted to Health~Holland for approval. Please note that the consortium agreement will only need to be signed by the start of the project.*

***[Describe here the current status of the negotiation with the partners]***

**6. Start date (dd-mm-yyyy): *[Fill here]***

**7. End date (dd-mm-yyyy): *[Fill here]***

**8. Duration of the project (max. 48 months): *[Fill here]***

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

**Fill in the word count:**

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

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

***[Fill here]***

**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 here]***

**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.*

***[Fill here]***

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

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

1. *Provide an explanation for the research type(s) chosen. Use the phrasing provided in the definition of the three types of research (see Appendix D).Please ensure that the type(s) of research correspond to the current and expected TRL-levels indicated in question 4C (see also Appendix).*

***[Fill here]***

1. *Please indicate per work package the budget and the applicable type(s) of research (more than one option possible); if more than one type of research is applicable for the work package, please indicate the relative contribution of each category to the WP budget.*

|  |  |  |
| --- | --- | --- |
| **WP** | % of total budget (WP budget/total budget \* 100%) | **Type of Research** |
| Fundamental research | Industrial Research | Experimental Development |
| 1 | … % | … % | … % | … % |
| 2 | … % | … % | … % | … % |
| Etc. | … % | … % | … % | … % |

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

**Fill in the word count:**

**1. Background (max. 350 words)**

*Describe the project background and topic. Include citations and list the relevant references under question B.8 “References”.*

***[Fill here]***

**2. State-of-the-art (max 250 words)**

**Fill in the word count:**

*Describe the current state-of-the-art in the field. Include a description of how the project expands on this state-of-the-art.*

***[Fill here]***

**3. Objective and hypothesis (max 200 words)**

**Fill in the word count:**

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

Objective of the project:

***[Fill here]***

Hypothesis of the project:

***[Fill here]***

**3.A. Alignment with the FORESIGHT strategy**

**Fill in the word count:**

 **(max 250 words)**

*Describe and explain how the project aligns with the FORESIGHT Program objectives and contributes to tackling the challenges identified in the Program description.*

***[Fill here]***

**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. 200 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?**

***[Fill the table – the question below can be left unanswered at pre-proposal phase]***

|  |  |
| --- | --- |
| *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?
 | [ ]  N/A[ ]  Requested |

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

**10. Animal experiments**

***[Fill the table – the question 11 below, if applicable, can be left unanswered at pre-proposal phase]***

|  |  |
| --- | --- |
| *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**

***[Fill the table]***

|  |  |
| --- | --- |
| *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 |

|  |
| --- |
| **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).*

|  |
| --- |
| 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.*

***[Fill here ]***

**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.*

***[Fill here ]***

**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:**

***[Fill here ]***

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:**

***[Fill here ]***

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

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

*Current TRL:* ***[check box here]***

[ ]  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):*

***[Fill here ]***

* 1. *Expected TRL: :* ***[check box here]***

[ ]  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 here ]***

**Fill in the word count:**

**5. Market introduction, reaching TRL 9 (max. 200 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.*

|  |
| --- |
| 1. **Collaboration (max. 500 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.*

***[Fill here ]***

**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).*

***[Fill here ]***

**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.)*

***[Fill here ]***

|  |
| --- |
| 1. **Budget specification**
 |

**Fill in the Health~Holland budget form. Use the version of the budget form specific for this Pilot 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):* ***[Fill here ]***

**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.*

 ***[check box here]***

Principal mission the project contributes to (select one):

[ ]  Mission I

[ ]  Mission II

[ ]  Mission III

[ ]  Mission IV

[ ]  Mission V

 ***[check box here]***

Secondary mission the project contributes to (if applicable):

[ ]  Mission I

[ ]  Mission II

[ ]  Mission III

[ ]  Mission IV

[ ]  Mission V

[ ]  Not applicable

*Argumentation:* ***[Fill here ]***

|  |
| --- |
| **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. 200 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 3.7 of the Pilot Call 2024.*

|  |  |
| --- | --- |
|  | **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** |

***[Fill both tables below for the KETs for KEM]***

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

*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; consequently, check the applicable underlying* [*subcategories*](https://www.nwo.nl/sleuteltechnologieen) *of the Key Enabling Technologies the project applies to. For more information on the Key Enabling Technologies, please visit the websites indicated above.Check the box of the respective, applicable, KET.*

|  |  |  |
| --- | --- | --- |
| **Key Enabling Technologies** | **Key Enabling Technologies Subcategories** | **Yes** |
| Advanced materials | Energy materials |[ ]
|  | Optical, electronic, magnetic and nanomechanical materials |[ ]
|  | Meta materials |[ ]
|  | Soft/bio materials |[ ]
|  | Thin films and coatings |[ ]
|  | Construction and structural materials |[ ]
|  | Smart materials |[ ]
| Chemical technologies | (Bio) Process technology, including process intensification |[ ]
|  | (Advanced) Reactor engineering |[ ]
|  | Separation technology |[ ]
|  | Catalysis |[ ]
|  | Analytical technologies |[ ]
|  | Electricity-driven chemical reaction technologies |[ ]
| Digital and information technologies | Artificial intelligence |[ ]
|  | Data science, data analytics and data spaces |[ ]
|  | Cyber security technologies |[ ]
|  | Software technologies and computing |[ ]
|  | Digital Connectivity Technologies |[ ]
|  | Digital Twinning and Immersive technologies |[ ]
|  | Neuromorphic technologies |[ ]
| Engineering and fabrication technologies | Sensor and actuator technologies |[ ]
|  | Imaging technologies |[ ]
|  | Mechatronics and opto-mechatronics |[ ]
|  | Additive manufacturing |[ ]
|  | Robotics |[ ]
|  | Digital manufacturing technologies |[ ]
|  | Micro electronics |[ ]
|  | Systems engineering |[ ]
| Life science and biotechnologies | Biomolecular and cell technologies |[ ]
|  | Biosystems and organoids |[ ]
|  | Biomanufacturing and bioprocessing |[ ]
|  | Bioinformatics |[ ]
| Quantum technologies | Quantum computing |[ ]
|  | Quantum communication |[ ]
|  | Quantum Sensing |[ ]
| Nanotechnology | Nanomanufacturing |[ ]
|  | Nanomaterials |[ ]
|  | Functional devices and structures (on nanoscale) |[ ]
|  | Micro- and nanofluidics |[ ]
|  | Nanobiotechnology / Bionanotechnology |[ ]
| Photonics and optical technologies | Photovoltaics |[ ]
|  | Optical systems and Integrated photonics |[ ]
|  | Photonic/Optical detection and processing |[ ]
|  | Photon generation technologies |[ ]
| Not applicable |  |[ ]

**2. Key Enabling Methodologies**

*Indicate which of the* [*Key Enabling Methodologies*](https://kems.nl/kem-categorieen/) *the project applies to*.*Check the box of the respective, applicable, KEM.*

|  |  |
| --- | --- |
| **Key Enabling Methodologies** | **Yes** |
| 1. Vision and imagination
 |[ ]
| 1. Participation and co-creation
 |[ ]
| 1. Behaviour and empowerment
 |[ ]
| 1. Experimental environments
 |[ ]
| 1. Value creation and upscaling
 |[ ]
| 1. Institutional change
 |[ ]
| 1. System change
 |[ ]
| 1. Monitoring and effect measurement
 |[ ]
| 1. Not applicable
 |[ ]

**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.
3.
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 (CoI)**

*This Appendix is also available in Dutch and can be requested by sending an email to* *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.

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.

*Note:* Please review the conflict of interest policies of the UMCG, which can be found on the [Research Code UMCG](https://researchcode.umcgresearch.org/en-GB/w/foreword) and/or of your institution (for other Consortium Partners) and provide any other information that you shall disclose in light of potential CoI.

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

**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.

**To determine the type of research the following table of Technology Readiness Level (TRL) may be of further assistance (please note that the definition of type of research given above prevails):**

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

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)