|  |
| --- |
| 1. **Registration** |

**Basic details**  
**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 | Maastricht University\* |
| 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 1) | Research organisation  For profit enterprise  Non-for-profit enterprise  Health fund  Other, namely: |
| SME (MKB)   * Type of SME   (for SME definition see Appendix 2) | Yes  No  If yes,  Micro  Small  Medium |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |

***\*Please note that the main applicant should be affiliated with UM***

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

**3. List of consortium partners (co-applicants)**

|  |  |
| --- | --- |
| **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 1) | Research organisation  For profit enterprise  Non-for-profit enterprise  Health fund  Other, namely: |
| SME (MKB)   * Type of SME   (for SME definition see Appendix 2) | Yes  No  If yes,  Micro  Small  Medium |
| 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** | |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Address for correspondence |  |
| E-mail: |  |
| Type of organisation  (for enterprise definition see Appendix 1) | Research organisation  For profit enterprise  Non-for-profit enterprise  Health fund  Other, namely: |
| SME (MKB)   * Type of SME   (for SME definition see Appendix 2) | Yes  No  If yes,  Micro  Small  Medium |
| 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. Consortium agreement and IP**

*The mandatory consortium agreement template can be downloaded from* [*intranet*](https://umployee.maastrichtuniversity.nl/onderzoek/onderzoek-fhml/intern-tki-grant-program---pps)*. Describe any amendments the consortium has made. In addition, describe the reasoning behind these amendments.*

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

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

**7. Duration of the project (max. 48 months):**

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

**Fill in the word count:**

**8A. Project summary (max. 300 words)**

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

**8B. 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:**

**8C. 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.*

**8D. Keywords (max. 5)**

**9. Research category (see Appendix 3)**

1. *Please indicate per work package the applicable type(s) of research (more than one option possible).*

|  |  |  |
| --- | --- | --- |
| **Types of research** |  | **WP** |
| 1. Fundamental research | Yes  No |  |
| 1. Industrial research | Yes  No |  |
| 1. Experimental development | Yes  No |  |

1. *Provide an explanation for the research type(s) chosen. Use the phrasing provided in de definition of the three types of research (see Appendix 3).*

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

**Fill in the word count:**

**1. Background (max. 300 words)**

*Describe the project background and topic. Include citations and list the relevant references under question B.7 “References”.*

**2. State-of-the-art (max 200 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.*

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

**Fill in the word count:**

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

**4. Outline per work package****(max. 1500 words)**

**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.*

**5. Success criteria**

1. *Describe the criteria that are utilized to determine success, the criteria should be written according to the SMART-principles 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. 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[[1]](#footnote-2).*

**7. 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** |

**8. Will the project involve experiments with 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  NA |
| 1. If ‘d’ is answered with ‘yes’: Do you already have ethical approval from a commission to perform the study? | Yes  No  NA  Requested |

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

**9. Animal experiments.**

|  |  |
| --- | --- |
|  | **Answer** |
| 1. Use of laboratory animals. If yes, please will out question 10 and 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  NA |
| 1. If ‘e’ is answered with ‘yes’: do you already have ethical approval from a commission to perform the study? | Yes  No  NA  Requested |

**10. Specification 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.*

**11. Justification for the requirement of experimental animals**

* 1. *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?*
  2. *What are the reasons that this project cannot be performed without experimental animals (replacement)?*
  3. *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.*
  4. *What are the reasons that this project cannot be performed with a lower species of animals?*

**12. 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  NA |

|  |
| --- |
| **B. Data management** |

**All data management should comply with the FAIR principles: Findable, Accessible, Interoperable, and Reusable.[[2]](#footnote-3)**

**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**

1. *Will data be collected or generated that is suitable for reuse by other parties? If yes, answer questions b to e. 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).*
2. *Where will the data be stored during the project?*
3. *How will data be stored long-term and how will it be made available for use by third parties after the project has been completed?*
4. *Who will the collected data be made accessible to after completion of the project?*
5. *Describe which facilities (ICT, (secure) archive, refrigerators, or legal expertise) are expected to be necessary for the storage of data during the project and after the project (1). Elaborate on whether these facilities are available or how these will be made available during the project (2).*   
   *ICT facilities for data storage are considered to be resources such as data storage capacity, bandwidth for data transport and calculating power for data processing.*

|  |
| --- |
| 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 (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, and public 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 5) 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:**

**5. Market introduction, reaching TRL 9**

**Fill in the word count:**

**(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.*

**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**

*Describe the responsibilities of each individual consortium partner within the project.*

**4. Collaboration activities**

*Describe how the consortium plans to collaborate (communication, sharing results, progress meetings, etc.)*

|  |
| --- |
| 1. **Project risks and mitigation strategies** |

**5. Risks**

*Describe all risks (scientific, operational etc.) relating to the execution of the project.*

**6. Mitigation strategies**

*List the risks 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.*

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

**Fill in the extended budget form. Use the most recent version of the budget form (2024). Outdated versions of the budget form will not be accepted.**

**7. Deployment of PPP Allowance**

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

*Notes:*

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Partner** | **Total Costs** | **PPP Allowance** | **Activities** |
| **Consortium Partner 1** |  |  |  |
| **Consortium Partner 2** |  |  |  |
| **Consortium Partner 3** |  |  |  |
| **Etc.** |  |  |  |
| **Total sum\*** |  |  |  |

**\****Make sure that the total sum of costs and the total sum of PPP Allowance in this table is in accordance with the total budget and total requested PPP Allowance in the budget form.*

**8. Budget specification**

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

**9. Have the consortium partners requested/received any additional grants for this project?**

**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. **Patient/end-user participation** |

**Fill in the word count:**

**1. Vision on patient/end-user participation**

**(max. 400 words)**

*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. In addition, in case of fundamental projects, also describe how citizens should be involved in follow-up projects. Address the following points in your answer:*

* *What is the consortium’s vision on participation of citizens in their role of patients in the organisation of the project, from project idea to the project’s end result (output and outcome)? In addition, in case of fundamental/industrial projects, please describe these factors for future projects*
* *Are these groups actively involved as partners in the formation of the consortium?*
* *Are these groups structurally and (pro)actively involved in the execution of the project?*
* *How are the experiences and wishes of these groups included in the process?*
* *Are these groups financially facilitated/compensated for their active involvement?*

|  |
| --- |
| 1. **Inclusivity and reduction of health disparities** |

**2. Inclusivity: Relevant differences within target groups**

*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. 200 words).*

**Fill in the word count:**

* 1. *Please 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 (max. 200 words).*

**Fill in the word count:**

**3. Inclusion of the Key Principles for reducing**

**Fill in the word count:**

**health disparities (max. 400 words)**

*Describe 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 following Key Principles in your description of how the project aims to reduce health disparities (2)*

* *Specific goals are set concerning the desired outcome in population groups with a low SES.*
* *People with a low SES are engaged in the design and development process, and they are a partner within the consortium (co-creation, quadruple helix).*
* *There is proportional representation in the project, and inclusive research methodologies are used (no bias, valid data, representative4All, non-discriminating algorithms).*
* *The usability and accessibility of envisaged data collection tools and innovations are tested for people with a low SES.*
* *Research design and innovations look beyond lifestyle and have specific attention for underlying factors as poverty, debts, loneliness, poor housing etc.*
* *Research design and innovations are to be embedded in the local/regional context with active involvement of local stakeholders throughout the course of the project.*

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

**4. Innovation guidance**

*Before answering the questions below, please see Appendix 6.*

|  |  |
| --- | --- |
|  | **Answer** |
| 1. Do the consortium partners intend to apply for CE marking for the health innovation during the project period or within two years after the project period? | Yes  No |
| 1. Did the consortium partners contact HI-NL no later than three weeks before the deadline for the Match Call? | Yes  No  Not applicable |
| 1. Does HI-NL believe that an innovation guide is valuable for this project?   *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  No  Not applicable |
| 1. What is your main question to be addressed by the HI-NL Round Table experts? (Multiple boxes can be checked) | Integration of your innovation in the Dutch healthcare system  Required (clinical) evidence for market entry  Reimbursement of innovation  Strategy for adoption by the market  Path for CE-marking  Scale-up of your innovation  Other, namely: |

|  |
| --- |
| **F. KIA, VWS Missions, National Research Agenda Roadmaps KET’s and KEM’s** |

**Fill in the word count:**

1. **Strategic importance (max 300 words)**

*Describe the strategic importance of the project to the broader (scientific) community (e.g. local (MUMC+/FHML), regional, national and/or international level)?*

**2. Kennis en Innovatie Agenda (KIA)**

**Fill in the word count:**

**(max 300 words)**

*Describe how the projects contributes to and fits within the Knowledge and Innovation Agenda (KIA) 2020-2023 and the general policy and theme depicted in it.*

**Fill in the word count:**

**3. VWS missions: central mission (max. 150 Words)**

*Describe how the project contributes to the Central Mission of the Ministry of Health, Welfare and Sport (VWS) (below) and describe how the project specifically targets groups in lower socio-economic positions to increase health equity, according to the SMART principles.*

*Consult, reference and use at least one of the aspects described in “Toekomstbeelden 2030”[[3]](#footnote-4) (p. 8-11) in your argumentation. Consult “Missiedocument Gezondheid en Zorg”[[4]](#footnote-5) for more information on the central mission. Include a description on how the project contributes to different elements in the quadruple helix. In addition, include a description of how, at the end of the project, the concrete contribution to the mission can be measured/evaluated.*

***Central Mission:*** *By 2040, all Dutch citizens 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:*

**4. VWS missions: mission I – mission IV**

**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 in “Toekomstbeelden 2030” (p. 12-24) per VWS mission in your argumentation. Consult “Missiedocument Gezondheid en Zorg” for more information on the different missions. Include a description on how the project includes the quadruple helix. 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 whocan 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%.*

Principal mission the project contributes to (select one):

Mission I Mission II Mission III Mission IV

Secondary mission(s) the project contributes to:

Mission I Mission II Mission III Mission IV Not applicable

*Argumentation:*

**5. Roadmaps**

*Indicate which roadmap(s) (see Appendix 4) is/are most applicable to the project (max. 2 roadmaps).*

|  |  |
| --- | --- |
| **LSH Roadmaps** | **yes/no** |
| Molecular diagnostics | Yes  No |
| Imaging & image-guided therapies | Yes  No |
| Homecare & self-management | Yes  No |
| Regenerative medicine | Yes  No |
| Pharmacotherapy | Yes  No |
| One health | Yes  No |
| Specialised nutrition, health & disease | Yes  No |
| Health technology assessment, individual functioning & quality of life | Yes  No |
| Enabling technologies & infrastructure | Yes  No |
| Global health, emerging diseases in emerging markets | Yes  No |

**6. LSH-related national Dutch Research Agenda routes**

*Indicate on which of the seven LSH-related Dutch National Research Agenda routes the project applies to (max. 2 routes).*

|  |  |
| --- | --- |
| **LSH-related Dutch National Research Agenda routes** | **yes/no** |
| Healthcare research, sickness prevention and treatment | Yes  No |
| Personalised medicine: the individual at the centre |  |
| Regenerative medicine: a game-changer moving to broad areas of application | Yes  No |
| Creating value through responsible access to big data and its use | Yes  No |
| NeuroLabNL: the ultimate living lab for brain, cognition and behavioural research | Yes  No |
| Sport and exercise | Yes  No |
| Quality of the environment: game-changer ‘Exposome’ | Yes  No |

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

1. *Indicate on which of the Key Enabling Technologies[[5]](#footnote-6) the project applies to*

|  |  |
| --- | --- |
| **Key Enabling Technologies** | **yes/no** |
| Advanced materials | Yes  No |
| Chemical technologies | Yes  No |
| Digital technologies | Yes  No |
| Engineering and fabrication technologies | Yes  No |
| Life science technologies | Yes  No |
| Quantum technologies | Yes  No |
| 1. Nanotechnologies | Yes  No |
| 1. Photonics and light technologies | Yes  No |
| 1. Not applicable | Yes  No |

1. *Name the applicable underlying subcategories[[6]](#footnote-7) of the Key Enabling Technologies the project applies to.*
2. *Describe why these Key Enabling Technologies are relevant for the project, and thus how the project helps in the application and/or development of these technologies (max. 200 words).*

**Fill in the word count:**

**8. Key Enabling Methodologies**

1. *Indicate which of the Key Enabling Methodologies[[7]](#footnote-8) 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 |

1. *Describe why these Key Enabling Methodologies are relevant for the project by addressing (max. 200 words):*

**Fill in the word count:**

* + *How they are embedded in the project’s approach.*
  + *How expertise on these methodologies is employed within the project (via which consortium partner or third party).*

1. *Describe whether the project aims at researching or developing methodologies and describe the aims of this part of the project (max. 200 words).*

**Fill in the word count:**

1. *Describe possible collaborations with other public-private partnerships or which of these public-private partnerships are relevant for a future collaboration (see the overview on the Health~Holland website[[8]](#footnote-9), max. 200 words).*

**Fill in the word count:**

|  |
| --- |
| **G. Disclosure of potential conflict of interest (COI)** |

**1. Individual potential COI**

*a) Does the Principal Investigator in the Project have any financial interest in the company(ies) involved in the consortium? If so, how many shares, options and/or benefits do you (or your relatives) have rights to?*

*Examples of financial interest may be: a) 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 industry participant(s) directly or indirectly related to the subject matter of the Project application.*

*b) Does any other investigator involved in the Project have any financial interest in the company(ies) involved in the consortium? If so, how many shares, options and/or benefits do you (or your relatives) have rights to?*

*c) In the last 12 months, did any commercial entity or any of the entities that are participating in the Project pay for or reimburse 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 outcome of the Project?*

**2. Institutional potential COI**

*a) Are any of the Consortium Partners in the Project affiliated or associated with another Consortium Partner in the Project? If so, how?*

*b) Does any Consortium Partner have directly or indirectly any shares, options and/or any other participation in the Industrial (or Private) Consortium Partners despite of not being an affiliated entity? If so, how many shares, options and/or participations? Does the Partner(s) has rights?*

*c) Or, if the financial interest as stated in a) or b) above does not apply, would a Consortium Partner exercise any control on any of the other Consortium Partners’ decision making? If so, how?*

*d) In the last 12 months, did any commercial entity or any of the entities that would be a Private partner in the Project pay for or reimburse 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?*

**3. If there is any potential COI, how would the consortium manage such a conflict?**

|  |
| --- |
| **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.

Name:

Place:

Date:

Please note: Information provided in relation to this application will be treated confidentially by Health~Holland. 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 private partners, in order to claim the requested PPP Allowance. RVO.nl will also treat this information confidentially. Upon granting, the project coordinator will receive a request to provide a summary of the project and other basic project details that will be published on the Health~Holland website and for other communication purposes. Other content of the project will not be communicated beyond Health~Holland.

**Main applicants must submit this application form and all required attachments by e-mail to** [**fhml-pps@maastrichtuniversity.nl**](mailto:fhml-pps@maastrichtuniversity.nl)

**Appendix 1: 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 2: 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).

**Appendix 3: Definitions of the three types of research[[9]](#footnote-10)**

**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 4: Definitions of the ten roadmaps**

The roadmaps are designed to address priorities in health outcomes (age-related, chronic, acute, infectious, orphan and neglected diseases) and along the healthcare chain (from prevention through diagnosis to cure and care). The roadmaps represent the areas in which public and private parties are committed to co-innovate and ask the government to co-invest. Companies, research institutes, practitioners, patient organizations, health foundations, health insurers, regulators, and many others have contributed and endorsed these roadmaps. Seven roadmaps (1 through 7) are product oriented. They are supported by two that deliver health technology assessment (8) and enabling technologies & infrastructure (9). The latter also links to other Top Sectors with a strong life sciences component, such as Agro-food, Horticulture and Chemistry. A final roadmap (10) is centred around diseases that cause a high burden mainly in the developing world, but for which the developed world can make strides in solving.

1. **Molecular diagnostics**: Development of candidate biomarkers into validated molecular diagnostics for clinical use
2. **Imaging & image-guided therapies**: Development of imaging applications for more accurate and less invasive diagnosis and treatment
3. **Homecare & self-management**: Development, assessment and implementation of technologies, infrastructure and services that promote clients’ abilities to live independently and manage their own care, adequately supported by healthcare professionals
4. **Regenerative medicine**: Development of curative therapies for diseases caused by tissue damage and ensuing organ dysfunction, through repair or renewed growth of the original tissue or replacement by a synthetic or natural substitute
5. **Pharmacotherapy**: Discovery, development and stratified use of new, safe and (cost-) effective medicines in order to cure or prevent progression along the healthcare chain
6. **One health**: Development of solutions like vaccines, optimized antimicrobial use and early warning systems that improve health status of humans and animals by coupling the know-how and infrastructure available in the human and veterinary/agricultural domains
7. **Specialized nutrition, health & disease**: Researching specialized nutrition for nutritional intervention as part of integrated health solutions in terms of prevention, cure and care of chronic, acute and rare diseases
8. **Health technology assessment, individual functioning & quality of life**: Development of methods and knowledge for health technology assessments in which the impact of health innovations on quality of life, cost-containment and productivity is assessed
9. **Enabling technologies & infrastructure**: Development and offering of expertise and infrastructure in cutting-edge molecular life science technologies (e.g. next generation sequencing, proteomics and bioinformatics), in biobanks and in ultramodern research facilities, all readily accessible to industry and academia, and with existing, strong links to other Top Sectors (Agro-food, Horticulture, Chemistry, Biobased Economy and High Tech Systems and Materials)
10. **Global health, emerging diseases in emerging markets**: Development and delivery of solutions to diseases associated with poverty, which affect more than 2 billion people in the developing world

**Appendix 5: Technology Readiness Levels**

|  |  |  |
| --- | --- | --- |
| **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 | Beyond the scope of the PPP Allowance Regulation |
| TRL 9 | Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space) | Beyond the scope of the PPP Allowance Regulation |

\*The TRL is an indication of the type of research but the definition of type of research (Appendix 3) prevails.

**Appendix 6: Evaluation of health and care innovations**

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

*HI-NL*

The number of health and care innovations is constantly increasing. These innovations vary from implants and high-tech diagnostic and prognostic machines to biomarker assays, AI-algorithms, medical apps and wearables for self- and home management. The evaluation methods, introduction, implementation and reimbursement of medicines are clearly described and regulated. However, this is not the case for non-medicinal (medtech) innovations. Health~Holland believes it is vital to analyse the actual impact and possibilities for implementation of innovations at an early stage, i.e. while these are still in the R&D phase. Therefore, Health~Holland collaborates with the [Health Innovation Netherlands (HI-NL)](https://www.healthinnovation.nl). HI-NL brings together all relevant parties, at the earliest possible stage, that play a crucial role in the medtech development, evaluation, use, scale-up, decisionmaking and reimbursement process to help innovators on the road to success. These meetings are called roundtable meetings.

*Innovation guidance by HI-NL*

The aim of a HI-NL roundtable is to draw up an overall picture at an early stage of how an innovation will fit in the healthcare and prevention landscape and to analyse what is needed to bring an innovation to the market. During the roundtable, the relevant parties discuss the following aspects:

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

After the roundtable, HI-NL issues a comprehensive and concrete advisory report, the innovation guide, and a follow-up telephone consultation is planned. The innovation guide contains a consensus opinion from the panel of all relevant parties. In addition, this document provides an overview of the most important steps that an innovator must take to successfully evaluate, scale-up and implement the innovation in the intended (health) context. The innovation guide is a confidential document and the property of the innovator.

*Which steps should the consortium undertake?*

If, for the application submitted, the consortium develops an innovation for which it is likely that CE marking will be applied for during the duration of the project, or within two years after the project period, the consortium may contact [HI-NL](https://www.healthinnovation.nl/contact) no later than three weeks before the closing of the deadline. HI-NL will subsequently analyze whether a round table and innovation guide may offer added value to the innovator and its new product. If, after contacting HI-NL, it appears that the development of an innovation guide would be of added value, this may be indicated on the application form (section 29. Innovation guidance). In addition, the project coordinator may include an earmarked budget of € 33.275 (incl. VAT) on the budget form for the drawing up the innovation guide. This amount can be included under the heading “costs owed to third parties” together with the specification “development innovation guide by HI-NL”. The costs for the development of an innovation guide can be funded with PPP allowance. After the application for PPP funding has been (conditionally) awarded the consortium will be asked to elaborate on the plans related to the development of the innovation guide in the application. The details of this elaboration will be included in the award letter. Contact person HI-NL The contact person at HI-NL can be reached via the following e-mail address: info@healthinnovation.nl.

1. Note: non-scientific dissemination costs are not eligible for funding withing the PPP allowance program, therefore, costs relating to this dissemination may not be incurred on the official budget form. [↑](#footnote-ref-2)
2. For more information please consult: <https://www.dtls.nl/fair-data/fair-data/> [↑](#footnote-ref-3)
3. <https://www.health-holland.com/2030/#p=1> [↑](#footnote-ref-4)
4. <https://www.health-holland.com/sites/default/files/downloads/missiedocument-gezondheid-en-zorg_1.pdf> [↑](#footnote-ref-5)
5. <https://www.hollandhightech.nl/kia-sleuteltechnologieen> [↑](#footnote-ref-6)
6. <https://www.nwo.nl/sleuteltechnologieen> [↑](#footnote-ref-7)
7. <https://www.clicknl.nl/de-creatieve-industrie/key-enabling-methodologies/> [↑](#footnote-ref-8)
8. <https://www.health-holland.com/public-private-partnerships> [↑](#footnote-ref-9)
9. In case of drug development, pre-clinical research in animals falls within the research category ‘industrial research’. In principle, the clinical phases 1 and 2 fall within the research category ‘experimental development’. Phase 3 clinical trials (and beyond) are seen as competitive development and fall outside the scope of the PPP Allowance Regulation. [↑](#footnote-ref-10)