**Full application form**

*“Human measurement models: next steps in model development”*

**Instructions:**

This form allows you to describe your application. The filled application form and accompanying documents will be used for the assessment process. The full application should be written in English. Please take notice of the explanations given in this form and ensure that you will answer or refer to all aspects mentioned. All questions should be answered in this form. Please be aware of the maximum number of pages or word count given at each section. Please complete the questions in each section within the maximum number of pages or word count. Use font Arial, 10pt. You are not allowed to change the margins of the text boxes. The form should be signed by the project coordinator on behalf of all applicants.

Besides the completed application form it is important that (at least) the following completed forms are included:

1. Completed LSH budget sheet
2. Draft consortium agreement
3. Letter(s) of commitment from all parties that make an in-kind or in-cash contribution to the project

The application and required attachments should be sent to **humanemeetmodellen@gezondheidsfondsen.nl** before **October 4th 2024, 2:00 pm CE(S)T.**

## Basic details

### Project title:

### Project acronym (if applicable):

### Contact details of main applicant (project coordinator)

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| **Main applicant** |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Male/female/other |  |
| Position |  |
| Address for correspondence |  |
| Chamber of commerce number or equivalent |  |
| Telephone |  |
| E-mail |  |
| Type of organisation (for enterprise definition see Appendix A) | [ ]  Research organisation[ ]  For profit enterprise[ ]  Non-for-profit enterprise[ ]  Health fund[ ]  Other, namely: |
| URL of own web page |  |

*If applicable, list all co-applicants affiliated to the same organisation as the main applicant in the designated table below.*

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| **Co-applicants from the same organisation as main applicant** |
| Department | Name of contact person, title(s) |
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### List of consortium partners (co-applicants)[[1]](#footnote-2)

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| **Consortium partner 2** |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Address for correspondence |  |
| E-mail |  |
| Type of organisation(for enterprise definition see Appendix A) | [ ]  Research organisation[ ]  For profit enterprise[ ]  Non-for-profit enterprise[ ]  Health fund[ ]  Other, namely: |
| SME (MKB)* Type of SME

(for SME definition see Appendix B) | [ ]  Yes 🡪 [ ]  Micro [ ]  Small [ ]  Medium[ ]  No[ ]  NA  |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |

*If applicable, list co-applicants affiliated to the same organisation as consortium partner 2 in the designated table below.*

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| **Co-applicants from the same organisation as consortium partner 2** |
| Department | Name of contact person, title(s) |
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| **Consortium partner 3** |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Address for correspondence |  |
| E-mail: |  |
| Type of organisation(for enterprise definition see Appendix A) | [ ]  Research organisation[ ]  For profit enterprise[ ]  Non-for-profit enterprise[ ]  Health fund[ ]  Other, namely: |
| SME (MKB)* Type of SME

(for SME definition see Appendix B) | [ ]  Yes 🡪 [ ]  Micro [ ]  Small [ ]  Medium[ ]  No[ ]  NA  |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |

*If applicable, list co-applicants affiliated to the same organisation as consortium partner 3 in the designated table below.*

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| **Co-applicants from the same organisation as consortium partner 3** |
| Department | Name of contact person, title(s) |
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*To add more (co-)applicants, please copy the tables above.*

### 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 the ZonMw* [*Code of Conduct on Conflict of Interest*](https://www.zonmw.nl/en/laws-and-regulations-concerning-zonmw) *for more information. If there is a potential conflict of interest, please also indicate how the consortium will manage such conflict.*

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### Suggestions for referees

*Please provide us a list of (maximum five) potential referees that can review the proposal. Please ensure you propose referees who are not expected to have a conflict of interest with the application or consortium members. When suggesting referees, provide their full names, affiliations, email addresses, and any other relevant information. Please include a brief explanation for each suggestion.*

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### Consortium agreement and IP

*The mandatory consortium agreement template can be downloaded from* [*our website*](https://www.gezondheidsfondsen.nl/subsidie-aanvraag/)*. Describe any amendments the consortium has made. In addition, describe the reasoning behind these amendments.*

*Note: The signed consortium agreement should be returned eight weeks after award decision. Therefore it is recommended to start discussing the content of the consortium agreement with the consortium partners during the application phase.*

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### Start date (dd-mm-yyyy):

*Note: Final start date: 1 September 2025*

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### End date (dd-mm-yyyy):

*Note: Final end date: 1 September 2029*

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### Duration of the project (max. 48 months):

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## Project overview

### Project summary (max. 300 words)

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

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### Layman’s summary in Dutch

**(max. 500 words, in lay language)**

This Dutch summary is intended for committee members assessing the proposals from a patient’s perspective. These members will assess the projects on the following relevance criteria: importance of the problem for patients, involvement of (end)users (and if relevant: patients), *and the communication to (future) patients about the results of the project. Describe the background, objective, design, and relevance of the project, focused on utilization potential in which the described relevance criteria above are incorporated.*

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### 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.*

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### Keywords (max. 5)

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### Research category (see Appendix C)

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. | … % | … % | … % | … % |

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 C).*

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## Project description (max. 11 pages w/o references)

*Note: References (question 23) will not be counted in the maximum of 11 pages.*

### Background

*Describe the project background and topic. Include citations and list the relevant references under question 23: “References”.*

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### Fit for purpose

1. *Describe how the proposal fits with the goals, objectives and scope of the Human Measurement Models programme (including the missions of SGF and ZonMw as described in Appendix A of the call text).*

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1. *Describe how the project will contribute to the (further) development of human measurement model development. In your answer, include elements related to the next steps in development, such as standardization, reproducibility and/or other validation aspects.*

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1. *How will the project contribute to reducing animal experimental research and making the use of animals in research unnecessary?*

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1. *Describe how the project will contribute to (for example) faster diagnostics or treatment of multiple diseases or be relevant to multiple patient groups?*

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### State-of-the-art

*Describe the current state-of-the-art of the concerned human measurement model in the field. Also, include a description of how the project expands on and is expected to improve this state-of-the-art.*

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### Objective and hypothesis of the project

1. *Describe the objective of the project:*

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1. *Describe the hypothesis of the project:*

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### Outline per work package

1. *Describe the work plan per work package (if more than one). Include a table or scheme, that shows the following (at a minimum): aim, time schedule, milestones and deliverables. Indicate the role and responsibilities of the applicants in the activities.*

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1. *Describe the coherence between the work packages (if more than one). Include a figure to clarify the coherence.*

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1. *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:

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### 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*

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

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### Risks & Mitigation strategies

1. *Fill in the table below. Describe all risks (scientific, operational etc., such as commercial propositions, patents or social acceptance) 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.*

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

### 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.*

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*Etc.* |

## Human subjects, laboratory animals, biological hazards

### Will the project involve experiments with patient material?

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| *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 ‘e’ is answered with ‘yes’: Do you already have ethical approval from a commission to perform the study?
 | [ ]  Yes [ ]  No[ ]  N/A[ ]  Requested |

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

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### Animal experiments

*This PPP programme aims to contribute to the development of better methods and models with high predictability for humans, that do not require animal studies. Within this PPP programme it is only permitted to make use of animal models to demonstrate the validity of the model. In case animal experiments are being performed for this purpose it should be substantiated that the mechanisms and effects studied in the animal are comparable to those in humans.*

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| *Animal experiments* | **Answer** |
| 1. Use of laboratory animals. If yes, please also fill out question 27.
 | [ ]  Yes [ ]  No |
| 1. Number of animals needed for the total project.
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| 1. Is ethical approval from a commission needed regarding experimental subjects?
 | [ ]  Yes [ ]  No [ ]  N/A |
| 1. If ‘c’ is answered with ‘yes’: do you already have ethical approval from a commission to perform the study?
 | [ ]  Yes [ ]  No[ ]  N/A[ ]  Requested |

### Specification and justification of animal experiments

**(max. 1200 words in total)**

1. *Describe the kind of animals (species, modifications, etc.) used in the project.*

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1. *Describe the nature of the animal interventions within the project.*

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1. *Describe how the mechanisms and effects studied in the animal are comparable to those in humans.*

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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?*

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1. *What are the reasons that this project cannot be performed without experimental animals (replacement)?*

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1. *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.*

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### Biological risks

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| *Biological risks* | **Answer** |
| 1. Use of recombinant DNA?
 | [ ]  Yes [ ]  No |
| 1. If ‘a’ is answered with ‘yes’: provide class of recombinant DNA
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| 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 |

## Collaboration (max. 3 pages)

### Added value of individual consortium partners to the project

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

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### 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).*

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### Responsibilities of consortium partners and collaboration activities

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

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### Expertise of the consortium partners

*Describe how the expertise of the project members is multidisciplinary and complementary to each other.*

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### (End) user involvement

*Describe how (end) users like clinicians, regulators and patients are involved in the design, execution, and dissemination/implementation of the project.*

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### Inclusivity

*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. Please describe to what extent the (health) problem affects men, women and/or other relevant subgroups. 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.*

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## Budget specification

*Fill in the budget form from Health~Holland, as provided on the* [*SGF webpage of the call*](https://www.gezondheidsfondsen.nl/subsidie-aanvraag/)*. Use the version of the budget form specific for this Human Measurement Models call. Other versions of the budget form will not be accepted.*

### 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.*

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| **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.*

### Budget specification

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

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### 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.*

### Is the proposal a resubmission of a previous SGF, ZonMw, NWO or Health~Holland proposal?

[ ]  **Yes** [ ]  **No**

*If yes, please attach a statement (in English) to the submission indicating previous submission title and call submitted to and explaining the conducted revisions*

## Impact (max. 7 pages)

### Output and outcome[[2]](#footnote-3) of the project

1. *Describe the expected output of the project and how consortium partners and other (end) users are involved. This may include deliverables as described in question 20, but may be extended with other insights or conclusions you expect to derive directly from the project.*

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1. *Describe the expected project outcome, including the outcome of eventual follow-up projects, and how they ain in achieving the described impact goals. Also describe the role of the involved consortium partners and other (end) users in achieving this outcome.*

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### Societal impact

*Describe the expected impact the project will have on society and the LSH sector (e.g. clinicians and patients) in particular. Please include a description of the current societal problem the project is aiming to solve.*

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### Economic impact

1. *Describe the expected 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).*

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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.*

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### Scientific impact

*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.*

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### Implementation and dissemination

1. *Describe the activities each consortium partner plans to engage in order to promote the implementation (including potential exploitation) of the results. Include a justification for the chosen approach for each individual consortium partner.*

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1. *Describe the activities each consortium partner plans to engage in order to promote the dissemination of the results. This should not be limited to scientific dissemination. Include a justification for the chosen approach for each individual consortium partner[[3]](#footnote-4).*

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### Current and expected TRL-levels

*Indicate the current (1) and expected (2) Technology Readiness Level (TRL; see Section 2.1 of the call text) 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

* 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:*

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### Market introduction, reaching TRL 9

*Describe who (1) and what (2) is needed to introduce the innovation into the market/clinic (TRL 9), including knowledge transfer. 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.*

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## Data management

*All data management should comply with the FAIR principles: Findable, Accessible, Interoperable, and Reusable.[[4]](#footnote-5) 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.*

### 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.*

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### Reuse of collected data

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

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## KIA, VWS Missions

### VWS missions: central mission

*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/?1715334102#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 socioeconomic status (SES) and low SES, 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):*

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### VWS missions: mission I – mission V

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

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

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

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

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

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

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

Principal mission the project contributes to (select one):

[ ]  Mission I

[ ]  Mission II

[ ]  Mission III

[ ]  Mission IV

[ ]  Mission V

Secondary mission the project contributes to (if applicable):

[ ]  Mission I

[ ]  Mission II

[ ]  Mission III

[ ]  Mission IV

[ ]  Mission V

[ ]  Not applicable

*Argumentation: (max. 300 words)*

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## KET’s and KEM’s

### Key Enabling Technologies (KET’s)

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

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

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

### Key Enabling Methodologies

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

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

## Statement by project coordinator

When submitting your application, please do not forget to include the required budget form file (Excel), letter(s) of commitment, (draft) consortium agreement and other necessary documents.

Please tick the boxes where applicable:

[ ]  By submitting this form, I declare that I have completed this form truthfully and I declare that the correct official(s) of my, and my co-applicant’s employing organisations have been informed of this submission.

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

[ ]  I hereby declare that the application is checked according to Appendix E.

*In our search for international referees that have the best expertise to assess your application, we want to be able to approach experts from various countries. Conform current privacy laws, we are obliged to ask your approval to send this application to countries outside the European Economic Area (EEA), if applicable. Referees and members of the assessment committee are obliged to declare they will treat your application confidentially and have no conflict of interest with your project, the applicants or involved companies. For more information, see also the* [*SGF Privacy statement*](https://www.gezondheidsfondsen.nl/wp-content/uploads/sites/3/2024/02/Privacyverklaring.pdf). *Please note that we will redact personal information that is not needed for the referees to make a proper content-related judgement of your proposal (e.g. sex, email addresses and telephone numbers).*

[ ]  I hereby give my consent on behalf of all consortium partners to send this proposal to referees from countries outside the EEA, if this is necessary for the assessment process.

Name:

Place:

Date:

Please note: Information provided in relation to this application will be treated confidentially by SGF, ZonMw and Health~Holland and shared with the assessment committee and referees as described in the call for proposals and application form. Health~Holland has to inform the Netherlands Enterprise Agency (RVO) on the participants of the project and the in cash and in kind contribution of the consortium partners, in order to claim the requested PPP Subsidy. RVO will also treat this information confidentially. Upon granting, the project coordinator will receive a request to provide a project profile, including a summary of the project and other basic project details (see Appendix D) that will be published on websites of the partners and for other communication purposes.

## Appendices

### 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: Definitions of the three types of research[[5]](#footnote-6)

**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 D: Project page content for Health~Holland website

**Health~Holland Project Page**

|  |
| --- |
|  |

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

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

**Project page content**

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

1. **Project number**

HH-PPS-…….

1. **Clear popular title**

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

1. **Clear scientific title**

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

1. **One liner**

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

1. **Short summary of the project**

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

1. **Public summary**

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

Health~Holland would like you to follow these guidelines:

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

Define a maximum of five clear keywords.

1. **Consortium partners**

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

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

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

1. **Link**

If possible a link to a webpage with more information.

**Project page filters**

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

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

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

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

**Comments**

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

**Editorial rights**

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

### Appendix E: Checklist application form

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

[ ]  The main applicant is a Knowledge Institute as defined in the call text, located in the Netherlands.

[ ]  The project meets the requirement for the maximum project duration (48 months).

[ ]  The starting date is after after the grant decision and before (or at) September 1st 2025

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

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

[ ]  The project consists of fundamental research, industrial research or experimental development, or a combination thereof. A description of the three types of research is provided in Appendix C.

[ ]  All consortium partners should at least incur payroll costs.

[ ]  All consortium partners should make an *in kind* contribution.

[ ]  Research organisations may finance a maximum of 70% of their costs (e.g. man hours, consumables and the use of equipment etc.) with PPP subsidy in the case of fundamental/industrial research and a maximum of 60% of their costs in the case of experimental development.

[ ]  Dutch SMEs may finance a maximum of 60% of their costs (e.g. man hours, consumables and the use of equipment etc.) with PPP subsidy in the case of fundamental/industrial research and a maximum of 40% of their costs in the case of experimental development.

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

[ ]  Depending on the type of research the enterprise(s) must contribute at least 15% to 30% of the total project costs.

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

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

[ ]  The consortium is aware that in case the project is awarded the PPP Subsidy, the consortium agreement should be completed (after approval of the final version by Health~Holland) and signed 8 weeks after the award decision is communicated

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

[ ]  All questions on the application form are answered.

[ ]  The right versions of the application form, budget form and consortium agreement specific to the current Human Measurement Models call have been used.

1. In case of a potential conflict of interest (at a personal or organizational level), please disclose the situation in question 5. [↑](#footnote-ref-2)
2. **Output**: Insights and conclusions derived directly from the project, e.g. publications, data and new methods. **Outcome**: Changes in behaviour, relationships, actions or activities of stakeholders as a result of the project’s output, e.g. skill development, policy changes, people engagement. [↑](#footnote-ref-3)
3. 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-4)
4. For more information please consult: <https://www.go-fair.org/fair-principles/> [↑](#footnote-ref-5)
5. 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-6)