|  |
| --- |
|  **Basic details** |

**1A. Full project title:**

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

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

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

|  |
| --- |
| **Consortium partner 1** |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Male/female/other |  |
| Position |  |
| Address for correspondence |  |
| Telephone |  |
| E-mail: |  |
| Type of organisation (for enterprise definition see Appendix A) | *Health fund/company (for profit enterprise)/research organisation/non-profit enterprise/other* |
| SME (MKB)* Type of SME

(for SME definition see Appendix B) | *Yes/No**Medium/Small/Micro/NA* |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |
| (Scientific) excellence and expertise of the main applicant and added value of the main applicant to the quality of the project |  |
| Benefit of this project for the main applicant |  |

|  |
| --- |
| Co-applicants from the same organisation as consortium partner 1 |
| Department | Name of contact person, title(s) | (scientific) excellence and expertise and added value of the co-applicant to the quality of the project | Benefit of this project for the co-applicant |
|  |  |  |  |

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

|  |
| --- |
| **Consortium partner 2** |
| Name of the organisation |  |
| Department |  |
| Name of contact person, title(s) |  |
| Address for correspondence |  |
| E-mail: |  |
| Type of organisation(for enterprise definition see Appendix A) | *Health fund/company (for profit enterprise)/research organisation/non-profit enterprise/other* |
| SME (MKB)* Type of SME

(for SME definition see Appendix B) | *Yes/No**Medium/Small/Micro/NA* |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |
| (Scientific) excellence and expertise of the main applicant of the organisation and added value of the applicant to the quality of the project |  |
| Benefit of this project for the applicant |  |

|  |
| --- |
| Co-applicants from the same organisation as consortium partner 2 |
| Department | Name of contact person, title(s) | (scientific) excellence and expertise and added value of the co-applicant to the quality of the project | Benefit of this project for the co-applicant |
|  |  |  |  |

|  |
| --- |
| **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) | *Health fund/company (for profit enterprise)/research organisation/non-profit enterprise/other* |
| SME (MKB)* Type of SME

(for SME definition see Appendix B) | *Yes/No**Medium/Small/Micro/NA* |
| Chamber of commerce number or equivalent |  |
| URL of own web page |  |
| (Scientific) excellence and expertise of the main applicant of the organisation and added value of the applicant to the quality of the project |  |
| Benefit of this project for the applicant |  |

|  |
| --- |
| Co-applicants from the same organisation as consortium partner 3 |
| Department | Name of contact person, title(s) | (scientific) excellence and expertise and added value of the co-applicant to the quality of the project | Benefit of this project for the co-applicant |
|  |  |  |  |

Etc.

**4. Consortium agreement and IP**

*Please describe the main aspects of the consortium agreement and the anticipated plan regarding intellectual property (IP) generated by the project.*

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

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

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

|  |
| --- |
| **Project content** |

**8A.** **Summary (max. 300 words)**

*Please describe the background, objective, design, and anticipated social and economic impact.*

**8B. Public summary in Dutch (max. 300 words, in lay language)**

*Please describe the background, objective, design, and anticipated social and economic impact.*

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

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

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

|  |  |  |
| --- | --- | --- |
| **Types of research** | **yes/no** | **WP** |
| 1. Fundamental research
 |  |  |
| 1. Industrial research
 |  |  |
| 1. Experimental development
 |  |  |

1. Please give an explanation of the chosen research type(s). Make use of the phrasing that has been used to define the three types of research (see Appendix D).

**10. Project description**

*Please address items a to d (max. 3500 words) and include relevant literature references. Insert citations in the text and list the references under point 11 in numerical sequence in the order in which they are first mentioned in the text.*

1. Describe the research topic/background, objectives and hypothesis, and the operationalisation of the concept(s) tested.
2. Outline the work plan per work package (if more than one) in a table or scheme, including: aim, time schedule, milestones and deliverables. Indicate the role and responsibilities of the applicants in the activities.
3. Describe the coherence between the work packages (if more than one).
4. When will the project be considered successful and which criteria will be used to validate this? Describe the overall outcome of each WP that defines the criterium for success with go/no-go criteria. The mere listing of the milestones and deliverables is not sufficient.

**11. Please provide a concise list of references**

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

**12. Importance of the project**

1. Please describe how does the project fits within the [Knowledge and Innovation Agenda 2020-2023](https://www.health-holland.com/sites/default/files/downloads/kennis-en-innovatieagenda-2020-2023-gezondheid-en-zorg.pdf) and the general policy theme that is depicted in it (max. 300 words).
2. Please describe below how the project contributes to the Central Mission of the Top Sector LSH (max. 150 words)
* Central Mission:

By 2040, all Dutch citizens 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%.

1. Please describe below how the project contributes to one or more of the underlying missions of the Top Sector LSH (max. 300 words):
* 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%.

**13. Applicable categories**

1. Please indicate below which roadmap(s) (see Appendix E) is/are most applicable to the project (max. 2 roadmaps).

|  |  |
| --- | --- |
| **LSH Roadmaps** | **yes/no** |
| 1. Molecular diagnostics
 |  |
| 1. Imaging & image-guided therapies
 |  |
| 1. Homecare & self-management
 |  |
| 1. Regenerative medicine
 |  |
| 1. Pharmacotherapy
 |  |
| 1. One health
 |  |
| 1. Specialised nutrition, health & disease
 |  |
| 1. Health technology assessment, individual functioning & quality of life
 |  |
| 1. Enabling technologies & infrastructure
 |  |
| 1. Global health, emerging diseases in emerging markets
 |  |

1. Indicate on which of the seven LSH-related Dutch National Research Agenda routes[[2]](#footnote-3) the project applies to (max. 2 routes).

|  |  |
| --- | --- |
| **LSH-related Dutch National Research Agenda routes** | **yes/no** |
| 1. Healthcare research, sickness prevention and treatment
 |  |
| 1. Personalised medicine: the individual at the centre
 |  |
| 1. Regenerative medicine: a game-changer moving to broad areas of application
 |  |
| 1. Creating value through responsible access to big data and its use
 |  |
| 1. NeuroLabNL: the ultimate living lab for brain, cognition and behavioural research
 |  |
| 1. Sport and exercise
 |  |
| 1. Quality of the environment: game-changer ‘Exposome’
 |  |

1. Indicate on which of the Key Enabling Technologies[[3]](#footnote-4) the project applies to.

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

1. Name the applicable underlying subcategories[[4]](#footnote-5) 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.
3. Indicate which of the Key Enabling Methodologies[[5]](#footnote-6) the project applies to.

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

1. Describe why these Key Enabling Methodologies are relevant for the project by addressing:
	* 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).
2. Describe if the project aims at researching or developing methodologies, and describe the aims of this part of the project.
3. 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[[6]](#footnote-7)).

|  |
| --- |
| **Prospects** |

**14. Originality/innovativeness**

*Please describe the originality of innovativeness of the project. What is new and unique? What are the novel clinical applications?*

**15. Project outcome and follow-up**

1. Describe the expected societal impact of the project.
2. Describe the expected economic (also for the companies) impact of the project. Please also include a cost-effectiveness analysis or a value-based reasoning to describe the economic impact. How does the project fit the strategic mission(s) of the parties involved?
3. Indicate what the effect on the Dutch economy will be and give an analysis of your position in your competitive environment.
4. Indicate the current and expected Technology Readiness Level (TRL; see Appendix F) of the project (level of development/readiness to go to the market), and why this is applicable for the project.
5. What and who will be needed to bring the innovation to the market/clinic (TRL 9)?
6. Describe the planned activities by each consortium partner in order to promote the dissemination and implementation (including potential exploitation) of the results. This should not be limited to scientific dissemination. Please also include a justification for the chosen approach for each partner.

**16. Data management**

*The data should comply with the FAIR principles (Findable, Accessible, Interoperable, and Reusable;* <https://www.dtls.nl/fair-data/fair-data/>*).*

1. Could the research question(s) be answered with existing data and a therefore suitable research methodology? If not, or only partially, please explain the added value of the new data to existing datasets.
2. Will data be collected or generated that are suitable for reuse? If yes, then answer questions c to e. If not, then explain why the project will not result in reusable data or in data that cannot be stored or data that for other reasons are not relevant for reuse.
3. Where will the data be stored during the project?
4. After the project has been completed, how will the data be stored for the long-term and made available for the use by third parties? To whom will the data be accessible?
5. Which facilities (ICT, (secure) archive, refrigerators or legal expertise) do you expect will be needed for the storage of data during the project and after the project? Are these available? 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.

**17. Patient/end user participation**

*Please describe if and 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 results. Please address the following points within your answer (max. 400 words):*

* *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)?*
* *Are these groups actively involved as partner 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?*

**18. Inclusion of the Key Principles for reducing health inequalities**

*Please describe to what extent the following Key Principles to reduce health inequalities are included in the project (max. 400 words):*

* *Specific goals are set concerning the desired outcome in population groups with a low SES (socio-economic status).*
* *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 innovations are tested for people with a low SES.*
* *Innovations look beyond lifestyle and have specific attention for underlying factors as poverty, debts, loneliness, poor housing etc.*
* *Innovations are to be embedded in the local/regional context with active involvement of local stakeholders.*

**19. Inclusivity: Relevant differences within target groups concerned**

*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.
	2. 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.

**20. Risks of the project**

*Are there any risks regarding the execution of the project? List the risks for each WP, the risk mitigation strategy already incorporated in the strategy or the proposed strategy adaptations once risks are encountered.*

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

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

|  |  |
| --- | --- |
|  | **Answer** |
| 1. Use of healthy volunteers?
 | 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/requested/NA |

**22. Will the project involve experiments with animals?**

|  |  |
| --- | --- |
|  | **Answer** |
| 1. Use of animals?
 | yes/no |
| 1. What kind of animals are used?
 |  |
| 1. Number of animals needed for the total project
 |  |
| 1. Nature of intervention
 |  |
| 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/requested/NA |

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

* 1. Indicate if alternative methods (besides experimental animals) have been considered? Have experts been consulted and has a systematic review 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)?
	4. What are the reasons that this project cannot be performed with a lower species of animals?

**24. Will the project involve 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 |

|  |
| --- |
| **Budget** |

**25. Budget**

*Please specify the project’s budget in the* [*TKI-LSH budget form*](https://www.health-holland.com/sites/default/files/downloads/2022-tki-lsh-match-budget-form.xlsx)*. Use a separate line per consortium partner for their contribution. Do not forget to add the numbers in the ‘total’ column and rows.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Contribution** | **cash** | **2022** | **2023** | **2024** | **2025** | **2026** | **Total** |
| **Research organisation** | In cash |   |   |   |   |   |   |
| In kind |  |  |  |  |  |  |
| **Company** | In cash |   |   |   |   |   |   |
| In kind |  |  |  |  |  |  |
| **Other partners** | In cash |   |   |   |   |   |   |
| In kind |  |  |  |  |  |  |
| **PPP Allowance** | In cash  |   |   |   |   |   |   |
| **Total funding (incl. PPP Allowance)** | In cash |   |   |   |   |   |   |
| In kind |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |
| **Total project costs** | **Total** |   |   |   |   |   |   |

**26. Deployment of PPP Allowance**

*Please indicate for each consortium partner 1) their total costs (incl. in kind contribution); 2) the amount of PPP Allowance that they will use; and 3) the activities that will be financed through the PPP Allowance.*

*Note: 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.*

**27. Budget specification**

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

**28. 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.*

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

**29. Innovation guidance**

*Before answering the questions below, please read section 3.2 of the Match Call 2022.*

|  |  |
| --- | --- |
|  | **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/NA |
| 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/NA |
| 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: |

|  |
| --- |
| **Statement by project coordinator** |

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

Please tick the boxes where applicable:

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

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

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

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 (see Appendix I) 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 TKI-LSH PPP Allowance application form by e-mail to

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

Attachments to be uploaded:

* TKI-LSH budget form.
* Letters of commitment of **all** parties involved, each stating the parties’ in cash & in kind (separately) contribution to the project. Only the main applicant does not need to upload a letter of commitment. See Appendix H for a template of a letter of commitment.
* Signed copy of the consortium agreement and IP settlements agreed upon in this project. If a signed consortium agreement is not yet available, a concept agreement must be submitted. The signed consortium agreement may be handed in within 16 weeks after the submission deadline.
* If the applicants want to use (part of) their temporarily reserved PPP Allowance (generated from the ‘grondslag’ 2020/2021): a statement from the research organisation’s/company’s TKI contact person (or other authorized person) indicating that (part of) reserved PPP Allowance can be used for this project.

**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).

**Appendix C: Conflict of Interest**

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

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

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

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

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

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

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

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

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

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

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

**Appendix D: Definitions of the three types of research[[7]](#footnote-8)**

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

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

well as of pilot lines, when necessary for the industrial research and notably for generic technology validation.

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

made to existing products, production lines, manufacturing processes, services and other operations in progress, even if those changes may represent improvements.

**Appendix E: 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 F: 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 D) prevails.

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

**Health~Holland Project Page**

|  |
| --- |
|  |

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

**The Top Sector Life Sciences & Health (LHS) wants to illustrate all its currently accepted and ongoing public private projects and partnerships to our international audience throughout the world. Therefore, the Health~Holland website will be complemented by the new Health~Holland project page. 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. **LSH project number**

LSHM …….

1. **Clear popular title**

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

1. **Clear scientific title**

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

1. **One liner**

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

1. **Short summary of the project**

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

1. **Public summary**

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

Health~Holland would like you to follow these guidelines:

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

Define a maximum of five clear keywords.

1. **Consortium partners**

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

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

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

1. **Link**

If possible a link to a webpage with more information.

**Project page filters**

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

1. **Objective:** prevention, cure or care *(select one)*
2. **Kind of research:** fundamental, industrial or experimental
3. **Major** [**TKI-LSH roadmap**](http://www.health-holland.com/public/downloads/tki-2016/tki-lsh-match-application-appendix-a-roadmaps.pdf) **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, individual functioning & quality of life
	9. enabling technologies & infrastructure
	10. global health, emerging diseases in emerging markets
4. **Minor** [**TKI-LSH roadmap**](http://www.health-holland.com/public/downloads/tki-2016/tki-lsh-match-application-appendix-a-roadmaps.pdf) **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, individual functioning & quality of life
	9. enabling technologies & infrastructure
	10. global health, emerging diseases in emerging markets
5. **Operating in:** bio(pharma), medical technology or healthcare *(select one)*
6. **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 Elise de Gier (gier@health-holland.com).

**Appendix H: Letter of commitment template**

[Use headed paper of party]

[Name and address of the main applicants' duly authorised representative (“bestuurlijk verantwoordelijke”)]

[Date]

***LETTER OF COMMITMENT***

*for the*

***[name of] PROJECT***

Dear [main applicants’ duly authorised representative],

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

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

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

Yours sincerely,

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

Name:

Position:

Date:

**Appendix I: Checklist application form**

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

[ ]  The main applicant is located in the Netherlands

[ ]  The project has a duration of a maximum of 48 months

[ ]  The starting date is after the deadline of the Match Call and within six months after the awarding letter will be received

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

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

[ ]  All consortium partners should make an *in kind* contribution. This means, for example, that all consortium partners should at least incur payroll costs

[ ]  Dutch SMEs may finance a maximum of 50% of their *in kind* costs (e.g. man hours, consumables and the use of equipment) with PPP-Allowance in the case of fundamental/industrial research and a maximum of 25% of their *in kind* costs in the case of experimental development.

[ ]  Depending on the type of research, a for profit enterprise must contribute at least 15%, 30% or 45% of the total project costs

[ ]  At least 2/3rd of the required minimum contribution of a large enterprise must consist of a cash contribution

[ ]  The research organisation must contribute at least 10% of the total project costs

[ ]  All parties, with the exception of the main applicant, must submit a letter of commitment; a letter of intent is not sufficient

[ ]  If a claim is made to the temporarily reserved PPP Allowance (generated from the *grondslag*) of a research organisation/enterprise, then a statement should also be sent. In this statement the PPP Allowance contact person or another authorised person states from which *grondslagjaar* and the amount of reserved PPP Allowance may be used for this specific project

[ ]  The consortium must submit a draft consortium agreement; a blank format is not sufficient

[ ]  The budgeted costs are directly related to the R&D activities, and do not include 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

1. In case of a potential conflict of interest (at a personal or organizational level), please disclose the situation following Appendix C. [↑](#footnote-ref-2)
2. <https://2.wetenschapsagenda.nl/overzicht-routes/> [↑](#footnote-ref-3)
3. <https://www.hollandhightech.nl/kia-sleuteltechnologieen> [↑](#footnote-ref-4)
4. <https://www.nwo.nl/sleuteltechnologieen> [↑](#footnote-ref-5)
5. <https://www.clicknl.nl/de-creatieve-industrie/key-enabling-methodologies/> [↑](#footnote-ref-6)
6. <https://www.health-holland.com/public-private-partnerships> [↑](#footnote-ref-7)
7. 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-8)