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Call for proposals, Partnership NWO Domain AES – SGF – ZonMW – Top Sector LSH, Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Human measurement models 2.0: for health research on disease and prevention

Aguideline for applicants is published separately

Deadlineforsubmissionofapplications: 16 June 2020; 14:00h CE(S)T(Central European(Summer)Time)

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Partnership programme 'Human measurement models 2.0: for health research on disease and prevention'

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1 Glossary

Consortium: Means a group of entities that work together on the research project. With respect to this programme the consortium consists of the research institutes involved, for-profit enterprises or not for



profit organisations that contribute to the project in kind and, if applicable, in cash (including SME). Together the consortium will prepare a project agreement.

Consortium partners: For-profit enterprises, SMEs or not for profit organisations that contribute to the project via an in kind and/or in cash contribution and research institutes.

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 aimed 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.

Financial resources: Financial contributions used to cover part of the project costs (in-cash co-funding) together with the funding from NWO Domain AES, ZonMw and by the PPP allowance made available by Top Sector LSH to NWO domain AES on behalf of SGF.

Fundamental research: Experimental or theoretical research activities that are predominantly performed to gain new knowledge on the fundamental aspects of phenomena and observable facts, without the intent of achieving a direct commercial application or direct commercial use; Industrial research: Methodical research which is explicitly aimed at gaining new knowledge and skills with the intention of developing new products, processes or services, or to substantially improve existing products, processes or services. It encompasses the creation of parts for complex systems as well as the building of prototypes in a laboratory environment and/or an environment of simulated interfaces for existing systems, as well as pilot systems, when needed for the industrial research and in particular for validating generic technology.

In-kind contributions: In-kind contributions means capitalised personnel and/or material contributions from users (see "Notes on Users, co-funding and letters of support" in the guideline for applicants that is published together with this call).

Publication: The disclosure of results by any means, such as a text (including publications, abstracts, announcements on a website), illustration or an image or sound carrier, with the exception of disclosure resulting from a patent or patent application

Small and Medium-sized Enterprises (SME): Enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million as defined by the European Commission.

Systems biology (Mathematical Modelling): Systems biology is a scientific approach in life sciences which aims to reach an integral and comprehensive understanding of the quantitative behaviour of biological systems that arises from the dynamic interplay of the various components thereof. As a basic prerequisite, systems biology research projects integrate mathematical models that simulate in silico the system's properties and predict its quantitative response to internal or external perturbations. Frequently, biological systems are represented as networks of interacting elements in which the phenotypic traits are determined by the structure and the dynamic behaviour of the network itself. The study of biological systems in this framework requires interdisciplinary cooperation and a division of labour between e.g., biologists, medical scientists, mathematicians, physicists, computer scientists, chemists and engineers.

Total project costs: Necessary financial resources required to carry out the project plus in-kind contributions from industrial partners (company; for-profit enterprises).

Users: Means natural persons or legal entities that are able to use the results of the Project. Examples are: companies, NGO's, patient organisations, clinicians, authorities etc. Among the users, the consortium partners are included. However, the project may include more users who do not contribute in kind and/or in cash to the project.

2 Introduction

This brochure details the conditions governing proposals submitted to NWO Domain AES for the funding of scientific research under the Partnership programme NWO Domain AES – The Association of Collaborating Health Foundations (SGF in Dutch: Samenwerkende Gezondheidsfondsen) – ZonMw – Top Sector Life Sciences and Health (LSH; Health Holland) entitled 'Human measurement models 2.0: for health research on disease and prevention'. It explains the objectives and working methods of NWO Domain Applied and Engineering Sciences (NL: NWO-domein Toegepaste en Technische Wetenschappen; further referred to as NWO Domain AES).

Before submitting your application electronically via ISAAC, NWO Domain AES recommends that you visit its websiteto verify that you have the latest version of this brochure, and that you read the



guidelines carefully. Moreover, please familiarize yourself with ISAAC (www.isaac.nwo.nl)before you start the submission of your proposal.

2.1 About the partners

NWO Domain AES, SGF, ZonMw and Top Sector LSH have initiated the Partnership programme to stimulate effective cooperation between academic and industrial researchers. This Partnership programme is financed by NWO Domain AES, ZonMw and by the PPP allowance made available by the Top Sector LSH, to NWO Domain AES, on behalf of SGF. These organisations are further referred to as Partners in this guideline. NWO Domain AES is the first point of contact for applicants for this partnership. It receives the submitted proposals, executes the assessment procedure and facilitates the monitoring of the awarded projects in this partnership programme. This will be done in close collaboration with the Partners.

2.1.1 NWO Domain AES

NWO Domain AES is part of the Dutch Research Council (NWO; see also www.nwo.nl)which supports a strong system of sciences in the Netherlands by encouraging quality and innovation in science. Responsibility for the national science and innovation policy lies with the Ministries of Education, Culture and Science (OCW) and Economic Affairs and Climate Policy (EZK). As such, NWO Domain AES provides government funding.

NWO Domain AES adheres to the NWO strategyand presented her Vision document 2019-2022"Technology for people and society". NWO Domain AES carries out its activities in an increasingly dynamic and complex arena. Politics, industry and society are asking science to help solve societal issues. Research in the applied and engineering sciences and the application of its outcomes play a crucial role in that. Yet at the same time, the vitality of the applied and engineering sciences field is under pressure.

The **mission** of NWO Domain AESis to facilitate research in applied and engineering sciences that yields applications and impact for people and society. To this end, NWO Domain AES will focus on the following three **objectives**:

- · a strengthened applied engineering sciences foundation;
- · efficient innovation chains;
- visible societal impact.

Research funded by NWO Domain AES generates valuable knowledge. In addition to excellent science, NWO Domain AES aims to promote transfer and application of knowledge. The term used by NWO Domain AES to refer to the set of activities aimed at maximising the possibility of research results being applied by third parties is 'utilisation'. In order to promote utilisation next to scientific quality, NWO Domain AES establishes a user committee involving third parties for every project. NWO Domain AES expects applicants and users to actively collaborate during the project towards promoting utilisation and towards NWO Domain AES's objective of transferring knowledge to users. Users, user committees and intellectual property play a crucial role in utilisation.

2.1.2 SGF

The SGF consists of nineteen independent public health organisations in the Netherlands that collectively address many of the most prevalent diseases in Dutch society. The SGF network was established in 2002 to streamline coordination and cooperation efforts across the foundations regarding commonly shared challenges. The **mission** of the SGF is to increase healthy life years for everyone living in the Netherlands. To that end, the nineteen foundations collaborate to improve conditions for prevention, to heal and treat different types of diseases, and to increase the societal impact of all efforts being made to improve overall health in the Netherlands. The SGF's programme consists of two main fields of interest:

- Setting the agenda to improve public health and to promote a healthy lifestyle in the Netherlands.
 This involves lobbying activities and implementing the multi-year programme 'Healthy Generation' which aims to enable Dutch youth in becoming the healthiest youth in the world by 2040. The SGF seeks to cooperate with various health institutions, the Dutch local and national governments, and Dutch society to achieve this ambitious goal.
- Supporting and funding important disease-transcending research. In these research programmes, the SGF is partnering with Top Sector LSH. Next to that, the collaborating health foundations strive to increase the involvement of patients throughout their work.

For more information about SGF and the aforementioned initiatives, please visit www.gezondheids-fondsen.nl

2.1.3 ZonMw

ZonMw (The Netherlands Organisation for Health Research and Development) funds health research



in the Netherlands and promotes the actual use of the knowledge this research produces. ZonMw promotes health research and care innovation throughout the entire knowledge chain from fundamental research to implementation. Through various subsidy programmes we promote and fund development and practical application in the area of prevention improvement, care and health. The work field of the knowledge chain as a whole is broad, making ZonMw a unique organisation. With regard to the call 'Human Measurement Models', ZonMw collaborates with the partners mentioned: NWO Domain AES, SGF and Top Sector LSH. ZonMw does so within the context of the funding programme 'More Knowledge with Fewer Animals'. This programme aims to develop new innovations free of animal testing and to encourage the use of existing innovations that do not use animal testing. The results of the projects funded under MKMD will also help with the development of new methods or models of safety and risk assessment. The ultimate aim is better and more relevant health and healthcare research for humans. For more info, see the webpage of the programme. Within this context, funds committed by ZonMw for the current call 'Human Measurement Models' as described in this document, are exclusively intended and to be used for research projects that are free of animal testing and any other use of animals, preferably also without the use of Foetal Calf Serum (FCS).

2.1.4 Top Sector Life Sciences & Health (Health~Holland)

The Dutch Life Sciences & Health (LSH)sector is one of nine "top sectors" in the Netherlands. The top sectors are designated by the Dutch Ministry of Economic Affairs and Climate Policy and are selected on their ability to contribute substantially to global societal challenges.

The Top Sector LSH covers a broad range of disciplines, from pharmaceuticals to medical technology and from healthcare infrastructure to vaccination. To realise its **mission** – vital functioning citizens in a healthy economy – the Top Sector builds on the strengths of the Dutch LSH sector to address the biggest societal challenges in prevention, cure and care: improving health while restraining the costs of healthcare.

Top Sector LSH initiates and stimulates interdisciplinary research and development in public-private partnerships (PPP) to valorise innovation. By attracting funding, sharing best practices, connecting organisations and communicating as one voice through Health Holland, the Top Sector is boosting a productive infrastructure.

3 Background

Millions of people have to deal every day with the consequences of serious and sometimes life-threatening diseases. SGF, ZonMw, Top Sector LSH and NWO AES are committed to achieving better and healthier lives for everyone, including people with a chronic or life-threatening disease. Scientific research, to develop better treatments for example, plays a crucial role in this. However, the possibilities for carrying out experimental research in human subjects are limited. To gather the necessary knowledge at the various biological levels and to make predictions and understand causes, scientists often use model systems. A substantial proportion of current health research makes use of animal models. There are various reasons for this: for example, the use of animal models may be required by laws and regulations, the researcher may regard it as the best option for the research, or there may be few or no alternatives available yet.

Research models based on human material such as cells and tissues, or computer models based on data collected in humans, are expected to resemble humans more closely than animal models do. The more closely a research model resembles the human situation, the sooner the corresponding research results can be applied in practice. In addition, the (further) development of human models provides scientists with a wider range of opportunities to carry out relevant, high-quality research, without extensive use of laboratory animals.

New scientific insights and innovative techniques facilitate the (further) development of new human measurement models. Targeted funding is being made available for this under the Public-Private Partnership (PPP) Programme "Human measurement models". This PPP programme has been set up by four partners: SGF, NWO Domain AES, ZonMw and Top Sector LSH. This collaboration so far has led to a programme in the area of Human measurement models which consists of two calls for applications, both concerning public-private partnership (PPP) programmes.

The first call 'Human measurement models. Towards better human measurement models' (Call I) is being issued by SGF with funding by means of the PPP Allowance made available by Top Sector LSH. The second call 'Human measurement models 2.0: for health research on disease and prevention' (Call II) is being issued by NWO Domain AES, SGF, ZonMw and with funding by means of the PPP allowance made available by Top Sector LSH, to NWO Domain AES, on behalf of SGF.

The programme objectives are in line with the ambitions of the national "Transition Programme for Innovation without the use of animals" (TPI) coordinated by the Dutch Ministry of Agriculture, Nature and Food Quality (LNV). Partners in this transition include SGF, Top Sector LSH, the Dutch Society for the Replacement of Animal Testing (Stichting Proefdiervrij) and ZonMw, together with various parties from government and society, industry and science. The TPI's ambition is to make the Netherlands a



forerunner in the international transition to animal-free innovation. The TPI is led by the Ministry of Agriculture, Nature and Food Quality in partnership with the Ministry of Education, Culture and Science, the Ministry of Health, Welfare and Sport, the Ministry of Economic Affairs and Climate Policy, and the Ministry of Infrastructure and Water Management. Further information on the "Transition Programme for Innovation without the use of animals" is available on its website.

4 Scope of the programme HMM

The scope of the PPP programme Human measurement models is to facilitate the development of new, more efficient human measurement models for health research to ensure that research results can be applied better and faster in humans. This will make science less dependent on the use of animal models. The (further) development of human models will contribute to answering research questions that otherwise could not be answered or could be answered only by using animal models. These models may aim either at diagnosing and treating diseases or at disease prevention. The definition of "measurement model" includes both human *in vitro* and *in/ex vivo* models (e.g. models based on human material/tissue/cell lines) as well as *in silico* models (e.g. models based on (big) data, systems biology and computational models).

4.1 Programme objectives:

- Development of human measurement models with good predictability for humans;
- Development of human measurement models for disease diagnosis, treatment and prevention of disease;
- Combine models that, together, can serve as a model to answer big questions in health research (e.g. working towards replacement of an entire organ or organism);
- Application of valorised models and/or methods by stakeholders;
- · Availability of (standardised) models and methods on a large scale;
- Impact in terms of reducing animal experimental research or preferably eliminating the use of animals in research.

4.2 Human measurement models and animal use

Funding under this programme aims to contribute to the development of better methods and models that have high predictability for humans and do not require animal studies. In addition, it is essential that these models and methods are applied by stakeholders. For many stakeholders (industry, researchers, authorities), the animal model is currently the gold standard and is in some cases legally required. Despite the shift towards models which do not involve animals, the large-scale application of such models is lagging behind. This is partly due to a lack of further development of human-based measurement. The aim of the research programmes to be launched here is to encourage the (further) development of such models and methods.

Together with its members and partners in the TPI, NWO-AES, ZonMw and SGF will strive to ensure that human measurement models are eventually developed sufficiently to be applied on a large scale and therefore replace the use of laboratory animals. The partners view the first call and this call as a prelude and a transitional phase in which projects will be permitted to demonstrate the validity of an innovative model using the current (animal) standard. A condition for this is that the mechanisms and effects studied in the animal model are shown to be comparable to those in humans. Where animal experiments- for validation purposes only- form part of the proposed research the project consortium should, upon start, register the research protocols (for example CCD protocol(s)) in https://preclinicaltrials.eu/.In addition they should adhere to the ARRIVE guidelinesupon publishing the animal studies. Where an application concerns *in vitro* models, the use of Foetal Calf Serum (FCS)-free media is preferred.

4.3 Objectives and scope of human measurement models 2.0 call (current call)

The primary objective of the second call under this programme, entitled "Human measurement models 2.0: for health research on disease and prevention", is to develop innovative human measurement models for health research on disease and prevention, including toxicity studies and or research with a focus on prevention of diseases. The results from health research and any developed model within an application under this programme has to be applicable for multiple diseases, and has to have an impact for multiple patient groups.

To facilitate the (further) development of human measurement models in the various research phases, this call has a broad scope, ranging from fundamental to industrial research and experimental development. This programme aims to fund research of very good quality having scientific and societal (including economic) relevance.

The application should bring an existing collaboration further or create a new collaboration that brings innovative human measurement models closer to utilisation. Applications for this call are required to



consist of multidisciplinary research between different scientific fields, preferably including technological sciences.

This call is the second call of the programme 'Human measurement models'. The scope of this second call differs from the scope of the first call. Below the scope of the current call (human measurement models 2.0) is provided including an explanation of the difference compared to the first human measurement models call.

Scope of the current call:

- Projects aimed at the (further) development of models for research into health and prevention of disease.
- Projects must be applicable for multiple diseases, having an impact and utilisation potential for multiple patient groups (multiple disease research/disease-transcending research). In the first call this kind of research was preferred, but disease-specific research was allowed;
- Research with a focus on prevention of diseases which also includes toxicological research (like the improvement of toxicity studies). This was not included in the first call;
- Multidisciplinary research is required, combining different technologies and or methods and models to answer the questions for health research without the use of animals, in the long term. In the first call, this kind of research was preferred, not required;
- The proposed projects must be a multidisciplinary collaboration and consist of a collaboration between at least two research institutes and four users, among which at least two industrial partners (for profit enterprises). In the first call the required collaboration was at least one research institute and one for profit enterprise.
- Projects that (in the long term) demonstrably reduce the use of animals or eliminate the need for research involving animal experiments;
- Projects will be permitted to demonstrate the validity of an innovative model using the current (animal) standard. This is allowed only, when this is unavoidable for standardisation purposes of the innovative model. And only for those mechanisms where effects studied in the animal model were proven to be comparable/relevant for humans.

4.4 Topics not eligible for funding within this Partnership programme

- Research focusing on one disease, or on the development of a model which only can be used for research on one disease.
- Technology development with research purposes/use only (no clear utilisation potential);
- Solely product development and/or testing (no clear technical scientific challenge);
- Research which can be categorised as Technology Readiness Level (TRL) 8 or 9 (see appendix A)
- Clinical trials, as defined by cohort studies or phase I/II studies and beyond;
- · Projects mainly aimed at improving animal welfare in existing animal measurement models;
- Improvement of a technique or application that does not require animal testing or contributes to the reduction of animal testing now or in the future, e.g. studies that are already taking place in humans;
- Improvement of surgical techniques, e.g. CT and MRI imaging.

4.5 Partnership programme duration and budget

Together the Partners have made a maximum budget of € 5,800,000 (inclusive of Dutch VAT) available for this Partnership programme. Out of the maximum programme budget, SGF will contribute € 3,300,000 with PPP allowance to this call. NWO Domain AES will contribute € 1,500,000 and ZonMw € 1,000,000. This budget includes a reservation for running and implementation costs, as well as programme activities leaving € 5,550,000 for research projects within this call. The funding committed by ZonMw (€ 1,000,000) is exclusively available for research projects that are free of animal testing and any other use of animals, preferably also without the use of FCS.

The duration of the Partnership programme will be determined by the conditions of the PPP Allowance of 2020 awarded by Top Sector LSH to NWO domain AES, on behalf of SGF. Information on the final start and end date of the project will be included in the award letter, taking into account the end date of the PPP allowance.

4.6 Partnership project duration and budget

The funding that can be requested for a project within this Partnership programme is € 500,000 − € 1,000,000 Euro (inclusive of Dutch VAT). A typical Partnership project has a minimum duration of two (2) years and a maximum duration of four (4) years, starting from initial expenditure on the project's budget. The **final start date** of a project is **six (6) months** after award of the project. The final start and end date of the project will be stated in the award letter.



5 Specific requirements to the programme

5.1 Who can apply

Scientists employed by Dutch Universities and institutes eligible for funding by NWO Domain AES (see 'Guideline for applicants' separately published with this call) can submit a proposal to this Partnership call.

5.2 Criteria for submission

Herewith the criteria for submission are included. Explanation of the terminology used is provided in the glossary of this call. We therefore kindly request you to take notice of the glossary before reading the criteria below.

The proposals must meet all of the following criteria:

- The obtained knowledge and results of the project should have a high utilisation potential and contribute to the mission statements of SGF, ZonMw, NWO Domain AES (see 'about the partners') and the PPP definitions (see below);
- The research has to fit in the research roadmaps of Top Sector LSH and societal challenge 'Health Care' as outlined in the Knowledge and Innovation Agenda 2020-2023 'Health & Care';
- The research contributes to the objectives of the programme 'Human Measurement Models' (see 'scope of the programme HMM');
- The Proposal includes a consortium of at least two research institutes and four users. Among the
 users, at least two industrial users (for profit enterprises) should be included and besides other
 users are welcome to join the consortium (see 5.5. Criteria for users and user committee composition). Foreign companies and foreign research / knowledge institutions are also encouraged to
 participate in the consortium as user, as long as the results of the research project benefit the
 Dutch knowledge infrastructure and economy;
- The Proposal covers fundamental research, industrial research or experimental development or a combination thereof; further development of fundamental research towards applications is encouraged;
- Co-funding, by industrial partners (for profit enterprises) is required on project level see the table 1' Funding by type of research' for details;
- All consortium partners should make an in-kind contribution. This means that all consortium
 partners incur costs, including personnel costs, and those costs are stated on the Budget Form
 (Excel)
- For validation purposes only, the use of animal models is allowed. But only if can be shown that
 the effects and/or mechanisms studied in these animal studies are proven to be of relevance for
 humans;
- If animal models are used, the research protocols (like CCD protocol) should at the start of the project be registered at www.preclinicaltrial.eu.The ARRIVE publication guidelines should be used upon publishing the animal studies;
- The application should consist of all requested forms among which a draft project agreement of the consortium (according to template as published with this call) is submitted with proposal

5.3 Criteria related to the use of PPP Allowance of Top Sector LSH

Within this Partnership programme Public-Private Partnership (PPP) Allowance has been made available to NWO Domain AES by Top Sector LSH on behalf of SGF. For this reason, the research has to fit in the research roadmaps of the Top Sector LSH and societal challenge 'Health Care' as outlined in the Knowledge and Innovation Agenda 2020- 2023 'Health & Care'. Furthermore specific conditions with respect to co-funding, financial accountability and duration and set up of the project are in place (see corresponding paragraph in this call for proposals). In particular, every project in this programme must consist of research work packages which are either fundamental and/or industrial research and/or experimental development. The PPP-definition of the type of research are leading for this classification. The type of research has to be addressed and substantiated for all work packages described in the application. It is possible that a project fully consists of either fundamental research or industrial research or experimental development.

5.3.1 Criteria for co-funding

The minimum and maximum project budget which can be requested for funding is € 500,000 to € 1,000,000. Due to the deployment of PPP Allowance in this programme, specific conditions are in place for co-funding on project level. Of the total eligible project costs per project, a maximum of 75% PPP Allowance may be used for funding of

fundamental research, a maximum of 50% for industrial research and a maximum of 25% for



experimental development. These maximum proportions are stated again in table 1. Additionally, this table shows the minimum percentage that the research institutes (employer of applicants) must contribute via an in kind contribution and the minimum percentage that a for-profit enterprise must contribute (in cash and in kind). For each project, at least 15% of the total project costs required to conduct the research must be co-funding from the industrial partners (company; for-profit enterprises). This depends on the type of research, for more information see table 1 and appendix D. In the case of industrial research and experimental development, the columns do not add up to 100% but to 90% and 80%, respectively. In these cases, the parties are free to decide how to obtain the remainder of the project funding required. Contributions from other parties (e.g. non-industrial or not for profit organisations like health foundations, other users) are allowed, however such contributions do *not* count towards the minimum requirement of 15%, 30% or 45% co-funding of the total project costs by for-profit enterprises.

Table 1: Funding by type of research

Type of research	Fundamental research	Industrial research	Experimental development		
Maximum funding to be deployed	75%	50%	25%		
Co-funding:					
For-profit enterprise(s)	min. 15%	min. 30%	min. 45%		
 Large enterprise SME¹ 	min. 2/3 in cash ² fully in kind	min. 2/3 in cash² fully in kind	min. 2/3 in cash ² fully in kind		
Not for profit organisations ³	no min	no min	no min		
Own contribution:					
Research institutes ⁴	min. 10%, fully in kind	min. 10%, fully in kind	min. 10%, fully in kind		

¹ May be fully in kind. However, a cash contribution is encouraged.

At least 2/3 of the required minimum contribution from a large enterprise must consist of a cash contribution. This minimum contribution depends on the type of research and is based on their total project contribution. It should be noted that it is obliged that consortium partners make an in-kind contribution which includes personnel costs.

3 Although such contributions do not count towards the minimum requirement of 15%, 30% or 45% co-funding of the total project costs by for-profit enterprises, it does count for additional co-funding needed in case of industrial research and experimental development (minimum percentages in these categories do not add up to 100%, see calculated examples 2 and 3 in Appendix D).

4 (In kind) Contribution of research institutes (employer of applicants) is a specific requirement of the PPP allowance and not of the NWO subsidy guidelines.

5.3.2 Co-funding from not for profit organisations

As indicated above not for profit organisations may also provide co-funding for the project in order to finance 100% of the project. The applicant is free to decide whether and which 'not for profit enterprise' is approached, but in this respect, we would like to provide you with the following information: The SGF consists of nineteen independent public health organisations in the Netherlands, that collectively address many of the most prevalent diseases in Dutch society. You can contact the health organisations separately for support or other advice on the intended project (see Appendix B). The Dutch Society for the Replacement of Animal Testing is providing a contribution of € 50,000 as co-funding at project level, subject to additional conditions (see Appendix C).

5.3.3 Points to note about co-funding for PPP Allowances

- The conditions for a PPP project are described in the "TKI LSH Match Regulation for public-private partnerships in 2019". We recommend that you start by reading these conditions.
- Private parties such as health foundations and the Dutch Society for the Replacement of Animal Testing are "not for-profit organisations". Co-funding by these parties does not count towards the minimum contribution of 15%, 30% or 45% (depending on type of research) by for-profit enterprises based on which the PPP Allowance can be granted;
- Appendix D provides some calculated examples for different budgets;
- If you have any questions about the PPP Allowance, definitions or conditions, please contact PPP Programme Manager Laila El Aziz directly and at an early stage via tki@health-holland.com.

5.4 Criteria for consortium composition and collaboration

Projects should be a collaborative effort of at least two research institutes eligible for funding and two industrial partners (for profit enterprises). Effective collaboration should take place. This means, for example, that the project is realized at joint cost and risk and that all consortium partners make a substantive contribution to the project. These **two for profit enterprises should be committed to the project before submission** of the application. We refer to the co-funding criteria for this Partnership programme and partnership specific IP&P conditions (see below). Besides in total each project should consist of four users (see 5.5).



5.5 Criteria for users and user committee composition

In total each project should consist of at least four users of which at least two users are for profit enterprises providing co-funding in the project (consortium partners, see 5.4). Users of research are defined as natural persons or legal persons (at national or international level) who are able to apply the results of the research. A distinction is sometimes drawn between direct users, usually companies, and end users. It is NWO Domain AES' explicit intention that potential technology users and end users outside the inner circle and outside the research field of the researchers submitting the proposal should be involved in the project from beginning to the end. Users should be able to apply the knowledge generated by the research in the medium to long term.

A user committee is established for all the awarded projects of this Partnership programme. A minimum of four (4) users will be part of the user committee and at least two (2) of the users should be from industry (for profit enterprise). Users should be clearly defined, it is not sufficient to solely state 'expert', 'the patient' or 'a clinic'.

The final composition of the user committee is subject to conditions of all NWO Domain AES projects. To enable monitoring of the progress of the project, besides representatives of NWO Domain AES, SGF, ZonMw and Top Sector LSH will participate in the user committee meetings and will receive all reporting that is shared among the user committee. Further information on users and user committees is provided later in this call text (see 'users' in After award chapter)

5.6 Partnership Framework Agreement

The Partnership programme is a cooperation between NWO Domain AES, SGF and ZonMw and a Partnership Framework Agreement has been signed between these partners. In addition, PPP allowance for this Partnership programme was made available to NWO Domain AES by Top Sector LSH on behalf of SGF and corresponding adjustments have been made to the programme.

5.7 Consortium project agreement

For each project in this programme, a consortium **project agreement**is required in which the legal and financial conditions, including IP&P arrangements (Intellectual Property policy & Publication, see below), are stated. The consortium partners are parties in this agreement. The grant is available only after this project agreement has been signed by all parties and returned to the NWO domain AES office before the date mentioned in the award letter.

The template project agreement which consortia are required to use has been made available to the applicants together with this call for proposals on the NWO website. A draft consortium project agreement should be included with your proposal. After award, this consortium project agreement can be finalised but no later than within 3 months.

5.8 Funding conditions, Intellectual Property Policy & Publication arrangements

This Partnership call is published by NWO Domain AES on behalf of the partners. This call for proposals and the NWO grant rules 2017 (version January 2019) are applicable to this Partnership programme. Management, administration and accountability of project (proposals) will take place according to procedures of NWO Domain AES and in accordance with the requirements of the PPP Allowance awarded to NWO Domain AES by Top Sector LSH (on behalf of SGF) with respect to substantive and financial reporting.

The consortium project agreement includes intellectual property and publication (IP&P) arrangements, which are mandatory for this Partnership programme and which are in line with the 'NWO grant rules 2017 (version January2019)'and Guidelines Users Committee NWO Domain AES 2017. In brief, ownership of results follows inventorship and depending on the level of co-funding committed to the project the consortium partners obtain access rights to foreground intellectual property. Arrangements with respect to confidentiality, data management, (fields of) use and commercialisation of the results (i.e. all inventions, know-how, materials, methods, processes, products, programmes, software, findings and discoveries and any IP rights pertaining thereto) must be in line with the Guidelines Users Committee NWO Domain AES 2017.

The Partners aim to exploit and publish the results of research as widely as possible, whilst retaining the possibility for inventors to claim IP rights, subsequently commercialize these rights and to stimulate collaboration between researchers and various external users.

5.9 Involvement in multiple projects

Within this Partnership programme, a researcher may associate his/her name to more than one (1) research proposal as co-applicant. However, a researcher is allowed to submit only one (1) research proposal as main applicant.



5.10 Resubmitting research proposals

Research proposals that were rejected in a previous SGF, ZonMw, STW or NWO evaluation procedure, including the NWA-ORC, cannot be resubmitted to this Partnership programme automatically. When a research proposal is resubmitted, the proposal must comply with requirements for this partnership programme (eg. scope, applicants, criteria, co-funding). In addition, for proposals that were submitted to STW and NWO before, the content has to be significantly revised. The earlier referees' comments and/or advice of the assessment committee may be used as a guideline in revising the proposal. The same applies for proposals submitted to the 'PPP programme Human measurement models. Towards better human measurement models' (first call) by SGF with funding by means of PPP Allowance made available by Top Sector LSH.

In case the research proposal is a resubmission of an previous STW of NWO proposal or the first human measurement models call, the applicant is obligated to inform NWO Domain AES and attach a statement (in English) to the submission indicating previous submission title and call/round submitted to and explaining the conducted revisions. If according to the partners the research proposal has not been revised sufficiently, it will not be eligible for funding.

5.11 Submission of project proposal for funding elsewhere

If identical or very similar research proposals have or will be submitted to the Partners or other funding bodies, this must be stated in the proposal. For the duration of the assessment procedure of this Partnership programme call, the submission of identical or very similar proposals (to be assessed by the Partners) to more than one of the following calls is not permitted: NWA-ORC, Open Technology Programme (OTP), Perspectief Programme, Top Sector LSH Match Call.

5.12 Open Access

All scientific publications resulting from research that is funded by grants derived from this call for proposals and approved by the user committee are to be immediately (at the time of publication) freely accessible worldwide (Open Access) taking into account the terms and conditions of the Partnership Programme call and the respective

Consortium project agreement. There are several ways for researchers to publish Open Access. A detailed explanation regarding Open Access can be found on http://www.nwo.nl/openscience-en.

5.13 Data management

Responsible data management is part of good research. The partners want research data that emerge from publicly funded research to become freely and sustainably available, as much as possible, for reuse by other researchers taking into account the terms and conditions of the Partnership agreement and the respective Partnership project agreement. Furthermore the partners want to raise awareness among researchers about the importance of responsible data management. Proposals should therefore satisfy the data management protocol of NWO. This protocol consists of two steps:

- 1. Data management section
 - The data management section is part of the research proposal. Researchers should answer four questions about data management within their intended research project. Therefore before the research starts the researcher will be asked to think about how the data collected must be ordered and categorised so that it can be made freely available. Measures will often need to be taken during the production and analysis of the data to make their later storage and dissemination possible. Researchers can state which research data they consider to be relevant for storage and reuse.
- 2. Data management plan
 - After a proposal has been awarded funding the researcher should elaborate the data management section into a data management plan. The plan should be submitted to NWO via ISAAC within a maximum of 3 months after the proposal has been awarded funding. NWO Domain AES will approve the plan as quickly as possible. Approval of the data management plan by NWO Domain AES is a condition for disbursement of the funding. The plan can be adjusted during the research. Data management is requested on project level. The Partnership programme committee will decide on a later date if and how to organize data management on the programme level. Further information about the data management protocol of NWO can be found http://www.nwo.nl/datamanagement-en.
 - Data management practices should adhere to the FAIR principlesas much as possible.

5.14 Nagoya Protocol

The Nagoya Protocol became effective on 12 October 2014 and ensures an honest and reasonable



distribution of benefits emerging from the use of genetic resources (Access and Benefit Sharing; ABS). Researchers who make use of genetic sources from the Netherlands or abroad for their research should familiarise themselves with the Nagoya Protocol (www.absfocalpoint.nl). NWO assumes that researchers will take all necessary actions with respect to the Nagoya Protocol.

5.15 Optimal use of existing knowledge and data

It is important to show in your application that you are making good use of knowledge that is already available (nationally and internationally). The partners encourage optimal use of data. In your funding application, describe the options for using existing measurement models, including data files, and substantiate the need for any new data collection.

5.16 Diversity

Good-quality research takes into account possible differences between people, such as in age, ethnicity, sex and gender. We request you to take this into account. For further information, see "Methods of Sex and Gender Analysis" from the Gendered Innovations project.

6 Deadlines and Time frame

6.1 Deadlines for the submission of full proposal

The submission deadline for complete research proposals to the Partnership NWO Domain AES – SGF – ZonMw – Top Sector LSH 'Human measurement models 2.0: for health research on disease and prevention' programme is **Tuesday June 16, 2020** at 14:00:00 hours CE(S)T (Central European (Summer) Time).

Before submitting your application electronically via ISAAC, NWO Domain AES recommends that you visit its websiteto verify that you have the latest version of this brochure, and that you read the guidelines for funding and the guideline for applicants (2 separate documents) carefully. NWO Domain AES adheres the NWO policy for deadlines (NL: 'Handhaving deadlines'). Your submission receives time and date of registration. Please be aware that submissions received after 14:00:00 CE(S)T on the day of the deadline will not be considered. For this reason we recommend to familiarize oneself with ISAAC (http://www.isaac.nwo.nl)in advance of the deadline and before you start the submission of your proposal. Of note, proposals which are not submitted electronically through ISAAC will not be considered.

6.2 Time frame

The overall envisioned timeframe of this Partnership programme NWO Domain AES – SGF- ZonMw – Top Sector LSH 'Human measurement models 2.0: for health research on disease and prevention' call is:

CALL OPEN
DEADLINE PROPOSALS

Assessment formal requirements by AES, SGF, ZonMw and LSH Applicants: Revision of proposal to fit formal requirements Assessment by international referees Applicants: Rebuttal Advice Assessment committee to NWO Domain AES Board Decision by the NWO Domain AES Board

Advice Assessment committee to NWO Domain A Decision by the NWO Domain AES Board Notification to applicants on Board decision Final start date of awarded projects March 2020
June 16, 2020; 14:00:00 hr CE(S)T
End of June
Last week of June 2020
July – September 2020
Last week of September (1 week)
November 2020
December 2020
End of December 2020/ Early January 2021
6 months after award

7 Assessment procedure

7.1 Formal requirements

NWO Domain AES confirms receipt of the full research proposal submitted to ISAAC. It then verifies the formal requirements to determine whether the research proposal is eligible for consideration together with SGF, ZonMw and Top Sector LSH. If the relevant conditions (see 'Specific requirements of the programme' and 'Guidelines for applicants' published together with call for proposals on the NWO website) are not fulfilled or the information requested is incomplete, the research proposal will not be considered. Together with the check for formal requirements, NWO Domain AES will consult SGF, ZonMw and Top Sector LSH for the evaluation of information provided for the type of research (fundamental, industrial or experimental, see above) per project/work package, respectively. In case adjustments are required, NWO Domain AES returns the research proposal to the main applicant within five to ten working days with a request for adjustments or additional information to comply with the requirements. The main applicant is given 5 workdays (1 week) - calculated from the



date of NWO Domain AES's notification – to submit a revised version (via ISAAC). If the information required is not provided, or is incomplete by the deadline, the research proposal is considered as withdrawn.

In order to manage the programme together with the partners, SGF, ZonMw and LSH, NWO Domain AES needs to collect personal data as present in the project (application) documents of the (co) applicants, personnel on the project, consortium members (users), (candidate) external referees and (candidate) committee members and share these data with the partners. This data will solely be processed for the purpose of the management of the programme and in accordance with the applicable data protection laws by the partners. See also the privacy notice on the programme website.

7.2 Preselection

If at least four (4) times more proposals are submitted than can be funded, NWO Domain AES retains the right to perform a preselection based on one (1) or a combination of the evaluation criteria (see below) or specific requirements of the Partnership programme (see above). The implications for the timeline of the assessment procedures will be communicated to the main applicants of the proposals.

7.3 Assessment by referees

NWO Domain AES in consultation with the Partners submits the research proposal to (inter)national experts in the relevant specialist area (peer review). For the purposes of this Partnership programme, the aim is to have the research proposal assessed by three to five referees. These referees are drawn from the scientific world, large research institutes, and industry. Referees remain anonymous. They assess the proposal on the basis of specific questions about scientific quality and potential for utilisation. The questions submitted to referees (evaluation items) are available on the website of the Partnership programme.NWO Domain AES recommends that applicants anticipate these questions in the research proposal. In general, the number of referees consulted by NWO Domain AES depends on the nature of the research proposal and the size of the budget requested in the research proposal. NWO Domain AES gives applicants the opportunity to provide suggestions for referees. For this, when submitting via ISAAC, please add a list of the names and contact information for a maximum of five independent (according to NWO code for dealing with Personal Interests, see below) international referees with relevant expertise.

NWO Domain AES does not use a non-referee list, which allows certain referees to be excluded in advance. However, the applicant(s) may ask NWO Domain AES to exclude up to two people or organisations from acting as referees. NWO Domain AES will grant this request **only if** the provision of information from the research proposal to that referee might obstruct the utilisation.

7.4 Applicants' rebuttal

In ISAAC the individual referees' comments are anonymised, if necessary paraphrased, and grouped together per question. NWO Domain AES then requests the main applicant by e-mail to respond in English to the referees' comments provided in ISAAC. The available text fields in ISAAC for the response to the comments are not restricted by word limits. The main applicant should respond to each question or each comment raised by the referees individually.

The combined referees' comments including the responses from the applicant(s) will be used by the assessment committee for their final assessment of the proposal.

7.5 Assessment committee

To guarantee objectivity of the assessment as much as possible the Partners put together a multidisciplinary Assessment Committee consisting of approximately 10 independent national and/or international experts from the field drawn for example from universities, large research institutes or industry and other societal sectors to guarantee the assessment of quality of the proposal. By using this approach, every assessment can take into account the societal needs that science and technology can address.

During the meeting of the Assessment Committee, all the project proposals submitted to the referees are discussed by the assessment committee members, taking into account the proposal, the review reports and the rebuttal, to evaluate each project proposal. After this discussion, each committee member assigns two ratings (between 1 (excellent) and 9 (moderate

/ poor) to each proposal, one for **scientific quality** and one for **utilisation** (**prospects**, **including societal relevance**). The two criteria are equal in weight and a ranking based on the sum of the calculated averages for both criteria is determined upon individual assessment by the Assessment Committee members. A final ranking for the research proposals is established and the advice of the assessment committee to NWO Domain AES Board is formulated.



7.5.1 Minimal quality criteria, resolution of ex aequos and allocation of budget intended for animal-free research.

Full proposals can only be considered for funding if both the scientific quality criterion and the utilisation quality criterion together score no more than 7.0 and the individual criterions score no more than 4.0. The explanation of the meaning of the quality scores can be found in the **Guideline for applicants**.

The funding committed by ZonMw (€ 1,000,000) is exclusively available for research projects that are free of animal testing and any other use of animals. For this reason, upon establishment of the ranking budget allocation occurs as follows: for projects performing animal-free research the budget for animal-free research is allocated first to projects that meet the quality criterion. The other part of the funding, € 4,550,000, is available for funding of animal-free research as well as research in which animal studies are used for validation purposes (see criteria for submission). This budget is allocated in parallel and will be allocated to the highest ranked research projects which meet the quality criterion. This includes animal- free projects which could not be funded with the budget for animal-free research. The available programme budget may not be sufficient to award funding to all proposals that meet the eligibility criteria for funding and the allocation approach described here may result in funding of non-consecutive projects on the ranking list.

In case of ex aequo, the proposal most relevant to programme goals, as assessed by the assessment committee, will be prioritized. If this will not result in a distinction between the proposals on ex aequo position, the proposal with the best score for utilisation (prospects) will be prioritized.

7.5.2 Datamanagement section

The data management section in the application is not evaluated and hence not included in the decision about whether or not to award funding. However, both the referees and the committee can issue advice with respect to the data management section.

7.6 Decision by the NWO Domain AES Board

The advice of the assessment committee will be presented to the Board of SGF and ZonMw prior to the decision by the NWO Domain AES Board. The NWO Domain AES Board bases its decision on the ranking of the research proposals and, if applicable, additional comments from SGF and ZonMw. The ranking established by the assessment committee is the primary starting point, however the available budget for the Partnership programme may result in deviation from the advice of the Assessment committee. In this case, the motivation for the final decision will be sent to the applicants. The NWO Domain AES Board does not assess the scientific content of the research proposals.

The NWO Domain AES Board may attach additional funding conditions to awarded projects. These conditions may relate to matters imposed by this call for proposals, the NWO Grant Rules 2017 and conditions of the PPP Allowance to SGF by Top Sector LSH, such as intellectual property, co-funding by (potential) users, major investments and/or special infrastructure facilities, accountability and financial reporting.

7.7 NWO Code for dealing with Personal (conflict of) Interests

NWO Domain AES asks active researchers from research institutes and specialists from other knowledge-intensive organisations to participate in assessment procedures. These people are themselves involved in ongoing or new research and often belong to large organisational associations and research networks. Therefore, any conflict of interest, or anything that remotely resembles this, must be avoided in the assessment of research proposals.

To ensure a fair assessment and transparency for applicants, NWO Domain AES uses the NWO Code for dealing withPersonal Interests. This Code identifies possible forms of conflicts of interest and indicates the steps to be taken to avoid (potential) conflicts of interest. Parties subject to the Code of conduct are: referees, jury members, committee members, members of decision-making bodies and AES Programme officers.

The full explanation including an illustrative video on the code used by NWO Domain AES is available on the websiteof NWO.

8 After award

(see also the 'NWO Grant rules 2017'or information for project leaderson NWO Domain AES website.)

8.1 After awarding

The main applicant becomes the project leader and penholder of the project consortium. In case of large projects with multiple work packages, it may be necessary to appoint separate sub-project



leaders. If the proposal is successful, the research institute of the project leader involved receives an award letter with appendices. If applicable, a copy of this award letter is sent to all other research institutes involved. This sets out the **legal and financial conditions** of funding and should be signed individually for approval by each research institute. The execution of the project should comply procedures of NWO Domain AES and the administrative and financial conditions related to the PPP Allowance awarded to NWO domain AES by Top Sector LSH on behalf of SGF.

After a proposal has been awarded funding the applicant should elaborate the data management section into a data management plan. Applicants can make use of the advice from the referees and committee when they write the data management plan. The data management plan must be submitted to and approved by NWO Domain AES before a project may start. Furthermore, the Consortium Project agreement should be finalised within 3 months.

Scientific quality is safeguarded and guided by university project applicants. Management, administration and accountability of projects will take place according to NWO Domain AES procedures and in accordance with the requirements of the PPP Allowance awarded to NWO Domain AES by Top Sector LSH on behalf of SGF with respect to substantive and financial reporting. Accountability by the 'Controle protocol' of Top Sector LSH is required. Any costs related to financial accountability (NL: Accountants verklaring) must be covered by the consortium partners and may not be part of the project budget.

8.2 Start and starting date of the project

The project starts no later than **six (6) months** after awarding. Project budgets do not become available until the necessary documents have been signed and received by NWO Domain AES and all relevant award conditions stated in the award letter have been fulfilled. If the latter is not yet the case, written permission to start the project can be requested from NWO Domain AES. However, potential financial risks are borne by the applicant(s). The starting date of the project is the date on which an initial expenditure of allocated funds is undertaken. This is generally not the date of award. It usually relates to the appointment of the first staff member at the project's expense.

8.3 User committees

NWO Domain AES ensures that the knowledge generated by the research is practically and effectively transferred to users by consulting with the project leader of each research project to set up a user committee on the basis of the industrial partners (for profit enterprises) and users proposed in the project plan.

8.4 Users

Users of research are defined as natural persons or legal persons (at national or inter-national level) who are able to apply the results of the research. A distinction is sometimes drawn between direct users, usually companies, and end users. In that case, it is not sufficient to designate end users only. It is NWO Domain AES's explicit intention that potential technology users and end users outside the immediate circle and outside the research field of the researchers submitting the proposal should be involved in the project from beginning to end. Users should be able to apply the knowledge generated by the research in the medium to long term.

User committee meetings are attended by the applicants/co-applicants, project/subproject leaders, the researchers temporarily appointed to the project, the user(s) including the industrial partners (for-profit enterprises; companies) and not

for profit organisations, programme coordinators of SGF and ZonMw and the programme officer of NWO Domain AES. Representatives of Top Sector LSH will participate in the user committee meetings and will receive all reporting that is shared among the user committee. NWO Domain AES runs the secretariat.

The user committee can advise the project leader on the direction the research should take in order to promote the application of the results. The project leader always holds ultimate responsibility for the realisation of the research in accordance with the approved project plan.

The instructions for participants in a user committee are included in the 'Guidelines Users Committee NWO Domain AES2017'on the NWO website. The members of the user committee are formally invited by NWO Domain AES to join the user committee. Those participating in the user committee commit themselves to the conditions included in the 'NWO GrantRules 2017'as published with this Partnership call and the conditions laid down in the Partnership project agreement.

During the course of a research project, the Partners together may decide that change in composition of the user committee is needed if there are grounds for doing so; such changes will always be made with the approval of the project leader and the users already on the user committee. In doing so, NWO Domain AES will take into account the advice of the users that are already involved in the project and the level of their pledged co-funding. The guiding principle will be to ensure that the composition of



the user committee maximises the likelihood of the results being applied and that the interchange of ideas, including confidential information, remains possible.

Within this Partnership programme, user committees may be extended with industrial partners. In this case, the industrial partner(s) (company; for-profit enterprises) are required comply with the co-funding criteria for industrial partner(s), e.g. an in-kind contribution *and* contribution of an entry fee as described in paragraph criteria for co-funding (see above).

8.5 Reporting

The project leader reports to the user committee on the progress of the project twice a year, in writing (progress report and/or results overview), and the user committee meets to discuss the progress made. As an exception – to be decided by NWO Domain AES – the user committee may meet in a different frequency. Utilisation of the research results is always on the meeting agenda. It covers collaboration with (potential) users and the protection and commercialisation of the knowledge generated. The results of the project are confidential until the user committee agrees to publication and NWO Domain AES has given permission for publication. Arrangements made between the project partners in terms of IP and publication (for further information, see Guideline for applicants and template consortium project agreement) will be upheld provided that they have been approved by NWO Domain AES.

All publications or any other dissemination related to the Programme, Project(s) and Result(s) by Parties shall include the following statement:

"This research is supported by the Association of Collaborating Health Foundations (SGF), NWO Domain AES and the Netherlands Organisation for Health Research and Development (ZonMw), as part of their joint strategic research programme: Human Measurement models. The collaboration project is co-funded by the PPP Allowance made available by Health~Holland, Top Sector Life Sciences & Health, to NWO Domain AES on behalf of SGF to stimulate public-private partnerships."

With respect to substantive and financial reports, projects awarded in this Partnership programme have to comply with the conditions of the PPP Allowance awarded to NWO Domain AES by Top Sector LSH on behalf of SGF related to financial reporting (NL: Kosten realisatie). The project leader is responsible for this. NWO Domain AES will coordinate substantive and financial reporting requirements with the project leaders and financial departments of the affiliated institutes. Further information on requirements will be communicated with the award letter or shortly thereafter.

8.6 Extension

Only in *very limited cases* it is possible to request an extension of the project. A written request, including a motivation for the extension, is submitted by e-mail to the NWO Programme Officer and NWO Domain AES will decide on this. The prospects in terms of utilisation are crucial for possible project extension.

Of note, an extension within this Partnership programme may not exceed the duration of the programme as determined by the conditions of the PPP Allowance. Information related to the final end date of the project will be included in the award letter.

Extensions of projects passing the Partnership programme end date and/or with an increase in budget will be decided on by NWO Domain AES. In this case, 50% co-funding by (one of the) users is a prerequisite.

8.7 Termination and termination date

The termination date of a project is the date on which the last appointment of temporary personnel is terminated or the termination date of the Partnership programme, whichever comes first. After termination of the project, the final report on project results and outcome, as well as the financial reporting – according to the 'Controle protocol' of Top Sector LSH and in concert with the conditions of the PPP Allowance – has to be provided to NWO Domain AES. Within six weeks after the termination date an unqualified audit report must be provided to NWO Domain AES according to the 'Controle protocol' of Top Sector LSH.

Any costs related to financial accountability (NL: Accountants verklaring) must be covered by the consortium partners.

The project leader receives the final forms from NWO Domain AES to finalise the project in terms of both content and funding. Unallocated budgets cease to be valid after the end of the project. The summaries requested in the final form are used for the purpose of publication on the websites of NWO domain AES, ZonMw, SGF and Top Sector LSH and in the utilisation report. NWO Domain AES publishes an annual utilisation report giving progress updates five and ten years after the start of a project.



8.8 Discontinuation

After consultation with users, NWO Domain AES may discontinue a project before the official termination date if the obligations based on the Partnership Project agreement and/or NWO Grant Rules 2017and/or conditions of the PPP Allowance made available by Top Sector LSH are not or are no longer fulfilled, or if the scientific quality of the research and/or utilisation of the results of the research are inadequate.

This means that NWO Domain AES, in amending or withdrawing the awarded funding, may change the amount or scope of the funding or terminate it and will be authorised to reclaim all or part of any funds not spent in a legitimate manner as undue payments.

9 Contact information

For questions regarding partnership guidelines contact NWO Domain Applied Engineering Sciences

Drs. Lisette Krul Programme Officer Tel: 030 – 600 1305

e-mail: l.krul@nwo.nl

Drs. Marjolein van Dalen Programme Officer

Tel: 030 - 600 1234

e-mail: m.vandalen@nwo.nl

Mrs. Brigitte van Dijk Management assistant Tel: 030 - 600 1231

e-mail: b.vandiik@nwo.nl

For questions regarding PPP definitions for types of research, please contact Top Sector LSH Laila el

Aziz

Programme Manager

e-mail: tki@health-holland.comand l.krul@nwo.nl(in cc)

9.1.1 Technical questions about the online application system ISAAC

For technical questions about the use of ISAAC please contact the ISAAC helpdesk. Please read the manual (tab 'Help') first before consulting the helpdesk. The ISAAC helpdesk can be contacted from Monday to Friday between 10:00 and 17:00 hours CE(S)T via +31 (0)20-3467179. You can also submit your question by e-mail to isaac.helpdesk@nwo.nl. You will then receive an answer within two working days.

9.1.2 Links

- Netherlands Organisation for Scientific Research (NWO) http://www.nwo.nl
- NWO Domain AES
 - www.nwo.nl/ttw/ www.nwo.nl/aes
- Partnerships www.nwo.nl/partnership
- ISAAC:
 - https://www.isaac.nwo.nl; An ISAAC manual can be found in ISAAC (tab 'Help')
- ISAAC helpdesk: isaac.helpdesk@nwo.nl
- Open calls NWO Domain AES: https://www.nwo.nl/en/funding/our-funding-instruments/Open+for+application/true/NWO+division/scienceareaTTW?initialized=true
- · Partnership programme page
 - https://www.nwo.nl/en/research-and-results/programmes/ttw/partnership/human-measurement-models-2.0-for-health-research-on-diseases-and-prevention.html
- General Funding Conditions / NWO Grant Rules 2017
 - www.nwo.nl/ttw-projectleader /www.nwo.nl/aes-projectleader
- Guidelines Users Committee NWO Domain AES 2017 http://www.nwo.nl/documents/ttw/ projectbeheer/brochure-richtlijnen-gebruikerscommissie-nwo-domein- ttw
- Code of Conduct on Conflicts of Interest:
 - https://www.nwo.nl/en/common/subsidies/funding-process-explained/code-for-dealing-with-personal-interests
- Cleanroom regulation
 - www.nwo.nl/ttw-aanvrager /www.nwo.nl/aes-applicant
- Fixed rates in salary tables personnel
 - www.nwo.nl/ttw-aanvrager /www.nwo.nl/aes-applicant
- Hourly rates in-kind personnel
 - www.nwo.nl/ttw-aanvrager /www.nwo.nl/aes-applicant
- Standard amounts for foreign accommodation expenses:www.nwo.nl/ttw-projectbeheer /www.nwo.nl/aes-projectmanagement
- Nagoya Protocol: https://www.absfocalpoint.nl/en/absfocalpoint.htm
- SGF www.gezondheidsfondsen.nl



- ZonMw www.ZonMw.nl
- Programme More Knowledge with Fewer Animals (ZonMw)
 https://www.zonmw.nl/en/research-and-results/fundamental-research/programmas/programme-detail/more-knowledge-with-fewer-animals/
- · FAIR data principles
- https://www.force11.org/group/fairgroup/fairprincipleshttps://www.nature.com/articles/sdata201618
- Knowledge and Innovation Agenda Top Sector Life Sciences & Health 2018-2022 https://www.health-holland.com/public/downloads/kia-kic/knowledge-and-innovation-agenda-2018-2021.pdf
- RvO
 - www.rvo.nl
- Public-Private Partnership (PPP) Allowance (NL: PPS-toeslag), in Dutch only: https://www.rvo.nl/subsidies-regelingen/pps-toeslag-onderzoek-en-innovatie
- PPP definitions regarding type of research (fundamental, industrial and experimental in nature)
 https://www.rvo.nl/subsidies-regelingen/pps-toeslag-onderzoek-en-innovatie/mogelijkheden/pps-projecttoeslag-voor-een-samenwerkingsverband-%E2%80%93-de-penvoerder
- Transition Programme for Innovation without the use of animals (TPI): https://www.transitieproefdiervrijeinnovatie.nl/english

Appendix A: Technology Readiness Levels (TRLs)

A TRL indicates the current or expected phase of a development project. Nine phases have been defined in total, spanning the entire development process. An overview of the nine phases with their translation to medical research is given below.

TRL level	Definition	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 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	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

Appendix B: Contact details of Health foundations united in SGF

The Association of Collaborating Health Foundations (SGF) consists of nineteen independent public health organisations in the Netherlands, that collectively address many of the most prevalent diseases in Dutch society.

Aidsfonds https://aidsfonds.nl/wat-doen-wij/subsidies/#weten

Contact: Marein De Jong research@aidsfonds.nl www.alzheimer-nederland.nl

Contact: Dinant Bekkenkamp

Diabetes Fonds

d.bekkenkamp@alzheimer-nederland.nl
www.diabetesfonds.nl

 Diabetes Fonds
 www.diabetesfonds.nl

 Contact: Rogier Van Gent
 r.vangent@diabetesfonds.nl

 Epilepsiefonds
 www.epilepsie.nlboer@epilepsiefonds.nlwww.handicap.nlbestedingen@handicap.nlw

Contact: Martin Boer k.eizema@hartstichting.nl

Contact: Martin Boer <u>k.eizema@hartstichting</u> **HandicapNL**

Hartstichting
Contact: Karin Eizema
Hersenstichting
Contact: Esther Hosli
www.hersenstichting.nl
ehosli@hersenstichting.nl

JKF Kinderfonds www.jkf-kinderfonds.nlhanselaar@jkfkinderfonds.nlwww.kwf.nl

Contact: Ellen Hanselaar skuijper@kwf.nl
KWF Kankerbestrijding

Contact: Sanne Kuijper

Longfonds www.longfonds.nl
Contact: Bas Holverda basholverda@longfonds.nl

Contact: Patricia van Wijnbergen



Maag Lever Darm Stichting

Contact: Marijke Boersma

MIND

Contact: Sander Slootmaker

MS Research

Contact: Kirstin Heutink

Nederlandse Brandwonden Stichting Contact: Carine van Schie

Nierstichting

Contact: Wouter Eijgelaar

Prinses Beatrix Spierfonds

Contact: Simone van den Berge ReumaNederland

Contact: Heidi van Vugt

Stichting ALS
Contact: Tom Bos

Trombosestichting Nederland

Contact: Rosalie Belder

www.mlds.nlmarijkeboersma@mlds.nlhttps://wijzijnmind.nl

info@wijzijnmind.nl

www.msresearch.nl onderzoek@msresearch.nl

www.brandwondenzorg.nl

cvanschie@brandwondenstichting.nl

www.nierstichting.nl/professionals/wetenschappelijk-onderzoek/calls-

proposals/pionier-programma-voor-cofinanciering/

WouterEijgelaar@nierstichting.nl

www.prinsesbeatrixspierfonds.nl

onderzoek@spierfonds.nl www.reumanederland.nl

research@reumanederland.nl

www.als.nl

t.bos@als.nl

www.trombosestichting.nl onderzoek@trombosestichting.nl

Appendix C: Conditions co funding Dutch Society for the Replacement of Animal Testing (Proefdiervrij)

The Dutch Society for the Replacement of Animal Testing (Proefdiervrij) endorses the objectives of the programme "Human measurement models 2.0: for health research on disease and prevention". In its view, this programme offers enormous added value to the transition to animal-free innovation. Proefdiervrij creates impact through collaboration. The Society is keen to work with parties aiming to bring about this paradigm shift and actively supports it. Proefdiervrij is a non-profit organisation that aims to replace animal testing. In financial terms, it is wholly dependent on donations from its supporters.

To qualify for our co-funding in this programme, applicants must meet the additional conditions required by the Society's policy, which are set out below:

- The research is both 100% free of laboratory animals and does not involve animals in any other
 way. This means that Proefdiervrij does not co-fund projects that use slaughterhouse material or
 animal species falling outside the definition of the Animal Experiments Act (Wet op de Dierproeven):
- 2. The consortium partners are willing to participate in communication about the research via the Society's channels of Proefdiervrij. Examples include interviews, blog writing, photos, videos, etc. These forms of communication are always agreed in advance with the parties involved;
- 3. Where the application concerns in vitro models, the use of Foetal Calf serum (FCS)-free media is preferred.

Do you meet the requirements and are you interested in co-funding of your project through Proefdiervrij? Make sure you contact Saskia Aan (staff member Science and Innovation- aan@proefdiervrij.nl) before 15 May 2020.

Proefdiervrij would like to receive a draft version of your proposal and a motivation for co-funding in order to decide on writing a letter of support.



Stichting Proefdiervrij: www.proefdiervrij.nl/english

Appendix D Calculated examples of project budgets

In the case of a project consisting entirely of fundamental research, 75% of funding may be requested. In addition, 25% matching is required of which min 10% of the total project budget should be contributed by the research organisation and min 15% must be provided by for profit enterprises.

Funding requested from Human measurements call Contribution from research organisation (10%) Contribution from companies (15%) € 1,000,000 € 133,333,33 € 200,000

Total matching (25%)

Total project budget

€ 1,333,333,33



In the case of a project consisting of two work packages of which one is fundamental research and one is industrial research, 62,5% of funding may be requested. In addition, 37.5% matching is required of which min 10% of the total project budget should be contributed by the research organisation and min 22.5% must be provided by for profit enterprises. Funding requested from Human measurements call € 1,000,000 Contribution from research organisation (10%) € 160,000 € 360,000 Contribution from for profit enterprises (22,5%) Contribution from other partners¹ (5%) € 80,000 € 600,000 Total matching (37,5%) Total project budget € 1,600,000

In the case of a project consisting entirely of industrial research, 50% of funding may be requested. In addition, 50% matching is required of which at least 10% of the total project budget should be contributed by the research organisation. In addition, at least 30% must be provided by for profit enterprises and possibly the remainder (10%) by other partners.

Funding requested from Human measurements call

Contribution from research organisation (10%)

Contribution from for profit enterprises (30%)

Contribution from Stichting Proefdiervrij

Contribution from other partners¹

Total matching (50%)

Figure 10% of funding may be requested. In addition, 50% matching is required to matching 40% of funding may be requested. In addition, 50% matching is required to matching is required to matching is provided by the research organisation. In addition, 50% matching is required to matching is provided by the research organisation. In addition, 50% matching is required to matching is provided by the research organisation. In addition, 50% matching is required to matching is provided by the research organisation. In addition, 50% matching is provided by the research organisation. In addition, 50% matching is required to matching is provided by the research organisation. In addition, 50% matching is provided by the research organisation. In addition, 50% matching is provided by the research organisation. In addition, 50% matching is provided by the research organisation. In addition, 50% matching is provided by the research organisation. In addition, 50% matching is provided by the research organisation. In addition, 50% matching is provided by the research organisation. In addition, 20% matching is provided by the research organisation. In addition, 20% matching is provided by the research organisation. In addition, 20% matching is provided by the research organisation. In addition, 20% matching is provided by the research organisation in addition, 20% matching is provided by the research organisation. In addition, 20%

other partners may be not for profit organisations but may also be for profit enterprises

other partners may be not for profit organisations but may also be for profit enterprises