



netherlands
centre for
one health

Health~Holland
SHARED CHALLENGES, SMART SOLUTIONS

Call for One Health applications

NCOH for Top Sector
Life Sciences & Health
2019

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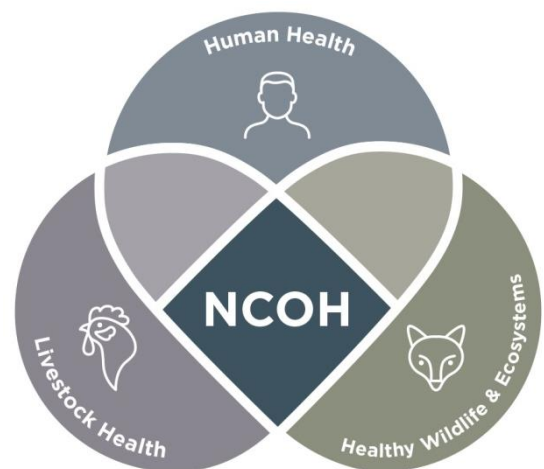
1. Netherlands Center for One Health

Global trends, such as climate change, population growth, urbanisation, deforestation, increased demand for food, and the strong increase in international trade and travel pose grand challenges to society as a whole. These challenges have in common that they pose serious risks to human, animal, and ecosystem health. Adequately meeting these challenges should, therefore, involve the development and implementation of durable interventions that emanate from an integrated and balanced perspective in which human, veterinary, wildlife, and environmental elements and considerations are integrated. Research adopting such an integrated perspective is called “[One Health research](#)”.

The Netherlands harbours world-leading academic research groups across different institutions that are active in various complementary fields of One Health research. These groups have initiated the [Netherlands Centre for One Health \(NCOH\)](#): a science-driven virtual institution, open for participation by *Dutch Universities, University Medical Centers, NWO and KNAW institutes, TNO and DLO institutes*.

The vision of the NCOH is to become an internationally-renowned research institute that performs excellent scientific research and education in pursuit of durable solutions to societal challenges requiring a One Health approach.

The NCOH functions as the national coordinating platform for One Health research, performing collaborative fundamental, translational, and applied scientific research that integrates human, veterinary, and environmental elements and considerations (Figure 1). In addition, the NCOH strengthens and consolidates the One Health knowledge and research basis in the Netherlands that guides international best practice on addressing grand challenges from a One Health perspective, holding to its core values of high level excellent, solution-driven research. The NCOH provides a trusted and excellent launching platform for public-private partnerships in One Health research and innovations of relevance to the NCOH Strategic Research Agenda with its Research Themes, in support of creating sustainable societal and economic impact. The NCOH is a national centre for One Health research of international stature, contributing to positioning the Netherlands as a guiding country (the Dutch approach) in One Health research. In this role, the NCOH also aspires to take a central and catalysing role in the envisaged European collaboration on One Health research (e.g. the European Joint Programme One Health and Article 185 of the Treaty on the Functioning of the European Union).



2. NCOH Strategic Research Themes and Solution Sets

2.1 Strategic Research Themes

The NCOH focuses its research on four complementary Strategic Research Themes, that combined constitute the long term strategic research scope of the NCOH:

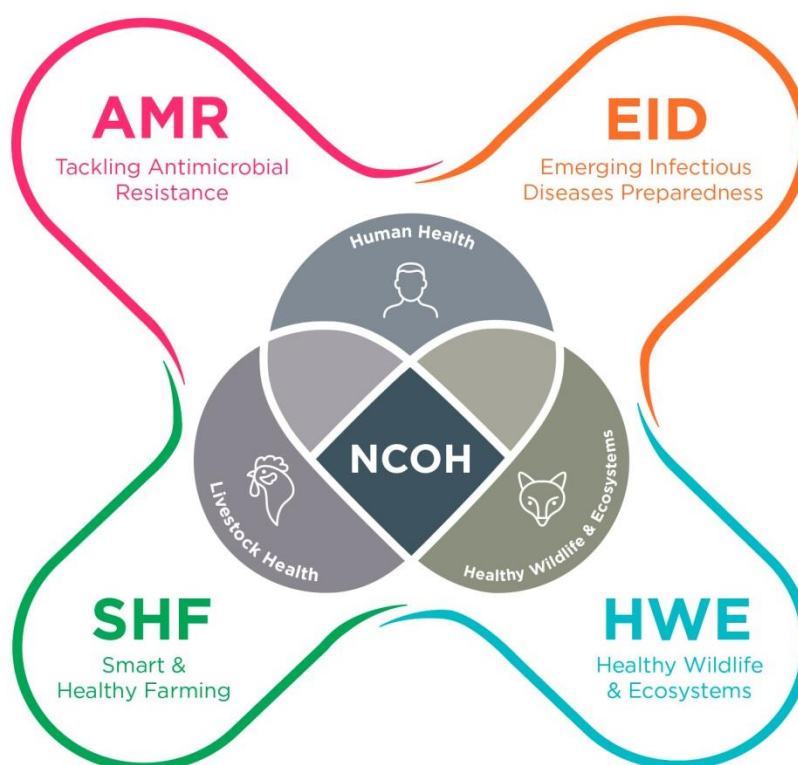


Figure 2. The four Strategic Research Themes of the NCOH.

The four Strategic Research Themes share a focus on Infectious Diseases, while recognising that other linked problems affecting human, veterinary, and environmental health, such as pollution (e.g. emissions, toxins, smell, and scenery) and other societal effects, should also be taken into account. The Netherlands harbours some of the world's leading research groups active in these four Strategic Research Themes. This combination makes the Netherlands an ideal environment for One Health research and perfectly positioned to take a leading international role in One Health research focused on infectious diseases.

Antimicrobial resistance and emerging infectious diseases both constitute major global challenges to human health. As such, they constitute the two Strategic Research Themes Tackling Antimicrobial Resistance and Emerging Infectious Disease Preparedness that predominantly, but not exclusively, focus on human health. Yet, their causes and possible solutions also include multiple components of healthy farming and healthy wildlife and ecosystems. Moreover, both antimicrobial resistance (AMR) and (re-) emerging infectious diseases (EID) also pose huge risks to animal health. Therefore, considering that the

Netherlands has one of the worlds' highest farming densities and is one of Europe's main transportation and trade gateways, our country is particularly vulnerable to these challenges. This supports inclusion of Smart and Healthy Farming (SHF) and Healthy Wildlife and Ecosystems (HWE) as two additional Strategic Research Themes in the NCOH Strategic Research Agenda.

2.2 Solution Sets

Scientific in its core, the NCOH is a solution-driven initiative, acknowledging that there is not one solution to the challenges addressed by the NCOH. Across the four Strategic Research Themes, the NCOH has therefore formulated a set of complementary Solution Sets (Figure 2) that combined provide for the long term research focus on the NCOH in any of its four Strategic Research Themes. A Solution Set is a combination of research projects that, individually or collectively, is geared towards the (long-term) development of solutions (knowledge, processes, strategies, recommendations, tools, products) to the key challenges targeted by the NCOH in any of the four Strategic Research Themes. Not all Solution Sets are covered by each of the four Strategic Research Themes. Some, such as New Antibiotics and Outbreak Control Strategies, are specific to a single Strategic Research Theme. However, the majority of the Solution Sets provide for a common grouping of highly interconnected research topics across two or more of the NCOH Strategic Research Themes, allowing for the highly needed interaction across the Strategic Research Themes.

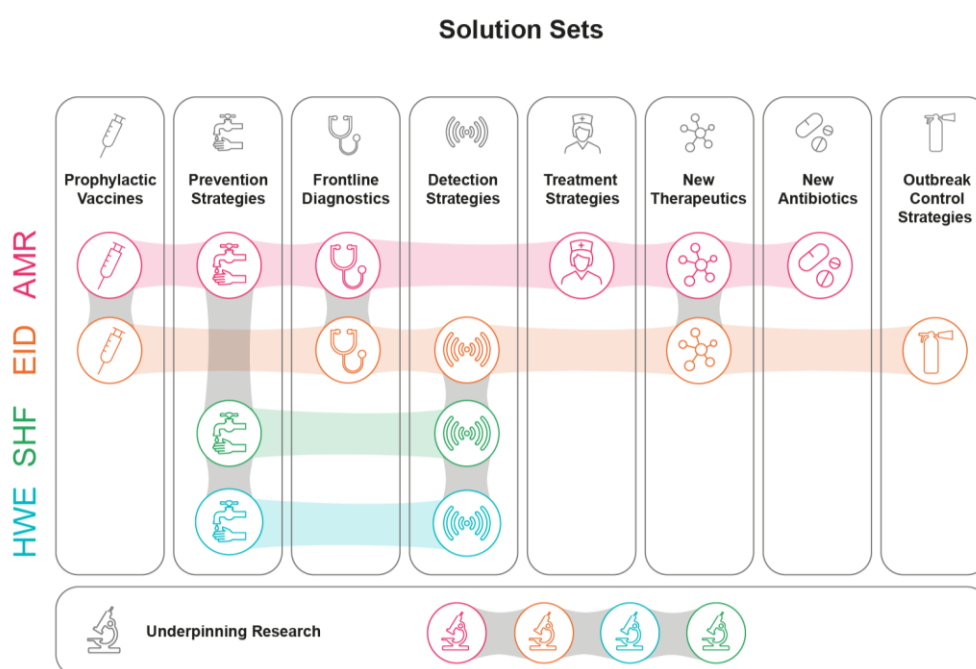


Figure 2. The NCOH Solution Sets.

Within each Strategic Research Theme, Research Projects are defined and implemented in the most relevant and urgent Solution Sets for that particular Strategic Research Theme. A Research Project (RP) is a project that is formally adopted as part of the NCOH Strategic Research Agenda and that fits within any of the four Strategic Research Themes, and – within the Strategic Research Theme – in any of the Solution Sets that comprise the research focus of that Theme. RPs in a Solution Set may be grouped into a Research Track.

At any given point in time, the NCOH research portfolio therefore comprises a set of RPs across the four Strategic Themes ranging from fundamental exploratory research to applied RPs and covering the Solution Sets of the NCOH (see Figure 3).

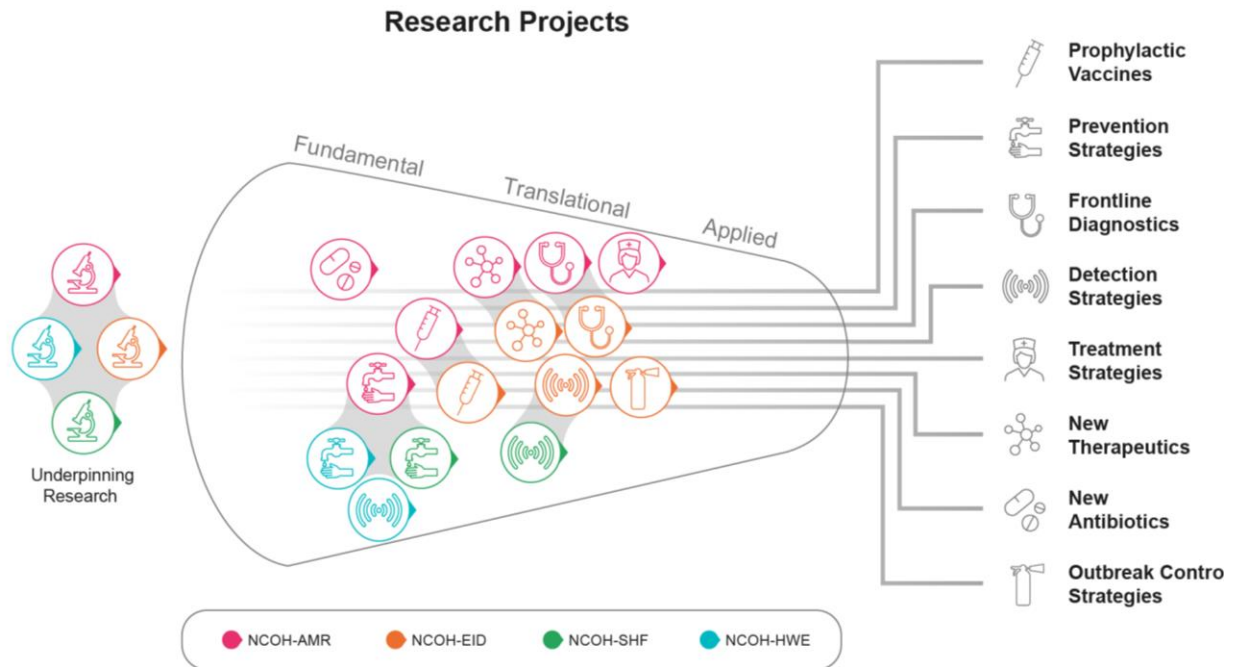


Figure 3. NCOH Research Projects. The NCOH RPs span from fundamental research to applied research in clinical studies and other pilot projects (number, type and location of RPs are indicative.)

RPs located at the far left side of this range, given their intrinsic fundamental character, may be less pronounced in their fit within a specific Solution Set than RPs that have already progressed along the funnel (e.g. an novel therapeutic evaluated in Phase I studies).

In the NCOH PhD call 2018 the above funnel was filled with new projects, some of which had a clear fundamental and other a more applied and exploratory character. This NCOH for Top Sector LSH Program 2019 call is mentioned to introduce projects with a clear industrial or translational character. To stress the applied character of the desired projects in this specific call, the call will address Solution Sets as topics (instead of research themes).

3. Solution Sets NCOH Top Sector LSH call

The choice for the research themes of this NCOH Top Sector LS&H call for 2018 are the result of two earlier round table meetings with industry and sectoral representatives in late 2016. During these meetings it was emphasized that prophylactic vaccines and preventive strategies (strategies beyond the use of prophylactic vaccines) are the most feasible solution sets to invest in as private parties at present, to combat emerging infectious diseases in the One health approach. Industry considers combatting infectious diseases also as key strategy to limit therapeutic use of antimicrobials in human and animals, in order to mitigate spread and emergence of antimicrobial resistance associated risks. The recent Castellum symposium (February 2019) confirmed the outcomes of previous round table meetings and emphasized the continuing importance of these topics at present. In brief, the topics are described as follows:

4.1 Prophylactic Vaccines



Vaccines have been instrumental in reducing the societal burden caused by infectious diseases. Both human and animal vaccines against several bacteria effectively prevent and contain infectious disease outbreaks. Proof-of-concept exists that vaccines can protect against a wide range of bacterial infections that could constitute a durable solution for the problem of AMR. Effective and cheap vaccines and accompanying vaccination strategies are a crucial element in EID prevention and preparedness. Collaboration between veterinary and human health - academically, governmentally, and industrially - is extremely important for the control of infectious diseases. In-depth knowledge on antigenic make-up of pathogens, the host response to these antigens, specific approaches to modifying this response through species-specific adjuvants, and vaccine delivery are needed for the development of effective vaccines. A specific target in zoonotic infections is the possibility to not only reduce disease in the reservoir hosts, but also to reduce pathogen circulation in the reservoir host, as has been used to control the Q fever outbreak. This may be a challenge and requires vaccines that can be distinguished from the response to wild-type infections. While vaccination of animals for prevention of human disease may seem a straightforward approach, acceptance of such vaccines is likely to be low if animals appear healthy unless delivery has limited costs and is simple. While such vaccines may not be acceptable for routine disease control, emergency vaccination strategies can be an added tool to combat an EID outbreak. However, R&D, registration and utilisation of new vaccines or vaccine platforms often meets problems with inappropriate or not accurate regulations and legislation.

4.2 Preventive Strategies



Continued efforts are needed in the development and implementation of infection prevention strategies that will be translated into evidence-based protocols and guidelines. Research on drivers of emergence and spread of livestock-related microorganisms through the food chain and through emission in the environment and resulting food consumption is required for evaluation of potential risks for human health.

When relations between these food- and emission-related exposures and human health have been established objectively, preventive strategies can be based on the principles of healthy and robust animals and smart farming or strategies beyond these domains; by modification of housing and production systems and herd management to reduce emissions and improve animal health. Farm

management, programming, nutrition, and genetic selection may be relevant strategies. Furthermore it is required to understand the key pathophysiological and epidemiological factors that influence immune competence and adaptability during all periods of the animal's life cycle, thereby focussing on critical transition periods. Application of immune modulating factors at the population level must also be taken into account. Thus, epidemiological studies and modelling, to understand the effect of interventions at the population level is pivotal. When measures for wildlife disease management focus on the host and parasite itself, this often requires that its environment needs to be taken into account. Management of their environment (e.g., water flow or vegetation management, landscape connectivity etc.), is often more effective but requires a thorough cost-benefit evaluation. Strategies will be developed using the previously collected information on disease prevalence, drivers of emergence and spread, contact patterns and vector dynamics.

4. Eligibility and funding criteria

NCOH was allocated, as being a 'strategic public-private partnership' under the Knowledge and Innovation agenda of the Top Sector Life Sciences & Health, a budget of 2 M€ PPP Allowance to organize and realize a first PPP call: NCOH for Top Sector LSH call 2019. All research organisations associated with the NCOH can apply for innovation collaborative projects. The call application form is the same as for the TKI-LSH Match Call (<https://www.health-holland.com/public/downloads/tki-lsh/2019-tki-lsh-match-application-form.docx>). The evaluation of applications will be different (Section 5).

4.1 Criteria for application

Each application must satisfy at least the following criteria:

- The research fits within the NCOH Strategic Research Agenda and one of the Solution Sets 'Preventive Strategies' or 'Prophylactic Vaccines' and is of a high quality.
- The consortium consists of at least two NCOH Partners, which have jointly contributed to a project in the 2017 (metagenomics) or 2018 (complex systems) NCOH PhD research programme with multiple PhD students, and at least one (national or foreign) for-profit enterprise. Foreign for-profit enterprises and research organisations are also encouraged to participate in the consortium, as long as the results of the research project also benefit the Dutch knowledge infrastructure and economy.
- The project covers fundamental research, industrial research, experimental development, or a combination thereof. A description of the three types of research is provided on the website of the Top Sector LSH (<https://www.health-holland.com/public/downloads/match/regulation-clarification-eu-pdf-.pdf>) and in Appendix B of the application form.
- The main applicant is located in the Netherlands.
- The research is of a qualitatively high level and the innovative products and services are deliverables that have an added societal and economic value.
- Effective collaboration (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XC0627%2801%29&rid=7>) takes place. This means, for example, that the project is realised at joint cost and risk and that all consortium partners make a substantive contribution to the project.
- The cash contribution of the enterprises and other private parties must be due to Dutch research organisations (and not to the project). Besides a possible cash contribution, all consortium partners should make an in-kind contribution. This means that all consortium partners incur payroll costs, for example. The NCOH PhD students on this project can serve as in-kind contribution for the duration of the project.
- The enterprises and other private parties may not send any invoices to the research organisations for the project submitted.
- The consortium has not or shall not receive other public funding for the project submitted (e.g. from NWO, ZonMw, TNO, TTW, or Health~Holland).
- The project may have a maximum duration of four years.
- The project must start within six months after the awarding letter was received.
- The deadline for applications is 9 October 2019.

4.2 Consortium composition

The PPP Allowance applicants put together a consortium in which research organisations and for-profit enterprises, which retain their own identity and responsibility, jointly realise a project based on a clear and optimal division of tasks and risks. All parties make a financial and substantive contribution to the project. The consortium provides a project coordinator (also principal applicant) who will be the point of contact for Health~Holland throughout the entire procedure. Each of the other parties within the consortium is a co-applicant. The regulation is open to co-applicants from Dutch and foreign research organisations, for-profit enterprises and other private or public parties, as long as the research contributes to the Dutch knowledge infrastructure.

4.3 Intellectual Property Policy

The consortium must make agreements about the intellectual property (IP) related to the knowledge and products that will be developed in the project. These agreements are recorded in the consortium agreement. A 'first option right' is one of the options. Agreements about IP are in accordance with the [Framework for State aid for research and development and innovation](#) (specifically Article 2.2.2.) and the PPP Allowance Regulation (Dutch Government Gazette of [4 September 2012](#) and [18 November 2016](#)). This states the for-profit enterprises and other private parties that participate in the project may acquire the IP from the research organisation against a remuneration (minus the already invested amount) and that the results for which no intellectual property rights can be derived may be widely disseminated. A model consortium agreement is available on the website of Health~Holland (<https://www.health-holland.com/calls/tki-match>).

4.4 Funding

Of the total eligible project costs, a maximum of 75% of the PPP Allowance may be used for fundamental research, a maximum of 50% for industrial research and a maximum of 25% for experimental development. These maximum amounts are stated again in Table 1. Additionally, this table shows which minimum percentage a research organisation must contribute*** and the minimum percentage that a for-profit enterprise must contribute. 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, parties are free to decide how to obtain the rest of the project funding required. In Table 1, a distinction is drawn between SMEs and large enterprises. A combination of the three types of research is possible.

Funds will be allocated on the basis of the availability of the PPP Allowance for this 'NCOH for Top Sector LSH' 2019 call, being 2,000,000 euro. Submitted projects should have a total size of max. 1,000,000 euro, including co-financing. This amounts to max. 250,000 euro to 750,000 euro of PPP allowance, depending on the type of research (fundamental research, industrial research and/or experimental development).

Table 1: Funding per type of research

Type of research	Fundamental research	Industrial research	Experimental development
Maximum % PPP Allowance to be deployed	75%	50%	25%
Research organisation(s) ***	min. 10%	min. 10%	min. 10%
For-profit enterprise(s)	min. 15%	min. 30%	min. 45%
- Large	- min. 2/3 rd in cash*	- min. 2/3 rd in cash*	- min. 2/3 rd in cash*
- SME**	- may be fully in kind	- may be fully in kind	- may be fully in kind

* At least 2/3 of the required minimum contribution of 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.

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

*** In case research organisation(s) have a linked and granted NCOH PhD project with two contributing NCOH Partners in place the obligated in-kind contribution is considered fulfilled.

4.5 Calculation of the project costs

Eligible costs

The project costs that can be incurred (eligible costs) must be directly related to the R&D activities. Examples are: scientific personnel, technicians, supporting staff, consumables and the use of equipment specifically required for the project (depreciation system). When entering costs for consumables, the historical cost price should be used. Commercial rates may not be entered. For a more detailed explanation of (the calculation of) eligible costs, please refer to the [Commission Regulation \(EU\) No 651/2014 of 17 June 2014](#), article 25 and the [Framework Decision National Grants of the Ministry of Economic Affairs](#), Chapter 4, articles 10-14. The PPP Allowance can only be used to cover part of the eligible costs. Parties that make no use of PPP Allowance are not required to make use of one of the salary costs systems described in the [Framework Decision National Grants of the Ministry of Economic Affairs](#). These parties may also use their own hourly rate. However, a condition for this is that the calculation of the hourly rate is based on a standard and controllable method and on commercial principles and standards that are considered to be acceptable in society and that the participants systematically apply in a collaborative project. On the budget form, these parties should choose 'fixed hourly rate' and change the standard hourly rate of 60 euros per hour to an hourly rate that they usually apply and that is verifiable.

Examples of ineligible costs

An overview of costs that are ineligible is given below. Therefore, these costs may not be entered on the budget form:

- Patent applications and costs for retaining a patent (patents purchased at arm's length conditions or for which external parties grant a licence are eligible for funding);
- Auditor's statement;
- Bench fee;
- Travel within the Netherlands;
- Supporting personnel who are not directly involved in the R&D activities, such as a project auditor, business developer, administrative employee;
- Drawing up a business case;

- Overheads;
- Project management tasks that are not directly related to the specific R&D activities, such as: escalating to a steering group, drawing up a risk management model, drawing up reports to satisfy funding requirements, administrative accountability. Project management tasks that are directly related to the R&D activities (e.g. discussions with employees, analysing technical risks, drawing up research reports, drawing up specifications) are eligible for funding.

4.6 Use of PPP Allowance

Research organisations, such as universities, university medical centres, universities of applied sciences, TO2 institutes, KNAW institutes and other organisations that satisfy the definition of a research organisation may use PPP Allowance. Dutch SMEs and other Dutch private parties may use PPP Allowance to a limited extent; a maximum of 25% of the in-kind costs they incur may be funded with PPP Allowance. Large enterprises, foreign SMEs and other foreign private parties may not use PPP Allowance; the costs they incur should be the same as the in-kind contribution that they provide.

4.7 Open access

Health~Holland believes that research results which are fully or partly funded with PPP Allowance (public funds) must be made freely accessible worldwide. All scientific publications emerging from research that is funded on the basis of awards from the Match Call should therefore be made freely accessible worldwide (open access) at the moment of publication. Via the website <http://www.openaccess.nl/nl/node/644> you can check whether your organisation has made agreements with traditional publishers concerning open access. This website provides, amongst other things, an overview of more than 8000 journals in which corresponding authors from Dutch universities and university medical centres can publish in open access form free of charge or for a discounted price. Costs that are associated with open access publication fall under the eligible project costs.

4.8 Data management

Health~Holland encourages the optimal use of research data and therefore wants this data to be stored according to the FAIR principles: findable, accessible, interoperable and reusable. Furthermore, Health~Holland wants to increase researchers' awareness about the importance of responsible data management. Therefore, the applicant should answer in Section 15 of the application form some questions about data management. The applicants only need to draw up a data management plan if an application is awarded funding. The approval of the data management plan by Health~Holland is a condition for the disbursement of the PPP Allowance.

5. Procedure

5.1. Application format

Applications must be submitted by email before 12.00 hours on 9 October 2019 by the main applicant. Only applications for PPP Allowance that are submitted to Jovanka Bestebroer at J.Bestebroer@umcutrecht.nl will be considered.

The call application form is the same as for the TKI-LSH Match Call (<https://www.health-holland.com/public/downloads/tki-lsh/2019-tki-lsh-match-application-form.docx>). Besides completing the application form, the project coordinator/official secretary must also send at least the following annexes:

- Specified budget. This is available for download from the website of Top Sector LSH (<https://www.health-holland.com/public/downloads/tki-lsh/2019-tki-lsh-match-budget-form.xlsx>).
- Letters of commitment. This contains the pledge of the co-funding and the size of the cash/in-kind is stated. The contribution by the parties is confirmed per participant (if this is not stated in the consortium agreement). Only the main applicant does not need to upload a letter of commitment. A letter of commitment template can be downloaded from <https://www.health-holland.com/public/downloads/tki-lsh/template-letter-of-commitment.docx>. Letters of intent will not be accepted.
- Consortium agreement. If a signed consortium agreement is not yet available, then at least a concept version needs to be provided. We would appreciate it if you would use the model consortium agreement that is available on the Health~Holland website (<https://www.health-holland.com/calls/tki-match>). A research organisation should use the services of an expert (technology transfer office (TTO) or a lawyer) to draw up the consortium agreement. The signed consortium agreement should be sent as soon as possible, but no later than 16 weeks after the deadline of 9 October 2019.

The NCOH advises applicants to use the services of their own Partner Organisations (e.g. experts from research support office, technology transfer office (TTO) or a lawyer) for details on the call and writing of the proposal; the same requirements apply for this call as for the TKI-LSH Match Call. Additional NCOH information can be requested through Vincent Rijsman, V.M.C.Rijsman@uu.nl.

5.2. Evaluation and timelines

Applications are evaluated for eligibility, scientific quality, and societal value. The following evaluation criteria apply:

- The consortium consists of at least two NCOH Partners, which have jointly contributed to a project in the 2017 (metagenomics) or 2018 (complex systems) NCOH PhD research programme with multiple PhD students, and at least one (national or foreign) for-profit enterprise. Foreign for-profit enterprises and research organisations are also encouraged to participate in the consortium.
- In the application form for the NCOH PhD research call 2018, applicants could indicate an expression of interest for translational or applied projects associated or linked to the specific PhD project proposals and eventual concrete contacts or intentions that already were in place. Applications with a previous expression of interest will be favoured above new applications.
- The project should comply with the matching requirements as described under Section 4.

- Projects with a high scientific quality should fit within the Knowledge and Innovation Agenda of the Top Sector LSH with Prophylactic Vaccines and Preventive Strategies as topics.
- Scientific quality will be evaluated by two independent reviewers from the international NCOH Scientific Advisory Board or additional external reviewers, when needed from the perspective of the topic area of a proposal (coverage of the topic by the SAB).
- Societal value will be evaluated by matching within national preventive programs ('Kabinetsmissie brief 2019) or the NWO track (Nationale Wetenschapsagenda sporen).
- Societal value will be scored by an independent *ad hoc* committee with representatives of relevant Ministries, patient organisations, etc., established by the NCOH Executive Board.
- On the basis of the combined scientific and societal value scores, the NCOH Executive Board will give an advice whether a proposal is eligible for funding and will advise on prioritisation of the eligible proposals to Top Sector LSH within 3 weeks after application deadline.
- The LSH Evaluation Committee will inform the Health~Holland Board which proposals receive a positive or negative advice.
- Funds will be allocated on the basis of the availability of the PPP Allowance available for this 'NCOH for Top Sector LSH' 2019 call, being 2,000,000 euro, compliance to the funding criteria herein, relevance (including the added value to the strategy of the NCOH) and the application's scientific quality and feasibility.
- The Health~Holland Board will ultimately decide on the awarding of the projects. Awarding or rejecting letters are expected about 10 weeks after the application deadline.

5.3. Award procedure, monitoring, and payments

After a PPP Allowance application has been awarded

- Within 16 weeks after the date of the deadline concerned, the project coordinator should submit a consortium agreement that has been signed by all partners.
- Once the consortium agreement is approved, Health~Holland will draw up a PPP Allowance Agreement. The PPP Allowance Agreement is a contract between Health~Holland and all consortium partners that states, amongst other things, the rights and obligations as well as (financial) contributions of the various partners. This agreement will be drawn up by Health~Holland and should be signed by all partners within a period of four weeks.
- A data management plan should be supplied together with the signed version of the PPP Allowance Agreement. Health~Holland will assess the plan as quickly as possible.
- Health~Holland will publish information about all projects awarded funding on the project page of its website (<http://www.health-holland.com/project>). A broadly understandable summary of the project should be submitted together with the signed version of the PPP Allowance Agreement.

Once Health~Holland has received and approved the signed PPP Allowance Agreement, the data management plan and the summary for the Health~Holland projects page, the first advance of the PPP Allowance can be disbursed. The other payments will take place on an annual basis after a progress report has been received and approved. The disbursements will be made to the institution where the project coordinator works; the project coordinator is responsible for any further distribution of the funding to other consortium partners as well as the collective accountability for how the funding is used.

During the course of a project

- During the project, a record of each employee's working hours should be kept.
- At the start of each calendar year, the project coordinator will receive an Excel form entitled 'request for information about project efforts'. The primary purpose of this request for information is the annual round of informing the Dutch House of Representatives and a broad public about the

progress of the top sectors policy within the area that the TKIs are responsible for. This form will be completed in advance by Health~Holland and only needs to be checked and supplemented (costs incurred over the previous calendar year).

- Within six weeks after the end of each project year, the project coordinator needs to submit a progress report. The template for this will be provided by Health~Holland. If the project has a duration of less than 18 months, then only a final report will be required.
- The consortium must hold a steering group meeting every six months. The project coordinator must inform Health~Holland about this, so that a representative from Health~Holland can attend the meetings.

After project end date

Within 8 weeks after the end date of the project, the project coordinator should submit the following documents to Health~Holland:

- A final report (for which the template will be supplied by Health~Holland).
- If a consortium partner has not used or has used less than 125,000 euros of PPP Allowance, then a board statement should be submitted concerning the total project costs of that consortium partner.
- If a consortium partner has used more than 125,000 euros in PPP Allowance, then an auditor's statement should be submitted concerning the total project costs of that consortium partner.

The final PPP Allowance payment will take place once the documents stated have been received and approved by Health~Holland.