Open program
Public private partnerships
2023

The Dutch Heart Foundation focuses on creating and implementing new ways to detect and treat cardiovascular diseases at an earlier stage.
With this program for public private partnerships (PPP), we aim to stimulate translational and innovative research projects that promote the application of cardiovascular research results in clinical care for cardiovascular patients and stimulate the involvement of relevant stakeholders.
We do this by making PPP funds available for cardiovascular research groups that must be matched by investments from private parties.

This program is an open call without a deadline for the submission of proposals.

Dutch Heart Foundation
Hartstichting

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General information

In the next twenty years the number of people suffering from cardiovascular disease (CVD) in the Netherlands is estimated to increase by 30%. If nothing changes, seven million people will suffer from a chronic disease in 2040 of which nearly two million will be chronically ill due to cardiovascular disease.

The Dutch Heart Foundation (DHF) is a Netherlands-based charity aimed to reduce the burden of cardiovascular disease and keep hearts healthy. One of the ways this is done is by stimulating (collaboration in) cardiovascular research and enhancing knowledge and awareness on the many cardiovascular diseases. The DHF depends solely on funds from the general public and works together with scientists, doctors, patients, and many volunteers on solutions to detect cardiovascular diseases earlier and to treat them better and faster. The DHF stimulates research and innovation, provides support and information to the (at-risk) population and patients.

In 2014, the first national cardiovascular research agenda was developed together with the Dutch general public and major stakeholders, including patients, healthcare professionals, scientists, volunteers and donors. This resulted in the following five research priorities:

- Earlier recognition of cardiovascular diseases
- Cardiovascular disease in women
- Better treatment of heart failure and arrhythmias
- Acute treatment of strokes
- New ways to keep up a healthy lifestyle

Based on the research agenda, our (long term) ambitions and in line with the ambition of the Dutch CardioVascular Alliance (DCVA), the DHF further strengthens her focus in finding and implementing new solutions for the detection and treatment of cardiovascular diseases at an earlier stage. Preventing damage due to cardiovascular disease as early as possible is essential to reduce the increase in chronic CVD and the accompanying loss in quality of life. Therefore, it is important to detect CVD earlier and develop better treatments to prevent, lower and/or repair (early) damage.

With this focus we endorse the research agenda for CVD and contribute to the roadmaps (Molecular diagnostics, Imaging, Homecare, Regenerative medicine, Enabling technologies and HTA) of the ‘Knowledge and Innovation agenda LSH-TKI’ as well as the ‘Personalized medicine’, ‘Regenerative Medicine’ and ‘Healthcare research, Prevention and Treatment’ routes of the ‘National Science agenda’.

Innovative solutions and research methods are essential

Preventing damage due to CVD as early as possible is essential to maintain a good quality of life and reduce complications, intensive treatments and premature death. Therefore, it is necessary to determine with more precision if someone is developing a CVD before clear symptoms are present. Additionally, we aim to contribute to earlier and better treatments to prevent, lessen and/or repair (early) damage.
This important societal challenge calls for the engagement of both excellent researchers and direct users and end users. Industrial parties will be among the users of the research results, which can help them develop new products and/or services.

Aim of this program

With this program for public private partnerships, we aim to stimulate innovative research projects that are necessary for the next step in translating cardiovascular research findings towards application in health care**.** The DHF focusses on creating and implementing new ways to detect and treat cardiovascular diseases at an earlier stage.

This program is looking for innovative, translational, and multidisciplinary research in which knowledge institutes and private partners are collaborating. It will be open for applications throughout 2023 in order to facilitate partnerships precisely when they are ready to use these funds, thereby maximizing the contribution of this program to the further development and implementation of research findings.

Who can apply?

Scientists employed by a Dutch knowledge institute can submit a proposal. There is a real collaboration with at least one private partner that contribute to the project. Upon approval of the research proposal, the applicant bears the ultimate responsibility for the realisation of the research project.

How can I apply?

If you are interested in applying for this program please contact the DHF in order to first discuss whether or not your project can be expected to be eligible. Before you can submit a full proposal we ask you to submit a pre-application. This will allow the DHF to perform a first eligibility check and judge whether the requested budget is available in the requested year or in light of budget constraints in the consecutive year. Please, always contact DHF first before starting a pre-application.
Only pre-applications with a positive review can be elaborated into a full application. Before submitting your application, we recommend that you visit the DHF website (www.hartstichting.nl) to check that you have the latest version of this brochure and the appendices.

Budget

For this program, the PPP allowance is used under the TKI Life Sciences & Health program allocated by Stichting LSH-TKI to the DHF from the Ministry of Economic Affairs, in accordance with the PPP Allowance Regulation. Consequently, specific rules apply for proposals submitted for this program. Please read the guidelines carefully and contact us in case you have any questions.

The project duration is min 1 year and max **3.5** years, depending on the start date of the project. Please note that the end date should be before 15 July 2027.

As building a public private partnership takes time, often more time than anticipated, we advise you to carefully consider the planned start and end date of the research project. Before applying for funding, you should thoroughly check if you can meet these timelines.

The minimum **PPP allowance to be deployed** for a project is €150,000. For 2023 the DHF has around €500,000 available for this program.

In accordance with the PPP Allowance Regulation, the amount of allowance that can be requested depends on the type of research. 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 proportions and the co-funding demands are depicted in Table 1. Please note the percentages of co-funding is different as compared to earlier programs.

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

Table 1 Funding model by type of research from 2023 onwards

The percentages in the table are the percentages regarding the total project financing.
** At least 2/3 of the required minimum contribution of a large enterprise must consist of a cash contribution. This minimum contribution is based on their total project contribution.*
***The contribution of a large non-profit enterprise may be fully in kind. However, a cash contribution is encouraged.*
**** May be fully in kind. However, a cash contribution is encouraged.*

This table also shows the minimum percentage that a research organisation must contribute and the minimum percentage that an enterprise must contribute (in cash and/or in kind). In the case of industrial research and experimental development, the columns do not add up to 100%. In these cases, the parties are free to decide how to obtain the remainder of the project funding required. A contribution by other private parties is preferred above extra contributions by knowledge institutes.

Conditions and points to note for PPP allowances:

- The conditions for a PPP project are described in the Health~Holland "TKI LSH Match Regulation for public-private partnerships ".
- Co-funding by private parties that are not enterprises, such as foundations are appreciated however, do not count towards the compulsory enterprise contribution. The DHF will not co-fund these applications.
- Dutch SMEs (for-profit and non-profit enterprises) may use PPP Allowance to a limited extent. In case of fundamental or industrial research, a maximum of 50% of the in kind incurred costs may be funded using PPP Allowance. In case of experimental development, a maximum of 25% of the in kind incurred costs may be funded using PPP Allowance. Large enterprises, foreign SMEs and other foreign private parties may not receive PPP Allowance; the costs they incur should be the same as the in-kind contribution that they provide.
- In the case of a cash contribution from a company, it must be a cash contribution payable to the research organization in the Netherlands (and not to the project concerned).
- Consortium partners may not send any invoices to the research organisations for project related costs.
- The definitions of small and medium-sized enterprises are explained in brief in Appendix A.
- The definition of an enterprise is given in appendix B.
- The project costs that can be incurred (eligible costs) must be directly related to the R&D activities.
- See appendix H for more information about the budget.

Eligibility requirements

The proposals must satisfy at least the following requirements:

- The proposed research must fit within the strategy of the DHF.
- The project proposal must be in line with the challenges as set out in the "Knowledge and Innovation Agenda 2020–2023" (KIA).
- The project duration must not exceed 3.5 years (note the maximum end date).
- The project covers fundamental research, industrial research or experimental development, or a combination thereof. For definitions of the types of research, see Appendix C.
- Its translational and innovative character should be clearly described in the proposal.
- The research described in the proposal is not already being funded in another ongoing research project of the DHF or other parties.
- The proposal and budget are in accordance with the PPP rules.
- The proposal is not eligible for funding by the First Fund of the DCVA (www.dcvalliance.nl).
- The project must start within six months after the letter confirming the award is received.
- The same application may not be submitted more than once within three years.

- An applicant may not submit more than two applications per year.

The consortium must satisfy the following eligibility requirements at least:

- A proposal must be jointly submitted by at least one partner from a public knowledge institute and one private partner.
- Scientists employed by a Dutch knowledge institute can submit a proposal.
- The main applicant is located in the Netherlands.
- There is a real collaboration, and the partners in the consortium will jointly bear the costs and risks of realising the project.
- Foreign for-profit enterprises and research organisations are also encouraged to participate in the consortium, as long as the results of the research project benefit the Dutch knowledge infrastructure and economy.
- If the proposal links to an existing consortium financed (in part) by the Dutch Heart Foundation, a letter confirming the collaboration with the existing consortium signed by the consortium leader(s) must be included in the proposal. The form and added synergistic value of the collaboration must be clearly described and substantiated. Collaboration with an existing consortium will be a positive asset but is not a requirement.
- The research leader and principal investigators involved must be employed throughout the entire duration of the research project.
- The contribution of all partners must comply with the PPP rules.
- Besides a possible cash contribution, all consortium partners should make an in-kind contribution. This means that at least all consortium partners incur payroll costs. These costs must appear on the budget form (Excel).
- The contribution by the parties is confirmed per participant. Upload for each partner a letter of commitment in which a pledge of co-funding and the size of the cash/in kind contribution is stated. The main applicant does not need to upload a letter of commitment. A template letter of commitment can be found in appendix E. Letters of intent will not be accepted.
- The consortium partners are willing to sign the agreement and intra-consortium agreement (see website). By submitting a proposal, all consortium partners agree with these agreements.

Theme and ambitions of the project

The following paragraphs are content parameters for writing the proposal.

Impact

With this program the DHF aims to create societal impact by focusing on creating and implementing solutions for cardiovascular healthcare problems. Scope, size and impact of the healthcare problem are important factors that contribute to realizing the ambition of the DHF and should be the starting point of the project.
The consortium must clearly indicate which elements of the ambition are addressed in the project proposal and which parts are beyond the scope of the current proposal. In case additional funding is required, a strategic plan on how to acquire these funds should be part of the proposal. It should be explained how the consortium contributes to the Dutch national cardiovascular research agenda and other relevant research agendas.

Scientific excellence

Part of the proposal is a clear and solid description of the anticipated scientific impact and the expected contribution of the project to reducing the burden of cardiovascular disease. The work packages of the proposal are coherent and synergistic. The aims and the description of work must be feasible in terms of project duration and available budget. The proposal is expected to be internationally competitive.

Route to Societal Impact

The aim of the DCVA and DHF to significantly reduce the burden of cardiovascular disease is ambitious. Solely focussing on defining a clear healthcare problem and the design of a (research) proposal that addresses this problem by finding a solution is not sufficient to realize this ambition. To create real societal impact, results should be implemented into healthcare routines and in society. Therefore, the plan includes a strategy to translate successful and positive research findings into solutions that benefit or improve current clinical practice. This strategy is called an Impact Plan (see appendix F).

An impact strategy involves both valorisation and implementation activities and includes collaboration with stakeholders. Part of the proposal is a description of the relevance, needs and requirements of (end) users related to the outcome of the project. How will the outcome of this project affect research and healthcare?

Short-term ambitions (outputs and outcomes) and a long-term impact ambition (2030-2040) must be included. For the short-term ambition (four to five years), clear objectives, deliverables and milestones need to be formulated. Define objectives, deliverables and milestones as specific as possible and preferably phrase them as possible solutions. See Appendix F for a schematic representation of an Impact Plan. Part of the Impact Plan approach are a valorisation and implementation strategy, an impact coordinator and a user committee.

Valorisation strategy

Valorisation is typically described as the utilization of scientific results in clinical practice. Depending on the specific solution or solutions a consortium is working on, valorisation can have different forms.
The consortium should present the steps needed to bring a solution towards clinical practice. This does not necessarily have to take place within the timeframe of the proposal. The applicants should describe the envisioned end product(s), the intended target group(s), and the impact of the product(s) on care. In addition, the consortium should indicate which stakeholders are essential to involve in this process and the budget required to guarantee a successful next step.

Part of the valorisation strategy can be collaborating with a Health Technology Assessment (HTA) expert to advise on a realistic strategy. The outcome of the consultation/analyses with this HTA expert forms part of the proposal as well as how HTA expertise will be part of the project.

An assessment of whether this strategy for valorisation is realistic and time- and cost-effective forms part of the evaluation of the application. The consortium can allocate a dedicated budget for valorisation activities; as a guideline, 10% of the total budget can be used. Please note that many valorisation activities (like an HTA) cannot be financed within the PPP framework. The budgeted costs should be directly related to the R&D activities. We would like to stress that we expect the consortium to investigate funding opportunities within the universities or the valorisation pillar of the DCVA.

The DCVA can provide extensive valorisation assistance to DCVA consortia. Using support under the '*TTT-regeling'* of the Dutch government the DCVA was able to appoint an Impact Officer who will not only scout for high potential results within the DCVA consortia but can also help to get these results investor-ready. As part of the *TTT-regeling* the DCVA, together with RegMed XB also established FIRST, an early-stage investment fund for start-ups in the field of cardiovascular disease and regenerative medicine. The Impact Officer will be your contact person for all valorisation related questions in the preparation phase of the proposal, but also during the execution of the project. The valorisation team of the DCVA can be contacted via email: valorisation@dcvalliance.nl.

Implementation strategy

As part of the impact plan, applicants develop a strategy outlining how results will be implemented in daily clinical practice. The DHF stimulates researchers and clinicians to implement new solutions in daily practice at hospitals and other healthcare institutions. To find treatment that is less intrusive or stressful and helps lower healthcare costs, new methods and instruments are needed. Caregivers have to be trained in working with them safely. Planning and organising this at an early stage of research helps creating fast tracks in this domain. Expertise and collaboration are key to develop and implement novel preventive and other therapies for cardiovascular disease. To increase the chances of your results being adopted into clinical practice as efficient as possible it is essential to involve relevant scientific, clinical and/or societal organisations already early in your project. Describe a strategy of how to implement new knowledge in cardiovascular healthcare practice. This strategy includes describing who will be involved, how implementation will be done, how implementation activities will be organized (also by others) and a stakeholder analysis. Please get in touch with the DCVA implementation pillar for support on this subject via email: implementation@dcvalliance.nl.

User committee

Relevant stakeholders are involved via a user committee. This committee advises the consortium on the steps needed to bring results to clinical practice and monitors the use of the acquired knowledge. Describe in the proposal how collaboration with stakeholders will be organized, what expertise is needed and how this expertise is present in the described composition of the committee. It is advised to reach out to the envisioned user committee members already in an early stage (proposal phase). By doing so, they can provide feedback to the proposal and align expectations. Patients are an essential part of a user committee. The consortium can contact patient organisation Harteraad for more information about patient participation. More information about user committees can be found on the website of the DHF. Please also take note of our user committee guidelines. It is advised to reserve budget for the user committee.

External Collaboration

The consortium describes their collaboration with other consortia working on relevant healthcare problems, relevant stakeholder organizations and end users. Possible stakeholder organizations are, for example, the partner organisations of the DCVA.

The proposal includes a description of which stakeholders are involved (including names), both national as well as international. The proposal also includes how support is created and how patient groups and societal stakeholders are involved.

Points of attention

Diversity

Including sex and gender in research is a condition for every research proposal because it is proven to be relevant in cardiovascular diseases and therefore enlarges scientific quality of the research project. In addition, there is a great societal demand for attention towards this topic. For these reasons, the research proposal must display efforts to include sex and gender differences in the study design or have a well-argued section why this is impossible or irrelevant for this specific research proposal. The term ‘sex’ refers to the biological attributes that distinguish male from female and the term ‘gender’ refers to men and women’s socially constructed roles, identities, and behaviours. See the website of Stanford university for tools that can be used to integrate sex and gender aspects in research applications. And check out the Online Training Modules of the CIHR on Integrating Sex & Gender in Health Research.

Apart from sex and gender differences, also other aspects of diversity, such as age, social background, ethnicity should be taken into account in all activities of the consortium. This should be clearly described in the proposal.

Open access & open science

A well-organized data infrastructure is essential for excellent science. The DHF promote this by focussing on the following aspects:

- Sustainable use and re-use of data
- Registry-based research
- Data communities
- Biobanks

Projects funded are strongly encouraged to make use of the services of the DCVA. The data infrastructure team of the DCVA can be contacted via data-infrastructure@dcvalliance.nl.

A project proposal should include a detailed description in the proposal on how the acquired data will be handled (data stewardship). Therefore, the consortium is strongly advised to involve a data-expert in their consortium and is obliged to allocate resources for data management in the budget. After having been awarded the grant, the consortium will be asked to hand in a Data Management Plan (DMP). The Durrer Center will provide a DMP-format and assistance and will monitor the DMP. A DMP is a dynamic document and will also be used to monitor progress on data management.
In addition to data management the DHF has the policy that all publications funded by the DHF are published in an open access journal.
More information about data-management policy and support can be found here on the website of the DCVA and DHF.

Agreements

Upon submission we expect that all partners are informed and agree with the conditions laid out in the agreements (see below). We explicitly advise applicants to carefully read the agreements and discuss them with the consortium partners before submitting the proposal.

Submission and Review process

Contact

For questions about the programme please contact Karin Eizema, k.eizema@hartstichting.nl, 070-3155566. Pre-applications are submitted via e-mail: research@hartstichting.nl.

Submission of a pre-application

This program has no deadline. If you are interested in applying for this program please contact the DHF in order to first discuss whether or not your project can be expected to be eligible and to answer any questions you may have. Before you can submit a full proposal we ask you to submit a pre-application. This will allow the DHF to perform a first eligibility check and judge whether the requested budget is available in the requested year or in light of budget constraints in the consecutive year. The pre-application form is available via the website (Open PPP-programma | Hartstichting).

Internal review by DHF

The DHF will review internally whether the pre-application is eligible based on the requirements, fit within the research strategy of the DHF and whether the requested budget is available. Only if the pre-

application is reviewed positively the applicant is invited to submit a full application using the grant management system www.cavaris.nl.

Submission of a full application

Full applications can only be submitted via the electronic system Cavaris, which can be reached via the website www.cavaris.nl . Registering and logging in to Cavaris is easy via the welcome portal. If you have any questions, please contact research@hartstichting.nl. You can reach the manuals for the application system via: Cavaris manuals

Talent Development
There is no separate talent development program possible within this program. Please fill in the application form: 'not applicable in agreement with DHF'.
Costs made for visits of conferences or courses necessary to execute the research are eligible for reimbursement and can be included in the budget under travel expenses or other expenses.

Mandatory additional uploads:

- Letters of commitment of all partners accept the applicant.
- If the proposal links to an existing consortium financed (in part) by the Dutch Heart Foundation, a letter confirming the collaboration with the existing consortium signed by the consortium leader(s).
- The 'Additional Questions' form. This form can be downloaded from the General Information page of the call in Cavaris.

Other uploads
Figures and references can be added by an additional upload.
You need to download the budget form from Cavaris. After filling all the fields, you upload it in Cavaris.
Each participant needs to upload a Curriculum Vitae. The format is provided in Appendix G.

Signing
All applicants, work package leaders and partners need to sign the application.
By signing the applicant declares to have completed the form truthfully and declares that the correct official(s) of his/her employing organisation of this submission are informed. Additionally the applicant declares to have read and agree to the agreements and that the obligatory letter(s) of commitment of the other consortium partner(s) has/have been submitted separately.
By signing the work package leaders and consortium partners declare to have read and agree to the agreements and the they authorise the applicant to submit the application form and to handle any further correspondence concerning this.

Intra Consortium Agreement
The intra-consortium agreement (ICA) (available in Cavaris and on the DHF website) contains paragraphs on IP, organisational and publication arrangements. The ICA becomes part of the consortium agreement. The ICA can be amended but the IP paragraphs are non-negotiable. The ICA (not signed) must be submitted two weeks before the committee meeting. You will receive a separate e-mail with this deadline after the committee meeting is planned.

Internal review by DHF

The DHF will check within two weeks after submission whether all the eligibility criteria are fulfilled. If the application is not eligible but can be amended, the DHF will invite the applicants to amend the application. If the application is not eligible based on the requirements or if there is not enough budget the application is excluded from the review process.

External review

After this internal review the external reviewing process will start. In 2023 there will be two selection meetings planned. Applications submitted before mid-April will be reviewed and discussed in a meeting at the end of May. Applicants will receive the result of the selection process at the end of June. Applications submitted before the beginning of September will be reviewed and discussed in a meeting at the end of October. The result will be communicated to the applicants at the end of November. Applications submitted after the beginning of September will be reviewed in 2024.
The application will be reviewed by a committee of members of the national Scientific Advisory Board (SAB) and, if appropriate members of the Committee Societal Quality (CSQ). The committee will judge whether additional reviews are necessary. The review of the application focuses on the criteria of Impact, Description of work, Route to Societal Impact, Internal and External Collaboration. The members of the committee are selected based on the topic, the proposal's size and whether or not there is a connection to existing consortia. The committee is supplemented if necessary by valorisation and/or implementation experts (e.g. impact officers of the DCVA) and chaired by the chair of the SAB. The committee selects the best applications. These will be presented by the applicant in a (video) meeting with the committee followed by a discussion. Project partners are very welcome during this interview.

Code of Conduct on Confidentiality and Conflicts of Interest

To ensure a fair assessment and transparency for researchers, the DHF uses a Code of Conduct on Confidentiality and Conflicts of Interest. This code stresses the necessity of confidentiality, identifies possible forms of conflicts of interest, and indicates the steps to be taken to avoid conflicts of interest. Parties subject to the code of conduct are referees, jury members, committee members, members of decision-making bodies and DHF officers. The full text of the code of conduct on conflicts of interest is available on the DHF website.

Decision process

The committee will advise whether the consortium is eligible for funding. The management board of the DHF decides on the allocation of funds, based on the committee's recommendation and the available funds.
When the proposal is eligible for funding, but not enough funding is available, there is a possibility of partly funding the consortium, or of postponing the funding decision. In this case the best strategy will be discussed with the consortium.

Post-decision process

Complaints procedure

A complaint can be submitted by the applicants after the decision of the DHF has been communicated. A form should be submitted to the Complaints Committee of DHF. It is not possible to appeal against the outcome of the procedure (funded or not funded) but only on execution of the procedure by the DHF. The form can be found on the DHF website. Complaints should be submitted within four weeks after receiving the notice from the DHF. More information about the complaints procedure can be found on the website of the DHF.

After granting

After granting, the consortium partners must sign two legal documents:

1. A consortium agreement between the DHF and the consortium partners (available on the website) in which the legal and financial conditions are stated. This agreement is non-negotiable.

2. An intra-consortium agreement (ICA) (available on the website) containing paragraphs on IP, organisational and publication arrangements. The ICA becomes part of the consortium agreement. The ICA (not signed) must be submitted two weeks before the committee meeting. The IP paragraphs are non-negotiable.

The consortium is obliged to deliver signed agreements to the DHF office and start within 6 months after receipt of the grant approval letter.
We explicitly advise you to read the agreements carefully and discuss them with the consortium partners before submitting your proposal. Upon submitting a proposal, all consortium partners are assumed to agree with the agreements.

Monitoring

The Heart Foundation will assign a contact person for each project. He/she will be in close contact with the research leader to stay informed about the progress and discuss issues regarding the project. Official monitoring according to the LSH-TKI rules means that the Research Leader shall provide the Heart Foundation with (more details are stated in the agreement):

1. within 1 (one) month after the end of each calendar year, a periodic (scientific and financial) report.
2. within 1 (one) month upon completion of the Research Project, an integrated final report providing an overview of the progress and results of the entire Research Project.
3. within 1 (one) month upon completion of the Research Project, a final audit of the Research Project costs, including an audit certificate prepared and certified by an independent auditor. The PPP Allowance may not be used to cover audit costs.

Depending on the size of the project, a midterm review can form part of the monitoring.
The Heart Foundation may participate in the user committee, this will be discussed after granting support of the project.

Appendix A: European Commission Recommendation 2003/361/EC regarding SME definition

Micro-enterprises are defined as enterprises that employ fewer than 10 persons and whose annual turnover or annual balance sheet total does not exceed EUR 2 million.

Small enterprises are defined as enterprises that employ fewer than 50 persons and whose annual turnover or annual balance sheet total does not exceed EUR 10 million.

Medium-sized enterprises are defined as enterprises that employ fewer than 250 persons and either have an annual turnover that does not exceed EUR 50 million, or an annual balance sheet not exceeding EUR 43 million.

For more details, 'The revised User Guide to the SME definition' can be downloaded here.

Appendix B: Definition of enterprise

According to established case law from the European Court of Justice, an enterprise is any unit that carries out economic activity irrespective of its legal status and manner of funding.

In this regard, the following points are important:

- The legal status (e.g., a private company or a foundation) of the entity is not important;
- A for-profit status is not required, competition on the market is sufficient (economic activities). This means that the entity participates in economic dealings and that there is business funding. Business funding means that the funding cannot consist entirely of grants, gifts and endowments. A turnover needs to be made and there has to be income from economic activity;
- An entity that carries out both economic and non-economic activities will only be designated as an enterprise with respect to the economic activities;
- The European Court of Justice has further determined that entities that (legally or de facto) fall under the authority of the same main entity should be viewed as a single enterprise;
- Having a Dutch ANBI or charitable status (serving the common interest, no profit-making status, 90% rule) means that such an entity with ANBI status cannot also be an enterprise. That is because an entity with ANBI status enjoys fiscal advantages that a business does not enjoy.

With respect to economic activity, the following aspects are, amongst others, considered in line with the Dutch Tax and Customs Administration:

- Registration with the Dutch Chamber of Commerce (KvK);
- Having a Dutch VAT (BTW) number and/or corporate income tax (VPB) number;
- Goods and/or services are delivered;
- The remuneration received for these is more than symbolic;
- The entity participates in the economic arena and enjoys income from this.

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Appendix C: Definitions of the three types of research[1]

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

Industrial research means the planned research or critical investigation aimed at the acquisition of new knowledge and skills for developing new products, processes or services or for bringing about a significant improvement in existing products, processes or services. It comprises the creation of component parts of complex systems, and may include the construction of prototypes in a laboratory environment or in an environment with simulated interfaces to existing systems as well as of pilot lines, when necessary for the industrial research and notably for generic technology validation.

Experimental development means acquiring, combining, shaping and using existing scientific, technological, business and other relevant knowledge and skills with the aim of developing new or improved products, processes or services. This may also include, for example, activities aiming at the conceptual definition, planning and documentation of new products, processes or services. Experimental development may comprise prototyping, demonstrating, piloting, testing and validation of new or improved products, processes or services in environments representative of real-life operating conditions where the primary objective is to make further technical improvements of 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.

Technology Readiness Levels

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/industrial research
TRL 5	Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)	Industrial research
TRL 6	Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)	Industrial research
TRL 7	System prototype demonstration in operational environment	Industrial research/experimental development
TRL 8	System complete and qualified	Beyond the scope of the PPP Allowance Regulation
TRL 9	Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)	Beyond the scope of the PPP Allowance Regulation

*The TRL is an indication of the type of research, but the definition of type of research prevails.

[1] In case of drug development, pre-clinical research in animals falls within the research category 'industrial research'. In principle, clinical phases 1 and 2 fall within the research category 'experimental development'. Phase 3 clinical trials (and beyond) are seen as competitive development and fall outside the scope of the PPP Allowance Regulation.

Dutch Heart Foundation
Hartstichting

Appendix D: Definitions of the ten roadmaps

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

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

Appendix E: Letter of commitment template

[Use headed paper of party]

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

[Date]

LETTER OF COMMITMENT
for the
[name of] PROJECT

Dear [main applicants’ duly authorised representative],

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

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

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

Yours sincerely,

_____

Name:
Position:
Date:

Appendix F: Impact Plan

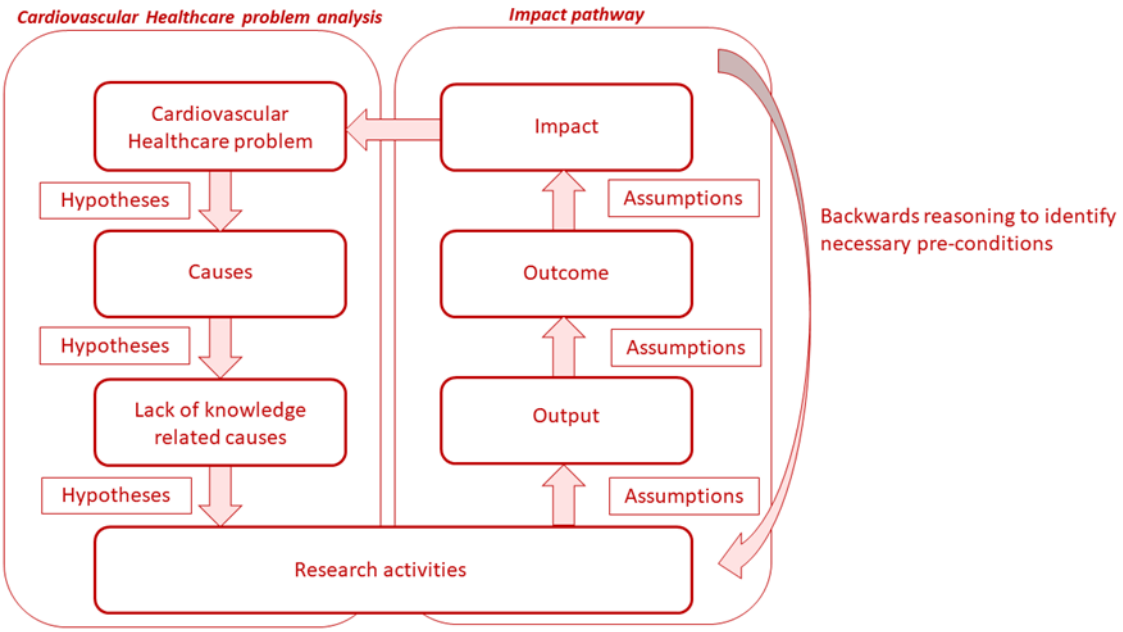
Why an Impact Plan approach?

The Dutch Heart Foundation and the Dutch CardioVascular Alliance aim to create societal impact by focusing on finding and implementing solutions for significant cardiovascular healthcare problems. Since the introduction of CVON, creating impact has become an important and growing aspect of research projects. Elements such as a description of the clinical problem, the envisioned solution, the role of relevant stakeholders and the route clinical adoption of the solution are now an integral part of all project proposals. Similar to other funding partners within the DCVA, the DHF introduces an impact-based monitoring strategy. This *Theory of Change* inspired method, called the *Impact Plan* approach, provides a more structured manner on how to achieve maximal impact with your consortium. This approach helps the consortium and the stakeholders to guide to project towards the envisioned impact goal.

Impact plan and the Theory of Change

With the Impact Plan approach, we ask a consortium to think already in an early stage about the steps that have to be taken in order to work towards the ultimate goal of the project. We call this more specifically the Theory of Change. A Theory of Change describes the problem to be tackled and the desired societal impact. After the ultimate impact of the study is defined, impact pathways are described. Impact pathways are the change paths necessary to reach the defined goal. These impact pathways are based on certain assumptions and actions in order to realize the ultimate change. A Theory of change offers a consortium the opportunity to start both an internal discussion and a discussion with external stakeholders about how the ultimate desired social effect can be achieved. A Theory of Change and therefore also the Impact Plan is not set in stone, but it facilitates a reflective approach and can be continuously adjusted/updated by the consortium during the course of the project.

Schematic presentation Impact Plan and theory of change



The left part of the figure above illustrates the cardiovascular problem analysis part of the Impact Plan. In your proposal this part includes the scientific part. It starts with a clear definition of the cardiovascular healthcare problem the consortium is working on, its underlying causes and the lack of knowledge related to these causes. This should result in the research activities of the project.

The part on the right illustrates the impact pathway part of the Impact Plan. Key in this part of the Theory of Change is a well-defined description of the ultimate goal of the study; what is the impact the consortium wants to achieve. Once this ultimate goal is defined, backward reasoning starts; what are the steps that have to be taken to achieve this goal; who are the stakeholders needed in this process, what has to be changed in the current situation to achieve the impact goals? Output and outcome are two important elements of this pathway. The various outputs of the project (direct insights, findings or results obtained through the study) will lead to outcomes (changes in behaviour, relationships and activities of stakeholders in the scientific and policy environment, as a result of knowledge exchange and the use of research output). Assumptions underlying the steps that need to be taken towards impact are essential as these assumptions largely define the chances of success. Assumptions might be adapted during the project and this might change outputs and outcomes of the consortium, making an Impact Plan a living document.
Inspiration on how to set up an implementation strategy can be found on the website of ZonMW.

Example

The healthcare problem: too many people die of cardiovascular disease X
The cause: there is no effective therapy available that can be used to treat patients suffering from disease X
The underlying knowledge cause: there is not sufficient knowledge of the pathophysiology, therefore it is not possible to find therapeutic targets

Project proposal

Deliverable 1: protein/gene Y causes the disease
Deliverable 2: a compound targeting protein/gene Y is identified
Objective 1: a company adopted the target and compound and developed a therapy
Objective 2: the treatment is taken up in guidelines
Objective 3: insurance companies reimburse the therapy
Impact: less people die of cardiovascular disease X because there are treatment options available

Appendix G: Curriculum Vitae

Provide the following information of all partners in the consortium. State relevant information for the application. Maximum of 1 A4 per CV.

Name:
Year of birth:
Education/Academic background: *(Specify degree, year of completion, field of study, and which institution)*
Current job title:
Affiliation: *(mention all institutions/organisations to which you are affiliated)*
Role in the consortium: *(e.g., research leader, WP leader, consortium partner, end user representative etc)*

Profile *(max 5 sentences*)
Introduce yourself in short. Explain which qualities and expertise you add to the consortium. Think of this summary as a snapshot of your skills, knowledge, accomplishments, and ambition.

A. Scientific track record

1. Best 5 selected peer-reviewed scientific publications, relevant for this proposal
2. Number of publications: 1) total, 2) as first author and 3) as second last and last author
3. Scientific honours and awards
4. Scientific grants

B. Professional track record

1. Relevant professional positions and activities: (e.g., management, board or advisory tasks, clinical tasks, teaching etc.) Please indicate how the different positions are proportionate to each other.
2. Other Experience and Professional Memberships (e.g. membership of a scientific society, membership of boards, participation in user committees, etc.)

C. Societal track record

1. Relevant societal positions and activities: (e.g. advisory role, volunteer work, organisation of events, collaboration with patients, communication activities for a broad public etc)
2. Best 5 selected non-scientific outputs, e.g. policy documents, guidelines, newspaper articles, etc.

D. Valorisation track record

1. Relevant positions and activities for valorisation of research: (e.g. collaboration with industry, IP rights claimed, contribution to start-up companies, seed money/valorisation grants, etc.)

Appendix H: Explanation of budget categories

General
PPP allowance is only obtained for research in a private public partnership.
For more information: https://www.rvo.nl/subsidie-en-financieringswijzer/subsidiespelregels/ministeries/ministerie-van-economische-zaken-en-klimaat

Eligible costs
The project costs that can be incurred (eligible costs) must be directly related to the R&D activities. Examples of this 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.

1. Labor costs

When entering the wage costs, one of the following options can be used:

1. Integral cost system
2. Wage costs + 50% direct storage system
3. Fixed rate

1. Integral cost system (Article 12 of the Framework Decision on National EZ Subsidies)
This method is especially suitable for large organizations that regularly apply for subsidy from RVO. The IKS method must be approved by RvO.

2. Wage costs + 50% direct storage system (Article 13 of the Framework Decision on National EZ Subsidies)
The direct wage costs of project employees will be increased and increased by a 50% mark-up. Direct costs consist of the costs directly attributable to the employee conducting the research, such as gross salary, employer's contributions, pension charges, bonuses (if laid down in the employment contract), etc.
The annual cost is divided by 1650 hours to get the hourly rate

3. Fixed hourly rate of € 60 (Article 14 of the Framework Decision on National EZ Subsidies)
A fixed hourly rate of € 60 per hour.

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, this is under the condition 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. Additionally, the participants should systematically apply these 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 the hourly rate they usually apply and is verifiable.

NB! An organization may only use one of the above methods!

It must be possible to submit an hour administration for all rates. In an integrated cost system and wage costs plus surcharge, the underlying documents can be submitted to substantiate the amount of

the rate.

2. Cost of Material and Tools
Materials from stock
You can increase the cost of the consumption of materials that were not purchased specifically for the project if you register the consumption. Use historical purchase prices. If you do not have an administration of the consumption of materials from stock, you cannot allocate the costs directly to the project.

3. Cost of using machines and equipment
Purchased for the project only.
You enter the costs of equipment that you buy and use especially for a project or certain eligible activities under 'Cost of use of machines and equipment'. These are costs of which the amount can be demonstrated on the basis of an invoice. However, for the determination of the eligible costs, you must deduct the residual value of the equipment from the purchase price (depreciation system). For the determination of the residual value of equipment specially purchased for a project, the residual value is determined on the basis of linear depreciation with a (minimum) depreciation period of 5 years. This is an accounting residual value.

Not purchased solely for the project
If you did not purchase the machine or equipment solely for the project, you may only include the depreciation charges or lease instalments if a conclusive time registration is kept. The costs are then included in proportion to the time during which the machine or device is used for the project, related to the normal occupancy. If you use an integral cost system, you can only enter costs here if the costs are not part of the integral cost rate.

4. Costs owed to third parties
This concerns all (other) costs for which you receive an invoice and are directly related to the execution of the project. If part of the project's activities is outsourced, the costs owed to third parties can be allocated to the project. It must be ensured that the costs owed to third parties are in proportion to the rest of the budget. If this cost item is very high, this may have an influence and will be included in the evaluation committee's assessment.

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 (Note: costs for consumables are eligible);
- 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;
- Conducting effectiveness studies (Health Technology Assessment, HTA);
- Overhead;
- Non-Scientific Dissemination. However, scientific dissemination, including attending a scientific conference or publishing a scientific article, is eligible;
- 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

Appendix I: Checklist application form

- ☐ The consortium must consist of at least one research organization and one for-profit enterprise
- ☐ The main applicant is located in the Netherlands
- ☐ The project has a duration of a maximum of 42 months
- ☐ The starting date is within six months after the awarding letter will be received
- ☐ The chamber of commerce number or equivalent is listed for all consortium partners
- ☐ Effective collaboration takes place and is clear from the application. This means, for example, that the project is realized at joint cost and risk
- ☐ All consortium partners should make an *in-kind* contribution. This means that all consortium partners should at least incur payroll costs
- ☐ Dutch SMEs (for-profit and non-profit enterprises) may use PPP Allowance to a limited extent. In case of fundamental or industrial research, a maximum of 50% of the in kind incurred costs may be funded using PPP Allowance. In case of experimental development, a maximum of 25% of the in kind incurred costs may be funded using PPP Allowance.
- ☐ An enterprise must contribute at least 15% of the total project costs
- ☐ At least 2/3rd of the required minimum contribution of a large enterprise must consist of a cash contribution
- ☐ The research organization must contribute at least 10% of the total project costs
- ☐ All parties, with the exception of the main applicant, must submit a letter of commitment; a letter of intent is not sufficient
- ☐ If the proposal links to an existing consortium financed (in part) by the Dutch Heart Foundation, a letter confirming the collaboration with the existing consortium signed by the consortium leader(s) must be included in the proposal.
- ☐ The budgeted costs are directly related to the R&D activities, and do not include for example: bench fee costs, travel within the Netherlands, supporting/project management tasks that are not directly related to the project's R&D activities

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