Public-Private partnership call for HIV-Cure

Scientific research call 2018

Together we can accelerate reaching an HIV cure!
Explanation of the ‘Public-private partnership for HIV-Cure call’

With this public-private partnership (PPP) call Aidsfonds and Health-Holland are combining our efforts. By working together we aim to facilitate the collaboration between research institutes, scientists, people living with HIV, healthcare providers and companies to accelerate the development of an HIV Cure. We call on researchers and private parties, such as bio-technology companies, medical devices companies, medical technology enterprises, ICT/ data analysis enterprises and pharmaceutical companies. With this call we mobilise two million euro for HIV Cure research.

Part 1: General information

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<tr>
<th>General information</th>
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<tr>
<td><strong>Submit deadline</strong></td>
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<td><strong>Expected date deadline rebuttal</strong></td>
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<td><strong>Expected date of decision</strong></td>
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<td><strong>Start date project</strong></td>
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<td><strong>Project budget including co-financing</strong></td>
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<tr>
<td><strong>Project duration</strong></td>
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What are we looking for

We are looking for high quality research projects which will significantly contribute to a cure for people living with HIV. Projects should be a complementary and effective collaboration¹ in a consortium consisting of at least one Dutch public knowledge institute and at least two private enterprises. International collaboration with research institutes or private enterprises are welcome.

What you can apply for

In this call applicants can apply for scientific research grants for public-private partnerships aiming at HIV cure. A maximum project budget of €2,000,000 can be submitted, lower budgets are welcome too. Depending on the type of research this will result in maximum €1,200,000 PPP allowance and €100,000 Aidsfonds contribution for the research institute. Co-funding from private parties and research institutes are mandatory (see paragraph ‘funding model’). With the funds available two Public Private Projects can be funded.

Projects must ultimately start before September 1st 2019 and end before September 1st 2022. This end date is not adjustable or negotiable. Not meeting the end date requirements will have financial consequences.

¹ ‘effective collaboration’ means collaboration between at least two independent parties to exchange knowledge or technology, or to achieve a common objective based on the division of labour where the parties jointly define the scope of the collaborative project, contribute to its implementation and share its risks, as well as its results. One or several parties may bear the full costs of the project and thus relieve other parties of its financial risks. Contract research and provision of research services are not considered forms of collaboration.
Who can apply
The applicant (project leader) must work for a widely recognised Dutch institute for scientific research, and should be a PhD scientist in the relevant discipline.

How to apply
Research proposals for the 2018 grants round need to be submitted via the online application form. Sending a copy by mail or e-mail is not necessary.

The complete application needs to be submitted no later than October 30, 2018, 12:00 noon. If you have any questions about your application or the application process, please contact us by e-mail before the deadline has passed at research@aidsfonds.nl and include your telephone number. If you have questions about the PPP-allowance or budget, please contact Laila El Aziz, via Aziz@health-holland.com or 070-3475440. We will aim to respond as quickly as possible. After the submittal deadline, incomplete or otherwise incorrect applications received will be declared inadmissible.

We kindly request you to take note of the admissibility criteria, as they will be applied strictly.

Admissibility criteria
• The applicant (project leader) must work for a widely recognized Dutch institute for scientific research, and should be a PhD scientist in the relevant discipline.
• An applicant is allowed to be part of an application only once, either as project leader or participant or collaborator. In cases where a person is listed on more than one application, the application we receive first will be taken into consideration, the others ignored.
• The project should consist of at least one Dutch institute for scientific research and at least two private enterprises.
• The proposal and budget must be in accordance with the rules and regulations of the PPP-Allowance.
• Commitment for co-financing must be present.
• The project must be aimed at a cure for HIV.
• The application must be written in English with exception of the specific questions in Dutch.
• The application must be submitted via the online application form, including all the mandatory documents and before the given deadline.
• The applicant has to agree with and meet the Aidsfonds conditions for submitting a grant (NL: https://aidsfonds.nl/media/1249/af_subsidievoorwaarden.pdf) excluding art. 7.

What should be submitted
• Application form including: general information applicant, scientific information and patient participation information; (see example) Submitted through the online portal only! online application form.
• Budget form (see budget form and https://www.health-holland.com/public/downloads/match/costs-systematics-nl.docx)
• Letters of commitment for consortium partners; for explanation see Appendix 1
• The consortium agreement and the laymen project information are provided for your information. These will only be required following a positive funding decision. (see form 'laymen information')
Part 2: Assessment procedure

See appendix 2 for the assessment criteria.

Eligibility assessment
In consultation with the chair of the Scientific Advisory Board and Health–Holland, Aidsfonds assesses the eligibility of the proposals for further assessment based on the admissibility criteria.

External advice
Applications that are eligible for further assessment will be send out for external advice. (Parts of the) applications will be reviewed by (international) scientific external referees and by people living with HIV. In addition a and a budget check for PPP regulation by Health–Holland will be done. We aim for a minimum of two and a maximum of four referees per application.

Rebuttal
The applicant has the opportunity to submit a rebuttal and - if needed - a revised budget form in response to the anonymized review reports and comments on the budget.

Advice to Aidsfonds
The quality of the review reports will be assessed by the Advisory Board after the rebuttal has been received. The Advisory Board is free to divert from the reviewer’s assessments.

- The Advisory Board weighs and internally discusses the applications, making use of the application, reviewer reports, rebuttals, Aidsfonds’ previous experiences with the applicants, the aim of this call, and Aidsfonds’ and Health–Holland’s organizational strategies.
- The Advisory Board may invite (a selection of) applicants to present their project. The applicants will be informed at least 30 days before the date of presentation.
- The Advisory Board will formulate a grant advice and submit this to the Executive Director of Aidsfonds.

Funding decision
- Based on the advice of the Advisory Board, the Executive Director of Aidsfonds decides whether an application is eligible for funding. In principle, the Board of Directors of Aidsfonds has discretionary power to decide which proposals will be funded.
- Health–Holland will evaluate whether the fundable projects are in compliance with the PPP-Allowance regulation.
- Aidsfonds and Health–Holland will decide collectively which projects are funded.
- Each applicant will receive an email about the decision taken.
- The signed consortium agreement has to be submitted no later than July 1st 2019.
Part 3: Funding model

A Public Private Project Grant awards up to € 1,200.000PPP allowance from Health–Holland and 5% contribution by Aidsfonds for the research institute for a research period of up to 3 years. Aidsfonds applies the Health–Holland cost systematics and budget form to calculate grant budgets. Use the Budget Sheet to indicate the project costs and the individual in kind and in cash contributions by the participants. The PPP-Allowance and Aidsfonds contribution can only be used to cover costs of the public knowledge institutes in the Public-Private Project. Private enterprises have to account for their own costs.

The following minimal contributions are required.

- In all cases private enterprises have to account for at least 25% of total project costs. Depending on the size of the enterprise this contribution can be in cash or in kind. (see application form appendix A)
- In case large companies have a major contribution and interest in the project, 2/3rd of their contribution needs to be in cash.
- At least 10% of the total project costs have to be contributed by the knowledge institutes in cash or in kind. This contribution is allowed to be 100% in kind. The remaining costs of the activities at the knowledge institutes can be funded by Aidsfonds contribution.
- Part of your budget may be used for communication, implementation and end-users participation (max 5% of project budget).

<table>
<thead>
<tr>
<th>Example fundamental research project costs: €800,000</th>
<th>Amount in Euro’s</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Subsidy: PPP-Allowance (fundamental research)</td>
<td>480,000</td>
<td>60%</td>
</tr>
<tr>
<td>Subsidy: Aidsfonds contribution</td>
<td>40,000</td>
<td>5%</td>
</tr>
<tr>
<td>Minimal contributions private enterprises</td>
<td>200,000</td>
<td>25%</td>
</tr>
<tr>
<td>Minimum contribution knowledge institute (in kind or cash)</td>
<td>80,000</td>
<td>10%</td>
</tr>
<tr>
<td>Total</td>
<td>800,000</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Example Industrial research project costs: €800,000</th>
<th>Amount in Euro’s</th>
<th>Percentage</th>
</tr>
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<tr>
<td>Subsidy: PPP-Allowance (fundamental research)</td>
<td>400,000</td>
<td>50%</td>
</tr>
<tr>
<td>Subsidy: Aidsfonds contribution</td>
<td>40,000</td>
<td>5%</td>
</tr>
<tr>
<td>Minimal contributions private enterprises</td>
<td>200,000-280,000</td>
<td>25%-35%</td>
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<tr>
<td>Minimum contribution knowledge institute (in kind or</td>
<td>80,000 - 160,000</td>
<td>10%-20%</td>
</tr>
<tr>
<td>cash</td>
<td>Total 800,000</td>
<td>100%</td>
</tr>
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**Budget requirements**
The amount of PPP-Allowance that can be used to fund a specific activity depends on the research type of that activity. Health-Holland distinguishes three types of research:

- **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. This allows for a maximum of 75% allowance.
- **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. This allows for a maximum of 50% allowance.
- **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 allows for a maximum of 25% allowance.

Activities not belonging to these research types cannot be part of the project. In case of doubt which research type applies, we refer to the Frascati manual of the OECD, specifically chapter 2 and for information of the calculations we refer to Kaderbesluit nationale EZ-subsidies, Hoofdstuk 4, artikel 10-14.

The following maximum PPP-Allowance funding percentages apply to the research types. The research phase of each individual work package (WP) must be indicated in the proposal and in the budget sheet. A work package (WP) must fall within 1 research type. If a WP to your opinion contains several research phases, this WP needs to be divided into separate WPs for each research type.

**Criteria relating to in-kind co-funding**
For commitment of material resources, charge the cost price. Commercial rates are not accepted.
For commitment of equipment, take previous depreciation and intensity of use into account.
Commitment in the form of supplies of services are possible only if the service can be itemized as an identifiable new endeavour. The service should not already be available at the knowledge institute(s) realizing the research. Research leaders may wish to claim services already supplied (such as a database or software) as in-kind co-funding. Acceptance is not automatic in such cases. Please contact Aidsfonds if such a case arises. Further consultations will take place to decide whether a specific value can be determined for this supply of services.

**NOT permissible as co-funding**
Co-funding from direct or indirect (NWO, KNAW) government funding (‘subsidiestapeling’) is not allowed.
The PPP-Allowance and Aidsfonds contribution cannot be used to buy or contract products or services among the participating organizations, to prevent improper mixing of funding and contributions.
Discounts on (commercial) rates for materials, equipment and/or services, for example do not count as co-funding.
Costs relating to overheads and/or participation in a user or advisory committee cannot be regarded co-funding.
Health–Holland requires a yearly financial report and a final report accompanied by an auditor’s report. The relevant forms and auditor’s instructions will be distributed timely by Aidsfonds/Health–Holland. Cost of the auditor’s report is non-fundable and will be borne by the organization the Project Leader is affiliated to.

Part 4: Consortium Agreements, Data Sharing and Intellectual property rights (IPR)

- After a Public-Private Project Grant has been awarded, the participants must sign a Consortium Agreement between themselves. Templates for the Consortium Agreement are provided by Health–Holland.
- Public-Private Project participants must comply to Open Access publishing and FAIR data principles. Participants must strive for rapid and wide availability without restrictions of research data resulting from research funded by the Public-Private Project Grant. Data availability may be delayed as a consequence of procedures for protection of intellectual property rights (IPR). A Data Sharing Plan is part of the Consortium Agreement.
- Public-Private Project participants agree to undertake any activities related to or beneficial to the project, including the application of a patent or the use of an awarded patent in a manner which serves the general welfare, which includes timely access to affordable medicines. Public-Private Project participants agree to include this obligation in any agreements it enters into with third parties related to the results of the project in the form of a perpetual clause (kettingbeding).
- IPR protection is handled using ownership-follows-inventorship principles.
- Transfer of ownership of IPR has to take place according to market conditions and must be in compliance with the EU Framework for State aid for research and development and innovation and the PPP-Allowance regulation.
- Opportunities and plans for IPR protection resulting from the Public-Private Project research must be reported to Aidsfonds.

Part 5: Specific aspects to consider in comparison to regular Aidsfonds grants:

- Public-Private collaboration offers great opportunities, but also brings complexities in the specific agreements that need to be drafted and signed. Please make sure all participants are aware of the rules and regulations regarding the agreements that need to be signed, as well as publication and Intellectual Property rights (IPR) and transfer thereof.
- Since this call is a collaboration between Aidsfonds and Health–Holland, distributing the contribution by the ministry of Economic Affairs and Climate, through PPP-Allowance that was granted to the Top Sector Life Sciences & Health for the stimulation of Public-Private Partnerships, specific requirements apply for proposals submitted in this call, e.g. specific requirements regarding ultimate start and end dates, financial reporting and agreements that need to be in place before the start of the project. These are comparable to other funding instruments of the Ministry of Economic Affairs and Climate, but more stringent than the requirements of regular Aidsfonds calls.
- The proposal and budget must be in accordance with the rules and regulations of the PPP-Allowance.
- Please be aware that the Aidsfonds Grant Application Regulations and Health–Holland/Aidsfonds terms and conditions are non-negotiable.
- Health–Holland has the final decision on compliance with PPP-allowance regulation.
Important documents:
- PPP-Allowance regulation (Regeling van de Minister van Economische Zaken van 11 juli 2014, nr. WJZ / 13125043, houdende vaststelling van nationale subsidie-instrumenten op het terrein van Economische Zaken (Regeling nationale EZ-subsidies)), with special attention to chapter 3.
- Aidsfonds conditions for submitting a grant. (NL: https://aidsfonds.nl/media/1249/af_subsidievoorwaarden.pdf)
- Aidsfonds grants terms and conditions
- Aidsfonds organisational strategy 'No Time to Lose'

Regulations Health–Holland
- PPP-Allowance regulation
- Definities Onderzoek & ontwikkeling uit het EU Steunkader
- Kaderregeling betreffende staatssteun voor onderzoek, ontwikkeling en innovatie
- Regeling nationale EZ-subsidies
- Kaderbesluit nationale EZ-subsidies
- TKI-toeslagregeling Staatscourant 2016
Appendix 1: Letters of commitment

The consortium must supply letters of commitment of all participants with the full proposal. Aidsfonds advises project leaders to ensure that the co-funders pay particular attention to endorsing the importance of the proposal for their operations. The letter of commitment should satisfy the following requirements.

A. General requirements
Letters of commitment must be printed on the letter paper of the participant.
Letters of commitment are addressed to the project leader.
Letters of commitment must be written in English.
The address of the project leader on the letter is correct.
Letters of commitment must be signed by an authorised signatory.

B. Specific requirements
Brief description of the participant and the core business (type of organization, size, which service, products). A statement that the participant is interested in and will commit itself to the research.
An explanation as to why the answering of the research question is important to the participating organization. How does this solution fit in their strategy?
A brief explanation as to why this particular research group and research proposal are receiving support.
What the participating organization will contribute in concrete terms, what activities will be performed, what materials or what type of cash will be contributed (incl. capitalization in man-hours and euros) and why this fits in organization activities (e.g. the research proposal/planning or end-users activities).
Further specification of the in-kind support, both hours (number and/or tariff applied) and if applicable materials (numbers; cost price; tariff; percentage that can be attributed to the project, etc.).
A statement that the participant provides the contribution described without additional conditions.

C. Declaration and signing by the participants
The participant states that it has read the proposal and signs for this.
Letters of commitment are unconditional and do not contain any opt-out clauses.
The amounts stated in the letters of commitment must correspond to the amounts stated in the budget presented.
A copy or scan of the letter will suffice for the submission of a proposal.
Appendix 2: Assessment criteria

With this call we aim to accelerate the development of an HIV Cure by encouraging collaborations between research institutes, scientists, people living with HIV, healthcare providers and private companies.

The following aspects play a role in the assessment process:

A. Research aim rationale
   Scientific relevance: Why is this research relevant for scientific progress?
   Societal relevance: Why is this research relevant for people living with HIV?
   Quality of the theoretical framework: Is the theoretical framework and the subsequent research aim sound?
   Innovation potential: To what extent is the research question innovative, timely and exceptional for the field of research, and could accelerate the development of an HIV Cure?

B. Project specification
   Feasibility: The research needs to be able to answer the research question at the end of the project. Feasibility thus also includes: quality of the work plan, adequacy of the method, realistic planning, identification of risk factors, and efficient staffing and budget for the duration of the project.
   Quality of the applicant: This includes the expertise and potential of the applicant and the surrounding research group. The quality of projects that received grants previously from Aidsfonds might be taken into consideration as well.
   Involvement and value for People living with HIV (see appendix 3 for ‘beoordeling ervaringsdeskundigen’)
   Knowledge transfer and implementation: This includes a.o. the dissemination and implementation of the results. E.g. How the applicant sees his/her role in the process to ensure knowledge transfer and implementation to the development of an HIV Cure.

C. Relevance for Aidsfonds and Health–Holland
   This includes relevance with the aim of this call and Aidsfonds' organizational strategy. It also includes urgency of the topic considering the Dutch (research)situation to make a difference for HIV cure and the diversity in proposed researches might play a role in the grant advice of SAB.
**Appendix 3: Beoordeling ervaringsdeskundigenpanel**

Het ervaringsdeskundigenpanel beoordeelt op relevantie voor de eindgebruiker en betrokkenheid van eindgebruikers bij de opzet, uitvoering en implementatie van het project.

**Beoordelingscriteria ervaringsdeskundigenpanel**

- **Relevante voor de doelgroep**
  Denk hierbij aan:
  - Sluit de onderzoeksvraag aan bij de behoeften van patiënten en/of hun naasten (nu of in de toekomst)?
  - Verbetert het de zelfredzaamheid (autonomie) van patiënten?
  - Verbetert het de kwaliteit van leven van patiënten?
  - Is het resultaat praktisch bruikbaar voor patiënten?
  - Draagt het bij aan verlenging van de verwachte levensduur?
  - Verbetert de kwaliteit van zorg voor patiënten en/of hun naasten (nu of in de toekomst)?
  - Zijn de uitkomstmaten relevant voor patiënten?
  - Zijn de resultaten (indien positief) naar verwachting goed te implementeren in de praktijk?

- **Relevante voor de Maatschappij**
  Denk hierbij aan:
  - Verbetert het onderzoek de maatschappelijke participatie van patiënten?
  - Draagt het bij aan een betere preventie?
  - Draagt het bij aan een betere diagnostiek?
  - Draagt het bij aan de beheersing van de kosten in de gezondheidszorg?

- **Risico’s voor de deelnemers**
  Denk hierbij aan:
  - Wordt in de aanvraag beschreven wat de risico’s voor deelnemers zijn?
  - Zijn de risico’s voor de deelnemers aanvaardbaar?

- **Belasting voor deelnemers**
  Denk hierbij aan:
  - Is de belasting voor de deelnemers duidelijk omschreven?
  - Is de belasting van het deelnemen aan het project aanvaardbaar?

- **Haalbaarheid van het onderzoek**
  Denk hierbij aan:
  - Denkt u dat dit onderzoek uitvoerbaar is?
  - Verwacht u dat er voldoende patiënten willen deelnemen?
  - Vindt er voldoende samenwerking plaats met relevante disciplines of partijen?

- **Betrokkenheid eindgebruikers**
  Denk hierbij aan:
  - Wordt in de aanvraag beschreven hoe (organisaties van) (eind)gebruikers meedoen in het project? Zo nee, is de toelichting, waarom dit niet gebeurt, voldoende? Zo ja, wordt deze groep naar uw mening voldoende betrokken?
  - Worden (organisaties van) (eind)gebruikers betrokken tijdens de uitvoering van het project?
  - Zijn de betrokken (organisaties van) (eind)gebruikers representatief voor de doelgroep?
  - Vindt er relevante terugkoppeling aan de (eind)gebruiker plaats over de resultaten van het onderzoek?
  - Is eindgebruiker participatie opgenomen in de begroting?
Communicatie
Denk hierbij aan:
  o Worden de studiedeelnemers voldoende geïnformeerd over de voortgang en resultaten?
  o Worden de resultaten gedeeld met (toekomstige) patiënten buiten de studie en/of met het publiek?