



Swiss Confederation

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Innosuisse and the Federal Office of Public Health





Call for R&D Project Proposals Switzerland – the Netherlands

Cell and Gene Therapy Towards Clinical Practice

Call opening on 12 February 2024

Online matchmaking platform opens on 12 February 2024 Online information webinar 22 March 2024 (12:00-13:00 CET) Visit of Swiss Biotech Day, Seminar & Matchmaking Event 22-25 April 2024 Submission Project Outline by 5 June 2024

Recommendations sent to applicants by mid-June 2024

Submission of Full project proposal by 25 September 2024 Funding decisions communicated November 2024 Project start at latest by 1 March 2025

EUREKA is an international co-operation programme supporting collaborative market oriented research and development projects that develop innovative products, processes and services. It is a decentralised network facilitating the coordination of national funding on R&D&I, the driving force of innovation in Europe for almost 40 years. Switzerland and the Netherlands collaborate continuously among the over 45 EUREKA member states and support all innovation topics with suitable EUREKA instruments (EUREKA Network-, EUREKA Cluster- and Eurostars projects).

Switzerland and the Netherlands are jointly announcing a bilateral call for project proposals. The call is managed in line with the EUREKA initiative (www.eurekanetwork.org) by the national EUREKA offices Innosuisse and Netherlands Enterprise Agency, in cooperation with the Federal Office of Public Health (Switzerland) and the Dutch Top Sector Life Sciences & Health (Health~Holland).

Background bilateral cooperation

The Netherlands and Switzerland have excellent healthcare systems and are both renowned for their innovation ecosystems, notably in the field of life sciences and health. Both countries have the ambition to strengthen bilateral cooperation and build a strategic partnership between both life sciences innovation ecosystems. By combining the strengths of both ecosystems, we can increase the success of our research and development communities, while leveraging economic opportunities for enterprises small and large, and most of all, creating societal impact with accessible and affordable healthcare.

As a concrete step in building a strategic relationship, a high-level strategic round table took place on March 20, 2023, focussing on 'cell & gene therapies'. After this round table session, both countries decided that this is an innovative and pioneering field to expand the bilateral cooperation. We need to join forces in order to tackle the existing hurdles within the field of cell & gene therapies.

Background thematic area

Untreatable diseases such as genetic disorders, rare diseases and cancer create an urgent need for innovative therapeutic approaches. These diseases have a significant impact on both patients and their environments and also result in an economic impact on society. Moreover, improving existing treatments is proving challenging, especially in cases where conventional drugs fall short. The need for safer, more effective and more personalized treatments is becoming increasingly evident. Cell and gene therapies can contribute to meet this need.

The present call for project proposals is connected to the Dutch-Swiss long-term strategies in health and care laid down in The Federal Council's health policy strategy 2020–2030 and the Biomedical research and technology masterplan 2022-2026 in Switzerland, and the Dutch Knowledge & Innovation Agenda (KIA) on Health and Care 2024-2027 and ambitions of expertise centre Future Affordable and Sustainable Therapy development (FAST) in the Netherlands.

Switzerland and the Netherlands strive for a small number of complementary and high-impact R&D projects. Therefore, both countries encourage and support the forming of appropriate interdisciplinary **public-private consortia** including key stakeholders and specialised organisations and the proper experimental contexts in both countries.

Scope

The call aims to promote knowledge sharing and allows for rapid technological advances in gene and cell therapy and new approaches in stakeholder engagement. Projects should, where applicable, bring together a broad range of healthcare stakeholders — including manufacturers, academia, payers, providers, and patient advocacy groups — to facilitate innovative solutions and mitigate the fragmentation of gene and cell therapy research efforts.

The primary focus of this call will be on stimulating **public-private partnerships** in **translational research and clinical development of cell and gene therapies**. The emphasis is on making these therapies not only **clinically effective** but also **sustainable** and **affordable**. Recognizing the industry-wide challenge of reducing regulatory obstacles, the goal is to expedite the process of cell and gene therapy development, ensuring faster, sustainable, and cost-effective therapies reach the market.

Public-private partnerships will help expand access to capital, stronger engagement, broader sharing of data, accelerated translational research, and support for the development of improved manufacturing and processing technologies. Moreover, a wide network of stakeholders spanning different geographies will facilitate long-term post-marketing surveillance efforts to monitor real-world efficacy and adverse events and support a broader understanding of the benefits and risks of gene and cell therapies.

The project can explore a diverse range of topics within the following areas (list is not exclusive):

- *Manufacturing and supply chain challenges:* Addressing issues related to the efficient production and distribution of advanced therapies, ensuring scalability and accessibility.
- Innovations in gene editing: Exploring novel approaches to gene editing technologies, enhancing precision, safety and efficacy.
- Enhancing personalized therapies: Developing strategies to tailor therapies on an individual basis, ensuring a more personalized and effective treatment approach.
- Gene therapy delivery innovations: Investigating advanced delivery systems such as liquid nano particles, to improve the targeted and efficient delivery of gene therapies.
- Integration of data, AI and software models/simulations/strategies: Implementing innovative data-driven and artificial intelligence solutions to enhance the cell and gene therapy R&D process. This includes identifying and accessing appropriate patients (stratification) and establishing long-term monitoring strategies for clinical research.

Participation and application

The call is set up in 3 steps:

1. Information, matchmaking and project building

The quality of the project and consortium is essential for its success. The organisers recommend to register the profiles of interested parties on the online B2match platform 'Connecting the Dutch and Swiss Life Sciences Ecosystems'. The platform offers a marketplace, where project ideas, cooperation offers or requests etc. can be exchanged with the ambition to find synergies, cluster and select and integrate project ideas. This interactive platform is the starting point of co-creating project proposals for high impact R&D projects and remains open for the whole duration of the call process until 25th of September 2024.

Online information webinar, Friday 22 March 2024, 12:00 - 13:00 CET

All interested in bilateral R&D collaboration are invited to join the online information webinar. Innosuisse, Health~Holland and Netherlands Enterprise Agency organise a sone-hour information session to explain call details. The agenda and registration will soon be available on the B2Match portal 'Connecting the Dutch and Swiss Life Sciences Ecosystems'.

Seminar "Cell and Gene Therapy Towards Clinical Practice", Basel, Thursday 25 April 2024
All relevant stakeholders are invited to participate in the seminar and matchmaking event in Basel, to share insights and explore the possibilities for Swiss-Dutch collaboration. There is ample opportunity for pitches, partnering and project building, within the context of this bilateral call and other schemes like Eurostars and HHINT Kickstarter. This seminar is part of the Dutch innovation mission to Switzerland, linked to the Swiss Biotech Day. The agenda and registration will soon be available on the B2Match portal 'Connecting the Dutch and Swiss Life Sciences Ecosystems'.

2. Submission project outline by Wednesday 5 June 2024, 12:00 (CEST)

NL-CH consortia are encouraged to draft a project outline fitting the scope of this call before 5th of June 2024, 12:00 (CEST). The completed project outlines should be submitted to the national EUREKA offices, Innosuisse and Netherlands Enterprise Agency. Application details can be found below. The outlines will be screened by the two EUREKA offices and Health~Holland. Consortia will be provided with detailed feedback and most promising projects are invited to prepare (adjusted) full project proposals. If applicable, applicants can be invited to integrate their project with other submitted initiatives. If necessary, applicants receive recommendations on which of the other (EUREKA) funding mechanisms best/better fit their project idea.

3. Submission full project proposal by Wednesday 25 September 2024, 12:00 (CEST)

After feedback on the project outlines, consortia are invited to submit a full proposal and apply for funding before September 25, 2024, 12:00 (CEST). The full project proposals should be submitted to the national EUREKA offices, Innosuisse and Netherlands Enterprise Agency. Application details can be found below. The proposals are evaluated by Health~Holland (supported by Netherlands Enterprise Agency) and Innosuisse based on their national funding criteria and conditions.

Financing

Funding support to approved full project applications will be given to each partner by its own national funding organization in accordance with the national laws, rules, regulations and procedures in effect.

- In the Netherlands, Health~Holland has allocated a budget of € 2.000.000.
- In Switzerland, Innosuisse has allocated a budget of € 2.000.000

Eligibility

In order to apply for this call, applications must meet the following EUREKA and national eligibility criteria:

- The R&D project must fit the scope of the call;
- The R&D project fits within the Dutch societal challenge 'Health & Care', as outlined in the Knowledge and Innovation Agenda (KIA) 2024-2027;
- The R&D project fits within the Swiss Federal Council's health policy strategy 2020-2030;
- The consortium includes at least two independent partners from Switzerland, one knowledge institute and one (for-profit) enterprise, and two independent partners from the Netherlands, one knowledge institute and one for-profit enterprise;
- In the project activities, there must be a technological risk involved (industrial research and/or experimental development TRL4-TRL7);
- The project must be directed at researching or developing a (set of) product(s), process(es) or service(s);
- The project must benefit all project partners in a well-balanced consortium and the project is significant to the health strategies in both countries involved;
- The project has an obvious advantage and added value resulting from the cooperation between the participants from the different countries (e.g. increased knowledge base, commercial leads, access to data, R&D infrastructure, etc.);
- Collected and/or generated data should comply with the FAIR principles. Data and code used and/or developed in the project should be shared and accessible for all consortium partners.
 A data management and stewardship plan is mandatory (drawn up if the application is awarded for funding);
- The project must start by March 1st, 2025, at the latest. The duration of the project may not exceed 36 months.

On national level, additional eligibility criteria may apply. Applicants are strongly advised to inform the national contact point and check if additional national eligibility criteria are applicable.

A signed consortium agreement on the execution of the project and the commercialisation of the project results is mandatory before the actual start of the project. The consortium agreement should include, amongst others, the ownership and use of the know-how and IPR agreements. Project partners should take appropriate measures to protect intellectual property rights arising from the cooperation projects under the framework of this call and in line with national legislations and international agreements in force. A final concept version of the consortium agreement must be submitted by January 31, 2025, at the latest.

Evaluation criteria

International EUREKA criteria

- Impact
 - o Is the market properly addressed (i.e. size, access and risks)?
 - Is the value creation properly addressed (i.e. employment opportunities and environmental and societal benefits)?
 - What are the competitive advantages of your project (i.e. strategic importance, enhanced capabilities and visibility)?
 - Are your commercialisation plans clear and realistic (i.e. return on investment, geographical and sectoral impact)?

Excellence

- What is the degree of innovation? (i.e. is the proposed product, process or service state-of-the-art? Is there sufficient technological maturity and risk)?
- o How is the new knowledge going to be used?
- o Is your project scientifically and technically challenging for consortium partners?
- o Is the technical achievability and risk properly addressed?
- Quality and efficiency of implementation
 - What is the quality of your consortium (i.e. balance of the partnership and technological, managerial and financial capabilities of each partner)?
 - o Is there added value through international cooperation?
 - Is your project management and planning realistic and clearly defined (i.e. methodology, planning approach, milestones and deliverables)?
 - Is your cost structure reasonable (i.e. costs and financial commitment for each consortium partner)?

Health~Holland (with support of Netherlands Enterprise Agency) and Innosuisse carry out a full evaluation (performed by the national project coordinator and technical experts) according to national rules before allocating funds to successful applicants.

Additional criteria CH and NL

The project partners should demonstrate:

- Complementary technological and societal excellence and qualifications;
- Strong base of partnership and aim for continuing collaboration even beyond the project duration;
- Management ability to successfully carry out the project and implement the results;
- Mutual advancement of R&D through the transfer of knowledge and expertise.

Application procedures

Project outline, submission deadline Wednesday 5 June 2024, 12:00 (CEST)

- Consortia have to submit a Project Outline, which can be downloaded from Innosuisse and Netherlands Enterprise Agency websites, and the B2Match portal 'Connecting the Dutch and Swiss Life Sciences Ecosystems'. The form must be completed in English. Swiss partners add a simplified Innosuisse application form to the Joint Call document (download from Innosuisse website).
- The completed project outlines should be submitted to the national EUREKA offices simultaneously **by email** to Innosuisse (eureka@innosuisse.ch), Health~Holland (tki@health-holland.com) and Netherlands Enterprise Agency (teamiris@rvo.nl), with copy to all partners of the consortium. Submission deadline is June 5, 2024, 12:00 (CEST).
- The project outlines will be screened by the two EUREKA offices and Health~Holland. Consortia will be provided with detailed feedback within the shortest possible delay after the submission (about 2 weeks). Qualified consortia will be invited to submit a full project proposal. If applicable, applicants can be invited to integrate their project with other submitted initiatives. If necessary, applicants receive recommendations on which of the other (EUREKA) funding mechanisms best/better fit their project idea.

Full project proposal, submission deadline Wednesday 25 September 2024, 12:00 (CEST)

- The completed full proposals must be submitted by 25 September 2024, 12:00 (CEST) as follows:
 - International EUREKA project form: Eureka Smart Simple
 All partners must complete the online Eureka project form. The form must be completed in English.
 - National applications: In parallel to the completion of the Eureka project form, all project partners are required to submit a related national funding application to their respective funding agencies, taking into account all relevant procedures and submission rules described in the chapter "National funding conditions". More detailed instructions will be communicated with the invitation to submit a full project proposal.
- The full project proposals will be evaluated by Innosuisse and Health~Holland (with support of Netherlands Enterprise Agency). Preliminary national evaluation results will be discussed during consensus meeting. Based on the national evaluation results both funders will agree which projects to approve and recommend for funding. Final results are expected within 10 weeks after submission deadline.

National funding conditions

Switzerland

Swiss consortia members apply for funding at Innosuisse according to the following rules:

- Minimum project consortium of 1 implementation partner and a Swiss research entity
- Maximum of 70 % of the total Swiss project costs to be covered by Innosuisse
- Funding rate for Swiss partners: start-ups and SMEs up to 50%, large companies up to 25%, research institutions up to 100% of total eligible costs

Eligible costs

- Personnel costs (salaries + employer's contribution to social security)
- Material costs
- Costs for project-related contracts with third parties
- Coordination costs (management of the consortium)
- Travel costs (covers international visits to project partners)

Requirements

- Development of innovative products, solutions, processes or services
- Sound risk mitigation strategy
- Innovative project content
- Added-value of international cooperation
- Clear project plan and realistic timelines

Netherlands

Dutch consortia members apply for funding at Health~Holland according to the following rules:

- The consortium consists of at least one for-profit enterprise and at least one Dutch research organisation.
- Research organisations and Small and Medium-sized Enterprises (SMEs) registered in the Netherlands are eligible for funding. The funding provided by Health~Holland depends on the type of organization and type of research. Research organizations may fund up to 70% of their own costs with PPP Allowance in case of industrial research, and up to 60% of their own costs in case of experimental development. Dutch SME's may fund up to 60% of their own costs in case of industrial research and up to 40% of their costs in cash of experimental development. See Table 1 for a summary.

Max % PPP allowance based on eligible costs partner	Industrial research	Experimental development
Research organisation	70%	60%
Dutch SME	60%	40%
Large enterprises, non-Dutch SMEs, Dutch and non-Dutch other parties	0%	0%

- For this call, Health~Holland requires a minimum of 15% (in case of industrial research) and 30% (in case of experimental development) contribution of project costs of (for-profit) enterprises in the consortium. This contribution can be in cash and/or in kind.
- Projects fit within the societal challenge 'Health & Care', as outlined in the <u>Knowledge and Innovation Agenda (KIA) 2024-2027</u>, and the objectives of the regulation.
- The project covers industrial research, experimental development, or a combination thereof. A description of the types of research is provided on the Health~Holland <u>website</u>.
- Effective collaboration takes place. The project will be realised at joint cost and risk and all consortium partners will make a substantive contribution to the project.
- The research is of a qualitatively high level and the innovative products and services are deliverables that have an added societal and economic value.
- The research project benefits the Dutch knowledge infrastructure and economy.
- Dutch companies get the right to exploit the project results in their specific business area. The project must start by 1st of March 2025, at the latest. The consortium agreement must be submitted by 31 January 2025, at the latest.

Please note!

The complete and detailed funding conditions for full project applications can be found on the respective websites of Innosuisse and Health~Holland, shortly after call launch.

Contact

Switzerland

Innosuisse (www.innosuisse.ch):

- Call management: Ms. Colette John, +41 58 466 77 32, colette.john@innosuisse.ch
- Submission project outline form: eureka@innosuisse.ch
- Matchmaking platform: Mr. Nicolas Lentze, +41 58 469 07 59, <u>nicolas.lentze@innosuisse.ch</u>

The Netherlands

Netherlands Enterprise Agency (www.rvo.nl/eureka):

- Call management and matchmaking platform: Mr. Niels van Leeuwen, +31 (0)6 52 56 33 10, niels.vanleeuwen@rvo.nl
- Submission project outline form: teamiris@rvo.nl

<u>Health~Holland</u> (<u>www.health-holland.com</u>):

- Call management: Ms. Jolande Zijlstra, +31 (0)6 24 92 68 82, zijlstra@health-holland.com
- Call management: Ms. Annebel Hendrix, +31 (0)6 18 61 18 38, hendrix@health-holland.com
- Submission project outline form: tki@health-holland.com