



Invitational call

Creating infrastructure for cardiovascular registry-based research in the Netherlands

*a fast lane for effective
treatment of heart failure*

A joint call by the Dutch Heart Foundation and ZonMw
(Rational Pharmacotherapy Program)

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1. ACCELERATING RESEARCH INTO CLINICAL PRACTICE

Cardiovascular registry-based research

Our healthcare system is changing. The number of patients with chronic cardiovascular diseases is increasing enormously. In the next ten years the number of people with a cardiovascular disease (CVD) in the Netherlands is estimated to increase by 30%. If nothing is done, seven million people will suffer from a chronic disease in 2030, of which nearly two million will be chronically ill due to CVD. In order to ensure that improvements in healthcare keep pace with this increase, it is necessary to accelerate the process from research studies to new treatments and to evaluate the (cost)effectiveness of existing treatments.

The changing healthcare system also has an impact on the research environment, both thematically and methodologically. For instance, it becomes more and more common to re-use data from clinical care for research purposes. These data are also referred to as *real-world data* to indicate that it concerns clinical data instead of data gathered in an experimental/controlled setting.

Patient registries are often used for real-world data research. Registry-based research is a relatively new type of research that has some important benefits in studying patients and healthcare (interventions). It can be used to address various relevant clinical questions, for instance, on the safety and (cost)effectiveness of drugs and medical devices in real-world use for which equipoise exists. It also helps evaluating the impact of clinical decision support tools on physician decision making and actions on patient care (e.g. guideline adherence). Registry-based research has various benefits compared to more traditional research methods: 1. efficient and targeted recruitment of patients for clinical trials; 2. reducing the burden of data collection and reporting; 3. accelerating time to market of new treatments; 4. contributing to cost-effective medicines and treatments; and 5. more affordable compared to more traditional research methods.

A good example of a high quality patient registry are SwedeHeart and SwedeHF, in which clinical data are collected from patients with acute coronary syndrome who are treated in Swedish hospitals. These data can also be connected to other registries and biobanks. For researchers this is a fantastic source of data for their research projects and it gives Sweden a huge head start on certain topics compared to countries that lack such an infrastructure.

In 2014, the first national cardiovascular research agenda, initiated by the DHF, was developed together with the patients, healthcare professionals, scientists, volunteers and donors of the Dutch Heart Foundation. In this research agenda priorities for solutions on specified diseases were described, as well as the infrastructure that is needed to realize these. There was an explicit aspiration for a high quality national infrastructure for registry-based research, starting with heart failure and arrhythmias. This enables to study the (long-term) effectiveness of treatments in patients that are difficult to include in traditional research studies, such as multimorbid elderly patients with heart failure. It also accelerates the availability of promising treatments into practice.

The establishment of the Netherlands Heart Registration in 2017 was an important step in achieving this ambition. The growing number of cardiovascular patient registries in the Netherlands provides a fruitful base for registry-based research in our country. The next step is creating a good-working research infrastructure that builds upon the Netherlands Heart Registration structure to enable research within the Dutch CardioVascular Alliance (DCVA).

With this invitational call, ZonMw and the Dutch Heart Foundation (DHF) as partners in the Dutch CardioVascular Alliance (DCVA) give cardiovascular (healthcare) professionals and researchers the opportunity to create a national infrastructure for cardiovascular registry-based research, including ethical, legal, financial and methodological aspects. Thematically, this call is related to the treatment of heart failure patients. With special attention for patients with preserved ejection fraction. This brochure is a result of meetings between ZonMw and the DHF. It is developed based on numerous fruitful discussions with partner organisations of the Dutch CardioVascular Alliance and stakeholders in the field.

Better treatment for patients with heart failure with preserved ejection fraction

In 2014, the first national cardiovascular research agenda, initiated by the DHF, was developed together with the patients, healthcare professionals, scientists, volunteers and donors of the DHF. This resulted in the following five research priorities:

1. [Earlier recognition of cardiovascular diseases](#)
2. [Cardiovascular disease in women](#)
3. [Better treatment of heart failure and arrhythmias](#)
4. [Acute treatment of strokes](#)
5. [New ways to keep up a healthy lifestyle](#)

One of the themes on this national research agenda is to have better treatment for patients with heart failure, so they can live with fewer symptoms and the accelerated ageing of their heart is slowed or even halted.

Heart failure is a chronic heart disease that requires lifelong treatment with medicines. In the Netherlands alone, around 242.000 people live with heart failure and are registered by general practitioners. This number is expected to increase to an estimated 342.000 by 2030. Heart failure causes an enormous and increasing disease burden, for patients as well as society. Patients with heart failure often struggle with symptoms like fatigue, shortness of breath and fluid accumulation in the body. Patients with heart failure take different kinds of medicine for a long time and must be admitted to hospital due to exacerbations often. This also makes heart failure an expensive condition. The annual cost for heart failure in the Netherlands is estimated at 800 million euros. The multitude of complications and its chronic course lead to a decrease in the quality of life. But in the first place, heart failure is a life-threatening disease with a very poor prognosis: around 60% of the patients die within 5 years of their first admission to hospital for heart failure.

A significant percentage of the patients with heart failure are elderly patients with multiple morbidities (such as patients with heart failure with preserved ejection fraction), and this proportion will continue to increase. There is currently not a single treatment for this group of patients that has been proven to be effective in improving the patient's prognosis. The thematic focus of this call therefore is to build an infrastructure to facilitate future research on this specific group of patients.

Research is needed that leads to widely accessible treatments for heart failure patients in the near future. A fundamental approach to reach this goal is to get better insight in the 'real-life' population of heart failure patients, and the relation between atrial fibrillation and heart failure to guide future clinical trials designs. Developing a registry-based infrastructure for research on heart failure (and atrial fibrillation) is an important goal of the national cardiovascular research agenda.

2. INVOLVED PARTNERS

Dutch Heart Foundation (DHF)

The DHF adopted the research agenda in her policy and goals for the upcoming years. By recognising cardiovascular diseases in an early stage and better treatment, we can significantly reduce the increasing disease burden. To work together with partners on this ambition, the DHF initiated the Dutch CardioVascular Alliance (DCVA).

Netherlands Organisation for Health Research and Development (ZonMw) | Program Rational Pharmacotherapy (Goed Gebruik Geneesmiddelen)

ZonMw funds health research in the Netherlands and promotes the use of the knowledge in healthcare practice. ZonMw promotes health research and healthcare innovation throughout the entire knowledge chain: from fundamental research to implementation through various funding programs. With regard to this project, ZonMw collaborates within the context of the funding program Rational Pharmacotherapy (Goed Gebruik Geneesmiddelen). This program is aimed at research on how existing medication can be used safer and more (cost) effectively, for example through personalised treatments, lower or shorter dosing or research into whether a cheaper alternative is just as effective. In addition, medication can be tested for groups where manufacturers do not or do very limited research, including rare diseases, pregnant women, children and the elderly. Also, research by healthcare organisations is being funded with the aim of improving pharmacotherapeutic care, e.g. where it concerns medication adherence or polypharmacy. This always concerns transcending social questions that contribute to the general public interest in improving the quality, affordability and accessibility of care in the Netherlands that are not addressed by the market. For example, this may be because from a financial point of view the market has no interest in addressing this. Market forces thus generate negative factors for society and inhibit positive factors that society can benefit from.

ZonMw is founding partner of the Dutch CardioVascular Alliance. In 2016, ZonMw Rational Pharmacotherapy and the DHF signed a collaboration agreement to work together to contribute to better pharmacotherapeutic treatment of heart failure and arrhythmias.

Dutch CardioVascular Alliance

In 2018, the Dutch CardioVascular Alliance (DCVA) was established by leading organisations representing patients, academia, cardiovascular healthcare professionals, and government. The DCVA builds onto the 'CardioVasculair Onderzoek Nederland' (CVON) initiative in which the cardiovascular field started with creating long term collaboration between the best cardiovascular researchers at a national level in the most promising research areas in the Netherlands. Consortia, funded within the DCVA initiative, are committed to solve important healthcare problems and are by nature multidisciplinary and translational.

The alliance is committed to reduce the cardiovascular disease burden by 25% in 2030 by earlier recognition of disease and rapid translation of excellent science into health improvement. The DCVA will contribute to the national cardiovascular research agenda by focussing on early detection of disease. This will reduce the number of chronic patients, prevent recurrence and counter the growth of healthcare costs by detecting cardiovascular disease before irreversible damage has occurred.

In five pillars, the DCVA contributes to the societal impact of cardiovascular research by aligning research policies, providing funding and support for valorisation and implementation, improving data infrastructure, and invest in talent development.

Since DHF and ZonMw are both founding partners of the DCVA, the newly granted national consortium will become part of the DCVA community. Therefore, the DCVA guidelines will be followed. For the latest version of the guidelines, please consult the [website](#) of the DCVA. In addition, it is expected that the consortium actively contributes to the aims of the DCVA and is encouraged to make use of its services and support.

3. PURPOSE/OBJECTIVES

With this project, the DHF and ZonMw aim to achieve the following goals:

1. to create a national and sustainable infrastructure for cardiovascular registry-based research, focused on heart failure. This infrastructure includes a framework/structure for the governance, and the ethical, legal, financial and methodological factors. It builds upon the national heart failure registry administrated by the Netherlands Heart Registration (NHR) and links with other relevant (NHR) registries and data sources.
2. to have a *proof of concept* of the infrastructure by conducting:
 - observational, longitudinal research on the whole spectrum of heart failure patients (including patients with a preserved ejection fraction) in the Netherlands
 - prospective interventional research on pharmacotherapeutic treatment in chronic heart failure patients, with a focus on multimorbid elderly patients with severe heart failure.

4. PROJECT OUTLINE

4.1 National consortium and partners

Initiators

The DHF and ZonMw appointed two initiators who will bring together national expertise on this topic for the consortium and coordinate the project proposal: dr. Dennis van Veghel (director of the Netherlands Heart Registration) and prof.dr. Folkert Asselbergs (professor of cardiology, UMC Utrecht). The initiators are appointed based on an application procedure by the DCVA. Details on the requirements of the initiators are described in the procedure for the appointment of initiators. This procedure is available at the DHF upon request.

Consortium partners

The cardiovascular registry-based research consortium is an inclusive, multidisciplinary group of national experts. The consortium consists of representatives of at least the Netherlands Heart Registration, Werkgroep Cardiologische centra Nederland (WCN), Dutch Society of Cardiology (NVVC) working group heart failure, and researchers/methodologists with expertise in (cardiovascular) registry-based research and/or heart failure.

Advisory committee

For the governance of this project an advisory committee is set up that consists of representatives of the following organisations: Nederlandse Vereniging voor Cardiologie (NVVC), Harteraad, DCVA, DHF and ZonMw.

User committee

Relevant stakeholders that are not part of the consortium are involved via an user committee. This committee advises the consortium on infrastructural aspects, 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 proposed composition of the committee. We advise to reach out to the envisioned user committee members already at an early stage. 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 Harteraad for more information about patient participation. More information about the use of user committees can be found on the [website](#) of the DHF. Please also take note of our [user committee guidelines](#).

4.2 Project

The main focus of the project is creating sustainable infrastructure for cardiovascular registry-based research in the Netherlands. The project consists of different coherent work packages that involve infrastructure and (clinical) research.

Infrastructure

Regarding infrastructure, the project includes (at least) the following activities:

- establishing the governance for registry-based research within the DCVA
- developing sustainable funding strategies for the maintenance of the infrastructure and future research projects
- reducing the data registration burden in the hospitals by - although not exclusively - improving automatic data-retrieval
- developing and implementing a procedure for acquiring informed consent and for the storage of the informed consent forms
- a detailed plan using the obtained insights to improve the quality of care, including the implementation of the NVVC guideline regarding heart failure

Additional infrastructural requirements:

- the project contributes to the significant increase of the number of registered patients and participating hospitals in the heart failure (and atrial fibrillation) registry administered by the Netherlands Heart Registration. At the end of the project at least half of the hospitals offering care for heart failure patients are involved, and >5000 heart failure patients are registered
- data are linked with general practitioners registries (aiming for coverage across the Netherlands). It is also recommended to involve other relevant data sources, as long as these are relevant for the Dutch situation
- the project develops solutions for several infrastructural gaps described in the DCVA roadmap 'registry-based research'

Research projects

The project also includes different research projects aimed at better pharmacotherapeutic treatment for heart failure patients, fitting within the scope of the ZonMw Rational Pharmacotherapy Program:

- project 1 concerns a project for acquiring national data on the profile of heart failure patients in the Netherlands, the status quo of heart failure treatment and NVVC guideline adherence. These data will be updated annually for a period of 4-5 years to keep track of the changes over time.
- project 2 involves a registry-based randomized clinical trial (or trials) (RBRCT) aimed at better pharmacotherapeutic treatment of heart failure patients with multi morbidities, such as heart failure patients with a preserved ejection fraction. A proposal for the outline and planning of this study will be submitted along with the overall project proposal on May 18th; the deadline for the specific details of the study is November 2nd 2021. The initiators will have monthly meetings with DHF and ZonMw about progress and feasibility of this study proposal.

Additional requirements:

- contribute to the treatment of the overall group of heart failure patients in an early stage and/or decrease of disease progression, and
- contribute to at least two of the following goals: a) decreasing disease burden, b) improving health and c) better cost-effectiveness for the care of heart failure patients

5. CRITERIA AND CONDITIONS

There are criteria and conditions for the involved personnel and the project in general.

5.1 Who can apply?

A research proposal can only be submitted by a Dutch research organisation or by a Dutch healthcare institution where research expertise is available. For this subsidy call, no subsidy will be awarded if this leads or can lead to the granting of unauthorized state aid. When undertakings apply for a subsidy within this subsidy round, ZonMw provides the subsidy under SGEI Exemption Decree¹, provided that the conditions are met (Exemption Decree for services of general economic interests).

For a more detailed explanation of state aid, its consequences and for the definitions of a research organisation and healthcare institution, please refer to the legal aspects in Appendix 6. Legal aspects.

5.2 Leadership

Initiators

The DHF and ZonMw appointed two initiators, based on an application procedure, who will bring together national expertise on this topic for the consortium and coordinate the project proposal. The initiators can also have an active role within the consortium, for instance as a consortium leader.

Consortium leaders

Two or three consortium leaders are appointed. At least one leader fits into the profile of infrastructural leader and at least one fits into the profile of clinical research leader. For the consortium leaders the following criteria and conditions apply:

- expertise with the Netherlands Heart Registration registries
- active role in the Dutch CardioVascular Alliance
- inspiring and binding capacities and able to oversee all activities of the consortium
- responsible for the performance and collaboration of the consortium
- a paid position throughout the entire duration of the project
- shown capable of leading a project of comparable size and complexity
- capability to attract additional funding
- will ensure the consortium contributes in a sustainable way to the research field, until a minimum of three years after this grant has finished

Leader with infrastructural expertise

- broad methodological experience in the field of cardiovascular registry-based research
- will manage the infrastructural part of the consortium

¹ Commission Decision 2012/21/EU on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest, (20th December, 2011), (C(2011) 9380)

Clinical research leader

- broad experience in the field of cardiovascular registry-based research
- will manage the research part of the consortium
- has an excellent track record, evident (inter)national reputation and has the potential to successfully face European competition (e.g. ERC advanced/consolidator level)

Workpackage leader

- responsible for a clearly defined part of the consortium objectives and is leading a work package
- a paid position throughout the entire duration of the project. If not, specific details must be supplied of what measures will be taken to deal with this
- must be capable of making/guaranteeing agreements on behalf of the institute/organisation where she/he is employed (probably in consultation with the head of the department)
- has a proven track record and reputation in relation to the specific workpackage

5.3 Project

There are some additional conditions applicable to this project:

- the research project must fit within the strategy of the DHF, ZonMw Rational Pharmacotherapy Program and DCVA.
- the duration of the project is four to five years
- the project starts within six months after the written grant allocation has been sent
- the project cannot study specific brands of medicines or treatments
- the budget provided by ZonMw and DHF is not allowed to be used for research on regulatory requirements by (pharmaceutical) companies

6. BUDGET

For this project, the DHF and ZonMw provide the following budget: max. €2.6 million for the project itself, consisting of a) approximately 1.6 million for the creation of infrastructure and maintenance of the heart failure registry administrated by the Netherlands Heart Registration and b) approximately €1 million for the thematic research projects (personnel and material costs)

The justification of the budget is part of the assessment of the proposal.

Some additional requirements for the budget:

- allocate budget for *all* activities described in the project proposal (e.g. communication, implementation, participation of the user committee). If no budget is allocated, please describe how the consortium plans to acquire budget for this
- allocate 2.5% of the budget for collaborative DCVA talent and networking activities, such as the DCVA annual conference
- allocate 7.5% of the budget for activities related to talent development, such as conference meetings and training on relevant topics

Other (private) organisations (e.g. pharmaceutical companies, health insurance companies, EMR software developers, and companies within the Life Science and Health) are encouraged to co-fund the consortium. If applicable, we expect that these organisations support the project by providing the studied medicine(s) and/or placebo.

7. POINTS OF ATTENTION

7.1 Open Science

Open access publications

All articles resulting from the project are published open access, preferably in an open access journal. Find out more on our policy on open access [here](#).

Reuse of data

- Data sharing: researchers are required to share their data to contribute to future, innovative research. Data should also be findable, accessible, interoperable and reusable (FAIR). See also [FAIR data](#).
- Data management: include a detailed description in the proposal how the acquired data of the research projects 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 consortium will be asked to hand in a Data Management Plan (DMP). For instructions on what you need to do for data management, please read [FAIR data and data management](#).
The DMP is considered to be a dynamic document and will also be used to monitor progress on data management.
- Research registration: the research projects need to be registered before the start of the projects in a (inter)national register, such as <http://www.clinicaltrials.gov>.
- The consortium provides metadata in support of the [DCVA data catalogue](#).

The project must address differences in cardiovascular disease between men and women in both sex and gender. 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. Apart from sex and gender differences, also consider other aspects of diversity, e.g. age, social background, ethnicity, in all activities of the consortium and describe them in the proposal.

7.2 Implementation plan

Implementation strategy

Applicants develop a strategy outlining how results of the clinical study will be implemented in daily clinical practice. The DHF and ZonMw stimulate 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 create fast tracks in this domain. Expertise and collaboration are key to develop and implement novel preventive and other therapies. Describe a strategy of how to implement new knowledge in cardiovascular healthcare practice. This strategy includes describing who will be involved, what the role of the user committee is, 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 implementation@dcvalliance.nl.

8. SUBMISSION OF PROPOSAL

The DHF is the coordinating organisation for this grant on behalf of ZonMw and DCVA. The proposal should be submitted via research@hartstichting.nl and needs to be written in English. Deadline for the project proposal is May 18th 2021, 14.00 hrs.

Funding will be administrated by ZonMw. Therefore, after approval, the proposal also needs to be submitted to ZonMw. Monitoring of the project will be coordinated by DHF.

Consortium building

DHF and ZonMw ask the initiators to keep them updated on the progress of building the consortium. This can be communicated via the contact person of the DHF: Mira Staphorst (m.staphorst@hartstichting.nl, 070-3155659).

Project proposal

On submission we expect the following documents:

- application form with necessary appendices (Appendices 2 and 3)
- budget sheet (Appendix 4)

Please note: upon submitting a proposal all project partners accept the funding conditions. Two weeks before the committee meeting we expect the submission of the amended consortium agreement.

9. REVIEW PROCEDURE

9.1 Eligibility check

After submission of the proposal, the DHF and ZonMw do an eligibility check:

- is the application in line with the purpose of the call?
- has the consortium correctly addressed all elements in the application and the budget?
- are all principles of the DHF, ZonMw and DCVA included in the application?
- is the application eligible in terms of the format used?

If the application is not eligible but can be amended on short notice, the DHF and ZonMw invite the applicants to amend the application within five working days. After the first check is done and if the application is eligible, the application will be sent to the assessment committee.

9.2 Evaluation by the assessment committee

The proposal will be reviewed by an assessment committee that involves representatives of the program committee (ZonMw Rational pharmacotherapy), the International Scientific Advisory Committee (DHF) and the Committee Societal Quality (CSQ) of the DHF.

Members of the committee will give scores to the proposal based on the assessment criteria (Appendix 1). The evaluation is done in writing and the applicant will be given the opportunity to react to the comments (rebuttal). The final discussion and qualification will be done in principal through a meeting, either live or by videoconference, by the committee where the applicants are invited to present their proposal.

9.3 Code of Conduct on Confidentiality and Conflicts of Interest

To ensure a fair assessment and transparency for researchers, the DHF and ZonMw use 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, DHF and ZonMw officers. The full text of the code of conduct on conflicts of interest is available [here](#) (in Dutch).

10. DECISION PROCESS

The assessment committee will advise whether the project is eligible for funding. With scores ranging between very good to excellent the consortium will be eligible for funding. With lower scores and/or serious doubts about (parts of) the proposal the committee can advise not to fund the proposal. The management board of the DHF and ZonMw decide on the allocation of funds, based on the advice of the assessment committee. If the proposal is eligible for funding, but not enough funding is available, the funding decision will be refused. The final approval is based on the grant allocation (subsidiebeschikking) and the [ZonMw subsidy requirements](#). The project should be started within six months after approval.

11. POST DECISION PROCESS

11.1 Objection procedure

Since funding is the administrative responsibility of ZonMw, the objection procedure of ZonMw is applicable. If you have a specific complaint about the DHF, you can submit [this form](#) to the DHF.

11.2 Consortium agreement

After granting, the consortium partners must sign a consortium agreement (CA) containing paragraphs on IP, organisational and publication arrangements. The CA becomes part of the grant allocation (subsidiebeschikking). The CA must be submitted two weeks before the committee meeting. A template is attached (Appendix 5), the text is amendable.

ZonMw reserves the right, when awarding the grant, to request a final draft (approved by the partners, but not yet signed) of the CA to assess it for compliance with the European law on state aid and ZonMw's general grant terms and conditions.

The signed CA must be submitted to the DHF office before the start of the project. The consortium is obliged to start within 6 months after approval. If not, the funding can be withdrawn. If applicable, approval by a formal medical ethics board (METC) is needed before the start of the clinical study.

11.3 Sponsor agreement

If the consortium is co-funded by other organisations, a sponsor agreement is needed. See appendix 6. Legal aspects for more details.

12. TIMELINE

Appointment initiators	7-11 december 2020
Final brochure available	29 January 2021
Deadline submission proposal	18 May 2021, 14.00 hrs
Eligibility check	28 May 2021
Adaptation of proposal (if applicable)	11 June 2021
Peer review committee	25 June 2021
Interview	Mid July 2021
Final decision	End of Augustus 2021 (or mid December 2021 if adaptation of proposal is needed)
Deadline start project	1 March 2022 (or July 2022)
Proposal prospective study/studies	2 November 2021, 14.00 hrs

13. CONTACT

For further information, please contact

- Mira Staphorst (DHF): M.Staphorst@hartstichting.nl, 070-3155659
- Hubert de Leeuw (DHF): H.deLeeuw@hartstichting.nl, 070-3155519
- Mariëlle van Avendonk (ZonMw): Avendonk@zonmw.nl, 070-3495464

APPENDICES

- Appendix 1. Assessment criteria
- Appendix 2. Application form
- Appendix 3. Instructions for application form
- Appendix 4. Budget sheet
- Appendix 5. Template Consortium Agreement
- Appendix 6. Instructions Template Consortium Agreement
- Appendix 7. Legal aspects
- Appendix 8. Socially responsible licensing