

# Regulations



## VIB Grand Challenges Program Regulations

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#### 1 Scope

#### 1.1 Art. 1. Scope and applicability

- §1 These regulations apply to the Grand Challenges Program of VIB (VIB-GCP).
- §2 These regulations explain:
- the general regulations that apply when applying for and participating to the VIB-Grand Challenges Program (VIB-GCP)
- any Funding schemes applied by VIB-GCP
- possible budget shifts during the project lifetime
- the preparation of the intermediary and final reports
- §3 A practical guide for preparing a VIB-GCP project application and any additional information can be obtained from the VIB-Grand Challenges Office.

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#### 2 Background

#### 2.1 Art. 2. General considerations

- §1 Pursuant to definitions within Title III, chapter I of the Decree of 30 April 2009 on the organization and financing of the science and innovation policy and Art. 16 of the Management Contract with the Flemish Government for the period 2017-2021 for the financing of a translational program, the Flemish Government provides a subsidy to support the Grand Challenges Program of VIB.
- §2 All provisions of the Management Agreement concerning the VIB-GCP decision apply, as well as any amendments, additions or substitutions made or to be made thereto and any implementation measures taken or to be taken by the VIB Board of Directors under the aforementioned decisions.

#### 2.2 Art. 3. Objective VIB-GCP

- §1 The objective of the VIB Grand Challenges Program is to significantly increase the societal impact of VIB, hence taking its scientific leadership to the next level of global visibility, while keeping to its formula of success of a bottom-up, excellence driven institute.
- §2 The Grand Challenge Program aims to structurally support translational and/or disruptive research programs around a specific 'Grand Challenge'. To this purpose the VIB-GCP thematic areas are linked to the challenges as defined by the United Nations in their 17 sustainable development goals (http://www.un.org/ sustainable development/sustainable-development-goals/) and more importantly Zero Hunger, Good health and well-being, climate action.
- §3 More specifically the following 5 thematic areas derived from these challenges:
- #1: innovative biomarkers: precision medicine will be improved by translation innovative molecular diagnostic paradigms into clinical practice
- #2: innovative treatments: precision medicine will be improved by translating new insights in molecular mechanisms of disease into clinical practice
- + #3: targeted treatment strategies: disease that prove difficult to target with classic drug delivery technologies, can be addressed using innovative treatment strategies



- #4: epidemic control: pathogen epidemics will be controlled of new molecular insights are translated to health and prevention policies
- #5: sustainable agriculture: the sustainability of agriculture can be significantly improved by translating new molecular insights and technologies into practice
- §4 Projects only qualify for a grant under the VIB-GCP program if each of the following mandatory conditions are met:
- impact in science and society on a global scale
- trans-disciplinary by definition
- multi-PI collaboration by necessity and
- beyond VIB borders by default.

#### 3 **Definitions**

- Applicants: the Partners jointly preparing a research project to apply for funding within the VIB-GCP.
- VIB-GCP Project Agreement: an Agreement between the VIB and other Partners, in which the modalities for funding are defined and the specifications for the performance of the Project and the parties' mutual rights and obligations are arranged.
- Multi-stakeholder Advisory Board: a group of different stakeholders that might have interest in or benefit from the VIB-GC project.
- Non-VIB Project Partner: a Partner not belonging to a VIB Center
- Partners: the parties to the VIB-GCP Project Agreement.
- Project Progress Group: a group of delegates from each Partner that meets on a monthly basis to discuss progress of the Project.
- Project Budget Plan: a detailed statement outlining estimated project costs to support the VIB-GCP project, including all the personnel and direct costs required to carry out the project objectives during the project timeline.
- Project Timeline: the duration of the project starting on the Start date and ending on the End
- Project Work Plan: a detailed Gantt chart depicting tasks, deliverables and milestones of the
   Project, and the roles and responsibilities of Partners
- Project Budget Plan: a detailed outline of the proposed cost structure for the project.
- Start/End Date: as defined in the VIB-GCP Project Agreement.
- VIB-GCP: the VIB Grand Challenges Program.
- VIB-GCP Project Steering Board: a group of delegates from each Partner that meets quarterly
  to discuss and decide on matters linked to the Project plans, Budget plans, progress and
  financial reports.
- VIB Project Partner: the VIB-GCP Project partner belonging to a VIB Center.
- VIB Promotor-spokesperson: the VIB scientific director in charge of the VIB-GCP project.



#### 4 General Principles when applying for VIB-GCP funding

#### 4.1 Art. 4. Applicants

- §1 VIB is not a granting body. At launch of an (internal) VIB-GCP call, the scientific directors of the VIB research centers are expected to explore their networks (and beyond) to identify partners which have complementary expertise, knowledge and technology to that of the respective research center and which will be required for the successful execution of a Grand Challenges project.
- §2 VIB PI's take the lead: Grand Challenges projects must originate specifically from VIB PI's (no non-VIB PI's can submit projects) and must go through a pre-selection at the level of the VIB research center, with involvement of the scientific director(s) of the center(s) involved.
- §3 A project application with concrete objectives is to be proposed by VIB PI's whereby the assembly of a VIB-GCP Consortium is the result of an iterative (reverse translation) process starting from VIB expertise and toolbox and complemented by non-VIB groups who provide the necessary complementary discipline, expertise, access to knowhow and materials, etc. not available within VIB.
- §4 PI's apply as a consortium (through the VIB scientific director); not as single PI's; VIB scientific directors coordinate the application from their research center. VIB PI's cannot participate in more than 1 project at the same time. Every scientific director can apply (in the name of the consortium) for only 1 project per call.
- Potential actors to collaborate with VIB within the VIB-GCP are Flemish research centers, such as e.g., partner universities of VIB, academic medical centers, agricultural research centers and strategic research centers. In addition, collaborations with international research centers and actors is possible, if required for the proper execution of the project.

#### 4.2 Art. 5. Governance of running VIB-GCP Projects

- VIB will appoint the Promotor-spokesperson (or formal delegate) of the VIB-GCP project to overview the proper execution of the project. The promotor-spokesperson acts as representative and spokesperson of the consortium vis-à-vis VIB and ensures the coordination of the activities of the allocated project support and the reporting on the project.
- §2 If the project is approved, all parties involved shall conclude a VIB-GCP Project Agreement.
- §3 All correspondence with the VIB-GCP occurs via the Promotor-spokesperson as responsible spokesperson.
- §4 For each VIB-GCP project, a Multi-stakeholder Advisory Board will be set up aiming at consultation rounds with different stakeholders that might have interest in or benefit from the VIB-GC program. Such consultation round will be held at least once over the project lifetime or in preparation of a project application. The involvement of the Stakeholders will allow leveraging the societal impact of the VIB-GCP projects.

#### 4.3 Art. 6. Third parties

In a project, the implementation of specific operational subtasks may also be outsourced to subcontractors. In this capacity, companies can also participate in a VIB-GCP project. These will always be routine tasks, without any innovative/creative input.

#### 5 Budget and cost model, payment and justification, funding grant

#### 5.1 Art. 8. Generally applicable principles cost model



- §1 The maximal project budget is 2.500.000 euros, and the project duration 3 years (with a maximum one year (no-cost) extension), depending on the Project Work Plan defined. The support percentage amounts to 100% of the accepted projects costs. Maximum 50% of the funding is to be allocated to VIB groups and minimum 50% to non-VIB groups.
- §2 The cost model uses real costs. For the project application, this means that the cost estimated must be as realistic as possible, based on the Project Work Plan. A project application is only admissible when it has been prepared in accordance with the modalities set out in the Budget and cost model.
- §3 For the intermediary reporting and the final settlement (see Reporting modalities article 15), acceptable costs are real costs that must be capable of being justified. These costs must be assignable to the project with the final aim to complete the proposed Project Work Plan.

#### 5.2 Art. 9. Description of the different cost categories

The budget plan should be predefined and final before the start of the project to avoid administrative burden of transfer of budgets between VIB-GCP partners (VAT rules, overhead).

Budget categories may contain (for both VIB and non-VIB partners):

#### A. Direct staff costs

- staff of VIB should be allocated to the partim VIB budget;
- staff of non-VIB partners should be allocated to the non-VIB partim budget.
- §1 The calculation of the staff costs of the various project employees is based upon actual salary costs, hence based on fixed salary categories (e.g., MD, researcher, technician, study nurse, data nurse, data manager).
- §2 The acceptable staff costs are calculated for all (knowledge-acquiring or valorization preparing) staff directly involved in the execution of the project and pro rata applied according to the actual time dedicated to the project execution.
- §3 Staff costs can be justified throughout the contractually defined project period. The number of days/hours in a person-year may correspond to the organization's own approach.

#### B. Direct other costs

- §1 The other costs must be real costs and related to the project. The total admissible amount for other costs is determined during the evaluation of the project application. In the case of purchases that are not related exclusively to the project, a reasonable allocation key must be used.
- §2 Typical examples of direct other costs are:
  - costs for consumables and raw materials, for resources, for the consumption of tools, etc.
  - IT costs including user licenses for project specific applications
- §3 The portion of indirect other costs (overhead) is fixed at 14%.



#### C. Costs estimated for services via VIB Core facilities (VIB-CF)

- §1 Costs estimated for services at the VIB-CF need to be specified in the project application.
- §2 It is possible to have all VIB-CF services ordered by the VIB Partner (for VIB and non-VIB partners), to avoid external invoicing.
- §3 VIB-rates apply for VIB-CF services provided to the VIB-GCP-project.

#### D. <u>Cost shifts during the implementation</u>

- §1 The project budget plan is to be finalized before the start of the project and will be attached as an Annex to the VIB-GCP Project Agreement.
- \$2 Shifts within the budget of a given Partner, VIB OR non-VIB, is allowed if required for the execution of the VIB-GCP Project. These shifts need to be clarified in the intermediary and final reporting. Any additional cost that is resulting from these shifts or transfers are to be covered by the non-VIB Partner and cannot be withheld from the VIB-GCP budget.
- §3 Shifts between budgets of non-VIB and VIB Partners are to be avoided. Exceptional shifts during the Project execution, must be requested in advance and substantiated by actual figures (old versus new situation). All parties involved must sign the request. After approval by VIB-GCP Office, an addendum to the contract containing the adapted budget will be drawn up. The payment schedule will be adjusted accordingly. The total accepted Project budget may not be exceeded.

#### 5.3 Art. 10. Payment – Justification

- §1 The Cost model of the Grand Challenges Program applies.
- §2 The payment schedule for the partim VIB and non-VIB budget is defined as follows (see also Annex 1, table 2):
  - 2 advance payments are paid to the VIB-GCP Project Partners throughout the duration of the VIB-GCP project as specified in the VIB-GCP Project Agreement:
    - 50% at the start of the project (including 14% overhead)
    - o 40% after intermediary reporting (including 14% overhead).
    - upon approval by VIB of the final report (see Reporting modalities art. 15), a balance of maximum 10%.
- §3 After signing of the VIB-GCP Project Agreement, an invoice can be issued to VIB by the non-VIB Project Partner to initiate the transfer of funding under the regime of transfer of subsidies ("stelsel doorstorting van subsidies"), which is free of VAT.

#### 5.4 Art. 11. Funding grant

- §1 VIB awards a grant in the form of a maximum amount and under the condition that the regulations are scrupulously and consistently adhered to.
- §2 The grant may only be used for the financing of the project.
- §3 Personnel and direct costs can be justified during the term of the agreement signed by the respective parties for the implementation of the project.

#### 6 Agreement

#### 6.1 Art. 12. VIB-GCP Project Agreement

In the case of a positive decision by the Board of Directors, a VIB-GCP Project Agreement is drafted by VIB in which the modalities for funding and the mutual rights and obligations of the Partners are arranged with respect to the Project. A form of VIB-GCP Project Agreement is attached hereto as Annex 2.



- §2 The Partners must furnish the signed VIB-GCP Project Agreement to the VIB-GCP within six months of approval of the Project by VIB.
- §3 Any animal tests/patient studies/studies on patient/volunteer material under the project shall not be started until all required approvals have been obtained from the ethics committee(s)/regulatory authorities for the respective animal tests/patient studies/studies on patient material. If amendments are made to the protocol for these studies that again require the approval of an ethics committee/regulatory authority, the amended protocol shall not be started up until these new approvals have been obtained. A copy of any approval of an ethics committee/regulatory authority must be submitted to the VIB-GCP.

#### 6.2 Art. 13. Review procedure project applications

- §1 After the submission, VIB-GCP administratively assesses whether the project applications are formally eligible based on the following criteria:
- The project application was submitted via GCProgram@vib.be and was received within the deadline;
- Each applicant from the consortium meets the definition of research center;
- The project application includes a research proposal which positions itself within the objective of the VIB-GCP call (see Call text and Guidelines for applicants); and hence meet the following criteria:
  - o thematic fit
  - o translational
  - trans-disciplinary
  - o multi PI
  - budget plan: ratio VIB/non VIB
- The project application is written in English to allow for its assessment by international experts;
- The project application includes a detailed project budget prepared in accordance with the cost model.
- §2 The project proposals, fitting these requirements will be sent out for peer review.
- §3 The VIB-GCP guidelines for external revision apply to External experts and the Institutional Advisory Board.
- §4 Project review will be timed with new Project Call launches to compare new proposals to running projects in terms of potential impact.
- §5 Irrespective of the review procedure, the Board of Directors may make a negative decision or set additional conditions spurred by the failure to meet additional obligations or authorizations imposed by the authorities.

#### 7 Monitoring and Reporting

#### 7.1 Art. 14. Monitoring of running projects

- §1 Running projects will be stringently reviewed before mid-term of the project and near end date of the project, leading to different options:
- Project continued, i.e. the second advance payment (40%) or final payment (maximum 10%) can be initiated following the modalities as described under Art. 10.
- Project stopped, i.e. no continuation of the funding (40% and final 10%)



- Detailed reporting timeline and flowchart are added to Annex 1.
- §2 According to the budget available new calls could be launched, by which new projects could be accepted.
- S3 During these new calls, most promising running projects (before mid-term or upon completion of the Project), for which excellent performance and results were demonstrated and that successfully achieved their aims, could apply for continuation during a next VIB-GCP call, in competition with new proposals. Accordingly, projects could additionally be funded with 1.25-2.5 M€ on top (in competition with new proposals).
- §4 Running projects (before mid-term or upon completion of the project) will hence be evaluated head-to-head with novel project proposals ideas submitted.

#### 7.2 Art. 15. Reporting Modalities

- §1 The follow-up by the VIB-GCP is to a large extent based on trust and correct and timely reporting (see also articles 13, 14 and 150f the Regulations).
- §2 The progress of VIB-GCP projects is closely monitored via monthly VIB-GCP Project Progress Group meetings and quarterly VIB-GCP Project Steering Board meetings as described in the VIB-GCP Project Agreement (Art. 2).
- §3 Formal reporting in addition is needed to assess the deployment of means and the progress (Project Work -Plan, deliverables and budget), as stipulated in the VIB-GCP Project Agreement, because the partim grant payments (at intermediary reporting 40% and at final settlement 10%) are linked to the proper progress of the project.
- §4 All VIB-GCP Project Partners shall prepare and the Promotor-spokesperson will coordinate:
  - an intermediary report on the project before mid-term of the project, date specified in the VIB-GCP Project Agreement depending on the final project work plan agreed upon
  - a final report of the project (at the latest 2 months after completion of the project) on the proper execution and progress of the project
- §5 The intermediary report (before mid-term of the project) consists of:
  - an intermediate financial report giving a detailed overview of the expenditure (staff, direct costs) of the relevant preceding grant month(s)
  - an intermediate project progress report giving a detailed overview of the overall research results of the project
  - a report on the societal impact of the project results: i.e. a detailed overview of the status of the valorization, utilization and outreach deliverables of the project
- §6 At the latest 2 months after completion of the Project: a final report indicating the outcome of the project (research results).
- §7 The VIB-GCP Project Partners will follow VIB guidelines for reporting, which may include the use of VIB-GCP templates for reporting.
- §8 All VIB-GCP Project Partners are equally responsible for timely reporting. For each VIB-GCP consortium the Promotor-spokesperson of the VIB-GCP project will combine the project application and the subsequent reporting.
- §9 The final financial reports are signed by the head of the Finance department of the VIB-GCP Project Partner to confirm that the necessary controls have been carried out. They certify the financial report to be "true and accurate".



§10 All reports should be submitted through GCProgram@VIB.be

§11 A report will in principle be evaluated by the expert panel that evaluated the initial application (IAB), unless otherwise specified.

#### 8 Project findings

#### 8.1 Art. 16. Use of findings

- §1 VIB will take the lead in commercializing Project Results and consults with the Partners with respect to commercialization, all as further set out in detail in the VIB-GCP Project Agreement.
- §2 The VIB-GCP project consortium commits to exploit the project findings as broadly as possible to achieve maximum added value and societal impact. To that effect among other things, outreaching, by the project consortium and supported by the VIB-GCP Program manager, to a broad stakeholder group, including by organizing knowledge dissemination and fundraising activities, is a must.

#### 9 Notification - Publication

#### 9.1 Art. 21. Outreach

Outreach and communication is expected from all VIB-GCP partners, to stimulate visibility and societal impact.

Any communication, publication or publicity by the host institution and its employees, relating to the project or the project findings shall refer to the VIB-GCP project grant, preferably including the following elements:

- Formal acknowledgement of VIB support:

This project has received funding within the Grand Challenges Program of VIB. This VIB Program received support from the Flemish Government under the Management Agreement 2017-2021 (VR 2016 2312 Doc.1521/4).

- A link to the VIB-GCP website
- VIB and partner logos

#### 9.2 Art. 22. Registration clinical trials

If a supported proposal includes a clinical trial, this study should be registered in an appropriate database for clinical trials (e.g., <a href="www.clinicaltrials.gov">www.clinicaltrials.gov</a>).

#### 10 Suspension, revision and recovery of the grant

#### 10.1 Art. 23. Suspension - revision of grant

§1 VIB-GCP can revise, suspend or recover the grant in accordance with the terms of the VIB-GCP Project Agreement.

#### 11 Responsible research, scientific integrity, liability

#### 11.1 Art. 25. Principles of responsible research

- §1 Project activities under the VIB-GCP need to comply with the principles of responsible research, in particular:
- They need to comply with applicable law.
- They need to be performed in a way that does not compromise the health of the worker, human health, or the environment.



- They need to be performed while applying high standards of quality and integrity.
- They need to deal with ethical issues responsibly.
- §2 To this end, the non-VIB partners shall apply integrity policy standards comparable to the standards of VIB (http://www.vib.be/en/about-vib/organization/Pages/Responsible-VIB-Research.aspx) in conformity with the elementary rules of behavior laid down in the Ethical Code for scientific research in Belgium (2009) and the European Code of Conduct for Research Integrity, and other deontological declarations and protocols.
- §3 As far as ethical issues relating to their research are concerned, researchers are required to strictly comply with all relevant legislative provisions at European and national level.
- In addition, they must carefully consider any other ethical issues that may be raised by their research. In doing so, they shall act in accordance with responsible research practices as laid down in, amongst others, the Ethical Code for scientific research in Belgium (2009) and other deontological declarations and protocols.
- §5 Researchers undertake to conduct their research in a rigorous and independent manner and to faithfully publish the results.

#### 11.2 Art. 26. breaches of scientific integrity

- §1 Procedure for breaches of scientific integrity
- The administration of the non-VIB Project Partner is required to inform VIB and all VIB-GCP partners as soon as they have established breaches of scientific integrity committed as part of the VIB-GCP project activities by one of the VIB-GCP Project Partners.
- The VIB-GCP Project Partner will thereupon initiate its customary procedure for breaches of scientific integrity. The VIB-GCP Project Partner will in that case conduct the investigation in accordance with its own rules and send its findings to VIB.
- In any report to VIB the following shall be described clearly and exhaustively: the findings made, the investigative methodology used, the further findings and, where appropriate, the advice of the Vlaamse Commissie voor Wetenschappelijke Integriteit ("VCWI"). Throughout the entire procedure, the VIB-GCP Project Partner shall make itself available to VIB to provide additional information and shall make all reasonable efforts to help avoid any financial loss and damage to the reputation of VIB and VIB-GCP Project Partner involved.
- The Board of Directors of VIB may terminate the participation to the VIB-GCP Project Agreement of the VIB-GCP Project Partner that committed a breach of scientific integrity.
- §2 Communication on breaches of scientific integrity by the VIB-GCP Project Partner to third parties and vice versa shall always take place after prior consultation with VIB.



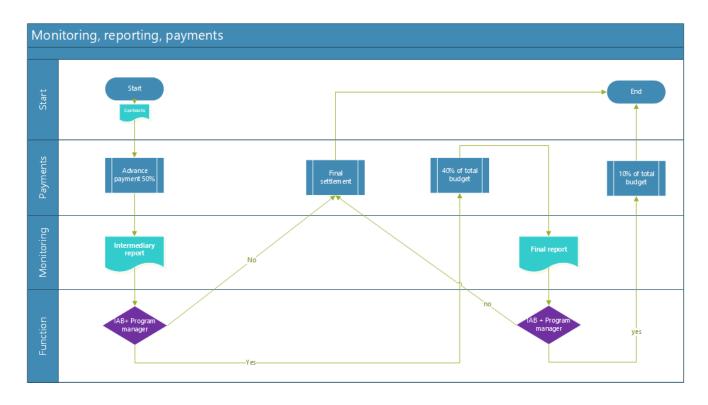
## Annex 1: Monitoring, Reporting, Payments

 $\underline{\textbf{Table1:}}\ \textbf{Overview monitoring and reporting timelines and responsibilities}$ 

timing		Expected report/document	lead
Year 1	kickoff	<ul> <li>Final Project plan</li> <li>Final budget plan</li> <li>Governance (+ interna Communication plan)</li> </ul>	Promotor- spokesperson + consortium / Program Manager
	Monthly Progress meeting	- Minutes	Project manager / Program manager
	Quarterly Steering Committee	- Minutes	Promotor- spokesperson / Program manager
Year 2	Between 12 months and 18 months after the Start Date as set forth in Article 1.5.	- Financial report - Progress report	Promotor- spokesperson + consortium
	Monthly Progress meeting	- Minutes	Project manager/Program manager
	Quarterly Steering Committee	- Minutes	Promotor- spokesperson / Program manager
Year 3	Monthly Progress meeting	- Minutes	Project manager/Program manager
	Quarterly Steering Committee	- Minutes	Promotor- spokesperson / Program manager
	Multistakeholder advisory board (at least 1 meeting during project duration)	- Short report	Promotor- spokesperson +consortium + program manager
	Max. 2 months after end of project; <3y = end date	- Final financial report - Final overall report	Promotor- spokesperson + consortium



### <u>Table 2:</u> Decision tree reporting and payment





Annex 2: Template VIB-GCP Project Agreement