Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Innosuisse – Schweizerische Agentur für Innovationsförderung

FAQ: Federal Funding Programme for COVID-19 Medicines

1 Important documents

- Form «Questionnaire» (Word, EN)
- Form «Self-Declaration» (PDF, EN)
- Checklist «Information and Documents» (PDF, EN)
- Model subsidy contract (PDF, EN)

2 General questions

2.1
Q: Is there a maximum project duration?
A: The project must be completed by end of December 2022 as the Federal Funding Programme for COVID-19 medicines will only run until the end of 2022. Currently, it is not foreseen to extend the duration of the Federal Funding Programme beyond 2022.

2.2
Q: What are the general criteria to participate in the Federal Funding Programme for COVID-19 Medicines?
A: Please see the details that have been published on the Innosuisse website concerning the Funding programme «www.innosuisse.ch/covid-19-medicines». Additional questions have been answered here in the Q&A.

2.3
Q: Is there a thematic focus of this Funding Programme?

A: Yes. The focus of this call is to contribute to the secure and rapid provision of COVID-19 medicines for the Swiss population.

2.4
Q: Can I apply for this programme if I am currently receiving other federal funding?
A: Yes. It is possible to apply for the “Federal Funding Programme for COVID-19 Medicines" even if the applicant has another project funded by the Swiss Federation.

2.5
Q: As of when can applications be submitted under this funding programme?
A: The submission portal PrivaSphere is open between 19.July – 16.August.2021 12:00 pm (CEST) (noon).

2.6
Q: Is there a defined deadline for submission?
A: Yes, the deadline for submission is 16. August 2021, 12:00 pm (CEST) (noon).

2.7
Q: What is the main difference of the “Federal Funding Programme for COVID-19 Medicines” compared to standard Innosuisse innovation projects?
A: The funded projects should make a significant contribution to the secure and rapid supply of COVID-19 medicines to the Swiss population. Funded drugs should be available to the Swiss population by the end of 2022.
The «Federal Funding Programme for COVID-19 Medicines» is organised as a cooperation between Innosuisse and the Federal Office of Public Health (FOPH). Unlike standard innovation projects, the focus of this programme lies on the advanced development of COVID-19 medicines and not on preclinical work. The active pharmaceutical ingredient must be proven to work against SARS-CoV-2 / COVID-19 preclinically or clinically. To summarise, this call is aimed at projects with high clinical innovation potential and are at an advanced stage so that the medicine can be made accessible to Swiss patients by the end of 2022 in accordance with applicable provisions of the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act: TPA; SR 812.21).

2.8
Q: When is the final decision of the evaluations expected?
A: The decision will be communicated by the FOPH at the end of October 2021.

2.9
Q: If my application is rejected, do I have the option of a resubmission?
A: An application is only possible within this Funding Call. There is no second call planned under the “Federal Funding Programme for COVID-19 Medicines” at this time.

3 Questions on the project itself

3.1
Q: Are all COVID-19 medicines (including vaccines) eligible for this Funding Programme?
A: No. Following medicines are not eligible:
- vaccines against SARS-CoV-2/COVID-19.
- medicines that are already approved in Switzerland for the use against COVID-19 in the indication, pharmaceutical form and dosage to be investigated.

3.2
Q: Can I also submit a project with e.g. a food supplement, a disinfectant or a medical device?
A: No. The scope of the funding programme is limited to medicines (i.e. medicinal products) according to the Therapeutic Products Act (TPA) Art. 4 para. 1 letter a.

3.3
Q: We have a promising active substance that we want to develop into a medicine against COVID-19. In order to participate, what do we already need to know about our active substance?
A: The mechanism of action against SARS-CoV-2/COVID-19 of your active substance needs to be proven to work pre-clinically or clinically. For instance, if your substance is intended to work directly against the SARS-CoV-2 virus, you need to be able to prove that your substance inhibits the replication of the SARS-CoV-2 virus. The proof needs to be substantiated with a pre-print, a peer-reviewed publication or the scientific advice of a regulatory authority. Submissions lacking substantiated proof-of-principle will be refused.

4 Questions on the project applicant

4.1
Q: Who is eligible as an applicant?
A: The applicant must be:

- A private company from the pharmaceutical and biotechnology industry with registered office or branch office in Switzerland

or

- A governmental or non-governmental university or non-commercial research institution outside the university sector based in Switzerland, provided it has a suitable industry partner from the pharmaceutical or biotechnology industry with registered office or branch office in Switzerland.

or

- A public or private hospital based in Switzerland, provided it has a suitable industry partner from the pharmaceutical or biotechnology industry with registered office or branch office in Switzerland.

The industry partner, which is required for applicants who are a university/research institution or a hospital, must provide the applicant with the necessary expertise in pharmaceutical development including regulatory affairs, clinical trials and manufacturing.

There can **only be one project applicant** to whom the funding is granted, and **only one industry partner**. The project can however include third party service providers.

4.2
Q: Can a public institution or NGO apply?
A: See question 4.1 above (eligible applicants).

4.3
Q: Can a company or research institution not located in Switzerland apply to the programme?
A: No, eligible applicants must have a registered office or branch office in Switzerland. The project can however include foreign third party service providers from outside of Switzerland. See also answer to question 4.1.

4.4
Q: Can foreign companies and research institutions be part of the proposed project?
A: Yes, they can be part of the project. However, they are not considered as applicant or industry partner, but rather as a third-party service provider. Applicants and industry partner (if applicable) must have a registered office or a branch in Switzerland at the time of submitting the funding application and for the entire duration of the funding.

4.5
Q: Can the applicant participate in 2 different “COVID-19 Medicines” project applications?
A: Yes. Yet it seems hardly possible that a single applicant would have the resources (staff,

infrastructure, finances, etc.) to be involved in two different projects running in parallel.

5 Questions on the industry partner and its role

5.1
Q: Who needs an industry partner?
A: If the applicant is a research institution or a hospital, it needs an industry partner from the pharma or biotech industry (see also Q4.1).

5.2
Q: Why is an industry partner needed for applicants being a research institution or a hospital?
A: The industry partner provides the applicant with the necessary expertise in pharmaceutical development including regulatory affairs, clinical trials and manufacturing. The industry partner does not need to provide all of these capabilities himself, but it needs to have the necessary experience to successfully deliver pharmaceutical development undertakings. Missing capabilities can be added to the project by engaging third party service providers (see also questions in section 6). The industry partner may also serve as the intended future marketing authorization holder for the medicine to be developed.

5.3
Q: Does the industry partner need to be located in Switzerland?
A: Yes, the industry partner must have a registered office or a branch office in Switzerland.

5.4
Q: How many industry partners can a project include?
A: Next to the applicant, the project can only include one industry partner. However, third party service providers can also be included in the project.

6 Questions on third party service providers and their role

6.1
Q: Who is a third party service provider?
A: A third party service provider provides specialised consulting, engineering or services that are required for the success of the project and that cannot be provided by the applicant or (required for research institutions or hospitals) the industry partner. For example, a contract manufacturing organisation (CMO), who manufactures the investigational medicinal product as a service for the applicant is a third party service provider.

6.2
Q: Do third party service providers need to be located in Switzerland?
A: No, third party service providers do not need to be located in Switzerland.

6.3
Q: How many third party service providers can be used in a project?
A: There is no limit on the number of the third party service providers. The type and number of third party service providers can vary according to the project. Usually a lot of different service providers (e.g. contract manufactures, clinical study partner) are required for a successful project execution.

7 Questions on the submission regulations

7.1
Q: Is this a single stage submission?
A: Yes.

7.2
Q: How and when can the application be submitted?
A: The application must be submitted exclusively via the PrivaSphere transfer platform. This transfer platform and the corresponding contact form is available on our webpage as of 19 July 2021 and will be open until 16 August 2021, 12:00 pm (CEST) (noon).

7.3
Q: Which documents do I need to submit in the application?
A: Please see Checklist «Information and Documents»

7.4
Q: Do I need to sign my submission?
A: The applicant needs to fully fill out the self-declaration form, sign it (either electronically or by wet-ink) and submit it as part of the application. Please also see Checklist «Information and Documents».

7.5
Q: What is the preferred language of the documents and information to be submitted?
A: The preferred language of all submission related information and documents is English. However, submissions in all three (German, French or Italian) official languages are accepted.

7.6
Q: What are the required minimum number of documents for submission?
A: Applicants are required to submit **8** types of mandatory documents (Checklist on call webpage). The ordering of the documents (ID) and their respective filenames have to be followed. The filename should begin with an ID (the numbering order as shown below) and should include the main Applicant's last name in the end. In case of availability of multiple documents for ID's 4-8, please consolidate them into one document per ID of mandatory documents (e.g. merge all documents related publications for proof of concept into one document as 5_POC_*Lastname*).

ID	Mandatory documents	Label
(1)	Completed «Questionnaire» (available on the call website)	1_Questionnaire_*LastName*
(2)	Clinical development plan (see section 2 of the «Questionnaire»)	2_CDP_*LastName*
(3)	Completed and signed «Self-declaration» form (available on the call website)	3_Self-declaration_*LastName*
(4)	Documentation of non-successful private funding initiatives (see section 4 of the «Questionnaire»)	4_OtherFunding_*LastName*
(5)	Documents proving the preclinical/clinical effect / proof of concept of the active substance (at least one of the following documents must be provided): Pre-print publication, peer-reviewed publication and/or scientific advice from regulatory authorities (see section 5 of the «Questionnaire»)	5_POC_*LastName*
(6)	Business plan 2021–2023 (see section 6 of the «Questionnaire»)	6_BusinessPlan_*LastName*
○	Only for applicants being research institutions or hospitals: Contract or letter-of-intent describing the collaboration with your industry partner (see section 6 of the «Questionnaire»)	6-1_LOI_*LastName*
(7)	Financial plan 2021–2023 (see section 7 of the «Questionnaire»)	7_FinancialPlan_*LastName*

7.7
Q: Can we upload additional documents?
A: Applicants are encouraged to submit the following facultative documents. The labelling (filename) for each is shown below.

ID	Facultative documents	Label
5.1.	Manufacturing agreements for investigational medicinal product (IMP) and marketable product (see section 5 of the «Questionaire»)	5-1_ManufactureAgreement_*LastName*
5.2.	Documents explaining the situation regarding intellectual property rights (see section 5 of the «Questionnaire»)	5-2_IPR_*LastName*
5.3.	Additional documents demonstrating the preclinical/clinical effect / proof of concept of the active substance such as slide kits (see section 5 of the «Questionnaire»)	5-3_Additional-POC_*LastName*
6.2.	Contracts with third parties (CDMO, CRO, etc.) providing key capabilities (see section 6 of the «Questionnaire»)	6-2_ThirdPartyContracts_*LastName*

7.8
Q: What are the preferred file formats for submission?
A: The acceptable document type for submission are PDF and Microsoft Office application formats.

8 Questions on budget and costs

8.1
Q: Does the 50/50 funding rule apply in this call?
A: Yes. In principle, a maximum of 50% of the project costs are covered by the federal government within the framework of a federal contribution.

8.2
Q: How do the project costs need to be documented for the submission?
A: As part of the documents to be provided, please submit a financial plan for the years 2021 to 2023 according to your internal planning and answer question 7.1 of the Questionnaire. No further guidelines for the project budget calculations are published at the moment. However, you might be asked to provide a budget plan according to an FOPH template after the preliminary check of your submission has been performed.

8.3
Q: What is the budget for the “Federal Funding Programme for COVID-19 Medicines”?
A: The total budget for this programme is CHF 50 million for the period 2021–2022. An undetermined number of projects can be funded within this budget.

8.4
Q: How many projects can/will be funded under this call?
A There is no predetermined number of projects to be funded with the budget of CHF 50 million. It will depend on the number, feasibility and the clinical value of the projects submitted.

8.5
Q: What is the maximum budget for one project?
A: There is in principle no maximum budget for one project. But the planned budget has to adequate in the light of the planned work, staff resources and material costs. The budget presented will be part of the evaluation and can influence the funding decision.

8.6
Q: Is the project funding paid before or after the project?

A: The project payments are linked to the project steps and will be paid in instalments according to the subsidy contract.

9 Questions on the subsidy contract and project reporting

9.1
Q: Is a subsidy contract required after project approval?
A: The applicant must conclude a subsidy contract with the FOPH. As part of your application, you must agree to the terms of the model subsidy contract. Please note that the terms of the final subsidy contract may differ from the model subsidy contract. Project payments require a subsidy contract signed by all parties before project begin.

9.2
Q: Can the project duration be extended?
A: No. The project must end by end of December 2022 as the Federal Funding Programme for COVID-19 medicines will only run until the end of 2022. Currently, it is not foreseen to extend the duration of the Federal Funding Programme beyond 2022.
9.3
Q: Do we need to submit a final project report?
A: Yes, upon completion of the project or by end of the funding programme at the latest, the grantee must submit a final report incl. a financial statement (see also model subsidy contract). FOPH will further specify the documents to be submitted.

9.4
Q: How will the procurement of the medicine proceed after project completion?
A: Upon successful completion of the project and if a promising medicine has been developed, the FOPH will review and assess the conditions, the public health need, the timelines and feasibility for the medicine to be delivered to the Swiss market. If this assessment is positive, the FOPH will exercise its pre-purchase right pursuant to the *subsidy contract* and enter into good faith negotiations with the grantee in order to procure the medicine. A potential purchase contract will be concluded under the conditions specified in the *subsidy contract*, unless FOPH deems it appropriate to deviate from these conditions.