|  |  |
| --- | --- |
|  | Federal Department of Home Affairs FDHA**Federal Office of Public Health FOPH** |

**Federal Funding Programme for COVID-19 Medicines:**

**Questionnaire**

**All applicants are required to submit a completely filled out questionnaire including the submission of the indicated documents. Incomplete applications will not be considered.**

If you want to provide documents in addition to the mandatory or facultative documents listed, please indicate this in the appropriate answer boxes of the questionnaire form below and label your additional documents with the corresponding question number.

|  |
| --- |
| **General Information** |
| **Applicant** | *Insert your affiliation such as company or institution here* |
| **Project Title** | *Insert project title here* |
| **Project Lead** | *Insert contact details (name, surname, address, mail, phone) of the project leader here* |

| **1. The funded projects must make a contribution to the secure and rapid provision of COVID-19 medicines for the Swiss population** |
| --- |
| **No** | **Question** | **Answer by Applicant** |
| 1.1 | How will your project contribute to the secure and rapid provision of COVID-19 medicines for the Swiss population? |  |

| **2. The funded projects should result in a medicine available for the Swiss population by the end of 2022** |
| --- |
| **No** | **Question** | **Answer by Applicant** |
| 2.1 | How will you achieve availability of your medicine for the Swiss population before the end of 2022? |  |
| 2.2 | Which regulatory route do you plan to use to make your medicine available in Switzerland before the end of 2022? |  |
| 2.3 | Do you already have the investigational medicinal product (IMP) produced for your clinical studies?For how many patients will the IMP suffice?If not available yet, by when will the IMP be available? |  |
| 2.4 | Overall, how confident are you as to reaching the following milestones before the end of 2022:  | *Please indicate your confidence (high/medium/low) and provide a rationale.* |
| 2.4a | a) complete a phase II study |  |
| 2.4b | b) start a phase III study |  |
| 2.4c | c) complete a phase III study |  |
| 2.5 | Where do you plan to perform your clinical studies? Please elaborate on how the epidemiological situation could affect your clinical development plan and how do you plan to mitigate this risk. |  |

**Mandatory document to be submitted:**

* Clinical development plan (Please label the document as 2\_CDP\_*LastName*.pdf)

| **3. The funded projects should have a high clinical innovation potential** |
| --- |
| **No** | **Question** | **Answer by Applicant** |
| 3.1 | What is innovative about your drug? What is the added value vs. similar drugs that are in phase II, III or already approved? |  |
| 3.2 | Why is an investment in your drug justified vs. investing in the competitors?  |  |

| **4. Projects may only be funded by the government if they cannot be funded by private funding, or if government funding is otherwise justified (subsidiarity and necessity principles need to be fulfilled)** |
| --- |
| **No** | **Question** | **Answer by Applicant** |
| 4 | Why are you seeking government funding for your project? Why can't the project be pursued with private funding alone? Please elaborate why you need the financial support of the government. |  |

**Mandatory document to be submitted**:

* Documentation of your non-successful private funding initiatives (Please label the document as 4\_OtherFunding\_*LastName*.pdf)

| **5. The funded projects must fulfil a high scientific and technical quality of the project setup** |
| --- |
| **No** | **Domain** | **Question** | **Answer by Applicant** |
| 5.1 | Proof-of-concept | Your project needs to have successfully finished at least the preclinical phase and proof of concept of its efficacy against COVID-19 has already been established.Why does your medicine show promise in the treatment or prevention of COVID-19 and how has this been proven so far? |  |
| 5.2 | Manufacturing of IMP | Who manufactured the IMP?If not manufactured yet, who will be manufacturing the IMP and are manufacturing agreements already in place? |  |
| 5.3 | Manufacturing of marketable product | Who will be manufacturing the active substance and the finished drug product of the marketable product?Are manufacturing agreements already in place? |  |
| 5.4 | Scientific Advice | Is there any scientific advice from any regulatory authority regarding any aspect of the project available? Please elaborate. |  |
| 5.5 | "Freedom-to-operate" | Can you certify that developing, manufacturing and eventually marketing your drug will not infringe any relevant intellectual property rights (IPR-situation)? Can you guarantee "freedom-to-operate"? Please elaborate. |  |

**Mandatory document to be submitted**:

* Documents proving the preclinical/clinical effect / proof of concept of the active substance (Please consolidate documents into one file and label as 5\_POC\_*LastName*.pdf):
* Pre-print publication (*and/or*)
* Peer-reviewed publication (*and/or*)
* Scientific advice from regulatory authorities.

**Facultative documents to be submitted:**

* Manufacturing agreements for IMP and marketable product (Please consolidate documents into one file and label as 5-1\_ManufactureAgreement\_*LastName*.pdf)
* Documents explaining the IPR-situation (Please consolidate documents into one file and label as 5-2\_IPR\_*LastName*.pdf)
* Additional documents demonstrating the preclinical/clinical effect / proof of concept of the active substance such as slide kits (Please consolidate documents into one file and label as 5-3\_AdditionalPOC\_ *LastName*.pdf)

| **6. The applicant must have a robust business plan and the necessary capabilities for pharmaceutical development projects** |
| --- |
| **No** | **Domain** | **Question** | **Answer by Applicant** |
| 6.1 | Capabilities of the applicant  | Please describe your capabilities, experience and track record in pharmaceutical development including regulatory, clinical trials and manufacturing. |  |
| 6.2 | Capabilities of the industry partner (required if you are a research institution or a hospital) | Please describe the capabilities, experience and track record of the industry partner in pharmaceutical development including regulatory, clinical trials and manufacturing.  |  |
| 6.3 | Third parties | If you do not have the required capabilities available in-house, please indicate with whom you will collaborate to gain access to these capabilities (CDMO, CRO, etc.) and whether contracts have already been signed. |  |
| 6.4 | Marketing authorisation holder | Which company will be the marketing authorisation holder in Switzerland? |  |
| 6.5 | Business plan | Please describe briefly the main points of your business plan. |  |

**Mandatory document to be submitted**:

* Business plan 2021–2023 from the applicant (Please label the document as 6\_BusinessPlan\_*LastName*.pdf)
* Only for applicants being research institutions or hospitals: Contract or letter-of-intent describing the collaboration with your industry partner (Please label the document as 6-1\_LOI\_*LastName*.pdf)

**Facultative document to be submitted**:

* Contracts with third parties (CDMO, CRO, etc.) providing key capabilities (Please consolidate documents into one file and label as 6-2\_ThirdPartyContracts\_*LastName*.pdf)

| **7. Financial aspects of your project** |
| --- |
| **No** | **Question** | **Answer by Applicant** |
|  |  | **Total costs** (per step) (CHF) | **Own funding**(per step) (CHF) | **Funding by third parties**(per step) (CHF) | **Funding requested from Swiss government**(per step) (CHF) | **Share of requested Swiss gov. funding in total costs** (per step)(percentage) | **Brief reasoning for requested amount** |
| 7.1 | What are the **total** **project costs and the total requested funding from Swiss Government**?Please break down the costs per step (7.1a–g) / total (7.1 h) and provide a brief reasoning for the requested amount. |  |  |  |  |  |  |
| 7.1a | a) preclinical phase |  |  |  | not fundable | not applicable |  |
| 7.1b | b) manufacturing of the investigational medicinal product (IMP) |  |  |  |  |  |  |
| 7.1c | c) clinical phase I |  |  |  |  |  |  |
| 7.1d | d) clinical phase II |  |  |  |  |  |  |
| 7.1e | e) clinical phase III |  |  |  |  |  |  |
| 7.1f | f) preparation of regulatory dossier for marketing authorisation application |  |  |  |  |  |  |
| 7.1g | g)other (please specify) |  |  |  |  |  |  |
| **7.1h** | **h) total costs for all phases** |  |  |  |  |  |  |
| 7.2 | How much will you cover from your own financial sources or are there any non-financial contributions/risk sharing that you cover by yourself? |  |
| 7.3 | Are parts of the Swiss government funding planned to be allocated to third parties (e.g. manufacturers)? |  |
| 7.3a | a) Which amount is planned to be allocated to third parties? |  |
| 7.3b | b) Which third partie(s) are considered? | *If applicable, please provide the name and function of third partie(s).* |
| 7.3c | c) Which form of collaboration is planned for this allocation of funds? |  |
| 7.4 | What is the financial plan for the project |  |
| 7.4a | a) until the end of 2021? |  |
| 7.4b | b) for 2022? |  |
| 7.4c | c) for the project overall (including years after 2022 if the project is planned to last longer)? |  |
| 7.5 | Do you receive or are you planning to receive funding from other contributors? | *If applicable, please specify the contributors, (budgeted) amount and project phase and include a brief reasoning.* |
| 7.5a | a) public funding in Switzerland (e.g. SNF, Innosuisse, cantons) |  |
| 7.5b | b) public funding from EU or other governments (e.g. Horizon, Innovation) |  |
| 7.5c | c) funding by private partners (e.g. private foundations, other industries, banks) |  |
| 7.5d | d) other funding |  |
| 7.6 | If you receive or are planning to receive funding from other contributors (7.5):  | *If you receive or are planning to receive funding from multiple contributors (7.5), please differentiate.* |
| 7.6a | a) What do you offer to the other contributors in return? |  |
| 7.6b | b) Could this affect the offers made to the Swiss government (e.g. regarding the timeline, quantity or application for market access)? |  |

**Mandatory document to be submitted**:

* Financial plan 2021–2023 (Please label the document as 7\_FinancialPlan\_*LastName*.pdf).