**Application Form Fast-Track**

# Purpose

This application form is intended for Sponsors seeking accelerated review of clinical trial submissions under the Fast-Track pilot project. It serves to determine whether a study meets the defined criteria of a clinical trial for high medical need.

The submitted information enables Swissmedic to assess suitability for the Fast-Track procedure.

# Fast-Track Application

Fast Track Application for:

[ ]  **High Medical Need:**
Trials addressing therapies for serious or life-threatening diseases for which there are no approved treatment options in Switzerland.
***🡪 IMPORTANT: Preassessment required for Fast-Track applications with High Medical Need.*** *Please refer to the submission process below.*

[ ]  **Known investigational medicinal products:**
Clinical trials testing active substances, combinations of active substances or investigational products that have already been reviewed and authorised by Swissmedic in earlier phases or previous clinical trials.

**Submission process:**

1. Applications for **high medical need** must be submitted for preassessment with Swissmedic for review of the criteria.
Preassessment procedure:
	1. Complete the Application Form Fast Track
	2. Submit cover letter and protocol synopsis together with the application form in eDok folder Structure.

During the preassessment, Swissmedic checks whether the criterion of ‘high medical need’ is met. The decision (confirmation as fast track or rejection) is communicated to the applicant. The following clinical trial application can be submitted subsequently as usual as new clinicl trial application.

1. Applications for studies with **known investigational medicinal products** can be submitted as usual , without an upfront submission for preassessment.
	1. Complete the application form: Application Form Fast Track
	2. Submit the application as usual as a new clinical trial. File the Fast Track application form under 00F, in addition to the KLV FO submission form

Upon receipt of the application, Swissmedic will check whether the criterion of ‘known investigational medicinal product’ is met during the formal review.

**Application processing by Swissmedic**

The processing of new clinical trials that meet the fast-track criteria is faster than the deadlines specified in the ClinO:

* Applications pursuant to Art. 33 para. 2 are processed within 20 days instead of 30 days.
* Applications pursuant to Art. 33 para. 3 are processed within 40 days instead of 60 days.

*The shortened deadlines in the fast-track procedure are not legally binding, but represent a performance promise by Swissmedic. Swissmedic makes every effort to meet these deadlines, but delays may occur in exceptional cases.*

# Administrative Information

## Sponsor

|  |  |
| --- | --- |
| First Name | Enter |
| Last Name | Enter |
| Company / Institution | Enter |
| Address | Enter |
| Phone Number | Enter |
| E-Mail Address | Enter |

## Swiss Representative

|  |  |
| --- | --- |
| First Name | Enter |
| Last Name | Enter |
| Company / Institution | Enter |
| Address | Enter |
| Phone Number | Enter |
| E-Mail Address | Enter |

# Trial Information

|  |  |
| --- | --- |
| Trial Code | Enter |
| Study Title | Enter |
| Indication | Enter |
| Trial Phase | Choose Trial Phase |
| Trial Type | Choose Trial Type |

# Justification for Fast Track

## [ ]  Justification for High Medical Need

Please explain why the target population of your study represents a high medical need. Include information on the severity of the condition, prevalence, current treatment limitations, and the potential of the investigational product to address an unmet therapeutic need.

|  |  |
| --- | --- |
| Please provide justification: |  |

IMP tested for High Medical Need:

|  |  |  |  |
| --- | --- | --- | --- |
| IMP Name | Active Substance | Dose Strength | Pharmaceutical Form |
| Enter | Enter | Enter | Enter |

|  |  |
| --- | --- |
| ATC Code (2nd level, therapeutic subgroup) | Enter |

## Anticipatted Submission Timeline

|  |  |
| --- | --- |
| Planned submission date of full clinical trial application | Enter Date  |

## Attachments

For the preassessment of High Medical Need Fast-Track applications, please submit the following documents:

|  |  |
| --- | --- |
| Document | Version & Date |
| [ ]  Protocol synopsis | Enter |
| [ ]  Cover letter | Enter |
| [ ]  IB summary (optional) | Enter |
| [ ]  Other, please specify: Enter | Enter |

## [ ]  Justification for known investigational medicinal products

Please list all IMPs (Testing and Comparators) in the below table (if more IMPs have to be entered, please list them additionally in the cover letter).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| IMP Name | Active Substance | Dose Strength | Pharmaceutical Form | IMP-ID (if available) or Swissmedic Trial Number(s) |
| Enter | Enter | Enter | Enter | Enter |
| Enter | Enter | Enter | Enter | Enter |
| Enter | Enter | Enter | Enter | Enter |
| Enter | Enter | Enter | Enter | Enter |
| Enter | Enter | Enter | Enter | Enter |
| Enter | Enter | Enter | Enter | Enter |

|  |  |
| --- | --- |
| Please provide justification: |  |

# Signature

*In my capacity as sponsor or sponsor representative I hereby confirm that all the information provided in this form is correct.*

|  |  |
| --- | --- |
| First Name | Enter |
| Last Name | Enter |
| Company / Institution | Enter |
| Place | Enter |
| Date | Enter Date |
| Signature |  |