**Information for the**

**Swiss National Clinical Trials Portal (SNCTP)**

see [HRA art. 56](https://www.admin.ch/opc/en/classified-compilation/20061313/index.html#a56) paragraph 1 ([DE](https://www.admin.ch/opc/de/classified-compilation/20061313/index.html#a56), [FR](https://www.admin.ch/opc/fr/classified-compilation/20061313/index.html#a56), [IT](https://www.admin.ch/opc/it/classified-compilation/20061313/index.html#a56)) and [ClinO art. 64](https://www.admin.ch/opc/en/classified-compilation/20121176/index.html#a64) paragraph 3 ([DE](https://www.admin.ch/opc/de/classified-compilation/20121176/index.html#a64), [FR](https://www.admin.ch/opc/fr/classified-compilation/20121176/index.html#a64), [IT](https://www.admin.ch/opc/it/classified-compilation/20121176/index.html#a64)).

**English:**

This form is for the subsequent entry of certain parameters required for the SNCTP for clinical studies with an authorisation date before the introduction of BASEC (i.e. pre-BASEC studies). It is applicable for:

1. updating pre-BASEC studies in the SNCTP (e.g. phase I studies with a deferred registration requirement)
2. entering SNCTP-relevant modifications of the published information based on authorised amendments of pre-BASEC studies.

The information in the section below will be published in the publicly accessible Swiss National Clinical Trial Portal [SNCTP](http://www.kofam.ch/en/swiss-clinical-trials-portal/). All text entries have to be written in one of the Swiss national languages (**German**, **French**, **or** **Italian**) and formulated in a way that is readily understood by a lay person.

I hereby confirm that the information is complete and correct and may be published:

Place, date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Study responsible person:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Company/Institution:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please send the completed form to the competent authority in the FOPH (Section Research involving Human Beings and Ethics) which will update the provided information in the SNCTP: snctp@bag.admin.ch

**Deutsch:**

Dieses Formular dient der Nacherfassung von bestimmten, für das SNCTP benötigten Parametern von klinischen Studien mit Bewilligungsdatum vor Einführung BASEC (d.h. prä-BASEC-Studien). Es ist anwendbar für:

1. Die Neuerfassung von prä-BASEC-Studien im SNCTP (z.B. Phase I-Studien mit aufgeschobener Registrierungspflicht)
2. Die Erfassung von SNCTP-relevanten Änderungen der publizierten Informationen aufgrund bewilligter Amendments von prä-BASEC-Studien

 Die Informationen im untenstehenden Abschnitt sind für das öffentlich zugängliche Swiss National Clinical Trial Portal [SNCTP](http://www.kofam.ch/de/studienportal/) bestimmt und müssen deshalb von medizinischen Laien verstanden werden.  Sprache: **Deutsch**, **Französisch** oder **Italienisch**.

Hiermit bestätige ich, dass die Informationen vollständig und korrekt sind und publiziert werden dürfen:

Ort, Datum:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Studienverantwortliche Person:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Firma/Institution\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Bitte senden Sie das ausgefüllte Formular an die zuständige Stelle im BAG (Sektion Forschung am Menschen und Ethik), welche die eingetragenen Informationen ins SNCTP einpflegt: snctp@bag.admin.ch

**Français:**

Le présent formulaire sert à saisir dans le SNCTP certains paramètres nécessaires qui concernent des études cliniques autorisées avant l’introduction de BASEC (études « pré-BASEC »). Il peut être utilisé pour :

1. Saisir dans le SNCTP des études pré-BASEC (p. ex., études de phase I avec obligation d’enregistrement sous un an après la fin d’étude).
2. Saisir des informations publiées concernant le SNCTP et modifiées suite à des adaptations autorisées d’études pré-BASEC.

Les informations demandées sur cet écran sont destinées au Swiss National Clinical Trial Portal [SNCTP](http://www.kofam.ch/fr/portail-snctp/), accessible au public.  Elles doivent être formulées en **allemand**, **français** ou **italien** et doivent être compréhensibles pour des personnes sans formation médicale.

Par la présente, je confirme l’exhaustivité et l'exactitude des informations, qui peuvent être publiées :

Lieu, date :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Responsable de l’étude :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Entreprise / Institution:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Merci de bien vouloir envoyer le formulaire dûment rempli au service de l’OFSP chargé de saisir les informations dans le SNCTP (section Recherche sur l'être humain et éthique) : snctp@bag.admin.ch.

**Italiano:**

Il presente modulo serve per iscrivere a posteriori determinati parametri necessari all’SNCTP di sperimentazioni cliniche autorizzate prima dell’introduzione di BASEC (sperimentazioni cliniche pre-BASEC). Può essere utilizzato per:

1. una nuova iscrizione nell’SNCTP di sperimentazioni cliniche pre-BASEC (p. es. sperimentazioni cliniche della fase I, con obbligo di registrazione sospeso);
2. l’iscrizione di modifiche, rilevanti per l’SNCTP, a informazioni pubblicate in seguito a emendamenti autorizzati di sperimentazioni cliniche pre-BASEC.

Le informazioni di questa schermata sono destinate al portale di pubblico accesso ‘Swiss National Clinical Trial Portal [SNCTP](http://www.kofam.ch/it/portale-snctp/)’ e devono quindi essere formulate in **tedesco**, **francese** o **italiano** in modo da essere capite da persone senza formazione medica.

Con la presente confermo che le informazioni fornite sono complete, corrette e possono essere pubblicate.

Luogo, data:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Responsabile della sperimentazione clinica:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Azienda/istituzione:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Inviare il modulo debitamente compilato al servizio competente dell’UFSP (Sezione ricerca sull’uomo ed etica) che gestisce le informazioni registrate nell’SNCTP: snctp@bag.admin.ch

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| --- |
| 1. **Laientitel / Titre public / Titolo per non esperti (max. 2000 characters) :**
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| 1. **Untersuchte Krankheit, Gesundheitsstatus / Maladie ou état de santé étudié / Malattia studiata, condizioni di salute (max. 2000 characters) :**
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|  |
| 1. **Laienzusammenfassung / Résumé / Sintesi (max. 2000 characters)** *(Use simple language without specialised terminology: "like the flip of a coin" instead of "randomised", "heart disease" instead of "cardiopathy", "neither you nor your doctor will know what treatment you receive" instead of "double blind" etc.)*
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|  |
| 1. **Untersuchte Intervention / Intervention étudiée / Interventi esaminati (max. 8000 characters)**
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|  |
| 1. **Einschlusskriterien / Critères d'inclusion / Criteri di inclusione (max. 8000 characters)** *(List only the most important inclusion criteria (maximum three criteria)*
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|  |
| 1. **Ausschlusskriterien / Critères d'exclusion / Criteri di esclusione (max. 8000 characters)** *(List only the most important exclusion criteria (maximum 3 criteria))*
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|  |
| 1. **Durchführungsorte / Lieux de déroulement / Luoghi di svolgimento dello studio (select one or several of the provided locations):**

 **Aarau**  **Basel**  **Bellinzona**  **Bern**  **Chur**  **Fribourg/Freiburg**  **Genève**  **Lausanne**  **Lugano**  **Luzern**  **Neuchâtel**  **Sion**  **St. Gallen**  **Winterthur**  **Zürich**  **Andere / Autre / Altri:** |
| 1. **Contact for further information?** *(This will be published on the SNCTP website, and may therefore lead to enquiries by the general public.)*
 |
| *Full name/E-mail/phone* |
| 1. **Name of Primary Registry:** *For information about Primary Registries in the WHO Registry Network, please visit* [*https://www.who.int/clinical-trials-registry-platform/network/primary-registries*](https://www.who.int/clinical-trials-registry-platform/network/primary-registries)*.*
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| 1. **WHO-identification number (External identification number (ID)):** *External identification number (ID) of the trial in the WHO primary registry or clinicaltrials.gov; You received the identification number after registration of your clinical trial in a WHO primary registry or at clinicaltrials.gov.*
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| 1. **Disease under investigation:** *Please select 1 or more keywords from the catalogue below. The keywords are used to narrow the search function for trials in the SNCTP.*

 **Arterial and venous diseases including deep venous thrombosis and lung embolism**  **Basic research (Anatomy/Physiology)** **Brain diseases (non cancer)**  **Cancer: Bladder**  **Cancer: Breast**  **Cancer: Colon and Rectal**  **Cancer: Endometrial**  **Cancer: Head and Neck**  **Cancer: Lymphoma**  **Cancer: Kidney**  **Cancer: Leukemia**  **Cancer: Lung**  **Cancer: Melanoma**  **Cancer: Non-Hodgkin Lymphoma**  **Cancer: Pancreatic**  **Cancer: Prostate**  **Cancer: Thyroid**  **Cancer: Other**  **Coronary Heart disease**  **Dementia and Alzheimer disease**  **Digestive Systems diseases (non cancer)**  **Ear, Nose, and Throat diseases (non cancer)**  **Endocrinological diseases (non cancer)**  **Eye diseases**  **Genetic disorders**  **Hematologic diseases (non cancer)**  **Infections and Infestations**  **Injury**  **Mental and Behavioural diseases**  **Musculoskeletal diseases (non cancer)**  **Neonatal diseases**  **Nervous System diseases**  **Nutritional and Metabolic diseases**  **Occupational diseases**  **Periodontal diseases**  **Pregnancy and Childbirth**  **Respiratory diseases (non cancer)**  **Skin and Connective Tissues diseases (non cancer)**  **Surgery**  **Urological and Genital diseases (non cancer)**  **Other** |
| 1. **Investigation of a rare disease? Yes/No?**
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| 1. **Recruitment of special populations** *(please tick all that apply, more than one possible):*

[ ]  **Children (0 to 13 years)**[ ]  **Adolescents (14 to 17 years)** [ ]  **Healthy volunteers** |