

Checklist for TpP/GT/GMO clinical trials

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1 Introduction

Checklist for applicants: Documents to be submitted to Swissmedic for clinical trials with transplant products, clinical trials involving somatic gene therapy or clinical trials with therapeutic products containing genetically modified organisms

1.1 Legal basis

- Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act; TPA) of 15 December 2000 (Status as of 1 January 2019)
- Federal Act on Research involving Human Beings (Human Research Act; HRA) of 30 September 2011 (Status as of 1 January 2014)
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance; ClinO) of 20 September 2013 (Status as of 24 April 2018)
- Ordinance concerning Authorisation for Medicinal Products (Medicinal Products Licensing Ordinance; MPLO) of 14 November 2018 (Status as of 1 January 2019) (available in German, French and Italian)
- Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic) of 14 September 2018 (Status as of 1 January 2019) (available in German, French and Italian)

2 Other valid documents

Which documents must be submitted?
<p>Please also refer to BW101_10_004e_AA Working instructions Clinical Trial Application Dossier</p> <p><i>and</i></p> <p>I-315.AA.01-A02e Information sheet on requirements for documentation to be submitted for clinical trials with TpP/GT/GMO</p> <p><i>and (if applicable)</i></p> <p>I-315.AA.01-A11e Guidance document gene therapy/GMO Environmental Data (for clinical trials with gene therapy and GMO)</p>

3 Description

<p>Section 1</p> <ul style="list-style-type: none"> - Cover letter with a list of documents submitted (incl. version data and/or version number) and where appropriate of the risk assessment (A, B1, B2) according to Guidance document gene therapy/GMO Environmental Data (only valid for in vivo gene therapy/GMO)
<p>Section 2</p> <ul style="list-style-type: none"> - BW101_10_001e_FO Clinic Trial Application Form for clinical trials with medicinal products, transplant products, gene therapy products and genetically modified organisms (GMO) (incl. completed page “Confirmation of notification/authorisation”)
<p>Section 3</p> <ul style="list-style-type: none"> - Information on approvals by the competent Ethics Committee(s), either pending or obtained, with all of the related correspondence. As soon as known, please also provide the reference number of the responsible Ethics Committees
<p>Section 4</p> <ul style="list-style-type: none"> - For international trials: Information on the status of the submission to the foreign authorities (if applicable), incl. the evaluation of the foreign authorities (List of Questions, Answer to List of Questions, etc.)
<p>Section 5</p> <ul style="list-style-type: none"> - Clinical trial protocol (dated with page numbers, including amendments), signed by the sponsor and the investigator (according to ICH GCP Guideline E 6, chapter 6) - Summary of the clinical trial protocol in non-technical language (official Swiss language) - Written information for trial participants / statement of consent for trial participants (date, language) in line with the template on the website of the Association of Swiss Ethics Committees on research involving humans (swissethics) - Other patient information / statements of consent in line with the template on the website of the Association of Swiss Ethics Committees on research involving humans (swissethics) (e.g. information for children, information/consent forms concerning biobanking and the collection of biological samples) (if applicable)
<p>Section 6</p> <ul style="list-style-type: none"> - Investigator’s brochure (IB) (date) no more than 18 months previously
<p>Section 7</p> <ul style="list-style-type: none"> - Pharmaceutical quality documentation concerning the Investigational Medicinal Product (IMP) (detailed description of the manufacturing process, of the transgene sequence and of the properties of the investigational medicinal product(s)), organised according to the Information sheet I-315.AA.01-A02e
<p>Section 8</p> <ul style="list-style-type: none"> - Proof of compliance with Good Manufacturing Practice - Form “Substances of animal or human origin” - Risk/benefit analysis with respect to trial participants - Environmental data: Data on public health and environmental risks (annex 4, number 4, ClinO). Information incl. risk assessment (A, B1, B2) according to Guidance document gene therapy/GMO Environmental Data (only applicable for in vivo gene therapy/GMO)
<p>Section 9</p> <ul style="list-style-type: none"> - Copy of the label(s) of the investigational medicinal product(s)
<p>Section 10</p> <ul style="list-style-type: none"> - CRF (printout of the eCRF) (only electronic submission sufficient, if applicable) - Patient questionnaires (if applicable) - Advertisements (if applicable) - Extent and nature of the compensation for the research subjects (if applicable)

<ul style="list-style-type: none"> - Extent and nature of the compensation for the investigators - Study site's insurance policy and its period of validity or confirmation from the sponsor of existing liability coverage including period of validity - Relevant aspects of any agreement between sponsor and investigator or between the contract research organisation and the sponsor or the investigator - For sponsors having their place of business outside of Switzerland: Contract between the sponsor and his representative in Switzerland (if applicable) - Contract between the sponsor and the contract research organisation (CRO) 	
<p>Section 11</p> <ul style="list-style-type: none"> - Scientific literature (Clinical, Pre-Clinical, Quality) as referenced in the protocol, IB (only electronic submission sufficient) 	
<p>Section 12</p> <ul style="list-style-type: none"> - Any other documents 	
<p>1 structured original documentation plus 1 CD-ROM (for GT/GMO trials, 3 additional copies and CD-Roms) are to be sent to:</p> <p>Swissmedic Swiss Agency for Therapeutic Products Division Inspectorates and Licences Section Transplants Hallerstrasse 7 3012 Bern</p>	<p>For inquiries contact:</p> <p>Telephone +41 58 462 03 32 Fax +41 58 463 04 20</p>

Change history

Version	Change	sig
8.0	Transfer ATM processes in the area of authorisations New ID number assigned Formal adjustments, new layout	dei