Medicinal Products for Human Use - AUSTRIA

Competent authority

Contact Details

Contact Name 1

Bundesamt für Sicherheit im Gesundheitswesen BASG/ Federal Office for Safety in Health Care

Contact Name 2

Agentur für Gesundheit und Ernährungssicherheit AGES/ Austrian Medicines and Medical Devices Agency

Phone

0043 50 555-36111, -36820

Email Department

clinicaltrials@ages.at

Address

Traisengasse 5

ZIP/City

1200 Vienna

Country

Austria (AT)

Web address

http://www.ages.at/ages/geschaeftsfelder/medizinmarktaufsicht/

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
Ethics committee(s)

CA - Submission for authorisation mandatory for

Clinical IMP trials
Clinical ATMP trials

CA - Registration/ notification without approval required for

–

CA - Submission required to

National CA

Specific Competent Authority for ATMP trials in place

Yes

Competent Authority for ATMP trials

Bundesministerium für Gesundheit BMfG (Federal Ministry of Health)

National trial registry - Registration mandatory

No

National legal framework in place

Yes

	Applicable national legal framework/ Reference Art 40 AMG
Submission of Application	**Responsible for study submission** Sponsor Legal representative domiciled in the EU/EEA **Entitled to study submission** Sponsor Legal representative domiciled in the EU/EEA **Prerequisites for submission** – **Guidance on submission of application available** Yes **Guidance on submission of application** L I206 Leitfaden KP Einreichung (de) L I209 Guidance CT submission (en) L I205 Verzeichnis der erforderlichen Unterlagen 01 (de) L I211 List of documentation required (en) **National legal framework in place** Yes **Applicable national legal framework/ Reference** Art 40(1) AMG
Submission Format	**Format option(s)** Electronically on data carrier (CD/USB stick) Data medium + cover letter to be sent by regular mail **Preferred format** – **Standard application form available** Yes **Standard application form** EudraCT Application Form (https://eudract.ema.europa.eu) also available on BASG website **Standard application form - Additional information** The accompanying documentation is provided in: L I205 Verzeichnis der erforderlichen Unterlagen (de) L I211 List of documentation required (en) **Use of standard application form binding** Yes **Guidance on submission format available** Yes **Guidance on submission format** L I206 Leitfaden KP Einreichung (de) L I209 Guidance CT submission (en) L I205 Verzeichnis der erforderlichen Unterlagen (de) L I211 List of documentation required (en)

Additional Information

The EudraCT application form (PDF and XML) and all documents required for assessment (Protocol, IB, IMPD, ...) need to be submitted in electronic form on an a data medium (e.g. CD).
The data medium and cover letter should be sent to the BASG by regular mail.
A paper version of the dossier will no longer be required as from 01.01.2016.

Language of Submission

Language(s) of application

German
English

Preferred language of application

–

English accepted

Yes
Partly, not for all documents

Documents mandatory to be in official national language

–

Additional Information

EudraCT form is to be completed in English with the exception of (address) information on Austrian sponsors, legal representatives, request for the competent authority, the study sites and clinical investigators (e.g. Departments of University Clinics etc.).

Submission Fees

Fees for trial submission mandatory

Yes

Fees

For initial clinical trial applications:
3000 € for clinical trials Phase I-III
1508 € for clinical trials Phase IV
Substantial amendment 500 €
Non-interventional studies 603 €.

NB: From 01.01.2016, non-commercial clinical (academic) trials are no longer exempt from fees upon application:
20% of applicable fees for clinical trials Phase I-III & IV (one-time charge!).
No fees for substantial amendments or inspections.

Waiver for academic (non-commercial) studies possible

Reduced fees are charged

Official guidance on required fees available

Yes

Official guidance on required fees

Latest version of “BASG Gebührentarifverordnung gemäß Gesundheits- und Ernährungssicherheitsgesetz GESG" (Regulation on Fees), published on the BASG/AGES website (also available in English).

National legal framework in place

Yes

Applicable national legal framework/ Reference

BASG Gebührentarifverordnung gemäß Gesundheits- und Ernährungssicherheitsgesetz GESG (de)/ Regulation on Fees (en);
Waiver for academic studies: Art 1a. (2)

Timelines Authorisation	**General timespan (max nr days)** 35 **Mode of approval (General)** Tacit (Silent) **ATMP/GMO trials (max nr days)** 90 **Mode of approval (ATMP/GMO trials)** Explicit **External expert advice required (max nr days)** – **Xenogeneic cell therapy (max nr days)** – **Mode of approval (Xenogeneic cell therapy)** Not specified **Timespan counted from** Not specified **National legal framework in place** Yes **Applicable national legal framework/ Reference** Art 40 AMG
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Any substantial amendments to the study protocol **Responsible for submission of SA** Sponsor Legal representative domiciled in the EU/EEA **Standard notification form available** Yes **Standard notification form** Substantial Amendment Notification Form (en) / Meldeformular für Substantielle Amendments (de) Content of application: Covering letter describing the planned changes + “Substantial Amendment Notification Form” + Summary of changes and the changed documents of the dossier The standard form and the documents required for the assessment shall be submitted electronically on a data medium (e.g. CD). The application should be sent to the BASG together with a covering letter by mail. **Timeline for approval of SA (max nr days)** 35 From automatic confirmation of receipt By silent (implicit) approval (explicit authorisation also possible)

Guidance on submission of SA available

Yes

Guidance on submission of SA

L I206 Leitfaden KP Einreichung (de) + L I207 Klassifizierung von Amendments (de)
L I209 Guidance CT submission (en) + L I219 Classification of Amendments (en)

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 37a AMG

Additional Information

NB: Substantial amendments for clinical trials with ATMPs need to be approved by written notification by BASG.

Safety Reporting

Responsible for AE reporting to CA

Sponsor
Legal representative domiciled in the EU/EEA

Sponsor must declare reportable events to

–

Reportable AEs

SAE (Serious Adverse Event)
SUSAR (Suspected Unexpected Serious Adverse Reaction)

SUSAR being life-thereatening or leading to death must be reported

As soon as possible
Within a max of 7d upon first knowledge

All other SUSARs

As soon as possible
Within a max of 15d upon first knowledge

SAE /SADE must be reported

–

National standard reporting form available

No, European standard SUSAR reporting form CIOMS-I recommended

Standard Reporting Form

CIOMS form available for download on the BASG website
NB: Only to be used if electronic reporting to Eudravigilance is not possible for technical reasons!

Reporting format - Options

Data carrier (USB key)
Paper hardcopy

Preferred format

Other: Electronic reporting in E2B-Format to Pharmacovigilance Database of the European Medicines Agency (EudraVigilance-Clinical Trial Module)

Online Safety Reporting Portal

Prerequisite for electronic reporting is the submission of the following form: F I437 SUSAR Ansuchen: Ansuchen um Befreiung von der Meldungsverpflichtung über schwerwiegende Nebenwirkungen gemäß § 41e AMG an das Bundesamt für Sicherheit im Gesundheitswesen (BASG) (de)/ Request for exemption from the notification obligation of SAEs according to Art 41e AMG to BASG) (en)
No further reporting to BASG, as described in Art 41e, will then be required.

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA
Not applicable

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

L I206 Leitfaden KP Einreichung (de)
L I209 Guidance CT submission (en)

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 41d + Art 41e AMG

Additional Information

Dual-reporting of SUSARs must be avoided (EudraVigilance-Clinical Trial Module and BASG); in case of electronic reporting in E2B-Format, no further reporting obligations to CA according to Art 41e apply (e.g Annual safety report). If electronic reporting to Eudravigilance is impossible, then SUSARs reports should be sent in paper (together with supporting documentation on CD, if necessary).

Investigator shall report SAE to

–

Reporting timeline

–

End of Trial

End of trial declaration mandatory for

All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration

Sponsor
Legal representative domiciled in the EU/EEA

Regular Termination - Declaration timespan (max nr days)

–

Timespan counted from

–

Early/premature Termination - Declaration timespan (max nr days)

–

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

Declaration of the end of the trial form (en) / Meldeformular für die Beendigung der Klinischen Prüfung (de)

Guidance on End of trial declaration available

Yes

Guidance on End of trial declaration

L I206 Leitfaden KP Einreichung (de) / L I209 Guidance CT submission (en)

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 32(1) AMG

Additional Information

Alternative declaration: Informal communication of the National End of Trial in addition to the subsequent reporting of the global End of Trial: In this case, the procedure is closed with the National End of Trial and only the provisions for the final study report remain.

Additional Information & Specifics

Additional Information

Detailed guidance documents published by the CA provide thorough information on submission modalities, conduct, reporting obligations, amendments, safety reports, follow-up procedures, labelling and import of IMP and ATMP (also available in English).

Ethics committee

Contact Details

Contact Name 1

Forum of Austrian Ethics Committees

Contact Name 2

"Forum Österreichischer Ethikkommissionen"

Web address

http://www.ethikkommissionen.at/

Additional Information

A list of all ECs (including local ECs) can be found on the website in section >EK-Liste:
27 local ECs & 7 lead ECs

Ethical Review – General

Submission for Ethical review mandatory for

All scientific health research projects
All clinical trials on Medicinal Products (MP)

Submission to CA and EC to be performed in the following order

–

Regulatory and ethics bodies involved in approval process

–

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

Local EC

	Additional Information 27 local ECs exist in Austria. According to the law (Hospital Act) every hospital needs to have a (research) ethics committee that has to review applications for clinical trials. Additionally the province authorities have to establish (research) ethics committees for clinical trials in institutions outside of hospitals (outpatients). It is possible that one Ethics Committee is the competent committee for several hospitals.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion) **Submission of application required to** Lead EC + All concerned local ECs for site-specific assessment **Additional Information** The lead EC can be chosen freely, but should be locally competent for one of the participating sites. The trial application needs to be submitted to the lead EC and in parallel to the local ethics committees of the trial sites (Art 41b AMG). This is mandatory for initial submission and submission of any amendments. Local ethics committees assess the appropriateness of the investigators and the sites. For multicentre trials a pharmacologist has to be member of the EC.
Submission of Application	**Responsible for study submission** Sponsor Legal representative domiciled in the EU/EEA **Entitled to study submission** – **Prerequisites for submission / approval** –
Submission Format	**Format option(s)** Email Paper hardcopy **Preferred format** – **Standard application form available** Yes **Standard application form** Antragsformular
Language of Submission	**Language(s) of application** German **Preferred language of application** – **English accepted** Yes **Documents mandatory to be in official national language** Not specified
Submission Fees	**Fees for Ethical review mandatory** Yes

	Waiver for academic (non-commercial) studies possible Yes **Fees for Ethical review** For single site clinical trials, as well as for multi-site clinical trials with only one centre in Austria: €1.800 For multi-site clinical trials submitted to an Ethics Committee authorized to review multi-site trials (“single opinion”): €4.500 For the administration of a multi-site clinical trial at each “local” Ethics Committee: €600 for academic applications (without industrial sponsor): may be waived Fees include the assessment and evaluation of any follow-up documents (amendments, reports, etc.)
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 60 **General timespan for multi-centre studies (max nr days)** 60 **ATMP/GMO trials (max nr days)** 90 **External expert advice required: Timespan (max nr days)** – **Xenogeneic cell therapy: Timespan (max nr days)** Not specified **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Date of submission of valid application **National legal framework in place** Yes **Applicable national legal framework/ Reference** 41(a) AMG **Additional Information** Meetings are monthly with set deadline dates for submission, which is usually about 3 weeks prior to the meeting. The general reviewing timeline is 60 days from day of submission or 35 days from submission deadline (Art 41a(5&6) AMG. An objection can be raised by the competent authority, which can also approve trials in case a negative opinion is made by the EC (by means of introduction of an 'Arzneimittelbeirat').
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** Sponsor Legal representative domiciled in the EU/EEA **Standard notification form available** Yes

Standard notification form

"Meldungsformular" (available in German only on the website of the Forum Österreichischer Ethikkommissionen (http://www.ethikkommissionen.at) in section: Formulare, Leitlinien, Informationen, Gesetze, etc. > Meldungen)

Timeline Ethical review of SA (max nr days)

35

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 37a AMG

Additional Information

All concerned ECs (lead and local) have to be notified.

Safety Reporting

Adverse Events (AE) - Definitions (pursuant to national law)

AE and ARs: see 2a AMG

Reportable AEs

SAE (Serious Adverse Event)
SUSAR (Suspected Unexpected Serious Adverse Reaction)

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately (without delay)

Responsible for AE reporting to relevant EC(s)

Sponsor
Legal representative domiciled in the EU/EEA

SUSAR being life-thereatening or leading to death must be reported

As soon as possible
Within a max of 7d upon first knowledge

All other SUSAR must be reported

As soon as possible
Within a max of 15d upon first knowledge

SAE/SADE must be reported

–

Sponsor is obliged to notify all investigators of SAE/ SADE occurrence

Yes

National Standard Reporting form available

Yes

Standard Reporting Form

"Meldungsformular" (available only in German: Form to be used for notification of amendments, AEs, and other nofitications to Austrian ECs)

Reporting format - Options

Email
Online portal
Regular mail
Fax
Other

Preferred reporting format

Other

Provision of Annual safety report mandatory

Yes

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

Guideline - Safety Reports to Austrian ECs (en)/ Leitlinien für Sicherheitsmeldungen (de)

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 41e AMG

Additional Information

1. Recipients of reports: a) Multicentre trials: the Lead EC b) Singlecentre trials: the responsible local EC
2. Guidance on AE reporting, submission of annual safety report and the standard reporting form is available on the website of the Forum Österreichischer Ethikkommissionen in section: Formulare, Leitlinien, Informationen, Gesetze, etc. > Meldungen

End of Trial

End of trial Declaration mandatory

Yes

Responsible for End of trial Declaration

Sponsor
Legal representative domiciled in the EU/EEA

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

–

Early/premature Termination - Declaration timespan (max nr days)

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

"Meldungsformular" (available in German only on the website of the Forum Österreichischer Ethikkommissionen (http://www.ethikkommissionen.at) in section: Formulare, Leitlinien, Informationen, Gesetze, etc. > Meldungen)

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 32 (1) 5 AMG

Additional Information

All involved ECs (lead and local) have to be notified.

Study specific Requirements

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Not specified

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

The investigator must inform the participant orally and in writing on the nature, benefits, risks and implication of the clinical trial as well as his/her right to withdraw from the clinical trial at any time for any reason without disadvantaging the participant. The written informed consent form should be signed and personally dated by the subject.

Applicable national legal framework/ Reference

Art 38 & 39 AMG

Additional Information

Specific provisions apply to certain groups of persons such as minors, incapacitated persons, pregnant women, subjects in emergency situations (At 42-44 AMG).

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

–

Specific provision

The consent is granted by the legal guardian(s) (in principle the parents). The consent must correspond to the minor's presumed will where such a will can be ascertained (informed assent).

Legal framework/Reference (Minors/Children)

Art 42 AMG

Incapacitated persons - Studies allowed

–

Legal framework / Reference (Incapacitated persons)

Art 43 AMG

Emergency situations - Studies allowed

–

Emergency situation without prior consent of patient or proxy - Studies allowed

–

Conditions allowing trial participation in emergency setting without prior consent

It is allowed - provided that approval of CA and EC is granted- to start with immediate treatment without prior consent and as soon as granting consent becomes possible, he or she (or the legal guardian) may subsequently give or withhold consent

Legal framework / Reference (Emergency Situation)

Art 43a AMG

Pregnant or breastfeeding women - Studies allowed

–

Specific provisions

NB: No specific provisions for lactation period existing

Legal framework / Reference (Pregnant or breastfeeding women)

Art 44 AMG

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

Art 42-45 AMG

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

No

Approval/ authorisation required

No

Specific notification timelines before operations start

–

Language of notification

–

Notification format

–

Data Protection Authority/ Agency - Contact Details

Austrian Data Protection Authority

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

National Data Protection Act
Other legislation covering DP related issues

National DP act

Datenschutzgesetz 2000 (DSG2000) - Federal Act concerning the Protection of Data (en)

Other applicable regulations (covering DP related issues)

Art 46 AMG

Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Investigator(s) **Responsible for covering insurance** Sponsor Legal representative domiciled in the EU/EEA **Insurance fee: A minimum coverage sum is defined** No **Minimum coverage sum** Adequacy assessed by ethics committee. **Additional Information** Insurance not required for non-interventional studies
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Compulsory **Audit by sponsor** Optional **Standard Operating Procedures (SOPs)** Compulsory
Archiving & Data Management	**Study documents must be kept at least (in years)** 15 **Applicable national legal framework/ Reference** Art 46 AMG

National legislation

General Information: Applicable Legislation & Conventions	**Official governmental legal database available** Yes **Official governmental legal database** Bundeskanzleramt RIS (Legal Information system) provides the latest versions of all Austrian laws (some English versions available)
Clinical Trials on IMPs in Humans	**Applicable national regulations** – **Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)** Arzneimittelgesetz AMG: applicable for clinical trials on medicinal products and ATMP; transposition of Directives 2001/20/EC and 2005/28/EC into national law. **Transposition of (GCP) Directive 2005/28/EC** Incorporated in transposition act(s) of Directive 2001/20/EC **Act transposing (GCP) Directive 2005/28/EC** Arzneimittelgesetz AMG

	Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc) -Krankenanstalten- und Kuranstaltengesetz §8c KAKuG-Hospital Act. -Datenschutzgesetz 2000 (DSG2000)- Data Protection Act: Federal Act concerning the Protection of Data (English version available) -Ärztegesetz: code of conduct for physicians
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** Yes **Applicable legal framework** Allgemeine Strahlenschutzverordnung AllgStrSchV (Austrian General Radiation protection ordinance) Link: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20004773 **Additional Information** Needs to be considered if radioactive compounds are used in the trial
Gene Therapy	**Specific requirements** Yes **Applicable legal framework** Gentechnikgesetz GTG (Gene technology Act) **Additional Information** This act only mentions but does not explicitely regulates clinical gene therapy
Biobanking	**Applicable legal framework** Austrian biobanks play an important role in medical research, however, there is currently no common legal regulation existing for research biobanks in Austria. Therefore, the Austrian Bioethics Commission published a comprehensive report entitled “Biobanks for Medical Research- Austrian Bioethics Commission” (2007, amended in 2011) which points out the necessity to develop and set up a generally applicable legal framework to ensure the protection of donors of specimens, in particular the rights of self-determination and data protection. **Additional Information** Currently, there are two biobanks in Austria: (1) Medical University of Graz- Biobank Graz: it provides services for internal academic research purposes, but also to external academic and industrial partners within the framework of research collaborations. Biobank Graz has been approved by the local ethics committee and the DVR of the Austrian Data Protection Commission. A comprehensive data protection policy has been developed and implemented to protect sample donor privacy. Informed consent has been established, being consistent with existing international guidelines, such as the OECD Guidelines for Biological Resource Centres BRC. Biobank Graz plays a leading role in the development of an international infrastructure network, the Biobanking and Biomolecular Resources Research Infrastructure BBMRI, aimed at the achievement of international standardization and harmonization. (2) Medical University of Vienna- Meduni Wien Biobank: All projects of the MedUni Wien Biobank need to be conducted according to the ethical standards of the Medical University Vienna. A project can only be initiated if specific criteria on Informed Consent, right to self-determination, transparency, data protection and quality assurance are met and the Ethics Committee has issued a favourable opinion.

Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** National Data Protection Act Other legislation covering DP related issues **National DP act** Datenschutzgesetz 2000 (DSG2000) - Federal Act concerning the Protection of Data (en) **Other applicable regulations (covering DP related issues)** Art 46 AMG
CA operations/ Fees	**Separate legal framework available** Yes **Applicable legal framework** Gebührentarifverordnung gemäß Gesundheits- und Ernährungssicherheitsgesetz GESG
Additional Information & Specifics	**Additional Information** If the clinical trial is conducted without the use of medical devices or medicinal products there is no specific legislation in Austria. According to § 8c KaKuG (see Gesamte Rechtsvorschrift für Krankenanstalten- und Kuranstaltengesetz (Austria)/KaKuG) only an opinion from the Ethics Committee is required for a new medical method. The Ethics Committee responsible for the physician involved must give this opinion according to the Ärztegesetz 1998 (Austria)/ Professional code of conduct for physicians 1998. In terms of the privacy of the participants, the Bundesdatenschutzgesetz (Austria) (see also the unofficial English translation Bundesdatenschutzgesetz - Data Protection Act (Austria), English version) has to be regarded. Furthermore the clinical trial has to be conducted in accordance with the Declaration of Helsinki.

Definition

IMP/IMP Study	**IMP - Definition available in national law** Yes **IMP - Definition** "Prüfpräparat" (according to Art 2a (14) AMG): The pharmaceutical form of a drug or placebo tested in a clinical trial or used as comparator; further any approved human medicine if applied in a form different from marketed approval or in a different therapeutic indication or if used to acquire additional information for the approved form. **IMP Study - Definition available in national law** Yes **IMP Study - Definition** "Klinische Prüfung": see Art 2a (1) AMG