Medical Devices - 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 **Contact Name 3** Institute Surveillance **Phone** +43 50 555-36111, -36820 **Email General** inspektionen@ages.at **Email Department** clinicaltrials@ages.at **Address** Traisengasse 5 **ZIP/City** 1200 Wien **Country** Austria (AT) **Web address** http://www.ages.at/ages/geschaeftsfelder/medizinmarktaufsicht/ **Additional Information** Webadress of BASG: http://www.basg.gv.at/
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** Active Implantable Medical Devices (AIMD) MD CE-marked, use within label + IMP MD CE-marked, use outside label MD CE-marked, use outside label + IMP MD without label MD without label + IMP MD Class III Other high-risk devices (Class IIa or IIb implantable and long-term invasive MDs) **CA - Registration/ notification without approval required for** Performance evaluations of in-vitro diagnostic MDs MD Class I

	CA - Submission required to – **CE-marked MD used within label are exempted from any notification obligation to CA** Yes **National trial registry - Registration mandatory** No registry in place **Applicable national legal framework/ Reference** Art 40 MPG **Additional Information** A detailed guidance on notification obligations is available on the BASG website for download in English and German: L I102 Overview about Notification Procedures (en)/ L I64 Meldeverfahren (de) **Submission to CA and EC to be performed in the following order** –
Submission of Application	**Responsible for study submission** Sponsor Legal representative domiciled in the EU/EEA **Entitled to study submission** – **Prerequisites for submission** Positive opinion by relevant EC(s) Appropriate insurance **Guidance on submission of application** A checklist on application dossier and detailed guidance on application procedure is available on the BASG website in German and English: ENGLISH: L I100_Required documentation MP (en) + L I99_Guidance Document for Clinical Investigations with Medical Devices (en) GERMAN: L I07 Unterlagen klinische Proofing MP (de) + Leitfaden für klinische Prüfung mit Medizinprodukten (de) **National legal framework in place** Yes **Applicable national legal framework/ Reference** Art 40 MPG **Additional Information** Combination studies: 2 separate applications required for combinations studies (1 according to AMG and 1 according to MPG)
Submission Format	**Format option(s)** Electronically As XML and PDF on a data medium **Preferred format** –

	Online portal As per March 24th, 2016, the new electronic submission form for initial applications of clinical investigations and performance evaluations will come into effect as an requirement for a valid submission. The list of fields is based on the mandatory content for the EUDAMED database and addtional information. The electronic form will replace all former paper forms. NB: Completing the application form does not lead to automatic submission to the BASG. For study notification, the completed application form must be submitted to the BASG as XML and PDF (together with the other required documents) on a data medium. **Standard application form available** Yes **Standard application form** Electronic submission form, available at BASG website. **Use of standard application form binding** Yes **Guidance on submission format available** Yes **Guidance on submission format** ENGLISH: L I99 Guidance Document for Clinical Investigations with Medical Devices (en) GERMAN: I192 Leitfaden für klinische Prüfung mit Medizinprodukten (de) **Additional Information** The application form and all documents required for assessment (Protocol, IB, certificates, ..) 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. NB: Paper version of the dossier no longer required.
Language of Submission	**Language(s) of application** German English **Preferred language of application** – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Information material, Documents and Forms intended for study participants and patient information Instructions for use (of CE-marked MD) **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** –
Submission Fees	**Fees for trial submission mandatory** Yes

	Fees - Clinical investigation: 3000 € - Substantial amendment: 500 € Clinical investigations on a medical device submitted together with a related medicinal product by the same applicant. In this case, the total fee for a clinical investigation on medical devices plus 35 % of the set fee for clinical trials on medicinal products (3000 € Phase I-III, 1500€ Phase IV) will be charged. NB: From 01.01.2016, new fees for non-commercial (academic) studies apply: 20% of regular fees for notification of a clinical investigation of a medical device or a performance test validation of an IVD (one-time charge!) No fees for substantial amendments or inspections are charged. **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)** 60 **Mode of approval (General)** Tacit (Silent) **Timespan counted from** Confirmation of formal completeness **Applicable national legal framework/ Reference** 40(2) +40(3) MPG **Additional Information** Explicit approval before expiration of the 60d- timespan is possible. Clinical investigations of low-risk MDs and performance evaluations of in vitro diagnostic MDs can start once the receipt of a complete and adequate notification has been confirmed by the BASG and the EC has issued a favourable opinion.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** Substantial amendments to clinical investigations according to MPG § 40 (2) and (3) **Authorisation mandatory for** Substantial amendments to clinical investigations according to MPG § 40 (2)

Responsible for submission of SA

Sponsor
Legal representative domiciled in the EU/EEA

Standard notification form available

Yes

Standard notification form

F I200 Amendment Form MPG (en/de): Bilingual amendment form for amendments to clinical investigations and performance evaluations
The amendment application form + additional documentation should be submitted on a data carrier.

Timeline for approval of SA (max nr days)

35
From date of receipt of valid application
Tacit approval (non- rejection procedure) for amendments to § 40 (2) MPG studies (explicit authorisation also possible)

Guidance on submission of SA available

Yes

Guidance on submission of SA

L I99 Guidance Document for Clinical Investigations with Medical Devices (en)
L I192 Leitfaden für klinische Prüfung mit Medizinprodukten (de)

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 40a MPG

Additional Information

Notification only (without approval process) for § 40 (3) MPG studies: low-risk MDs and performance evaluations of in vitro diagnostic MDs
Approval/ authorization required for § 40 (2) MPG studies : High risk devices (AIMDs, class III medical devices, implantable and long-term invasive medical devices of class IIa or IIb)

Urgent amendments such as the temporary suspension of an investigation for reasons of participant safety or the introduction of additional monitoring measures can be implemented without prior notification to the BASG (§ 40a (5) MPG).

Non-substantial amendments should be documented and brought to the BASG's attention with the next substantial amendment and do not have to be immediately notified to the BASG with two exceptions:
• Non-substantial changes that relate to the application form should be submitted to the BASG timely to ensure actuality of the database.
• Changes to the protocol required by the ethics committee that relate to the safety monitoring of the patients should be promptly submitted to the BASG.
If a separate notification is desired, the amendment notification form F_I200 should be used.

Safety Reporting

Responsible for AE reporting to CA

Sponsor
Legal representative domiciled in the EU/EEA

Sponsor must declare reportable events to

National CA
CA(s) of EU&EFTA Member States concerned

Reportable AEs

SAE (Serious Adverse Event)

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

–

All other SUSARs

–

SAE /SADE must be reported

Immediately (without delay)

National standard reporting form available

Only for reportable events occurring in the respective country
Other

Standard Reporting Form

2 different forms available:
1. Form to be used for SAEs having occurred at an Austrian study site:
F I209 SAE (en) / F I208 SAE Klinische Pruefung MP (de)
2. Form (line listing) to be used for reporting of ALL SAEs having occurred in the clinical investigation:
F I287 SAE_Report_Table (en) / F I287 SAE EWR Meldung MP (de)
Use of European standard SAE reporting form MEDDEV 2.7/3 (or similar) is also accepted.

Reporting format - Options

–

Preferred format

–

Annual safety report shall be provided by sponsor to

–

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

ENGLISH: L I99 Guidance CI MPG - Guidance Document for Clinical Investigations with Medical Devices (en)
GERMAN: L I192 Leitfaden KP MPG - Leitfaden für klinische Prüfung mit Medizinprodukten (de)

Applicable national legal framework/ Reference

Art 42 (8) MPG)

Investigator shall report SAE to

–

Reporting timeline

–

End of Trial

End of trial declaration mandatory for

All clinical trials requiring notification to CA (without approval process)
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)

No timeline specified in national law

Timespan counted from

–

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

No timeline specified in national law

Standard Declaration form available

Yes

Standard Declaration form

F I207 ENG Beendigung Studie MP Leistungsbewertungspruefung (en/de): Bilingual global end notification form for clinical investigations/performance evaluations

Guidance on End of trial declaration available

Yes

Guidance on End of trial declaration

ENGLISH: L I99 Guidance Document for Clinical Investigations with Medical Devices (en)
GERMAN: I192 Leitfaden für klinische Prüfung mit Medizinprodukten (de)

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 42 (8) MPG)

Ethics committee

Contact Details

Contact Name 1

There are 27 local & 7 lead ECs

Contact Name 2

Forum of Austrian Ethics Committees/ Forum Österreichischer Ethikkommissionen

Web address

http://www.ethikkommissionen.at

Additional Information

A list of all ECs (including lead and local ECs) can be found on the website in section >EK-Liste.

Ethical Review – General

Submission for Ethical review mandatory for

All clinical investigations of MD
All combination studies (MD+IMP)

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

–

Additional Information

Investigations of MD bearing the CE-mark and used for their intended purpose only need approval from the competent EC!

	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** According to the law every hospital needs to have a (research) ethics committee that has to review applications for clinical trials with medical devices. 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** All local ECs of participating sites **Submission of application required to** All local ECs of participating sites **Additional Information** A 'single opinion' or mutual recognition is not established for studies with medical devices. However, any local EC can accept the opinion provided from another EC in Austria. In this case, the EC assessing the clinical investigation or performance evaluation must be provided with information regarding all additional investigators and with any documentation allowing the professional qualification and experience of the investigators, the available facilities, and the qualification of the supporting staff to be assessed (MPG § 57 (2))
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** – **Applicable national legal framework/ Reference** Art 57(1), Art 65a MPG
Submission Format	**Format option(s)** Email Paper hardcopy Other **Preferred format** – **Standard application form** "Antragsformular"(available on the website of the "Forum Österreichischer Ethikkommissionen" in section: Formulare (Download)) **Additional Information** Submission format depends on EC; some ECs have an online application form to fill in
Language of Submission	**Language(s) of application** German

	Preferred language of application – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Information material, Documents and Forms intended for study participants and patient information **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
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 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 **External expert advice required: Timespan (max nr days)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** – **Applicable national legal framework/ Reference** Art 60(2) MPG **Additional Information** Meetings are monthly, with set deadline for submission usually about 3 weeks prior to the meeting.
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

"Meldungsformular" (available in German only on the website of the "Forum Österreichischer Ethikkommissionen" in section: Meldungen)

Timeline Ethical review of SA (max nr days)

–

Applicable national legal framework/ Reference

Art 60(2) MPG

Additional Information

The favourable opinion is sent to CA.

Safety Reporting

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

Adverse Device Effect (ADE): any undesirable clinical event occurring under and related to the normal conditions of use of a medical device, i.e., a device-related adverse event (Art 2(17) MPG)
SAE/SADE: an adverse event or an adverse device effect in accordance with § 2 (17) is to be considered serious if it is fatal or life-threatening, causes permanent damage, or requires or prolongs hospitalization. Any adverse event or adverse device effect causing fetal damage, fetal death, or a congenital anomaly as well as any occurrence of a malignant tumour shall, without exception, be classified as serious (Art 3(16) MPG).

Reportable AEs

SAE (Serious Adverse Event)
ADE (Adverse Device Effect)
SADE (Serious Adverse Device Effect)

Investigator shall report SAE to

Relevant EC(s)
Sponsor

Reporting timeline

No specific deadline indicated

Responsible for AE reporting to relevant EC(s)

Principal Investigator
Investigator

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

–

All other SUSAR must be reported

–

SAE/SADE must be reported

–

National Standard Reporting form available

–

Standard Reporting Form

"Meldungsformular" (provided on website of Forum Österreichischer Ethikkommissionen in section "Meldungen": Form to be used for notification of amendments, AEs, and other nofitications to Austrian ECs, available only in German)

Reporting format - Options

Email

Preferred reporting format

–

Guidance on AE reporting procedure

Guideline - Safety Reports to Austrian ECs (en)/ Leitlinien für Sicherheitsmeldungen (de) (Link: http://www.ethikkommissionen.at)

Applicable national legal framework/ Reference

Art 61 + 64(5) MPG

Additional Information

1. SUSARs only have to be reported if IMP involved 2. Reporting format depends on concerned EC (Email, Fax, Mail/post, Online portal, Delivery service)
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: 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)

No timeline specified in national law

Timespan counted from

–

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

No timeline specified in national law

Standard Declaration form

"Meldungsformular" (available in German only on the website of the Forum Österreichischer Ethikkommissionen in section: Meldungen)

Applicable national legal framework/ Reference

Art 40(6) MPG

Study specific Requirements

Sponsor

Sponsor - Definition available in national law

Yes

Sponsor - Definition (pursuant to national law)

Art 3(5) MPG:
„Sponsor“ ist jede natürliche oder juristische Person, welche die Verantwortung für die Planung, die Initiierung, die Durchführung und die Finanzierung einer klinischen Prüfung übernimmt. Der Sponsor muss in einer Vertragspartei des EWR niedergelassen sein. Der klinische Prüfer hat die Pflichten und die Verantwortung des Sponsors zusätzlich zu übernehmen, wenn er eine klinische Prüfung unabhängig vom Hersteller des Medizinproduktes und in voller Eigenverantwortung durchführt.

Sponsorship mandatory

Yes

Co-Sponsor - Definition available in national law

No

Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:

Yes

Study Participants - Informed Consent (IC)

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 49-50 MPG

Additional Information

Specific provisions apply to certain groups of persons such as minors, incapacitated persons, pregnant women, subjects in emergency situations (Art 51-54 MPG).

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

–

Specific provision

Studies with minors are possible under special provisions
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 51 MPG

Incapacitated persons - Studies allowed

–

Specific provisions

Studies with MD involving permanently incapacitated persons are prohibited

Legal framework / Reference (Incapacitated persons)

Art 52 MPG

Emergency situations - Studies allowed

–

Specific provisions

Studies with subjects being in emergency situations are possible under special provisions.

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 (pursuant to Art 52a MPG).

Legal framework / Reference (Emergency Situation)

Art 52a MPG

Pregnant or breastfeeding women - Studies allowed

–

Legal framework / Reference (Pregnant or breastfeeding women)

Art 53 MPG

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

Art 51-54 MPG

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

Additional Information

Applicable legisaltion:
Datenschutzgesetz 2000 (DSG2000) - Data Protection Act: Federal Act concerning the Protection of Data
The handling of patient-related data is also covered in §55/1-4 MPG.

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)/
Available in English: Federal Act concerning the Protection of Data

Other applicable regulations (covering DP related issues)

AMG (Art 46) + MPG (Art 55/1-4)

Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Investigator(s) Study participants **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** For studies of marketed devices and in vitro diagnostics and used within CE marking an investigator insurance is sufficient, if no additional diagnostic or therapeutic interventions are planned. The sponsor is obliged to cover all damage.
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Compulsory **Audit by sponsor** Optional **Standard Operating Procedures (SOPs)** Compulsory

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation** Official website: BASG website in section: About us > Legal basis > Medical devices **Official governmental legal database** Bundeskanzleramt RIS (Legal Information system) provides the latest versions of all Austrian laws (some English versions available)
Investigations on Medical Devices	**Applicable national regulations** Transposition of Directive 90/385/EEC Transposition of Directive 93/42/EEC Transposition of Directive 98/79/EC **Act on Medical Devices (or comparable national legal framework)** Medizinproduktegesetz MPG (Medical Devices Act) (de): Transposition of the Eurpean Directives **Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** - Krankenanstalten- und Kuranstaltengesetz §8c KAKuG (Hospital Act) Link: - Ärztegesetz 1998 (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)

Gene Therapy	**Applicable legal framework** Gentechnikgesetz GTG (Gene Technology Act) **Additional Information** This act only mentions but does not explicitely regulates clinical gene therapy
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)/ Available in English: Federal Act concerning the Protection of Data **Other applicable regulations (covering DP related issues)** AMG (Art 46) + MPG (Art 55/1-4)
CA operations/ Fees	**Separate legal framework available** Yes **Applicable legal framework** Regulation on fees: Gebührentarifverordnung gemäß Gesundheits- und Ernährungssicherheitsgesetz GESG **Additional Information** It regulates the fees charged by the CA for assessment of clinical investigations.

Definition

MD/MD Investigation	**MD - Definition available in national law** Yes **MD - Definition** Definition provided in Art 2(1) MPG: „medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means” **Investigation of MD - Definition available in national law** Yes **Investigation of MD - Definition** Definition provided in Art 3(2) MPG (in German only). **Additional Information** "Medical Device for Clinical Investigations" : Definition provided in Art 3 (3) MPG