German Net PaeT
German Network for Paediatric Trials

Regulatory and Start-up Guideline for Clinical Trials

Germany

1. Definitions

AMG	Medicinal Products Act / German Pharmaceutical Act
AMGKostV	AMG Fee Regulation
BfArM	Federal Institute for Drugs and Medical Devices
BtMG	German Narcotic Drugs Act
CMC	Chemistry, Manufacturing and Control
CT	Clinical Trial
CTA	Application for the Authorisation of Clinical Trials
CTR	Clinical Trial Regulation
EC	Ethics Committee for investigation of medicinal products
GCP	Good Clinical Practice
GCP-V	GCP Ordinance
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
IB	Investigator's Brochure
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
MP	Medicinal Product
NCA	National Competent Authority
PEI	Federal Agency for Sera and Vaccines (Paul-Ehrlich-Institut)
PIP	Paediatric Investigational Plan
PP	Pilot Project
SmPC	Summary of Product Characteristics
SNIF	Summary of Notification Formats

2. The Application

The CT documentation is evaluated by NCA and one or more ECs.

The Application can only be submitted with a EudraCT number and the European application form and should be structured according to the sample folder provided by the BfArM: https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/KlinischePruefung/Genehmigungs-Verfahren/unterlagen.html

The Application documents have to be submitted electronically and paper-based:

- Application documents as PDF and XML file on CD-ROM or DVD + 1 printed and signed paper copy for NCA
- PDF and XML file on CD-ROM or DVD or USB flash drive + at least 9 printed and signed paper copies for leading EC (exact number depending on EC). Increasing numbers of ECs use online-submission systems.
- PDF and XML file on CD-ROM or DVD or USB flash drive + at least 1 printed and signed paper copy for each participating EC (exact number depending on EC)

Documentation	**BfArM/ PEI**	**EC**
01 Cover letter	√	√
02 EudraCT	√	√
03 Protocol	√	√
04 Investigator's Brochure	√	√
05 Investigational Medicinal Product Dossier	√	
06 Risk-Benefit	√	√
07 Non-IMPD	√	
08 GMP	√	
09 Labelling	√	
10 Administrative Documents	√	√
11 Scientific Advice	√	√
12 GMO	√	
13 Xenogeneic Products	√	
14 Other Documents	√	√
15 Reporting	√	√
Module 1 of the CTA [3]		

Module 2 of the CTA [4]		√
Patient / Guardian Information and Informed Consent Forms / Assent Forms where applicable		√
Proof of Site Qualification		√
CV / GCP-certificate (16h/8h) / Financial Disclosure for investigator and deputy investigator of each site		√
Synopsis in German		√
Checklist provided by EC		√

2a. National Competent Authorities

In Germany there are two NCAs with separate responsibilities depending on the character of the IMP

BfArM:

Responsible for: all medicinal products / classic pharmaceuticals for human use, except PEI is competent

PEI:

Responsible for: Sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, cell preparations, stem cells, tissues, allergens, advanced therapy medicinal products, xenogeneic medicinal products and blood components manufactured using genetic engineering

Special requirements:

- **Controlled substances**: additional permit from the **Federal Opium Agency** (department of BfArM) according to Section 3 of the BtMG is required

  Additional documents to be submitted to the Federal Opium Agency:

  - **Sponsor**: copy of cover letter and study protocol
  - **Investigator**:
    - Name of investigator (all first names, last name, when applicable birth name)

- Medical license to verify the required expertise according to Section 6 of the BtMG or BtM number, if available
- Type and quantity of controlled substances that will be used in the CT with name of supplier
- Exact name and address of institution conducting the CT with telephone and when applicable fax number
- Description of safety against unauthorized removal of controlled substances with information about type of safes and rooms
- Date and signature of principal investigator

- **Drug supplier**: permit according to Section 3 of the BtMG to grow, manufacture, trade, import and export controlled substances

- **Radioactive substances**: additional permit from the **Federal Office for Radiation Protection (BfS)**

Address for application BfArM:

Bundesinstitut für Arzneimittel und Medizinprodukte
Fachregistratur Klinische Prüfung von Arzneimitteln
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
Germany

For more information:
Email: ct@bfarm.de or info-esubmission@bfarm.de
Phone: +49 (0)228 99 307-4318

Address for application PEI:

Paul-Ehrlich-Institut
Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Referat für Klinische Prüfungen
Paul-Ehrlich-Straße 51-59
63225 Langen
Germany

For more information:
Email: klinpruefung@pei.de
Phone: +49 (0)6103 77 1810
Documentation [2]

Application form Module 1 [3] **has to be submitted to NCA and EC together with documentation mentioned below (01-15). All required information according to Section 7 of the GCP-V has to be covered by the submitted documentation.**

01 Cover letter

- Signed by sponsor or authorised representative
- Language: German
- Name / company name & address of sponsor and, where applicable, of authorised representative in EU/EWR
- EudraCT number
- Protocol code
- Title of CT
- Special features of the CT with reference to information in documentation (e.g. first in human etc.)
- Confirmation of similarity of documentation in electronic and paper form
- When applicable national consultation procedure with date

02 EudraCT

- Application form as PDF file (electronic and paper)
- Application form as XML file (only electronic)
- Copy of email with EudraCT number and protocol code
- If applicable Substantial Amendment Notification Form
- If applicable Declaration of the End of Trial Form

03 Protocol

- Signed by sponsor or authorised representative and principal investigator
- Cover page with:
    - EudraCT number
    - Full title of CT and working title of CT
    - Protocol code
    - Version
    - Date of protocol version

04 Investigator's Brochure

- ICH GCP-compliant
- Separate document or part of the IMPD
- For non-approved IMP: ICH GCP compliant IB

- For placebo: no separate IB required
- For approved IMP applied within the framework of the approval: latest SmPC
- For approved IMP applied outside the framework of the approval: SmPC + additional information (IMPD)

05 Investigational Medicinal Product Dossier

- IMPD-QUA or simplified IMPD:
  - Documentation about quality and manufacturing
  - IMPs with chemical defined or herbal active agents: Documentation according to "Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal product in clinical trials (CHMP/QWP/185401/2004 final)"
  - IMPs with biotechnologically manufactured active agents: Documentation according to "Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials (EMA/CHMP/BWP/534898/2008)"
  - Virus safety of IMPs: Documentation according to "Guideline on virus safety evaluation of biotechnological investigational medicinal products (EMEA/CHMP/BWP/398498/2005)"
- IMPD-TOX:
  - Documentation about pharmacological and toxicological testing
  - Reference to preclinical part of IB is possible
- IMPD-KLI:
  - Documentation of results of previous CTs and further known clinical results
  - Reference to clinical part of IB is possible

06 Risk-Benefit

- Summarising risk-benefit-analysis of CT
- Reference to relevant part of protocol is possible

07 Non-IMPD

- Documentation for Non-IMPs
- Documentation according to "Guidance documents applying to clinical trials guidance on investigational medicinal products and "non-investigational medicinal products" (NIMPs) [SANCO/C/8/SF/cg/a.5.001(2011)332855]"

08 GMP

- Manufacturing authorisation:

- Copy of manufacturing authorisation of all involved manufacturers based in the EU/EWR

- Import authorisation:
  - Copy of import authorisation of importer based in the EU/EWR
- GP-declaration:
  - Declaration about GMP-compliant manufacturing in third countries according to section 13 (3) of the guideline 2001/20/EG

09 Labelling

- Labelling of IMPs according to Section 5 GCP-V with specification of packaging level
- Additional labelling of radioactive IMPs according to section 3 (2) AMRadV

10 Administrative Documents

- Gender distribution: rationale for selected gender distribution to evaluate gender specific differences in safety and efficacy of IMP (reference to appropriate sections of the study protocol is possible)
- Plan for follow-up treatment and medical care after end of trial IMP (reference to appropriate sections of the study protocol is possible)
- Data protection declaration: declaration about information and consent of study participants about pseudonymous data transfer
- Competent EC and authorities of other countries:
  - Name and address of competent EC according to section 42 (1) sentence 1 and 2 of the AMG
  - Name and address of competent NCAs of other countries in the EU/EWR in which the clinical trial is conducted
- Rejection of other authorities:
  - Reasons for previous rejection of other NCAs in countries in the EU/EWR
  - Previous approvals of other NCAs in countries in the EU/EWR, where applicable, with additional requirements
- Votes of ECs:
  - Reasons for previous rejections of other competent ECs in countries in the EU/EWR
  - Previous positive opinions of competent ECs in the EU/EWR, where applicable, with additional requirements
  - Previous positive opinions of competent ECs in Germany, if existing, where applicable, with additional official requirements
- Authorisations, where applicable:

- In case the application is not made by the sponsor himself but by an authorised representative

- Declaration of cost absorption, where applicable:
  - In case of differing invoice address
  - Declaration of cost absorption of the approval procedure

11 Scientific Advice

- Results of scientific advice from the EMA or other NCAs (incl. BfArM/PEI)
- PIP

12 GMO

- SNIF application form of the Joint Research Institute as Microsoft®Word file for information to the public
- Explanation and assessment of the risks to the health of non-trial subjects and the environment and observation plan to establish the effects
- Explanation of the intended precautions and information on the GMO
- Information on the conditions of the clinical trial and the environment which may exposed to the GMO and on interactions
- Description of the planned supervision measures and information on resulting residues and their treatment and on emergency plans

13 Xenogeneic Products

- Certificate of insurance according to section 40 (1) sentence 3 No. 8 of the AMG

14 Other Documents

- Documents not fitting in any of the other sample folders

15 Reporting

- Reporting about changes in risk-benefit-analysis
- Notifications of urgent safety measures
- Annual safety reports
- Final study report

2b. Ethics Committee assessment

In Germany there is no central EC. There are separate ECs for every federal state and university hospital (see Annex 1). Regarding multicentre CTs a distinction is made between the leading EC (study site of coordinating investigator) and the participating ECs (participating study sites).

Application form Module 2 [4] **has to be submitted only to ECs (leading and participating) including the information and documents mentioned below.**

! Please be aware that each EC has its own additional specific requirements and templates for submission. In case you are not sure what documentation is needed exactly and what are the content-related requirements contact the German Hub or the competent EC for detailed information!

The following shall also be submitted to the competent EC:

1. Explanation of the importance of the clinical trial,
2. Assessment and evaluation of the foreseeable risks and disadvantages of the clinical trial compared with the expected benefits for the trial subjects and persons becoming ill in future,
3. Justification of the inclusion of subjects under Section 40 (4) and Section 41 (2) and (3) of the AMG in the clinical trial (minor, minor who suffers from a disease in the treatment of which the investigational medicinal product is to be used, person of legal age who is incapable of understanding the nature, significance and implications of the clinical trial and of determining his/her will in the light of these facts and who is suffering from a disease in the treatment of which the investigational medicinal product is to be used),
4. Explanation concerning inclusion of persons who may be dependent on the sponsor or investigator,
5. Information concerning the financing of the clinical trial,
6. Curricula vitae or other appropriate evidence of qualifications of investigators, and GCP training (German EC currently expect at least 16h GCP-training for PI and deputy investigator at each site (and other physician members of the investigator team with full delegation) and 8h GCP training for other physician-members of the investigator team with limited delegation.)
7. Information concerning possible financial and other interests of investigators in connection with the investigational medicinal products,
8. Information concerning the suitability of the trial site, especially concerning the adequacy of the existing resources and facilities and of the personnel available for the conduct of the clinical trial and concerning experience in the conduct of similar clinical trials,
9. Information and documents (patient information sheets, informed consent form etc.; often templates are provided by the respective EC) received by the trial subjects, in German, and an explanation of the procedure for informed consent,
10. Description of the intended investigation methods and any deviations from the investigations which are usual in medical practice,
11. Description of the intended procedure to ensure that trial subjects are not taking part at the same time in any other clinical trials or research projects or are taking part in the clinical trial before the end of a necessary waiting period,

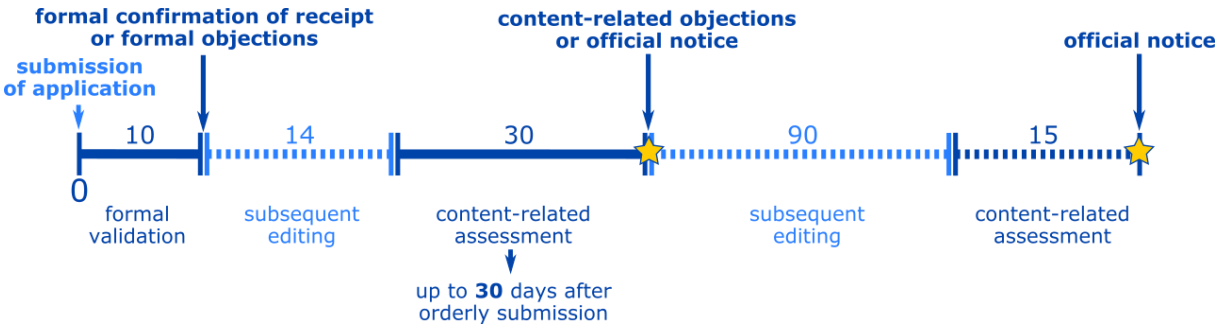
12. Description of the way in which the state of health of healthy trial subjects is to be documented,
13. Evidence of insurance cover under Section 40 (1) sentence 3 no. 8 and Section 40 (3) of the AMG,
14. Arrangements made with respect to the remuneration of investigators and payment of trial subjects,
15. Statement concerning compliance with data protection requirements,
16. All essential elements of the contracts envisaged between the sponsor and the trial site,
17. Criteria for the suspension or premature termination of the clinical trial,
18. In the case of multicentre clinical trials taking place at more than one trial site within the scope of the AMG, a list of the names and addresses of the participating ethics committees,
19. A summary of the main content of the protocol in German, if the protocol is submitted in English in accordance with Section 2 (3).

3. Time to get the approval [1; 2]

National Competent Authority:

Group A (30):

- MPs for human use *(BfArM)*
- Allergens *(PEI)*
- Vaccines *(PEI)*
- Biotechnological products *(PEI)*



Group B (60):

- Biological products (human/animal) *(PEI)*

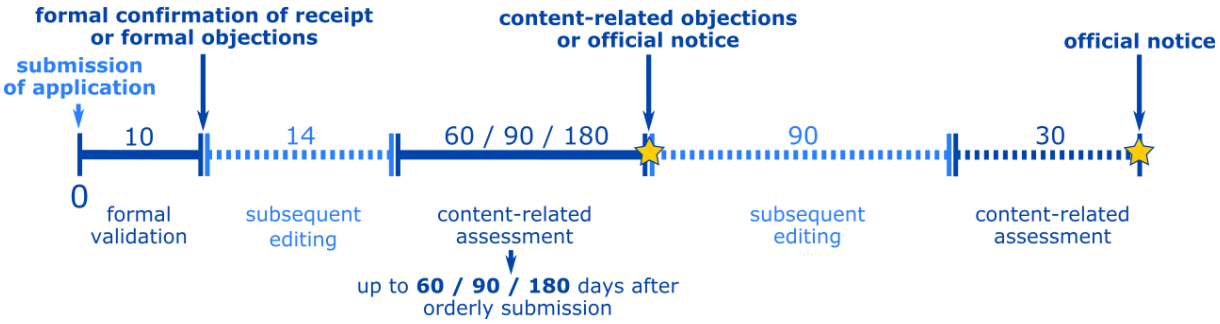
Group C (90):

- Novel therapies (*BfArM/PEI)*
- Somatic cell therapy MPs *(PEI)*

- Gene transfer drugs / GMO *(PEI)*

Group D (180):

- MPs in Group C, if consultation of expert or expert report is crucial for assessment



Group E:

- Xenogeneic cell therapy MPs *(PEI)*

  → No deadline for content-related assessment of submission

Ethics Committee:

Group I (60):

- MPs for Human Use
- Multicentre Trial

Group II (30):

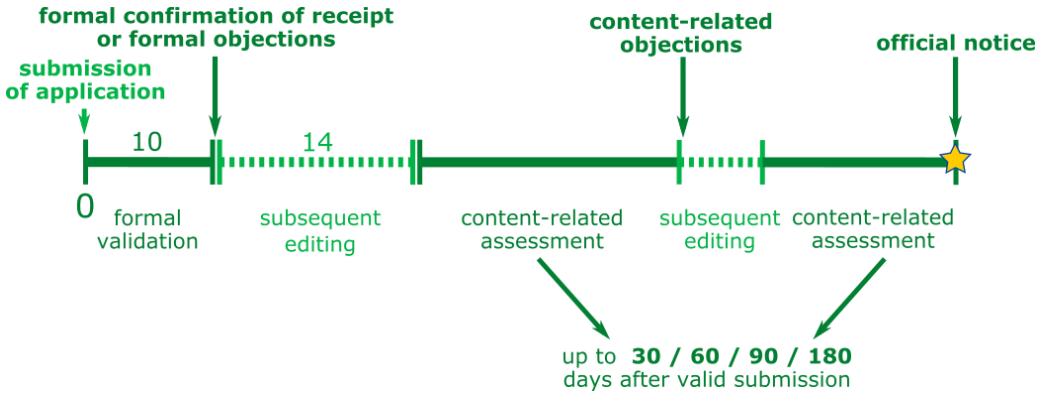
- Monocentric Trial
- Multicentre trial with not more than 1 site in Germany

Group III (90):

- Somatic cell therapy medicinal products
- GMO

Group IV (180):

- Gene transfer drugs
- MPs in Group III, if consultation of expert or expert report is crucial for assessment



Group V:

- Xenogeneic cell therapy medicinal products

  → No deadline for content-related assessment

4. Costs to get the approval

National Competent Authority [5]

Excerpt of the relevant sections of the AMGKostV:

Fee item	Individually attributable public services subject to charge	Fee [€]
12	**Examination of marketing authorisation-related information in accordance with Section 25(5) AMG, depending on the staff costs and operational expenditures**	5 000 - 25 000
13	**Individually attributable public services within the scope of clinical trials**	
13.1	Marketing authorisation granted in accordance with Section 40 (1) Sentence 2 AMG, Section 42 (2) AMG	
13.1.1	First submission of an trial plan for an investigational drug in Phase I, II or III	
13.1.1.1	Basic fee	3 800
13.1.1.2	For submission of an integrated study protocol with additional sub-studies in accordance with fee item 13.1.1 per additional sub-study, in addition to the basic fee	900
13.1.2	Follow-up study of an investigational drug assessed in accordance with fee item 13.1.1 in phase I, II or III	
13.1.2.1	Follow-up study without new assessment of documents	1 500
13.1.2.2	Follow-up study with new assessment of documents in phase I	
13.1.2.2.1	Basic fee	1 900

13.1.2.2.2	For submission of an integrated study protocol with additional sub-studies in accordance with fee item 13.1.2.2 per additional sub-study, in addition to the basic fee	800
13.1.2.3	Follow-up study with new assessment of documents in phase II or III	
13.1.2.3.1	Basic fee	2 100
13.1.2.3.2	For submission of an integrated study protocol with additional sub-studies in accordance with fee item 13.1.2.3 per additional sub-study, in addition to the basic fee	900
13.1.3	Approval of a clinical trial with an investigational drug which has a marketing authorisation in an EU member state at the time the application is filed; the application of the investigational drug occurs within or outside the authorised application conditions specified in the product characteristics.	
13.1.3.1	Basic fee	1 700
13.1.3.2	For submission of an integrated study protocol with additional sub-studies in accordance with fee item 13.1.3 per additional sub-study, in addition to the basic fee	900
13.1.4	Examination for proof of bioequivalence	2 100
13.1.5	Approval in accordance with Section 42 (3) conjunction with Section 9 (2) Sentence 2 and 3 GCP-V upon submission of additional documents which require a scientific processing	740
13.1.6	Approval of clinical trials with medicinal drugs which consist of or contain a genetically modified organism or a combination of genetically modified organisms	9 500
13.1.7	Approval of variations after start of a clinical trial in accordance with Section 42 (3) AMG in conjunction with Section 10 GCP-V	
13.1.7.1	Variations subject to approval, which require a scientific processing	
13.1.7.1.1	Basic fee	1 100
13.1.7.1.2	Variations subject to approval, which contains several variations subject to approval in accordance with fee item 13.1.7.1, per additional variation	700
13.1.7.2	Other variations	730
13.2	Assessment of annual reports on the safety of the participants in the trial in accordance with Section 42 (3) AMG in conjunction with Section 13 (6) GCP-V	
13.2.1	Annual reports on monocentre clinical trials	500
13.2.2	Annual reports on multicentre clinical trials	1 000
13.2.3	Annual reports on more than five clinical trials with the same	2 500

	investigational drug	
13.3	Examination of authorisation-related information in accordance with Section 42 (3) AMG in conjunction with Section 9 (5) GCP-V (GCP inspections), depending on the personnel and material costs	5 000 - 50 000
13.4	Examination, comparison and submission of the information for the EudraCT database in accordance with Section 14 (3) GCP-V, where not covered by fee item 13.1	250

Ethics Committee

The costs for services with regard to clinical trials of the ECs in Germany are based on local law. Every EC can charge different fees according to their own fees regulation.

E.g.: Excerpt of the relevant sections of the fees regulation of the Landesärztekammer Baden-Württemberg (23.01.2019):

Fee item	**Individually attributable public service subject to charge**	**Fee [€]**
6.1	**Assessment according to Sections 40 and 42 AMG**	
6.1.1	For monocentric clinical trials	2 500
6.1.2	As leading EC in multicentre clinical trials	3 500 – 6 000
6.2	**As participating EC in multicentre clinical trials according to Section 8 (5) GCP-V**	
	Up to 3 trial sites	900
	Any further trial site	150
6.3	**Subsequent amendments according to Section 10 GCP-V**	
6.3.1	Assessment according to Section 10 (1) GCP-V	
6.3.1.1	For monocentric clinical trials	100 - 700
6.3.1.2	As leading EC in multicentre clinical trials	100 - 1 000
6.3.1.3	As participating EC in multicentre clinical trials	50 - 500
6.3.2	Assessment according to Section 10 (4) GCP-V	
6.3.2.1	As competent/leading EC	
	Basic administration fee	300

	Every trial site in its own region	150
	Every EC contributing to the procedure according to Section 10 (4) GCP-V	150
6.3.2.2	As participating EC	
	a) first assesssment of the clinical trial	
	- administration fee incl. 3 trial sites	900
	- any further trial site	150
	b) previous assessment of the clinical trial – basic administration fee	
	- administration fee	300
	- every trial site	150

5. General notification requirement

General notification requirement of the sponsor according to Section 67 subsection 1 of the AMG

The sponsor shall notify the competent authorities and, in the case of a clinical trial on human beings the competent higher federal authority (see Annex 2) as well, before taking up these activities. Notification is to be given of a clinical trial on human beings, the competent authority, the sponsor of the clinical trial, his/her representative if any, as well as all investigators, where necessary also indicating their status as Principal Investigator (Hauptprüfer) or Chief Investigator (Leiter der klinischen Prüfung), shall also be designated by name.

General notification requirement of the investigator according to Section 12 subsection 1 of the GCP-V

The investigator shall notify the competent authorities and, in the case of a clinical trial on human beings the competent higher federal authority as well, before taking up these activities. The investigator may transfer the obligation to notify the competent authority to the sponsor, and shall document this. (Section 12 subsection 3of the GCP-V)

6. Pilot Project according to REGULATION (EU) No. 536/2014 [6]

Joint pilot project between federal higher authorities and ethics committees for processing of applications for the authorisation of clinical trials on medicinal products for human use in

accordance with Regulation (EU) No. 536/2014 under consideration of the legal stipulations laid down in AMG and GCP-V

Since the CTR is currently not legally effective, authorisation and positive opinion are issued on the AMG and GCP-V. Moreover the submission of the CTA exclusively via email or web-portal is not yet possible. CTAs have to be submitted separately to NCA and EC in written form and on an electronic data carrier.

Prerequisites:

- EC responsible for coordinating investigator has to be part of the pilot project.
  Participating ECs:
  https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/KlinischePruefung/Pilotprojekt/Ethik-Kommissionen.html
- Communication during the procedure will take place via unencrypted email.
  NCA: ct-pilot@bfarm.de or ct-pilot@pei.de
  ECs: listed on the internet pages of the NCAs

Procedure for sponsors:

I. Initial Authorisation

Ia. Preparation

"Letter of intent": email to NCA and leading EC **14 days** prior to planned submission of CT requesting participating in the PP with the CTA

Email must contain:

- EUDRA-CT number of the CT
- sponsor's trial code as stated when applying for the EUDRA-CT number
- title of the CT
- name and official address of the coordinating investigator of the CT
- name and address of the EC competent for the coordinating investigator of the CT
- number of planned trial centres in Germany
- planned date of submission to the NCA and EC (at the earliest 14 days after having sent the email)
- list of concerned EC as an attachment

→ Capacity assessment by NCA and EC

! A legal entitlement to participation in the PP does not exist!

a) Positive decision:

NCA will send the sponsor a pilot project number and confirm the date of submission. In any communication between sponsor and NCA or EC, this pilot project number must be the first entry in the subject line of emails or letters in order to allow internal allocation.

b) Rejection:
NCA will inform the sponsor at the latest within one week. Sponsor can submit a regular CTA in accordance with AMG and GCP-V separately with the NCA and the EC.

Ib. Submission of the CTA (Day 0 initial CTA)

Simultaneous submission of the CTA to NCA, leading EC and participating ECs

The cover letter is to point out that participation in the PP has been confirmed and must contain the pilot project number. The submission must completely fulfil the specifications in Section 7 of the GCP-V with regard to form and extent.

Ic. Validation Phase (max. 10 days)

If one of the two institutions receives the CTA with a delay of more than two days, a timely processing within the PP cannot be ensured.
→ Authorisation procedure takes its regular course outside the PP separately for each institution in accordance with the specifications of AMG and GCP-V.

Separate notices of validation from the NCA and leading EC but harmonized with regard to Part I (except CMC aspects) + notices regarding Part II from EC.

Deficiencies or relevant documentation is missing
→ 10 day period to remove deficiencies

Validation of supplemented/edited documentation within 5 calendar days

If the CTA is still not valid or sponsor neglects timely submission of the supplement, it can no longer be processed within the PP

a) Withdrawal of the CTA & submission of a new application in the course of the PP or
b) Maintain CTA within the regular procedure according to AMG and GCP-V

Id. Assessment Phase (max. 26 + 12 + 7 days)

Compilation of an internal Assessment Report within 26 days after receipt of valid application by NCA and EC

→ Sponsor receives

a) separate positive notes from NCA and EC or

b) deficiency letter(s) (harmonized between NCA and EC if deficiencies concern Part I; positive note from NCA and deficiency letter from EC if deficiencies exclusively concern Part II → NCA only continues to play an administrative role in the PP)

As before, the answer of the sponsor should be a single response sent in parallel to both institutions in any case.

Sponsor neglects timely submission of the edited application

→ CTA can no longer be processed within the PP and is further assessed by NCA and EC within the regular procedure according to AMG and GCP-V.

Ie. Issuing notices

Compilation on the basis of the internal Assessment Report:

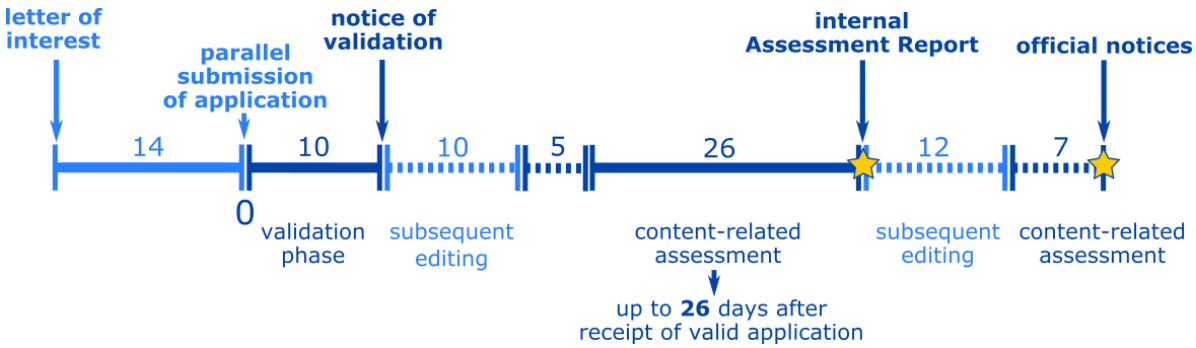
Part I:

a) Official notices with the same content by NCA and leading EC if they agree or

b) Official notices with different content if they disagree

Part II:

Official notices regarding Part II by leading EC, especially information with regard to suitability of the individual investigators and trial centres



II. Substantial Modifications

Assessment during the PP is possible.

Prerequisites:

a) Initial authorisation of the clinical trial in the pilot project and

b) Contents of the modifications applied for fall primarily under Part I of the Assessment Report in accordance with the CTR and do not exclusively concern CMC contents.

For further information use attached document “Germany_Regulation (EU) No. 536_2014 incl AMG and GCP-V_Guideline joint project NCA and ECs”

7. Insurance and damage compensation

According to the AMG it is mandatory to take out a special insurance for test persons in clinical trials that is regardless of culpability (strict liability) and subsidiary to other fault-based insurances if the IMP is not used exactly within the framework of the drug’s approval:

Chapter 6, Section 40 of the AMG:

General conditions for clinical trials

(1) The sponsor, the investigator and all of the other persons involved in the clinical trial shall, in the conduct of the clinical trial of a medicinal product on human beings, fulfil the requirements of good clinical practice laid down in Article 1 paragraph 3 of Directive 2001/20/EG. The clinical trial of a medicinal product on human beings may only be commenced by the sponsor if the competent ethics committee has issued a favourable opinion on it pursuant to Section 42 sub-section 1 and the competent higher federal authority has given its approval pursuant to Section 42 sub-section 2. The clinical trial of a medicinal product may only be conducted on human beings if and as long as:

[…]

8. in the event that a person is killed or a person's body or health is injured during the course of the clinical trial, an **insurance policy which provides benefits, even when no one else is liable for the damage**, exists in accordance with the provisions contained in sub-section 3,

[…]

(2) The insurance pursuant to sub-section 1 sentence 3 number 8 must be taken out in favour of the person concerned in a clinical trial with an insurance carrier authorised to conduct business in a Member State of the European Union or another State Party to the Agreement on the European Economic Area. Its scope must be **reasonably commensurate with the risks involved in the clinical trial and determined on the basis of the risk assessment** in such a way as to ensure that for every case of the death or permanent occupational disability of a person concerned by clinical trial, at least **500,000 €** will be available. In so far as benefits are paid by the insurance, all claims to damages shall be extinguished.

8. Bibliography

Supporting documents:

1 Germany_AMG_English

2 Germany_GCP-V_English

3 Germany_Module 1_English

4 Germany_Module 2_English

5 Germany_AMGKostV_English

6 Germany_Regulation (EU) No. 536_2014 incl AMG and GCP-V_Guideline joint project NCA and ECs

Additional Links:

https://www.ak-med-ethik-komm.de/index.php?option=com_content&view=article&id=144&Itemid=151&lang=de

https://www.bfarm.de/EN/Drugs/licensing/clinicalTrials/_node.html;jsessionid=4B9DC3071FC2D1B2B4F0004CB80D60F1.2_cid354

https://www.bfarm.de/EN/Service/FAQ/_functions/drugs/clinTrials/_node.html

Annex 1

Independent Ethics Committees Germany

Independent Ethics Committees of the Landesärztekammern and federal states GERMANY

01.10.2019

Baden-Württemberg

Ethik-Kommission bei der Landesärztekammer Baden-Württemberg
Liebknechtstr. 33
70565 Stuttgart
Phone +49 (0) 711-76989-831
Fax +49 (0) 711-76989-856
ethikkommission@laek-bw.de
http://www.aerztekammer-bw.de/ethik

Bayern

Ethik-Kommission der Bayerischen Landesärztekammer
Mühlbaurstraße 16
81677 München
Phone +49 (0) 89-4147165
Fax +49 (0) 89-4147334
ethikkommission@blaek.de
http://ethikkommission.blaek.de/

Brandenburg

Ethik-Kommission der Landesärztekammer Brandenburg
Dreifertstraße 12
03044 Cottbus/
PF 101445
03014 Cottbus
Phone +49 (0) 355-78010151 or 78010152
Fax +49 (0) 355-78010159
ethik@laekb.de
https://www.laekb.de

Hamburg

Ethik-Kommission der Ärztekammer Hamburg
Weidestraße 122b
22083 Hamburg
Phone +49 (0) 40-20 2299-240
Fax +49 (0) 40-20 2299-410
ethik@aekhh.de
http://www.aerztekammer-hamburg.org/ethikkommission.html

Hessen

Ethik-Kommission der Landesärztekammer Hessen
Hanauer Landtsraße 152
60314Frankfurt am Main
Phone +49 (0) 69-97672-314
Fax +49 (0) 69-97672-377
ethikkommission@laekh.de
www.laekh.de/aerzte/rund-ums-recht/ethik-kommission

Niedersachsen

Ethik-Kommission bei der Ärztekammer Niedersachsen
Unterkommission zur Beurteilung medizinischer Forschung am Menschen
Karl-Wiechert-Allee 18-22
30625 Hannover
Phone +49 (0) 511-380-2208
Fax +49 (0) 511-3 80-2119
ethikkommission@aekn.de
http://www.aekn.de/aekn/die-kommissionen/ethikkommission

Nordrhein

Ethik-Kommission der Ärztekammer Nordrhein
Tersteegenstraße 9
40474 Düsseldorf
Phone +49 (0) 211-430222-72
Fax +49 (0) 211-430222-79
ethik@aekno.de
http://www.aekno.de/

Westfalen-Lippe

Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Westälischen
Wilhelms-Universität Münster
Gartenstr. 210 – 214
48147 Münster
Phone +49 (0) 251-9292460
Fax +49 (0) 251-9292478
ethikkommission@aekwl.de
http://www.ethik-kommission.uni-muenster.de/

Rheinland-Pfalz

Ethik-Kommission der Landesärztekammer Rheinland-Pfalz
Deutschhausplatz 3
55116 Mainz
Phone +49 (0) 6131-28822-62/–64/–65/–67
Fax +49 (0) 6131-28822-66
ethik-kommission@laek-rlp.de
www.laek-rlp.de/ethik

Saarland

Ethik-Kommission bei der Ärztekammer des Saarlandes
Faktoreistraße 4
66111 Saarbrücken
Phone +49 (0) 681-4003-216 oder -218
Fax +49 (0) 681-40 03-394
ethikkommission@aeksaar.de
http://www.aerztekammer-saarland.de/aerzte/ethikkommission/

Sachsen

Ethik-Kommission der Sächsischen Landesärztekammer
Schützenhöhe 16
01099 Dresden
Phone +49 (0) 351-8267333
Fax +49 (0) 351-8267332
ethik@slaek.de
http://www.slaek.de/de/01/ethikkommission.php

Sachsen-Anhalt

Ethik-Kommission der Ärztekammer Sachsen-Anhalt
Am Kirchtor 9
06108 Halle (Saale)
Phone +49 (0) 345-3880936
Fax +49 (0) 345-2902025
ethik@aeksa.de
http://www.aeksa.de/www/website/PublicNavigation/arzt/ethikkommission/
Ethik-Kommission des Landes Sachsen-Anhalt
Kühnauer Strasse 70
06846 Dessau-Rosslau/
Postfach 18 02
06815 Dessau-Rosslau
Phone +49 (0) 340-6501291
Fax +49 (0) 340-6501199
lav-ek@sachsen-anhalt.de
http://www.verbraucherschutz.sachsen-anhalt.de/wir-ueber-uns-service/ethikkommission/

Schleswig-Holstein

Ethikkommissionen bei der Ärztekammer Schleswig-Holstein
Bismarckallee 8-12
23795 Bad Segeberg
Phone +49 (0) 4551-803433 or 803432
Fax +49 (0) 4551-803431
ethik@aeksh.org
http://ethikkommissionen.aeksh.de/

Thüringen

Ethik-Kommission der Landesärztekammer Thüringen
Im Semmicht 33
07751 Jena-Maua
Phone +49 (0) 3641-614201
Fax +49 (0) 3641-614209
ethikkommission@laek-thueringen.de
www.laek-thueringen.de

Berlin

Landesamt für Gesundheit und Soziales Berlin
Geschäftsstelle der Ethik-Kommission des Landes Berlin
Turmstr. 21
10559 Berlin
Phone +49 (0) 30-90229-1220
Fax +49 (0) 30-90229-3383
ethik-kommission@lageso.berlin.de
https://www.berlin.de/lageso/gesundheit/ethik-kommission/

Bremen

Ethik-Kommission des Landes Bremen
Institut für Pharmakologie Klinikum Bremen-Mitte
St.-Jürgen-Straße 1
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Phone +49 (0) 421-497 3206 / 3480
Fax +49 (0) 421-497 3326
geschaeftsstelle@ethikkommission-bremen.de

http://www.ethikkommission-bremen.de

Independent Ethics Committees at universities GERMANY

01.10.2019

Baden-Württemberg
Freiburg

Ethik-Kommission der Albert-Ludwigs-Universität Freiburg
Engelberger Str. 21
79106 Freiburg
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Fax +49 (0) 761-27072630
ethikkommission@uniklinik-freiburg.de
http://www.ethikkommission.uniklinik-freiburg.de

Tübingen

Ethik-Kommission der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen
Gartenstaße 47
72074 Tübingen
Phone +49 (0) 7071-2977661
Fax +49 (0) 7071-295965
Ethik.Kommission@med.uni-tuebingen.de
www.medizin.uni-tuebingen.de/Forschung/Ethik_Kommission

Ulm

Ethikkommission der Universität Ulm
Helmholtzstraße 20
89081 Ulm
Phone +49 (0) 731-50022050 or +49 (0) 731-50022052
Fax +49 (0) 731-50022036
ethik-kommission@uni-ulm.de
http://www.uni-ulm.de/einrichtungen/ethikkommission-der-universitaet-ulm.html

Heidelberg

Ethik-Kommission der Medizinischen Fakultät Heidelberg
Alte Glockengießerei 11/1
69115 Heidelberg
Phone +49 (0) 6221 5626460
Fax +49 (0) 6221 5626480
ethikkommission-I@med.uni-heidelberg.de
www.medizinische-fakultaet-hd.uni-heidelberg.de/Ethikkommission

Mannheim

Medizinische Ethik-Kommission II
Medizinische Fakultät Mannheim der Universität Heidelberg
Haus 42 — Ebene 3, Theodor-Kutzer-Ufer 1 – 3
68167 Mannheim
Phone +49 (0) 621-383-71770
Fax +49 (0) 621-383-71772
ethikkommission-II@medma.uni-heidelberg.de
http://www.umm.uni-heidelberg.de/forschung/medizinische-ethikkommission-ii

Bayern

Regensburg

Ethik-Kommission bei der Universität Regensburg
Landshuter Straße 4 "Altes Finanzamt"
93047 Regensburg
Phone +49 (0) 941-9435370
Fax +49 (0) 941-9435369
ethikkommission@ur.de
http://ethikkommission.uni-regensburg.de

München

Ethikkommission der Fakultät für Medizin der Technischen Universität München
Ismaninger Straße 22
81675 München
Phone +49 (0) 89-41404371
Fax +49 (0) 89-41404199
ethikkommission@mri.tum.de
http://www.ek-med-muenchen.de

Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians Universität München
Pettenkoferstr. 8 IV, Zi. I 4.07 — I 4.10
80336 München
Phone +49 (0) 89-440055191
Fax +49 (0) 89-440055192
ethikkommission@med.uni-muenchen.de
http://www.med.uni-muenchen.de/forschung/ethik/index.html

Erlangen-Nürnberg

Ethik-Kommission der Medizinischen Fakultät Friedrich-Alexander-Universität Erlangen-Nürnberg
Krankenhausstraße 12
91054 Erlangen
Phone +49 (0) 9131-8526209
Fax +49 (0) 9131-8526021
ethikkommission@fau.de
http://www.ethikkommission.fau.de/

Würzburg

Ethik-Kommission der Medizinischen Fakultät der Universität Würzburg
Versbacher Str. 9
97078 Würzburg
Phone +49 (0) 931-3148315
Fax +49 (0) 931-3187520
ethikkommission@uni-wuerzburg.de
http://www.ethik-kommission.medizin.uni-wuerzburg.de/startseite/

Brandenburg

Neuruppin

Ethikkommission der Medizinischen Hochschule Brandenburg (MHB) Theodor Fontane
c/o Medizinische Hochschule Brandenburg CAMPUS GmbH
Fehrbelliner Straße 38
16816 Neuruppin
Phone +49 (0) 3391 39 - 3110
Fax +49 (0) 3391 39 - 3109
kjg.schmailzl@mhb-fontane.de
http://www.mhb-fontane.de/kommissionenausschuesse.html

Hessen

Gießen

Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen
Klinikstrasse 29
35385 Gießen/
Poststelle des Klinikums
Frankfurter Str. 51 – 53
35392 Gießen
Phone +49 (0) 641-9942470
Fax +49 (0) 641-9942479
ethik.kommission@pharma.med.uni-giessen.de
http://www.uni-giessen.de/cms/fbz/fb11/dekanat/ethikkommission

Frankfurt

Ethik-Kommission des Fachbereichs Medizin der Johann Wolfgang Goethe-Universität Frankfurt
Theodor-Stern-Kai 7
60590 Frankfurt am Main
Phone +49 (0) 69-63013758
Fax +49 (0) 69-630183434
ethikkommission@kgu.de
http://ethik-kommission.klinik.uni-frankfurt.de

Marburg

Kommission für Ethik in der ärztlichen Forschung des Fachbereiches Humanmedizin der Philipps-Universität Marburg
Postfach 2360
35033 Marburg
Phone +49 (0) 6421-5866487 or +49 (0) 6421-5866488
Fax +49 (0) 6421-5866585
ethikkom@staff.uni-marburg.de
http://www.uni-marburg.de/fb20/ethikkommission

Berlin

Berlin

Ethik-Kommission der Medizinischen Fakultät der Charité Universitätsmedizin Berlin
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10117 Berlin
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Fax +49 (0) 30-450517952
ethikkommission@charite.de
http://ethikkommission.charite.de

Mecklenburg-Vorpommern

Rostock

Ethik-Kommission an der Medizinischen Fakultät der Universität Rostock
St.-Georg-Straße 108
18055 Rostock
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Fax +49 (0) 381-4949902
ethik@med.uni-rostock.de
https://ethik.med.uni-rostock.de/

Greifswald

Ethik-Kommission an der Universitätsmedizin Greifswald
Institut für Pharmakologie
Felix-Hausdorff-Str.3
17487 Greifswald
Phone +49 (0) 3834-865644
Fax +49 (0) 3834-865631
ethik@uni-greifswald.de
http://www2.medizin.uni-greifswald.de/ethik/

Niedersachsen

Göttingen

Ethikkommission der Universitätsmedizin Göttingen
Von-Siebold-Straße 3
37075 Göttingen
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Fax +49 (0) 551-39-69536
ethik@med.uni-goettingen.de
http://www.ethikkommission.med.uni-goettingen.de

Hannover

Ethik-Kommission der Medizinischen Hochschule Hannover
Carl-Neuberg-Straße 1
30625 Hannover
Phone +49 (0) 511-5323443 or 0511-5329812
Fax +49 (0) 511-532163443
Ethikkommission@mh-hannover.de
https://www.mh-hannover.de/3371.html

Oldenburg

Medizinische Ethikkommission der Carl von Ossietzky Universität Oldenburg
Carl-von Ossietzky-Str. 9-11
26129 Oldenburg
Phone +49 (0) 441-798-3109
Fax +49 (0) 441-798-4745
med.ethikkommission@uni-oldenburg.de
www.uni-oldenburg.de/medizin/medizinische-ethikkommission/

Nordrhein-Westfalen

Bonn

Ethik-Kommission an der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität Bonn
Sigmund-Freud-Str. 25
53105 Bonn
Phone +49 (0) 228-28751931
Fax +49 (0) 228-28751932
ethik@uni-bonn.de
http://ethik.meb.uni-bonn.de

Aachen

Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen
Pauwelsstraße 30
52074 Aachen
Phone +49 (0) 241-8089963
Fax +49 (0) 241-8082012
ekaachen@ukaachen.de
www.medizin.rwth-aachen.de/cms/Medizin/Die-Fakultaet/Organisation/Kommissionen/~coeq/Ethik-Kommission/

Münster

Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Westfälischen Wilhelms-Universität Münster
Gartenstraße 210-214
48147 Münster
Phone +49 (0) 251-9292460
Fax +49 (0) 251-9292478
ethikkommission@aekwl.de
http://www.ethik-kommission.uni-muenster.de

Düsseldorf

Ethikkommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf
Kinderklinik, Gebäude 13.41
Moorenstraße 5
40225 Düsseldorf
Phone +49 (0) 211-8119591
Fax +49 (0) 211-8119592
ethikkommission@med.uni-duesseldorf.de
http://www.medizin.hhu.de/dekanat/gremien-und-kommissionen/kommissionen/ethikkommission.html

Bad Oeynhausen

Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum - Sitz Bad Oeynhausen
Georgstr. 11
32545 Bad Oeynhausen
Phone +49 (0) 5731-972877
Fax +49 (0) 5731-972876
ethikkommission@hdz-nrw.de
http://www.hdz-nrw.de/forschung-lehre/wissenschaftliche-ethik-kommission.html

Duisburg-Essen

Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen
Robert-Koch-Str. 9 – 11
45147 Essen
Phone 0201-7233448
Fax 0201-7235837
ethikkommission@uk-essen.de
https://www.uni-due.de/ethikkommission/

Witten

Ethik-Kommission der Universität Witten-Herdecke
Alfred-Herrhausen-Straße 50
58448 Witten
Phone +49 (0) 2302-926740
Fax +49 (0) 2302-926739
sekretariat-ethik@uni-wh.de andrea.pleger@uni-wh.de
http://www.ethik-kommission-uwh.de

Bochum

Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum
Gesundheitscampus 33
44801 Bochum
Phone +49 (0) 234-79816555
Fax +49 (0) 234-79816556
ethik@rub.de
http://www.ruhr-uni-bochum.de/ethik/

Köln

Ethikkommission der Medizinischen Fakultät der Universität zu Köln
Uniklinik Köln
Gebäude 55
Kerpener Str. 62
50937 Köln
Phone +49 (0) 221-478 82900
Fax +49 (0) 221-478 82905
ek-med@uni-koeln.de
http://www.ek-koeln.de

Sachsen

Leipzig

Ethik-Kommission an der Medizinischen Fakultät der Universität Leipzig
Käthe-Kollwitz-Str. 82
04109 Leipzig
Phone +49 (0) 341-9725605
Fax +49 (0) 341-9715499
ethik@medizin.uni-leipzig.de
http://home.uni-leipzig.de/ethik/

Dresden

Ethikkommission an der TU Dresden
Fiedlerstrasse 33, Haus 101
01307 Dresden
Phone +49 (0) 351-4582992
Fax +49 (0) 351-4584369
ethikkommission@mailbox.tu-dresden.de
http://tu-dresden.de/die_tu_dresden/gremien_und_beauftragte/kommissionen/ethikkommission

Sachsen-Anhalt

Halle (Saale)

Ethik-Kommission der Medizinischen Fakultät der Martin-Luther-Universität Halle-Wittenberg
Magdeburger Str. 16
06112 Halle (Saale)
Phone +49 (0) 345-5574476
Fax +49 (0) 345-5574477
ethik-kommission@uk-halle.de
https://www.medizin.uni-halle.de/index.php?id=361

Magdeburg

Ethik-Kommission der Otto-von-Guericke-Universität an der Medizinischen Fakultät und am Universitätsklinikum Magdeburg A. ö. R.
Leipziger Straße 44
39120 Magdeburg
Phone +49 (0) 391-6714314
Fax +49 (0) 391-6714354 or 0391-67290185
ethikkommission@ovgu.de
http://www.ethikkommission.ovgu.de/Ethikkommission.html

Schleswig-Holstein
Kiel

Ethik-Kommission der Medizinischen Fakultät der Christian-Albrechts-Universität zu Kiel
Schwanenweg 20/
Arnold-Heller-Straße 3, Haus 9
24105 Kiel
Phone +49 (0) 431500-14191
Fax +49 (0) 431 500-14195
ethikkomm@email.uni-kiel.de
http://www.ethik-komm.med-fak.uni-kiel.de

Lübeck

Ethik-Kommission der Universität zu Lübeck
Ratzeburger Allee 160
23538 Lübeck
Phone +49 (0) 451-31011008
Fax +49 (0) 451-31011024
ethikkommission@uni-luebeck.de
https://www.uni-luebeck.de/forschung/kommissionen/ethikkommission.html

Thüringen
Jena

Ethik-Kommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät
Bachstraße 18
07740 Jena
Phone +49 (0) 3641-9391190
Fax +49 (0) 3641-9391192
ethikkommission@med.uni-jena.de
http://www.ethikkommission.uniklinikum-jena.de

Annex 2

Competent higher federal authorities

Competent higher federal authorities GERMANY

01.10.2019

Baden-Württemberg
Competent higher federal authority

Ministerium für Soziales und Integration Baden-Württemberg
Referat 53

Gesundheitsschutz, Arzneimittel, Digitalisierung im Gesundheitswesen
Else-Josenhans-Straße 6
70173 Stuttgart
Phone +49-711-123-0
Fax +49-711-123-3997
poststelle@sm.bwl.de
http://www.sozialministerium-bw.de

Bayern

Competent higher federal authority

Bayerisches Staatsministerium für Gesundheit und Pflege
Referat 34 - Pharmazie
Haidenauplatz 1
81667 München
Phone +49-89-540233-0
poststelle@stmgp.bayern.de
http://www.stmgp.bayern.de

Berlin

Competent higher federal authority

Senatsverwaltung für Gesundheit, Pflege und Gleichstellung
Referat I E
Oranienstraße 106
10969 Berlin
Phone +49-30-9028-0
Fax +49-30-9028-2060
gesundheit@sengpg.berlin.de
http://www.berlin.de/sen/gpg

Brandenburg

Competent higher federal authority

Ministerium für Arbeit, Soziales, Gesundheit, Frauen und Familie des Landes Brandenburg
Referat 11 B Apotheken, Arzneimittel, Medizinprodukteaufsicht
Henning-von-Tresckow-Straße 2-13, Haus S
14467 Potsdam
Phone +49-331-866-0
Fax +49-331-866-5409
pharmazie@masgf.brandenburg.de
http://www.masgf.brandenburg.de/

Bremen

Competent higher federal authority

Der Senator/ die Senatorin für Wissenschaft, Gesundheit und Verbraucherschutz der Freien Referat 44
Pharmazie, Umwelthygiene, Toxikologie
Contrescarpe 72
28195 Bremen
Phone +49-421-361-0
Fax +49-421-496-9567
pharmazie@gesundheit.bremen.de
http://www.gesundheit.bremen.de

Hamburg

Competent higher federal authority

Behörde für Gesundheit und Verbraucherschutz der Freien und Hansestadt Hamburg
Abteilung V4
Pharmaziewesen und Medizinprodukte
Billstraße 80
20539 Hamburg
Phone +49-40-428 37-0
Fax +49-40-4273-10017
pharmaziewesen@bgv.hamburg.de
http://www.hamburg.de/bgv

Hessen

Competent higher federal authority

Hessisches Ministerium für Soziales und Integration
Gesundheitsabteilung/
Referat V 3A Arzneimittel- und Apothekenwesen
Sonnenberger Straße 2 / 2a
65193 Wiesbaden
Phone +49-611-3219-0
poststelle@hsm.hessen.de
http://www.hsm.hessen.de

Mecklenburg-Vorpommern

Competent higher federal authority

Ministerium für Wirtschaft, Arbeit und Gesundheit Mecklenburg-Vorpommern
Referat Krankenversicherung und Arzneimittelwesen
Johannes-Stelling-Straße 14
19053 Schwerin
Postfach
19048 Schwerin
Phone +49-385-588-0
Fax +49-385-588-9700
poststelle@wm.mv-regierung.de
http://www.regierung-mv.de/Landesregierung/wm/

Niedersachsen

Competent higher federal authority

Niedersächsisches Ministerium für Soziales, Gesundheit und Gleichstellung
Referat 402
Prävention und Gesundheitsförderung, Arzneimittel, Medizinprodukte, Biotechnologie
Hannah-Arendt-Platz 2
30159 Hannover
Phone +49-511-120-0
Fax +49-511-120-3058
402-posteingaenge@ms.niedersachsen.de
http://www.ms.niedersachsen.de/master/C675_L20_D0.html

Nordrhein-Westfahlen

Competent higher federal authority

Ministerium für Arbeit, Gesundheit und Soziales des Nordrhein-Westfalen
Referat für Pharmazie, Gesundheit
Fürstenwall 25
40219 Düsseldorf

Phone +49-211 855-5
Fax +49-211-855-3683
poststelle@mags.nrw.de
http://www.mags.nrw

Rheinland-Pfalz

Competent higher federal authority

Ministerium für Soziales, Arbeit, Gesundheit und Demografie Rheinland-Pfalz
Referat 638
Arzneimittel, Tierarzneimittel
Bauhofstraße 9
55116 Mainz
Phone +49-6131-16-0
Fax +49-6131-16-2452
poststelle@msagd.rlp.de
http://www.msagd.rlp.de

Saarland

Competent higher federal authority

Ministerium für Soziales, Gesundheit, Frauen und Familie des Saarlandes
Referat E 3 Arzneimittelüberwachung
Referat E 4 Pharmazie
Franz-Josef-Röder-Straße 23
66119 Saarbrücken
Phone +49-681-501-00
Fax +49-681-501-4524
t.rohn@soziales.saarland.de
Ref_E4@soziales.saarland.de
http://www.saarland.de/ministerium_soziales_gesundheit_frauen_familie.htm

Sachsen

Competent higher federal authority

Sächsisches Staatsministerium für Soziales und Verbraucherschutz
Referat 21
Grundsatzangelegenheiten der Abteilung 2
Albertstraße 10
01097 Dresden
Phone +49-351-564-0
Fax +49-351-564-5770
poststelle@sms.sachsen.de
Website http://www.sms.sachsen.de

Sachsen-Anhalt

Competent higher federal authority

Ministerium für Arbeit, Soziales und Integration Sachsen-Anhalt
Referat 21
Prävention, umweltbezogener Gesundheitsschutz, Pharmazie, Verbraucherschutz, Verbraucherberatung, sozialer und medizinischer Arbeitsschutz
Turmschanzenstraße 25
39114 Magdeburg
www.ms.sachsen-anhalt.de

Schleswig-Holstein

Competent higher federal authority

Ministerium für Soziales, Gesundheit, Jugend, Familie und Senioren des Landes

Schleswig-Holstein
Referat VIII 41
Gesundheitsberufe, Apotheken, Arzneimittel und Medizinprodukte
Adolf-Westphal-Straße 4
24143 Kiel
Phone +49-431-988-0
Fax +49-431-988-5416
poststelle@sozmi.landsh.de
www.sozialministerium.schleswig-holstein.de

Thüringen

Competent higher federal authority

Thüringer Ministerium für Arbeit, Soziales, Gesundheit, Frauen und Familie
Referat 41
Medizinische Grundsatzfragen, Heilberufe, Pharmaziewesen
Werner-Seelenbinder-Straße 6
99096 Erfurt
Phone +49-361-57-3811-401
Fax +49-361-57-3811-840
poststelle@tmasgff.thueringen.de
http://www.thueringer-sozialministerium.de