

## Praktische Aspekte zur Einreichung von Klinischen Prüfungen



# AGES

Österreichische Agentur für Gesundheit  
und Ernährungssicherheit GmbH

*Gesundheit. Ernährung. Sicherheit.  
Unsere Verantwortung.*

## Die praktischen Seiten der Einreichung

- EudraCT Nummer und xml File
- EudraLex Volume 10
- ICH – Kategorisierung Klinischer Prüfungen
- Leitfaden KP Österreich

## Herstellungsunterlagen

- Herstellungsunterlagen
- Gutachter-Konzepte

# http://eudract.emea.europa.eu



EudraCT Home page - Microsoft Internet Explorer bereitgestellt von AGES

http://eudract.emea.europa.eu/index.html

European Clinical Trials Database

## EudraCT

**Welcome to the Community Clinical Trial System Public Home Page**

EudraCT is a database of all clinical trials commencing in the Community from 1 May 2004 onwards. It has been established in accordance with Directive 2001/20/EC.

This site is the sponsor interface which gives the sponsor access to the EudraCT application in order to:

- Get a EudraCT number
- Complete, save as a .xml file on your computer and print a pdf version of the clinical trial application form

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### Access to EudraCT Application

You must save the xml files and the pdf files of your Clinical Trial Application Form to your own computer.

You are unable to save xml and pdf files to the EudraCT system.

Only the Member State Competent Authorities are able to do this when you send them your xml file.

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**NEW Access to EudraCT Supporting Documentation**

This section includes the latest EC directives, guidelines and forms on EudraLex and EudraCT user and technical documentation, as well as monthly statistics.


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**NEW EC Guidance Affecting Future Versions of EudraCT Published**

Guidelines relating to the operation of EudraCT have been finalised and are now published by the European Commission. The guidelines cover the Clinical Trials Application Form and the sharing, in the public domain, of Clinical Trials information from EudraCT.

Interested parties are invited to refer to [Chapter V of Vol. 10 'Clinical Trials' of the Rules Governing Medicinal Products in the European Union](#).

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 Last Updated: 10/02/2009  
© 1996-2009 EMEA.  
Application hosted on behalf of the European Commission <http://ec.europa.eu>  
EudraCT Helpdesk email: [eudradt@emea.europa.eu](mailto:eudradt@emea.europa.eu)  
EudraCT Helpdesk Tel. (44-20) 75 23 75 23 Fax: (44-20) 74 18 88 89  
Queries on Web functionality to: [emeawebservices@emea.europa.eu](mailto:emeawebservices@emea.europa.eu)  
7 Westferry Circus, Canary Wharf, London E14 4HB

Fertig

Internet 100%

# EUDRA-CT Nummer

- <http://eudract.emea.europa.eu/>
- Die EUDRA-CT Nummer dient der eindeutigen Identifikation Klinischer Studien – eine Nummer per Protokoll, egal ob national oder international
- Der Sponsor generiert die Nummer
- Der Sponsor befüllt die xml File-Vorlage mit den Details der Studie (und speichert sie!!!!)
- Der Sponsor reicht die Studie bei Behörde und EK ein
- Die Behörde spielt das xml File ins europäische System ein und ergänzt Daten zur Bewilligung, Updates etc.

EudraCT Public Website Documentation page - Microsoft Internet Explorer bereitgestellt von AGES

http://eudract.emea.europa.eu/document.html

European Clinical Trials Database

## EudraCT

### EudraCT Supporting Documentation

#### Directives, Guidance and Forms NEW

Stakeholders should now retrieve information on Directives, Guidance and Forms relating to Clinical Trials from **EudraLex Volume 10**.

**Note:** Please contact the EudraCT Helpdesk ([eudract@emea.europa.eu](mailto:eudract@emea.europa.eu)) if you have any problems finding the information you require.

[Directives, Guidelines, Forms](#)  
[User Guides](#)  
[Member States' Contacts](#)  
[Useful Links](#)  
[EudraCT Statistics](#)  
[Technical Information](#)

#### User Guides **(English only)** NEW

[EudraCT Frequently Asked Questions](#)  
[EudraCT User Manual](#)

### Member States' Contacts List

[EudraCT - NCA Clinical Trial Contacts](#) (.pdf file) NEW

### Useful Links

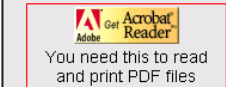

[MedDRA](#) - the Medical Dictionary for Regulatory Activities  
[MedDRA](#) - Presentation  
[ATC](#) - WHO Anatomical Therapeutic Chemical Codes  
[ICD](#) - The International Statistical Classification of Diseases and Related Health Problems  
[ISRCTN](#) - International Standard Randomised Controlled Trial Numbers  
[CAS Numbers](#) - The largest and most current database of chemical substance information in the world containing more than 23 million organic and inorganic substances and 41 million sequences

### EudraCT Statistics

[December Statistics 2008](#) (.pdf file) NEW  
[January Statistics 2009](#) (.pdf file) NEW  
[February Statistics 2009](#) (.pdf file) NEW

#### Statistics from Previous Years

[Statistics Archive 2008](#) (zip file) NEW  
[Statistics Archive 2007](#) (7in file)



# EudraLex Vol. 10 Clinical trials



- I. Application and Application Form
- II. Monitoring/Clinical Safety
- III. Quality of the IMP  
GMP, IMPD, ...
- IV. Recommendations on Inspections
- V. Additional Information  
CT Masterfile, GCP, Q&A
- VI. Legislation

# ICH Int. Conf. Harmonisation



ICH - Microsoft Internet Explorer bereitgestellt von AGES  
http://www.ich.org/cache/compo/276-254-1.html

News... search [ ] ok

Guidelines >> Multidisciplinary...  
Q S E M

Gene Therapy Discussion Group SURVEY available here Your comments are welcome  
'Considerations' from the Gene Therapy Discussion Group and Communication Paper  
SC Press Release Chicago, October 2006  
General E14 related GCG related MedDRA related  
text size: s m l

**PUBLICATIONS**  
Guidelines  
Questions & Answers  
Concept Papers & Business Plans  
Press Releases  
SC Reports & Other Documents  
New Topics  
C T D  
M2/ESTRI

**CONFERENCES**  
ICH Previous Conferences

**ABOUT ICH**  
History and Future  
Structure of ICH  
Process for Harmonisation  
Glossary  
Frequently Asked Questions  
Contact Us  
Meetings Schedule

**Global Cooperation Group**  
Introduction  
Documents  
Reports  
Members

**MedDRA**  
Introduction  
Press Releases  
MedDRA Documents  
Management Board

**GENE THERAPY**  
Gene Therapy Discussion Group

**ICH Guidelines**

The ICH Topics are divided into four major categories and ICH Topic Codes are assigned according to these categories.

**Q**

*"Quality" Topics*, i.e., those relating to chemical and pharmaceutical Quality Assurance.  
Examples: Q1 Stability Testing, Q3 Impurity Testing

**S**

*"Safety" Topics*, i.e., those relating to in vitro and in vivo pre-clinical studies.  
Examples: S1 Carcinogenicity Testing, S2 Genotoxicity Testing

**E**

*"Efficacy" Topics*, i.e., those relating to clinical studies in human subject.  
Examples: E4 Dose Response Studies, Carcinogenicity Testing, E6 Good Clinical Practices. (Note Clinical Safety Data Management is also classified as an "Efficacy" topic - E2)

**M**

*"Multidisciplinary" Topics*, i.e., cross-cutting Topics which do not fit uniquely into one of the above categories.

- o M1: Medical Terminology (MedDRA)
- o M2: Electronic Standards for Transmission of Regulatory Information (ESTRI)
- o M3: Timing of Pre-clinical Studies in Relation to Clinical Trials
- o M4: The Common Technical Document (CTD)
- o M5: Data Elements and Standards for Drug Dictionaries

**Notes on implementation in the three ICH Regions**

**EU**

The ICH guidelines are submitted to the Committee for Proprietary Medicinal Products (CPMP) for endorsement once they have reached *Step 2* or *Step 4* of the ICH Process. The CPMP decides on the duration for consultation with interested parties (usually 6 months).

The European Agency for the Evaluation of Medicinal Products (EMA) publishes and distributes the *Step 2* guidelines for comments. At *Step 4* the guidelines are endorsed by the CPMP and a timeframe for implementation is established (usually 6 months).

MEMBERS ONLY

Internet 100%

# Studienziele und Beispiele ICH E8

## ICH E8 Note for Guidance on General Considerations for Clinical Trials

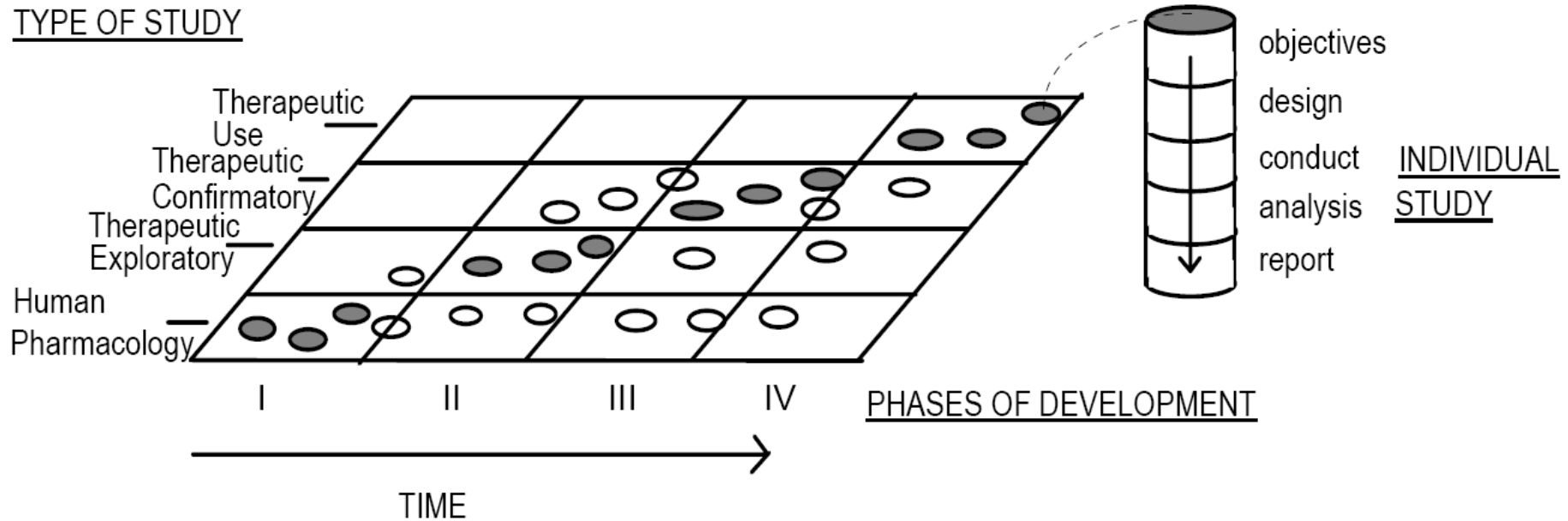
<i>Type of Study</i>	<i>Objective of Study</i>	<i>Study Examples</i>
<b>Human Pharmacology</b>	<ul style="list-style-type: none"> <li>• Assess tolerance</li> <li>• Define/describe PK<sup>1</sup> and PD<sup>2</sup></li> <li>• Explore drug metabolism and drug interactions</li> <li>• Estimate activity</li> </ul>	<ul style="list-style-type: none"> <li>• Dose-tolerance studies</li> <li>• Single and multiple dose PK and/or PD studies</li> <li>• Drug interaction studies</li> </ul>
<b>Therapeutic Exploratory</b>	<ul style="list-style-type: none"> <li>• Explore use for the targeted indication</li> <li>• Estimate dosage for subsequent studies</li> <li>• Provide basis for confirmatory study design, endpoints, methodologies</li> </ul>	<ul style="list-style-type: none"> <li>• Earliest trials of relatively short duration in well-defined narrow patient populations, using surrogate or pharmacological endpoints or clinical measures</li> <li>• Dose-response exploration studies</li> </ul>

# Studienziele und Beispiele ICH E8

<p><b>Therapeutic Confirmatory</b></p>	<ul style="list-style-type: none"> <li>• Demonstrate/confirm efficacy</li> <li>• Establish safety profile</li> <li>• Provide an adequate basis for assessing the benefit/risk relationship to support licensing</li> <li>• Establish dose-response relationship</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate, and well controlled studies to establish efficacy</li> <li>• Randomised parallel dose-response studies</li> <li>• Clinical safety studies</li> <li>• Studies of mortality/morbidity outcomes</li> <li>• Large simple trials</li> <li>• Comparative studies</li> </ul>
<p><b>Therapeutic Use</b></p>	<ul style="list-style-type: none"> <li>• Refine understanding of benefit/risk relationship in general or special populations and/or environments</li> <li>• Identify less common adverse reactions</li> <li>• Refine dosing recommendation</li> </ul>	<ul style="list-style-type: none"> <li>• Comparative effectiveness studies</li> <li>• Studies of mortality/morbidity outcomes</li> <li>• Studies of additional endpoints</li> <li>• Large simple trials</li> <li>• Pharmacoeconomic studies</li> </ul>

# Phasen der klinischen Prüfung

## Correlation between Development Phases and Types of Study



Shaded circles show types of study most usually conducted in a certain phase, open circles show less usual types. Each circle represents an individual study.

*ICH E8 Note for Guidance on General Considerations for Clinical Trials (CPMP/ICH/291/95)*

# Definition

- Phase IV Studien sind jene mit einem....
  - zugelassenen Produkt
  - in der zugelassenen Dosis **und**
  - Indikation
- Das Produkt darf nicht verändert sein (markiert, umformuliert etc.)
- Die Dosis darf nicht höher als zugelassen sein
- Die Fachinformation (SmPC) reicht nur aus, wenn obige Punkte zutreffen

www.basg.at

➤ **Formulare**

➤ **Formulare  
Klinische Prüfung**



**Bundesamt für Sicherheit im Gesundheitswesen**

- Struktur des BASG
- Amtliche Nachrichten BASG
- Tagesordnungen und Protokolle des BASG
- Archiv der Protokolle und Tagesordnungen des BASG
- Archiv der BASG
- Geschäftsteilungen
- Gesetzliche Grundlagen
- Abgrenzungsbeirat
- Formulare
- Tarife
- Arzneispezialitätenregister / PharmaIS Web
- AGES PharmaIS-Portal
- Pharmakovigilanz
- Amtliche Mitteilungen
- Mustertexte
- Gesetzliche Grundlagen
- Formulare
- FAQs
- Kontakt
- Arzneimittel
- Qualitätsinformationen
- Kinderarzneimittel
- Elektronische Einreichung
- MRP/DCP
- FAQ
- Gewebesicherheit
- FAQ Gewebesicherheit
- Formulare Gewebesicherheit
- Blutsicherheit
- FAQ Blutsicherheit
- Formulare Blutsicherheit
- Österreichisches Arzneibuch
- Neue Monographien
- Monographieentwürfe
- Archiv Monographieentwürfe
- Publikationen/Publications
- Folder
- Statistiken
- Newsletter
- English Documents
- FAQ
- Veranstaltungen
- Veranstaltungsarchiv
- News
- Kontakt

Home	AGBs	Schnellsuche	About us
Impressum	Sitemap	...	Go
Kontakt	Erweiterte Suche Go		
Telefonliste	Nutzungshinweise		

**Formulare Klinische Prüfung**

- **Klinische Studien nach Arzneimittelgesetz (AMG)**
- **Klinische Studien nach Medizinproduktegesetz (MPG)**

**1. Klinische Studien nach Arzneimittelgesetz (AMG)**

- **Leitfaden zur Einreichung einer Klinischen Prüfung**

Wir weisen Sie darauf hin, dass durch die Kundmachung der Novelle bezüglich der Verordnung des Bundesamtes für Sicherheit im Gesundheitswesen über den Gebührentarif gemäß Gesundheits- und Ernährungssicherheitsgesetz alle Anträge auf Durchführung einer klinischen Prüfung gebührenpflichtig werden, die nach dem **2. November 2008** beim Bundesamt für Sicherheit im Gesundheitswesen einlangen.

<p><b>Leitfaden Klinische Prüfung</b> Dateiformat: Adobe Acrobat Datei Größe: 76 KByte</p>	 <a href="#">L_W04_Leitfaden_KP_Einreichung.pdf</a>
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- **Guidance for the submission of Clinical Trial**

Please be advised that with the coming into force of the amended Regulation regarding the Schedule of Fees of the BASG according to the Act on Safety in Health and Food, a fee becomes payable for all initial clinical trial applications received by the BASG after **November 2nd 2008**.

<p><b>Guidance Clinical Trial</b> Dateiformat: Adobe Acrobat Datei Größe: 76 KByte</p>	 <a href="#">L_W05_Guidance_CT_submission_en.pdf</a>
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**Formulare für Klinische Prüfungen nach Neuem Recht (Seit AMG Novelle B.GBl. I Nr. 35/2004)**

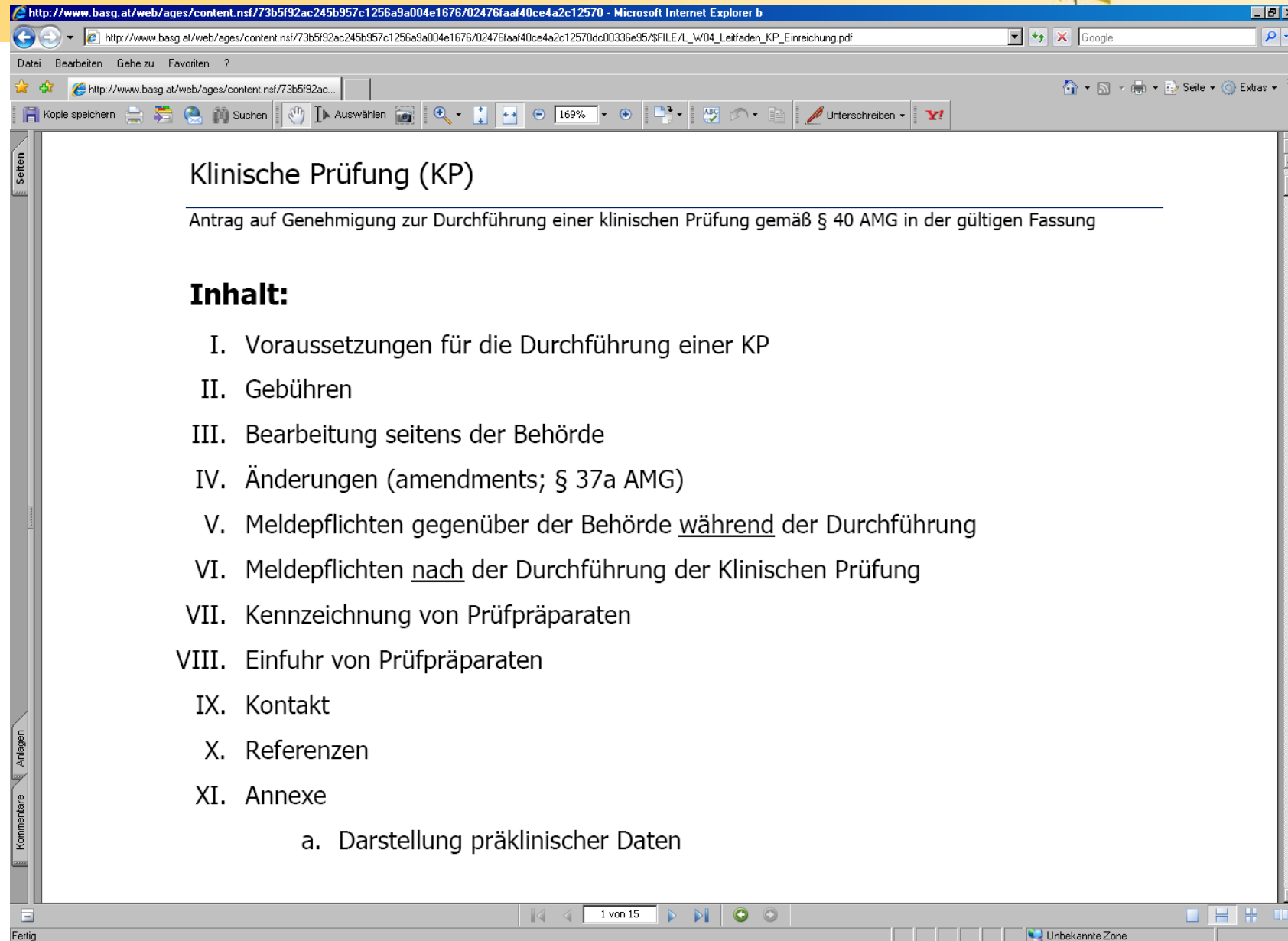
<p><b>Antragsformular Klinische Prüfung (siehe Website EMEA)</b> <b>Application form Clinical Trials (see EMEA Website)</b></p>	<a href="http://eudract.emea.europa.eu/document.html">http://eudract.emea.europa.eu/document.html</a>
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<p><b>J-Checkliste Nationale Anforderungen für die Einreichung von Klinischen Prüfungen</b> <b>Requirement for the submission of a clinical trial</b></p>	 <a href="#">L_W01_J_CHECK_List.pdf</a>
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<p><b>Checkliste als Beilage zum Antrag</b> <b>checklist for the submission</b></p>	 <a href="#">L_W01_J_CHECK_List.doc</a>
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<p><b>SUSAR-Formblatt</b></p>	 <a href="#">F_W02_SUSARreport.doc</a>
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# Leitfaden KP



http://www.basg.at/web/ages/content.nsf/73b5f92ac245b957c1256a9a004e1676/02476faaf40ce4a2c12570dc00336e95/\$FILE/L\_W04\_Leitfaden\_KP\_Einreichung.pdf

Seiten

## Klinische Prüfung (KP)

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Antrag auf Genehmigung zur Durchführung einer klinischen Prüfung gemäß § 40 AMG in der gültigen Fassung

**Inhalt:**

- I. Voraussetzungen für die Durchführung einer KP
- II. Gebühren
- III. Bearbeitung seitens der Behörde
- IV. Änderungen (amendments; § 37a AMG)
- V. Meldepflichten gegenüber der Behörde während der Durchführung
- VI. Meldepflichten nach der Durchführung der Klinischen Prüfung
- VII. Kennzeichnung von Prüfpräparaten
- VIII. Einfuhr von Prüfpräparaten
- IX. Kontakt
- X. Referenzen
- XI. Annexe
  - a. Darstellung präklinischer Daten

Kommentare

Anlagen

Fertig

1 von 15

Unbekannte Zone

# Checkliste J - Österreich

		<b>4</b>	<b>IMP related</b>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.1</b>	Investigator's brochure
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.2</b>	Investigational Medicinal Product Dossier (IMPD)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.3</b>	Simplified IMPD for known products (see table 1)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.4</b>	Summary of Product Characteristics (SmPC) (for products with marketing authorisation in the Community)
<input type="checkbox"/>	<input type="checkbox"/>	<b>4.5</b>	Outline of all active trials with the same IMP
		<b>4.6</b>	If IMP manufactured in E.U. and if no marketing authorisation in EU:
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.6.1</b>	Copy of the manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
		<b>4.7</b>	If IMP not manufactured in E.U. and if no marketing authorisation in EU:
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.7.1</b>	Certification of the QP that the manufacturing site works in compliance with GMP at least equivalent to EU GMP, or that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.7.2</b>	Certification of GMP status of active biological substance
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.7.3</b>	Copy of the importers manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
		<b>4.8</b>	Certificate of analysis for test product in exceptional cases :
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.8.1</b>	Where impurities are not justified by the specification or when unexpected impurities (not covered by specification) are detected
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.9</b>	Viral safety studies when applicable.
<input type="checkbox"/>	<input type="checkbox"/>	<b>4.10</b>	Applicable authorisations to cover trials or products with special characteristics (if available) e.g. GMOs, radiopharmaceuticals
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>4.11</b>	TSE Certificate when applicable
<input type="checkbox"/>	<input type="checkbox"/>	<b>4.12</b>	Examples of the label in the national language

# Vol 10, Chapter 1, IMPD

Types of Previous Assessment	Quality Data	Nonclinical Data	Clinical Data
<p>The IMP has a MA in any EU Member State and is used in the trial:</p> <ul style="list-style-type: none"> <li>* Within the conditions of the SmPC</li> <li>* Outside the conditions of the SmPC</li> <li>* After it has been blinded</li> </ul>	<p>SmPC SmPC P+A</p>	<p>SmPC Yes (if appropriate) SmPC</p>	<p>SmPC Yes (if appropriate) SmPC</p>
<p>Another pharmaceutical form or strength of the IMP has a MA in any EU Member State and:</p> <ul style="list-style-type: none"> <li>* the IMP is supplied by the MAH</li> </ul>	<p>P+A</p>	<p>Yes</p>	<p>Yes</p>
<p>The IMP has no MA in any EU Member State but drug substance is part of a product with a marketing authorisation in a MS and:</p> <ul style="list-style-type: none"> <li>* is supplied from the same manufacturer</li> <li>* is supplied from another manufacturer</li> </ul>	<p>P+A S+P+A</p>	<p>Yes Yes</p>	<p>Yes Yes</p>
<p>The IMP has a previous CTA in the Member State(s) concerned:</p> <ul style="list-style-type: none"> <li>* no new data available since CTA</li> <li>* new data available since CTA</li> </ul>	<p>No New Data</p>	<p>No New Data</p>	<p>No New Data</p>
<p>The IMP is a placebo</p> <p><i>S: Drug substance data</i></p>	<p>P+A</p> <p><i>P : Drug product</i></p>	<p>No</p> <p><i>A : appendices IMPD</i></p>	<p>No</p> <p><i>SmPC: summ.Prod.char.</i></p>

# Was ist ein Hersteller?

- **Herstellen:** das Gewinnen, das Anfertigen, das Zubereiten, das Be- und Verarbeiten, das Umfüllen einschließlich des Abfüllens, das Abpacken von Arzneimitteln sowie das Kennzeichnen von Arzneyspezialitäten und Prüfpräparaten;  
(Ausnahmeregelungen für Apotheken)
- **Hersteller:** alle Personen, die mit Tätigkeiten des Herstellens gemäß Z 10 befasst sind, für die eine entsprechende Bewilligung gemäß § 63 Abs. 1 des Arzneimittelgesetzes erforderlich ist
- Siehe AMBO idgF

# Volume 10 – IMPs

- Investigational medicinal products (IMPs) should be produced in accordance with the principles and the detailed guidelines of GMP for Medicinal Products.
- ....
- In clinical trials there may be added risk to participating subjects compared to patients treated with marketed products. The application of GMP to the manufacture of IMPs is intended to ensure that trial subjects are not placed at risk, and that the results of clinical trials are unaffected by inadequate safety, quality or efficacy arising from unsatisfactory manufacture.
- Equally, it is intended to ensure that there is consistency between batches of the same IMP used in the same or different clinical trials, and that changes during the development of an IMP are adequately documented and justified.

## AMBO § 4. Zulassung und Klinische Prüfung

- (1) Der Hersteller hat sicher zu stellen, dass alle Vorgänge zur Herstellung von Arzneimitteln, die einer Zulassung bedürfen, in Übereinstimmung mit den Informationen des ... genehmigten Zulassungsantrages erfolgen.
- (2) Bei Prüfpräparaten hat der Hersteller sicher zu stellen, dass alle Vorgänge zur Herstellung in Übereinstimmung mit den Informationen des Sponsors in dem ... genehmigten Antrag gemäß § 40 AMG erfolgen.
- (3) Der Hersteller hat seine Herstellungsverfahren **regelmäßig** unter Berücksichtigung des wissenschaftlichen und technischen Fortschrittes und der Entwicklung des Prüfpräparates zu überprüfen. Ist eine Änderung an den Zulassungsunterlagen oder am Inhalt des Antrages gemäß § 40 Arzneimittelgesetz erforderlich, muss ... ein Änderungsantrag vorgelegt werden.

# Shelf life extensions

- Der österreichische Standpunkt zu EudraLex Vol. 10 Chapter III, CPMP "Guideline on the Requirements to the Chemical and Pharmaceutical Quality Documentation Concerning Investigational Medicinal Products in Clinical Trials„:
- Shelf life extensions sind dann keine substantiellen Amendments, **wenn** im Grundantrag die geplante Vorgangsweise dargelegt wurde und es dabei keine Änderungen gibt. D.h. Testintervalle entsprechen den Vorgaben, Methodik und Spezifizierungen sind unverändert.

# Gesetzliche Grundlagen

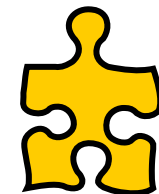


... für die klinische Prüfung:

- **Arzneimittelgesetz idgF**
- **Arzneimittelbetriebsordnung idgF (Hersteller)**
- **Gewebesicherheitsgesetz idgF  
(Zell- und Gewebeentnahme und Verarbeitung)**

# Die Neugier des Gutachters...

- .. sind Daten und Plan schlüssig?
- .. wird den Vorgaben entsprechend vorgegangen?
- .. sind präsentierte Daten vertrauenswürdig?
- .. wie managed der Sponsor die Studie(n)?
- .. ist die Erfahrung der Beteiligten adäquat für das Prüfpräparat/die Präparate?
- .. wird das Risiko für Patienten minimiert?





# AGES

Österreichische Agentur für Gesundheit  
und Ernährungssicherheit GmbH

*Danke für Ihre Aufmerksamkeit*

*Gesundheit. Ernährung. Sicherheit.  
Unsere Verantwortung.*

**[www.ages.at](http://www.ages.at)**

## Kapitel I:

„Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial“

## Kapitel III:

„Guideline on the Requirements to the Chemical and Pharmaceutical Quality Documentation concerning Investigational Medicinal Products in Clinical Trials“

# EudraLex - The Rules Governing Medicinal Products in the European Union



## [Volume 1 – Pharmaceutical Legislation](#)

Medicinal Products for Human use.

## [Volume 2 - Notice to Applicants.](#)

Medicinal Products for Human use.

## [Volume 3 - Guidelines.](#)

Medicinal Products for Human use.

## [Volume 4 - Good Manufacturing Practices](#)

Medicinal Products for Human and Veterinary use.

## [Volume 5 - Pharmaceutical Legislation.](#)

Veterinary Medicinal Products.

## [Volume 6 - Notice to Applicants.](#)

Veterinary Medicinal Products.

## [Volume 7 - Guidelines.](#)

Veterinary Medicinal Products.

## [Volume 8 - Maximum residue limits.](#)

Veterinary Medicinal Products.

## [Volume 9 - Pharmacovigilance](#)

Medicinal Products for Human and Veterinary use.

## [Volume 10 - Clinical trials](#)

Medicinal Products for human use in clinical trials (investigational medicinal products).

# Zusammenfassung

- Herstellung – GMP  
Dir 2003/94/EC
- Präklinik – GLP  
Dir 2004/10/EC
- Klinische Prüfung – GCP  
Dir 2001/20/EC

Das Common Technical Document Format ist eine international (Europa, USA, Japan) harmonisierte Grundstruktur zum Aufbau eines Zulassungsdossiers.

Vol. 10 Chapter I: „Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial“; Attachment 2

Vorteile:

- Langfristig - Arbeitersparnis
- Graduelles Befüllen im Entwicklungsprozeß
- Auffindbarkeit von Daten für Externe/Gutachter
- „Gemeinsame Sprache“ bei Verhandlungen

# CTD MODULE 3 : QUALITY

## 3.2.S.3 Characterisation

3.2.S.3.1 Elucidation of Structure and other Characteristics

3.2.S.3.2 Impurities

## 3.2.S.4 Control of Drug Substance

3.2.S.4.1 Specification

3.2.S.4.2 Analytical Procedures

3.2.S.4.3 Validation of Analytical Procedures

3.2.S.4.4 Batch Analyses

3.2.S.4.5 Justification of Specification

## 3.2.S.5 Reference Standards or Materials

## 3.2.S.6 Container Closure System

## 3.2.S.7 Stability

3.2.S.7.1 Stability Summary and Conclusions

3.2.S.7.2 Post-approval Stability Protocol and Stability Commitment

3.2.S.7.3 Stability Data

## Der sichere Weg ...

**..auf eine Wunschliste zur Inspektion zu kommen...**

Schlampige, unorganisierte Einreichung

Fehlende Unterlagen

Mangelnde Beschreibung des Prüfpräparats (CoA)

Fehlende Rückmeldung beim Mängeln

Unwissenheit der Beteiligten

▶ **Regulatory Division !!!!**

Die Komplexität der Studie

European Medicines Agency - Microsoft Internet Explorer

Adresse: <http://www.emea.europa.eu>

European Medicines Agency  
Website address: [www.emea.europa.eu](http://www.emea.europa.eu)

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**EMEA consulting on draft guideline on 'first-in-man' clinical trials**  
Published 26/03/2007

The European Medicines Agency has today published a draft guideline on requirements for first-in-man clinical trials for potential high-risk medicinal products. The guideline aims to provide a common approach across EU Member States to the design and conduct of such trials, and is released for public consultation until 23 May 2007.

Read more in the press release [here](#)  
Access the draft guideline [here](#)

**EMEA annual report published: Record volume of applications handled in 2006**  
Published 14/03/2007

The European Medicines Agency has published its annual report for 2006, following its adoption by the EMEA Management Board on 8 March.

The report details the record numbers of applications received in 2006 and substantially reduced assessment times for Agency procedures in what the EMEA Executive Director calls "one of the busiest years ever" for the Agency.

Read the Management Board press release [here](#)  
Find EMEA annual reports [here](#)

**Latest Press Releases**  
See [Press Office](#) for archived press releases

Date	Agency	Topic
04/04/07	HMPC	Meeting Report from the March meeting
30/03/07	EMEA	Press Release - European Medicines Agency recommends restricted use and strengthened warnings for Ketek
29/03/07	CHMP	Monthly Report from the March meeting
26/03/07	EMEA	Press Release - Insmed withdraws its marketing authorisation application for IPLEX
26/03/07	EMEA	Press Release - 'First-in-man' clinical trials guideline released for public consultation
23/03/07	CHMP	Press Release from the March meeting
23/03/07	EMEA	Press Release - European Medicines Agency statement on safety of Tamiflu
16/03/07	CVMP	Press Release from the March meeting
16/03/07	CVMP	Press Release - European Medicines Agency positive on third avian influenza vaccine for birds
15/03/07	EMEA	Press Release - Eli Lilly withdraws its marketing authorisation application for ARXXANT
14/03/07	Management Board	Press Release - EMEA annual report for 2006 shows record numbers of applications; assessment times in core processes significantly reduced
12/03/07	COMP	Press Release from the March meeting
05/03/07	CHMP	Public Statement - Baraclud (entecavir) Occurrence of a resistant HIV variant in a patient co-infected with HIV and HBV
05/02/07	EMEA	Press release - Closer ties on medicines safety between EU and Japan (includes exchange of letters from EU to Japan, exchange of letters from Japan to EU)
12/01/07	EMEA	Press Release - EMEA prepares for entry into force of a new legislation on paediatric medicines

See [Press Office](#) for archived press releases

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# Referenz-Webseiten

- [eudract.emea.europa.eu](http://eudract.emea.europa.eu)
- [www.emea.europa.eu](http://www.emea.europa.eu)
- [www.ich.org](http://www.ich.org)
- [www.fda.gov](http://www.fda.gov)
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