

# KDE LZE NAJÍT INFORMACE O KH

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## Obsah

 Web SÚKL a databáze KH SÚKL

 Clinical Trials Register EU

 ClinicalTrials.gov (FDA)


 EMA

 EudraLex Volume 10


 HMA (CTFG)

## Web SÚKL

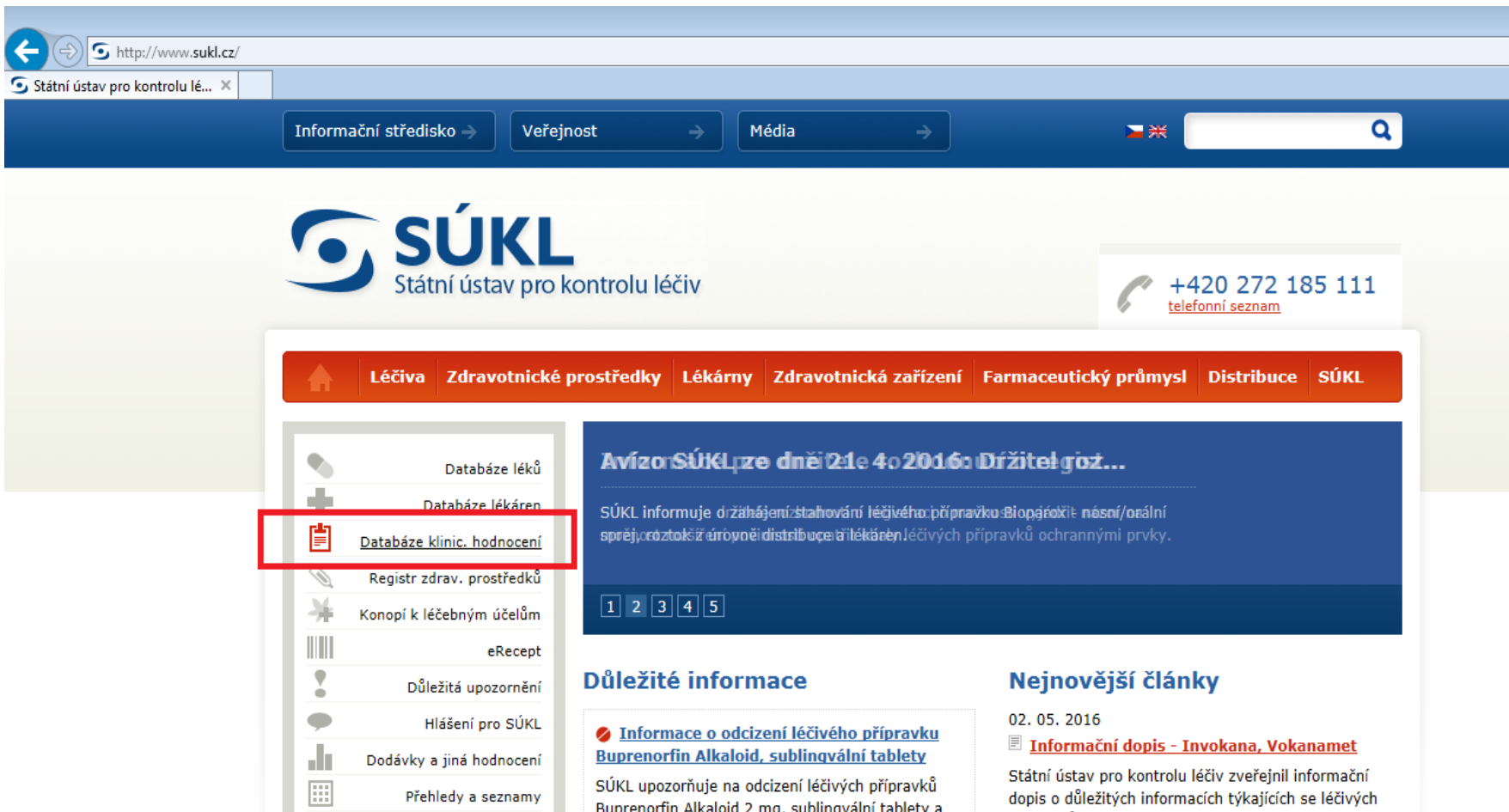
 <http://www.sukl.cz/>

 **Databáze KH SÚKL:** V souladu s § 99 odst. 1 písm. f) bod. 2. ZoL, přehled zahrnuje všechna klinická hodnocení schválená od účinnosti zákona, tj. od 31.12.2007.

Informace o klinických hodnoceních z let 2004-2007 jsou doplňovány postupně.

 Přehled, v souladu se ZoL, nezahrnuje studie bioekvivalence a studie, v nichž dochází k prvnímu podání léčivé látky člověku.

# Databáze KH SÚKL



http://www.sukl.cz/

Státní ústav pro kontrolu lé... x

Informační středisko → Veřejnost → Média →

🇨🇵 🇸🇰 🔍

**SÚKL**  
Státní ústav pro kontrolu léčiv

+420 272 185 111  
[telefonní seznam](#)

🏠 Léčiva Zdravotnické prostředky Lékárný Zdravotnická zařízení Farmaceutický průmysl Distribuce SÚKL

Databáze léků  
Databáze lékáren  
**Databáze klinic, hodnocení**  
Registr zdrav. prostředků  
Konopí k léčebným účelům  
eRecept  
Důležitá upozornění  
Hlášení pro SÚKL  
Dodávky a jiná hodnocení  
Přehledy a seznamy

**Avízo SÚKL ze dne 21. 4. 2016: Držitel goz...**

SÚKL informuje o zahájení stahování léčivého přípravku Bioprogit nosní/orální sprej, roztok z úrovně distribuce a lékáren. Léčivých přípravků ochrannými prvky.

1 2 3 4 5

**Důležité informace**

🚫 **Informace o odcizení léčivého přípravku Buprenorfin Alkaloid, sublingvální tablety**

SÚKL upozorňuje na odcizení léčivých přípravků Buprenorfin Alkaloid 2 mg, sublingvální tablety a

**Nejnovější články**

02. 05. 2016

📄 **Informační dopis - Invokana, Vokanamet**

Státní ústav pro kontrolu léčiv zveřejnil informační dopis o důležitých informacích týkajících se léčivých

## Vyhledávání

Pro vyhledání zvolte alespoň jednu možnost (např. indikační skupinu...)

Část názvu studie:

Indikační skupina:

Část názvu diagnózy:

Rok předložení žádosti:

Místo/město:





Definované požadavky  
na populaci:

- In utero
- Předčasně narození novorozenci (  $\leq$  37 týdnů)
- Novorozenci (0 - 27 dnů)
- Kojenci a batolata (28 dnů - 23 měsíců)
- Děti předškolní a nižší školní věk (2 - 11 let)
- Dospívající (12 - 17 let)
- Dospělí (18 - 65 let)
- Dospělí vyššího věku (  $>$  65 let)
- Muži
- Ženy
- Zdraví dobrovolníci
- Nemocní
- Všechny
- Probíhající
- Ukončené

Stav studie:

**Vyhledat**

# Web SÚKL – odběr novinek

|  |   |  |   |
|--|---|--|---|
|  <p><b>www.olecich.cz</b></p> |  <p><b>nebezpecneleky.cz</b></p> |  <p><b>eRecept</b></p> |  <p><b>lekarny.sukl.cz</b></p> |
| <p><a href="#">Informační portál pro veřejnost</a></p>   | <p><a href="#">Mohou nelegální léky poškodit Vaše zdraví?</a></p>   | <p><a href="#">Informace k elektronickému receptu</a></p>  | <p><a href="#">Zabezpečený portál pro lékárny</a></p>   |

## Ostatní činnosti

- [Legislativa a pokyny](#)
- [Konzultace SÚKL](#)
- [Administrační činnost](#)
- [Publikační činnost](#)
- [Mezinárodní aktivity](#)
- [Externí spolupráce](#)
- [Plné moci](#)

## Úřední deska SÚKL

- [Doručování veřejnou vyhláškou](#)
- [Informace o průběhu správních řízení](#)
- [Opatření obecné povahy](#)
- [Výzvy SÚKL](#)
- [Návrhy dokumentů SÚKL k připomínkování](#)

[zobrazit celou sekci](#)

## Sazebník a poplatky

- [Formulář pro platbu náhrad výdajů ...](#)
- [Pokyny k úhradám poplatků](#)
- [Úhrada náhrad výdajů za odborné úkony ...](#)
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## Další informace

- [Pověření inspektorů](#)
- [Veřejné zakázky](#)
- [Vzdělávací akce](#)
- [Kariéra](#)
- [Etické komise](#)
- [Krajské úřady](#)

## Kontakty

- [Telefonní seznam](#)
- [Regionální pracoviště SÚKL](#)
- [Centrální kontakty](#)
- [Podatelna - pokladna](#)
- [Elektronická podatelna](#)
- [Knihovna](#)

[zobrazit celou sekci](#)

[Archiv](#) | [Webmaster](#) | [Prohlášení o přístupnosti](#) | [Podmínky využívání služeb webové prezentace](#) | [Zásady ochrany soukromí návštěvníků stránek](#) | [Povinné informace](#) | [Kontakty](#) | [Mapa stránek](#) | [Novinky e-mailem](#) | [RSS](#)

[Přihlášení](#) →

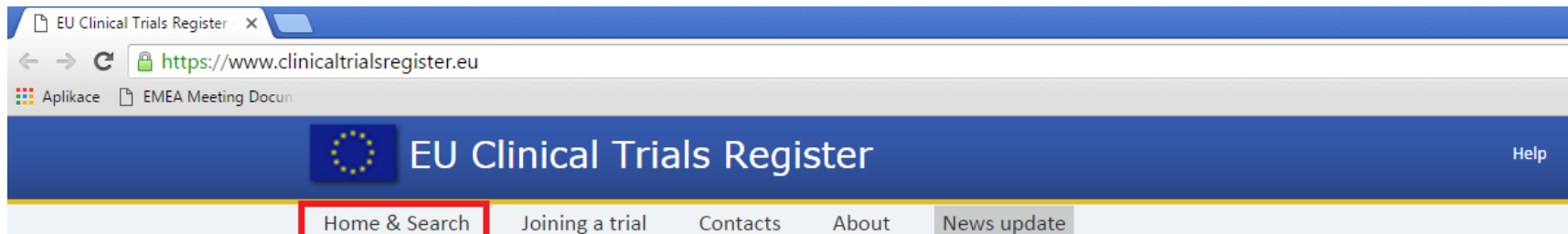


PODPORUJEME  
VAŠI BUDOUCNOST  
[www.esfcr.cz](http://www.esfcr.cz)

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+420 272 185 111  
[posta@sukl.cz](mailto:posta@sukl.cz)



# ClinicalTrialsRegister.eu



The screenshot shows the top part of the website. The browser address bar displays 'https://www.clinicaltrialsregister.eu'. The main header features the EU flag and the text 'EU Clinical Trials Register' with a 'Help' link on the right. Below the header is a navigation menu with the following items: 'Home & Search' (highlighted with a red box), 'Joining a trial', 'Contacts', 'About', and 'News update'.

## News update

The system has been made available on 13 January 2016. The summary results will be gradually made available for public access from that date, once the information has been reviewed and verified. Full access for sponsors has also been restored from that date.

In the context of clinical trial sponsors' or PIP addressees' inability to meet regulatory reporting timeframes while the system was offline: The new deadline for submission for all summary results affected by the period that the system was offline will be 13 July 2016, allowing a period of six months from the date of re-opening of the system. Affected results are those whose submission deadline fell due during the period that the system was offline, as well as those whose submission deadline falls within a period of two months from the re-opening date.

In addition, for trials categorised as to be posted  $\leq 24$  months after finalisation of the programming (see document "[Trial results: modalities and timing of posting](#)"), the deadline for submission of summary results will be 21 December 2016, being five months from the current deadline in July 2016.

The issues causing errors in data recording have been fixed. These are described in the [release notes](#) (see "timestamp" and "category" issues). The results presented are correct. However, the issue that causes the order of display of reporting groups and results to differ through the results set has not been addressed. The reporting groups and results themselves are correct; it is only the display order that is affected.


[Please click here to continue to the site](#)

### Version of the website

EU Clinical Trials Register version 2.1

#### See also:

[Glossary](#) 


[How to search](#) 

[FAQs](#) 

[Patients' and Consumers'](#)

[Organisations' contact information](#) 

[Healthcare Professionals'](#)

[Organisations contact information](#) 

[Sponsors' contact information](#) 

X

**Examples:** Cancer AND drug name. Pneumonia AND sponsor name.  
[How to search \[pdf\]](#)

**Advanced Search:** [Search tools](#)

|   |  |
|---|--|
| Select Country:   | Select Age Range:  |
| <input type="text" value="Austria"/><br><input type="text" value="Belgium"/><br><input type="text" value="Bulgaria"/><br><input type="text" value="Croatia"/> | <input type="text" value="Adolescent"/><br><input type="text" value="Adult"/><br><input type="text" value="Children"/><br><input type="text" value="Elderly"/> |



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|   |   |
|---|---|
| Select Trial Status:  | Select Trial Phase:   |
| <input type="text" value="Completed"/><br><input type="text" value="Not Authorised"/><br><input type="text" value="Ongoing"/><br><input type="text" value="Prematurely Ended"/> | <input type="text" value="Phase One"/><br><input type="text" value="Phase Two"/><br><input type="text" value="Phase Three"/><br><input type="text" value="Phase Four"/> |

---

Select Gender:

---

Select Date Range:  
  to  

---

Select Rare Disease:

---

IMP with orphan designation in the indication

---

Orphan Designation Number:

---

Results Status:

---

[Clear advanced search filters](#)



# ClinicalTrials.gov

## ClinicalTrials.gov

A service of the U.S. National Institutes of Health

*ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more [about clinical studies](#) and [about this site](#), including relevant [history](#), [policies](#), and [laws](#).*

Find Studies ▾
About Clinical Studies ▾
Submit Studies ▾
Resources ▾
About This Site ▾

ClinicalTrials.gov currently lists **214,362 studies** with locations in all 50 States and in **193 countries**. Text Size ▾

### Search for Studies

Example: "Heart attack" AND "Los Angeles"

[Advanced Search](#) | [See Studies by Topic](#)  
[See Studies on Map](#)

### Search Help

- How to search
- How to find results of studies
- How to read a study record

### Locations of Recruiting Studies



- Non-U.S. only (54%)
- U.S. only (40%)
- Both U.S. and non-U.S. (6%)

Total N = 37,871 studies  
(Data as of May 01, 2016)

- See more trends, charts, and maps

#### For Patients and Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more

#### For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more

#### For Study Record Managers

- Why register?
- How to register your study
- FDAAA 801 requirements
- Learn more

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# EMA (<http://www.ema.europa.eu>)



An agency of the European Union



Text size: [A](#) [A](#) [A](#)

Site-wide search



Search document library



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Human regulatory information

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Pre-authorisation

Post-opinion

Post-authorisation

Product information

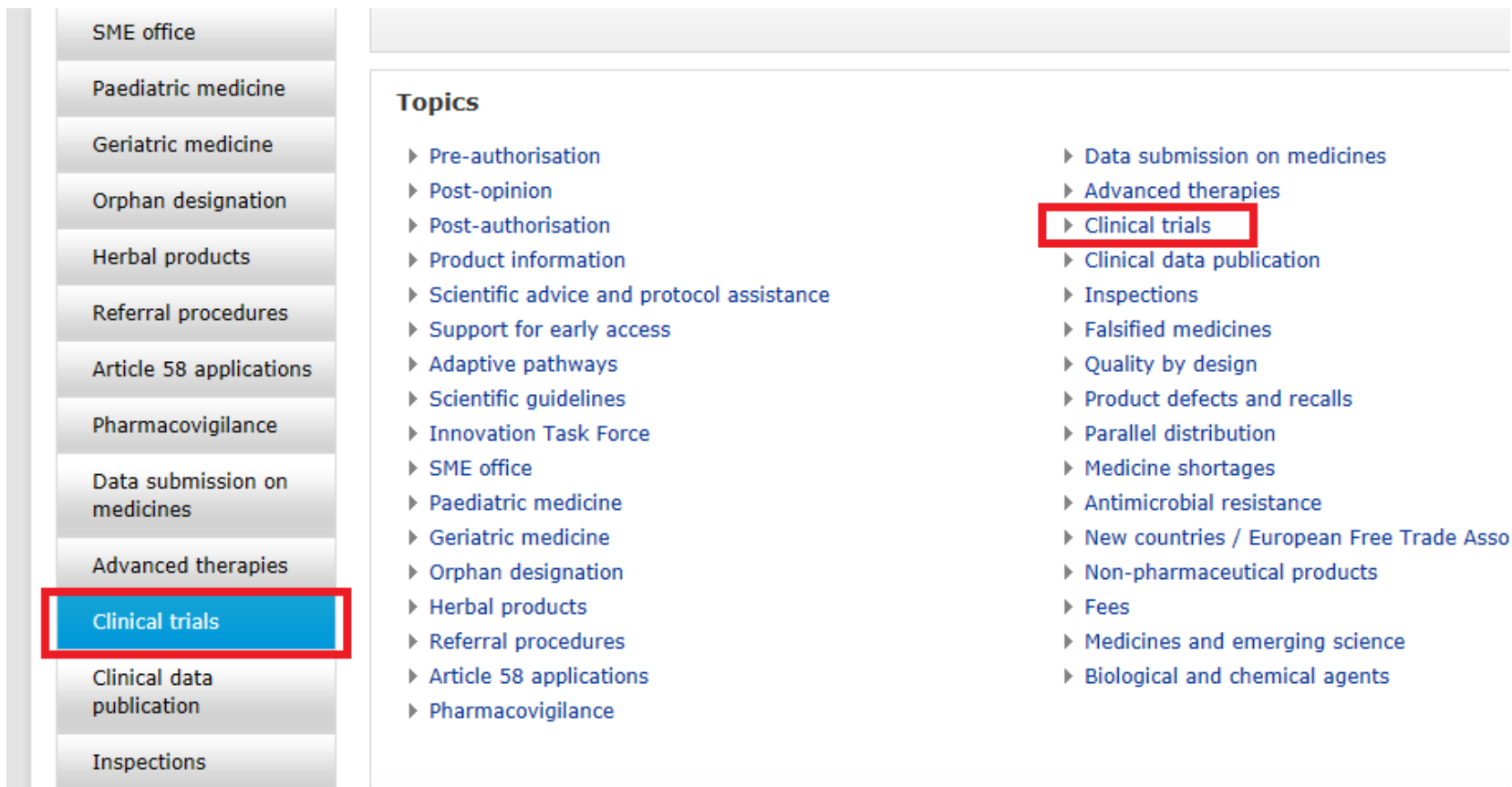
## Human medicines: regulatory information

[Email](#) [Print](#) [Help](#) [Share](#)

**This section of the website provides information for companies and individuals involved in developing and marketing medicines for human use in the European Union**



# EMA (<http://www.ema.europa.eu>)



The image shows a screenshot of the EMA website. On the left is a vertical navigation menu with buttons for various topics. The 'Clinical trials' button is highlighted with a red border. To the right is a 'Topics' section with a list of sub-topics. The 'Clinical trials' sub-topic is also highlighted with a red border.

**Navigation Menu:**

- SME office
- Paediatric medicine
- Geriatric medicine
- Orphan designation
- Herbal products
- Referral procedures
- Article 58 applications
- Pharmacovigilance
- Data submission on medicines
- Advanced therapies
- Clinical trials**
- Clinical data publication
- Inspections











**Topics**

- ▶ Pre-authorisation
- ▶ Post-opinion
- ▶ Post-authorisation
- ▶ Product information
- ▶ Scientific advice and protocol assistance
- ▶ Support for early access
- ▶ Adaptive pathways
- ▶ Scientific guidelines
- ▶ Innovation Task Force
- ▶ SME office
- ▶ Paediatric medicine
- ▶ Geriatric medicine
- ▶ Orphan designation
- ▶ Herbal products
- ▶ Referral procedures
- ▶ Article 58 applications
- ▶ Pharmacovigilance
- ▶ Data submission on medicines
- ▶ Advanced therapies
- ▶ Clinical trials**
- ▶ Clinical data publication
- ▶ Inspections
- ▶ Falsified medicines
- ▶ Quality by design
- ▶ Product defects and recalls
- ▶ Parallel distribution
- ▶ Medicine shortages
- ▶ Antimicrobial resistance
- ▶ New countries / European Free Trade Asso
- ▶ Non-pharmaceutical products
- ▶ Fees
- ▶ Medicines and emerging science
- ▶ Biological and chemical agents

# EudraLex Volume 10

 <http://ec.europa.eu/health/documents/eudralex/vol-10/>

## Chapter I: Application and Application Form

- 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  (1022 KB)  (revision 3 of March 2010)
  - Annex 1 revised Pdf version  (86 KB) Word version  (313 KB) (revision 4 of November 2009) - EudraCT Version 8.0 uses the Revision 4 dated November 2009 of the Clinical Trials Application Form. For more information please refer to the [EudraCT website](#)
  - Substantial Amendment Notification Form : PDF version  (47 KB) - Word version  (109 KB) (revision 3 of June 2010)
  - Declaration of the End of Trial Form : PDF version  (27 KB) - Word version  (47 KB) (revision 3 of June 2010)
- Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use  (135 KB) (revision 1 of February 2006)
- Detailed guidance on the European clinical trials database (EUDRACT Database)  (230 KB) (revision of April 2004)

# EudraLex Volume 10

## Chapter II: Safety Reporting

- Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3')  (2 MB)  (June 2011)
- ICH guideline E2F - Note for guidance on development safety update reports  (September 2010)

## Chapter III: Quality of the Investigational Medicinal Product

- Template for the qualified person's declaration equivalence to EU GMP for Investigational Medicinal Products manufactured in third countries  
[pdf version]  (30 KB) - [word version]  (72 KB) (may 2013)
- Good manufacturing practices for manufacture of investigational medicinal products  (67 KB)(February 2010)
- Union Basic Format for Manufacturer's Authorisation  (2 MB)(June 2013)
- Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials  (140 KB)
- Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials  (186 KB) (May 2012)
- Guidance on Investigational Medicinal Products (IMPs) and 'non investigational medicinal products' (NIMPs)  (48 KB) (rev. 1, March 2011)






# EudraLex Volume 10

## Chapter IV: Inspections

- [Guidance for the preparation of GCP inspections](#)  (46 KB) (June 2008)
- [Recommendation on inspection procedures for the verification of good clinical practice compliance](#)  (170 KB) (July 2006)
- [Guidance for the conduct of GCP inspections](#)  (26 KB) (June 2008)
- [Annex I to Guidance for the conduct of GCP inspections - investigator site](#)  (45 KB) (June 2008)
- [Annex II to Guidance for the conduct of GCP inspection - clinical laboratories](#)  (38 KB) (June 2008)
- [Annex III to Guidance for the conduct of GCP inspections - computer systems](#)  (13 KB) (June 2008)
- [Annex IV to Guidance for the conduct of GCP inspections - Sponsor and CRO](#)  (42 KB) (June 2008)
- [Annex V to Guidance for the conduct of GCP inspections - Phase I Units](#)  (34 KB) (November 2008)
- [Annex VI to Guidance for the conduct of GCP inspections - Record keeping and archiving of documents](#)  (32 KB) (March 2010)
- [Annex VII to Guidance for the conduct of GCP inspections - Bioanalytical part, Pharmacokinetic and Statistical Analyses of Bioequivalence Trials](#)  (38 KB) (November 2008)
- [Guidance for coordination of GCP inspections and co-operation between GCP inspectors, the reference and concerned Member States and CMD\(h\) , in the context of the evaluation of the GCP compliance of marketing authorization applications for mutual recognition and decentralized procedures](#)  (66 KB) (June 2009)
- [Guidance for exchange of GCP Inspection Reports according to Article 15\(2\) of Directive 2001/20/EC](#)  (27 KB) (revision 1 - May 2009)
- [Guidance for the communication on GCP inspections and findings](#)  (23 KB) (June 2008)
- [Procedure for standardisation of GCP inspection entries in EudraCT](#)  (32 KB) (November 2008)
- [Guidance for the preparation of Good Clinical Practice inspection reports](#)  (30 KB) (June 2008)
- [Recommendations on the qualifications of inspectors verifying compliance in clinical trials with the provisions of Good Clinical Practice](#)  (125 KB) (July 2006)





# EudraLex Volume 10

## Chapter V: Additional Information

- Guidelines on good clinical practice (ICH E6: Good Clinical Practice: Consolidated guideline, CPMP/ICH/135/95)  (216 KB) (1996)
- Detailed guidelines on good clinical practice specific to advanced therapy medicinal products  (86 KB) (December 2009)
- Recommendation on the content of the trial master file and archiving  (279 KB) (July 2006)
- "Questions & Answers" Document - Version 11.0  (100 KB) (May 2013)
- Ethical considerations for clinical trials on medicinal products conducted with the paediatric population  (233 KB) (2008)
- Guideline 2008/C168/02 on the data fields from the European clinical trials database (EudraCT) that may be included in the European database on Medicinal Products  (53 KB) (July 2008)
- List of fields contained in the 'EudraCT' clinical trials database to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004 and its implementing guideline 2008/C168/02  (98 KB) (February 2009)
- Guideline 2009/C28/01 on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the European Medicines Agency (EMA), in accordance with Article 41 of Regulation (EC) No 1901/2006  (71 KB)  (February 2009)
- List of fields to be made public from EudraCT for Paediatric Clinical Trials in accordance with Article 41 of Regulation (EC) No 1901/2006 and its implementing guideline 2009/C28/01  (100 KB) (February 2009)
- Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006  (774 KB)  (October 2012)
- Technical guidance on the format of the data fields of result-related information on clinical trials submitted in accordance with Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006  (278 KB) (January 2013)
- EudraCT - List of additional fields contained in EudraCT (reasons for negative opinions of the Ethics Committee)  (21 KB) (November 2010)

# EudraLex Volume 10

## Chapter VI: Legislation

- Directive 2001/20/EC OF the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.  (67 KB) 
- Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (Official Journal L 262, 14/10/2003 p. 22 - 26).  (115 KB) 



# HMA (CTFG)

 [www.hma.eu](http://www.hma.eu)



About HMA

Human Medicines

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You are here: [Home](#) > [About HMA](#) > [Working Groups](#) > [Clinical Trials Facilitation Group](#)

Vision and mission

Structure



# HMA (CTFG)



## CLINICAL TRIAL FACILITATION GROUP (CTFG)

|                                    |          |
|------------------------------------|----------|
| <b>Introduction/Overview</b>       | <b>+</b> |
| <b>Mandate</b>                     | <b>+</b> |
| <b>Members and Representatives</b> | <b>+</b> |
| <b>Contact</b>                     | <b>+</b> |
| <b>Activities and achievements</b> | <b>+</b> |
| <b>Key documents list</b>          | <b>+</b> |

## Clinical Trials Authorisations (CTAs)

### The Voluntary Harmonised Procedure (VHP)

- [Guidance document for a Voluntary Harmonised Procedure for the assessment of multinational Clinical Trial Applications, December 2014 |pdf](#)
- [List of participating member states in VHP, December 2014 | pdf](#)
- [Results of the Voluntary Harmonisation Procedure \(VHP\), July 2015 |pdf](#)
- [Metrics on participation of NCA \(01/01/2015 - 01/07/2015\) |pdf](#)

### Guidance

- [Recommendations related to contraception and pregnancy testing in clinical trials, September 2014 |pdf](#)
- [GLP in clinical trials |pdf](#)

### National fees/information

- [Overview of the fees charged by NCAs for submission of different types of clinical trial or amendments, January 2012 | pdf](#)
- [Q and As - Frequently asked questions on CTs, updated January 2012 | pdf](#)

### Clinical Trials Safety

- [DSUR Q and As, 2012 | pdf](#)
- [Reference Safety Information, 2013 | pdf](#)
- [Reference Safety Information Q and A](#)