KDE LZE NAJÍT INFORMACE O KH

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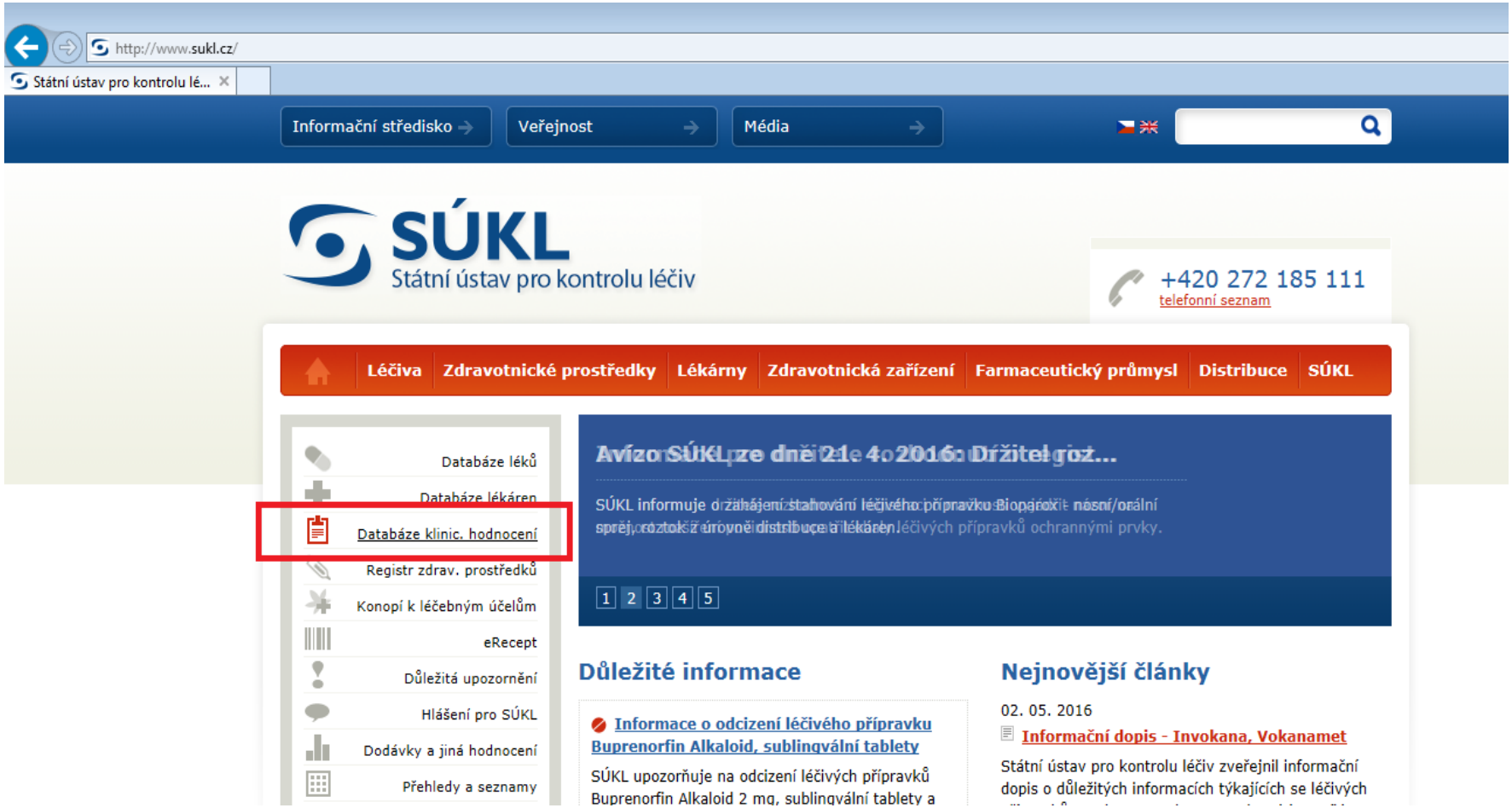
Obsah

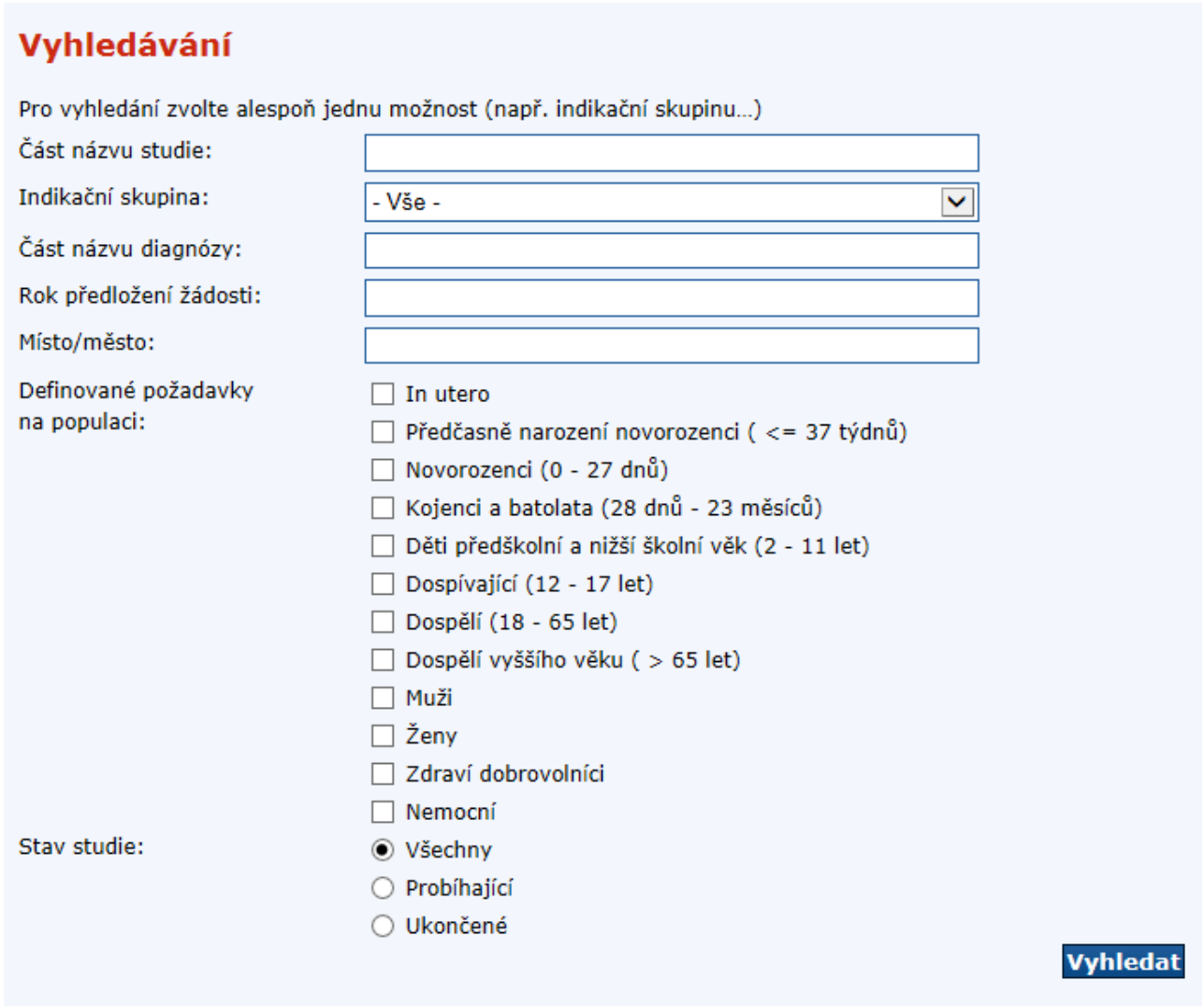
- Web SÚKL a databáze KH SÚKL
- Clinical Trials Register EU
- ClinicalTrials.gov (FDA)
- EMA
- EudraLex Volume 10
- HMA (CTFG)

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





Vyhledávání

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

Část názvu studie:

Indikační skupina: - Vše -

Část názvu diagnózy:

Rok předložení žádosti:

Místo/město:

Definované požadavky na populaci:

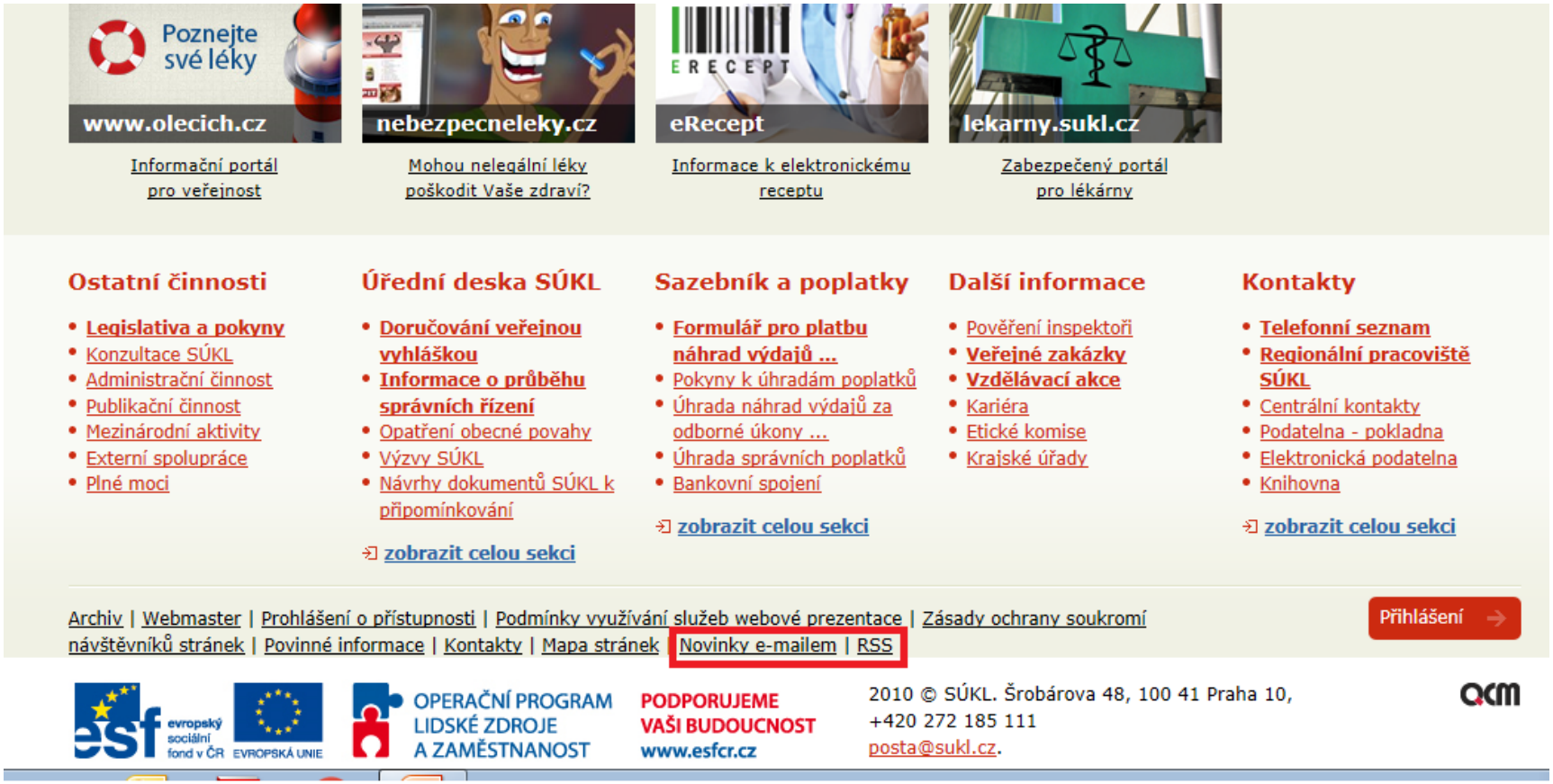
- ☐ In utero
- ☐ Předčasně narození novorozenci (<= 37 týdnů)
- ☐ Novorozenci (0 - 27 dnů)
- ☐ Kojenci a batolata (28 dnů - 23 měsíců)
- ☐ Děti předškolní a nižší školní věk (2 - 11 let)
- ☐ Dospívající (12 - 17 let)
- ☐ Dospělí (18 - 65 let)
- ☐ Dospělí vyššího věku (> 65 let)
- ☐ Muži
- ☐ Ženy
- ☐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

Stav studie:

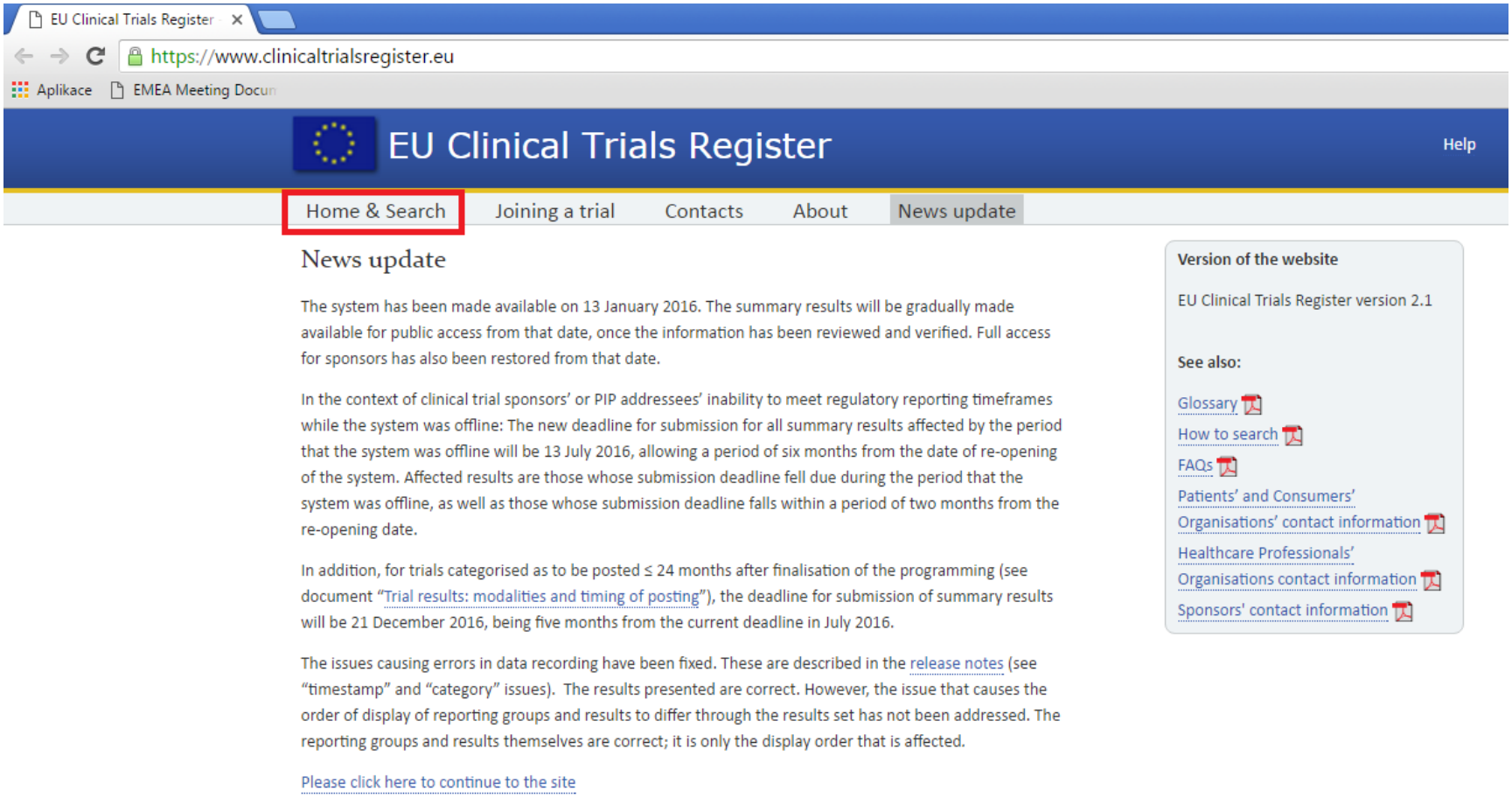
- ◉ Všechny
- ○ Probíhající
- ○ Ukončené

Vyhledat

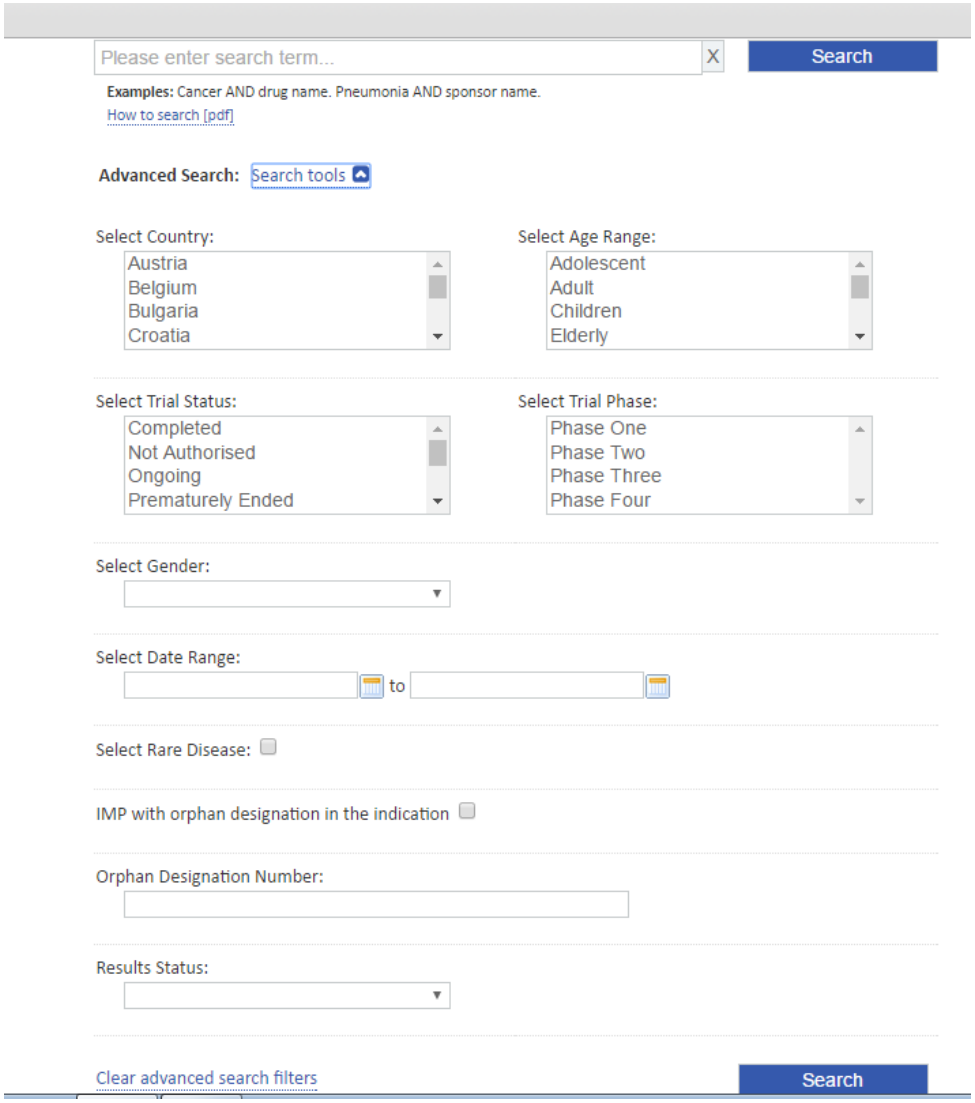
Web SÚKL – odběr novinek



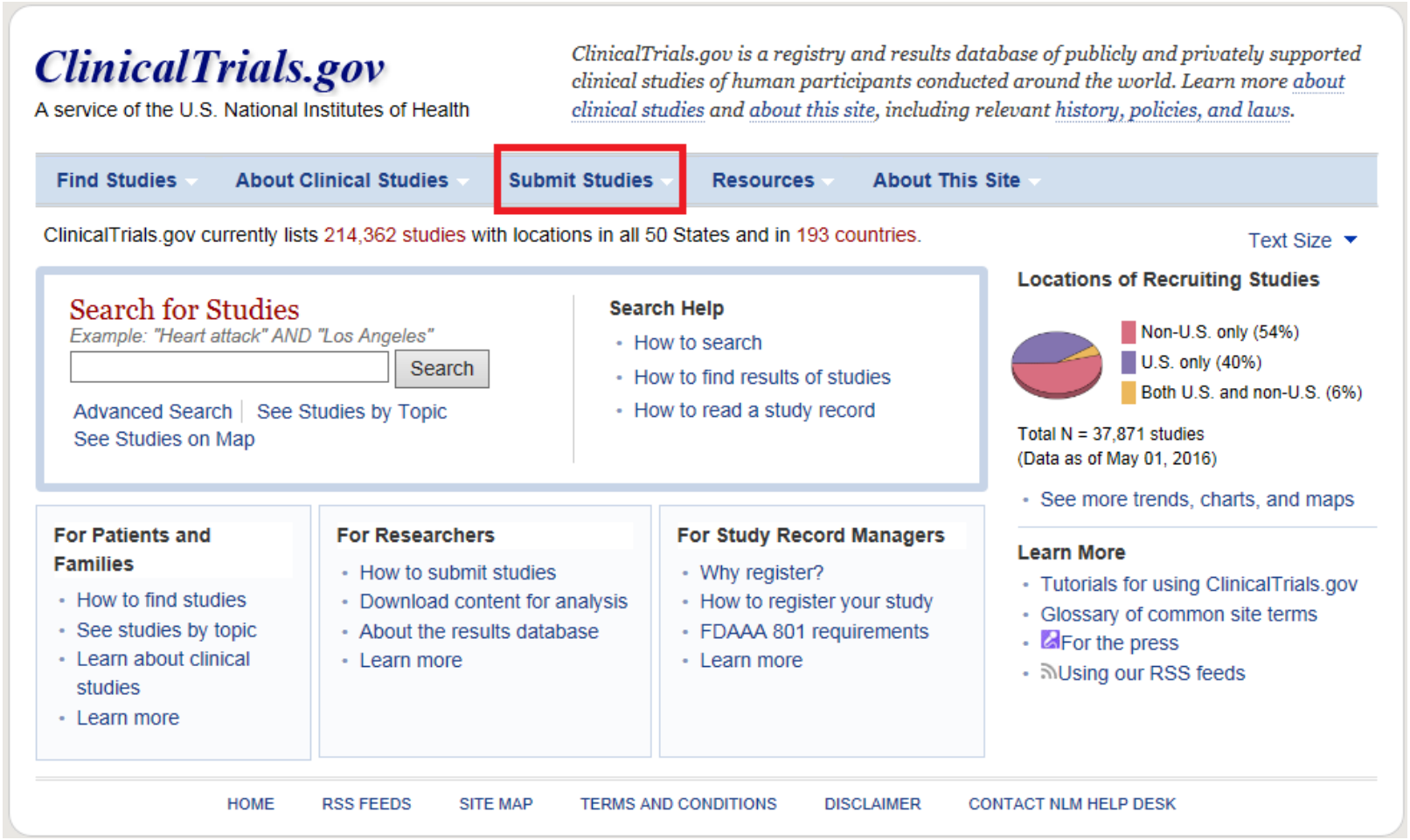
ClinicalTrialsRegister.eu



Kde lze najít informace o KH



ClinicalTrials.gov



EMA (http://www.ema.europa.eu)

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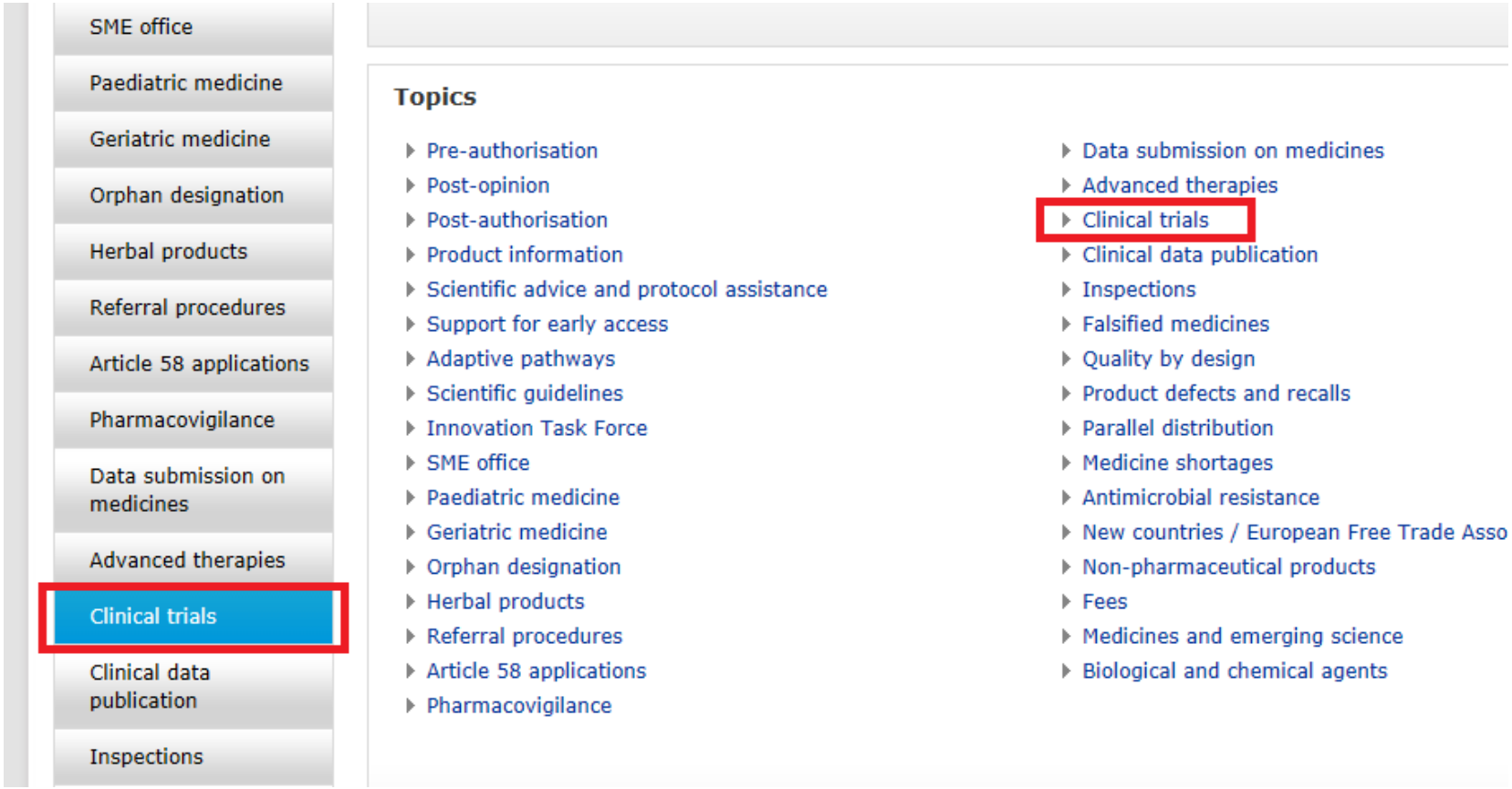

EudraLex Volume 10

- 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)

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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)

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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)

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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 (EMEA), 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)

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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

HMA (CTFG)

CLINICAL TRIAL FACILITATION GROUP (CTFG)

- Introduction/Overview +
- Mandate +
- Members and Representatives +
- Contact +
- Activities and achievements +
- Key documents list +

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