CTU News Archive 2011

11.11.2011 19:06

Quality Guidelines for Swiss Interdisciplinary Academic Trial Centres

Within the framework of the harmonisation concept for the improvement of the clinical trial culture in Switzerland, the SCTO has published the first volume of the «**Guidelines for Good Operational Practice**».

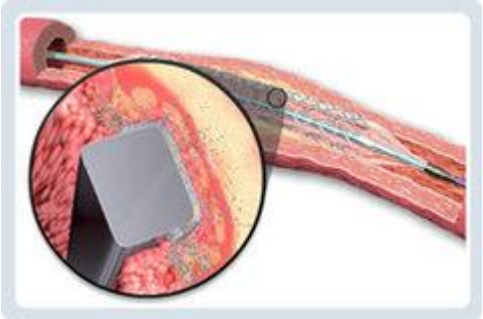
These quality guidelines for Swiss interdisciplinary academic trial centres – a binding quality-standard for members of the network in terms of planning and conducting clinical trial projects – were elaborated in close collaboration with the Clinical Trial Units and the Swiss Group for Clinical Cancer Research.
By releasing the quality guidelines, the SCTO significantly contributes to a continuous service quality improvement within the CTU-network and hence, to the recognition of its professional competence on a national and international level.
The related Data Management Guidelines will be available soon.

(authority: SCTO.ch)

09.11.2011 20:49

Trial on the long-term safety and effectiveness of novel drug-eluting stents published

Paper by ISPM and CTU Bern on the safety and effectiveness of a novel drug-eluting stent published today in The Lancet.



The 4 year results of LEADERS were published today in The Lancet, simultaneously with a talk given at TCT 2011 in San Francisco. The article by Bindu Kalesan, Giulio Stefanini, Dik Heg, Stephan Windecker, Peter Jüni and colleagues from 10 European sites, describes a randomised controlled multi-centric non-inferiority trial in 1700 patients with chronic stable coronary artery disease or acute coronary syndromes comparing a novel drug-eluting stent using a biodegradable polymer with one of the most effective drug-eluting stents to date, which uses a non-degradable polymer.

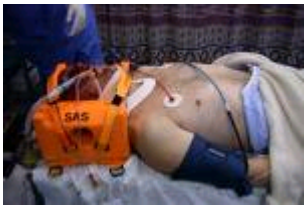
Use of drug-eluting stents with controlled release of anti-proliferative drugs from durable polymer surface coatings reduce the risk of restenosis compared with use of bare metal stents. However, early generation, durable polymer drug-eluting stents were associated with an increased risk of very late stent thrombosis that occur one year or later after stent implantation. The persistence of polymer material on the stent surface after completion of drug release was suggested as a potential trigger for a chronic inflammatory response that leads to very late stent thrombosis. The biodegradable polymer of the novel stent completely disintegrates into water and carbon dioxide after 6 to 9 months, once the drug is released. This should in turn reduce the risk of very late stent thrombosis.

The 4 year follow-up of LEADERS indicates that the novel stent with a biodegradable polymer is not only non-inferior, but appears to improve long-term clinical outcomes compared with the conventional drug-eluting stent with a non-degradable polymer. During the first year, clinical outcomes were comparable. After one year, however, the risk of very late stent thrombosis in patients who had received the novel stent was reduced by 80%.

Link to publication

10.10.2011 17:29

Interpretation of article 56 of the Federal Law on Therapeutic Products (Heilmittelgesetz)



Swissmedic and the Swiss Working Group of Medical Ethics Committees provide a joint interpretation on legal requirements for clinical studies in medical emergency situations.

Swissmedic and the Swiss Working Group of Medical Ethics Committees (Arbeitsgemeinschaft der Ethikkommissionen, AGEK) just published a joint interpretation on article 56 of the Federal Law on Therapeutic Products (Heilmittelgesetz, HMG). Article 56 describes requirements for clinical studies in medical emergency situations. In the past, these studies and the interpretation of the related article 56 caused some discussions between sponsors, ethics committees, and Swissmedic. It is hoped that the new joint interpretation will clarify the regulation and conduct of such studies.

Joint interpretation in German

Joint interpretation in French

24.09.2011 17:33

Registrations open

Wednesday, 11.January, 2012: Clinical Investigators I: Basic GCP and clinical research training
Monday 13. February and Monday 20 February 2012: Clinical Investigators II: Advanced GCP and clinical research training

15.09.2011 16:20

Swissmedic workshop: Investigator-initiated clinical trials (IITs) with drugs and Clinical investigations of medical devices

Second workshop will take place on October 25 from 13.30 to 17.00 at Swissmedic in Bern. You can find further informations here.

15.09.2011 16:10

HWI-Trial granted from SNF

The HWI trial, a randomized-controlled double-blind study comparing symptomatic therapy of uncomplicated lower urinary tract infections with antibiotic treatment in the ambulatory setting has been granted research funding from the Swiss National Fund of CHF 250000 over two years. CTU Bern is involved in methodological consulting, database development and data management, and statistics.

31.08.2011 10:10

Clinical Research Day 2011

This year Department of Clinical Research of the University of Bern follows its tradition too and holds the Clinical Research Day at the Inselspital in Bern.

The Clinical Research Day 2011 will take place on 2nd of November at the Langhans Auditorium, Pathology Building, Murtenstrasse 31 in Bern.

More information can be found here www.dkf.unibe.ch/271

08.08.2011 09:21

2011 4th Call for proposals, Innovative Medicines Initiative

Last month the Innovative Medicines Initiative (IMI) launched it's 4th call for proposals.

Deadline for submission: October 18th 2011

Following topics are included in the call:

- An European medical information framework of patient-level data to support a wide range of medical research
- European translational information & knowledge management services
- Delivery and targeting mechanisms for biological macromolecules
- In vivo predictive biopharmaceutics tools for oral drug delivery
- Sustainable chemistry - delivering medicines for the 21st century
- Human induced pluripotent stem cells for drug discovery and safety assessment
- Understanding and optimisiing kinetics in drug discovery

Deadline for submissions of expression of interest is October 18th 2011. The call will follow a two stage submission and evaluation procedure.

Further eligibility criteria, relevant documents as well as a detailed description of the topics can be found on the IMI website.

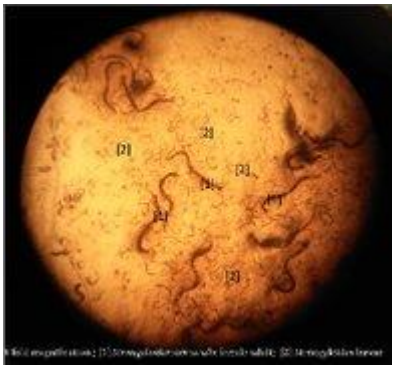
02.08.2011 17:45

Lichen-Trial granted from SNF

The Lichen Trial ("Efficacy of topical progesterone versus topical clobetasolepropionate in patients with vulvar Lichen sclerosus - A double blind randomized phase II study") has been granted research funding from the Swiss National Fund of CHF 206000 over 30 months. CTU Bern is involved in methodological consulting, grant application, database development and datamanagment, and statistics.

13.05.2011 14:04

Antihelminthic treatment and HIV progression



Recruitmend and follow-up of patients in Tanzania completed

This randomised controlled trial aims to assess if anthelminthic treatment can delay the progression of HIV in ART-naïve patients in rural Africa.

After approximately two years the recruitment and follow up of HIV infected patients in Tanzania, enrolled in this study, has been completed.

Currently the data is being cleaned and prepared for statistical analysis.

12.05.2011 18:20

Comfortable AMI trial: target sample size reached

After one and half year of recruitment, the Comfortable AMI trial has reached its target accrual of 1100 patients.

The Comfortable AMI trial, a randomized controlled trial comparing a biolimus-eluting stent (Biomatrix) with a bare-metal stent (Gazelle) in STEMI patients, has reached its target sample size of 1100 patients. The recruitment period ended in January 2011 after one and half year of recruitment at eleven sites in Switzerland, Denmark, Serbia, United Kingdom, Israel and the Netherlands. The objectives of the trial are to compare the safety and efficacy of the two stent types and, in a subgroup of patients, to assess the vascular wall response using OCT/ IVUS imaging. First trial results are expected in 2012.

28.03.2011 15:40

EMA launches a Clinical Trials Register

EU Clinical Trials Register goes online

On March 22nd the European Medicines Agency (EMA) launched the EU Clinical Trials Register which, should provide for the first time public access to information on interventional clinical trials for medicines authorized in 27 EU Member States and Iceland, Liechtenstein and Norway.

In addition information can be found on clinical trials carried out outside the EU if these are part of a paediatric investigation plan (PIP).

The EU Clinical Trials Register can be found at https://www.clinicaltrialsregister.eu

The website is managed by the EMA and includes information from EudraCT (https://eudract.ema.europa.eu/) which, is collected and entered by national medicine regulatory authorities or by the addressee of a PIP decision for trials conducted outside the EU.

In contrast to the clinicaltrials.gov, the EU register provides less information on the trials and does not include detailed information on the investigator(s) in charge.

However it was already communicated by the EMA that the Agency will continue to work to work with stakeholders to improve the functioning of the EU Clinical Trials Register, in particular by enhancing the quality and completeness of data, and improving the search functionality

Press release »» EU Clinical Trials Register

25.03.2011 15:50

Second Scientific Symposium of the Swiss Clinical Trial Organisation (SCTO)

The second Symposium of the Swiss Clinical Trial Organisation (SCTO) will be held on 9th of June 2011 in Basel. The focus of this year's symposium is "Clinical Research in Paediatrics".

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SCTO Website **»»**

Registration **»»**

28.02.2011 10:38

Public consultation: Clinical Trials Directive 2001/20/EC

Deadline for comments: May 13.2011

The concept paper issued by the European Commission on the revision of the clinical trials directive 2001/20/EC is now submitted for public consultation.

The deadline for comments is 13 May 2011

Concept Paper »»

02.02.2011 12:13

Next Clinical Investigators I: Basic GCP and clinical research training

Second chance to attend Basic GCP & clinical research training this year!

Because of the high demand for this course and the limited places, the CTU Bern is pleased to offer a second basic training session next 9 May 2011.

Please register online here if you are interested in attending this course. »»

04.01.2011 09:10

ICH Meeting in Japan

The Steering Committee and working groups of the International Conference on Harmonization (ICH) Steering Committee met in Fukuoka, Japan last 6-11Nov. 2010.

The meeting in Japan marked the 20th anniversary of ICH. In recognition, ICH published a brochure, “The Value & Benefits of ICH to Drug Regulatory Authorities—Advancing Harmonization for Public Health. ”

As a member of the European Free Trade Association (EFTA) Switzerland represented by Swissmedic attended the meeting as an observer. Swissmedic is actively involved in the different working groups.

ICH encouraged to open further technical collaboration with non-ICH regions, reported progress in harmonizing quality and safety initiatives, and discussed benefit–risk approaches in pharmaco-vigilance.
The ICH SC endorsed opening the ICH technical working groups to qualifying members of the Global Cooperation Group, which includes representatives from Australia, Brazil, China, Chinese Taipei, India, Russia, South Korea, and Singapore, as well the Asia-Pacific Economic Cooperation, the Association of Southeast Asian Nations, Gulf Cooperation Countries, the Pan American Network on Drug Regulatory Harmonization, and the Southern African Development Community. “This represents a new level of involvement of the GCG and will provide an opportunity for direct technical contributions to the work of ICH, a more global perspective, and will advance implementation of ICH guidelines,” according to an ICH Nov. 11, 2010