

CTU News Archive 2015

New GCP courses recognized by swissethics



18.12.2015 - Both GCP courses provided by CTU Bern, Basic and Advanced, were completely revised according to the new requirements stipulated by swissethics. Both courses have received formal recognition by swissethics.

As of January 1st, 2014, [swissethics](#) instead of Swissmedic is responsible for formal recognition of GCP and research ethics courses in Switzerland. Swissethics [defined new requirements](#) for courses for both, Investigator and Sponsor-Investigator Level. These new requirements made a complete revision necessary of the two courses provided by CTU Bern: Clinical Investigators I: Basic GCP & clinical research training (Investigator Level) and Clinical Investigators II: Advanced GCP & clinical research training (Sponsor-Investigator Level). The Basic course consists of a self-learning module and a one-day course with attendance. The Advanced course is now only one day with attendance instead of a two-day course. More information can be found [here](#). Ethics committees will, however, accept old certificates as long as they are from previously recognized courses.

CTU Lecture am 8.12.2015: «Wer weiss denn sowas?» CTU Quiz zur klinischen Forschung



Testen Sie ihr Wissen im Themenbereich der klinischen Forschung im CTU Weihnachtsquiz am Inselspital. Um live beim Quiz in REDCap™ mitspielen zu können, benötigen Sie ein internetfähiges Mobiltelefon oder Ihren Laptop. Das Mitspielen ist selbstverständlich freiwillig und nicht Voraussetzung für die Teilnahme an der Lecture.

Weitere Informationen zur Veranstaltung finden Sie [hier](#).

CTU Lecture am 10.11.2015: «Update zur Biobank des Inselspitals»



Am kommenden Dienstag, 10. November 2015 findet die zweite CTU Lecture am Inselspital statt.

Sie sind herzlich eingeladen am Vortrag «Update zur Biobank des Inselspitals» von Herrn PD Dr. med. Alexander Leichtle, Oberarzt am Universitätsinstitut für Klinische Chemie UKC, teilzunehmen.

Weitere Informationen zur Veranstaltung finden Sie [hier](#).

New services on Inselspital campus: CTU Lectures & CTU Sprechstunde/Consulting



09.10.2015 - As of October 2015 CTU Bern offers new regular services for all clinical researchers and study personnel on the Inselspital campus: the CTU Sprechstunde and the CTU Lectures. To learn more about the new services, you are cordially invited to join the first CTU Lecture on Tuesday, 13th of October, 12:45 – 13:30 in the Kursraum D 517 (Polikliniktrakt 2).

CTU Lectures (held in German / in Deutsch)

Ab Oktober 2015 bietet die CTU Bern neu jeweils am zweiten Dienstag des Monats eine CTU Lecture an. Angesprochen werden alle Mitarbeitenden und Forschenden, die in der klinischen Studienarbeit tätig sind.

An den CTU Lectures bieten wir Ihnen:

Aktuelle, studienspezifische Themen aus der klinischen Forschung, vorgestellt von Fachpersonen

Ein neues Forum für den regelmässigen Austausch von Ideen, Erfahrungswerten, Vorgehensweisen etc. mit anwesenden Kolleginnen und Kollegen

Die Teilnahme ist kostenlos und ohne Anmeldung möglich.

Weitere Informationen finden Sie [hier](#).

CTU Sprechstunde/Consulting

Regular 'open door' consulting on the Inselspital campus for clinical researchers, who seek support in the planning phase of a clinical study project or have specific questions regarding statistical analyses.

The Sprechstunde/Consulting takes place every Tuesday and Friday, between 12 and 2 pm.

Experienced epidemiologists and statisticians will be present during the consulting hours, which take place at the Personalhaus 4, floor E, room 401.

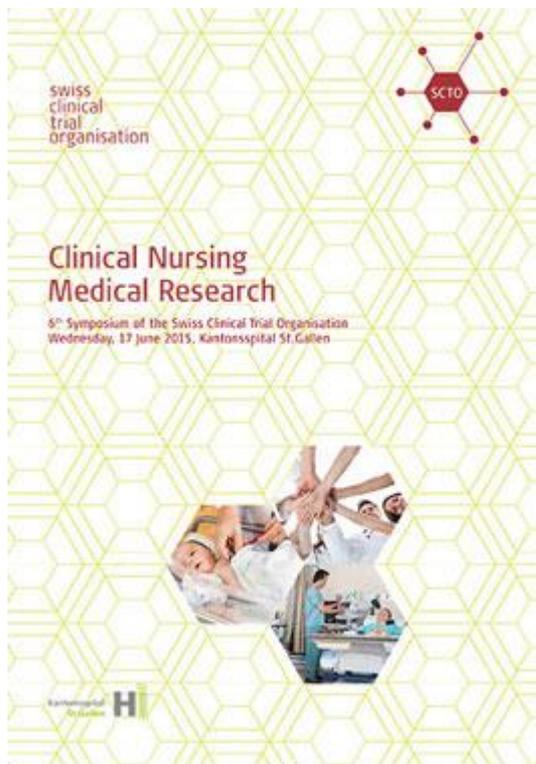
For registration and further information, please click [here](#).

CTU Newsletter September 2015

Die neuen Kodirektoren der CTU Bern - Kuratorium -
Aktuelles aus den Arbeitsbereichen - CTU Lectures -
Kursangebot - Die nächsten Kurstermine

[CTU Newsletter September 2015 \(PDF, 621KB\)](#)

6th Symposium of the Swiss Clinical Trial Organisation SCTO: Clinical Nursing – Medical Research



12.06.2015

The 6th Symposium of the Swiss Clinical Trial Organisation SCTO will take place at Kantonsspital St. Gallen on Wednesday, June 17 2015. This year's symposium will address the topic "Clinical Nursing – Medical Research: Interfaces in clinical research – a convergence of two disciplines".

In three sessions, leading experts and stakeholders of both fields will speak about the important role of clinical nursing research in advancing evidence-based practice. With this event, the SCTO aims to call attention to the hitherto mostly untapped interdisciplinary potential of clinical nursing and medical clinical research. So far, the interaction between the disciplines has been rather modest, although significant synergies are expected.

On June 17, SCTO brings together experts to provide an analysis of interfaces between the two disciplines. The programme further includes a presentation of ongoing interdisciplinary and multinational research projects, as well as a discussion of the current state of clinical nursing research in Switzerland.

For further event details, please consult the programme flyer and the links given below.

Fees & Registration: [Online registration](#)

For more information visit: <http://scto.ch/>

[Programme flyer \(PDF, 903KB\)](#)

GCP Refresher Course at the Inselspital on Tuesday, 9th of June

27.05.2015

CTU Bern offers a free half day course at the Inselspital for GCP certificate holders, who wish to refresh and update their good clinical practice knowledge ([read more](#))

On Tuesday, 9 June 2015, CTU Bern offers a GCP refresher course for study personnel who have already acquired a GCP certificate but want to refresh their knowledge in research ethics and GCP.

The following topics will be covered in the half day course:

- Human Research Act and related ordinances
- Good Clinical Practice
- Safety
- Monitoring
- Interpretation of study results

Please find all necessary course information below:

Date & time:

Tuesday, 9 June 2015, 9.00 – 12.00

Venue:

Inselspital - Kinderklinik, Kursraum 1

Registration & fees:

You do not need to register for the course. A certificate will be sent to all participants who provide their contact details at the course day. The course is free of charge.

If you have any questions please contact us by sending an email to training@ctu.unibe.ch

Ebola Vaccine Trials in Guinea



11.03.2015

The number of Ebola Virus Disease cases continues to fluctuate in Guinea. At the same time phase 1 studies of vaccine candidates have produced promising immunogenicity and safety results. These vaccines now need to be evaluated further for safety, efficacy and effectiveness.

Matthias Egger, Sven Trelle and Stefanie Hossmann from ISPM and CTU Bern have contributed to the design of two trials, a randomized ring vaccination trial and a single-arm trial, in Guinea, under the auspices of the World Health Organization. The ring vaccination trial will be performed as a randomized phase 3 trial to evaluate the efficacy, effectiveness and safety of one dose of VSV-EBOV vaccine in the prevention of EVD when implemented as ring vaccination.

CTU Bern and ISPM are responsible for the data management and statistical analysis, together with colleagues at WHO, the Norwegian Public Health Institute, the London School of Hygiene and Tropical Medicine and the University of Florida. The trial is implemented by Médecins Sans Frontières who have been supporting the Ebola response in Guinea since the start of the epidemic.

Ebola vaccine tested successfully for the first time



31.07.2015 - A vaccine against the Ebola virus, tested in West Africa for the first time in a field trial, has proved to be effective according to the first interim analysis published today in The Lancet. CTU Bern together with the ISPM was heavily involved in designing and conducting the World Health Organization (WHO) «Ebola ça Suffit» vaccine trial.

The Ebola virus disease epidemic in West Africa has not been defeated yet, although the number of cases has dropped substantially since the start of the year. Two vaccines that were recently developed have already undergone preliminary tests in humans. One of the vaccines, «rVSV-ZEBOV», has now been tested in the first large field trial of efficacy and effectiveness in Guinea, West Africa. CTU Bern was involved in the development of the study design of this «Ebola ça suffit» trial and responsible for the data management. The initial results of the study show that the vaccine can effectively contain the further spread of the Ebola virus. The results of the field study and the innovative study methods were just published in the «Lancet» and «BMJ».

Links:

- Efficacy and effectiveness of a rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomized trial. Lancet, 31.7.2015. Available at <http://www.thelancet.com/pb/assets/raw/Lancet/pdfs/S0140673615611175.pdf>
- Ebola ça Suffit Trial Consortium. BMJ, 27.7.2015. Available at <http://www.bmj.com/content/351/bmj.h3740>