



www.ctueoc.ch

Dr.
Capo
e ind
Presi
Steering
ormazione

Paol

act lavoro di

Area Clinica dell-

onio



Clinical Trial Unit EOC (CTU-EOC)

4. Clinical Trial Unit EOC (CTU-EOC)

The mission of CTU is to promote clinical research and education to provide services to implement and perform clinical and translational studies in compliance with the Good Clinical Practice (GCP) and national laws. Since it started in 2012, the CTU-EOC has increased its activity by building fruitful collaborations with new departments (Fig. 1), it has undertaken the full development and conduct of projects and has provided more complex services (Fig. 2).

Fig. 1

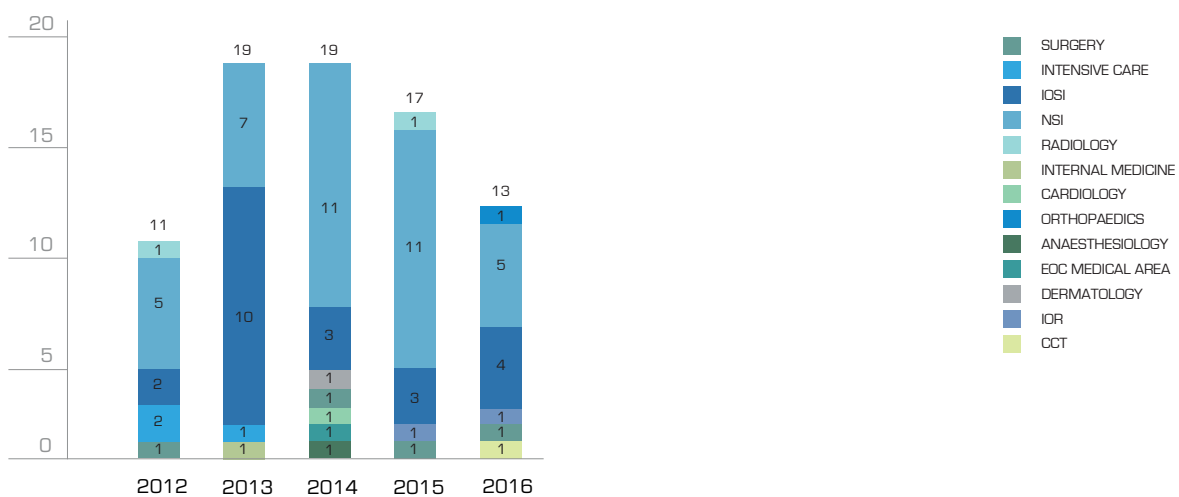
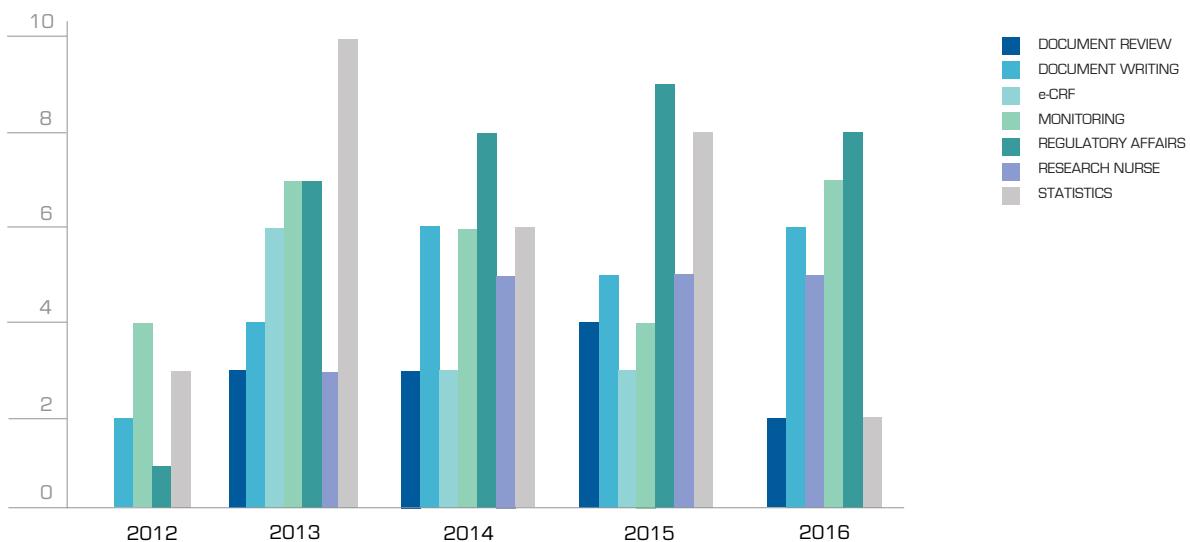


Fig. 2



Quality Assurance

In order to promote quality, in 2016 the EOC Directorate for Internal Audit audited some clinical studies completed or ongoing at the EOC. The Clinical Trials Center (CTC) of Zurich was in charge of the audit

with the logistical support of CTU-EOC. As a result of this first assessment, the development of a future plan of regular audits is under discussion.

Quality control will be also an essential component of the two projects developed by CTU in 2016, which will be carried out in 2017 with the coordination of CTU. These include: the establishment of the EOC Biobank, in collaboration with EOLAB, that will be part of the Swiss biobanking platform and the introduction of the national general consent in all the EOC facilities.

Education and training

In 2016, 4 courses on Good Clinical Practice and ethics in research were organised (3 for Investigators, 1 for Sponsor-Investigator) with a total of 42 participants.

The program and the structure of the courses were modified to comply with Swissethics requirements. In 2016, the online platform was implemented with the possibility of uploading the program, the course material, the evaluation form and the multiple choice exam (MCE).

The certificate of attendance, if the MCE is passed, can be downloaded as well.

Face to face activity and direct interaction between speakers and attendants are essential components of the learning process and are requested by Swissethics for the accreditation of the courses.

Events

CTU-EOC, together with Università della Svizzera Italiana (USI), organised the 6th Clinical Research Day of Southern Switzerland. The participation increased, compared to 2015, with 243 attendees, 123 abstracts and 90 posters exposed.

The 7th Clinical Research Day will be held on March 10th at the University of Lugano, again in collaboration with Università della Svizzera Italiana (USI).

Swiss Clinical Trial Organisation (SCTO)

Swiss Clinical Trial Organisation (SCTO) is a non-profit organisation acting as the central cooperation platform for patient-oriented clinical research in Switzerland. It contributes to creating a favourable environment for a high-quality clinical research in Switzerland by promoting:

- A nationally harmonised research culture, including continuing education needed for this purpose
- The establishment of national networks
- The integration of national clinical research in international networks
- The transfer of knowledge between basic research and therapeutic applications
- The dialogue between academia, industry and authorities, as well as trade organisations and professional associations
- Favourable conditions in the field of clinical research in general.

The SCTO founding members include the Swiss Academy of Medical Sciences (SAMS), the boards of directors of the University Hospitals of Basel, Bern, Geneva, Lausanne and Zurich, the board of directors of the Cantonal Hospital of St. Gallen, and the Collège des Doyens.

In 2016, the EOC was accepted as an associate member, and a representative of the EOC can participate in the SCTO Steering Board as an observer without voting rights.

Through the Clinical Trial Unit, the EOC participates in some of the SCTO projects and is a member of the EUPATI Advisory Board of Switzerland. EUPATI is the European Patients' Academy on Therapeutic Innovation, which provides education and training tools for representatives of patient organisations.

The national platform EUPATI Switzerland helps distribute these tools and serves as a point of contact for questions and information. SCTO and Swissmedic support the national platform.