



# Annual Report 2016

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## EDITORIAL

March 2017

Dear Reader

ETOP has entered already its seventh year of vivid life and is moving forward with energy and enthusiasm.

2016 was another successful year, with several ETOP contributions to international congresses, two new clinical trials activated, the first ETOP trial published, and five additional manuscripts in the pipeline, of which two have already been submitted.

We take this opportunity to thank you for your continued partnership and collaboration and for your valuable contribution to the success of ETOP.

On the following pages we would like to provide you with an update on the various ETOP projects, trials and activities. We hope you enjoy reading this report!

Kind regards



Prof. Rolf A. Stahel  
President, ETOP Foundation Council



Prof. Solange Peters  
Scientific Coordinator ETOP and  
Member of the Foundation Council

## KEY DATA

<b>Publications</b>	<b>2016</b>	<b>Overall</b>
Full publications	1	6
Published abstracts	4	23
<b>Meeting contributions</b>	<b>2016</b>	<b>Overall</b>
Oral presentations	--	11
Posters	5	16
<b>Clinical trials overall</b>		
Closed trials	<b>1</b>	
Open trials	<b>8</b>	
Trials that are closed to accrual	<b>2</b>	
Newly activated trials that are not yet recruiting	<b>2</b>	
Recruiting trials	<b>4</b>	
<b>Number of patients in ETOP studies</b>	<b>2016</b>	<b>Overall</b>
ETOP sponsored clinical trials	<b>219</b>	<b>701</b>
From ETOP sites in non-ETOP sponsored clinical trial	<b>63</b>	<b>63</b>
Observational studies	<b>254</b>	<b>2989</b>

## ETOP PROJECTS AND TRIALS

### TRANSLATIONAL RESEARCH PROJECTS

#### LUNGSCAPE

The **005 PD-L1 project** was the main focus for Lungscape in 2016. Starting in January with an extensive two-day training by DAKO hosted by VUMC Amsterdam, all Lungscape pathologists proved to be proficient in PD-L1 IHC scoring. In a close out conversation the DAKO pathologist highly praised the Lungscape biobanking project and the involved ETOP pathologists.

An External Quality Assessment (EQA) followed, revealing that assessing PD-L1 is far from trivial. After some extra efforts to calibrate PD-L1 scoring across laboratories, the full Lungscape cohort (2182 of the 2709 samples of the iBiobank) was scored and analysis is ongoing at the ETOP Statistical Centre in Athens.

The results for the **002 PTEN project** were analysed and presented by Alex Soltermann at two international congresses in 2016: a poster with the EQA results on PTEN at the 28th Congress of the European Society of Pathology (ESP) in Cologne and a poster with the results of the Lungscape PTEN cohort at the ESMO 2016 Congress in Copenhagen.

Stephen Finn presented the NGS results for the Lungscape **001 ALK RT-PCR NGS subproject** on a poster at the IASLC World Congress on Lung Cancer (WCLC) in Vienna, Austria.

#### Lungscape manuscripts in preparation

A manuscript reporting on c-MET overexpression and amplification has been submitted (Bubendorf L. *et al.*).

Two other manuscripts are almost ready to be submitted: an NGS and RT-PCR analysis of aberrant ALK (Finn S, Letonavec I. *et al.*) and a Multiplex Mutation analysis of the Lungscape cohort (Kerr K. *et al.*). An addition manuscript on loss of PTEN is in preparation (Soltermann A. *et al.*).

## **MESOSCAPE**

Mesoscape is a project to study the molecular epidemiology of malignant mesothelioma in Europe and has a similar set-up as Lungscape, but with a more centralised approach to process the samples. A number of major cancer centres will contribute up to 1100 cases diagnosed in the last years.

**Mesoscape 001 pS6** is the first module of the Mesoscape project and describes the prevalence of phosphorylated ribosomal protein S6 in patients with mesothelioma and the clinical outcomes according to pS6. PS6 is a marker of the PI3K pathway and its description within this module may guide the development and testing of targeted therapies. This module was activated along with the master Mesoscape protocol.

## **FIXATION EFFECT STUDY**

This pathology pre-analytical effects study was initiated by ETOP in 2015 and is led by Erik Thunnissen. The aim is to examine the effect of fixation delay and over-fixation on NSCLC and normal components on protein (IHC), DNA (mutation analysis) and RNA level in order to obtain a list of proteins which are associated with changes in fixation delay / over fixation. TMA's were centrally constructed at the VUMC, and sections distributed to the participating labs for analysis.

## **CLINICAL TRIALS**

### **ETOP 2-11 BELIEF**

BELIEF is an open-label, single-arm, phase II multicentre trial exploring whether first-line erlotinib plus bevacizumab improves progression-free survival in NSCLC patients with activating EGFR mutations (del19 or L858R). The outcomes are tested overall and separately in patients with and without the pre-treatment EGFR T790M gatekeeper mutation. The accrual goal of 102 patients was reached in October 2014. Treatment and follow-up is still ongoing. A manuscript with the results of the final analysis, submitted in December 2016, has been accepted for publication in Lancet Respiratory Medicine.

### **ETOP 3-12 EMPHASIS-lung**

EMPHASIS is a multi-centre, open-label randomised phase III trial. The trial aimed at exploring a predictive effect of Veristat, a serum proteomic test, regarding the efficacy of erlotinib versus docetaxel in patients with squamous NSCLC. The trial closed prematurely because of low accrual and results from other trials. The final analysis includes an exploratory combined analysis with results from the PROSE trial.

The manuscript has been accepted for publication by the Journal of Thoracic Oncology: Peters S. *et al.*, JTO 2016 Dec 23 DOI: <http://dx.doi.org/10.1016/j.jtho.2016.12.017> [Epub ahead of print].

### **ETOP / IFCT 4-12 STIMULI**

STIMULI is a randomised open-label phase II trial of consolidation checkpoint inhibitors ipilimumab and nivolumab in limited-stage SCLC after chemo-radiotherapy. Progression-free survival and overall survival are the combined primary endpoints. ETOP is the sponsor of the trial that is conducted in collaboration with the IFCT.

The trial is activated in Switzerland, Belgium, Germany, France, and Spain. Activation in the United Kingdom is ongoing. The accrual by the end of 2016 was 82 patients, of which 41 had been randomised (21 under amendment 1). A trial in progress poster has been presented by Dirk De Ruyscher at the ESMO Congress in Copenhagen.

### **ETOP 5-12 / EORTC 08111 SPLENDOUR**

SPLENDOUR is a randomised, open-label, phase III trial evaluating the addition of denosumab, a monoclonal antibody targeting and inhibiting RANKL, to standard first-line anticancer treatment in advanced NSCLC. The purpose of this study is to investigate the potential of the combination of standard treatment (chemotherapy) with denosumab as compared to the standard treatment alone to increase survival of patients with advanced NSCLC with or without bone metastasis in advanced unselected treatment-naïve patients. ETOP is the sponsor of this trial, which is conducted in collaboration with EORTC as coordinating group. The accrual by the end of 2016 was 398 randomised patients, with 279 being contributed by ETOP and 116 by EORTC sites.

### **ETOP 6-14 NICOLAS**

Over the past decade, sequential or concomitant chemo-radiotherapy have become the treatment of choice for stage III NSCLC. One attempt to improve the long-term survival is an immunotherapeutic strategy targeting PD-1, a cell surface molecule on activated T-cells that abrogates the anti-cancer immune response.

NICOLAS is an international, multi-centre phase II feasibility trial evaluating the addition of anti-PD-1 nivolumab concomitantly with standard first-line chemotherapy and radiotherapy in locally advanced stage IIIA/B NSCLC.

The trial is activated in Belgium, Germany, the Netherlands, Spain, and Switzerland. The accrual by the end of 2016 was 17 patients.

### **ETOP 7-14 NICHE**

NICHE is a phase II, international multi-centre clinical trial sponsored and conducted by ETOP. The primary objective is to evaluate the potential of afatinib to control disease in pre-treated patients with advanced NSCLC harbouring HER2 exon 20 mutations.

The trial was activated at the beginning of 2015. In total, 13 patients from Spain, Germany and the Netherlands have been enrolled. The accrual into the trial has been closed in November 2016.

### **ETOP 8-15 / EORTC 1416 PEARLS / KEYNOTE-091**

PEARLS is an international, triple-blinded, placebo-controlled randomized phase III trial. It will prospectively investigate the benefit of adjuvant treatment with pembrolizumab for one year versus placebo for early stage NSCLC patients, after completion of radical surgery (lobectomy/pneumonectomy) with or without standard adjuvant chemotherapy. The target sample size is 1380 randomised patients, 690 in each arm. Merck Sharp & Dohme is the sponsor of this trial in all participating countries. The accrual by the end of 2016 was 117 randomised patients, 63 patients from ETOP sites.

### **ETOP 9-15 PROMISE-meso**

PROMISE-meso is a randomised, open-label, phase III trial comparing pembrolizumab versus standard chemotherapy for advanced pre-treated malignant pleural mesothelioma. The trial protocol was released on 15 November 2016 and activation of the total 12 sites (five in the United Kingdom and seven in Switzerland) is ongoing.

### **ETOP 10-16 BOOSTER**

BOOSTER is a randomised, open-label, phase II trial comparing the third generation EGFR TKI osimertinib in combination with the angiogenesis inhibitor bevacizumab versus osimertinib alone as second-line treatment in stage IIIb-IVb NSCLC with activating EGFR and T790M resistance mutation. Switzerland, Ireland, the Netherlands, Spain, South Korea, and Singapore will participate in this trial with a total of 27 sites.

The trial protocol was released on 13 December 2016 and site activation is ongoing.

### **TRIALS UNDER DEVELOPMENT**

**ETOP ALERT** is a single arm phase II trial, evaluating the activity of alectinib in pre-treated patients with RET-rearranged advanced NSCLC. ETOP will be the sponsor of this trial that will be run in collaboration with the Lung Cancer Group Cologne and the EORTC.

**Phase II trial on large cell neuro-endocrine lung tumours** assessing the efficacy of two different chemotherapy regimen (cisplatin-etoposide versus cisplatin-gemcitabine) followed by an immune-checkpoint inhibitor. ETOP will be the sponsor of this trial.

## SCIENTIFIC CONTRIBUTIONS IN 2016

### FULL PUBLICATIONS

Peters S, Stahel RA, Dafni U, Ponce Aix S, Massutí B, Gautschi O, Coate L, López Martín A, van Heemst R, Berghmans T, Meldgaard P, Cobo Dols M, Garde Noguera J, Curioni-Fontecedro A, Rauch D, Mark MT, Cuffe S, Biesma B, van Henten AMJ, Juan Vidal O, Palmero Sanchez R, Villa Guzmán JC, Collado Martin R, Peralta S, Insa A, Summers Y, Láng I, Horgan A, Ciardiello F, de Hosson S, Pieterman R, Groen HJM, van den Berg PM, Zielinski CC, Chittazhathu Kurian Kuruvilla Y, Gasca-Ruchti A, Kasapian M, Novello S, Torri V, Tsourti Z, Gregorc V, Smit EF, for the EMPHASIS-lung collaborative group. Randomized phase III trial of erlotinib versus docetaxel in patients with advanced squamous cell non-small cell lung cancer failing first line platinum-based doublet chemotherapy stratified by Veristat good versus Veristat poor. The European Thoracic Oncology Platform (ETOP) EMPHASIS-lung trial. *Journal of Thoracic Oncology* 2017; 12 (4): 752–762.

### PUBLISHED ABSTRACTS

Finn S, Letovanec I, Zygoura P, Smyth P, Soltermann A, Bubendorf L, Speel EJ, Marchetti A, Nonaka D, Monkhorst K, Hager H, Martorell M, Sejda A, Cheney R, Hernandez-Losa J, Verbeken E, Weder W, Savic S, Di Lorito A, Navarro A, Felip E, Warth A, Baas P, Meldgaard P, Blackhall F, Dingemans AM, Dienemann H, Dziadziuszko R, Vansteenkiste J, Geiger T, Sherlock J, Schageman J, Dafni U, Kammler R, Kerr K, Thunnissen E, Peters S, Stahel R, On Behalf Of The ETOP Lungscape Consortium. P1.02-025 Evaluation of NGS and rt-PCR methods for ALK assessment in European NSCLC patients: Results from the ETOP Lungscape project. *Journal of Thoracic Oncology*. 2017; 12 (Suppl 1): S501–S502.

De Ruyscher D, Pujol JL, Popat S, Reck M, Le Pechoux C, Liston A, Speiser Dd, Coukos G, Kammler R, Dafni U, Tsourti Z, Roschitzki H, Finlayson M, Piguet AC, Ruepp B, Maibach R, Stahel RA, Peters S. STIMULI: A randomised open-label phase II trial of consolidation with nivolumab and ipilimumab in limited-stage SCLC after standard of

care chemo-radiotherapy conducted by ETOP and IFCT *Annals of Oncology*. 2016; 27 (Suppl 6): vi493–vi496.

Soltermann A, Rulle U, Dafni U, Verbeken E, Thunnissen E, Warth A, Cheney R, Sejda A, Speel EJ, Bille Madsen L, Nonaka D, Navarro A, Sansano I, Marchetti A, Finn S, Kammler R, Schulze K, Bubendorf L, Stahel RA, on behalf of Lungscope. Prevalence and clinical associations of PTEN loss in non-small cell lung carcinoma (NSCLC) patients (pts) of the European Thoracic Oncology Platform (ETOP) Lungscope cohort. *Annals of Oncology*. 2016; 27 (Suppl 6): vi526–vi544.

Rosell R, Karachaliou N, Giménez-Capitán A, Codony-Servat C, Gautschi O, Felip E, Curioni-Fontecedro A, Peters S, Ponce-Aix S, Früh M, Pless M, Popat S, Cuffe S, Bidoli P, Favaretto A, Kammler R, Dafni U, Tsourti Z, Molina-Vila MA, Stahel RA. The role of BRCA1 and AEG1 mRNA expression in advanced non-small-cell lung cancer (NSCLC) patients (p) with EGFR activating and pretreatment T790M mutations receiving the combination of erlotinib plus bevacizumab (E+B) in the BELIEF trial. *Proceedings of the AACR*. 2016; 57 (A), #270.

## POSTER PRESENTATIONS

Rosell R. *et al.* The role of BRCA1 and AEG1 mRNA expression in advanced non-small-cell lung cancer (NSCLC) patients (p) with EGFR activating and pre-treatment T790M mutations receiving the combination of erlotinib plus bevacizumab (E+B) in the BELIEF trial. Presented at the AACR Annual Meeting 2016 in New Orleans, LA, USA. Poster #270

Soltermann A. *et al.* Prevalence and clinical associations of PTEN loss in non-small cell lung carcinoma (NSCLC) patients (pts) of the European Thoracic Oncology Platform (ETOP) Lungscope cohort. Presented at the ESMO Congress 2016 in Copenhagen, Denmark. Poster #1525P.

De Ruyscher D. *et al.* STIMULI: A randomised open-label phase II trial of consolidation with nivolumab and ipilimumab in limited-stage SCLC after standard of care chemo-

radiotherapy conducted by ETOP and IFCT. Presented at the ESMO Congress 2016 in Copenhagen, Denmark. Poster #1430TiP.

Finn S. *et al.* Evaluation of NGS and rt-PCR methods for ALK assessment in European NSCLC patients: Results from the ETOP Lungscope project. Presented at the WCLC 2016 in Vienna, Austria. Poster #P1.02-025.

## ETOP ACTIVITIES IN 2016

### ETOP PARTICIPATION AT THE RACE FOR LIFE 2016

The “Race for Life” is a fund raising event to support cancer research in Switzerland. This charity bicycle marathon has been held in Switzerland since 2010 and stopped over in Bern on Sunday 11 September 2016. For the first time ETOP was a partner of “Race for Life”. The donated or rather “cycled” money was funneled directly into the various



cancer research projects of the involved partner organisations. Besides the sportive aspect, “Race for Life” was also a social event with an attractive entertainment and educational program in front of the parliament building in Bern, where also ETOP was present with a booth.

### **MOVING OF THE ETOP COORDINATING OFFICE**

In June 2016, the ETOP Coordinating Office moved into new facilities at Effingerstrasse 33 in Berne. From an ETOP Coordinating Office perspective this was definitively one of the highlights of the past year. We are all very happy with the new work environment and are looking forward to welcoming you in our new offices. Come and visit us!



Helpers at the clean-up campaign before the moving (left) and our new offices at Effingerstrasse 33 (right).  
Pictures: M. Wenger

### **ETOP PRESENCE ON THE WORLD WIDE WEB**

Since 2015, ETOP has an own company page on LinkedIn ([www.linkedin.com/company/european-thoracic-oncology-platform-etop](http://www.linkedin.com/company/european-thoracic-oncology-platform-etop)) and since the end of 2016 we are also present on Twitter (@ETOP\_eu). We use these channels to keep our followers updated about our activities and to inform about the latest news in the field of thoracic oncology.

## MEETINGS IN 2016

Several meetings with a high-level scientific exchange took place in 2016. Furthermore, various ETOP representatives participated in a number of meetings with the pharmaceutical industry regarding further ETOP research avenues.

### FOUNDATION COUNCIL MEETINGS

- 15 April 2016, during the ELCC in Geneva
- 12 November 2016, during the ETOP Annual Meeting in Amsterdam, Netherlands

### INDEPENDENT DATA MONITORING COMMITTEE MEETINGS

- 13 January 2016 by telephone conference
- 7 April 2016 by telephone conference
- 05 July 2016 by telephone conference
- 05 October 2016 by telephone conference
- 29 November 2016 by telephone conference

### MEETINGS UNDER AUSPICES/IN COLLABORATION WITH ETOP

- European Lung Cancer Congress (ELCC), 13 - 17 April 2016, Geneva, Switzerland

### LUNGSCAPE PATHOLOGIST MEETINGS

- The 4th Lungscape Pathologist Meeting took place on 21 January in Amsterdam, the Netherlands, alongside the two-day PD-L1 DAKO training, hosted by the VUMC.
- A condensed 5<sup>th</sup> Lungscape Pathologist Meeting took place at the NKI in Amsterdam, as part of the ETOP Annual Meeting.

### ETOP ANNUAL MEETING

The ETOP Annual Meeting was held 11 – 12 November, 2016 in Amsterdam, organised by Paul Baas and Suresh Senan. Ongoing projects and trials as well as new ideas and concepts were presented and discussed either during the plenary meeting or in the break-out sessions. Ninety participants from over 18 countries attended the meeting and used the occasion as an opportunity to engage in stimulating high-level scientific exchange with other ETOP participants. The ETOP Annual Meeting was financed through the kind support of BMS, Lilly, and Pfizer.

## ETOP RESIDENTIAL WORKSHOP

The ETOP Residential Workshops have become a successful tradition. The format of bringing young investigators and experienced faculty together offers a unique opportunity to young researchers to exchange research ideas and learn from the experts in the field of thoracic oncology. The Workshop 2016 was held 1–3 September in Amsterdam, the Netherlands. Twenty-seven young investigators from 13 countries attended the workshop that was led by 18 faculty members, all leading experts in the field of thoracic oncology.

The program focused on current trends in research and cancer care with a special emphasis on targeting molecular cell pathways, immunotherapy, surgery, radiotherapy and molecular testing. One of the key elements of the ETOP Residential Workshops are the participants' presentation of their own research projects. These excellent presentations were followed by lively discussions chaired by the senior scientists from the faculty.

This 5th edition of the ETOP Residential Workshop was another great success and we certainly look forward to continuing this tradition and welcoming you at the next edition. The workshop was financed by ESMO through an educational grant and the generous support from Amgen, Boehringer Ingelheim, BMS and Lilly.



*Beautiful Amsterdam. Picture: K. Beese.*

## EDUCATIONAL AND COLLABORATION ACTIVITIES

One of ETOP's missions is to serve as a meeting platform for European study groups and institutions engaged in research on lung cancer. ETOP promotes the exchange of ideas and research in the field and sponsors and manages an increasing number of translational research projects and clinical trials with an emphasis on advancing the knowledge in thoracic malignancies. Our website ([www.etop-eu.org](http://www.etop-eu.org)) hosts a series of scientific resources for scientists in the field of lung cancer, such as conferences slide decks, video news, as well as access to the journal "Lung Cancer".

### ETOP CONFERENCES SLIDE DECKS

The ETOP conferences slide decks are designed to highlight and summarise key findings in thoracic oncology from the major congresses like the ASCO annual meeting, the ESMO congress and the World Conference on Lung Cancer (WCLC). These slide sets are realized with the kind support of Eli Lilly and are available on the ETOP website. The slide decks find widespread recognition as indicated by the number of downloads (see table below).

	ASCO 2016	ESMO 2016	WCLC 2016
English	269	1058	1019
Any language	387	--	--
French	38	177	118
Japanese	747	481	479
Chinese	79	220	127
<b>Total downloads</b>	<b>1520</b>	<b>1936</b>	<b>1743</b>

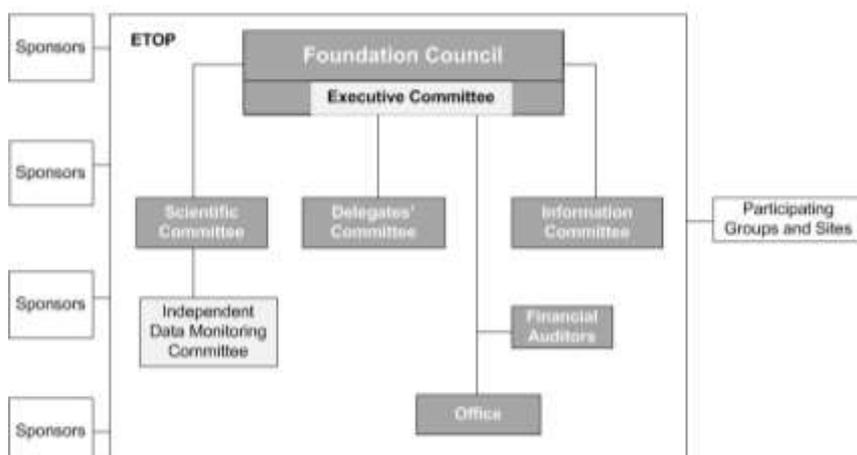
## ETOP COLLABORATION WITH IBCSG

In order to complete the various tasks entailed by the many projects, ETOP has undergone a strategic collaboration with the International Breast Cancer Study Group IBCSG and its Coordinating Centre in Bern. The ETOP Coordinating Office is hosted by IBCSG and supports all activities in the above projects. In addition, Frontier Science Hellas, a not-for-profit organisation based in Athens, Greece, provides statistical expertise for all ETOP projects.

## GROUP STRUCTURE

The European Thoracic Oncology Platform (ETOP) is a not-for-profit foundation under Swiss law with the purpose to promote the exchange of ideas and research in the field of thoracic malignancies.

## ETOP ORGANIGRAM



## ETOP MEMBERS

ETOP includes 55 leading European groups and institutions, as well as an institution each in the USA and in China with a focus on clinical and translational research in thoracic oncology.



## ETOP ORGANIZATION

### ETOP FOUNDATION COUNCIL

**President:** Rolf. A. Stahel, Switzerland

Paul Baas, Netherlands; Keith Kerr, United Kingdom; Solange Peters, Switzerland; Sanjay Popat, United Kingdom; Rafael Rosell, Spain; Suresh Senan, Netherlands; Walter Weder, Switzerland; Christoph Zielinski, Austria.

### ETOP SCIENTIFIC COMMITTEE

**Chair:** Rolf A. Stahel, Switzerland

**Scientific Coordinator:** Solange Peters, Switzerland

Dirk de Ruyscher, Netherlands; Rafal Dziadziusko, Poland; Martin Edelman, USA; Corinne Faivre-Finn, United Kingdom; Enriqueta Felip, Spain; Tetsuya Mitsudomi, Japan; Maurice Perol, France; Martin Reck, Germany; Egbert Smit, Netherlands.

### ETOP INDEPENDENT DATA MONITORING COMMITTEE

Jean-Pierre Armand, France

Suzanne E. Dahlberg, USA

Nick Thatcher, United Kingdom

Renato Galeazzi, Switzerland

Paul Van Houtte, Belgium

Oncologist, **IDMC chairman**

Biostatistician

Oncologist

Bioethics

Radiation Oncologist

## FUNDING OF RESEARCH

The various clinical research projects of ETOP are partially or fully funded by the pharmaceutical industry. This collaboration, which is based on full academic independency, gives ETOP the opportunity to offer our patients access to new drugs.

## FINANCIAL STATEMENT 2016 (IN THOUSAND CHF)

The financial statements have been audited and approved by KPMG on March 24th, 2017.

<b>Income</b>	<b>2016</b>	<b>2015</b>
Income from collaboration with industry	4'493	4'304.8
Further research grants	215	76.8
<b>Total</b>	<b>4'708.0</b>	<b>4'381.6</b>
<b>Expenses</b>	<b>2016</b>	<b>2015</b>
Contributions to members, participating centres	1'761	1'326.2
Pathology, translational research	187.8	213.7
Production slide decks, training	10.9	10.8
Website, internet	1.9	0.5
Scientific exchange and coordination, travel expenses	157.7	161.2
Personnel costs and external services (database, statistics, etc.)	2'009.2	1'961.6
Insurance, consulting, financial audit	128.4	68.2
Administrative costs	39.3	55.9
Currency exchange	116.8	492.9
<b>Total</b>	<b>4'413.0</b>	<b>4'291.0</b>