



# Annual Report 2013



**etop**

European Thoracic Oncology Platform  
c/o IBCSG  
Effingerstrasse 40  
3008 Bern

Phone +41 31 389 93 91

Fax +41 31 389 92 35

[www.etop-eu.org](http://www.etop-eu.org)

UBS AG

Postfach

CH-8098 Zürich

Switzerland

Account no: 230-282934.01Q

IBAN: CH54 0023 0230 2829 3401 Q

SWIFT: UBSWCHZH80A

## Index

Editorial	4
Key data	5
Ongoing projects and trials	5 - 7
Planned projects and trials	7
Publications / Abstracts	7 - 8
Meetings / Activities	8 - 9
ETOP collaboration with IBCSG	9
Group structure	9 – 10
Organigram	
Members	
ETOP organization	10 - 11
Foundation Council	
Scientific Committee	
Scientific Coordinator	
Independent Data Monitoring Committee	
Financial statement	11

## Editorial

January 2014

Dear Reader

2013 was another successful year for ETOP. Interesting new projects were launched, and important decisions were taken to ensure a strong fundament for the long-term growth of the group.

Over fifty individual research groups and trial institutions are working together to

- establish research priorities
- combine resources and expertise in a modular system
- accelerate accrual
- foster translational research
- integrate younger investigators
- help to preserve academic independence.

We take this opportunity to thank you for your continued partnership and collaboration.

With this annual report we would like to provide you with an update on ETOP projects, trials and activities. Enjoy reading!

Kind regards



Prof. Rolf A. Stahel  
President, ETOP Foundation Council



Dr. Solange Peters  
Scientific Coordinator

## Key Data

Abstracts/presentations	2
Number of newly activated clinical trials	1
Number of participating patients	
• In clinical trials	133
• In observational studies	>2600

## Ongoing projects and trials

### Lungscope

Lungscope is a project to study the molecular epidemiology of lung cancer in Europe. Fifteen major cancer centers have created a decentralized biobank of tumor samples from over 2600 patients who are fully documented with comprehensive demographic and clinical data. Several evaluations of specific biomolecular markers are in various stages of implementation.

#### Lungscope 001 – ALK

This is a retrospective cohort study of ALK gene rearrangement: prevalence and clinical outcomes in patients with non-small cell lung cancer in Europe. The goals are to describe the expression of ALK and its clinical significance for the patients, their long-term outcome, the correlation of ALK with other biomolecular markers, and to determine the optimal method of ALK evaluation in clinical practice. The results have been presented at ESMO 2012 in Vienna and will be published soon.

#### Lungscope 002 – MET/PI3K/PTEN

This is a retrospective cohort study of MET/PI3K/PTEN protein expression and MET/PI3K gene amplification for patients in the Lungscope study. The goals are to describe the expression and amplification of these three markers and their clinical significance. The tumor material secured from patients during the conduct of the ALK module is being used for this study. The project will help in the identification of patient groups likely to benefit from inhibitors of the PI3K and the c-MET pathways. PI3K amplification and PTEN loss may constitute predictive biomarkers for selective inhibitors. This study will be conducted on biomaterial and clinical information previously collected for over 2000 patients. It is currently in activation in Lungscope sites across Europe.

### **Lungscope 003 – Multiplex Mutation Testing**

This is a retrospective cohort study of multiple biomarkers by multiplex mutation testing: prevalence and clinical outcomes in patients with non-small cell lung cancer. The prevalence and clinical significance of 120 selected somatic mutations, considered to harbour a potential pro-oncogenic or driver characteristic, from 11 cancer related genes will be established on tumor material from about 2400 patients which form the current Lungscope cohort. The study is in the activation process.

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

This is the first therapeutic trial sponsored by ETOP. BELIEF aims at determining the long-term outcome of patients with advanced non-small cell lung cancer and activating EGFR mutations treated with erlotinib and bevacizumab. The trial is being conducted in collaboration with the Spanish Lung Cancer Group, and about 50 hospitals in Europe are participating. The trial will reach the accrual goal in 2014.

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

The predictive value of a blood based proteomic test is being assessed in this trial for patients with advanced squamous cell lung cancer. The recruitment to the trial was unfortunately too low to reach the goal in reasonable time, which led to the decision to stop the recruitment prematurely. Follow up continues, and the trial results will be analyzed.

### **ETOP 4-12 / EORTC 08111 SPLENDOUR**

This will be a large trial for 1000 patients with advanced NSCLC and will evaluate the addition of an agent called denosumab to standard anticancer treatment. The drug is used to treat osteoporosis. Interesting results from lung cancer patients have shown that the drug may prolong the survival. This hypothesis will be tested in the SPLENDOUR trial in a systematic fashion. The trial will be conducted as a collaboration between ETOP (Sponsor), the European Organization for the Research and Treatment of Cancer EORTC (Coordinating Group) and the Central European Cooperative Oncology Group CECOG. Activation of the trial is planned for Q2 2014.

### **ETOP 5-12 STIMULI**

The primary objective of the STIMULI trial is to evaluate if the survival of patients with limited-disease small cell lung cancer treated with standard chemo-radiotherapy and prophylactic cranial irradiation can be improved by subsequent consolidation treatment with ipilimumab.

This is an immune therapeutic which has shown activity in other types of cancer. The trial has been activated in December 2013.

## Planned projects and trials

### Mesoscape

Mesoscape is a project to study the molecular epidemiology of malignant mesothelioma in Europe and has a similar set-up as Lungscope. A number of major cancers will contribute at least 1100 cases diagnosed in the last years. The master protocol is under development.

#### Mesoscape 001 pS6

The first module of the Mesoscape project will describe 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 will be activated along with the master Mesoscape protocol in 2014.

### Radioscape

The Radioscape program aims to address challenges of studying the molecular characteristics of lung cancer in relation to radiation therapy by coordinating and harmonizing the procedures of a group of lung cancer specialists working in translational research across Europe, and facilitating analysis of larger series of cases. This will expedite knowledge of the influence of current and emerging molecular biomarkers on the outcome of radiotherapy, delivered with or without systemic therapies, thus facilitating more rapid translation of biomarker knowledge to the clinic, and provide a platform for future molecular correlative studies conducted in prospective trials of novel therapeutics.

## Publications / Abstracts

### Publications 2013

Blackhall FH, Peters S, Bubendorf L, Dafni U, Hager H, Soltermann A, O'Byrne KJ, Dooms C, Sejda A, Hernández-Losa J, Marchetti A, Savic S, Kerr KM, Tan Q, Thunnissen E, Cheney R, Nonaka D, de Jong J, Martorell M, Rosell R, Stahel RA on behalf of the ETOP. Prevalence and clinical outcomes for patients with ALK-positive resected stage I-III adenocarcinoma: Results from the European Thoracic Oncology Platform Lungscope Project. (submitted)

Peters S, Weder W, Dafni U, Kerr KM, Bubendorf L, Meldgaard P, O'Byrne KJ, Wrona A, Vansteenkiste J, Felip E, Marchetti A, Savic S, Lu S, Smit EF, Dingemans AM, Blackhall FH, Baas P, Camps C, Rosell R, Stahel RA on behalf of the ETOP. Lungscape: resected non-small cell lung cancer outcome by clinical and pathological parameters. (submitted)

## Meetings / Activities

Several meetings with a high-level scientific exchange took place in 2013.

Furthermore, various ETOP representatives participated to a number of meetings with pharmaceutical industry regarding further ETOP study options, website updates and general improvements.

### 6<sup>th</sup> ETOP Annual Meeting in Barcelona, Spain

On November 22<sup>nd</sup> and 23<sup>rd</sup> 2013, 111 Participants attended the 6<sup>th</sup> ETOP Annual Meeting in Barcelona, hosted by the Spanish Lung Cancer Group. Ongoing projects and trials, new ideas and concepts were presented and discussed either at the plenary meeting, in break-out sessions or working groups. On Friday evening, everyone enjoyed a wonderful dinner together.

### Foundation Council Meetings

- 08.05.2013 EMCTO, Lugano
- 23.11.2013 ETOP Annual Meeting, Barcelona

### Independent Data Monitoring Committee Meeting

- 30.09.2013 ESMO, Amsterdam

### Workshops

- 29.-31.08.2013 2nd ETOP Residential Workshop, Lugano

### Meetings under auspices/in collaboration with ETOP

- 23.-25.01.2013 BTOG Meeting 2013, Dublin
- 04.-06.04.2013 2nd Symposium on Thoracic and Upper Aerodigestive Malignancies, Athens
- 09.-11.05.2013 European Multidisciplinary Conference in Thoracic Oncology (EMCTO) 2013 with ETOP as an official partner, Lugano.

### Educational and collaboration activities

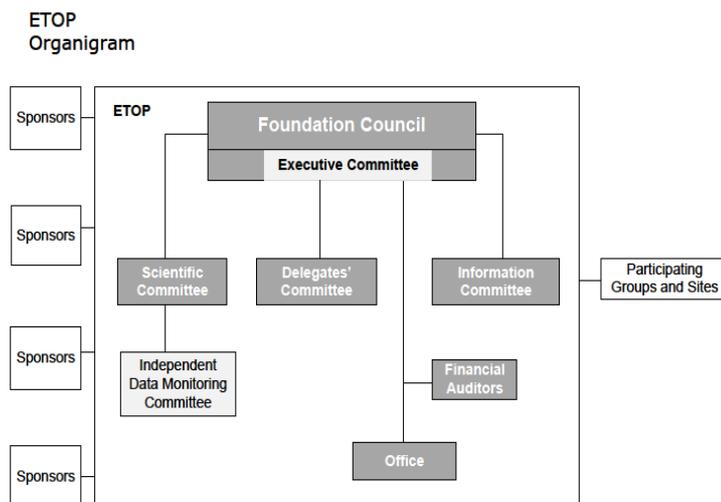
- 12.09.2013 BIG/ETOP Meeting, Zurich – discussing study opportunities with pharmaceutical industry
- Slide decks from ASCO 2013, ESMO 2013 and WCLC 2013
- Video Highlights from WCLC 2013
- Support in the foundation of a patient advocacy group in the field of lung cancer together with ESO (European School of Oncology)
- Founding Assembly of Lung Cancer Europe LuCE on September 27, 2013

### ETOP collaboration with IBCSG

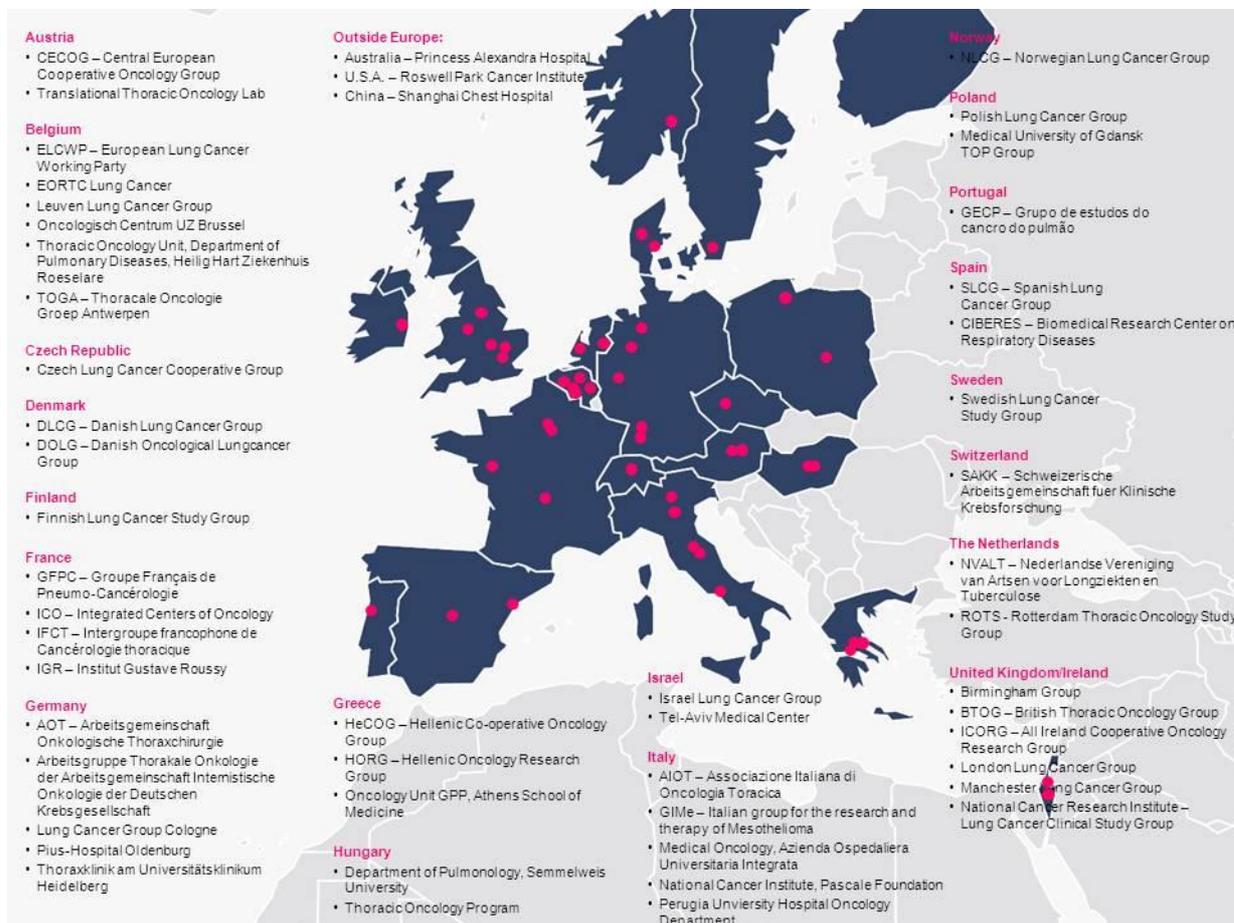
ETOP works in close collaboration with IBCSG and has appointed the IBCSG Coordinating Center with its long standing experience in clinical trials to take care of the organizational and logistical aspects of the ETOP trials.

### Group structure

The European Thoracic Oncology Platform (ETOP) is a foundation with the purpose to promote exchange and research in the field of thoracic malignancies in Europe. It is a non-profit organisation with its legal seat in Bern, Switzerland



## ETOP Members



## ETOP organization

### Foundation Council

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

Paul Baas, Netherlands, Keith Kerr, U.K., Kenneth O’Byrne, Australia, Rafael Rosell, Spain, Suresh Senan, Netherlands, Walter Weder, Switzerland, Christoph Zielinski, Austria

### Scientific Committee

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

Tetsuya Mitsudomi, Japan, Paris Kosmidis, Greece, Fortunato Ciardiello, Italy

### Scientific Coordinator

Solange Peters, Switzerland

### Independent Data Monitoring Committee

**Chair:** Jean-Pierre Armand, France

Nick Thatcher, U.K., Renato Galeazzi, Switzerland, Rich Gelber, USA, Paul Van Houtte, Belgium

### Financial statement 2013 (in thousand CHF)

All ETOP trials with full academic independence from the pharmaceutical industry, even if sponsored wholly or in part by industry. The financial statements have been audited and approved by KPMG on March 14, 2014.

<b>Income</b>	<b>2013</b>	<b>2012</b>
Income from collaboration with industry	2'253.2	2'046.5
Further research grants	32.4	13.0
<b>Total</b>	<b>2'285.6</b>	<b>2'059.5</b>
<b>Expenses</b>	<b>2013</b>	<b>2012</b>
Contributions to members, participating centers	531.9	470.9
Pathology, translational research	201.7	315.1
Production slide decks, training	20.9	20.9
Website, internet	39.5	30.6
Scientific exchange and coordination, travel expenses	221.2	141.5
Personnel costs and external services (database, statistics, etc.)	1'157.4	884.7
Insurance, consulting, financial audit	105.0	100.1
Administrative costs	52.9	82.7
Currency exchange	17.6	6.8
<b>Total</b>	<b>2'348.1</b>	<b>2'053.3</b>