

Croatian Society for Clinical Pharmacology
and Therapeutics bids for the organization of:

EACPT Focus Meeting 2016



Title

How to Assess Medicines from Research to Clinical Practice?

Efficacy, Effectiveness, and Economic - 3E Assessment

Objective

To increase awareness, knowledge and use of critical assessment pillars for medicinal products in everyday clinical practice in order to improve healthcare outcomes in affordable manner.

Background

For the Focus Meeting 2016, we would like to propose a combination of scientific podium lectures, interactive workshops and guided poster sessions covering three main pillars important for the critical assessment of medicinal products - efficacy, effectiveness, and economics (3E assessment). There are several hurdles on the path from an identified molecule, a candidate for drug development, to a registered medicine used to treat patients in everyday clinical practice and the three pillars, in addition to safety which is embedded in these pillars, are recognized to be the most relevant for modern clinical practitioners.

Efficacy is the capacity for a therapeutic effect of a medicine (or intervention which could also include, medical device, surgical procedure, or a public health intervention) tested in a defined clinical condition i.e. controlled clinical trial. In randomized controlled trials (RCTs) new therapy is compared to placebo or standard therapy. RCTs are the gold standard in evaluating the effects of treatments and therefore, the efficacy could be defined as the extent to which a medicine has the ability to accomplish the specific effect under ideal circumstances. It should be emphasized that many patients or subjects are screened before only a few of them are chosen according to inclusion criteria in a study, and the results of the study will be later applied to all the population of patients, and the patients who were excluded as well. The medicines are licensed for use almost exclusively on the results of RCT and therapeutics guidelines are mostly based on evidence gathered from them as well.

Effectiveness can be defined as the extent to which a medicine achieves its effect in the usual clinical setting i.e. if it works in real life in non-ideal circumstances. This can be evaluated through observational or non-interventional studies of real practice, because

medicines in such a conditions are used in different doses, dosage intervals, in combinations with other drugs, in patients with comorbidities, dependent on adherence to therapy, etc., which was not assessed in RCTs. Progression from efficacy trials to effectiveness studies could be defined as a part of a continuum which will end with efficiency and economic assessment of medicines as a part of the health technology assessment (HTA) procedure.

Economic evaluation serves as a tool to assess the value of a medicine by comparing the costs and outcomes of a medicine with those of an accepted therapy (comparator). The most frequently used technic for economic or pharmacoeconomic evaluation is a cost-effectiveness analysis. The results of this evaluation are presented as incremental cost-effectiveness ratio (ICER), which is the difference in costs between a medicine and the comparator and the difference in outcomes. This economic assessment is used to inform pharmaceutical pricing and reimbursement decisions worldwide, which will certainly have direct impact on the availability of the specific medicine to the individual patient.

Outline (draft agenda)

Day 1:

Welcome and introduction

Part I: Efficacy assessment

Interactive Workshop I: Efficacy assessment

Guided poster session

Day 2:

Part II: Effectiveness assessment

Interactive Workshop II: Effectiveness assessment

Guided poster session

Day 3:

Part III: Economic assessment

Interactive Workshop III: Economic assessment

Guided poster session

Closing remarks

In addition to the main meeting, we can offer two pre or post meeting workshops:

- How to develop and conduct clinical trial - introduction to GCP
- How to conduct pharmacoeconomic research



Scientific Organizer

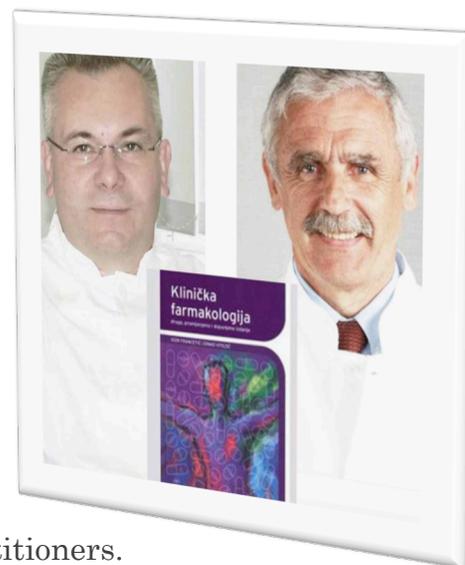
Croatian Society for Clinical Pharmacology and Therapeutics, Croatian Medical Association in collaboration with European Association of Clinical Pharmacology and Therapeutics.

Croatian Society for Clinical Pharmacology and Therapeutics (CSCPT) is a professional society operating under the umbrella organization of Croatian Medical Association (CMA), which comprises more than 130 societies in different fields of medicine. CMA has been established more than 140 years ago and today has more than 10.000 members. Main activities of CMA are: education, organization of conferences, symposia and congresses, development of national treatment guidelines etc.

Since 2010, the CSCPT has organized 6 Adriatic and Croatian Congresses of Pharmacoeconomics and Outcomes Research, (<http://www.pharmacoeconomics.com.hr>) which were well attended, with increasing number of participants, reaching more than 220 participants in 2015. These congresses have been recognized by the scientific community in the region, but also by the pharmaceutical and associated industry which were supporting these congresses through unrestricted educational grants which ensured that topics for discussion were included based on professional interest without any commercially sponsored satellite symposia.

Furthermore, the CSCPT holds regular monthly meetings, ten times per year, covering different topics related to clinical pharmacology. These meetings serve as an excellent platform for multi-disciplinary scientific debate for the members, but they often attract participation from non-members too.

The CSCPT members are also reputable authors of the third edition of the book 'Clinical Pharmacology' which serves many undergraduate and postgraduate students and healthcare practitioners.



In September 2014, the CSCPT had elections and prof. Dinko Vitezić, MD, PhD had been elected as the President of the Society, while prof. Igor Francetić, had been elected as the Honorary President. The Secretary General of the Society is Viktorija Erdeljić, MD, PhD. In addition to the core interests in clinical pharmacology, the CSCPT is, through its formally established Sections, actively involved in the fields of pharmacoeconomics and outcomes research as well as drug utilization research.

Technical Organizer (PCO)

O-Tours is a leading provider of meeting support in Croatia and the region. We specialize in organizing meetings, conferences and social events. Established in 1996, O-Tours now has a very professional team of more than 30 PCO specialists operating actively and directly in 3 countries (Croatia, Slovenia and Bosnia and Herzegovina), but also collaborating with other PCOs on different projects in the region, both EU and non EU countries.

In 2001, O-Tours became partner of Hogg Robinson Group, the international corporate services provider specializing in travel management and is also a member of IATA (International Air Transport Association) what ensures O-Tours is capable and well resourced to organize the most difficult projects by itself. Striving to accommodate the specific nature of each event, our conference team design and provide full service to the client /organizer, bearing the brunt of logistic effort and allowing the organizer to deal with more sophisticated tasks and their primary business. Over the years, O-Tours has gained considerable experience in meeting organization and support for both small and large events as well as international congresses with over 1000 participants.



Venue and Date

Opatija, Croatia

October 6-9, 2016.

Opatija lies at the centre of the Riviera with the longest tradition of providing quality conference venues in Croatia.

Opatija's very attractive geographic position, lush green scenery and a pleasant climate (45° 20' north latitude) were some of the main reasons for its beginning and the quick development of its tourism at the end of the 19th century. Built mainly at the turn of the

20th century, Opatija has remained in complete harmony with Nature right up until the present day. Well-maintained public gardens, the illuminated 12-km-long coastal promenade known as the "Lungomare", well-kept beaches and fountains provide a stunning backdrop for the hotels that cater comfortably for up to 6,000 guests. The contrasts of sea and mountains, green parks and blue ocean, old buildings and modern comforts, noisy entertainment venues and quiet destinations for excursions all combine to make Opatija and its surroundings a very attractive tourist destination at any time of the year.

The Grand Hotel 4 Opatijska Cvijeta is located in the very centre of Opatija and includes four buildings that were named after Opatija's best-known flowers. The hotel has 223 rooms. The Camellia restaurant of the Grand Hotel 4 Opatijska Cvijeta offers its guests traditional Croatian dishes prepared with fresh local ingredients. This is the only hotel in Croatia that meets the special 'Croatian autochtone cuisine' standard, which is a guarantee that exclusively Croatian dishes are served here. The hotel also includes the large Tamaris congress centre, which has 7 multifunctional halls and the latest congress equipment.



Budget estimate

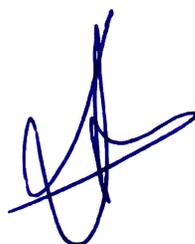
With the assumption of 3 full days meeting and 150 participants, the expected meeting expenses are as follows:

Expense type	Price (€)	VAT (25%)	Total cost (€)
Meeting facilities	3500.00	875.00	4375.00
Technical equipment and support	7800.00	1950.00	9750.00
Meeting materials, design and printing	5600.00	1400.00	7000.00
Travel and accommodation for invited speakers	7500.00	1875.00	9375.00
Meals and coffee breaks, incl. networking dinner	22500.00	5625.00	28125.00
Other, unaccounted, incidental expenses	2500.00	625.00	3125.00
Total	49,400.00	12,350.00	61,750.00

Based on 6 years of continuous experience with organization of scientific conferences and related sponsorship management, our estimate for the final financial outcome of the Focus meeting 2016 is as follows:

Expected financial outcome	Price (€)	VAT (25%)	Total cost (€)
Meeting expenses	-49400.00	-12350.00	-61750.00
Financial contribution from registration fees (175 €)	26250.00	6562.50	32812.50
Financial contribution from grants and sponsorships	28000.00	7000.00	35000.00
Expected in kind contributions	2000.00	500.00	2500.00
Total	6,850.00	1712.50	8,562.50

By signing this document, I confirm the validity of this offer:



Prof. Dinko Vitezić, MD, PhD

Focus Meeting Coordinator

President, Croatian Society of Clinical Pharmacology and Therapeutics