

**CHALLENGES IN THE ASSESSMENT OF  
SIMILARITY OR EQUIVALENCE OF  
BIOLOGICALS AND  
COMPLEX DRUGS**



**2<sup>nd</sup> International Symposium  
on Scientific and Regulatory  
Advances in Complex Drugs  
(SRACD 2016)**

Hotel Danubius Health Spa Resort Margitsziget\*\*\*\*Superior  
Margaret Island, Budapest, Hungary  
October 10-11, 2016



Call for Exhibition and  
Sponsorship

[sracd.hu](http://sracd.hu)



## Dear Sponsor, Dear Exhibitor,

The **2<sup>nd</sup> International Symposium on Scientific and Regulatory Advances in Complex Drugs** (SRACD 2016) is organized in Budapest, Hungary, October 10-11, 2016 as a follow-up of very successful series of Bioequivalence Workshops (BEW series) and the 1<sup>st</sup> SRACD in 2014 which was the first Symposium in Europe in the field of Biologicals and Complex Drugs. As the science and technologies are advancing, the pharmaceutical world is entering into more complex drug delivery systems and dosage forms. The aim of this symposium is to discuss the scientific advances and regulatory challenges for generic equivalence of the complex dosage forms.

The symposium will focus on biologicals and non-biological complex drugs (NBCDs). These complex drugs require a paradigm shift for regulatory approval compared to the requirements for small molecules. These complex drugs are difficult to fully characterize and the tight control of the manufacturing process makes the specific product. The symposium will discuss biologicals and NBCDs, what are they and why are they different, scientific and regulatory advances in bioanalytical methodologies to characterize these biologicals, complex drugs and nanoparticles. SRACD 2016 will present similarities between biologicals and NBCDs. It will focus on potential challenges in therapeutic equivalence evaluation of NBCDs like nanomedicines, iron sucrose complexes, glatiramoids, liposomes and complex ophthalmic emulsions.

To help young research scientists participate in the international symposium, posters are welcome. Panel discussions will be held to discuss various viewpoints (two on each day). The symposium will also provide ample opportunities for the participants to interact with international speakers on different topics. Prominent representatives of pharmaceutical authorities are invited from several continents to contribute to the scientific program.

We wish all participants an enriching stay in the beautiful milieu of Margaret Island in Budapest with a special atmosphere of the UNESCO protected Music Fountain and Water Tower and exciting science that will be presented.

## Main Topics of the Symposium

- **Biosimilars: Challenges and Regulatory Pathways**
  - Introduction and use of biosimilars in Europe
  - Regulatory and market concerns
  - Regulatory landscape in Europe and USA
  - WHO Standard for regulatory evaluation biotherapeutics including biosimilars
  - Evaluation of monoclonal antibodies developed as biosimilars: WHO approach
- **Non-Biological Complex Drugs**
  - Complex peptide mixtures
  - Liposomes
  - Complex ocular emulsions
  - Iron carbohydrate complexes
  - Nanomedicines
- **Advances in Bioanalytical Testing**
  - Drug release from nano medicines
  - “Non-inferiority” assessment
  - Size and charge measurement of nanoparticulate system
  - The man and his spectrometer: a human-centered modus operandi of structure elucidation by NMR and MS in biosimilars
  - Bioanalytical challenges for biologics, biosimilar, non-biological complex drugs
  - Analytical toolbox for proteins: moving to full characterization
  - Semi-quantitative extractables & leachables (E&Ls) in protein preparations
- **Bioequivalence/Biosimilarity of Complex Drugs**
  - Equivalence of generic complex drug products
  - Challenges in the assessment of similarity or equivalence of complex drugs
  - Biosimilar version of infliximab
- **Compendial Approaches**
  - Ensuring the quality and safety of complex drugs: the international landscape of pharmacopeias
- **Clinical Aspects**
  - Equivalence and interchangeability of complex drugs
  - Precision medicine, personalized targeted therapy against the driver genes and related pathways

We are looking forward to meeting you in Budapest.



Prof. Imre Klebovich



Prof. Daan J. A. Crommelin



Prof. Stefan Mühlebach



Prof. Vinod P. Shah

Co-Chairs of the Workshop



## Information on Sponsorship and Advertising

**SRACD 2016 Symposium** provides a range of opportunities advantage of this event to promote your company among leading scientists dealing with scientific and regulatory advances in complex drugs coming from academic and institutional background from all around Europe and from overseas. We offer a wide range of sponsorship packages as well as supplementary options to achieve the biggest exposure to your company. We are convinced that this event presents an excellent options to exhibit your technology and services to a large number of counterparts and, further, to become a sponsor of this event to make it more attractive. SRACD 2016 Symposium will also be an excellent opportunity to develop effective advertisements that will meet your requirements for high-quality sponsorship. For advertising, exhibiting and sponsorship opportunities, please contact:



**Mr. Attila Varga**

H-1255, Budapest P.O.B. 48., Hungary

**Phone:** +36 1 225 0210

**E-mail:** [diamond@diamond-congress.hu](mailto:diamond@diamond-congress.hu)

**Web:** [www.diamond-congress.hu](http://www.diamond-congress.hu)



# Sponsoring Packages

Below you can read our offers for our graded sponsors and further options for your company. The sponsoring packages are priced in EUR and all prices are exclusive of VAT.

	<b>Platinum Package</b>	<b>Gold Package</b>	<b>Silver Package</b>
<b>Number of sponsors limited to</b>	2	4	6
<b>Complimentary full conference registrations</b>	2	1	1
<b>Complimentary exhibition stand place</b>	6 m <sup>2</sup>	4 m <sup>2</sup>	4 m <sup>2</sup>
<b>Display of company logo in the main session hall during the breaks as:</b>	Platinum Sponsor	Gold Sponsor	Silver Sponsor
<b>Acknowledgement in all conference publications</b>	✓	✓	✓
<b>Flyer insert in the conference bag up to:</b>	2 flyers or brochures	1 flyer or brochure	1 flyer or brochure
<b>Full page color advertisement on one of the covers of the Final Program, depending on availability</b>	✓		
<b>Full page color advertisement on one of inner pages of the Final Program</b>		✓	✓
<b>Full page color advertisement in the Book of Abstracts</b>	✓	✓	✓
<b>Placement of company logo or banner with link in a frequent place on the conference website as a:</b>	Platinum Sponsor	Gold Sponsor	Silver Sponsor
<b>Brief description of your company profile with logo in the Final Program</b>	✓	✓	✓
<b>Placement of a roll-up/X-display in the lecture hall</b>	✓	✓	
<b>Verbal acknowledgement at the opening and closing of the conference</b>	✓	✓	✓
<b>Cost:</b>	<b>7,000 EUR +VAT</b>	<b>5,000 EUR +VAT</b>	<b>3,000 EUR +VAT</b>



## Additional Sponsoring, Opportunities & Benefits

### Exclusive Sponsorship of Lunches

- Available for 2 companies
- Acknowledgement in all conference materials
- Acknowledgement on signage prominently displayed at the conference registration area
- Acknowledgement on signage prominently displayed at lunch time

**Commercial Rate:** 2500 EUR+VAT / lunch

### Exclusive sponsorship of Delegates' Bag

- Available for 1 company
- The sponsor name and logo silk-screened or embroidered on the outside front cover of each bag
- Acknowledgement in all conference materials
- Acknowledgement on signage prominently displayed at the conference registration area
- Option to include one promotional piece in the delegate bags (limited to one, single-page, double-sided insert provided at the cost of the sponsor)

**Commercial Rate:** 2000 EUR+VAT

### Exclusive Sponsorship of Participant Name Badges and Lanyards

- Available for 1 company
- Sponsor logo/name printed on the lanyards
- Acknowledgement in all conference materials
- Acknowledgement on signage prominently displayed at the conference registration area

**Commercial Rate:** 1500 EUR+VAT

### Exclusive Sponsorship of Delegate Notepaper and Pens

- Available for 1 company
- Notepaper and pens printed with your company logo will be included in the conference bags
- Sponsor logo printed on the notepad and pens
- Acknowledgement in all conference materials
- Acknowledgement on signage prominently displayed at the conference registration area

**Commercial Rate:** 1500 EUR+VAT

### Exclusive Sponsorship of Coffee Breaks

- Available for 4 companies
- Acknowledgement in all conference materials
- Acknowledgement on signage prominently displayed at the conference registration area
- Acknowledgement on signage prominently displayed at the break

**Commercial Rate:** 1250 EUR+VAT / break



## Advertisements Possibilities

We provide a possibility for companies to insert advertisements in our symposium's working materials. Please note that cover pages of the Final Program are not available for advertising (except two pages reserved for our Platinum Sponsors). All prices are exclusive of VAT.

### Advertisement packages:

#### **Advertisement in the Final Program**

This material will be printed in DIN A5 format

Deadline for advertising:

Inner full page (full color) 500 EUR+VAT

Inner full page (B&W) 350 EUR+VAT

#### **Advertisement in the Book of Abstracts**

This material will be printed in DIN A5 format

Deadline for advertising:

Inner full page (full color) 500 EUR+VAT

Inner full page (B&W) 350 EUR+VAT

#### **Flyer insert in the Participants' Pack**

Maximum size: DIN A4 format, the exact quantity will be finalized before the Conference, depending on the number of applicants.

Deadline for advertising:

Flyers not exceeding 12 pages: 500 EUR+VAT/insert  
(company should provide the inserts)

All advertisements should be sent to the Congress Secretariat before September 1, 2016.

Further details and technical parameters are sent upon the order.



## Exhibition Opportunities

As one of the exhibitors at our Symposium you have the possibility to present your company to motivated and well-informed scholars and professionals.

If you are interested in exhibiting, we can offer floor space for your own stand. Diamond Congress Ltd., our partner for the conference organization offers numerous alternatives to publicize and promote your business and can work closely with you to create a package tailored to your company's need. All prices are exclusive of VAT.

### Size and fees for space (width x depth):

4 m<sup>2</sup> (2x2 m) 1000 EUR+VAT

6 m<sup>2</sup> (3x2 m) 1400 EUR+VAT

### The exhibition package fee includes:

- net stand area
- tables for displaying your company products/services
- waste paper bin
- 3 sockets for electricity (230 V, 50 Hz, European standard)  
including energy usage of max 3 kW
- 1 complimentary full registration
- logo display at the conference webpage





## Application and General Payment Conditions

All advertisers wishing to apply for any of the services listed in this brochure are required to register by submitting the enclosed registration form to Diamond Congress Ltd. with an authorized signature. Application are handled at first-come first-served basis, but priorities are given to main sponsors, in terms of advertisements, exhibition space, and selection of sponsorship opportunities. Space will not be reserve without a written application. Exhibition space cannot be occupied unless the full amount is paid before the dates shown below. The organizers of the exhibition retain the right to rearrange the stands in case the overall concept or organizational matters force them to do so. Advertisement will not be printed if the full amount of the advert is not paid before the deadline indicated. Signing and submitting the application form is binding agreement, provided exhibition space is available, and considered to be written commitment that all conditions stated therein are understood and accepted by the applicant. All prices stated herein exclude VAT which is 27% for Hungarian seated companies. (For international companies reversed charge VAT applies). Payment should be arranged upon receipt of our pro forma invoice, according to the following terms.

**Payment of sponsorship, fee:** August 31, 2016

### **Cancellation Policy**

Cancellation and changes to your orders must be made in writing to the Conference Secretariat. Refundable amounts and penalties depend on the date of cancellation and are as follows:

<b>Before August 31, 2016:</b>	50% refunded, 50% retained
<b>After August 31, 2016:</b>	no refund



**Diamond Congress Ltd.**

**Mr. Attila Varga**

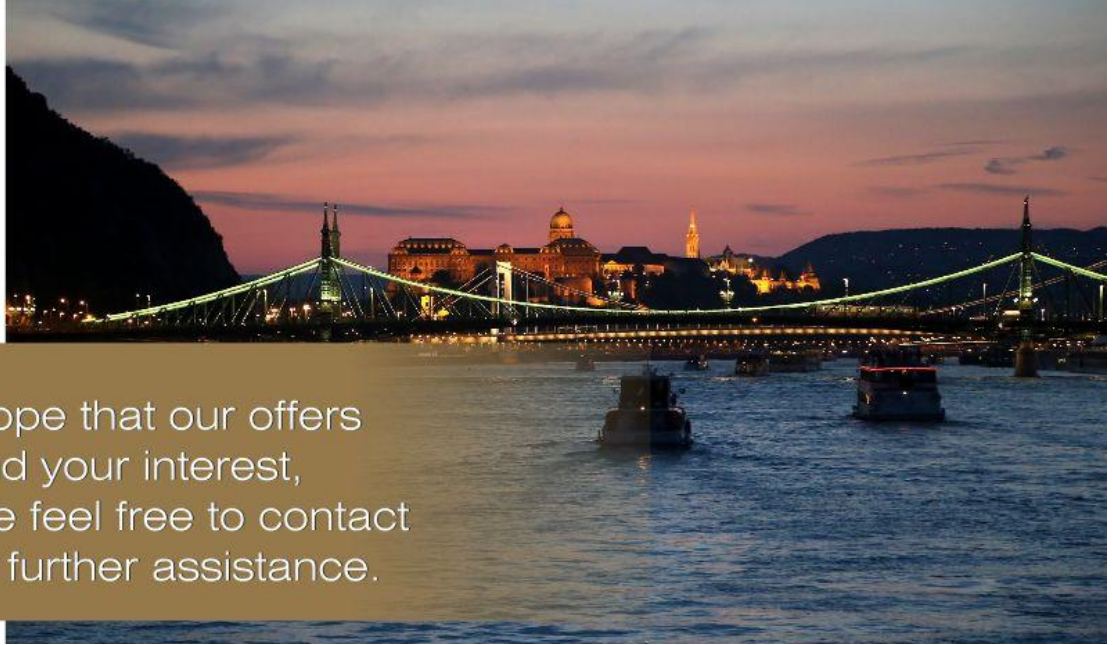
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**Web:** [www.diamond-congress.hu](http://www.diamond-congress.hu)



We hope that our offers will find your interest, please feel free to contact us for further assistance.



## 2<sup>nd</sup> International Symposium on Scientific and Regulatory Advances in Complex Drugs

Budapest, Hungary, October 10-11, 2016

### Sponsorship and Exhibition Order Form

(Please return this form preferably before July 15, 2016)

Name of the company: .....

Postal address: .....

Invoice address (if different from above): .....

Name of the contact person: .....

Phone: ..... Fax: ..... E-mail: .....

VAT Number: .....

*Please tick the appropriate boxes*

#### 1. Sponsorship categories

Platinum Package	7000 EUR+VAT	<input type="checkbox"/>
Gold Package	5000 EUR+VAT	<input type="checkbox"/>
Silver Package	3000 EUR+VAT	<input type="checkbox"/>

#### 2. Sponsoring Opportunities and Benefits

Sponsorship of the Conference Bag	2000 EUR+VAT	<input type="checkbox"/>
Sponsorship of Notepaper and Pens	1500 EUR+VAT	<input type="checkbox"/>
Sponsorship of Name Badges and Lanyards	1500 EUR+VAT	<input type="checkbox"/>
Sponsorship of Coffee Breaks (per coffee break)	1250 EUR+VAT	<input type="checkbox"/>
Sponsorship of Lunches (per lunch)	2500 EUR+VAT	<input type="checkbox"/>

### 3. Advertisements

#### Final Program

Inner page (full color)	500 EUR+VAT	<input type="checkbox"/>
Inner page (B&W)	350 EUR+VAT	<input type="checkbox"/>

#### Book of Abstracts

Inner page (full color)	500 EUR+VAT	<input type="checkbox"/>
Inner page (B&W)	350 EUR+VAT	<input type="checkbox"/>
Flyer insert (in the conference bag)	500 EUR +VAT/insert	<input type="checkbox"/>

### 4. Exhibition

Size of the stand place (width x depth)

4 m <sup>2</sup> (2x2 m)	1000 EUR+VAT	<input type="checkbox"/>
6 m <sup>2</sup> (3x2 m)	1400 EUR+VAT	<input type="checkbox"/>

### 5. Prices and payment conditions

*All prices stated above exclude VAT, which is 27 % (as of 2016). Payment should be arranged upon receipt of our pro forma invoice, according to the following terms:*

**Deadline of sponsorship and advertisement fees**

**August 31, 2016**

*Payment should be arranged upon receipt of our pro forma invoice.*

### 6. Cancellation Policy

*Cancellation is not possible from the side of the sponsor, after having sent the expression of intent, as the service (communication towards the participants) is started by the organizers immediately.*

*Refundable amounts depend on the date of cancellation and are stated as follows:*

Before August 31, 2016: 50% refunded, 50% retained

After August 31, 2016: no refund.

**By signing this application form, I hereby declare that I understood and accepted the conditions of participation, payment and cancellation.**

**Date:** .....

**Signature:** .....

**Please send this form to the Symposium Secretariat preferably before July 15, 2016.**

**Diamond Congress Ltd.**

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