



ctmd2017

The 3rd International Congress on

Clinical Trials for Medical Devices

7-8 September 2017 | Budapest, Hungary

General Information



Dates

7 - 8 September, 2017

Congress Venue

Hilton Budapest City
Vaci UT 1-3
Budapest
1062
Hungary

Participants

Expected 100 attendees

Congress Organiser

Bioevents

Tel: +1-857-400-0035

Tel: +44-203-051-4032

Email: ctmd@bioevents.net

Project Manager

Rachel Katzir

Tel UK: +44 203 051 4032 ext 521

Tel US: +1 857 400 0035 ext 521

Email: rachel@bioevents-congress.com

Exhibition & Sponsorship

Joanne Golibroda

Tel UK: +44 203 051 4032 ext 520

Tel US: +1 857 400 0035 ext 520

Email: joanne@bioevents-congress.com

Hotels & Registration

Tel: +1-857-400-0035

Tel: +44-203-051-4032

Email: ctmd@bioevents.net

Welcome Letter

Dear Colleague,

It is our pleasure to invite you to participate in **The 3rd International Congress on Clinical Trials for Medical Devices** (CTMD2017), which will take place 7-8 September 2017, in Budapest, Hungary.

Following the success of CTMD2016 held in Berlin and CTMD2015 held in Vienna, **CTMD2017** will continue to focus on the latest developments and upcoming regulations on clinical trials for medical devices internationally. Deciding on a clinical site and investigator? Lost in the regulatory maze?

CTMD2017 is a pragmatic event directed at filtering through the information overload of the digital age to deliver targeted information. CTMD2017 will directly address the 3 'hot topics' in the field of medical device clinical trials:

- Selecting a clinical site and investigator
- Understanding the process for obtaining approval to conduct a clinical trial
- What are the new regulations for planning and executing clinical trials?

Participants at CTMD2017 will once again have the unique opportunity to gain first-hand knowledge from key opinion leaders by scheduling one-on-one meetings during the coffee and lunch breaks at the congress. **CTMD2017** would like to welcome professionals worldwide with a target audience of CEOs, general managers, R&D personnel, clinical professionals, regulatory affairs specialists, engineers, CROs, application specialists and QA personnel.

We look forward to seeing you at CTMD2017 in the exciting and historical city of Budapest.



Adi Ickowicz
MedicSense, Israel



Bioevents
Congress Organizer

Preliminary Program

Please note this program is preliminary and may be subject to change.

Thursday, 7 September 2017

07:30	Registration
	Plenary Hall
08:50	Congress Opening Welcome Address Adi Ickowicz
09:00	Session 1:
	Presentation1: Deciding when to perform a clinical trial with medical devices Presentation 2: Medical device clinical trials vs. drug trials Presentation 3: Clinical Trials with drug-device combinations
10:30	Coffee Break and visit the Exhibition One-on-One Meetings with KOL
11:00	Session 2:
	Presentation1: Safety verification prior to safety validation Presentation 2: EU MDR and clinical evidence – what is in between Presentation 3: Clinical Evaluation and the new EU MEDDEV 2.7.1/rev 4
12:30	Lunch Break and visit the Exhibition One-on-One Meetings with KOL
13:30	Session 3:
	Presentation1: How to do a Clinical Trial in China Presentation 2: Clinical Trials for Medical Devices In India Presentation 3: Current regulations of clinical trials with medical devices in Brazil
15:00	Coffee Break and visit the Exhibition
15:30	Session 4:
	Presentation1: The role of academia in medical device validation and translation Presentation 2: Data management and data integrity Presentation 3: Information Security Management Systems (ISMS) in clinical trials
17:00	End of Day One

Friday, 8 September 2017

08:00	Registration
	Plenary Hall
09:00	Session 5:
	Presentation1: The different types of clinical trials for medical devices Presentation 2: FDA Significant Risk (SR) and Nonsignificant Risk (NSR) medical device studies Presentation 3: FDA Expedited Access Pathway (EAP) for unmet medical need for life threatening or irreversibly debilitating diseases or conditions
10:30	Coffee Break and visit the Exhibition One-on-One Meetings with KOL
11:00	Session 6:
	Presentation1: Basic statistical methods for planning a sample size Presentation 2: Advanced tools for statistical analysis Presentation 3: Medical Significance vs. statistical significance
12:30	Lunch Break and visit the Exhibition One-on-One Meetings with KOL
14:00	Session 7:
	Presentation1: How to ensure a clinical site is ready for a regulatory audit Presentation 2: Usability studies, evaluating Man-Machine Interface (MMI)
15:00	Coffee Break and visit the Exhibition
15:30	Session 8:
	Presentation1: Designing Medical Device Studies to Address Multiple Purposes – From Regulatory Submissions to Market Education Presentation 2: Professionalism of Clinical Research Associates (CRAs)
16:30	Congress Closing

Sponsorship

Build your own Sponsorship Package

Sponsorship level will be determined by the total amount of contribution and

Sponsors will be acknowledged as follows:

Category
Gold Sponsor
Silver Sponsor
Bronze Sponsor

Sponsorship Benefits

Benefits will be allocated to Sponsors based on the following table:

Benefit	Gold Sponsor	Silver Sponsor	Bronze Sponsor
Back Cover or inside front cover advert in program book (allocated on a first come first served basis)	√		
Exhibition Space (3x2)	√	√	√
Full page advert	√	√	√
Sponsor's logo with hyperlink on congress website	√	√	√
Sponsor's logo in program	√	√	√
Delegate registrations	4	2	1
Acknowledgment on-site signage	√	√	√

Promotional Items

Welcome Reception (Sole Sponsorship)

An opportunity for your company to promote itself through the welcome reception on the first evening to which all Congress attendees are invited

- Sponsor's name and logo printed on invitation and menu
- Sponsor's logo on sign at the entrance to the event
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

1:1 Meeting Tables (Exclusive Sponsorship)

Opportunity to Sponsor 1:1 meeting tables.

- Company logo on a table top signage
- Support will be recognised with signage at the entrance to the area with "Supported by..." and a company logo
- Opportunity to provide items bearing company logo for use during the supported break (napkins etc) subject to approval
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

10 minute Spotlight on the Company Session

Company Spotlight Lecture in the last 10 Minutes of a session.

- Time Slots: allocated on a first come, first served basis
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

Chair Covering* (Exclusive Sponsorship)

Chair covers to be provided by client.

- Final design to be approved by Congress Chairperson and Congress Organizer.
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

Notepad and Pens (Exclusive Sponsorship)

The sponsoring company will provide Notepads and Pens

- Notepad and pens to be provided by client
- The sponsoring company will provide Notepads and Pens
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

Lanyards* (Exclusive Sponsorship)

Lanyards to be provided by client

- An opportunity to include company logo on lanyard
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

Napkins and Coasters (Exclusive Sponsorship per day)

Napkins and coasters to be provided by client

- Final design to be approved by Congress Chairperson and Congress Organizer
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

Coffee Break* (Exclusive Sponsorship per Break)

Coffee will be served during the networking breaks in the exhibition area.

- Opportunity to provide items bearing company logo for use during the supported break (napkins etc) subject to approval
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

ADVERTISEMENT

Full inside page colour advertisement in designated section of the Program.

PROGRAM	INSIDE PAGE	BACK PAGE
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The Program will be distributed to all registered participants. It will contain the timetable, information about the scientific Program and other useful information.

Printed Program

Every participant will receive this program upon their arrival to the Congress.

- Exclusive advertisement on the back cover of the printed program
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

Promotional Mailshot

Gain additional exposure by sending out a Mailshot to the pre-registered delegates and database who have agreed to disclose their details. Mailshot to be sent in advance of the Congress at a date and time coordinated with Bioevents.

- Mailshot to be designed and provided by the supporter by agreed deadline and according to design specifications
- Sponsor's logo on Congress website
- Acknowledgement in the Sponsor's list in the program
- Acknowledgment on-site signage

Exhibition

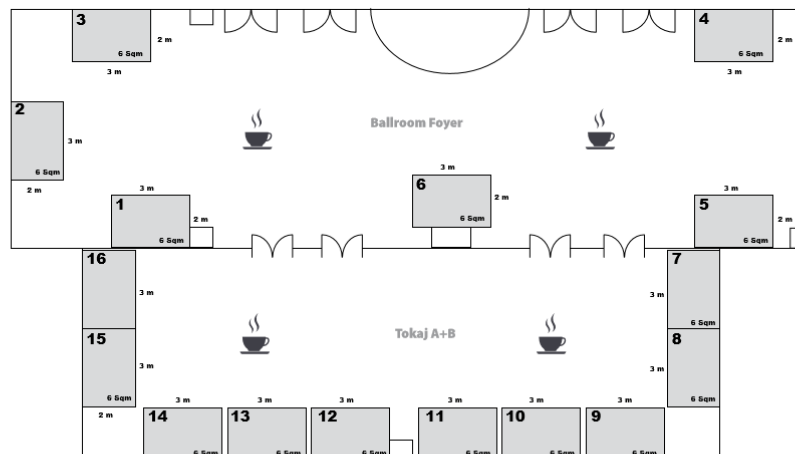
The floorplan has been designed to maximise exhibitors' exposure to the delegates

Exhibition space

- Exhibition space of 6 m² (3x2)
- Company logo on Congress website with a hyperlink to website of your choice
- 100 word company profile on the Congress Website
- 1 Exhibitor badge
- Table including 2 chairs and electrical point

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Bioevents
Sharing Biomed knowledge



We welcome all start-ups to join us at CTMD.
Start-ups are integral to industry and innovation.

A discounted rate is offered to start-up companies and this is negotiated on an individual basis.

- Exhibition space of 6 sqm (3x2)
- Table including 2 chairs
- 1 Delegate badge
- Additional delegate badges at a rate of \$700
- 100 word company profile on the Congress Website
- Company logo on Congress website with a hyperlink
- Acknowledgement in the printed program

For further information please contact

Joanne Golibroda

Tel UK: +44 203 051 4032 ext 520

Tel US: +1 857 400 0035 ext 520

Email: joanne@bioevents-congress.com

To ensure you benefit from being at
the CTMD Congress contact

ctmd@bioevents.net

Exhibition Booking Form

Please complete and send back by email or fax to:

Joanne Golibroda – **CTMD 2017**

joanne@bioevents-congress.com

Fax: + 44 203 051 4032

Contact Name: _____

Company Name: _____

Name (As to appear in all Congress Publications): _____

Address: _____ City: _____

Post / Zip Code: _____ Country: _____

Telephone: _____ Fax: _____

Email: _____ Website: _____

We hereby apply to book exhibition space the cost of 6 sqm

Choice	Stand Number	Total Price
1 st choice		
2 nd choice		

Company Logo to be received in eps or jpeg format. **Short Company Description** (up to 100 words). Sponsor company/product profile will be published in the list of Sponsors and Exhibitors in the official congress program.

Signature: _____

Date: _____

Payment Methods

Payment by credit card

Card No: _____

Expiry Date: _____ CVV2 Code: _____

Full Name of Cardholder: _____

Payment by bank transfer

Details have been provided in the Pro-forma invoice*

Banking Information:

Please make bank transfers payable to: Forum Media Ltd (CTMD 2017)

Bank Account: Bank Hapoalim, Hadar Yosef, Tel-Aviv, Israel

Branch number: 610

Swift code: POALILIT

IBAN number: IL53 0126 1000 0000 0304056

Currency USD

Bank charges are the responsibility of the payer.

*Invoice/receipt to be issued upon receipt of payment

Cancellation / Modification Policy

Cancellation / modification of items must be made in writing to the Industry Sales Manager joanne@bioevents-congress.com

Cancellations received up to 30 days prior to start of exhibition will be entitled to a 70% reimbursement (less \$50 handling fee) of payments received. Cancellations received 29-14 days prior to start of exhibition will be entitled to a 50% reimbursement (less \$50 handling fee) of payments received. Cancellations received from 13 days prior to start of exhibition, will not receive a reimbursement.

General Conditions

- This agreement must be signed and returned within 4 weeks of receipt with 1st payment or proof of transfer to Bioevents.
- Bioevents reserves the right to change the venue, time and date of any activities in the above agreement. Sponsor will be notified in writing as soon as a change is made.
- Bioevents accepts no responsibility for any damages if the sponsored event is not performed due to an obstacle or hindrance outside their control, which could not have been foreseen when signing this agreement and which they could not have avoided at a reasonable effort or cost. Such obstacles and hindrances include, but are not limited to, the outbreak of war, terrorist activity, riots, governmental or other obstacles for the freedom of travel, union actions, natural disasters, fire, flooding that takes place during the Congress. If, however, Bioevents cancels the sponsored event for any reason including the above listed reasons, all monies paid by the Sponsor will be repaid in full.
- An exhibition stand / space is a workplace in itself and the exhibitor is responsible for the Health and Safety of that workplace during the construction, use and dismantling of the stand. The Exhibitor thus has a legal duty of care for anyone on or near the site who may be affected by the actions or omissions of the stand contractors or exhibiting staff.
- Promotion of Sponsor' s activities is only permitted from a company exhibition stand, from an assigned lecture hall in which the Sponsor' s activities are taking place or with prior permission from Bioevents. Any other promotional activity, such as distribution of leaflets or materials to delegates on the Congress premises, is not allowed.
- Hanging of all signs for symposia should be coordinated and approved by Bioevents.
- All congress material supplied by Bioevents in relation to the Congress is accurate to the best of their knowledge. Any inaccuracy, mistake or omission shall not entitle the Sponsor to cancel their sponsorship.
- Confidentiality. For a period of five (5) years following the 7 September, 2017 or, in the event of earlier termination of this Agreement, for a period of five (5) years following such termination, the Parties hereto shall hold in confidence information and materials received from the other Party (the "Confidential Information") unless the receiving Party can demonstrate that the information was (i) rightfully in its possession or known by it prior to receipt from the disclosing Party, or (ii) was rightfully disclosed to it by another person without restriction, or (iii) was independently developed without use of any Confidential Information of the disclosing Party by employees of the receiving Party who had no access to such information, or (iv) is or becomes (through no improper action or inaction by the receiving Party or any agent, consultant or employee thereof) generally available to the public. For the avoidance of doubt, all information and materials which are distributed to the public during the CTMD2017 shall not be considered Confidential Information.
- The parties to this contract hereby agree that, all communications among them including this agreement are protected from disclosure by each of them it is agreed that all information, whether oral, written or otherwise, that is supplied in the course or as a result of so meeting shall be treated as confidential by the receiving party. The receiving party undertakes not to use the information for any purpose, other than for the purpose of considering the said collaboration, without obtaining the written agreement of the disclosing party.