WCTD 2016

The World Congress on

Clinical Trials in Diabetes

30 November - 1 December 2016 | Berlin | Germany

Sponsorship and Exhibition Prospectus

Bioevents
Sharing Biomed knowledge

Dear Colleagues

The International Congress on Clinical Trials in Diabetes (WCTD2016), will take place 30 November - 1 December 2016, in Berlin, Germany.

With the multitude of complex issues associated with clinical trials in diabetes, it is clear that there is a necessity to streamline these issues into a process that will improve drug development in terms of approval and commercialization and address the various aspects of drug and device development and the way to enhance them.

The world renowned faculty will tackle these issues head on through a comprehensive scientific program which will focus on four key areas;

- Design the Best Study
- Improve Regulatory Process; Better Understanding of How to Collaborate with Regulatory Authorities
- Involvement of Digital Medicine
- Power Post-Marketing Surveillance

WCTD 2016 is intended for the below target audience:
Phsyicians & Medical Professionals | R&D personnel | CEOs | Regulatory Affairs specialists | CROs | CRAs | Clinical Trial Managers | QA personnel

We invite you to participate in the WCTD 2016 industry exhibition and take advantage of this unique opportunity to showcase your products and brand, and network with your target market.

Prof. Itamar Raz
Congress Chairperson

General Information

Organizing Committee

Itamar Raz, *Israel* – Congress Chairperson
Stefano del Prato, *Italy*
Philip Home, *UK*
Oliver Schnell, *Germany*

Dates

Wednesday, 30 November 2016 - Thursday, 1 December 2016

Congress Venue

Maritim proArte Hotel
Friedrichstrasse 151
10117 Berlin, Germany

Language

The official language of the Congress is English

Liability & Insurance

The Congress secretariat and organizers cannot accept any liability for personal accidents or loss of/damage to private property of participants of WCTD2016.

Congress Organizer

*Bio*events
US: +1-857-400-0035
UK: Tel/Fax: +44-203-051-4032
E-mail: wctd@bioevents.net
Website: www.wctd2016.com

WCTD 2016

Organizing Committee

Itamar Raz, *Israel* – Congress Chairperson

Prof. Raz holds an MD from Hadassah Medical School at the Hebrew University of Jerusalem where he is a professor of Internal Medicine and the Director Emeritus of the Diabetes Unit at Hadassah University Hospital.

Prof. Raz is the head of the Israel National Council of Diabetes which is responsible for formulating national policies. In addition, Prof. Raz is President of D-Cure, a non-profit organization that promotes and funds scientific research in Israel for finding a cure, prevention and better treatments for diabetes. At Hadassah, Prof. Raz has been active in basic and clinical research and is currently leading several large international outcome diabetes studies involving the heart and kidney in diabetic patients.

He has over 290 publications to his credit in professional peer-reviewed journals, lectures widely at national and international diabetes meetings and serves on several international advisory boards. In addition he serves as associate editor of The Review of Diabetic Studies, co-editor of Diabetes Metabolism Research and Reviews (DMRR) and 6 other editorial positions.

Stefano del Prato, *Italy*

Dr. Del Prato is Professor of Endocrinology and Metabolism at the School of Medicine, University of Pisa and Chief of the Section of Diabetes, University of Pisa, Italy. He graduated MD cum laude from the University of Padova and undertook post-graduate specialization in both Endocrinology and Internal Medicine.

Dr. Del Prato's research interests have always been concerned with diabetes and in particular the physiopathology and therapy of type 2 diabetes and insulin resistance syndrome. He is a member of many societies and associations including the European Association for the Study of Diabetes, the American Diabetes Association, the Mediterranean Group for the Study of Diabetes, the International Diabetes Federation. He acts as referee for numerous major journals. Furthermore, Dr. Del Prato has served on the Editorial Boards for Diabetes Care, Journal of Endocrinological Investigation, Diabetes, Nutrition, and Metabolism, and the European Journal of Clinical Investigation (Diabetes and Metabolism section), and presently for Acta Diabetologica, Diabetes & Vascular Disease Research, Journal of Endocrinology, Diabetes/Metabolism Research & Reviews andDiabetes & Metabolism, Journal of Clinical Endocrinoloy and Metabolism, and Diabetes Care. Dr Del Prato has published over 500 articles on national and international journals and has been awarded several honors, including the Prize of the Italian Society of Diabetology for outstanding scientific activity. He is Vice President of the European Association for the Study of Diabetes (EASD) for the period of 2011-2014. Moreover he was President of the Italian Society of Diabetology for the period May 2012 - May 2014.

Philip Home, *UK*

Philip Home trained in medicine at Oxford University and Guy's Hospital, coming under the influence of Harry Keen, and thus gravitating into diabetes research. Continuing this research career in Newcastle upon Tyne, initially under the guidance of George Alberti, he has published over 390 papers, books and reviews on aspects of diabetes, from basic studies on metabolism to RCTs of new therapies, and aspects of the organization and delivery of diabetes health-care.

In Newcastle he is Professor of Diabetes Medicine, and practised in diabetes care and disorders of lipid metabolism at the Newcastle Diabetes Centre and at the Newcastle Hospitals until end 2011.

A background in pharmacology and medicine led to appointment to the external panel of the Committee of Safety of Medicines (UK) and later the MHRA, and subsequently to membership/ Vice-chairman of the Appraisal Committee of the National Institute for Clinical Excellence (UK) (2000-2011). He has given evidence at Federal Drugs Administration (USA) hearings and advised EMA on diabetes medication regulation.

Oliver Schnell, *Germany*

Professor Oliver Schnell is the Executive Member of the Managing Board of the Forschergruppe Diabetes e.V. at the Munich Helmholtz Center and Professor at the Ludwig- Maximilians-University in Munich. He has received multiple national and international scientific awards and is also member of several guideline committees. He is a member of the Steering Committee of the "Diabetes and Cardiovascular Disease EASD Study Group" and President of the Annual Meeting of the D&CVD EASD Study Group in 2015. He serves as an official instructor of the German Diabetes Association.

Prof. Schnell's research interest focuses on diabetes and vascular diseases; cardiac disease in diabetes, new treatment strategies, blood glucose monitoring, telemedicine and new media. He is a member of the German Diabetes Association, European Association for the Study of Diabetes (EASD), American Diabetes Association, German Association of Cardiology and the European Society of Cardiology.

He has published more than 110 original articles, review articles and book chapters in high-ranking national and internal peer-reviewed journals. He currently serves as the Editor-in-chief of the Journal "Diabetes Metabolism and the Heart".

Scientific Program

Wednesday, 30 November

07:30	Registration
08:30	**Session I: Opening and Keynote Presentations**
08:30-08:50	Past and Future in Diabetes Drug Development **Peter Stein,** Merck, USA
08:50-09:10	Lessons Learned from a Century of Diabetes Drug Development TBA
09:10-09:30	Discussion
09:30	Coffee Break and visit the Exhibition
10:00	**Session II: Current Regulatory Trends in Diabetes Drug Development**
10:20-10:40	EMA Perspective TBA
10:40-11:00	FDA Perspective **Alexander Fleming,** Kinexum, USA
11:00-11:20	Brazil and LATAM key Countries **Andrea Saud Martinez,** Avanti Pesqusa Clinica, Brazil
11:20-11:40	Industry Perspective **Murray Stewart,** GSK, USA
11:40-12:00	Scientific/Professional Associations Perspective **Paolo Pozzilli,** Italy
12:00-12:20	A Novel Modelling and Simulation Approach to Estimate the Efficacy of a Drug **Hiddo J. Lambers Heerspink,** The Netherlands
12:20-12:30	Short Discussion
12:30	Lunch Break, Sponsored Lunchtime Symposium and visit the Exhibition
14:00	**Session III: Design a Clinical Program for Success**
14:00-14:20	Can we Reduce Real Time and Costs? **John New,** UK
14:20-14:40	Setting the Grounds for Successful Market Access **Arie Katz,** USA

14:40-15:00	Investigator Initiated Trials and the Role of Industry **Markolf Hanefeld,** Germany
15:00-15:20	Real World Evidence (RWE); Big Data **Anselm Gitt,** Germany
15:20-15:40	Why are IITs (Investigator Initiated Trials) essential in Drug Evaluation - Panel Discussion **Antonio Ceriello,** Spain **Paul Valensi,** France **Markolf Hanefeld,** Germany
15:40-16:00	Discussion
16:00	Coffee Break and visit the Exhibition
16:30	**Session IV: Operational Aspects in Diabetes CT'S**
16:30-16:45	Public Perception of Clinical Trials for Diabetes **Emily Regier, Close Concerns,** USA
16:45-17:00	Rule of Thumb for Successful Site Selection **Andreas Pfuetzner,** Germany
17:00-17:15	Tools and Best Practices to Help Clinical Sites Optimize Performance and Maintain Compliance with GCP **Thomas Forst, Profil,** Germany
17:15-17:30	Study Management - CRO vs In-house **Thomas Forst, Profil,** Germany
17:30-18:00	Discussion
18:00	Welcome Reception in the Exhibition Area

Thursday, 1 December

07:00	Registration
08:00	**Session V: Phase 2 / 3 Studies**
08:00-08:20	Why are Phase 2 Studies so Often Misleading? **Arie Katz,** USA
08:20-08:40	Why is it so Difficult to Design a Dose Finding Study? **Roy Eldor,** Israel

08:40-09:00	Geographical Trends **Paolo Pozzili,** Italy
09:00-09:20	Sites Selection in a Continental Country with focus on DM only **Andrea Saud Martinez, Avanti Pesqusa Clinica,** Brazil
09:20-09:30	Question and Answers
09:30	**Session VI: Cardiovascular Outcome Studies Part 1: Relevant Data Collection**
09:30-09:50	Relevant Data Collection in CVOT - Medical Scientific and Clinical Safety Perspective **Ingrid Gause-Nilsson, Boehringer Ingelheim,** Sweden
09:50-10:10	Will HbA1c remain a valid surrogate endpoint? Implication of recent CVOT results in diabetes **Maximilian von Eynatten, Boehringer Ingelheim,** Germany
10:10-10:30	Discussion
10:30	Coffee Break and visit the Exhibition
11:00	**Session VII: Cardiovascular Outcome Studies Part 2: Design, Interpretation and Translation**
11:00-11:15	Who Should Constitute the Population Studied? **John Lachin,** USA
11:15-11:30	Difficulty of Interim Analysis/Handle Missing Data **John Lachin,** USA
11:30-11:45	Role Selection Analysis of Secondary Endpoints **Stefano Del Prato,** Italy
11:45-12:00	The Value of Post Hoc Analyses Avivit Cahn, Israel
12:00-12:30	Debate: In a Clinical Development Program clinically meaningful Safety Signals can be reliably determined
12:00-12:15	CON - **Philip Home,** UK
12:15-12:30	PRO - **Robert Heine, Lilly,** The Netherlands
12:30-12:45	Translating CVOTs into Clinical Practice **Oliver Schnell,** Germany
12:45-13:00	Questions and Answers
13:00	Lunch Break, Sponsored Lunchtime Symposium and visit the Exhibition

14:30	**Session VIII: GCP Learning and Best Practice**
14:30-14:50	Pharmaceutical Companies Involvement **Eberhard Standl,** Germany
14:50-15:10	An Auditor Perspective/Preparing Yourself for a Successful Audit **Andrea Saud Martinez, Avanti Pesqusa Clinica,** Brazil
15:10-15:30	Discussion
15:30	Coffee Break, visit the Exhibition and Guided Poster Walk
16:30	**Session X: Special National Program to Enhance Drug Development**
16:30-16:50	Special National Program to Enhance Drug Development **Itamar Raz,** Israel **Avi Karasik,** Israel
16:50-17:10	Panel Discussion **Itamar Raz,** Israel, **Philip Home,** UK, **Alexander Fleming,** USA, **Stefano Del Prato,** Italy, **Oliver Schnell,** Germany
17:10	**Closing Remarks**

WCTD 2016

Information For Supporters And Exhibitors

You will be given a support category status dependent upon the total amount of your support contribution.
The total contribution will consist of items such as advertisements, sponsored items and exhibition space. Benefit from outstanding advantages linked to the supporter category of your choice.

Sponsorship Status is as per the table below:

Category	Contribution
Platinum Sponsor	US $30,000
Diamond Sponsor	US $20,000
Gold Sponsor	US $15,000
Silver Sponsor	US $9,000

Support Benefits:
Benefits will be allocated to supporters based on the following table.

Benefit	Platinum	Diamond	Gold	Silver
Exhibition Space (6m^2 area)	√	√	√	√
Company Logo on Congress website with hyperlink to page of choice	√	√	√	√
Company logo on Sponsors Board on-site	√	√	√	√
Company logo in the Program Book	√	√	√	√
100 Word Company Profile in the Program Book	√	√	√	√
Participant Registrations	10	8	6	4
Full Page color advert in Program Book	√	√	√	√
Acknowledgment as Sponsor of WCTD Welcome Reception		√		
Acknowledgment as Sponsor of Coffee Break			√	
Lunchtime Sympsium (1 Hour session)	√			

Sponsorship & Exhibition Opportunities

Exhibition Opportunities

Exhibition Space

- Company logo on Congress website and all promotional material including sponsors board on-site
- 6 m^2 (3x2) area
- 1 Exhibitor badge
- 1 Participant registration
- Table including 2 chairs

Sponsorship Opportunities

Poster Area with Exhibition Space (exclusive Sponsorship)

Poster Area Sponsorship includes:

- Branding with Company logo on a sign stating " Supported by…"
- Support will be acknowledged on the sponsorship page of the congress website and sponsors board onsite
- Company logo in the Congress Program Book

Program Book

- Includes back cover full page color advert
- Support will be acknowledged on the sponsorship page of the congress website and sponsors board onsite
- Company logo in the Congress Program Book

Inside Page Advert

- Inside full color page advert in the Congress Program Book
- Support will be acknowledged on the sponsorship page of the congress website and sponsors board onsite
- Company logo in the Congress Program Book

Lanyards (exclusive sponsorship)

- Company logo to appear on lanyards provided (with badge) to each participant
- Support will be acknowledged on the sponsorship page of the congress website and sponsors board onsite
- Company logo in the Congress Program Book

Lanyards are to be provided by the sponsor

Coffee Break (exclusive sponsorship per break)

- Acknowledgement signage with company logo displayed during break
- Company logo on break in session schedule
- Support will be acknowledged on the sponsorship page of the congress website and sponsors board onsite
- Company logo in the Congress Program Book

Lunch Break (exclusive sponsorship per break)

- Acknowledgement signage with company logo displayed during break
- Company logo on break in session schedule
- Support will be acknowledged on the sponsorship page of the congress website and sponsors board onsite
- Company logo in the Congress Program Book

Special Offer:

Combine your Exhibition Space with a Coffee Break

Would you prefer a more tailor made sponsorship package? We will be happy to assist.

Terms and Conditions

The Exhibition Terms and Conditions are included in this agreement.

Terms of Payment

50% due with signed contract
50% due by 1 October, 2016
The total amount should be received before the opening date of the Congress.

Cancellation Policy

Notification of cancellations must be made in writing only. Cancellations received up to 30 days prior to start of exhibition will be entitled to a 70% reimbursement of payments received. Cancellations received 14-29 days prior to start of exhibition will be entitled to a 50% reimbursement of payments received. Cancellations received from 13 days prior to start of exhibition, will not receive a reimbursement.

Exhibition Terms and Conditions

1. You, the exhibitor, are responsible for maintaining and cleaning the booth area. All equipment, accessories, furniture, advertising mediums, etc. that are placed in the booth area by the exhibitor, must be submitted in writing to Bioevents for pre-approval. It is strictly forbidden to bring or place any exhibition equipment, accessories, furniture, advertising mediums, etc., that may cause harm or damage to those attending the exhibition or to third parties, or damage the surrounding area, or to bring or place on the ground any flammable, hazardous material, explosives and anything that is determined as dangerous, by us or by anyone on our behalf or at the venue. At the end of the exhibition, the booth area must be left in good condition, free of any objects and debris including equipment of any kind.

2. You are obliged to observe all safety and security rules, including any safety instructions on fire, required by law or required as part of the exhibition, by us or any person acting on our behalf, or by the owners, as amended from time to time. All responsibility under the law preserving and maintaining all of the above, including with respect to fire safety provisions in connection with any act or omission, and / or anyone acting on your behalf or as part of an exhibition, rests solely with you and we are exempt from all responsibility.

3. You agree that your participation in the exhibition is at your own risk and you are solely responsible for any claims and/or demands of third parties and any injury, damage, loss, direct or indirect, including loss of profits or revenue, loss or expense incurred by you, your employees, your suppliers, your guests, visitors to the booth, by any third party whatsoever, the venue owners or their representatives, to us or our representatives, and/ or to equipment as a result or in connection with any act or omission by you, and/ or anyone on your behalf at the exhibition as a result of non-compliance or breach of obligations in accordance with this agreement. Participation in the exhibition is conditional upon that you comply with provisions of the law relating to your activity in the exhibition, including that that you have all licenses, approvals and permits required by law for managing and operating the exhibits and perform all obligations as per this document throughout the exhibition. You declare that your company holds valid product liability insurance.

4. In the event of cancellation, the following conditions will apply: For cancellation notifications received 30 days prior to start of the exhibition - 20% of payments received will be non-refundable. Notifications received between 14-29 days prior to the start of the of the exhibition - 50% of payments received will be non-refundable; Notifications of cancellation received less than 14 days prior to the start of the exhibition – all payments received will be non-refundable. Failure to arrive up to an hour prior to the exhibition opening, will result in the loss of your right to the exhibition area and exhibition, and will be considered as a cancellation by you of your participation, and we will have the right to use the exhibition area as we decide.

For more information contact
Vanessa Fisher
US: +1-857-400-0035
UK: Tel/Fax: +44-203-051-4032
E-mail: vanessa@bioevents.net
Website: www.wctd2016.com

Bioevents
Sharing Biomed knowledge

WCTD 2016