
The VIth International Symposium on Biopharmaceutical Statistics

ISBS2019

Sponsorship and Exhibition Opportunities Brochure

Co-chaired by

Jie Chen

Merck & Co., Inc.

Toshimitsu Hamasaki

National Cerebral and Cardiovascular Center

Satoshi Morita

Kyoto University

Date: August 26 - 30, 2019

Venue: Kyoto International Conference Center

Website: <https://www2.aeplan.co.jp/isbs2019/>

Sponsorship and Exhibition Opportunities for ISBS2019

Invitation to Sponsors and Exhibitors

The International Society for Biopharmaceutical Statistics (ISBS), a non-profit statistics organization, is pleased to invite you to sponsor our VI international symposium on biopharmaceutical statistics (ISBS2019) on August 26 - 30, 2019, in Kyoto, Japan.

The purpose of the symposium is to bring together statisticians, quantitative scientists, medical product development professionals and regulators across the world to share and exchange information, experiences, challenges and research findings, and to promote international standards for statistical practice in the biopharmaceutical industry. The theme of the 2019 symposium is "Statistical Innovation and Contribution in the Era of Precision healthcare".

The ISBS2019 is offering sponsorship opportunities to support this important event, to market and showcase your products, services and achievements to an international audience of over 500 statistics-related researchers in the life sciences, including academia statisticians and faculty, biopharmaceutical statisticians, regulators and epidemiologists.

Your sponsorship will permit to increase the attractiveness of the ISBS2019 and will give you the opportunity to meet your target audience. We look forward to seeing you at the ISBS2019 in Kyoto.

Contacts and Information

Fundraising Committee

Jie Chen	Merck & Co., Inc. E-mail: jie_chen@merck.com
Toshimitsu Hamasaki	National Cerebral and Cardiovascular Center E-mail: toshi.hamasaki@ncvc.go.jp
Norisuke Kawai	Pfizer Japan Inc. E-mail: Norisuke.Kawai@pfizer.com
Akira Wakana	MSD K.K. E-mail: akira.wakana@merck.com

Website <https://www2.aeplan.co.jp/isbs2019/index.html>

e-mail address isbs2019@aeplan.co.jp.

Conference Schedule

The conference will include one full-day and five half-day short courses on August 26, and four keynote lectures, 20 invited sessions, 80 topic-contributed and contributed sessions, one poster session and three featured sessions in regulatory science on August 28-31. Social events will include a welcome mixer (August 27) and a conference dinner (August 29). The information on keynote lectures, invited sessions and short courses will be published on the website

(<https://www2.aeplan.co.jp/isbs2019/index.html>).

	Pre-Conference	Main Conference			
	Monday August 26	Tuesday August 27	Wednesday August 28	Thursday August 29	Friday August 30
Morning		Opening and Welcome			
	Short Courses	Keynote/ Plenary Sessions	Keynote/ Plenary Sessions	Keynote/ Plenary Sessions	Keynote/ Plenary Sessions
	Stretch Break	Refreshment Break			
	Short Courses	Scientific Sessions	Scientific Sessions	Scientific Sessions	Regulatory Sessions
Afternoon	Lunch Break	Lunch Break			
	Short Courses	Scientific Sessions	Scientific Sessions	Regulatory Sessions	
	Stretch Break	Refreshment Break			
	Short Courses	Scientific Sessions	Scientific Sessions	Regulatory Sessions	
Evening		Poster Session and Welcome Mixer		Conference Dinner	

Scientific Topics

The symposiums will cover a broad range of topics from discovery, early development, clinical trials, post-licensure life-cycle management of biopharmaceutical products including drugs, biologics, medical devices, and biotechnological products. The symposium will also include a regulatory mini-symposium bringing together major regulatory bodies to discuss regulatory sciences and related topics. Specifically, the ISBS2019 covers the following topics in statistics, quantitative science, and regulatory science:

- pre-clinical research & discovery,
- PK/PD modeling and simulations,
- chemistry, manufacturing and control (CMC),
- design and analysis of clinical trials,
- pharmacoepidemiology and safety,
- pharmacogenomics, pharmacogenetics and system biology,
- regulatory sciences,
- biopharmaceutical globalization,
- real world data, real world evidence and decision analytics,
- statistical programming, computation, and simulation,
- information and statistical consulting

Important Dates

Call for topic-contributed session proposals	15 January 2019
Call for contributed abstracts (oral/poster)	31 March 2019
Notification of acceptance of topic-contributed session proposals	28 February 2019
Notification of contributed abstracts acceptance (oral/poster)	15 May 2019
Deadline for early bird registration	31 May 2019
Deadline for all abstracts	30 June 2019
Conference	26-30 August 2019

Advisory Board

Frank Bretz
Novartis AG

Yutaka Matsuyama
University of Tokyo

Yasuo Ohashi
Chuo University

Scientific Program Committee

Yuki Ando
Pharmaceuticals and Medical Devices Agency

Scott Berry
Berry Consulting

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Food and Drug Administration

Seung-Ho Kang
Yonsei University

Florian Klinglmueller
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Pfizer Inc

Guo Tong
QVIA

Mey Wang
The Center for Drug Evaluation

William Wang
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Novartis Institutes for BioMedical Research

Haiyan Xu
Johnson and Johnson

Guosheng Yin
The University of Hong Kong

Ying Yuan
University of Texas MD Anderson Cancer Center

Helen Zhang
University of Arizona

Sarah Zohar
Centre de Recherche des Cordeliers

Short Courses Committee

Martin Posch
Medical University of Vienna

Wenjin Wang
Pfizer Inc.

Fundraising Committee

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Akira Wakana
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Local Organizing Committee

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Kentaro Sakamaki
University of Tokyo

Masataka Taguri
Yokohama City University

Fumihiko Takahashi
Mitsubishi Tanabe Pharma Corp

Ryuji Uozumi
Kyoto University

Keynote Speakers

Tze Leung Lai, Stanford University

Robert Hemmings, Medicines and Healthcare products Regulatory Agency

TBD

TBD

Short Courses

Missing Data Analysis in Clinical Trials Using SAS®

Instructor (s): **G. Frank Liu**, Merck, Sharp & Dohme, Corp; **Fang Chen**, SAS Institute Inc.

Confirmatory Adaptive Designs with Multiple Objectives: Methods and Regulatory Experiences

Instructor (s): **Frank Bretz**, Novartis AG; **Franz König**, Medical University of Vienna; **H.M. James Hung**, Food and Drug Administration; **Martin Posch**, Medical University of Vienna

Accelerating Drug Discovery through Precision Medicine and Innovative Designs: Concepts, Rationale, and Case Studies

Instructor (s): **Sandeep M Menon**, Pfizer Inc.; **Weidong Zhang**, Pfizer Inc.

Novel Adaptive Clinical Trial Designs for Immunotherapy and Modern Drug Development

Instructor (s): **Ying Yuan**, University of Texas MD Anderson Cancer Center; **Guosheng Yin**, University of Hong Kong; **Cong Chen**, Merck & Co., Inc.

Artificial Intelligence for Medicine and Health

Instructor (s): **Mark Chang**, Boston University

Hot Topics in Clinical Trials: Multiple Outcomes and Benefit:risk

Instructor (s): **Scott R Evans**, George Washington University; **Toshimitsu Hamasaki**, National Cerebral and Cardiovascular Center

Invited Sessions

Enhancing Regulatory Decision Making to Support Drug Development: US FDA Pilot Programs on Complex Innovative Designs and Model-Informed Drug Development

Organizer(s): **Olga Marchenko**, Bayer; **José Pinheiro**, Johnson & Johnson

Statistical Designs and Considerations in Early Clinical Development

Organizer(s): **Chin-Fu Hsiao**, National Health Research Institutes

Recent Development and Challenges in Bioequivalent or Biosimilar assessment

Organizer(s): **Seung-Ho Kang**, Yonsei University; **Hsiao-Hui Tsou**, National Health Research Institutes

Rethinking Estimators within the Estimand Framework

Organizer(s): **Dong Xi**, Novartis Pharma

Demystifying Estimands for Life History Processes

Organizer(s): **Jiawei Wei**, Novartis Institutes for BioMedical Research

Use of Machine Learning and AI for Precision Medicine in Drug Development

Organizer(s): **Ivan SF Chan**, AbbVie

Adaptive Designs for Small Population Clinical Trials

Organizer(s): **Frank Bretz**, Novartis AG

Statistical Issues and Methods for Vaccine Development

Organizer(s): **Frank Liu**, Merck & Co., Inc.; **Jie Chen**, Merck & Co., Inc.

Recent Development on Missing Data Issues under ICH E9 (R1) Estimand Framework

Organizer(s): **Frank Liu**, Merck & Co., Inc.; **Jie Chen**, Merck & Co., Inc.

Methodology Research for Biopharmaceutical Industry

Organizer(s): **Frank Liu**, Merck & Co., Inc.; **Jie Chen**, Merck & Co., Inc.

Some Innovative Clinical Trial Designs in CNS and Renal Diseases

Organizer(s): **Toshimitsu Hamasaki**, National Cerebral and Cardiovascular Center; **H.M. James Hung**, Food and Drug Administration

Statistical Methods in Drug Development

Organizer(s): **Hongyuan Cao**, Florida State University

Innovative Approaches for Trial Design and Analysis

Organizer(s): **Jie Chen**, Merck & Co., Inc.

Issues in Adaptive and Complex Clinical Trial Design

Organizer(s): **Franz König**, Medical University of Vienna

Oncology Trials with Non-Proportional Hazards

Organizer(s): **Franz König**, Medical University of Vienna; **Martin Posch**, Medical University of Vienna

Statistical methodology for the comparative assessment of quality attributes

Organizer(s): **Florian Klinglmueller**, Austrian Medicines & Medical Devices Agency

Bayesian Methods in Medical Product Development

Organizer(s): **Satoshi Morita**, Kyoto University

Harmonization of Model-Informed Drug Development Approaches in Regulatory Review and Decisions

Organizer(s): **Olga Marchenko**, Bayer; **José Pinheiro**, Johnson & Johnson

Estimand, Missing Data, and Sensitivity Analysis

Organizer(s): **Mey Wang**, Center for Drug Evaluation

Industry Leadership Panel Discussion

Organizer(s): **Jie Chen**, Merck & Co., Inc.

Partnership Categories

Sponsors will be given a sponsorship category according to the overall contribution to the ISBS2019 (direct financial support, advertisements, etc.) and exhibition space booked, as follows:

<p>Platinum Partners JPY 324,000 (including tax)</p>
<p>Privileges Platinum partner will have their logos prominently displayed on the almost all pages of the ISBS2019 website except registration and abstract submission pages. Prominent organization’s signage is displayed at the venue.</p> <ul style="list-style-type: none"> ● Organization’s signage at the venue such as registration, main hall and coffee break area. ● Organization’s logo on the almost all pages of the website and hyperlink form the website directly to your website. ● One full-page advertisement in the program which is available to download from the website. ● First-priority placement in exhibition area if you apply for the exhibition. <p>If you would like to apply for the exhibition, application form is different from sponsor one.</p>
<p>Gold Partners JPY 216,000 (including tax)</p>
<p>Privileges Gold partner will have their logos on the top page of the ISBS2019 website and organization’s signage is displayed at the venue.</p> <ul style="list-style-type: none"> ● Organization’s signage is displayed at registration area ● Organization’s logo will be displayed on the top page of the website.
<p>Silver Partners JPY 108,000 (including tax)</p>
<p>Privileges Silver partner will have their logos on the top page of the ISBS2019 website.</p>

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Application Form for Platinum, Gold and Silver Partners

- Application Deadline: June 14th, 2019-

Date: _____

We hereby apply for the Sponsorships below.

Sponsorship category

- Platinum Partner
 Gold Partner
 Silver Partner

Organization Information

Organization name: _____
 Address: Street: _____
 City: _____ State/Province _____
 ZIP: _____ Country _____

Person in charge:

Name First Name _____
 Last Name _____
 Title _____
 Department: _____
 Telephone _____
 Fax _____
 E-mail: _____

Please fill out the application form and send it to the secretariat (A&E Planning co., Ltd) by fax or e-mail below. An invoice will be sent to you by e-mail within a week of receiving. In case you do not hear from us, please let us know as soon as possible.

Cancellation after application cannot be accepted. Please note that your application is confirmed upon full payment. No refund after the payment.

Send to: A&E Planning Co., Ltd.
 Fax: +81-3-3230-2479
 E-mail: isbs2019@aeplan.co.jp

Sponsorship Opportunities

1. Short Courses /Scientific Invited Sessions

Short courses/invited sessions are a highlight of the meeting and draw large numbers of attendees. The sponsor's name will be listed at the selected session on the website, in the final program and the sponsor will be introduced at the start of the session.

Please note that this does not give the sponsor any control over the content of the session. Dates and times for each session will be posted as they become available

Short Course JPY 54,000 per session
 Invited Session Sponsor: JPY 108,000 per session

2. Student and Early Career Travel Awards

Help support students and recent graduates who would otherwise not be able to attend because of travel costs.

Travel Award..... JPY 32,400 per award

3. Conference Dinner

Enjoy an evening filled with networking and sharing opportunities during a delicious plated meal following an informal reception.

Conference Dinner JPY 54,000

4. Poster Session and Opening Mixer

Poster sessions are a highlight of the meeting and draw large numbers of attendees. Sponsorship will provide for light meals and beverages to accompany the poster session. Sponsors will be recognized in the program and with onsite signage.

Poster Session and Opening Mixer JPY 108,000

5. Refreshment & coffee Breaks

Refreshments breaks provide a great opportunity for attendees to network and socialize in a relaxed environment. Breaks are offered in the morning and afternoon between concurrent sessions. Sponsors will be recognized in the program and with onsite signage.

Refreshment Break Sliver JPY 54,000
 Refreshment Break Gold JPY 108,000
 Refreshment Break Platinum JPY 162,000

*Platinum Sponsor's signage will be displayed first and the largest in size, and Gold and Silver sponsors' ones will come next.

6. Lunch Break

Lunch breaks provide a great opportunity for attendees to network and socialize in a relaxed environment. Sponsors will be recognized in the program and with onsite signage.

Lunch Break Sliver JPY 54,000
 Lunch Break Gold JPY 108,000
 Lunch Break Platinum JPY 162,000

*Platinum Sponsor's signage will be displayed first and the largest in size, and Gold and Silver sponsors' ones will come next.

7. Attendee Wi-Fi

Attendees will be able to multitask with your support of Wi-Fi. Your logo will be prominently featured on onsite signage and in program materials.

Wi-Fi: JPY 378,000

*The number of to be accepted: 1 organization only

*The number of to be accepted: 3 organizations

8. Conference Digital Advertisement

Your digital ad (30 second) will be displayed on electronic displays in high-traffic areas of the conference, including the registration area, the keynote session, and the exhibit area.

Conference Hall Screen Advertisement JPY 162,000

*The number of to be accepted: 8 organizations

9. Onsite Advertisement

Provide us with your organization’s insert, and we will include them in the conference bag for each registrant. This is a highly visible marketing option.

Onsite Advertisement 162,000JPY

*The number of to be accepted: 5 organizations

*The number of pages of insert is up to 4.

10. Badge Lanyards

Your logo will be prominently displayed on this lanyard used by attendees to hold their name badges and tickets.

Badge Lanyard..... 216,000JPY

*The number of to be accepted: 1 organization

11. Conference Bag

Take advantage of one of the most prominent sponsorship options available. Your logo will be on the conference bag given to every registrant.

Conference Bag 216,000JPY

*The number of to be accepted: 1 organization only

Note: The above each fee includes the consumption tax.



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Application Form for Sponsorship Opportunities

- Application Deadline: June 14th, 2019-

Date: _____

We hereby apply for the Sponsorship Opportunities below.

Organization Information

Organization name: _____

Address: Street: _____

City: _____ State/Province _____

ZIP: _____ Country _____

Person in charge:

Name First Name: _____

Last Name: _____

Title _____

Department: _____

Telephone _____

Fax _____

E-mail: _____

1. Short Courses /Scientific Invited Sessions

Short courses Sponsor..... JPY 54,000/session

Please specify session name(s) you wish to be a sponsor. The session titles and contents will be announced on the website.

Session's name: _____

Session's name: _____

Scientific Invited Sessions Sponsor Fee: 108,000JPY/session

Please specify session name(s) you wish to be a sponsor. Please refer to the page 6 regarding session titles.

Session's name: _____

Session's name: _____

- 2. Student and Early Career Travel Awards**
Fee: 32,400JPY/award _____award(s)
- 3. Conference Dinner**
Fee: 54,000JPY
- 4. Poster Session and Opening Mixer**
Fee: 108,000 JPY/unit
- 5. Refreshment & coffee Breaks**
 - Refreshment Break Sliver JPY 54,000
 - Refreshment Break Gold JPY 108,000
 - Refreshment Break Platinum JPY 162,000
- 6. Lunch Boxes**
 - Refreshment Break Sliver JPY 54,000
 - Refreshment Break Gold JPY 108,000
 - Refreshment Break Platinum JPY 162,000
- 7. Attendee Wi-Fi**
Fee: JPY 378,000
- 9. Conference Hall Screen Advertisement**
Fee: 162,000JPY
- 10. Onsite Advertisement**
Fee: 162,000JPY
- 11. Badge Lanyards**
Fee: 216,000JPY
- 12. Conference Bag**
Fee: 216,000JPY

Please fill out the application form and send it to the secretariat (A&E Planning co., Ltd) by fax or e-mail below. An invoice will be sent to you by e-mail within a week of receiving. In case you do not hear from us, please let us know as soon as possible.

Cancellation after application cannot be accepted. Please note that your application is confirmed upon full payment. No refund after the payment.

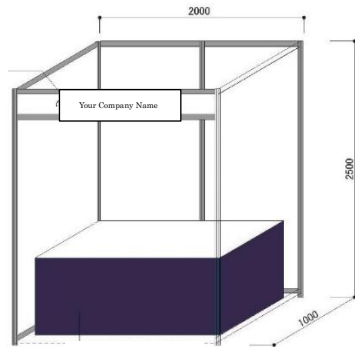
Send to: A&E Planning Co., Ltd.

Fax: +81-3-3230-2479

E-mail: isbs2019@aeplan.co.jp

Exhibition Opportunities

- Exhibition date: August 27 & 28 9:00 - 17:00
August 29 9:00 - 15:00
 - Venue: Kyoto International Conference Center (Room H)
Takaragaike, Sakyo-ku, Kyoto 606-0001 Japan
 - Installation & Dismantle: Installation: August 26 14:00 - 17:00
Dismantle: August 29 15:00 -
 - Application deadline: June 14th, 2019
- *The number of booths available is limited. Please note that an application is not acceptable when there is no vacancy, even if it is before the dead line.



- **Exhibition Fee:** JPY 216,000 / booth
Entry fee & poster mixer for one person are included in the exhibition fee.
※incl. tax & bank transfer commission

- **Electric Power Supply:**
Electricity charge is not included in the exhibition fee. If you need, please apply in addition.
100W-500W ----- JPY32,400
501W-1KW ----- JPY37,800 ※incl. tax
*Using over 1KW, JPY10,800 per 1KW will be added.
200V power supply requires extra charge.

- Size: W2000mm ×D1000mm ×H2500mm
- Furniture:
 - *Display table (W1800 X D900 X 750mm)
Covered with cloths in white
 - *Organization's name board
 - *Fluorescent light (40W)
 - *Exhibitor's Badges :2 Badges

● How to apply:

Please fill out the application form on the next page and send it to the secretariat (A&E Planning co., Ltd) by fax or e-mail below.

An invoice will be sent to you by e-mail within a week of receiving. In case you do not hear from us, please let us know as soon as possible.

Please note that your application is confirmed upon full payment.

No refund after the payment.

◆Cancellation Policy

Cancellation after application cannot be accepted. Exhibition fee is required to be paid even if they do not participate.

The VIth International Symposium on Biopharmaceutical Statistics (ISBS2019)

Application Form for Exhibition Opportunities

- Application Deadline: June 14th, 2019-

Date: _____

We hereby apply for the exhibition as follows.

1. Organization name: _____
- Address: Street: _____
- City: _____ State/Province _____
- ZIP: _____ Country _____

Person in charge:

Name First Name: _____ Last Name: _____

Title _____

Department: _____

Telephone _____ Fax _____

E-mail: _____

2. Booth

The number of booths () booth(s)

Electricity: 100V ()W

Display Table: Necessary Unnecessary

3. Total Amount

Booth fee: JPY _____ Electricity: JPY _____

4. Exhibits details

Exhibits details	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)	Note

Send to: A&E Planning Co., Ltd.
 Fax: +81-3-3230-2479
 E-mail: isbs2019@aeplan.co.jp