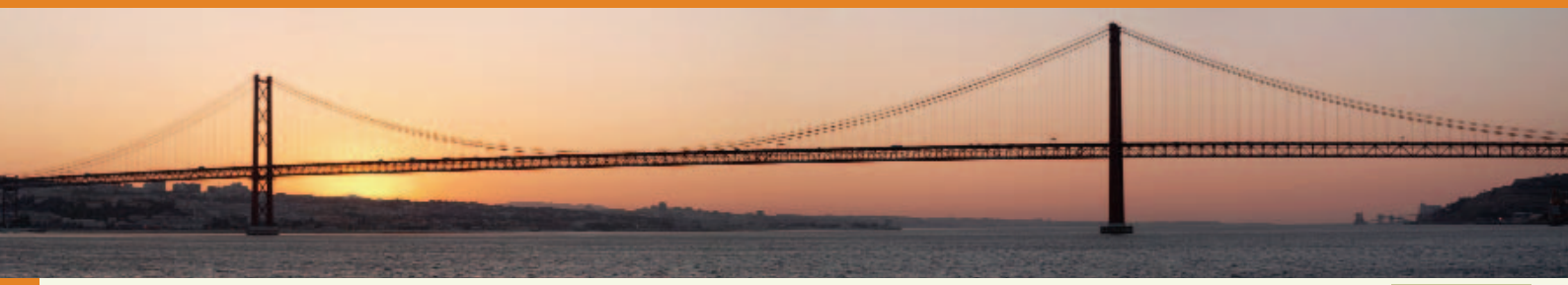


DRUG INFORMATION ASSOCIATION

infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde I.P.

JOINT DIA/INFARMED WORKSHOP ON

EXPLORATORY PHASE I CLINICAL TRIALS (expCTAs) - PRACTICAL EXPERIENCES FROM THE INDUSTRY AND REGULATORY PERSPECTIVES

PROGRAMME COMMITTEE

Vasco Maria
Professor, President, Infarmed, Portugal

Beatriz Silva Lima
Professor, iMEDUL, Infarmed, Portugal

William T. Robinson
Consultant, Novartis Pharmaceuticals Corporation, USA

David Laurie
Regulatory Policy Expert, DRA Management,
Novartis Pharma AG, Switzerland

Per Spindler
Director, BioLogue, University of Copenhagen, Denmark

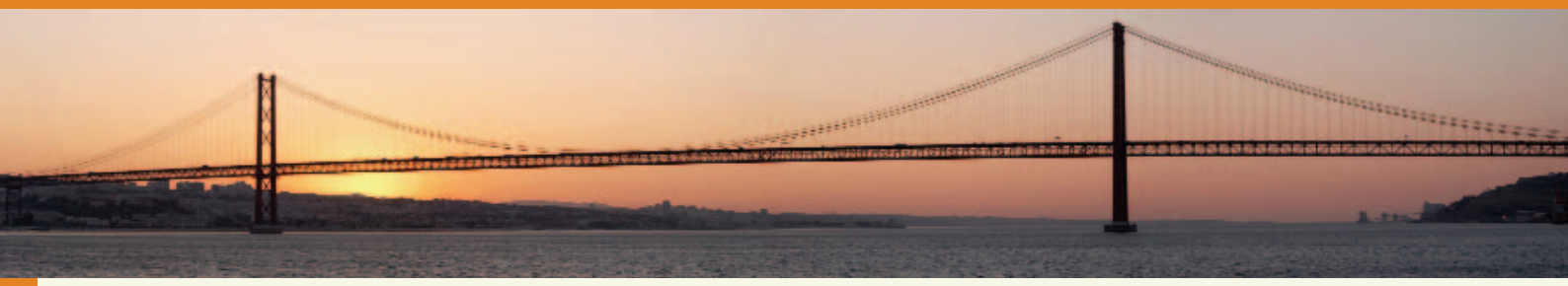
KEY TOPICS

- Objectives of the Project and Justification on 'expCTAs' Approach
- Pre-Clinical Programme and Issues
- Clinical Protocol
- Starting Dose Justification
- Stop Dose Justification/Experiences
- Regulatory Approach
  (What worked, what could be done differently)
- Role for Biologics
- Regulatory Perspectives
- Types and Numbers of CTAs/INDs Filed by Region
- What Industry Could Improve in the Process
- Opportunities for the Future

SCIENTIFIC COMMITTEE

- **Timothy D. Anderson**
  Senior Vice President, Pfizer Inc., USA
- **Joseph DeGeorge**
  Vice President, Safety Assessment, Merck and Company, Inc., USA
- **Chris Jensen**
  Consultant, Speedel Experimenta Ltd., Switzerland
- **Lewis B. Kinter**
  Senior Director, Safety Assessment-US, AstraZeneca, USA
- **David Laurie**
  Regulatory Policy Expert, Novartis Pharma AG, Switzerland
- **Beatriz Silva Lima**
  Professor, iMEDUL, Infarmed, Portugal
- **James Francis McLeod**
  Vice President, Early Clinical Research and Experimental Medicine, Schering-Plough Research Institute, USA
- **Richard Peck**
  Global Head Clinical Pharmacology, Roche, UK
- **William T. Robinson**
  Consultant, Novartis Pharmaceuticals Cooperation, USA
- **Alfred P. Tonelli**
  Vice President, Pre-clinical Drug Evaluation, Johnson and Johnson PRD, LLC, USA
- **Andreas Wallnoefer**
  Global Head of Clinical Research and Exploratory Development, F. Hoffmann-La Roche Ltd., Switzerland
- **Phil Wilcox**
  Vice President, WW Non-Clinical Safety Projects, GlaxoSmithKline, UK

INFARMED, LISBON, PORTUGAL
MARCH 27-28, 2009



PROGRAMME OVERVIEW

Exploratory approaches for first-in-human studies have been available through regulatory guidance in Europe and the USA for the last few years. These approaches have been employed usually with objectives to select a drug candidate for further development or test a biochemical hypothesis using various endpoints designed to make a clear go/no go decision. The purpose of this workshop is to review from both a regulatory and industrial perspective how these approaches have been used – successes, what worked, what did not work - focusing on the applied science and the regulatory process. The expectations are that issues and opportunities can be identified to help improve the ability of industry and regulators to appropriately manage/assess exploratory approaches for small molecules as well as biologics. For those not directly involved with expCTAs, it will be a learning experience on the opportunities offered with this novel approach.

WHO SHOULD ATTEND

- Professionals working in the fields of medicinal product development at the level of Pharmaceutical Industry, Regulatory Agencies, Contract Research Organisations, Ethics and Academia. Also scientists in pre-clinical and/or clinical research, particularly those involved in early clinical trials, project management, regulatory affairs and medical writing.
- Assessors from Regulatory Agencies, particularly those involved in the decision process of clinical trials. This workshop is valuable for professionals in regulatory agencies outside Europe.
- Members from Academia also involved and or interested in the concepts of translational research and translational medicine.

LEARNING OBJECTIVES

At the conclusion of this workshop, participants should be able to:

- Describe the new paradigms for early clinical trials of exploratory nature as described in the revision of the ICH M3 guideline
- Discuss the scope and design of exploratory clinical trials and the supportive non-clinical packages needed
- Identify industrial and regulatory bottlenecks needing to be solved to facilitate expCTAs in Europe and other regions
- Explain the relevance of expCTAs as a driver for clinical research and as a factor of reduction of late attrition in drug development

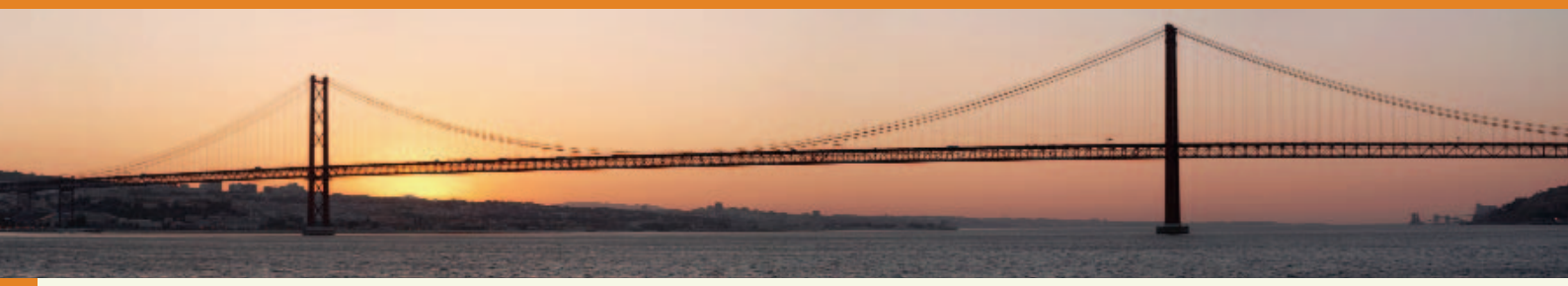
AUTHORIZED IACET PROVIDER

The Drug Information Association (DIA) has been approved as an 'Authorized Provider' by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102.

DIA is authorised by IACET to offer .7 **IACET CEUs** for this programme.
If you would like to receive a statement of credit, you must attend the programme, return your evaluation form and complete the online credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request.

Disclosure Policy

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.



FRIDAY, MARCH 27, 2009

08:00 REGISTRATION AND WELCOME COFFEE

08:30 OPENING REMARKS AND INTRODUCTION
Vasco Maria, Professor, President, Infarmed, Portugal
Beatriz Silva Lima, Professor, iMEDUL, Infarmed, Portugal

Competent Authority Perspectives on expCTAs and Opportunities for Biologics

09:00 SESSION 1
Session Co-Chairpersons:
Vasco Maria, Professor, President, Infarmed, Portugal
Beatriz Silva Lima, Professor, iMEDUL, Infarmed, Portugal

Summary of BfArM Workshop September 2007 and German Perspective
Thomas Sudhop, Head of Clinical Trials and Clinical Inspections Unit, BfArM, Germany

Belgian Experiences and Perspectives
Walter Janssen, Senior Assessor Pre-clinical Department Research & Development Belgian Drug Agency, Federal Agency for Medicines and Health Products, Belgium

UK Experiences and Perspectives
David R. Jones, Expert Scientific Officer, Pharmacotoxicologist, MHRA, UK

10:30 COFFEE BREAK

"Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association."

11:00 SESSION 2
Session Co-Chairpersons:
Chantal Belorgey-Bismut, Head of Clinical Trials and ATU Department, Afssaps, France
Joseph DeGeorge, Vice President, Safety Assessment, Merck, USA

Risk Mitigation for First-in-Man Studies
Beatriz Silva Lima, Professor, iMEDUL, Infarmed, Portugal

FDA Experience with Exploratory INDs
David Carlson, Toxicologist, DMEP, CDER, FDA, USA

An Ethics Committees Experience with expCTAs
Ethics Committee Representative invited

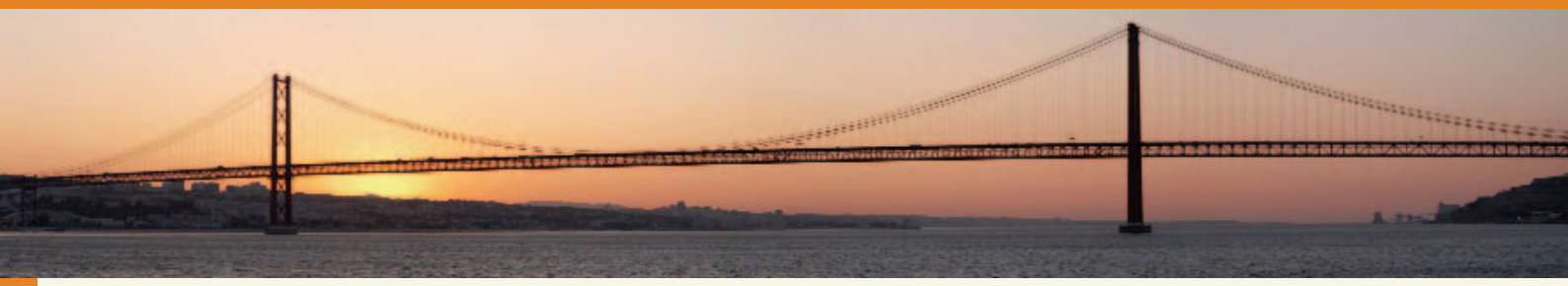
Opportunities for Biologics Using expCTAs
Jennifer Sims, Director Head NBx Translational Sciences and Services, Novartis Pharma AG, Switzerland

12:30 LUNCH BREAK

Industry Experiences by Examples

14:00 SESSION 3
Session Co-Chairpersons:
Phil Wilcox, Vice President, WW Non-Clinical Safety Projects, GlaxoSmithKline, UK
David R. Jones, Expert Scientific Officer, Pharmacotoxicologist, MHRA, UK

- **Dan Meyers,** Translational Medicine Expert, Cardiovascular and Metabolism, Novartis Corporation, USA
- **Clive Joseph,** Senior Director, Safety Evaluation, Pfizer Inc., USA
- **John Wagner,** Director of Clinical Pharmacology, Merck & Co. Inc., USA
- **Chris Jensen,** Consultant, Speedel Experimenta Ltd., Switzerland



SATURDAY, MARCH 28, 2009

Future Challenges and Opportunities

15:40 COFFEE BREAK

16:00 SESSION 3 CONTINUED

Session Co-Chairpersons:
Phil Wilcox, Vice President, WW Non-Clinical Safety Projects, GlaxoSmithKline, UK
David R. Jones, Expert Scientific Officer, Pharmacotoxicologist, MHRA, UK

- **Alfred P. Tonelli,** Vice President, Pre-clinical Drug Evaluation, Johnson and Johnson PRD, LLC, USA
- **Andreas Wallnoefer,** Global Head of Clinical Research and Exploratory Development, F. Hoffmann-La Roche Ltd., Switzerland
- **Phil Wilcox,** Vice President, WW Non-Clinical Safety Projects, GlaxoSmithKline, UK
- **Lewis B. Kinter,** Senior Director, Safety Assessment-US, AstraZeneca, USA

16:40 PANEL DISCUSSION ON INDUSTRY PERSPECTIVES

Session Co-Chairpersons:
Thomas Sudhop, Head of Clinical Trials and Clinical Inspections Unit, BfArM, Germany
William T. Robinson, Consultant, Novartis Pharmaceuticals Corporation, USA

- All Industry Speakers

18:15 ADJOURN FOR EVENING

Beatriz Silva Lima, Professor, iMEDUL, Infarmed, Portugal

09:00 PANEL DISCUSSION ON OPPORTUNITIES FOR THE FUTURE

Session Co-Chairpersons:
Eric Abadie, Chairman, CHMP, EMEA, EU, General Directorate, Afssaps, France
Abby Jacobs, Associate Director for Pharmacology/ Toxicology for Offices of Drug Evaluation ODEs, (CDER)/FDA, USA

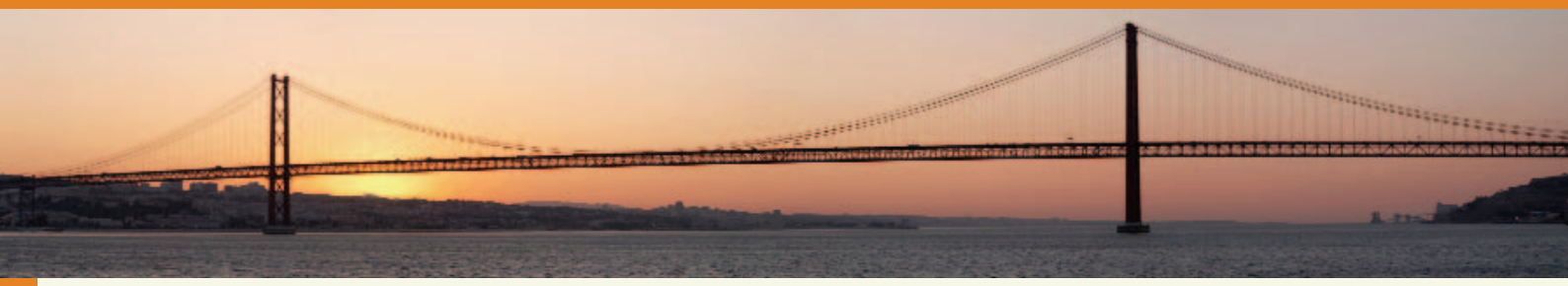
- **Joseph DeGeorge,** Vice President, Safety Assessment, Merck and Company, Inc., USA
- **Phil Wilcox**, Vice President, WW Non-Clinical Safety Projects, GlaxoSmithKline, UK
- **Ethics Committee Representative** invited
- **Bengt Danielsson,** Vice President, PharmaNet Consulting, Sweden
- **Thomas Sudhop,** Head of Clinical Trials and Clinical Inspections Unit, BfArM, Germany
- **Walter Janssens,** Senior Assessor Pre-clinical Department Research & Development, Belgian Drug Agency, Federal Agency for Medicines and Health Products, Belgium

10:00 BREAK-OUT GROUPS

Teams are asked to consider opportunities and issues in conducting expCTAs and propose solutions to move forward in the following areas:

- **Clinical design (PK/PD; SD/MD; Healthy Volunteers/Patients)**
- **Logistics in the Conduct of expCTAs**
- **Non-clinical supportive programmes**
- **Geographical differences**
- **Drug substance requirements (GMP/GMP-like/Tox-Qualified)**
- **Biologics**

"Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association."



BREAK-OUT GROUPS

GROUP 1

Chairperson/Note Taker:
- **Timothy Anderson,** Senior Vice President - Research, Drug Safety R&D, Pfizer Inc., USA
- **David Jones,** Expert Scientific Officer, Pharmacotoxicologist, MHRA, UK

GROUP 2

Chairperson/Note Taker:
- **David Laurie,** Regulatory Policy Expert, DRA Management, Novartis Pharma AG, Switzerland
- **Richard Peck,** Global Head Clinical Pharmacology Roche, UK

GROUP 3

Chairperson/Note Taker:
- **Chris Jensen,** Consultant, Speedel Experimenta Ltd., Switzerland
- **Clive Joseph,** Senior Director, Safety Evaluation, Pfizer Inc., USA

GROUP 4

Chairperson/Note Taker:
- **Lewis B. Kinter,** Senior Director, Safety Assessment-US, AstraZeneca, USA
- **Jennifer Sims,** Director Head NBx Translational Sciences and Services, Novartis Pharma AG, Switzerland

GROUP 5

Chairperson/Note Taker:
- **Alfred P. Tonelli,** Vice President, Pre-clinical Drug Evaluation, Johnson and Johnson PRD, LLC, USA
- **James Francis McLeod,** Vice President, Early Clinical Research and Experimental Medicine, Schering-Plough Research Institute, USA

11:30 PLENARY REPORTING OF PROPOSALS BY BREAK-OUT GROUPS

Chairperson:
Beatriz Silva Lima, Professor, iMEDUL, Infarmed, Portugal

12:30 CLOSING OF WORKSHOP

TRAVEL INFORMATION

Lisbon is easy to get to. It is a short flight away from most European cities, and is just as easily accessible by road, railway or sea. Lisbon International Airport, 7 km from the city centre, has daily flights to and from the major cities in Europe and the world. The Portuguese airlines TAP - Air Portugal and PGA - Portugália Airlines, as well as major international airlines and low cost carriers, fly to and from Lisbon.

IMPORTANT INFORMATION:

Passports must be valid for up to six months. Citizens from the European Community do not need a Visa. Please check with your consulate/embassy as to whether a VISA is required.

HOTEL INFORMATION

Hotel reservation information will be available from January 19, 2009.

Please visit:

http://www.diahome.org/DIAHOME/Education/FindEducationalOffering.aspx?productID=18572&eventType=Meeting&rpex=N&kw=09102&sdt=12-16-2008 and click on the travel/hotel information tab.

All reservations should be made with the hotel(s) directly, DIA does not process hotel reservations.

FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52

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Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET, or email diaeurope@diaeurope.org

REGISTRATION FORM - ID# 09102

Joint DIA/Infarmed Workshop on Exploratory Phase I Clinical Trials (expCTAs), Practical Experiences from the Industry and Regulatory Perspectives

Infarmed, Lisbon, Portugal - March 27-28, 2009

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration includes conference material and refreshment breaks for the value of € 400.00.

Registration will be accepted by mail, fax, email or online at www.diahome.org

Early-Bird rates available for Members:
Deadline on or before February 13, 2009

Join DIA now to qualify for the early-bird member fee! To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.
Does not apply to government/academia/nonprofit members

Early-Bird Fee (on or before February 13, 2009)	Fee	VAT 20%	TOTAL
Join DIA now to qualify for the Early-Bird Rate	€ 130.00	n/a	€ 130.00 ❑
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Industry	€ **950.00**	€ 190.00	€ 1'140.00 ❑
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Non-Member (with optional membership)	FEE	VAT 20%	Membership	TOTAL
Industry	€ **950.00**	€ 190.00	€ 130.00	€ 1'270.00 ❑
Charitable/Non-profit/Academia (Full-Time)	€ **713.00**	€ 142.60	€ 130.00	€ 985.60 ❑
Government (Full-Time)	€ **475.00**	€ 95.00	€ 130.00	€ 700.00 ❑

Non-Member (without optional membership)	FEE	VAT 20%	TOTAL
Industry	€ **1'080.00**	€ 216.00	€ 1'296.00 ❑
Charitable/Non-profit/Academia (Full-Time)	€ **843.00**	€ 168.60	€ 1'011.60 ❑
Government (Full-Time)	€ **605.00**	€ 121.00	€ 726.00 ❑

❑ **TOTAL AMOUNT DUE:** € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the event

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- ❑ CL - Clinical Laboratory Data
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- ❑ CS - Clinical Supplies
- ❑ DC - Dictionaries / Data Standards
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- ❑ GM - GMP
- ❑ IM - Information Management
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- ❑ MC - Medical Communications / Information
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- ❑ MN - Manufacturing: Drug Substance, Drug Product, Packaging
- ❑ MW - Medical / Scientific Writing
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❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payment should be in EURO and your name and company, as well as the Meeting ID# 09102 and invoice number, must be included on the transfer document to ensure correct allocation of your payment. **Payments must be net of all charges and bank charges must be borne by the payee.**

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All cancellations must be in writing and be received at the DIA office by 17:00 CET on March 22, 2009

Cancellations received in writing on or before March 22, 2009 – Cancellations received by the date above are subject to an administrative fee: Full Meeting Cancellation: Member/Non-member = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00. Registrants who do not cancel by the date above, and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. DIA reserves the right to alter the venue if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Transfer Policy
You may transfer your registration to a colleague prior to the workshop start but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA.
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