Facilitating Innovation for Better Health Outcomes

46th DIA Annual Meeting
June 13-17, 2010
Walter E. Washington Convention Center • Washington, DC

PROGRAM CHAIRPERSON
Gaby L. Danan, MD, PhD
sanofi-aventis, France
June 2009

Dear 2010 Annual Meeting Session Chair,

The 46th Annual Meeting Session Chair Resource Guide is provided to you as a reference guide to DIA's policies related to the development of sessions, speaker recruitment, and overall timeline schedule for the Annual Meeting program.

The contents of this guide include 5 tabs that detail the following:

- 2010 Annual Meeting Program Committee Contact List
- Session Chair Responsibilities, DIA Policies and Procedures and DIA Volunteer Code of Conduct
- 2010 Annual Meeting Program Development Timeline
- Guideline Summary for Track and Session Chairperson, Continuing Education Summary, and a helpful question and answer document describing the purpose of Disclosure Statements
- DIA’s Policy Concerning Promotion of Products and Services from the Podium at DIA-Sponsored Programs

While this guide is not inclusive of all information related to the Annual Meeting, we hope that the information provided will guide you as you communicate with your Session Chairs and Speakers that are involved in your Track.

Your support in the development of this program, ensuring the quality and standards of the Drug Information Association are implemented are greatly appreciated.

We look forward to working with you in the coming months.

Sincerely

The 2010 DIA Annual Meeting Team

Dr. Gaby L. Danan
46th Annual Meeting Program Chairperson

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There are 25 tracks that define the DIA Annual Meeting Program. The following summaries suggest issues and topics that the program committee would like to have addressed and should serve as a valuable guide as you develop your session abstracts.

**AD—Advertising**
The topics relate to the advertising and promotion of pharmaceuticals and how marketing/advertising materials and programs are regulated by regulatory authorities, including:
- FDA enforcement activities
- Policies involving CME, off-label uses, DTC advertising, and promotional programs
- Justice Department, US Attorney’s Offices, and OIG activities to pursue fraud and abuse cases

**BT—Biotechnology**
The biotechnology track will present topics related to discovery and early development of novel products including:
- Somatic and stem cell therapies: science, ethics, politics
- Quality-by-design, risk-based approaches for manufacturing biotechnology products
- Follow-on and improved biologics; lessons learned for forging a path forward
- Novel vaccine strategies

**CMC/GMP—Chemistry, Manufacturing, and Controls/Good Manufacturing Practices**
Abstracts should contribute to the dialogue and discussion on technical and regulatory issues related to:
- Risk-based regulatory oversight
- Use of quality risk management (QRM) in pharmaceutical development
- Implementation of real-time release testing
- Knowledge management over the entire pharmaceutical product life cycle from development to commercialization
- Science and risk-based CMC and GMP initiatives
- Quality-by-design approaches to pharmaceutical development
- Updates on ICH quality guidances and FDA’s recent CMC and GMP guidances
- Scientific challenges in technology transfer from laboratory to pilot to production scales
- Regulatory challenges in global CMC submissions
- Modern regulatory analytical methods and manufacturing controls

**CROs and CDM**

**CDM—Clinical Data Management**
Abstracts should focus on topics triggering discussions among the speakers and with the audience. Sessions should cover current challenges in the area of CDM, addressing controversial topics and those covering future directions CDM may or will take.

**CR/CS—Clinical Research/Clinical Supplies**
Clinical Research abstracts should address topics related to:
CR abstracts should address:
- Managing clinical research in times of constraint – doing more with less
- Evolving technology in Clinical Research management (including social networking e.g. Twitter, Facebook, etc)
- Cracking the globalization code – how to do it smarter, faster, better while still conforming to evolving regulatory framework
- Transitioning from conservative/traditional methods to an innovative approach to conducting clinical trials – who’s doing what?
- Conducting Clinical Trials in a virtual or semi-virtual environment
- Assessing and measuring performance in clinical research – a focus on quality and efficiency

Clinical Supplies abstracts should address:
- Leading-edge technologies to improve the efficiency and logistics of the clinical supply chain
- Information technology to streamline communication between CR and CS
- Procedures to minimize the traditional overage of CS needed to conduct clinical trials

**CP—Clinical Safety and Pharmacovigilance**
The practice of clinical safety and pharmacovigilance includes many opportunities that cover a wide and ever-increasing range that ultimately enhances the safe use of products for the patient.

The underlying theme of this track will be to assess current opportunities and approaches in the optimization of benefits and minimization of risks of medicines and medical devices to patients who need these medical interventions. Dialogue and future vision for the protection of patient safety will be encouraged.

Topics include:
- New and emerging safety regulations, including reports on CIOMS and ICH topics
- Practical aspects of safety data management and safety databases, and safety sourcing (outsourcing, offshoring, etc)
- Implications of and solutions to collaborations between companies (various licensing, co-development and co-promotion situations,
Archiving of information created
- Standards, policies and procedures
- Development of technology
- EEC–eClinical
- Systematic reviews and meta-analyses
- Comparative effectiveness reviews

Document Management
- Global eSubmissions: EU, US, Canada, Japan – regional variations
- SEND – current status and impact
- EDQM – European bioequivalence guidelines

IT–Information Technology
- The Information Technology track focuses on the technologies and techniques necessary to build and maintain the equipment, software, and skills infrastructure to support our industry. We present a mix of leading-edge research and recent project work within these subject areas.
- Members and their teams are welcome and encouraged to submit and share their IT experiences with their colleagues.

GCP–Good Clinical Practices
- Abstracts should address topics related to auditing, domestic and international GCP, clinical trial disclosure, enterprise quality risk management, and process excellence. The quality assurance professional is an important member of the clinical trials team, providing regulatory compliance activities to prevent and/or resolve issues that may arise during the conduct of a clinical trial. Clinical Trial Disclosure professionals provide guidance and activities ensuring compliance with disclosure of clinical trial protocol and results information. We strongly encourage thought-provoking session abstracts that provide real case studies and examples of practical issue management and issue resolution.

MC–Medical Communications
- Session abstracts should address topics related to the practice and provision of drug or medical information as it relates to internal business partners or external customers (including healthcare professionals and consumers). Topics may include, but are not limited to:
- Provision of on-label and off-label information
- Response document creation and maintenance
- Literature evaluation
- Contact center issues

MA–Marketing
- Abstracts should address the following topics.
- Life cycle management
- Portfolio analysis/techniques
- Market preparation

EC–eClinical
- eClinical session abstracts should focus on the following topics:
- Development of technology
- Standards, policies and procedures for the reporting, capture, analysis, submission
- Archiving of information created both internally and across the broader healthcare system during the process of clinical development
- New proposals and reports of methodologies and experiences with evolving standards and technologies are encouraged

ERS/DM–Electronic Regulatory Submissions/Document Management
- Session abstracts should address areas of strong interest to attendees associated with electronic regulatory submissions. We expect attendance by electronic regulatory submission development professionals, as well as professionals associated with the management of active electronic document/record collections and archives. Appropriate topics may address one or more of the following hot-topic areas.
- Electronic submissions – impact of format/process changes
- eLabeling: SPL, PIM, eDRL, PLR – challenges and opportunities
- eSubmission standards: eSignatures, RPS, SDRAM, AcaM, SEND – current status and impact
- Global eSubmissions: EU, US, Canada, Japan – regional variations
- eCTD life cycles within and across applications – management in the real world
- Regulatory authority readiness and future directions
- eRecords collaboration – The EDM Reference Model project
- Managing electronic collections – emerging technological advances
- Metadata for Advantage in eCollections
- Content management – enhancing the user experience

EBM–Evidence-based Medicine
- This track focuses on current issues related to the generation, systematic evaluation of evidence-based medicines, and impact of medical products on health outcomes, patient-reported outcomes, and health expenditures in clinical practice and drug coverage issues.
- Examples of clinical guideline development, comparative effectiveness, and the use of actual case examples are strongly encouraged.
- Suggested topics include:
  - Methods for evidence generation and synthesis for evidence-based medicine
  - Comparative effectiveness reviews
  - Systematic reviews and meta-analyses for guidelines development
  - Pragmatic clinical trials
  - Health outcomes and health economics studies
  - Medical communication and evidence dissemination strategies for evidence-based medicine

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- Literature evaluation
- Contact center issues
**MW—Medical Writing**
The focus of this track will be on sharing experiences and best practices, defining skills required, and the impact of changes in this global environment.

Topics include:
- CONSORT Guidelines and Abstract Checklist
- ICH E3 guidance
- MW competencies
- eINDs to eCTDs

**NC—Nonclinical Laboratory Safety Assessment**
The nonclinical laboratory safety assessment track will focus on emerging scientific and regulatory issues related to the assessment of the safety of regulated products.

Topics for abstracts include:
- New methodologies and experimental techniques and current guidance on their use in preclearance testing
- ICH updates (S6, S9, M3)
- Laboratory studies evaluating pharmacokinetics and effectiveness of products, biomarkers of toxicity, predictive pharmacology, predictive models for preclinical safety, and animal disease models
- Use of non-animal alternatives in pharmaceutical development
- New methods for/ evaluation of/ an integrated assessment and labelling for repro/developmental toxicology

**NHP—Natural Health Products**
The natural health products track will represent complex or “poly molecular” products and ingredients from any source.

Abstracts should relate to:
- Key to new NHP regulatory applications and approvals
- New botanical drug health claims, marketing and registration
- Targeted disease approach
- Safety perspectives in NHP including how to avoid adulteration to achieve optimal safety
- New dimensions in NHP regulations
- Good clinical practices in NHP development

**OS—Outsourcing**
Abstracts should address topics related to the outsourcing of activities in connection with the drug development process. Session chairs are encouraged to include the use of case studies of successes (as well as less successful case studies) with any of these topics.

- Clinical research
- Investigative sites
- Project management

**PM/FI—Project Management/Finance**
The PM/FI track is designed to assist Project/Program Managers, Portfolio Planners, Alliance Managers, Project Leaders, and Finance Managers/associates stay abreast of the principles, practices, and trends associated with applied project and portfolio management and financing of drug development in the Pharmaceutical and Biotechnology industries. In addition, the program will consider evolving methods for managing portfolios and getting the most out of limited resources, and explore approaches to maximizing the effectiveness of alliances and collaborations across our industry.

- Specific application and best practices in the planning, scheduling, execution, risk management, and leadership of drug development projects
- Integrating Project, Portfolio and Finance management in large and small organizations – use of PMO’s, enterprise-wide systems, value-driv- en portfolio management, and practical approaches to budgeting and capacity management
- Best practices in developing, leading, and enabling high performance teams
- Training, development and accreditation of Project Managers in the Biopharmaceutical Industry
- Effective partnering/contracting with CROs
- Alliance Management: trends & best practices

**PD/TR—Professional Development/Training**
Sessions should focus on new, updated, or redesigned ideas and techniques that can be applied to the training, education, and development of pharmaceutical professionals. Models should include novel approaches to long-standing problems, identification of emerging trends, and ways to take advantage of new technologies to advance the boundaries of traditional training and education.

These should highlight or focus on:
- Global training and education strategies
- Career development strategies in the changing global environment
- eLearning, online training, and distance learning strategies
- Training in multicultural environments
- Educating the next generation of pharmaceutical professionals
- Use of metrics for decision making
- Identification of emerging regulatory issues

**PP—Public Policy/Law/Corporate Compliance**
Topics should relate to issues and concerns in the following areas:

- Liability
- Intellectual property
- Legislation (current and future) regarding: approval (authorization), manufacturing, exportation/importation, licensing, prescribing, competition, pricing, and/or reimbursement

**RA—Regulatory Affairs**
Session topics should include drugs and biologics and developments on recent legislative initiatives concerning emerging therapies, without neglecting the field of medical devices and combination products. The track tends to be 50% “international” by design, so as to reflect the strong globalization and harmonization trends of today.

Perspectives in practical, everyday issues, case studies, innovative approaches, and challenges of today or tomorrow in the following topics include:

- Strategic regulatory issues and approaches
- Social and economic issues that impact the regulatory process
- The perspective of governmental regulators
- Political and regulatory environment

**RD—R&D Strategy**
This track focuses on strategic issues that relate to R&D performance, the external environment, and overall corporate strategy.

Topics include:
- Efforts to improve R&D efficiency
- Economics of pharmaceutical development
- How changes in company structure and organization affect performance
- Impact of new regulatory initiatives
- External forces that influence industrial R&D
- Use of metrics for decision making at various levels

- Technical and commercial risk in R&D development: Will personalized medicines help or hurt?
- Industry-academia collaborations under the new conflict-of-interest scrutiny: How are we managing?
- Translational medicine: Emergent field or fading fad?
- Are biomarkers streamlining or complicating R&D?
For the 46th DIA Annual Meeting, several tracks will collaborate to form the following mega tracks:

- Advertising/Marketing/Medical Communications Mega Track
- Clinical Research Mega Track
- Information Technology Mega Track

**ADVERTISING/MARKETING/MEDICAL COMMUNICATIONS MEGA TRACK**

The following tracks are included in the Advertising/Marketing/Medical Communications Mega Track:
- AD-Advertising
- MA-Marketing
- MC-Medical Communications

**CLINICAL RESEARCH MEGA TRACK**

The following tracks are included in the Clinical Research Mega Track:
- AHC/IS-Academic Health Centers/Investigator Sites
- CR/CS-Clinical Research and Development/Clinical Supplies
- OS-Outsourcing
- PM/FI-Project Management/Finance

**INFORMATION TECHNOLOGY MEGA TRACK**

The following tracks are included in the Information Technology Mega Track:
- CDM-Clinical Data Management
- EC-eClinical
- ERS/DM-Electronic Regulatory Submissions/Document Management
- IT-Information Technology
- VA-Validation

The DIA Annual Meeting Program Committee recognizes the overwhelming task in identifying which track to submit your abstract for consideration. In order to minimize the overlap of similar session topics in different tracks and promote broader discussion and fuller understanding of topics presented, the Committee has collaborated in forming mega tracks to address this issue.
Start the dialogue early and tell your network of contacts about your session at the 46th DIA Annual Meeting.

- **Press Release**
  We’ve made it easy for you to issue a press release. Just [download](#) the speaker press release template and fill in your company information.

- **46th DIA Annual Meeting Banner**
  Post our meeting banner on your event listings page and link directly to the [46th DIA Annual Meeting website](#). Just follow these simple steps:
  - Click [here](#)
  - Right click then “save as” to save this banner to your computer
  - Link your banner [here](#)
  - You MUST use the following language if you wish to display accompanying text:

  [Name] will be speaking at the 46th DIA Annual Meeting (June 13-17, 2010 in Washington, DC.)

- **Social Media**
  Share ideas, anecdotes, expectations, and provide updates and information about your session – even articles and links. Connect with DIA and its members on [LinkedIn](#), [Facebook](#), [Twitter](#).
Responsibilities include:

✓ Maintain communication with Track chair(s) and DIA regarding the development of your session.
✓ Implement DIA’s policy on session structure and speaker recruitment.
✓ Adhere to DIA Annual Meeting deadlines and assist DIA in ensuring that all speakers meet their deadlines.
  o All confirmed speakers and participants of the Annual Meeting program must return an Audio Visual Release form and a Speaker disclosure form to DIA.
  o All presentations must be submitted by the established designated deadline to the EP@C system.
✓ Maintain close working relationship with speakers as they develop their presentation.
  o Meet with speakers well before the session via teleconference and/or email. Provide speakers with session learning objectives and difficulty level.
  o Request and review speaker’s draft outline of presentation.
  o Ensure there is no overlap of content between speakers.
  o Encourage speakers to attend 1 speaker webinar, schedule to be announced.
  o Speaker clothing may not carry logos or other company-specific emblems.
  o Advise speakers representing a Contract Research Organization or independent consultant that their presentation must not be commercial or promotional.
✓ Attend 1 session chair webinar, schedule to be announced.
✓ Review and approve speaker presentations after they have been submitted to the EP@C system to confirm that each presentation:
  o Features the presenter’s company logo only once, on the first slide of his/her presentation.
  o Meets the content level criteria designated for the session.
  o Fits within the written session overview.
  o Helps meet the learning objectives outlined for the session.
  o Is non-commercial, objective, fairly balanced and otherwise adheres to the “DIA Policy Concerning Promotion of Products and Services from the Podium at DIA-Sponsored Programs.”
  o Does not overlap with others in the session; if it does, consider modifying overlapping presentations to avoid redundancy.
✓ Create Session chair PowerPoint Presentation to include session learning objectives utilizing the designated DIA Annual Meeting Session chair PowerPoint template.
✓ During the session:
  o Maintain timing of each presenter and allow ample time for questions and answers from the audience.
  o Ensure all presenters properly use the podium microphone and laptop provided.
  o Prepare sample questions for your session to engage audience participation.
<table>
<thead>
<tr>
<th>Deadline</th>
<th>Task item</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 17, 2009 10:30am ET</td>
<td>Live Session Chair Webinar with 46th Annual Meeting Program Chair, Dr. Gaby Danan. For more details to log in and additional instructions, please <a href="#">click here</a>.</td>
</tr>
</tbody>
</table>
| December 17, 2009             | Names of speakers and presentation titles to DIA, including FDA participant requests  
|                               | (provide detail to DIA by this deadline and book your hotel room prior to the room block opening to the public)                                                                                       |
| January 13, 2010              | **Deadline** for session details, speakers to make  
|                               | PRELIMINARY PROGRAM ANNOUNCEMENT                                                                                                                                  |
| February 5, 2010              | PRELIMINARY PROGRAM to print                                                                                                                                                                               |
| March 1, 2010                 | Final requests for FDA participants to DIA                                                                                                                                                                 |
| April (late)                 | The official 46th DIA Annual Meeting PowerPoint Template is now available!  
|                               | - **2010 Annual Meeting PowerPoint Template**  
|                               | - **2010 Annual Meeting PowerPoint Template-for US Government Employees**                                                                                                                                   |
| April (month of)             | Best Practices in Presenting at the DIA Annual Meeting-Webinar for Speakers  
|                               | Best Practices in Leading a Session at the DIA Annual Meeting-Webinar for Session Chairs                                                                                                                     |
| May 3, 2010                   | Completion of ONSITE FINAL PROGRAM                                                                                                                                                                          |
|                               | **1st upload of presentation**                                                                                                                                                                              |
|                               | Drawing #1 Speakers, submit your presentation* to the EPAC system by the June 2nd COB deadline and you’ll be placed in a random drawing to win (1) 8GB Apple iPod touch.                                      |
|                               | Drawing #2 Session chairs who have all of their speaker presentations* and session chair presentation* to the EPAC system by the June 2nd COB deadline will be placed in a random drawing to win (1) 8GB Apple iPod touch. |
|                               | *To qualify:  
|                               | • Presentations must be on a designated 46th Annual Meeting PowerPoint Template.  
|                               | • Only one company logo should appear within the entire presentation.  
|                               | Please refer to the [DIA Policy Concerning Promotion of Products and Services from the Podium at DIA-sponsored Programs](#).                                                                          |
|                               | NOTE: Presentations submitted by June 2 may be updated afterwards. Please plan to have your completed presentations to the EPAC system no later than June 7 COB as Session chairs will begin their review of your presentation. |
| June 2, 2010                  | **FINAL upload of PowerPoint presentations to be submitted to EP@C system**                                                                                                                                   |
| June 7, 2010                  | Session chairs to review all submitted presentations and conduct follow up calls or emails to speakers who have not submitted their presentation for review.                                                                 |
| June 8-11, 2010               |                                                                                                                                                                                                       |
| June 13-17, 2010              | 46th DIA Annual Meeting  
|                               | Walter E. Washington Convention Center  
|                               | 801 Mount Vernon Place NW  
|                               | Washington, DC 20001                                                                                                                                                                                     |
Helpful hints for a successful DIA Annual Meeting Speaker’s Experience

Promotion at the Podium
• All presentations must be fair, balanced and free of commercial bias.
• Presentation must not be commercial or promotional
• Company (including consultants and institution) logo may appear only on slide 1.
• Speaker clothing may not carry logos or other company specific emblems.

During the Session:
• Project your voice and speak clearly. Lectern microphone should be placed hands width away and just below your mouth. Face your audience and avoid turning your head away from the microphone.
• Repeat questions that were asked without the use of a microphone.
• Turn off cell phones
• Turn off Blackberry/PDAs during the session.

Session Chairs:
• Start session on time. Request to have cell phones and blackberries disabled.
• Ensure the audience can hear your speakers.
• Remind any speaker or attendee not using the microphone effectively to move closer or reposition the microphone.
• Provide adequate time for audience question & answer time.
• Finish the session on time.
Sessions will be scheduled as follows:
- Monday, June 14 – Plenary session at 8:30am and concurrent sessions at 10:30am, 1:30pm and 3:30pm.
- Tuesday, June 15 – Track Plenary session at 8:00-9:30am and concurrent sessions at 10:00am, 2:00pm and 4:00pm.
- Wednesday, June 16 – Sessions at 8:30am, 10:30am, 1:30pm and 3:30pm.
- Thursday, June 17 – Sessions at 8:30am and 10:30am.

Each concurrent session will last for 90 minutes. There will be 30-minute refreshment break between sessions and a 90-minute luncheon break Monday, Wednesday and Thursday. Tuesday’s luncheon will begin at 11:30 and end at 2:00pm.
- Notification of the exact day and time of each session will be made in early January.

Recording of Sessions / Speaker Disclosures
All sessions will be recorded and made available to DIA members and meeting attendees. All session participants (session chairs, speakers and panelists) are required to complete an online consent form. All session participants must also disclose any significant financial interest or other relationship with the manufacturer(s) of any commercial product(s) and/or providers of commercial services discussed in an educational presentation, as well as any discussion of unlabeled or unapproved drugs or devices. An online recording consent form/speaker disclosure form must be completed by all session participants in order to participate in the program. In support of the ACCME guidelines, DIA has implemented a process where anyone in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest. Should a conflict of interest exist as a result of the financial relationship, this must be resolved prior to the activity. **Individuals who do not complete the online AV consent and disclosure form may be ineligible to participate as a faculty member for this program.**

Session Participants:
- Each session is limited to a total of 4 individuals, including the session chairperson. This allows each speaker 20-25 minutes for presentations and 15-30 minutes for questions and answers in the session. Written approval from the DIA office is required for any session which is requesting to include more than 4 individuals. Session chairs may also present.
- The meeting registration fee is waived for up to 4 individuals per session, including the session chairperson (provided speakers are from different organizations). DIA will register confirmed participants. Tours, tutorials and the networking reception require separate registration and payment. Session participants are responsible for their own travel/hotel expenses (unless they qualify for support – see Speaker Support below).
- DIA discourages the use of co-session chairs and co-presenters for presentations. All requests for co-presenters must be sent to the US DIA office for approval before presenters are invited. Approved co-chairs or co-presenters should not be from the same organization (see Speaker Affiliations below).

Speaker Support:
- Each session is limited to no more than one supported participant per session. Supported speakers include full-time government/ regulatory employees. Full-time academic and not-for-profit employees will be considered if budget allows. All requests for support must be sent to the US DIA office for approval before session chairs/speakers are invited and before the Preliminary Program is developed.
- Supported speakers will receive roundtrip coach/economy airfare (arranged through the DIA travel agent), plus 2 nights hotel room and tax, and per diem of up to $50 per day for no more than 3 days to cover food and miscellaneous expenses. Local transportation and airport parking costs will be covered outside of the per diem if the amount is significant. Receipts must be submitted at time of reimbursement.
- It has been brought to DIA’s attention that unauthorized third party providers are contacting our speakers and exhibitors to book their hotel reservations. These providers may require reservations be fully prepaid, are non-refundable and may be subject to steep cancellation and change fees. Please note that Travel Planners is the exclusive housing provider of the 46th DIA Annual Meeting. Should you choose to book with any provider other than Travel Planners, DIA will not have the ability to assist you with any issues you may have with the terms of their agreement.
Speaker Affiliations

- Please ensure that there is good representation/diversity in each session. If applicable, government, academia, CSO and industry perspectives should be represented.
- More than 1 participant from the same company in any given session is not permitted unless discussed with DIA in advance. Should an exception be made, one complimentary registration for the meeting will be given to the company.
- DIA meetings will be educational, not commercial and promotional. Speakers who represent a CSO or are independent consultants, etc. must be advised that their presentation is not to be of a commercial or promotional nature, and that logos and company information may only be included on the first page of the PowerPoint presentation and printed materials. In addition, speaker clothing may not carry logos or other company-specific emblems. All session participants must follow the “DIA Policy Concerning Promotion of Products and Services from the Podium” (attached).
- When selecting speakers, please note that it is DIA’s goal to have 50% of the sessions globally oriented.

Government Speakers

- Individuals from the following regulatory organizations may not be contacted directly to participate: FDA, EMEA, EU, MHRA, SFDA and Health Canada. Per regulatory agency policy, DIA is to officially request the participation of speakers from these organizations. The session chair is to provide DIA with the requested speaker’s name and topic to be presented as early as possible to ensure the best opportunity for receiving approval from the respective agency. Speakers from other organizations may be contacted directly by the session chair.
Continuing Education Guidelines for the Annual Meeting

- All presentations are to be fair balanced and free of commercial bias.

- All sessions must have at least two (2) learning objectives that clearly indicate what participants will be able to do after attending the session.

- All program participants in a position to control content (this includes program chairperson and committee members, track chairs, session chairs, speakers, and panelists) must provide DIA with any significant financial relationships they have with the manufacturer of products or services as discussed within their presentation or with regard to the content of the session/meeting (for those who are not speaking).*

- If a program participant (as noted above) has a conflict of interest as a result of the financial relationship, this will need to be resolved prior to the meeting.

- If a program participant does not provide disclosure to DIA, he/she will not be permitted to participate in the meeting.

- When discussing therapeutic options, it is DIA’s preference that only generic names and not trade names be used. If it is necessary to use trade names, please use the trade names of all products being discussed.

- All recommendations involving clinical medicine in a CME session must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.

* Please see attached Disclosure Question and Answer document.
Disclosure Questions and Answers

DIA is accredited by the Accreditation Council for Continuing Medical Education (ACCME) and the International Association for Continuing Education and Training (IACET). Frequently asked questions regarding participant disclosure and responses are noted below.

Why do volunteers need to disclose?
As an accredited provider DIA is required to provide its activity participants with any conflict of interest a program participant may have.

Who needs to disclose?
Anyone in a position to control content:
Program chairperson(s)
Track chairs
Session chairs
Speakers
Panelists
Authors
DIA staff developing content
(The above are referred to in this document as program participants)

What needs to be disclosed?
All relevant financial relationships between the commercial supporter (if applicable) or manufacturer of services discussed within the activity and/or presentation.

Program chairpersons and track chairs need to provide disclosure related to the development of the activity; session chairs, speakers, and authors need to provide disclosure related to the content of their presentation.

If a program participant has no financial relationships, that also needs to be disclosed.

Does a program participant need to disclose all financial relationships?
No, only those that pertain to the content of the educational activity or presentation.

Does a program participant need to disclose the amount of the financial relationship?
No.

If a volunteer participates as a program participant in multiple activities, does he/she have to complete a disclosure form for each activity?
Yes. The disclosure is pertinent to the content/presentation of the given activity.

Do the new Accreditation Council for Continuing Education (ACCME) Standards affect all DIA activities?
No. The policies and procedure established to support the new ACCME Standards only apply to CME activities (those activities offering category 1 credit).

How do the new Standards impact DIA’s CME program?
All program participants must provide disclosure in order to participate in the educational activity.

If a program participant has a conflict of interest, the conflict must be addressed prior to the educational activity. If resolution cannot be made, CME credit may or may not be offered for the activity.
The Drug Information Association encourages and supports the exchange and dissemination of information pertaining to research and development of health care products, regulatory processes, emerging technologies, and information management. The Association does this by providing its members a neutral forum for education and discussion opportunities concerning the latest technologies and processes. Preservation of the neutrality of this forum, fostering collaborative efforts among academia, contract houses, contract research organizations, health regulatory authorities, industry, practitioners, and vendors, is essential to the success of DIA. The Association draws a clear distinction between the dissemination of information and outright commercial promotion of a consultant, commercial product, research institution, or service.

At DIA-sponsored programs, presentations by persons affiliated with commercial organizations or educational institutions that provide services or products must be limited to scientific, technical or process issues. Presentations should not overtly endorse or recommend a specific product or service. The theme and content of slides, overheads, handouts and other presentation aids should not promote a commercial product or service. This also applies to the use of company logos, which may only appear on the first slide of a slide presentation. In addition, speaker clothing may not carry logos or other company specific emblems. In this way, DIA meetings will be educational, rather than commercial and promotional.

The DIA Office will create and disseminate publicity pertinent to a DIA meeting, workshop, training course, tutorial, or any other DIA-sponsored activity. All such publicity will be distributed directly from the DIA Office. Individuals and organizations can, at their option, make tasteful announcements of their participation in DIA-sponsored meetings, but should refrain from doing so until confirmation of participation has been received from the DIA Office. Any advertising of participation in a DIA-sponsored meeting by an individual or an organization shall not use any copyrighted material from DIA or the DIA trademark.

The DIA Board of Directors encourages the membership to provide feedback to the DIA Executive Director regarding violations of this policy. The Executive Director will address such violations directly with those involved. Remedies may include restriction on future participation at DIA events.
46th DIA Annual Meeting Program Participant Webinar

Attend one of the live webinars to learn best practices in leading or presenting at the DIA Annual Meeting!

<table>
<thead>
<tr>
<th>Webinar</th>
<th>Date and Time</th>
<th>Webex Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session chair Webinar *for session chairs new to the DIA Annual Meeting Program</td>
<td>April 19, 2010 10:00am ET</td>
<td><a href="https://diahome.webex.com/diahome/onstage/g.php?d=713126585&amp;t=a">https://diahome.webex.com/diahome/onstage/g.php?d=713126585&amp;t=a</a></td>
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<td></td>
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<td>Password: washingtondc (all one word, no space)</td>
</tr>
<tr>
<td>Speaker Webinar *for speakers new to the DIA Annual Meeting Program</td>
<td>April 22, 2010 10:00am ET</td>
<td><a href="https://diahome.webex.com/diahome/onstage/g.php?d=710130602&amp;t=a">https://diahome.webex.com/diahome/onstage/g.php?d=710130602&amp;t=a</a></td>
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<tr>
<td>Veteran Session chair and Speaker Webinar *for veteran participants of the DIA Annual Meeting Program</td>
<td>April 19, 2010 11:30-12:30pm ET</td>
<td><a href="https://diahome.webex.com/diahome/onstage/g.php?d=713514430&amp;t=a">https://diahome.webex.com/diahome/onstage/g.php?d=713514430&amp;t=a</a></td>
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<td>Password: washingtondc (all one word, no space)</td>
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</tbody>
</table>

**Step #1**

It is imperative that you perform a system test at least 24 hours before the webinar. Webex, our provider, periodically makes changes to their platform, which may affect the webinar performance on your computer. Even if you have participated in a DIA webinar before, you must test your system in advance to assure that everything is functioning properly. Please go to the Test Site below to perform this system check.

To receive the Webinar over the Internet, your computer must have:

**Browser**

Microsoft® Internet Explorer 5.2 or higher
Netscape® Navigator 7

**Computer**

166Mhz Pentium-based PC with Microsoft® Windows® 98, NT, ME, XP or 2000
Sun JVM 1.4* for Microsoft JVM (all versions supported by Microsoft Windows OS shown above)
Sun SPARCstation with Solaris 8 or 9
Audience: 64 MB RAM

*If you need to install Java Virtual Machine (JVM) on your system, please download it from the Sun Microsystems website.

**Internet Connection Speed**

56k or faster

**Display**

800x600 pixel resolution or greater (1024x768 pixels recommended)

**Attendees using Macintosh OS**

Microsoft IE 5.2
Macintosh OS 10.2X

To test your system compatibility, click on the link below.


**Step #2**

To join the event Please choose which webinar you would like to join and click on the web link above
Password: washingtondc (all one word, no space)

**After you click on the link, here are some additional instructions:**

1. Click the Join button
2. Enter your name and email address
3. Enter the password: washingtondc (all one word, no space)
4. Click to join the event

There is no dial in number. All sound will be broadcast through your computer’s speakers. Please make sure the volume is all the way up. DIA representatives will be making periodic announcements prior to the live event, but there is no hold music.
Welcome to the Annual Meeting Program Development Website

Go to the DIA Homepage, www.diahome.org and click on the 46th DIA Annual Meeting Icon

At the DIA’s 46th Annual Meeting pages, click on “Responsibilities” from the Speaker’s Corner tab.
1. Log into the pages with your user id and password.
2. If you do not know your id, Click Here to be directed to the login reminder page.

Please note that due to DIA’s database upgrade, passwords are now case sensitive.

You may be asked to update your user id if you have not logged into the website within the past year.
If this is your first time accessing the Program Development Website for the 46th Annual Meeting, you will see the Profile Disclosure Terms & Conditions page noted below, please review and click “Next” button when complete.

Profile Page
Update contact information and Scroll down to bottom of page. Please make sure all fields with a red asterisk next to them are completed.

You will have an opportunity to provide a brief 300 character biography on this page or you will be able to edit a biography that we currently have on file.

Click Next
Program Participant Disclosure Page
Please review; complete all areas by scrolling to the bottom of the page and clicking the next button.
Program Participant AV (audio-visual release) Page
Please review and complete all areas by scrolling to bottom of page and clicking the submit button.

My Responsibilities Page
This page will show you all of your responsibilities up to date for the Annual Meeting Program. Click on Edit button to advance to the next page.
Edit Session Page
This page will detail all information already submitted to DIA. It is here where you may edit and update information. Please click the Next button to advance to the next page.

Please note that if you step away from your computer while editing, you may risk losing edited information. Please be sure to hit the submit button (which can be found in at the end of the site to capture your information that you have updated).

Continuing Education Request Page
This page displays current request for continuing education for your session. You will be able to edit this information before it is locked down and submitted for review to the DIA CE Committee. Click on Next button.
**Edit Session Chair Detail Page**
Details as session chair will be displayed here, if edits are necessary click back to edit your profile or click next.

**Edit Speakers Page**
Please review the [2010 Session Chair Resource Guide](#) before inviting speakers to present in your session. The following page is where you can update with your speakers after they have been invited. Click next on the bottom of the page.
Speaker Detail Page
After you have submitted your speakers, you will be able to include presentation titles as you see appropriate. At a later stage, speakers will have access to this site to update their titles as needed.
Session Confirmation Page
This page displays all information that will be submitted to DIA. Scroll to bottom of page and click the SUBMIT button. Information will not be updated and saved unless you complete this last step. An email will be sent to verify that the information has been submitted successfully.

Please allow 24-48 hours for the information to be reviewed by the DIA Annual Meeting Team. Once approved, your edits will be reflected on the website and seen when you access again.
My Responsibilities Page

Contacts
You have the option of sending an email to anyone associated with your session from the website. If you have more than one role for the meeting, select your criteria from the dropdown menu.

At the Speaker’s Corner Tab, click on Contacts
1. Go to Speakers Corner, Contacts, and an email template will appear.
2. Enter a Subject in the Subject line, type your message, highlight the names to be included in your message and hit the send email button.