CALL FOR SESSION ABSTRACTS

ABSTRACT SUBMISSION DETAILS and GUIDELINES

SUBMISSION DEADLINE: FRIDAY, NOVEMBER 1

Abstract Overview and Topics:
Abstracts may address, but are not limited to, the following topics:

Business Track
- Regulatory Policy, Intelligence and Compliance Issues, Challenges, and Opportunities
- Clinical Trial Transparency and Data Disclosure
- Impact of FDASIA on Drug Development
- Effective Use Of Approval Packages for Setting Strategy
- Impact of Regulations Beyond Major Markets
- Effect of Major Market Regulations on Global Strategies
- Managing Regulatory Information Management (RIM) During Mergers, Acquisitions, and In- or Out-Licensing
- Management of Correspondence and Commitments
- Current and Upcoming Standards and Real/Potential Impacts (XEVMPD, IDMP, RPS)
- Challenges With Global Information Management and Solutions To Overcome Obstacles
- Outsourcing Regulatory – Impact, Challenges, and Opportunities in a Global Marketplace

Tools and Technology Track
- Best Practices for Management of Regulatory Activities Using Electronic Tools
- Creating a Business Case for a RIM System
- Challenges for Multi-national Organizations With Implementation of RIM Tools
- Maintaining and Complying With Regulatory Standards
- Using RIM Tools to Achieve Compliance
- Regulatory Intelligence: Using Tools to Aid Business Decisions
- Transitioning a Business to a Global RIM System
- Change Management: Lessons Learned

Plenary Sessions
- FDASIA and its Impact on Submissions Over the Last Year
- Emerging Markets
- Electronic Standards
- Regulatory Departments: What Will 2020 Look Like?

Abstract Submission Deadline:
Friday, November 1

Notification:
Monday, November 22

Final PowerPoint presentations Due:
Monday, February 10, 2014

Meeting Date:
February 25-26, 2014

Location:
Washington, DC Area

The date and venue are being finalized. Monitor the DIA website for the meeting details.

Please submit all abstracts using the online form at: diahome.org/Abstract

Submit Your Abstract at diahome.org/Abstract
GENERAL SUBMISSION REQUIREMENTS
(Please read the following instructions carefully; incorrect or incomplete abstracts will not be considered.)

1. All abstracts must be submitted online to diahome.org/Abstract.
2. Title must reflect the abstract content accurately and concisely.
3. Preference will be given to submitted abstracts that address real life applications and case studies.
4. Final PowerPoint presentation for all accepted abstracts will be due to DIA to be reviewed by the Committee and included on the DIA website for registered attendees. Should you choose to submit an abstract for consideration, please mark your calendars with the deadline.
5. Final PowerPoint presentations for all accepted abstracts may have a company logo on slide number one. Any company logo appearing on any other slides will be removed by DIA.
6. Time allotted for individual presentations will be approximately 15-20 minutes. Final timing will be determined by the session chair and based on the number of presentations selected for the session.

7. DIA will provide complimentary meeting attendance for the selected speaker(s).
8. Please note: Only one speaker per presentation will be allowed. Any exceptions to this policy must be discussed with the DIA office in advance.

REQUIRED DOCUMENTATION FOR ALL ABSTRACTS
• Participant Disclosure Information: all abstract authors must disclose any relevant financial relationships with any commercial interest associated with this activity that exist or have existed within the past 12 months, as well as any discussion of unlabeled or unapproved drugs or devices. If you are proposing an abstract on behalf of the author, as the submitter you will not be asked to disclose. However, should the abstract be accepted, the author will be informed that he or she must complete and submit a Participant Disclosure in order to participate in the program.
• All submitters and authors must agree to the DIA Speaker Authorization for Use of Presentation Materials in order for the abstract to be a part of the Program. Speaker slide presentations will be available on DIA’s website for attendee download after the event.

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Visit diahome.org/benefits for complete details.
SUBMISSION GUIDELINES  The following information will be requested at the time of submission.

Submitting a SESSION ABSTRACT (All abstracts must be submitted online.)

• A session is a 90-minute concept delivered lecture-style from the podium. The abstract author is considered the session chair and must coordinate efforts in recruiting speakers (no more than three in a 90-minute session), adhere to DIA guidelines, and manage the session (including the facilitation of questions and answers from the audience) at the Program.

• The session chair must ensure good representation/diversity in the selection of speakers; no more than one participant from the same company is permitted. PowerPoint presentations are required from each speaker.

To streamline your submission process and avoid possible delays, DIA strongly encourages you to submit your abstract as early as possible. Do not wait until the last day.

Prepare your abstract in advance of accessing the DIA website. Abstract information should be copied and pasted from a prepared document as plain text. All of the below fields are required

Submitter or Author Information

Prefix:  Country:
First Name:  Address Line:
Middle Name:  City:
Last Name:  State/Province:
Name Suffix:  Zip/Postal Code:
Company:

NOTES: If you are submitting on behalf of the author, you are considered the SUBMITTER and will need to complete the required information for yourself AND ALSO for the AUTHOR. Submitters will be the contact regarding the status of the abstract.

If you are submitting your own abstract, you are considered the AUTHOR and will be the direct contact for this abstract.

Abstract Title (maximum 125 characters, including spaces): Titles should briefly describe the focus of the abstract as well as accurately reflect the content of the session.

Interest Area/Track: Your abstract must be submitted in one of the interest areas/tracks identified.

Key Words (maximum 100 characters, including spaces): One or more key words are to be provided to highlight your workshop. Examples of key words: Personalized Medicine, Health Technology Assessment, Clinical Trial Agreements.

Level of Difficulty (Select one):

- Basic: Appropriate for individuals new to the topic/subject area.
- Intermediate: Appropriate for individuals who already have a basic understanding of the topic/subject area.
- Advanced: Appropriate for individuals with an in-depth knowledge of the topic/subject area.

Learning Objectives (maximum 400 characters, including spaces): Please provide 2-3 learning objectives that clearly explain what participants should be able to do after attending this session. For a list of suggested verbs to create these objectives, please visit the Learning Objectives link.

Overview (maximum 250 characters, including spaces): Please provide 2-3 sentences summarizing your abstract. This summary will be used as the overview description in the DIA program for marketing purposes.

Abstract Details (maximum 2,000 characters, including spaces): Please provide complete details about your abstract. Information such as scientific, technical, process issues, design/methods, results/outcomes, case studies, statistics, key findings, etc., that would support your abstract should be included here. This information will be used by the Program Committee to learn more about the purpose of your abstract.

Submit Your Abstract at diahome.org/Abstract