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DIA
Drug Information Association

The 6th Annual Electronic Submissions Conference

eCTD: The Future Is Now

November 14, 2007 Tutorials
November 15-16, 2007 Conference

Omni San Diego Hotel, San Diego, CA

PROGRAM CHAIRS

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Director, Regulatory and Industry Relations
Image Solutions, Inc.

GARY M. GENSINGER
Director, Regulatory Review Support Staff,
CDER, FDA

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Managing Director, West Coast Operations
Octagon Research Solutions, Inc.

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Business Process Support, CDER, FDA

GARY G. WALKER
Associate Regulatory Director, Global Data
Management, Quintiles Transnational Corp.

Are You Prepared for January 1, 2008? This is the date when eCTD will become the single electronic submission format.

This conference provides the perfect forum for industry to get clarification and guidance on what this means to the life sciences industry as a whole, as well as for companies that submit electronically. Specially tailored parallel tracks allow participants to select from intermediate- or advanced-level sessions.

FEATURED TOPICS

- Preparing the Organization for Electronic Submissions
- Leveraging Content Management and Emerging Standards
- Making the Change: The Workflow Impact of the Transition to eCTD
- eCTD — INDs
- Being Prepared for Your FDA eCTD Pilot and eCTD Submission
- eCTD; multiregional Marketing Applications
- Tool Selection: From Low Budget to Deep Pockets
- Beyond the eCTD Format: Managing the Lifecycle and eLabeling

CONFERENCE HIGHLIGHTS

- **Full- and half-day tutorials,** November 14 (see page 2 for complete details.)
  - eSubmission Basics (half day morning)
  - INDs in eCTD Format (half day morning)
  - eCTD Lifecycle Management (half day afternoon)
  - An Electronic Odyssey: Document Management and the eCTD (full day)
- **Plenary Sessions**
  - Regulatory Updates
  - Inside the FDA
  - FDA Insights on eCTD: Getting It Right the First Time

WHO SHOULD ATTEND

- Regulatory affairs/operations personnel
- Document and data managers
- Technical and medical writers
- Project managers
- Information technology professionals

CONTACT INFORMATION

Meeting: Jessica Kusma, Program Manager
Phone +1.215.442.6182 / Fax: +1.215.442.6199
email Jessica.Kusma@diahome.org

THIS PROGRAM HAS BEEN DEVELOPED BY THE DOCUMENT AND RECORDS MANAGEMENT, eCLINICAL, ELECTRONIC REGULATORY SUBMISSIONS, MEDICAL WRITING, AND REGULATORY AFFAIRS SPECIAL INTEREST AREA COMMUNITIES

SIAC

TUESDAY • NOVEMBER 13	4:00-6:00 PM	REGISTRATION
WEDNESDAY • NOVEMBER 14	7:30 AM-6:00 PM	REGISTRATION

Tutorials

8:30 AM-12:00 PM *Morning*

Tutorial #1 eSubmission Basics

INSTRUCTORS

Jeanie Kwon, Director, Regulatory Submissions, Image Solutions, Inc.
Robin Zumbrunnen, Director, Regulatory Operations, ePublishing and Technical Services, Quintiles, Inc.

This tutorial is aimed at individuals who have little or no experience with preparing electronic submissions to the FDA. It will provide an overview of what is involved in the preparation of electronic documents for inclusion into eCTD submissions. This tutorial will also cover proper eCTD document granularity, fundamental publishing requirements, and highlight differences in various applications types in eCTD format.

Learning Objectives

- Prepare eSub-ready documents and other file types that are acceptable to regulatory agencies
- Explain eCTD document granularity
- Recognize different application types in eCTD format
- Describe eCTD lifecyle management
- Prepare an eCTD demo for FDA
- Recall different transfer methods for submitting electronically to the FDA

Tutorial #2 INDs in eCTD Format

INSTRUCTORS

Nancy Smerkanich, Vice President, Regulatory Affairs, Octagon Research Solutions, Inc.
Peggy Boe, RN, Senior Director, Medical Writing, Image Solutions, Inc.

This half-day tutorial will focus on the practicalities and processes of creating and maintaining INDs in the eCTD format. Use of XML and the specifications needed for various types of submissions will be presented along with common pitfalls and issues. Practical examples of how to track continuous applications will be discussed, an activity on gathering metadata, and case studies will all be part of this interactive workshop.

Learning Objectives

- Implement practical planning, recognizing the following:
  - Effect on authors of IND sections, specifically around document granularity
  - Importance of tracking documents across functional areas
  - Document mapping from 21 CFR 312 to CTD Modules
- Identify process change and improvement needs when preparing for eCTD
- Explain how to effectively collect and organize metadata
- Recognize the study tagging file utility

Tutorial #3 eCTD Lifecycle Management

INSTRUCTOR

Kenneth R. VanLuvanee, President and Chief Executive Officer, Apyx, Inc.

The eCTD life-cycle specification changes how we view submissions. This tutorial will discuss the practical challenges of submitting and maintaining an eCTD submission, including strengths and weaknesses of the model. Specific issues to be discussed will include a discussion of the eCTD life-cycle model itself, challenges and opportunities posed by the model, and options for specific solutions that can be applied to managing the inherently dynamic life cycle of an eCTD.

Learning Objectives

- Describe the eCTD life-cycle model starting from initial submission
- Explain the functionality of the life-cycle model
- Summarize the issues surrounding eCTD life-cycle management from a records management perspective

Tutorial #4 An Electronic Odyssey: Document Management and the eCTD

INSTRUCTORS

John Aitken, PhD, Managing Director, West Coast Operations, Octagon Research Solutions, Inc.
Nancie E. Celini, President, CAB, inc.

Electronic document management (EDM) and eCTD compilation/life-cycle management are often treated as completely separate processes in their planning and execution. They are, however, highly interdependent stages of an integrated document life-cycle management process. The tutorial will provide a comprehensive grounding in all of the components and stages of this integrated process, including:

- Standardizing software
  - Computer systems validation
  - Document standards for authoring and granularity
  - Electronic document management
- Document repository
- Taxonomy
- Metadata
- Version control
- Workflows
- Collaboration
  - Introduction to the eCTD
  - Integrating EDM and the eCTD
- Document publishing
- Preparing eSub-ready documents
- Preparing a sample eCTD
- Compiling and submitting the eCTD
- eCTD life-cycle management

Learning Objectives

- Discuss authoring and publishing electronic documents for the eCTD
- Explain the vital role of good document management in compiling and submitting an eCTD
- Recognize the key components of the eCTD process and its life-cycle management

THURSDAY • NOVEMBER 15

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-8:45 AM WELCOME AND OPENING REMARKS

PROGRAM CHAIRPERSONS

Mary L. Collins, Director, Regulatory and Industry Relations, Image Solutions, Inc.

Representative Invited, Regulatory Review Support Staff, CDER, FDA

8:45-10:00 AM *Plenary Session 1*

REGULATORY UPDATES

CHAIRPERSON: **Mary L. Collins,** Director, Regulatory and Industry Relations, Image Solutions, Inc.

This session opens the conference with an overview and progress report, provided by FDA and European regulators, on electronic submissions. This year's Regulatory Update session also includes an update on the safety review in the United States.

US Update eCTD – The Electronic Format as of January 1, 2008: What Does it Mean for the Agency?
Representative Invited
Regulatory Review Support Staff, CDER, FDA

CTD, eCTD and the Safety Review: Putting All the Pieces Together
Representative Invited
Office of New Drugs, Immediate Office, CDER, FDA

European Update
Representative Invited
Project Management, Communications and Networking, PIM Project Manager, EMEA, EU

10:00-10:30 AM **REFRESHMENT BREAK**

10:30 AM-12:00 PM *Plenary Session 2*

INSIDE THE FDA

CHAIRPERSON: **Representative Invited,** Regulatory Review Support Staff, CDER, FDA

Presentations in this session provide insight and updates directly from FDA staff on the status of electronic submissions within CDER. Topics to be discussed include the electronic secure gateway, the most current guidance documents, reviewer and project manager experiences, and future directions for electronic submission initiatives.

Reviewer's Perspective on eCTD and Lifecycle
Representative Invited
CDER, FDA

Project Manager's Perspective – Process, Workflow and Management: How the eCTD Impacts This
Representative Invited
Division of Gastroenterology Products, Office of New Drugs, CDER, FDA

Inside FDA, Future Directions: How Will They Impact the Industry?
Representative Invited
Regulatory Review Support Staff, CDER, FDA

12:00-1:30 PM **LUNCHEON**

1:30-3:00 PM
TRACK 1 *(Intermediate Level)*

Preparing the Organization for Electronic Submissions

CHAIRPERSON

Gary G. Walker
Associate Regulatory Director, Global Data Management
Quintiles Transnational Corp.

Organizing documents and data are not the only steps necessary to creating electronic submissions. Organizations must build the framework necessary for managing all of the aspects of electronic submissions. This session will provide an understanding of some of these organizational considerations, from planning through execution.

Nuts and Bolts: eCTD Tools, Costs and Other Considerations
Kenneth R. VanLuvanee
President and Chief Executive Officer
Apyx Inc.

Electronic Submission Standards: An Overview of Applicable Standards
Gary G. Walker
Associate Regulatory Director, Global Data Management
Quintiles Transnational Corp.

Organizational Considerations for Building the eCTD
Fred Miller
Associate Director
Genentech, Inc.

1:30-3:00 PM
TRACK 2 (*Advanced Level*)

Leveraging Content Management and Emerging Standards

CHAIRPERSON

Nancie E. Celini
President, CAB, inc.

Companies that have experience developing regulatory submissions using the CTD/eCTD format have found that internal processes need to be reengineered. Maximizing the benefits requires an unparalleled combination of people, well-designed processes and the rapid adoption of standards. This session will focus on how to leverage content management and emerging standards to meet the demands of a complex informatics environment.

A Bridge Between Clinical and Regulatory Operations to Facilitate the eCTD Transition
Christian A. Buckley
Senior Manager, Regulatory Operations
OSI Pharmaceuticals Inc.
David Ramroth
Director, Medical Writing
OSI Pharmaceuticals, Inc.

A Case Study of a Mid-size Pharmaceutical Company's Biostatistics and Data Management Group with NDA Submissions: Past, Recent and Future
Jameelah H. Aziz
Senior Manager, Clinical Data Management
Cubist Pharmaceuticals Inc.

3:00-3:30 PM **REFRESHMENT BREAK**

Continuing Education

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 1.3 continuing education units (CEUs) to participants who successfully complete this program.

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

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 unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

Learning Objectives: At the conclusion of this conference, participants should be able to:

- Describe the impact of CDER's withdrawal of the eNDA guidances
- Discuss future trends in electronic submissions including Regulated Product Submission (RPS)
- Identify challenges and benefits of transitioning from paper to eCTD
- Differentiate requirements and manage multi-regional electronic submissions
- Explain the various methods of electronic transmissions to FDA, such as the FDA Electronic Secure Gateway (ESG)
- Create guidance-compliant INDs and NDAs in eCTD format
- Differentiate between guidance and regulation and their impact to the process
- Express the vital role of good document management in the overall process of preparing electronic documents for the eCTD

Continuing Education Credit Allocation **Tutorials 1, 2 and 3:** .3 IACET CEUs **Tutorial 4:** .7 IACET CEUs **Conference:** .6 IACET CEUs
No CEUs will be awarded for the three Plenary Sessions.

3:30-5:00 PM
TRACK 1 *(Intermediate Level)*

Making the Change: The Workflow Impact of the Transition to eCTD

CHAIRPERSON

Kenneth R. VanLuvanee
President and Chief Executive Officer
Apyx, Inc.

This session will discuss the changes that must happen beyond regulatory operations for successful, effective, and practical organizational transition to eCTD. This session will discuss changes in thinking to support eCTD, best practices for standards and SOPs, broader organizational impact of eCTD, and the practicalities of supporting multiple electronic submission formats during and after the transition period.

After the session, an attendee should have a broader understanding of eCTD's impact across the organization and have a starting point for beginning to assess his/her organization's eCTD needs.

From Paper Submissions (Humdrum) to eCTD Submissions (Easy and Exciting)
Annette Nilsen
Senior Regulatory Consultant
Image Solutions, Inc.

Managing the Successful Transition to eCTD
Patricia Santos-Serrao
Manager, Global Regulatory Solutions
QUMAS

Creating and Maintaining eCTDs while Maintaining Legacy eBLA's
Speaker Invited

3:30-5:00 PM
TRACK 2 (*Advanced Level*)

eCTD – INDs

CHAIRPERSON

Jeanie Kwon
Director, Regulatory Submissions
Image Solutions, Inc.

This session will focus on experiences with the submission of INDs in the eCTD format, covering the preparation of granular components, mapping IND documents to the eCTD structure, lifecycle management of the IND in eCTD, and the benefits and challenges of this submission format.

Attendees of the session should be able to:

- Recognize the benefits of lifecycle management
- Explain the structure of documents in an IND and how they map to CTD/eCTD
- Understand the document granularity of eCTD submissions
- Recognize the needs for insourcing versus outsourcing

Transitioning from Paper IND to eCTD IND: Are You (and Your Documents) Ready?
Robin L. Zumbrunnen
Director, Regulatory Operations, ePublishing, and Technical Services
Quintiles, Inc.

Case Study: IND in eCTD Format – Outsourcing Perspective
Aarati Sridharan
Senior Regulatory Affairs Associate
EPIX Pharmaceuticals, Inc.

Case Study: IND in eCTD Format – Insourcing Perspective
Speaker Invited

5:00-6:00 PM **NETWORKING RECEPTION**

This program has been developed by the **DOCUMENT AND RECORDS MANAGEMENT, eCLINICAL, ELECTRONIC REGULATORY SUBMISSIONS, MEDICAL WRITING,** AND **REGULATORY AFFAIRS** Special Interest Area Communities

TRAVEL AND HOTEL The most convenient airport is San Diego Airport and attendees should make airline reservations as early as possible to ensure availability. The Omni San Diego Hotel is holding a block of rooms at the reduced rate below until October 22, 2007, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $259 **Double $259**

Please contact the Omni San Diego Hotel by telephone at +800-THE-OMNI and mention the DIA event. The hotel is located at 675 L Street, San Diego, CA 92101, USA.

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GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! ***All 4 individuals must register and prepay at the same time – no exceptions***. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

▶ **To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.**

Participants with Disabilities: *DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.*

FRIDAY • NOVEMBER 16

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00 AM
TRACK 1 *(Intermediate Level)*

Being Prepared for Your FDA eCTD Pilot and eCTD Submission

CHAIRPERSON

Laura Sherman, MA
Vice President, Enterprise Publishing Solutions
Impact Systems, Inc.

During the transition to eCTD, there are many considerations in regards to all of the regulatory guidances as well as internal company processes to assess and evaluate for strategically being eCTD ready. This session will focus on the various aspects for preparing and submitting the FDA pilot as a key milestone prior to the submission filing. We will explore an approach to regulatory preparation, guidance interpretation and internal standards to establish including a sampling of checks to be planned and performed to help ensure a success pilot. Once the pilot is received at the FDA, gain an understanding of what to expect in regards to agency sponsor correspondence.

Internalizing the eCTD Guidance Documents through an eCTD Guidance Interpretation
Lisa Miller
Process Solutions, Senior Consultant
Octagon Research Solutions, Inc.
Ben Manning
Associate Director, Quality Systems, Regulatory Affairs
Abbott Laboratories

Preparing for the FDA Pilot
Frank Ha
Manager, Global Regulatory Affairs and Safety
Amgen Inc.

The FDA Pilot
Representative Invited
Office of Business Process Support, CDER, FDA

8:30-10:00 AM
TRACK 2 (*Advanced Level*)

eCTD: Multiregional Marketing Applications

CHAIRPERSON

John Aitken, PhD
Managing Director, West Coast Operations
Octagon Research Solutions, Inc.

The US, EU and Canada all accept the eCTD for marketing applications. However, each region has its own specification for module 1, and takes a different approach to the use of study tagging files in modules 4 and 5. The timelines for implementation of the eCTD are also being handled differently. The three speakers in this session will cover the use of the eCTD format for marketing applications in the US, Europe and Canada, and will discuss issues related to eCTD life-cycle management.

Transitioning to eCTD-only Submissions in the EU: Life-cycle Management Issues
Joerg Schnitzler
Regulatory Operations Manager
Merck Serono, Germany

Canadian eCTD: An Important Piece in the Global Regulatory Puzzle
Ted Hanebach
Director, Regulatory Standards
CanReg Inc., Canada

The US eCTD NDA: Are You Ready?
Theresa Maloney, RPh
Director, Regulatory Affairs
ALTANA Pharma US, Inc.

10:00-10:30 AM **REFRESHMENT BREAK**

10:30 AM-12:00 PM
TRACK 1 *(Intermediate Level)*

Tool Selection: From Low Budget to Deep Pockets

CHAIRPERSON

Guy Pawson, PhD
Manager, Electronic Submissions
Genentech, Inc.

This session addresses the variety of tools available for assembling the eCTD and its internal components. A common assumption is that major investment in technology-based solutions is required to ensure the efficient publication of documents and data for a submission. In this session, we will present the alternative view that tools and technology should always fit the eCTD process rather than drive it. Presentations from a sponsor and two eCTD solution providers will show that in the presence of well-thought-out process and work flow, eCTD submissions do not necessarily require a large budget and extensive toolset to be effective.

The eCTD: It's All about the Planning
Shylendra Kumar
President
Datafarm, Inc.

Challenges in the Adoption of Regulatory Submission Tools
Jascha Minow
Director, Regulatory Solutions
Image Solutions, Inc.

Doing It on a Budget: Effective Submissions for the Smaller Company
Guy Pawson, PhD
Manager, Electronic Submissions
Genentech, Inc.

10:30 AM-12:00 PM
TRACK 2 (*Advanced Level*)

Beyond the eCTD Format: Managing the Lifecycle and eLabeling

CHAIRPERSON

Terry D. Hardin
Senior IT Architect, Healthcare & Life Sciences Standards
IBM Software Group

As the number of eCTD submissions being filed globally is increasing, sponsors face the challenge of managing the lifecycle of their submissions and the issues of knowledge management around the eCTD. In addition, as eLabeling standards have progressed, lifecycle issues are also showing up in the labeling arena and need to be taken into consideration – whether as a stand-alone labeling submission or as part of an eCTD. This session will examine the lifecyle issue for both the eCTD and eLabeling and provide a brief update on the EU PIM and US SPL standards.

After this session an attendee should have a broader understanding of the issues to take into consideration for lifecycle management for eLabeling and for eCTD's and knowledge as to where the PIM and SPL standards are at this time.

Terry D. Hardin
Senior IT Architect, Healthcare & Life Sciences Standards
IBM Software Group

Speaker Invited
EMEA, EU

Speaker Invited
FDA

12:00-1:30 PM **LUNCHEON**

1:30-3:00 PM *Plenary Session 3*

FDA INSIGHTS ON eCTD: GETTING IT RIGHT THE FIRST TIME

CHAIRPERSONS: **Representative Invited,** Office of Business Process Support, CDER, FDA
Representative Invited, Regulatory Review Support Staff, CDER, FDA

This session will focus on practical advice and feedback from FDA staff who work directly with electronic submission receipt, validation and troubleshooting. To be discussed are best practices to ensure a successful eCTD submission, and the important topic of what will be accepted or rejected according to new guidance, and how to avoid the dreaded RTF. The session concludes with a full-FDA panel of experts to answer your questions.

Top 10 eCTD and Gateway Considerations
Representative Invited, Office of Business Process Support, CDER, FDA

eCTD Compliance and Validation
Representative Invited, Regulatory Review Support Staff, CDER, FDA

Question & Answer Period – FDA Panel

3:00 PM **CONFERENCE CONCLUDES**

The 6th Annual DIA Electronic Submissions Conference

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Omni San Diego Hotel, San Diego, CA, USA

NOVEMBER 14, 2007 – Tutorials

NOVEMBER 15-16, 2007 – Conference

Event ID #07023

MEMBER EARLY BIRD *Register by OCTOBER 24, 2007* **SAVE $175**

Are You Prepared for January 1, 2008?

This is the date when eCTD will become the single electronic submission format.

This conference provides clarification and guidance on what this means.

- **Four tutorials**
  eSubmission Basics; INDs in eCTD Format; eCTD Lifecycle Management; An Electronic Odyssey: Document Management and the eCTD
- **Three Plenary Sessions**
  Regulatory Updates; Inside the FDA; FDA Insights on eCTD – Getting It Right the First Time
- **Parallel tracks offering intermediate- or advanced-level sessions**

Register online or fax this page to +1-215-442-6199

DRUG INFORMATION ASSOCIATION
800 Enterprise Road, Suite 200
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CONTACT & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the event and during receptions (if applicable).

Event information: Contact Jessica Kusma at the DIA office by telephone +1-215-442-6182, fax +1-215-442-6199 or email Jessica.Kusma@diahome.org.

Tabletop exhibit information: Contact Erin Gilliland, Exhibits Associate, at the DIA office by telephone +1-215-442-6149, fax +1-215-442-6199 or email Erin.Gilliland@diahome.org. For tabletop exhibit space, please check the box below.

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GROUP DISCOUNTS (not available online or on already discounted fees)

Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions.
See page 5 for complete details.

Registration Fees *If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.*

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TUTORIALS

#1	8:30 am-12:00 pm	US $ 375 ❑	**#3**	1:30-5:00 pm	US $ 375 ❑
#2	8:30 am-12:00 pm	US $ 375 ❑	**#4**	9:00 am-5:00 pm	US $ 650 ❑

CANCELLATION POLICY: On or before NOVEMBER 8, 2007

Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

❑ **I cannot attend but please keep me informed of DIA's future events.**

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Signature _____

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