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Winning Strategies for Achieving a Quality EDC Clinical Trial Process

Sponsor/CRO, Investigator, IRB Approver and IT/IS

DRUG INFORMATION ASSOCIATION

November 13-14, 2007 | **Hyatt Regency Bonaventure Conference and Spa Center, Weston, FL, USA**

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VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA
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Developing a Practical, Standard Approach for EDC Planning, Assessment, and Delivery

According to *Health Industry Insights*, 2007 will be the watershed year for industry's move to broad scale use of electronic data capture (EDC) in clinical trials. The FDA has also recognized the move to EDC with a new guidance on computerized systems used in clinical investigations. This workshop will provide sponsors, CROs, investigational sites, IRB members, and EDC and electronic health records (EHRs) vendors the opportunity to discuss and propose process changes, assessment/audit methods, and delivery practices for assuring the quality of electronically captured data across the whole chain of clinical trial activities.

5 Co-located Events

This Event is Co-located with 4 other DIA Conferences for Added Networking Opportunities!

- **DIA Outsourcing Summit**
- **Publication Writing and Building Partnerships**
- ***PMI Pharmaceutical SIG/DIA PM SIAC Joint Conference:* The Future of Pharmaceutical Project Management – Is a Paradigm Shift Needed?**
- **Clinical Trial Disclosure**

FEATURED SESSIONS

- FDA's new guidance for computer systems used by investigators in clinical trials
- Practical guidance on EDC necessities versus expectations by auditors/inspectors
- EDC as the "glue" across the clinical trial production process from protocol development to eCTD submissions
- Future of EDC (validation, CDISC, data cleaning)
- HL7 and Euro-Rec certification of source systems
- Ways to use EDC for quality monitoring and auditing (data mining for quality)
- ***Special Town Hall Session:*** Industry standards and issues of compliance with EDC

WHO SHOULD ATTEND

- GCP and QA auditors with 2+ years of auditing experience
- Study site coordinators
- Study monitors
- Protocol development team members (trial designers with electronic data capture)
- Investigational site staff using EDC and EHRs during the conduct of clinical studies
- IRB members who evaluate studies using EDC
- EDC and EHRs vendors and service suppliers
- Sponsor and site informatics and IT professionals

IACET

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 1.1 continuing education units (CEUs) to participants who successfully complete this program.

Learning Objectives: *At the conclusion of this meeting, participants should be able to:* 1) Describe the impact of recent regulatory guidance related to electronic data quality and EDC; 2) Discuss the various quality standards that could be applied to EDC (ISO, CGMP, Six Sigma); 3) Perform a risk analysis of EDC and EHR use in a clinical protocol; 4) Perform a risk analysis of EDC use across multiple suppliers and internal to the sponsor; 5) Develop and implement an audit plan for EDC site audit; 6) Improve auditing skills and take away sample audit plans; 7) Develop study protocols and clinical trial processes that support the quality of EDC use and outcomes

THIS PROGRAM WAS DEVELOPED BY THE GOOD CLINICAL PRACTICES AND QUALITY ASSURANCE, INVESTIGATOR AND INVESTIGATIVE SITES, VALIDATION, AND eCLINICAL SPECIAL INTEREST AREA COMMUNITIES

SIAC

TRAVEL AND HOTEL The most convenient airport is Fort Lauderdale/Hollywood International Airport and attendees should make airline reservations as early as possible to ensure availability. The Hyatt Regency Bonaventure Conference Center and Spa 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 $189 Double $214

Please contact the Conference Center by telephone at +1-954-616-1234 or +1-800-233-1234 and mention the DIA event. The hotel is located at 250 Racquet Club Road, Weston, FL 33326, USA.

CONFERENCE & TABLETOP EXHIBITS Attendees may visit the tabletop exhibits during the event and receptions. **Event**: Contact Rachel Villareal, Program Developer, by telephone +1-215-442-6131, fax +1-215-442-6199 or email Rachel.Villareal@diahome.org. **Tabletop exhibits**: Contact Erin Gilliland, Exhibits Associate, 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 in the registration area below.**

UNITED AIRLINES & US AIRWAYS

Save through Area Pricing and Discount Fees

To obtain schedule information and the best fares, call United Airlines's Specialized Meeting Reservations Center at **1-800-521-4041**. ***Make sure you refer to Meeting ID Number 571AK.*** Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

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.

CANCELLATION POLICY: On or before NOVEMBER 6, 2007

Administrative fee that will be withheld from refund amount: Member/Nonmember = $200 • Government/Academia/Nonprofit (Member/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.

PLEASE CONSIDER THIS FORM AN INVOICE

Winning Strategies for Achieving a Quality EDC Clinical Trial Process: Sponsor/CRO, Investigator, IRB Approver and IT/IS

Meeting I.D. # 07038 – November 13-14, 2007
Hyatt Regency Bonaventure Conference Center and Spa, Weston, FL, USA

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 and will be accepted by mail, fax, or online.

MEMBER EARLY-BIRD OPPORTUNITY *Available on nondiscount member fee only.*	On or before OCT. 23, 2007	After OCT. 23, 2007
Member Fee	US $1165 ❑	US $1340 ❑

Join DIA now to qualify for the early-bird member fee! **www.diahome.org/en/Membership/AboutMembership/AboutMembership**

MEMBERSHIP US $ 130 ❑

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.

Nonmember Fee US $1470 ❑

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER*
Government (Full-time)	US $ 300 ❑	US $ 430 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 675 ❑	US $ 805 ❑

**If paying a nonmember fee, please check one box above, indicating whether you want membership.*

❑ To receive a tabletop exhibit application, please check.

PAYMENT **REGISTER ONLINE AT www.diahome.org** or please check payment method:

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX *Expiration Date* _____

Card # _____

Signature _____

❑ **BANK TRANSFER** 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 made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

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.

❑ *Please indicate that this form is part of a group registration by checking this box.*

Please list below the names of the other three registrants from your company.

1. _____

2. _____

3. _____

Please complete the information below.

Please check the applicable category: ❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student *(Call for registration information)*

Last Name First Name M.I. Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title Affiliation (Company)

Address (Please write your address in the format required for delivery to your country.) City State Zip Country

email (Required for confirmation.) Telephone Number Fax Number (Required for confirmation.)

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