



CALL FOR ABSTRACTS

DEADLINE: Friday, September 14, 2007

Boston, Massachusetts

44TH

Annual Meeting
Boston Convention &
Exhibition Center

June 22-26, 2008

PROGRAM CHAIRPERSON

Jeffrey W. Sherman, MD, FACP

Takeda Global Research & Development



 **DIA** 
DRUG INFORMATION ASSOCIATION

INTEREST AREAS

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 abstracts. See back page for submission instructions.

AD - ADVERTISING

The topics relate to the advertising and promotion of pharmaceuticals and how marketing/advertising materials and programs are regulated by the FDA. Issues include enforcement activities by the FDA; policies involving CME, off-label policies, direct-to-consumer advertising and promotional programs; activities by the Justice Department, U.S. Attorney's Offices and OIG to pursue fraud and abuse cases; and legislative or other initiatives that deal with the marketing and promotion of pharmaceuticals. Also included are discussions of internal company procedures and policies relating to compliance with all applicable regulations and policies.

AHC/IS - ACADEMIC HEALTH CENTERS/ INVESTIGATOR SITES

AHC topics/issues in drug development should focus on special significance and complexity for academic health centers including contracts and budgets, investigator-initiated protocols and grants, IRBs and human subject protections, data collection and management, health information technology, HIPAA, risk management, education and training, clinical research monitoring, regulatory requirements, publication, and compliance to ensure quality data and the integrity of the clinical trials process in the academic health center.

Investigator Sites abstracts should address topics and issues related to the operations, conduct and management of clinical trials at investigatory sites, e.g., subject recruitment, retention, and management; organizing your practice for successful and profitable studies; finding and attracting the right studies for your site; grant negotiation and management; IRB and HIPAA requirements and how they could affect you; training and education for you and your staff; the use of metrics to manage studies and personnel; and other topics of interest to investigators and other study site personnel.

BT - BIOTECHNOLOGY

The biotechnology track will present topics related to discovery and early development of novel products including somatic cell and stem cell therapies, gene therapies, vaccines, combination products and tissue-engineered products. The sessions will cover a variety of issues such as manufacturing and quality control, novel assays and novel delivery technologies (e.g. nanotechnology), immunogenicity, bioethics and case studies of successful early development strategies. Discussions will also include enabling translational research from academia and identifying key elements of due diligence exercises for novel products or technologies to expand product pipelines.

CDM - CLINICAL DATA MANAGEMENT

The objective of this track is to select the most current and forward-thinking topics as they relate to the clinical data management function and its future role in the industry, such as challenges in global cooperation, interactions with other functions or topics related to broadening the responsibilities of data management. We encourage abstracts to be thought-provoking and even controversial, if necessary. In addition, abstracts focusing on novel approaches and ideas as they apply to the spectrum of data management activities are desired.

CMC/GMP - CHEMISTRY, MANUFACTURING AND CONTROLS

Abstracts should contribute to the dialogue and discussion on technical and regulatory issues related to science- and risk-based CMC and GMP initiatives, quality-by-design approaches to pharmaceutical development, updates on ICH quality guidances, 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, etc.

CP - CLINICAL SAFETY AND PHARMACOVIGILANCE

Multidisciplinary issues on a global basis affecting the collection, management, assessment, regulatory reporting (expedited, periodic, special), use, and communication of patient safety data (signs, symptoms, diagnoses, laboratory data) during development and post-approval. Includes new regulatory requirements, technology (e.g., MedDRA®, SNOMED and other coding terminologies, electronic case reporting, software, management and use of safety databases, data mining, signal detection), compliance and auditing, product safety information ("labeling"), clinical science applied to adverse experiences (causality, pharmacology, pharmacogenetics), pharmacoepidemiology, and risk management.

CR - CLINICAL RESEARCH AND DEVELOPMENT

Abstracts should address topics related to clinical trial methodology and

implementation, including clinical/regulatory strategy for specific indications, clinical plan and protocol development, tactics/processes/tools, and patient enrollment and retention, for efficient execution of clinical trials.

CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES

CTM Abstracts should address topics/issues related to the operations, conduct and management of clinical trials, e.g., site recruitment and management, clinical team structure, roles and responsibilities, communications and performance, audit readiness (site and sponsor), clinical project management, and the use of metrics to manage studies and training of CTM personnel.

CS Abstracts should address leading edge technologies used to improve the efficiency and logistics of the clinical supply chain, information technology used to streamline the communication between clinical research and clinical supplies, and procedures to minimize the traditional overage of CS needed to conduct clinical trials.

EC - ECLINICAL

Abstracts should focus on the development of technology, standards, policies and procedures for the reporting, capture, analysis, submission, and archiving of information created within the process of clinical development. New proposals and reports of methodologies are encouraged, as the realm of clinical trials begins to embrace the sharing of data along the continuum of discovery through patient care.

ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/ DOCUMENT MANAGEMENT

Abstracts should address topics of interest to document and records management (DRM), and electronic regulatory submission development (ERS) professionals. This includes DRM topics such as: fundamentals of document management, workflow, document tracking, streamlining the document management process, managing documents in the global context, the challenge of managing documents in an electronic environment, and document archiving. Topics of interest concerning ERS development and delivery include: electronic submission formats (eCTD, eINDs, eNDA, eBLAs, hybrids), submission standards, technologies, PLR, SPL, PIM, RPS, Global eLabeling challenges and opportunities for harmonization, global submissions (challenges, regional differences, etc.), the impact to the sponsor's organization, and regulatory authority readiness and future directions.

GCP - GOOD CLINICAL PRACTICES

The topics/issues related to the good clinical practices aspects of both global and local clinical trials, including internal QA programs and audit outcomes, regulatory inspection results and processes (FDA, EMEA, other countries, comparison of FDA and EMEA), discussion of the latest issues in the clinical trial process including impact of new developments in GCP to speed up the clinical trial process, human subject protection issues such as informed consent and IRB/ethics committee procedures, compliance and oversight of clinical trials, use of electronic systems in clinical trials, including validation and audit of these systems, detection and prevention of fraud and misconduct in clinical trials, financial aspects of clinical trials, GCP inspections, training of investigators, IRBs, and industry personnel, auditing practices and techniques, and discussion of evolving international clinical trial disclosure law and guidance and effects on the clinical trial life cycle.

IMP/EBM - IMPACT (IMPACT OF MEDICAL PRODUCTS AND THERAPIES)/ EVIDENCE-BASED MEDICINES

This interest area focuses on current issues related to the generation, analysis, and utilization of evidence to assess the impact of medical products on health outcomes, patient-reported outcomes, and health expenditures as they relate to clinical practice and drug coverage issues. Sessions may focus on issues related to obtaining, measuring, and evaluating evidence, pharmacoeconomics and cost-effectiveness, health services research, and pharmacoepidemiology (non-safety related). The use of actual case examples is strongly encouraged. Data, methods, and case examples come from a variety of sources and settings, including but not limited to clinical trials, observational or claims databases, surveys, and registries.

IT - INFORMATION TECHNOLOGY

Abstracts should be oriented around topics of interest to the information technology professional, but because of the broad reach of the annual meeting, should be presented in a way to provide insight and information to any

attendee. Topics could include any major application development area (e.g., web services, security, electronic data capture, electronic publishing, e-collaboration, archiving, data integration or document management). Application topics should focus on the underlying technology issues around these areas, and not people and process issues. Other areas of interest such as technology infrastructure, how to deploy applications globally, technology-specific validation topics, and evolving technology standards are also of interest.

MA - MARKETING

Topics should address lifecycle management, portfolio analysis/techniques, market preparation, marketing research, and tactical program implementation in the development, communication, pricing, labeling, distribution, and utilization of pharmaceutical and medical products.

MC - MEDICAL COMMUNICATIONS

Session abstracts should address topics related to the practice and provision of drug or medical information as it relates to internal or external customers including healthcare professional and consumers. Examples of appropriate topics include, but are not limited to, the provision of on-label and off-label information, response document creation and maintenance, literature evaluation, contact center issues, innovative technologies, legal and regulatory issues of medical communications, and the social and technical issues regarding field-based medical communications.

MW - MEDICAL/SCIENTIFIC WRITING

Medical/Scientific writing is an essential and established core function for drug development, registration, and marketing within the pharmaceutical industry. The focus of this track will be on updating skills and keeping abreast of changes in this global environment. Topics/issues related to first-hand experience with writing components of the CTD, progress in the electronic environment (including e-CTD, e-IND, HTML, templates, electronic style guides), medical writing in cross-functional teams, changes in pharmacovigilance requirements and writing of safety documents, and the emergent role of medical writing in Japan, China, India, and South East Asia will be included. Abstracts on writing for a website and the needs of the freelance writer are also invited. Abstracts from session leaders who plan to have a mix of speakers from other disciplines as well as MW are particularly welcome.

NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT

The nonclinical laboratory safety assessment track will present discussions of emerging scientific and regulatory issues related to the assessment of the safety of regulated products. The track will also cover issues related to laboratory studies evaluating pharmacokinetics and effectiveness of products, biomarkers of toxicity, predictive pharmacology, predictive models for preclinical safety and animal disease models. Sessions will relate these issues to their impact on the initiation of clinical trials and the protection of subjects in clinical trials. The views of industry and regulatory authorities on new methodologies and experimental techniques and current guidance on their use in pre-clearance testing will be addressed. Sessions will also cover operational and management issues related to international harmonization, regulatory compliance, quality management, and the reporting and presentation of study results.

NHP - NATURAL HEALTH PRODUCTS

Natural Health Products (NHPs) Track will represent complex or "poly molecular" products and ingredients from any source, including but not limited to botanicals, animal, insect, and microbial sources; or combination products from traditional medicinal use, prior dietary or nutritional use, or novel ingredient combinations. Abstracts should be related to the discovery, development, regulation, growing/harvesting, manufacturing, preclinical and clinical evaluation, safety monitoring, sale, advertising and promotion of NHPs. Particular emphasis will be given to abstracts focusing on product characterization, sourcing, lot-to-lot standardization, design and implementation of preclinical and clinical trials, GxPs, dose selection, methodologies, trial management, novel study designs, regulatory filing requirements for the mainstream development of poly molecular products in the US and in foreign countries, utilization of "prior human use" data, bioassays, CMC approaches, and the impact of domestic and foreign policy directives on this specific area of drug development.

OS - OUTSOURCING

Abstracts should address topics related to the outsourcing of activities in connection with the drug development process. Consideration should be given to experiences (both positive and negative) relating to the outsourcing of the following activities: Clinical Research, Data Management/Biostatistics, Medical Writing, and Regulatory Affairs. Whenever possible, representatives from pharmaceutical companies and their outsourcing partner(s) should collaborate for an integrated, balanced session. Additionally, experiences where a single partner was chosen to provide "full service" versus multiple outsourcing partners ("unbundled services") used for a given program could be informative. Presenters are encouraged to include the use of case studies of successes (as well as less successful case studies) with any of the above topics.

PM/FI - PROJECT MANAGEMENT/FINANCE

Project Management abstracts should address topics and issues related to the project and portfolio management of the drug development process, e.g., planning, scheduling, resource management, risk management, team creation and development, leadership, negotiation and conflict resolution, establishing a project management culture, and training of project managers. Particular interests include the best practices and new paradigms which will address the new challenges the pharma industry is currently facing, and the value added by the project management.

Finance abstracts should address topics and issues associated with the financial aspects of product development including the acquisition of venture capital, mergers and acquisitions, budgeting for R&D (corporate and/or project level), and contracting with CROs and investigators. Ancillary topics can also include negotiation skills and practices and standardizing accounting practices within pharmaceutical companies, particularly from global perspective. Presenters are encouraged to include the use of case studies of successes with any of the above topics.

PP - PUBLIC POLICY/LAW

Topics should be related to legal issues (product liability, patents and trademarks, contracting with suppliers and CROs), pending legislation that may become effective in the near future, reimbursement and ethical issues in the research and development and marketing of drug products.

RA - REGULATORY AFFAIRS

Session topics need to cover the discipline broadly and globally, yet provide content, depth, diversity and value. The topics to be covered should include drugs and biologics, developments on emerging therapies, without neglecting the field of medical devices, as member interest is growing in this area. The primary focus is on drugs and biologics, but coverage of emerging therapies and medical devices is rising due to member interest. The track tends to be 50% "international" by design, so as to reflect the strong globalization and harmonization trends of today, including interactions between regulatory authorities worldwide. Abstracts may address the regulatory process and mechanisms, technical issues that impact the regulatory process, the regulatory profession and its daily practice, special regulatory challenges of today or tomorrow, solutions to age-old or newfangled problems, practical, everyday issues for regulatory professionals and their employers, the perspective of government regulators, political and regulatory pressures, case studies and war stories. Abstracts will be selected on the basis of content, originality, relevance, timeliness, value added, and fit with these general guidelines.

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, industry structure, implementation of regulatory initiatives, and external forces that influence industrial R&D.

ST - STATISTICS

Abstracts should address topics related to the use of statistics during the entire drug development process. These topics may involve: Innovative or novel clinical trial designs (including: adaptive trials, Bayesian trials, Phase II dose response estimation, Phase II/III trials, noninferiority trials), sample size considerations (including: sample size re-estimation), analysis of pharmacogenomic data, modeling and trial simulation, statistical monitoring/interim analysis of safety and efficacy, statistical methods for analyzing data (including: multiple endpoints, data mining, meta-analyses), novel visual/graphical displays of data or automated/IT tools to enhance statistical analysis, recent developments in "regulatory statistics" (including: ICH guidelines, CPMP Points to Consider) and statistical methods for portfolio optimization and prioritization of drugs in development.

TR - TRAINING

Sessions should focus on models for global training, training the investigator, training at the investigator site, using multimedia for effective training, and training and career development of pharmaceutical professionals through human resources-based programs and through formal academic programs. Our sessions address standard operating procedures training, delivery of training on corporate as well as drug development issues, and career development and career change. We encourage submissions that reflect innovative design of training delivery and also those that reflect personal experiences of career enhancement.

VA - VALIDATION

Sessions will focus on various effective, efficient and quality methodologies for computerized system validation, maintenance and retirement of global and single site computerized systems in the various GXP areas. Also included are sessions on effective auditing of vendor or investigator computerized systems for compliance, quality and integrity; risk assessment and management techniques; and current federal and international regulatory expectations and initiatives relating to computerized systems. Our sessions encourage the "sharing of actual case studies or inspection experiences" to promote information exchange.

CALL FOR ABSTRACTS DEADLINE: FRIDAY, SEPTEMBER 14, 2007

SUBMISSION INSTRUCTIONS

To submit an abstract for the 2008 Annual Meeting, please visit the DIA website <http://www.diahome.org/DIAHOME/GetInvolved/AbstractSubmissionLauncher.aspx>

SESSION ABSTRACTS

- Session abstracts must be for a complete 90-minute session.
- Individual presentation abstracts will not be considered.
- The author of the selected abstract will serve as the session chair.
- As the session chair, you will be responsible for recruiting at least two additional speakers representing other companies.
- All authors of abstracts will be required to complete a speaker disclosure form at the time of submission.
- **Session Chairperson Disclosure Information**

All session chairs and speakers must 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 education presentation, as well as any discussion of unlabeled or unapproved drugs or devices.

If your session abstract is accepted, you will serve as the session chair. You are responsible for the following:

- Adherence to the DIA policy and procedures regarding session design, supported speaker(s), and promotion at the podium. (A complete 44th Annual Meeting Program Development Timeline and Session Chair Resource Guide will be provided after session selection is complete.)
- Providing complete speaker information to the DIA office no later than **Friday, December 7, 2007**.

To submit a session abstract, please visit <http://www.diahome.org/DIAHOME/GetInvolved/AbstractSubmissionLauncher.aspx>

The following information will be requested at the time of submission:

- Session chairperson name and contact information
- Session abstract title
- Primary interest area
- Subcategory interest area (as needed)
- Level of session difficulty
- Option to request continuing education credits
- Learning objectives (500 characters)
- Abstract summary (300 characters)
 - This abstract summary will be used to publicize the session within the Annual Meeting program guide.
- Session Abstract Full Description (4000 characters)
 - This information will be used to determine whether a session based on your abstract will be included in a DIA program.

TUTORIAL ABSTRACTS

A tutorial is a “hands-on,” interactive learning experience for a group of 25-50 and if selected will be scheduled on **Saturday, June 21** or **Sunday, June 22, 2008**.

- A half-day tutorial consists of 3 hours and 15 minutes of instruction with no more than two instructors.
- A full-day tutorial consists of 6 hours and 30 minutes of instruction with no more than three instructors.
- The author of the selected tutorial abstract will serve as the lead instructor.
- **Instructor Disclosure Information**
Instructors must 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 education presentation, as well as any discussion of unlabeled or unapproved drugs or devices.

If your tutorial abstract is accepted, the lead instructor will be responsible for the following:

- Adherence to the DIA policy and procedures regarding tutorial design, promotion at the podium, and tutorial development timelines.
- Providing complete tutorial detail and co-instructor detail to the DIA office no later than **Friday, November 20, 2007**.

To submit a tutorial abstract, please visit <http://www.diahome.org/DIAHOME/GetInvolved/AbstractSubmissionLauncher.aspx>

The following information will be requested at the time of submission:

- Tutorial title
- Number of co-instructors
- Primary interest area
- Subcategory interest area (as needed)
- Level of tutorial difficulty
- Option to request continuing education credits
- Learning objectives (300 characters)
- Target audience: (300 characters)
- Tutorial overview: (2000 characters)
 - This overview will be used to review the abstract as well as to publicize the tutorial, should it be accepted.

Should you have questions regarding your abstract submission, please contact 2008program@diahome.org.

