FDAnews has convened the clinical trial industry's top regulators, medical affairs, operations and legal experts to dissect the growing requirements and pressures for more disclosure and transparency. This Summit is the most unique and vital intelligence-gathering event of the year. Register today!

July 23 – 24, 2013 • Doubletree Bethesda Hotel • Bethesda, MD

Clinical Trials Disclosure and Transparency Summit

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KEYNOTE SPEAKERS:

DR. JANET WOODCOCK
Director, CDER, FDA

SIR ALASDAIR BRECKENRIDGE
Chair, Emerging Science and Bioethics Advisory Committee, Department of Health, UK; formerly Chairman, Medicines and Healthcare Products Regulatory Agency, UK

SPEAKERS:

- **Peter Pitts**, President, Co-founder, Center for Medicine in the Public Interest (Chairperson)
- **Dr. Deborah Zarin**, Director, ClinicalTrials.gov
- **Dr. Robert Temple**, Director, Office of Medical Policy, CDER, FDA (invited)
- **Dr. Joseph Ross**, Co-Investigator, Yale Open Data Access Project (YODA), Yale University
- **Dr. Lisa Schwartz**, Co-Director, The Center for Medicine and the Media, The Dartmouth Institute for Health Policy and Clinical Practice
- **Dr. Gregory Curfman**, Executive Editor, New England Journal of Medicine
- **Dr. Steven Woloshin**, Director, The Center for Medicine and the Media, The Dartmouth Institute for Health Policy and Clinical Practice
- **Dr. Phil Fontanarosa**, Executive Editor, JAMA
- **Dr. Jose Merino**, Research Editor, British Medical Journal
- **Dr. Christine Laine**, Editor, Annals of Internal Medicine
- **Dr. Jesse Berlin**, Vice President, Pharmacoepidemiology, Johnson & Johnson Pharmaceutical Research and Development (invited)
- **Jessica Gilbart**, President and CEO, Lupus Foundation of America
- **Dr. Garry Neil**, Partner, Apple Tree Partners; formerly Corporate Vice President, Science & Technology, Johnson & Johnson (invited)
- **Christopher Dedels**, Global Product Manager – Clinical Trial Disclosure Solutions, Virtify
- **Dr. Bruce Haffty**, Associate Editor, Journal of Clinical Oncology
- **Susan Randall**, Senior Director of Science and Education, National Osteoporosis Foundation (invited)
- **Louise Vetter**, CEO, Huntington's Disease Society of America (invited)

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WORKSHOP AGENDA

DAY ONE - Tues., July 23, 2013

8:30 a.m. – 9:30 a.m.
Registration and Continental Breakfast

9:30 a.m. – 9:45 a.m.
Introduction and Opening Comments From Chairperson

Peter Pitts, President, Co-founder, Center for Medicine in the Public Interest

9:45 a.m. – 10:15 a.m.
Keynote From Dr. Janet Woodcock, Director, CDER, FDA – CDER's Views on Clinical Trial Disclosure and Transparency

A broad societal consensus about public availability of clinical trial results and data has been building over the last two decades. In the U.S., this has been instantiated by the development of the clinical trial registry at ClinTrials.gov and the evolving requirements for disclosure. Public goods from this approach include wider use of data, greater confidence in results claimed by investigators, availability of results from negative trials (often not otherwise published) and ability to evaluate the overall clinical trial enterprise. Caveats include concerns about misuse of data, competitive disadvantages and release of personally identifiable information. At this point, release of patient-level data is not widely practiced. The EMA has announced it will begin to release data submitted in marketing applications upon request. FDA's FOI practices do not include release of patient-level data. Such data are extremely voluminous and require conformance to regulations involving redaction. Release of data generated by medical product sponsors and submitted in applications to regulatory agencies may not be the best path to widespread availability.

10:15 a.m. – 11:00 a.m.
Keynote From Sir Alasdair Breckenridge, Chair, Emerging Science and Bioethics Advisory Committee, Department of Health, UK — Open Clinical Trial Data for All?

The potential benefits for public health of independent (re)analysis of data are not disputed and, in an open society, trial sponsors and regulators do not have a monopoly on analyzing and assessing drug trial results. Yet the different responsibilities of regulators and independent analysts have to be acknowledged. Regulators, unlike academics, are legally obliged to make timely decisions on the availability of drugs for patients, even under conditions of uncertainty. There are indeed many good arguments for unrestricted and easy access to full RCT data; yet simply uploading all trial data to a website entails its own problems.

Attendees will learn:

- Development and agreement upon adequate standards for protection of personal data when publicizing complete datasets
- Ensure general adoption of established quality standards of meta-analyses and other types of (confirmatory) data reanalysis that may warrant regulatory action
- Establish rules of engagement that provide balance between sponsor concerns and public health benefits

11:00 a.m. – 11:15 a.m.
Morning Break

11:15 a.m. – 1:00 p.m.
Interactive Panel Discussion: Got Registered Trials? Seeking Common Ground Between Medical Journal Editors and Industry

Publication of the results of a clinical trial in prestigious international medical journals carries substantial weight, as companies frequently use articles for a variety of marketing and outreach. But what would happen if journal editors flexed their publishing muscles? Can industry survive on less-prominent medical journals? Can editors work together with industry to find common ground?

Attendees will learn:

- What editors mean when they use words like "disclosure" and "transparency"
- Prominent versus less-prominent journals — is there a controversy brewing
- Latest developments among editor groups as to official polices going forward

1:00 p.m. – 2:00 p.m.
Lunch Break

2:00 p.m. – 2:45 p.m.
The Role and Importance of Clinical Trial Registries & Results Databases

Clinical and policy decisions should be informed by evidence regarding the benefits, risks and other burdens associated with all possible alternatives. Clinical trials are a key component of the body of scientific evidence that must be used to make decisions. Most decisionmakers depend on summary data from journal articles, but three key problems have arisen: (1) not all trials are published, (2) publications do not always include all prespecified outcome measures and (3) unacknowledged changes are made to the trial protocol that would affect the interpretation of the findings — e.g., changes to the prespecified outcome measures. This presentation will address the current state of clinical trial registries and results databases and specifically what ClinicalTrials.gov is doing to improve clinical effectiveness.

2:45 p.m. – 3:30 p.m.
Why Dartmouth Chose to Become the First Academic Medical Center to Join AllTrials

Recently the AllTrials Campaign announced that Dartmouth's Geisel School of Medicine and the Dartmouth Institute for Health Policy & Clinical Practice signed on to be the first US academic center in the campaign and will take the lead in urging all medical schools and patient advocacy groups in the US to join AllTrials.net. The AllTrials campaign, which calls for all clinical trials to be registered and results reported, was launched in the United Kingdom in January 2013. The campaign seeks to encourage academic medical centers throughout the world to join AllTrials' call for the registration and timely full publication of all clinical trial protocols, methods and results

3:30 p.m. – 3:45 p.m.
Afternoon Break

3:45 p.m. – 5:00 p.m.
Interactive Panel Discussion: Beyond Basic Research — Understanding Patient Advocacy and the Push to Help Shape the Process

The need to disseminate clinical trial information to patients is critical. Patients cannot enroll in a new treatment study if they're not aware of its existence and may have concerns over privacy when patient-level data is made

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publicly available. Methods to publicly convey clinical trial data in a patient-friendly yet non-promotional manner often overlook the insight and constructive criticism patient advocacy organizations can offer.

Attendees will learn:

- Transparency as a means to increasing clinical trial participation
- Rare diseases and de-identifying patient-level data for public access
- Distilling clinical trial results for patients

5:00 p.m. – 6:30 p.m.
Cocktail Reception and Networking

DAY TWO - Wed., July 24, 2013

9:00 a.m. – 9:30 a.m.
Continental Breakfast

9:30 a.m. – 9:45 a.m.
Chairperson Welcome and Recap of Previous Day's Discussions

Peter Pitts, President, Co-founder, Center for Medicine in the Public Interest

9:45 a.m. – 10:30 a.m.

Understanding Data Sharing and Investigator Databanks To Improve Clinical Practice

At the beginning of every clinical trial, drug developers must pick a clinical trial site and make sure it is prequalified to conduct the trial and the clinicians are trained in trial protocols. The process can be paperwork-heavy and time-consuming for trial sponsors and investigators alike. By housing critical information about investigators and trial sites in one place, databanks will reduce time, cost and duplicative efforts, making it easier for companies to identify appropriate trial sites and investigators for future clinical trials. Investigator sites that have opted-in to data sharing will have their relevant information accessible to pharmaceutical companies participating in the collaboration. Databanks will not include any patient data.

10:30 a.m. – 11:15 a.m.

Legal Issues Related to the Balancing of Disclosure Of Trial Data and Commercially Sensitive Materials/ Trade Secrets

Drug and biotech manufacturers have long considered clinical data collected during a drug's trial to be confidential information or "trade secrets", sometimes even after submission to FDA. But how are calls for increased disclosure and transparency — and recent court decisions — shaping legal strategies?

11:15 a.m. – 11:30 a.m.
Morning Break

11:30 a.m. – 1:00 p.m.

Interactive Panel Discussion: How Trial Data Disclosure and Transparency Might Affect Advertising and Promotion Activities

If drug and device companies are required to provide greater disclosure and transparency of trial data, will it upset corporate marketing strategies? There's always the fear that one firm could use less than stellar trial data against another in advertising or PR campaigns. This panel will discuss and debate how the advertising and promotion teams need to be prepared for the new "leveled" playing field.

1:00 p.m. – 2:00 p.m.
Lunch Break

2:00 p.m. – 2:45 p.m.

Yale University Open Data Access Project (YODA) — A Model for Dissemination and Independent Analysis of Clinical Trial Program Data

Each day, patients and their physicians make treatment decisions with access to only a fraction of the relevant clinical research data. Many clinical studies, including randomized clinical trials, are never published in the biomedical literature. The Yale University Open Data Access project has developed a model to facilitate access to patient-level clinical research data to promote wider availability of clinical trial data and independent analysis by external investigators. The YODA project model provides a means for rigorous and objective evaluation of clinical trial data to ensure that patients and physicians possess all necessary information about a drug or device when making treatment decisions.

Attendees will learn:

- How the process includes both coordinating independent examinations of all relevant product data by two separate qualified research groups
- How the model is designed to provide industry with confidence that the analyses will be scientifically rigorous, objective and fair

2:45 p.m. – 3:30 p.m.

Automating Data Uploading From Company/Academic Databases/ Spreadsheets Into Clinicaltrials.gov and Other Clinical Trial Registries

Collecting the data is one thing, but properly loading it into ClinicalTrial.gov or other registries is another. This presentation will discuss the challenges and solutions for achieving cross-registry conformity, best practices for auditing posted data across registries and synchronizing registry data. Also includes tips and tricks for overcoming registry nuances and language barriers.

3:30 p.m. – 3:45 p.m.
Closing Comments

WHAT COMPANIES WILL BENEFIT:

- DRUG COMPANIES
- BIOTECH COMPANIES
- BIOLOGIC COMPANIES
- CROS
- ACADEMIC MEDICAL CENTERS
- GOVERNMENT RESEARCH CENTERS
- MEDICAL JOURNALS
- PATIENT ADVOCACY GROUPS

WHO SHOULD ATTEND

- CLINICAL RESEARCH DIRECTORS
- MEDICAL AFFAIRS DIRECTORS
- REGULATORY AFFAIRS
- LEGAL AND COMPLIANCE OFFICERS
- CONSULTANTS/SERVICE PROVIDERS

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TUITION

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