

# Genomic Information: Practical & Legal Effects on Clinical Trials

**Presented by Dr. Joshua Sharlin & Dr. Joe Veltmann**  
**Thursday, February 25, 2010, 1:00pm to 2:30pm EST (GMT -5)**

**For decades, clinical trials have been conducted with broad patient populations. But today, with inexpensive access to a person's genome, an individual's genetic information can be learned and applied to improve the development and use of drugs and biologics.**

For example, common DNA variations in just one enzyme system metabolizes more than 30 classes of drugs, including antidepressants, antipsychotics, antiarrhythmics, pain medications and beta-blockers -- drugs that add up to roughly 60% of prescriptions written. One change in a DNA base can increase or decrease a person's ability to metabolize a drug. This has significant implications for speeding up drug development, individualizing drug dosage levels, and defending against lawsuits about adverse events.

On Thursday, February 25, beginning at 1:00pm EST, join FOI Services and Drs. Joshua Sharlin and Joe Veltmann for a 90-minute teleconference to learn about the advantages, uses, potential pitfalls, and legal implications of using of genomic information in an FDA-regulated environment.

## What You'll Learn:

- The basis for using genomic data to develop new drugs and biologics
- When genomic data must be submitted to an IND, NDA or BLA
- FDA's recommendations on content and format of genomic data
- The contents of a Voluntary Genomic Data Submission (VGDS) to FDA and when it should be used
- Biomarker qualification process
- Changes you must make to your informed consent documents
- How to apply genomic data after product approval
- Opportunities for a CRO to use genomic data to improve their services
- Some legal issues to address before a clinical trial
- The legal defenses that genomic data may offer drug manufacturers

## What You'll Get:

- FDA-authored guidances and related documents about pharmacogenomic submissions and the pharmacogenomic regulatory process
- Step-by-step instructions to determine if your product's safety and effectiveness can be affected by common genetic defects
- Checklists to improve your compliance

- Presenters experienced in both the science of genomics and FDA's regulatory concerns
- Time for questions & answers

### **Who Will Benefit:**

- Anyone involved in developing a product approval strategy
- R&D
- Statisticians
- Medical writers dealing regulatory submissions or clinical study documentation
- Regulatory affairs staff
- Food and drug attorneys
- Principal investigators and study staff
- Study auditors
- Recruiters for clinical trials

### **About Your Presenters:**

**Joshua Sharlin, Ph.D.**, is the President of Sharlin Consulting and a former FDA reviewer. He has trained tens of thousands of people from hundreds of FDA regulated companies on a wide variety of technical and regulatory topics. Applied to this presentation will be his practical knowledge acquired during his 15+ years of consulting to FDA-regulated industry. For more information about Dr. Sharlin, or to learn more about the coverage of this presentation, he can be contacted via his website at [www.speedupfda.com](http://www.speedupfda.com) or emailed directly at [jsharlin@pipeline.com](mailto:jsharlin@pipeline.com)

**Joe Veltmann, Ph.D.**, is the CEO of the Institute for Individualized Medicine. He has over a decade of experience applying genomic data to improve an individual's health and wellness and reduce health care costs. Additional information about Dr. Veltmann's background is available at [www.iimsite.com](http://www.iimsite.com)

### **How it Works:**

Each toll-free (even if international) dial in is \$449; put the teleconference on your speakerphone and have as many attendees as you like for this price. FOI Services will provide a handout 2 days before the teleconference. The materials may be duplicated for anyone attending.

### **Where:**

In your office or conference room.

## **To Register:**

To register online, or for details on additional upcoming teleconferences, go to [www.foiservices.com/tc](http://www.foiservices.com/tc). You may also call 1-800-654-1147 (outside the US and Canada call +1-301-975-9400) to register by phone.