

Program — Day One

Thursday, October 15

7:30 am	<i>Registration Opens</i>	12:00 pm – 1:30 pm	<i>Lunch</i>
7:30 am – 8:30 am	<i>Breakfast</i>	1:30 pm – 2:45 pm	Utilizing TrialWorks to Meet FDAAA Requirements: ClinicalTrials.gov Trial Registration
8:30 am – 9:00 am	General Welcome and Introduction <i>Steve Kent, President — Perceptive Informatics</i> <i>Sara Diamond, Senior Director, TrialWorks Development Operations — Perceptive Informatics</i>	2:45 pm – 3:15 pm	<i>Taryn R. Joswick, Director, Clinical Development — Sucampo Pharma Americas, Inc.</i> <i>Break</i>
9:00 am – 10:15 am	Using TrialWorks as a Clinical Operations Communication Tool for a Global Oncology CRO and a Clinical Research Network <i>David Colborn, Vice President, Data Management and Information Technology — Veeda Oncology</i> <i>Shari Gaylor, Project Manager — Veeda Oncology</i>	3:15 pm – 4:30 pm	Trials and Tribulations of Implementing the TrialWorks Monitoring Module <i>Edwin M. Van der Jagt, Regional CRA — Medicis</i>
10:15 am – 10:45 am	<i>Break</i>	4:30 pm – 5:45 pm	Using TrialWorks to Measure and Forecast Monitoring Demand <i>Kris Bentvelsen, Director, Global Clinical Operations Planning & Analytics — Abraxis Bioscience Canada, Inc.</i>
10:45 am – 12:00 pm	A Step-by-Step Approach for Using TrialWorks to Track Essential Documents for a Clinical Study from Site Certification Through Study Close-Out <i>Lisa Dodson, Clinical Consultant — Rocky Mountain Clinical Consulting, LLC</i>	5:45 pm – 6:00 pm	Day 1 Closing Remarks <i>Sara Diamond, Senior Director, TrialWorks Development Operations — Perceptive Informatics</i>
		7:00 pm – 9:30 pm	<i>Welcome Reception & Dinner</i>

REGISTER TODAY!

To register, go to: www.perceptive.com/CTMS/TrialWorks/User-Group and click on the Registration button.

Program — Day Two

Friday, October 16

7:15 am – 8:15 am	<i>Breakfast</i>	11:45 am – 12:45 pm	<i>Lunch</i>
8:00 am – 8:15 am	Day 2 Opening Remarks <i>Sara Diamond, Senior Director, TrialWorks Development Operations — Perceptive Informatics</i>	12:45 pm – 1:45 pm	Future TrialWorks Enhancements <i>Sara Diamond, Senior Director, TrialWorks Development Operations — Perceptive Informatics</i>
8:15 am – 9:15 am	The Value of TrialWorks: Defining, Understanding and Measuring ROI <i>Jennifer Durham, Manager, Logistics, Clinical Operations — Pierrel Research USA, Inc. (formerly Encorium Group)</i> <i>Michael Shilling, Director, Business Development — Perceptive Informatics</i>	1:45 pm – 2:00 pm	Closing Remarks <i>Sara Diamond, Senior Director, TrialWorks Development Operations — Perceptive Informatics</i>
9:15 am – 10:15 am	Interactive Breakout Sessions: The Value of TrialWorks <i>Jennifer Durham, Manager, Logistics, Clinical Operations — Pierrel Research USA, Inc. (formerly Encorium Group)</i> <i>Michael Shilling, Director, Business Development — Perceptive Informatics</i>		
10:15 am – 10:45 am	<i>Break</i>		
10:45 am – 11:45 am	Interactive Breakout Session Summary: The Value of TrialWorks <i>Jennifer Durham, Manager, Logistics, Clinical Operations — Pierrel Research USA, Inc. (formerly Encorium Group)</i> <i>Michael Shilling, Director, Business Development — Perceptive Informatics</i>		

EVENT VENUE

Sheraton Boston Hotel (Back Bay)
39 Dalton Street
Boston, MA 02199



SPECIAL HOTEL ROOM RATE

Perceptive Informatics has secured a block of rooms at the Sheraton Boston Hotel at a reduced rate. To take advantage of our special rate, click on the registration button at: www.perceptive.com/CTMS/TrialWorks/User-Group

Presentations

Thursday, October 15

**Using TrialWorks as a Clinical Operations
Communication Tool for a Global Oncology CRO and
Clinical Research Network**

Veeda Oncology® provides international clinical oncology research services for the pharmaceutical and biotech industries. We have established offices in the US, Europe and India to meet both the regional and global needs of our sponsors in conducting Phase I – IV clinical oncology programs. To help reduce the time to open clinical sites and provide rapid access to patients, Veeda Oncology also manages a network of approximately 50 community clinical oncology practices that conduct research. Veeda leverages the functionality of TrialWorks to communicate the status of clinical trial activity being conducted worldwide and to track metrics that can be used to provide feedback to our clients regarding performance expectations for current and future trials. Additionally, Veeda uses TrialWorks to maintain a repository of current reference information for all Veeda Oncology Network sites.

**A Step-by-Step Approach for Using TrialWorks to
Track Essential Documents for a Clinical Study from
Site Certification Through Study Close-Out**

With the amount of paperwork for each study and each individual site, just the paper filing alone can become a handicap of conducting your study according to the ICH/GCP guidelines. TrialWorks is a great tool to track your study/site essential documents. With some “out of the box” thinking and approaches there are many ways that practically every level of documentation for your study/site can be tracked in the system. This presentation is a step by step approach on just that – tracking ICH/GCP Essential Documents for study start up through study close out – in TrialWorks.

**Utilizing TrialWorks to Meet FDAAA Requirements:
ClinicalTrials.gov Trial Registration**

The Food and Drug Administration Amendments Act (FDAAA) of 2007 (US Public Law 110-85) expanded the scope of registration of clinical trials at ClinicalTrials.gov, increased the amount of information that must be provided at the time of registration, required the inclusion of trials results, and imposed penalties for non-compliance. This presentation will provide an overview of the ClinicalTrials.gov export function within the TrialWorks system, an explanation of the requisite data elements for registration within the ClinicalTrials.gov Protocol Registration System (PRS), and best practices for use of both systems.

**Trials and Tribulations of Implementing the
TrialWorks Monitoring Module**

The presentation will focus on our experiences at Medicis implementing the TrialWorks Monitoring Module by looking at preparation, testing of the module in a small scale study and subsequent use by multiple CRAs and the impact on the in-house team. The preparation review will focus on automating certain aspects of the Monitoring Visit Reports and Follow-up letters. The test study will focus on the experiences and lessons learned by using the module in a small scale study (one CRA using the module, Clinical Trial Coordinator and Clinical Study Manager). The last part of the presentation will focus on the experiences of up scaling use of the Module in a larger team.

**Using TrialWorks to Measure and Forecast
Monitoring Demand**

Most small to medium-sized pharmaceutical companies have a strong need to plan and predict demand associated with monitoring resources, whether these services are provided by in-house or external (CRO) staff. In this presentation, we will explore how TrialWorks can be used to measure current demand, and how future demand can be estimated. The output can be used to manage current resources, justify future headcount requests, measure productivity, and to geographically allocate new resources most efficiently.

Presentations

Friday, October 16

The Value of TrialWorks: Defining, Understanding and Measuring ROI

Determining Return on Investment (ROI) for TrialWorks is not only an undertaking prior to making a purchase but an on-going analysis and justification of the subsequent use and cost of the system. ROI and value should be a continuous measure of success with TrialWorks as with any application investment. This workshop explores measures related to calculating a total ROI and helps facilitate an on-going analysis of an investment in TrialWorks. The results may help with the continuous commitment and “buy-in” from key business holders as well as the on-going financial justification of TrialWorks.

Interactive Breakout Sessions: The Value of TrialWorks

The interactive breakout sessions will explore experiences and ideas from all attendees. A focus will be placed on the identification of areas/processes enhanced or needing enhancement by TrialWorks and to debate the reality of the measures, techniques for continuous justification, obstacles encountered and handling objections.

Interactive Breakout Session Summary: The Value of TrialWorks

A summary of the individual ROI breakouts will be shared with the rest of the TrialWorks User’s Group along with a final word from the speakers. Additionally, a session summary and a proposed ROI model will be prepared in a whitepaper for future use by the TrialWorks user community.

Future TrialWorks Enhancements

Perceptive values your feedback on future enhancements to TrialWorks! During this presentation, a brief summary of the methodology used for ranking and selecting enhancements for inclusion in future product releases will be presented. We will also review the results from last year’s user group enhancement session and describe how your feedback resulted in product enhancements included in this year’s release. Lastly, we will present the results of the survey conducted to prioritize 20 major enhancements to TrialWorks, many of which have been submitted by you!