

Program - Day One

Thursday, October 16, 2008

7:00	<i>Registration and Breakfast</i>	2:45	<i>Afternoon Break</i>
8:30	General Welcome and Introduction <i>Sara Diamond, Senior Director, TrialWorks Development Operations – ClinPhone</i> <i>Wade Wirta, VP eClinical Services, Perceptive Informatics</i>	3:15	Using TrialWorks® to Streamline your Clinical Project Management <ul style="list-style-type: none">• Implementing the system• Getting the data into the system• Getting the data out of the system• Analyzing the data• Reports, reports and more reports <i>Lisa Dodson, Clinical Consultant – Rocky Mountain Clinical Consulting</i>
9:00	Validation of CTMS Systems – Costs and Benefits <ul style="list-style-type: none">• Defining the “intended use” of the system• What is validation?• Assessing your level of risk aversion• The decision to validate or not• Customization vs. configuration• Alternatives to validation• Change management <i>Stuart E. Nixon, Manager, CTMS and Document Management – BioMarin Pharmaceutical Inc.</i>	4:30	CTMS Payments: The Way We Use It and Our Approach to Overcoming Obstacles <ul style="list-style-type: none">• Set-up in global and study administration• Entering sites and investigators into CTMS• Entering investigator contracts information into CTMS• Processing site start up payments• Processing interim and close out payments• Using CTMS to complete accruals and budget projections• Ad hoc and canned reports• Lessons learned <i>Maureen Cleaver, CRA III – Sucampo Pharmaceuticals, Inc.</i> <i>Lydia Z. Dyett, Clinical Trial Manager – Sucampo Pharmaceuticals, Inc.</i>
10:15	<i>Morning Break</i>	5:45	Closing Remarks <i>Sara Diamond, Senior Director, TrialWorks Development Operations – ClinPhone</i>
10:45	Using TrialWorks® for Feasibilities and Site Selection <ul style="list-style-type: none">• Preparing TrialWorks® for feasibilities and site selection• Therapeutic areas: their critical role• The site assessment questions• Getting the ‘top of the funnel’• Filtering the site list <i>Jennifer Durham, Manager, Global Logistics, Clinical Operations – Encorium Group, Inc.</i>	7:00	<i>Welcome Reception Dinner</i>
12:00	<i>Lunch</i>		
1:30	The Benefits and Challenges of Integrating TrialWorks® and IVR <ul style="list-style-type: none">• Why we integrated IVR and TrialWorks®• Integration implementation process• Challenges encountered• Resulting efficiencies• Future integration possibilities <i>Sindia Bernard, Associate Clinical Trial Manager – MannKind Corporation</i>		

REGISTER TODAY!

To register, go to www.clinphone.com/ctms/usergroup and click on the “Register” button.

Program - Day Two

Friday, October 17, 2008

8:00 Opening Remarks

Sara Diamond, Senior Director, TrialWorks Development Operations – ClinPhone

8:30 CTMS Deployment to CROs

- Clinical operations and IT partnership
- CRO deployment strategy
- CRO on boarding process
- Ongoing CRO support
- Lessons learned

Kathleen Ventura, Sr. Business Systems Analyst, Clinical Information Systems Management (CISM) – Genentech, Inc.

Myra K. Imperial, Sr. Project Manager, Product Development IT, Corporate Information Technology – Genentech, Inc.

9:15 CRO/Sponsor Breakout

This session follows a presentation on CRO/Sponsor relations and the collaborative use of TrialWorks®. Users from CRO and Sponsor organizations will divide into two groups to further discuss these relationships and other related topics. Each breakout session will be facilitated by a fellow TrialWorks® user from either a CRO or Sponsor organization. The facilitator will promote healthy and constructive discussion, take notes and present a summary of the discussion to the combined group of users. Discussion topics may include: strategies to promote a collaborative partnership, value-add when working in a shared system, identifying success criteria, and issue detection and resolution techniques.

CRO Facilitator: Robbie Franks, VP of Clinical Operations – Trio

Sponsor Facilitator: Marie Steffens, Sr. Clinical Systems Analyst – ZymoGenetics, Inc.

10:15 Morning Break

10:45 CRO/Sponsor Breakout Discussion

11:45 Working Lunch Product Enhancements

Sara Diamond, Senior Director, TrialWorks Development Operations – ClinPhone

12:45 User Interactive Session - Prioritizing Future TrialWorks® Enhancements

ClinPhone is seeking your feedback on future enhancements to TrialWorks®! Over lunch ClinPhone will present a brief summary of the methodology used for ranking and selecting enhancements for inclusion in future product releases. We will then present what we believe to be the top 20 major enhancements, many of which have been submitted by you! After lunch we will have the group discuss these enhancements with the goal of achieving consensus around the top 5 enhancements. Individual rankings, as well as the group ranking, will be collected and used in decision-making for future product releases.

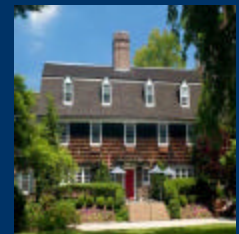
1:30 Closing Remarks

Sara Diamond, Senior Director, TrialWorks Development Operations – ClinPhone

2:30 Event Concludes

EVENT VENUE

The Nassau Inn
10 Palmer Square
Princeton, NJ



* SPECIAL HOTEL ROOM RATE *

ClinPhone has secured a block of rooms at The Nassau Inn at a reduced rate. To take advantage of our special rate, click on the register button at: www.clinphone.com/ctms/usergroup.

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