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UK ePHARMA DAY 2012



ARITHMOS
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UNDER THE PATRONAGE OF:



Traceability in Clinical Trials: from Study Design to Submission

Wednesday, October 31st 2012

Royal Society of Chemistry

Burlington House, Piccadilly, London, W1J 0BA UK

09:00 – 17:10

ePharma Day 2012 will allow delegates to learn more about data traceability in clinical trials and safety - from trial design to authority submission encompassing trial design, patient data acquisition, trial monitoring, safety cases management and signal detection. David Morgan, VP/Chief Statistical Scientist, IPSEN and Andrew MacGarvey, Vice President, CROS NT will share best practices, results and experiences in this field.

What You'll Learn:

- Traceability: what does it mean and why is it important?
- How do the rules and responsibilities in e-clinical trials differ to paper based studies?
- How should researchers handle e-source documents?
- Aspects of the e-Common Technical Document (e-CTD): European Situation and local status
- Strategies for e-Trial Master file creation and maintenance
- Integrating Electronic Data Capture (EDC) with other clinical systems
- The importance of CDISC in traceability
- EudraCT/OssC
- Strategies for e-management of pharmacovigilance (Eudravigilance)-xml
- Technologies and methodologies that drive standards and traceability

Target audience:

We welcome delegates from **Pharmaceutical and Biotechnology companies, Clinical Research Organisations, Academic Centres, Hospital Centres, and Clinical Technology companies** in the following disciplines: Clinical Research and Development, Quality Assurance (CSV) Unit, Pharmacovigilance, Clinical Operations, Statistics and Data Management, Epidemiology, Information Technology.

Oracle Health Sciences and CROS NT
are pleased to invite you to an **exclusive VIP dinner** on:
Tuesday, October 30th - 07:00 pm

*The dinner will provide an opportunity for you to network informally with your industry peers and discuss sponsors' products and strategic development plans. More information available soon.
Please confirm your interest on the registration form >>*

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ASSOCIATION OF CLINICAL
RESEARCH PROFESSIONALS

Traceability in Clinical Trials: from Study Design to Submission

Programme

- 09:00 - 09:30 **Registration**
- 09:30 - 09:40 **Welcome**
David Morgan, VP / Chief Statistical Scientist, IPSEN
Andrew MacGarvey, VP CROS NT UK and USA
- 09:40 - 10:20 **Getting the end deliverable right in an e-clinical world**
Karen Redding, Global Business Development Director, Phlexglobal Ltd.
- 10:20 - 11:00 **Today's CSV with Tomorrow's challenges – a PV case study**
Nazrul Khan, Associate Director of PV and CSV, Zig Zag
- 11:00 - 11:30 **Coffee break**
- 11:30 - 12:10 **Solutions to streamline traceability in your clinical trials and enable cross-department analysis**
Gilbert Bellachen, Director, Global Customer Experiences, Oracle Health Science
- 12:10 - 12:50 **The Ipsen HERMES project, case study on a Siebel CTMS implementation in a mid size pharma company**
Kamel Lakehal, R&D IT Project Manager, Ipsen Innovation
- 12:50 - 13:50 **Networking Lunch and Exhibitor Area**
- 13:50 - 14:30 **Traceability through standards: how difficult is it really**
Paul Fardy, Chief Operations Officer, CROS NT
- 14:30 - 15:10 **The Clinical Data Repository Initiative in Novartis Vaccines: changing the way we manage and analyse clinical trial data**
Pantaleo Nacci, Global Head Statistical Reporting, Novartis Vaccines & Diagnostics
- 15:10 - 15:50 **The process, challenges and benefits of centralizing the storage of clinical data**
Stefano Piccoli, Chief Operating Officer, Arithmos
- 15:50 - 16:00 **Q&A - Closing remarks from the Chair**
- 16:00 - 16:30 **Coffee break**
- Tech Corner by Sponsors:**
- 16:30 - 16:50 **Oracle Health Sciences Solutions for Traceability in Clinical Trials**
Hervé Fouché, Principal Sales Consultant, Oracle Health Science
- 16:50 - 17:10 **Project governance using ArithmosCentrum (Software Demonstration)**
Chris Hamilton, Director of Business Development and Marketing, Arithmos

Closure of Conference



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HOW TO PARTICIPATE

In order to attend the Meeting the registration form should be completed and faxed to **(+39) 035 4501262** or emailed to: enrico.pedroni@epharmaday.org
Please use one form for each participant.

REGISTRATION FEE

GBP 250,00 Early Bird Fee before 24th October, 2012

GBP 320,00 Ordinary Fee on or after 24th October, 2012

GBP 100,00 for Academy and Patronage

The fee includes: seat at the conference, copy of presentations will be made available by the Speakers, informative literature for the day, networking lunch, coffee breaks, exclusive VIP dinner, organisational assistance from registration to event day, certificate of attendance.

PAYMENT

Payment should be made by bank transfer (please see details below), on-line (www.epharmaday.org) or by mailing a cheque, along with the registration form:

EasyB S.r.l.

Via Roma, 25 - 24022 Alzano Lombardo (BERGAMO) VAT: IT03633040161

Banca Popolare di Vicenza - Filiale di Nese

IBAN: IT27H0572852521820570697999

(Invoice will be sent following receipt of payment).

Upon receipt of payment, the registration will be confirmed. Please, send proof of bank transfer via fax or email.

HOW TO REACH THE ROYAL SOCIETY OF CHEMISTRY

For detailed information on how to reach the location, please visit our website: www.epharmaday.org or visit the official site of Royal Society of Chemistry: www.rsc.org

CANCELLATION POLICY

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received before October 24th, 2012. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

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REGISTRATION FORM

PLEASE FILL IN AND SEND VIA FAX: (+39) 035 4501262
OR EMAIL: enrico.pedroni@epharmaday.org

For any additional information, please contact at any time the Event Manager:
Enrico Pedroni - enrico.pedroni@epharmaday.org
Tel.: (+39) 035 51 56 84 - Mobile: (+39) 33 88 42 25 61

Early Bird Registration fee is applicable until October 24th, 2012

I will participate to the **exclusive VIP dinner**

Yes No

Academy and ACRP Members

Cheque No

Bank transfer

Online

Name

Surname

Company name

Job Title

Address

City

ZIP code

Tel.

Fax

E-mail

special dietary requests:

INVOICING DETAILS:

Company name

Address

Mail Address (if different)

City

Post code

VAT Number

Limited seats available

Information collection and use

Participants information is collected and utilised by EasyB s.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.

Date Signature.....