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# SPANISH ePHARMA DAY 2012



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CONTRACT RESEARCH ORGANISATION



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UNDER THE PATRONAGE OF:



## Traceability in Clinical Trials: from Study Design to Submission

Thursday, October 25th 2012

TRYP Madrid Ambassador Hotel

Cuesta de Santo Domingo, 5  
Madrid, SPAIN

10:00 – 17:30

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. Fernando Martinez, Vice President Business Development, PharmaNet/i3 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.

**Official language: Spanish and English**

**Oracle Health Sciences and CROS NT**  
are pleased to invite you to an **exclusive VIP dinner** on:  
**Wednesday, October 24th - 09:30 pm**  
**Espazo Enxebre - Calle Hileras, 4 - Madrid**

*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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**ACRP**  
ASOCIACIÓN DE PROFESIONALES  
DE INVESTIGACIÓN CLÍNICA  
ESPAÑA

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OCTOBER, 25th - TRYP MADRID AMBASSADOR HOTEL

## Traceability in Clinical Trials: from Study Design to Submission

### Programme

Official languages: Spanish and English

- 09:30 - 10:00 **Registration & Coffee**
- 10:00 - 10:10 **Welcome**  
*Fernando Martinez, Vice President Business Development, PharmaNet/i3*  
*Cedric Burg, Former Deputy Head of Global Clinical Operations, Teva Spain*  
*Antonio Yeste Coordinator, Clinical Project Information, GCO, Global Development R&D, Almirall, S.A* **ESP**
- 10:10 - 10:50 **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* **ENG**
- 10:50 - 11:30 **Use of Study Management Systems in CRO Performance at Almirall**  
*Natalia Zurita, Coordinator Senior Monitoring Trial Coordinator GCO & SR; Antonio Yeste Coordinator, Clinical Project Information, GCO, Global Development R&D, Almirall, S.A* **ENG**
- 11:30 - 11:50 **Coffee break**
- 11:50 - 12:30 **The process, challenges and benefits of centralizing the storage of clinical data**  
*Gianluigi Albertini, IT Manager, Life Science Application Analyst, Arithmos* **ENG**
- 12:30 - 13:10 **Solutions to streamline traceability in your clinical trials and enable cross-department analysis**  
*Gilbert Bellachen, Director, Global Customer Experiences, Oracle Health Sciences* **ENG**
- 13:10 - 14:10 **Networking Lunch and Exhibitor Area**
- 14:10 - 14:50 **Trazabilidad de datos de los Ensayos Clínicos: Desde la entrada de los datos hasta el informe final**  
*José Fernández Sardiña, Data Management Manager, Fundació Clínic,*  
*Jose Rios, Asesor Estadístico, IDIBAPS, Hospital Clinic Barcelona* **ESP**
- 14:50 - 15:30 **Traceability in Building Analysis Datasets in Clinical Studies**  
*Valeria Visonà, Head of Statistical Programming, Cros NT* **ENG**
- 15:30 - 16:10 **Técnica de Virtualización Open Source a la hora de implementar una plataforma de cuaderno de recogida de datos electrónico**  
*Antonio Jorge Escudero Masa, Data Manager, CAIBER* **ESP**
- 16:10 - 16:30 **Coffee break**
- 17:10 - 17:30 **Q&A - Closing remarks from the Chair**
- 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* **ENG**
- 16:50 - 17:10 **Project governance using ArithmosCentrum (Software Demonstration)**  
*Chris Hamilton, Director of Business Development & Marketing, Arithmos* **ENG**
- 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](mailto:enrico.pedroni@epharmaday.org)  
Please use one form for each participant.

### REGISTRATION FEE

€ 300,00 before 18<sup>th</sup> October, 2012  
€ 350,00 on or after 18<sup>th</sup> October, 2012  
€ 100,00 for Academy and ACRP Members\*.

*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.*

*\* Non-ACRP members have the possibility to register as a member when paying the regular registration fee at no extra costs.*

### PAYMENT

Payment should be made by bank transfer (please see details below), on-line ([www.epharmaday.org](http://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 TRYP MADRID AMBASSADOR HOTEL

For detailed information on how to reach the location, please visit our website: [www.epharmaday.org](http://www.epharmaday.org) or visit the official site of TRYP Madrid Ambassador Hotel: [www.tryphotels.com](http://www.tryphotels.com)

### CANCELLATION POLICY

Please note that refunds (70% refund of the registration fee ) will only be given if cancellation is received before October 18th, 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](mailto:enrico.pedroni@epharmaday.org)

For any additional information, please contact at any time the Event Manager:  
Enrico Pedroni - [enrico.pedroni@epharmaday.org](mailto: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 18<sup>th</sup>, 2012**

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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.....