

## **SPANISH ePHARMA DAY 2011**

# Optimizing Value and Quality in Clinical Data with Standards and Data Integration



Thursday, 27th October 2011

Barcelona, Grand Hotel Central Calle Laietana, 30 08003 - Barcelona

10:00 - 17:30



Facing pipeline difficulties, increasing costs and timeline pressures, more R&D companies are using eSystems standards and moving to integrated system to allow better and faster decisions.

The event will focus on the implementation of effective data quality strategies, evaluations of computerized system and usage of state of the art electronic standards.

UNDER THE PATRONAGE OF:





**Pharmaceutical, Biotech, Medical Device Companies:** Medical Director, Medical Affairs Director, Clinical Operations, Medical Informatics, R&D Manager, Pharmacovigilance Operation Managers, Clinical Research Associates, Clinical Project Manager, Statisticians and Data Managers.

**CROs:** Clinical Project Managers, Clinical Research Associates, data Managers, Statisticians, Pharmacovigilance and Drug Safety, Informatics.

**Hospital/Academic Research Centres/University/Private Institutions**: Clinical Research Teams, Principal Investigators, Site study co-ordinators, study nurses.

Oracle Health Sciences and CROS NT are pleased to invite you to an exclusive VIP dinner on:

Wednesday, October 26 - 9:30 pm El Asador De Aranda - Avenida del Tibidabo, 31 - Barcelona

The dinner will provide an opportunity for you to network informally with your industry peers and discuss Sponsor's products and strategic development plans. The Restaurant offers a traditional Castilian gastronomy in a cosy environment with close attention to every last detail. Please confirm your interest on the registration form >>>

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## Optimizing Value and Quality in Clinical Data with Standards and Data Integration



#### **Programme**

09:30 - 10:00 Registration & Coffee

Official languages: Spanish and English

ESP

ENG

**ENG** 

ENG

**ESP** 

**ESP** 

**ESP** 

ESP

**ESP** 

ESP

**ESP** 



10:00 - 10:10 Welcome
Cedric Burg, Deputy Head of Global Clinical Operations, TEVA

10:50 - 11:20 Integration of different data sources in Oracle RDC

10:10 - 10:50 Study Metrics for Value and Quality - Just Historical Data or Pointers for the Future? John Shillingford, VP Early Phase Clinical Operations, Aptiv Solutions

Valentina Cavestro, Lead Data Manager, CROSnt

11:20 - 11:50

Killing Two Birds with One Stone: Pooling Legacy Data Using CDISC Data Standards
Pantaleo Nacci, Global Head, Statistical Reporting, Novartis Vaccines & Diagnostics

HEALTH SCIENCES

11:50 - 12:10 **Coffee break** 

12:10 - 12:40 **Development of Data Standards and Data Integration tools**Rafael Romero, Rafael Romero: Rafael Romero: Director Global Clinical
Data Management & eTrials

12:40 - 13:10 Leveraging data from existing information systems for a complete redisign of the standard monitoring visit report used in clinical trials. Impact on the CRA's work and efficiencies created accross the organisation. Overcoming resistance to change for successful implementation

Cedric Burg, Deputy Head of Global Clinical Operations, TEVA



UNDER THE PATRONAGE OF:

13:10 - 13:40 Formación on-line para equipos de investigación a nivel internacional Marta Manjón, Project Director, Grupo Rater Training Intenacional, i3

13:40 - 14:10 Optimise your CTMS according to your Business needs & Information System Resources

Diego Herrera, Study Information Manager - Toni Yeste: Clinical Study Information

14:10 - 15:10 Networking Lunch and Exhibitor Area

Coordinator, Almirall

15:10 - 15:40 New trends in Clinical development

Juan Diego Polo Santos, Business Development Director EMEA, Oracle Ibérica

Gilbert Bellachen, Director, Global Customer Experience - Oracle Health Sciences Global

Business Unit, Oracle France

15:40 - 16:10 Análisis de los factores críticos de éxito (CSF's) en la implantación de un sistema de recogida de datos electrónico Luis Luengo, Managing Director, 3dHealth

16:10 - 16:30 **Coffee Break** 

16:30 - 17:10 Análisis de riesgos (Risk Management) aplicado a la gestión de datos clínicos Natalia Arroyo, Biomedical Research Advisor, Telstar Life Science Value Services

17:10 - 17:30 Beneficios y Riesgos del archivo electrónico de un Ensayo Clínico Sonia Marimón, Clinical Trial Assistant, Country Clinical Operations, Pfizer

17:30 - 17:50 Global Survey Results: Analysis of Electronic Data Capture Use in Clinical Trials Mary Wieder, Marketing Officer, Arithmos

17:30 - 17:50 Networking Cocktail













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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**

€ 300,00 before 14th October, 2011

€ 350,00 on or after 15<sup>th</sup> October, 2011

€ 100,00 for Academy and ACRP Members\*.

**The fee includes**: seat at the conference, copy of speakers' presentations, 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) or by mailing a cheque, along with the registration form:

EasyB S.r.I.

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 GRAND HOTEL CENTRAL

For detailed information on how to reach the location, please visit our website: www.epharmaday.org or visit the official site of Grand Hotel Central: www.grandhotelcentral.com

#### **CANCELLATION POLICY**

Please note that refunds (70% refund of the registration fee ) will only be given if cancellation is received before October 20th, 2011. 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 adevrtised 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 14th, 2011

INDED THE DATE OF A TO	Larry Bird Registration fee is applicable until October 14 , 2011
UNDER THE PATRONAGE OF:	I will participate to the <b>exclusive VIP dinner</b> Yes No
ACRP AGOLION DE PRIFESSIMALES DE HINGSTRADOR CLARICA ESTARIA	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.....

