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20th Anniversary

SMi presents the 8th conference and exhibition series...

Clinical Trial Logistics

21ST - 22ND MAY 2014 | MARRIOTT REGENTS PARK | LONDON, UK

EUROPE'S LEADING CLINICAL TRIAL LOGISTICS EVENT

KEY SPEAKERS:

- **Lesley George,** Supply Chain Lead, **Pfizer**
- **Riekert Bruinink,** Member of the GDP drafting Group of the EMA, **Dutch Health Care**
- **Vimal Unewal,** Planning manager, **Ferring Pharmaceuticals Ltd**
- **Vanessa Simm,** Senior Operations Manager, **Allergan**
- **Frauke Bruns,** Clinical Trial Supplies Group Leader, **Actelion Pharmaceuticals**
- **Janice Kite,** Traceability Director Healthcare, **GS1**
- **Layla Hannbeck,** Head of Pharmacy Services, **National Pharmaceutical Association**
- **Andrea Gruber,** Manager Business Process & Standards, **IATA**

And many more...

NEW EXPANDED EVENT FOR 2014:

- More panel discussions, more case studies and more speakers than ever before
- Find out the latest information on **GDP regulations** and their application to clinical trials
- In its 8th year this is the longest established Clinical Trial Logistics event globally
- **Enhanced networking** for delegates through the use of roundtables
- Focus sessions on GDP regulations and trials in emerging markets
- **Refreshed programme** focusing on the latest issues from across the globe

PHARMA ATTEND FOR: £999

PLUS INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOP

A: Virtual logics: Managing quality and user acceptance testing

Tuesday 20th May 2014, Marriott Regents Park, London, UK
Workshop Leader: **Nimer Yusef,** Consultant and Founder, **Trial-Brain**
12.30pm - 4.30pm

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CPD CERTIFIED The CPD Certification Service

8.30 **REGISTRATION & COFFEE**

9.00 **Chairman's Opening Remarks**

Andrea Gruber, Manager Business Process & Standards, **IATA**

OPENING ADDRESS / KEYNOTE ADDRESS

9.30 **Dispelling the myths on GDP compliance in clinical trials**

- Legal requirements or best practices: A look at variation between EU member states
- What is legally required
- What is likely to be enforced

Riekert Bruinink, Member of the GDP drafting Group of the EMA, **Dutch Health Care Inspectorate**

10.10 **Morning refreshments and networking in the exhibition area**

10.40 **PANEL: Clinical trial supply chain challenges and comparisons**

- What measures do you have to consider with a clinical trial chain compared to a commercial chain?
- How and when should your CTL comply with GDP regulations?
- Managing temperature controlled products in emerging markets

PANEL

Moderator: Bob Hayes, Director, **Cold Chain Consultants**

Panellists:

Vanessa Simm, Senior Operations Manager, **Allergan**

Vimal Unewal, Planning manager, **Ferring Pharmaceuticals Ltd**

Prof. Dr. Vladimir V. Anisimov, Sr Strategic Biostatistics Director, **University of Glasgow**

11.30 **GS1 Standards: Enabling supply efficiency**

- Who we are and what we do
- The case for global supply chain standards
- Enabling regulatory compliance, e.g. EU Falsified Medicines Directive
- Improving Patient Safety and Supply Chain Security through Traceability: Products, People, Processes

Janice Kite, Traceability Director Healthcare, **GS1**

12.10 **Networking Lunch in the exhibition area**

SUPPLY CHAIN EFFICIENCY AND OPPORTUNITIES

1.50 **Managing supply chain efficiency**

- When should you have your regulatory process in place
- Which nations should you plan individually
- What risks can you plan for

Vimal Unewal, Planning Manager, **Ferring Pharmaceuticals Ltd**

2.30 **How can you optimise pharmaceutical road transit**

- Current supply chain challenges
- Where are the delays occurring?
- What can you do to reduce cost and optimise deliveries

Peter J Cullum, Head of International Affairs, **Road Haulage Association**

3.10 **Afternoon refreshments in the exhibition area**

3.40 **NPA: How can big pharma support pharmacy distribution in product development stages?**

- About the NPA
- Key challenges in pharmacy supply
- EU distribution challenges

Layla Hannbeck, Head of Pharmacy Services, **National Pharmaceutical Association**

4.20 **KEYNOTE SESSION: Overcoming key inefficiencies in your supply chain**

AFTERNOON KEYNOTE

- How can efficient management ensure cost savings in CTS chains?
- Effectively monitor delays in trial shipping
- Identifying your weak spots and how to overcome these

Harvey Rubin, Professor of Medicine, Microbiology and Computer Science, **University of Pennsylvania**

5.00 **Chairman's Closing Remarks and Close of Day One**

8.30 **REGISTRATION & COFFEE**

9.00 **Chairman's Opening Remarks**

Andrea Gruber, Manager Business Process & Standards, **IATA**

OPENING ADDRESS / KEYNOTE ADDRESS

9.10 **Managing the challenges of clinical supplies in third party blinded studies**

- Review of different scenarios that may be encountered
- What are the options when defining your blinding strategy?
- What can go wrong? Identifying risks and mitigations

Lesly George, Supply Chain Lead, **Pfizer**

MANAGING RISK IN THE SUPPLY CHAIN

9.50 **Logistical challenges and strategies for emerging markets: Russia and Ukraine**

- Case studies in emerging markets for clinical trials
- How to accelerate clinical trials
- Supply chain optimization

Angus McLeod, Sr. Manager, CTS, **Catalent**

10.30 **Morning coffee and refreshments in the exhibition area**

11.00 **CASE STUDY: Overcoming challenges in the clinical supply chain**

CASE STUDY

- Identifying a smart approach to ambient temperature controlled shipments
- At which development stage does a switch from cost of goods to transfer prices make commercial sense
- How can we implement the IVRS in a smart way, with regards to costs, for reconciliation

Frauke Bruns, Clinical Trial Supplies Group Leader, **Actelion Pharmaceuticals**

11.40 **CASE STUDY: Clinical Trial Supply Chain & Risk**

CASE STUDY

- Not Measuring the Risk
- Tools to measure Risk
- Which Risk Level is acceptable

Nimer Yusef, Consultant and Founder, **Trial-Brain**

12.20 **Networking Lunch in the exhibition area**

1.50 **Managing your cold chain in clinical trials**

- Managing air transportation challenges
- Utilising validated transportation solutions
- Importance of cold chain in avoiding wastage and legitimising trials

Bev Nicol, Distribution Specialist, **Pfizer**

2.30 **PANEL: Discussing efficient methods used when labelling and packaging products**

PANEL

- What's the right solution for global labelling inefficiency?
- Managing time and temperature sensitive labelling

Peter J Cullum, Head of International Affairs, **Road Haulage Association**

3.10 **Afternoon refreshments in the exhibition area**

3.40 **INTERACTIVE ROUND TABLE: Crisis management: What to do when the worst has come to pass**

- Best practices when dealing with crises
- How can you ensure trial validity
- What you can do to get back on track

Bob Hayes, Director, **Cold Chain Consultants**

4.20 **Avoiding counterfeit medicines entering trials**

- Falsified Medicines Directive and its impact on logistics
- Opportunities and threats
- How to protect your supply chain

Mike Isles, Executive Director, **European Alliance for Access to Safe Medicines**

5.10 **Chairman's Closing Remarks and Close of Day Two**

HALF-DAY PRE-CONFERENCE PM WORKSHOP

TUESDAY 20TH MAY 2014 | MARRIOTT REGENTS PARK | LONDON, UK

A: Virtual logics: Managing quality and user acceptance testing

Workshop Leader: **Nimer Yusef,** Consultant and Founder, **Trial-Brain**

Overview

Learn how to effectively approach UATs for IVRS in clinical Trials. Why are we performing UAT, how we are performing them and what tools you need to support them. And get a glimpse in to what happens and can happen during UAT and how to deal with it.

Agenda

12.30 **Registration & Coffee**

1.00 **Welcome & Introductions**

1.10 **Session 1**
Why performing IVRS UATs
- Regulatory Background
- Why IVRS is so critical

1.45 **Session 2**
The Performance
- Case Studies
- Vendor Scripts

2.45 **Refreshment break**

3.00 **Session 3**
Support your UAT
- Processes Overview
- Tools you need

3.40 **Session 4**
The UAT
- Examples
- Typicals Problems and how to deal with them

4.20 **Chairman's Closing Remarks**

4.30 **Close of Workshop**

About the workshop host

My name is Nimer Yusef, I am a mathematician with a strong IT background. I had my first contact with the clinical research industry in 1998 at the CRO ICRC Weyer. From 2002 to 2012 I worked for Parexel International in the areas of IVRS and Clinical Trial Logistics, holding different positions. I was involved as software developer and validation engineer for IVRS. I experienced all the day to day problems with these systems and was also responsible for the 24/7 hotline, which enabled me to identify and solve the key issues for the business. Later I took over responsibility as project manager for the setup and operations of these systems and developed innovative systems in the area of Inventory Management, Dynamic Labeling, Cold Chain Management and the regular requirements for narcotics in Germany. I gained essential experiences as a Clinical Trial Supply Manager and was responsible for the setup of studies in the area of Clinical Trial Supply, which has influenced my perspective of IVRS in clinical trials dramatically. Within the logistics department, I was responsible for the training and coaching of colleagues for the implementation of clinical studies with IVRS. This included the study setup, change implementation and trouble shooting. I trained and mentored colleagues to take over responsibility as IVRS consultants. Moreover, I developed standards with IVRS vendors. Since 2010 I offer my expertise as an independent trainer & consultant under the label Trial Brain. I operate on the tactical as well as on the strategical level. I am also an expert in the area of Clinical Supply Simulations and Forecasting.

About Trial Brain

Trial Brain is a management organization that can perform up to the full IVRS Management from Vendor Selection through URS development to study conduct including also UAT preparation and performance. It is support from highly professional trainings in the area of IVRS & Logistics in Clinical Trials.

Clinical Trial Logistics 2014

Enhanced Networking
More networking lunches, dinners and roundtable discussions to help you build new contacts and strengthen existing relationships

Renewed Programme
Focus your business plans with discussions from some of the leading figures in Clinical Trial Logistics and supply globally existing relationships

Interactive Panel Discussions
Share your view points, and have your questions answered during interactive debate sessions

Workshop
Gain in-depth knowledge and advice in how to solve the key challenges affecting your supply chain by attending our half day workshop

Online networking
Maximise your effectiveness at the conference by contacting delegates before the event on the dedicated LinkedIn Group

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CLINICAL TRIAL LOGISTICS 2014

Conference: Wednesday 21st and Thursday 22nd May 2014, Marriott Regents Park Hotel, London, UK **Workshop: Tuesday 20th May 2014, London**

4 WAYS TO REGISTER

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☐ **Book by 28th February to receive a £300 discount off the conference price**

☐ **Book by 31st March to receive a £100 discount off the conference price**

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I would like to attend: (Please tick as appropriate)	**Fee**		**Total**
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☐ The Conference Presentations - paper copy (or only £300 if ordered with the Document Portal)	**£499.00**	**-**	**£499.00**

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