EUROPE’S LEADING CLINICAL TRIAL LOGISTICS CONFERENCE

SMi present their 6th annual conference on...

Clinical Trial Logistics

New Focus for 2012: Clinical Trial Supply Chain

Tuesday 22nd & Wednesday 23rd May 2012
Marriott Regents Park, London

KEY SPEAKERS INCLUDE:

Rosemarie Corrigan
VP, Global Quality
Norgine

Paul Fitton
Cleaning & Shipping Validation Lead
Johnson & Johnson

Alison Rees
UK CRA Manager – Oncology
Novartis

Andrea Graf-Gruber
Manager, Cargo Business Process and Standards
IATA

Hitendra Parmar
Medical Director
Pfizer

Jane Maureen Valentin
Logistics & Shipping Analyst
Novo Nordisk

Csilla Wolf
Senior Manager Clinical Logistics, Clinical Drug Supply
Biogen Idec

Frauke Bruns
Clinical Trial Supplies Group Leader
Actelion

WHY ATTEND THIS EVENT:

• Hear from leading industry speakers from major Pharmaceutical companies providing case study analysis and real data examples from their Clinical Trial Supply Chain.
• Learn how to plan your clinical trial strategy from start to finish.
• Plan how to deal with supply interruptions such as natural disaster and ensure that your logistical operation is not compromised.
• Analyse the latest regulations, including CRT regulation, and the effect that this has on your supply chain.
• Discuss subcontractor selection and decision making - how do you maximise your partnerships?
• Examine how to adapt to tax, customs & cultural differences in multi-national trials.
• Explore the possibilities of opening up opportunities in emerging and expanding markets.

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS

Thursday 24th May 2012, London Marriott Hotel Regents Park

Workshop A: A Measured Approach Towards Temperature Controlled Shipments

Workshop Leader:
Jane Seeley, Managing Director, GeoStasis Ltd
8.30-12.30pm

Workshop B: Optimal Clinical Supply Planning for Global Clinical Trials

Workshop leader:
Vlad Shnaydman, President, ORBee Consulting
1.30pm – 5.30pm

www.clinical-trial-logistics.com

Register online and receive full information on all of SMi’s conferences
Alternatively fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711
Clinical Trial Logistics
Day One | Tuesday 22nd May 2012

8.30 Registration and Coffee

9.00 Chairman’s Opening Remarks
Andrea Graf-Gruber, Manager, Cargo Business Process and Standards, International Air Transport Association

Session 1: Customs, Duties and Regulations

9.10 Adapting to new regulatory challenges
- What are the new regulations?
- How new regulations affect your supply chain
- Predicting and planning
- What will come in future?
Andrea Graf-Gruber, Manager, Cargo Business Process and Standards, International Air Transport Association

9.50 Session Reserved for World Courier
Senior Representative, World Courier

10.30 Morning Coffee

11.00 Management of time critical sample logistics
- Unique challenges posed
- Carrier selection and verification
- Managing time & temperature sensitive samples
Scott Vincent, Logistics Director, A4P Consulting

11.40 Maintaining data security throughout the distribution network
- Role of Standards
- Traceability in Healthcare
- Coding in Traceability
- Implementing Traceability
Roger Lamb, Healthcare Manager, GS1 UK

12.20 Networking lunch

13.40 Panel Discussion
Dynamic, flexible packaging & labelling materials
- What is available in the market currently?
- What can be improved?
- Advantages to be gained
- Improving cost efficiency
Panellists: Andrea Graf-Gruber, Manager, Cargo Business Process and Standards, International Air Transport Association
Paul Fitton, Cleaning & Shipping Validation Lead, Johnson & Johnson
Frauke Bruns, Clinical Trial Supplies Group Leader, Actelion

Session 2: Packaging and Labelling

14.20 Shipping validation & selection
- Challenges involved in partnering
- Tendering
- Selecting the right partner
- Building relationships
Paul Fitton, Cleaning & Shipping Validation Lead, Johnson & Johnson

15.00 Afternoon Tea

15.30 Delivering clinical trials on time and on target
- Partner carrier selection
- Site selection
- Patient recruitment strategy
- Patient retention and monitoring
Alison Rees, UK CRA Manager – Oncology, Novartis

16.10 Data management – modelling & simulation
- What does data modelling offer?
- Cost saving and efficiency improvements
- Accurate modelling of clinical trials
- Simulation and prediction of end results
- Adaptation to the supply chain
Vladimir Anisimov, Senior Director, Quantitative Sciences, GlaxoSmithKline

16.50 Chairman’s Closing Remarks and Close of Day One

17.00 Drinks Reception - Hosted by
Please join us for a drinks reception immediately after the panel discussion which closes the first day. This will be a relaxed and social setting for you to network with delegates and sponsors and to follow up any questions you may have with speakers.

18.30 Close of Day One

Register online at www.clinical-trial-logistics.com • Alternatively

Who should attend?
- Clinical Trial Supplies
- Global Logistics Cold Chain Planning
- Global Outsourcing Clinical R&D Management
- Clinical Trial Material Distribution
- Head of Clinical Trial Supply Outsourcing
- Planning and Co-ordination
- Research Operations
- Supply Chain Management
- Clinical Research Manager
- Clinical Supplies Project Coordinator
- Clinical Supply Chain Manager
- Distribution & Channel Management
- Global Clinical Supplies Unit
- Clinical Trial Supply Coordinator
- Global Logistics
- Clinical Logistics and Distribution
- Quality Assurance
- Supply Chain Optimisation
- Logistics
- Packaging Department
- Clinical Packaging Operations
- Logistics Quality and Efficiency
- Transportation
- Clinical Supply Planning
- Quality & Compliance
- Clinical Supplies Forecasting and Infrastructure
- Clinical Supply Management Systems & Planning
- Shipping & Trade Compliance
- Clinical Supply Logistics

Supported by
8.30 Re-registration and Coffee

9.00 Chairman’s opening remarks

Andrea Graf-Gruber, Manager, Cargo Business Process and Standards, International Air Transport Association

Session 4: Transportation & Security

9.10 Transportation + storage of at risk products

• Critical responsibility
• Good storage practices
• Information management and audit trials
• Partner selection

Jane Maureen Valentin, Logistics & Shipping Analyst, Novo Nordisk

9.50 Managing clinical trial logistics challenges in emerging markets.

• Distribution timeline
• Regulatory difference
• Management of logistics within the country

Stewart Rimmer, Logistic Manager, Catalent Development and Clinical Services

10.30 Morning Coffee

11.00 The Olympics: Potential Logistical Challenges

• Impacts we are aware of e.g. road closures
• Unforeseen hazards and issues e.g. airport closures
• Contingency Planning: What can be done to ensure minimum impact

Mike Bradshaw, Global Sales & Marketing Director, Biocair

Session 5: Planning the Clinical Trial

11.40 Patient recruitment & retention in Clinical Trials – CNS case study

• Features of CNS trials that affect patient recruitment and retention
• Getting the patient into the trial in the first place
• Retaining the enrolled patient in the trial
• Recruitment and retention issues in Alzheimer’s Disease and dementia clinical trials

Hitendra Parmar, Medical Director, Pfizer

12.20 Networking Lunch

13.50 Distribution strategy for a virtual company

• Distribution via contract packager versus transport specialist
• Importer of record challenges
• Product cost versus transfer price
• Working with different CROs in 1 country on drug distribution, import license application and site monitoring

Frauke Bruns, Clinical Trial Supplies Group Leader, Actelion

Session 6: Integration and Quality control

14.30 Integrated clinical supply chain: IMPs, KITS, ancillary materials

• Packaging & labeling of clinical supplies
• Why should these be of interest to the packaging/distribution vendor?
• Drug shipping procedures and distribution metrics
• Management of depots and ancillary items
• Management of drug laws
• Project Management

Csilla Wolf, Senior Manager Clinical Logistics, Clinical Drug Supply, Biogen Idec

15.10 Afternoon Tea

15.40 GDP and QA strategy

• ICH and PICS guidelines
• Application of QA Systems and SOPs
• Meeting International Standards in handling and distribution
• Applying best practices

Rosemarie Corrigan, VP, Global Quality, Norgine

16.20 Optimizing site selection for global clinical trials

• Problems and analysis of identifying and selecting investigator sites
• Analysis of current approaches and tools for site selection
• Optimization of site selection aligned with site value, trial budget, enrollment target, site capacity, and trial power
• Contingency planning in site selection process
• Case study for a Phase 3 global trial

Vladimir Shnaydman, President, ORBee Consulting

17.00 Chairman’s Closing Remarks and Close of Day Two

*subject to final confirmation

fax your registration to +44 (0)870 9090 712 or call +44 (0)870 9090 711

SMi’s Pharmaceutical Forward Planner 2012

FEBRUARY

Parallel Trade 6-7 February 2012
Advances and Progress in Drug Design 20-21 February 2012

MARCH

Superbabs & Superdrugs – A Focus on Antibacterials 5-6 March 2012

Imaging in Cancer Drug Development 14-15 March 2012
Paediatric Clinical Trials 21-22 March 2012
Adaptive Designs 26-27 March 2012
Controlled Release 28-29 March 2012
APRIL

Asthma & COPD 16-17 April 2012
Pharmaceutical Portfolio & Lifecycle Management 18-19 April 2012
MAY

Pain Therapeutics 27-28 May 2012
Clinical Trial Logistics 22-23 May 2012

ADC Summit 2012 23-24 May 2012
JUNE

RNAi & Nanotechnology 11-12 June 2012
JULY

KOL Management and MSL Best Practice in Europe (Switzerland) 2-3 July 2012

All conferences take place in central London, UK – unless indicated otherwise in brackets

Want to know how you can get involved?

Interested in promoting your pharmaceutical services to this market?

Contact Margaret Mugema, SMi Marketing on +44 (0)20 7827 6072, or email: mmugema@smi-online.co.uk

Norgine
Biogen Idec
Actelion
## Workshop A: A Measured Approach Towards Temperature Controlled Shipments

**Workshop Leader:** Jane Seeley, Managing Director, GeoStasis Ltd

### Programme

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.30</td>
<td>Registration &amp; Coffee</td>
</tr>
<tr>
<td>9.00</td>
<td>Welcome &amp; Introductions</td>
</tr>
<tr>
<td>9.10</td>
<td>Short overview and simulation ‘warm-up’</td>
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<tr>
<td>9.30</td>
<td>Facilitated simulation that will:</td>
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<td></td>
<td>• Experience the supply chain in action</td>
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<td></td>
<td>• Reflect on observations</td>
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<td></td>
<td>• Draw upon conclusions &amp; learning’s</td>
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<td></td>
<td>• Put these learning’s into practice</td>
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<tr>
<td>10.30</td>
<td>Afternoon Coffee</td>
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<tr>
<td>11.00</td>
<td>Simulation session completion</td>
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<tr>
<td>11.30</td>
<td>Workshop conclusions on how to make a step change towards a measured approach to temperature controlled shipments.</td>
</tr>
<tr>
<td>12.30</td>
<td>Close of Workshop</td>
</tr>
</tbody>
</table>

### Overview of workshop

The workshop will provide a high-impact, in-room business simulation to accelerate your awareness and understanding of the Cold Chain. This interactive workshop reviews the challenges that exist as we explore the journey, the products and services that are on offer and benefits of a ‘Service Management’ approach to temperature controlled shipments. Following this workshop you will have an appreciation of how to benchmark your supply chain in order to drive a continuous improvement culture.

### Why you should attend:

- **Learn** more about service management in the Cold Chain
- **Experience** the Cold Chain in action in an interactive business simulation
- **Analyse** your own solutions and findings and how they can be used in your business
- **Increase** your awareness and understanding of the Cold Chain

### About the workshop host

**Jane Seeley** has over 28 years’ experience of delivering international best practice and innovative solutions in support of supply chain excellence. Having worked for one of the world’s largest logistics companies, responsible for strategic direction, development and delivery of innovative solutions, Jane has a comprehensive understanding of the international challenges that exist, the components required and the alignment of multiple service partners that is critical to prove a true end to end service.

This understanding along with the vision and passion to mature the management of perishable cargo drove Jane to co-found GeoStasis Ltd.

**GeoStasis Ltd** brings together best of breed products and services to focus on the provision of quality logistics solutions with special attention to performance based operating processes.

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## Workshop B: Optimal Clinical Supply Planning for Global Clinical Trials

**Workshop Leader:** Vlad Shnaydman, President, ORBee Consulting

### Programme

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1.30</td>
<td>Registration &amp; Coffee</td>
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<tr>
<td>1.40</td>
<td>Overview of clinical supply problem</td>
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<tr>
<td></td>
<td>• Analysis of different approaches and tools for clinical supply planning</td>
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<td></td>
<td>• Mini-tutorial in mathematical modelling (how models work)</td>
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<tr>
<td>2.30</td>
<td>Optimal planning for clinical supply</td>
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<td></td>
<td>• How to minimize clinical trial supply chain costs (packaging, labelling, storage, and shipping)?</td>
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<td>• How to align deterministic supply schedule and uncertain drug demand?</td>
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<td>• How to optimize inventory levels?</td>
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<td>• How to minimize material waste?</td>
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<td></td>
<td>• How to optimize shipment schedules &amp; package sizes?</td>
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<tr>
<td>3.30</td>
<td>Networking Coffee Break</td>
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<tr>
<td>4.00</td>
<td>Clinical supply simulation - visual simulation/animation of clinical supply workflow</td>
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<tr>
<td></td>
<td>• How to validate proposed supply plan?</td>
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<td></td>
<td>• Is risk of stock-out acceptable?</td>
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<td></td>
<td>• How to integrate risk in clinical supply planning?</td>
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<td></td>
<td>• Contingency planning – how to make real time corrections due to uncertainties during plan execution</td>
</tr>
<tr>
<td>5.30</td>
<td>Close of Workshop</td>
</tr>
</tbody>
</table>

### Overview of workshop

Clinical supply planning is one of most challenging problems in clinical operations. Proposed approach is based on combined usage of powerful mathematical tools optimizing clinical supply costs, and aligning uncertain drug demand, delivery schedule stock-out risk, overage, and other parameters.

### Why you should attend:

- **Learn** more about service management in the Cold Chain
- **Experience** the Cold Chain in action in an interactive business simulation
- **Analyse** your own solutions and findings and how they can be used in your business
- **Increase** your awareness and understanding of the Cold Chain

### About the workshop host

**Vladimir Shnaydman,** Ph.D., is President of ORBee Consulting. Vladimir has BS & MS Electrical Engineering & Computer Science, MS in Applied Mathematics & Operations Research, and Ph.D. in Engineering. He contributed to many industries such as biotechnology, computer networking, data storages, water resources planning and management, telecommunications, transportation, and others. Dr. Shnaydman published more than 50 papers. He is co-author of three books.

### About ORBee Consulting

ORBee Consulting focus is design and development of analytical tools and techniques for corporate decision support for life science business and consulting service. Company frameworks include portfolio optimization and simulation for portfolio selection, risk assessment and analysis of risk mitigation strategies, capacity planning and resource allocation for portfolio of clinical trials, optimal deal structuring and negotiation strategy, clinical supply optimization and simulation.
Almac Clinical Services, part of the Almac Group, has over 20 years experience delivering a full range of global clinical trial supply and innovative technology solutions to Pharmaceutical and Biotech Companies worldwide. We are the most trusted and stable name in the clinical supply marketplace. We are differentiated by our exceptional client service powered by experienced and knowledge based Project Management. Our clinical supply services include: • Global comparator sourcing • Blinding and over-encapsulation • Packaging and labelling of trial supplies • Online Label Approval System • Global distribution and depot network • Shipping Temperature Electronic Monitoring System • Project Management and Qualified Person consulting • Range of analytical services • Drug supply management Headquartered in Craigavon, Northern Ireland, with US operations based in our North American Headquarters in Philadelphia, Almac champions integrated clinical supply and technological excellence to make your clinical trials more effective and efficient. www.almacgroup.com

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QuickSTAT For over 30 years, QuickSTAT has played a critical role in managing clinical trial logistics for all phases of research and drug development. We specialise in global shipping of time and temperature-sensitive clinical research samples, investigational drugs, clinical trial supplies, vaccines and dangerous goods. www.qicstat.com

Incorporated in 1969 and headquartered in Stamford, Connecticut, USA, World Courier is the largest and most experienced specialty courier service with a network of over 150 company-owned ISO 9001 & 14001 certified and GxP compliant offices operating in more than 51 countries worldwide. World Courier has set the benchmark for worldwide time-sensitive transportation and is the acknowledged leader in delivering customized solutions, cold chain and value-added services in growth markets such as the bio-pharmaceutical, automotive and high-tech industries. Through its company-owned offices and agents World Courier provides door-to-door, customs-cleared service to more than 220 countries and territories. www.worldcourier.com

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CONFERENCE PRICES

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<tr>
<th>Description</th>
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<tr>
<td>Conference &amp; Two Half-Day Workshops</td>
<td>£2597.00</td>
<td>+ VAT £3116.40</td>
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<td>+ VAT £2397.60</td>
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<td>£1399.00</td>
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<td>£599.00</td>
<td>+ VAT £718.80</td>
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<td>Workshop B</td>
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PROMOTIONAL LITERATURE DISTRIBUTION

- Distribution of your company's promotional literature to all conference attendees: £999.00 + VAT £1198.80

GROUP DISCOUNTS AVAILABLE

- Early Bird Discount: Book by 29th February 2012 to receive a £300 off the conference price

VENUE

Marriott Hotel Regents Park, 128 King Henry’s Road, London, NW3 3ST

Please contact me to book my hotel
Alternatively call us on +44 (0) 870 9090 711, email: hotels@smi-online.co.uk or fax +44 (0) 870 9090 712

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I cannot attend but would like to purchase access to the following Document Portal/paper copy documentation
- Access to the conference documentation on the Document Portal: £499.00 + VAT £598.80
- The Conference Presentations – paper copy (or £300 if ordered with the Document Portal): £499.00

PAYMENT

Payment must be made to SMi Group Ltd, and received before the event, by one of the following methods quoting reference P-028 and the delegate’s name. Bookings made within 7 days of the event require payment on booking, methods of payment are below. Please indicate method of payment:

- UK BACS: Sort Code 300009, Account 00936418
- Wire Transfer: Lloyds TSB Bank plc, 39 Threadneedle Street, London, EC2R 8AU
- Swift (BIC): LOYDGB21013, Account 00936418
- IBAN: GB48 LOYD 3000 0900 9364 18

- Cheque: We can only accept Sterling cheques drawn on a UK bank.
- Credit Card: Visa, MasterCard, American Express

All credit card payments will be subject to standard credit card charges.

CARDHOLDER'S NAME

Signature: Date:

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Substitutions/Name Changes: If you are unable to attend for any reason, then we will make a full refund immediately, but disclaim any further liability.

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