The number of trials initiated in Central and Eastern Europe has more than tripled over the past five years due to the attraction of patient recruitment statistics and the reliability of approval processes and data collection. These congresses will review the special issues of running a clinical trial in an emerging market while also reviewing wider global strategic developments designed to streamline and effectively manage clinical trial procedures & operations.

The strategies for running trials and the development of trial designs are constantly evolving. Not least among the factors affecting the future direction of clinical trials in oncology is the advent of personalised medicine. It is expected that this will transform trial design and, over the long term, may mean replacing large-scale clinical trials with a more targeted approach, focused on a smaller number of individuals with known genetic profiles.

These themes will be discussed from the point of view of anyone interested in or continuing to conduct oncology clinical trials. Our speaker panel will cover: Oncology Clinical Trials Strategy, Trial Design, Personalised Medicine/Biomarkers Impact On Oncology Clinical Operations, Challenges in Oncology Clinical Trials, Regional Focus on CEE, CIS, and MENA, Oncology Clinical Trials Strategy, Legal & Regulatory Requirements in Emerging Regions, Clinical Operations and Management Efficiency, Data Collection, Management & Safety.

Confirmed Speakers include

- Yafit Stark, Vice President, Regional Clinical Development (EMIA) & Global Clinical Advisor, Teva Pharmaceuticals, Israel
- Károly Fáller, Clinical Operations Director (Bulgaria, Israel, Romania), Site Management & Monitoring Organization, EMEA region, Area CEEMEA, AstraZeneca, Hungary
- Lenna Kimball, Head of Oncology Program and Study Management, Genentech, USA
- Amer Alghabban, Director, Global Quality Assurance Auditing, Merck Serono, Switzerland
- Éva Carrier, Vice President, Medical Affairs, NovaRx Corporation, USA
- Jeff Heckman, Project Leader, Teva Pharmaceuticals, USA
- Lynnae Jackson, Director, Clinical Research & Development, Agensys, USA
- Blake Morrison, Senior Director, Global Medical Research and Scientific Liaisons, Onyx Pharmaceuticals, USA
- Maria Noskovicova, Director of Compliance Oversight, Head of Country Clinical Operations, Pfizer, Slovakia
- Dmitri Pavlov, Director, Clinical Biostatistics, Oncology Business Unit, Pfizer, USA
- Emmanuel Pham, Senior Director, Global R&D Statistics, IPSEN Innovation, France
- Tomas Skacel, Medical Director, Amgen, Switzerland
- Lothar Tremmel, VP, Biostatistics and Programming, Incyte, USA
- Bart Vandael, Assistant Director, Global Trial Manager, Johnson & Johnson, Belgium
- Ralf Wolter, Director Operations, Corporate Clinical Research, Biotest AG, Germany
- Oleh Zahriychuk, Head of Clinical & Scientific Affairs, QPPV, AOP Orphan, Austria

www.clinical-trials-events.com/oncology.html
www.clinical-trials-events.com/octc.html

The 6th Oncology Clinical Trials in Emerging Regions and the Oncology Clinical Trials Congress

May 13th – 14th 2013, Prague, Czech Republic
Conference Agenda

**Oncology Clinical Trials Strategy**
- Challenges in a global trial landscape
- Panel discussion
- Academia & pharma collaborations
- Reforms to the clinical trial directive
- Virtual clinical trials
- Market access, health outcomes and reimbursement

**Trial Design**
- Designing and implementing oncology adaptive clinical trials
  - Regulatory guidance on adaptive designs
  - Innovative methodologies
  - Successful statistical design of adaptive clinical trials
- Optimising effective oncology clinical trial design & product development
  - Risk management in trial design

**Personalised Medicine’s Impact on Oncology Clinical Operations**
- Personalised medicine and issues with patient rights, privacy and confidentiality
- Use of biomarkers to optimise oncology clinical trials
- Decision making tools, endpoints & companion diagnostics

**Challenges in Oncology Clinical Trials**
- Patient recruitment
  - Improving recruitment in western clinical trials
  - Overcoming inadequate access to patients
- Regulatory affairs:
  - Regulatory issues for oncology clinical trials
  - Assuring GCP compliance in oncology trials
- CRO selection & management
- Site selection & monitoring
- Data collection & management
  - Randomised clinical trials
  - EDC platforms

**Regional Focus Throughout Both Days**
- Case Studies: Conducting oncology clinical trials in
  - CEE, CIS, Middle East, Africa, Latin America

**Oncology Clinical Trials Strategy**
- Current landscape: conducting clinical trials in CEE
- Challenges in conducting oncology clinical trials in CEE
- Opportunities for first in man/phase 1 clinical trials
- Approvals in emerging regions
- Cultural and infrastructure considerations
- Optimising oncology clinical trial design in CEE

**Legal & Regulatory Requirements in Emerging Regions**
- Regulatory & IP issues
- GCP adherence & issues
- Protocol violations experienced
- Assuring the ethical conduct of the trial

**Clinical Operations and Management Efficiency**
- Patient recruitment – what works?
  - Case studies from different emerging nations
  - Use of social media and other innovative strategies
- Strategic CRO selection & management for CEE oncology clinical trials
  - Benchmarking CROs & matching expectations & identifying weaknesses
  - Site selection & optimising performance
  - Oversight, monitoring & site management

**Data Collection, Management & Safety**
- Improving the integrity, quality and efficiency of data collection and standards in emerging regions
- Enabling consistent quality data from your oncology Clinical trial
- Pharmacovigilance, risk management & patient safety in Oncology clinical trials in CEE
- Role of PROs as a measure of clinical benefit

Who should attend
Delegates are pre-qualified dependent on seniority, budget, responsibility & are senior-level decision makers the Pharma & Biotech institutions mainly in Europe but also worldwide & typically include, VPs, Directors, Medical Directors, Managers, Heads and Scientists working in:

- Clinical Development
- Clinical Operations
- Clinical Management
- Clinical Programmes
- Clinical R&D
- Clinical Oversight
- Clinical Budgeting
- Clinical Outsourcing
- CRO Management
- Vendor Scouting
- Contracts
- Purchasing/Procurement
- Alliances/Licensing
- Partnering
- Market Access
- Regulatory Affairs
- Quality Assurance (QA)
- Quality Control (QC)
- Good Clinical Practice
- Compliance
- Intellectual Property
- Legal Counsel
- Emerging Markets
- Medical Directors
- Medical Affairs
- Operation & Planning
- Supply Chain
- Logistics
- Pharmacovigilance
- Drug Safety
- Clinical Data
- Business Development
- Statistics
- Biostatistics
- Biometry

For more information please contact Nick Noakes, Marketing Director, Global Engage Ltd.
nnoakes@globalengage.co.uk  +44 (0) 1865 849841
### Agenda Day One – Monday 13th May 2013

**08.00 – 08.50** Registration & Coffee

**08.50 – 09.00** Chairman’s Opening Remarks – Senior Representative, EastHORN

**09.00 – 09.45** Shared Keynote Address

*New Trends in Global Clinical Trials and the Role in Emerging Markets in Europe*

RESERVED:
Menghis Bairu, Executive Vice President & Head, Onclave Therapeutics, USA

**09.45-10.15** The Innovation and Challenges in Oncology Clinical Development and the Role of Emerging Countries and Regions

CONFIRMED:
Yafit Stark, Vice President, Regional Clinical Development (EMIA) & Global Clinical Advisor, Teva Pharmaceuticals, Israel

**10.15-10.45** Solution Provider Presentation

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**10.45-10.55** Morning Refreshments

**10.55-11.55** One-to-One Meetings – Poster Presentation Sessions

**11.55-12.25** Case Study – Conducting Clinical Trials in CEE

- Experiences and challenges overcome
- Regulatory updates
- Patient recruitment
- Supply chain

RESERVED:
Carolyn A. Blanckmeister, Emerging Markets Development Lead–Oncology, Pfizer Inc., USA

**12.25-12.55** Geographic of a Clinical Development Program: Country Selection by Type and Setting of Cancer During Development of Personalized Oncology Therapeutics

- epidemiology data
- changing classifications and disease severity scores
- potential impact on the clinical program
- splitting of the indications
- availability of eligibility defining (pre- and backbone) treatments
- diagnostic methods
- survival expectations
- referral structure
- cultural differences
- acceptability of foreign data across ICH regions,
- post-study treatment
- supportive care heterogeneity
- what is different in case of specific studies
- liver and renal impairment
- rare cancers
- early to mid vs. late stage studies

CONFIRMED:
Oleh Zahriychuk, Head of Clinical & Scientific Affairs, QPPP, AOP Orphan, Austria

**Oncology Clinical Trials Data**

**Oncology Clinical Trials Congress**

**Designing and Implementing a Successful Oncology Adaptive Clinical Trial**

- EMEA draft guidance on adaptive designs
- Regulatory requirements for adaptive clinical trials
- Innovative methodologies
- Successful statistical design of adaptive clinical trials
- Protocol design

CONFIRMED:
Emmanuel Pham, Senior Director, Global R&D Statistics, IPSEN Innovation, France

**Adaptive Clinical Trials – Statistical Perspective**

CONFIRMED:
Emmanuel Pham, Senior Director, Global R&D Statistics, IPSEN Innovation, France

**Panel Discussion: Improving Success Rate of Late Phase Oncology Clinical Trials**

- Why so low?
- Improving phase II trials

CONFIRMED:
Panel Chair – Jeff Heckman, Project Leader, Teva Pharmaceuticals, USA
Dmitri Pavlov, Director, Clinical Biostatistics, Oncology Business Unit, Pfizer, USA

**For more information please contact Nick Noakes, Marketing Director, Global Engage Ltd.**
nnoakes@globalengage.co.uk  +44 (0) 1865 849841
**Agenda Day One – Monday 13th May 2013**

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<tr>
<th>Time</th>
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<tr>
<td>12.55-13.55</td>
<td><strong>Lunch</strong></td>
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<td>One-to-One Meeting at 13.30</td>
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<td>13.55-14.25</td>
<td><strong>Oncology Clinical Trials Data</strong></td>
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<td>Strategic CRO Selection &amp; Management for CEE Oncology Clinical Trials</td>
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<td>Elizabeth Shewell, Senior Director Outsourcing, Incyte Pharmaceuticals, USA</td>
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<td>14.25-14.55</td>
<td><strong>Case Study – The Operational Challenges of Trial Management and Oversight in a Large Global Phase III Oncology Study:</strong></td>
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<td>• Regional regulatory requirements</td>
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<td>CONFIRMED:</td>
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<td></td>
<td>Bart Vandael, Associate Director, Global Clinical Operations, Janssen R&amp;D, Pharmaceutical Companies of Johnson–Johnson, Belgium</td>
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<td>14.55-15.25</td>
<td>Solution Provider Presentation</td>
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<td>For sponsorship opportunities please contact Nick Best at <a href="mailto:nick@globalengage.co.uk">nick@globalengage.co.uk</a></td>
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<td>15.25-15.35</td>
<td><strong>Afternoon Refreshments</strong></td>
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<td>15.35-16.35</td>
<td><strong>One-to-One Meetings</strong></td>
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<td>Poster Presentation Sessions</td>
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<td>16.35-17.05</td>
<td><strong>Case Study – Conducting Clinical Trials in MENA</strong></td>
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<td>• Experiences and challenges overcome</td>
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<td>• Regulatory updates</td>
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<td>• Patient Recruitment</td>
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<td>RESERVED:</td>
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<td>Mohamed Hammam, Medical Director, Emerging Markets, AstraZeneca, UAE</td>
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<td>17.05-17.35</td>
<td><strong>Personalised Medicine Impact On Oncology Clinical Trials – Russia, Turkey, CEE</strong></td>
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<td>Ana Zlateva, Clinical Project Leader, Site Management &amp; Monitoring Organization, EMEA Region, Area CEEMEA, AstraZeneca, Bulgaria</td>
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<td>17.35-18.35</td>
<td><strong>One Hour Roundtable Discussions</strong></td>
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<td>1. CEE (General Discussion Group)</td>
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<td>6. Regulatory Issues</td>
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<td>8. Latin America (General Discussion Group)</td>
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<td>18.35</td>
<td><strong>Chairman’s Closing Remarks and End of Day 1</strong></td>
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<td>18.35-19.35</td>
<td><strong>Drinks Reception</strong></td>
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The Emerging Role Of PROs as Measures of Clinical Benefit in the US’s Clinical Environment

In a series of guidance documents, FDA has clarified how efficacy should be measured in oncology trials. From this, a hierarchy of endpoints is deducted, from true measures of clinical benefit (CBE) over validated and unvalidated surrogate endpoints to biomarkers. Overall Survival (OS) is a true measure of CBE, but in many settings, OS trials are not feasible. FDA also has made clear that symptomatic improvements, as measured by patient reported outcomes, may be accepted as direct measures of CBE as well, as long as these instruments follow stringent standards in their development. This talk will introduce the hierarchy of endpoints, show with historical examples how indirect (surrogate) endpoints can lead us astray, and show by means of a recent case study how a PRO was used successfully in a recent NDA in a rare cancer.

CONFIRMED:
Lothar Tremmel, VP, Biostatistics and Programming, Incyte, USA

Patient Recruitment and Retention Case Studies from Different CEE & CIS Nations: What Works?

• Reasons for considering countries for conduct of clinical studies
• Differences and barriers
• How to stay competitive in the region – Balancing pros and cons

CONFIRMED:
Károly Fáller, Clinical Operations Director (Bulgaria, Israel, Romania), Site Management & Monitoring Organization, EMEA region, Area CEE, AstraZeneca, Hungary

Oversight Monitoring and Site Management in Emerging Regions

CONFIRMED:
Maria Noskovicova, Director of Compliance Oversight, Head of Country Clinical Operations, Pfizer, Slovakia

Solution Provider Presentation

For sponsorship opportunities please contact Nick Best at nick@globalengage.co.uk

Case Study – Xalkori CDx Program

RESERVED:
Hakan Sakul, Executive Director and Head of Diagnostics, Pfizer, USA

Case Study – Eighty Centre Global Clinical Trial

CONFIRMED:
Ewa Carrier, Vice President, Medical Affairs, NovaRx Corporation
Agenda Day Two – Tuesday 14th May 2013

**Oncology Clinical Trials Data**

13.50-14.20 Case Study – Conducting Clinical Trials in CIS
- Experiences and challenges overcome
- Regulatory updates
- Patient recruitment
- Supply chain

Speaker to be confirmed


CONFIRMED:
- Jeff Heckman, Project Leader, Teva Pharmaceuticals, USA

14.50-15.20 Regulatory and GCP Considerations when Running Clinical Trials in Emerging Regions
- GCP adherence and issues
- Protocol violations experience
- Compliance risks

Speaker to be confirmed

15.20-15.50 Overcoming the Supply Chain and Logistical Challenges of Conducting Clinical Trials in CEE, CIS & MENA

Speaker to be confirmed

15.50-16.20 Overcoming the Cultural and Infrastructure Considerations of Running Clinical Trials in CEE, CIS and MENA
- Avoiding miscommunication in documentation
- Informed consent
- Attitudes and patient compliance
- Incorporation to your clinical trial planning

Speaker to be confirmed

**Oncology Clinical Trials Congress**

The Operational Challenges of Clinical Trial Management and Oversight

RESERVED:
- Ulrike Nuber, Director Clinical Trials, Global Clinical Operations, ImClone Systems International, Switzerland

Study Planning, Management and Oversight

CONFIRMED:
- Ralf Wolter, Director Operations, Corporate Clinical Research, Biotest AG

Title to be confirmed

CONFIRMED:
- Blake Morrison, Senior Director, Global Medical Research and Scientific Liaisons, Onyx Pharmaceuticals, USA

Patient Safety in Oncology Clinical Trials

RESERVED:
- Sean Darcy, Senior Director Global Patient Safety/Global Medical Information, Vertex Pharmaceuticals

Safety Analysis and Monitoring

CONFIRMED:
- Nicole F. Li, Associate Director, Biostatistics, Genentech, Inc., USA

Chairman’s Closing Remarks and Conference Close

Afternoon Refreshments
Global Engage - 2013 Events

- 5th China Clinical Trials Outsourcing Congress (Morristown, NJ, USA, 4th–5th March 2013)
- 3rd Asia Clinical Trials Outsourcing Congress (Morristown, NJ, USA, 4th–5th March 2013)
- 6th Oncology Clinical Trials in Emerging Regions Congress (Prague, Czech Republic, 13th–14th May 2013)
- 1st Oncology Clinical Trials Congress (USA and Europe) (Prague, Czech Republic, 13th–14th May 2013)
- 1st Plant Genomics Congress (London, UK, 13th–14th May 2013)
- 2nd Global Clinical Trials Outsourcing Summit (Seoul, Korea, 20th–21st May 2013)
- QPCR Congress (Lyons, France, 9th–10th September 2013)
- Plant Genomics Congress USA (St Louis, Missouri, USA, 10th–11th October 2013)
- Oligonucleotide & Peptide Based Therapeutics Congress (Philadelphia, USA, 18th–19th November 2012)
- 3rd Asia Pharma R&D Outsourcing Congress (Philadelphia, USA, 21st–22nd November 2013)
- Plant Genomics Congress Asia (Singapore, 17th–18th February 2014)

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# Conference Fees

## Venue

**London Heathrow Marriott Hotel, Bath Road, Hayes UB3 5AN, United Kingdom.**

http://www.marriott.co.uk/hotels/travel/lhrhr-london-heathrow-marriott-hotel/

Tel 0044 20 8990 1100
Fax 0044 20-8990 1110

## Accommodation

Hotel accommodation is not included in your fee. To reserve a room at the conference hotel, please send an email to Scott Taylor at Scott@globalengage.co.uk.

## OTHER DETAILS

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## Conference Dates

May 13th - 14th 2013

## Conference Fees

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<th>Delegates</th>
<th>ONE</th>
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<td>Industry Delegate</td>
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## Conference Documentation

Full documentation costs £199 + VAT.

To order, complete the registration form and method of payment. Payment must be received before the documentation and password can be despatched.

## Payment Details

**Total:** Cheques should be made out to: Global Engage Ltd.

**Name of card holder:**

**Card No:**

**Security code:**

**Expiry Date:**

**Issue Date:**

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If payment has not been received before the conference date Global Engage reserves the right to ask for a credit or debit card guarantee of payment when you register at the conference.

**CANCELLATIONS/SUBSTITUTIONS:** Delegates cancelling more than one calendar month prior to event receive a full refund, one calendar month or less prior to event there is no refund. A substitute delegate of equal standing can be nominated within a week of the event and must be approved by the Organiser in advance in order to avoid cancellation charges.

**ORDER CONFERENCE DOCUMENTATION:** I cannot attend the conference but wish to buy the event documentation pack, which includes the speakers presentations.

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