2nd annual event

Exploratory Clinical DEVELOPMENT WORLD

Americas 09

20 – 23 October 2009, Hyatt Regency, Boston, United States

Limited special offer save up to $735!

The earlier you book the more you save!

Hear from

Dr Giora Feuerstein,
Assistant Vice President,
Head Discovery Medicine
Wyeth Research

Dr David Nicholson
Vice President, Global Product Management
Schering Plough

Dr Francis Kalush
Network Leader, Diagnostics,
Office of the Centre Director,
Centre for Devices and Radiological Health
Food and Drug Administration

Dr Irina Antonijevic
Director, Translational Research
Lundbeck Research

Dr Gary Gintant
Senior Group Leader, Department Integrative Pharmacology
Abbott Laboratories

More highlights Page 3 >>
Full programme Pages 4 - 6 >>

Breakthrough

Achieving seamless first-in-man studies

Meet the experts in their field

Hear fresh ideas shaping exploratory development and address the bottlenecks in early clinical trials pages 4 and 5 >>

Comprehensive content

Over 25 sessions addressing proof-of-concept, risk management, the regulatory environment, adaptive trials & study design, biomarkers, QT, PK/PD, outsourcing, modeling and simulation: pages 4 and 5 >>

Highly interactive 4 days

An interactive agenda with unique networking opportunities including speed networking, the online contact system, workshops and multiple presentation streams: page 6>>

Pre & post conference workshops

Pre-conference workshop 20 October
Strategies to identify and mitigate risk in first-in-man clinical trials

Post-conference workshop 23 October
Biomarkers - hype or true value?

All details page 6 >>

Book early and SAVE up to $735!

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iCardiac Technologies

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See page 8

> **"Excellent helicopter view of exploratory clinical development with appropriate landings for a closer view of topical areas"**
>
> Medical Director, **Parexel**

> **"Topics of interest, well covered with practical examples"**
>
> Director Early Drug Development, **Prosensa Therapeutics**

> **"Excellent speakers with focused coverage of cutting edge topics in exploratory clinical development"**
>
> Senior Director, Global Head Imaging Biomarkers, **Eisai**

Addressing the key challenges in early development; what are the strategies and the principles?

The 2nd annual *Exploratory Clinical Development World Americas* is the premier event for exploratory and phase I professionals to discuss strategy and solutions to bottlenecks in early development. The cost and time of clinical development is still rising yet IND approval rates continue to decrease. Pharmaceutical companies are re-evaluating their strategies to revolutionize R&D in order to make more effective and informed go / no-go decisions as early as possible in the drug development process to reduce attrition rates and shorten drug development timescales.

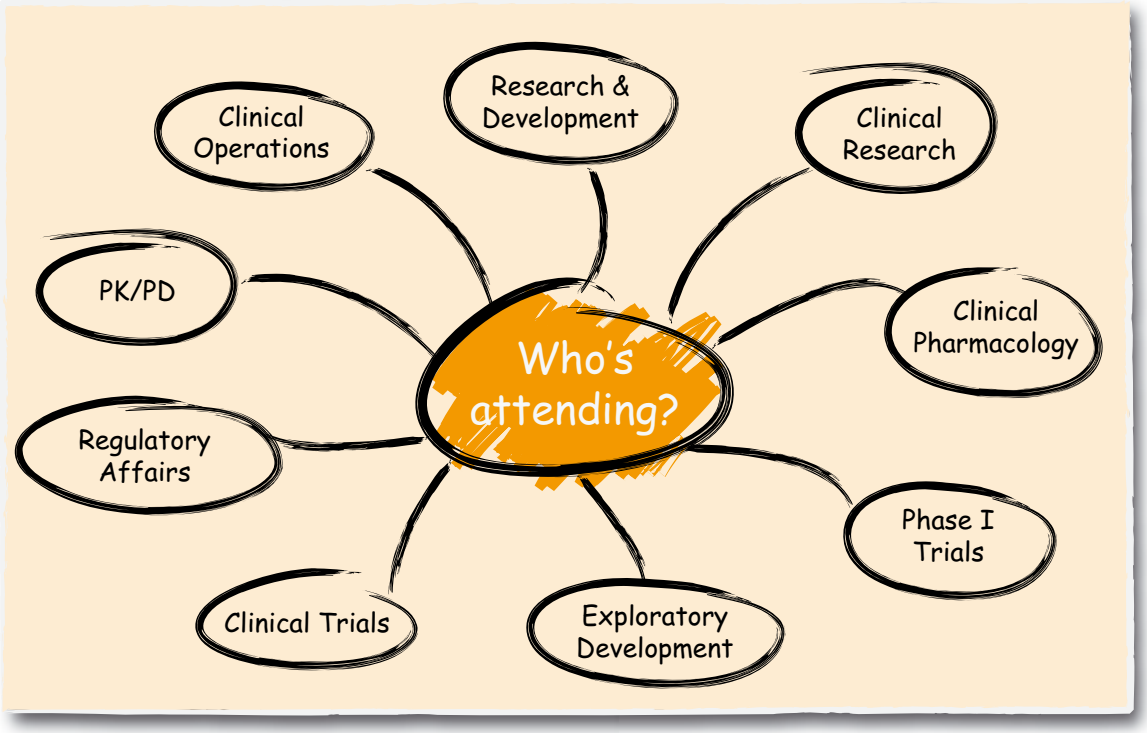
This congress will provide a forum for discussion where top pharmaceutical, biotech and regulatory representatives can address the key challenges faced by the industry. Extensive in-depth research has been carried out with senior representatives within the early clinical development community; highlighting the following topics as key issues to be addressed over the four-days.

Key issues to be addressed:

- How do we eliminate the uncertainty in early clinical development and **implement early proof-of-concept**?
- What are the global strategies and **new approaches for early clinical development**?
- How to alleviate current challenges in drug development
- What are the benefits of using **exploratory and adaptive clinical trials**?
- What technologies are there to aid **biomarker development** in early development?
- **safety pharmacology**
- What is the value of **preclinical animal models** and data when transitioning to man?
- Application of **PK / PD** modelling in late stage research and early development
- What are the considerations for **FIM trials**?
- What are the challenges when **outsourcing** early phase clinical trials and what role will India play?
- How will the **Critical Path Initiative** aid drug development?
- **Biomarker regulatory review**

One year on from the excellently received inaugural event, we bring you a **packed agenda,** larger speaker panel, **more sessions** and wider reaching content. You will hear from industry thoughts leaders from **Pfizer, GlaxoSmithKline, Novartis, AstraZeneca, Merck & Co., Wyeth, Bristol Meyers Squibb, Eli Lilly & Co., Schering Plough, Millennium: The Takeda Oncology Company, Abbott, Genentech, Lundbeck, SuperGen, Emergent Biosolutions, The Critical Path Initiative and the FDA** who will provide you with discussion, summary and knowledge of the best current practices that will help you drive compounds through phase I proving proof of concept.

This event will be attended by Senior Directors and Heads working in the pharmaceutical & biotech industry in the following departments:



8 REASONS

8 reasons not to miss the meeting that your peers will be attending

1. Fantastic speaker panel including Pfizer, GSK, Novartis, AstraZeneca, Merck, Wyeth, Genentech and the FDA

2. Comprehensive agenda – We have over 25 in-depth sessions, keep track on our website as the number is set to grow

3. Quality content – we listen to you and your peers to ensure our program address the issues of key importance

4. A choice of streams and workshops – tailor the congress to meet your information and networking needs

5. Extensive networking opportunities – plan who to meet and arrange meetings before the conference with the 'contact system', take part in speed networking and continue those conversations into the complimentary evening drinks reception

6. A proven track record – the success of *Exploratory Clinical Development World* speaks for itself – read the testimonials elsewhere in this brochure!

7. Join the A-list crowd – The only event tailored for those at the fore front of exploratory clinical development

8. Learn how to overcome the latest issues shaping exploratory clinical development from leading industry speakers

The Health Network difference

Health Network events create exciting places to...

- interact and grow knowledge
- meet and make contacts
- become inspired and reenergised

use your brain

A-list industry executives

***Exploratory Clinical Development World Americas* brings together a record number of early development leaders.**

Biomarkers in early development - value and pitfalls

Michael Burczynski, Associate Director, Biomarker Laboratory, Clinical Translational Medicine, **Wyeth Research**

Outsourcing phase I trials to India

Dr Gangadhar Sunkara, Associate Director, Translational Sciences, Lead Coordinator, TS India Business Strategy, **Novartis**

Life along the Critical Path (Initiative): how the PSTC is changing drug development

Dr William Mattes, Director of Toxicology, **The Critical Path Institute**

Outsourcing in phase I; a sponsors perspective

Dr Gavin Choy, Vice President Clinical Research Operations, **SuperGen**

Issues of concern in vaccine exploratory trials

Dr Stephen Lockhart, Senior Vice President Product Development, **Emergent BioSolutions**

Potential of using adaptive clinical trial design in early development

Dr Sergei Leonov, Director, Research Statistics, **GlaxoSmithKline**

> **"Diverse, relevant, interesting topics"**
>
> Director Business Development, **AAI Pharma Inc.**

> **"Excellent knowledgeable experienced speakers"**
>
> Assistant Director, Biostatistics Development Partners, **GlaxoSmithKline**

Your event contact is
Bernadette Stansfield
+44 (0) 207 608 7057
bstansfield@
healthnetworkcommunications.com

Improve decision making in early clinical trials

Day One Wednesday 21 October 2009

9:00 **How should we be developing drugs in the 21st century?**

- Prevalent causes of attrition rate
- Translational medicine principles
- Case studies (SAD and MAD studies)

Dr Giora Feuerstein, Assistant Vice President, Head Discovery Translational Medicine, **Wyeth Research**

9:30 **Implementing early proof of concept, readdressing the traditional development model**

- Biomarkers for prediction of contact with drug targets
- Strategies to show efficacy to decrease attrition rates
- Validation of biomarkers to aid new drug developments

Dr Irina Antonijevic, Director, Translational Research, **Lundbeck Research**

10:00 **Global strategies for early clinical drug development**

- Key design requirements to optimize the development of an IND
- Use of adaptive design methodology
- Disease models for proof of mechanism

Dr John Lambert, Chief Medical Officer, Early Phase Services, **PAREXEL International**

10:30 **Speed networking and coffee break**

11:30 **Life along the Critical Path (Initiative): how the PSCT is changing exploratory drug development**

- Tools make the differences: safety assessment past and future
- Power of scale: collaboration for robust biomarker data sets
- Bridging the preclinical and clinical divide

Dr William Mattes, Director of Toxicology, **The Critical Path Institute**

12:00 **New approaches in early clinical development**

- The transforming and reforming industry
- Introducing the latest advanced approaches and technologies
- Cases of combined approaches for efficient POC

Dr Dongzhou (Jeffery) Liu, Asstistant Director, New Products Research and Development, **GlaxoSmithKline**

12:30 **The role of the clinical pharmacologist in addressing the current challenges in drug development**

- The role of the clinical pharmacologist in experimental design
- New approaches to study design

Dr Andrea Pellacani, Senior Director, Clinical Pharmacology, **Merck Research Laboratories**

13:00 **Lunch**

14:00 **Using exploratory clinical trials in pharmaceutical discovery: planning to fail, or to WIN?**

- Summary of latest eCTA options as per ICH M3 (R2) 2009
- Regulatory and industry experience
- Impact of eCTAs pipeline attrition

Dr Lewis Kinter, Senior Director Safety Assessment, **AstraZeneca**

14:30 **Gaining accreditation for protecting human rights of subjects enrolled in early stage clinical trials**

- Commitment to scientifically and ethically sound research
- Path to winning accreditation

Dr Howard Uderman, Medical Director, New Haven Clinical Research Unit, **Pfizer**

15:00 **Afternoon coffee**

OR

STREAM 1: APPLICATION OF BIOMARKERS IN EARLY DEVELOPMENT

15:25 **Opening remarks from the chair: Dr Jochen Theis,** Principal Physician & Principal Consultant, **InHeCon**

15:30 **Biomarkers in early development - value and pitfalls**

- Biomarker technology evaluation
- Analytical validation of assays
- Biomarker-based decision making

Michael Burczynski, Associate Director, Biomarker Laboratory, Clinical Translational Medicine, **Wyeth Research**

16:00 **Regulatory review: biomarkers and the development of personalized medicine**

- Paradigms on development of personalized medicine
- Case studies

Dr Francis Kalush, Network Leader, Diagnostics, Office of the Centre Director, Centre for Devices and Radiological Health, **Food and Drug Administration**

16:30 **Personalized healthcare biomarkers in exploratory clinical development**

- Discovering and qualifying biomarkers
- Commercializing biomarkers

Dr Ruth March, Head of Personalized Healthcare team, **AstraZeneca**

17:00 **What potential can imaging biomarkers offer in early clinical development?**

- Impact of quantitative imaging
- Critical features of imaging implementation

Dr David Geho, Director Imaging, **Merck & Co.**

STREAM 2: SAFETY PHARMACOLOGY

15:25 **Opening remarks from the chair**

15:30 **Maximizing predictive preclinical cardiac safety data**

- Preclinical cardiac safety
- Timing and value of studies
- Maximizing translational fidelity

Dr Gary Gintant, Senior Group Leader, Department Integrative Pharmacology, **Abbott Laboratories**

16:00 **Advanced cardiac safety: de-risking drug candidates in early clinical development**

- Statistically significant QT results
- Define and model dose response relationships
- Achieve overall cost reduction

Dr Anthony Fossa, Vice President, Cardiovascular Safety, **iCardiac**

16:30 **Challenges, regulatory expectations, and potential strategies for assessing key aspects of cardiac safety during early development using a risk management approach**

- The risk of QT prolongation
- The risk of drug-induced cardiotoxicity
- The effects on other cardiac biomarkers

Dr Andrew Erdman, Senior Drug Safety Scientist, **Genentech, Inc**

17:00 **Pharmacology studies for early selection of drug candidates with regard to CV risk**

- Not only QT matters
- What are the considerations?
- What are scientific and corporate expectations?

Dr Malcolm Mitchell, Medical Director, Product Phase EPM, **Eli Lilly & Co**

17:30 **End of day one and networking drinks reception**

Day Two Thursday 22 October 2009

8:50 **Opening remarks from the chair**

9:00 **Innovating strategies to revolutionize research and development**

KEY NOTE

- Ideal organizational business models
- What are the opportunities for transformation of the pharma R&D model to deliver innovative new therapies cost-effectively?
- How much progress is being made in pursuit of these changes?

Dr David Nicholson, Senior Vice President, Global Project Management, **Schering Plough**

9:30 **Predictive value of preclinical animal models**

- High translation value of data and quantitative evaluation to aid development
- What does a comprehensive pre-clinical data package contain?
- Measurable in vitro and in vivo mechanism of action

Dr Carl Alden, Vice President, Toxicology, **Millennium: The Takeda Oncology Company**

10:00 **Application of preclinical PK-PD modeling in late stage research and early development**

- Application of PK-PD modeling in understanding concentration-effect relationships
- Concentration-biomarker-effect relationships in preclinical models
- Impact on compound assessment and clinical trial design

Dr Harvey Wong, Drug Metabolism and Pharmacokinetics, **Genentech Inc.**

10:30 **Morning coffee**

11:00 **Translational pharmaceutics: interactive pharmaceutical and clinical development to enable rapid formulation optimization during early clinical and proof of concept studies in drug development**

- Formulation strategies for flexible designs
- Focus on diagnosis of bioavailability and pharmacokinetic issues
- Early identification of the gap between PK performance and the target product profile
- Rapid make-and-test formulation development
- Flexible decision making within as well as between protocols
- Reducing attrition caused by failure of formulation or delivery

Dr Lloyd Stevens, Senior Research Fellow, **Pharmaceutical Profiles**

11:30 **Considerations for FIM trials**

- Effective use of pre-clinical data in the transition into man
- Finding the right dose and dose escalations
- Maintaining patient safety
- Regulatory compliance

Dr Jonathan Jaffe, Translational Medicine-Respiratory, **Novartis Pharmaceutical Corporation**

12:00 **Challenges and innovative solutions to safety testing of drug metabolites**

- Impact of MIST Guidance on current practices
- Methods for gathering metabolite data early in development
- Bioanalytical challenges and solutions for comparing metabolite exposures in preclinical species and humans

Dr Larry Tremaine, Senior Director Pharmacokinetics, Dynamics & Metabolism, **Pfizer**

12:30 **Lunch**

13:30 U turn is your turn. Because your knowledge and experience is important to us, this is where you select the topic and speakers for a session.

14:00 **Potential of using adaptive clinical trial design in early development**

- Study background (drug being developed, indication, endpoints, primary model)
- Constrained dose selection
- Developing software to construct adaptive optimal designs
- Simulation scenarios
- Possible extensions

Dr Sergei Leonov, Director, Research Statistics, **GlaxoSmithKline**

14:30 **Model based early drug development of monoclonal antibodies**

- Concept of model-based drug development
- Pharmacology of the TMabs
- Case study: illustrating the use of innovative modeling and simulation strategies to guide early development of TMabs

Dr Chee Ng, Model-Based Drug Development (MBDD), Oncology Programs, **Bristol Myers Squibb & Co.**

15:00 **Afternoon coffee**

15:30 **Issues of concern in vaccine exploratory trials**

- Biomarkers for vaccine response
- Strategies for assessing dose, schedule, route of administration and formulation selection
- Use of challenge models for early assessment of efficacy

Dr Stephen Lockhart, Senior Vice President Product Development, **Emergent BioSolutions**

OUTSOURCING

16:00 **Outsourcing in phase I; a sponsor's perspective**

- Factors to consider in selecting a phase I unit
- Implementation and experience with service providers
- Benefits and lessons learnt

Dr Gavin Choy, Vice President Clinical Research Operations, **SuperGen**

16:30 **Outsourcing phase I trials to India**

- Strategic and operational factors for conducting and managing early phase clinical trials in India
- Contributing factors and improving efficiencies
- Success stories from trials outsourced to India

Dr Gangadhar Sunkara, Associate Director, Translational Sciences, Lead Coordinator, TS India Business Strategy, **Novartis**

17:00 **Closing remarks from the chair**

Hear from phase I thought leaders

Get the most from your conference

SPEED NETWORKING

Fun, high speed breaks in the conference day for making new contacts and exchanging details. Bring plenty of business cards!

contact

Arrange meetings and email conference attendees before you arrive. Access event resources, such as white papers and presentations after you leave.

U TURN your conference agenda

U turn is your turn. Because your knowledge and experience is important to us, this is where you select the topic and speakers for a session.

An opportunity to relax and network over a few drinks with your fellow attendees

Pre and post-conference workshops

Tuesday 20 October 2009

Pre conference workshop

Strategies to identify and mitigate risk in first in man clinical trials

Objectives:
The safety of subjects in the transition to first-in-man studies presents particular risks with their safety being paramount. This practical and interactive session will provide a stimulating review on best practices used in safety management and keeping the risk to a minimum.

9:00 **Registration and coffee**

9:30 **New developments at the FDA**
- Scope of the guidelines
- Definition of potential high-risk IMP
- Review and potential of phase 0 studies in mitigating risk

10:30 **Morning coffee**

11:00 **Non-clinical aspects**
- Determination of strength and potency
- Pharmacokinetics, pharmacodynamics and metabolism
- Relevance of the animal model
- Safety pharmacology and toxicology
- Comparability with material used in non-clinical studies

12:00 **Lunch**

13:00 **Clinical aspects**
- Design of phase I clinical trials
- Calculation of the first dose and escalation scheme
- Route and rate of administration
- Monitoring for adverse events/reactions
- Site selection for the clinical trial

14:00 **Afternoon coffee**

14:30 **Risk management plan**
- Precaution to apply between cohorts
- Precaution to apply between doses within a cohort
- Stopping rules and decision making
- Long term monitoring

Please visit the website **www.healthnetworkcommunications.com/2009/explorusa** for updates on who will be presenting these topics.

Friday 23 October 2009

Post conference workshop

Biomarkers - hype or true value?

Objectives:
This highly interactive workshop will address if the expectations of biomarkers are realistic and what it will take to realize the full potential of biomarker in an effective way?

9:00 **Registration and coffee**

9:30 **Subclasses of biomarkers**
- PD & predictive biomarkers
- Disease surrogate biomarkers

10:30 **Morning coffee**

11:00 **Biomarker technologies overview – how can they provide critical value?**
- DN, RNA, Proteins, Metabolism
- Imaging

12:00 **Lunch**

13:00 **Logistical and operational challenges of biomarker utilization**
- Clinical studies and effective partnering
- Projects at various development stages

14:00 **Afternoon coffee**

14:30 **Commercial aspects of biomarker**
- Ensuring cost effective biomarker provisions
- Translating biomarkers approaches into commercial value
- Pharmacodiagnostics

Your workshop leader:

Dr Jochen Theis, Principal Physician & Principal Consultant, **InHeCon**
Jochen Theis is a physician with clinical training in paediatrics and board certification in clinical pharmacology. He held positions of increasing responsibility in all phases of clinical development. His last position in Roche prior to founding his consultancy was Global Head of Biomarkers and Experimental Medicine with responsibility for all clinical biomarker and pharmacodiagnostic activities.
Jochen Theis is the founder and principle consultant of InHeCon, an integrated healthcare consultancy serving clients in the pharma/biotech, diagnostics, and venture capital industries.

4 day Gold pass. **Save up to $735.** And another **$100** if you book and pay online

See Page 8

Group bookings. Why not send your team and save more? Send 3 delegates and save 15%, send 4 delegates and save 25%

Becoming a sponsor or exhibitor

Exploratory Clinical Development World is where people come to look for advice, guidance and support to the key challenges they face. As a CRO, laboratory or technology provider with solutions to offer, this conference represents an exceptional opportunity to develop new business relationships.

Questions to determine your involvement

- Do you offer services and solutions that support the challenges of early clinical development?
- Could you benefit from introductions to and time with early phase decision makers?
- Are you actively looking for new leads and clients to work with?

If your answer is yes to these questions you should be participating in this event, and by doing so you will increase your chances of being selected as a partner.

Sponsorship opportunities can be tailored to your specific objectives and marketing requirements, let us know what you want to achieve and we will develop a promotional solution with you.

To sponsor or exhibit contact Claire Conway on + 44 (0) 207 608 7058 or email cconway@healthnetworkcommunications.com

Meet and do business with industry decision makers.

"The speed networking was new to me, but I like the concept. Very good opportunity to meet several people in short amount of time to exchange information. Excellent speakers and good choice of topics."

Team Leader, **MDS Pharma Services**

"Great event – speakers and content were an excellent standard"

Director Corporate Marketing, **Pharmaceutical Profiles**

Got something to say?
Talk to us about how we can help! Call Claire Conway +44 (0) 207 608 7058

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The venue

Experience the excitement of the city at Hyatt Regency Boston. Just one block from the Boston Common and within walking distance of attractions, shopping and theaters, our downtown Boston hotel is ideal for leisure or business. Tour the Freedom Trail, shop at Faneuil Hall, visit museums, or catch a game at Fenway Park. Delight in this newly renovated Boston Commons hotel – just steps from Chinatown and connected to the T. Rejuvenate your body and spirit in our spa, sauna, Eucalyptus steam room, pool, sun terrace and lounge. The first Boston member of the Green Hotels Association, our award-winning accommodations are eco-, family- and pet-friendly. Contemporary-style rooms, delicious dining and more await you at this luxurious Hyatt hotel in downtown Boston.

Exploratory Clinical DEVELOPMENT WORLD

Americas 09

Breakthrough

20 – 23 October 2009, Hyatt Regency, Boston, United States

Use our online calculator at www.healthnetworkcommunications.com/2009/explorusa
You can use our online calculator to tailor your ticket and buy multiple tickets.
The calculator automatically selects the most favourable discount for you.
If you book and pay online you also save a further $100

Register now

Package	Before 31 July 09	Before 11 Sept 09	Before 2 Oct 09	After 2 Oct 09	How many	Calculate your ticket
Gold pass – all 4 days 20 – 23 Oct	$3310	$3675	$3860	$4045	☐	
2 main days plus pre conference workshop 20 – 22 Oct	$2505	$2785	$2925	$3065	☐	
2 main days plus post conference workshop 21 – 23 Oct	$2505	$2785	$2925	$3065	☐	
2 day conference 21 – 22 Oct	$1700	$1890	$1985	$2080	☐	

*Registrations without credit/debit card payments are subject to a $100 booking fee.

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All tickets include refreshments, lunch and full conference documentation. The fee does not include hotel accommodation.

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Payment is due in 7 days. By signing and returning this form you are accepting our terms and conditions. If you reserve your ticket but pay by bank transfer or cheque payment must be received in 7 days

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How to book your ticket

Online

It's quicker and easier to book and pay online go to www.healthnetworkcommunications.com/2009/explorusa and click on register now

Offline

Complete this form and fax it back to +44 (0) 207 608 7050 or call Prithibah Irving on +44 (0) 207 608 7055 and we'll take your booking over the phone.

Group bookings

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Send 3 delegates and save 15%
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3.Health Network Communications will make available course documentation to a delegate who is unable to attend and who has paid
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If you reserve your ticket but pay by invoice or bank transfer payment must be received in 7 days