3rd annual event

50% discount for Pharma/Biotech delegates

see back page for details

LATE PHASE DRUG DEVELOPMENT WORLD AMERICAS 2012

20 - 22 March 2012, Hyatt Regency, Boston, United States

Hear from

Dr Craig Lipset
Head of Clinical Innovation
Pfizer

Dr Weinong Guo
Senior Director, Program Section Leader, CVM Development Franchise
Novartis

Alex Dusek
Global Launch Team, Riociguat
Bayer

Dr Pol Vandenbroucke
Vice President, Clinical Development, Emerging Markets Business Unit
Pfizer

Dr Coleman Obasaju
Senior Medical Director, Oncology
Eli Lilly

Dr Steve Niemcryk
Head, Global Surveillance and Pharmacoepidemiology
Abbott

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

Real life

Driving value in phase IIIb & IV trials

Hear from and meet leaders in late phase research including:
Pfizer, Novartis, Bayer, Eli Lilly, Johnson & Johnson, Abbott, Takeda, Boehringer-Ingelheim and AstraZeneca page 4 and 5 >>

Key strategic drivers:
Benchmark your strategies against top pharma and biotech companies page 4 and 5 >>

Don't just sit there!
Interactive and flexible agenda with unique networking opportunities, panel discussions and workshops page 6 >>

Pre conference workshop:

20 March 2012
Innovative solutions to data capture

All details page 6 >>

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INVENTIV HEALTH

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50% discount for Pharma/ Biotech delegates

See page 8

"Broad range of speakers who are informed and engaging"

Senior Project Manager, **Genzyme**

"Generated great discussions and was an excellent opportunity for networking"

Senior Medical Director, **Abbott**

"I thought the conference was very well done – the best of these I've participated in"

Senior Director/Team Lead, **Pfizer**

Benchmark your late phase strategy alongside the industry's best

Phase IIIb/IV is a vital part of drug development. No matter how many patients are studied in pre-marketing clinical trials the real world effectiveness of a drug can only be evaluated through observational, non-interventional studies. This real world evidence-based data is quite simply essential to support drug safety, benefit-risk assessment and of course a drug's value proposition. But there are all sorts of questions facing the industry today.

How do you manage online, innovative, patient-centred trials and get targeted safety and efficacy data?

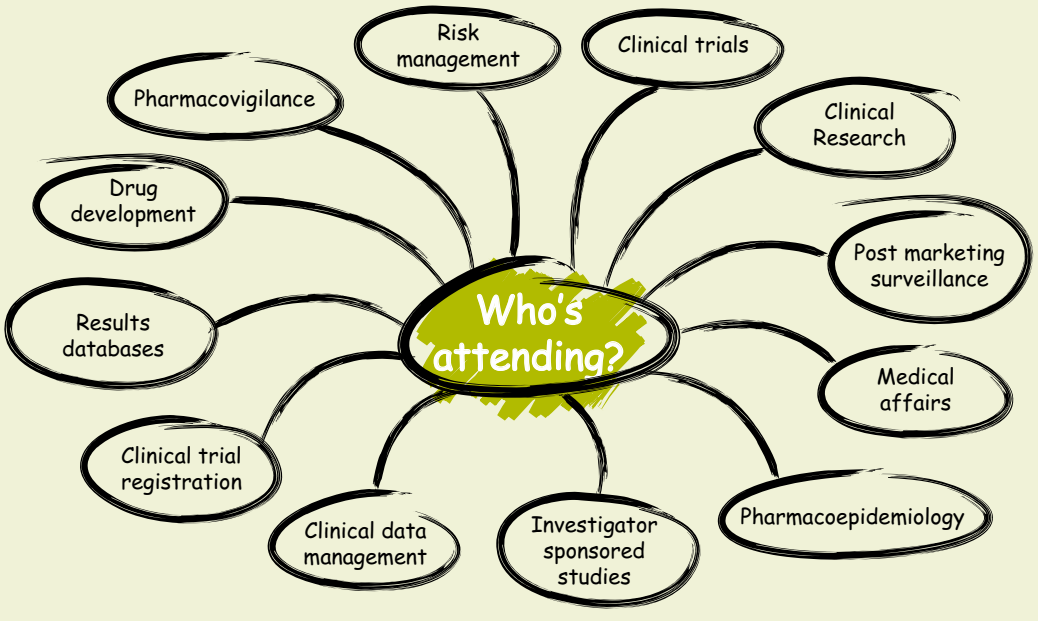
How is clinical data from a variety of geographical regions mix impacting our ability to bring drugs to market?

Health Network has shaped a programme which provides answers to the challenges in rolling out an effective late phase strategy. All the key strategic and operational challenges are tackled:

- Strategic challenges in late phase trials – how can we structure the late phase apparatus and turn insight from the real world into a competitive commercial asset?
- Presenting results to maximise value to regulators, payers and health technology authorities - How is product reimbursement linked in a healthcare system undergoing real reform, and can we differentiate our drugs from competitors in the eyes of the payer?
- Tackling the complexities of regulatory-mandated post-marketing studies
- What considerations need to be made for Phase IIIb/IV studies in emerging markets – building cost-effective non interventional studies using multi-trial sites and handling a variety of regulatory requirements
- Providing real-world evidence to support product claims and develop data in expanded populations of patients
- How to get population-based real-life information from health registries and electronic health record systems
- What are the challenges and opportunities of post-approval safety surveillance – developing product specific risk management plans?
- Peri-approval strategy trials for combination therapies, what specific challenges do you face?
- Real case studies in a range of therapeutic areas: Cardiovascular, Multiple Sclerosis, Infectious Disease, Oncology

This meeting brings an extensive and diverse agenda, giving you everything you need to know about late phase. You will hear from industry thought leaders from an impressive list of companies including: **Pfizer, Novartis, AstraZeneca, Abbott, Eli Lilly & Co, Bayer, Takeda, Boehringer-Ingelheim** and **Johnson & Johnson** who will provide you with the best possible advice on how to improve performance in late phase research. The whole agenda is built so that you get the most out of it with every presentation followed by a Q&A sessions.

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



8 REASONS

Why you should attend Late Phase Drug Development World Americas 2012:

1. **Comprehensive agenda** - we have over 20 unique and informative sessions, keep track on our website for developments
2. **Pfizer, Novartis, AstraZeneca, Abbott, Eli Lilly & Co, Bayer, Takeda, Boehringer-Ingelheim and Johnson & Johnson** - hear industry insights from our expert speaker panel!
3. **Quality content! -** we listen to you and your peers to ensure our program confronts the topics you want to hear
4. **Case studies -** hear therapeutic area specific presentations, including Cardiovascular, Multiple Sclerosis, Infectious Disease, Oncology
5. **Extensive global reach** - We have speakers that have worked extensively in the international landscape
6. Pre conference workshop, focused networking sessions, panel discussions, delegate led questions. **Tailor the packed congress to meet your own information and networking needs**
7. **Proven track record!** - Health Network have a demonstrable track record in delivering high quality well attended events for the life sciences sector
8. **Extensive networking opportunities** - make contact, plan who to meet and arrange meetings prior to the conference, take part in multiple networking sessions and continue to build these relationships following the event

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 of industry experts

Drug safety and active surveillance

Dr Xiaofeng Zhou, Director of Epidemiology, **Pfizer**

Phase IV Clinical Studies – How flexible can these be?

Dr Vipin Arora, Director, Statistics, Global Biostatistics and Data Management, **Abbott**

Best practices in ePROs in late phase studies

Dr Toshio Kimura, Associate Director, Biostatistics, **Boehringer-Ingelheim**

CASE STUDY **Thyroid cancer development program – case study from vandetanib (Zactima)**

Dr Peter Langmuir, Medical Science Director – Zactima, **AstraZeneca**

Real world, outcomes research and how this feeds into commercialization strategies

Dr Amy Guo, Senior Director & Head Health Economics & Outcomes Reseach, **Novartis**

Multiple Sclerosis and long-term outcomes

Dr Volker Knappertz, Global Medical Affairs, Drug Development, **Bayer**

Patient registries in orphan diseases

Maria Madison, Director, Global Outcome Surveys, **Shire**

Using data from Electronic Health Record systems for Clinical Research

Mats Sundgren, Scientific Advisor, **AstraZeneca**

> "Only wish I could have attended more of the sessions"
> Senior Director, Clinical Neuroscience, **Merck**

> "Good quality speakers/experts in their field"
> Market Access Manager, **MSD**

20 top industry and policy experts under one roof and counting....

Your event contact is
Rachel Arthurson
+44 (0) 207 608 7045
rarthurson@healthnetworkcommunications.com

Day One Wednesday 21 March 2012

08.00 **Registration & coffee**

09.00 **Opening remarks - Maria Harrison,** Vice President of Late Phase Services**, PRA Late Phase Services**

STRATEGIC CHALLENGES IN LATE PHASE DRUG DEVELOPMENT

09.10 **Innovation in late phase development**

KEY NOTE

- Highlighting patient-centered trials
- Providing information on a specific Pfizer case study (virtual trial)

Dr Craig Lipset, Head of Clinical Innovation**, Pfizer**

09.40 **Phase IV Clinical Studies – How flexible can these be?**

- Do's and Don'ts for designing Phase IV studies
- General tips for communications to gain overall efficiency without impact on quality
- Benefits of early involvement of Analytical Sciences with Medical Affairs, Clinical and Regulatory

Dr Vipin Arora, Director, Statistics, Global Biostatistics and Data Management**, Abbott**

10.10 **Regulatory-mandated post-marketing studies**

- History and current trends in post-marketing requirements from regulatory agencies
- Common challenges to the planning and execution of post-marketing research
- Stakeholder involvement and value of post-approval study participation
- Utilizing data to drive the management of post-marketing research

Kathleen (Kushner) Mandziuk, MPH, RN, Senior Scientific Affairs Director**, PRA Late Phase Services**

10.40 SPEED NETWORKING **Followed by morning refreshments**
Fun, high speed breaks in the conference day for making new contacts and exchanging details. Bring plenty of business cards!

11.40 **Late phase drug development strategies for emerging markets**

KEY NOTE

- Why and how geographic mix for clinical research impacts our ability to bring drugs to market
- Top regulatory and commercial requirements in major emerging market countries
- Examples from selected emerging markets; recommendations for successful development and pitfalls to avoid

Dr Pol Vandenbroucke, Vice President, Clinical Development, Emerging Markets Business Unit, **Pfizer**

CONDUCTING POST-APPROVAL STUDIES

12.10 CASE STUDY **Thyroid cancer development program – case study from vandetanib (Zactima)**

- Development in a rare cancer, predictive biomarkers, risk/benefit assessment
- Interactions with FDA/EMA

Dr Peter Langmuir, Medical Science Director – Zactima, **AstraZeneca**

12.40 CASE STUDY **Peri-approval strategy trials during evolving combination therapy standards of care: Learnings from HIV and PAH**

- Providing evidence to support product claims and develop data in expanded populations of patients
- Clinical program design to evaluate real-world outcomes
- Addressing the challenges of US and EU regulatory requirements

Alex Dusek, Global Launch Team, Riociguat**, Bayer**

13.10 **Lunch**

DEMONSTRATING VALUE IN LATE PHASE

14.10 **Opening remarks from the chair**

14:20 **Real world, outcomes research and how this feeds into commercialization strategies**

- Challenges in showing evidence-based value in a payer-dominated marketplace
- Package study results to maximise value to regulators, payers and health technology authorities

Dr Amy Guo, Senior Director & Head Health Economics & Outcomes Research, **Novartis**

14.50 **Getting the right evidence from your late stage activities: the importance of planning ahead**

- Predict late phase considerations earlier in the life cycle
- Fill evidence gaps within and alongside the clinical development program
- Prioritize activities that need to be done in the peri-approval period

Teresa (Terry) K. Wilcox, RPh, PhD,Senior Research Scientist, Evidence Generation Strategy Practice Lead,**United BioSource Corporation**

15.20 **Afternoon refreshments**

15.50 **Providing late phase evidence for informed healthcare decision-making**

- The place of Comparative Effectiveness Research in defining the value of treatment interventions
- Hierarchy of evidence

Craig Plauschinat, Director, Value Integration, HEOR, **Novartis**

16.20 PANEL SESSION **Identifying the commercial opportunity from real-world data**

LATE PHASE CLINICAL TRIAL DESIGN

16.50 **Using the right clinical designs in Phase IV oncology studies**

- Analysing safety and efficacy data for first in line treatments
- Research aims achieved, challenges encountered and lessons learned

Dr Tibor Tar, Study Director, **AstraZeneca**

17.20 **Improving diversity in clinical trials**

- Designing observational studies that can increase minority participation in clinical trials
- Developing tailored therapies that can be effective over different racial groups
- Assessing the impact of protocol design on minority participation

Dr Coleman Obasaju, Senior Medical Director, Oncology, **Eli Lilly**

17.50 **Closing remarks from the chair**

18.00 **Drinks reception: join your peers and relax with a drink after a busy conference day.**
To sponsor the drinks reception contact Roope Ghosh on +44 (0) 207 608 7037

Part of the international series

LATE PHASE DRUG DEVELOPMENT WORLD AMERICAS 2012

LATE PHASE DRUG DEVELOPMENT WORLD 2012

Day Two Thursday 22 March 2012

08.00 **Registration & refreshments**

09.00 **Opening Remarks from the Chair**

CHALLENGES IN OUTCOME TRIALS

09.10 **Transformational changes in conducting CV outcome trials**
- Innovative thinkings to streamline and execute large CV outcome trials
- Managing large outcomes studies to reduced cost and accelerate timelines without compromising study quality and integrity

Dr Weinong Guo, Senior Director, Program Section Leader, CVM Development Franchise, **Novartis**

09.40 **Multiple Sclerosis and long-term outcomes**
- Long-term clinical outcome of primary progressive MS
- Predictive value of clinical and MRI data
- Mortality outcomes for Interferon Beta-1b
- Factors indicative of a benign/malignant disease course

Dr Volker Knappertz, Global Medical Affairs, Drug Development, **Bayer**

EMPOWERING PATIENTS AND ENABLING TECHNOLOGIES

10.10 **High patient compliance and retention through engaging online data capture**
- Higher scientific value of patient reported outcomes via online tools
- Ways to improve patient compliance and retention in long studies

Rauha Tulkki-White, Director of Product Management, **CRF Health**

10.40 **Morning Refreshments**

11.10 **Generate Patient Reported and Third Party Observational Data for Late Phase Studies**
- Mechanisms to collect direct patient outcome data
- Types of measurements that can be collected
- Current trends in data collection methods

Scott Dixon, Global Strategist, Late Phase and ePRO, **Oracle**

11.40 **Best practices in ePROs in late phase studies**
- How patient-centered online research platforms can give a rich understanding of therapeutics postmarket
- Collecting a broad range of data: prevalence, treatment purpose, evaluations of effectiveness, side effects and burden

Dr Toshio Kimura, Associate Director, Biostatistics, **Boehringer-Ingelheim**

OBSERVATIONAL STUDIES AND REAL WORLD SAFETY SURVEILLANCE

12.10 **Observational research: areas of consensus and divergence**
- The operational concerns and expectations of sponsors
- Challenges to be addressed to optimise observational research

Jeff Trotter, Executive Vice President – Phase IV Development, **PharmaNet/i3**

12.40 **Lunch**

13.40 **Managing post-approval safety surveillance and data management**

KEY NOTE
- Supporting the development of product specific risk management plans and REMS
- Managing adverse events reports and ad hoc safety surveillance
- Using large electronic medical records or medical claims data bases

Dr Steve Niemcryk, Head, Global Surveillance and Pharmacoepidemiology, **Abbott**

14.10 **Challenges and opportunities in Active Surveillance and lessons learnt as a member of the OMOP Extended Consortium**
- Discuss the key concepts of active surveillance and the potential prospects for wide spread use
- Present an overview of OMOP activities and its value for active surveillance activities at a large pharmaceutical company
- Introduce and discuss other initiatives in the field of active surveillance

Dr Xiaofeng Zhou, Director of Epidemiology, **Pfizer**

14.40 **Using data from Electronic Health Record systems for Clinical Research**
- How the EHRCR project, one of the largest public-private partnerships, is providing solutions for using EHR
- Outputs of the project including pilots for validating solutions in different scenarios, therapeutic areas and several countries
- Managing effective patient identification and recruitment, clinical trial execution, adverse event reporting
- Coordinating regional diversity and individual approaches

Mats Sundgren, Scientific Advisor, **AstraZeneca**

15.10 **Registries for evaluating patient outcomes – New initiatives by the AHRQ**
- Supporting research focused on the outcomes, effectiveness, comparative clinical effectiveness and appropriateness of pharmaceuticals
- Evaluating the success of registries to collect data about patient outcomes

AHRQ representative

COMMUNICATIONS IN PHASE IIIB/IV

15.40 **Establishing firm clinical trial disclosures in late phase**
- Being committed to transparency on clinical trial sponsorship and disclosing all results on marketed products
- Managing result publication so not to compromise submissions to peer-reviewed journals or national laws and regulations
- Compliance with Pharmaceutical Industry Associations commitments

Speaker to be announced

16.10 **Medical communications & publication planning**

16.40 **Closing remarks from the chair**

16.50 **End of conference**

Strength in numbers

Bring your team and receive a group discount of up to 25%

Get the most from your conference experience

contact

Arrange meetings online before you arrive. Access event resources, such as papers and presentations, after you've left.

SPEED NETWORKING

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

PANEL SESSION

Meet and talk about the business issues on your brain.

Workshops: a relaxed environment for you to network with your peers and focus more directly on topical issues.

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See page 8

Pre-conference workshops

Tuesday 20 March 2012

Innovative solutions to data capture

Overview

This interactive workshop will review different technical innovative solutions in data capture; eg. Smartphones, and the advantages/disadvantages of their application. The day will then demonstrate real world scenarios and different approaches for using these data capture tools. Attendees will come away from this workshop with practical and usable information to share with their product teams.

The workshop will begin at 09:00 and end at 16:00. Lunch and refreshments will be provided.

Workshop content

- Treatment centred Phase III Clinical Trial & Phase IV Post Marketing Surveillance studies
- Using a single platform to capture and analyze study data
- Increasing study design efficiencies and supporting midstudy changes
- Multistudy coordination across global investigations
- Patient centred Electronic Records and Management Systems
- Community wide Electronic Health Records
- Health Informatics Methodology
- Data collection flow of current real world processes with desired enhacements
- Developed applications in a range of therapeutic areas

See www.healthnetworkcommunications.com/lpddusa for futher details

Organisations previously attended:

- Abbott Products Operations
- Amgen
- Analgesic Research
- Astrazeneca
- Bayer Business Services GmbH
- Bayer Schering A.G.
- Biogen Idec
- Boehringer Ingelheim Pharmaceuticals Inc
- Booz and Company GmbH
- Bristol Myers Squibb Co
- Cubist Pharmaceuitcals Inc
- Dr Reddy's Laboratories
- Eisai
- Eli Lilly and Company USA
- F. Hoffmann-La Roche Ltd
- F.D.A.
- Genzyme Corporation
- GI Dynamics
- Gilead Sciences Inc
- HealthCore Inc
- Ironwood Pharmaceuticals , Inc.
- Kyowa Hakko Kirin Pharma Inc
- Merick & Co Inc.
- Millennium Pharmaceuticals
- NicOx S.A.
- Novartis Drug Safety and Epidemiology
- Novo Nordisk Pharmaceuticals Inc
- Ortho Janssen Scientific Affairs, LLC
- Otsuka Pharmaceutical Development And Commercialization Inc.
- Outcome
- Pfizer Inc
- PharmaNet LLC
- Quintiles
- Roche
- Strativa Pharmaceuticals
- Teva Pharmaceuticals
- Vertex Pharmaceuticals Inc

Part of the leading international Late Phase Drug Development series

LATE PHASE DRUG DEVELOPMENT WORLD AMERICAS 2012

LATE PHASE DRUG DEVELOPMENT WORLD 2012

Your event contact is
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phone +44 (0) 207 608 7045
rarthurson@healthnetworkcommunications.com

Becoming a sponsor or exhibitor

The 3rd Annual Health Network Communications' *Late Phase Drug Development World Americas* has been met with unprecedented interest. With over 25 industry speakers on the programme this event is the leading strategic late phase conference in the US calendar.

Late Phase Drug Development World Americas is where people come to look for advice, guidance and support to the key challenges they face. As a CRO 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 faced in phase IIIb/IV?
- Could you benefit from introductions to and time with decision makers in late phase?
- Are you actively looking for new leads and clients to work with in late phase drug development?

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 Roope Ghosh on + 44 (0) 207 608 7037 or email rghosh@healthnetworkcommunications.com

"Excellent – the team did a great job ensuring that we had the chance to speak with sponsors"
Account Director, **PRA**

"Good organisation, got a decent ratio of vendors versus pharma/biotech… this is one of the few late phase specific conferences with opportunities to present and network with peers"
Director, **Late Phase Solutions, Medidata Solutions**

Sponsors

PRA's Late Phase Services group supports global and regional Post-Approval studies of all sizes. Our highly-experienced team assists sponsors with the Post-Marketing process by planning and conducting Post-Authorization Safety Studies/Safety-Surveillance Studies, Drug Utilization Studies, Registries, Restricted Access Programs, Risk Evaluation and Mitigation Strategies/EU-RMP, and Diagnostic and Biomarker Research.

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The venue

Hyatt Regency, Boston, USA

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.

LATE PHASE DRUG DEVELOPMENT WORLD AMERICAS 2012

20 - 22 March 2012, Hyatt Regency, Boston, United States

Real life

Use our online calculator at www.healthnetworkcommunications.com/lpddusa
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 Dec 2011	Before 11 Feb 2012	Before 3 Mar 2012	After 3 Mar 2012	How many	Calculate your ticket
Pharma/biotech: 2 main days plus workshop 20 - 22 March	$1,297	$1,442	$1,515	$1,587	☐	
Pharma/biotech: 2 days conference 21 - 22 March	$895	$995	$1,045	$1,095	☐	
Vendor: 2 main days plus workshop 20 - 22 March	$2,595	$2,885	$3,030	$3,175	☐	
Vendor: 2 days conference 21- 22 March	$1,790	$1,990	$2,090	$2,190	☐	

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

How do you want to pay?		
Credit / Debit card	☐	$ 0
Cheque / Bank transfer	☐	$ 100
Total		

Your voucher code

(you'll need to quote this for telephone and online bookings)

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

Your details

Delegate name.....

Job title.....Organization.....

Address.....

Post code.....Country.....

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Authorizing manager.....Authorizing manager signature.....

Payment details

Payment is due in 14 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 14 days

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Reference: please quote 100060 and the delegate's name

How to book your ticket

Online

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If you reserve your ticket but pay by invoice or bank transfer payment must be received in 14 days