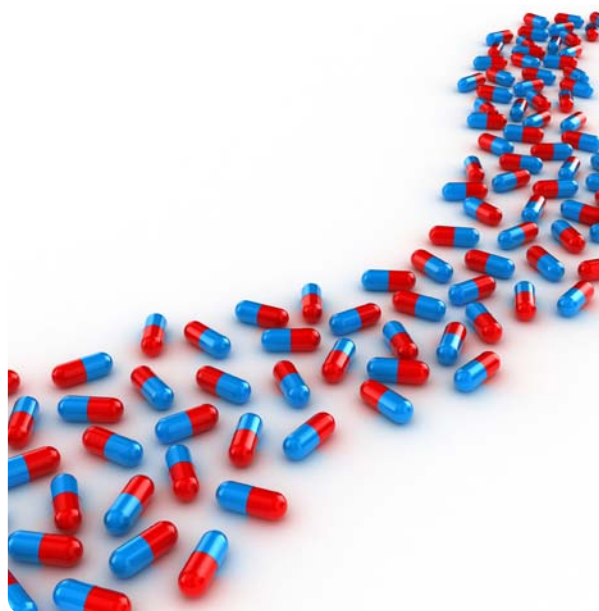


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2nd World Orphan Drug Summit

Driving business performance through partnering, networking & in-depth discussion

15th – 17th November 2011, Boston, MA

Benefits of attending

- Explore strategies to **encourage investment, secure funding and maximize partnership potential** to sustain orphan drug development
- **Apply lessons that big pharma have used** to your own business to **successfully enter the orphan drug space**
- Discuss how you can **design and implement improved clinical trials** for orphan drugs
- Learn what **approaches leading biotech companies** are taking to **turn promising therapies into treatment realities**
- Discover how a **patient centred approach** to orphan drug R&D and **collaboration with patient advocacy groups** will **improve patient access**
- **Benchmark your market access strategies** to **boost orphan drug portfolios**

Workshops: 15th November 2011

- A) **The Japanese Regulatory Environment: Achieving Orphan Drug Designation**
Richard Lowenthal, President, Co-founder & Officer, **Pacific-Link Consulting LLC, San Diego & Pacific-Link Consulting Corporation, Tokyo**
- B) **The Search for New and Future Therapies for Rare Diseases: Advancing Understanding and Development to Improve Availability of Treatment Options**
Ian Phillips, Norris Professor of Life Sciences, Director of the Center for Rare Disease Therapies, Faculty Director, PreMed Program, **Keck Graduate Institute**

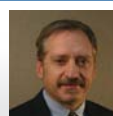
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Swedish Orphan Biovitrum

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Senior Director, Orphan & Genetic Diseases
Pfizer



Chris Dandrea
R&D Program Director - Pompe Disease Franchise, Personalized Genetic Health Business Unit, **Genzyme**



Bill Martin
Group VP, Business Development
Accredo Health



Pol Boudes
CMO
Amicus Therapeutics



Pat Furlong
Founding President & CEO
Parent Project Muscular Dystrophy



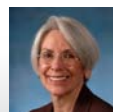
Howard Yuwen
Senior Director, Regulatory Affairs
Shire



Patrick Enright
Managing Director
Longitude Capital



Francois Nader
CEO
NPS Pharmaceuticals



Carol Lee Koski
Medical Director
GBS/CIDP Foundation International



Patrick Reichenberger
VP, Commercial Operations
Raptor Pharmaceuticals

Tel: +1 212 537 5898 Email: info@hansonwade.com

www.orphandrug-summit.com



Benefits of attending

To get anywhere in the orphan drug space, meeting the right people is absolutely crucial.

Whether its **patient advocacy groups, large pharma, healthcare insurance companies, investors, regulatory agencies, speciality orphan biotechs...**

You've told us you want a **highly focused BD meeting, packed with more networking opportunities** where the commercial and scientific issues can be debated, discussed and outlined in a frank and refreshing way. A meeting that **exclusively attracts key decision-makers** that work in the orphan drugs sector, which brings together more **patient organizations** than any other meeting.

The **2nd World Orphan Drug Summit** will score on all counts. Following on from the great success of our first World Orphan Drug Summit, this meeting will feature unparalleled insights from the pioneering experts to discuss commercial approaches to drive orphan drug development forward and provide you with the strategies to grow business in your area.

1. **Align your business needs with best practice** by meeting and networking with **the key stakeholders** in the orphan drug community
2. Recognize how patient advocacy groups can improve your business and scientific orphan drug activities and discover how a patient centred approach to orphan drug R&D can improve patient access with **Parent Project Muscular Dystrophy, Shire, Novartis and RARE Project**
3. Explore strategies to encourage investment, secure funding and maximize partnership potential with **Accredo Health, AstraZeneca, and Longitude Capital**
4. Hear from **Pfizer** and **Genzyme** about how they are approaching the orphan drug market and advancing therapies for orphan diseases
5. Gain a detailed insight into how to design clinical trials for orphan drugs and improve diagnosis and treatment with **Amicus Therapeutics, GBS/CIDP Foundation International, Duke University School of Medicine and Alkaptonuria Society**
6. Drive commercial success and maintain momentum throughout your marketing campaign with **Raptor Pharmaceuticals, Cystinosis Research Foundation, Spectrum Pharmaceuticals and Generation Health**
7. Optimize the multi-indication brand and other orphan pricing strategies with insights from **Infusion Pharma Consulting LLC**
8. Discuss different orphan drug approaches with **NPS Pharmaceuticals** and **DelMar Pharmaceuticals** and accelerate your development timelines

Who should attend?

This meeting has been designed to provide cutting edge, exclusive insights from industry, patient advocacy groups, insurance companies, the venture capital community and academic leaders into how to grow business and drive orphan drug development forward. That means everyone involved in:

- Regulatory/governmental/public affairs
- Strategy
- Business development/marketing & sales
- Commercial operations
- Reimbursement/pricing
- Market access
- Clinical R&D
- Scientific/medical affairs
- Health policy
- Patient relations



Search groups for: **Orphan Drug Forum**
to join the online community

Hear what attendees said about the World Orphan Drug Summit in Frankfurt, May 2011:

"Great and inspirational"

Only for Children Pharmaceuticals

"Very interesting and diverse presentations"

Celgene

"Absolutely inspirational/interactive/engaging"

Cure Progeria Ltd

"Highly skilled, knowledgeable speakers and excellent networking"

Quintiles

"Timely and informative leading to stimulating debate"

Masters Pharmaceuticals

"Extremely valuable initiating new ideas for future developments"

Myasthenia Gravis Association

Day 1

16th November 2011

8.15 Registration, Coffee and Networking

- 8.55 **Chair's Opening Remarks**
Patrick Reichenberger, VP, Commercial Operations,
Raptor Pharmaceuticals

Pharma Perspective on Entering The Orphan Disease Space

- 9.00 **Orphan and Genetic Diseases: An Industry Perspective**
- Pfizer commitment to orphan diseases
 - Why orphan diseases?
 - Genetic basis of disease
 - Regulatory environment for orphan drug development
 - Pfizer orphan and genetic diseases research
 - Working together to advance therapies for orphan diseases
- William Brubaker**, Senior Director, Orphan & Genetic Diseases, **Pfizer**
- 9.35 **Drug Development Robustness and Sustainability Through the Identification and Management of Challenges Unique to the Orphan Space**
- The need for transformative therapies as the basis for orphan drug development success
 - The challenges unique to orphan disease drug development
 - Set expectations and outline approaches to designing orphan disease drug development programs
- Chris Dandrea**, R&D Program Director - Pompe Disease Franchise, Personalized Genetic Health Business Unit, **Genzyme**

Orphan Drug Pricing Strategies

- 10.10 **Adventures in Orphan Drug Pricing**
- Approaches to orphan drug pricing
 - Emerging trends that may impact orphan pricing
 - Optimizing the multi-indication brand
 - The danger of losing perspective
 - Five lessons we've learned in getting it right
- John J Maddox Jr**, Managing Director, **Infusion Pharma Consulting LLC**

10.40 Speed Networking Session

11.40 Morning Refreshments

Biotech Orphan Drug Innovation

- 12.10 **Case Study: Developing Therapeutics for Rare Gastrointestinal and Endocrine Disorders**
- Successful development through collaboration
 - Partnering with patient organizations, healthcare professionals and payers
 - Turning a promising drug candidate into a treatment reality
- Francois Nader**, CEO, **NPS Pharmaceuticals**
- 12.45 **Case Study: Development of Orphan Drug Products for Brain Tumors**
- Leveraging existing clinical and commercial data to accelerate development timelines
 - Personalized medicine approach
 - Attractive reimbursement strategies
- Jeff Bacha**, CEO, **DelMar Pharmaceuticals**

1.20 Lunch

Optimizing Orphan Drug Clinical Development

- 2.20 **Teaching Old Drugs New Tricks: Challenges in Designing a Clinical Trial for an Orphan Disease**
- Limitations of orphan drug status
 - Choosing the right endpoint for a phase III trial
 - PRO input to a rationally designed clinical trial for an orphan disease
- Duncan Batty**, Scientific Advisor & Patient Liaison, **Alkaptonuria Society**
- 2.55 **Use of Surrogate Biomarkers and Biomarker Assay Development to Facilitate Informative Orphan Drug Development**
- Urine biomarkers are valuable, non-invasive, and appropriate for many storage disorders
 - UPLC-MS/MS is arguably the best available technology for development of biomarker assays
 - Stable isotope internal standards are critical to these assays
- David Millington**, Professor of Pediatrics, Director, Biochemical Genetics Laboratory, **Duke University School of Medicine**

3.30 Afternoon Refreshments

- 4.00 **Design and Implementation Challenges for Rare Disease Clinical Studies: The Example of Fabry Disease**
- How to define a clinical outcome when none is widely acceptable?
 - How to scientifically select patients for individualized therapy?
 - How to enroll patients with an orphan disease when a treatment is already available?
 - How to expand your global reach for recruitment activities?
- Pol Boudes**, CMO, **Amicus Therapeutics**

- 4.35 **Improving the Diagnosis and Treatment of the Inflammatory Neuropathies, a Group of Rare Disorders**
- Incidence and characteristics of Guillain Barré Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy and Multifocal Motor Neuropathy
 - Spectrum of treatments used
 - Sequelae of late diagnosis and treatment as determined by a survey of 889 CIDP patients, 2010
 - Future goals
- Carol Lee Koski**, Medical Director, **GBS/CIDP Foundation International**

5.10 Chair's Closing Remarks

7.30 Networking Dinner

Share discussions with your peers and enjoy a relaxing and informal dinner in comfortable surroundings. Good food, good wine, good company!

Day 2

17th November 2011

8.00 Registration, Coffee and Networking

8.45 Chair's Opening Remarks

Pol Boudes, CMO, **Amicus Therapeutics**

Incentives, Investment, Partnering & Commercialization

8.50 Encouraging Investment into Orphan Diseases

- Understanding the current environment
- Learning about the stakeholders - their interests, benefits, and motives
- Recognizing opportunities, pitfalls, and strategic options

Bill Martin, Group VP, Business Development,
Accredo Health

9.25 Effective Partnering Leading to Pharmaceutical Innovation

- Orphan diseases embedded in larger patient populations versus those that are not associated with the larger group
- Why reimbursement of the two settings may have different levels of sustainability
- Unique collaborative partnerships with non-profit, for-profit and academics
- Why the orphan model provides a different structure for return in pricing than other disease indications

Robert Ward, VP, Head of Strategy & New Opportunities,
AstraZeneca

10.00 Venture Capital Firms: How can you Raise Long Term Funding to Sustain Development and Commercialization of Orphan Drugs?

- What makes a biotech an attractive investment prospect?
- Emerging trends in the investment of orphan drug development
- Lessons learned from successful partnerships

Patrick Enright, Managing Director, **Longitude Capital**

10.35 Morning Refreshments

Market Access Strategies for Orphan Products

11.05 Laying the Groundwork to Ensure a Successful Launch: Utilizing an MSL Team

- Finding the patients
- Who are the KOLs? How do you define them?
- Raising disease awareness and increasing the index of suspicion
- Maintaining the momentum

Natalia Raphael, Senior Medical Science Liaison,
Spectrum Pharmaceuticals

11.40 Marketing Orphan Drugs

- Review the regulations that allow market exclusivity of orphan drugs
- Describe marketing challenges and success stories
- Discuss the future within a growing industry

Lori Correia, Director, Operations, **Generation Health**

12.15 Translating the Patient Experience into Commercial Success

- Who really speaks for the patients?
- How do you find common ground with your patient advocacy organizations?

Patrick Reichenberger, VP, Commercial Operations,
Raptor Pharmaceuticals &
Nancy Stack, President, **Cystinosis Research Foundation**

12.50 Lunch

Improving Patient Access to Orphan Drugs

1.50 Accelerating Orphan Drug Development: The VPRIV Story

- Clinical and regulatory challenges in VPRIV development
- Orphan drug designations in major markets
- Accelerating market applications
- Early access of VPRIV for patients with Gaucher disease

Howard Yuwen, Senior Director, Regulatory Affairs, **Shire**

2.25 Building and Utilizing Patient Registries

- From orphan drug development to commercialization: How patient registries can help
- Success factors

Pat Furlong, President & CEO,
Parent Project Muscular Dystrophy

3.00 Afternoon Refreshments

3.30 Stem Cell-Derived Models for Orphan Drug Development: A Patient-Centric Approach to R&D

- Drug development for orphan diseases presents unique challenges
- Models with higher disease-relevance, and sometimes patient-specificity, would improve pharma's ability to generate scalable models for orphan drug discovery and toxicology studies
- Access to patient-derived samples can be particularly difficult
- Advantages of stem-cell derived models for research and drug development
- Integrating stem-cell-based technologies into the classic "Pharma Model" of drug discovery and development

Arnaud Lacoste, Project Team Leader, Stem Cells & Regenerative Medicine, **Novartis**

4.05 Improving Patient Access Through Partnering with Patient Advocacy Groups, Government and Industry

- Rare disease is too big to not partner
- It's what the patients want and what we need to succeed
- As a group, our identities, and our successes, are enhanced
- The time is now

Dean Suhr, COO, **RARE Project**

4.40 Chair's Closing Remarks

**Workshop A: The Japanese Regulatory Environment:
Achieving Orphan Drug Designation**
Date: 15th November 2011
Time: 10am – 1pm

Several examples will be provided to illustrate effective strategies for registration of orphan products. Specifically, attendees will discuss and understand:

- The **current regulatory climate** towards orphan medicinal products
- Overall **regulatory requirements and procedures in obtaining orphan medicinal product designations** and registration of these products in Japan
- Descriptions of the methods by which **regulators in the corresponding agencies process filings and registrations** for orphan products
- Unique **CMC, pre-clinical and clinical** requirements
- How Japan interacts with and **utilizes ICH standards** and how they relate with other national regulatory agencies
- Differences between Japan, Europe and the United States on **implementation and interpretation of ICH guidelines**

This workshop will be of benefit to pharma/biotech company representatives whose responsibilities include obtaining orphan medicinal product designation and registration of these products in Japan, and those working with Japanese partners on such registrations.


Workshop leader
Richard Lowenthal

President, Co-founder & Officer

Pacific-Link Consulting LLC, San Diego & Pacific-Link Consulting Corporation, Tokyo

Mr. Lowenthal is an executive with over 20 years of Regulatory Affairs and Quality Assurance experience in various roles at both small and large pharmaceutical or biotechnology companies. Currently, Mr. Lowenthal is president of Pacific-Link Consulting LLC located in San Diego, CA, and is also co-founder and officer of Pacific-Link Consulting Corporation in Tokyo, Japan. Mr Lowenthal holds an M.S. in Organic Chemistry from Florida State University and Masters in Business Science for Executive Leadership (MBA equivalent) from the University of San Diego.

Workshop B: The Search for New and Future Therapies for Rare Diseases: Advancing Understanding and Development to Improve Availability of Treatment Options
Date: 15th November 2011
Time: 2pm-5pm

There is a need for more therapies for rare diseases. Gene therapy is close to being an actuality and FDA has several gene therapy applications lined up. Stem cells are further away but research on stem cells (using the patients' own skin cells) has potential for understanding the cause of the disease.

This workshop will discuss ideas and developments that could lead to an increase in therapies now and in the future:

- **Therapies that have been developed but not used**
- **Therapies that need reprofiling or repurposing**
- **Gene therapies**
- **Stem cell research benefits**

Examples will be given and some technical background information shared. The audience is encouraged to actively participate with questions and discussion.


Workshop leader
Ian Phillips

Norris Professor of Life Sciences & Director of the Center for Rare Disease Therapies Faculty Director, PreMed Program

Keck Graduate Institute

Ian Phillips is the Norris Professor of Life Sciences and director of the Center for Rare Disease Therapies at the Keck Graduate Institute in Claremont, California. He received his PhD and DSc in Pharmacology from the University of Birmingham. He holds patents on gene therapy and stem cells. He discovered angiotensin in the brain and other tissues. Dr Phillips has published over 300 papers and 11 books.

Media partners


Speakers



Jeff Bacha
CEO
DelMar Pharmaceuticals

Mr. Bacha is the President & CEO of Del Mar Pharmaceuticals. He is a seasoned executive leader with nearly twenty years of life sciences experience in the areas of operations, strategy and finance.



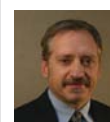
Duncan Batty
Scientific Advisor &
Patient Liaison
Alkaptonuria Society

Duncan moved into the Biotech Sector in 1998. He now volunteers as a Scientific Advisor and Patient Liaison for the AKU Society. Duncan gained his PhD in Synthetic Organic Chemistry from University College London in 1992.



Pol Boudes
CMO
Amicus Therapeutics

Dr. Pol Boudes joined Amicus Therapeutics in January 2009 as Chief Medical Officer. He brings to Amicus more than 15 years of industry experience in clinical drug development.



William Brubaker
Senior Director, Orphan
& Genetic Diseases
Pfizer

Dr. Brubaker is primarily responsible for comprehensive evaluation of new opportunities and guidance of non-clinical R&D in the orphan and genetic disease space.



Lori Correia
Director, Operations
Generation Health

Lori Ann Correia is a clinical operations and genetics professional with over 18 years of experience. She worked for over 5 years as a genetic counselor where she experienced genetic conditions first hand, working with patients and their families.



Chris Dandrea
R&D Program Director
- Pompe Disease
Franchise, Personalized
Genetic Health Business
Unit, **Genzyme**

Chris Dandrea is Director, Pompe Disease R&D Programs at Genzyme. He has gained undergraduate degrees in Electrical and Biomedical Engineering from Duke University and a Masters in Business Administration from Carnegie Mellon University.



Patrick Enright
Managing Director
Longitude Capital

Patrick Enright is a founder and Managing Director of Longitude Capital. He holds an M.B.A. from the Wharton School of Business at the University of Pennsylvania and a B.S. in Biological Sciences from Stanford University.



Pat Furlong
Founding President
& CEO
**Parent Project Muscular
Dystrophy**

Pat Furlong is the Founding President and CEO of Parent Project Muscular Dystrophy (PPMD), the largest non-profit organization in the United States solely focused on Duchenne muscular dystrophy (Duchenne).



Carol Lee Koski
Medical Director
**GBS/CIDP Foundation
International**

Dr Koski is the Medical Director and a member of the medical advisory Board for the GBS/CIDP Foundation International. Dr. Koski received her medical degree from the University of Maryland School of Medicine.



Arnaud Lacoste
Project Team Leader,
Stem Cells &
Regenerative Medicine
Novartis

Arnaud Lacoste is a Project Team Leader at Novartis where he pioneered the use of reprogramming technologies and patient-derived pluripotent stem cells for drug discovery and development.



John Maddox
Managing Director
**Infusion Pharma
Consulting**

Bill Martin leads the Specialty Pharmaceuticals Business Development function for Accredo Health Group. In this role he is responsible for manufacturer relations, contracting, service delivery and pipeline strategy for Accredo Health Group.



Bill Martin
Group VP, Business
Development
Accredo Health

Bill Martin leads the Specialty Pharmaceuticals Business Development function for Accredo Health Group. In this role he is responsible for manufacturer relations, contracting, service delivery and pipeline strategy for Accredo Health Group.



David Millington
Professor of Pediatrics,
Director, Biochemical
Genetics Laboratory
Duke University

David S. Millington is currently research professor of pediatrics and director of the Pediatric Biochemical Genetics Laboratory and Mass Spectrometry Facility. He obtained his Bachelor's degree in 1966 and Doctorate in organic chemistry in 1969 from the University of Liverpool, England.



Francois Nader
CEO
NPS Pharmaceuticals

Francois Nader has been president and chief executive officer of NPS Pharmaceuticals, Inc. since March 2008. Dr. Nader joined NPS in June 2006 and served as executive vice president and chief operating officer until March 2008.



Natalia Raphael
Senior Medical
Science Liaison
**Spectrum
Pharmaceuticals**

Natalia Raphael currently works in the Medical Affairs division of Spectrum Pharmaceuticals. She received her B.A. from Rice University and her Ph.D. from the University of California, Berkeley.



Patrick Reichenberger
VP, Commercial
Operations
Raptor Pharmaceuticals

Patrick Reichenberger is the Vice President, Commercial Operations at Raptor Pharmaceuticals. He has over 20 years of experience in biotech/pharma sales and marketing including orphan product development and commercialization.



Nancy Stack
President
**Cystinosis Research
Foundation**

Nancy Stack is the president of the Cystinosis Research Foundation. She will be discussing alongside Patrick Reichenberger how to translate the patient experience into a commercial success.



Dean Suhr
COO
**The Children's Rare
Disease Network**

Dean Suhr is the Chief Operating Officer of the RARE Project, which exists to raise rare disease awareness, unify and empower a vibrant global rare disease community, and fund innovations to support 'in-their-lifetime' rare disease research.



Robert Ward
VP, Head of Strategy &
New Opportunities
AstraZeneca

Robert Ward is the VP and head of strategy and new opportunities at AstraZeneca. He has extensive experience in expanding the commercial footprint of biologic and small molecule therapeutics to increase sales and product lifecycle.



Howard Yuwen
Senior Director,
Regulatory Affairs
Shire

Howard Yuwen is responsible for regulatory strategies for Shire HGT product portfolio. Prior to this, Howard was director of Regulatory affairs at CancerVax Corporation and associate director of regulatory affairs at Elan Biopharmaceuticals.

Sponsorship opportunities



Miles Harley

If your organization needs to raise profile, promote products and services or develop new partnership opportunities in the orphan drug sector, contact:

tel: +44 (0)20 3141 8700

email: miles.harley@hansonwade.com

Working with Hanson Wade

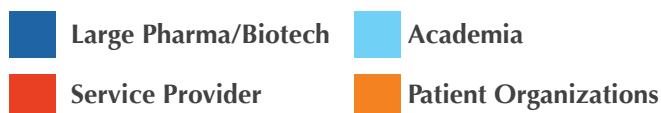
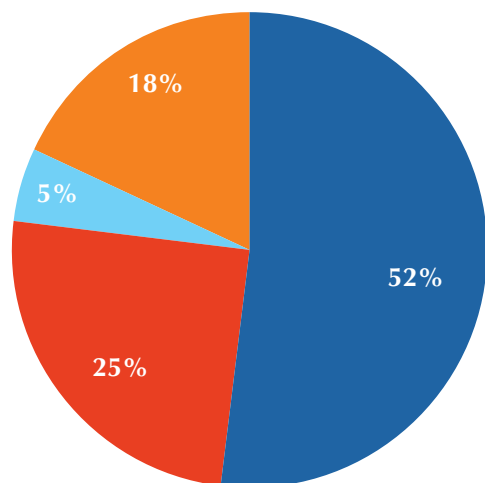
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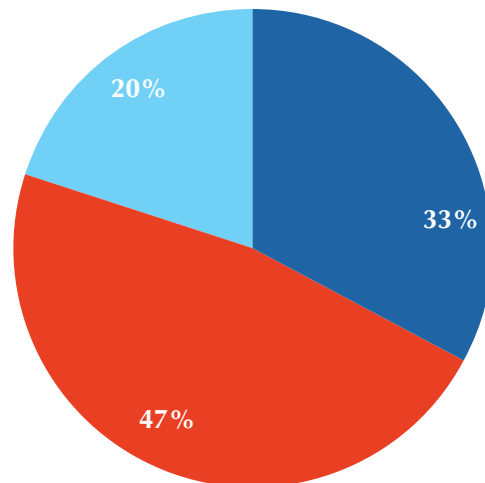
Our research identifies ground breaking issues and allows you to influence industry thinking at an early stage. Our expertise is recognised and respected by the industry. And our events are focussed, leading edge and attended by people looking for knowledge before making decisions.

Attendee breakdown

Attendee breakdown at the last meeting



Seniority breakdown at the last meeting



Program partner


Infusion Pharma Consulting LLC – Orphan Drug and Rare Disease Specialists

Infusion Pharma Consulting is a leader in orphan drug commercial strategy. Through specialty practices in strategic pricing and brand strategy, Infusion has provided strategic guidance for clients worldwide in addressing complex orphan and ultra-orphan commercialization challenges.

The firm's orphan product experience includes brands in virtually every treatment setting and reimbursement situation and across a wide range of therapeutic categories. Infusion offers particular expertise in:

- Orphan drug strategic pricing and market access
- Multi-indication brand optimization
- Orphan drug market sizing
- Orphan drug business development

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<input type="checkbox"/> Half day workshop	US\$599		
Please select your choice of workshop: Workshop A <input type="checkbox"/> Workshop B <input type="checkbox"/>			
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*All discount offers (including team discounts) require payment at the time of registration to receive any discount. 'Early Bird' discounts require payment at time of registration and on or before the cut-off date to receive any discount. All discount offers cannot be combined with any other offer. The conference fee includes lunch, refreshments and course documentation. The fee does not include travel or hotel accommodation.

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