

COPPERBERG



5th Edition

Orphan Drugs Summit

17th – 18th September 2015, Carlsberg Museum & Business Centre, Copenhagen, Denmark



Fostering the right relations and bringing the right discussions
to collaboratively shape the future of orphan drugs

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www.orphandrugssummit.com

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a **midfield media** Group
event

Editor's note:

Changing times ask for solid relationships.

Times are changing. A renewed interest from big pharma in the rare disease landscape has awakened due to large-scale patent expirations, competition from generics & biosimilars, anemic pipelines, escalating clinical trial costs and a global health-care reform. This means that the traditional blockbuster model has become less viable while the revenue-generating potential of orphan drugs has shown to be huge with a greater return on investment than non-orphan drugs. According to EvaluatePharma, the orphan drugs sales will grow at an annual rate of 11% and constitute 19% of the total share of prescription drugs by 2020, totalling 176 billion dollars.

The rare disease landscape is very complex due to the large amount of stakeholders involved. Despite their different interests they have one goal in common: getting an orphan drug approval that will help save or improve lives. But there are many challenges on the road to orphan drug designation:

- *Complex and changing national and regional regulations*
- *Clinical trial design and finding & keeping patients*
- *The lack of a central database designed specifically to list patient registries, which asks for close stakeholder engagement*
- *Partnering and establishing financing for future development*
- *Establishing a foundation for price that is balanced and sustainable*
- *Achieving an efficient and timely access to market with equal access for patients around the world*
- *Achieving timely and correct diagnosis to enable higher quality of life and more time and information for developers*

Changing environments ask for a changing conference. With the help of the audience we have been able to map the complex orphan drugs ecosystem, resulting in a whole new concept at the Orphan Drugs Summit 2015. This conference is specifically designed to enable future stakeholder interactions, which is much needed. Each session brings together different groups of stakeholders on specifically selected topics to help them build relationships and reach their goals. With the right relations and the right discussions we can help shape the future of healthcare by collaboration.

Flip the pages to see your ecosystem map and what sessions are specially designed for you. Start building your solid relationships right here, right now!

Welcome to the 5th annual Orphan Drugs Summit.

Sincerely,

A handwritten signature in black ink, appearing to read 'Maaïke Gerritse'.

Maaïke Gerritse
Editorial Content Director, Orphan Drugs Summit

Advisory Board - 2015

The Advisory Board is instrumental in setting the tone and direction of the event, thanks to the accumulated years of experience of all the members within the Orphan Drugs community.



Robert Derham
Founder & President
CheckOrphan

Robert Derham is the founder and President of CheckOrphan (501c3 and registered non-profit in Switzerland), which is best described as the CNN/BBC for rare diseases. In the past, he has successfully launched interactive and dynamic life-science-based websites for the following companies: Axxora, BioValley, mondoBIOTECH, Novartis, and Syngenta. Robert is also a member and co-founder of the Global Web-Strategy Network, which consists of representatives from international companies such as: Novartis, Credit Suisse, UN, Nestlé and more. Robert blends 12 years of industry experience and 7 years of research experience, which helps to understand the evolving field of rare diseases and healthcare.



Anders Waas
CEO
Tikomed

Anders Waas has over two decades of experience in the pharmaceutical, biotech and medical device industries. Mr. Waas has been the Director of Karo Bio since July 2011 and serves as a member of the Biotech Investment Committee at Life Science Angels, Inc.. From 2004 to 2008, he was Vice President Business Development at CV Therapeutics in Palo Alto (US). Between 1992 and 2004 he held various senior management positions in product development, marketing and business development at Astra and AstraZeneca. These included: Director of Cardiovascular Global Licensing activities at AstraZeneca and Director of Strategic Planning and Business Development for cardiovascular, metabolic and gastrointestinal products at Astra. In this position he was responsible for the global strategic support of products such as Losec, Nexium, Toprol XL, Atacand, Exanta and for the overall R&D efforts in cardiovascular, metabolic and gastrointestinal diseases. Anders was also active in the medical device industry as European Sales Leader and Medical Advisor at WL Gore & associates. Dr Anders Waas received his DDS (Dr Dental Surgery) from University of Umea, Sweden.



Marlene E. Haffner
MD, MPH, CEO, Haffner
Associates, LLC (former
Director of OOPD at
US FDA)

Marlene E. Haffner, MD, MPH is the CEO of Haffner Associates, LLC a firm dedicated to the strategy, development and policy of drug development with a special emphasis on rare diseases and the products that treatment them. Prior to establishing her own company, in March 2009, she served as Executive Director, Global Regulatory Policy and Intelligence at Amgen, Inc. For 20 years, Dr. Haffner served as Director of the Office of Orphan Products Development (OOPD) of the Food and Drug Administration (FDA). As OOPD Director she was responsible for the leadership and management of the FDA orphan products development program, the first Orphan Products program in the world. She is well known as an expert in orphan drug development and is a sought after speaker and consultant in that area of regulatory science. In addition to her consulting activities Marlene is Adjunct Professor, Department of Preventive Medicine and Biometrics, and Clinical Professor, Department of Medicine, at the F. Edward Hébert School of Medicine, Uniformed Services University of the Health Sciences (USUHS) in Bethesda, Maryland. For 36 years she served in the United States Public Health Service beginning her career with the Indian Health Service in Gallup, New Mexico. She received her MD from the George Washington University School of Medicine where she then interned in Internal Medicine. She received further training in internal medicine, dermatology and hematology at the Presbyterian Hospital, New York and that the Albert Einstein College of Medicine, New York. She received an MPH from the Johns Hopkins University Bloomberg School of Public Health. During her Public Health career, she rose to the rank of Rear Admiral in the USPHS. Dr. Haffner has received many awards for her work in drug development including The Outstanding Contributions to Pharmaceutical Medicine Award from the American Academy of Pharmaceutical Physicians, and in May 2009, the Woodrow Wilson Award for Outstanding Government Service from the Johns Hopkins University.

Advisory Board - 2015

Donald Macarthur is an independent industry consultant and report writer on international pharmaceutical business issues. Specialities include orphan drugs (Europe, Asia), pricing & reimbursement (all Europe, Japan/Korea/Taiwan), GP & hospital market access, funding of medicines, generics/biosimilars, wholesale and retail distribution, parallel trade/US importation, homecare, and mail order/online pharmacy. Qualifying as a pharmacist, 16 years industry experience followed employment in hospital and community pharmacy. In 1996, Mr Macarthur founded the world's first periodical in its field, Pharma Pricing Review, which he published and edited for four years. He has also written over 80 major pharmaceutical business reports.



Donald Macarthur
Principal
Justpharmareports

Elizabeth Vroom is founder and president of the Duchenne Parent Project Netherlands since 1995. This organisation has played an active role in drug development for Duchenne Muscular Dystrophy. Elizabeth is Chair and co-founder of the worldwide organisation UPPMD (United Parent Projects Muscular Dystrophy). She serves on several advisory boards regarding Care, Research, Ethics, Development of new medicines and Regulatory Issues in the Netherlands as well as international. She received the Biofarmind Innovation Award for her "creative and innovative activities in the field of drug development". As President of the foundation 'The Meeting' she works on projects to optimize the role of patient organisations in drug development.



Elizabeth Vroom
Founder and President
Duchenne Parent Project

Dr. Hoss A Dowlat has more than 31 years of drug development experience in the majority of therapeutic areas in the European and North American Pharma industry, 24 years of which have been in Regulatory Affairs of generics, biosimilars, and original drugs or biologics. Until 2010, Hoss was Vice President, Technical, Drug Development and Regulatory Global Strategy Services, at the leading CRO PAREXEL. In PAREXEL CONSULTING 2000-2010 he served 50 client companies from across Europe, America, Canada, Korea, Japan, and India, leading multidisciplinary teams of up to 40. He currently provides drug development, registration and due diligence support, for Pharma industry and Financial institutions with regional and international presence.



Dr. Hoss A Dowlat
Vice President
Regulatory Affairs,
Global Strategy
PharmaBio Consulting

Conference at a glance

Day 1

12:00 Registration opens

12:45 Chairman opens the conference

13:00 Regulatory market update: what are the major changes and differences worldwide?

13:45 Patient registries: Enabling database access for all stakeholders

14:30 Who's Health is it anyway?	Strategies for regulatory fast tracks and global market access
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15:00 Networking break & 1-to-1 meetings

15:30 Problems with reimbursement and economic burden of ACE inhibitor induced angioedema	Case study: Building a patient registry - lessons learned
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16:00 Opportunity of A New Class of Biosimilar Orphan Biologic Medicines Offering Access to Affordable Medicines?	Round table: Collaboratively fighting for patient rights: equal access for everyone
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16:30 Pricing of orphan drugs: establishing a reimbursement foundation

17:15 Early access to Orphan Drugs: The evolving changing environment and additional benefits of Early Access

18:00 The social club: Networking cocktail and Dinner

13:00 - 17:15 Consulting corner

Day 2

08:45 Chairman opens day 2

09:00 The Cathedral and the Bazaar: Orphan Drugs and the Genomic Revolution

09:45 The voice of patients living with rare diseases in Europe

10:30 Networking break & 1-to-1 meetings

11:00 Masterclass: Crowdfunding - new strategy for financing clinical research	Masterclass: Innovative Pricing and Reimbursement Models for Orphan / Ultra-orphan Drugs
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11:30 Research discussion - Budget impact of orphan drugs in the Netherlands	Round table: Practical Implementation Issues of Innovative Pricing and Reimbursement Models for Orphan / Ultra-orphan Drugs
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12:00 Masterclass: International clinical trials registry platform	Debate: Engaging policy makers & driving clinical trial development
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12:30 Networking lunch

13:30 Case study: The patient as a partner - lessons learned from an impatient patient organization	Round table: Orphan drugs in emerging markets - how to ensure market access?
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14:00 Market access panel - Advocacy for approval all over the world	Research discussion: Safety issues from use of C1-inhibitors and bradykinin receptor antagonist in treatment of angioedema
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14:30 Networking break & 1-to-1 meetings

15:00 Case study: An approved or soon-to-be approved orphan drug - How did they do it?

15:45 Ground breaking research: Personalized medicine by using zebrafish models

16:30 Chairman closes the conference

17:00 One for the road

09:00 - 16:30 Consulting corner

09:00 - 16:30 Shark tank

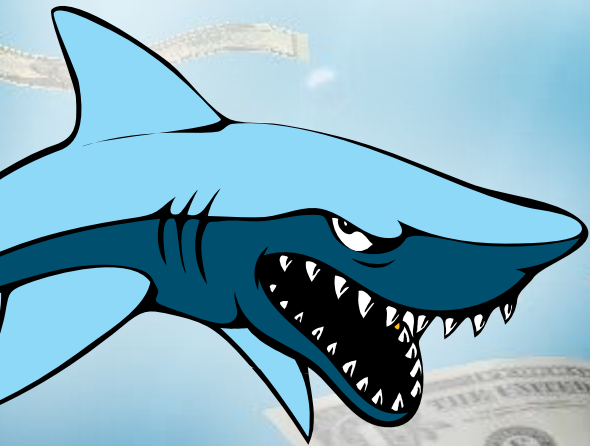
Summit concept

The Orphan Drugs Summit 2015 is tailored according to stakeholder needs. With the help of Copperbergs Orphan Drugs Survey we have been able to specifically design this conference to bring the right stakeholders together to discuss critical topics. The survey report can be downloaded via www.orphandrugssummit.com. All stakeholders are visualised with the use of icons. All sessions are coded according to these icons to show you what sessions are specifically designed for you.

Take a look at the agenda and see what we have in store for you!



Are you ready to enter



PALO ALTO INVESTORS
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NOVO

BAY CITY CAPITAL



John Doux
Analyst/Investor
Palo Alto Investors



Nanna Lüneborg
Investment Director
Novo A/S



Rob Hopfner
Managing Director,
Bay City Capital

THE SHARK TANK

The shark tank is a platform that brings successful **drug developers**, **patient organisations** or **industry associations** together with venture capitalists - sharks.

Whether you have a breakthrough research, a far advanced clinical trial or already operating successfully and looking to expand and could use financial backing, the shark tank is the platform for you.

We are looking for **drug developers**, **patient organisations** or **industry associations** who can pitch their breakthrough business concepts, products, properties and services to our sharks in the hopes of receiving investment funds. If selected, our sharks could be willing to part with their resources to give you the funding you need.

You can apply soon for your chance to enter the shark tank and see if your business is ready for a shark investment. For more information send an email to maaike.gerritse@copperberg.com

Program:

The agenda is coded with the use of symbols to show you what sessions are specifically designed for you. The big symbols show who will be speaking during a certain session. The small symbols show who should be attending a certain session. So remember your symbol and see what this agenda has in store for you!



PAYERS



HOSPITAL
REPRESENTATIVES



PATIENT
ORGANISATIONS



VENTURE
CAPITALISTS



REGULATORY
BODY



DRUG
DEVELOPERS



RESEARCHERS



INDUSTRY
ASSOCIATIONS

Day 1

■ 12:00 Registration opens

■ 12:45 Chairman opens the conference



Robert Derham, Founder & President, CheckOrphan

■ 13:00 Regulatory market update: what are the major changes and differences worldwide?

The regulatory landscape of orphan drugs imposes a lot of challenges and has shown a great deal of complexity. Not only are the regulations different across borders, making it extremely difficult to market your drugs in different countries, they are also changing quite rapidly. That is why we will start this conference with a regulatory market update, providing you with insights in the recent changes and differences across borders.

+ Learning points:

- What has changed over the year?
- What are important differences in regulations across borders?



Consulting corner:
Meet the industry's best consultants and book your 30 minutes of quality advice!



Marlene E. Haffner
MD, MPH, CEO,
Haffner Associates,
LLC (former
Director of OOPD
at US FDA)



Sukhwinder Singh
Jossan, M.Sc.
Pharm., PhD in
Pharmacology,
Associate Vice
President, Global
Regulatory Affairs,
Development
Projects, Ferring
Pharmaceuticals



Ingbritt Madsen
M.Sc. Pharm.,
Senior Global
Regulatory Affairs
Manager, Ferring
Pharmaceuticals



■ 13:45 Patient registries: enabling database access for all stakeholders

Registries are necessary to speed up the acquisition of knowledge on rare diseases, the development of clinical research and to meet the post-marketing obligations. Patient registries need to be internationally interoperable to allow pooling of data to reach sufficient numbers for clinical research and public health purposes. Communication technology evolves very quickly and offers solutions to set up real data warehouses but obstacles remain, mainly legal and behavioural ones.

+ Learning points:

- Up-to-date presentation of the European RD registries landscape
- Review of technological options and new innovative projects



Segolene Ayme,
Emeritus Director of Research,
INSERM



Program:

■ 14:30 Who's Health is it anyway?

The whole world is tuning in to Black Pearls. Somehow the innovation curve for most common diseases has reached the point where there is no economic value in further development. For better or for worse, government agencies like NICE are introducing rational drug use based on genuine innovation, and raising the bar for differentiation. The new goal is the rare disease where, perhaps, the authority can be persuaded to pay for very expensive therapies, because the patient pool is so small. But is this tenable?

+ Learning points:

- Why would you save the life of one child with a rare disease, if the same investment can prevent a childhood disease for a generation?
- How do you find patients?
- Opening a door on a technique Bayer has been pioneering



Malcolm Allison,
Head of Pulmonology & Anti-Infectives,
Bayer HealthCare Pharmaceuticals



■ 14:30 Debate: regulation on cross border healthcare: how to overcome this?

Different countries, different regulations, but the same disease. Right now the country you live in might decide whether or not you have access to a drug that saves, or improve your life. The access to drugs suffers from inequality due to the different regulations across borders. It makes it very difficult for drug developers to market their drugs and reach all potential patients. But it is not that simple to overcome this issue, since there are many parties involved. The question is: how can we overcome this?

+ Learning points:

- How can we deal with different regulations across borders?
- How do these differences influence patient's access



Lincoln Tsang,
Partner, Arnold &
Porter LLP

ARNOLD & PORTER LLP



15:00 Networking break & 1-to-1 meetings

■ 15:30 Debate: Problems with reimbursement and economic burden of ACE inhibitor induced angioedema

This session will be about reimbursement in patients suffering from bradykinin mediated angioedema due to antihypertensive (ACE inhibitors) and anti-diabetic drugs (DPP-IV inhibitors). These patients are "shared" between emergency medicine, oto-rhino-laryngology, internal medicine and intensive care units, but who are to pay for the expensive medications?

+ Learning points:

- Icatibant in ACE inhibitor induced angioedema
- "Shared" care: who is paying?
- How are reimbursement managed in other countries?



Eva Rye Rasmussen, Specialty
registrar of Oto-Rhoni-Laryngology
– Head and Neck Surgery, University
hospital of Copenhagen



■ 15:30 Case study: Building a patient registry - lessons learned

Building a patient registry is a big challenge. As the advocate for a rare disease I realised this and learned the hard way. In this case study I will share my story on building a patient registry and share my best practices and lessons learned.

+ Learning points:

- Best practices on building a patient registry
- Lessons learned from building a patient registry



Blair van Brunt, Founder, Rare
Disease Perspectives



Consulting corner:

Meet the industry's best consultants and book your 30 minutes of quality advice!



Program:

■ 16:00 Opportunity of A New Class of Biosimilar Orphan Biologic Medicines Offering Access to Affordable Medicines?

The European Legislation for medicines has formed the basis of a regulatory pathway laid down by the European Medicines Agency (EMA) since 2004 by which biologics similar to ones already on the market can get approved with an abbreviated development programme. What opportunities does this bring in terms of affordable medicine?

+ Learning points:

- Understanding the opportunities of a new class of biosimilar orphan biologic medicines
- Understanding the opportunities of a new group of affordable medicines



Dr. Hoss Dowlat,
Vice President, PharmaBio
Consulting (Life Sciences)
Regulatory Affairs EU-USA



■ 16:00 Round table: Collaboratively fighting for patient rights: equal access for everyone

As a patient organisation you are constantly trying to fight for patient rights. The country you are living in, the type of insurance you have, the doctor you are meeting etc should not be factors preventing you from getting the best care and access to treatments. But how can we establish equal access for everyone?

+ Learning points:

- Patient rights
- Establishing equal access



Henrik Balle Boysen,
Executive Director,
HAEi



■ 16:30 Pricing of orphan drugs: Establishing a reimbursement foundation

Pricing of orphan drugs is a delicate question, since it needs to be balanced and sustainable. Establishing the right reimbursement foundation that satisfies the developer whilst enables equal access for patients is easier said than done. It asks for close collaboration between different stakeholders.



TBA Bang & Olufsen, Medicom

+ Learning points:

- How to establish a foundation for reimbursement
- How to price orphan drugs in a way that is balanced and sustainable



Medicom
Shortcut to better health

■ 17:15 Early Access to Orphan Drugs: The evolving changing environment and additional benefits of Early Access

+ Learning points:

- Understand the changes in the regulatory environment, including UK EAMS and Cure Act in the USA
- Learn about the practical considerations for providing early access
- Patients and patients groups role in early access
- Can an Early access program provide additional Real World Evidence for Orphan Drugs



Kieron Lewis, Business Development Manager, Clinigen



CLINIGEN
Global Access Programme

Consulting corner:
Meet the industry's best
consultants and book
your 30 minutes of
quality advice!



WELCOME TO THE SOCIAL CLUB

September 17th 2015

18:00 Networking Cocktail

19.00 Networking Dinner

Big announcement coming soon:

Stay tuned for our amazing venue!

18:00

Copenhagen

Program:

Day 2

■ 08:45 Chairman opens day 2 of the conference



Robert Derham, Founder & President, CheckOrphan

■ 09:00 The Cathedral and the Bazaar: Orphan Drugs and the Genomic Revolution

Bottom-up collaborative infrastructures have revolutionized information technology; the same is happening in genomics and rare diseases. Partnering with patient advocacy groups, biotechnology companies, pharmaceutical companies, and academic, we at Rare Genomics Institute are building systems for crowdsourcing knowledge, funding, genomic information, biospecimen and other and to contribute to the bigger revolution that is underway for orphan drugs.



Jimmy Cheng-Ho Lin, MD, PhD, MHS, President, Rare Genomics Institute



+ Learning points:

- Rare diseases follow the classic long tail distribution and thus require an alternative paradigm from the traditional blockbuster drug approach
- The sharp decline in genome sequencing prices has democratized the technology and has allowed a distributed collaborative mechanism of data generation and sharing
- At Rare Genomics Institute, we empowering patients by connecting them with researchers, doctors, industry, and funders and provide them with all the tools and connections to advance understanding for their research. New disease are being discovered using this approach



■ 09:45 The voice of patients living with rare diseases in Europe

In Europe alone there are about 30 million people living with a rare disease. Therefore there is the need to build a European community of patient organisations and people living with rare diseases at a European level.



Birthe Holm, President, Rare Diseases Denmark, Board member EURORDIS



+ Learning points:

- Building a strong European community
- Uniting patient organisations and people living with rare diseases



10:30 Networking break & 1-to-1 meetings



Consulting corner:
Meet the industry's best consultants and book your 30 minutes of quality advice!



Shark tank:
Apply to pitch venture capitalists!



NOVO



PALO ALTO INVESTORS



BAY CITY CAPITAL



Program:

■ 11:00 Masterclass: Crowdfunding: New strategy for financing clinical research

This master class will introduce case studies where crowdfunding has successfully funded clinical research, such as observational studies and clinical trials. The interactive session will then delve into the key steps you will need to run a successful campaign, ranging from building a supporter base to active donation generation.

+ Learning points:

- Crowdfunding as a form of social financing
- The benefits associated with running a crowdfunding campaign to support clinical research
- The strategic steps involved in developing a successful campaign



**Flóra Raffai, Head of Development,
Findacure: The Fundamental Diseases
Partnership**



findacure

■ 11:30 Research discussion: budget impact of orphan drugs in the Netherlands

In this study the number of orphan drugs, number of patients using them and the annual budget impact of orphan drugs in the Netherlands over a six-year period is researched. What is found is that the budget impact has grown both in absolute terms as well as relative to total pharmaceutical spending. Tim Kanters who conducted this study, will discuss the research and its results.

+ Learning points:

- Budget impact of orphan drugs in the Netherlands



**Tim Kanters - Researcher - Erasmus
University Rotterdam Institute for
Medical Technology Assessment (iMTA)**



■ 11:00 Masterclass: Innovative Pricing and Reimbursement Models for Orphan / Ultra- orphan Drugs

There are many challenges that drug developers are facing when it comes to their pricing models. Especially for ultra-rare diseases, where it is necessary to have highly innovative pricing and reimbursement models in place. They are based on annuity payments and subject to confirmation of continued efficacy of the treatment. This masterclass will help you in setting innovative pricing and reimbursement models for ultra rare diseases.

+ Learning points:

- How to set up an innovative pricing and reimbursement model for ultra rare diseases
- The main challenges explained for innovative pricing



**Dr. Renato Dellamano, President,
MME Europe**



MME® Learn From Our Experience,
Profit From Our Thinking®

■ 11:30 Round table: Practical Implementation Issues of Innovative Pricing and Reimbursement Models for Orphan / Ultra-orphan Drugs

Setting the right reimbursement model that satisfies all parties is easier said than done. The implementation of the model is even more complicated. In this round table we will discuss practical issues of implementing innovative pricing and reimbursement models.

+ Learning points:

- How can we overcome implementation issues of pricing and reimbursement models?
- What are the most common practical issues you face?



**Dr. Renato Dellamano, President,
MME Europe**



MME® Learn From Our Experience,
Profit From Our Thinking®

Consulting
corner:
Meet the
industry's
best
consultants
and book
your 30
minutes of
quality
advice!



Shark tank:
Apply to
pitch
venture
capitalists!



NOVO



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BAY CITY CAPITAL



Program:

■ 12:00 Masterclass: International clinical trials registry platform

The International Clinical Trials Registry Platform (ICTRP) is a global initiative that aims to make information about all clinical trials involving human beings publicly available. It was established in 2006 in response to demand from countries through the World Health Assembly resolution that called for "a voluntary platform to link clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials with a view to enhancing access to information by patients, families, patient groups and others". In this session Ghassan will explain more about the International Clinical Trials Registry Platform.

+ Learning points:

- The International Clinical Trials Registry Platform
- Linking clinical trials registers to have a single point of access



Ghassan Karam,
Technical Officer,
International Clinical
Trials Registry Platform
- World Health
Organization



12:30 Networking lunch

■ 13:30 Case study: The patient as a partner: lessons learnt from an impatient patient organization

From basic disease understanding to preclinical models and clinical trials, working with rare diseases poses particular challenges for drug developers. Patient organizations can play a major role in identifying these challenges and partnering with academia and industry to solve them. This session covers some of the misconceptions around the role of patient organizations in promoting drug development for their disease, structured around the lessons learnt by a young patient organization.

+ Learning points:

- What are some of the main misconceptions around the role of patient organizations in drug development
- The concept of impatient patients: why patient organizations can and should play a major role in orphan drug development



**Ana Mingorance-Le Meur, PhD, Scientific
Director, Dravet Syndrome
Foundation Spain**



■ 12:00 Debate: Engaging policy makers & driving clinical trial development

The huge amount of policies slow down clinical trial development. By engaging policy makers, clinical development can be stimulated and speeded up. But how can we engage policy makers? In this debate we will discuss the question of how to engage policy makers and come up with ways to drive clinical development.

+ Learning points:

- How to engage policy makers?
- Finding ways to drive clinical development



**Barbara McLaughlan - Head of External
Affairs, Acting Head of Market Access,
Oncology -Novartis Pharmaceuticals UK
Limited**



**Kieron Lewis, Business Development
Manager, Clinigen**



Consulting
corner:
Meet the
industry's
best
consultants
and book
your 30
minutes of
quality
advice!



Shark tank:
Apply to
pitch
venture
capitalists!



PALEO ALTO INVESTORS



BAY CITY CAPITAL



Program:

■ 14:00 Market access panel - Advocacy for approval all over the world

In this panel discussion we will have panellists with different expertise to discuss a cross country view on drug assessment and market access. There are many questions about the different market access policies in different countries and the assessment of medicines after marketing authorisation. This panel will help you get a better understanding of market access policies and assessment of medicines.

+ Learning points:

- Clarification on health technology assessment of orphan drugs after marketing authorisation
- Get an understanding of the different market access policies across countries



Meriem Bouslouk, Officer Pharmaceuticals Department, Federal Joint Committee (G-BA)



Jean Nordstrom, CEO, Sixera Pharma
SIXERA



Liliana Otero, Secretary of the Board & Programmes Coordinator, Center of Studies on Economic Integration



Gülce Belgin, Founder & Director, Proceutica
PROCEUTICA

■ 14:00 Research discussion: Safety issues from use of C1-inhibitors and bradykinin receptor antagonist in treatment of angioedema

Long-term safety aspects from use of orphan drugs (C1-inhibitors and bradykinin receptor antagonists) in treatment of hereditary angioedema are scarce. The lack of sufficient knowledge about adverse drug reactions (ADRs) at the time of licensing makes spontaneous ADR reports an important source of information. Since 2012 researchers were allowed to access the EU ADR database, EudraVigilance (EV) and this has opened for cross-sectional analysis based on standardized reporting format. In this session ADRs reported to the EV database by healthcare professionals, ADR reports from consumers and ADR information found in the literature are being presented.

+ Learning points:

- Few data on safety from use of C1-inhibitors and bradykinin receptor antagonists are available
- Studies of spontaneous ADR reports on HAE medications submitted to national pharmacovigilance databases must be conducted



Lise Agaard, Professor, Institute of Public Health, University of Southern Denmark



14:30 Networking break & 1-to-1 meetings

■ 15:00 Case study: An approved or soon-to-be approved orphan drug - How did they do it?

The road to an approved orphan drug is long, challenging and costly. There are many challenges concerning regulations, clinical trial design, finding and keeping patients, and let's not forget the financing. In this session we will present a case study of a success story and share the best practices and lessons learned from the road to drug designation.



Martin Andrews, Senior Vice President, GSK Rare Diseases



+ Learning points:

- Best practices of an orphan drug designation success story
- Lessons learned on the road to designation

■ 15:45 Ground breaking research: Personalized medicine by using zebrafish models

Theracule is a young start-up that is using genetically modified zebrafish models to do personalized medicine in rare diseases. The technology has a huge potential for all genetic rare diseases. In this session the CEO of Theracule will discuss the possibilities of personalized medicine by using zebrafish models.



Alexander D Crawford, CEO, Theracule



+ Learning points:

- Personalized medicine
- New potential for genetic rare diseases

16:30 Chairman closes the conference

17:00 One for the road - Close the conference in a relaxed atmosphere with a drink in your hand

Consulting corner:
Meet the industry's best consultants and book your 30 minutes of quality advice!



Shark tank:
Apply to pitch venture capitalists!



NOVO



PALO ALTO INVESTORS



BAY CITY CAPITAL



Speakers:

Ségolène Ayme, Emeritus Director of Research, INSERM

Ségolène Aymé is Emeritus Director of Research at the French Institute of Health and Medical Research (INSERM). She dedicated her professional life to the development of tools and innovative practices to improve the diagnosis and management of rare diseases, the access to expert services and the development of appropriate policies at national and international level. She was the first president of the International Federation of Human Genetics Societies in 1996. She chaired from 1998 until 2007 the Public and Professional Policy Committee of the European Society of Human Genetics. She was the founder of Orphanet in 1997 and Executive Manager up to 2011. She chaired the EU Committee of Experts on rare Diseases from 2010 to 2013 and is now a member of the Commission Expert Group on Rare diseases. She also chairs the WHO Topic Advisory Group for Rare Diseases and serves as Editor-in-Chief of the Orphanet Journal of Rare Diseases (www.ajrd.com). She is the project leader of "Support IRDiRC", which provides the services of a scientific secretariat to the International Rare Diseases Research Consortium (www.irdirc.org).



Ana Mingorance Le Meur, Scientific Director, Dravet Foundation

Dr Ana Mingorance is the Scientific Director of the Dravet Syndrome Foundation in Spain, a non-profit patient organization focused on running and promoting research on Dravet syndrome and related neurological rare diseases. In this role, she is responsible for long-term research strategy and for building and managing a portfolio of research collaborations ranging from diagnostics to clinical research. Ana has prior experience in neuroscience and drug discovery from both industry and academia, as a lab head and discovery project leader at the global pharmaceutical company UCB and the recipient of multiple awards for her research at the Universities of British Columbia in Canada and Barcelona in Spain, where she obtained her PhD. She is also an independent consultant to universities, companies and patient organizations in the areas of neuroscience and rare diseases via her company Dracaena Consulting.



Jean Nordstrom, CEO, Sixera Pharma

Industrialist and seasoned manager with 40 years of International Management positions in several Industry sectors. Last 25 years in Pharmaceutical and Biotech. Thorough experience from managing companies with substantial context in development and R&D. Have worked with large companies as well as SMEs. Former Executive President of Farmacia Spain and member of the Corporate Management group, VP Corporate and Business Development at Arexis AB, Swedish Biotech Company. CEO of Labiana Group, Spanish CMO and producer of own products for human and animal health. Accustomed to work with companies with financial owners as well as industrial partners. Mr. Nordstrom has in parallel to his employments as executive also carried out various assignments as advisor in strategy and development issues. Since 10 years special interest in developing Orphan Drugs. Sixera Pharma is now main focus and Jean Nordstrom is also co-founder and shareholder of the company.



Nanna Lüneborg, Investment Director, Novo A/S

Nanna is Investment Director of Novo Seeds, the early stage investment arm of Novo A/S. Novo Seeds is a leading early stage investor, actively creating new biotech companies primarily in Scandinavia through seed and venture investments. Nanna joined Novo A/S in 2012. Prior to this, she worked for Apposite Capital, a successful London-based healthcare venture fund, where she was responsible for diligence of new investment opportunities and involved in all aspects of investment activities, deal structuring and portfolio management of companies in drug development, medical devices and healthcare services. Earlier in her career, she worked at Cancer Research UK as a research manager. Nanna completed undergraduate studies at University of Oxford, a PhD in Neuroscience at University College London, and MBA at University of Cambridge. She currently serves on the board of Directors of Affinicon, Glionova, IO Biotech, Minervax and Pcovery, and she is an observer on the board of Galecto.



Henrik Balle Boysen, Executive Director, HAEi

Henrik Balle Boysen is the Executive Director of HAEi – International Patient Organization for C1Inhibitor Deficiencies (www.haei.org) – and President of the Patient Association for HAE in Denmark, Norway and Sweden (HAE Scandinavia). He assumed his position as the HAEi's Executive Director on 1 September 2009 after spending 5 years on its Executive Committee. Henrik has a background in sales and marketing and has held management positions in several global corporations. Since 2000, most of Henrik's spare time has involved hereditary angioedema. He was diagnosed with HAE (type I) at the age of 17 – more than 10 years after his symptoms first appeared.



Ghassan Karam, Technical Officer, International Clinical Trials Registry Platform - World Health Organization

Ghassan has been managing the International Clinical Trials Registry Platform (ICTRP) in the World Health Organization since 2011. He is an expert in clinical trial design, clinical trials registration and ethics committees. He has many years of professional experience in the private sector and within different areas of work in the World Health Organization. Ghassan has a BS in Computer Science, PG Diploma in International Management and MSc candidate with the University of London.



Speakers:

John Doux, Analyst/Investor, Palo Alto Investors

John Doux, MD obtained a B.S. with distinction and an MD from Stanford University, where he was a Howard Hughes Medical Institute Fellow. After an internship at Brigham and Women's Hospital in Boston, he returned to Stanford to complete his residency training in dermatology. He also completed an MBA at the Wharton School of Business where he was a Palmer Scholar. He is board certified in dermatology and maintains an active clinical practice. Since 2004 he has also served as an analyst at Palo Alto Investors, an investment fund specializing in healthcare with \$2B in assets under management, with a historical focus in therapeutics for rare diseases.



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Birthe Byskov Holm, President, Rare Diseases Denmark / Eurordis

Birthe has a long history of active participation in patient organizations. She became involved in the field of rare diseases because her now grown up son was born with the rare disease Osteogenesis Imperfecta. Birthe has been a member of the Danish OI Association since 1983 where she has acted as president and she is also the co-founder and currently the president of the Danish rare disease alliance (Rare Diseases Denmark). Birthe has until June 2015 been a Eurordis nominated patient representative for 12 years at the committee of orphan medicinal products (COMP) of the European Medicines Agency (EMA) where she held the position of vice chair until 2012. She is currently member of the Eurordis board of directors since 2012.



Blair van Brunt, Founder, Rare Disease Perspectives LLC

Blair Van Brunt, Founder of Rare Disease Perspectives LLC, brings her unique patient organization and patient insights and marketing experience to emerging biotech to help them incorporate the patient voice in their business strategies as well as aiding them in communicating with the patient communities that they are involved with. In 2011 Blair partnered with the Massachusetts Biotechnology Council to create the 1st ever Rare Disease Day Celebration in a State House to create an event that brings together rare disease patients, executives and scientists from pharma and biotech, doctors, congress people, and patient advocacy groups to highlight why rare disease focus and funding matters to everyone. She and Mass Bio were honored with the Power of Partnership Award in 2012 by the National Organization of Rare Disorders and asked to create a toolbox for others to be inspired by and learn how to create a similar event at their state's capital. To date there were 26 State House events created this past 2015 rare Disease Day. Her daughter has the rare disease, Shwachman Diamond Syndrome, and she was president of the SDS Foundation 2004-2012. She personally fundraised over \$900,000 for SDSF.



RARE DISEASE PERSPECTIVES LLC
Creating patient centered communication

Jimmy Cheng-Ho Lin, MD, PhD, MHS, President, Rare Genomics Institute

Jimmy Lin, MD, PhD, MHS, is a 2012 TED Fellow and Founder & President of Rare Genomics Institute, the world's first platform to enable any community to leverage cutting-edge biotechnology to advance understanding of any rare disease. Partnering with top medical institutions, RGI helps custom design personalized research projects for rare diseases. Dr. Lin is also the Director of Clinical Genomics at the Genetics Branch of the National Institute of Health/National Cancer Institute (NIH/NCI). Prior to this, he led the computational analysis of the first ever exome sequencing studies for any human disease at Johns Hopkins and was a research instructor at Washington University in St. Louis. He has numerous publications in Science, Nature, Cell, Nature Genetics, and Nature Biotechnology, and has been featured in Forbes, Bloomberg, Wall Street Journal, Washington Post, BBC, TIME, and the Huffington Post.



Dr Meriem Bouslouk Officer, Pharmaceuticals Department Federal Joint Committee (G-BA) Germany

Meriem Bouslouk (PhD in dentistry, MSc International Health) joined the Pharmaceuticals Department of Germany's Federal Joint Committee (G-BA) in 2011, and has worked on the implementation of AMNOG, the Act on the Reform of the Market for Medicinal Products, from the start, principally in the field of orphan drugs. Her main responsibilities include conducting consultations with industry representatives on clinical study design and appropriate comparators, assessing reports by the Institute for Quality and Efficiency in Health Care (IQWiG), and drafting G-BA resolutions under AMNOG (with an emphasis on orphan drugs) which become amendments to the German Pharmaceutical Directive. Meriem works closely with the voting members of the G-BA and numerous other stakeholders. In addition, she regularly conducts lectures and workshops at national and international level.



Lise Aagaard, Professor, Institute of Public Health, University of Southern Denmark

Dr. Aagaard is professor of clinical pharmacy at the University of Southern Denmark. She has been working with different aspects of medicine use and health policy, and conducted several studies on medicine use in children and adolescents. She graduated as a pharmacist (Msc pharm) in 2001, and in 2008 she earned her PhD degree for analyses of how knowledge about adverse drug reactions can be improved. From 2004 to 2008 she was employed as a pharmacovigilance officer at the Danish Medicines Agency. During the period in the Danish Medicines she also attended monthly meetings in the European Medicines Agency representing Denmark in the Pharmacovigilance Working Party.



Speakers:

Flóra Raffai, Head of Development, Findacure

Flóra Raffai is the Head of Development at Findacure, a UK charity building the rare disease community to drive research and develop treatments. She was the first hire at Findacure, developing the charity's projects, funding, and community. Flóra organises Findacure's patient group empowerment programmes, runs scientific community engagement projects, develops the charity strategy, and oversees major funding applications and online communications. She also line manages other members of staff. Flóra graduated from the London School of Economics and Political Science with a BSc (hons) in International Relations. She is a founding member of the Cambridge Rare Diseases Network and volunteers as Co-Organiser for the Cambridge Chapter of Good for Nothing.



Tim Kanters, Researcher, Erasmus University Rotterdam Institute for Medical Technology Assessment (iMTA)

Tim Kanters has been involved in orphan drug research since 2008. He performed cost-effectiveness studies for a broad range of orphan drugs, most notably alglucosidase alfa in Pompe disease, for submission to the Health Care Insurance Board in the Netherlands. Furthermore, he is performing a methodological study regarding the appropriateness of guidelines for health technology assessment to support decision making on orphan drugs.



Rob Hopfner RPh, PhD, MBA, Managing Director, Bay City Capital

Rob Hopfner, RPh, PhD, MBA, is a Managing Director of Bay City Capital and has been with the firm since 2002. Dr. Hopfner's work at Bay City has included discovery science, product development, and commercial and business development projects. Before joining Bay City Capital, Dr. Hopfner worked in DuPont Pharmaceuticals' Business Development & Strategic Planning group and at Ag-West Biotech, a Western Canadian seed-stage biotech venture capital firm. Dr. Hopfner holds a PhD in Pharmacology and a degree in Pharmacy from the University of Saskatchewan, and an MBA from the University of Chicago Booth School of Business. His biomedical research focused on endocrine pharmacology and he completed his post-doctoral work at Harvard Medical School. Dr. Hopfner's numerous awards include the Governor General of Canada Gold Medal Award, and he has published several articles in top medical journals based on his work. Dr. Hopfner started his career as a pharmacist.



Ingbritt Madsen M.Sc. Pharm., Senior Global Regulatory Affairs Manager, Ferring Pharmaceuticals

Ingbritt joined Ferring Pharmaceuticals A/S in 2003 in the Global Regulatory Affairs Department, where she has held various different positions. For the last 5 years she has been working in the department of Development Projects within Global Regulatory Affairs. In this position she has been responsible for the regulatory strategies of several development projects, planning and conduct of meetings with health authorities and submission of orphan drug application. Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group active in global markets. The company identifies, develops and markets innovative products in the areas of reproductive health, urology, gastroenterology, endocrinology and orthopaedics. Ferring has its own operating subsidiaries in nearly 60 countries and markets its products in 110 countries.



Sukhwinder Singh Jossan, M.Sc. Pharm., PhD in Pharmacology, Associate Vice President, Global Regulatory Affairs, Development Projects, Ferring Pharmaceuticals

Sukhwinder has an extensive research background with among others 25 original publications, as well as several overview publications and abstracts. His background includes more than five years as a Research Scientist with the Medical Pharmacology University of Uppsala in Sweden and several years with the Swedish Medical Products Agency. He joined Ferring in 2001 as Director of Regulatory Intelligence and has since had different positions within Regulatory Affairs. As of 2010 he has been Associate Vice President within Global Regulatory Affairs with responsibility for development projects for all therapeutic areas within Ferring. Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group active in global markets. The company identifies, develops and markets innovative products in the areas of reproductive health, urology, gastroenterology, endocrinology and orthopaedics. Ferring has its own operating subsidiaries in nearly 60 countries and markets its products in 110 countries.



Dr. Renato Dellamano, President, MME Europe

Dr. Renato Dellamano is representing MME that was established in 2001 and has offices in Oxford, MS; Montclair, NJ; and Oxford, UK. MME's client base includes large and emerging bio/pharmaceutical firms. In the past 3 years, MME has completed more than 125 biopharma pricing strategies in the US and EU. MME's areas of expertise include orphan drugs, biotech, oncology, hospital, and managed care. We specialize in developing value-based marketing strategies for health care goods and services with the ultimate goal being for our clients to make the most informed and profitable decisions.



Speakers:

Gülce Belgin, Founder & Director, Proceutica

Mrs Belgin holds a B.Sc degree in Chemistry from Bogaziçi University and an M.B.A from Koç University, Istanbul. Since completing her MBA she worked as a consultant to pharmaceutical industry for the last 13 years in Turkey. During this period she developed special interest in Orphan Drugs. Gülce's entrepreneurial experience already includes successfully founding and running a business consultancy company since 2008. She is the founder and Director of Proceutica, a company based in Istanbul providing market access services to global Orphan Drug companies. Gülce's experience in the area of Named Patient / Early Access and Compassionate Use Programs enables patients to have access to therapies as early as possible through existing and innovative early access mechanisms.



PROCEUTICA

Eva Rye Rasmussen, Specialty registrar of Oto-Rhino-Laryngology – Head and Neck Surgery, University hospital of Copenhagen

Dr. Rasmussen is a member of the Danish research group on BradyKinin-mediated Angioedema (DABKA) which performs epidemiological and basal research within the fields of hereditary and acquired angioedema including angiotensin converting enzyme-inhibitor and angiotensin II antagonist mediated angioedema. She has published a number of papers on the topic in various national and international medical journals. Furthermore she is currently taking part in an international multicentre study regarding antihypertensive drugs and angioedema in co-operation with the EU sponsored PREDICTION-ADR group. Furthermore she is educating staff at the emergency departments, internal medicine, intensive care units and otolaryngology department in the assessment and management of angioedema including hereditary angioedema.



Kieron Lewis, Business Development Director, Idis Managed Access, Part of Clinigen Group plc

Kieron joined Clinigen in 2014 and is responsible for sourcing new opportunities for the business, which specializes in the consultancy, development, set up and implementation of Managed Access Programs on behalf of Biotech and Pharmaceutical companies. Prior to joining Clinigen, Kieron spent 15 years within the Pharmaceutical industry fulfilling a range of roles including Head of Cardiovascular Division at Servier Laboratories Ltd contributing to European and Global development plans. Within this time, Kieron has led a number of global pre-launch and launch activities for treatments addressing areas of high unmet medical need. Kieron now focusses his energies on working alongside Pharma and Biotech Companies to consider their strategy for Early Access, developing Global Programs and allowing patients to gain access to treatments that would otherwise be unavailable within their respective countries.



CLINIGEN
Global Access Programs

Dr Lincoln Tsang, Partner, Arnold & Porter LLP

Dr Lincoln Tsang is a partner of Arnold & Porter LLP based in its London office. His practice is focused on regulatory, compliance, enforcement matters concerning the life sciences industry. He assists both industry and not-for-profit organizations in developing regulatory and market access strategies for new medical products including those intended for rare conditions. By ministerial appointment, he currently serves as a Commissioner of the British Pharmacopoeia Commission chairing its biologicals and biotechnology sub-committee and co-chairing the nomenclature committee. He was appointed by UK Health Ministers to serve for two terms as a board member of the National Institute for Biological Standards and Control; a Member of the Ministerial Industry Strategic Group for Pharmaceuticals. He was Chair of BioIndustry Association Regulatory Affairs Committee for two terms; and a Council Member of the UCL School of Pharmacy and a member of its governance and audit committees. He was with the UK Regulatory Authority for 13 years and latterly as its head of biologics. During his tenure, he served as an advisor to the European Medicines Agency on its various advisory committees; European Commission; European Directorate for the Quality of Medicines, the Council of Europe as well as the World Health Organisation on matters relating to regulation and international trade of pharmaceutical, biological and medical technology products. Most recently, he served as special advisor to the Council of Europe to prepare the MediCrime Convention against counterfeited medical products.



ARNOLD & PORTER LLP

Barbara McLaughlan - Head of External Affairs, Acting Head of Market Access, Oncology – Novartis Pharmaceuticals UK Limited

Barbara McLaughlan is Head of External Affairs and Acting Head of Market Access at Novartis Oncology, UK. In both roles Barbara's focus is on shaping the external environment to ensure that all eligible patients in England, Scotland and Wales are able to access the innovative treatments for rare cancers and rare diseases developed by Novartis. Patients benefiting from the company's commitment to rare diseases include those with Chronic Myeloid Leukaemia, myelofibrosis, pancreatic neuroendocrine tumours, sickle cell, thalassaemia and tuberous sclerosis complex. Before joining Novartis in 2011, Barbara worked as Eye Health Campaigns Manager at the Royal National Institute of Blind People and previously in Government Affairs, education and communications roles in Germany, Belgium and the UK.



NOVARTIS

Speakers:

Alexander D. Crawford, CEO, Theracule



Malcolm Allison, Head of Pulmonology & Anti-Infectives, Bayer HealthCare Pharmaceuticals



Liliana Otero, Secretary of the Board & Programmes Coordinator, Center of Studies on Economic Integration



Martin Andrews, Senior Vice President, GSK Rare Diseases



Register - 2015

Please use the chart below to determine your registration fee

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Conference venue

Carlsberg Museum & Business Centre
Valby Langgade 1
1799 Copenhagen

The Carlsberg Museum

The museum was originally named the Glyptotek and housed Carl and Ottillia Jacobsen's extensive art collection. Most of the art collection has been moved to the famous Ny Carlsberg Glyptotek in Copenhagen, but the museum still offers an exclusive collection of paintings and statues, and has beautifully decorated rooms which make this a unique meeting place.



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Conference venue

Carlsberg Museum & Business Centre
Valby Langgade 1
1799 Copenhagen



1

VISIT CARLSBERG

Visitor center & Brand Store
 Jacobsen Brewhouse & Bar / Bar 1847
 Entrances:
 - Gamle Carlsberg Vej 11, 1799 Cph. V
 - Bryggerhesten 1, 1799 Cph. V

2

CARLSBERG MUSEUM & BUSINESS CENTRE

Valby Langgade 1, 1799 Cph. V (entrance via Ny Carlsberg Vej)

3

ELEPHANT GATE

Ny Carlsberg Vej

4

CARLSBERG ACADEMY

Entrance via the gate at Olivia Hansens Gade

5

BUS DROP-OFF

No bus parking

6

BUS PARKING

7

ENGHAVE TRAIN STATION

Train B & C

8

BUS STOP

Bus 18 & 26



ENTRANCE

Main entrances to the Carlsberg district



CAR PARKING

Payment



CAR PARKING FOR DISABLED



CONSTRUCTION WORK

Road currently blocked

COPPERBERG



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