

Biotech Clinical Outsourcing Partnerships

Best practices in alliances between small/medium sized biotechs and CROs to overcome the hurdles in developing new small & large molecule drugs

Venue: Sheraton Westpark, Munich, Germany - Dates: 1st-2nd February, 2012 (1,5 days)

Event Overview

Smaller & medium-sized "biotech" companies (large and small molecule drug developers) are clearly much more heavily dependant on outsourcing clinical research than larger pharmaceutical companies. Biotechs usually do not have the extensive experience of running clinical programs like big pharma do and often do not have the internal resources to run studies in-house. Smaller, early-phase studies can be quite manageable, but as a drug advances into phase II and then global phase III clinical trials, the operational complexity becomes immense. Biotechs need to rely on expert CROs with a strong international presence and direct experience in the therapeutic area of research. Biotech companies do not have broad R&D portfolios and therefore the risks are extremely high that a molecule will not make it to the market and the company may not survive. Furthermore, many biotechs face intensive funding pressures, especially in times of stockmarket uncertainty and turmoil. As a result, it is even more essential that small drug developers get clinical outsourcing right for the first time as the margin for error is small. It is paramount that biotechs find the right CRO, who will be dedicated to their project instead of a larger pharma company with many projects and deep pockets. That CRO must be skilled in selecting the right sites, in the right countries that are going to recruit and retain the most patients in the indication of study as quickly as possible. It is essential that clinical supplies are manufactured and delivered to the trial sites on time. Operational inefficiencies and delays can really put pressure on the trial sponsor's limited finances. It is also imperative that the sponsor and the CRO negotiate the right contract that benefits both parties and motivates the CRO. A clear understanding of obligations, timelines and deliverables must be agreed to from the beginning. This event will look at best practices in outsourcing from the perspective of smaller biotechs and how to develop a mutual beneficial partnership that maximizes efficiency in clinical development and ensures that all possible hurdles to that stand in the way of an eventual launch are overcome as much as possible.



AREAS OF FOCUS:

- * Clinical phases I-III
- * Drug safety & immunogenicity
- * Biomarker development & validation
- * Pharmacology & translational medicine
- * Modelling & simulation
- * Regulatory affairs
- * Biosimilars



Why Attend?

- ◆ Meet directly with experienced industry professionals to understand how to develop the most efficient partnership model to maximise the performance of your CRO.
- ◆ Hear case study presentations from small and medium sized biotechs who have lower resources than large pharma and their unique experiences in outsourcing.
- ◆ Understand best practices in early-phase trials to speed-up proof of concept, as well as larger scale phase II & III trials.
- ◆ Engage in 1 to 1 partnering with leading CROs who specialize in dealing with smaller clinical trial sponsors.
- ◆ Overcome challenges surrounding selection, evaluation & contract negotiation.
- ◆ Develop clearer communication & coordination between sponsors & CROs.
- ◆ Discover what your partners' requirements & what obstacles exist in order to determine the optimum solution.

Who will benefit?

Biotech/pharma:
CEOs, Vice Presidents, Directors, Managers of:
R&D, Clinical development & operations, outsourcing, contract management, chief scientific officers

CROs and solution providers:
CEOs, clinical operations, business development, contract management, customer relationship management

Your Prestigious Speaker Panel:

BIOPHARMA COMPANIES

Diane Chisholm
Head of Clinical Operations
Santhera Pharmaceuticals Ltd., Switzerland

Mary Reilly
Vice President,
Pharmaceutical
Development & Operations
Opsona Therapeutics, Ireland

Siegfried Roesch
Director, Clinical Operations
Bavarian Nordic GmbH, Germany

Sascha Tillmanns
Medical Director
SuppreMol GmbH, Germany

Moti Gal, B.Sc, MBA
CEO, **MedPal Health Solutions, Ltd.**
Former Clinical
Operations Manager,
BioLineRx, Ltd., Israel

Mikael Brönnegård
Chief Executive Officer
NeuroVive Pharmaceutical AB, Sweden

Soraya Allas, MD, PhD
Medical Director
Alizé Pharma, France

LEADING CROs

Lajos Sarosi M.D.
CEO
HungaroTrial, Hungary

Prof. Mika Scheinin, M.D. Ph.D.
Director & Professor of
Pharmacology
CRST (Clinical Research Services Turku), Finland

Dr. Sabine Häussermann
Sr. Director Scientific and
Regulatory Service
Inamed GmbH, Germany

C. Meghann Smith
Sr. Director, Global
Therapeutic Strategic
Development & CRO
Business Development
OckhamCRO, USA

Antonio Molinari Ph. D.
Head of Analytical
Biology Unit
Accelera Srl, Italy

Dr. Andrew Griffiths PhD,
Chief Operating Officer,
Cmed Group, UK

Dr. Norbert Clemens,
Head of Clinical Development
CRS Clinical Research Services, Germany

Event Partners



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08.00 Registration & Coffee
08.30 Chairperson's opening remarks:

ENHANCING EARLY -PHASE TRIALS TO ACHIEVE RAPID PROOF OF CONCEPT

08.40 A roadmap through early-phase development

Overview and experiences in:

- ✦ CMC
- ✦ Nonclinical Toxicology..
- ✦ Pre-clin to clinical cross-over.
- ✦ Orphan drug status and proceeding to First in Human.
- ✦ Phase 1 overview and Phase 2 study design.
- ✦ Managing subcontracting and contract organizations and challenges .

Mary Reilly, Vice President, Pharmaceutical Development & Operations
Opsona Therapeutics, Ireland

09.20 What virtual biotech expect from CROs and what to do to select the right vendor and manage the relationship

- ✦ Preparing for early clinical trials –what does a virtual biotech need?
- ✦ What needs to be finalized in the lab to maximize the chance of clinical success?
- ✦ Working with external providers to provide expertise in: clinical operations, toxicity, pharmacology, manufacturing, quality control, analytical, regulatory.

Soraya Allas, MD, PhD, Medical Director, **Alizé Pharma, France**

10.00 Case study: Early-phase clinical development in-vitro fertilisation

Overview of an outsourced clinical development program for a combined product to enable an active transdermal drug delivery of large molecules via a medical device (laser) in combination with hormone patch.

Dr. Norbert Clemens, Head of Clinical Development,
CRS Clinical Research Services, Germany

10.40 Networking & Coffee Session



11.00 Case Study: Inhaled Alpha-1-Antitrypsin for the Treatment of Alpha-1-Antitrypsin Deficiency

- ✦ State of the Art: Treatment of the Deficiency by Supplemental i.v. Alpha-1-Antitrypsin
- ✦ Worldwide lack of drug calls for a reduction of used drug per patient
 - ✦ Which could be reached by inhaling the drug
- ✦ Inamed providing consulting supporting the development of an inhaled formulation and device selection
- ✦ Successful inhalation needs to be efficient in several aspects:
 - ✦ Right dosage in the lungs
 - ✦ Easy handling of device
 - ✦ Short treatment time
 - ✦ All patients need to be able to follow treatment
- ✦ Which patients are unable?
- ✦ Consulting resulted in the:
 - ✦ Chosen inhalation device
 - ✦ Clinical trial design and implementation to establish the:
 - ✦ deposited dose in the lungs syntigraphically,
 - ✦ the influence of disease severity, treatment time, and device handling.

Dr. Sabine Häussermann, Sr. Director Scientific and Regulatory Service
Inamed GmbH, Germany

11.40 Strategy and Risk Mitigation in Conducting Trial in Biologics/Biosimilars: Pre-clinical through POC/early Phase Trials

- ✦ Preclinical and Regulatory Considerations.
- ✦ Site and enrollment optimization.
- ✦ Endpoints.
- ✦ CRO partnering strategies.
- ✦ Common Pitfalls.

C. Meghann Smith, Sr. Director, Global Therapeutic Strategic Development & CRO Business Development, **OckhamCRO, USA**

12.20 Homogeneous Sandwich Immunoassay: A novel bioanalytical approach to support clinical development of biologics

- ✦ Bullets TBC

Antonio Molinari Ph. D., Head of Analytical Biology Unit, **Accelera Srl, Italy**

13.00 Luncheon Break

14.00 PET imaging in neuropsychiatric drug development

- ✦ Pharmacokinetics, selection of dose and dose interval - potential for significant savings in phase II and III trials.
- ✦ Proof of concept: early assessment of efficacy.
- ✦ Patient selection and stratification.
- ✦ Translation from preclinical to clinical development
- ✦ Case studies: development of antidepressants, opioid antagonists and drugs for Alzheimer's disease.
- ✦ The technology platform; concerns and challenges.

Prof. Mika Scheinin, M.D. Ph.D., Director & Professor of Pharmacology
CRST (Clinical Research Services Turku), Finland

14.40 Panel discussion: How can we improve the efficiency of early-phase trials to accelerate proof of concept?

Mary Reilly, Vice President, Pharmaceutical Development & Operations
Opsona Therapeutics, Ireland

Dr. Sabine Häussermann, Sr. Director Scientific and Regulatory Service
Inamed GmbH, Germany

C. Meghann Smith, Sr. Director, Global Therapeutic Strategic Development & CRO Business Development, **OckhamCRO, USA**

Prof. Mika Scheinin, M.D. Ph.D., Director & Professor of Pharmacology
CRST (Clinical Research Services Turku), Finland

15.10 Networking & Coffee Break



CRO SELECTION, PARTNERSHIP MODELS & CONTRACT MANAGEMENT

15.30 CRO Selection and Efficient Contract Negotiating with your CRO

- ✦ Analyze your project and know what you want from the CRO: What's in it for me and what's in it for them.
- ✦ Preparation of proposal: Timelines, protocols, geographical site distribution, services requested, responsibilities list, etc.
- ✦ Negotiating the contract: Milestone and unit-based contracts, outcomes for time and material, and payment schedules.

Siegfried Roesch, Director, Clinical Operations, **Bavarian Nordic GmbH, Germany**

16.10 Assessing realistic feasibility with the right CRO and the right contract

- ✦ What are the unique outsourcing requirements of a small biotech with 16 employees?
- ✦ How can feasibility studies become more realistic and accurate?
- ✦ What are the essential points in getting a contract right?
- ✦ Risk-minimisation through performance guarantees: realistic timelines and recruitment targets.
- ✦ Lessons learnt from outsourcing orphan drug studies.

Sascha Tillmanns, Medical Director, **SuppreMol GmbH, Germany**

16.50 Panel discussion: What partnership models work best and with which partners?

Siegfried Roesch, Director, Clinical Operations, **Bavarian Nordic GmbH, Germany**

Moti Gal, B.Sc, MBA, CEO, MedPal Health Solutions, Ltd.
Former Clinical Operations Manager, **BioLineRx, Ltd., Israel**

Lajos Sarosi M.D., CEO, **HungaroTrial, Hungary**

Diane Chisholm, Head of Clinical Operations, **Santhera Pharmaceuticals Ltd., Switzerland**

17:20 Chairperson's closing remarks

17:30 End of Day 1

17:20 - 19:30 One-on-one partnering sessions



Biotech Clinical Outsourcing Partnerships

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08.00 Registration & Coffee

08.30 Chairperson's opening remarks:

08.40 Biotech/CRO strategic alliances to share risk and returns

- ◆ The identification of the preferred strategic partner and investor.
- ◆ How can a deal be structured to minimise risk and maximize performance?
- ◆ What are the key milestones?
- ◆ Lessons learnt.

Mikael Brönnegård, Chief Executive Officer
NeuroVive Pharmaceutical AB, Sweden

09.20 How to get the best out of a biotech-CRO relationship illustrated via case studies

- ◆ Is it really all about the contract?
- ◆ One project team or two? Sponsor and -Who is running this trial?
- ◆ "Hygiene" factors.

Dr. Andrew Griffiths PhD, Chief Operating Officer, Cmed Group, UK

10.00 - 11.10 One-on-one partnering sessions



11.10 Finding the right vendor/CRO for a small startup

- ◆ Identification and Selection process; ethical, scientific, geographical, and cultural considerations.
- ◆ Contracting: common pitfalls of the contract and how to avoid them.
- ◆ Managing the selected vendor (or how to get what you paid for): how to ensure study progress, keep timelines and remain within the budget
- ◆ Case study – Replacing a CRO during a clinical study.

Moti Gal, B.Sc, MBA, CEO, MedPal Health Solutions, Ltd.
Former Clinical Operations Manager, BioLineRx, Ltd., Israel

PATIENT RECRUITMENT IN CENTRAL & EASTERN EUROPE

11.50 Case study experiences with outsourcing clinical trials to Central & Eastern Europe

- ◆ Why CEE? What are the benefits and challenges? Which countries?
- ◆ Does CEE still offer patient recruitment advantages over saturated Western markets?
- ◆ Why are some smaller biotechs still hesitant to run studies in CEE?

Lajos Sarosi M.D., CEO, HungaroTrial, Hungary

THE UNIQUE REQUIREMENTS OF ORPHAN DRUG STUDIES

12.30 Overcoming challenges in outsourcing for orphan drug trials

- ◆ When to choose a large full-service CRO vs a small CRO and functional outsourcing?
- ◆ What the major problems to solve when running studies for rare diseases?
- ◆ Overcoming patient recruitment and site selection issues.

Diane Chisholm, Head of Clinical Operations
Santhera Pharmaceuticals Ltd., Switzerland

13.10 Chairperson's closing remarks

13.30 End of day 2

1-on-1 PARTNERING SESSIONS:

Throughout this meeting, there will be opportunities to have pre-scheduled 15min "speed" partnering meetings between biopharma companies who are looking to outsource as well as CROs and other expert solution providers. If you have any questions or would like to join such sessions, **please contact geoff.cable@nextlevelpharma.com**



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Venue: Sheraton Westpark, Munich, Germany - Conference Dates: 1st-2nd February, 2012 (1,5 days)

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- THIRD ANNUAL -

Advancing Biologics from the Lab to the Clinic

Overcoming the challenges of demonstrating proof of concept in early stage development

Venue: Sheraton Westpark, Munich, Germany - Conference Dates: January 30th-31st, 2012

Speaker Biographies

Mary Reilly, Vice President, Pharmaceutical Development & Operations **Opsona Therapeutics, Ireland**

VP Pharmaceutical Development and Operations Mary Reilly joined the Opsona management team in March 2005 to head up the pharmaceutical development of its pre-clinical candidates. Her role is to direct the development of lead compounds from discovery through pharmaceutical development including chemistry, manufacturing and controls (CMC) and their progression into the clinic. She has extensive experience in drug development from late-stage discovery to registration and approval of products at all stages of the development cycle within Europe and the USA. Before joining Opsona, Mary Reilly worked for 15 years with Elan Pharmaceuticals where she was Associate Director and Project Leader for development projects. She also has experience in parenteral sterile drug development, manufacture and registration. Mary currently oversees programme management, pharmaceutical and clinical development and operational activities. Mary has QP qualifications in line with EU clinical directive 2001/20/EC.



Sascha Tillmanns, Medical Director **SuppreMol GmbH, Germany**

In January 2009, Sascha Tillmanns joined SuppreMol as Medical Director from PARI Pharma GmbH, Munich, Germany, where he served as Director Clinical Development in the lung transplant- and cystic fibrosis area. From 2002-2005, he was Senior Manager Clinical Research at Fujisawa GmbH, Munich. From 1999-2002, Sascha Tillmanns was Clinical Research Manager and Clinical Research Coordinator at Amersham GmbH. Prior to that, he worked as Clinical Product Specialist and Clinical Research Associate at AstraZeneca GmbH, Germany. Sascha holds a Master's degree in Biology from Philipps-University in Marburg, Germany, and a Master's degree in Pharmacology and Pharmaceutical Medicine from Free University of Brussels, Belgium.



Mikael Brönnegård, Chief Executive Officer **NeuroVive Pharmaceutical AB, Sweden**

Mikael has an MD., PhD degree from the Karolinska Institute, in Stockholm Sweden where he still holds a position as Associate Professor. He is a specialist in Paediatrics and Paediatric Endocrinology and Diabetes, and has extensive experiences in clinical research and in basic science / research including molecular biology, protein biochemistry and immunology. His reference list includes over 100 publications in scientific journals, textbooks of Medicine and business reviews. Mikael also has several years of pharmaceutical industry experience at both local market company (Clinical Research Physician and Medical Director, Eli Lilly) and corporate level including global business management (Vice President and Head of Global Medical Affairs, Pharmacia Corporation). He has a broad experience from operative positions in the biotechnology and pharmaceutical industry. He has been working at an executive level in the venture capital industry focusing on start-up and early stage investments (InnovationKapital) and as director of business development within the biotechnology and life sciences sector in UK and US. Mikael has been sitting on several boards and still holds a number of board positions. At present Mikael is the CEO of the pharmaceutical company NeuroVive Pharmaceutical AB.



Soraya Allas, MD, PhD, Medical Director **Alizé Pharma, France**

Soraya Allas joined Alizé Pharma in June 2008. Soraya holds an M.D. from the University of Algiers and a Ph.D. in biomedical science from the University of Montréal and has gained international experience in drug development including preclinical and clinical research. Soraya was trained as a pathologist and began her career in the Pharma industry in 1998 with ITR Laboratories, a CRO specialised in non clinical toxicology studies located in the Montreal area. In 2001, she joined Theratechnologies, a Canadian biopharmaceutical company listed on the Toronto Stock Exchange, where she then held increasingly responsible positions in clinical development including Associate Director, Clinical Science, Director, Clinical Science and Medical Director. She was notably involved in the design, implementation and data analysis of Phase I, Phase II and Phase III programs of an analog of the Growth Hormone Releasing Factor and in interactions with regulatory authorities including FDA, Health Canada and EMEA.



Dr. Sabine Häussermann, Sr. Director Scientific and Regulatory Service, **Inamed GmbH, Germany**

Dr. Häussermann has worked for Inamed in her current role, since March 2010 and is responsible for scientific advice and regulatory services. Dr. Häussermann is an engineer by training and started out her carrier in basic research on the inhalation of aerosols in the Institute of Inhalation Biology at the Helmholtz Center in Neuherberg, Munich. This was followed by a PhD on nasal application of aerosol in at the University of Southampton (UK). After obtaining her PhD, she worked for Inamed from 2000 to 2006, applying her research to the pharmaceutical field of respiratory aerosol medicine. Initially functioning as a project manager, in 2002 she assumed responsibility for the clinical research group at Inamed in Gauting. Moving to France, she headed the inhalation device development section in the medical gases research group at Air Liquid from 2006 to 2010. Dr. Häussermann is an active member of the International Society for Aerosol Medicine (ISAM), DDL-The British Aerosol Society, and DGP-The German Pulmology Society. She has chaired the ISAM Awards Committee from 2006 to 2011 and is now a member of the ISAM board.



Dr. Andrew Griffiths PhD, Chief Operating Officer, **Cmed Group, UK**

Andrew Griffiths has over 25 years experience in the pharmaceutical and CRO industries. Before joining Cmed in 2004, Dr Griffiths served as Senior Vice President, Clinical Pharmacology at ICON Clinical Research. Dr Griffiths also held posts as Vice President, Business Development (Europe) and Head of European Operations in the same organisation. Prior to joining the CRO sector he worked in Programme Management and Clinical Research with Boots Pharmaceuticals and Abbott Laboratories respectively. He has extensive experience of drug development and the design/management/conduct of clinical research in most therapeutic areas in many geographic locations (Europe, US and ROW). Dr Griffiths has a PhD in Clinical Pharmacology and has lived and worked in the UK and US.



Prof. Mika Scheinin, M.D. Ph.D., Director & Professor of Pharmacology, **CRST (Clinical Research Services Turku), Finland**

Mika Scheinin is Director of CRST. He has experience in clinical studies for the pharmaceutical industry since the 1980's. At the University of Turku, he leads his own research group focusing on G-protein coupled receptors and is Director of a postgraduate training programme, the Drug Discovery Graduate School. He is chairman of the Ethics Committee of South-West Finland Hospital District and has previously served as President of the Finnish Pharmacological Society



Lajos Sarosi M.D., CEO, **HungaroTrial, Hungary**

Dr Sarosi is the CEO of HungaroTrial, a leading CRO with operations in many countries across Central & Eastern Europe. Dr Sarosi established HungaroTrial in Budapest in 1999 which was one of the first CROs with set up with local headquarters in this emerging region. Since then, Dr Sarosi's company has extensive experience in managing a wide range of clinical trials in many therapeutic areas, from oncology, cardiovascular, rheumatology, psychiatry, gastroenterology, urology and allergology, amongst others. Before starting HungaroTrial, Dr Sarosi worked in the clinical research team of Zeneca and Quintiles, as well as a physician in emergency care in Budapest. Dr Sarosi obtained his medical qualification at Budapest's Semmelweis University's Medical School in 1995.



Siegfried Roesch, Director, Clinical Operations **Bavarian Nordic GmbH, Germany**

Siegfried Roesch has recently moved into the new role of Clinical Operations Director at Bavarian Nordic after working there as clinical operations manager since 2007. Previously, Mr Roesch has built up extensive clinical experience at the CRO Kendle International, as well as large pharma like Bristol-Myers Squibb and Takeda. He had also years of academic experience, achieving his Masters of Science in Biology at Albert-Ludwig-University, in Freiburg and a Postgraduate Degree in Biotechnology at The Technical University of Munich. Much of his time studying he spent as a toxicology scientist at The Technical University in Munich and the GSF, Neuherberg.



Antonio Molinari Ph. D., Head of Analytical Biology Unit **Accelera Srl, Italy**

Antonio Molinari is heading the Analytical Biology Unit at Accelera srl with focus on development, optimization and validation of assays for biotechnology-derived pharmaceuticals to support both preclinical and clinical phases of drug development. Antonio obtained his degree in Biology and afterwards a Master in Experimental Pharmacology at the University of Milan (Italy). He started his training in immunoassay development at the University of Bari (Italy) which then continued at the Hematology Department of the Mayo Clinic (MN, USA) and at the International Training Center for Hemophilia and Thrombosis, Milan (Italy). Antonio began his career in Farmitalia Carlo Erba in 1984 as senior investigator and continued in Pharmacia, Pharmacia & Upjohn, Pharmacia Italia, Pfizer and Nerviano Medical Sciences. He gained huge experience in the development of bioassays for anticoagulant and fibrinolytic agents, protein kinases, phosphatases, ATP-ases and in their adaptation, miniaturization and robotization for HTS purposes



Moti Gal, B.Sc, MBA CEO, **MedPal Health Solutions, Ltd.** Former Clinical Operations Manager, **BioLineRx, Ltd., Israel**

Moti is a senior clinical trials consultant, with extensive management experience in the Biotech and Pharmaceutical industries. Moti currently acts the CEO and co-founder of Medpal Health Solution Ltd and as a private consultant to BioLineRx Ltd.



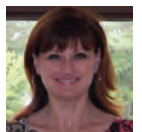
Moti previously worked as the Clinical Operations Manager of BioLineRx, a drug development company that successfully developed several ethical drugs and innovative medical devices. As the Clinical Operations Manager of the company Moti was supervising BioLineRx' clinical team and was responsible for the company's overall clinical activities. These included global project management of Phase I-III clinical studies, including financial and budgetary responsibilities, contract negotiations, design of protocols, leading Investigator Meetings and interactions with regulatory agencies in the US, Europe, India and Israel.

Prior to BioLineRx Moti worked for several years as Monitor for leading global CROs (Quintiles, PPD) where he acquired the foundations of running GCP-standard clinical trials.

Moti holds an MBA from the Interdisciplinary Centre, Herzliya (2011, Global Entrepreneurship track) and a B.Sc. in Medical Sciences from the Hebrew University, Hadassah school of Dental Medicine (2001).

C. Meghann Smith, Sr. Director, Global Therapeutic Strategic Development & CRO Business Development, **OckhamCRO, USA**

With over two decades of clinical and research expertise in a broad variety of therapeutic indications, Ms. Smith provides Ockham clients and functional teams with senior-level strategic guidance, risk mitigation analysis and solutions. She also provides support and risk mitigation strategies throughout the life-cycle of projects to help ensure study and program optimization on the regional, global and project/program levels.



Prior to joining Ockham CRO, Ms. Smith implemented senior-level program management oversight and risk mitigation strategies in all phases of study development at PPD, Inc., a global CRO, where she was given ever-increasing responsibility for development of risk strategies, assessment of protocol conduct, and strategic evaluation of studies and programs. This evaluation included assessment of the shifting competitive landscape and current treatment paradigms as well as study information analysis that translated into solid support of projects and facilitated robust strategies for project optimization.

While Ms. Smith's primary therapeutic focus is Hematology/Oncology, she also has significant experience in Cardiovascular/Critical Care, Device Trials, Infectious Disease, Neurology, Women's Health and General Medicine.

Dr. Norbert Clemens, Head of Clinical Development **CRS Clinical Research Services, Germany**

After gaining his MD in 1987 and his PhD three years later from the Ruhr-University of Bochum, Germany, Dr. Clemens pursued a successful academic career in a number of positions, including a year as an AIDS researcher in the public health service. He is a Board Certified Physiologist. His introduction to the pharmaceutical industry was as a project manager at Intersan GmbH, Ettlingen, Germany, a subsidiary of the IPSEN group, where he had responsibilities across several therapeutic areas including endocrinology, neurology, dermatology and gastroenterology. Dr. Clemens was Medical Director of Intersan/ipsen Pharma and at the biotech company PAION for several years, during which he had a broad exposure to worldwide clinical research, project management and drug safety. Furthermore he was Medical Director R & D at Valeant Pharmaceuticals International in Switzerland.



Dr. Clemens was General Manager and Head Global Clinical Trial Services at Analytica International GmbH located in Loerrach, Germany. He is now Head of Clinical Development at CRS-Mannheim.

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