Clinical Operations in Oncology Trials
Europe 2017 | 5&6 DECEMBER 2017 MUNICH, GERMANY

The 4th Annual Clinical Operations in Oncology Europe Conference

5th – 6th December 2017
Munich, Germany

Confirmed Speakers 2017

Daniela van Eickels, Former Head of Medical Affairs Oncology - **Takeda Oncology**
Dick Schaap, Director of Vendor Management **– Argenx**
Tarja Jalava, Head Global Clinical Project Management Oncology II **- Bayer Healthcare**
Martin Orlovius, Head of Clinical Operations **- 4SC AG**
Jose Manuel Ordonez, Spain CCO Therapeutic Area Leader Onco-Haematology - **Roche**
Kerstin Westritschnig, Chief Medical Officer - **Apeiron Biologics**
Ann Marinus, Assistant Director, Head of Clinical Operations Department – **EORTC**
Amer Alghabban, VP Quality Assurance, Compliance & Training - **Karyopharm Therapeutics**
Salvatore Febbraro, Medical Director **– Oxford BioTherapeutics**
Isabella Testa, Study Medical Expert - **Bayer S.p.A.**
Jessica Cordes, Clinical Trial Manager - **Medigene**
Martine Westendorp, Director Clinical Operations - **Merus**
Kim Ellefsen, Associate Director Operations **- Dept of Oncology at CHUV Oncology**
Robert Greene, President & Founder - **HungerNdThirst Foundation**
Sheela Medahunsi, Clinical Trials Set Up Specialist - **Guys & St Thomas' NHS Trust**
Amit Vasanji, Ph.D., Chief Technology Officer, Imaging, **ERT**
Ursula Garczarek, PhD, Statistician, **Cytel**
Reynald Castaneda, Journalist**, BioPharm Insight**
Dr. med. Nikolas Offenhauser, Medical Director, **Viomedo**
David Bonnet, Associate Clinical Operations Manager, **University Hospital of Lausanne - Oncology Department**

Clinical Operations in Oncology Trials Europe 2017

5&6 DECEMBER 2017
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	Clinical Operations in Oncology, Munich **Day One | Dec 5th 2017**
08:15	Registration and Refreshments
08:50	Chair's Opening Remarks: **Jose Manuel Ordonez**, Spain CCO Therapeutic Area Leader Onco-Haematology, Roche
	Protocol Development & Optimising Oncology Trial Design
09.00	**KEYNOTE SESSION** **Balancing clinical trial perspectives by involving patients in the protocol design phase of oncology trials** • Aligning goals and insuring objectives are synchronised by sharing insights into our protocol processes with patients • Simplifying the trial procedures for the patients benefit to increase understanding and engagement • Developing internal education strategies to reduce the perception that patient involvement slows down clinical development • Adopting methods to make clinical trials more relevant to patients encouraging faster recruitment • Implementing patient-orientated improvements to increase engagement **Daniela van Eickels, MP PhD MPH,** Former Head of Medical Affairs, **Takeda Oncology, Germany**
09:30	***Presentation reserved for Quintiles Sponsor***
10:00	**Evaluating protocol development strategies to enhance your oncology trial design and increase efficiencies** • Avoiding costly amendments by viewing early phase protocol development holistically and working with vendors to optimize design development • Prioritizing scanning procedures within specific timeframes reducing unnecessary patient delays • Ascertaining turnaround time for procedures to ensure trial design is optimal for oncology patients • Identifying the importance of selecting the right IVRS system based upon your protocol design • Reducing costs in protocol design by limiting unnecessary data collection in early phase research **Isabella Testa**, Study Medical Expert, **Bayer S.p.A.**

10:30	Morning Refreshments and Networking
11:00	**Considering global regulations and good clinical practices with your international oncology studies to remain compliant** • Identifying realistic timelines during protocol design when working in multiple global locations to reduce delays • Outlining the advantage of utilizing one protocol as a template for multiple sites world-wide to be more time-effective • Investigating good clinical practices early on to discover how this may affect your oncology trial in that region to minimize risk • Assessing in-house experiences and vendor knowledge to conduct a successful oncology trial internationally **Tarja Jalava,** Head Global Clinical Project Management Oncology II, Oncology Strategic Business Unit, **Bayer Healthcare**
11:30	**Leveraging Technology to Manage Risk in Imaging Scoring Systems** • Assessment of tumor response is unstructured, prone to errors, and inefficient • Given the significant number of oncologic scoring systems with complicated workflows and guidelines, which system is the most appropriate for your protocol? • How can you leverage technology to manage multiple scoring systems in one trial? • Explore how technology eliminates common errors, improves documentation and increases reader efficiency for improved trial outcomes at a reduced cost **Amit Vasanji,** Ph.D., Chief Technology Officer, Imaging, **ERT**
12:00	**Analysing the umbrella protocol design approach to identify advantages and challenges for patient and sponsor** • Considering a more complex trial design to achieve a positive signal and shorten drug development cycle • Identifying design strategies to combine all components of an umbrella study into one protocol • Overcoming the hurdle of having multiple parties involved to ensure safety reporting is completed effectively • Assessing the regulatory and ethics approval aspect of your umbrella trial early on

	to ensure a timely start up • Highlighting the advantage of umbrella studies for oncology patients by increasing their exposure to different treatments **Ann Marinus,** Assistant Director, Head of Clinical Operations Department, **EORTC**
12:30	Lunch and Networking
	Patient Centricity in Oncology Trials
13:30	**PANEL DISCUSSION** **Exploring the benefits of partnering with Patient Advocacy Groups to improve patient engagement and retention in oncology trials** • Identifying the importance of working with groups to gain patients input into protocol design and address logistical concerns • Balancing what is important to the physician vs what is important to the patient- How do you square off all aspects? • Addressing ways to incorporate patient experiences into future protocols to develop patient engagement throughout the study • Establishing at what point in your oncology study is it best to collaborate with Patient Advocacy Groups to develop a more patient centric trial *Chair:* **Reynald Castaneda,** Journalist**, BioPharm Insight** *Confirmed Panellists:* **Daniela van Eickels, MP PhD MPH,** Former Head of Medical Affairs, **Takeda Oncology, Germany; Robert Greene,** President & Founder, **HungerNdThirst Foundation**
14:15	**TECHNOLOGY SPOTLIGHT** **Moving closer to the patient: Leveraging data and digital patient recruitment to conduct trials faster** • Analysis of recruitment dataset of 20,000 patients showing remote potential • Recruiting oncology patients directly via online tools, networks and platforms • Using data to select sites that maximize patient exposure while minimizing exposure to competitive trials **Dr. med. Nikolas Offenhauser,** Medical Director, **Viomedo**
14:30	**Discussing challenges associated with patient screening and recruitment to reduce pre-clinical timeline delays**

Agenda Highlight

	• Outlining the role of patient screening in your clinical trial to ensure the correct patient population is selected • Addressing the implications of multiple screening processes to reduce unnecessary costs and burden on patients • Identifying challenges with informed consent in oncology trials to ensure compliance • Exploring options for patient data for those incompatible in your clinical trial • Adopting the process of returning pre-screening data to physicians to enable quick identification for suitable trials for patients in the future **Jose Manuel Ordonez**, Spain CCO Therapeutic Area Leader Onco-Haematology , **Roche Farma SA**
15:00	Afternoon Refreshments and Networking
	Data Management, RBM & Budgets
15:30	**Exploring the ways to manage oncology study budgets effectively to ensure resources are allocated efficiently: a site's perspective** • Finance and feasibility: financial considerations when setting up and running an oncology study at an NHS site • Identifying the role of the clinical trials set up specialist in budgeting oncology studies • Highlighting the importance of stakeholder engagement for timely and efficient communication and collaboration, with research teams, hospital specialist departments, CROs and pharma • Non-commercial studies with commercial funding: how are these handled at site level? **Sheela Medahunsi**, Clinical Trials Set Up Specialist, **Guys and St Thomas' NHS Foundation Trust**
16:00	**Risk-Based Monitoring in Oncology Trials: All data are equal but some data are more equal than others** • Exploring Risk-Based Monitoring, what is in the name? • Why RBM in Oncology? • Examining Risk-Based Monitoring in oncology and identifying lessons learnt

Agenda Highlight

	Amer Alghabban, VP GxP Quality Assurance, Compliance and Training, **Karyopharm Therapeutics**
16:30	Chair's Closing Remarks

	Clinical Operations in Oncology, Munich **Day Two | Dec 6th 2017**
08:30	Registration and Refreshments
08:55	Chair's Opening Remarks: **Martin Orlovius**, Head of Clinical Operations, 4SC AG
09:00	**Speaker Hosted Roundtables** Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable session lasts for 45 minutes, and delegates may attend up to 2 roundtables**.**
Roundtable 1	**Discussing the biggest hurdles faced with patient recruitment in oncology trials** **Jose Manuel Ordonez,** Spain CCO Therapeutic Area Leader Onco-Haematology, **Roche**
Roundtable 2	**Exploring best practices for CRO management in your study** **Martine Westendorp,** Director Clinical Operations, **Merus**
Roundtable 3	**Pre-screening & Screening: timelines, challenges, best practice and real-life** **David Bonnet**, Associate Clinical Operations Manager, **University Hospital of Lausanne - Oncology Department**
10:30	Morning Refreshments and Networking

11:00	**CASE STUDY: Outlining the considerations to be made for a successful global oncology trial** Agenda Highlight The following aspects will be taken into account: • Outlining key cultural differences • Using feasibility tests to understand patient populations and availability • Patient recruitment and screening processes • Best practices for vendor selection for that region • Assess the regulatory landscape and ethical requirements • Identify competitive advantage **Salvatore Febbaro**, Medical Director, **Oxford BioTherapeutics**

11:30	**Modern ways to collect and deploy clinical information**: Two case studies
	
	• The two case studies will highlight two basic strategies to make drug development more efficient and faster:
	  ○ Efficient use of information with pharmacometric modelling
	  ○ Timely use of information with adaptive trials designs
	• Requirements and costs of these strategies will be discussed
	• Are costs or unmet requirements the only hurdles that need to be taken to use these approaches more widely?
	
	Ursula Garczarek, PhD, Statistician**, Cytel**

12:00	**CASE STUDY: Exploring Oncology Recruitment Challenges** • Analysing the 'sources' of potential patients • Identifying recruitment obstacles • Creating appropriate recruitment initiatives and assessing their outcome/efficacy • Building and maintaining relationships with all relevant stakeholders **Martin Orlovius,** Head of Clinical Operations**, 4SC AG**
12:30	Lunch and Networking
	Site & Vendor Selection & Management

13:30	**Selecting the right CRO for your clinical trial from a young biotech companies perspective** • Outlining the trial requirements prior to CRO engagement • Considerations for midsize versus large CRO • Considerations for preferred partner versus open bidding • Selection criteria • Create joint commitment and success with CRO • Actively setup contingency plans, create win-win **Dick Schaap,** Director of Vendor Management, **Argenx**
14:00	**Establishing strategies for vendor management to strengthen collaboration and achieve goals throughout your oncology trial** • Highlighting the specific requirements you need from your vendor during protocol design to ensure everyone is on the same page • Best practices for establishing good communications between both internal departments and vendors to minimize delays • Exploring successful strategies for active monitoring to allow for timely problem solving • Assessing vendor performance after your study to incorporate lessons learned into future projects **Jessica Cordes**, Clinical Trial Manager, **Medigene**
14:30	Afternoon Refreshments and Networking
15:00	**CASE STUDY**: **Exploring lessons learned in an oncology study from the perspective of a small biotech company to gain EMA approval** • Hurdles faced and strategies put in place to successfully apply to EMA for regulatory approval • Identifying challenges associated with setting up a clinical trial with limited resources to achieve a robust protocol design • Implementing methods for locating the best sites and CROs to partner with ensuring your trial is a high priority **Kerstin Westritschnig,** Chief Medical Officer**, Apeiron Biologics**
15:30	**Optimization of operation flow for increased investigator efficacy, data quality and patient recruitment: best practices from site's perspective**

Agenda Highlight

	• Identifying the most efficient method of finding which sites will deliver the best patient recruitment process for your trial • Examining site facilities at an early stage in trial development to assess if they have the requirements on a study-by-study basis • Outlining the benefit of selecting a site with previous experience in oncology trials to ensure your priorities align early on • Highlighting the advantages of strong communication and relationships with sites to deliver on current and future trials **Kim Ellefsen,** Associate Director- Operational Management and Head of Clinical Investigational Unit**, CHUV Dept. of Oncology, Centre of Experimental Therapeutics**
16:00	Chairman's Summation and Close of Conference