2018 Speakers Include:

Werner Gladdines, Executive Director and Head of European Clinical Operations, BioClin Therapeutics
Jose Manuel Ordonez, Spain CCO Therapeutic Area Leader Onco-Haematology, Roche
Santiago Esteva, Head Clinical Operations, SOM Biotech
Estrella Garcia Alvarez, Director Global Clinical Operations, Almirall
Sara Pich, Head Clinical Development, Gendiag
Edwin Spaans, Chief Medical Officer, Khondrion
Francoise Bruyère, Clinical Manager, Mithra Pharmaceuticals
Iryna Berchak, Head of Clinical & Preclinical Trials, Yuria Pharma
Lidia Cappellina, Head of R&D Outsourcing Management, Chiesi Farmaceutici
Véronique Freund, Quality Head Europe & APAC, Sanofi
Gaspar Amat, International Associate Medical Director, Medical Affairs, PharmaMar
Tanja Ouimet, Director of Clinical Development, Pharmaleads
José Alfón, R&D Director, Ability Pharmaceuticals
Olga Claros, CEO, Archivel Farma
Frank Verheggen, Director Clinical Program Management, Astellas Pharmaceuticals
Peter Clompen, Director Vendor Management at Ablynx
Kai Langel, Director R&D Operations Innovation, Janssen
Di Peng, Chief Procurement Leader Research and Innovation, Danone Nurticia
Sandra van Wetering, Chief Operations Officer, DCPrime
Fabio Miceli, Associate Director, Country and Clinical Quality, Norgine
Oriol Serra Oritz, Director Study Optimization, Pfizer
István Udvaros, Chief Medical Officer, Cristal Therapeutics
Patrick Rambaud, Chief Executive Officer, Organic Vaccines
William Faria, Global Manager Data Management, Galderma
Robert Greene, President, HungerndThirst Foundation
Anna Cascante, R&D Director, Sagetis Biotech

Further Information

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	Conference Name: Outsourcing in Clinical Trials Europe **Conference Date: 15th May 2018** **Programme Day One**
08:15	Registration and refreshments
08:50	Chair's opening remarks **Estrella García, PhD,** Director Global Clinical Operations & Site Coordinator in Lugano**, Almirall**
09:00	**Discussing how pharmaceutical companies and service providers can collaborate to drive forward innovation in the clinical trial industry** • Considering how trial sponsors and CROs can move away from fixed processes to different ways of working which support innovative trial design • Debating whether smaller CROs are more agile and creative or if only large CROs have the resources to truly innovate • Assessing how CROs and sponsors can increase their partnerships with innovative vendors to give investigators, patients and internal employees more opportunity to utilise beneficial technologies • Discussing how new innovation in clinical trials have the potential to change traditional outsourcing partnership models to assess how the outsourcing landscape may look in the future **Frank Verheggen,** Director Clinical Science**, Astellas Pharmaceuticals**
09:30	**Session Reserved for Lead Sponsor**
10:00	**Assessing what qualities make for the perfect trial partner to evaluate how you can improve your vendor selection process** • Highlighting the key qualities trial sponsors want in their service provider to determine what makes a successful partnership • Assessing whether therapeutic or regional expertise is more important when considering the right match for your clinical programme • Debating how to balance cost and quality to find a service provider that can meet your specific needs • Highlighting the importance of considering chemistry and other non-quantifiable qualities when choosing your service provider to make the right choice when you are comparing companies with similar skills and expertise • Discovering strategies to evaluate vendors' engagement in your study to find a proactive and solution-orientated partner **Francoise Bruyère,** Clinical Manager**, Mithra Pharmaceuticals**
10:30	Morning refreshments and networking

	Stream A: Outsourcing Clinical Trials **Chairperson: Estrella García, PhD,** Director Global Clinical Operations & Site Coordinator in Lugano**, Almirall**	**Stream B: Clinical Data and Trial Technology**

11:00	**Session Reserved for World Courier**	**Session Reserved for Medidata**
11:30	**Think-tank: Organising an effective bid defence meeting to negotiate the best partnership for your clinical study** *In this session, the host will share current practices and compile creative ideas from the audience to determine best practices for an effective bid defence meeting* • Evaluating key questions to ask to gauge the vendor's level of engagement and capabilities to ensure they can deliver to your expectations • Developing strategies for effective negotiation during the bid defence to ensure you get the best possible contract terms • Exploring key questions to ask to identify the vendor's depth of knowledge and relationships with KOLs in your therapeutic area • Underlining the importance of meeting the proposed study manager to interrogate their full capabilities and personal chemistry **Peter Clompen,** Director Vendor Management**, Ablynx**	**Overcoming the challenges of implementing new technologies to reap the time and cost-saving benefits of new innovations** • Highlighting how technologies such as cloud storage can minimise your trial expenses with minimum investment of time and money • Discussing how to assess the cost of training and support for staff to determine the overall cost-benefit of the new technology • Accounting for long-term as well as up-front costs of technology to gain a realistic picture of the cost vs benefits • Debating whether technology vendors should introduce different pricing models for small vs large companies to accelerate technology uptake in the industry **Di Peng,** Chief Procurement Leader Research and Innovation**, Danone Nutricia Research**
12:00		**Evaluating key considerations when choosing a technology vendor for your study to avoid unforeseen challenges in applying the technology to your operations** • Highlighting the importance of considering how the

		technology will integrate with your vendor and sites' systems to ensure compatibility • Assessing how small technology companies can be best supported in the scale up of their products to support multi-centre global clinical trials • Discussing the best questions to ask technology vendors to evaluate whether new inventions can be translated to practical outcomes for your trial • Discussing how to source and compare the best technology for your needs in a time-efficient way when there is so much choice on the market **Sara Pich,** Head Clinical Development**, Gendiag**
12:30	Lunch and networking	
13:30	**Session Reserved for Bracket**	**Session Reserved for Medpace**
14:00	**Fireside Chat: Establishing KPIs to encourage vendors to act proactively throughout your study** *An informal discussion on-stage between the moderator and speaker. Delegates will have the opportunity to submit questions beforehand* • Choosing the correct KPIs to accurately represent your vendor's quality of work • Determining how to phrase KPIs in the vendor contract to ensure you partner is solution-orientated if a problem arises • Assessing how your contingency plans for various trial risks can be more flexible to allow for creative problem-solving from your vendor • Highlighting the benefits of involving a third-party, such as a representative from the Business or Quality departments, when KPIs are not being met to ensure a good relationship is maintained on an operational level between vendor and trial sponsor **Lidia Cappellina,** Head of R&D Outsourcing Management**, CHIESI FARMACEUTICI S.p.A.** **&** **Istvan Udvaros**, Chief Medical Officer, **Cristal Therapeutics**	**Partnering with young innovative technology companies – tips, tricks & success stories** • Appreciating how being the first to pilot new trial technologies can enable you to better engage sites and patients • Assessing how a lengthy contracting process can damage the partnership between trial sponsors and start-up technology vendors • Determining how you can best adapt to working with technology partners that are agile and flexible to ensure a harmonious working relationship • Exploring how you can adapt your own internal structures and processes to better align with a fast-moving digital space **Kai Langel,** Director, Janssen Clinical Innovation**, Janssen**
14:30		**Exploring new data-driven approaches of site selection to reduce a trial and error approach** • Detailing databases and software available which aggregates site data to enable better decision-making • Determining how to effectively utilize the large amount of data available to create an ideal site profile based on feasibility, study start-up data and site experience • Underlining how new databases and software can highlight new sites to trial sponsors and CROs to avoid over-reliance on existing relationships • Defining how aggregated data from sites can improve transparency and result in decreased study start-up time and overall successful trial execution

		Oriol Serra Oritz, Director Study Optimization, **Pfizer**
15:00	Afternoon refreshments and networking	
15:30	**Session Reserved for Sponsor**	**Session Reserved for SynteractHCR**
16:00	**Evaluating how trial sponsors can best manage 3rd party vendor contracts to mitigate risk to data quality** • Defining trial sponsor accountability for subcontracted 3rd parties to evaluate how you can safeguard your interests • Assessing how trial sponsors can ensure they still have a point of contact when a service providers works with multiple 3rd parties to maintain control over the study • Evaluating how to best manage a situation in which a subcontracted vendor is not performing well to ensure overall quality does not suffer in the long-term • Determining how to prevent the dilution of training when work is subcontracted to ensure all parties are providing the same level of quality service **Véronique Freund,** Deputy Head Third Parties Quality Management**, Sanofi**	**Overcoming the challenges of implementing ePRO or eDiaries in your trial to increase patient engagement** • Outlining the full capabilities of ePRO vs traditional data collection methods to determine how you can make full use of the interface to acquire more accurate data • Determining how to decide whether ePRO is suitable for the parameters of your trial • Addressing concerns that ePRO is not suitable for older patient populations to assess compliance amongst this demographic • Assessing how vendors and trial sponsors can collaborate to decrease the time taken to process and translate questionnaires to avoid trial delays **Tanja Ouimet,** Director of Clinical Development**, Pharmaleads**
16:30	**Enabling small biotechs to work effectively with large CROs to gain access to valuable resources** • Highlighting the benefits of small biotechs working with large CROs as opposed to smaller service providers to assess which partnership is most beneficial for your clinical trial • Determining how small companies can remain cost-effective while working with large CROs to ensure a realistic budget is maintained • Evaluating how you can ensure your study remains a priority despite being a small client to secure the resources you require • Questioning how small, agile biotechs can best adapt to the sometimes stringent, fixed processes of large CROs to find an effective way of working together **Santiago Esteva,** Head Scientific Operations**, SOM Biotech**	**Describing how trial sponsors and their partners can best align with ICHE6 R2 to ensure compliance** • Outlining amendments to the sponsor's oversight responsibilities as detailed in the regulation to evaluate how you can integrate the updates into your processes • Identifying to what extent trial sponsors need to make their QA more robust to comply fully with the regulations • Evaluating the benefits of expanding your internal QA department to ensure an efficient QMS is in place • Assessing the changes in CRO oversight requirements to determine how sponsors can efficiently document CRO sub-contracting **Fabio Miceli**, Associate Director Country and Clinical Quality**, Norgine**
17:00	Chair's summary and close of conference	

	Conference Name: Outsourcing in Clinical Trials Europe **Conference Date: 16th May 2018** **Programme Day Two**	
08:15	Registration and refreshments	
08:50	Chair's opening remarks	
	Stream A: Engaging your Trial Partners from Early Phase Development and Beyond	**Stream B: Innovation in Trial Operations**
09.00	**Session Reserved for Omnicomm Systems**	**Considering how the rise of predictive analytics will optimize clinical trial operations** • Highlighting how aggregating trial data into one database allows you to spot issues in real-time to enable quick deployment of problem-solving measures • Evaluating the current capabilities of analytics software and models to determine how they can be utilised to make strategic decisions across your portfolio • Determining which information to measure to ensure you acquire meaningful insights • Exploring the capabilities of real time analytics to compliment adaptive trial designs **Session Reserved for ERT**
09:30	**Evaluating how to best prepare for clinical trials to ensure a smooth transition from the preclinical phase** • Highlighting the importance of seeking advice from KOLs and experts with a wide-range of experience in your therapeutic area to discover key challenges and risks • Evaluating the benefits of determining your product goals at an early stage to develop a clear clinical strategy • Investigating how to best spread your budget across your clinical programme to ensure each phase is properly resourced • Assessing the benefits of considering patient stratification early to ensure your data accurately reflects your product's target population • **Iryna Berchak,** Head of the Department of Preclinical & Clinical Trials**, Yuria-Pharm**	**Data visualisation and centralised monitoring: adapting to the new GCP guidelines** • Exploring how to develop centralized monitoring tools in compliance with GCP guidelines • Assessing how to turn your CRAs into data scientists • Highlighting how database visualization can help you make the most of larger volumes of data being garnered from clinical trials **William Faria, G**lobal Manager Data Management**, Galderma**
10:00	***Session Reserved for Anna Cascante, R&D Director, Sagetis Biotech***	**Assessing the tangible benefits of implementing a risk-based monitoring approach for small companies** • Recognising how recent regulatory developments are making the adoption of RBM more urgent for companies of all sizes • Highlighting the importance of working with your

		vendor to determine the best RBM approach for your trial to ensure optimum use of resources and time • Determining the potential cost-saving benefits of remote monitoring to assess the ROI of this approach • Evaluating the benefits of RBM for different study types and sizes to find the right approach for your trial **Edwin Spaans,** Chief Medical Officer**, Khondrion**
10.30	Morning refreshments and networking	
11:00	**Session Reserved for Sponsor**	**Session Reserved for Sponsor**
11:30	**Running clinical trials from the viewpoint of a small biotech to establish how to make the best use of limited funding and human resources** • Establishing how to spread limited resources across your clinical programme • Determining how to make the most of limited human resources to ensure everyone is working effectively together • Driving the success of your clinical study through quality partnerships with the industry **Olga Claros Rue,** CEO**, Archivel Farma**	**Workshop: Identifying the new tools and processes required to successfully implement a risk-based monitoring approach in your trials** *During this session, delegates will be split into small working groups and tasked to identify what new tools and processes are required to successfully implement a RBM approach* • Highlighting the benefits of listening to employees queries and concerns about implementing an RBM approach to assess what training is required • Determining how to evaluate how prepared your CRO is to implement an RBM approach to ensure that the correct SOPs are in place • Considering what systems and tools you need to implement internally to support RBM • Exploring what organisational structure is necessary for RBM to determine what new roles and departments are needed to implement this approach **Jose Manuel Ordoñez,** Spain-CCO Therapeutic Area Leader Oncology/Hematology**, Roche** **WORKSHOP**
12:00	**Exploring Pharmacokinetic/Pharmacodynamic considerations in Translational Oncology; from preclinical development to Phase II operations** • Appreciating the unique operational challenges oncology presents as a therapeutic area • Highlighting some common challenges in translational research • Evaluating the importance of preparing appropriately for early phase clinical trials to ensure success in the later phases **Jose Alfon,** VP Research & Development**, Ability Pharmaceuticals SL**	
12:30	Lunch and networking	
13:30	**Establishing successful relationships with academia to leverage world-class expertise in the development of next-generation therapies** • Assessing how academia and the pharmaceutical industry can work together more effectively to explore new frontiers in drug development • Determining how to build your network with academia to ensure you have access to expertise in your therapeutic area • Exploring the Organic Vaccines story to determine	**Assessing the unique challenges that next-generation cell therapy companies face in clinical operations and outsourcing** • Describing the different operational risk factors to take into account in cell therapy clinical trials • Highlighting the specific challenges for manufacturing scale-up for cell therapy clinical trials • Navigating the complex site approval process for gene therapy studies

	how a successful partnership has resulted in the potential Next Vaccine Frontier **Patrick Rambaud,** CEO**, Organic Vaccines**	**Sandra Van Wetering, Chief Operations Officer, DC Prime**
14:00	**Session Reserved for Sponsor**	**Session Reserved for Sponsor**
14:30	**Determining how to get early involvement from patients and investigators in your trial to enhance engagement for the duration of the study** • Underlining the benefits of discussing protocol with both patients and investigators to ensure both parties are fully engaged with the trial • Assessing new technologies which make it easier for investigators to find and be involved in trials to determine how you can best leverage these to your advantage • Evaluating how to increase interactivity during investigator meetings • Determining the benefits of data exchange programmes between hospitals and trial sponsors to enable better protocol design and greater investigator involvement in trials **Werner Gladdines,** Executive Director and Head of European Clinical Operations**, BioClin Therapeutics**	
15:00	Afternoon refreshments and networking	
15:30	**Patient Recruitment and Centricity Workshops** *Patients are absolutely vital to any clinical trial but the pharmaceutical industry still struggles to meet recruitment timelines and account for patients' needs within their trial designs. These interactive sessions are designed to provide trial sponsors and solution providers with the opportunity to discuss how they can work better with patients to ensure trial success.*	
	Think-Tank: Developing patient-centric clinical trials through collaboration with patients, advocacy groups and other stakeholders *In this session, the host will share current practices and compile creative ideas from the audience to develop patient-centric clinical trials* • Outlining the current state-of-play in the industry to understand what more we can do	**Workshop: Developing innovative patient recruitment strategies to increase recruitment and engagement rates for your trial** *During this session, delegates will be split into small working groups and tasked to identify innovative patient recruitment strategies* **WORKSHOP** • Providing an overview of the new tools and techniques available to trial sponsors which can

THINK-TANK

	• Defining the concept of patient-centricty • Discussing how best to consider patient needs and challenges within your trial design • Avoiding common mistakes and misconceptions when designing patient-centric trials **Robert Greene,** President**, HungerNdThirst Foundation**	compliment traditional recruitment strategies • Exploring new ways of using social media to increase recruitment rates • Evaluating potential pitfalls of an online patient community to determine strategies for preventing the creation of placebo effects and breaches in confidentiality • Assessing which metrics to consider to measure the effectiveness of your social media campaigns in guiding the right patients towards your clinical trial **Gaspar Amat**, International Associate Medical Director, Medical Affairs, **PharmaMar**
16:30	Chair's summary and close of conference	