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KEY STRATEGIES FOR DELIVERING EFFICIENT MULTI-REGIONAL CLINICAL TRIALS

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THE SPEAKER PANEL FOR 2018

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Secretary-General - Patient Access Partnership (PACT), Secretary-General, CEE4Health Chairperson, National Patients' Organisation (NPO)

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Chief Medical Officer, Head of Clinical Development and Regulatory, R-Pharm (Russia)

Piotr Iwanowski
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SPEAKER'S FACULTY INCLUDE:

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A truly unique opportunity to:

- Discuss the globalisation of clinical research,
- Discuss common regulatory and ethical challenges
- Share the expertise of conducting trails in Central, Eastern & Southern Europe, Turkey & MENA, Russia & EAEU.

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Day One. Monday, 22 October 2018

08.30 - 09:00 Registration

09.00 - 10:30 Session 1: Conducting clinical trials across multiple regions: factors influencing regional differences and attractiveness

– Analytical review of the global clinical trials markets: prospects of the development, their specific characteristics, as well as an in-depth analysis of the regional markets and emerging trends.

– What are the challenges and opportunities that multiregional clinical trials (MRCT) face at present? What makes a country a prime destination for clinical trials?

– Benchmarking the performance of individual countries against compliance metrics, patient and investigator satisfaction globally. Leveraging access to a larger and more diverse patient base: recruitment, retention in non-European countries. Comparing safety reporting and budgeting implications of conducting trials

10:30 - 11:45 Session 2: Streamlining the regulatory process

– Embracing expected international regulations – how will the new European laws affect the clinical trials landscape globally?

– How can a local CRO help to communicate with government officials, logistical and customs challenges, site management process and the retention of the study protocol?

14:15 - 15:10 Lunch

– Aiming at exceeding the required quality standards – current discussion topics

– Standardising the regulatory pathways – latest updates from the regions.

– Overview of the economic programs supporting regional integration and the market R&D incentives in the countries – impact on the markets

11:45 - 12:15 Coffee & Networking

12:15 - 13.15 Spotlight session "Beyond the Borders Projects."

13.15 - 14:15 Session 3: Achieving excellence through effective partnerships

– How are service providers changing the collaboration framework and incorporating innovative approaches and solutions in order to ensure efficient, patient-centric and compliant clinical trials?

– What are the factors to look for in selecting the right partner? How to manage the risks and liabilities?

– How can a local CRO help to communicate with government officials, logistical and customs challenges, site management process and the retention of the study protocol?

14:15 - 15:10 Lunch

15:10 - 16:20 Session 4: Increasing efficiency while managing multi-regional trials

– Meeting demands of increasingly sophisticated clinical trials: optimization, automation & efficiency measures used to achieve faster, safer and cost-efficient clinical studies.

– Data Management: tackling inefficient data reviews; Advances in Data Management: The role of AI in achieving cost efficiencies

16:20 - 17:00 Discussion: Risk-Based Monitoring for MRCTs

– How far along the road is RBM from when the concept was first introduced and how has it evolved?

– What are the common stumbling blocks in the identification of risks?

– Where are the communication gaps in a robust RBM methodology and how can we circumvent these?

– The role of FDA, EMA and other regulatory bodies in the endorsement of RBM
methodologies

– Are there any case studies that could demonstrate the effectiveness of RBM/that could be used as benchmarks by other companies looking to implement RBM?

17:00 - 17:30 Coffee and Networking

17:30 - 18:30 One-2-One Meetings & Cocktail Reception

Day Two. Tuesday, 23 October 2018

Series of spotlights on the regional markets

During the day, the conference will offer country-specific presentations of the smaller European and non-European regions. The sessions will provide an overview of the regional clinical research facilities, regulations and patient recruitment opportunities that the regions can offer to support the sponsors outside of the home market.

09:00 - 10:30 Session 5: Spotlight on CEE & South Europe

10:30 - 11:00 Session 6: Spotlight on Turkey & MENA

11:00 - 11:30 Coffee and Networking

11:30 - 13:00 Session 7: Spotlight on Russia, EAEU & Ukraine

13:00 - 14:00 Lunch

14:00 - 15:00 Session 8: Site Management

– Do sites in different regions require different levels of site management? What support do investigators and the sites require from sponsors and CROs?

– With the innovative solutions advancing and study procedures becoming more complex – would new sites and emerging clinical trials players be able to meet new expectations standards?

– Reducing expenditures in site management – what are the cost-saving monitoring models and cost optimizing solutions that being used?

– Working with complex protocols: how could the changing role of a clinical monitor affect a site's ability to manage complex studies?

– Liaison with the local ethics committees – how significant is the problem for established and new markets?

15:00 - 15:30 Coffee and Networking

15:30 - 17:00 Session 9: Budgets, Contracts & Payments Management

– What are the key budgeting and forecasting challenges for MRCTs?

– Contracting process – what should, and could, be considered? Overview of varying standards for site contracts; import license requirements

– Specific concerns for sponsors and CROs working in the non-EU markets

17:30 Closure of the Conference

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Phoenix Progressive Certifications Enterprise Pvt. Ltd.(PPCE):

Established in 1997, PPCE provides Data Management, Biostatistics and Medical Writing services for biopharma and medical devices.

Medidata Rave, Oracle Clinical and IBM Merge are used to conduct Oncology, Urology, Autoimmune Disorders, Respiratory, Cardiovascular and Immunology studies for FDA submission.

Identifying and communicating areas that could derail a project, cause delays or create regulatory hurdles are critical to a Sponsor. We see the final outcome of a trial being a responsibility in which PPCE plays a big part.

A risk-based approach and an organization culture of engagement and ownership has resulted in long-term, loyal customers across the globe. Human evolution is as strongly supported as process upgrades in the achievement of our objectives.

Global Clinical Trials (GCT) is a premium contract-research organization (CRO) that offers support for the preclinical and clinical Phase I-IV studies as well as post-marketing activities to Big Pharma, small and medium-sized biotech enterprises, groups and funds, as well as large universities and institutions.

Headquartered in Princeton, USA, GCT offers both local and global support through 8 operational offices in Bulgaria, Czech Republic, Hungary, Moldova, India, Poland, Romania, Russia, Slovakia, Ukraine, USA and it is a founding partner of a network of reliable partners in Scandinavia, Asia and EU.

GCT team, that now consists of over 100 full-time clinical research professionals, gives individualized attention to each project and provides full range of services following the latest GCP, EMA and FDA guidelines at every stage of product development path. Monitors and project managers are all certified clinicians experienced in GCP clinical research.

August Research is an American- owned CRO working exclusively in Central and Eastern Europe (CEE). Founded in April 2012 by former AbCRO/PPD executives, August Research is now the leading CRO in Central and Eastern Europe designed to meet the needs of small and medium-sized bio-pharmaceutical companies.

August Research is operationally oriented on providing all in-country clinical trials services with a focus on high quality and cost efficiencies. Our team has been conducting clinical trials in the region for over 15 years and our unique combination of American management with local expertise provides the highest level of customer service and delivery.

Our experience spreads across a variety of therapeutic areas, which include Cardiovascular, Oncology, Respiratory, Infectious Disease, Ophthalmology and Endocrinology, with most of our studies in Oncology, Cardiovascular and Infectious Diseases.

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