AICROS
Association of International CROs

WORKSHOP

»PROJECT MANAGEMENT FOR SPONSORS OF CLINICAL TRIALS«

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PROVIDER:	Association of International CROs Ltd. (AICROS)
DATE:	18.05.2015
TIME:	09:00 - 17:00
PRICE:	150.00 Euro per attendee
LOCATION:	Swissôtel Düsseldorf/Neuss Rheinallee 1 D-41460 Neuss
REGISTRATION:	via email: info@aicros.com via phone: +49 (0)421 24 68 78 26 via internet: www.aicros.com/contact/PM_workshop Minimum number of participants: 5

ARRIVAL BY PUBLIC TRANSPORT

FROM DUSSELDORF INTERNATIONAL AIRPORT:
Take the S11 train in direction Bergisch Gladbach, get off at Neuss RheinparkCenter, then a 5 minute walk to the hotel.

FROM DUSSELDORF RAILWAY STATION:
Take the S8 / S11 / S28 train or the 709 / 704 tram to Neuss and get off at Neuss Rheinpark Center.
Take the 704 / 709 / 719 trams to Neuss Rheinpark Center or the S8 / S11 / S28 train to Dusseldorf and get off at Neuss Rheinpark Center.
After exiting the train station, walk towards Neuss Rheinpark Center and turn left at the first intersection. After 5 minutes walk you will arrive at the Swissôtel.

ARRIVAL BY CAR

FROM MOTORWAY A57:
Take the exit Neuss-Hafen and thean turn right at the second traffic light.
Go straight on until you reach the hotel on the right.

THE TRAINERS:

ANDREAS GRUND (MSC, PHD) has worked in the clinical research area since 1997. His specialty areas include clinical monitoring, quality assurance, project management and training for the University Kiel and global CROs. Mr. Grund founded the CRO "GCP-Service International" in Germany in 2004. GCP-Service International is an innovative midsize CRO which conducts clinical phase I to IV drug and medical device studies within Europe and the USA. Currently Mr. Grund focuses on consulting and training for pharmaceutical and medical device companies in regulatory requirements, national laws and international guidelines. With his acute sence for recognizing inefficient processes in clinical studies, he invented an online quality risk management tool (QCTMS) in 2009 which streamlines traditional quality control processes to reduce costs and improve quality in multicentre trials. Mr. Grund has been the president of AICROS since 2013.

ANDREI STOICESCU (MD, MBA) has over 15 years experience in life sciences. He has held executive management positions in various operational roles within international pharmaceutical companies and has extensive expertise in a number of therapeutic areas. Following his university degree in odontology, he joined Glaxo Wellcome Romania to manage the sales department. He was later appointed by Boehringer Ingelheim to several management positions in field force and business development, including his final position as general manager at the Romanian operative unit of Boehringer Ingelheim. Since 2009, Mr. Stoicescu is managing partner at Rotrial International, a privately-owned regional CRO acting in Romania, Bulgaria, Moldova and Serbia and providing clinical research services to the pharmaceutical, biotechnology and medical device industry. Mr. Stoicescu is treasurer of AICROS since 2003. During his career, Mr. Stoicescu gained invaluable international experience within a multitude of areas including training & development, personnel management, business development and strategic account management.

JIRI PASEKA (M.D.) joined the pharmaceutical industry in 1999 after having worked in the OB/GYN Department of Masaryk University in Brno, Czech Republic. He gained clinical research and general management experience with Janssen-Cilag, a pharmaceutical division of Johnson and Johnson, and with DUX Consulting, a midsize Czech CRO, where he acted as head of Clinical Operation and as country manager in Slovakia. Now he is appointed as managing director of Leading Clinical Research (LCR), a privately held CRO focusing on operations in Central Europe. He is also a lecturer and consultant in clinical research and runs the clinical research educational program within LCR. He co-authored the textbook "Monitoring, audit and inspection of clinical trials" and is board member of the Czech Association of Pharmaceutical Medicine. He serves as vice-president of AICROS since 2013.

WHY SHOULD YOU ATTEND?

Managing clinical trials is a huge challenge for most small to midsize sponsors. Restrictions in manpower, budget, tight timelines and high quality standards in clinical research require project managers to know how to manage clinical studies cost effectively to meet the expectations of, on the one hand, regulatory authorities and notified bodies and on the other hand often of investors. The trainers of this workshop have worked with number of companies of varying sizes and the problems they experienced were very similar. This workshop will identify inefficient processes and typical mistakes or misconceptions in project management. The participants will receive a practical guideline on how to plan, conduct and supervise clinical studies in an efficient and successful manner.

WHO SHOULD ATTEND?

Persons who are or who will be responsible for managing clinical trials with pharmaceutical products or medical devices, contract managers, medical directors, clinical operation managers and all other persons involved in outsourcing for clinical trials who need to ensure vendor surveillance and oversight within clinical trials.

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AGENDA:

09:00 - 09:15 • **Welcome and introduction**

09:15 - 10:15 • **Planning a clinical study**
- Roles and responsibilities of project managers
- General items to be considered when planning a study
- Different products have different needs
- Risk analysis
- Regulations
- Cultural aspects
- Timelines
- Costs
- Effective management of timelines and milestones

10:00 - 10:30 • **Statistical considerations**
- Study size
- Study design
- Choosing the best endpoint

10:30 - 10:45 • **Break**

10:45 - 11:45 • **Finding the right vendors**
- Outsourcing options
- Vendor evaluation
- Bidding for clinical trials
- Review of proposals
- Bid defense meetings
- Vendor audits
- Contract management
- Tasks vs. responsibilities

11:45 - 12:15 • **Management of project budget**
- Service fees vs. pass-through costs
- Fix costs
- Variable costs
- Cost control
- Correlation between input and output

12:15 - 13:00 • **Lunch Break**

AGENDA:

13:00 - 14:00 • **Communication and team building**
- How to work together?
- Team training
- Team building
- Motivating and mentoring team members
- conflict resolution, de-escalation
- communication strategies
- effective communication skills

14:00 - 15:30 • **Project oversight**
- Sponsor responsibilities
- Expectations of the authorities
- Quality control of multicentre trials
- Vendor surveillance
- Quality risk management
- Product safety

15:30:-15:45 • **Break**

15:45-16:30 • **Audits and inspections**

16:30-17:00 • **Managing trials outside EU**
- Regulations
- Authorities
- Timelines
- Export/Import
- Issues to be expected

17:00 • **Discussion and end of workshop**

CONTACT FOR FURTHER QUESTIONS:
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