

NEWSLETTER October 2015

Next Webinar: Are you prepared for the New ICH GCP Addendum?

The ICH has decided to modernize its approach to GCP in order to keep pace with the scale and complexity of clinical trials and to ensure appropriate use of technology. In this webinar you will receive:

- Preview of modern GCP and its likely impact on your organization
- · Advice on how to prepare for it
- Demonstration of risk-based study oversight technology
 Date and time: 20 October 2015 10-11 am EST / 4-5 pm CET

 Register for Webinar

Success Story: Patient Recruitment with Biotech Study in Istanbul

Towards the end of 2014, the largest Biotech company in the world started using Clinerion's PRS (Patient Recruitment System) for an ongoing dyslipidemia clinical trial. This was an exciting time for the study team as the principal investigator (PI) was hoping to exceed her committed number of enrolled patients and become one of the best perfoming sites with the help of this "new innovative technology".

3 months into the trial the study team had enrolled about one third of the required number of patients. After activating PRS, the PI to reach the remaining 64% of her commitment within only 6 weeks! This result was achieved by only validating 15% of the patient

candidates identified by PRS. The recruiting process had an early closure due to this high performance of clinical trial sites.

One of the study team members reported: "Normally it takes hours to screen the archives for eligible patients. However with such an online tool we spent much less time finding patients and consequently had more time for other tasks. This had a great positive impact on our study quality!"

For further information, please contact Roland Haag, Head of Global Business Development at Clinerion at:

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ACRES Synergy Conference

The Alliance for Clinical Research Excellence and Safety (ACRES) held a hands-on collaboration event called SYNERGY on October 1-2 in which Clinerion and other ACRES Strategic Allies explored the challenges, opportunities and benefits of collaboratively building an innovative, open, integrated global clinical research system, based on systems thinking and principles of Accountable Research.TM

Three areas of opportunity and their interconnections were explored, namely:

- Patient Engagement
- Study Protocol Design
- Leveraging Technology

Briggs Morrison, CEO of Syndax Pharmaceuticals, Prof. Brendan Buckley, CMO of ICON and Leslie Platt, Senior Advisor to MITRE Health and Human Services, among others

shared some "Misadventures in Pharmaland" as well as illuminating and provocative insights into possible paths of improvement by means of Systems Thinking. These and other contributions paved the way to the identification of projects in which globally accredited clinical trial sites, risk-based quality management, standards-based data integration and secure cloud-based study management technology and services become a reality for a wide-array of clinical research stakeholders at an affordable price. For more information:

Contact: Randy Ramin-Wright. Head of Quality Risk Management

International Clinical Trial Center Network (ICN)

On 17 Sep 2015, Clinerion led the inaugural meeting of the International Clinical Trial Center Network (ICN) in Zurich in which representatives from ten sites of eight countries came together, shared and launched the joint enterprise.

The International Clinical Trial Center Network (ICN) connects Clinical Trial Centers of international renowed hospitals and research institutions worldwide. ICN's Clinical Trial Units are core elements that enable and promote excellence in clinical research by means of its quality management and portfolio of services.

For more information:	
	<u>Visit ICN Website</u>
	<u>Visit Clinerion Website</u>



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