



Stronger Through Collaboration

Anne Zielinski at Bioclinica eHealth Solutions tells *ICT* about her company's recent collaboration with ARISGlobal, and what implications this has on the eClinical landscape

ICT: Can you tell us more about your recent partnership with ARISGlobal?

Anne Zielinski: Pharmacovigilance as a service, which enables sponsors to reliably outsource safety reporting, is a rapidly growing area for Bioclinica. Under this partnership, we have named ARISg from ArisGlobal as our preferred safety platform, and ArisGlobal has chosen Bioclinica as its preferred vendor for implementation and business processes consulting.

How is this initiative contributing to the eClinical environment?

We are increasingly seeing clinical trial sponsors express a preference for enabling technologies within an integrated platform as a service model. Our collaboration with ArisGlobal responds to this shift by bringing an end-to-end platform solution to the industry that minimises sponsors' concerns as to which technologies are being used and how they are connected. The integrated Bioclinica Express electronic data capture (EDC) and ARISg offer many advantages for sponsors, including optimised processing of adverse events.

And how, in particular, is ARISGlobal's Safety Cloud enhancing Bioclinica's pharmacovigilance services?

Traditionally, sponsors have licensed safety systems and hosted them in their own premises – a model known as 'on premise'. It requires sponsors to assume all responsibility for hosting and maintaining hardware, implementing upgrades and applying software patches. By comparison, ArisGlobal's Safety Cloud allows sponsors to outsource these functions, while simultaneously achieving high availability and up-to-date regulatory compliance. Bioclinica's safety case reporting leverages ArisGlobal Safety Cloud features.

What are the current challenges of pharmacovigilance and the eClinical landscape respectively?

Getting all clinical research systems to work together so that the end user has the experience of using a single system is a major challenge. Another hurdle is how to leverage the richness of the data that comes with



Anne Zielinski is responsible for Bioclinica's App xChange, a programme offering clinical researchers and patients innovative technologies and services that complement Bioclinica eHealth offerings. A pioneer in the field, Anne brought an early EDC system to market at CB

Technologies, and spent the last 10 years with Medidata, where she designed, built and grew a successful technology partner programme. She has a BS in Biology from Edgewood College, and an MBA from the Wharton School at the University of Pennsylvania.

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predictive analytics and machine learning to extract insights for improved quality in the overall research process.

Bearing in mind the benefits of eClinical solutions, are there any disadvantages/issues that need to be considered?

Innovative eClinical solutions hold promise to yield even greater value than they do now, but sponsors' concern over regulatory acceptance can impede adoption. Our industry will greatly benefit from sponsors and regulators working more closely to explore and implement the full capability of technologies. At the end of the day, it is about a shared goal to improve research efficiency and productivity, while protecting patients at the same time.

What is next in the pipeline?

More robust and predictive analytics incorporated in smart ways in the planning and conduct of trials; leveraging mobility to reduce subject time at the site and to enhance data comprehensiveness; and increased fluidity and ease in the user experience.

What do you think clinical trials will look like in 10 years' time?

While clinical research will continue to be carried out rigorously, the apparent differences between clinical research and routine care will become blurred. Smaller and smaller cohorts will be analysed as more data – genotypic, phenotypic and behavioural – allow for greater population segmentation.