Using EHRs for Research

An Interview with Susan Mitchell, RN, Florida Hospital

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Using EHRs for research is not a thing of the future. It is being done in the present. Read below about the success Florida Hospital has had in utilizing EHRs for research.

On 19 June, CDISC (Landen Bain, CDISC Liaison to Healthcare) participated in a meeting with representatives of FDA Office of Scientific Investigation, CDER, where Susan Mitchell, Senior Manager of Research Information Systems at Florida Hospital, spoke about how her organization is already utilizing EHRs for research. Jane Griffin from Cerner and representatives from Quintiles also participated in this meeting at FDA. FDA representatives who attended this meeting were very pleased with this progress and the opportunity that is afforded by using EHRs for research, including the ability to support ‘auditing/monitoring from afar’.

Later, we had the additional advantage to speak to Ms. Mitchell personally about the success Florida Hospital has seen in this regard. Ms. Mitchell is a Registered Nurse by training, and has spent almost all of her career in clinical research. She was brought into MIS (Management Information Systems) at Florida Hospital to develop its research IT infrastructure, with the vision to pilot this infrastructure within a single research institute and ultimately roll it out to the entire research enterprise. This is accomplished through incorporating research documentation into the existing EHR, when appropriate, and leveraging clinical trial solutions that integrate with the EHR, creating an “RFD type” of workflow. Just two weeks ago, Florida Hospital officially launched this integrated workflow. (Note: RFD or Retrieve Form for Data Capture is the integration profile developed by CDISC and IHE to integrate research workflow into the EHR setting.)

When prompted to describe the benefits of using EHRs for research, Ms. Mitchell stated that a key driver is human subject protection/safety. The EHR enables greater opportunity for complete and accurate eligibility assessment, improved adverse event monitoring, and better communication among the study team as well as with those outside of the study team providing clinical care.

Ms. Mitchell described how Florida Hospital is continually finding the benefits of integrating the EHR with clinical trial solutions. “We were able to document research without rebuilding the EHR each time—this was something that was inspired by CDISC, and it allows us to document seamlessly without interrupting the workflow,” she stated.
This case study of the Florida Hospital and how they are currently using their Cerner EHR for a research study was presented by Jane Griffin at DIA Session on 26 June in Philadelphia. During this session, a Challenge was issued by CDISC, FDA and HHS/Office of the National Coordinator for a sponsor to conduct a multi-center study using EHRs for regulated research. Watch for additional information about this!

A more in-depth article focusing on recent breakthroughs and future aims for EHRs in research will be also be announced soon through the CDISC website; this article will include a more comprehensive look into how Florida Hospital accomplished their EHR integration and what is now feasible using RFD and other IHE integration profiles developed by Landen and his colleagues through the IHE QRPH (Quality, Research and Public Health workgroup). Please stay tuned for details!