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Suzanne Bishop

eClinical Forum, USA

Clinical research site e-Source Readiness Assessment tool (eSRA) – A free tool to assist sites in determining if their systems are ready for regulated clinical research data

The eClinical Forum – a non-profit, non-commercial discussion/action group comprised of members of the Pharmaceutical and Clinical Research Services industry have developed a regulatory-based assessment tool for EHR vendors or sites to determine if their EHR system is appropriate to hold regulated clinical trial data. This tool will help make the clinical research process more efficient, while furthering the use of EHR records for clinical research. It is offered free; there are no advertisements on the website and your information will not be used for other purposes. The eClinical Forum's only intent is to make the process more efficient for everyone. Through the use of the eSource Readiness Assessment Tool (eSRA), EHR vendors can provide information to their customers who do clinical research, to help these clinical research sites determine if they are meeting regulations. The clinical research sites are already being asked these questions by their clinical research sponsors (pharmaceutical companies) and it can be timely to complete a different form for each research sponsor. By using the eClinical Forum tool, the site can complete just one assessment and give it to each of their sponsors. We have already shown this tool to regulators and had a favorable response – some are even presenting it at industry conferences. The more EHR vendors participate, the easier it is for their sites to participate and the more sites that participate, and the easier it is for their sponsors to participate. If everyone uses this assessment form then it really does become a highly efficient way to gather the information that regulators want – information that shows that the systems that may originate data that could end up in a clinical trial has integrity.

Biography

Suzanne Bishop is the North American Facilitator for the eClinical Forum, a non-profit global discussion and action group representing members of the pharmaceutical, biotechnology, and allied industries focusing on electronic capture, handling, and submission of clinical data. Recent projects have focused on Electronic Health Records for Clinical Research. She was the project manager of the EHRCR project which resulted in an HL7 and ANSI Standard Functional Profile and a EuroRec-approved profile, and the eSource Readiness Assessment (eSRA) tool. She holds an MA in Organizational Leadership and a BS in Computer Science and has worked for the past 30 years in the area of software application support for clinical research.

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