The Heart of Clinical Research Lies in the Attention to Quality, Regulations and Training For Ultimate Patient Safety in Today's Digital Era

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Abstract

Clinical Research is ever evolving as we move further into this digital era. What can we do to keep patients and researchers focused on ethical principles while using e-source, e-consent, e-regs, and e-everything? Furthermore, how do we train and engage new, young investigators on the key aspects of the lifecycle of a clinical trial? Research sites and Sponsors have to be more vigilant of the regulations surrounding patient safety as in-person site visits diminish, especially the informed consent visit where face-to-face, patient-to-physician interaction occurs via the web for many sites. For us that have a complete understanding of clinical research today, where understanding translates to knowing all the ins and outs surrounding robust protocols, paper source documents, a 25-page informed consent process, contracting, budget negotiations and Institutional Review Board (IRB) responsibilities, we can really say that we are industry experts to have seen research migrate away from being 100% on paper. Now, we rely on the highly qualified research professionals, the FDA/EMA, and the IRBs to ensure research safety, effective enrollment strategies, and investigator oversight that all together yields patient safety. We are all patients whether we volunteer to take investigational drugs or we take some of the same approved drugs post market. Drug discovery must stay ahead of today's modern diseases, and for this, ethical and highly compliant clinical research is key.

Biography: Claudia Gomes completed her Master's in Cell and Molecular Biology at the age of 25 from New York University. Claudia has 12 years of experience in the research field where she started her research career in a Phase I unit. She moved on to do Phase II-IV research at Envision Healthcare (formerly Sheridan Healthcare), a physician-management organization. She has published a research white paper, won a first place award for best innovative research project, and directed over 400+ clinical trials in her career.

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