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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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.

Recent Publication:

1. Emmanuel Ameyaw, Serwah B Asafo-Agyei, SumithiraThavapalan, Angela C Middlehurst, Graham D Ogle (2017) Clinical profile of diabetes at diagnosis among children and adolescents at an endocrine clinic in Ghana. World J Diabetes 2017; 8(9): 429-435. DOI: 10.4239/wjd.v8.i9.429
2. Ameyaw E, Asafo-Agyei SB, Rhule GP (2017) Spectrum of Diseases seen on Neonatal Ward at KomfoAnokye Teaching Hospital, Kumasi, Ghana. Pediatric Infect Dis. 2017; 2 (3):1-4.
3. Asafo-Agyei S, B, Ameyaw E, Chanoine J, -P, Zacharin M, Nguah S, B, Jarrett O, O (2017)Anogenital Distance in Term Newborns in Kumasi, Ghana. Horm Res Paediatr. 396-400. doi: 10.1159/000479689
4. Rowlands A, Ameyaw E, Rutagarama F Joel D et al (2018) Insights from the WHO and National Lists of Essential Medicines: Focus on Pediatric Diabetes Care in Africa. Horm Res Paediatr, DOI: 10.1159/000490467

5. Ameyaw E, Asafo-Agyei SB, Hughes IA, Zacharin M, Chanoine JP (2019)Incidence of disorders of sexual development in neonates in Ghana: prospective study. Arch Dis Child. 104(7):636-638. doi: 10.1136/archdischild-2019-316986.

II. Biography (Up to 100 words)

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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