Stephen P Arneric, J Genet Syndr Gene Ther 2016, 7:5 (Suppl)
http://dx.doi.org/10.4172/2157-7412.C1.009

Digital measurements of health-regulatory science challenges opportunities in rare diseases

Stephen P Arneric
Critical Path Institute, USA

Interest in identifying, evaluating and qualifying innovative technologies for use in drug development is growing. While FDA guidance documents exist for pursuing novel Drug Development Tools (DDTs) and Medical Devices Development Tools (MDDTs) for qualification, the use of Digital Measurements of Health (DMH) (i.e., measured biological events or patient function captured through a device or sensor technology) for use in clinical development remains ill-defined. FDA issued in 4Q2015 a Federal Register request for comments that could accelerate the assessment of innovative drug treatments. The Coalition Against Major Diseases (CAMD), a consortium within the Critical Path Institute, aims to accelerate the development of tools that increase the efficiency of delivering innovative treatments for Alzheimer's Disease and related neurodegenerative/Rare Diseases that impair cognition and function. This presentation highlights CAMD's perspective on use of DMHs as drug development tools, the challenges faced and the need for; Data standards: Consensus on standardized ways to record, structure and report data generated by digital biosensors, employing CDISC standards to provide the consistent data model/structure to enable data sharing across technology platforms; DMHs as drug development tools: Development of standards for validating the analytic performance of devices; and Context of Use (COU) statements: Implementation of COU statements based on the current state-of-evidence for their application in drug development. CAMD's perspective supports the use of DMHs in clinical trials for; Function: Electronic monitoring of activities in/outside of home (patterns of sleep, drug adherence, walking, social interactions via phone and computer, cognitive task assessments) and fine motor skills (e.g., typing or key stroking on computer/smartphone); and Physiological measures: ECG, EEG, movement (accelerometer), speech/voice analysis, etc. Having open/frequent dialogue with regulators is critical to shape the development, validation and clinical relevance of this research.

Biography

Stephen P Arneric has joined the Critical Path Institute as Executive Director of the Coalition Against Major Diseases (CAMD), a consortium focused on developing Drug Development Tools for advancing innovative treatments of Alzheimer's disease and related dementias in 2015. Previously he was VP Research/Preclinical Development (Neuromed Pharmaceuticals), CSO of the Pain/Migraine Drug Hunting Team (Lilly) and held senior management positions at Pfizer, Pharmacia, DuPont Pharmaceuticals and Abbott. He has extensive leadership and scientific expertise in the areas of neurology, pain, psychiatry and urology and over the last 25 years his teams have delivered more than 30+ drug candidates into clinical development. He has earned BS degree in Physical Sciences from Michigan State University and PhD in Pharmacology from University of Iowa, USA. He is an accomplished author with 145 peer-reviewed articles, 190 abstracts, 17 chapters, 1 book & numerous IND submissions and is Co-Inventor of 15 patents. He is also the President of Horizons Pharma Consulting, LLC.

sarneric@c-path.org

Notes: