Extended Abstract Pediatric Dental Care 2019
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Current Challenges in Clinical Trials

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We take extreme pleasure to uphold that Journal of Clinical Trials had a promising journey since its inception and is being hailed as a revolutionary in the industry of open access journals. We appreciatively give thanks to all our marvelous Authors, Reviewers, teamed with the assistance of our honorable Editorial board members has played a major role in our success for creating Clinical Trails 2019 the simplest ever! Benevolent response and active contribution was received from our authors of various fields of Clinical Trials Design & Methodology, Outsourcing in Clinical Trials, Adaptive designs in Clinical Trials, Imaging in Clinical trials, who made this a grand success. Scientific people from all over the globe focused on learning about emerging technologies about Clinical Trials and Advanced Drug Design Technology in the latest application. This is a best globalized opportunity to reach the largest assemblage of researchers from the scientific community and research. Clinical Trials includes Phases of Clinical Research: Current Trends & Future Developments, Clinical Trials Design & Methodology, Future of Clinical trials & Clinical Research, Clinical Trials Supply & Management, Clinical Research Operations & Project Management, Outsourcing in Clinical Trials, Risk Management in Clinical Research & Clinical Trials, Risk Management in Clinical Research & Clinical Trials, Patient Recruitment & Site Selection in Clinical trials, Adaptive designs in Clinical Trials, Clinical Trials Budgeting & Financial Management, Clinical Trials Data Disclosure & Data Transparency, Imaging in Clinical trials, Challenges in Clinical Trials, Data & Technology Driven Clinical trials, Interactive Response Technology (IRT) in Clinical Trials, Clinical Trials for various Diseases, Pharmacovigillance and Drug Safety, Clinical Trials for Medical Devices, Clinical Trials Regulations, Bioethics and Regulatory Compliance in Clinical trials. In Clinical Trials 2019, most of the topics were about the current problems and the long-term solution to it. It does not just talk about the now, but what's in store for the upcoming years in Clinical Trials field. This event had given readers a several ideas on the current trends and how to utilize them to their own advantage. The 9th volume addressed the deep-seated research done by authors from across the globe. In his research study, Carlijn M Van Der Aalst, et al., stated that his study describe the rationale, study design, and the recruitment process of the Dutch Risk or Benefit in Screening for Cardiovascular Disease (ROBINSCA) trial, worldwide the first population-based randomizedcontrolled Computed-Tomography (CT) screening trial for cardiovascular disease, powered to detect a benefit of 15% reduced Coronary Heart Disease (CHD) morbidity and mortality [1]. Supriya H Raut, in her research article promulgated about the THROZEN (Cough lozenges formulation) having herbal ingredients used for sore throat and cough mainly contains Anacyclus pyrethrum, zinc and menthol. Anacyclus pyrethrum is effective against sore throat as well as cough, dry mouth and redness of throat. In the present study, clinical evaluation of THROZEN cough lozenges has been done in human subjects [2]. Raquel Ciervide, et al., in their research article, reaching a complete pathological response (pCR) after primary systemic treatment (PST), specifically in the subgroup of patients with triple negative (TNBC) or HER2-positive tumors, is associated with a significant survival gain. The combination of chemotherapy and radiotherapy could increase this synergistic benefit [3]. Mahmoud Reda Badr, et al., in their case report, presented Leiomyoma is a benign tumor of smooth muscle cells that may arise from the genitourinary or gastrointestinal systems. It is not common to arise from the urethra or Para urethral areas with few reported cases [4]. Abdullah Al Wahbi, in his research article, presented Saphenous varicosities, from Great Saphenous Vein (GSV) and Saphenofemoral Junction (SFJ) are treated by surgery or Endovenous Laser Treatment (EVLT). To treat tributaries, secondary procedures (foam Sclerotherapy or multiple phlebectomy) are used concomitantly as one-stage or sequentially as two-stage procedure [5].

Toshihiko Masui, et al., in their research article, they diagnosed and the treated patients with neuroendocrine neoplasm (NEN) have recently improved globally. Since little data has been presented on the current situation of NEN treatment in Japan [6]. With the grand success of Clinical Trails 2019, enclosed a large vary of scientists as editorial board, reviewers, and authors. The Clinical Trails 2019 anticipates renowned eminent researchers across the globe to share their valuable presentation and galvanize the scientific community in upcoming issues.

PRIORITIZING OF CLINICAL RESEARCH QUESTIONS

Fewer than half of all the medical treatments delivered today are supported by evidence (IOM, 2007), yet the United States lacks a clear prioritization of the gaps in medical evidence and an allocation of clinical research resources to efficiently and effectively fill these evidence gaps. The federal government, industry, academic institutions, patient advocacy organizations, voluntary health organizations, and payers each have incentives to develop research questions that suit their unique interests. The value of a particular research effort is judged by stakeholders according to their own cost–benefit calculation. Reflecting the diversity of stakeholder value judgments, and in the absence of a broad national agenda, clinical trials are conducted in a "one-off," narrowly focused fashion.

Because clinical trials are necessary to obtain regulatory approval in the United States, they are a high priority to companies. It was noted by a number of workshop participants that the prioritization of clinical research questions by companies seeking regulatory approval is distinctly different from the priorities of society in general, which may prioritize the comparison of two commonly used therapies. This divergence between the priorities of society and industry is notable as the nation discusses how to address the current gaps in clinical research and medical decision making.

As an example, in investigator-initiated research, academic investigators seek federal funding (primarily from the National Institutes of Health [NIH]) to conduct research they deem important to advancing science and/or medical practice. But James McNulty, Vice President of Peer Support for the Depression and Bipolar Support Alliance (DBSA), believes the NIH peer review process for research grants is inherently conservative and fails to reward innovative research into areas about which little is known. McNulty believes this conservative approach has contributed to serious gaps in knowledge in the area of mental health, specifically in schizophrenia, depression, and bipolar disorder. In terms of formulating relevant research hypotheses, the U.S. Department of Veterans Affairs (VA) was cited as one example of a health system that successfully engages practicing physicians in noting potential research questions that arise in the day-to-day care of patients. The VA Cooperative Studies Program works to ultimately take physicians' questions into the clinical trial setting.

Industry-sponsored trials are conducted largely to gain U.S. Food and Drug Administration (FDA) approval to market a new drug or a previously approved drug for a new indication. Preapproval trials include a simple protocol (i.e., ask a limited number of questions) and test a drug in a highly selected patient group designed to provide the most robust evidence on the drug's benefits and risks. Conversely, the federal government conducts large clinical trials to answer medical questions unrelated to gaining regulatory approval for a new drug or therapy. These studies can involve a wide range of patients and seek to answer a number of relevant clinical questions at once. Several presenters in the diabetes session of the workshop suggested that government-funded clinical trials for diabetes would not be conducted by industry or other sectors. New therapies for type 1 diabetes are often of limited interest to pharmaceutical companies because of the small patient population, whereas drugs for the exponentially larger type 2 diabetes population are avidly pursued.

The beginnings of a coordinated prioritization of research needs can be seen in the recent increased interest in comparative effectiveness research (CER). To enhance the ability of clinical research to generate knowledge that can better inform clinical practice, Congress included in the American Recovery and Reinvestment Act (ARRA) of 2009 an allocation of $1.1 billion for federal agencies (the Agency for Healthcare Research and Quality [AHRQ], NIH, and the Department of Health and Human Services [HHS]) to jumpstart the national CER effort. CER seeks to identify what works for which patients under what circumstances, providing evidence about the costs and benefits of different medical options. One-third of ARRA funds ($400 million) were designated as discretionary spending by the Secretary of HHS to accelerate CER efforts. The Institute of Medicine (IOM) was tasked with recommending national CER priorities to be supported with these discretionary funds and to guide the nation's creation of a long-term, sustainable national CER enterprise.2 Recently enacted health care reform legislation (Patient Protection and Affordable Care Act passed in March 2010) created the Patient-Centered Outcomes Research Institute (PCORI)—a nonprofit institution positioned outside the federal government to define and execute comparative effectiveness research methods.

Several speakers and workshop participants raised questions about the ability of the current clinical trials system, which is already showing signs of strain, to absorb a substantial amount of the anticipated CER studies. Many voiced concern regarding the overall organization of clinical research in the United States: how it is prioritized, where it is conducted, who oversees it, how it is funded, who participates, and who staffs it. Presenters and participants also described the diminished capacity of the current clinical trials system. These observations, and proposed solutions, informed the discussion over the course of the 2-day workshop