Clinical Trials 2017

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Scientific Tracks & Abstracts

Day 1

Oleg V Tcheremissine et al., J Clin Trials 2017, 7:5 (Suppl)
DOI: 10.4172/2167-0870-C1-019

Developing an Alzheimer's clinical trial network with the Carolinas healthcare system, a large fully integrated health care system

Oleg V Tcheremissine and **James C Rachal**
Carolinas HealthCare System, USA

Alzheimer's disease (AD) is a progressive neurogenerative disorder with a wide range of symptoms affecting memory, concentration, volition, and almost all aspects of human behavior. The prevalence of patients with AD is increasing due to an aging population. There is real possibility that without medical breakthroughs, the current 5.3 million Americans diagnosed will triple to 13.8 million by 2050. Delivery of compressive care is facing a crisis stemming from a combination of factors like the growing demand for such care, insufficient number of those specialized in this therapeutic area, rising costs of care, the complexity of the diseases and lack of effective treatment. Despite massive research efforts in recent decades, new treatments for AD remain elusive. Since 1998, there have been more than 100 attempts to develop new pharmacological agents, and all have failed. Patient population included in these clinical trials typically suffered from mild-moderate AD. Most of them were initially diagnosed and treated by their primary care providers. Early identification of a cohort of those who will benefit from clinical trial participation by is a strategic priority. CHS has made an investment in developing a comprehensive dementia care though a collaboration of different service lines including Neurosciences, Behavioral Health, Primary Care and Geriatrics. This bidirectional reciprocity allows aligning the process of drug development with information derived at the point of care, and provides an opportunity to further breech the efficacy-effectiveness gap, commonly defined as the differences between two populations of patients, those enrolled in clinical trials and those who will be treated in real clinical settings.

Biography

Oleg V Tcheremissine, MD, is a Professor of Psychiatry and Research Director for the Carolinas HealthCare System Department of Psychiatry and Behavioral Sciences. He is a board-certified Psychiatrist and Clinical Investigator with more than 25 years of medical and more than 20 years of research experience in human behavioral and clinical psychopharmacology. He has successfully combined his research interest, teaching, clinical, and administrative responsibilities while focusing on eliminating external and internal barriers to development of novel and innovative treatments with the overall goal of reducing health disparities, improving access to care and increasing the generalizability of clinical trials results.

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Notes:

David Vulcano, J Clin Trials 2017, 7:5 (Suppl)
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Current events in pre-approval access in the United States

David Vulcano
HCA Healthcare, USA

Over the past several years there has been a resurgence of efforts to gain access to investigational products outside of clinical trials. Previously failed attempts a decade or so ago at the federal judicial level has turned advocates' strategy to pushing states to pass variants of so-called "right to try" laws in an effort to circumvent the FDA's expanded access policies. Over the past several years, a majority of states have now done so. While ethicists debate the battle of the good vs. the good of this kind of access, and lawyers debate the state's rights to have these kinds of laws, the FDA and the advocates debate their respective track records. Nevertheless, the issue has gotten the attention of the federal legislators through passed acts as well as putting forth proposed legislation for a national Right to try Act. With the current congress and the executive branch leaning towards the advocates' position, it is likely that we will see continued movement. This session provides a comparison of the varying state "right to try" laws and summaries of the most recently passed and proposed federal laws related to this topic.

Biography

David is a well-known leader and change agent in the clinical research industry. He was born and raised in New Orleans, Louisiana. He has a Masters degree in both Social Work and Business Administration and holds the additional status of Certified IRB Professional (CIP) and Regulatory Affairs Certification (RAC). He is the Responsible Executive for Clinical Research for Hospital Corporation of America (HCA). He is and has been in many industry leader roles both in the United States and globally, including Chair of the Board of Trustees for the Association of Clinical Research Professionals (ACRP). He is also the President of the Nashville Angel Capital Group. He is married with 2 children and lives south of Nashville, Tennessee where he involves himself in work, family life as well as other charitable and entrepreneurial opportunities. David was recently honored with the "Outstanding Speaker" award, presented at the 2015 MAGI West conference.

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Notes:

Valerie G Sams et al., J Clin Trials 2017, 7:5 (Suppl)
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Spontaneous hyphema in patient proned for acute respiratory distress syndrome

Valerie G Sams, Heather M Hancock, Irene Folaron zAaron D Grant
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Hyphema is blood that is grossly visible in the anterior chamber of the eye and can cause permanent vision loss. It is a rare complication that usually occurs after ocular trauma. Spontaneous or nontraumatic hyphema may result from underlying bleeding disorders, anticoagulation or antiplatelet medications, vascular malformations, ocular abnormalities, closed-angle glaucoma, sickle cell anemia, acute leukemia, rheumatologic disorders, or lymphoma. Rarely, spontaneous hyphema may present after non-ophthalmic surgery due to intra-operative heparin administration, coagulopathy, severe hypertension, or during emergence from anesthesia. Here we present a case of a man with acute respiratory distress syndrome (ARDS) as a result of Influenza B infection who underwent lung protective mechanical ventilation strategy, sedation, paralysis, and prone positioning to assist with oxygenation. This is the first reported case of non-traumatic hyphema in a patient undergoing prone positioning as part of the management of ARDS. We postulate that the patient's thrombocytopenic state coupled with the increased venous drainage pressure in the eyes from the face-down prone positioning likely led to his development of bilateral spontaneous hyphemas. Positioning his head to the side normalized venous drainage pressure and allowed rapid reabsorption of the anterior chamber blood. Hyphema should be considered a potential complication of prone positioning in patients with ARDS, especially in patients with a concomitant bleeding diathesis. In our patient, early recognition and medical intervention led to complete resolution. Ophthalmology evaluation and management is important for successful recovery.

Biography

Valerie G Sams has completed her fellowship in Trauma and Surgical Critical Care at San Antonio Military Medical Center (SAMMC), San Antonio, Texas in 2015. She is a Trauma and General Surgeon at SAMMC and an extracorporeal membrane oxygenation (ECMO) provider. She has published more than 15 papers in reputed journals and is active in multiple funded research projects.

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Notes:

Richard Entsuah, J Clin Trials 2017, 7:5 (Suppl)
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A new class of distribution-free models in analysis of adverse events in drug safety

Richard Entsuah
Merck Research Laboratories, USA

In the area of pharmaceutical drug safety, one of the primary goals in analysis of adverse events (AEs) is to detect any signal of a difference between the treatment and control groups. Traditionally, crude incidence rate, chi-square test or Fisher's exact test, and Miettinen and Nurminen are the useful methods in analysis of single AE data depending on what level of importance it belongs to, such as Tier 1, Tier 2, or Tier 3, which were defined by Merck. Actually, the occurrence of AEs is very complicated. Simple measurement of AE data without enough information including duration effect, severity effect, or recurrent event, the estimation and inference could be biased. Moreover, multiple AEs within the same system organ class (SOC) are usually correlated with each other. So analysis of single AE over simplifies comparison among treatment arms in drug safety. In this presentation, we would like to propose a new class of distribution-free approaches to address the effects of duration, severity, and recurrence of AE data by using a new measurement within certain specified class. The good asymptotic properties and robustness for the proposed models have been shown in this study. The numerical simulation studies and a case study example are provided for illustrations.

Biography

Richard Entsuah is a Fellow of the American Statistical Association. He completed his PhD from University of Michigan. He was an Assistant Professor of Biometry at University of Illinois in Chicago. He joined Wyeth Research from 1988 to 2007 and left as an Assistant Vice President of Global Biostatistics and Programming. He joined Merck Research Labs as Executive Director of Late Development Statistics and is the Research Group 4 Head for Neuroscience and Respiratory Immunology.

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Notes:

JoAnn Pfeiffer, J Clin Trials 2017, 7:5 (Suppl)
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Management of clinical trial agreements

JoAnn Pfeiffer
Arizona State University, USA

Clincal trial agreements are legal and binding, forming the foundation for a successful partnership between study sites and sponsors. Not understanding the legal language and the terms of the contract can lead to financial and legal ramifications for the site, the investigator, and study staff. Terms and language of the contract will be reviewed focusing on risk areas and protecting the site. Through interactive activities participants will review and revise contract language to meet the needs of the site. Proper management of contracts includes knowing what you are agreeing to, prioritizing site needs, and utilizing site metrics and successful strategies to negotiate a fair and balanded contract. Strategies include redlining contracts with preferred language, naming and version control, reviewing related study documents for consistency, contract definitions, addressing the responsibilities of the contract parties, and asking questions for clarification. The session will finish with contract tips.

Biography

JoAnn Pfeiffer has completed her Doctorate of Science, in Regulatory Science from the University of Southern California. She is currently the Director and an Associate Professor, in the Clinical Research Managment Graduate Program at Arizona State University. She has published several books related to managing contracts and budgets in clinical trials, conducting clinical trials at study sites, as well as articles in peer reviewed journals. Her expereince includes over 20 years in the management of clinical trial operations in both academic and non-academic settings.

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Notes:

Manuel A Castro, J Clin Trials 2017, 7:5 (Suppl)
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Utlizing emerging virtual care methods to improve access to behavioural health services within the ambulatory care setting

Manuel A Castro
Carolinas HealthCare System, USA

In March 2014, the Behavioral Health Service Line within Carolinas HealthCare System launched a transformative integrative care model utilizing virtual and population health management tools to reach out to patients with behavior health symptoms through ambulatory care settings (primary care, internal medicine, and pediatric clinics). The goal of the collaborative care initiative is to improve access to behavioral health services by providing evidence-based, innovative, timely, seamless and coordinated care that meets patients' individual needs; by increasing the detection of mental illness through appropriate screening; increasing access to behavioral health coaching; providing treatment and medication oversight, improving clinical outcomes; strengthening relationship with ambulatory care providers; decreasing avoidable healthcare utilization and achieving higher rates of treatment adherence; while decreasing the overall cost of care overtime. In 2016, the program achieved a dramatic 43% decrease in depression (PHQ-9) and 38% decrease in anxiety (GAD-7) symptoms scores. 49% of the patients achieved 50% or more reduction in their raw depression scores as a result of telephonic health coaching. Over 80% of the program participants with suicidal ideations at baseline denied suicidal ideations at the completion of the program. Through implementation of the virtual model, ambulatory care clinics have immediate access to behavioral health services via video technology and other resources. Thus, assessment and treatment planning can begin immediately, and follow-up care can be coordinated between the behavioral health team and medical providers all in one visit.

Biography

Manuel A Castro has been with Carolinas Healthcare System for 9 years and serves as the Vice-Chief Department of Psychiatry, Medical Director of Behavioral Health Integration, and Assistant Medical Director of Outpatient Medication Services. In 2016, he was honored to become a Fellow for the American Psychiatric Association. He leads the Behavioral Health Integration team in servicing ambulatory care practices across the healthcare system through a virtual platform. He is Board Certified in Adult Psychiatry. He is the recipient of the Brian R Nagy MD teaching award at CMC-Randolph and is an adjunct Associate Professor of Psychiatry with UNC-Chapel Hill.

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Notes:

Sarah Attwood et al., J Clin Trials 2017, 7:5 (Suppl)
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Final revisions to the common rule-How will this affect human subject protection?

Sarah Attwood and **Melanie Flores**
IntegReview IRB, USA

Have you considered how the revisions to the common rule may affect your next research project? There are a number of questions circulating on how these changes will be implemented effectively and efficiently within the academic communities and other institutions, but also the impact that they may have on all industry sponsored research. Important elements in the final rule issued include: The requirement for consent forms to provide potential research subjects with a better understanding; requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies; for studies on stored identifiable data or identifiable biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement; the establishment of new exempt categories of research based on the level of risk they pose to participants; removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects and requirement that consent forms for certain federally funded clinical trials be posted on a public website. This session will look at the changes and discuss the impact on human subject protection, informed consent for research sites and IRBs.

Biography

Sarah Attwood has over 20 years of experience in Operations and Business Development in clinical research and is currently Director of Client Services at IntegReview IRB. Prior to joining IntegReview, she was the Vice President for a research site organization. She was responsible for the clinical operations of their multiple Phase I – IV clinical research sites and developing the CRO business to provide project management and monitoring services. Prior to management, she has held various positions including Clinical Research Coordinator, CRA, Project Manager and Consultant for CROs and Sponsors and has a background in hospital research, pharma, medical devices, nutraceuticals and biotech.

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Melanie Flores is the Vice President of Compliance and is responsible for the daily leadership, management and full responsibility for the Company's compliance program. She has worked in the IRB industry since 1999 and has been with IntegReview since 2001. Prior to leading the Regulatory Compliance Department, her main focus for 9 years was spent providing training to IRB staff and IRB members to ensure compliance with Federal Regulations, ICH Guidelines, IntegReview IRB Standard Operating Procedures and standards of the AAHRPP.

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Chris Chan, J Clin Trials 2017, 7:5 (Suppl)
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Exploration of common pet peeves within the sponsor/CRO relationship

Chris Chan
FibroGen, Inc., USA

Like many marriages, the sponsor/CRO relationship is often fraught with strife and adversity. These conflicts typically center around issues including lack of good communications, misaligned expectations, and other common challenges. This presentation explores common pet peeves frequently observed and experienced by both sides. Real-life case studies/anecdotes from various companies will be used and respective conflicts and resolutions will be examined in detail. Common lessons learned that may be applied to current and future sponsor/CRO relationships will be discussed.

Biography

Chris Chan is an Executive Director of R&D Finance at FibroGen, Inc., and has over 25 years of industrial experience, including 20 managing clinical trial and R&D finances for biopharmaceutical companies of various sizes. He holds an MBA from UC Berkeley's Haas School of Business and is a Certified Management Accountant (CMA) and Certified Financial Manager (CFM). He served as speaker and chair at numerous industry conferences, and has authored multiple published articles on clinical trials budgeting, accruals, and outsourcing.

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Notes:

Brian M Toglia, J Clin Trials 2017, 7:5 (Suppl)
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Insurance considerations for global clinical trials

Brian M Toglia
Tanner-Ibbotson, Inc., USA

A key component of international clinical trials that is often overlooked is insurance considerations for the country where the study will be performed. Failure to comply with jurisdictional or IRB insurance requirements can delay approval for the start of a trial. In drug development, any delay could cost the sponsor millions of dollars. Having the proper insurance program structure is also critical to avoid any gaps in protection. Working with a qualified insurance broker that has key relationship with global insurance companies is critical. A proactive approach and understanding of the parameters of insurance procurement for global clinical trial will produce a well-managed clinical trials insurance process as it relates to efficiency, affordability, protection and ease of administration.

Biography

Brian M Toglia is Principal and Vice President at Tanner-Ibbotson, Inc., an insurance brokerage located in the Northeast part of the United States. With a focus on providing insurance solutions for pharmaceutical and medical device companies, he brings over a decade of experience in the industry. His practice helps companies procure insurance both domestically and internationally. He holds a Bachelors' degree in Business Administration and Political Science from Pepperdine University in Southern California.

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Notes:

Michael Zeitlin, J Clin Trials 2017, 7:5 (Suppl)
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Using interactive 3D visualization for rapid discovery of "hidden" outliers and correlations in clinical trial studies

Michael Zeitlin
Aqumin LLC, USA

As precision medicine advances, a dramatic increase in data collection, complexity and analysis is occurring. Traditional statistical techniques employed to hunt for relationships between parameters will be more tedious than ever and exploratory analysis of novel datasets could miss answers to important questions one didn't even know to ask. An innovative approach using interactive 3D visualization is presented showing outlier identification and rapid iteration over investigative questions with multiple datasets. The mind's eye is a powerful pattern recognition machine that can detect subtle changes in data when it is presented as 3D geometry using color and motion. The observer can quickly see through the complexity to identify patterns and anomalies, empowering investigators to discover the right questions to ask. Interactive 3D visualization techniques which draw data as geometry with relative movement enable finding answers quickly. Datasets can be merged, re-arranged and displayed on-the-fly while the eye is watching. A single solitary outlier can be detected and understood while observing millions of data points. Software to perform this rapid data ingestion, integration and display now exists which can help process huge datasets effortlessly. A live example will be presented.

Biography

With over 30 years experience in scientific and business computing Michael is a recognized leader in visualization technology worldwide. He created the oil industry's first commercial 3D visualization center. He received the Carnegie Mellon and American Management Institute Award for Innovation in Information Technology. His work was honored with a permanent position in the Archives of the Smithsonian Institution. He founded Magic Earth, LLC. in 2000, and as Chairman and CEO, achieved profitability in three months and was acquired by Halliburton that same year for $100 million. Michael holds a B.Sc. in Earth and Space Sciences and M.Sc. in Marine Environmental Science from the State University of New York at StonyBrook.

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Notes:

Lauren E Ballina, J Clin Trials 2017, 7:5 (Suppl)
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Re-inventing the entry-level clinical research coordinator

Lauren E Ballina
Clinical Research Fastrack, USA

The varying level of knowledge, competency, and professionalism of clinical research coordinators at the site level is problematic in clinical research. The role of clinical research coordinator (CRC) is a technical position requiring working knowledge of ICH GCP and the code of federal regulations. CRCs are required to collect and document data appropriately and accurately. Their work can have direct impact on the efficiency and quality of a trial. Of 60 current clinical research professionals surveyed, 4 (7%) reported purposefully seeking a position in clinical research. The remaining 56 reported that they fell into clinical research and stayed because the field is so rewarding. All reported on the job training in their entry-level position as inconsistent and incomplete. Many felt overwhelmed in their first position and that experience and mistakes have been their best teachers. Clinical Research Fastrack (CRF) has sought to standardize entry-level training for CRCs. By delivering a robust curriculum focused on ICH GCP, code of federal regulations, protocol, good documentation practices, adverse events, protocol deviations, clinical trial operations, participant recruitment and retention, responsibilities of study team members including PI, informed consent, and research skills all coupled with a hands-on internship at a clinical trial site, CRF is re-inventing the entry-level CRC. Through training standardization and utilizing an innovative educational approach of massed practice CRF is helping transform the role of coordinator to a profession and not just a job. As more well-trained individuals obtain positions in the field, the industry as a whole will benefit.

Biography

Lauren E Ballina has a degree in Psychology and Master's in Biomedical Science. She is a SOCRA certified Clinical Research Coordinator. She coordinated clinical trials at the University of North Carolina at Chapel Hill and The Mayo Clinic Arizona. She is currently the National Program Director at Clinical Research Fastrack. She is a natural educator and passionate about making the field of Clinical Research a respectable profession and not just a job.

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Notes:

Scott Gelfand, J Clin Trials 2017, 7:5 (Suppl)
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Equipoise: The guiding ethical principle pertaining to randomized clinical trials

Scott Gelfand
Oklahoma State University, USA

In 1972, Charles Fried, in Medical Experimentation: Personal Integrity and Social Policy asserted that physician-researchers have an ethical obligation to be in a state of equipoise during all stages of randomized clinical trials. Fried's equipoise requirement dictates that a physician engaged in research must not believe that one experimental arm of a randomized clinical trial is better or more efficacious than the other arms (must be in a state of equipoise). Although the equipoise requirement has been modified over the course of the last 45 years, the equipoise requirement is currently the fundamental or guiding principle concerning the ethics of enrolling patients in randomized clinical trials. In this talk I will discuss the ethical foundation for the equipoise requirement, what is the current equipoise requirement and ethical/practical problems associated with the equipoise requirement.

Biography

Scott Gelfand received his Ph.D. in Philosophy from the University of Maryland and his J.D. from Georgetown University Law Center. He is a tenured professor and Head of the Department of Philosophy at Oklahoma State University. His research is focused primarily on issues in biomedical ethics and research ethics. In 2010 he received an NSF grant to develop a novel research ethics course for scientists and engineers.

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Notes:

Xichun Sun, J Clin Trials 2017, 7:5 (Suppl)
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Cancer metastasis: Enactment of the script for human reproductive drama

Xichun Sun
Virginia Commonwealth University School of Medicine, USA

In parallel to the appearance of primordial germ cells during early embryogenesis, the cancer reproductive saga starts with the separation of metastasis initiating cells (MICs) from cancer initiating cells when the primary cancer is still in its infancy. Prime MICs embark on a journey to the host bone marrow where they undergo further development and regulation. Migrating MICs are guided by the same CXCR4/CYCL12 axis as used in the migration of primordial germ cells to the genital ridge. Like the ovary, the host bone marrow features immune privileges, coolness, hypoxia and acidity which are essential for stemness maintenance and regulation. Opportune activation of the MICs via fusion with bone marrow stem cells triggers a frenzy of cellular proliferation and sets them on the move again. This scenario is akin to oocyte fertilization in the fallopian tube and its subsequent journey towards the decidum. Just as the human reproductive process is plagued with undesirable outcomes so is the cancer metastasis highly inefficient. The climax of the cancer metastatic drama (colonization) is reached when proliferating MIC clusters attempt to settle down on decidum-like premetastatic sites. Successfully colonized clusters blossom into overt macrometastases only after the execution of sophisticated immunomodulation, angiogenesis and vascular remodeling. Similarly, the implanted blastomere needs to orchestrate these feats before flourishing into a new life. What is more, the cancer reproductive drama seems to be directed by a primordial Hypothalamus -Pituitary -Gonad axis. Pursuing this reproductive trail could lead to new frontiers and breakthroughs in cancer research and therapeutics.

Biography

Xichun Sun is a practicing Surgical Pathologist and Cytopathologist. He graduated from medical school in China. He completed his PhD, Post-doctoral, Residency Training and Fellowships in the USA. His current research interest centers about cancer diagnosis, carcinogenesis and cancer metastasis. He is the author of one monograph and has proposed a new theory on cancer metastasis.

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Notes:

Mohsin Shaikh, J Clin Trials 2017, 7:5 (Suppl)
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Effective eCRF designing – Data management approach

Mohsin Shaikh
Axiom Real-Time Metrics, Canada

An effective eCRF design is always a key to the successful outcome of a clinical trial. The main objective is to offer improved data quality, online discrepancy management, faster database lock and at the same to time preserve and maintain quality and integrity of the data. eCRF design should be standardized to address the needs of all user roles enrolled within the clinical trials. Data should be organized in a format that facilitates and simplifies data analysis for submission. Review of the primary and secondary study end points as well as well-planned study design and safety/efficacy outcomes will assist the process of effective eCRF designing. Use of CDISC standards variables will also enhance the process of effective eCRF building. Effective measures taken while conducting eCRF design as well as post production changes (changes deployed on production environment of the eCRF design) will result in reduced query generations and improved data integrity. This presentation will also describe the methods of CRF designing in clinical research and discusses the challenges encountered in this process.

Biography

Mohsin Shaikh has completed his MD from MS University, Gujarat and Post-graduate studies from AAPS Toronto. He is a lead Clinical Data Manager at Axiom Real-Time Metrics, a premier clinical data management service organization providing expert solutions into the EDC/DM/IWRS sector. He has published more than 15 papers in reputed journals and has been serving as an Editorial Board Member of repute. He is an international medical graduate with more than eight years of experience in clinical research industry mainly in clinical data management.

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Notes:

Thiago Mamoru Sakae, J Clin Trials 2017, 7:5 (Suppl)
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Dexamethasone as a ropivacaine adjuvant for ultrasound-guided interscalene brachial plexus block: A randomized, double-blinded clinical trial

Thiago Mamoru Sakae
University of Southern Santa Catarina, Brazil

Objective: The purpose of this study was to evaluate the effect of intravenous or perineural dexamethasone added to ropivacaine on the duration of ultrasound-guided interscalene brachial plexus blocks (BPB).

Methods: Randomized Clinical Trial. Setting, Patients and Interventions: Sixty ASA physical status I–II patients with elective shoulder arthroscopic surgeries under interscalene brachial plexus blocks were randomly allocated to receive 20 ml of 0.75% ropivacaine with 1 ml of isotonic saline (C group, n=20), 20 ml of 0.75% ropivacaine with 1 ml (4 mg) of perineural dexamethasone (Dpn group, n=20), or 20 ml of 0.75% ropivacaine with 1 ml of isotonic saline and intravenous 4 mg dexamethasone (IV) (Div group, n=20). A nerve stimulation technique with ultrasound was used in all patients.

Measurements: The onset time and duration of sensory blocks were assessed. Secondary outcomes were pain scores (VAS) and postoperative vomiting and nausea (PONV).

Results: The duration of the motor and sensory block was extended in group Dpn compared with group Div and group C ($P<0.05$). In addition, within 24 h, group Dpn presented lower levels of VAS and lower incidence of PONV as compared with the other groups. Moreover, there was a significant reduction on onset time between group Dpn and the other groups.

Conclusions: Perineural 4 mg dexamethasone was more effective than intravenous in extending the duration of ropivacaine in ultrasound-guided interscalene BPB. Moreover, Dpn has significant effects on onset time, PONV, and VAS.

Biography

Thiago Mamoru Sakae has completed his PhD from Federal University of Santa Catarina, South Brazil and Post-doctoral studies from University of Southern Santa Catarina – UNISUL, Brazil. He is the Anesthesiologist and Epidemiology Professor at UNISUL, an University in Southern Brazil. He has published more than 130 papers in reputed journals and has been serving as an Editorial Board Member of repute.

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Notes:

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Workshop

Day 2

Richard Entsuah, J Clin Trials 2017, 7:5 (Suppl)
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Richard Entsuah

Merck Research Laboratories, USA

Current state of statistical methods in handling missing data in clinical trials

The issue of missing data in clinical trials seems to be an ongoing challenge resulting in different statistical methods that have been proposed to deal this ongoing problem. We shall discuss mitigation strategies to prevent missing data which can help minimize dropout rates. This workshop will provide an overview of various methods that have been adopted by applied statisticians in drug submissions in recent years. The focus will be on longitudinal continuous data using both parametric and non-parametric methods. The choice of primary estimands is gaining lots of attention in the filed recently and we shall discuss these points. The concept of missing at Random (MAR) and missing not at random (MNAR) which has gained much attention in the last two decades will be discussed. This will include techniques like mixed model repeated measure (MMRM), selection models, pattern mixture models, jump to reference, dipping point, multiple imputations and ETRANK®-A nonparametric method.

Biography

Richard Entsuah is a Fellow of the American Statistical Association. He completed his PhD from University of Michigan. He was an Assistant Professor of Biometry at University of Illinois in Chicago. He joined Wyeth Research from 1988 to 2007 and left as an Assistant Vice President of Global Biostatistics and Programming. He joined Merck Research Labs as Executive Director of Late Development Statistics and is the Research Group 4 Head for Neuroscience and Respiratory Immunology.

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Scientific Tracks & Abstracts

Day 2

F Buck Willis, J Clin Trials 2017, 7:5 (Suppl)
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Research on connective tissue rehabilitation: A meta-analysis

F Buck Willis
Galveston Clinical Research Foundation, USA

Abundant research has been conducted on connective tissue rehabilitation, focusing on contracture reduction. The purpose of this study was to examine the different testing methods and experimental designs used to conclusively prove protocols and modalities for contracture reduction. Sequential papers following the level of evidence (increases) have shown benefits in case studies, cohort trials (for population confirmation) followed by randomized, controlled trials with cross-over arms and or blinding. The highest level of evidence is the Meta Analysis or Systematic Review which is meaningful in proving efficacy of a therapeutic protocol with one dependent variable. An example of this was the series of studies on dynamic splinting for contracture reduction of joints including jaw, shoulder, elbow, wrist, knee, ankle, and toe. The connective tissue of these joints have different lengths and alignment but the molecular structures are similar so protocols for contracture reduction (low load, prolonged duration stretch) were hypothesized to yield the same results. This was proven in a systematic review by Furia *et.al.* (2013) which showed that a direct linear correlation existed between the hours of therapeutic stretching and reduced contracture as measured with active range of motion. Other variables were examined separately including animal studies for reducing surgically induced contracture, but the aggregate change in controlled trials was proven in the meta-analysis with change in AROM as the dependent variable. Different studies are beneficial in testing unique variables, and a progressive sequence of studies building the level of evidence to a meta-analysis is best to prove therapeutic protocols.

Biography

F Buck Willis after suffering an unsurvivable plane crash conquered the challenges of a brain injury and a 3-year series of operations to rebuild his legs by earning four degrees and squatting 505lbs. He earned his Medical degree (MBBS) in the British Commonwealth with a PhD in Kinesiology before publishing 25 manuscripts in eight years and being chosen as a Fellow of the American College of Sports Medicine.

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Notes:

Katja Reuter, J Clin Trials 2017, 7:5 (Suppl)
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Trial promoter: A web-based tool for boosting the promotion of clinical research through social media

Katja Reuter
University of Southern California, USA

Participant recruitment into clinical trials represents a major barrier to clinical and translational research and is often associated with implementation delays and high costs. This hinders the translation of scientific discoveries into interventions that improve the health of individuals and the public across populations. Numerous barriers to clinical trial participant recruitment have been identified, including the lack of awareness among patients that trials are available. Several groups have demonstrated that social media such as Facebook and Twitter can be used to reach and enroll participants efficiently into clinical studies. To scale up the number of clinical trials that could potentially benefit from dissemination via SM, we developed and successfully tested trial promoter, a tool that automates the generation, distribution and assessment of clinical trial recruitment messages via social media. In order to test the tool and the correctness of the generated messages, clinical trials (n=46) were randomized into social media messages and distributed via the microblogging social media platform Twitter and the social network Facebook. The percent correct was calculated to determine the probability with which trial promoter generates accurate messages. During a 10-week testing phase, Trial Promoter automatically generated and published 525 social media messages on Twitter and Facebook. On average, trial promoter correctly used the message templates and substituted the message parameters (text, URLs, and disease hashtags) 97.7% of the time (1563/1600). Trial promoter may serve as a promising tool to render clinical trial promotion more efficient while requiring limited resources.

Biography

Katja Reuter is an Assistant Professor of Clinical Preventive Medicine at the Institute for Health Promotion and Disease Prevention Research at the Department of Preventive Medicine, Keck School of Medicine of the University of Southern California (USC), and Director of Digital Innovation and Communication at the Southern California Clinical and Translational Science Institute at USC. She is a Scientist, Educator, and a Communications Professional trained and employed in Germany, New Zealand and the United States of America (USA) with over 15 years' experience. She received her PhD in Developmental Neuroscience from the Free University in Berlin, Germany.

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Notes:

Raj Bandaru, J Clin Trials 2017, 7:5 (Suppl)
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Integration of clinical study data to support trial simulation activities

Raj Bandaru
Sanofi Pharmaceuticals, USA

Like much of the pharmaceutical industries, we at Sanofi are also experiencing a shift in clinical development strategies to adopt more digital technologies and analytics placing greater emphasis on data and model driven approaches. We have set up a strong integrated capability across quantitative systems models, disease progression models and empirical models driving a rigorous clinical trial simulation process to inform design and key decisions in our clinical research. To this end, access to historical clinical trial data has been central. However, using clinical study data for broader clinical research use has several limitations and challenges. We are implementing several processes and intelligent informatics solutions to enable easier access to clinical study results and conducting integrated analytics using state of the art methods and tools. Here we describe some of the informatics solutions we are developing and how these could eventually be applied to support trial submission activities. One example is in the use of a machine learning methods to index data and make it searchable without compromising data security or patient privacy. We are also applying intelligent approaches to data de-identification and harmonization across multiple studies to support meta-analysis. A pilot effort using a learning based approach to data harmonization has shown significant promise and we are exploring other applications including management of metadata and terminologies using machine learning approaches. Some challenges however still exist primarily in the governance of data access and patient privacy issues. We are working on developing clear rules and guidelines that will eventually also help with automating data governance activities. Another challenging area will be in handling genomic and digital health data and we foresee an opportunity for automated machine learning algorithms to help in not only managing the data, but to also discover patterns and associations to clinical outcomes.

Biography

Raj Bandaru heads a data analytics and knowledge management function in Translational Informatics at Sanofi Pasteur. He is championing the adoption of cloud and big data analytics at Sanofi, bringing advances in clinical research together with big data and digital technologies. Over the past two decades, he has led data management and analysis across research and clinical development at various pharmacy and biotech companies and most recently led a data and analytics consulting practice. He has an MBA from Babson College, with a focus on clinical informatics and operations research and also holds graduate degrees in statistics and genetics.

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Notes:

Jing Bao, J Clin Trials 2017, 7:5 (Suppl)
DOI: 10.4172/2167-0870-C1-019

More is not better: The result from a US government sponsored multi-center randomized international clinical trial to prevent tuberculosis in HIV/AIDS population

Jing Bao
National Institutes of Health, USA

Background: Tuberculosis (TB) and HIV/AIDS have been closely linked since the beginning of AIDS epidemic. TB is the most common co-infection and cause of death among the AIDS population. And yet, there isn't rapid, accurate, and reliable diagnosis methodology for TB testing, especially in resource-limited countries. Treating HIV/AIDS patients with the available 4 TB drugs has been utilized in in some African countries to manage AIDS patients that were potentially afflicted with TB not diagnosed. In order to evaluate this treatment/prevention strategy for such patient population, the Division of AIDS at the National Institute of Allergy and Infectious Diseases, one of the 27 institutes and Centers of the National Institutes of Health, funded/sponsored a multicenter international clinical trial project.

Methods: An open label, randomized clinical trial was conceived in 2008 and the first patient was enrolled in October 2011. The study completed the last patient follow-up in June 2014. The protocol included two arms. Arm A received standard anti-HIV treatment therapy plus four anti-TB drugs, Isonizid (INH), Rifampin (RIF), Pyrozinamide (PZA), and Ethambutol (EMB). Arm B received standard anti- HIV treatment plus isoniazid, a WHO recommended strategy to prevent TB. All participants had CD4 counts less than 50 per μL.

Results & Conclusion: The trial enrolled 850 patients and conducted in 18 clinical trial sites in Malawi, South Africa, Haiti, Kenya, Zambia, India, Brazil, Zimbabwe, Peru, and Uganda. We hypothesized the empirical treatment would reduce the mortality in this patient population. However, the results from the trial showed that the mortality rate was same for both study arms. Furthermore, the TB incident rates in Arm A were significantly higher in the treatment arm compared to control arm (33 versus 19). The results illustrated that that adding RIF, PZA, and EMB were not helpful, and possibly harmful. Drug-drug interactions maybe one of the reasons and the real-time drug concentration tests are among the other measurements to explain these study results.

Biography

Jing Bao is a Medical Officer at the division of AIDS, National Institute of Allergy and Infectious Diseases, Columbus Technologies and Services, Inc., with extensive experience in international clinical trial oversight and global regulations. She manages and oversees the US government (National Institutes of Health) funded/sponsored international multi-center clinical trials on treatment development for HIV/AIDS and co-infections. She received her MD from China and was a Medical Director for two hospitals before she received a PhD from Israel. She has published influential research findings in world leading journals. She is the Member of Asian American Executives Network and will be graduated from its Senior Executive Service Candidate Development Program in April 2017.

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Notes:

Geraldine E Baggs, J Clin Trials 2017, 7:5 (Suppl)
DOI: 10.4172/2167-0870-C1-019

Primary outcome is not significant, now what?

Geraldine E Baggs
Abbott Nutrition Research and Development, USA

Randomized controlled trials provide a high level of evidence regarding the cause and effect relationship between intervention and a predefined primary outcome. Adequate well-controlled trials do not come with a low price tag. When the primary outcome show small non-significant positive trends, what can be done to salvage the trial? While these neutral trials fall short of providing convincing evidence of efficacy, sponsors are well served in mining the data for potential answers to the following: Are there any subgroups that may potentially benefit from the intervention?, and are there any posthoc analyses that may help elucidate the treatment effect? Posthoc analyses may help improve study design and in some cases establish care pathway. Subgroup analyses are a useful hypotheses generating activity for future trials. Preferably, they have been prespecified in the study protocol, based on the study primary outcome, found by tests for interactions and based on baseline risk categorization. We present examples based on the sponsor experience and from the literature.

Biography

Geraldine E Baggs has completed her PhD in Statistics from The Ohio State University. She is currently working as a Section Manager of the Statistical Sciences Department at Abbott Nutrition R&D. In this role, she provides statistical leadership in the design, monitoring, analysis, and interpretation of clinical trial data, contributes to regulatory submissions and registration efforts globally, assists legal, QA and food safety groups, and manages the strategic direction of the statistical sciences group.

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Notes:

Hamid Najafi, J Clin Trials 2017, 7:5 (Suppl)
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A high prescision gait analysis system for in community monitoring of patients with neurological and musculoskeletal disorders

Hamid Najafi
Sensoplex, Inc., USA

Neurological disorders, such as Parkinson's, amyotrophic lateral sclerosis (ALS), and multiple sclerosis (MS) and musculoskeletal disorders, such as muscular dystrophy, significantly affect the patients' gait. Monitoring, analyzing, and quantifying patients' gait with high precision is achieved in motion analysis laboratories using optical systems as well as pressure sensitive mats. This method has inherent limitations and disadvantages such as having the patient to go to these labs, the expense of conducting the tests, the limitation of time when data is collected, and more. By contrast, an in community wearable system does not suffer from the disadvantages listed above, as long as it is accurate enough to produce medical/clinical quality data. The system presented here consists of a small wearable device worn around the ankle of the patient and high precision motion analysis algorithms and software that accurately measures gait parameters such as stride length, stride speed, double support time, cadence, distance traveled, 25-ft straight walk speed, six-minute walk speed and distance and more. It also detects context such as walking up/down stairs, running vs. walking, walking on a non-straight line, etc. The above information is used as a biomarker of how the patient is doing, the severity of the disease, its progression over time, and the effectiveness of treatments. Case studies for sroke, MS, and muscular dystrophy patients are presented from patient data collected over extended periods of time.

Biography

Hamid Najafi is currently the CEO of Sensoplex, Inc., a company specialized in development of wearables, software, and algorithms for clinical trials, which he co-founded in 2012. Prior to Sensoplex, he was General Manager of Invensense International at Invensense, a leading Silicon Valley manufacturer of MEMS motion sensors. He co-founded Broadlink Research Inc., in 2005 which developed the first disney mobile phone which was marketed by Vodafone in Europe. He was the Founder of wireless link, a developer of advanced wireless products. He has 14 patents and received his PhD in Electrical Engineering from Stanford University in 1983.

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Notes:

Lindsay Lowe et al., J Clin Trials 2017, 7:5 (Suppl)
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Innovations from a family medicine department engaged in clinical trial research

Lindsay Lowe, Shane Gavin, Abuu Diwani, Susan Standridge, Lindsay Shade and **Hazel Tapp**
Carolinas HealthCare System, USA

Clinical trials actively engage participants in their healthcare, exposing them to innovative treatments that may improve their condition and help others. Effective programs select studies that positively impact their patients' health. Carolinas HealthCare System (CHS) is one of the nation's largest healthcare systems. The CHS Department of Family Medicine Clinical Trials Division is home to the Mecklenburg Area Partnership for Primary Care Research, a practice-based research network. The research group is physically collocated within a family medicine residency training program, offering convenient access to providers and patients within a network of 6 ambulatory primary care practices with 30 faculty physicians, 69 resident physicians, and 5 advanced care practitioners, caring for 22,000 patients. A unified electronic medical record provides seamless communication amongst the large multidisciplinary research team and referring providers. Partnerships with the healthcare system's advanced analytics and research finance departments support screening and fiscal efforts respectively. Over the past 8 years, the department has generated over 10 million dollars in revenue, brought on 14 clinical trials and enrolled nearly 600 participants. The team has maintained high rates of retention as a result of exceptional participant and teammate satisfaction. Most clinical studies have been phase 4 trials, funded by federal agencies and pharmaceutical companies, studying diabetes, hypertension, dementia, chest pain, retinopathy, and gastroesophageal reflux disease. Having varied funding source has allowed for low turn-over of team members, which maintains continuity for the study participants, and has enabled growth within the department.

Biography

Lindsay Lowe currently serves as a Research Coordinator for the Department of Family Medicine. She has been with Carolinas HealthCare System for nine years and spent the last three years working in research on medication and software studies. She has a BS degree in Exercise Science from the University of North Carolina at Charlotte.

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Notes:

David Vulcano, J Clin Trials 2017, 7:5 (Suppl)
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Innovation starts with people: A new paradigm in workforce development

David Vulcano
HCA Healthcare, USA

This session will explore innovative approaches to workforce development, including collaborative initiatives to develop and standardize core competencies for clinical research professionals. While many initiatives are bringing forth process and technology solutions to clinical development, less focus has been given to workforce development despite the persistence of FDA inspection findings, shortages in the workforce, and considerable variance in overall trial conduct. This session will outline the changing roles and responsibilities of CRAs and CRCs, and ACRP-led, collaborative initiatives to define competence standards for professionals conducting monitoring and study conduct activities.

Biography

David Vulcano is a well-known leader and change agent in the clinical research industry. He lives outside Nashville, TN where he involves himself in work, family life and other charitable and entrepreneurial opportunities.

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Notes:

Ujwala V Salvi, J Clin Trials 2017, 7:5 (Suppl)
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PVG and drug safety- pharmacovigilance in India and emerging markets: An industrial perspective

Ujwala V Salvi
Nucleon Therapeutics LLP, India

Development and implementation of evidence-based, public-health focused, collaborative, globally electronic and regulatory compliant approach is need of hour to gain comprehensive Pharmacovigilance (PV) system. The authors discuss development of a model for uniform PV data input-output across industry. Authors contemplate data collection; data analysis; data processing; medical review and data distribution systems as basic PV process. Data collection systems should include detailed process of collecting various adverse events (AEs) from literature searches, healthcare professionals (HCP), non-HCP, spontaneous, clinical trials, patient registries, post marketing surveillance etc. Data should be processed in CIOMS form I by using ARGUS, ARISg, MedDRA, WHO drug dictionary and company drug repository or local regulatory AE form, etc. It should be medically reviewed followed by distribution to respective regulatory authorities where thorough signal identification, prioritisation and investigation will be performed. Signal detection can be done by using Medline/PubMed, Springer, OVID database, reactions weekly, local publications etc. Non-english cases/literature reports should be translated to english via authorised vendor or in-house translation system. Safety data from license partners and third party manufacturers should be collected and processed by maintaining safety data exchange agreements (SDEA). PV model can be fully in-house end to end or part in-house and part outsourced or fully outsourced. In conclusion, an effective implementation of PV activities like robust PV systems, signal detection and SDEAs could definitely yield robust patient safety data from India and emerging markets.

Biography

Ujwala V Salvi has over 15 years of experience across the globe and local Pharmaceutical/CRO, tier I Medical Devices and BPO industry. She has an MBA from Indian Institute of Management, Kolkata and Doctorate in Applied Biology. She is trained in Six Sigma Black Belt and various project management tools, with core experience in a wide range of therapeutic areas, and worked at all stages of clinical development from Phase II to production of clinical documentation necessary for product license applications. She has worked in large global operations, managed strategic relationships, and played a key role in winning new business, setting up off-shored partnerships and in identifying new BU service lines and growing existing ones. Her areas of expertise include clinical trial operations, risk based monitoring, medical writing and data publication, clinical data management, and feasibilities of new drug development and analytics. She is an industry expert, has been involved in key global industry forums such as the DIA, SCDM, CII and CPHI.

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Notes:

Sergio Guerrero, J Clin Trials 2017, 7:5 (Suppl)
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The good, the bad, and the unknown of executing clinical trials in Mexico and Latin America

Sergio Guerrero
Universidad Autonoma de Ciudad Juárez, México

The globalization of R&D into emerging regions has continue to grow more in the last decade in Latin America, driven by many factors including improved regulatory environment, commercial markets, favorable economics with lower relative costs, access to highly skilled professional and a large pool of patients in the region. But, now with a better established atmosphere and a strong healthcare infrastructure, Latin America offers a number of advantages as a location for clinical trials, and at the same time, the region presents other challenges particularly related to the industry that must be anticipated and managed appropriately, because we still confronting significant logistical battles and delays in implementing clinical trials in the region due to improper planning of the developments by the industry, that potentially could interfere with any new regional improvements and potentially interrupt results. If the clinical research industry is willing to take the moment and better understand their processes adapting new approaches to support an efficient global drug development program in the region, the results can be notable on time and manner. This session is intended to analyze key issues, opportunities (Good), challenges (Bad) and the unknown of doing clinical trials implementation in Latin America, and to review and understand a better planning when selecting the Latin American region to participate in a Global Clinical Trial.

Biography

Sergio Guerrero received his Medical Degree from the School of Medicine of the Universidad in Juarez, Mexico. He initiated his Medical research career in Bethesda, MD (USA) participating in the transplant research technology that later lead him to manage the operation according to the Food and Drug Administration of the United States. In the last 20 years, he dedicated to the organization, managing and conducting clinical trials in the US and Latin American region for the international pharmaceutical industry on new drug/medical devices development according to US FDA, ICH/GCP guidelines, EMA, and local regulations. For numerous years, he worked as Director of a Clinical Research Center in Mexico where he managed a multispecialty medical group and investigators in the conduct of clinical trials phase I-IV. Presently, he is responsible for the Operations of a CRO in Mexico.

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Notes:

Samir K Ballas, J Clin Trials 2017, 7:5 (Suppl)
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Conceptual progress in the management of sickle cell pain from individualized trial and error approach to a specific pharmacologic precision medicine

Samir K Ballas
Thomas Jefferson University, USA

Sickle cell disease (SCD) is an inherited disorder that affects 100, 000 African Americans and about 100 million individuals globally. Upon deoxygenation, the sickle hemoglobin polymerizes and initiates a series of events leading to vascular occlusion, tissue hypoxia, pain and progressive organ damage. Recurrent acute painful episodes are the hallmark of SCD that require treatment in the emergency department and/or hospital with relatively large doses of opioids. Up to the 1960s, SCD was primarily a disease of children. In the 1970s, survival increased and transfer to adult care increased progressively. Soon adult programs were overwhelmed with a large number of patients with frequent utilization of medical facilities, heavy consumption of opioids and suboptimal insurance coverage. As a result, patients with SCD were accused of drug-seeking behavior and addiction. Consequently, pain was under treated and, at best, was on the basis of trial and error for each patient. As the controversy about the treatment of sickle cell pain was brewing, the advent of precision medicine came to the rescue. Pharmacodynamically, opioids function as ligands that bind to and activate specific helical receptors in the central nervous system. If an opioid does not activate receptors, its analgesic effect would be absent. Pharmacokinetically, each drug is metabolized into specific active or inactive metabolites depending on the presence of genetically determined enzymes. The net effect of an opioid depends on the specific receptors and enzymes in each patient. This explains why different patients responded differently to an opioid. Pain management should be precision medicine-dependent.

Biography

Samir K Ballas received his MD with distinction from the American University of Beirut-Lebanon in 1967. He completed his training in Hematology at Thomas Jefferson University in Philadelphia, Pennsylvania. He is board certified in Internal Medicine, Hematology, Blood Banking, Pain Medicine and Pain Management. He is currently Emeritus Professor of Medicine and Pediatrics at Thomas Jefferson University and honorary Staff Member of Hemorio, the Hematology Institute in Rio de Janeiro, Brazil. He has authored or co-authored over 800 articles, book chapters and abstracts. He also published two editions of a book on sickle cell pain in 1998 and 2014 respectively.

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Notes:

Lennox Graham et al., J Clin Trials 2017, 7:5 (Suppl)
DOI: 10.4172/2167-0870-C1-019

Best strategies to recruit and enroll elderly blacks into clinical and biomedical research

Lennox Graham, Julius Ngwa, Oyonumo Ntekim, Oludolapo Ogunlana, Saba Wolday, Steven Johnson, Megan Johnson, Chimene Castor, Thomas V Fungwe and **Thomas O Obisesan**
Howard University, USA

Historically, blacks have been disproportionately, underrepresented in clinical trials. In addition to limiting the generalizability of results of these clinical trials to the black's population, the determinants of their participation in clinical research remain poorly understood. Outcomes of suboptimal participation include poor understanding of the predictors and treatment of the disease, increasing health disparities, poor health equity, and suboptimal wellness of the nation. To address this gap in the literature, we analyzed our recruitment data to identify the most effective strategies for enrolling older Blacks in clinical trials. Of the total 3,266 screened, we included 2,830 blacks' volunteers for further analysis. Overall more women than men (73.8% vs. 26.2%) participated in our recruitment activities. However, a significantly higher proportion of men than women were engaged through family (3.86% vs. 1.30%, p=0.0004) and referral sources (5.89% vs. 2.59%, p=0.0005). Compared to other recruitment sources, we encountered a higher proportion of volunteers at health fairs (42.95%), and through advertisements (14.97%). In our sample, years of education and age did not appear to influence the likelihood of an encounter, screening and potential participation. These findings indicate that we mostly recruited black men and women from health fairs, and through advertisements tailored to their health needs and interests. Conversely, we mostly recruited blacks men through family referrals and persons known to them, indicating a need for trust in their decision to engage study personnel and or participate in clinical trials.

Biography

Lennox Graham is an innovative Educator and Practitioner with extensive experience in the design, delivery, evaluation, and enhancement of effective instructional programs and management assessment models. He is a highly articulate and effective communicator with excellent team building and interpersonal skills. His training, inclusive of his Master of Science degree in education and his Doctoral degree in management and organizational leadership, has equipped him for leadership. He has several notable awards which affirm the significance of his experience; and he understands and acts with integrity in all of his pursuits.

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Notes:

Wasif Ali Khan, J Clin Trials 2017, 7:5 (Suppl)
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Bangladesh: Can be a potential new hub for global CROs for global clinical trials

Wasif Ali Khan
Icddr, b, Bangladesh

Lower costs to conduct clinical trials and availability of treatment-naïve patients have attracted many pharmaceutical companies to conduct clinical trials in developing countries in Africa, China, India, and parts of Eurasia. However, despite having a large patient base and diverse disease profiles, until recently Bangladesh could not appropriately participate in global clinical trials due to the lack of clinical research infrastructure. In a recently conducted study in lupus nephritis (LN) study conducted over 80 sites from 23 countries – Bangladesh was included as second tier when recruitment was alarmingly slow with the first tier. LN is a rare disease requiring the use of a global approach to recruitment. The total time required in Bangladesh to obtain central as well as the site IRB approvals was 4 months. Although the initial country target was to enroll a maximum of 25 patients from Bangladesh, quality in clinical care and ensuring the ICH-GCP guidelines were closely and constantly maintained allowed for an increase in countrywide enrollment. This resulted in ultimate highest patient enrollment from Bangladesh (n=46) out of total n=265 patients enrolled globally. In this study 80% of clinical studies fail to meet enrollment deadlines, and 50% of sites enroll 1 or no patients.

Bangladesh a country of over 160 million with many treatment naïve patients; increased number of lifestyle diseases are emerging with the change of the economy of the country from low to middle income country. Young physician Investigator has the medical training in English and trained in the same standard as UK Investigators. The combination of population availability, high quality Investigators and the common use of English points to Bangladesh as a potential new hub for international clinical trials and global CROs to explore in this newly emerged clinical research country. That results in faster recruitment, saving unnecessary investigations and reducing overall study cost. Most importantly new drugs those are in the pipeline are evaluated much faster through Clinical trials for regulatory approval and thus the neediest patients are privileged with newer medicines that could benefit both morbidity and mortality.

Biography

Wasif Khan, medical graduate from Bangladesh obtained Graduate Training Program in Clinical Investigation (GTPCI) from Johns Hopkins Univ. (JHU). He completed fellowship in Clinical Pharmacology from Division of Pharmacology, JHU as Merck International Fellow. He has over 26 years of experience in Clinical Trials. He is leading the clinical trial unit of icddr, b; pioneers opportunities for multi-national Pharmaceuticals and global CROs to explore Bangladesh as a new hub for clinical trials. Constantly interacts / delivers presentations related to this venture in different local institutes and maintains close liaison with the relevant authorities of Govt. of Bangladesh. He has published more than 90 papers in peer reviewed journals.

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Notes:

Myoung-Gwi Ryou, J Clin Trials 2017, 7:5 (Suppl)
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Old chemicals, now as potential life savers against ischemic and reperfusion injuries

Myoung-Gwi Ryou
Tarleton State University, USA

Ischemia and reperfusion (I/R) injuries are critical life-threatening diseases and may end up with serious adult disability, but FDA-approved treatment is limited. Classical chemicals such as methylene blue (MB) and pyruvate have been revisited to evaluate protective roles in I/R injuries including ischemic stroke and myocardial infarction. Oxidative stress and inefficient energy metabolism are the pivotal contributors to I/R diseases. Results from bench studies support that both pyruvate and MB increases ATP production and have potent antioxidant effect. However, detailed mechanisms of beneficial effects are different between pyruvate and MB. MB rather prevents electron leakage through electron transport chain in the mitochondria and by which energy metabolism enhanced. On the other hand, pyruvate enhanced endogenous redox state, such as the ratio of GSH to GSSG, and improves ATP production by providing metabolic resources required for the glucose metabolism. Furthermore, the effects of MB and pyruvate on the gene regulation have been investigated. Both MB and pyruvate enhances cellular ability to resist against ischemic stress by activating hypoxia inducible factor-1. In conclusion, pyruvate and MB, old chemicals, have two-phase effects on I/R injury. Short-term effect, MB and pyruvate can protect the victims of various I/R diseases by reducing oxidative stress and enhancing energy metabolisms. The long-term effects of MB and pyruvate allow the conversion of gene profiles to help protect and restore from I/R damage.

Biography

Myoung-Gwi Ryou has completed his PhD in 2008 from University of North Texas Health Science Center and Post-doctoral studies from University of Texas Southwestern Medical School. He is the Director and an Assistant Professor, Dept. of Medical Laboratory Science and Adjunct Faculty in the UNTHSC. He has published more than 23 papers and chapters in reputed journals and has been serving as an Editorial Board Member of several peer reviewed journals.

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Notes:

Clinical Trials 2017

4th International Conference on

Clinical Trials

September 11-13, 2017 San Antonio, USA

Workshop

Day 3

Jing Bao, J Clin Trials 2017, 7:5 (Suppl)
DOI: 10.4172/2167-0870-C1-019

Jing Bao

National Institutes of Health, USA

Advantages and challenges conducting clinical trials in china

As the rising economic superpower in the world, China is now striving to be at the forefront of clinical research and drug development. There are many advantages to conducting clinical trials in China including large patient populations, a large and growing network of hospitals qualified to conduct high standard clinical trials, skilled clinical trial and laboratory professionals and project leaders, strong support from the government for international partnerships, improved regulatory environment for clinical trials and new drug approval, and strong enthusiasm for international collaborations. However, several challenges remain, such as large migrant populations, language and cultural differences, and the uncontrolled use of traditional Chinese medicine. Timely importation of study agents is one other significant challenge. Quality control is the key to ensure clinical research projects meet the highest standards. The recent changing drug regulatory landscapes have also brought attention and galvanized international companies that intend to conduct drug trials in China. This workshop, using the real examples, will present and discuss the advantages and challenges of conducting clinical trials in China. The pitfalls to avoid and possible solutions to conducting high quality clinical trials in China will be emphasized.

Biography

Jing Bao is a Medical Officer at the division of AIDS, National Institute of Allergy and Infectious Diseases, Columbus Technologies and Services, Inc. with extensive experience in international clinical trial oversight and global regulations. She manages and oversees the US government (National Institutes of Health) funded/sponsored international multi-center clinical trials on treatment development for HIV/AIDS and co-infections. She received her MD from China and was a Medical Director for two hospitals before she received a PhD from Israel. She has published influential research findings in world leading journals. She is the Member of Asian American Executives Network and will be graduated from its Senior Executive Service Candidate Development Program in April 2017.

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Scientific Tracks & Abstracts

Day 3

Kim Walpole, J Clin Trials 2017, 7:5 (Suppl)
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Future visions in clinical trials: The role of artificial intelligence and how it changes clinical research

Kim Walpole
Trials.ai, USA

The synergy of advances in diverse areas of artificial intelligence holds considerable promise for improving the efficiency and efficacy of clinical trials. Of particular interest to Trials.ai is improving the design and execution of protocols. Poorly constructed protocols lead to poor research and costly amendments, protocol deviations, delays in obtained appropriate data and more.

Opportunities for Artificial Intelligence to Improve Outcomes: The Trials.ai system is designed to accept a protocol document, scan it and assess for opportunities and threats. This includes, for example, consistency between the time and events (T&E) table and the in-text description of events, and consistency between the synopsis and the body of the protocol. Natural language processing tools are helpful in this regard. Additionally, AI tools are used to scan completed protocols based on a similarity. Similar protocols coupled with published and internal data are mined to predict the degree of success from the proposed design as well as identify any problematic items.

Addressing Enrollment and Retention: Clinical trials often fail because of poor enrollment. Trials.ai can warn the study designer, for example, that particular inclusion/exclusion criteria may be too limiting for subject enrollment can save the sponsor considerable funds and time that can be invested in a better clinical design or an alternative effort. Clinical trials also fail because of poor subject retention. To address this, we have created and are refining what we call a Patient Burden Index (PBI), which is an AI-derived quantitative measure of the impact that the protocol design has on the subject. Protocols can then be scored based on their PBI, and alternative designs can be explored. We believe this is an entirely novel approach to improving subject retention and cooperation at all stages of a clinical trial.

Executing the Trial More Effectively and Efficiently: Once the trial has started, AI will play additional roles to help ensure a best outcome. In our case, our client partners provide a protocol that is uploaded into our system. The system then maps the T&E schedule into a dashboard-driven user interface that shows when each event is to be completed. With available personnel assignments and schedules, the system can also identify who is to do which task in support of which patient at which time. Practitioners are alerted ahead of time for events, which helps to reduce protocol deviations.

Biography

Trials.ai is Kim's 3rd company yet her passion for fixing logistical problems with clinical trials drives her as if it were her first. Her expertise in organizational development enabled her build Corporate Development Programs for companies like Pfizer, Merck and Wyeth Ayerst. Ms Walpole understands the complex clinical trials space and the needs of sponsors, CROs and sites. Her goal is to use technology to as a catalyst for helping organizations in study design and execution so that patients can be exposed to better quality treatments, faster.

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Notes:

Mohsin Shaikh, J Clin Trials 2017, 7:5 (Suppl)
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Clinical data management and statistics and clinical coding for clinical data management professional

Mohsin Shaikh
Axiom Real-Time Metrics, Canada

Complete, accurate and consistently coded datasets are continuously required for study analysis and its impact on the study results. Many times, in multicentric clinical trials, investigator(s) or medically qualified experts are from sites or centers across the globe, involved in recording the clinical term(s) uniformly is a big challenge. Medical coders from clinical data management teams process these clinical terms and perform medical coding. Medical coding is performed to categorize the clinical terms reported appropriately so that they can be analyzed/reviewed using either traditional or new coding models via MedDRA and WHO drug dictionaries. Understanding the process of medical coding and the workflow including dictionary up-versioning will positively impact the outcome of the study significantly. Medical coders always work closely with the clinical data manager to assist the query management process and address critical variable data points. Coded data transfer analysis predicts the trend of the primary end point variables and its outcome. This presentation will highlight the whole process, common problems and its resolution while executing the process of clinical coding.

Biography

Mohsin Shaikh has completed his MD from MS University, Gujarat and Post-graduate studies from AAPS Toronto. He is a lead Clinical Data Manager at Axiom Real-Time Metrics, a premier clinical data management service organization providing expert solutions into the EDC/DM/IWRS sector. He has published more than 15 papers in reputed journals and has been serving as an Editorial Board Member of Repute. He is an International Medical Graduate with more than eight years of experience in clinical research industry mainly in clinical data management.

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Notes:

Efe Egharevba, J Clin Trials 2017, 7:5 (Suppl)
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The role of corruption and unethical behaviour in precluding the placement of industry sponsored clinical trials in Sub-Saharan Africa: Stakeholder views

Efe Egharevba
Glasgow University of Health and Wellbeing, UK

Clinical trials still represent the gold standard in testing the safety and efficacy of new and existing treatments. However, developing regions including sub-Saharan Africa remain underrepresented in pharmaceutical industry sponsored trials for a number of reasons including fear of corruption and unethical behaviour. This fear exists both on the part of pharmaceutical companies, and investigators carrying out research in the region. The objective of this research was to understand the ethical considerations associated with the conduct of pharmaceutical industry sponsored clinical trials in sub-Saharan Africa. Corruption was identified as a significant issue by a number of stakeholders who participated in semi-structured interviews and completed questionnaires. Additionally, fear of being perceived as corrupt or unethical even when conducting ethically sound research was raised as a concern. Thus corruption, whether actual or perceived, is one of a number of issues which have precluded the placement of a greater number of pharmaceutical sponsored clinical trials in this region. More discussion around corruption with all relevant stakeholders is required in order for progress to be made and to enable greater involvement of sub-Saharan African countries in the conduct of industry sponsored clinical trials.

Biography

Efe Egharevba is a final year part-time PhD student at Glasgow University's Institute of Health and Wellbeing. He completed a Master's degree in Clinical Research at Cardiff University's Welsh School of Pharmacy in 2008 and obtained a Bachelor's degree in Biology from the University of North Texas. He has spent 13 years working for various pharmaceutical companies in clinical operations, overseeing the conduct of clinical trials around the world.

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Oladapo Michael Olagbegi et al., J Clin Trials 2017, 7:5 (Suppl)
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Efficacy of combined versus open and closed kinetic-chain exercises on selected physical performance indices and health-related quality of life of individuals with knee osteoarthritis

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Background: Effects of combined kinetic-chain exercises on physical performance and quality of life in knee osteoarthritis (OA) has not been reported. This study was designed to investigate and compare the effects open, closed and combined kinetic-chain exercises (OKCE, CKCE and CCE) on performance-based physical function and health-related quality of life (HRQoL) of patients with knee OA.

Method: The randomized clinical trial involved ninety-six consecutive patients with knee OA who were randomly assigned to one of OKCE, CKCE or CCE groups. Comfortable and fast pace walking time (CPWT, FPWT) and HRQoL were assessed using a stopwatch and Arthritis Impact Measurement respectively at baseline and at the end of weeks 4, 8 and 12.

Results: The groups were comparable regarding their demographic and dependent variables at baseline; there were no significant intergroup differences in CPWT, FPWT and HRQoL at the end of weeks 4, 8 and 12. CCE group (-2.38±2.52 s) however demonstrated significantly higher mean change in CPWT than either OKCE (-1.31±1.03 s) or CKCE group (-1.44±1.19 s) between baseline and week12. Walking times and HRQoL scores significantly reduced across all-time points of the study indicating improvement for all measures.

Conclusion: Combined kinetic-chain exercises are more effective than either OKCE or CKCE alone for improvement of physical performance in knee OA.

Biography

Oladapo M Olagbegi has completed his PhD from University of Ibadan, Nigeria. He is currently pursuing Post-doctoral studies at Rhodes University, Grahamstown, South Africa. He has published more than 10 papers in reputed journals.

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Victor Ngu Ngwa, J Clin Trials 2017, 7:5 (Suppl)
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Clinical evaluation of the use of enrofloxacin against *Staphylococcus aureus* clinical mastitis in sheep

Victor Ngu Ngwa
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The aims of this work were to evaluate the potential role of enrofloxacin in controlling the severity of the clinical mastitis in sheep caused by *Staphylococcus aureus*; to improve cure rates and to minimize the related effects of the disease on the mammary glands. This study was conducted in commercial dairy flocks, where there was ongoing intensive monitoring of subclinical mastitis by Somatic Cell Count (SCC) and bacteriology. Two groups of animals were selected from these flocks. Group A (n=34 animals) and Group B (n=39 animals) were treated with 2.5 mg/kg bw and 5 mg/kg bw, respectively of enrofloxacin (Baytril®5% injectable solution, Bayer, Italy) for three consecutive days (two doses per day). The effectiveness of the enrofloxacin in curing the S. aureus-induced clinical mastitis was monitored through SCC, rectal temperature, and by systemic and local mammary gland reactions from the 1st to the 14th day post treatment. The presence of *S. aureus* in milk samples was confirmed by bacteriological examination and PCR before and after treatment. Bacteriological cure was 39% in Group A and 82% in Group B. Both doses significantly reduced SCC ($P<0.001$), while the reduction in Group B was also significantly higher than Group A. Mean rectal temperature as well as local mammary gland and systemic reactions, also decreased significantly in both groups ($P<0.001$). In conclusion, both enrofloxacin concentrations provide bacteriological cure but the higher concentration resulted in greater reduction of clinical mastitis in sheep caused by *S. aureus*.

Biography

Victor Ngu Ngwa has completed his PhD from the University of Camerino School of Biosciences and Veterinary Medicine, Italy, and MSc (Pathology) from the Swedish University of Agricultural Sciences, Uppsala. He is a Senior Lecturer and the current Head of Microbiology and Infectious Diseases Department of the University of Ngaoundere School of Veterinary Medicine and Sciences. He has published more than 16 papers in reputed journals and has been serving as a reviewer in quite a number of peer-reviewed journals.

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Etsubdink Abera Aboye, J Clin Trials 2017, 7:5 (Suppl)
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The challenges of clinical trials in developing nations: Ethiopian perspectives

Etsubdink Abera Aboye
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Clinical trials in Ethiopia and other developing nations can generally be considered to be in its embryonic stages. The share of studies registered from Africa is (in Clinicaltrials.gov) updated as of June 2017 is only 0.025%, although the region represents about 15% of the population of the world; and Ethiopia represents only 1.5% of all the studies from Africa. Though clinical trials provide the highest degree of evidence to support new interventions and decisions about disease management, the challenges of conducting clinical trials in Ethiopia are enormous. The basic problem arises from the country's poor economy that resulted in underdeveloped research infrastructure such as space, supplies and maintenance affecting clinical work, communication, access, availability of basic needed inputs, and lack of trained workforce in clinical research. Besides, there is lower prioritization of research in academic institutions considering research as a luxury; time and money consuming; and this has resulted in the establishment of very few clinical trials units nationwide. There is lack of equitable incentives for researchers due to limited sources of funding and very minimal budget allocation to clinical research activities by the government. The regulatory frameworks are also bureaucratic; and this has been discouraging to the few clinical researchers resulting in brain drain; that is a challenge in health facilities in resource-limited settings as it is associated with increasing workloads, lowering the quality of services, reducing team efficiency and causing a loss of institutional knowledge. Moreover, poor and/or illiterate study participants and differing cultural values and beliefs may lead to recruitment, consent and follow up difficulties, which slow down trial progress from my experience in Ethiopia.

Biography

Etsubdink Abera Aboye has earned his Medical Doctorate from St. Paul's Hospital Millennium Medical College in Ethiopia, in November 12, 2013. He is graduated with distinction and retained in the Medical College with academic rank of Lecturer and Early Career Researcher. He has participated in various researches that brought positive change to the community, and he is currently participating in the evaluation of a standardized treatment regimen of anti-tuberculosis drugs for patients with MDR-TB, multicenter trial involving five hospitals in the city. He worked as President of the Medical Students' Association, Assistant Student Dean, Modular Coordinator, and Undergraduate Students' Coordinator. He is currently a Fellow at Harvard Medical School-Global Clinical Scholars Research Training Program with clinical trial concentration, and Member of Research Ethical Review Committee of his academic institution since 2016.

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Ming Hong et al., J Clin Trials 2017, 7:5 (Suppl)
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A network-based pharmacology study of the potential hepatotoxicity of two common hepatoprotective Chinese herbal medicines

Ming Hong and **Yibin Feng**
The University of Hong Kong, China

Liver injury caused by hepatotoxic agents is a major health problem that challenges not only health care professionals but also the drug regulatory agencies and the pharmaceutical industry in recent years. Traditional Chinese herbal medicines such as Xiao chai hu tang (XCHT) and Heshouwu are widely used for chronic liver diseases and generally regarded as safe due to their extensive clinical use. However, in recent years, there have been increased clinical case reports regarding the long-term hepatotoxicity risks of these two hepatoprotective Chinese herbal medicines in patients with liver dysfunctions. Herein, based on the network pharmacology framework, we analyzed the potential hepatotoxicity of XCHT and Heshouwu by predicting the hepatotoxic ingredients and identify the molecular targets of hepatotoxicity in XCHT and Heshouwu. As a result, two drug-target networks of hepatotoxicity of XCHT and Heshouwu were constructed and analyzed through network pharmacology assays. This network pharmacology research on herbal hepatotoxicity may provide a forceful tool for exploring the potential toxic ingredients and related intracellular mechanisms of Chinese herbal medicines. However, further experimental verification of the potential hepatotoxicity compounds is needed to validate the accurate interactions between these herbal ingredients and protein targets predicted by the *in-silico* method.

Biography

Ming Hong is a fourth year PhD student at the University of Hong Kong. His researches are mainly focused on Chinese medicines and liver diseases.

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Notes:

Liora Bosch, J Clin Trials 2017, 7:5 (Suppl)
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Detailing key considerations and challenges of EDC in terms of implementation and statistical aspects

Liora Bosch
Omrix Biopharmaceuticals, Israel

Worldwide, in the past few decades the emerging incorporation of electronic systems has accelerated rapidly. We witness many official services like banking or government services and others like shopping or even gambling that has moved on-line, yielding huge efficiency gains for suppliers along with improved customer experience. The question that we should ask is: Where does the clinical trials industry incorporate in that sense? or being more specific, how does the implementation of an EDC system affect the clinical trial working procedures? We will start by reviewing the FDA prospective on eSource as a means of clinical data collection followed by examples of electronic data originators. Then continue by giving an overview of the modified data collection and handling procedures and presenting the existence of data element identifiers driven by EDC deployment. When considering EDC implementation there are still barriers to be overcome, all of which can be categorized into the following: High upfront cost, lack of technical knowledge and resistance to change. On a personal note, in my lecture I will try to address these issues by presenting the available types of EDC systems in the market today trying to address the economic considerations via a case study describing a full EDC implementation. In addition, the two last sections will be dedicated to the importance of statistical knowledge when designing an eCRF. Finally, I will conclude by intriguing future availabilities in terms of statistical process control. Incorporating such controls into the EDC system could detect real time unusual data variations and deprive the loss of statistical power.

Biography

Liora Bosch has been working at Omrix as a Biostatistician for the past 4 years and has broad-based experience in study design and data analysis. In her former role, she filled the position of a Clinical Data Manager, overseeing multisite clinical trials across the US and EU. In that capacity, she worked with leading and cutting edge EDC systems and conducted training for system users. In parallel to her work, she is also pursuing a Master's in Biostatistics. As part of her thesis, she provides statistical support and analysis for an upcoming clinical trial. Her thesis work is mentored by a fellowship of Tel-Aviv University and Harvard University.

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Notes:

Amanda M Brock, J Clin Trials 2017, 7:5 (Suppl)
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The role of palliative care on phase 1 oncology clinical trial participants

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Integration of Palliative Care into oncology care has been a challenge since the inception of palliative care programs. Phase 1 oncology clinical trial participants are considered a distinctly vulnerable population. They are at high risk for lack of follow through by the healthcare system after being withdrawn from the clinical trial. In addition, they are at risk for therapeutic misconception and major challenges associated with dual enrollment on the trial and hospice programs. Patients with dual enrollment in palliative care and phase 1 trials could live longer lives, remain on trials for longer, have higher rates of advance directive completion, and may be more likely to die comfortably at home. Palliative Care consultation upon phase 1 trial enrollment can could improve the quality of the research being conducted as well as improve Quality of Life for trial participants.

Biography

Amanda M Brock has completed her Master of Bioethics and Master of Science in Nursing at the University of Pennsylvania. She has ten years' experience in direct patient care including inpatient and outpatient, nursing administration, and clinical research. She is experienced in leading committee work and creating nursing policies. She is a firm believer in systems thinking and the importance of clear and thoughtful communication in clinical care.

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Notes:

Francesco Piacenza, J Clin Trials 2017, 7:5 (Suppl)
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Precision and accuracy of the new Xprecia stride mobile coagulometer

Francesco Piacenza
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Oral anticoagulation therapy (OAT) with coumarins (vitamin K antagonist) is the most used against thromboembolism. Prothrombin time International Normalized Ratio (PT-INR) monitoring is fundamental to determine coumarins dosage and prevent bleeding complications or thrombotic events. In this contest, the method used for providing the INR measurements is crucial. Several studies measured both PT-INR precision and accuracy of the most known mobile coagulometer. However, no data on the new XPrecia Stride Mobile Coagulometer (Siemens) are available in literature. The aim of this work is to analyze precision and accuracy of the new XPrecia Stride mobile coagulometer to provide recommendations for clinical use and quality control. A total of 163 patients (mean age=77.4 years old) under Warfarin OAT for whom the INR was assessed by both the traditional cs 2100i Sysmex and the new Xprecia Stride Mobile Coagulometer were included in this study. The precision of the new mobile coagulometer resulted very well (CV<3%). The analytical accuracy was also in line with other known devices (MRD=6.78%). Finally, the clinical accuracy was acceptable (deviation>15% from the true value in 20% of cases). Considering the overall results obtained by the new Xprecia Stride in comparison to that one's obtained from the other commercial devices, we can conclude that the new coagulometer is enough reliable for clinical settings. However, a larger trial to confirm these data is needed.

Biography

Francesco Piacenza has completed his PhD from the Polytechnic University of Marche. He continued the research activity on age related diseases by leading the Post-doctoral studies at the National Institute of Health and Aging. In 2011, he also acquired the title of Clinical and Epidemiological Research Coordinator at the same institute. He is actually a Specialist in Clinical Biochemistry at the National Institute of Health and Aging in Ancona, Italy. He has published more than 40 papers in peer-reviewed journals with impact factor and is an Editorial Board Member of various journals.

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