HEZEKIAH ADESANYA MD

DansetH LLC
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OVERVIEW

I am a physician with experience on a variety of clinical practice, clinical development and drug safety, epidemiological and outcomes research, business development and product acquisitions during the last 29 years. My clinical practice experience as a physician includes: Pediatric and general medicine ICU/NICU, ward, emergency room, clinics, and research center management for years.

My Global pharmaceutical experience ranges across all therapeutic areas of drug development, including but not limited to: cardiovascular, anti-infectives, metabolism and endocrinology, oncology, Opiod and Pain Medicine, Respiratory and allergy, vaccines, internal medicine, CNS, pain and psychiatry. I have global management experience and have managed several groups with increasing responsibilities across multiple companies. Set up reimbursement accounts with large wholesalers and HMOs in the US.

Conducted Pharmaco-economic assessments on product portfolios for acquisition and in licensing across several therapeutic areas, disease burden and product positioning in the US and Europe. Assessed several products for acquisitions, in licensing and conducted several co-marketing agreements with smaller companies.

Served as consultant to foreign governments in assessments of healthcare systems & capacities, population epidemiology and disease burdens, pharmaco-economics and drug formulary portfolios. (Caribbean, West Africa Health Organization and other African countries)

Medico-Legal Consulting Expertise: 16yrs

1. Providing expertise on Standard of Care in Ongoing Litigation against Pharmaceutical Companies for drug Injury cases..
2. Advise Company Legal Employees on quality of drug injury claims against company
3. Performing overall review and authoring opinion on cases with drug injury.
4. Advise Client companies on settlements where appropriate and Chances of Success if case moves to Court/Trial.
5. Advise Client on Discovery questions and Documents appropriate to case.
6. Guide Clients to focus on Standard of Care issues critical to case.
7. Medical Case and Literature Review Expert

WORK EXPERIENCE

DansetH LLC Independent Medical Consultant
Nov. 2009-Present
Managing Partner
(Clinical development/safety/medical affairs consulting roles for global large/small pharma)

- Safety Risk Lead (SRL) for major pharmaceutical companies
  - Chair the Risk Management Committees
  - Provide continued monitoring of compounds in development and post-marketed
  - Lead safety member of global product teams
  - Present to executive teams outside of safety on newly determined risk findings
  - Continuous benefit risk assessment of all assigned products
  - Act on behalf of TA leaders
  - Member, internal DMCs for assigned products
  - Safety representative on external IDMCs
  - Safety authorship and reviews of IBs, DSUR, PBRER, ISS and SCS
- Member, clinical teams responsible for study and CRF designs, medical monitoring and data cleaning
- Lead teams on investigator/site qualifications
- Manage several client safety risk management programs
- Provide oversight and management of drug safety department, mentoring of safety physicians and associates at client companies
- Leading company-client teams in responses to regulatory audits and questions
- Responsible for final authoring of PBRERs, ISS, SCS and other safety documents for clients
- Clinical Safety monitoring and overview of clinical trials (Phases 1-3)
- Review and monitor study for protocol discontinuation rules
- Serve as a resource to the clinical investigators for advice about management of AE/SAEs, interpretation of inclusion/exclusion criteria, and other clinical and safety related questions
- Initiate and implement signal detection and tracking tools across multiple therapeutic areas
- Interact and lead clinical and regulatory teams in safety reviews for clients in house
- Oversight and coordination of call center and feedback responses to inquiries from HCP and consumers

- Business/Medical Affairs Responsibilities:
  - Performed scientific evaluation of pre-clinical proof-of-concept human health licensing, collaboration and acquisition projects.
  - Guiding the team that scientifically executes the therapeutic area licensing strategy by leading the Search & Evaluation component of the overall licensing process.
  - Leading the cross-functional scientific teams that are responsible for due diligence and scientific negotiations/approvals on major licensing projects.
  - Ensure medical quality, patient safety and scientific innovation as appropriate. Drive proposal review and ensure US/worldwide coordination of respective support programs
  - Drive US/worldwide Medical Affairs disease strategy and plan enhancing product profile, generating superior competitive value and aligned to client company disease strategy, franchise strategy and respective product strategies
  - Ensure suitable coverage of aspects of medical practice and patient management, drug combinations, health economics and outcomes research into plan
  - Develop publication trial strategy as well as strategy to support third-party sponsored research (e.g., investigator sponsored trials and cooperative study group sponsored trials) supportive of and aligned to respective development strategy

Merck Research Laboratories. North Wales, PA **Sept 2007- Nov 2009**
Senior Director, Therapeutic Area Head. Clinical Development, Risk Management/Safety Surveillance

Clinical development and post marketing for drugs in CNS, Diabetes, Vaccines and Oncology TA areas with the following:

- Provided clinical and strategic input to clinical development plan and relevant documents (e.g., protocols, study reports, investigator brochure, integrated safety summaries and other documents needed for product approval).
- Core Product team Member, responsible for overall strategic planning and execution of clinical programs for assigned products.
- Streamlined PSUR operational efficiencies for improved delivery and high quality reports
- Interacted with clinical teams, regulatory affairs, external bodies (DSMBs, and regulatory agencies), marketing regarding all safety issues
- Member medical/legal review board:
    - Ensured that promotional marketing materials were medically accurate and in line with DDMAC guidelines and product claims were supported by available clinical data claims and studies used for marketing materials met FDA requirements for the data validity and fair balance
    - Review of branded and generic online information for patient lifestyle and medication support
    - Review of speaker text, video and audio transcripts to ensure alignment with guidelines
- Provided mentoring and support for physician staff for medical evaluation and review of serious adverse events, spontaneously reported globally and also for those SAEs reported for clinical trials and post marketing surveillance, both local and global to ensure compliance with global and local regulatory requirements
- Collection, analyzation, and understanding clinical safety and epidemiologic data throughout drug life cycle
- Developed and conceptualized risk management plans for drugs and vaccines supporting drug application to health authorities. This was done in collaboration with clinical safety, marketing, legal, pre-clinical, and drug regulatory affairs
- Participated in internal research/safety meetings/boards including: DSMB, labeling, medico-legal, and others
- Performed evidence-based benefit-risk assessment
- Participated in several and multiple physician education/information sessions.
- Responded to safety inquiries from large HMOs and pricing bodies in the US and Ex-US for assigned products.

<u>Direct reports:</u>

1 Physician as line manager.
5 Scientists for operational deliverables and support for products.

Cephalon Inc. **March 2006-Sept 2007**
Senior Director, Corporate Chief Safety Officer, all therapeutic areas (CNS, oncology, medical devices and pain)

Pre and Post marketing support:

- Responsible for providing technical, scientific and managerial oversight of the managers of each of the functions within GPS and provide strategic oversight in integrating and coordinating the individual function activities. Responsible for ensuring compliance, preparing and managing the budget and overseeing performance management.
- Led and Provided oversight for training of company personnel and external vendor staff on drug safety processes, establishing company processes in line with local and global SOPs.

- Led review of Multiple vendors in assessment and choice of Safety Databases. Implemented testing and deployment of Safety Database.
- Provided clinical and strategic input to clinical development plan and relevant documents (e.g., protocols, study reports, investigator brochure, integrated safety summaries and other documents needed for product approval). Led investigator and monitor training
- Led clinical teams in site qualifications and safety monitoring plans
- Member, clinical teams responsible for study and CRF designs, medical monitoring and data cleaning
- Led teams on investigator/site qualifications
- Led clinical/regulatory teams for GCP and pharmacovigilance audits by regulatory agencies
- Interacted with clinical teams, regulatory affairs, external bodies (DSMBs and regulatory agencies), marketing regarding all safety issues
- Provided medical evaluation and review for serious adverse events, spontaneously reported globally and also for those SAEs reported for clinical trials and post marketing surveillance, both local and global to ensure compliance with global and local regulatory requirements
- Responsible for surveillance and medical review activities for all Cephalon products, providing medical and strategic guidance for all surveillance activities
- Initiate and implement Signal detection and tracking tools across multiple therapeutic areas
- Coordination of safety surveillance activities for clinical projects, study teams and initiatives, including signal detection and analysis
- Provided medical support to case processing, ensuring high quality outputs for both clinical safety and post marketing cases
- Member for Investigator Initiated Studies review team, approval of protocols
- Member, Corporate Risk Management Policy and Strategic team
    - Ensured that promotional marketing materials were medically accurate and were in line with DDMAC guidelines, product claims were supported by available clinical data claims, and studies used for marketing materials met the FDA requirements for the data validity and fair balance
    - Review of branded and generic online information for patient lifestyle and medication support
    - Review of speaker text, video and audio transcripts to ensure alignment with guidelines
- Responsible for executive level safety presentations and review
- Responsible for final review of regulatory documents for submissions
- Safety representative for regulatory interface meetings
- Member, Corporate Labelling Review Board. Participated in several and multiple physician education/information sessions.
- Responded to safety inquiries from large HMOs and pricing bodies in the US and Ex-US for assigned products.
- Responsible for Corporate Safety communication to external stake holders.

Direct Reports:

20 locally and internationally

- Safety physicians for surveillance activities and medical review of cases
- Risk management operations group
- Case operations group for ICSR processing
- Contracts group for managing alliance partners
- Safety writing group for aggregate reports
- Oversaw EU QP and local pharmacovigilance affiliates worldwide in meeting safety needs

Sanofi-Aventis Pharma **Oct 2002-March 2006**
Senior Director/Global Safety Officer, Global Pharmacovigilance and Epidemiology

Therapeutic areas: Cardiovascular, CNS, anti-infectives, respiratory/pulmonary, and oncology
Phase 1-4 (early phase development, NDA support and post-marketing)

Global and US risk management roles:

- Oversaw local and international reporting and pharmacovigilance activities, supporting affiliates in analytic reviews and third party questions on safety for assigned products
- Coordination of safety surveillance activities for assigned local and global clinical projects, study teams and initiatives, including signal detection and analysis
- Served as expert for all safety issues for assigned investigational products. Documented and evaluated the risk profile with the local and global project/study team, ensured ongoing risk/benefit assessment in cooperation with the global clinical director, communicated ongoing benefit/risk analysis to project and clinical study teams
- Provided pharmacovigilance input to clinical development plan and relevant documents (e.g., protocols, study reports, investigator brochure, integrated safety summaries and other documents needed for product approval). Contributed to investigator and monitor training. Interacted with clinical teams, regulatory affairs, external bodies (DSMBs, steering committees and regulatory agencies), marketing, regarding all safety issues
- Coordinated and directed activities of study safety physicians and managers at regional and local levels, ensured compliance with corporate standards in receipt and handling of safety information
- Aggregate safety data review: For assigned products, ongoing global clinical overview of all adverse event reports, including review of relevant literature for safety information pertinent to product safety, detection and evaluation of potential safety signals, periodic review/documentation of all safety data
- Communication and documentation of product safety assessment: including writing and coordination of all PSURs, SERs, labeling update proposals for the global labeling committee and US Package Insert Committee, development of safety action plans as appropriate, preparation/review of all company internal and external safety documentation
- Communication of benefit/risk analysis with relevant units (including regulatory, marketing, legal, QA, labeling and medical affairs), provide expert advice for internal/external customers regarding product safety profile
- Led global and local teams in responding to safety queries from regulatory authorities or third parties worldwide for all assigned products
- Participated in training of company personnel and external vendor staff on drug safety processes, establishing company processes in line with local and global SOPs
- Involved in interviewing, hiring, mentoring and training of employees, locally and internationally
- Had knowledge and experience of EU MRP and central submission process, EU label variation and other international regulatory agency submission support
- Had very good working knowledge of pharmacoepidemiology principles and initiated epidemiology searches and studies as appropriate

Eli Lilly and Company **August 1999-Oct 2002**
Director (Pharmacovigilance), global safety monitoring physician role – cardiovascular, CNS and endocrinology (Phase I-3 and Post marketing surveillance)

- Provided medical evaluation and review for serious adverse events, spontaneously reported globally and also for those SAEs reported for clinical trials and post marketing surveillance, both local and global to ensure compliance with global and local regulatory requirements
- Aggregate safety data review: For assigned products, ongoing global clinical overview of all adverse event reports, including review of relevant literature for safety information pertinent to

product safety, detection and evaluation of potential safety signals, periodic review/documentation of all safety data

- Communication and documentation of product safety assessment including writing and coordination of all PSURs, SERs, labeling update proposals for the global labeling committee and US Package Insert Committee, development of safety action plans as appropriate, preparation/review of all company internal and external safety documentation. Communication of benefit-risk analysis with relevant units, provided expert advice for internal/external customers regarding product safety profile
- Coordination of safety surveillance activities for assigned local and global clinical projects, study teams and initiatives, including signal detection and analysis.
- Served as expert for all safety issues for assigned investigational products.
- Documented and evaluated the risk profile with the local and global project/study team, ensured ongoing risk/benefit assessment in cooperation with the director medical research and project team leaders, communicated ongoing safety analysis and benefit/risk analysis to project and clinical study teams
- Coordinated and directed activities of study safety managers at regional and local levels, ensured compliance with corporate standards in receipt and handling of safety information. Provides pharmacovigilance input to clinical development plan and relevant documents (e.g., protocols, study reports, investigator brochure, integrated safety summaries and other documents needed for product approval)
- Contributed to investigator and monitor training
- Interacted with clinical teams, regulatory affairs, external bodies (DSMBs), marketing regarding all safety issues
- Supervised development, training and day-to-day activities of safety associates and scientists
- Led physician global safety team; reviewing AEs, MedDRA coding, reviewing for trends and important signals, responding to safety requests from global IRBs and regulatory authorities
- Provided medical expertise to program and product teams and Vendors on Safety data and SAE reconciliation process. Determination of safety parameters required for clinical trials, monitoring of safety trends in clinical trials, and ensuring proper documentation of AEs.
- Provided leadership for review and assessments of adverse events relationship to study drugs and follow up action on events
- Good knowledge of pharmacoepidemiology principles

Direct Reports:

Safety Associates
Regional safety MDs/local affiliate MDs in TA areas

FMAS Drug Safety and Clinical Research **Jan 1998-August 1999**
Associate Director (CNS, CV and metabolic areas)

Safety physician responsible for:

- Managed large phase 2-4 therapeutic and safety studies, coordinating SAE review with clinical research teams. Assessment of AEs and ADRs for signal detection and analysis
- Provided drug safety input to clinical trial protocols, clinical development sessions, and study development phases for clinical trials phase 4 trials
- Medical monitor clinical trials, responding to client and investigational site requests for safety information
- Monitored and prepared sites for GCP compliance audits
- Provided medical expertise to program and product teams and Vendors on Safety data and SAE reconciliation process. Determination of safety parameters required for clinical trials, monitoring of safety trends in clinical trials, and ensuring proper documentation of AEs.
- Provided leadership for review and assessments of adverse events relationship to study drugs and follow up action on events
- Responsible for clinical contents of study development, protocols and other study documentation
- Involved in interviewing, hiring, and training of staff

The Medical Clinic and Research center, San Fernando. Trinidad **Jan 1995-Dec 1997**
Collaborative regional center for international pharmaceutical companies
Medical Director

Director responsible for:

- Supervised and conducted multiple site clinical trials and epidemiology studies
- Execution of clinical trials phases 3-4
- Patient selection and enrollment in studies
- Monitored patient response in clinical trials for safety and efficacy
- Assessment and reporting of AEs, SAEs to sponsors, monitoring of trends and signals for products
- Analysis of clinical data collected from studies
- Assessment of adverse events in relationship to study drug
- Initiated and closed out of sites

San Fernando, Trinidad **Jan 1994-Dec 1997**
Community Lecturer

Diagnosis, prevention, treatment of common conditions in children

San Fernando General Hospital, Trinidad, West Indies **March 1994-Dec 1994**
Senior Medical Officer, Emergency Medicine and Surgery

San Fernando General Hospital, Trinidad, West Indies **June 1989-March 1994**
Clinical Residency, Pediatrics and Family Medicine

Clinical Internship Rotations **Nov 1987-May 1989**
Internal Medicine, Surgery, OB&GYN, Pediatrics

EDUCATION

University of Lagos, November 1987
MD College of Medicine
Residency: Pediatrics & Family Practice 1994 Trinidad & Tobago

MEDICAL CERTIFICATIONS AND LICENSES

Full Registration, Nigerian Medical Council 1990

Board & Permanent registration, Trinidad and Tobago Medical Council 1994

American Medical Association (AMA)

PROFESSIONAL MEMBERSHIPS

Drug Information Association (DIA)

American Academy of Pharmaceutical Physicians (AAPP)

American Medical Association

Clinical reviewer, AJHP