ROBERT SARHAN, MD

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EDUCATION

M.D., Medicine
University of South Carolina School of Medicine, Columbia, SC
June 1992

Bachelor of Science, Microbiology And Chemistry
University of Florida, Gainesville, FL
June 1985

- Graduated with Honors

PROFESSIONAL SUMMARY

Experienced medical doctor with a strong background in drug safety, pharmacovigilance, risk management, and regulatory compliance. Adept at leading cross-functional teams to develop and implement integrated risk management strategies, ensuring optimal benefit-risk throughout the lifecycle of pharmaceutical development. Proven ability to collaborate effectively with Clinical Development, Regulatory Affairs, Biostatistics, and other departments to drive successful outcomes. Recognized for strong leadership, communication, and analytical skills, and committed to fostering collaboration across diverse teams. Dedicated to advancing patient safety and regulatory compliance while adapting to the dynamic needs of clinical development.

SKILLS

- **Leadership & Team Management**: Leading cross-functional teams, training and coaching team members, fostering collaboration.
- **Safety Signal Detection & Data Analysis**: Analyzing clinical and post-marketing data to identify and mitigate safety signals.
- **Cross-Functional Collaboration**: Representing CSPV on Global Product Teams and collaborating with clinical, regulatory, and project management teams.
- **Risk Management Strategy Development**: Designing and implementing strategies to assess and manage risks throughout the product lifecycle.
- **Regulatory Interaction & Compliance**: Leading safety-related regulatory interactions and ensuring compliance with regulatory safety requirements.
- **Resource & Project Management**: Managing resources and coordinating efforts to deliver safety evaluation documents and regulatory submissions on time.
- **Advisory & Communication**: Providing expert safety advice and leading internal and external safety-related meetings.
- **Post-marketing surveillance, Pharmacovigilance expertise, Clinical trial monitoring, Adverse Event Assessment, Literature Review Quality Control, MedDRA coding of AEs, Development Safety Update Reports (DSUR), Periodic Benefit-Risk Evaluation Reports (PBRER), US Periodic Adverse Drug Experience Report (PADER), Periodic benefit-risk assessment reports, Risk Evaluation and Mitigation Strategy (REMS), Proficient in Argus Safety Database**

RESPONSIBILITIES

- Lead and manage a team of physicians and scientists, ensuring high-quality safety evaluation output and training for team members.

- Represent CSPV on the Global Product Team, serving as the primary safety point of contact and providing leadership across functions.
- Review and analyze clinical trial, post-marketing, and other safety data to identify and act on safety signals.
- Lead internal and external interactions with regulatory bodies and expert advisors to ensure effective risk evaluation and management.
- Define and implement risk management strategies and action plans for product safety throughout the product lifecycle.
- Coordinate resources to deliver safety evaluation documents and reports, ensuring timely and high-quality outcomes.
- Participate in safety-related regulatory meetings and post-approval commitments, ensuring ongoing compliance and safety management.

WORK HISTORY

July 2021 - Current
Daiichi Sankyo - Medical Drug Safety Physician-Medical Reviewer

- Medical review adverse events and provide assessment of causality. expectedness, and seriousness of AE/SAE reports, including evaluating the MedDRA coding and the case narrative for accuracy and completeness.
- Perform monthly Literature Review Quality Control, to identify case reports that meet criteria for entry into the safety database, identify relevant safety articles of marketed products and products in development: and the vendor creates literature summary sections to be included in Periodic Safety Update Reports.
- Compiling analysis of similar events (AOSE), individual case comments, RIMP analyses, and ad-hoc safety analyses as required by health authorities or corporate policy.
- Provide medical input for maintaining RIMP and post-marketing safety monitoring commitments.
- Provide periodic benefit-risk assessment reports for internal use.
- Investigating and reviewing emerging safety data from various sources including individual clinical trial AE/SAE case reports, spontaneous Adverse Drug Reaction (ADR) reports, published literature, aggregate reports, toxicology reports, non-clinical studies, and other sources.
- Contributes to the preparation and review of aggregate safety reports required by health authorities such as: Development Safety Update Reports (DSUR), Periodic Benefit-Risk Evaluation Reports (PBRER), US Periodic Adverse Drug Experience Report (PADER), etc.
- Authors, reviews and provides input for drug-safety related regulatory reports and clinical study documents including clinical study protocols, Informed Consent Forms, Investigator Brochures, Integrated Summary of Safety (ISS), Integrated Summary of Efficacy (ISE), MedDRA coding of AEs, product package and labeling.
- Uses medical knowledge, product knowledge and experience to determine potential causes of reported adverse events.
- Determines or confirms the company causality and authors and oversees the causality statement.
- As requested by management, participates in safety meetings to enhance medical assessment of adverse events of special interest or complex adverse events.
- Fosters and maintains a communication channel to SMTs or Clinical Safety physicians assigned to DSI products.

- Communicates clinically notable adverse events to SMTs/assigned physicians; appropriately reacts to new information provided by SMTs/CS/ physicians.
- Maintains regular and strong communication with other DS regions in Japan and Europe.
- Engages other relevant stakeholders such as CROs and Clinical Operations to provide robust ICSR management.
- Review ICS-related external communication such as analyses of similar events.
- Escalate problems to management.
- Streamlined adverse event case processing through the implementation of efficient workflows and procedures.
- Assisted in the preparation of periodic safety update reports, ensuring timely submission to relevant regulatory authorities.

April 2011 - April 2021
Celgene - Medical Drug Safety Physician-Medical Reviewer

- As Medical Director, my responsibilities were to provide medical management and professional medical support for clinical research projects as the assigned Medical Monitor.
- To assist in activities requiring Medical & Scientific support, including but not limited to assistance with feasibility assessments, medical training and provision of medical/clinical input to the design of study protocols and/or clinical development programs as well as assistance with business development activities, as directed by the department head.
- Collaborates with physicians, scientists, clinical trials staff, regulatory officials, medical affairs, and other members to ensure we meet FDA requirements and good clinical practice guidelines.
- Medically monitoring oncological clinical trials with 'Lenalidomide,' including inclusion/exclusion criteria, study design, safety monitoring in collaboration with CRO and processed all serious adverse events.
- Phase 2 clinical trials were conducted on patients with Lenalidomide that had B Cell Chronic Lymphocytic Leukemia, Monoclonal B-Cell Lymphocytosis, Stage 0 Chronic Lymphocytic Leukemia, Stage 1 Chronic Lymphocytic Leukemia, Stage 1 Chronic Lymphocytic Lymphoma.
- Phase 3 Clinical Trials were conducted on patients with Lenalidomide that had B-Cell Chronic Lymphocytic Leukemia, 450 patients in this study.
- Safety data flow sheet and data analysis understanding for New Drug Applications (NDA).
- New Drug Applications Submissions with Integrated Summary of Safety identify Serious Adverse Events that could be related to the drug. Adverse Events, predict occurrence of Adverse events and adequacy of exposure and how long followed subject.
- Produce reliable estimates of Safety Parameters, Safety Profile, Best Characterize from the Studies.
- Produce precise reliable estimates of safety parameters.
- Efficacy Analysis Integrates summary of the data demonstrating effectiveness, in which data supports dosage and administration.
- Development of Risk Management Plans and module 2.74, Summary of Clinical Safety.
- Pharmacovigilance reporting or Management Safety Database Management.
- Participated in safety data and content verification for module 2.73 Summary of Clinical Efficacy and Module 2.74 Summary of Clinical Safety.

- Clinical overview-risk/benefit analysis and Summary of Safety as well as module 2.5 of Clinical overview of risk/benefit analysis and Treatment Emergent Adverse Events.
- Experience in Risk Management Plan writing and responded to queries by Health Authorities.
- Ability to work on large volumes of data and Tables, Listings and Figures.
- Provides therapeutic and protocol-specific training to the project teams.
- Contributes medical input into the design of Clinical Development Programs and writing Study Protocols, Amending Protocols, Standard Operating Procedure, Case Report Forms, Research Documents and Clinical Study Reports.
- Perform routine Pharmacovigilance activities, daily Serious Adverse Events reviews, running reports from safety database, quarterly safety data overview reports and power point presentation for safety review meetings in collaboration with global safety leads.
- Phase II and Phase III writing Protocols, Clinical Study Reports, Institutional Brochures before submission to the regulatory authorities.
- Performs activities of Pharmacovigilance Physician responsible for data preparation and analysis of global Pharmacovigilance Physicians.
- Worked on Selective estrogen receptor modulators (SERMs) which are medications that can both mimic and block estrogen's effects in different tissues.
- Responsible for development of documents for Regulatory authorities on safety matters.
- Provides after hours medical support for projects in which assigned.
- Independently supports Business Development through participation in proposal generation, feasibility assessments, review of proposals/contracts for medical services, and attendance at meetings with sponsors as director.

June 1994 - March 2011
Department of Justice/Veterans Affairs - Family Physician

- Treat patients for all type of illnesses including Myocardial Infarctions, Hypertension, Atherosclerotic Cardiovascular Disease, Treat patients for Asthma, COPD, Pneumonia, Diabetes, HIV, Herpes, Headaches Multiple Sclerosis, Gastrosophageal Reflux Disease. Ulcerative Colitis, Crohn's Disease, Dermatological Disease such as Psoriasis and Eczema, Arthritis, Wound Care, Fractures and Other medical problems seen in a general practice.
- Referrals to Cardiologist for stress test, Pneumonologist for Pulmonary Function Test, Urologist to rule out Prostate Cancer, Renal Cell Carcinoma, Gastric Endoscopy's to Rule Out Peptic Ulcer Disease, Colonoscopy's to rule out Colon Cancer and more.

June 1992 - June 1994
Jackson Memorial Hospital - House Physician

- General Surgery-Assistant General Surgeon in Hernia Operations: Colon Resections, Laparoscopic Cholecystectomies and much more.
- Vascular Surgery- Assist Vascular Surgeon in Carotid Endarterectomies, Femoral/Popliteal Bypass Surgery, Strip Leg Veins for Cardiac Bypass Surgery, Angioplasty, Stent Placement, and placed patients on anticoagulants such as heparin and warfarin or coumadin.
- Plastic and Reconstructive Surgery-Facial Plastic Surgery for Car Accident and Assault with knives to the face and Suturing Lacerations, Assist Surgeon in Breast Reconstructive Surgery in Bilateral Mastectomy to rebuild Breast.
- Breast Implants, Liposuction, Skin Transplants and Cosmetic Surgery.
- Orthopedic Surgery-Arthroscopic Surgery, Hip Replacement Surgery and more.

- Wound Care-Specialty in treating Vascular Stasis Ulcers and Bed Sores and Ulcers.
- OB/GYN- 106 Deliveries, with Surgical Episiotomy Repair.
- Lumbar Puncture, Paracentesis, Thoracentesis, Chest Tubes, Central Lines, Swan Ganz Catheters and more.
- Emergency Room Physician-Patient Care and Trauma.
- Emergency Triage to treat Myocardial Infarctions, Assaults such as Stab Wounds, Gunshot Wounds, Facial Lacerations and Lacerations and Trauma from Work Injury, Car Accidents, Fractures and more.