BINDU TEJURA, B.SC MBBCH MD
btejura@arujetpharmaceuticals.com
UK +44 (0) 1633-422535 USA + 1 (617) 500-4246

PROFILE:
Medical Director and Clinical Research Investigator with over 10 years of experience in Phases I through III pharmaceutical development, including assessment of tolerability, pharmacokinetics and pharmacodynamics of new drugs.

- Excellent understanding of all processes involved with drug development and each department's critical role; intimately familiar with processes related to business functions such as in-licensing, development, and fundraising
- Solid background in protocol development, FDA and BLA submissions and responses, strategic planning of clinical trials, recruitment, summation of clinical safety reports, and invention submissions
- Chief medical officer, with willingness to take on challenges such as making presentations to key investors, interfacing with key opinion leaders, and appearing before scientific advisory boards and regulatory committees
- Hands on experience in all cross-functional teams and areas such as toxicology, clinical, medical affairs, regulatory, chemistry and manufacturing, quality, legal, marketing, sales, and business development
- Expertise in oncology and orphan diseases

CLINICAL AREAS OF EXPERIENCE:

• Cardiovascular • Hepatology • Infectious Disease •Internal Medicine
• Oncology • Orphan Diseases • Pediatrics • Renal • Virology

CREDENTIALS:

Board Certified, Internal Medicine
American Boards of Internal Medicine (Equivalent to MRCP) **1999**
ECFMG Certification
Federal Licensing Examinations
Registered with the General Medical Council of the United Kingdom
Medical License, State of California

PROFESSIONAL:

Medical Director ***2009-present***
ANTISOMA, Cambridge, MA
Antisoma, a biotechnology company specialising in the development of novel drugs for the treatment of cancer, was founded in 1988 with offices in London and Boston, MA.

- Significant involvement as medical monitor for the company's lead Phase 3 program, AS1413 ACCEDE trial, in secondary acute myeloid leukemia (sAML)
- Work closely with the Pharmacovigilance Manager review SAEs and other safety data
- Ensured SAE reports are medically correct and that diagnosis / signs & symptoms are recorded and coded accurately, identifying any further follow up information required
- Review the need for safety information to be updated e.g. in Patient information Sheets, Investigator Brochures
- Review line listings of study-specific AEs/ SAEs for safety trends and issues to identify unexpected and medically important events escalating them to the Chief Medical Officer
- Provide medical review and significant input into clinical trial Annual Safety Reports, other regulatory reports and the IB
- Review all clinical data for the sAML Phase 3 program and support clinical operations, clinical research organizations and clinical trial sites as needed

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Director of Clinical Development ***2009***
AMSTERDAM MOLECULAR THERAPEUTICS, Amsterdam, The Netherlands

- Responsible for planning, implementing, directing and managing clinical development of orphan disease programs including AMT's lead product for lipoprotein lipase deficiency
- Provided clinical expertise on a cross-functional team in the development and publication of clinical trial protocols and in the writing and publication of scientific manuscripts
- Assured that all protocols, clinical trial data bases, and SOPs were fully accurate, timely, and compliant with FDA, ICH or any other governing regulatory agency
- Reviewed AMT's products for efficacy or adverse effects

Practice Manager ***2009***
KBT MEDICAL CORP, Corona, CA
A well established medical practice in Corona, CA since 1978, that has provided a wide range of medical care for children of all ages, adolescents, and young adults through age 21 years.

- Reporting to the primary physician duties involved supporting, developing and implementing the medical office practice administrative and healthcare capabilities
- Planned, supervised and coordinated patient care delivery to assure efficient management and utilization of resources at the clinic
- Ensured that standards of care, operations and practice were in compliance with State and Federal Regulations, JCAHO standards, safety regulations, infection control standards and hospital policies
- Oversaw budget, payroll, policies, hiring, coaching/counseling and staff evaluations

Medical Director, Experimental Medicine ***2008-2009***
DYAX CORPORATION, Cambridge, MA
A biotech company specializing in phage display technology allowing the generation of large diverse libraries of human antibodies, peptides, and proteins which are screened against disease-associated target molecules in oncology, immunology and inflammation to identify potential binders.

- Conducted toxicology studies and worked with animal models to mimic Phase I data, conducting preclinical studies and investigating biomarkers, surrogate markers, and indications related to IgG antibody and oncology products
- Provided medical expertise, particularly related to oncology and immunology (Dx-2400 and Dx2500), in interpretation and communication of preclinical and clinical data for scientific advisory board
- Submitted invention proposals to legal department for consideration for development, including ideas for oncology, autoimmune disease products and joint venture related to antibody.
- Completed summary of clinical safety reports and reviewed efficacy report as part of BLA submission for Dyax's main product, Dx-88, a plasma kallikrein inhibitor for use in the orphan disease HAE
- Assisted scientific advisory committee by participating in preparation of slides, questioning speakers, and functioning as secondary medical expert at FDA hearings.
- Developed pediatric investigational plan for MAA submission regarding Dx-88 and presented plan to European colleagues
- Contributed to efforts involved with medical monitoring, protocol generation and review, clinical data review, and generation of responses to review boards and ethics committees

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Medical Director, Clinical Research **2007-2008**
CUBIST PHARMACEUTICALS, INC., Lexington, MA
A biopharmaceutical company that develops novel therapies for use in hospitals and other acute care settings

- Managed in-licensing process and clinical development of hepatitis and clostridium difficile products.
- Performed due diligence at various companies and recommended in-licensing of hepatitis C product developed by Illumigen, which was ultimately purchased by Cubist
- Designed Phase I-2 studies for clostridium difficile and hepatitis agents
- Wrote and presented to principal investigators Phase IV renal pediatric protocol; developed plan for recruitment of pediatric chronic ambulatory (CAPD) dialysis patients for renal study; finalized identification and selection of 11 out of 12 required patients
- Spearheaded progress of phase IV trials and protocol development by applying FDA recommendations while ensuring studies' inclusion and exclusion criteria were not prohibitive

Assistant/Interim Chief Medical Officer ***2005-2007***
MANHATTAN PHARMACEUTICALS, New York, NY
Chief Medical Officer less than one week after start date, following unexpected departure of predecessor; defended protocol before FDA committee very shortly thereafter.

- Managed all operational aspects of a small biotech company with frequent interactions with representatives in toxicology, CMC, regulatory, financial and legal departments
- Focused on development of products related to metabolism, obesity, sedation, and dermatology
- Oversaw safety and tolerability evaluations and pharmacovigilance for Phase I and early Phase II clinical trials of new drug candidates in various populations and conditions
- Reviewed budgets and contracts with clinical trials manager
- Made presentations before investors, raising approximately $25 million in funding
- Grew clinical development department from one person to four with assistance of recruiters
- Collaborated with team members, investigators, and thought leaders in identifying clinical study design strategies and evaluated study sites in compliance with applicable SOPs
- Evaluated clinical significance of pre-IND efficacy and safety information in support of regulatory submissions and clinical studies. Maintain safety information within investigator's brochure for each project
- Spearheaded progress of compound Oleyl-esterone (OE) through Phase I and Phase II; contributed to writing of protocol and review of safety data and updates
- Reviewed patent information with legal team; ensured fees and submissions were dispatched according to deadlines
- Reviewed clinical data on OE and identified application in treatment of polycystic ovary disease in addition to original use for obesity treatment; filed and received two patents for OE; developed dosing regimen for OE, successfully minimizing toxicity
- Hands on contributor to in-licensing process for Hedrin, anti-lice medication

Acting Medical Director/Senior Clinical Research Physician ***2003-2004***
Clinical research Physician ***2000-2000***
SIMBEC RESEARCH LTD., Merthyr Tydfil, UK

- Planned, designed, and directed Phase I, II and III trials; wrote protocols, screened volunteers
- Attended ethics meetings, verified suitability of labs involved in multi-site trials, and oversaw gathering of basic pharmacokinetic data.
- Made decisions related to research and development strategy, operations, manufacturing, and preclinical research.
- Established and maintained partnerships in academia and industry, particularly in the areas of anesthetics and metabolic medicine.

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Clinical Research Physician ***2000-2003***
HAMMERSMITH MEDICINES RESEARCH, London, UK

- Collaborated with investigative teams to study novel compounds in Phase I, II and III of development
- Recruited healthy volunteers and patients; conducted full medical histories and physical exams for specific studies
- Obtained and interpreted preclinical and clinical data and monitored and responded to adverse drug reactions
- Developed novel methodology for assessment of pharmacodynamic effects of new drugs
- Liaised with University College of London to recruit 12 thallasemia patients for Phase III study

HAMMERSMITH HOSPITAL, London, UK
Specialist Registrar Clinical Pharmacology/Cardiology

RESIDENCY AND FELLOWSHIPS:

ALBERT EINSTEIN MEDICAL CENTER, Philadelphia, PA, Internal Medicine
LEICESTER GENERAL HOSPITAL, Leicester, UK Nephrology, Cardiology, and Internal Medicine
LEICESTER ROYAL INFIRMARY, Leicester, UK Coronary Care, Pharmacology and Therapeutics, Internal Medicine
LLANDOUGH HOSPITAL, Cardiff, UK Elderly Care and Internal Medicine Internal Medicine and Pharmacology
STANFORD UNIVERSITY MEDICAL CENTER, Stanford, CA, Pharmacology and Therapeutics
UNIVERSITY OF WALES, Llandough and Heath Hospitals, Cardiff, UK Medicine and Surgery

EDUCATION: 1992, MBBCh,
UNIVERSITY OF WALES COLLEGE OF MEDICINE, Heath Park, Cardiff, Wales
1991, B.Sc., Pharmacology,
UNIVERSITY OF WALES COLLEGE OF MEDICINE, Heath Park, Cardiff, Wales (First Class Honors), Thesis: The effect of prolactin and staurosporine on nitric oxide release in the rabbit aorta

HONORS AND AWARDS:

- Stanley Levick Award for Outstanding Intern in Oncology (1997) ACP Regional Medical "Doctors Dilemma Champion" (1997, 1998)
- Medical Insurance Agency Award (1991)
- Medical Defense Union Award (1991)
- Jane Hodge Award (1991)

PATENTS AND PUBLICATIONS:

- Methods Of Reducing The Body Weight Of A Subject By Administering A Fatty Acid Ester Of An Estrogen Or Estrogen Derivative In An Oil And Compositions Containing The Same; Inventors: Michael B. Maurin Nutan K. Gangrade Kristi O. Lenz Bindu Tejura; IPC8 Class: AA61K3156FI; USPC Class: 514178
- Methods Of Treating Hyperandrogenism And Conditions Associated Therewith By Administering A Fatty Acid Ester Of An Estrogen Or An Estrogen Derivative Pub. No.:WO/2008/042260 International Application No:PCT/US2007/020932; Publication Date: 10.04.2008 International Filing Date: 28.09.2007; IPC: A61K 31/56 (2006.01), A61K 35/22

(2006.01), A61K 38/24 (2006.01)

- Society for Ambulatory Anesthesia - 20th Annual Meeting: Pilot Safety, Tolerability, and Pharmacokinetic Human Trial of Propofol Lingual Spray Christine Broestl, M.S., Gary Shangold, M.D., Marc Sine, M.S., Bina Tejura, M.D, Drug Development, Manhattan Pharmaceuticals, New York, New York, United States Anesthesiology 2005; 103: A742
- 14th European Congress on Obesity, Athens, Greece, Investigating an Anti-Obesity Hormone 6/22/05
- Alimentary Pharmacology and Therapeutics Journal:Effects of rabeprazole, 20 mg, or esomeprazole, 20 mg, on 24-h intragastric pH and serum gastrin in healthy subjects S. Warrington, K. Baisley, M. Boyce, B. Tejura, A. Morocutti & N. Miller 2002; 16: 1301–1307
- Clinical Pharmacology & Therapeutics - Abstract of article: Clinical Pharmacology & Therapeutics (1999) 65, 58– 65; Inhibition of angiotensin-converting enzyme in human hand veins Stephan Chalon MD, Gabriella V. Bedarida MD, Heitor Moreno Jr MD, PhD, Bina Tejura MD, Akinori Urae MD, Brian B. Hoffman MD and Terrence F. Blaschke MD
- Transfusion-Associated Falciparum Malaria Successfully Treated with Red Blood Cell Exchange Transfusion Bina Tejura, David A Sass, Robert A Fischer, Ierachmiel Daskal, Glenn Eiger American Journal of the Medical Sciences, ISSN: 0002-9629, Vol: 320, Issue: 5, Date: 2000, and
- Centre for Disease Control (CDC) publication Morbidity and Mortality Weekly Report (April 02, 1999 / 48(12);253- 256)
- Pseudotumour of the orbit: bilateral metachronous presentation. Br J Clin Pract. 1995 Mar-Apr;49(2):102-4. Anwar S, Davies KG, Tejura B, White AE, Neal JW, Lane C