VASUNDHRA KASHYAP

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EDUCATION

CORNELL UNIVERSITY, S.C. Johnson Graduate School of Management, Ithaca, NY **May 2012**
Master of Business Administration

CORNELL UNIVERSITY, Weill Graduate School of Biomedical Sciences, New York, NY **May 2011**
PhD in Pharmacology

- Thesis title "Transcriptional regulatory mechanisms mediated by retinoids and RARγ in stem cells and fibroblasts"
- Research work culminated in 6 publications with a total of 400+ citations
- **Explanation of dissertation:** Delineated the transcriptional regulatory pathways mediated by retinoic acid during stem cells differentiation and cancer; using stem cells and fibroblasts as model systems chromatin immunoprecipitation assays were performed in combination with gene expression studies to probe the dynamics of RA induced transcription at many genes that are important in differentiation and development
- Research funded by **US Department of Defense** through the prestigious Breast & Prostate Cancer Fellowship

INDIAN INSTITUTE OF TECHNOLOGY, Delhi, India **May 2004**
Master of Science (Chemistry)

- Dissertation title "Immobilization of trypsin on smart copolymer of N-isopropyl acrylamide (NIPAAm) with 5-mol% 6-Acryl aminohexanoic acid"
- **Explanation of dissertation**: Synthesized a temperature sensitive smart polymer which finds applications in drug delivery and tissue engineering; utilized the smart polymer for purification of enzymes used in food and textile industry

ST. STEPHEN'S COLLEGE, UNIVERSITY OF DELHI, Delhi, India **July 2002**
B.Sc. (Honors) Chemistry, July 2002

EXPERIENCE

SHIRE, Lexington, MA **Jan 2017- Present**
Manager R&D Business Analytics

- **Conduct and lead portfolio prioritization of 40+ pipeline programs to inform R&D decision making**
  + Analysis is informed by extensive primary and secondary research to characterize disease pathophysiology, unmet need, biological link between asset and disease manifestation across >40 indications spanning oncology, GI, ophthalmology, hematology, genetic and neurology disorders
  + Review and analyze existing clinical data on available products to develop and benchmark target product profile of pipeline programs, and validate clinical impact of pipeline assets based on extensive physician focused interviews
  + Assess clinical trial and regulatory pathways to delineate feasibility of clinical development

BACK BAY LIFE SCIENCES ADVISORS, Boston, MA **June 2014- Dec 2016**
Medical Research Scientist

Examples of selected executed projects:

- **Project 1: Conducted an extensive review of scientific and clinical publications to analyze over 70 preclinical and clinical stage rare disease focused drug candidates under development to advise a rare disease focused bio-pharma company on selection of suitable assets for further clinical development**
  + Researched pathophysiology of disease, current diagnostic and treatment paradigm, and assessed the potential ability of drug candidates to modify the disease pathway(s)

+ Evaluated the drug development path to delineate clinical trial enrollment, patient inclusion/exclusion criterion and endpoint selection
+ Developed a scoring framework encompassing scientific, clinical and business elements to prioritize all the drug candidates
+ Conduced detailed assessment of 15 drug candidates with highest score to delineate the underlying disease pathways, epidemiology, prevalence of diagnostic tools, degree of unmet need, impact of asset on addressing the clinical need, regulatory pathway and market access considerations such as pricing and patient/physician awareness

- **Project 2: Reviewed scientific and clinical publications to identify ~30 diseases with complement dysregulation; selected the optimal indications for clinical development for a complement targeted asset under development by a rare disease biopharma company**
    + Conducted extensive review of scientific/clinical publications to delineate the pathophysiology, current treatment approaches and unmet clinical needs for over 20 disorders
    + Reviewed epidemiological studies to estimate the incidence/prevalence burden
    + Evaluated potential design of trials including endpoint selection, duration of treatment, patient inclusion/exclusion criterion, timeline of trial completion to characterize the development pathway to regulatory approval
    + Assessed the competitive landscape, development path, and potential clinical impact of novel drugs under development
    + Synthesized the analysis to estimate patients eligible for a novel therapy based on different Target product profile scenarios

- **Project 3: Identified and evaluated over 30 vascular diseases to identify new clinical stage medical devices and/or therapeutics for a specialty healthcare company to support growth of vascular medicine business unit**
    + Reviewed medical literature and developed patient care pathways to identify and assess over 40 different relevant indications
    + Profiled each of the indication based on epidemiology, level of clinical unmet need, developmental feasibility, availability of drugs/ devices in development and overlap with current commercial footprint
    + Conducted interviews with clinicians and vascular medicine researchers, and performed extensive secondary research utilizing publications and clinical trial databases to characterize clinical need and identify innovative treatments, including novel drugs and medical devices that address clinical need
    + Synthesized the analysis to develop multiple franchise scenarios encompassing development of drugs and/or devices that address related or overlapping vascular conditions

- **Project 4: Conducted a landscape analysis of hospital infections to identify unmet clinical needs for development of novel antibiotics, and developed target product profiles for novel antibiotics with activity against gram negative resistant bacterial strains**
    + Undertook a systematic analysis based on review of public health databases and in-depth discussions with Infectious disease KOLs to identify infectious diseases associated with highest clinical burden and unmet clinical need based on mortality rates, incidence of secondary complications, prevalence of resistant pathogens and hospital length of stay
    + Developed target product profiles for new antibiotic drugs delineating minimal and optimal benchmarks required for efficacy, safety and dosing
    + Reviewed FDA's guidance on antibiotic development and evaluated trials conducted for analogous antibiotics to outline the development path based on inclusion/exclusion criterion for patient selection

- **Project 5: Developed and validated a target product profile for a novel clinical stage asset for relapsed/refractory diffuse large cell B-Cell lymphoma through in-depth primary research with key opinion leaders (KOLs) in US and EU5 markets**
    + Conducted primary market research to delineate the current treatment paradigm and unmet needs in relapsed/refractory DLBCL
    + Reviewed clinical studies and trials to delineate efficacy of existing therapies in different lines of treatment, and identified minimal and ideal benchmarks for safety and efficacy required for the novel asset under development
    + Provided feedback on clinical trial design based on evaluation of ongoing and completed clinical trials, and feedback from KOLs
    + Investigated additional opportunities for clinical development of the asset based on unmet need in front-line DLBCL and additional types of lymphoma in combination with alternative novel assets

- **Project 6: Conducted assessment of clinical and commercial landscape of treatment of lymphoma therapy in conjunction with the companion diagnostic (CDx) in 7 emerging markets (e.g. Brazil, Turkey, Russia, Mexico) based on focused research with ~50 physicians and pathologists**
    + Conducted primary research with hematologists, oncologists and pathology lab directors in each market to delineate existing diagnostic and treatment protocol
    + Characterized the landscape and use of CDx, prevalence of different diagnostic technologies, and market specific drivers and barriers for adoption of a new CDx
    + Validated the clinical value of CDx in identifying appropriate patient groups for treatment
    + Delineated regulatory pathways and reimbursement infrastructure for CDx in all the markets
    + Developed a strategic roadmap outlining actionable tactical steps to commercialize lymphoma therapy alongside CDx

- **Project 7: Assessed the clinical value and analyzed the commercial opportunity of a novel hepatobiliary MRI contrast agent that is in late stage development for chronic kidney disease patients**
    + Reviewed the clinical publications to delineate the toxic effects of gadolinium based MRI contrast agents in chronic kidney patients
    + Conducted extensive discussions with radiology KOLs to assess unmet diagnostic needs to identify patient populations that are unserved
    + Created a target product profile of the novel MRI contrast agent and obtained feedback from over 25 radiologists to validate need for a new MRI agent and identified clinical performance parameters
    + Synthesized these findings to build a revenue forecast model and provided recommendations on clinical development and commercialization strategy to the management team

SCIENTIA ADVISORS, A Precision for Medicine Company, Cambridge, MA **Aug 2012- May 2014**
Senior Analyst, Promoted to Consultant in Mar 2013
Examples of selected executed projects:

- **Project 1: Evaluated biomarker candidates under development for treatment guidance in late stage chronic kidney disease to inform biomarker R&D efforts of a leading provider of dialysis services**
    + Reviewed and analyzed scientific/clinical publications and engaged KOLs to identify all the potential biomarkers that may serve a role in treatment of CKD
    + Developed a scoring framework to rank these biomarker candidates based on their potential clinical utility
    + Identified research groups with significant scientific/clinical experience for high priority biomarker candidates, and outlined clinical studies required to validate biomarker for widespread clinical use

- **Project 2: Conducted technology and market assessment of novel diagnostic platform and diagnostic assays for fatty liver disease, therapeutic monitoring of chemotherapy regimen (5-FU) and lyme disease, to inform investment recommendations of a biopharma investor**
  + Engaged key opinion leaders and reviewed scientific and clinical publications to evaluate the clinical need of novel diagnostic assays and establish the benchmarks of clinical performance
  + Synthesized the technology, clinical and market analysis to develop a revenue forecast for each diagnostic assay and performed valuation of the company

- **Project 3: Identified novel opportunities for developing diagnostics for prostate cancer patients for a fortune 100 healthcare company based on extensive primary research with leading oncology KOLs**
  + Conducted detailed analysis of diagnostic and treatment paradigm through extensive review of guidelines of key cancer societies (National Comprehensive Cancer Network, American Cancer Society), and leading academic medical centers (Memorial Sloan Kettering Cancer Center) and focused discussions with KOLs (medical oncologists, surgical oncologists), identified unmet needs in diagnosis of prostate cancer through the lens of patient journey
  + Identified clinical attributes and commercial requirements of the newly identified diagnostic opportunities
  + Conducted health economic research to compute potential health savings attainable from availability of diagnostic tests, and quantified the associated market opportunity

- **Project 4: Delineated the clinical utility and market opportunity for a novel molecular diagnostic platform based on primary research with lab directors and market assessment**
  + Developed a product profile of a new diagnostic platform; conducted interviews with lab directors and physicians to gain feedback on product
  + Performed competitive benchmarking analysis to compare attributes of the client's product to ultimately identify advantages and limitations of the client's product
  + Translated feedback from interviews and market insights into actionable recommendations for near to long-term strategic planning to further improve the product and mitigate commercial risks

- **Project 6: Developed, characterized and prioritized a database of novel solutions in patient monitoring across multiple healthcare settings for an internal VC group of a Fortune 100 company to support their investment strategy and guide decision making on**
  + Conducted extensive analysis encompassing identification of most attractive disease from multiple sources of healthcare data to identify attractive disease areas based on unmet needs, market opportunity, and availability of venture backed solutions to guide mid to long term investment strategy
  + Built a database of 100+ novel patient monitoring devices and software solutions under development for patients across multiple care settings- home, hospital, long term care facilities
  + Performed technology assessments of different solutions to delineate advantages and disadvantages of different technologies, while mapping these solutions to patient care journey
  + Translated the analysis into a strategic roadmap for investment opportunities in patient monitoring

CORNELL UNIVERSITY, Weill Graduate School of Biomedical Sciences **New York, NY**
Graduate Research Assistant

- Reviewed over 10 manuscripts submitted for publication in journals such as Cancer Research, FASEB, Molecular and Cellular Biology
- Gained extensive experience in biochemical, molecular biology and cell culture techniques- Real-time and semi-quantitative PCR analysis, microarray analysis, cell culture of embryonic stem cells, primary cells and cancer cells, Western, Northern and Southern blot analysis, ELISA, Stable and Transient transfection of siRNA, Cloning, Chromatin immunoprecipitation assays, DNA methylation

assays, Luciferase reporter assays, Cell-proliferation assays, Stable and Transient cell transfection techniques, In vitro transcription/ translation assays, Immunoprecipitation assays

- Led weekly teaching laboratory sessions for freshmen level general chemistry, evaluated student progress and assisted in improving their performance (Cornell Ithaca campus)
- Supervised and trained junior graduate students and technicians in developing experiments and learning research techniques

HONORS AND AWARDS

CORNELL UNIVERSITY, Johnson Graduate School of Management, Ithaca, NY

- Recipient of Lee full-tuition scholarship awarded to one or two students every year

CORNELL UNIVERSITY, Weill Graduate School of Biomedical Sciences, New York, NY

- Recipient of $200,000 Predoctoral Prostate Cancer Fellowship awarded by U.S Department of Defense (2008-2011)
    + Research proposal: The Functional Relationship between Polycomb Group Proteins and the Retinoid Signaling Pathway in Human Prostate Cancer

- Recipient of $200,000 Predoctoral Breast Cancer Fellowship awarded by U.S Department of Defense (2008-2011)
    + Research proposal: The Role of RAR beta 2 in the Regulation of the Human DAB2 (disabled2) Gene in Human Breast Cancer

St. Stephen's College, University of Delhi, India

- Awarded Sumitomo Scholarship (top 2 %) by Sumitomo Corporation for academic excellence
- Awarded Professor Seshadri Prize for being the topper in University of Delhi, B.Sc.(Honours) Chemistry, amongst 400 enrolled students
- Awarded Ramesh Goel Memorial Prize (top 1%) for best academic performance
- Awarded Science Academic excellence Award (top 10%) by Delhi University for two consecutive years

PUBLICATIONS

- **Kashyap V**, Rezende NC, Scotland KB, Shaffer SM, Persson JL, Gudas LJ, Mongan NP. Regulation of Stem Cell Pluripotency and Differentiation Involves a Mutual Regulatory Circuit of the NANOG, OCT4, and SOX2 Pluripotency Transcription Factors with Polycomb Repressive Complexes and Stem Cell MicroRNAs. Stem Cells Dev. 2010, Sep;18(7):1093-108. PMID: 19480567
- **Kashyap V**, Gudas LJ. Epigenetic Regulatory Mechanisms Distinguish Retinoic Acid Mediated Transcriptional Responses in Stem Cells and Fibroblasts. J Biol Chem. 2010, May 7; 285(19):14534-48. PMID: 20231276
- **Kashyap V**, Gudas LJ, Brenet F, Funk P, Viale A, Scandura JM. Epigenomic Reorganization of the Clustered Hox Genes in Embryonic Stem Cells Induced by Retinoic Acid. J Biol Chem. 2011, Feb 4; 286(5):3250-60. PMID: 21087926
- **Kashyap V,** Ahmad S, Nilsson EM, Helczynski L, Kenna S, Persson JL, Gudas LJ, Mongan NP. The lysine specific demethylase-1 (LSD1/KDM1A) regulates VEGF-A expression in prostate cancer. Mol Oncol. 2013 Jun;7(3):555-66. PMID: 23384557
- **Kashyap V,** Laursen KB, Brenet F, Viale AJ, Scandura JM, and Gudas LJ. RARγ is essential for retinoic acid induced chromatin remodeling and transcriptional activation in embryonic stem cells. J Cell Sci. 2013 Feb 15; 126(4): 999–1008. PMID 23264745
- Laursen KB, **Kashyap V,** Scandura J, Gudas LJ. An alternative retinoic acid-responsive Stra6 promoter regulated in response to retinol deficiency. J Biol Chem. 2015 Feb 13;290(7):4356-66. PMID: 25544292

POSTER AND PODIUM PRESENTATIONS

- Annually presented poster on thesis research at the Vincent du Vigneaud Memorial Research Symposium, Weill Cornell Graduate School of Medical Sciences/Memorial Sloan Kettering Cancer Center, 2007-2011
- Presentation on "The cross talk between polycomb group proteins and Retinoid signaling" at the Pharmacology Annual Retreat, Weill Cornell Graduate School of Medical Sciences 2008 and 2010
- Presented a poster on "Epigenetic Regulatory Mechanisms Distinguish Retinoic Acid Mediated
- Transcriptional Responses in Stem Cells and Fibroblasts" at Keystone Symposia, Deregulation of Transcription in Cancer: Controlling Cell Fate Decisions transcription in Cancer, Ireland, June 2009
- Presented a poster titled "Functional role of polycomb group proteins in retinoid signaling" at The FASEB Summer Research Conference, Transcriptional Regulation During Cell Growth, Differentiation, and Development, Colorado, 2008
- Formulated and presented a research proposal focused upon elucidating the role of BRIT1 in DNA damage and cell cycle arrest as part of the thesis qualifying exam

PRIOR REVIEW EXPERIENCE

- Reviewer for journal **Heterocyclic Letters**
    + "SBCL3-SIO2 as an efficient and heterogeneous catalyst for the synthesis of polyhydroquinoline derivatives under solvent-free conditions", **Feb 2017**

- Reviewer for **Journal of Advanced Pharmaceutical Science and Technology**
    + "Chronic atrial fibrillation(AF), coexisting with a history of recent coronary angioplasty with stent (PCI-S) represents an encoded indication for oral anticoagulation with warfarin (OAC) plus dual antiplatelet therapy (DAPT)", **May 2016**

- Reviewed book "Diagnosing Rare Diseases -Giving Families Hope Through DNA Testing, Crowdfunding and Access to Experts" by Ana Sanfilippo and Dr. Jimmy Lin (**2014**)