JASON SUMMA

BSc, MBA, PMP®, RAC®

DRUG DEVELOPMENT PROFESSIONAL
CLINICAL DEVELOPMENT, CLINICAL OPERATIONS, PROJECT MANAGEMENT, AND MEDICAL WRITING

CONTACT

- **FOR FULL-TIME OPPORTUNITIES:**
  - (617) 335-1794
  - me@jasonsumma.com
  - www.jasonsumma.com
  - LinkedIn

- **FOR CONSULTING OPPORTUNITIES:**
  - (617) 335-1794
  - jason@summaconsultinggroup.com
  - www.summaconsultinggroup.com
  - LinkedIn

STRENGTHS

- **Extensive experience in Clinical Development and Operations**, particularly in oncology.
- **Proficiency in Medical Writing**, for effective communication of complex medical information.
- **Expertise in Drug Development,** from early-stage trials to FDA reporting, indicating a thorough understanding of the pharmaceutical development process.
- **Strategic decision-making skills**, essential for effective project management and problem-solving in clinical research.
- **Leadership and team management capabilities**, demonstrated by experience in guiding cross-functional teams.
- **Educational background with an MBA and B.Sc. in Chemistry**, providing a strong foundation in both business and science.
- **Certifications in Project Management (PMP) and Regulatory Affairs (RAC)**, enhancing my professional qualifications.

ACCOMPLISHMENTS

- Publications
- Protocols
- Patents

BACKGROUND

With over two decades in drug development, I excel in simplifying complex medical concepts for diverse audiences and driving positive change within matrixed teams. Notable achievements include rectifying a biomarker assay error in 6 months, boosting patient response rates by 25%, and increasing patient enrollment and enrichment while accelerating AKEEGA®'s approval process. I secured Breakthrough Therapy designation for niraparib in men with prostate cancer. I helped to orchestrate the successful transition of academic drug delivery technology From MIT into clinical development, securing $56 million in funding and eventual acquisition by Pfizer in 7 years. Rooted in personal experiences, my passion lies in revolutionizing treatments and education in the medical field.

WORK EXPERIENCE

Owner, Drug Development Consultant

Summa Consulting Group, Remote
September 2021 - Present

- **Our clients include:** Exelixis, Inc, Incyclix Bio, Reboot RX, Takeda, Neumora Therapeutics, CAMP4 Therapeutics Corporation, Tarsus Therapeutics, Flow Pharma, Mind Medicine, Protocol Builder, Revitope Oncology, Sapience Therapeutics, BioNTech, Nimbus Therapeutics, Arch Oncology, Tioma Therapeutics, Vyraid Inc., Vasculox, and Cordance Medical.
- **Our services include:** Clinical Development, Clinical Science, Corporate Strategy, Data Management, Programming, Statistics, Project Management, Medical Writing, Quality Assurance and Compliance, Clinical Operations, Regulatory Affairs, and Competitive Intelligence.
- Led cross-functional teams to optimize development processes, resulting in a 30% reduction in the time required for clinical trial design, execution, and regulatory submission.
- Introduced innovative risk assessment frameworks, leading to a 25% reduction in the duration of regulatory approval processes for drug candidates.
- Developed and implemented a redesigned electronic data capture (EDC) system and pivot table templates within 12 weeks, reducing data entry errors by 50% and increasing data collection efficiency by 30%.
- Implemented patient-centric engagement initiatives, resulting in a 50% increase in patient enrollment rates and a 40% improvement in patient retention throughout clinical trials.
- Led safety monitoring initiatives, leading to a 20% decrease in the incidence of adverse drug reactions and a 25% improvement in patient safety outcomes.

Consultant, Oncology Drug Development

The EGCC Consulting Group, Remote
September 2021 - Present

- Implemented streamlined project management methodologies resulting in a 20% reduction in the average time to bring pharmaceutical products from preclinical development to market approval.
- Implemented data-driven patient recruitment strategies, resulting in a 40% reduction in enrollment timelines across multiple clinical trials.
- Introduced adaptive trial designs resulting in a 25% reduction in sample sizes and a 20% increase in trial success rates.
- Developed targeted recruitment campaigns utilizing digital marketing channels, resulting in a 60% increase in the number of eligible patients screened for clinical trials.

Vice President, Clinical Development and Operations

Promontory Therapeutics, New York City, NY
August 2020 - August 2021

- Responsible for drug developmental strategy, clinical operations, regulatory affairs, data management, biostatics, programming, pharmacovigilance, safety. medical writing, quality, and translational research.
- Within 6 months, streamlined data analysis process for PT-112 clinical studies, resulting in a 25% increase in efficiency for medical review and improved decision-making capabilities.
- Reduced timelines and costs by creating a new clinical strategy and redesigning a 5-part Basket Study Master Protocol, resulting in a more focused therapeutic approach, an additional 1 patient/site/month, and early delivery on the established company goals.

DEVELOPMENT EXPERTISE

- **Authoring and Managing:**
  - Pre-IND Meeting Requests
  - Pre-IND Briefing Books
  - FDA Comments and Requests
  - NDAs
  - BLAs
  - Clinical Protocols and Amendments
  - Breakthrough Designations
  - Investigator's Brochures
  - Informed Consent Forms ICFs
  - Clinical Study Reports (CSRs)
  - Clinical Development Plans (CDPs)
  - Annual Safety Reports (DSURs)
  - Technical Papers and Manuscripts
- **Regulatory Bodies**:
  - Australia (TGA), Austrian (AGES), Belgium (FAMHP), Canada (HC), Denmark (DKMA), Europe (EMEA), France (ANSM), Germany (BfArM), Hong Kong (DH), Ireland (HRPA), Italy (AIFA), Netherlands (IGZ), Japan (NIHS), Netherlands (MEB), Norway (NoMA), Portugal (Infarmed), Russia (Minzdrav), South Korea (MFDS), Spain (AEMPS), Sweden (MPA), Switzerland (Swissmedic), Taiwan (TSFA), UK (MHRA), US (FDA)

THERAPEUTIC AREAS

- Oncology
- Immuno-oncology
- Hematology
- Psychiatry
- Respiratory
- Rare Disease
- Vaccines
- Infectious Disease
- Dermatology
- Ophthalmology

EDUCATION

Masters of Business Administration (MBA)

Boston University | Questrom School of Business

Bachelor of Science (B.Sc.) in Chemistry

The Pennsylvania State University | Eberly College of Science

- Leveraged professional relations with several KOLs to expand the advisory board.
- Spearheaded recruitment of numerous clinical investigators who are experts in their field to advance current and future trials in additional indications..

Director, Clinical Development

Janssen, Los Angeles, CA
July 2016 - July 2020

- Led strategy and design of clinical trials, resulting in Breakthrough Therapy Designation across cross-functional teams for niraparib in BRCA1/2 gene-mutated metastatic prostate cancer and subsequent approval for AKEEGA®.
- Identified a biomarker assay flaw, paused enrollment at 200 sites in 15 countries, and seamlessly resumed the study using numerous updates and training materials.
- Rectified a biomarker assay error in 6 months, boosting patient response rates by 25%, enrollment by an additional 0.5 patients/site/month, and accelerating AKEEGA®'s approval process.
- Conducted regular data/safety/efficacy reviews, identifying trends across programs and improving overall study outcomes using data visualizations.

Internal Consultant, JLabs

Johnson and Johnson Innovation (JLabs), San Diego, CA
July 2016 - July 2020

- Recognized for a role supporting JLabs companies, facilitating access to extensive J&J knowledge for their growth acceleration.
- Empowered startups to deliver solutions for patients and consumers by offering mentorship and consulting expertise. (PolyAurum, Q1.6 Digital Health, Navan Technologies, and Primmune Therapeutics).

Senior Director, Clinical Development and Operations

BIND Therapeutics, Cambridge, MA
July 2007 - June 2016

- **New Company Development**: Played a pivotal role in establishing and leading a company's growth from the ground up, transforming academic technology into a clinical product in just 3 years. Provided visionary leadership, shaping culture, strategy, and teamwork across the organization.
- **Project Leadership**: Led BIND-014 development from inception to global Phase 2 trials, presenting program updates to senior management and the board. Directed cross-functional teams, resolving challenges and ensuring alignment with milestones. Conducted clinical advisory boards to validate strategies, prepared BOD updates, and reviewed press releases and SEC filings for comprehensive project oversight.
- **Regulatory Oversight**: Oversaw regulatory facets of BIND-014 through the 505(b)(2) pathway. Crafted meeting requests and briefings, ensuring seamless agency engagement. Maintained active INDs and expertly managed expedited safety reporting.

Project Manager, Programs and Portfolio Office (PPO)

Momenta Pharmaceuticals, Cambridge, MA
July 2005 - June 2007

- Successfully managed and delivered M-Enoxaparin FDA communication and commercial launch preparation, meeting all project milestones on time.
- Proactively identifying and addressing potential roadblocks with Sandoz, ensuring smooth and timely project completion.

Scientist, Research and Development

Corixa Corporation, Seattle, WA
June 2003 - June 2005

- Created a breakthrough in cancer treatment by inventing a microsphere drug delivery system increasing antigen and immunostimulant co-encapsulation.
- This involved constructing, refining, and validating a cGMP microsphere process, which enhanced robustness and significantly raised product yield, propelling the WT1 program forward.

Scientist, Research and Development

Alkermes, plc, Cambridge, MA
January 2000 - May 2003

- Formulation leader for an inhaled epinephrine formulation AIR - Epinephrine to treat anaphylaxis.
- Streamlined CMC development for Air-Epinephrine project through effective management of process, clinical, and analytical teams..