Travis Che Jarrell, BSPH, MPIA, RAC

tcjarrell@milestoneregulatory.com / **301.905.6702**

Summary

Accomplished professional with over 20 years of biomedical product research and development experience, I provide contracting and consulting services in regulatory affairs, regulatory submissions, GCP auditing / monitoring / compliance, project management, and professional speaking engagements, etc. through my consulting firm, *Milestone Regulatory Experts, LLC*.

Academic Degrees

University of California at San Diego, CA **2005**
Master of Pacific International Affairs – International Relations and Pacific Studies (IRPS)
(rebranded School of Global Policy and Strategy (GPS) in 2014)

University of North Carolina at Chapel Hill, NC **1998**
Bachelor of Science in Public Health - Biostatistics

Academic Certifications

Johns Hopkins University Bloomberg School of Public Health, MD **2013**
Science of Clinical Investigation (SOCI) Certification

Other Accredited Continuing Education

Johns Hopkins University Advanced Academic Studies Program, MD **2009**
Graduate course in US Food and Drug Law – Fall 2009

Professional Certifications

Regulatory Affairs Professional Society - RAC (US) Certification **2006**

Professional Experience

Milestone Regulatory Experts, LLC **2017 to Present**
Title: Proprietor and Principal Consultant

Provide expertise/assistance in the following areas:

- FDA DMF/IND/IDE submission assistance (paper and electronic format)
- FDA meeting preparation (e.g., Pre-IND and IDE Pre-sub submission assistance)
- FDA clinical investigator / sponsor audit preparation / follow-up and mock audit services
- Full service clinical trial auditing and monitoring services
- Quality Assurance (QA) department development and Quality Management Systems (QMS) guidance
- Standard Operating Procedure (SOP) and template development assistance
- Trial Master File (TMF) document management
- IRB / DSMB review preparation and assistance
- Site management assistance
- File management / document control / archival process management
- 3rd Party vendor qualification assistance
- Product due diligence review
- Discovery assistance relating to litigation
- Education / curriculum development and speaking engagements
- Research participant advocacy

Select Clients / Protocols / Marketing Applications:

- Sonnet Bio Therapeutics, Inc.
- Tapimmune / Marker Therapeutics, Inc.
- Access Bio - CareStart Flu A&B Plus – 510k clearance, 2020
- Dr. Peter Campochiaro - A Phase 1 Open-Label Extension Study to Assess the Long-Term Safety and Tolerability of N-Acetylcysteine (NAC) in Patients with Retinitis Pigmentosa (FIGHT-RP1 Ext. Study)

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Johns Hopkins Health System **2008 – 2017**
Johns Hopkins All Children's Hospital (JHACH), St Petersburg, FL **2014 – 2017**

Title: Regulatory Affairs/Quality Assurance Manager

- Developed, implemented, and maintained clinical research Standard Operating Procedures (SOPs), guidelines, and tools/templates, and developed/executed all related training
- Assisted with the development, management, and presentation of Johns Hopkins Medicine-accredited research educational sessions for faculty and other staff and developed recommendations for new educational resources to improve existing programs
- Monitored and disseminated clinical research-related FDA regulation and guidance document updates to the JHACH/Johns Hopkins Medicine (JHM) research community and updated existing systems as needed
- Assigned study-specific monitoring plans for all prospective clinical research trials and performed and/or supervised the conduct of all routine internal monitoring activities (including regulatory, subject chart, and investigational product reviews) and coordinated with the JHM institutional review board (IRB) as needed
- Compiled and disseminated monitoring reports to study teams that summarized all findings, including relevant recommendations, and any related corrective and preventive action plans, if applicable
- Maintained a comprehensive REDCap database containing the results of all internal monitoring reviews and prepared and presented summary reports to leadership on a periodic basis
- Oversaw, monitored, and provided direct expertise for support personnel
- Drafted, developed, and compiled Sponsor-Investigator FDA regulatory filings, including routine IND and IDE file maintenance, and liaised with FDA and other regulatory bodies as a designated sponsor representative
- Functioned as a liaison between government agencies such as the FDA and NIH, and trial sponsors or other clinical trials monitoring services regarding external audits and quality assurance issues
- Assisted with the creation, implementation, and coordination of a local Institutional Biosafety Committee
- Managed the Trial Master File (TMF) on a 50-site multi-national NIH-funded Phase 3 pediatric study and conducted routine informed consent reviews relative to the study's biorepository specimen inventory

Johns Hopkins University (JHU) – School of Medicine – Baltimore, MD **2008 – 2014**

Title: Quality Assurance Manager/Clinical Trial Monitor (2008 – 2014)

- Developed and executed IND/IDE Sponsor/Sponsor-Investigator monitoring plans
- Managed daily operations and all auditor/monitoring staff of the Sidney Kimmel Comprehensive Cancer Center (SKCCC) Quality Assurance Group
- Developed and maintained standard operating policies and procedures for research operations
- Ensured all research activities complied with local, state, and federal laws/regulations and assisted in the preparation and conduct of several FDA clinical investigator audits
- Evaluated IND/IDE trial requirements at pre-IRB protocol review development stage
- Developed and presented GCP-based educational/training sessions
- Oversaw the management of the SKCCC Data and Safety Monitoring Plan
- Conducted periodic overseas audits of JHU Singapore
- Designed and maintained the department's quality assurance review database
- Managed SKCCC Safety Monitoring Committee meeting proceedings
- Acted as a liaison between the Clinical Research Office and the JHM IRB to facilitate implementation of and compliance with Institutional Policies
- Developed and implemented departmental operations manual
- Developed and standardized study review and audit/monitoring report templates
- Analyzed and evaluated audit and monitoring metrics to ensure optimal departmental performance

Algorithme Pharma USA / BASi – Baltimore, MD **2008**
Title: Associate Director, Quality Assurance

- Designed, implemented and managed a site-based Quality Assurance (QA) system that ensured compliance with all applicable international, federal, state and local laws/regulations and guidelines
- Conducted project, vendor, SOP, and facility (software, hardware, training, etc.) audits to evaluate and ensure compliance with company policies, sponsor protocols and GCP
- Managed all FDA, sponsor, and IRB audits and any official responses to said audits, and provided all post-audit recommendations to management
- Crafted, implemented and managed all observed deviations via a fully-integrated Corrective and Preventative Action (CAPA) database system
- Managed the local/corporate-wide SOP document control system via SharePoint/Master Control™
- Interacted daily with project managers and associate directors from the Clinical Operations and Data Management departments on project- and policy-related developments
- Set department priorities and supervised/mentored QA staff in order to realize department and company goals
- Managed all regulatory communications between sponsor, FDA, IRB and local health agencies
- Reviewed and approved the release of all databases, study-related documentation and/or study reports
- Supervised the archiving of all study-and non-study related inventories located on- and off-site
- Managed employee training files to ensure GCP compliance

Summit Drug Development Services – Rockville, MD **2006 – 2008**
Title: Manager of Regulatory Submissions (2007 – 2008)
Senior Regulatory Affairs Associate (2006 – 2007)

- Managed the compilation, formatting, validation and submission of all regulatory filings that included Pre-IND/Type B Meeting briefing packages, INDs (CTD and US format - drugs, biologics, and combination products) and TPP regulatory dossiers
- Developed and managed the firm's transition to electronic Common Technical Document (eCTD) submission capacity
- Participated in Type B Meetings with FDA and attended several FDA Advisory Committee meetings
- Served as a company representative to FDA and other regulatory agencies
- Compiled specialized regulatory dossiers such as FDA's Request for Orphan Drug Designation, FDA's Special Protocol Assessment, and NIH's Appendix M submission for federally funded recombinant DNA research
- Performed IND maintenance (e.g., Annual Reports, Information/Protocol Amendments, Safety Reports)
- Conducted regulatory due diligence for client-driven Strategic Assessment Plans (SAPs)

CBH Health, LLC – Rockville, MD **2005 – 2006**
Title: Regulatory Compliance Officer

- Managed regulatory and quality assurance (QA) processes for this site management organization (SMO) dedicated to central nervous system (CNS) clinical research, specializing in Phase 1, 2 and 3 clinical trials
- Designed and maintained centralized regulatory database that facilitated the management of 25+ active clinical studies, 100+ inactive studies and several small-scale on-site laboratories
- Developed, implemented and evaluated ICH-GCP-compliant SOPs/QA instruments
- Compiled and managed all clinical study regulatory documentation (start-up/interim/close-out) between firm, applicable central/local IRBs, and investigational product sponsors
- Coordinated with FDA clinical site inspection (BIMO) agents during an FDA audit, managed the official response to the establishment inspection report (EIR) and distributed results to affected sponsors and IRBs

Maxim Pharmaceuticals – San Diego, CA **2000 – 2004**
Title: Clinical Research Analyst/Research Analyst Consultant

- Prepared statistical analysis summary reports and presentation slides that supported briefing packages for several Type B and C FDA meetings, and an Oncology Drug Advisory Committee (ODAC) meeting
- Produced Integrated Summary of Safety (ISS) SAE/subject death narrative summary reports in support of the company's NDA and assisted with the production of the 120-Day Safety Update NDA Amendment
- Produced statistical analysis plan/ad-hoc statistical reports summarizing various IND clinical trials
- Assisted the firm's regulatory and quality assurance departments in the review and compilation of the company's NDA (granted Orphan status and assigned Priority Review)
- Generated 15-day IND Safety Reports, IND Annual Reports and Data Safety Monitoring Board (DSMB)-required safety summary reports that summarized the firm's ongoing Phase 1-3 oncology clinical trials
- Managed the firm's CRF template design project and the activities of several interns that assisted with the administration of the final product
- Designed SAS Macro tools that produced validated statistical reports (ex: Kaplan-Meier, Cox, GLM and Mixed Model summary tables and figures)
- Managed, audited and supported the data management and statistical programming for several contract research organizations
- Designed and managed a Serious Adverse Event (SAE) legacy data COSTART-to-MedDRA conversion project that entailed recoding 20,000+ archived unique adverse event terms (utilizing SAS and Oracle software environments)

Agouron (Pfizer) Pharmaceuticals – La Jolla, CA **1999 – 2000**
Title: Clinical Programmer 2

- Generated statistical tables and data listings for several Phase 3 and 4 HIV clinical trials
- Reconciled Serious Adverse Event/Case Report Form database discrepancies
- Managed PK, hematology, chemistry and urinalysis lab database transfers from a South American lab/research center participating in a pediatric HIV trial
- Developed complex efficacy-oriented algorithms for a Phase 3 trial investigating the safety and efficacy of an investigational influenza medication
- Assisted medical writing and clinical data management personnel via the production of ad hoc and statistical analysis plan-specific study reports that supported the final NDA package (including ISS and ISE summary reports) of a conditionally approved HIV medication (Viracept) under 21 CFR 314 subpart H
- Produced Periodic Safety Update Reports (PSUR) line listing reports
- Prepared SAS transport files and dataset codebooks for electronic FDA submission filings

Parexel International – San Diego, CA / RTP, NC **1997 – 1999**
Title: SAS Statistical Programmer

- Produced demographic and safety profile statistical reports and provided Quality Control (QC) programming support through query writing and edit check programming

Student Internships

Institute on Global Conflict and Cooperation – La Jolla, CA **2004 – 2005**
Title: UCSD Graduate Student Research Assistant

- Coordinated curriculum development activities for the 2004-2005 Public Policy and Nuclear Threats and Public Policy and Biological Threats professional programs, managed all logistics for associated meetings and events, and hosted/interacted with high-level domestic and foreign government officials

FPG Pediatric Research Statistics – Chapel Hill, NC **1995 – 1996**
Title: UNC Undergraduate SAS Data Management Associate

- Provided data entry support and assisted data validation efforts via QC programming support and data query generation/resolution, and developed/validated an on-screen SAS FSP data entry system

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Authored & Accredited 1-hr Lectures for JHM Office of Human Subjects Research

- Best Pharmaceuticals for Children Act (BPCA) – Overview and Case Studies
- Clinicaltrials.gov Registration and Reporting
- FDA Inspections and 483s/Warning Letters
- Good Clinical Practice (GCP) Overview and Practical Scenarios
- *In Vitro* Diagnostic Device Regulation Overview
- Principal Investigator and Local Site Investigator Roles and Responsibilities
- Single Patient IND Applications and Sponsor-Investigator INDs Applications

Authored Publications

- Gallia GL, Holdhoff M, Brem H, Joshi AD, Hann CL, Bai RY, Staedtke V, Blakeley JO, Sengupta S, Jarrell TC, Wollett J, Szajna K, Helie N, Mattox AK, Ye X, Rudek MA, Riggins GJ. *Mebendazole and temozolomide in patients with newly diagnosed high-grade gliomas: results of a phase 1 clinical trial.* Neurooncol Adv. 2020 Nov 12;3(1):vdaa154. doi: 10.1093/noajnl/vdaa154. PMID: 33506200; PMCID: PMC7817892.
- T. Che Jarrell, RAC, Frances Hamblin, MSHS, Daniel Ford, MD, Sylvia Powell, MBA, Jonathan Ellen, MD, and Neil A Goldenberg, MD, PhD, *Development, Implementation, and Outcome Measurement of a Paired Training Curriculum and Internal Monitoring Program for Clinical Research Regulatory Compliance in the Emerging Era of the Single Institutional Review Board.* Journal of Clinical and Translational Science. Oct 2017
- Jarrell T, Wilder R, Shull B, Shirazi J. *Hitting the Hydrogen Highway*. Power and Energy Continuity. Summer 2004.
- Jarrell T. *Politics of the Environment (Book Review)*. Journal of Environment and Development. Dec 2002.
- Jarrell T. *Population – Environment: Methods of Analysis (Book Review)*. Journal of Environment and Development. Sep 2002.

Analytical / Computer Skills

- Performed non-parametric, categorical, multivariable linear/logistic regression (Least Squares and Maximum Likelihood) and time-to-event (KM and Cox) analysis
- Intermediate SAS user (Base, Stat, Macro, Graph, FSP)
- Advanced MS Office (2003, 2007, 2013 - Word, Excel, Access, Power Point), Adobe, and Lorenz Docubridge user and intermediate Master Control document management system user
- Experience with Oracle, SQL, Adobe/Adobe FrameMaker, Dreamweaver, HTML, XML, and REDCap

Speaking Engagements / Other Activities

- Session presenter for CBI's Annual Product Complaints Congress for Life Sciences – topics: Mastering the Adverse Event Reporting System for Efficient Complaint Handling, Jun 2017, and How to Create Complaint Trending Systems for Drug and Device Products, Jun 2018
- Lecturer for the Johns Hopkins University School of Nursing Research Coordinator Training Program – lecture topics: Adverse Events and Protocol Deviations, Best Pharmaceuticals for Children Act, GCP, Regulatory File Maintenance, Sponsor-Investigator INDs, 2011-Present
- Guest lecturer for the Johns Hopkins University's Master of Science in Bioscience Regulatory Affairs Program – lecture topic: electronic regulatory submissions, Oct 2008
- Speaker for the Society of Clinical Research Associates (SOCRA)
  - 2019 SOCRA Annual Conference – *Unpacking the FDA Clinical Investigator Inspection Process to Maximize the Probability of a Successful Inspection Outcome*
  - 2017 SOCRA Annual Conference – *Sponsor-Investigator INDs*
  - Local SOCRA Chapter (Southern PA: *FDA Clinical Investigator Inspection Readiness*) (Baltimore, MD: *GCP* (2012), *Clinicaltrials.gov* (2014), *Investigator Site File/TMF Maintenance* (2018), and *FDA Clinical Investigator Inspections* (2019)
- Teaching assistant for undergraduate UCSD Environmental Law course, Spring 2003

References

- Available upon request