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# Objective

To lead and innovative change in the field of clinical research by capitalizing on advancements in current technology that will enable real-time analysis of trial data to identify risks, issues or trends that require implementation of appropriate mitigations and/or strategic changes to maintain research integrity while protecting the endpoints. Possess unique skill sets in the fields of clinical project management, data analytics, technical understanding of Immuno-Oncology translational medicine and numerous programming languages, valuable assets for any company seeking to advance clinical research by championing the use of real-time data analysis, implementing creative, compliant strategies to ensure success while maintaining budgetary and timeline considerations.

# Skills & Abilities

* Project Management (6 years)
* Clinical Team Management (10 years)
* Clinical Development Phase Experience: Pre-Clinical, Phase 1, Phase 2, Phase 3

\**See “Immuno-Oncology Experience” Summary Section for details*

* Formal training and extensive experience in Biotechnology, bench laboratory research (pre-clinical) and pharmaceutical development (translational medicine)
* Adaptive Monitoring, Risk Evaluation, Mitigation Strategy plan development
* Audit preparation and crafting of responses to findings
* CRF Design (including data capture for AEs of Special Interest)
* Data Analytics:
  + “Expert-level” Excel user (including Excel 2016 Data Extraction and Transformation capabilities)
  + Proficient in Python, SQL, HTML, Javascript
  + Conversant in R Studio
* Therapeutic Expertise: Oncology (Solid and Liquid tumors), Psoriasis, Immunology, Hematology, Myelofibrosis, Women’s Health

# Experience

## Independent Consultant/Owner, Protect the Endpoint Clinical Consulting, LLC **July 2020 - Present**

### Home-Based, Southampton, NJ

* Responsible for managing and overseeing all functional groups for global Phase 1b/3 Follicular Lymphoma study
* Currently overseeing country-level submissions
* Serve as lead contact for global-level matters
* Understands and manages contractual obligations, organizational and relationship needs/expectations
* Provides regular reporting on project metrics, status of deliverables and risks/issues with the associated management plan to client

## Senior Project Manager, PRA HealthSciences **April 2019 – July 2020**

### Raleigh, NC

* Project financial oversight: managing costs according to approved budget, change orders, proactively identifies “scope creep” or “out of scope” activities (actual or potential)
* Acts as primary liaison with client:
  + Chairs and leads customer meetings, acts as lead contact for global-level matters
  + Understands and manages contractual obligations, organizational and relationship needs/expectations
  + Provides regular reporting on project metrics, status of deliverables and risks/issues with the associated management plan to client
* Develop in-depth analysis and projections of project timelines and financials for executive-level and customer management
* Collaborates on process development and process improvement initiatives
* Steering Committee Manager - Oversee and facilitate Key Opinion Leader and Sponsor meetings.

## Clinical Team Manager/Project Manager (“CTM 3”), PRA Health Sciences **September 2013 – April 2019**

### Raleigh, NC

* Served as primary liaison with client, vendors, and other PRA functional groups (same responsibilities as described as Senior Project Manager)
* Provides oversight to all aspects of monitoring: site qualification, initiation, patient recruitment strategies, subject safety, data quality, ICH/GCP
* Provides leadership and instruction to cross-functional project team members and third parties/vendors
* Provides scientific expertise to clinical team, including development of protocol-specific training materials
* Leads the team on a project, providing study specific and therapeutic training
* Liaises with Operations Managers to resolve resource and performance issues
* Collaborates on process development and process improvement initiatives
* Liaises with functional leads/managers to optimize performance and utilization of project team members.

## Clinical Team Lead, Research Pharmaceutical Services (“RPS” – Acquired by PRA Health Sciences in September 2013) **November 2009 – September 2013**

### Fort Washington, PA

* Functioned as primary point of contact for CRAs as well as Sponsor Managers/Directors
* eCRF design
* Performed and coordinated site management activities (PSSV, SIV, IMV, COV) per project milestones
* Created, developed, edited and reviewed departmental SOPs, Work Instructions and Related documents; responsible for providing Departmental-specific SOP training to Global employees
* Provides scientific expertise to clinical team, including development of protocol-specific training materials
* Trained CRAs and site personnel on study-specific processes and procedures (RECIST 1.1, therapeutic background, scientific rationale of study)

## Senior CRA/Ockham Development Group **June 2008– November 2009**

### Cary, NC

* Assisted with creation of CRF completion guidelines Assisted in site identification and qualification
* Responsible for the monitoring and oversight of three commercial oncology studies, conducted at over 30 sites in the US (all visit types: PSSV, SIV, IMV, COV)
* Created monitoring tools for three oncology studies, which were implemented by monitoring team as well as site personnel

## Regional CRA/Theradex Systems, Inc. **September 2007– June 2008**

### Princeton, NJ

* Audited Cooperative Group Study monitoring visits (ie: ECOG, SWOG, etc)
* Audited NCI-sponsored studies conducted at major oncology institutions throughout the US and Canada
* Monitoring and oversight of oncology studies (Phase I & II)
* Contributed positively to quality audits leading to repeat government contracts for NCI-sponsored oncology studies

## In-House CRA / Duramed (through Feabhas, contract agency) – Bala Cynwyd, PA **August 2006– August 2007 (1 year contract)**

* Wrote, edited and reviewed sections of the clinical protocol and Clinical Study Report Authored Adverse Event and Pregnancy narratives
* Reviewed concomitant medications (post-study) for the purposes of calculating "per protocol" and "intent to treat" populations for CSR

## Scientist 2 / GlaxoSmithKline – Collegeville, PA **July 2003– March 2006**

* Generated, analyzed and collated data in a timely, coherent manner to executive management, present summary and analyses of data in weekly departmental meetings
* Created and presented formal PowerPoint presentation of experimental rationale, methods, results and discussion during departmental, collaborative and project team meetings as well as poster seminars
* Performed in vitro testing of experimental chemotherapy compounds; supported research of compounds currently in clinical trials by performing experiments requested by physicians
* /clinicians involved in clinical studies (primarily breast and colon) Investigated novel cellular targets as potential oncology therapeutic agents
* Responsible for reviewing scientific literature for the purposes of potential research projects, experiments and to maintain knowledge of the most current clinical oncology therapies

# Education

## Thomas Jefferson University – Philadelphia, PA – Master of Science in Laboratory Sciences

## Thomas Jefferson University – Philadelphia, PA – Bachelor of Biotechnology

## Rutgers University – Remote – Certificate of Data Science (October 2020 to May 2021)

# Systems & Vendor Experience

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| --- | --- |
| Type | Systems |
| CTMS | Siebel, Salesforce |
| EDC | Medidata – RAVE, Inform, DataLabs, AptivAdvantage |
| ePRO | ERT |
| IXRS | Parexel, Bracket, Clinphone |
| eTMF | NextDocs |
| Central Lab | Q2 (Infosario), Covance, LabCorp, Eurofins |
| Central IRB | Advarra, Quorum, WIRB, Shulman, Copernicus |
| Central Radiology | Parexel |
| Translation Vendors | TransPerfect, Lionbridge |

# **Immuno-Oncology Translational and Biomarker Experience Summary**

## Pre-Clinical (2002-2006) – 4.5 Years Total

### Scientist (GSK) – 3 years

* Responsible for the development, conduct and analysis of *in* *vitro* translational research data (including but not limited to immunohistochemistry (ICH), immunofluorescence cell cycle/apoptosis analyses, flow-cytometry, Western Blot, ELISA techniques)
* “Hands-on” bench research of molecules targeting:
  + Tyrosine Kinase (Tyk2); Jak/STAT pathway entities; EGFR (conducted ancillary *in vitro* analysis of lapatinib (Tykerb©) to support GSK clinical trials in patients with HER2+ breast cancer);VEGF; BRAF; KRAS; ER, PR, HER2 (Erb-B2); PI3K; MDM2
  + Emphasis in conducting combinational studies and analysis using Chou & Talalay method

### Graduate Student (Thomas Jefferson University) – 1.5 years

* + Telomerase
  + P53

## Clinical (2006 – 2016)

### Clinical Research Associate – 2006 to 2009 (3 years)

* Phase II EGFR-Positive (Tyk2 inhibitor) Studies [Metastatic Breast, Pancreatic, NSCLC); 2 years
* Phase I telomerase inhibitor (oligonucleotide molecule); 1 year

### Clinical Team Manager – 2009-2016 (6.5 years)

* Phase II telomerase inhibitor (NSCLC, metastatic breast, Multiple Myeloma, Essential Thrombocythemia); 2.5 years
* Phase IIb/III NSCLC (T790M+ mutation); 2 years
* Phase III Myelofibrosis (Selective Jak 1 & 2 inhibitor); 2 years

### Project Manager – 2016-2020 (4 years)

* Global Phase III Psoriasis studies (Tyk2 inhibitor); 2 years

# Certifications

## SQL for Data Science – UC Davis (offered through Coursera) – December 2019

## Project Management – Project Management and Leadership Group (PMLG) – October 2009

## Python for Everybody – University of Michigan (offered through Coursera) – August 2020

## Statistics with Python Specialization – University of Michigan (offered through Coursera) – *August 2020-Present*