STEVEN PONCE

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Clinical Trial Data Analytics | Data Visualization & Insights | Risk-Based Monitoring

AREAS OF EXPERTISE

- ✓ Data Visualization
- ✓ Clinical Trial Risk Analytics & Monitoring
- ✓ Text & Statistical Analysis
- ✓ Dashboard Development
- ✓ Pharmaceutical R&D & Inspection Readiness
- ✓ Cross-Functional Collaboration & Stakeholder Engagement
- ✓ Continuous Improvement & Risk Assessment
- ✓ Training & Enablement

CAREER HIGHLIGHTS

- **Data Science & Analysis:** Bring **over a decade of combined experience** in data analysis and laboratory science to deliver actionable insights for pharmaceutical research.
- **Data Visualization & Storytelling:** Skilled in transforming complex data into insights using **R, Spotfire, Tableau, and Quarto**; developed visual narratives that guided executive decision-making and inspection readiness.
- **Data Analysis & Dashboard Development:** Develop **R scripts** and **Spotfire dashboards** to support centralized monitoring, streamline reporting, and reduce manual review effort.
- **Cross-Functional Collaboration:** Partner with scientists, analysts, and leadership to **achieve milestones, mitigate risks, and improve communication**, enabling effective execution of clinical research initiatives.
- **Communication & Stakeholder Engagement:** Present complex analyses to **non-technical audiences**, facilitate workshops, and build alignment across study teams and leadership.

PROFESSIONAL EXPERIENCE

Senior Manager – GDO, Clinical Trial Risk Management, Bristol Myers Squibb (BMS), *Lawrenceville, NJ* | January 2023 – Present

Perform centralized monitoring and advanced analytics to evaluate clinical trial risks, assess global site data, and deliver actionable insights to study teams and leadership.

- **Centralized Monitoring & Risk Analytics:** Conducted **CMN quarterly reviews** for 10+ studies; created summary visualizations and presented risk signals to study teams.
- **Inspection Readiness:** Pulled and analyzed **AE/SAE, protocol deviation, and enrollment datasets** (2 studies); used **R** for data cleaning and analysis, generating **Quarto HTML site risk-assessment reports**.
- **Training & Enablement:** Designed and facilitated workshops on **KRI signal writing** and **Data Quality Assessment (DQA)** for BMS's **STAR+ Risk-Based Monitoring system**.
- **Dashboard Development:** Built the **Study Plan Alignment Dashboard** (**R** back-end**, Spotfire** front-end) to verify study plan compliance prior to **FPFV**. Supporting a **Tour of Duty (~20%, in progress)** as Technical Advisor; contributing to metric design and early **Power BI dashboard development**.
- **Exploratory Data Analysis (EDA):** Applied **z-score and normalized analyses** to cross-protocol *"other-other"* issues; delivered insights via **interactive Quarto reports**.
- **Text Analytics:** Applied **N-gram** and **LDA topic modeling** to classify unstructured *"other-other"* issue text (IM047-010), surfacing themes in **safety tracking, IP management, training, and documentation**.
- **Industry Contribution:** Collaborated with **PHUSE RBM working group** to analyze QTL survey data and **co-authored** the white paper *Assessing the Use of Quality Tolerance Limits in the Pharmaceutical Industry*.

Senior Scientist/Manager – BD, Method Trending & Monitoring, Bristol Myers Squibb, New Brunswick, NJ | Jul. 2020 – Jan. 2023

- **R Programming & Reporting:** Developed **R scripts** for data wrangling and visualization of early- and late-stage **SEC-PAV** data across **28 biologic products**; delivered insights through **R Markdown reports** to support study progression.

Professional Experience Continued

(Senior Scientist/Manager at BMS continued)

- **Comparative Analyses:** Performed **method performance reviews** by comparing analytical data against **validation criteria**, ensuring data met quality and regulatory standards.
- **Quality by Design:** Conducted data analysis using **Python** across five analytical methods (**icIEF, SEC, CEX, CGE-nr, CGE-r**) for 10+ biologic molecules, identifying changes and supporting method reliability.
- **Collaboration & Communication:** Partnered with cross-functional teams, translating technical data into actionable findings for scientists and project leads.
- **SharePoint Development:** Designed custom **SharePoint sites** to improve collaboration, streamline document management, and enhance data accessibility for multiple teams.

Earlier Roles at BMS | 2014 - 2020

- **Scientist I/II – Methods & Analytical Development**
- **Associate Scientist II – Analytical Development**
- **Associate Scientist II – Mass Spec & Biophysics**
    - Conducted **method development, validation, and characterization** for monoclonal antibodies.
    - Supported product progression by performing **trend analysis** and **stability visualization in Spotfire**.

Early Career Experience

- **Associate Scientist I – Analytical and Bioanalytical Development,** BMS | 2012 – 2014
- **Scientist – Development Analytical,** Pfizer | 2010 – 2011
- **Senior Associate Scientist – Development Analytical,** Pfizer | 2008 – 2010
- **API Associate Technical Specialist – Global Manufacturing,** Pfizer | 2006 – 2008
- **QC Laboratory Technician III – Global Manufacturing,** Pfizer | 2002 – 2006

Technical Proficiencies

Programming Languages	R, Python
Statistics Software	Minitab 17, JMP 13
Data Visualization Tools	TIBCO Spotfire, Tableau, ggplot2, R Shiny
Risk-Based Monitoring Platform	Medidata RAVE CSA, Cyntegrity MyRBQM, CluePoints

Education

Bachelor of Science, Chemistry, University of Puerto Rico, *Mayaguez, PR*

Additional Training

Cornell University: Data Analytics 360 Certificate | Machine Learning Certificate | Project Management Certificate
Business Science University (BSU): 5-Course R-Track
Coursera: Python for Everybody | Applied Data Science with Python | Data Visualization with Tableau
Analyst Academy: Data Viz for Consultants | Advanced PowerPoint for Consultants | Advanced Presentations for Consultants
Strategy.com / Overnight Strategist: Think Like a Strategy Consultant | Strategist Toolkit