# Bernice Simon

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## Professional Summary

Results-driven and highly skilled Data Manager, Biospecimen Solutions with over two years of clinical data management experience in the pharmaceutical and biotechnology industries. Adept at managing complex clinical trials, leading cross-functional teams, and delivering clean, analyzable data for clinical studies. Strong background in data processing systems, data pipeline engineering, automation, technical troubleshooting, and client relationship management. Known for collaborating effectively across technical and clinical teams, creating innovative tools, and delivering high-quality data solutions that improve speed, accuracy, and scalability.

## Professional Experience

**Data Manager, Biospecimen Solutions**
**QuartzBio** | Buckeystown, Maryland (Remote)
**Feb 2023 – Present**

- Lead data management activities for complex clinical trials across portfolios including Takeda, Blueprint, and GSK, ensuring data integrity, accuracy, and regulatory compliance.
- Manage project timelines, deliverables, and internal/external team communications, including coordination for UAT, DB lock, and CRF reconciliation.
- Design and maintain internal pipelines using Linux/Ubuntu environments for report generation, report validation, local file ingestion, and QA workflows, leveraging shell scripting, R, and Python for data wrangling and automation.
- Run local vSIM pipelines in Linux environments to create and troubleshoot internal JSON configuration files, validate data outputs, and ensure proper syncing of biomarker datasets across multiple studies.
- Troubleshoot configuration-related pipeline errors using system logs, custom-built scripts, and exploratory analysis, applying version control via GitLab to manage and resolve issues efficiently.
- Piloted the Data Mapper PoC with SolveBio API to transform vSIM data using EDP templates, collaborating closely with engineering and data product teams.
- Provided technical evaluations and hands-on feedback on AI tools like Zipstack/Unstract to assess integration feasibility for expected samples scheduling.
- Served as the primary technical mentor and ambassador for new team members, conducting regular onboarding sessions, technical walkthroughs, and training in custom workflows and Linux-based toolsets.

- Developed custom R functions to enhance the flexibility and scalability of data checks across portfolios, including complex flagging systems for consent date discrepancies, duplicate detection, and assay result interpretation.

**Key Achievements:**

- **Built robust local pipelines** using Linux to process and transform large biomarker datasets, vendor inventory manifests, and assay results, drastically reducing run times and minimizing downstream QC issues.
- Created a **Python utility** to split a massive, system-crashing CSV file locally, enabling timely validation and report generation despite client-side delays.
- Authored a **portfolio-wide R-based custom check** to automatically flag pipeline-breaking errors, adopted across multiple studies to improve QC.
- Achieved a 4.0 "Above Standards" rating for technical excellence and collaboration across departments and product teams.
- Received client accolades for timely, proactive support and high-quality deliverables, including recognition from Turnstone and internal leadership.

## Education

**Bachelor of Science, Chemistry**
University of Maryland, Baltimore County

## Skills

- **Clinical Data Management**: Database lock processes, CRF design and review, audit support, query review, reconciliation workflows.
- **Data Processing & Pipelines**: Custom script creation for local and cloud-based pipelines; experience managing JSON-based configuration files for biomarker data platforms.
- **Linux/Ubuntu Proficiency**: Comfortable navigating terminal environments; executing shell scripts; managing CRON jobs for data automation; using local virtual environments to test and validate pipeline changes.
- **Programming & Automation**: Python (data utilities, file handling), R (custom checks, QC reports), Power Automate (email parsing, notification workflows).
- **Collaboration & Leadership**: Cross-functional team leadership, mentoring, client relationship management, technical documentation.
- **Quality Assurance & Testing**: Debugging pipeline runs, UAT coordination, code review, validation of CRF and eCRF systems.

## Technical Tools & Proficiencies

- **EDC Systems**: RAVE, Veeva, IBM
- **Programming & Scripting**: Python, R, Bash, Power Automate, HTML, CSS, JS
- **Data Management Tools**: GitLab, JSON configs, internal pipeline frameworks
- **Office & Productivity**: Microsoft Excel, Word, Outlook, LibreOffice
- **Documentation & Tracking**: Confluence, Jira, Asana, SmartSheets
- **Operating Systems**: Linux (Ubuntu), macOS, Windows
- **Data Pipeline Environments**: Custom CLI utilities, CRON jobs, shell scripting, log parsing, local validation/testing tools