School of Pharmaceutical Sciences & Technology

Curriculum for
Fellowship Program in

PHARMA INFORMATION TECHNOLOGY SAS

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Course Title: Pharma Information Technology SAS
Course Type: FELLOWSHIP
Duration: 360 Hours (can be structured as 24 Credits)
Mode: Lectures, Practicals/Hands-on, Project

Overview

This fellowship is an intensive, professional program designed for healthcare and IT professionals. It bridges the gap between pharmaceutical domain knowledge and technical SAS programming. The curriculum focuses on the end-to-end clinical data pipeline—from raw data acquisition and cleaning to the generation of regulatory-compliant SDTM/ADaM datasets and final TLFs (Tables, Listings, and Figures) for clinical study reports.

Objectives:

Upon completion of the fellowship, participants will be able to:

- ✓ Master SAS Programming: Write efficient code using Base SAS, Advanced SAS, Macros, and SQL within a pharmaceutical context.
- ✓ Implement Global Standards: Apply CDISC (SDTM & ADaM) standards to raw clinical data for regulatory submissions (FDA/EMA).
- ✓ Analyze Clinical Trials: Interpret clinical protocols and translate statistical analysis plans (SAP) into executable SAS programs.
- ✓ Ensure Data Integrity: Validate clinical data and programming outputs using rigorous quality control (QC) and validation techniques.
- ✓ Manage Pharma IT Infrastructure: Understand the technical environment of clinical trials, including 21 CFR Part 11 compliance and electronic data capture (EDC) systems.

Course Outcome:

CO1. Explain the clinical trial lifecycle, regulatory requirements (ICH-GCP, FDA/EMA), and principles of clinical data management applicable to pharmaceutical research.
CO2. Apply core SAS programming concepts, including DATA step logic, conditional processing, and dataset management, to manipulate and analyze clinical trial data.
CO3. Implement global clinical data standards by mapping raw clinical data to CDISC-compliant SDTM and ADaM datasets with ensured traceability.
CO4. Generate statistically valid Tables, Listings, and Figures (TLFs) using SAS procedures and macros in accordance with Clinical Study Report requirements.
CO5. Perform data integration, cleaning, validation, and automation tasks using SAS, SQL, macros, and CDISC validation tools to support regulatory-ready datasets.

Teaching Methods:

The program employs a "Blended Learning" approach to ensure both theoretical depth and technical proficiency:

- ✓ Interactive Lectures: Faculty-led sessions focusing on the "Why" behind clinical standards and regulatory logic.
- ✓ Case-Based Learning: Reviewing historical clinical trial datasets and real-world "Statistical Analysis Plans" to understand industry challenges.
- ✓ Code-Walkthroughs: Live demonstration of complex programming logic and debugging techniques.
- ✓ Guest Seminars: Periodic sessions led by industry experts (Clinical Data Managers and Lead Biostatisticians) on current 2026 trends in Pharma IT.

Learning (Practical) Methods

To achieve the 8 practical credits and 6 project credits, the following methods are used:

- ✓ Hands-on Lab Simulations: Students work in a dedicated SAS environment (SAS Studio or Enterprise Guide) to solve daily programming tasks.
- ✓ Peer Code Review: A collaborative environment where students critique each other's code for efficiency, logic, and adherence to CDISC standards.
- ✓ Guided Project Work: A 12-week mentored project where students build a complete submission package for a simulated Phase II trial.
- ✓ Validation Exercises: Practical "Double-Programming" exercises where two students program the same output independently to ensure 100% accuracy, mimicking industry QC processes.

Syllabus

Theory - 10 Credits (150 Lecture Hours)

Module 1: Foundations of Clinical Research & Pharma IT

- Clinical Trial Lifecycle: Phases I–IV and drug development processes.
- Regulatory Framework: ICH-GCP guidelines, 21 CFR Part 11, and FDA/EMA electronic submission requirements.
- Data Management: Principles of Clinical Data Management (CDM) and Case Report Form (CRF) design.

Module 2: Core SAS Programming Logic

- SAS Architecture: Understanding the Compilation and Execution phases of the DATA step.
- Syntax & File Management: SAS libraries, naming conventions, and dataset structures.
- Conditional Logic: Logic of `IF-THEN`, `DO loops`, and `Array` processing.

Module 3: Global Data Standards (CDISC)

- SDTM (Study Data Tabulation Model): Theory of domain classifications (DM, AE, VS) and mapping raw data to standard variables.
- ADaM (Analysis Data Model): Principles of analysis-ready datasets and the concept of traceability.

Module 4: Advanced Analytics & Statistical Reporting

- Macro Language: Concepts of macro variables, parameters, and automated workflows.
- Biostatistics: Overview of ANOVA, Regression, and Survival Analysis (LIFETEST).

- TLF Framework: Theory of generating Tables, Listings, and Figures for Clinical Study Reports (CSR).

Practical/Hands-on Component: 8 Credits (120 Lab Hours)

1. **Lab 1: Data Integration & Cleaning**

a) Importing Data: Hands-on with `PROC IMPORT` and `INFILE` for Excel, CSV, and raw text files.

b) Manipulation: Cleaning clinical data using `PROC SORT`, `PROC FORMAT`, and merging datasets with `SET` and `MERGE` statements.

Lab 2: Advanced Programming (SQL & Macros)

a) PROC SQL: Writing queries for data retrieval, complex joins, and subqueries.

b) Automation: Building reusable macros to validate data integrity across multiple study sites.

Lab 3: Implementing CDISC Standards

a) SDTM Mapping: Practical mapping of "raw" patient data to SDTM domains.

b) ADaM Development: Creating Analysis Data Subject Level (ADSL) and Basic Data Structure (BDS) datasets.

Lab 4: Reporting & Validation

a) Output Generation: Using `PROC REPORT` and `PROC TABULATE` to create safety and efficacy tables.

b) Data Validation: Using tools like Pinnacle 21 for CDISC compliance checking.

Project: 6 Credits (90 Self Study/Research Hours)

End-to-end build of a clinical study package, starting from raw data to the final generation of TLFs.

References:

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