

Clinical Data Management Portfolio (Mock) – Data Process Associate

Role aligned: Data Process Associate (Clinical Data Management / Data Processing).

Candidate: Pritamjit Konar | M.Sc. Biotechnology | PC: Excel, Word | Entry-level CDM (Mock Portfolio)

1) Portfolio Overview -

This portfolio demonstrates readiness for an entry-level clinical data processing role through simulated (mock) work: CRF/eCRF-style data entry into an EDC-like dataset, verification and QC checks, discrepancy tracking, database testing documentation, and user access management documentation.

It also includes a starter medical coding practice workflow (training-only) to reflect the “medical coding activities” requirement in the JD.

All samples are created for educational/portfolio purposes and do not contain any real subject/patient-identifiable data.

2) Key Skills Demonstrated

- Accurate CRF-to-database transcription mindset + verification discipline (completeness, format, consistency).
- QC and data integrity checks to support reliable clinical trial data processing in a regulated environment.
- Documentation readiness: maintaining logs, version control, and traceable records suitable for audits/inspections.
- Support for EDC operations: basic user access documentation and controlled access tracking.
- Medical coding workflow awareness and willingness to learn standard dictionaries used in CDM coding activities.

3) Portfolio Projects (Mock)

Project 1 — CRF to EDC Data Entry & Verification Log (Excel)

Objective: Accurately enter and verify clinical data from CRFs/eCRFs into a study database format using defined entry guidelines.

Subject ID	Visit	CRF Field	Entered Value	Rule (format/type)	Verified (Y/N)	Issue Found	Correction Notes
CDM-0001	Screening	Date of Birth	1999-08-14	YYYY-MM-DD	Y	—	—
CDM-0001	Visit 1	Weight (kg)	63.2	Numeric (1 decimal)	Y	—	—
CDM-0002	Visit 1	Visit Date	2026-01-05	Not a future date	N	Future date	Corrected after re-check

Project 2 — QC + Discrepancy (Query) Management Pack (Excel)

Objective: Perform quality control checks to ensure data integrity and document discrepancies for resolution.

A) QC log (sample entries)

QC Area	Check (rule)	Result	Action
Completeness	Critical fields not blank (visit date/dose/AE start date)	Fail	Raise query
Range	Values within plausible range (labs/vitals)	Pass	None
Date logic	Visit date \geq consent date	Fail	Verify + correct/query
Consistency	Cross-form consistency (sex vs pregnancy field)	Pass	None

B)) Query/Discrepancy log (sample entries)

Query ID	Subject	Form	Field	Issue Type	Query Text	Owner	Status	Close Date
Q-001	CDM-0002	Labs	ALT	Unit/value mismatch	Please confirm ALT unit and value; mismatch with reference range.	Site	Open	—

Project 3 — Database Testing / UAT Documentation Pack

Objective: Support database testing and documentation preparation by recording test cases and results (UAT-style).

Test Case ID	Feature	Steps	Expected Result	Actual Result	Pass/Fail	Comments
UAT-01	Edit check: future visit date	Enter future Visit Date	System blocks or raises query	Query displayed	Pass	—
UAT-02	Required field	Leave Consent Date blank	System prompts required field	Prompt shown	Pass	—
UAT-03	Numeric format	Enter “abc” in Weight	System rejects non-numeric	Rejected	Pass	—

Project 4 — EDC User Access + Medical Coding + Delivery Tracker

Objective: Support EDC user access management and medical coding tasks while tracking delivery across multiple tasks and documenting improvement opportunities.

A) User access management log (sample entries)

Request ID	Name/Role	Access Level	Study	Date Requested	Approved By	Date Granted	Date Revoked	Notes
UA-001	Data Entry	Data Entry	Study-A	2026-01-02	DM Lead	2026-01-02	—	Onboarding
UA-002	QC Reviewer	Read + Review	Study-A	2026-01-03	DM Lead	2026-01-03	—	QC support

B) Medical coding mini log (training-only)

Subject	Verbatim Term	Coded Term (training)	Coder	QC Status	Notes
CDM-0003	Headache	Headache	Self	Pending	Training-only; dictionary access not claimed.

C) Delivery/prioritization tracker (sample)

Task	Project	Due Date	Status	Risk/Blocker	Improvement Note
Data entry batch-1	P1	2026-01-06	Done	—	Use dropdown lists to reduce typos
QC review batch-1	P2	2026-01-07	In progress	Pending site response	Add QC checklist before query send

Disclaimer

This is a self-learning mock project.

No real patient data, company data, EDC screenshots, or confidential materials are used.