

Clinical Trial Data Management Plan Template

1. Study Identification

| | |
|------------------------|--|
| Study Title | |
| Protocol Number | |
| Sponsor | |
| Principal Investigator | |
| Version/Date | |

2. Data Collection

- Data Sources:
- Case Report Forms (CRFs):
- Electronic Data Capture (EDC) System:
- Data Entry Process:
- Data Collection Timeline:

3. Data Handling and Storage

- Data Storage Locations:
- Data Backup Procedures:
- Data Security Measures:
- Access Control:

4. Data Quality Assurance

- Data Cleaning Procedures:
- Data Validation Methods:
- Query Management:
- Monitoring and Auditing:

5. Confidentiality and Privacy

- De-identification/Anonymization Procedures:
- Participant Confidentiality:

6. Data Sharing and Access

- Data Sharing Policy:
- External Data Requests:
- Data Use Agreements:

7. Archiving and Retention

- Archiving Procedures:
- Data Retention Period:
- Destruction Procedures:

8. Roles and Responsibilities

| Role | Name | Responsibilities |
|------------------------|------|------------------|
| Data Manager | | |
| Principal Investigator | | |
| Statistician | | |
| Others | | |

9. Amendments and Version Control

- Amendment Process:
- Version Control Table:

| Version | Date | Description of Changes |
|---------|------|------------------------|
| | | |