

Module title	Scope
Introduction	• What is research data, types of data and metadata • What is data sharing, why share data • Benefits and risks of sharing data • Open access/open science/open data • F.A.I.R data principles
Data sharing requirements	• Data sharing requirements by funding agencies and publishers • Comparing data-sharing requirements by different stakeholders • Data policies and regulations
Data Management I	• Developing a data management and sharing plan • Data sources and methods of data collection • Data curation and preparation • Standardizing datasets • Databases and storage technologies
Ethical Considerations	• Respecting participants and communities- informed consent, handling data on vulnerable populations • Privacy and confidentiality • Promoting equity for researchers, participants
Research set up	• Implications of data sharing on study design • Data management and sharing provisions in protocols, Informed Consent Forms, CRF/Questionnaires
Data Quality	• Data validation • Software and tools • Monitoring and quality assurance • Data quality metrics • Compliance with guidance and regulation, e.g. GCP, FDA CFR Part 11, including audits and inspections
Data governance & policies	• Players: Data custodians, stewards, trustees • Modes of data access: managed versus open access • Data Access Committees- constitution and mandate • Elements of an institutional data-sharing policy • Monitoring compliance with an institutional policy • Legal implications for researchers and research institutions in data sharing
Data re-use principles	• Research outputs- papers, source code, data • Persistent identification of data outputs • Data attribution and citation • Monitoring re-use of data • Selecting appropriate licenses for shared datasets • Managing relationships in data sharing and reuse
Data repositories	• Digital repositories for health data • Selecting a repository • How to deposit data in a repository • Data retention
Data Management II	• Data storage • Backup and disaster recovery • Integration of data systems • Information Security Standards
Before pressing send (preparing data for sharing)	• Documentation • Data standardisation • Data de-identification/anonymisation techniques
Costing	• Costs associated with data curation, storage and sharing: • Cost recovery options • Budgeting for data management and sharing