DATA MANAGEMENT FOR RESEARCH IN A HEALTH CARE SETTING

Learning outcomes & assessment criteria			
	Learning Outcome		**Assessment Criteria**
	The Learner will understand:		**The Learner can:**
1.	**The clinical trial process** Understand the clinical research process with a focus on clinical trials		
		1.1.1	Explain the clinical research process including the purpose of the clinical trial protocol, statistical analysis plan and clinical study report
		1.1.2	Describe the typical study team roles and responsibilities in a clinical trial
.2	**The data management function** Understand the role of the data management function within the clinical trial process and how this might be adapted for other interventional and non-interventional health and care research		

	Learning Outcome		Assessment Criteria
		1.2.1	Describe the purpose of the Data Management plan
		1.2.2	Explain the aims of data validation
		1.2.3	Describe different types of database lock and their appropriate use
3.	**Data collection tools** Designing a CRF and other data capture tools	1.3.1	Describe the principles of a good CRF and other data collection tools
		1.3.2	Explain methods of ensuring all data requirements are captured
4	**Vendor selection** Know what to consider when selecting a vendor to perform data management functions		
		1.4.1	Explain the key criteria for vendor selection and how to be assured as a Sponsor that vendors are appropriate
		1.4.2	Understand what Sponsors need to put in place to ensure good oversight of a subcontracted data management function

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5	**Regulation & Quality Assurance** Know how clinical research is regulated with a focus on data management & what to include in Data Management SOPS		
		1.5.1	Explain the key elements of the International Conference on Harmonisation of Good Clinical Practice (ICH GCP) and purpose of the regulatory bodies in Europe, USA and Japan
		1.5.3	Explain the purpose of SOPs
		1.5.4	Describe what to include in data management SOPS as a Sponsor and host organisation
.6	**Data quality** Understand how to deliver high quality clinical data for analysis		
		1.6.1	Describe a suite of data validation checks for a sample study
		1.6.2	Explain how a manual data query could be resolved by the responder on the first attempt
		1.6.3	Explain the purpose of coding clinical data with the medical Dictionary for Regulatory Activities (MedDRA)