Conceptualisation	Design	Set-up & Implementation	Analysis	Research into Practice
OVERSIGHT				
		• Obtain sponsor approval of protocol • Set-up oversight committees stated in QA Plan • Study or Trial Steering Committee (TSC) • Endpoint assessment/adjudication committees • Protocol Review Committee		
GOVERNANCE				
• Characterise study and identify regulations • Identify source of funding	• Identify sponsor and funder • Identify source of funding • Identify insurance required • Budget planning • Secure funding • Electronic TMF or SMF • The Trial or Study Master File • Assemble essential documents in Study Master File or Trial Master File (TMF) • Other essential documents • Undertake peer review	• Budget planning • Study initiation visit • Obtain sponsor approval of protocol • Prepare regulatory and ethics approval submissions • Register clinical trial or research study • Undertake peer review • Drafting a clinical trial or study agreement (CTA) • Drafting contracts or agreements • Other agreements and contracts that may be needed in health research • Organise appropriate legal cover • Electronic TMF or SMF • The Trial or Study Master File • Assemble essential documents in Study Master File or Trial Master File (TMF) • Other essential documents	• Study close out and site closure	• Study close out and site closure
OPERATIONS				
• Consider study design • Define study endpoints and outcome measures • Define study population, sample size and study statistics	• Consider data management requirements • Data management plan • Risk assessment • Risk management • Develop quality assurance • Develop clinical trial management system • Develop questionnaires or topic guides • Consider study design • Define study endpoints and outcome measures • Define study population, sample size and study statistics	• Data management plan • Risk assessment • Risk management • Develop clinical trial management system • Consider data management requirements • Study implementation • Audit trails and monitoring • Data archiving • Design and edit checks • Establishing a Data Safety and Monitoring Board (DSMB) • Safety reporting • Set-up Clinical Data Management System (CDMS) • Security access controls • System and database validation • The Data Safety and Monitoring Board (DSMB)	• Prepare your data for analysis • Explore and analyse your data	• Translating research to practise • Write up and publish your findings
PROTOCOL				
• Developing a research question • Conduct literature review • Developing the clinical research study protocol	• Developing a research question • Developing the clinical research study protocol • Patient and community engagement • Finalise the protocol	• Patient and community engagement • Finalise the protocol • Finalise intervention and laboratory requirements, supply and logistics		
INTERVENTION				
• Defining the intervention, exposure and comparator	• Defining the intervention, exposure and comparator • Intervention and lab organisation • Procurement, supply logistics • Develop a pharmacovigilance plan	• Intervention and lab organisation • Procurement, supply logistics		

THE GLOBAL HEALTH NETWORK

Enabling Research by sharing knowledge