EDCTP Knowledge Hub

EDCTP 11th Forum Paris, France
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edctpknowledgheub.tghn.org
Facilitating meaningful data sharing

Information about data sharing is dispersed, difficult to find and researchers report numerous challenges in the way of data sharing.

Therefore, simple, comprehensive tools to guide researchers through the ‘how, where and when’ of data sharing are needed.

We are committed to providing the appropriate guidance and support to help researchers achieve our data sharing objectives.

Together with The Global Health Network, we developed three online tools to facilitate open-source clinical trials and data sharing:

- **Data management portal** for better clinical data management for LMIC researchers
- One-stop **data sharing toolkit** and repository finder
- Clinical trial **protocol builder** for the development and crowd review of clinical trial protocols
The Global Health Network

Equity in where research happens, who leads & who benefits

Health research methods are evolving fast – new approaches should benefit everyone, everywhere

Too few studies are undertaken in the Global South – the 90:10 Gap persists

Of those, too few are led by local researchers and are not tackling local priorities

Old norms of capacity building focus on one disease, product or protocol

A trusted facility used by researchers and research organisations for mobilizing knowledge and delivering capacity and abilities to teams over the long-term in the workplace; Enabling research where evidence is lacking

A WHO collaborating Centre for research information sharing and capacity development
Globally Unique – transferring know-how across disease areas, types of research and between organisations, networks & regions

**Communities of Practice**

Vast interconnected communities of Practice mobilizing know-how across research topics and diseases

Active dissemination: raising standards & creating efficiency by transferring excellence and know-how between research projects and programmes

Applying the strongest information management technology so researchers anywhere can have the same access to the best methods, processes and training

**Workplace based implementation of research skills – by doing**

Working within existing networks, research organisations and in communities

Cascading research skills across healthcare settings

Delivering learning-by-doing in specific studies to share expertise beyond centers of excellence, to support lasting, leading and internationally competitive research teams.

This knowledge mobilisation works as the barriers and knowledge don’t differ between diseases

A WHO collaborating Centre for research information sharing and capacity development
The EDCTP Knowledge Hub - where are we now?

Data management portal

Protocol development

Data sharing toolkit

Steps
- Concept Protocol
- Crowd review
- SEPTRE Electronic Protocol Tool
- Study Walk-through toolkit
- Resources

Data management basics
- Steps
- Data Management Plan
- Resources

Data management basics
- Steps
- Repository Finder
- Resources
Protocol Development Toolkit

Protocol Development Steps
The Protocol Development Steps provide guidance on all elements of Protocol development in addition to practical advice on how to navigate regulations and guidelines...

Concept Protocol Crowd Review
Use the Concept Protocol Crowd Review Tool to invite feedback and advice on your concept protocol from the EDCTP Knowledge Hub and The Global Health Network community.

SEPTRE Electronic Protocol Tool
SEPTRE (SPIRIT Electronic Protocol Tool & Resource) is an innovative, web-based software solution that makes it easier to create, manage, and register high-quality...

Study Walk-through Toolkit
The ‘Study Walk-through’ is a method to help translate your protocol into an accurate and successful study. This toolkit describes the study walkthrough approach, why it might...

Resources
We have also collated an extensive collection of resources linked to Protocol Development which can be searched and filtered depending on their type.
Data Management

Getting started

Planning is a critical step in Data Management and this should commence before the protocol has been finalised. See the steps below for getting started with Data Management. The link in the sidebar will take you to more detailed resources on the topic covered.

Requirements and guidelines

Make sure you are familiar with the regulations associated with your data and any funded and/or institutional requirements with regard to data management. They may have policies or guidelines stipulating how data should be monitored, stored, archived and then deleted for these activities.

Protocol Development

The concept of Data Management (DM) is to have a clinical trial begin with the end in mind. This means that while the whole process is designed to deliver the available information, the DM in mind is to ensure that the research question the DM is designed to answer the research question. The DM is designed to deliver an accurate, valid and useful database. This database is designed to deliver an accurate, valid and useful database. To meet this objective, the DM process starts early and before the finalisation of the study protocol.

Good data management requires proper planning and should begin in parallel with protocol development to ensure that all the protocol-specific data is accurately captured. Plans for how assessments will be performed, what and how data will be captured, how assessments will be performed, and how data will be captured, are made.

Data Entry

The entry process is designed to deliver an accurate, valid and useful database. This database is designed to deliver an accurate, valid and useful database. To meet this objective, the DM process starts early and before the finalisation of the study protocol.

Data Processing

Example from an SAP

Data Organisation

System Design

Data Monitor

Data Analysis

Database Closure

Data Sharing

Storage and Archiving

Data Management Portal

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Data Sharing Toolkit

How do I share my data?
OVERVIEW OF THE MAIN STEPS

1. CHOOSE A SUITABLE REPOSITORY & SET UP AN ACCOUNT
   - Your funding body may require you to submit the data to a specific repository. Some funders have strict requirements, while others provide a list of recommended repositories.
   - Journals may allow deposit to a specific repository and/or may require deposit to one.
   - There may be discipline-specific and funder/organisation-specific requirements that are applicable. You can also look up requirements in your discipline.

2. ORGANISE YOUR DATA
   - Decide on the best way to organise your data - sometimes it is best to merge several files into one, but in other cases, depositing separate files makes sense.
   - Select and name your files well - for your own use and to assist others.

3. PREPARE YOUR DATA
   - Are your data clean and labelled consistently? Do you explain in your naming to ensure that others can understand your data.
   - Are your data using non-proprietary formats, to allow accessibility now and in the future? If you need to use a proprietary format you may first need to convert it.

4. DESIGN THE METADATA
   - Describe the data, the code, the methods, the results.

5. SHARE THE DATA
   - Make sure to deposit your data to a suitable repository.

6. CONSENT, PERMISSIONS
   - Make sure to get consent from all individuals to share their data.

Example: README file
- Checklist of potential files to include
- Example: patient consent form for data sharing
- Example: submission process

Example: Data ownership
- Copyrights
- Use licenses

Example: patient dataset
- Non-proprietary formats
- Data, documentation files
- Consent to share

Example: submission process
- Data ownership
- Use licenses
- Consent to share
Sharing expertise through **joined-up** tools, resources, webinars, workshops, training & career development

- Many different collaborators
- Open access, globally applicable
- Peer reviewed, regularly updated
- Certificate issued: 80% in
Access to Resources and Training – discovering what they didn’t know

Accessible to anyone, 24/7, and covering topics in essential research skills, essential topics related to health research.

Tool which captures core competencies, qualifications, training and experience. Measures skills and impact of training.

Person-centered, to foster effective learning strategies.

Free eLearning courses + certificates

Research Toolkits

Professional Development Scheme (PDS)

Webinars and Workshops

Supported Learning sessions

Data Science Clubs and Clinics

Step-by-step guides to conducting and managing a research project in low-resource settings, Sharing protocols, guidelines, best practices

Online or in-person seminars, for skills transfer and information sharing

Forums for engagement, to exchange opinions, raise questions

The Global Health Network Research Cycle Resource Centre

Data Science

Operations

Community Engagement

The Question

Uptake and Impact

The Global Health Network

Enabling research sharing friendship
Community stories
Barriers to research
– Interim data from two studies (n = 6,000)
What next? – what would you find useful to support your studies?
Research into policy and practice

Where do you need help?

What sort of help?
- Toolkits?
- Training courses?
- Online Workshops?
- In person / regional

Share some ideas ..... What has worked for you?
The Health Research Ecosystem - The whole set of evidence vital to understand, treat, prevent and manage any disease
The Health Research Cycle - The required steps and processes for all studies – that don’t vary between diseases

Turning research findings into policy and practice is a key element within the research cycle

The EDCTP knowledge hub aims connect you to resources and training to support the whole cycle for your studies
Thank you!

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