



# EDCTP Knowledge Hub

Supported by the  
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**EDCTP 11<sup>th</sup> Forum Paris, France  
9 November 2023**



[edctpknowledgehub.tghn.org](https://edctpknowledgehub.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

The collage features logos for various research networks and communities of practice, such as COVID-19, sSCoRN, Global Health Data Science, ABCI, DAC Trials, IIR-SP, Virtual Bio, Systemic Processors Innovations, Global Consortium for Injury Research, CONNECT, UK-PIBCT, The Global Health Network Africa, The Global Health Network Asia, and The Global Health Network LAC. It also includes several photographs of researchers working together in a laboratory or office setting.

## Workplace based implementation of research skills – by doing

Working within existing networks, research organisations and in communities

Cascading research skills across healthcare settings

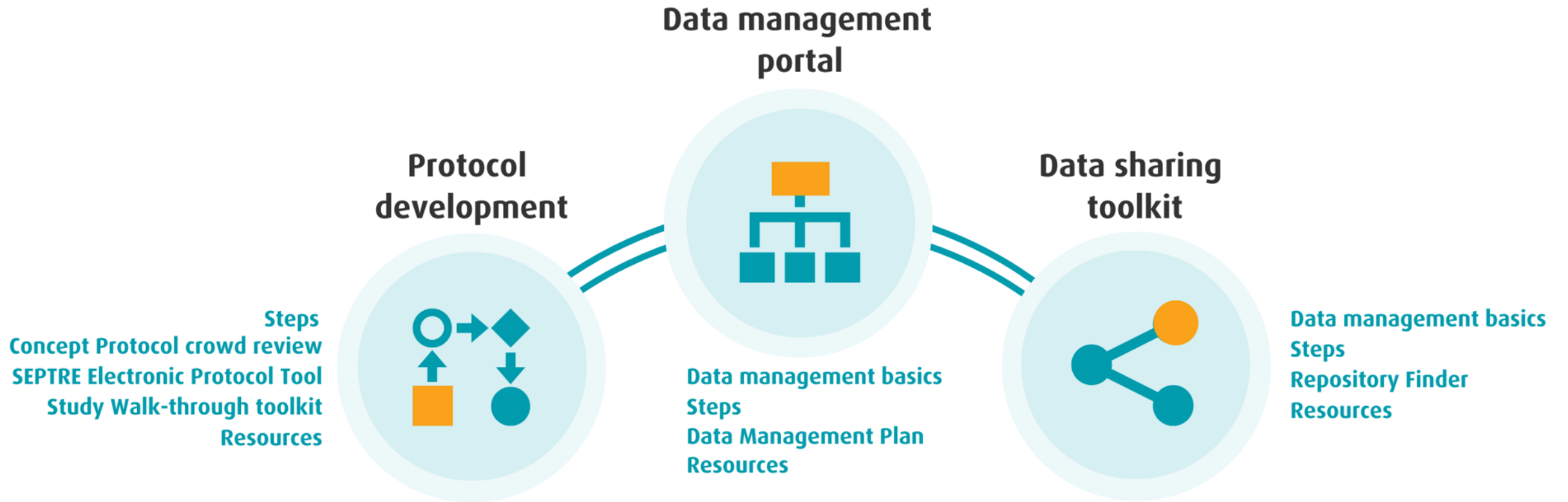
Delivering learning-by-doing in specific studies to share expertise beyond centers of excellence, to support lasting, leading and internationally competitive research teams.

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?



# 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.



PROTOCOL DEVELOPMENT STEPS »



# Data Management Portal

## 1 Getting started

# 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 sections on the topics covered.

### Requirements and Guidelines

Make sure you are familiar with the regulations associated with your data and any funder and/or institutional requirements with regard to data management, they may have policies or guidance stipulating how data should be monitored, shared, archived and timeframes for these activities.

### Protocol Development

'The Clinical Data Management (CDM) process, like a clinical trial, begins with the end in mind. This means that the whole process is designed keeping the deliverable in view. As a clinical trial is designed to answer the research question, the CDM process is designed to deliver an error-free, valid, and statistically sound database. To meet this objective, the CDM process starts early, even before the finalisation of the study protocol.' [Data management in clinical research: An overview](#)

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

**1 Getting started**  
Protocol Development Toolkit  
TGHN Process Map: Protocol  
The SPIRIT Checklist  
Data Management Plan

**2 System Design**  
CRF Design & examples  
Choosing a CDMS

**3 Data Organisation**

**4 Data Entry**

**5 Data Processing**  
Example from an SOP



the protocol or separately with a reference to where this information  
The **SPIRIT Checklist** provides a list of recommended items to address  
protocol several of which are focused on data management.

Information on developing your protocol see node 4 on the **Process Map Development Toolkit**.

**Data Management Plan**  
The **Data Management Plan (DMP)** is a very important piece of study  
should be included as **annex** to the protocol. Depending on the  
it is made up of several documents. It should give a complete  
overview of how data will be handled throughout the study by outlining all of the  
study's data management procedures.

Factors to consider when writing a DMP are covered in the **Data**

Factors that relate to data management are likely to affect the cost of  
data collection. You will need to consider the long-term requirements for  
data storage in addition to the cost of data collection.

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## 6 Data Monitoring

## 7 Interim Data Lock

## 8 Data Analysis

Prepare data for analysis

## 9 Database Closure

## 10 Data Sharing

Data Sharing Toolkit  
Repository Finder

## 11 Storage and Archiving

How to keep your data safe

←  
Back:  
Overview

→  
Next:  
System Design

# Data Sharing Toolkit

## How do I share my data?

### OVERVIEW OF THE MAIN STEPS

#### 1. CHOOSE A SUITABLE REPOSITORY & SET UP AN ACCOUNT

- Your funder 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 also require deposits to a specific repository and/or may recommend repositories.
- There may be discipline-specific and disease-specific repositories that are preferable. You can also look up repositories in your discipline using re3data and FAIRsharing.
- If your funder/journal do not provide any guidance, or if you are not familiar with repositories used in your field, we provide guidance on how to choose a suitable repository in the Repository Checklist.
- Make sure to familiarise yourself with the repository guidelines.

#### 2. ORGANISE YOUR DATA

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

#### 3. PREPARE YOUR DATA

- Are your data clean and labelled consistently? Be explicit in your naming to ensure that others can understand your data.
- Are you using non-proprietary formats to ensure accessibility now and in the future? If you need to use discipline-specific format you may



1

Repository Finder

Different models of access

Options offered by repositories

List of funder & journal recommended repositories

Funder requirements

Data organisation

File organisation

File naming



3

Example: data structure

Example: data labelling

Non-proprietary formats list

Anonymisation and de-identification



Toolkit



...ing two versions of the file - one in the discipline-  
and one in non-proprietary format.  
...discipline-specific format you should double check that  
accept that format.

#### ARE DOCUMENTATION FILES

codes and acronyms should be either self-  
defined (this can be done in a separate 'README.txt'  
to include a user guide.  
your methodology, protocols and any other  
Is it clear how the data were collected and

#### IT, CONSENT, PERMISSIONS

right to share the data: are you sure that you  
n from all right-holders? This includes patient  
itive data are sufficiently anonymised.  
g to share your data under?

#### ING THE DATA

ly and you have chosen an appropriate  
it your data. Each repository has its own  
, so you will need to follow their

an identifier (DOI) keep it for future  
provide your funder and/or institution

4



Example: README file

Checklist of potential files to include



5

Data ownership

Deposit licences

Use licences

Example: patient consent for data sharing

6



Example: submission process



# Sharing expertise through **joined-up** tools, resources, webinars, workshops, training & career development

**Global Health Training Centre**

Home | eLearning Courses | Professional Development | Webinars and Workshops | Community | Resources | About This Site | FAQ

## Welcome to the Global Health Training Centre

**Online training**

Free eLearning courses in global health research for staff of all roles, in all regions and covering all disease areas, developed by The Global Health Network in collaboration with respected partners such as the World Health Organization

**Webinars**

Online workshops and seminars in global health research, spanning research disciplines, regions, and therapeutic areas, aiming to foster collaboration, facilitate discussion, and celebrate advances and achievements towards faster and better research for health

**Professional development**

Build your professional profile, create your CV and track your career in global health research as it develops. This flexible framework covers all the competencies that should be demonstrated by a research team to carry out a successful study

RESEARCH PROCESSES & METHODS | SOCIAL SCIENCE, ETHICS & COMMUNITIES

### Workshops

Workshops are a valuable and engaging way to learn, providing a fantastic opportunity for collective training sessions, skills transfer, networking and information sharing.

The range of workshops and format for delivering these sessions can be creatively designed to best serve the context of the learning, institutes such as these help to support and strengthen capacity at both an individual and institutional level. We set up and facilitate a wide range of practical workshops in close collaboration with coordinators and study teams in diverse settings. Please do review the variety of workshops hosted across the regions that cover a breadth of topics, which have generated rich outputs from these sessions to benefit researchers globally.

**AFRICA**

Research in Global Health Emergencies	Africa CDC One Health workshops	Research Ethics during epidemics
Laboratory Quality Control	Infection Prevention and Control AHB	Grant Writing Workshop
Introduction to Scientific Writing	Laboratory Quality Control	PCR-NHS Workshop
Nigeria Workshop 2021	Treatment protocols and approaches from different countries: The African Story	Africa's capacity for real-time polymase chain reaction (RT-PCR) diagnosis of infectious diseases
Implementation of Novel Diagnostics	Improving clinical trial conduct in Africa	

**GLOBAL**

### Essential Research Skills Training Curriculum

This study was developed as a collaboration between the Special Programme for Research and Training in Tropical Diseases (SPRTD) and the Global Health Network (GHN).

The aim of the Essential Research Skills Training Curriculum study is to identify the treatment of all skills, knowledge and key principles that would enable those with limited or no previous experience to undertake high-quality research for health. The study design was underpinned by a three-stage mixed methods consensus methodology to ensure an evidence-led approach to establishing the curriculum.

[Download final report \(PDF\)](#)

[The study chart](#)

[The research methodology and findings](#)

[Conclusions and Recommendations](#)

### Developing an Evidence-led Essential Research Skills Training Curriculum

#### Delphi Study

**Stage 1: Knowledge Gap Analysis**

**Stage 2: Panelist selection**

**Stage 3: Delphi rounds**

### Good Clinical Laboratory Practice

GLOBAL HEALTH CLINICAL CONSORTIUM

### Research Ethics Online Training

World Health Organization

### Introduction to Clinical Research 1 module

An overview of the basic concepts of clinical research, focusing on the main areas of why and how clinical research is carried out, the importance of ethics in research, and an outline of the five main clinical study designs.

English | Español | Français | Português | Swahili | Việt | 中文

- Many different collaborators
- Open access, globally applicable
- Peer reviewed, regularly updated
- Certificate issued > 80% in

**Professional Skills**

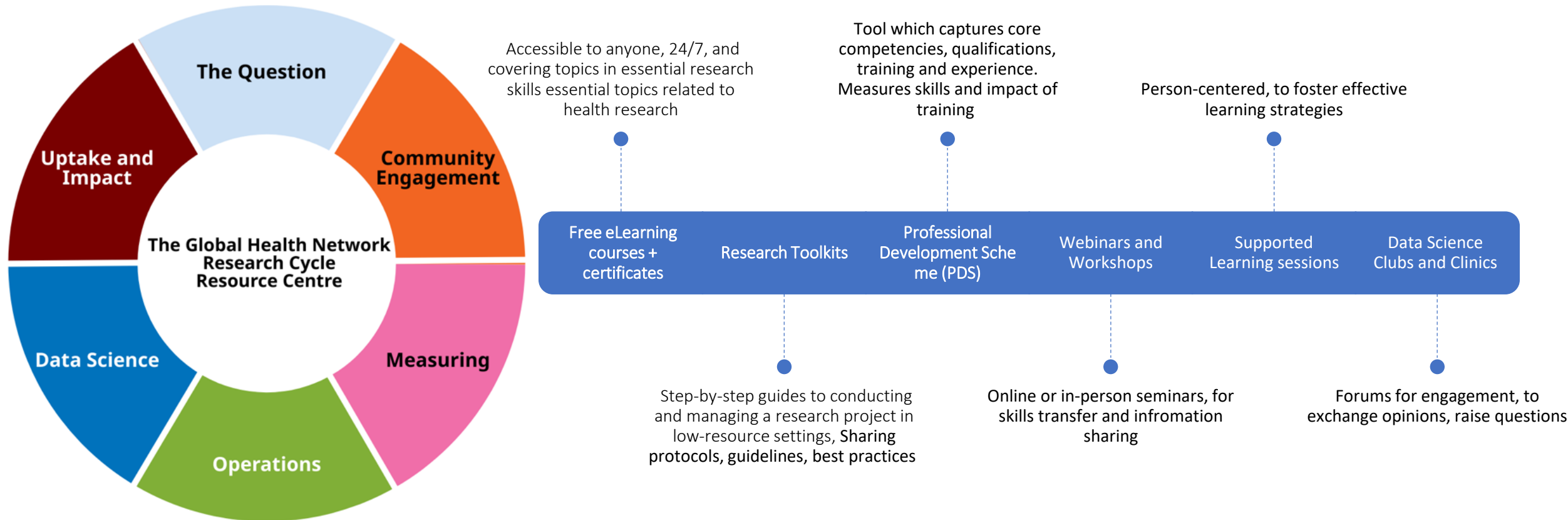
- Scientific Thinking
- Ethics, Quality & Risk management
- Research Operations
- Study & Site(s) management

**Core competencies**

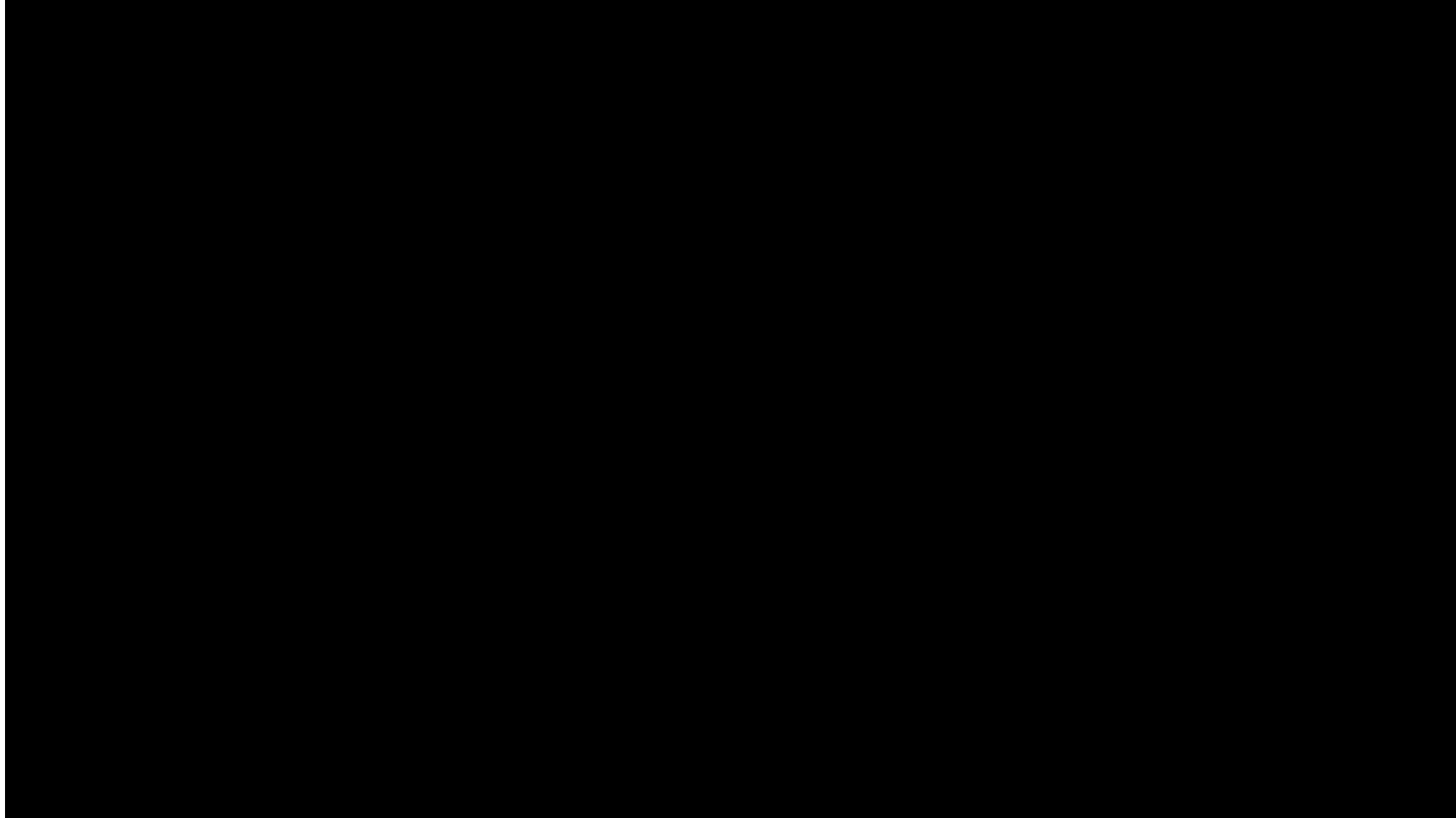
Ethics, Quality & Risk management Area

Global Health Clinical Exchange Platform - Critical Care of the Neurologic System in COVID-19

# Access to Resources and Training – discovering what they didn't know

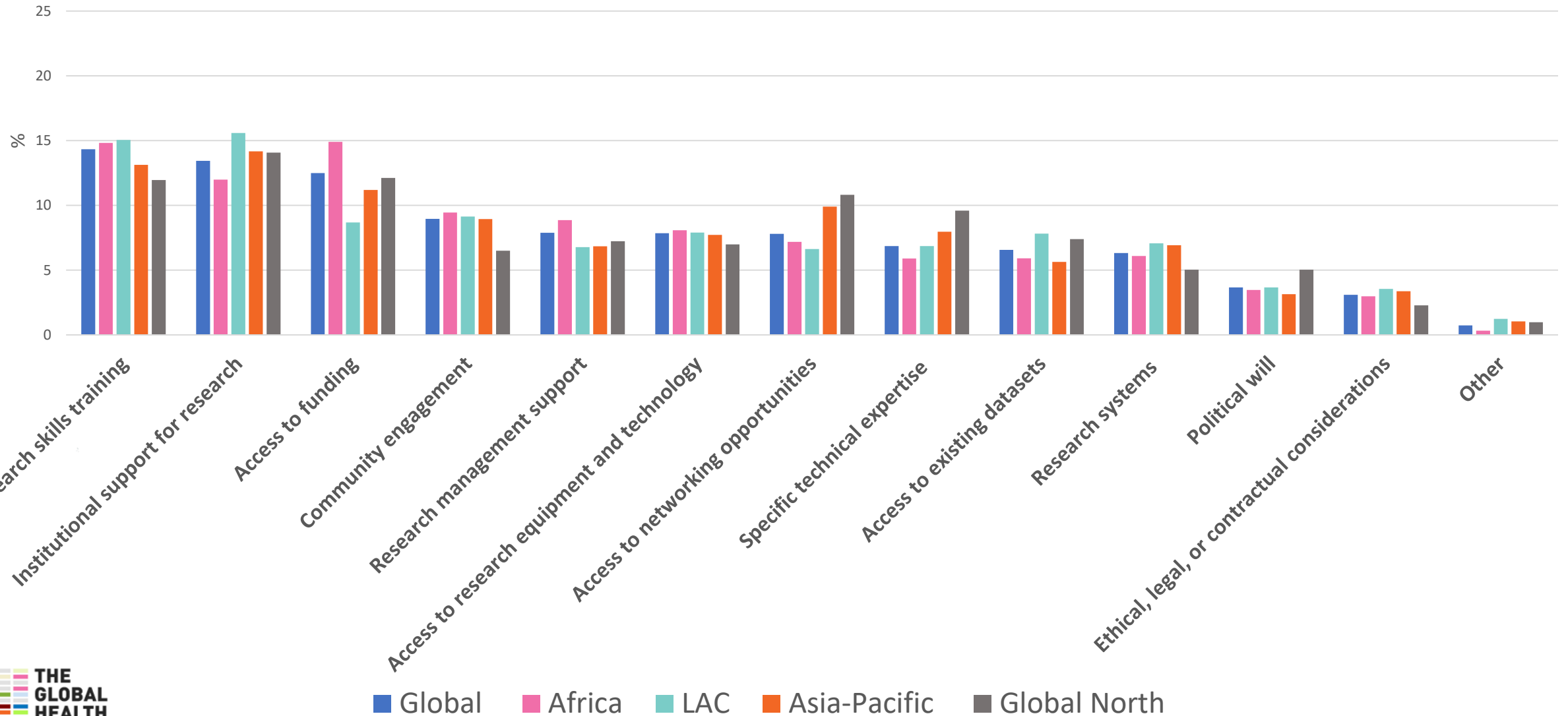


# Community stories

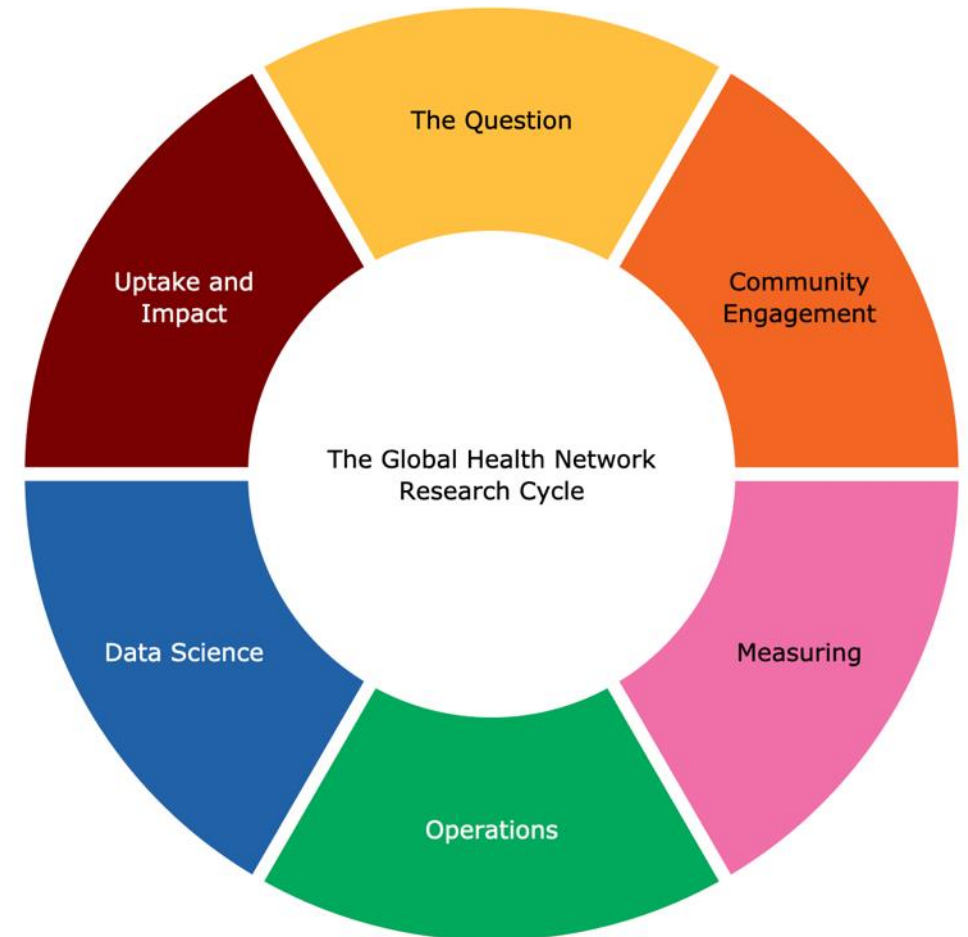
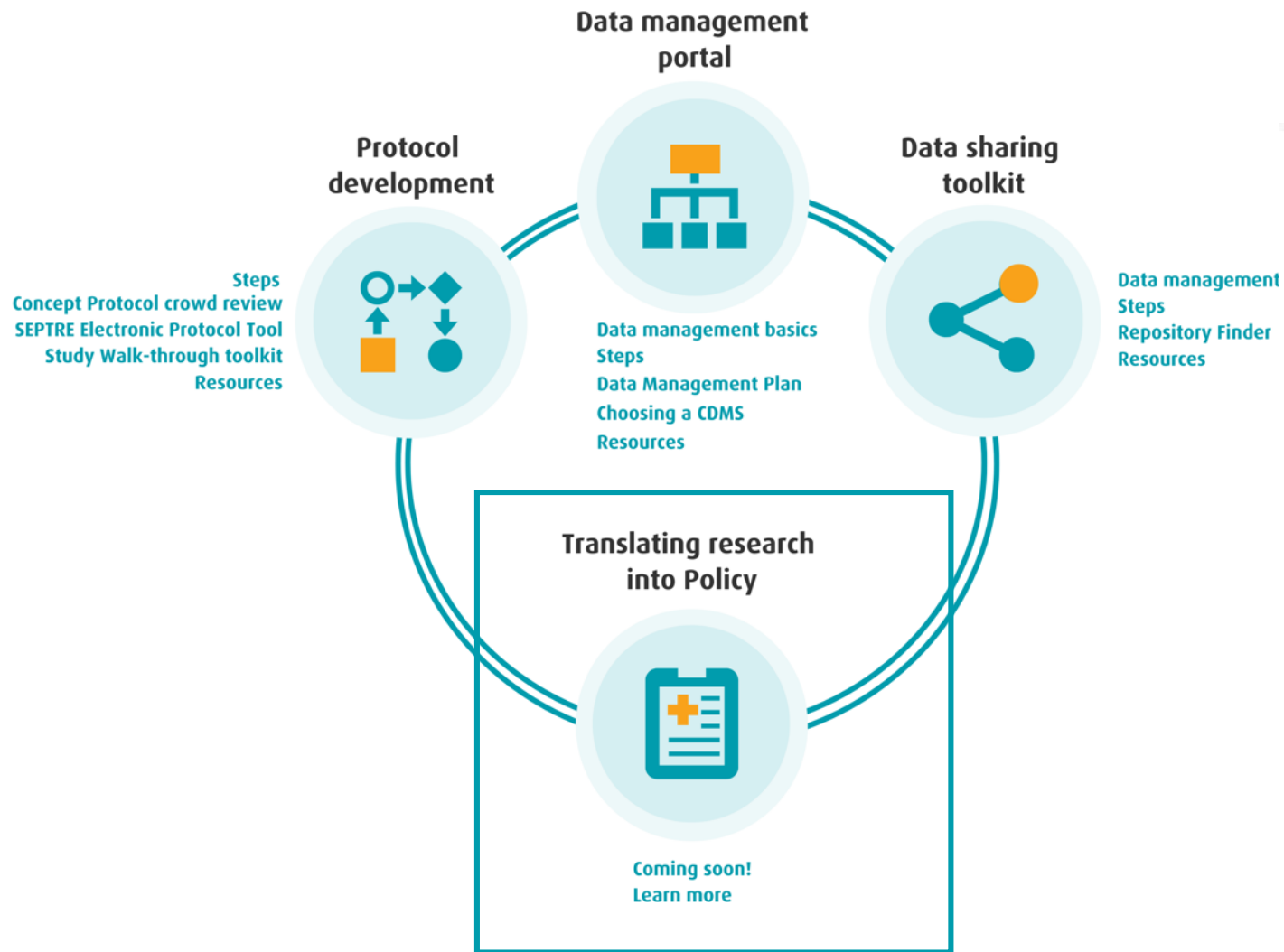


# Barriers to research

– 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?

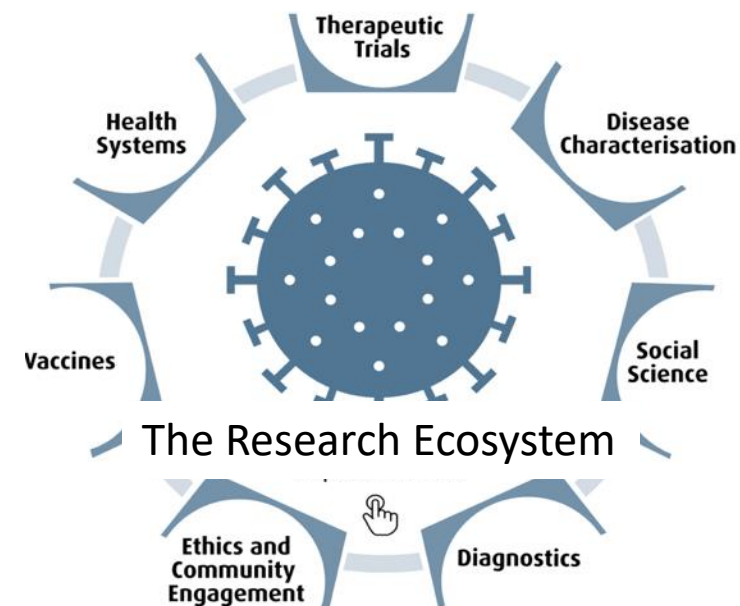
- Toolkits?
- Training courses?
- Online Workshops?
- In person / regional

Share some ideas .....

What has worked for you?



# EDCTP Knowledge Hub



**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!

[edctpknowledgehub.tghn.org/  
translating-research-policy/](https://edctpknowledgehub.tghn.org/translating-research-policy/)

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