



EDCTP

The power of sharing science



EDCTP Knowledge Hub webinar

Providing tools and guidance for conducting clinical research

30 November 2020



EDCTP Knowledge Hub



About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership between 14 European and 16 African countries, supported by the European Union.

EDCTP's vision is to reduce the individual, social and economic burden of poverty-related infectious diseases affecting sub-Saharan Africa.

EDCTP's mission is to accelerate the development of new or improved medicinal products for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre- and post-registration clinical studies, with emphasis on phase II and III clinical trials. Our approach integrates conduct of research with development of African clinical research capacity and networking.

About The Global Health Network

The Global Health Network is a global open community of practice for health workers, research teams, and research organisations. It facilitates, supports, and enables research in diseases, places, and settings where evidence is lacking. It works by sharing research methods, know-how, and data between organisations, projects, regions, and roles, and delivers capacity building, support, and training to research teams and frontline health workers.

EDCTP Knowledge Hub

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Contents

1	Introduction	5
2	Summary of presentations and discussion	6
3	Closing remarks and next steps	8



Introduction

As part of the global initiatives contributing towards global health data sharing and open access to clinical trials data, clinical trials protocols and clinical trials reports, the European & Developing Countries Clinical Trials Partnership (EDCTP) has commissioned The Global Health Network (TGHN) to develop the EDCTP Knowledge Hub. The EDCTP Knowledge Hub is a one-stop open online portal to provide researchers involved in clinical trials, non-interventional studies and product-focused implementation research in low-resource settings with tools and guidance to enable them to undertake high-quality health research.

On 30 November 2020, EDCTP and TGHN convened the first in a series of webinars to present and elicit feedback on the EDCTP Knowledge Hub, with over 650 participants from across the globe. This first webinar, which focused on data management and sharing, included a live demo, as well as a panel of speakers who gave their feedback on the EDCTP Knowledge Hub, followed by an open conversation about the experiences and issues faced with increasing requirements for open access research data.

Speakers and attendees shared their thoughts and questions regarding the challenges that they face, as well as highlighting the needs from the research and patient communities. The EDCTP Knowledge Hub was presented as a resource that can be used by researchers involved in clinical trials, non-interventional studies and product-focused implementation research in low-resource settings to facilitate good data management and sharing.

Meeting highlights:

1. Good data management is critical for ensuring the validity and quality of data in all types of clinical research and is an essential precursor for data sharing
2. We need to have and promote open science, being mindful of the multifaceted nature of data sharing
3. While there is generally a lot of support for data sharing, researchers face many challenges in doing so; building public trust is essential and a change in the culture of data sharing is needed
4. There needs to be a paradigm shift from data ownership to the custodial responsibilities of the data community
5. Improved data management capacity and better tools for data sharing are needed to ensure equitable access to data and to achieve a balance in its benefits
6. The EDCTP Knowledge Hub plays a critical role in addressing these needs and serves as a good resource containing very practical how-to guidance, all together in one place.

Summary of presentations and discussion

This first EDCTP Knowledge Hub webinar was chaired by **Professor Catherine Hankins** (Amsterdam Institute for Global Health and Development) and **Professor Jeffrey Mphahlele** (South African Medical Research Council).

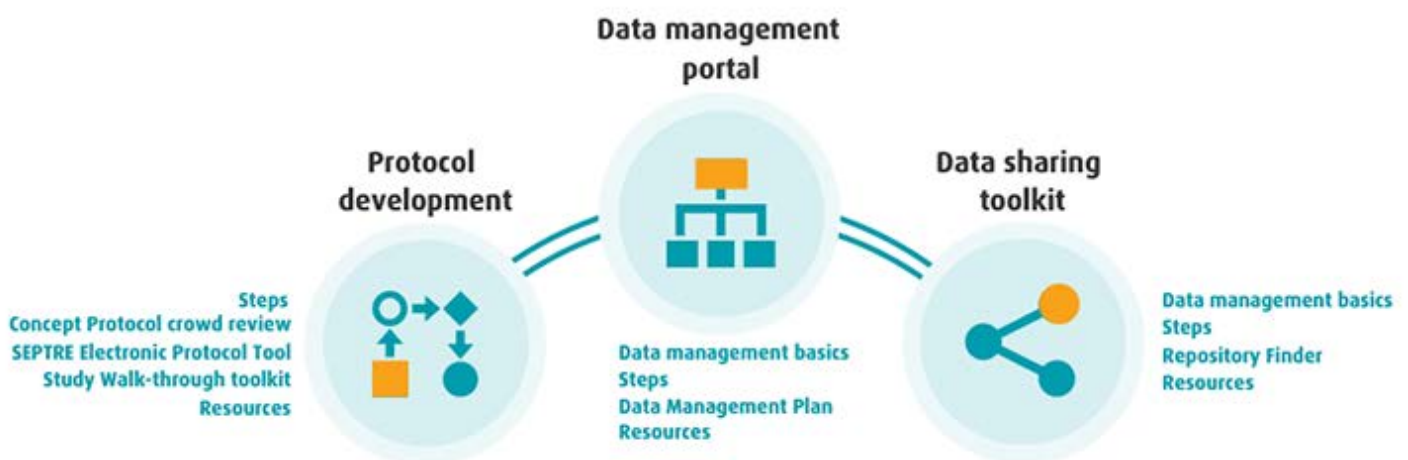
Dr Barbara Kerstiëns (European Commission (EC)) opened the webinar and highlighted the importance of good data management and sharing, in clinical research and particularly in the context of infectious disease outbreaks. She mentioned two important challenges identified in the GloPID-R Roadmap for data sharing in public health emergencies as being the need for improved data management capacity and improved tools to support data sharing, and considered that this is where the EDCTP Knowledge Hub could add value with practical and accessible tools.

Ms Lara Pandya (EDCTP) provided a short introduction to EDCTP and outlined the rationale for the development of the EDCTP Knowledge Hub. She acknowledged the increased requirements from many funders and relevant stakeholders for open access data sharing, outlining EDCTP's approach to this and its commitment to providing the necessary guidance and support to help researchers to achieve these data sharing objectives.

Professor Trudie Lang (TGHN, University of Oxford) introduced TGHN and the EDCTP Knowledge Hub and positioned it in the context of other activities being conducted by TGHN. Professor Lang also highlighted the relevance of the EDCTP Knowledge Hub in the COVID-19 context, emphasising Dr Kerstiëns' earlier message. **Mr Samuel Driver** (TGHN, University of Oxford) summarised the initial scoping exercises that had been conducted by TGHN and provided an in-depth look at the Data Management Portal and the Data Sharing Toolkit through a live demo.

Three panellists were invited to provide feedback in the context of relevant activities and case studies from their own work:

Dr Jenniffer Mabuka-Maroa (African Academy of Sciences) explained that when setting up Africa's Scientific Priorities (ASP), one of the issues that came up was data and biospecimen governance. It was noted that while there is generally a lot of support for data sharing, researchers face many challenges in doing so and building public trust is essential. Therefore, she emphasised the need for tools that can support equitable access to data.



Professor Francine Ntoumi (Congolese Foundation for Medical Research) presented the EDCTP-funded Central African Network on TB, HIV/AIDS and malaria (CANTAM) and consortium for Preparedness for Infectious Diseases Epidemics and the African Coalition for Epidemic Research, Response and Training (PANDORA-ID-NET), highlighting the impact these consortia have in terms of information sharing, career development, networking and training. Professor Ntoumi commented that there was a large amount of data generated that was currently not being optimally exploited, which she attributed to a lack of knowledge on data sharing and - in some cases - a hesitation to do so. In light of this, she welcomed the EDCTP Knowledge Hub and the necessary tools and useful guidance it would provide for researchers involved in clinical studies. Additionally, she noted its potential for helping people to understand and contribute to developing a new culture of data sharing.

Mr Rob Terry (TDR, the Special Programme for Research and Training in Tropical Diseases at the World Health Organization) shared Prof. Ntoumi's view that researchers don't necessarily know how to share their data and the best way of doing it and considered that the EDCTP Knowledge Hub would go some way to overcoming that barrier. In addition to highlighting the need for building capacity training into data sharing, he stressed that

the current tendency to focus on the technical aspects of data sharing meant that other important ethical, political, social, legal and economic aspects were often overlooked. Finally, he emphasised the importance of taking the wider context into consideration and for recognising that data sharing is part of the broader agenda of open science.

Overall, panel members found the EDCTP Knowledge Hub a good resource containing very practical how-to guidance, all together in one place, which they look forward to seeing populated with more information and tools.

An open conversation ensued, during which several questions from the webinar attendees were addressed by the various speakers, covering issues around the motives for data sharing and the need to ensure equity and parity in the benefits of doing so. The aspect of data management systems and collection of data ready to be shared for clinical research was raised and the need to ensure high-quality data management and handling to support good data storage and sharing was highlighted. It was noted that the impetus of data sharing had increased in the wake of COVID-19 and that creating a transparent research agenda as well as greater use of digital technology were lessons to be learnt for improving community engagement in clinical trials participation during a pandemic.



From top left: Professor Catherine Hankins, Professor Trudie Lang, Professor Jeffrey Mphahlele, Dr Jennifer Mabuka-Maroa, Professor Francine Ntoumi and Mr Rob Terry

Closing remarks and next steps

In his closing remarks, **Dr Michael Makanga** (EDCTP) provided a summary of the feedback received. He reflected on the clear message conveyed about the need to have and promote open science by supporting equitable data sharing and balancing the benefits of this, being mindful of the multifaceted nature of data sharing, the legitimate interests that need to be protected and the public trust that needs to be built to achieve this. He further noted the aspiration to achieve a paradigm shift from data ownership to the custodial responsibilities of the data community, taking into account the perspective of the communities involved. Finally, he summarised that three major challenges had been highlighted:

1. data governance and access;
2. ethical and regulatory oversight of the benefit of data sharing; and
3. translation, innovation and intellectual property rights.

Dr Makanga concluded that the EDCTP Knowledge Hub was playing a critical role in addressing these challenges and that EDCTP was glad to partner with TGHN to deliver this platform.

To this end, all attendees were encouraged to visit the EDCTP Knowledge Hub and provide their feedback on the resources available, in addition to attending the second webinar scheduled to take place on **25 February 2021 at 12:30-14:00 CET**, which would be focusing on the [Protocol Development Toolkit](#).

More information and registration details for the second webinar can be found on the [event page](#). A recording of this first webinar on data management and sharing is available [here](#).



Dr Michael Makanga



European & Developing Countries Clinical Trials Partnership

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