Website pools clinical trial forms for use in developing countries

Healthcare advances in low-income countries are chronically hampered by a lack of locally run clinical trials. To wit: a whopping 80,771 clinical trials have been registered in the US since 1999, compared with only 216 in Bangladesh and 93 in Nigeria over the same time period, according to a database maintained by the World Health Organization. Although the movement of some commercial drug trials to resource-poor countries has sparked ethical concerns, global health advocates are clear in their assertion that more locally initiated research trials in those countries would benefit developing world populations.

Now, a new online resource scheduled to launch on 8 July aims to help by providing a trial initiation 'process map': an interactive flow chart that summarizes all the various stages of a clinical trial and links to guidance articles to assist local researchers in setting up new studies. It is part of the Global Health Trials website of the Global Health Network, a collection of online research forums that has received \$5 million in funding from the Seattle-based Bill & Melinda Gates Foundation since 2010.

According to Trudie Lang, who heads the Oxford-based Global Health Trials site, "People find it difficult to find out the basics of how to run a study, so the process map gives a route map with all the steps." The new flow chart provides a generic guide to all aspects of running a trial, from developing research questions to beginning patient recruitment. It provides information relevant to all countries, diseases and types of studies. "It doesn't really matter whether you are working on a malaria study in Kenya or a visceral leishmaniasis study in Nepal," Lang explains, "there are still things that you do that are the same."

At each trial step, the flow chart provides links to relevant examples of standard documents and templates. These documents, many already available on the Global Health Trials website (<http://globalhealthtrials.tghn.org/>), have been donated from researchers in Europe and the developing world so that they can be adapted for use by other developing world researchers. Lang says that of the templates presently on the

Due process: New website provides an interactive flow to guide clinical researchers in the developing world.

website, the most accessed documents are examples of informed consent forms and standard laboratory operating procedures. Without specific training, consent forms are particularly difficult to create, owing to complicated legal requirements as well as requirements from trial sponsors.

Users will also be able to ask questions and post advice to others through a users' forum. Once contributions reach a critical mass, Lang plans to implement an Amazon.com-style users' ranking system, to allow the most popular contributions to be listed first.

Forum for change

According to Elizabeth Allen, a clinical research manager from the University of Cape Town in South Africa, additional benefits lie in the local context that the online flow chart can provide through the users' forum. Allen runs antimalarial efficacy trials in Mozambique, South Africa and Swaziland, and she has set up a South African members' network on the Global Health Trials website. Using the new flow chart users' forum, she plans to share her own local information with

the whole community, such as information on South African trial registration requirements in addition to standard general requirements. Allen says that many of the problems are practical issues, for example, "it's knowing the tips on how to complete a trial application so it will be successful in terms of its regulatory review."

Since 2010, 183,000 users have visited the Global Health Trials site, with 80% coming from low- and middle-income countries, with the largest proportion of users being from Africa. Lang says she does not have a specific target for the number of users but thinks the site is on track to reach 1 million visits within three years.

Haleema Shakur, a trial design expert who co-directs the Clinical Trials Unit at the London School of Hygiene & Tropical Medicine, is supportive of the site's information-sharing aims but feels that capacity building needs training through direct mentoring. Shakur says that at the moment there is a "chicken and egg situation," with funders unwilling to fund inexperienced staff who subsequently lack opportunities to gain training. "Unless funding bodies are willing to invest in developing units within countries," she says, "I don't know if you are ever going to change the situation."

Rachel Brazil

"The new flow chart provides a generic guide to all aspects of running a trial."