University of Basel

African Contributions to Global Health

Video Transcript

Drug development challenges in Africa

Developing drugs is a lengthy and challenging journey with many obstacles. It is a step-by-step process that spans everything from basic research to large-scale activities and involves multidisciplinary specialists. Naturally, things can go wrong at any time. Therefore, the process is strictly regulated. Let's look at the individual steps in the drug development process.

The first stage starts with biochemical research, after new compounds are discovered, investigated and synthesised. This is followed by preclinical tests that further narrow down and refine the selection of compounds. During the following clinical development stage, the compounds are tested on human volunteers for the first time. The clinical trials run through three phases, during which the safety and efficacy of the candidate drugs are evaluated. Finally, the drug regulatory authorities assess the complete documentation and decide on the marketing authorisation. This whole process usually takes between 10 and 20 years. After the marketing authorisation, phase IV studies called pharmacovigilance studies are conducted. You can find a more detailed map of this pathway attached to this step.

As you can see, this pathway is highly regulated. Clinical drug development requires sensitive planning and is often conducted in several research sites.

But clinical trial protocols were mainly developed in the Global North, without considering settings and locations. It is challenging to apply them one-to-one to African settings.

To this day, researchers often do not adapt clinical trials to local contexts. This can then lead to unrealistic agendas where researchers underestimate the time needed for logistics or to train staff. This can make it challenging to stay within the budget or to maintain an acceptable level of quality. It is crucial to take these aspects into account when planning clinical trials. Another important aspect is infrastructure. African settings sometimes don't have suitable infrastructure; or their existing infrastructure is insufficiently equipped to conduct clinical trials. This shortcoming has been addressed in some cases through "research grants" or "North-South collaborations". These are collaborations between institutes in the Global North with those in the Global South. For example, the Swiss Tropical and Public Health Institute contributed to establishing clinical research sites in several countries including Côte d'Ivoire, Tanzania and Congo.

The ethical aspects of clinical trials must also be taken into account. It is ethically problematic to do medical research in communities that are not intended to be the major markets for the products that are being tested. Therefore, the Council for International Organizations of Medical Sciences has set up ethical guidelines. Concerning research conducted in low-resource settings, they state that "the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out". Furthermore, informed consent of the participants of clinical trials is mandatory, as is ensuring access to the drugs after the trial. The issue of compensation should also be well considered - whether it is in kind or cash, the main objective should be to avoid undue inducements.

Other challenges in the conduct of clinical trials in Africa may arise from the fact that trials these days are becoming digital. This digitalisation ranges from the use of electronic patient files to electronic data collection tools in clinical trials and also cohort surveys. Also, remote quality control is now happening, as well as remote sampling for biomarkers to predict treatment outcomes. The conduct of digital clinical trials is currently challenging in settings with limited access to power, cell phones and other electronic and digital infrastructure. To address these challenges, researchers have made considerable efforts in recent years. For example, well-equipped, modern excellence research centres are being established in various locations across the continent.

African countries are increasing the capacity of local researchers and well-trained local personnel. They are also making Health and Demographic Surveillance Systems more widely available and serving as excellent platforms for clinical trials.

And finally, international collaborations and partnerships are also thriving in order to potentially accelerate drug development processes, especially regarding the development of drugs for neglected diseases.