University of Basel

African Contributions to Global Health

Audio Transcript

Discussions on clinical trials conducted in Africa

CORNELIS WINNIPS

0:00-1:26
CHRISTIAN BURRI: So good afternoon, Dr Cornelis Winnips. It's a great pleasure to have you in this session of the MOOC on African Contributions to Global Health. We would like to know from you a little bit on your experiences with drug development with Africa. And we have invited you because we know that you have a very, very important role in this matter, because you are at Novartis as the Global Program Clinical Head. And working in malaria drug development, we know that you are at the moment responsible for the development of one of the new antimalarials that Novartis is developing, the KF156. And that you also are working on a paediatric dose for *Coartem*, one of the main drugs that are used to treat children against malaria. As a physician and an executive who has had many different roles in clinical development Phases I to IV and who has also worked in marketing and finance – in big pharma, in start-ups – we expect you to have the big picture of these developments. That's why we are extremely pleased to have you here. With this, I would like to hand over to Eric Nébié to start the discussion with you.

1:27-1:32
ERIC NÉBIÉ: Could you please share with us your most successful drug development story in Africa?

1:33-3:30
CORNELIS WINNIPS: Happy to do that. To give you some very recent experience on a successful project that we had in Africa, where we have been running a Phase II clinical trial in 11 clinical sites spread across sub-Saharan Africa for a new antimalarial drug. I should say, and we've just closed this trial, that it has been a very successful experience in different ways. We have been positively surprised by the dedication and professionality of the clinical staff that has been working on this project with us – the local clinical staff in the different African countries. We have also been surprised in a positive sense by the good quality of work and the dedication of the teams, the local teams on the floor, to deliver excellent service to our project. What also was, I think, a very positive experience in addition is that it was very good to see that patient recruitment in all sites was above expectations. And that Africa is also a great place to find patients and motivate them to participate into clinical trials. So overall, I think, in terms of quality, the recruitment speed and project management, we had really a very positive impression. And I think, having worked with

Africa already in the past and over many years altogether, I think we clearly see that the latest generation of medical professionals and their staff is now also on a strong international level and overall, it is really an excellent development and a great place to do clinical research. The only downside is that not many people know that yet, but it is absolutely comparable to doing clinical research in other parts of the world.

3:31-3:33
ERIC NÉBIÉ: Thank you, Dr Cornelis Winnips.

3:34-3:50
CHRISTIAN BURRI: Thank you so much. That was a really interesting insight and also for us a very positive one, to see that the constant work and the efforts in capacity-building are really paying off, and that we see the centres now get really on their own feet. Thank you very much, Cornelis.

University of Basel

JOERG MOEHRLE

3:51-4:53
CHRISTIAN BURRI: So, I would like to welcome Dr Joerg Moehrle, who is Vice President and Head of Translational Medicine at the Medicines for Malaria Venture (MMV). I'm very, very glad you joined us for a question, to respond to a very, very important question. I would like to underline that Dr Moehrle has a very prominent career with a start in biochemistry. He holds an MBA, he also did a PhD thesis in Biochemistry and has been working in pharmaceutical companies for quite a long time, before he joined the Medicines for Malaria Venture in 2005. So he has the real background to discuss with us this translation from pharmaceutical industry into PDP world and into academia, because Joerg is also a senior lecturer at the University of Basel, so he has seen all the three worlds. With this introduction, I hand over to Eric Nébié, please.

4:54-4:59
ERIC NÉBIÉ: Could you please share with us your most successful drug development story in Africa?

5:00-8:21
JOERG MOEHRLE: Thanks, Eric, for the question, and the most successful drug development story in Africa personally for me is not about a certain project or a certain drug which I accompanied, but it's more a process, which I could see how African study centres developed and got better and better and more qualified to conduct trials and also to conduct new trials, new translational medical [inaudible]. When I joined MMV 15 years ago, there were few centres in Africa that could conduct Phase II, Phase III trials. And an African-led initiative was started which was called "The Malaria Clinical Trials Alliance" (MCTA), with the objective to get sites ready for Phase III trials; Phase III trials for drugs, but also for vaccines in malaria. This initiative, "The Malaria Clinical Trials Alliance", was supported by the Gates Foundation, and over several years, I worked with MCTA in providing funds, providing expertise, but also providing training. And what I see now is that some of the centres that we supported, and we supported not only in the first few years, but throughout the development in the last 15 years, really grew up. And I'm still collaborating with them, and indeed collaborating with the Gates Foundation, collaborating with other institutions to do malaria trials. But they have also widened their expertise; they're doing trials in other indications. I'm speaking with some of these investigators on trials that test drugs against COVID-19; they're working in TB, they're working in HIV. And, what we've seen now, they're also doing really new concepts [inaudible]. I'm doing now a lot of trials where we infect healthy volunteers with malaria; we study new drugs, but also we study vaccines. There are centres in Africa, centres from the MCTA, who are capable of performing these trials in Africa. Similar sites can now do transmission-blocking studies, so not only seeing whether a drug cures malaria, but also whether the patients are infected from mosquitoes, and if the drugs work in transmission-blocking, you can break the transmission process. So that's for me the most successful

project in Africa I have been involved in: developing 15 sites to be able to conduct clinical trials on their own, sponsoring clinical trials not only in malaria, but also in other indications, and moving from, let's say, less complex Phase III trials into more complex, more risky trials in the early phase development. One other thing at MMV: we conducted the first ever, first-in-human study, with a drug that was actually discovered in Africa, the MMV048, was discovered at the University of Cape Town. And the Phase I study was also conducted at the University of Cape Town. These are two things I'm really proud of that I was part of them.

8:22-8:24
CHRISTIAN BURRI: Big thank you to you, Joerg.

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MANUEL BATTEGAY

8:25-9:22
CHRISTIAN BURRI: So, good afternoon, Professor Battegay. It's a great pleasure to have you for this interview for this MOOC. I would quickly like to introduce you as the Head of Infectiology and Hospital Hygiene at the University Hospital of Basel. Professor Battegay has had a very, very long career in infectiology, in infectious diseases, but not only in Switzerland, because he has also massively contributed not only to HIV and AIDS treatment and treatment of other infectious diseases in the North, but also with huge effort in the South, particularly in Tanzania, where he has built up an HIV cohort and has been involved in many, many other projects, developing medicines against tropical and Neglected Diseases. I would like to hand over to Eric Nébié, who will do this interview with Professor Battegay.

9:23-9:27
ERIC NÉBIÉ: Could you please share with us your most successful drug development story in Africa?

9:28-11:59
MANUEL BATTEGAY: Thank you very much. I'm really happy to share my view, also because it was indeed one of my most impressive insights in my career. So it was actually in 2000 when it became very clear that the drugs against HIV are working extremely well, are saving lives, not only of single persons, but at large. And it was then with the Clinton Plan in 2002 where we were aware – actually colleagues also from the Swiss Tropical and Public Health Institutes – but many colleagues in Europe, to introduce the treatments in Africa, as well in sub-Saharan Africa. And I was fortunate and privileged to introduce the drugs together with colleagues in Tanzania, in rural Tanzania, as one of the first clinics in sub-Saharan Africa from 2003 on. It was then a lot of work to organise the cascade of care – that is most important – and then as of 1st of May 2005, we could start indeed the treatments, where now more than 10'000 patients are cared for. One of the most important aspects were the treatments of pregnant women to prevent transmission of HIV to the newborn, and that was extremely successful, as well as the treatment of so many people, and we have to know that this clinic gave rise to other clinics – served as a model. So that was very successful. And what was one of the most wonderful experiences was also the collaboration with Tanzanian colleagues. I think this is very important, be it with physicians, nurses, assistant medical officers. So that was really, I think, one of the most important experiences in my life, not only in my professional career. What was important is to gain the trust; that was important in Switzerland, in Europe, and of course also in sub-Saharan Africa, because the cascade of care includes as few as possible lost to follow-up, so that people really remain in the programme and we know that the prognosis is good for life and changes life and also makes life safer for partners. So that is my experience. Thank you that I could share my thoughts on this.

12:00-12:25

CHRISTIAN BURRI: So thank you, Professor Battegay. This is fantastic, and it feels familiar, as we all have worked in such situations and I think this is a really fantastic example of collaboration South-North, North-South and also for the successes demonstrating the progress we have actually made in the past about 30 years in tropical and poverty-related diseases. Thank you very, very much.