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# Harnessing Africa's potential to develop medicines for its people

# Establish relevant discovery tools and create the environment for more clinical trials, urges leading UCT researcher

Africa makes up 15% of the global population and 25% of the global disease burden yet the discovery and development of medicines that end up in Africa has historically only happened in the global North. It is time for the situation to change, says Professor Kelly Chibale, the director and founder of the University of Cape Town's Drug Discovery and Development Centre, H3D.

Professor Chibale is on a drive to highlight the need to create developing research platforms that allow medicines to be customised to the needs of African patients, and an environment for more clinical trials to take place in Africa. Currently less than 2% of global clinical trials take place on the continent.

"The low volume of clinical trials in Africa is a disaster and a serious indictment on all of us. The devastating Ebola crisis of 2014 highlighted just how unprepared the continent is to rapidly deploy clinical trials," said Professor Chibale.

During a high-level panel at the Financial Times Africa Summit in London this week, Professor Chibale explained that medicines are not optimised for African patient populations. The dosage and the dosage intervals are optimised in developed countries and then the therapies are brought to Africa.

"Africans are not getting medicines that are customised and optimised for their needs, leading to inferior health outcomes," commented Professor Chibale.

He said Africa was not an attractive destination for the innovative pharmaceutical industry, which is the main funder of clinical trials. Long timelines and lack of predictability for the approval of clinical trials are some of the major reasons for this.

The capacity and capabilities to do regulatory quality clinical trials is concentrated in only a few centres on the continent, mostly in South Africa and Egypt.

Uncertainty about regulatory and ethics approval processes in Africa appears to be a major bottleneck to more clinical trials being done on the continent. Professor Chibale said there was also the challenge of multi-country trials, as each country had a different set of regulatory and ethical requirements, standards and processes.

Professor Chibale, who is also the Neville Isdell Chair in African-centric Drug Discovery and Development and South Africa Research Chair in Drug Discovery, said governments have a key role to play in addressing these barriers and creating an innovation-friendly environment.

"We need to harmonise the regulatory environment in Africa and make it easier to conduct clinical trials in Africa. There is much at stake. The poor health outcomes for African patients, the high cost of medicines and economic loss are amongst the consequences of not doing so. Africa needs to have a solid regulatory environment as this will provide opportunities for product development and access to new medicines. Commendable and encouraging progress has been made through some regional initiatives and work towards the African Medicines Agency but there is more work to be done."

There is some positive momentum.

"My own experience has been as part of a programme with an innovative pharmaceutical company to get our Drug Discovery and Development Centre, H3D, ready to conduct our First-in-Human study for the malaria drug candidate that we discovered in Cape Town in collaboration with international partners. This was part of a programme to build skills in this special area of clinical trials which explores the clinical pharmacology of new and existing drugs," said Professor Chibale.

He said medicine discovery, clinical testing, approval and post-marketing surveillance need to be viewed as a continuum. Addressing one component will simply not suffice. It is necessary to build an ecosystem between academia, industry and regulators.

"We need to increase collaboration between regulators and industry with academia on training that will strengthen student understanding on innovation, drug development, and registration from both industry and regulators perspectives."

Professor Chibale said regulatory agencies would need to enhance their review capacity and efficiency to allow the simultaneous introduction of innovative products across African countries.

He said historically it has taken between five and 10 years before a new medicine, available in the US or Europe, reaches the African continent, but that harmonisation of the regulatory environment could go a long way in reducing this lag-time.

"If we unite around a common goal and streamline processes, there is hope that we can develop an innovative pharmaceutical R&D [research and development] industry across Africa. H3D has shown that this is possible by strengthening and integrating medicinal chemistry, biology and pharmacology under one umbrella in partnership with the innovative pharmaceutical industry, philanthropic organisations, product development partnerships and government. This would enable us to work towards discovering new medicines, ensure dosages are optimised for different African populations and start to develop an industry that could not only improve the health of our people but also build skills and create jobs."

Professor Chibale also recently outlined these views as a keynote speaker at the recent 4<sup>th</sup> Biennial Scientific Conference on Medical Products Regulation in Africa, 2019 (SCoMRA IV) at the Victoria Falls, Zimbabwe.

In 2018 Professor Chibale was recognised as one of Fortune magazine's top 50 World's Greatest Leaders.

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#### Note to editors

H3D is Africa's first integrated drug discovery and development centre. The Centre was founded at the University of Cape Town in April 2010 and pioneers world-class drug discovery in Africa.

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