Costly, lengthy, and safe process before drugs hit the shelves

Whether it's a remedy for the common cold or sophisticated drugs to treat cancer, all medicines go through a very costly and lengthy research process before being approved for prescription to patients. The cumulative time from the beginning of trials to marketing approval has increased over the past 10 years.

Dr Nathaniel Mofolo, Dr Rita Nathan and Dr Mojalefa Maseloa. Photo: Leonie Bolleurs

South Africans would not have had access to safe and effective medicines, had it not been for the intensive research conducted on new medicines, Dr Vathi Papu-Zamxaka from the South African Clinical Research Association (Sacra) said at a SACRA clinical trials capacity-building workshop at the University of the Free State.

$2,1bn to develop one successful drug

“One out of 10 drugs entering human research will be approved. The cost of development of one successful drug is approximately $2,1bn, and the time to develop a drug, from submission of the Investigational New Drug Application (IND) to approval by the Food and Drug Administration (FDA), is between 12 and 15 years," said Dr Michelle Middle, chief medical officer at Farmovs.

Drug development is one of the most regulated processes, with ethics and patient safety governing the undertaking. “With South African Health Products Regulatory Agency (Sahpra) having some of the strictest regulations in the world, South Africa has a good history of running trials. In addition, fast growth is expected for the pharmaceutical market on the African continent, necessitating the need for increased clinical trials on this continent,” she said.

Very few clinical trials hosted in South Africa

Although Africa has the broadest genetic variability of all human populations and carries 17% of the global population, very few clinical trials are hosted on the continent. Globally, there are currently approximately 322,000 clinical trials being actively conducted, of which only 1,700 are conducted in Africa, less than 3%. Even worse, only 304 of the 1,700 trials running in Africa are conducted in South Africa. There is, therefore, a critical need for South Africa as a country to market itself as a clinical trial destination and to attract more trials to the country.

South Africa’s competitive edge lies in being known for its ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)-compliant top-quality research, racial and genetic diverse trial participants, good medical infrastructure and expertise, and the good reputation of the regulator (SAHPRA). “There are, however, a need for transformation and capacity building in clinical research in the country,” Middle said.

Dr Rita Nathan, head of clinical services in the clinical department at the Universitas Hospital, who was representing government at the workshop, is looking to strengthen clinical trials across government and industry by focusing on, among others, funding models, operations management, and service delivery.

From the UFS Faculty of Health Sciences, Dr Nathaniel Mofolo, head of the School of Clinical Medicine, said collaboration between stakeholders is important. “This initiative is giving direction to the UFS vision of being a research-led university.”

Other topics discussed at the workshop include the clinical trials landscape, how clinical trials work, the patient factor, ethics in clinical trials, and the economic aspect of clinical trials.