

The importance of capacity building and development of a clinical research infrastructure in Africa, 17 June 2021

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Background

- Health research is fundamental not only for health but also for economic development and progress
- Clinical trials and implementation research are essential components of health research. When integrated with health systems, they are key instruments for the development of effective prevention, diagnosis, and treatment strategies, as well as their implementation in the real-life environment
- The health research value chain comprises upstream activities, including basic research, research & development (R&D) (e.g., drugs, diagnostics, and vaccines), clinical and epidemiological research, as well as downstream activities, including applied field research and health technology assessments, which are crucial in contributing to effective, efficient, and equitable implementation of interventions and evidence-based health policies
- The upstream part (clinical research) requires advanced laboratory capacity and highly developed and specialised research teams, and the downstream part (implementation research) depends on the creativity and skills of multidisciplinary researchers close to the supply of, and demand for, health services and implementation of health services
- Key health research challenges in sub-Saharan Africa include: a) funding mainly being provided by international sponsors and donors; b) poor research policies and facilities; c) lack of synergy for more collaborative research with many researchers working in isolation; d) limited pool of highly skilled and experienced clinical research individuals and brain drain due to the lack of appropriate health research systems
- Establishing a robust and equitable clinical research infrastructure is a highly important development step to address region-specific health challenges faced within particular health systems
- Needs-based health research priority setting coupled with sustainable funding are the cornerstones for national and international collaborations to achieve the Sustainable Development Goals (SDGs).

Recommendations

- 1. Galvanise existing models and networks through clear medium and long-term commitments.**
Models and networks that greatly contribute to capacity building and the creation of clinical research infrastructure in Africa already exist, but they need to be adapted to the current demands and, thus, must be further developed. These networks are currently working collaboratively and strengthening them with continued funding in a sustainable way is crucial. As part of this process, it is essential to recognise the role of low-income countries in the global fight against emerging diseases and therefore work in closest partnership with them.
- 2. Correct the existing lack of equity in access to health and innovation by investing (in an equitable manner) in capacity strengthening and infrastructure in limited resource settings.**
There is considerable variation in capacity for health research within and across countries in Africa and external support is often concentrated in particular countries and institutions. This has an impact

in health systems and contributes to the existing lack of equity in access to health and innovation. Ensuring that funding is allocated in a more equitable manner is necessary as funders often use excellence as a key criterion in making awards, with the aim of enabling highly performing researchers to undertake high quality research. Excellence and equity may be seen as competing considerations if decisions to award funding remains based on excellence at the expense of equity. Aspects such as gender equity and geographical diversity should be considered. Moreover, funding decisions should be guided by decisions that consider team expertise and experience (in contrast to Principal Investigator-focussed excellence), patient-needs, structure of a center's portfolio and status/potential of infrastructures in place.

- 3. Support the creation of an ecosystem**, including a wide range of disciplines, areas and expertise that are essential across the entire health research spectrum (e.g., biosafety/biosecurity, quality, IT and data management, data quality and sharing, supply chain, social sciences, biobanking). This is the only way for research institutions in Africa to nationally and internationally engage in research.
- 4. Support infrastructure at the national level with a view of developing Centres of Excellence with state-of-the-art equipment and highly qualified professionals, that attract both industry and academic trials. Linked to recommendation #2**, support is needed for research infrastructure development in academic and non-academic research institutions and networks at the national level, including support for investigators and clinical research facilities through personnel and equipment. This is critically important to attract industry trials as organisational and capacity needs must be in place at the level of the current global Good Clinical Practice (GCP)/ Good Manufacturing Practice (GMP) and Good Clinical Laboratory Practice (GCLP) standards to generate the data and follow patients. There is also a need to support trial management units, which must be able to design and manage trials, and this is critical for academic trials. Infrastructure support must consider local context, sustainability, maintenance, and affordability.
- 5. Support development of local expertise (scientific excellence and leadership) with strong international collaboration** as this will be required to solve local problems in alignment with related global strategies and initiatives. Investments should be made horizontally and not only to support one particular initiative or training degree, but rather looking at global health priorities as well as the local centre portfolio as a whole. Career plans should be offered by research institutions and national structures to attract/re attract and retain qualified and motivated scientists.
- 6. Support research network building, coordination, and harmonisation efforts.** Resources (including costs and benefits), tools, and best practices should be shared. The cost of this coordination is relatively low when compared to the costs of creating the necessary infrastructure. EU funded initiatives such as ECRIN and EDCTP have a track record in supporting capacity building and infrastructure but also important networking and coordination activities. Encouraging research network building, coordination and harmonisation will support the sustainable conduct of complex research, build trust, and increase effectiveness and preparedness.
- 7. Development cooperation funding must leverage domestic cofunding to enable sustainable research capacity**, especially for late-stage clinical development and implementation research that will facilitate access to new and improved interventions to populations in most need. Building sustainable capacity for implementation research includes the development of: 1) institutional base

and research infrastructure; 2) relevant training programmes (individuals and teams), career development pathways and research portfolio; 3) ethics and regulatory environment and networks.

- 8. Support innovative ways to raise ethics oversight of clinical trials** and deliberately target ethics committees/review boards involved in reviews of clinical trial applications for interventions which promote R&D and access to new medicines. Policy-makers and partners must aim at systems which support expedited reviews of clinical trial applications for priority public health products (Tuberculosis, HIV, Malaria, Neglected Tropical Diseases) as well as for emergency reviews in public health emergencies of international concern (PHEICs). The use of digital solutions and online platforms is essential in relation to clinical trial reviews and approvals. Policy-makers and partners should support implementations of digital platforms across the continent with additional IT support and accompanying infrastructure.
- 9. Increase investments in cross-disease health demographic surveillance systems and further integration of health research into health care systems** that facilitate ongoing disease surveillance systems that can, when needed, be tailored to targeted disease responses. The link of research and trial centres with health demographic surveillance is essential and will make it possible to progress from phase I clinical trials to phase 4 and implementation science. By doing so, it is possible to effectively bring products not just to registration but to health systems based validation and thus application.
- 10. Support more patient-centred approaches** that promote cross disease, interdisciplinary research, and exploration of opportunities offered by new technologies in the context of integrated patient care and to tackle co- and multi-morbidity across the lifespan.
- 11. Capitalise on the digital revolution to extend the reach and impact of training and networks and closely monitor mega-trends in digital technologies** drawing lessons from the COVID-19 pandemic as they will impact on the effective and efficient implementation of future R&D and related capacity.