**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**

**WELCOMING REMARKS MADE BY MR. ADAM MITANGU FIMBO - DG - TMDA**

**AT THE KICK OFF MEETING OF THE ASCEND PROJECT**

**APC HOTEL, DAR ES SALAAM**

**26th November 2020**

* Guest of Honor – The Chief Medical Officer - Ministry of Health, Community Development, Gender, Elderly and Children,
* ASCEND Project Consortium Partners present,
* Recognizing the virtual presence of those who have joined us online or through live streaming,
* TMDA Directors,
* Media Representatives,
* Ladies and Gentlemen

**Guest of Honor**

Let me first and foremost begin by thanking you for accepting our invitation to officiate this important kick off meeting despite your busy schedule.

I know the 21st Joint Annual Health Sector Technical Review Meeting is currently ongoing in Dodoma and you were scheduled to attend, but you decided to join us in this meeting. This to us is clearly a rhetoric that signifies your interest, commitment and support of what we do in the health sector.

We thank you so very much for being here.

**Guest of Honor**

We have gathered this morning to witness the launching of our project dubbed **ASCEND** which is a short version of “***Moving Tanzania’s Clinical Research Ethics and Medicines Regulatory Capacity to the Next Level: Fostering Medicines Quality, Safety and GCP on Clinical Trials***”

This project has finally been able to secure funding from the ***European and Developing Countries Clinical Trials Partnership*** or in short **EDCTP**. The process for funding acquisition from EDCTP began back in October 2019 and seven (7) institutions were engaged in the process. Representatives from these institutions are all here – KCRI, MUHAS, NIMR, ZFDA, ZAHRI, UStAN and TMDA.

The impetus to apply for such funding was mainly attributed to the challenges we all face in regulatory and ethical review capacities within our organizations and how these could be addressed to bolster regulation of clinical trials and research undertakings in Tanzania.

We began by putting together our proposal with contributions from all of us and after a series of back and forth communications with EDCTP, finally the same was accepted and approved for funding in October 2020. So the process took around one year to completion.

**Guest of Honor**

The project will run for two and half years (around 30months) and at the end we expect to realize the following milestones:

* Strengthening regulatory and ethical reviews including linkages amongst participating institutions;
* Promoting the adoption, domestication and implementation of harmonized guidelines in clinical trials control including those promulgated by the African Vaccines Regulators Forum;
* Supporting training institutions (i.e. MUHAS) to provide both innovative and mentorship training to National Ethics Committees and National Regulatory Authorities;
* Improving efficiency within National Ethics Committees and National Regulatory Authorities through reliance and technologies that would facilitate quality outputs including reduction in review and approval timelines;
* Strengthening pharmacovigilance systems to increase reports on adverse events and reactions originating from clinical trials; and
* Establishing an effective system for information sharing.

**Guest of Honor**

You will note that the project will engage regulators and ethical committees from Tanzania Mainland and Zanzibar. In this way we will unequivocally work and cooperate together in the course of implementation of the project leading to improved relationships, exchange of expertise, conducting joint reviews and sharing of information to safeguard the interests of research participants.

I wish to assure you that, collaborating institutions in this project are looking forward towards moving the ethical and regulatory oversight of clinical research in Tanzania at a higher level in line with global practices to ensure research is conducted following the principles laid down in the Declaration of Helsinki, GCP guidelines and regulatory requirements.

**Guest of Honor**

I would like to wind up my remarks by thanking my fellow consortium partners for devoting their time, energy and passion since drafting of the proposal, responding to queries from EDCTP until finally we are here today observing the kick starting of our project.

More importantly I would wish to thank Ms. Kissa Mwamwitwa – TMDA Manager for Clinical Trials Control and Pharmacovigilance for being upfront in providing guidance and leading us through communications with EDCTP. We sincerely appreciate your efforts Madame Kissa.

Lastly, I pledge the full support from TMDA in implementation of this project. I also urge my fellow partners to cooperate with us particularly when sending periodic reports to EDCTP. I have experience on how daunting and frustrating this task is especially when members delay in sending reports for onward submission to the funding agency. Nonetheless, I anticipate full cooperation from you.

**Guest of Honor, Ladies and Gentlemen**

With these few remarks, may I now take the opportunity to humbly welcome you to the podium for remarks and official launching of our project.

**Thank you for your attention**

**END**