1. Project title

The project for developing basis of expanding Japanese medical devices in Africa under the projects for global growth of medical technologies,systems and Services by Ministry of Health,Labor and Welfare/MoHLW,Japan

2. Country name

The Federal Democratic Republic of Ethiopia and The Federal Republic of Nigeria

3. Background

Japanese regulations and laws in term of approval of medical devices by the MoHLW and the Pharmaceutical and Medical Devices Agency (PMDA) are not known in the target countries. In the future, to appove and introduce Japanese medical devices in those countries for strengthening quality health and medical services, it is important to increase the understanding of counterparts on the Japanese regulatory system and regulatory authorities.

4. Objective

・To promote the understanding on Japanese medical equipment laws and regulations and on the consistency of the medical devices regulatory system for medical devices including Rapid Test Kits between Japan and World Health Organization(WHO)
・To make a place of the point of contact with PMDA

5. Project outline

Between May and September in 2019 for 1week per one country,a Japanese expert will visit regulatory authority in each country to explain this project and necessary preparation.

The training will held at PMDA for 1week and at National Center for Global Health and Medicine(NCGM) for another 1 week (total for 2 weeks) in November 2019. The main topics of the training at PMDA are Japanese regulatory system for medical devices and rapid test kits(RDT),comparison on the regulatory system for medical devices and IVDs among Japan-PMDA,US FDA and EMA-CE and site tour.

The main topics of the training at NCGM is WHO Regulatory system for medical devices including RDT and the comparison on the regulatory system for medical devices and IVDs among Japan-PMDA and WHO system.The target trainees for the trainings are staffs who are working for reviewing medical devices and rapid test kits at the medical device regulatory authorities.

6. Implementation structure

6-1. Japanese side

・Bureau of International Health Cooperation(BIHC) of
Center for Clinical Sciences /CCS of NCGM,National Research and Development Agency (Under MoHLW,Japan)
・Pharmaceutical and Medical Devices Agency (PMDA) ,Independent Administrative Agency (Under MoHLW,Japan)

6-2. Counterpart country

・The Federal Democratic Republic of Ethiopia,
Food, Medicine and Healthcare Administration and Control Authority of Ethiopia (FMHACA)
・The Federal Republic of Nigeria, National Agency for Food & Drug Administration & Control (NAFDAC)

7. Indicator	
7-1. Output	· Number of training participants in Japan 2 people from FMHACA,The Federal Democratic Republic of Ethiopia, 2 people from NAFDAC, The Federal Republic of Nigeria · Understanding level at completion of training: 80% · Number of Japanese companythat participated in the report meeting at the end of the trainings in Japan
7-2. Outcome	·Comparing with EU countires and USA, If there are any unfair obstacles for Japanese manufactiures at the regulatory authorities, such obstacles will be eliminated. (Example: In addition to the medical equipment which acquired PMDA approval in Japan, further acquisition of US FDA or Europe CE is required,the futuer request is deleted) · Knowledge and finidngs learnet in Japan is shared with each organization as a whole. · Good relationship between PMDA officials in Japan and medical device regulatory authorities in both countries will be established.
7-3. Impact	Japanese medical device(+RDT) manufactures will consider embarking on both countries - positive advancement. · Japanese medical devices (+RDT) are approved more than now and will be used at medical service sites in both countries. · Easy deployment of Japanese test kits and medical devices to countries in Western and Eatsern Africa regions other than the two countries. · In both countries, there is a possibility of regulatory mutual cooperation not only for medical devices but also for drugs/ pharmaceuticals. · Improvement of operation/administration of the medical device regulatory authorities of both countries

8. Main activities	
8-1. Training in 2019	
1)	Between May and July in 2019 for 1week per one country, 1-2 Japanese expert(s) will visit regulatory authority in each country to explain this project and necessary preparation.
2)	In November 2019, the training will held at PMDA for 1week and at National Center for Global Health and Medicine(NCGM) for another 1 week (total for 2weeks) .