THE ASSEMBLY OF THE AFRICAN VACCINE REGULATORY FORUM (AVAREF)

AVAREF 2/R2/2017

29 November 2017, Accra, Ghana

RESOLUTION

THE AVAREF GUIDELINE FOR JOINT AND ASSISTED REVIEWS OF CLINICAL TRIAL APPLICATIONS FOR NATIONAL REGULATORY AUTHORITIES (NRAs) AND ETHICS COMMITTEES (ECs)

(Document AVAREF/3/3/2017)

The AVAREF Assembly,

Recalling that the regulatory and product development landscape in Africa has evolved substantially since the launch of AVAREF in 2006;

Recognizing also that clinical trial applications are often submitted to more than one country and across more than one Regional Economic Community (RECs);

Acknowledging that over the years clinical trials have become sophisticated and the number and complexity of products have increased;

Having also identified the need to promote the sharing of best practices, joint reviews by ECs and NRAs, to optimize timelines for regulatory and ethics processes related to clinical trials and to accelerate R&D;

Concerned that the different processes and timelines of individual countries and RECs for approval of clinical trials may impact negatively on access;

1. APPROVES the AVAREF format, timelines for clinical trial reviews and approvals and Guideline for joint and assisted reviews of clinical trial applications;

2. URGES ECs and NRAs to:

(a) participate in joint or assisted reviews according to the AVAREF joint and assisted review guideline when criteria for such reviews are met.

(b) ensure that agreed upon timelines for completing the scientific review of outstanding questions are respected and that timely decisions are made on the authorization of the trial.

(c) share information about submissions of CTAs and to increase the efficiency in the screening of clinical trial applications, scheduling of review meetings and communication of outcomes with timeliness and transparency;

(d) adopt and use the common format for clinical trial applications;

(e) aim at completing reviews and communicating of outcomes for clinical trial applications within 60 working days;

(f) adopt a parallel review system of CTAs by NRAs and ECs, while at the same time promoting collaboration between the NRAs and ECs;

(g) publish timelines for clinical trial application processing on their websites;

(h) provide quarterly updates on the progress of implementation of the above to the WHO AVAREF secretariat.

3. REQUESTS the WHO AVAREF Secretariat, AVAREF members and partners to:

(a) strengthen the capacity of the AVAREF network and NRAs and ECs to review and authorize clinical trials;

(b) advocate for resources to support AVAREF to strengthen the capacities of the ECs and NRAs to realize the goal of meeting the 60 working days timeline;

(c) continue monitoring the implementation of the processes and CTA timelines;

(d) foster continued collaboration between international and regional agencies; donor organizations and ethics committees and NRAs;

(e) report to the Assembly on the progress made.