

IMPROVING PATIENT ACCESS & PUBLIC HEALTH:

HOW GLOBAL HEALTH AUTHORITIES AND INDUSTRY CAN COLLABORATE ON CMC EXPECTATIONS .

THE AVAREF EXPERIENCE.

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AVAREF – AFRICAN VACCINES REGULATORY FORUM

INTRODUCTION - Global Product Development Challenges.

- Growing public health needs and limited resources.
- Duplication due to overlapping reviews of Applications.
- Significant and rising portion of R&D budgets is spent on differing regulatory requirements.
- Harmonization of procedures and processes is too slow.
- Enhanced collaboration would ensure that the best possible science, standards, and practice drive the regulatory process, resulting in improved safety, innovation, and access.

KEY ELEMENTS OF AVAREF STRATEGY

Goal

To strengthen clinical trials regulatory authorization and oversight in Africa by increasing system's efficiency and building an optimal clinical trial infrastructure

Key objectives

- Develop/update harmonized requirements for clinical trial regulatory authorization and ethics committee approval
- Develop and implement guidelines for joint review of clinical trial applications at regional or multi-country level for vaccines and drugs candidates

Key principles of new AVAREF vision

- Development of benchmark data on baseline review / approval timelines and annual improvement targets
- Expansion of scope to medicines (in addition to vaccines)
- Adoption of a regional approach (vs. country-focused engagement), aligning with and leveraging AMRH platform
- Practical capacity building for work sharing and promotion of joint activities

GLOBAL EFFORTS TOWARDS IMPROVING PATIENT ACCESS

GROUP

EFFORT

African Vaccine
Regulatory Forum
(AVAREF)

Accelerated and quality review and approval of applications by NRAs.

African Medicines
Regulatory
Harmonization

Regional guidelines and process for joint reviews.

Examples of Joint Reviews/Inspections– by **AVAREF**

- Conjugate meningitis A vaccine phase II trial: The Gambia – June 2006 and GCP inspection in Mali in 2007
- Conjugate meningitis A vaccine phase III trial: Senegal – June 2007 and GCP inspection in Senegal .
- RTS,S malaria vaccine Phase III trial – 2008
- Expedited review of MenAfricaVac dossier- 2009
- Expedited review of inactivated polio vaccine dossiers – 2012
- Joint reviews of ebola vaccine clinical trial application in Geneva – December 2014
- Joint review of ebola vaccine clinical trial February 2015, in Arusha, Tanzania
- Assisted review for ebola clinical trial application for Sierra Leone, Ghana, 2015
- Assisted review of clinical trial application for medicine against eumycetoma in Sudan.

CASE STUDY - VSV/EBOLA VIRUS

LEVERAGING ON PRIOR KNOWLEDGE- REDUCED CMC REQs.

FORMAL STABILITY WAS WAIVED –PHASE III STUDIES

PPQ BATCHES WERE NOT REQUIRED – PHASE III APPROVAL

ESTABLISHMENT OF RELEASE SPECIFICATIONS WAS EASY-PHASE II EXEMPTED

CASE STUDY - VSV/EBOLA VIRUS contd.

JOINT ASSESSMENT OF APPLICATIONS

Collaborative/ Joint assessment of application:

- 1.NMRAs(AVAREF)
- 2.EMA
- 3.WHO
- 4.USFDA

CONCLUDING REMARKS

- Consideration be given to a globally harmonized established platform for review of applications by experts with different technical backgrounds and competence.
- Promotion of collaboration, information sharing between NRAs and open doors to industry for discussions, and scientific advice on CMC challenges.
- Evaluation in a timely manner without compromise in the quality of the review.
- Encourage harmonization of procedures and decision criteria.

Thank you for your attention