



International Alliance for
Biological Standardization

**Maintaining the Quality of Vaccines through the Use of Standards:
Current Challenges and Future Opportunities
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Abstract**

Current approaches in the establishment of International Reference Standards for Vaccines

World Health Organization (WHO) International Standards (IS) are biological reference materials that support a wide range biological medicines, including vaccines. These IS are considered to be the 'gold standard' against which regional, national and international laboratories and manufacturers should calibrate their own working standards. They are calibrated in units of biological activity and the processes to develop such standards typically includes an international collaborative study with multiple laboratories and assay methods. Proposals resulting from such studies regarding an assigned potency for the IS and its intended use are discussed and endorsed by the WHO Expert Committee on Biological Standardisation (ECBS) before formal establishment and availability to users.

An overview of the challenges and issues encountered during the establishment process will be presented, including appropriate collaborative study design and analysis, calibration and unitage assignment to new and replacement standards, the assessment and prediction of stability and the evaluation of commutability. Current approaches will be presented, such as the inclusion of representative test samples in the collaborative study to assess commutability and stability assessment using accelerated thermal degradation samples of the candidate standard. The limitations of these approaches and issues arising from their use will be discussed.