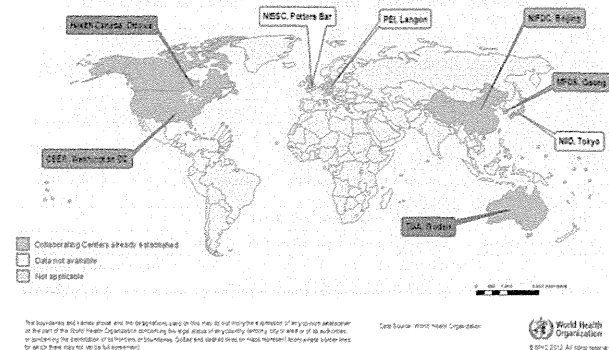




NIID activities for WHO Collaborating Center for Biological Standardization and Evaluation of Biologicals

Designated WHO Collaborating Centers that support Standardization of Vaccines



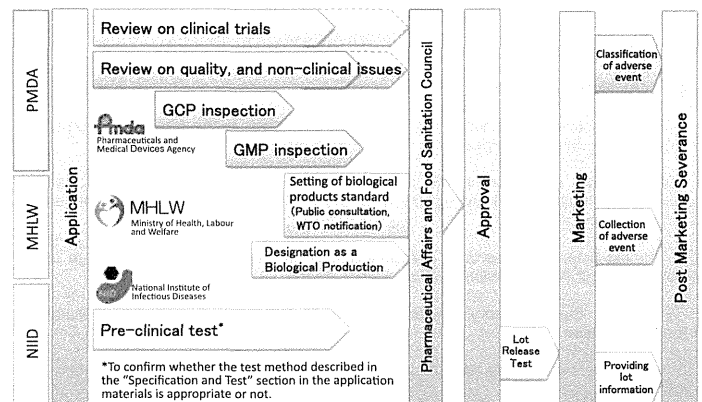
WHO Collaborating Centre for Standardization and Evaluation of Biologicals

- National Institute for Biological Standards and Control, (NIBSC), UK (1954): RD July 2013 - July 2017
- National Institute of Infectious Diseases (NIID), Japan (1971): RD August 2014 - Aug 2018
- Therapeutic Goods Administration (TGA), Australia (1983): RD August 2014 - Aug 2018
- Center for Biologics Evaluation and Research (CBER) FDA, USA (1998): RD Feb 2012 - Feb 2016
- National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety, Republic of Korea (2011): D Jan 2011 - Jan 2015
- Biologics and Genetic Therapies Directorate, Health Canada, Canada: D July 2012 - July 2016
- Institute for for Biological Product Control (IBPC) of the National Institutes for Food and Drug Control (NIFDC), China (2013): D Jan 2013 - Jan 2017
- Division of Virology, Paul-Ehrlich-Institute (PEI), Germany (2013): D Aug 2013 - Aug 2017

NIID's Terms of Reference (2014-2018)

- ToR1:** To support WHO in developing *international written standards & guidelines* for regulatory evaluation of vaccines and biologicals as well as *implementing these standards into regulatory practices*.
- ToR2:** To contribute to the development and use of *international measurement standards & reference reagents* for vaccines and biologicals.
- ToR3:** To support WHO on *research & development of quality control assays* for vaccines and biologicals, particularly the development of new and improved test methods following WHO priorities.
- ToR4:** To support WHO in *developing and implementing of a training curriculum* for standardization and regulation of vaccine and biologicals.
- ToR5:** To contribute to strengthening institutional capacity of regulatory authorities *through regional NRA alliance framework in WPR* or other regions.

Review system on vaccine quality in Japan



Contribution to International Trainings

GENERAL INFORMATION ON Strengthening the administrative function for Vaccine's Quality and Safe Security (collaboration with WHO)

4-weeks-program, once in a year

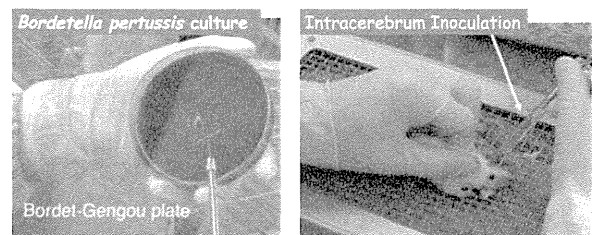
Function 1: Licensing
 Function 2: Adverse Event Following Immunization
 Function 5: Regulatory Inspection
 Function 6: Clinical Evaluation

Function 3: Lot release
 Function 4: Labo access

Manufacture visit

Logos: PMDA, MHLW, NIID, BIKEN, JICA

Contribution on vaccine lot release hands-on training



Contribution to provide measurement standards



JE vaccine standard stockpiled in the NIID provide to assist the quality control of JE vaccine productions in the SEARO region.

Contribution to strengthening NRA function



- Joining to the WHO Missions as an Expert:
1. to assess the systems and functions of NRA using WHO NRA tool;
 2. to review the NRA documents;
 3. to validate and finalize the institutional development plan;
 4. to provide necessary recommendations

Importance of 8 WHO-CCs Network on Vaccine Standardization

An opportunity to achieve more, become more efficient, reach more and respond better

- To make progress toward regulatory convergence
- To respond to WHO's need for scientific advice
- To strengthen technical skills and help WHO building the expertise in NRAs

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