Draft template for biennial activity report from JCTLM Member organizations

All JCTLM Members are invited to attend the Members' and Stakeholders' Meeting, which is held once every two years, and submit a report of their activities in support of traceability in laboratory medicine over the preceding period.

For that purpose this template document provides guidance to JCTLM Members for drafting their biennial activity report. Organizations are invited to provide the information below for submission to the Executive Committee.

Organization: Paul-Ehrlich-Institut

JCTLM Member status: Stakeholder

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Period covered: 2015 – 2017

1. Major achievement(s) in support of standardization in laboratory medicine

Established WHO International Reference Preparations (International Standard; International Reference Panels); WHO written standards

2015:

- 1st WHO International Reference Panel for Hepatitis E Virus RNA Genotypes for Nucleic Acid Amplification Technique (NAT)-Based Assays;
- 1st WHO International Repository for Transfusion Relevant Bacteria Strains (10 add. strains Bacteria Reference Panel (enlargement).

2016:

- 1st WHO International Standard for Zika Virus for Nucleic Acid Amplification Technique (NAT)-Based Assays
- WHO manual for the preparation of secondary reference materials for in vitro diagnostic assays designed for infectious disease nucleic acid or antigen detection: calibration to WHO International Standards (published 2017; WHO TRS 1004, Annex 6; 389-455)

2017:

- 1st WHO International Standard for Detection of IgG antibodies to Cytomegalovirus (anti-CMV IgG)
- 1st WHO International Standard for Chikungunya Virus for Nucleic Acid Amplification Technique (NAT)-Based Assays

Relevant publications in the period 2015 – 2017:

Baylis SA, Chudy M, Nübling CM (2015): Standardization of NAT for Blood-Borne Pathogens. Transfus Med Hemother 42: 211-218.

Nübling CM, **Baylis SA**, **Hanschmann KM, Montag-Lessing T†, Chudy M, Kreß J**, Ulrych U, Czurda S, Rosengarten R, Mycoplasma Collaborative Study Group (2015): World Health Organization International Standard to Harmonize Assays for Detection of Mycoplasma DNA.
Appl Environ Microbiol 81: 5694-5702.

Zimmer J, Vieths S, Kaul S (2016): Standardization and Regulation of Allergen Products in the European Union.
Curr Allergy Asthma Rep 16: 21.

Baylis SA, Hanschmann KO, Schnierle BS, Trösemeier JH, Blümel J, Zika Virus Collaborative Study Group (2017): Harmonization of nucleic acid testing for Zika virus: development of the 1st World Health Organization International Standard.
Transfusion 57: 748-761.

Kaiser M, Kamili S, Hayden T, **Blümel J, Baylis SA** (2017): Genome Sequence of a Genotype 2 Hepatitis E Virus World Health Organization Reference Strain.
Genome Announc 5: e01664-16.

Mellmann A, **Spindler-Raffel E**, Bletz S, **Prax M, Bekeredjian-Ding I** (2017): Genome Sequences of the First WHO Repository of Platelet Transfusion-Relevant Bacterial Reference Strains.
Genome Announc 5: e00001-17.

Spindler-Raffel E, Benjamin RJ, McDonald CP, Ramirez-Arcos S, Aplin K, **Bekeredjian-Ding I**, de Korte D, Gabriel C, Gathof B, **Hanschmann KM**, Hourfar K, Ingram C, Jacobs MR, Keil SD, Kou Y, Lambrecht B, Marcelis J, Mukhtar Z, Nagumo H, Niekerk T, Rojo J, Marschner S, Satake M, Seltsam A, Seifried E, Sharafat S, Störmer M, Süßner S, Wagner SJ, Yomtovian R for the ISBT Working Party Transfusion-Transmitted Infectious Diseases (WP-TTID) Subgroup on Bacteria (2017): Enlargement of the WHO international repository for platelet transfusion-relevant bacteria reference strains.
Vox Sang Sep 27

Spiric J, **Reuter A**, Rabin RL (2017): Mass spectrometry to complement standardization of house dust mite and other complex allergenic extracts.
Clin Exp Allergy 47: 604-617.

2. Planned activity(ies) in support of standardization in laboratory medicine

Endorsed projects for the development of WHO International Reference Preparations (International Standard; International Reference Panel)

- Proposal for extension of WHO 1st International Repository by Red Blood Cell Transfusion-Relevant Bacteria Strains (endorsed by WHO Expert Committee on Biological Standardization, ECBS in 2015; envisaged establishment 2018);
- WHO International Hepatitis E Virus Serology Panel (endorsed by ECBS in 2015; envisaged establishment 2019);
- WHO international Chikungunya virus reference reagent for serology (IgM und IgG) (endorsed by ECBS in 2016; envisaged establishment 2019).

3. Promoting traceability in laboratory medicine

Joint-Meeting Paul-Ehrlich-Institut and Physikalisch-Technische Bundesanstalt Braunschweig-Berlin to address the activities in the field metrology and traceability in laboratory medicine; Langen, Germany, 2017-02-24.

4. Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems

The Paul-Ehrlich-Institut has been designated as WHO Collaborating Centre for Quality Assurance of Blood Products and in vitro Diagnostic Devices since 2005 and is part of the network of WHO Collaborating Centres involved in the WHO Biological Standardization Programme. One of the main activities of the network is to strengthen the development of WHO International Biological Reference Preparations for the control of in vitro diagnostic tests related to blood safety and the control of infectious disease markers.

5. Open questions and suggestions to be addressed by JCTLM

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Note: This report can be published on the relevant JCTLM Members webpage.