9th ESLHO Symposium
IVDR workshop

ESLHO european scientific foundation of laboratory hemato oncology

EHA SWG SCIENTIFIC WORKING GROUPS

Thursday, 5 November 2020

Zoom webinar

9:00 - 9:30 **Introduction: position of European consortia in the IVDR era**

Jacques J.M. van Dongen (LUMC)

Contents: Introduction; Overview and aims of workshop

9:30 - 9:50 **IVDR: a case study at a large Belgian University Hospital Laboratory**

Pieter Vermeersch (KU Leuven)

Contents: Results of IVD inventory

9:50 - 10:30 **How to prepare your lab for the IVDR: a practical approach**

Jeanine Kruijsbeek (Kerteza)

Contents: Context of the IVDR; Key principles IVDR; Requirements for LDTs (Art. 5.5 & Annex I); Steps to prepare for the IVDR

10:30 - 11:10 **Clinical evidence requirements under the IVDR for LDTs/in-house developed tests**

Anja Wiersma (mi-CE consultancy)

Contents: Clinical evidence: scientific validity, analytical and clinical performance; Evaluation of clinical use/post-market surveillance; ISO standard for clinical studies (ISO 20916); CE-IVDs vs LDTs: what will be expected from labs

11:10 - 11:25 Break

11:25 - 12:05 **Without proper guidance we risk losing *in vitro* diagnostic tests that are essential for the health and well-being of all European citizens**

Leo Jacobs (Meander Medisch Centrum)

Contents: Aims and activities of Dutch task force on LDTs; Comparison of ISO 15189 and IVDR; Advice on IVDR interpretation; Next steps

12:05 - 12:25 **Working with LDTs and adapted CE-IVD kits, how to prepare to comply with the IVDR. Pooling initiatives across borders?**

Elisabeth Dequeker (KU Leuven)

Contents: Concerns with the regulation of LDTs and adapted CE-IVD kits under the IVDR; examples of preparation of some Belgium laboratories; Working groups on IVDR implementation

12:25 - 13:00 **Discussion**

All speakers

Panel discussion on selected topics and questions from participants