



WHO workshop on post-market surveillance of in vitro diagnostics (IVDs) for testing providers and regulators in the WHO European region

**Victoria Olimp Hotel, Minsk, Belarus
4 to 5 July 2018**

Provisional programme

Day 1	Wednesday	
8:00 - 9:00	Registration of participants	
9:00 - 9:30	Opening remarks	TBC
9:30 - 10:00	Meeting objectives and expected outcomes, tour de table	WHO
9:45 - 10:15	Overview of WHO guidance for post-market surveillance of IVDs	WHO HQ
10:15 - 10:30	How to scale-up capacity for post-market surveillance – aide memoire, survey of PMS implementation, database	WHO HQ
<i>10:30 - 11:00</i>	<i>Tea and coffee break</i>	
11:00 - 11:15	Country experiences - Belarus	TBC
11:15 - 11:30	Country experiences – Armenia	TBC
11:30 - 12:00	What is expected of end-users – preliminary investigation and documentation of complaints	FIND
12:00 - 12:30	Group work – how to document a complaint	All
<i>12:30 - 14:00</i>	<i>Lunch</i>	
14:00 - 15:00	Group work – how to document a complaint cont'd	All
15:00 – 15:30	What is expected of manufacturers – using risk management principles to fulfil post-market obligations	TBC – local IVD distributor
<i>15:30 - 16:00</i>	<i>Tea and coffee break</i>	
16:00 - 17:00	Group work	All

Day 2	Thursday	
9:00 - 9:15	Overview of WHO guidance on external quality assessment schemes	WHO HQ
9:15 - 9:30	What is expected of end-users – trend analysis and use of external quality assessment data for post-market surveillance	TBC
9:30 - 10:30	Group work	All
10:30 - 11:00	<i>Tea and coffee break</i>	
11:00 - 11:30	What is expected of regulators – act on field safety corrective actions, disseminate field safety notices, exchange on information with other regulators	Kazakhstan
11:30 - 12:30	Group work	All
12:30 - 14:00	<i>Lunch</i>	
14:00 - 14:30	What is expected of the testing laboratory – assist the national regulatory authority to conduct lot verification testing	Kyrgyzstan
14:30 - 15:30	Group work – protocol for lot testing (physical inspection and panel testing)	All
15:30 - 16:00	<i>Tea and coffee break</i>	
16:00 - 16:30	Establishment of a global early warning system	All
16:30 - 17:00	Next steps and closing of meeting	WHO