

SoGATS 2025 Workshop Programme
24th – 26th September 2025, MHRA Science Campus

Day 1: Wednesday 24th September

10:00-10:45	Registration	
10:45-10:50	Welcome	Nicola Rose (MHRA)
10:50-11:00	Workshop Objectives	Neil Almond (MHRA)
11:00-12:00	Session 1: Progress with new/replacement standards and reference materials Chairs: Neil Almond (MHRA) & Ben Cowper (MHRA)	
	<ul style="list-style-type: none"> • Overview of ongoing MHRA reference material projects; Mpox NAT, Influenza NAT, Aspergillus GM, Rubella Ig • Proposed WHO reference reagents for whole genome High Throughput sequencing of Oral Polio vaccines • Update on the HEV replacement standard and other activities 	<ul style="list-style-type: none"> • Jacqueline Fryer, Graham Prescott, Carmelina Vinci, Emma Bentley (MHRA) • Manasi Majumdar (MHRA) • Karin Metzner (PEI)
12:00-12:30	Discussion Session 1: Are there any themes that need to be added to the current programme? Are there any areas that may be de-prioritised? If so, why? Where/how should we best publicise this programme?	
12:30-13:30	Lunch	
13:30-14:45	Session 2: Evidence highlighting need for new standards and reference materials Chairs: Karin Metzner (PEI) & Jacqueline Fryer (MHRA)	
	<ul style="list-style-type: none"> • EURL-IVD: Role, Activities, and Future Needs • Detection of H5N1 clade 2.3.4.4b in external quality assessment programs: A pandemic preparedness initiative • EQA topics of interest: OQUASTA • EQAs for viral sequencing – new challenges and new opportunities with next generation sequencing (NGS) • Use of Reference Materials for In Vitro Molecular Devices (<i>virtual</i>) 	<ul style="list-style-type: none"> • Jennifer Rosendahl (RISE) • Martin Kammel (INSTAND) • Christoph Buchta (ÖQUASTA) • Martin Obermeier (MVZ MIB) • John McManus (CDRH)
14:45-15:15	Discussion Session 2: In what areas/themes/topics is there greatest need for new reference materials? What do these missing reference materials need to do? Calibrate assays, assure breadth of diagnostic detection? Anything else?	
15:15-15:30	Break	
15:30-16:30	Tour of MHRA Science Campus	
End of day 1		

Day 2: Thursday 25th September

10:00-10:30	MHRA Science campus activities. ctDNA reference materials	Leandro Lo-Cascio (MHRA)
10:30-11:00	Break	
11:00-12:00	Session 3: Commutability in infectious disease diagnostics Chairs: Jim Huggett (LGC) & Ben Cowper (MHRA)	
	<ul style="list-style-type: none"> Replacement of the HCMV WHO International Standard; update on CoMET project Whole genome sequencing of BK virus from clinical specimens The application of reference reagents and standards to assess the performance of molecular screening for cervical cancer Supporting laboratory testing through international committees: The IFCC Committee on Molecular Diagnostics in Infectious Diseases (C-MDID) 	<ul style="list-style-type: none"> Jacqueline Fryer (MHRA) Kathryn Harris (Barts NHS) Dan Yara (MHRA) Denise O'Sullivan (LGC)
12:00-12:30	Discussion Session 3: Are there other infectious diseases where an improved diagnostic reference material is required? What does that material need to do? How can we encourage research into the nature of the target analyte in clinical samples? On which diseases does this programme need to focus?	
12:30-13:30	Lunch	
13:30-14:30	Session 4: Digital PCR supporting pandemic preparedness Chairs: Martin Kammel (INSTAND) & Neil Almond (MHRA)	
	<ul style="list-style-type: none"> CCQM Nucleic Acids Working Group - current activities dPCR for SARS-CoV-2 Roadmap on technical capabilities to enable production of molecular biology supplies to support molecular diagnostics in Colombia (<i>virtual</i>) Development of H5N1 synthetic RNA fragments as reference materials (<i>virtual</i>) Digital PCR as a potential reference method to support monkeypox virus external quality assessment schemes 	<ul style="list-style-type: none"> Jim Huggett (LGC) Jhon Emerson Leguizamon Guerrero (INMC) Eileen Moran (NIST) Samreen Falak (PTB)
14:30-15:00	Discussion Session 4: When is dPCR needed in the development of reference materials for infectious disease? How do we assure that dPCR data is of sufficient quality for inclusion in collaborative studies? What is the evidence that dPCR is not skewed in a similar manner as limiting dilution versus qPCR?	
15:00-15:30	Break	
15:30-16:30	CoMET CMV break-out session (open meeting)	
End of day 2		

Day 3: Friday 26th September

10:00-10:25	MHRA Science campus activities. Developing WHO DNA Reference Reagents for bacterial metagenomics	Chrysi Sergaki (MHRA)
10:25-10:40	Break	
10:40-11:40	Session 5: Assuring the HTS for Metagenomics Chairs: Denise O'Sullivan (LGC) & Neil Almond (MHRA)	
	<ul style="list-style-type: none"> • Outcomes of the ENNGS Survey: Metagenome in a Bottle (<i>virtual</i>) • Quantitative enrichment in targeted metagenomics (<i>virtual</i>) • Ensuring Accuracy: Control Strategies in Clinical Metagenomics Workflows • UKAS accreditation of a metagenomics service (<i>virtual</i>) 	<ul style="list-style-type: none"> • Jutte de Vries (LUMC) • Tanya Golubchik (Sydney ID) • Adela Medina (GSST NHS) • Julianne Brown (GOSH)
11:40-12:10	Discussion Session 5: What features are essential for a reference material for NGS / metagenomics? How do we deal with the issue of excipient for a universal reference material for NGS? What do end users need a reference material for metagenomics to do? How do we deal with extraction efficiencies of different pathogens – viruses/bacteria/fungi?	
12:10-13:10	Lunch	
13:10-13:40	Session 6: Assuring HTS for detection genetic variants/drug resistance Chairs: TBC & Neil Almond (MHRA)	
	<ul style="list-style-type: none"> • Development and Applications of WHO Reference materials for HTS of adventitious viruses in biologics (<i>virtual</i>) • SNP detection in WHO IS for HIV-1 RNA and development of new reference materials for HIV-1 SNP detection 	<ul style="list-style-type: none"> • Arifa Khan (CBER) • Eleni Nastouli (UCL)
13:40-14:10	Discussion Session 6: Are contrived reference materials required for SNP/indel detection? Are accidental reference materials sufficient? What levels of SNP/indel detection are appropriate for impacting clinical management?	
14:10-14:25	Round-up	
14:25-14:45	Break	
14:45-15:30	SoGATS NGS breakout session (open meeting)	
Close of workshop		