

Summary of the process (1)

- **1st September 2010**, NEJM published the first results of the Xpert MTB/RIF assay from a large multi-centre laboratory validation study: *Boehme CC, Nabeta P, Hillemann D, Nicol MP, Shenai S, Krapp F, et al. Rapid molecular detection of tuberculosis and rifampin resistance. New England Journal of Medicine, 2010; Sep;363(11):1005-15;*
- **2nd September 2010** An Expert Group meeting was convened by WHO-STB in Geneva where all available data on Xpert MTB/RIF were reviewed following the GRADE process. The Expert Group unanimously recommended wide-spread use of the assay given excellent performance characteristics.
- **27 September 2010** Recommendations from the Expert Group Meeting were presented to the WHO Strategic and Technical Advisory Group for Tuberculosis (STAG-TB). STAG-TB acknowledged the transforming potential of the new technology and the solid evidence base to support its widespread use for detection of TB and rifampicin resistance. STAG-TB also acknowledged the need for access to this innovation in individuals at risk of TB and MDR-TB in resource-constrained settings.
- **29 September 2010.** The STAG-TB recommendations were presented to DG on, who requested STB to develop a Roadmap to guide roll-out of Xpert MTB/RIF and to proceed with the Global Consultation recommended by STAG-TB. The Roadmap was subsequently cleared by DGO and issued to WHO country offices and Member States.

Summary of the process (2)

- **8 December 2011.** Formal WHO endorsement of the Xpert MTB/RIF assay was announced at an international press conference in London. The endorsement attracted major international press coverage and was accompanied by support statements from global agencies (including USAID, PEPFAR, CDC and others).
- **30 November-2 December 2010.** A Global Consultation involving around 100 participants was called by STB where implementation considerations for roll-out of Xpert MTB/RIF were discussed and broad consensus on the way forward was achieved. Key outcomes of the consultation were agreement on interim diagnostic algorithms, the positioning of Xpert MTB/RIF in risk groups at different levels of health services, and implementation considerations for programmatic roll-out of Xpert MTB/RIF to optimize use and benefits of the technology.
- **6th March 2010,** a Rapid Implementation document developed by STB was issued and shared widely with Member States, regional and country offices, and other stakeholders. The Rapid Implementation document provides the 'how-to' for systematic roll-out of Xpert MTB/RIF in different epidemiological and resource settings, with a view towards large-scale implementation based on programmatic data collected during the roll-out phase.
- **7-8 April 2011,** a Training Workshop for early implementers of the Xpert MTB/RIF technology convened by STB to focus on the practical application of the Rapid Implementation document within country-specific context.