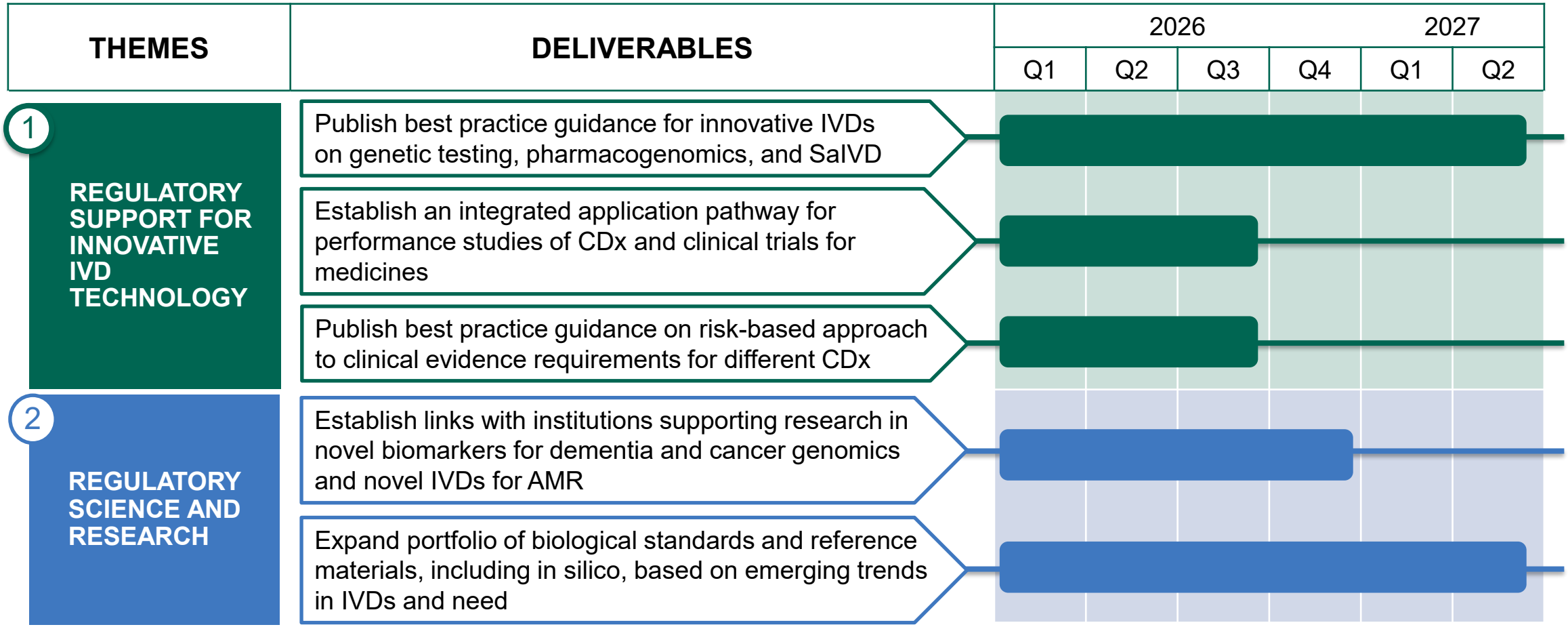
Medicines & Healthcare products Regulatory Agency

In Vitro Diagnostics Medical Device Roadmap

Version 1.0 (December 2025)

This is a ‘living’ document that is subject to changes and additions

In Vitro Diagnostics (IVD) Medical Device roadmap



In Vitro Diagnostics (IVD) Medical Device roadmap

THEMES	DELIVERABLES	2026 Q1	2026 Q2	2026 Q3	2026 Q4	2027 Q1	2027 Q2
3 PANDEMIC PREPAREDNESS AND RESILIENCE	Publish a statement on addressing the gaps identified by the IPPS for diagnostic regulation						
	Adopt the IMDRF clinical evidence framework for IVD medical devices intended for pandemic pathogens						
	Embed collaborations with national and international organisations, to ensure rapid development and dissemination of reference materials						

Glossary			
AMR	Anti microbial resistance	CDx	Companion diagnostic
IMDRF	International Medical Device Regulators Forum	IPPS	International Pandemic Preparedness Secretariat
SaIVD	Software as an *in vitro* diagnostic		