

eCTD 4.0

Region	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
 ANVISA, Brazil						 2026 4Q Technical Pilot	 2027 Voluntary			
 EMA, Europe				 2024 - 2025 Technical Pilot CAPS ✓	 2025 Voluntary for CAPs ✓	 2026 Voluntary for MRP/DCP/NP	 2027 Mandatory for CAPs		 TBC Mandatory for MRP/DCP/NP	
 FDA, United States		 2022 - 2023 2Q Technical Pilot ✓		 2024 Voluntary ✓					 2029 Mandatory	
 Health Canada, Canada						 2026 - 2027 Technical Pilot	 2027 Voluntary		 2029 Mandatory	
 MFDS, Republic of Korea							 2027 Voluntary		 TBD Mandatory	
 MHLW/PMDA, Japan	 2021 2Q Technical Pilot ✓	 April 2022 Voluntary				 April 2026 Mandatory				
 Swissmedic, Switzerland						 2026 Technical Pilot	 2027 Voluntary		 2030 Mandatory	
 TGA, Australia						 2026 Technical Pilot	 2027 Voluntary		 TBD Mandatory	