eCTD 4.0 Implementation Timeline

eNNOV Software for Life

Region	2021 – 2030
ANVISA, Brazil	**2025 4Q** Technical Pilot; **2026 1Q** Production Pilot; **2026** 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	**2025** Technical Pilot; **2026** Voluntary; **2028** 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	**2025 4Q** Technical Pilot; **2026** Voluntary; **TBD** Mandatory