eCTD 4.0 Implementation Timeline

eNNOV Software for Life

Region	2021 – 2030
ANVISA Brazil	**2025 Q4** Technical Pilot; **2026 Q1** Production Pilot; **2026** Voluntary
EMA Europe	**2024** 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 Q2** 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 Q2** Technical Pilot ✓; **2022** Voluntary ✓; **2026** Mandatory
Swissmedic Switzerland	**2026** Technical Pilot; **2027** Voluntary; **2030** Mandatory
TGA Australia	**2025 Q4** Technical Pilot; **2026** Voluntary; **TBD** Mandatory