Table 1. Key RWE and AI Regulatory Policy Developments January – June 2026 (*non-exhaustive*)

REGULATORY UPDATE	DATE	WHY IT MATTERS FOR RWE
NMPA adopts ICH M14 guideline	January 2026	Signals alignment of China's expectations for RWE safety studies with broader international standards and supports greater consistency across regions.
FDA issues draft guidance on Bayesian Methodology in Clinical Trials	January 2026	Expands regulatory clarity on the use of external evidence, such as RWE, to support clinical trial design and inference.
FDA and EMA publish guiding principles for AI in drug development	January 2026	Establishes a shared framework for trustworthy AI across the drug development lifecycle, including governance, validation, transparency, and lifecycle management.
FDA issues draft Plausible Mechanism Framework guidance for individualized therapies	February 2026	Clarifies how RWE such as natural history studies and external controls can support evidence generation in ultra-rare and individualized treatment settings.
EMA-HMA publishes fourth report on the RWE Framework	February 2026	Demonstrates continued expansion of regulator-led RWE generation through DARWIN EU and related initiatives.
EMA releases final Real-World Data chapter of the EU Data Quality Framework	March 2026	Formalizes expectations for data provenance, quality, traceability, interoperability, and governance for use of RWD in regulatory decision-making.
FDA and EMA adopt ICH M14 guideline	March 2026	Marks a major milestone toward globally harmonized standards for non-interventional safety studies using RWD.
EMA-HMA publish 2026–2028 Data and AI Workplan	March 2026	Advances European efforts around AI governance, interoperability, data quality, and expansion of DARWIN EU.
Saudi FDA finalizes RWD/RWE framework for medicinal products	April 2026	Establishes formal expectations for the use of RWD and RWE in marketing authorization and lifecycle regulatory decision-making.
FDA publishes updated examples of RWE used in medical device regulatory decisions	April 2026	Highlights increasing use of RWE, including examples where it served as primary clinical evidence in regulatory submissions.
Health Canada releases multiple medical device guidance documents incorporating RWD/RWE	April 2026	Formalizes the role of RWE across pre-market and post-market medical device evidence generation, including machine-learning-enabled devices.
FDA launches AI-enabled clinical trial pilot initiative	April 2026	Signals growing regulatory interest in leveraging AI to improve clinical development efficiency, monitoring, and decision-making.
FDA issues final guidance on post-approval pregnancy safety studies	May 2026	Reinforces the role of RWE in maternal-fetal safety surveillance and long-term lifecycle evidence generation.
NESTcc releases draft RWD Source Tool (NEST Mark)	May 2026	Moves toward standardized evaluation of RWD sources for regulatory use in medical device programs.
MHRA-NICE completes RWE Scientific Dialogue Pilot and expands to medical devices	May 2026	Demonstrates the value of early regulator engagement and creates a model for future evidence-planning discussions for RWE generation and creates a new pathway for aligning regulatory and HTA expectations for device-related RWE generation.
FDA expands internal AI capabilities and data infrastructure	May 2026	Demonstrates increasing regulator investment in AI-enabled review and evidence evaluation capabilities.
DIA AI Consortium Panel at the DIA Global Annual Meeting	June 2026	Readout of year 1 DIA AI Consortium activities: “Building AI Governance Frameworks: Classification, Validation and Regulatory Alignment in Life Sciences”
ICH finalizes and adopts GCP E6(R3) Annex 2	June 2026	Extends GCP expectations to innovative trial designs and reinforces quality and oversight requirements for RWD used in regulatory studies.
FDA updates public listing of regulatory decisions supported by RWE	June 2026	Adds further transparency and a growing body of precedent illustrating successful regulatory applications of RWE.
FDA publishes revised draft guidance on substantial evidence of effectiveness	June 2026	Reinforces the evolving paradigm of one adequate and well-controlled study supplemented by confirmatory evidence, creating additional opportunities for RWE to contribute to evidence packages.
FDA launches dedicated CDRH RWE webpage	June 2026	Further institutionalizes the role of RWE within medical device regulation while centralizing guidance, resources, and examples.