Paper RE02

FHIR for RWD Submissions: Why a U.S. Regulation Signals a Global Shift—and What You Need to Do Now

Sanyogeeta H. Andhale, Sycamore Informatics Pvt. Ltd., Pune, India
Bill Qubeck, Sycamore Informatics Pvt. Ltd., North Carolina, USA
Nachiket Thakkar, Sycamore Informatics Pvt. Ltd., Boston, USA

ABSTRACT

In June 2025, the U.S. FDA closed public consultation on a landmark proposal: to accept HL7 FHIR as a standard for the submission of clinical data derived from real-world data (RWD) sources [1]. While this may appear to be a U.S.-specific regulatory development, its implications are global. FHIR is already widely adopted across European health systems for EHR exchange, and its potential role in regulatory submissions will directly affect EU sponsors, CROs, and vendors engaged in multi-region trials [2].

This session explains why the FDA's move toward FHIR-based submissions represents a critical inflection point—not only for U.S. compliance, but for any organization leveraging EHR, claims, or registry data for global trials. Attendees will gain clarity on how this intersects with USCDI, TEFCA, and broader interoperability initiatives, and why now is the time to assess internal readiness, contribute to global alignment, and build a future-proof RWD strategy.

Keywords: HL7 FHIR, Real-World Data (RWD), FDA, Regulatory Submissions, Interoperability, USCDI, TEFCA, Multi-Region Trials, Clinical Data Exchange

1. INTRODUCTION

Clinical research is undergoing a major shift with the growing use of real-world data (RWD) in drug development and regulatory decisions [3]. Drawn from sources like electronic health records, insurance claims, and patient registries, RWD complements traditional trials by showing how treatments work in everyday settings. Regulators are increasingly recognizing its value [4].

Yet, challenges such as data heterogeneity, poor standardization, and manual transformations have limited RWD's use in submissions. HL7® FHIR® (Fast Healthcare Interoperability Resources) now offers a scalable, standardized framework to overcome these barriers [5].

A key milestone came in June 2025, when the FDA closed its consultation on accepting FHIR-based formats for RWD submissions [1]. This proposal not only validates FHIR for regulatory use but also marks a turning point in how RWD will be governed. Though U.S.-led, the move has global implications. Sponsors, CROs, and vendors worldwide must adapt to its impact on trials, data exchange, and harmonization.

This paper explores why the FDA's endorsement of FHIR is transformative and how it aligns with initiatives like USCDI, TEFCA, and other international interoperability efforts.

2. UNDERSTANDING HL7 FHIR AND REAL-WORLD DATA

2.1 WHAT IS HL7 FHIR?

The Fast Healthcare Interoperability Resources (FHIR) standard, developed by HL7 in 2012, reimagines digital health interoperability rather than incrementally updating older protocols [5]. Earlier standards like HL7 v2 and v3 advanced healthcare integration but faced issues: v2 suffered from inconsistent implementations, while v3/CDA was too complex and slow to adopt [6].

FHIR addressed these challenges by leveraging modern web technologies—RESTful APIs, HTTP, JSON, XML, and OAuth—familiar to developers worldwide. This lowered adoption barriers, reduced implementation costs, and enabled real-time data exchange [7]. Designed with implementers in mind, FHIR prioritizes practicality and speed, driving agile innovation in healthcare apps, cloud services, and interoperability at scale.

2.2 REAL WORLD DATA (RWD) SOURCES AND THEIR VALUES

Real-World Data (RWD), as defined by regulatory bodies like the U.S. FDA, refers to data relating to patient health status and/or the delivery of healthcare that is routinely collected from a variety of sources outside the context of traditional, highly controlled clinical trials [3]. Primary sources include:

- **Electronic Health Records (EHRs)**
- **Medical Claims and Billing Data**
- **Patient/Disease Registries**
- **Patient-Generated Health Data:** Data captured directly from patients, including information from mobile devices, wearables (e.g., glucose monitors, smartwatches), and patient-reported outcome surveys.

RWD provides a longitudinal view of how medical products and interventions perform in diverse, everyday clinical settings, generating Real-World Evidence (RWE) to support regulatory decisions [4,8].

2.3 THE RATIONALE FOR FHIR IN RWD SUBMISSIONS

Healthcare increasingly relies on RWD to inform regulatory decision-making. Without a common standard, diverse data sources remain fragmented, complicating aggregation and interpretation. FHIR standardizes the way data is structured and exchanged, enabling clinical notes, lab values, and medication records to be transported seamlessly between apps, systems, and regulators [5,7].

This is where FHIR becomes essential, and a logistics analogy helps illustrate why.

RWD = Goods of all shapes and sizes

Think of RWD as products coming off different “factories”: EHR entries, lab results, claims data, and device readings. Like crates, barrels, and packages of every shape and size, each dataset is valuable, but packed and labeled differently, which complicates handling.

FHIR = The Standard Shipping Container

The breakthrough in global trade came when shipping containers provided a uniform way to transport goods. Suddenly, it didn’t matter whether a container held furniture, electronics, or food - the same ports, ships, trucks, and warehouses - could handle them all. In healthcare, FHIR plays this exact role. By standardizing the way data is structured and exchanged, FHIR makes it possible for clinical notes, lab values, and medication records to be transported seamlessly between apps, systems, and regulators.

The takeaway: RWD is the content, and FHIR is the container. Together, they make healthcare data universally transportable, trustworthy, and ready for meaningful use in regulatory review and beyond.

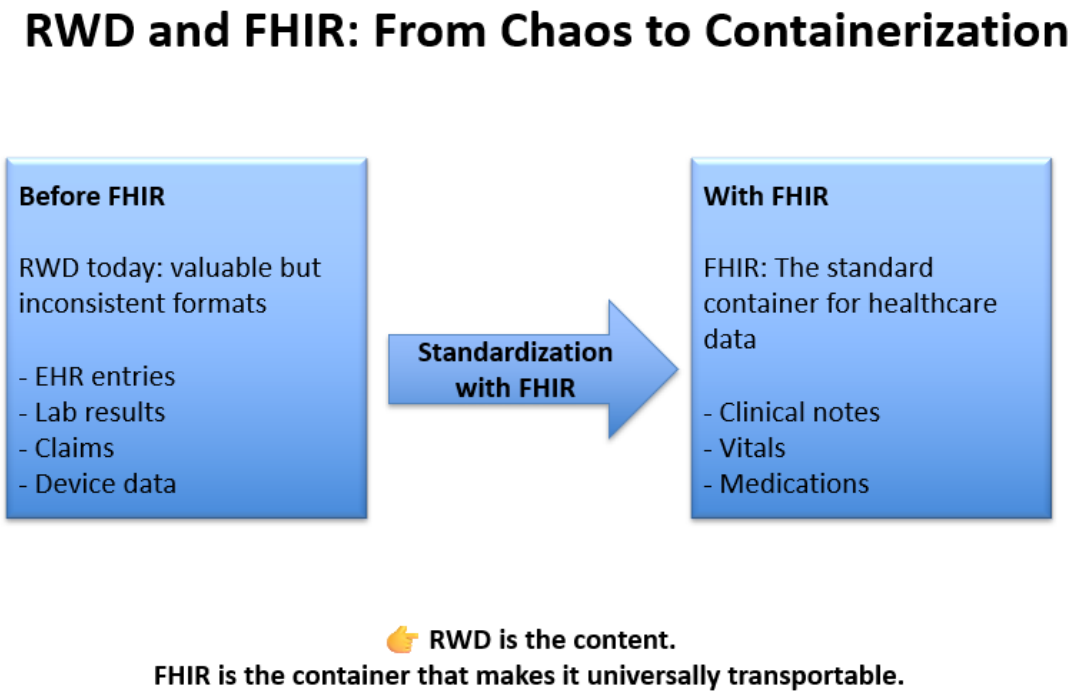

Figure 1

3. UNDERSTANDING HL7 FHIR AND REAL-WORLD DATA

3.1 Details of the FDA's FHIR RWD Submission Proposal

The FDA's proposal establishes FHIR as an acceptable format for RWD submissions, emphasizing the importance of interoperability, provenance, and compliance with USCDI, TEFCA, and ONC Cures Act requirements [1,9]. This ensures structured, semantically consistent data flow from EHRs to regulatory review.

3.2 Intersection with U.S. Interoperability Initiatives

Having a standard shipping container (FHIR) is only part of the story—containers are only useful if there are roads, ports, and rules to guide them. In healthcare, U.S. interoperability initiatives serve as this infrastructure: they provide the highways, checkpoints, and agreements that allow RWD, packaged in FHIR containers, to flow seamlessly between hospitals, labs, payers, and regulators. Without such coordination, even the most perfectly designed containers would sit idle, unable to deliver their valuable contents to the places where they matter most.

If FHIR is the container, then U.S. interoperability initiatives like USCDI, TEFCA, and the ONC Cures Act rules are the supporting transport system:

USCDI = The Essential Goods List — defining the minimum set of items every container must carry (e.g., demographics, medications, vitals).

TEFCA = The National Trade Route Agreement — creating common pathways so containers can move freely across states and networks without bottlenecks.

Cures Act Rules = The Transportation Regulations — ensuring no one hoards containers and that all participants have fair access to the network.

Together, these initiatives form the infrastructure that makes large-scale data exchange possible. Just as global trade relies on both containers and coordinated transport networks, healthcare interoperability depends on both FHIR and the policy frameworks that enable its widespread use.

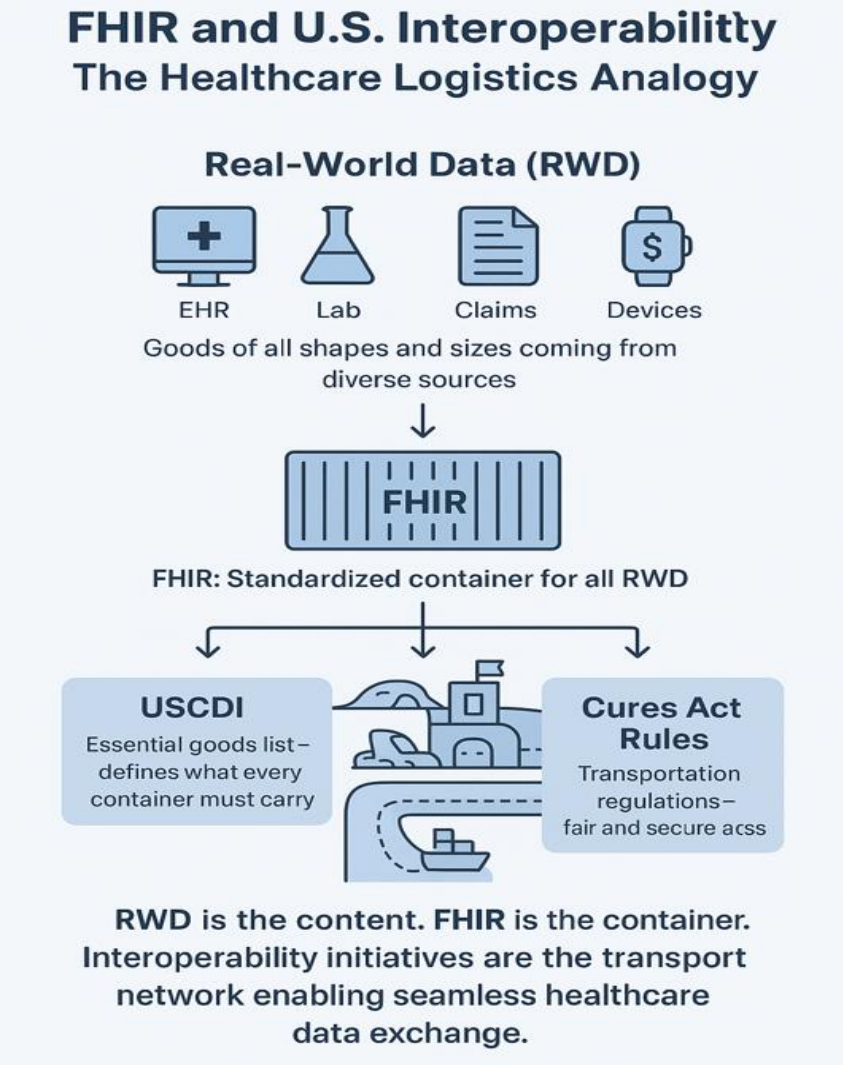

Figure 2

4. Global Ramifications: Impact Beyond U.S. Borders

4.1 FHIR Adoption in European Health Systems:

Europe's digital health landscape blends regulation, pan-European projects, and national strategies, with FHIR playing a key role [2,10].

4.1.a The European Health Data Space (EHDS) as an Interoperability Engine

The European Health Data Space (EHDS), a major regulation set to take effect in 2025, is the key driver of health data interoperability in Europe. It aims to create a single digital health market by providing secure, cross-border access to personal health data and enabling secondary uses for research and policy. A core part of the EHDS is the mandatory expansion of MyHealth@EU infrastructure for data exchange, which requires a common technical language, such as FHIR, for seamless interoperability. The regulation also seeks to build a single market for electronic health record systems, medical devices, and AI, making FHIR adoption essential for certification and market access. This regulatory push contrasts with the U.S., where adoption is driven by a mix of rules and private sector innovation. The EHDS makes FHIR adoption a commercial necessity for vendors, with specific FHIR Implementation Guides tailored to meet EHDS requirements for key data categories [10,11].

4.1.b Pan-European Initiatives and the Role of HL7 Europe

Europe's push for health data interoperability under the EHDS is supported by a collaborative ecosystem of projects and standards organizations that translate top-down policy into practical, interoperable solutions. At the core is HL7 Europe, which adapts the global FHIR standard to EU needs by developing tailored Implementation Guides (IGs) for key data domains, along with tools and sandboxes to support adoption.

Complementing this are organizations like IHE-Europe, which creates Integration Profiles that address real-world use cases and are tested at large-scale Connectathons. The European Interoperability Framework (EIF) further supports cross-border IT alignment.

The European Commission also funds FHIR-based research projects such as:

- **FAIR4Health** – applies FHIR to make research data FAIR-compliant
- **i2X** – tests cross-border FHIR solutions across 12 EU countries
- **NextGen** – develops governance for genomic data sharing using FHIR
- **PanCareSurPass** – supports survivorship care with FHIR-driven data exchange

This layered approach—regulatory direction from EHDS, bottom-up innovation from research projects, and standardization by bodies like HL7 Europe and IHE-Europe—creates a robust, co-developed model where standards are shaped through real-world testing and broad stakeholder involvement [12,13].

4.1.c National Adoption: A Mosaic of Progress and Challenges

Despite strong EU-level coordination, FHIR adoption across Europe remains uneven. There is no unified "European health system"—instead, organizations face a fragmented landscape of national digital health systems, each with its own standards, regulations, and maturity levels. This poses a significant challenge for sourcing real-world data (RWD) across the region.

According to the 2024 *State of FHIR Survey*, countries fall into three broad tiers:

- **Leaders & Advanced Adopters**: Nations like Switzerland, the Netherlands, France, and Germany have made significant progress. Switzerland uses FHIR as its main standard, France mandates FHIR nationally, and Germany promotes it through regulation and funding.
- **In-Progress Adopters**: Countries such as the UK, Belgium, Finland, Sweden, and Italy use FHIR for limited cases and are developing national standards. Italy is advancing via EU recovery funds, though regional variation persists.
- **Early-Stage & Lagging Adopters**: Countries like Croatia and Slovenia have minimal FHIR adoption. Slovenia, for instance, relies more on openEHR and is only starting to implement FHIR in select areas.

For clinical trial sponsors and CROs, this diversity means sourcing RWD in Europe which isn't a uniform process. Each country may use different FHIR versions, implementation guides, and regulations. Therefore, "European RWD" is not a single asset but a collection of distinct, country-specific data systems—each requiring customized strategies for access, transformation, and quality control. This complexity must be factored into planning, budgeting, and timelines for any pan-European research effort [12].

4.2 Direct Impact on EU Sponsors, CROs, and Vendors in Multi-Region Trials:

The FDA's adoption of FHIR for RWD submissions significantly impacts European organizations involved in multi-region clinical trials submitted for U.S. regulatory review. This creates new complexities related to data harmonization across differing standards, operational challenges and opportunities for the clinical trial service industry, and a heightened focus on RWD quality and provenance.

4.2.a The Data Harmonization Imperative: Bridging the FHIR-to-CDISC Chasm

European stakeholders must navigate the complex challenge of converting HL7 FHIR data into CDISC-compliant formats (e.g., SDTM, ADaM) for FDA submissions. FHIR and CDISC serve different purposes, so translation isn't straightforward - it requires structural and semantic re-engineering.

Key challenges include:

- **Structural mismatches**: A single FHIR Observation may map to different CDISC domains (e.g., VS vs. LB), requiring custom logic.
- **Semantic gaps**: Concepts like "ongoing medication" or "pre-specified medical history" may be missing or need derivation from FHIR data.
- **Format differences**: FHIR uses ISO 8601 datetime, while CDISC splits date and time and reconstructs them into character-based variables.

Without global standard alignment, sponsors may need parallel data pipelines—converting FHIR to CDISC for the FDA, while retaining FHIR for EMA or EHDS use. This dual-track approach adds cost, complexity, and risk of regulatory inconsistencies [14,15].

4.2.b Operational Realities for EU Sponsors, CROs, and Vendors

The complex journey of data from European hospital EHRs to FDA submission packages poses significant operational challenges—and opens new business opportunities. European pharmaceutical sponsors must manage an increasingly fragmented data supply chain, sourcing heterogeneous real-world data (RWD) from diverse sites with varying FHIR maturity. Their goal: transform this disparate data into a single, high-quality, submission-ready dataset that meets rigorous FDA standards.

This high-stakes challenge has spurred growth in a new niche within clinical trial services. Contract Research Organizations (CROs) and specialized health tech vendors are rapidly positioning themselves as essential partners, absorbing the complexity on behalf of sponsors. They are developing next-generation clinical trial management software and services, featuring capabilities such as “FHIR Seamless Data Exchange,” interoperability gateways connecting disparate systems, and platforms that combine FHIR integration with AI-powered analytics and data visualization.

The core business opportunity lies in automating manual processes, improving data quality through programmatic validation, and expertly managing the transformation from source formats to submission-ready CDISC standards. As FHIR adoption and standardized RWD frameworks expand globally, sponsors face the challenge of integrating heterogeneous data from multiple regions, each with different standards and formats. Leveraging FHIR-based interoperability to align these datasets can streamline submissions, enhance data quality, and accelerate patient access to new therapies worldwide [16].

Case Study: Navigating RWD Challenges in a Global Oncology Trial

A global pharmaceutical sponsor preparing a regulatory submission for a new oncology therapy faces the challenge of integrating RWD from both the U.S. and Europe.

- **Step 1 — U.S. Data:**
  Hospitals provide RWD through FHIR APIs aligned with US Core and USCDI elements (diagnoses, labs, medications). Data exchange occurs securely under TEFCA, ensuring provenance and trust. The sponsor receives well-structured FHIR bundles that cleanly map to regulatory endpoints like progression-free survival and adverse events.

- **Step 2 — European Data:**
  A German partner hospital initially supplies RWD in its national EHR export format, requiring extensive harmonization to fit the U.S. submission package. However, leveraging new FHIR-based export capabilities modeled on U.S. standards, the hospital quickly delivers semantically consistent FHIR data packages. This enables near-seamless data pooling and analysis within weeks, avoiding months of manual ETL work.

Figure 3

Impact:

- **Submission Efficiency:** Faster assembly of global submission packages with less data wrangling.
- **Regulatory Convergence:** Early alignment prepares European partners for upcoming EMA and MHRA FHIR-based requirements, reducing rework.
- **Patient Benefit:** Accelerated and harmonized evidence submission supports earlier access to therapies across multiple markets.

4.2.c The RWD Quality and Provenance Challenge

While technical standards like FHIR enable data exchange, regulators such as the FDA prioritize the trustworthiness of evidence derived from real-world data (RWD). For RWE to support drug effectiveness, it must meet the same rigor as RCTs, requiring sponsors to ensure quality, integrity, and provenance, especially for international sources.

RWD, collected during routine care, is often unstructured, incomplete, and variable across systems and clinicians. A key limitation of FHIR is missing provenance metadata—details about how, when, and by whom data was collected—which is essential for assessing reliability and bias.

Sponsors must therefore move beyond simple data extraction to maintaining a complete, auditable record of the data lifecycle, including EHR configurations, workflows, transformations, and quality controls. Investments in API infrastructure must be matched by robust data governance and metadata management. Provenance tracking has become as critical as the data itself, shifting the focus from data access to metadata and regulatory-grade documentation across the EU-to-US pipeline [17,18].

4.3 Potential for Global Alignment and Harmonization

The FDA's focus on FHIR for RWD supports global harmonization of clinical research standards, potentially accelerating international alignment among SDOs. The goal is, to have seamless data flow from care to regulatory review worldwide. This section examines international stakeholders, prospects for a unified standard, and future scenarios [5,19,20,21].

4.3.a The Role of International Standards Development Organizations (SDOs)

Global alignment on RWD standards necessitates coordinated efforts from various SDOs, with the FDA's initiative promoting tighter integration of their roadmaps. Key players in this harmonization include ICH, CDISC, HL7, and ISO.

SDO	Primary Role in Ecosystem	Key Relevant Initiative(s)	Relationship with FHIR/RWD
ICH	Global harmonization of regulatory requirements for medical products.	**M11 (CeSHarP):** Creating a structured, digital clinical protocol. **RWE Guidance:** Aligning global regulatory principles for RWE.	Defines the *what*: the scientific and regulatory requirements for RWD collection and evidence generation.
CDISC	Development of standards for clinical research data acquisition, exchange, submission, and analysis.	**SDTM/ADaM:** Required data submission formats. **Vulcan Accelerator:** Collaboration to bridge research and care. **FHIR-to-CDISC Mapping:** Practical guidance for data transformation.	Defines the *how (research)*: the target format for RWD after it has been curated for regulatory submission.
HL7	Development of standards for the exchange, integration, and retrieval of electronic health information.	**FHIR:** The global standard for real-time healthcare data exchange via APIs. **Vulcan Accelerator:** Co-leads the effort to use FHIR for research.	Defines the *how (care)*: the primary standard for extracting RWD from source EHR systems.

ISO	Development of foundational, cross-industry international standards for quality, security, and interoperability.	**TC 215 (Health Informatics):** Develops standards like the International Patient Summary. **ISO 8000 (Data Quality):** Provides a formal framework for data quality management.	Provides the foundational layer of trust, quality, and security that underpins the entire health data ecosystem.

5. Strategic Imperatives for Organizations

5.1 Assessing Internal Readiness

Organizations aiming to leverage FHIR-based RWD for regulatory submissions must first evaluate their internal capabilities. Readiness is not just about technology - it encompasses people, processes, and governance. Establishing a strong foundation ensures that RWD can be ingested, validated, and transformed consistently while maintaining regulatory compliance. This assessment sets the stage for building scalable and auditable data pipelines [1,5,17].

Capabilities to Develop:

- **Data Ingestion:** Ability to receive structured and unstructured RWD from multiple sources, including EHRs, claims, patient registries, and wearable devices. Tools like FHIR APIs, ETL pipelines, and integration engines are critical.
- **Data Transformation & Mapping:** Ability to convert FHIR resources into regulatory-ready formats (e.g., CDISC SDTM/ADaM) while preserving semantics. Mapping tools and FHIR Implementation Guides (IGs) are essential.
- **Data Validation & Quality Checks:** Implement automated validation of structure, completeness, consistency, and provenance. Example: FDA RWE guidance emphasizes reproducibility and traceability of all RWD [17].
- **Security & Privacy:** Compliance with HIPAA, GDPR, and other local regulations. FHIR supports OAuth2.0 and SMART on FHIR protocols for secure access.
- **Infrastructure Needs:** Cloud-enabled platforms, scalable storage, API management, and workflow orchestration tools. Many organizations are adopting hybrid cloud setups to allow global access to RWD.
- **Skilled Personnel:** Roles include data engineers, FHIR developers, clinical data managers, and regulatory affairs specialists trained in RWD/RWE. Surveys suggest <40% of global sponsors currently feel fully equipped for FHIR-based submission, highlighting a talent gap.

5.2 Contributing to Global Alignment

Global harmonization of RWD standards is a collective endeavor. Organizations that actively participate in standardization efforts help shape the future of clinical data exchange while aligning their own operations. Contributing to global alignment ensures smoother multi-region trials, reduces duplication of work, and fosters collaboration with regulators and industry peers [2,20,21].

Key Actions:

- **Industry Participation:** Engage with HL7 Vulcan FHIR Accelerator, ICH RWE reflection group, CDISC-FHIR mapping projects, and regional working groups.
- **Advocacy & Standardization:** Contribute to FHIR Implementation Guides and public consultations to promote harmonized global standards.
- **Knowledge Sharing:** Participate in Connectathons, publish lessons learned, and develop shared tooling for RWD extraction and transformation.

5.3 Building a Future-Proof RWD Strategy

A future-proof RWD strategy positions organizations to proactively address regulatory expectations and technological evolution. By embedding FHIR-native processes and automation, organizations can improve efficiency, reduce errors, and accelerate evidence generation. A robust strategy not only addresses today's compliance needs but also prepares for emerging international standards and multi-region trial requirements [1,3,5].

Strategic Actions:

- **Proactive RWD Planning:** Design pipelines that are scalable, auditable, and regulatory-ready from the outset.
- **Invest in FHIR-Native Platforms:** Modern platforms enable seamless ingestion, storage, and analytics of RWD, and facilitate mapping to CDISC submission formats.
- **Efficiency Gains:** Automation reduces manual ETL work; harmonized pipelines shorten submission timelines. Case studies report up to 30–50% faster RWD processing with end-to-end FHIR adoption.
- **Data Quality & Provenance:** Maintain metadata-driven pipelines capturing source, transformation, and validation history, ensuring regulatory trustworthiness.
- **Regulatory Strategy Alignment:** Align RWD strategy with EMA/FDA guidance, EHDS implementation, and international SDO roadmaps for long-term readiness.

6. Conclusion

6.1 Recapitulation of Key Points

The FDA's 2025 proposal to accept HL7 FHIR as a standard for real-world data (RWD) submissions represents a watershed moment in regulatory science. By endorsing FHIR, the FDA not only sets a new benchmark for U.S. compliance but also signals the need for global stakeholders—sponsors, CROs, and vendors—to align their multi-region clinical data strategies. This dual impact underscores the interconnectedness of digital health initiatives such as the U.S. Core Data for Interoperability (USCDI) and the Trusted Exchange Framework and Common Agreement (TEFCA), which together form the infrastructure for efficient, high-quality RWD exchange.

In essence, the FDA's move emphasizes:

- The strategic necessity of harmonizing RWD standards across regulatory jurisdictions.
- The operational and technical readiness required to manage FHIR-based data pipelines.
- The broader interoperability ecosystem that enables real-time, trustable clinical data flow from care to regulatory decision-making.

6.2 Call to Action/Future Outlook

Organizations must act decisively to build internal capabilities, contribute to global standards harmonization, and adopt forward-looking RWD strategies. Waiting until FHIR adoption is mandated may limit operational flexibility and reduce competitive advantage in multi-region trials. Early engagement in standards initiatives, participation in industry consortia, and investment in FHIR-native platforms will ensure organizations are well-positioned for the future.

Looking ahead, FHIR is poised to become a core enabler of RWD-driven drug development and regulatory submissions. It can accelerate evidence generation, reduce data transformation inefficiencies, and facilitate the integration of care and research data on a global scale. By embracing these changes proactively, organizations can transform the clinical data submission landscape - moving from reactive compliance to strategic innovation, ultimately supporting faster patient access to safe and effective therapies.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Author Name: Sanyogeeta Hiraji Andhale
Company: Sycamore Informatics India Pvt. Ltd.
Address: NA
Work Phone: NA
Email: sanyogeeta.andhale@sycamoreinformatics.com
Website: NA