Risk Evaluation and Mitigation Strategies (REMS)

The Challenge

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication.

Due to the lack of standardization and interoperability, the current REMS process is burdensome, costly and can impact patient access. The lack of interoperability hampers communication and coordination amongst REMS stakeholders resulting in delays in therapy, limited access to REMS drugs, and sub-optimal patient care.

CodeX Use Case

The goal of this use case is to create an interoperable, efficient, and effective REMS ecosystem. This interoperable ecosystem would be established via a standards-based technical framework for REMS integration into workflows, enabling data sharing, reducing undue burden and cost, and empowering optimal patient care for therapies that require a REMS.

CodeX is a member-driven HL7® FHIR® Accelerator, building communities to create interoperable data models and applications leading to step-change improvements in cancer patient care and research.

CodeX projects center on use cases that address cancer care and research. CodeX members are achieving interoperability by implementing the FHIR standard mCODE (m inimal C ommon O ncology D ata Elements), which defines key cancer characteristics in an interoperable framework.

To learn more about CodeX, visit www.hl7.org/codex.

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