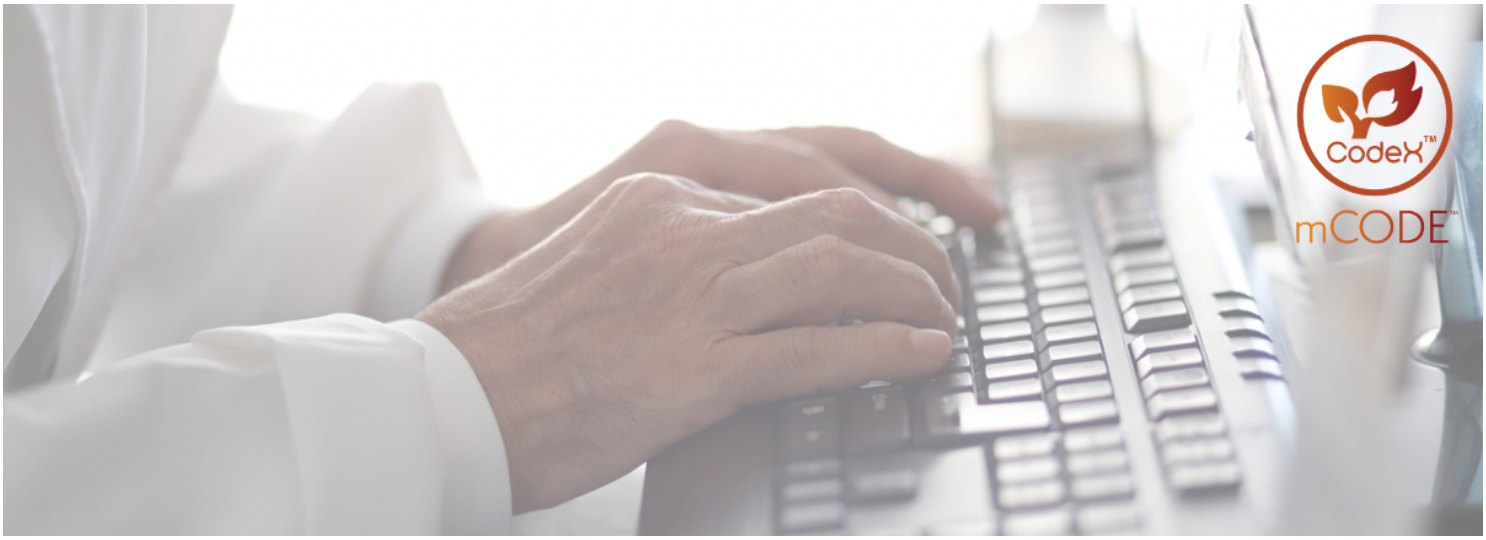

Risk Evaluation and Mitigation Strategies (REMS)

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 REMS Use Case

The goal of the CodeX REMS 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.

REMS on FHIR Value for REMS Administrators

With an interoperable REMS on FHIR system, **REMS Administrators** will

- Have opportunities to generate additional value and innovate in light of reduced time spent on manual processes through **automation and access to select EHR data**
- Help **increase** patient **access** to medications through **decreased** stakeholder **burden**
- **Have access to higher quality, standardized data** for better REMS evaluations