CodeX Risk Evaluation and Mitigation Strategies (REMS) Integration Use Case

Public Call
July 28, 2022
If This Is Your First Time Attending...Welcome!

- **REMS Integration Use Case** - You are Here!
  - The home of the community seeking an automated, efficient, and effective REMS ecosystem
  - Public call participation is open to all interested parties

- **CodeX - an HL7 FHIR accelerator**
  - Use case-driven approach to implement and expand CodeX clinical specialty data standards

- **mCODE = minimal Common Oncology Data Elements**
  - A small number of data elements (~90)
    - ... enable a large number of use cases
    - ... allow high-fidelity use and reuse of data with low incremental burden

New to FHIR? [https://wiki.hl7.org/FHIR_Starter](https://wiki.hl7.org/FHIR_Starter)
REMS: Pilot Pass Opportunity

- As part of our commitment to transparency and collaboration, we offer a “Pilot Pass” to organizations with ideas and opportunities to create a pilot, allowing temporary insight into the leadership community through the end of August.

- Pilot Pass participants from 21 organizations join weekly Leadership Meetings, informing pilot development and use case next steps.
## Agenda

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenters</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome and REMS Integration Use Case Introduction and Review</td>
<td>Cathy Becker</td>
<td>5 minutes</td>
</tr>
<tr>
<td>High Level Roadmap and Pilot Discussion</td>
<td>Nicole Ng</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Current REMS Process and Lessons Learned from ePA</td>
<td>Pooja Babbrah</td>
<td>15 minutes</td>
</tr>
<tr>
<td>REMSv0.5 Demo and Discussion</td>
<td>Technical Team</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Next Steps</td>
<td>Cathy Becker</td>
<td>10 minutes</td>
</tr>
</tbody>
</table>
REMS Integration Use Case

**Problem**
- Multiple stakeholders play an important role in the complex REMS administration process:
  - Verification of completed REMS requirements
  - Dispensing the drug with no unified way to:
    - Coordinate the process
    - Share data among one another
- Gaps in data interoperability make REMS communication and coordination burdensome
- Not in current workflow
- The complexity of these leads to increased burden for stakeholders and the healthcare system overall

**Solution**
- Leverage data standards and create a data infrastructure to integrate REMS processes into stakeholder workflows
- Facilitate integration, enabling:
  - Prescribers and pharmacists to:
    - Be alerted to a REMS requirement
    - Complete requirements (training, education, clinical actions)
    - Attest and easily confirm in workflow that REMS requirements have been met
  - Patients to receive REMS drugs efficiently—without undue burden or delay—via effective, interoperable workflows across all REMS stakeholders
REMS Ecosystem

*dotted line reflects inpatient / infusion processes
Explore how the REMS community can harness the FHIR standard to develop open-source, interoperable REMS solutions that reduce stakeholder burden and address your needs

Contribute your real-world expertise to REMS prototype development – possible work on grant with NCPDP

Consider opportunities to leverage this work in pilots to drive adoption in real-world healthcare settings

- **Join other upcoming REMS Public Calls**
  Registration information is available on the REMS confluence page: [https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration](https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration)

- **“Pilot Pass” Participation**
  Offers an inside peek into member discussions and the ability to be hands on in the project – a fast track to membership through pilot opportunities. Collaborate with members on ideas and projects that may benefit from utilizing the prototype.

- **Share your REMS implementation experiences and recommendations**
  Champion a CodeX REMS Integration Use Case

- **Spread the word to friends and colleagues and encourage them to participate**

- **Recognize the value of stakeholder-focused workflow input**
  Examine prescriber and pharmacist workflows to identify and address gaps in reference implementation resources
    - Please email Kelee Petzelt (kelee.petzelt@pocp.com) with any ideas or requests
## Roadmap to REMS Pilot Implementation

### Design

<table>
<thead>
<tr>
<th>Activities</th>
<th>Momentum</th>
<th>Planning - Contracting</th>
<th>Pilot Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prototype Design and Iterations</td>
<td>Stakeholder Engagement</td>
<td>Pilot Planning - Contracting</td>
<td>Pilot Implementation</td>
</tr>
<tr>
<td>Research stakeholder roles</td>
<td>Identify key players – outreach</td>
<td>Interested pilot party discussion</td>
<td>Timeline focused implementation</td>
</tr>
<tr>
<td>Understand industry demand/processes</td>
<td>Remove barriers to pilot implementation</td>
<td>Pilot parameters set-synthetic data</td>
<td>Iterations to pilot product</td>
</tr>
<tr>
<td>Proof of concept discussions</td>
<td>Gauge opportunities to pilot</td>
<td>Contractual commitment discussion</td>
<td>Real-world issues and set back discussion</td>
</tr>
<tr>
<td>Understand industry barriers and gaps</td>
<td>Channel public call input/survey</td>
<td>Timeline creation discussions</td>
<td>Pilot phase to execution planning</td>
</tr>
<tr>
<td>Create Prototype</td>
<td>“Why” stakeholder group parameters</td>
<td>Brainstorm partners that may enhance pilot actors</td>
<td>Marketing and real-world education</td>
</tr>
<tr>
<td>Prototype iterations – technology focus</td>
<td>Industry engagement – events</td>
<td>Exploration of opportunities to utilize data</td>
<td>Redundancy and gap review</td>
</tr>
<tr>
<td>Technical validation processes – cyber security focus</td>
<td>Create workflow focused input.</td>
<td>Interoperability and transparency focus.</td>
<td>Launch</td>
</tr>
<tr>
<td>Final Prototype Iteration</td>
<td>Identify Pilot Participants</td>
<td>Pilot Contracting</td>
<td></td>
</tr>
<tr>
<td>Vision and concept organization</td>
<td>Scope and process detail</td>
<td>Contracting and legal detail</td>
<td>Identify/address redundancy and gaps</td>
</tr>
<tr>
<td>Public call conversions to membership</td>
<td>Pilot opportunities</td>
<td>Pilot planning and creation into EHR and PIS workflow</td>
<td>Continued member engagement</td>
</tr>
<tr>
<td>Member input focused iterations</td>
<td>Pilot parameter whiteboarding</td>
<td>Discover any barriers or gaps to implementation</td>
<td>Product launch discussion</td>
</tr>
<tr>
<td>Prototype iterations-final pilot phase</td>
<td>Key actors identified in process</td>
<td>Continued research and iterations</td>
<td>Product launch discussion</td>
</tr>
<tr>
<td>Process and key stakeholders identified with key initiatives and next steps</td>
<td>Workflow focused input/ meetings outcomes</td>
<td>Gain any partners or necessary additions to enhance pilot</td>
<td>Continued added support from industry</td>
</tr>
</tbody>
</table>

### Outcomes

<table>
<thead>
<tr>
<th>Activities</th>
<th>Stakeholder Engagement</th>
<th>Pilot Contracting</th>
<th>Product Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Prototype Iteration</td>
<td>Find Pilot Participants</td>
<td>Contractor and legal detail</td>
<td>Identify/address redundancy and gaps</td>
</tr>
<tr>
<td>Vision and concept organization</td>
<td>Scope and process detail</td>
<td>Pilot planning and creation into EHR and PIS workflow</td>
<td>Continued member engagement</td>
</tr>
<tr>
<td>Public call conversions to membership</td>
<td>Pilot opportunities</td>
<td>Discover any barriers or gaps to implementation</td>
<td>Product launch discussion</td>
</tr>
<tr>
<td>Member input focused iterations</td>
<td>Pilot parameter whiteboarding</td>
<td>Continued research and iterations</td>
<td>Product launch discussion</td>
</tr>
<tr>
<td>Prototype iterations-final pilot phase</td>
<td>Key actors identified in process</td>
<td>Gain any partners or necessary additions to enhance pilot</td>
<td>Product launch discussion</td>
</tr>
<tr>
<td>Process and key stakeholders identified with key initiatives and next steps</td>
<td>Workflow focused input/ meetings outcomes</td>
<td>Continued added support from industry</td>
<td></td>
</tr>
</tbody>
</table>
# REMS Prototype Release Schedule

<table>
<thead>
<tr>
<th>February</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>August</th>
<th>September</th>
</tr>
</thead>
<tbody>
<tr>
<td>REMSv0.1</td>
<td>REMSv0.2</td>
<td>REMSv0.3</td>
<td>REMSv0.4</td>
<td>REMSv0.5</td>
<td>REMSv0.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>January 31</td>
<td>March 14</td>
<td>April 25</td>
<td>June 6</td>
<td>July 18</td>
<td>August 29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescriber Workflow</td>
<td>Prescriber and Pharmacist Interaction</td>
<td>REMS Administrator Workflow</td>
<td>Pharmacy Verification of REMS ETASU, Extended Education Support, and Initial Patient Support</td>
<td>Improvements to Existing Stakeholder Workflows, Initial Education Support, and REMS Administrator Database</td>
<td>Potential Features: Extended Patient Support &amp; Improvements to all Workflows and User Interfaces, Expanded support of ETASU for TIRFs (stretch goal: Revlimid and PLEDGE)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Community input can help drive the direction of the prototype

### Complete Proof of Concept Phase

- Potential Features:
  - Remaining Key Features
  - Cleanup
  - Remaining Documentation
Current REMS Process: Physician, Patient and Pharmacist

**Prescriber is notified of REMS**
- Can you use existing drug databases as "flag" to trigger CDS hook?

**Prescriber writes Rx for patient and gives patient REMS agreement to sign**
- Will prescriber "hold" eRx until REMS requirements are met?

**Pharmacist/Dispenser confirms prescriber REMS requirements**
- Multisource Drugs - 11 of 61 – How do we handle as Provider does not go by NDC

**Pharmacist/Dispenser contacts help desk and/or prescriber to obtain missing information**
- How will pharmacist/Provider/REMS administrator communicate if missing information?

**Patient or caregiver counseled at pharmacy per REMS requirements**
- Is there a need for pharmacist to communicate back to provider if they have requirements to meet?

**Prescription filled/dispensed**
- Is there a need for pharmacist to communicate back to provider if they have requirements to meet?

**Patient monitoring, reporting and auditing**

Including questions and comments we've heard from Pilot Pass participants!
Potential Points of Failure: Summary of Provider View

Accuracy of PA Flags in F&B Data Files
Gap in understanding whether incoming payer data and ePA vendor processed data is accurate; Critical to have view into data to identify potential gaps and trace “errors” back to source.

Delay in Updating Formulary Files
Perceived accuracy of formulary data is compromised if timely updates are not pushed out to prescriber.
Largest formulary changes happen in first month of the year; those updates often lag 2-3 months behind.

Patient Eligibility Mismatch
Formulary Data will not display if patient eligibility not found.

Display of Formulary Information in EHRs
Disparate reasons for inconsistency; results in prescriber perception of inaccurate and unusable data.

Response Time From Payer
A potential delay in a response from a payer without any notification to the pharmacy that a PA has been started may result in duplicate efforts.
REMS Prototype Release Schedule

Click here for link to demo video

REMSv0.1
January 31
Prescriber Workflow

REMSv0.2
March 14
Prescriber and Pharmacist Interaction

REMSv0.3
April 25
REMS Administrator Workflow

REMSv0.4
June 6
Improvements to Existing Stakeholder Workflows, Initial Education Support, and Initial Patient Support

REMSv0.5
July 18
Pharmacy Verification of REMS ETASU, Extended Education Support, and Initial Patient Support

REMSv0.6
August 29
Potential Features:
- Extended Patient Support
- Improvements to all Workflows and User Interfaces
- Expanded support of ETASU for TIRFs (stretch goal: Revlimid and PLEDGE)

Complete Proof of Concept Phase
September 29
Potential Features:
- Remaining Key Features
- Cleanup
- Remaining Documentation

Community input can help drive the direction of the prototype
Given the challenges and opportunities discussed over the past few calls, we continue to see a viable path forward for improving REMS integration. Next steps:

- Continue outreach to build a collaborative community
  - Gathering key stakeholder views and ideas to address these challenges and opportunities collectively, creating a pathway to piloting the prototype
  - Making iterations to the demo that you saw today based on your feedback and input

- Together as a community, we can better
  - Specify sources of burden by leveraging electronic integration
  - Leverage the CodeX FHIR accelerator community, continually iterating towards a better solution
**REMS: Call to Action**

**Explore** how the REMS community can harness the FHIR standard to develop open-source, interoperable REMS solutions that reduce stakeholder burden and address your needs.

**Contribute** your real-world expertise to REMS prototype development.

**Consider** opportunities to leverage this work in pilots to drive adoption in real-world healthcare settings.

- **Join other upcoming REMS Public Calls**
  Registration information is available on the REMS confluence page: [https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration](https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration)

- **Share your REMS implementation experiences and recommendations**
  Champion a CodeX REMS Integration Use Case

- **Spread the word to friends and colleagues and encourage them to participate**

- **Recognize the value of stakeholder-focused workflow input**
  Examine prescriber and pharmacist workflows to identify and address gaps in reference implementation resources
    - Please email Kelee Petzelt ([kelee.petzelt@pocp.com](mailto:kelee.petzelt@pocp.com)) with any ideas or requests

- **“Pilot Pass” Participation**
  Offers an inside peek into member discussions and the ability to be hands on in the project – a fast track to membership through pilot opportunities. Collaborate with members on ideas and projects that may benefit from utilizing the prototype.
Get Involved

- **Visit** the REMS Integration Confluence Public Page

- **Join** upcoming REMS public calls
  - Help identify future public call dates and times via this [poll](#) by August 1st

- **Contact** CodeX REMS Co-Use Case Coordinators for more information:
  - Kelee Petzelt [Kelee.Petzelt@pocp.com](mailto:Kelee.Petzelt@pocp.com)
  - Cathy Becker [cdbecker@mitre.org](mailto:cdbecker@mitre.org)
Next Steps