2022-09-27 CodeX REMS Integration Use Case Public Call

2:00 - 3:00 pm ET

**Attendees:**

Doaa Alkiswany  
Colleen Brennan  
Liz Canzone, MITRE  
Ethan Chan  
Jennifer Chapman  
Su Chen, MITRE  
Kristol Chism  
Jennifer Church  
Ben Deppen, Kroger Health  
Ajit Dhavle  
Lauren DiCristofaro  
Robert Dingwell  
Pritam Dodeja  
Michael Dugan  
Kal Elhoregy  
Michelle Kershaw  
Michelle Kidd  
Dure Kim  
Jason Leedy  
Claudia Manzo, FDA  
Sahil Malhotra, MITRE  
Ed Millikan, FDA  
Peter Muir  
George Neyarapally, FDA  
Nicole Ng, MITRE  
Scott Robinson, Kaiser Permanente  
Dewey Seto  
Jonathan Sin  
Thomas So, FDB  
Stephanie Streib, Jazz Pharmaceutical  
Jennifer Church-Viatris  
Kevin White  

Kelee Petzelt, CodeX PMO, POCP  
Michele Galioto, CodeX PMO, POCP
Key Info:

- Welcome to our CodeX REMS Integration Use Case Public Call!
  - Participation and input from all those involved in REMS processes is critical to this project's success.
  - We encourage you to invite interested colleagues to further enrich our discussion on key REMS workflow challenges and potential solutions.
  - REMS Integration Use Case home page: REMS Confluence Page
- Today's resources:
  - Meeting recording
  - Demo resources:
    - REMS v0.6 Demo Slides
    - REMS v0.6 Video (part 1)
    - REMS v0.6 Video (part 2, technical)
- CodeX Membership: For information on becoming a CodeX Member to champion change in oncology, please reach out to Michele Galioto at michele.galioto@pocp.com
- Future public calls: Mark your calendars for the next public calls and register by clicking the meeting date below
  - October 27, 2022 3:00 - 4:00 PM ET
  - December 6, 2022 2:00 - 3:00 PM ET

Facilitator: Use Case Coordinator Kelee Petzelt - kelee.petzelt@pocp.com.

Meeting Norms

- Please add your name and organization in the chat or hover over your name, choose "more" then "rename," and add your organization.
- When speaking, please start with your name and organization.
- Feel free to use the hand-raising feature or enter questions in the chat. Your input is encouraged!

Agenda

1. Welcome
2. REMS v0.6 Demo and Discussion
3. REMS Integration Use Case Review
4. REMS Process Overview
5. Next Steps

Discussion Summary

Action Items and Next Steps

<table>
<thead>
<tr>
<th>Problem</th>
<th>Targeted Outcome of CodeX REMS Use Case</th>
<th>Value</th>
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### Discovery Session Summary

## Barriers/Obstacles

**Brainstorming conversations:**

1. Stakeholders - Who else should be in partnership with this use case endeavor?
2. Have we defined the minimum stakeholder representation? (Data senders, receivers, other important contributors/actors)
3. What is the level of impact of REMS on your organization and support to change how REMS functions today?
4. Does the use case fill a compelling and urgent need that leads to better, safer, faster care, and lower burden and cost?
5. What steps must we take to establish a flexible seamless platform inclusive for use by the prescriber, patient, care organizations, payer, pharmacist and intermediaries?
6. How can FHIR/APIs be leveraged to achieve standardization for things like Initial REMS Identification and prescriber processes?
7. How can we assure the API/FHIR work in the upstream processes (EHR, etc.) are harmonized downstream with the pharmacy process and pharmacy existing standards (Harmonization)?
8. Is there anything we have missed in the problem statement?

## The REMS Prototype will:

- Seek to integrate REMS into the healthcare system, with a current focus on prescriber system integration, by using contemporary data standards such as FHIR to reduce undue REMS program implementation burden and advance REMS implementation and evaluation
- Advance this integration through a proof-of-concept prototype and seek collaboration through a stakeholder driven use case under HL7/CodeX FHIR Accelerator that can be piloted and scaled relatively rapidly
- Build on FDA’s work in recent years to standardize REMS and a Prescription Drug Use Fee Act (PDUFA) VI mandate
- Build on this foundational work in future years