

FDA Drug Topics: Advancing Transparency and Regulatory Science Activities on Risk Evaluation and Mitigation Strategy (REMS)

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Learning Objectives

- Review how the REMS SPL files can assist health care professionals in identifying REMS drugs and their corresponding requirements
- Describe the approach for the REMS Integration Prototype and Use Case and how it can reduce REMS implementation burden
- Explain the REMS integration pilots and opportunities to contribute to the REMS Integration Use Case
- Discuss the REMS Public Dashboard and how it can be used

A Risk Evaluation and Mitigation Strategy (REMS)



- Is a drug safety program that FDA has the authority to require to help ensure the benefits of the medication outweigh its risks
- May include a number of interventions, including elements to assure safe use (ETASU), like labs and certification, to help reduce the occurrence and/or severity of a serious risks
- Designed to achieve specific goals to mitigate risks associated with use of a drug
- Our REMS authorities have allowed for the approval of drugs that would not have been approved or may have been removed from the market
- There are significant challenges in implementing and evaluating the effectiveness of REMS programs



REMS Modernization through Integration and Standardization



REMS – Current State

- Manual phone and fax implementation
- Not integrated into prescriber and pharmacist workflow
- Suboptimal patient engagement and transparency
- Lack of quality standardized data for feedback and evaluation
- No unified way to share data between REMS stakeholders
- Delays in therapy for patients and suboptimal care for the patient

REMS – Future State

- Automated, low burden implementation
- Integrated into clinician workflow
- Patients complete requirements, report & monitor status through apps
- Standardized, quality data for timely feedback and more robust evaluations
- Reduced friction in exchange of REMS data
- Patients safely use their medications and achieve timely access to them



[Guidance: F&C REMS Document \(final\)](#)



[REMS Document Technical Conformance Guide](#)

What is published?

1. Guidance: Format & Content of a REMS Document (final)
2. **REMS Document Technical Conformance Guide**
 - A. REMS Document Template**
 - B. Bifurcated REMS Document Outline**

Published in January 2023

REMS Document Technical Conformance Guide



REMS DOCUMENT TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This document is incorporated by reference into the following Guidance Document:

Format and Content of a REMS Document

For questions regarding this technical specifications document, contact CDER at OSE.PMKTREGS@fda.hhs.gov or CBER at the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010, ocod@fda.hhs.gov.

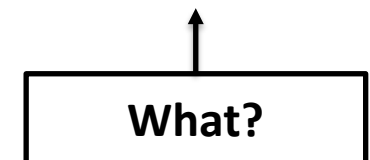
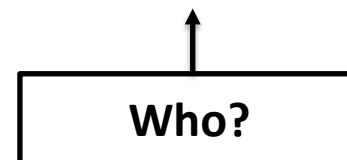
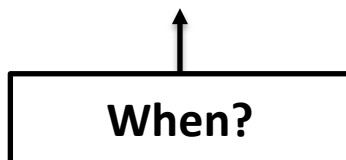
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

January 2023

REMS Document



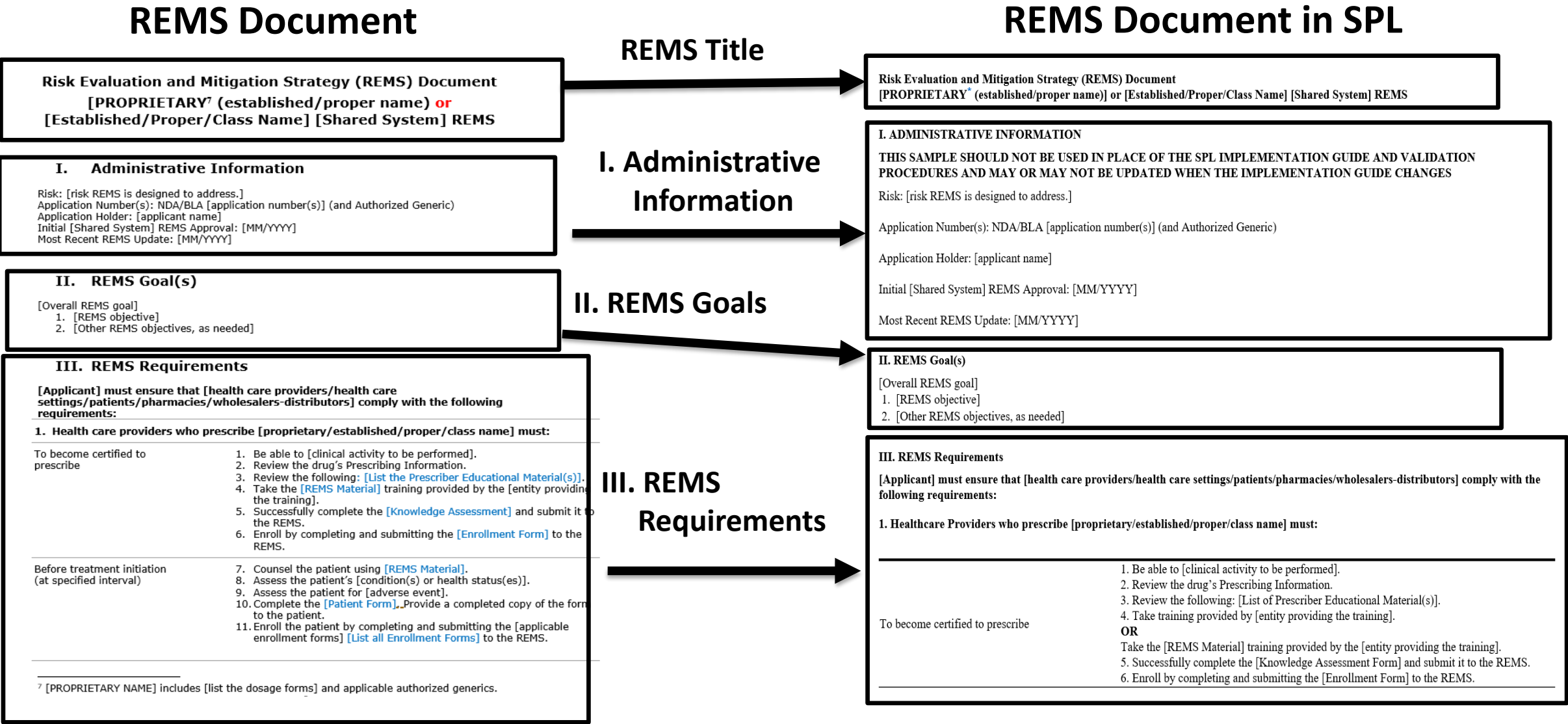
- The 'face' of the REMS
 - Establishes the goal and requirements of the REMS
- Purpose:
 - Communicate the required activities for sponsors
 - Communicate the required activities for participants (e.g., prescribers, pharmacists, patients, healthcare administrators, distributors)
- Captures the requirements for all applicable stakeholders
- REMS requirements are organized by participant and timing
 - e.g., *Before treatment initiation*, Health care providers who prescribe must counsel the patient



What is Structured Product Labeling (SPL)?

- SPL is a data standard for capturing information about drug products
 - “Structured Product Labeling” but covers product information beyond labeling
 - Developed by Health Level Seven International (HL7), a Standards Development Organization (SDO)
 - Allows for structuring text and data for easier computer processing
 - Machine-readable or computer-readable format

REMS Document Technical Conformance Guide template versus REMS Document in SPL[†]



[†] Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7[®]) and adopted by FDA as a mechanism for exchanging product, facility, and REMS information

REMS Document Technical Conformance Guide template corresponds to REMS Document SPL section codes



REMS Document in SPL

New!

Risk Evaluation and Mitigation Strategy (REMS) Document
[PROPRIETARY* (established/proper name)] or [Established/Proper/Class Name] [Shared System] REMS

I. ADMINISTRATIVE INFORMATION

THIS SAMPLE SHOULD NOT BE USED IN PLACE OF THE SPL IMPLEMENTATION GUIDE AND VALIDATION PROCEDURES AND MAY OR MAY NOT BE UPDATED WHEN THE IMPLEMENTATION GUIDE CHANGES

Risk: [risk REMS is designed to address.]

Application Number(s): NDA/BLA [application number(s)] (and Authorized Generic)

Application Holder: [applicant name]

Initial [Shared System] REMS Approval: [MM/YYYY]

Most Recent REMS Update: [MM/YYYY]

II. REMS Goal(s)

[Overall REMS goal]

1. [REMS objective]

2. [Other REMS objectives, as needed]

III. REMS Requirements

[Applicant] must ensure that [health care providers/health care settings/patients/pharmacies/wholesalers-distributors] comply with the following requirements:

1. Healthcare Providers who prescribe [proprietary/established/proper/class name] must:

To become certified to prescribe

1. Be able to [clinical activity to be performed].

2. Review the drug's Prescribing Information.

3. Review the following: [List of Prescriber Educational Material(s)].

4. Take training provided by [entity providing the training].

OR

Take the [REMS Material] training provided by the [entity providing the training].

5. Successfully complete the [Knowledge Assessment Form] and submit it to the REMS.

6. Enroll by completing and submitting the [Enrollment Form] to the REMS.

I. Administrative Information
(87523-7)

II. REMS Goals
(82349-2)

III. REMS Requirement
(87524-5)

REMS Document Technical Conformance Guide template corresponds to REMS Document SPL section codes



REMS Document in SPL

| | |
|--|--|
| <p>IV. REMS Assessment Timetable</p> <p>[NDA/BLA Holder(s)] must submit REMS Assessments at [time intervals/frequency]. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. [NDA/BLA Holder(s)] must submit each assessment so that it will be received by the FDA on or before the due date.</p> | <p>IV. REMS Assessment Timetable</p> <p>(82349-2)</p> |
| <p>V. REMS Materials</p> <p>The following materials are part of the [proprietary/established/proper/class name] REMS:</p> <p>Enrollment Form(s):</p> <p>Prescriber:</p> <ol style="list-style-type: none">[Prescriber Enrollment Form] <p>Patient:</p> <ol style="list-style-type: none">[Patient Enrollment Form][Patient Enrollment Form for [type of patient]] <p>Pharmacy:</p> <ol style="list-style-type: none">[Pharmacy Enrollment Form][[Type of pharmacy] Pharmacy Enrollment Form] <p>Health Care Setting:</p> <ol style="list-style-type: none">[Health Care Setting Enrollment Form][Other setting-specific Enrollment Forms, as needed] | <p>V. REMS Materials</p> <p>(82346-8)</p> |
| <p>VI. Statutory Elements</p> <p>This REMS is approved under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:</p> <ol style="list-style-type: none">Medication GuidePackaging and DisposalCommunication PlanElements to Assure Safe Use (ETASU):<ul style="list-style-type: none">Health care providers who prescribe [proprietary/established/proper/class name] are specially certified under 505-1(f)(3)(A)Pharmacies and health care settings that dispense [proprietary/established/proper/class name] are specially certified under 505-1(f)(3)(B)[proprietary/established/proper/class name] is dispensed to patients only in certain health care settings under 505-1(f)(3)(C)[proprietary/established/proper/class name] is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)Each patient using [proprietary/established/proper/class name] is subject to certain monitoring under 505-1(f)(3)(E)Each patient using [proprietary/established/proper/class name] is enrolled in the [proprietary/established/proper/class name] REMS program/Registry under 505-1(f)(3)(F)Implementation SystemTimetable for Submission of Assessments | <p>VI. Statutory Elements</p> <p>(82348-4)</p> |

New!

REMS Technical Document and REMS Requirements



REMS Document

Risk Evaluation and Mitigation Strategy (REMS) Document
[PROPRIETARY? (established/proper name) **or**
[Established/Proper/Class Name] [Shared System] REMS

I. Administrative Information

Risk: [risk REMS is designed to address.]
Application Number(s): NDA/BLA [application number(s)] (and Authorized Generic)
Application Holder: [applicant name]
Initial [Shared System] REMS Approval: [MM/YYYY]
Most Recent REMS Update: [MM/YYYY]

II. REMS Goal(s)

[Overall REMS goal]
1. [REMS objective]
2. [Other REMS objectives, as needed]

III. REMS Requirements

[Applicant] must ensure that [health care providers/health care settings/patients/pharmacies/wholesalers-distributors] comply with the following requirements:

1. Health care providers who prescribe [proprietary/established/proper/class name] must:

| | |
|---|---|
| To become certified to prescribe | <ol style="list-style-type: none">1. Be able to [clinical activity to be performed].2. Review the drug's Prescribing Information.3. Review the following: [List the Prescriber Educational Material(s)].4. Take the [REMS Material] training provided by the [entity providing the training].5. Successfully complete the [Knowledge Assessment] and submit it to the REMS.6. Enroll by completing and submitting the [Enrollment Form] to the REMS. |
| Before treatment initiation (at specified interval) | <ol style="list-style-type: none">7. Counsel the patient using [REMS Material].8. Assess the patient's [condition(s) or health status(es)].9. Assess the patient for [adverse event].10. Complete the [Patient Form]. Provide a completed copy of the form to the patient.11. Enroll the patient by completing and submitting the [applicable enrollment forms] [List all Enrollment Forms] to the REMS. |

⁷ [PROPRIETARY NAME] includes [list the dosage forms] and applicable authorized generics.

III. REMS Requirements

1. Health care providers who prescribe [proprietary/established/proper/class name] must:

To become certified to prescribe

1. Be able to [clinical activity to be performed].
2. Review the drug's Prescribing Information.
3. Review the following: [List the Prescriber Educational Material(s)].
4. Take the [REMS Material] training provided by the [entity providing the training].
5. Successfully complete the [Knowledge Assessment] and submit it to the REMS.
6. Enroll by completing and submitting the [Enrollment Form] to the REMS.

REMS Requirements are then transformed into standardized data elements



REMS Requirements

Standardized Data Elements

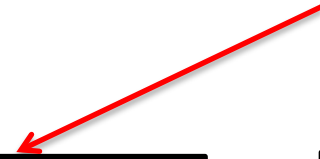
1. Health care providers who prescribe [proprietary/established/proper/class name] must:

To become certified to prescribe

- 1. Be able to [clinical activity to be performed].
- 2. Review the drug's Prescribing Information.
- 3. Review the following: [List the Prescriber Educational Material(s)].
- 4. Take the [REMS Material] training provided by the [entity providing the training].
- 5. Successfully complete the [Knowledge Assessment] and submit it to the REMS.
- 6. Enroll by completing and submitting the [Enrollment Form] to the REMS.

| | |
|-----------------------------------|--------------------|
| <stakeholder> ("Who") | Prescribers |
| <protocol> ("When") | REMS Certification |
| <requirement> ("What") | Enroll in REMS |
| <documentReference> ("With What") | [Enrollment Form] |

Coded REMS SPL information can be displayed in many different ways



<protocol>

<stakeholder>

<requirement>

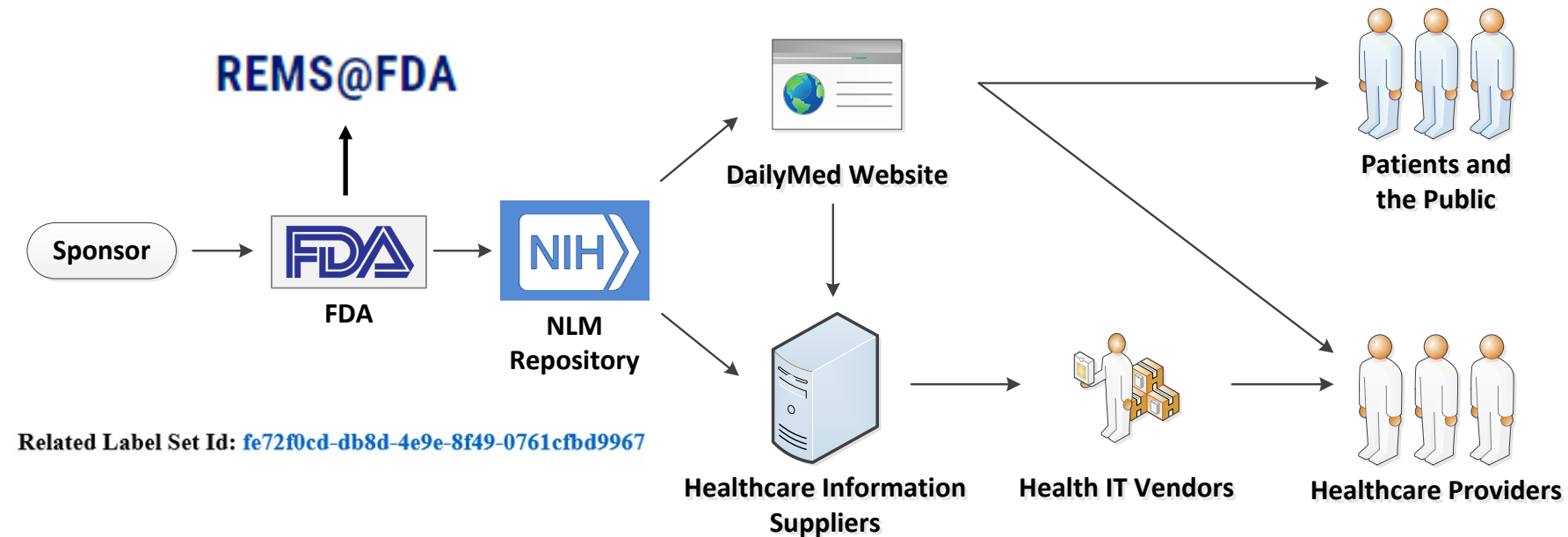
<documentReference>

| Before/During/After | Activity | Stakeholder | Requirement | Document |
|---------------------|----------------------------|-----------------------|---|----------------------------|
| before | REMS Certification | Medication Prescriber | Be Able To Perform a Clinical Activity | |
| before | REMS Certification | Medication Prescriber | Review Prescribing Information | |
| before | REMS Certification | Medication Prescriber | Review Training or Educational Materials | Prescriber Education |
| before | REMS Certification | Medication Prescriber | Participate in Training Session | Prescriber Education |
| before | REMS Certification | Medication Prescriber | Complete Knowledge Assessment | Knowledge Assessment |
| before | REMS Certification | Medication Prescriber | Enroll in the REMS | Prescriber Enrollment Form |
| before | Pharmacotherapy Initiation | Medication Prescriber | Counsel Patient | |
| before | Pharmacotherapy Initiation | Medication Prescriber | Assess Patient Condition, Health Status, or Adverse Event | |
| before | Pharmacotherapy Initiation | Medication Prescriber | Assess Patient Condition, Health Status, or Adverse Event | |
| before | Pharmacotherapy Initiation | Medication Prescriber | Complete Patient Form | Patient Enrollment Form |

SPL information is shared across the healthcare system



SPL data is transmitted from the sponsor to patients, healthcare providers, and the public



REMS SPL Submissions to FDA



Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2020
Electronic Submissions

[Providing Regulatory Submissions in Electronic Format --Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling](#)

REMS SPL Submissions to FDA‡



– WHEN:

- ***NOW!***

– WHO:

- Applicants must submit their REMS document electronically using SPL

– WHAT:

- All REMS documents submitted to FDA on or after December 28, 2022, must be in SPL format, which include:
 - REMS documents associated with a **new** REMS
 - REMS documents submitted as part of REMS **modifications**
 - REMS documents that are **already in SPL format** must remain in SPL format
- Components of a REMS required to be filed in SPL format:

| Component of a REMS Submission | Submitted in SPL Format? |
|--------------------------------|---|
| REMS document | Yes |
| REMS supporting document | No |
| REMS materials | Referenced in SPL file (see Structured Product Labeling Implementation Guide with Validation Procedures at https://www.fda.gov/media/84201/download) |

‡ [Providing Regulatory Submissions in Electronic Format -- Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling](#)

REMS SPL submissions as of November 9, 2023



- 17 single product REMS SPLs
- 5 shared system REMS SPLs
- National Library of Medicine (NLM) DailyMed website:
 - <https://dailymed.nlm.nih.gov/dailymed/spl-resources-all-indexing-files.cfm>

REMS & REMS INDEXING FILES

 [rems_document_and_rems_indexing_spl_files.zip](#) [[HTTPS](#) / [FTP](#)]

Number of REMS files: 22 | Number of REMS Indexing files: 0

File size: 202.05MB | MD5 checksum: 714be7b434e0cd11e765768415832b89 | Last Modified: Nov 9, 2023

Background/Definitions



Health Level 7 (HL7®): Standards development organization (SDO)



HL7® Fast Healthcare Interoperability Resources (FHIR®):
Contemporary health data exchange standard



Minimal Common Oncology Data Elements (mCODE™):
HL7® FHIR®-based cancer data standard (a “lingua franca” for cancer
care/research/public health purposes)



HL7® FHIR® Accelerator: Collaborative initiatives focused on solving
health problems with FHIR® standards-based solutions



CodeX™: HL7® FHIR® Accelerator building a community around
mCODE™ to solve problems through stakeholder-driven use cases

HL7[®] FHIR Data Standard



F – Fast (to design & implement)

H – Healthcare

I – Interoperability

R – Resources (building blocks)

Fast, Efficient, & Flexible

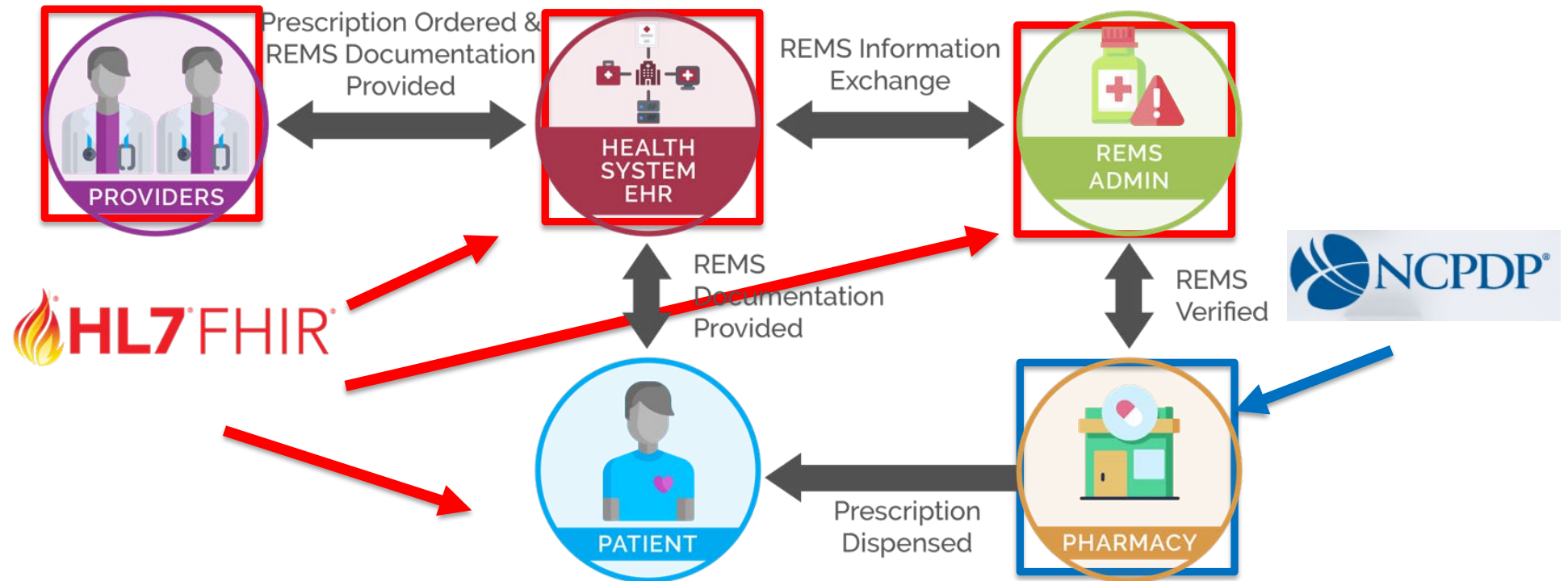
- Uses 80/20 Rule: 20% of the requirements satisfy 80% of the needs
- **FREE** to use
- Uses mainstream web technology
- Solutions built from modular components called “Resources”
- Option to develop custom extensions

FHIR[®] is a standard for exchanging healthcare information electronically

- Standards establish a common language and process for all health information technology (IT) systems to communicate, allowing information to be shared seamlessly and efficiently
- FHIR[®] can be used as a stand-alone data exchange standard or with existing standards

CodeX REMS Integration Use Case

Develop a standards-based approach to improve REMS interoperability and reduce burden



HL7® FHIR® Accelerator



<http://hl7.org/CodeX>

A Member-driven **community**
accelerating **interoperable** data
modeling and **implementation** around
the **FHIR®** and **mCODE™** HL7®
standards,
leading to **substantial improvements**
in **health care** and **research**
in cancer and beyond

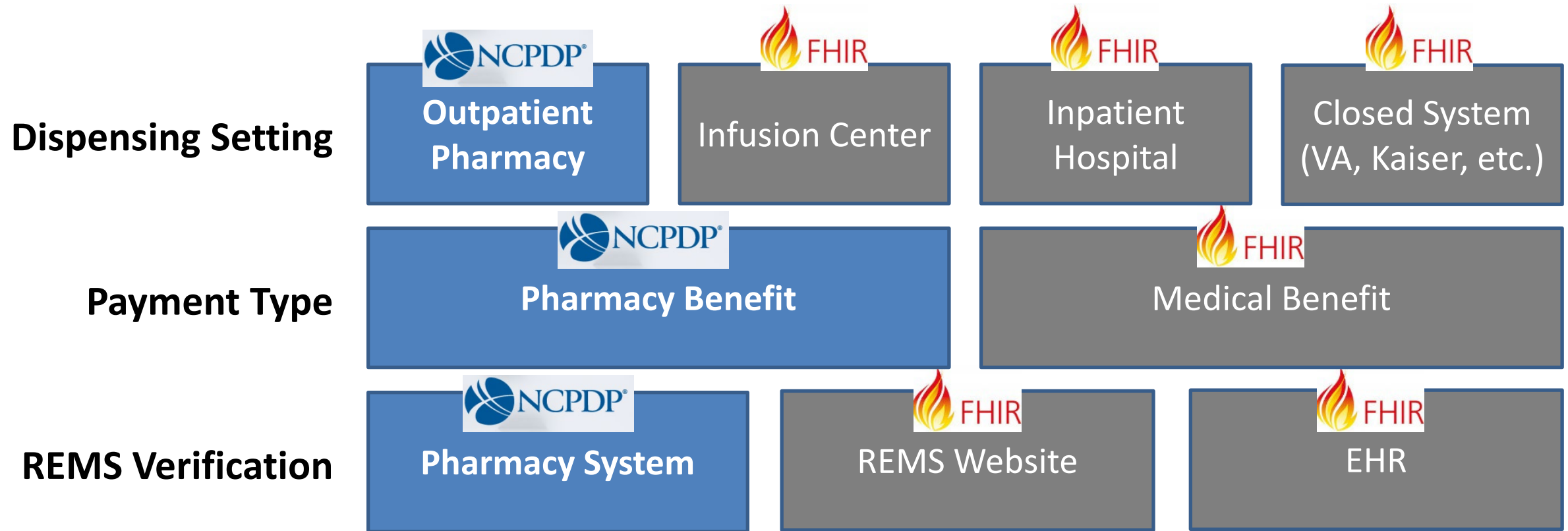
CodeX™ HL7® FHIR® Accelerator

(Members as of October 2023)

| PREMIER | | | | | CodeX Founders ★ | |
|---|---|---|--|---|---|---|
|  |  |  |  |  | | |
|  |  |  |  |  | | |
| PRINCIPAL | | BENEFACTOR | | | GOVERNMENT AGENCY | |
|  |  |  |  |  |  |  |
| | |  |  |  |  | |
| | |  |  |  |  |  |
| | | | | |  | |
| SPONSORED MEMBER | | DEVELOPER/IMPLEMENTER | | | | |
|  |  |  |  |  |  |  |
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HL7® FHIR® can address gaps in current REMS standards

(Potential future state)



Blue boxes show the workflow addressed by current NCPDP Standards (Telecommunication, SCRIPT)

REMS Integration Project Status



- **REMS use case:** Most recent public use case call on 10/16; next public use case call on 11/30
 - Sign up for the upcoming 11/30 REMS Public Call under “Quick Links” at:
<https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+-+REMS>
- **Prototype development:** v0.13 released on 9/12/23
- **Public workshop on REMS Integration:** Held on 10/11/2022
- **Pilots:** See upcoming slide

REMS Integration Use Case Update

Synthetic sub-pilot planning is in progress

| | Pilot 1 | Pilot 2 |
|---------------------|--|---|
| Manufacturer | Bristol Myers Squibb (BMS) Working with a vendor (InfoWerks) | Otsuka |
| Drug | Camzyos (mavacamten) | Jynarque (tolvaptan) |
| REMS Admin | BMS | United BioSource Corporation (UBC) |
| Status | Development team formed and familiarizing themselves with FHIR components. | Familiarized with CDS Hooks and SMART app launch using the prototype. Working with manufacturer to set scope, budget, and timing for pilot project. |
| Approach | Will leverage CDS Hooks and SMART app launch. Planning to combine existing assets with new FHIR components. Specifics TBD. | Will leverage CDS Hooks and SMART app launch. Specifics TBD. |

Select Patient and Medication



SELECT A PATIENT

No patient selected

| | | | |
|--|--|---|-------------------|
| <div>ID: pat1234 Name: Bobby Tables Gender: male Age: 26</div> | <div>Request: No requests</div> | <div>In Progress Form: </div> <div>No in progress forms</div> | <div>SELECT</div> |
| <div>ID: pat017 Name: Jon Snow Gender: male Age: 27</div> | <div>Request: <div>Isotretinoin 20 MG Oral Capsule (Medication request: 6064)</div><div>6064 (MedicationRequest) Isotretinoin 20 MG Oral Capsule</div><div>1237051 (MedicationRequest) TIRF 200 UG Oral Transmucosal Lozenge</div><div>2183126 (MedicationRequest) Turalio 200 MG Oral Capsule</div></div> | <div>In Progress Form: </div> <div>No in progress forms</div> | <div>SELECT</div> |

OPEN DEVELOPER CONSOLE

Selection Shows that Drug has REMS



SELECT A PATIENT

Patient ID: pat017

Demographics

Name: Jon Snow

Age: 27

Gender: male

State: empty

Coding

Code: 2183126

System: RxNorm

Display: Turalio 200 MG Oral Capsule

Prefetched

patient Resources

Patient: Patient/pat017 ✓

practitioner Resources

Practitioner: Practitioner/practitioner ✓

request Resources

MedicationRequest: MedicationRequest/pat017-mr-turalio ✓

Deidentify Records

OPEN IN-PROGRESS FORM

LAUNCH SMART ON FHIR APP

SEND RX TO PHARMACY

SIGN ORDER

CLOSE CONSOLE

Sending Rx to PIMS

Successfully sent Rx to PIMS

Initiating form submission

Notification Cards (2)

Summary

Turalio REMS Patient Requirements

Details

Documentation Required, please complete form via Smart App link.

Source: MCODE REMS Administrator Prototype

DOCUMENTATION REQUIREMENTS

MEDICATION GUIDE

PATIENT GUIDE

PATIENT ENROLLMENT FORM

PATIENT STATUS UPDATE FORM FORM

Summary

Turalio REMS Prescriber Requirements

Details

Documentation Required, please complete form via Smart App link.

Source: MCODE REMS Administrator Prototype

DOCUMENTATION REQUIREMENTS

PROGRAM OVERVIEW

PRESCRIBER TRAINING

PRESCRIBER ENROLLMENT FORM

PRESCRIBER KNOWLEDGE ASSESSMENT FORM

Ariel Virgulto, MITRE. CodeX Risk Evaluation and Mitigation Strategies (REMS) Integration Prototype. September 2023.

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Patient Enrollment Form Opens

Turalio Rems Patient Enrollment

Only Show Unfilled Fields 

Patient: Jon Snow

Patient Information

Address Line 2

Type a value

Telephone

Type a value

Email

Type a value

Body height

Type a number

ft

Type a number

in

Race

Select one or type a value

Is the patient currently taking pexidartinib (i.e., started prior to REMS enrollment)?

☒

If yes: Was this part of a clinical study?

☐

Comment

Type a value

Prescriber Information

Provider who performed the in-person evaluation

Last Name

First Name

Middle Initial

NPI

Type a value

Type a value

Type a value

Type a value

Practice/Facility Name (where you see this patient)

Type a value

Address Line 2

Type a value

Please visit www.turaliorems.com or contact the TURALIO REMS Coordinating Center at 1-833-TURALIO (833-887-2546) to designate up to two additional REMS certified prescribers who can view, edit, and submit REMS paperwork for your TURALIO patients.

Current Medication (including prescription, non-prescription and herbal or dietary supplements)

Check box if there are no current medications

☐

Hepatic Medical History

Check box in this section if there is no hepatic medical history

☐

Prescriber Agreement

I have reviewed and discussed the risks of TURALIO and the requirements of the TURALIO REMS with this patient.

Provider Signature

Signature *

Name (Printed) *

Date *

NPI *

Type a value

Type a value

08/03/2023

 Type a value

Patient Attestation

In order to receive TURALIO I must be enrolled in the TURALIO REMS. The TURALIO REMS will collect data to assess the risk of serious liver problems which can be severe and lead to death as described in the Patient Guide. • I agree to enroll in the Patient Registry. • I agree to review the Patient Guide. • I must get blood tests to test my liver as directed by my healthcare provider. • I agree to tell my healthcare provider if I have signs and/or symptoms of liver injury. • My personal information will be shared to enroll me in the Patient Registry so that my health and any liver injury can be evaluated while I am receiving TURALIO. • Daiichi Sankyo, Inc., and its agents, may contact me or my prescriber by phone, mail or email to manage the TURALIO REMS. • Daiichi Sankyo, Inc., and its agents, may use and share my personal health information, including lab tests and prescriptions as part of the TURALIO REMS. My information will be protected and will be used to enroll me into and manage the TURALIO REMS. My health information may be shared with the U.S. Food and Drug Administration (FDA) to evaluate the TURALIO REMS.

Patient Signature

Signature *

Name (Printed) *

Date *

Jon Snow

Jon S Snow

08/03/2023



Patient Enrollment Form Prepopulated



State

NY

Zip

14210

Telephone

716-873-1557

Email

jane.betty@myhospital.com

Please visit www.turaliorems.com or contact the TURALIO REMS Coordinating Center at 1-833-TURALIO (833-887-2546) to designate up to two additional REMS certified prescribers who can view, edit, and submit REMS paperwork for your TURALIO patients.

Baseline Labs

Assess the patient by obtaining liver tests as stated in the Prescribing Information. If Albumin or PT/INR were not obtained, indicate "not applicable." Please provide the results below.

| Laboratory Test | Baseline Value (units, reference range) | Date |
|----------------------|---|------------|
| AST or SGOT | 23 U/L | 06/15/2021 |
| ALT or SGPT | 12 U/L | 03/11/2021 |
| GGT | 13 U/L | 12/04/2021 |
| Total Bilirubin | 0.8 mg/dL | 04/11/2021 |
| Direct Bilirubin | 0.2 mg/dL | 04/18/2021 |
| Alkaline Phosphatase | 27 U/L | 06/15/2021 |
| Albumin | 4.8 g/dL | 01/25/2020 |
| PT/INR | 9.7 s | 12/25/2020 |

Current Medication (including prescription, non-prescription and herbal or dietary supplements)

Check box if there are no current medications

☐

Medication

metformin - 6809,,Turalio - 2183102

Hepatic Medical History

Check box in this section if there is no hepatic medical history

☐

Prescriber Agreement

I have reviewed and discussed the risks of TURALIO and the requirements of the TURALIO REMS with this patient.

Provider Signature

| Signature * | Name (Printed) * | Date * | NPI * |
|--------------|------------------|------------|--------------|
| Type a value | Type a value | 08/03/2023 | Type a value |

Patient Attestation

In order to receive TURALIO I must be enrolled in the TURALIO REMS. The TURALIO REMS will collect data to assess the risk of serious liver problems which can be severe and lead to death as described in the Patient Guide. • I agree to enroll in the Patient Registry. • I agree to review the Patient Guide. • I must get blood tests to test my liver as directed by my healthcare provider. • I agree to tell my healthcare provider if I have signs and/or symptoms of liver injury. • My personal information will be shared to enroll me in the Patient Registry so that my health and any liver injury can be evaluated while I am receiving TURALIO. • Daiichi Sankyo, Inc., and its agents, may contact me or my prescriber by phone, mail or email to manage the TURALIO REMS. • Daiichi Sankyo, Inc., and its agents, may use and share my personal health information, including lab tests and prescriptions as part of the TURALIO REMS. My information will be protected and will be used to enroll me into and manage the TURALIO REMS. My health information may be shared with the U.S. Food and Drug Administration (FDA) to evaluate the TURALIO REMS.

Patient Signature

| Signature * | Name (Printed) * | Date * |
|-------------|------------------|------------|
| Jon Snow | Jon S Snow | 08/03/2023 |

Check Status in REMS Admin & Pharmacy



REMS Admin Status

Case Number : a94e33a8c83

Status: Pending

VIEW BUNDLE

VIEW ETASU

ETASU

| | |
|---------------------------------|---|
| Patient Enrollment | ✓ |
| Prescriber Enrollment | ✗ |
| Prescriber Knowledge Assessment | ✗ |
| Pharmacist Enrollment | ✓ |
| Pharmacist Knowledge Assessment | ✓ |

Pharmacy Status

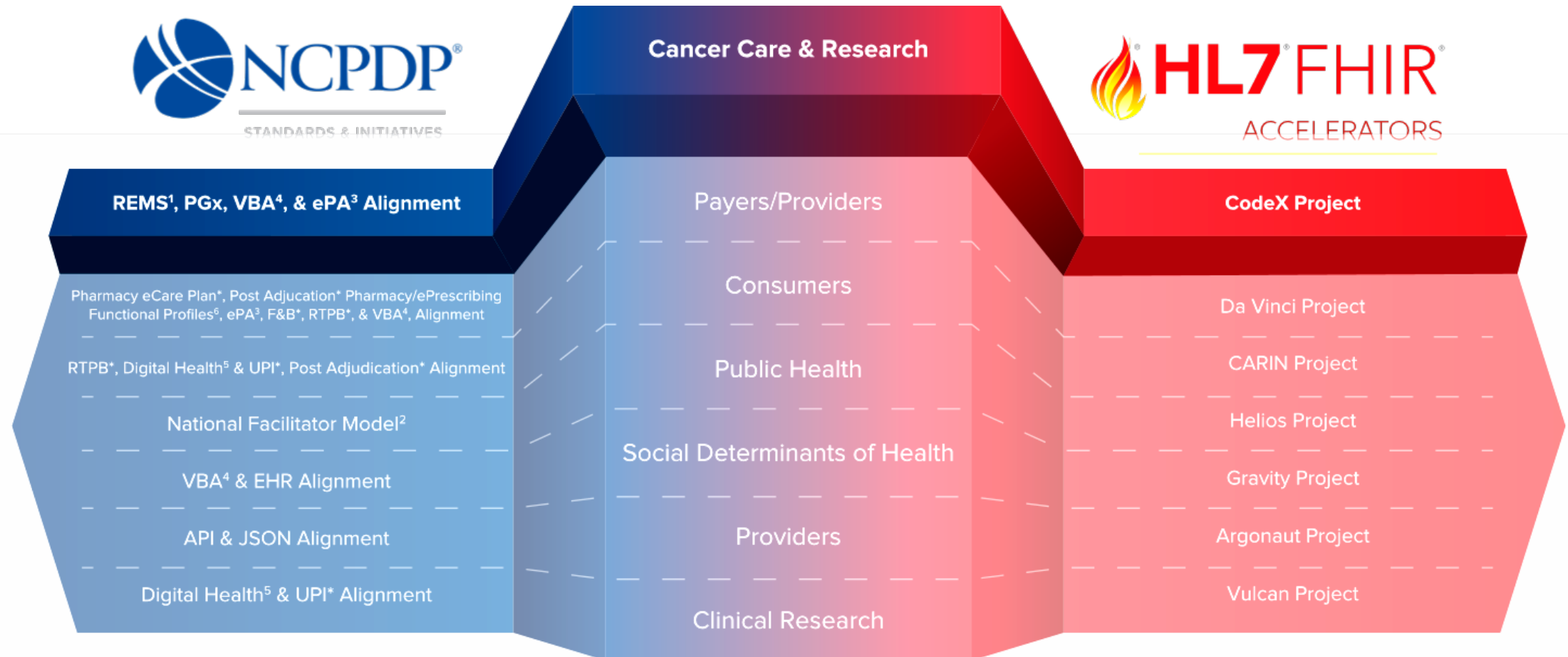
ID : 63ea6daad1aa5a6905456576

Status: Pending

NCPDP® & HL7® FHIR® Cross-Pollination



| Legend | |
|--|---|
| * Existing NCPDP Standard | ⁴ Supported by SCRIPT, Telecom & Pharmacist eCare Plan Standards |
| ¹ Supported by Telecom & SCRIPT Standards | ⁵ Supported by Billing Unit, Product Identifiers, SCRIPT, Telecom, F&B, RTPB & Benefit Integration Standards |
| ² Supported by SCRIPT, Telecom, & UPI Standards | ⁶ Separate standards developed jointly between NCPDP and HL7 |
| ³ Supported by SCRIPT Standard | |



Get Involved

- **Mark your calendars and engage in future public calls for the CodeX REMS Integration Use Case. Registration information is available on the REMS confluence page:**
 - <https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration>
- **CodeX REMS Contact Information:**
 - Ed Millikan Edward.Millikan@fda.hhs.gov
 - George Neyarapally George.Neyarapally@fda.hhs.gov
 - Kelee Petzelt Kelee.Petzelt@pocp.com
 - Michele Galioto michele.galioto@pocp.com
 - Nicole Ng nng@mitre.org
 - Ammu Irivinti ammu@mitre.org

Resources

- [CodeX REMS Integration Use Case](#)
- [CodeX FHIR Accelerator](#)
- [FHIR data standard specification](#)
- [Minimal Common Oncology Data Elements \(mCODE\)](#)



REMS

PUBLIC DASHBOARD

Gita A. Toyserkani, PharmD MBA

Associate Director for Strategic Initiatives and Research | Division of Mitigation
Assessment and Medication Error Surveillance | Office of Surveillance and
Epidemiology | U.S. Food and Drug Administration

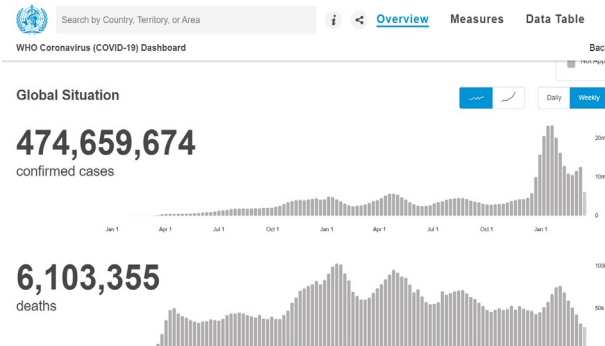
*“No one ever made
a decision because
of a number.
They need a story.”*

~Daniel Kahneman

Car Dashboard



Financial Dashboard



WHO COVID Dashboard



JHU COVID Dashboard



What is the REMS Public Dashboard?

- An interactive web-based tool that allows for visualization and analysis of REMS program data
 - Uses publicly available REMS data files – REMS@FDA website
 - Can combine any number of data sources
 - Can be customized
 - Is interactive
- Uses Qlik Sense Application
 - Used currently for FDA Adverse Event Reporting System ([FAERS](#)) Public Dashboard
- Launched December 17, 2021

[Risk Evaluation and Mitigation Strategy \(REMS\) Public Dashboard](#) | FDA

Motivation

- Since the implementation of REMS authorities in 2008, REMS data has accumulated over time
 - ~300 REMS approvals, > 700 REMS modifications
- Needed the ability to visualize ALL data at a glance and be able to drill down
- Information in REMS@FDA files in excel format are not easy to read and analyze
 - Data was manually processed, aggregated, and reports generated
 - Each quarter/monthly the process would need to be repeated
- Data from the files were being misinterpreted

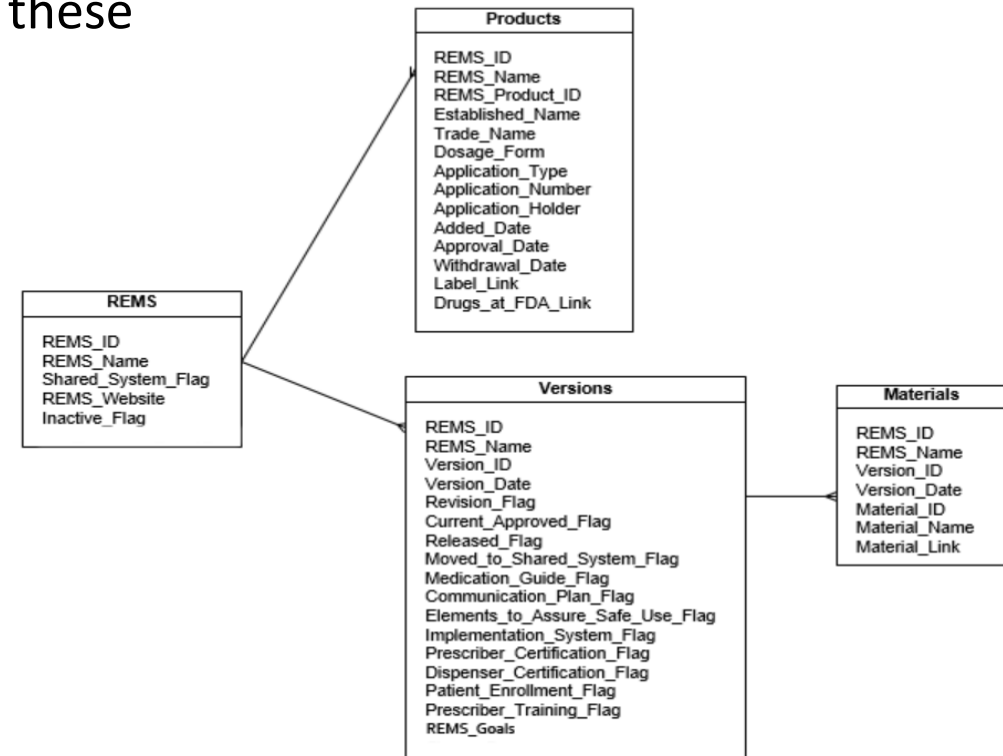
What are the benefits of the REMS Dashboard?

- Allow efficient access and visualization to improve transparency for FDA drug safety programs
- Increased awareness and understanding of REMS programs
- Interactive and can be customized
- Ability to export graphs and tables
- Allow for informed decision making

What are the limitations of the REMS Dashboard?

- The data in the REMS dashboard are currently limited to the information in the data files on REMS@FDA website
- The results of data retrieved are dependent on the accuracy of these data files
- The dashboard is intended for descriptive analyses

REMS@FDA: Entity-Relationship Diagram



REMS@FDA

Home > Drug Databases > REMS

Approved Risk Evaluation and Mitigation Strategies (REMS)

[f SHARE](#) [TWEET](#) [in LINKEDIN](#) [PIN IT](#) [EMAIL](#) [PRINT](#)

REMS@FDA

[Contact Us](#) | [REMS Resources](#) | [Get REMS Email Alerts](#) | [Reports & Data Files](#) | [REMS Public Dashboard \(NEW\)](#)

Persons with disabilities having problems accessing the PDF file(s) below may call (301) 796-3634 for assistance.

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

The table below provides links to currently approved individual and shared system REMS.

Information on historical and released REMS is available in downloadable: [data files](#).

The REMS@FDA webpage is currently undergoing maintenance. As a result, any changes or updates to REMS will not be reflected on this website until after 04/08/2022. Thank you for your patience.

Filter by Keyword (e.g. REMS name, active ingredient, element)

Excel CSV Print

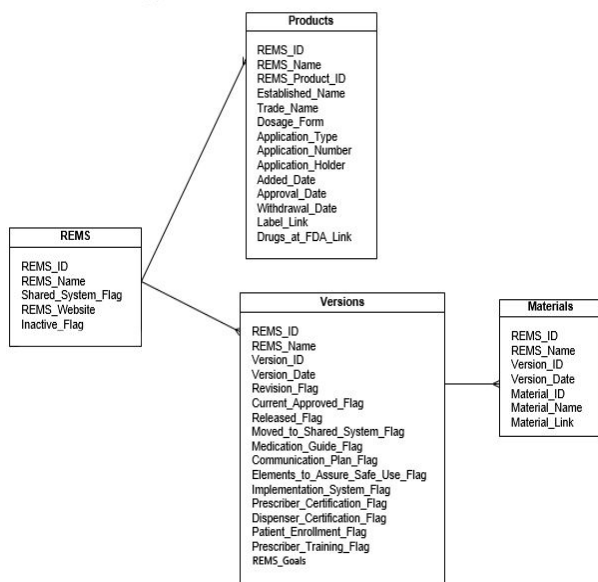
| Name | REMS Approved | Last Updated | MedGuide (MG)* | Comm. Plan (CP) | ETASU | Imp. System (IS) |
|--|---------------|--------------|----------------|-----------------|-----------------------|------------------|
| Abecma (<i>Idecabtagene vicleuce</i>), suspension, for intravenous infusion BLA #125736 | 03/26/2021 | 04/20/2021 | | | ETASU | IS |
| Adasuve (<i>loxapine</i>), aerosol, powder NDA #022549 | 12/21/2012 | 01/27/2022 | | | ETASU | IS |
| Addyi (<i>flibanserin</i>), tablet NDA #022526 | 08/18/2015 | 10/09/2019 | MG | | | |
| Adempas (<i>riociguat</i>), tablet, film coated NDA #204819 | 10/08/2013 | 11/30/2020 | | | ETASU | IS |

REMS@FDA Website

Data Description

The data available on this page is organized into four tables, each of which can be viewed on its own or in combination with other tables as part of a relational database. The entity-relationship diagram below shows the fields in each of these tables and how they should be linked together to form a comprehensive REMS database:

REMS@FDA: Entity-Relationship Diagram



REMS Data Files and Historic REMS Information

The information presented on this website, as well as historic information about REMS and their modifications, is compiled in the REMS Data Files below. All files below include information about current REMS as well as REMS that are no longer in place.

Download REMS data (Includes Released REMS) (REMS.csv)

This file presents a list of all approved REMS, including REMS that are no longer in place.

Download REMS Versions data (REMS_Versions.csv)

This file includes details on all modifications and revisions to each REMS program, including information on no-longer-current revisions and modifications.

Download REMS Products data (REMS_Products.csv)

This file includes data on all of the drugs that have ever been part of a REMS program, including information on products that are no longer marketed and/or no longer subject to a REMS.

Download REMS Materials data (REMS_Materials.csv)

This file includes a list of all materials that have been a part of the REMS, and provides links to REMS materials stored at FDA's website, when available. This includes materials that are no longer part of a current REMS.

| REMSID | Drug Name | REMS Shared Sys | Website | Inactive_Flag |
|--------|------------------|-----------------|---------|---------------|
| 282 | Abstral | No | | Active |
| 1 | Actemra | No | | Active |
| 279 | Actiq | No | | Active |
| 151 | Actonel | No | | Active |
| 152 | Actonel with cal | No | | Active |
| 153 | Actoplus Met | No | | Active |

| REMSID | REMS_Name | Version_ID | Version_Date | Material_ID | Material_Name | Material_Link |
|--------|-------------------|------------|--------------|-------------|--|---------------|
| 24 | Isotretinoin (RA) | 172 | 10/22/2018 | | 95 Guide to Isotretinoin for Male Patients and Female Patients who Cannot Get Pre | |
| 17 | Mycophenolate | 178 | 9/25/2012 | 177 | Clostridium/Synecologist Referral Template Letters for Contraception Counsel | |
| 49 | Soliris | 137 | 9/28/2011 | 250 | Soliris Patient Safety Card | |
| 61 | Tysabri | 143 | 1/20/2012 | 329 | Guidance for Evaluation of New Neurologic Symptoms | |
| 149 | Adempas | 240 | 6/11/2014 | 356 | Prescriber Guide http://www.accessdata.fda.gov/drugsatfda_docs/remis/adempas | |
| 113 | Avastin | 723 | 9/2/2014 | 425 | AVASTIN REMS Info http://www.accessdata.fda.gov/drugsatfda_docs/remis/avastin | |
| 28 | Letairis | 260 | 1/31/2014 | 568 | Patient Enrollment http://www.accessdata.fda.gov/drugsatfda_docs/remis/letairis | |
| 46 | Revlimid | 164 | 11/15/2013 | 677 | Empressor Card http://www.accessdata.fda.gov/drugsatfda_docs/remis/revlimid | |
| 71 | Xarelto | | | | | |
| 17 | Opdivo | | | | | |
| 35 | Mifeprex | | | | | |
| 60 | Transmucor | | | | | |
| 43 | Prolia | | | | | |
| 17 | Opdivo | | | | | |
| 25 | Lotnecor | | | | | |
| 172 | Cimzia | | | | | |
| 174 | Copegut | | | | | |
| 175 | Creon | | | | | |
| 176 | Dilatene | | | | | |
| 177 | Duetact | | | | | |
| 178 | Dulera | | | | | |
| 179 | Dysport | | | | | |
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What information is available in the REMS Dashboard?

- Approved REMS information is organized by:
 - Total REMS
 - Active REMS
 - REMS with Elements to Assure Safe Use (ETASU)
 - Shared Systems REMS
 - REMS Modifications
 - REMS Revisions
 - Released REMS
 - REMS Summary
- Exploring other data sources to further expand the data analysis capabilities of this dashboard in the future (e.g., indication, risk information, assessment information)

Examples of Basic REMS Dashboard Queries?

- REMS Program Data
 - # of REMS approved by year?
 - # of modifications approved by year?
 - # of REMS released?
 - # of REMS with ETASU?
 - How many shared system REMS are approved?
 - # of REMS approved for BLAs or NDAs by year?
 - # of REMS with patient enrollment?
 - How many times has a REMS been modified?
 - Which REMS were released in a given year (e.g., 2011)?

REMS Dashboard Features



FDA Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard

[Total REMS](#) [Active REMS](#) [ETASU](#) [Shared REMS](#) [Modifications](#) [REMS Revisions](#) [REMS Released](#) [REMS Summary](#)

Key Performance Indicators (KPI)

[Disclaimer](#) [User Manual](#) [FAQ](#) [Site Feedback](#)

Ever Approved

311

User Selection

-NA-

Currently Active

66

Yearly

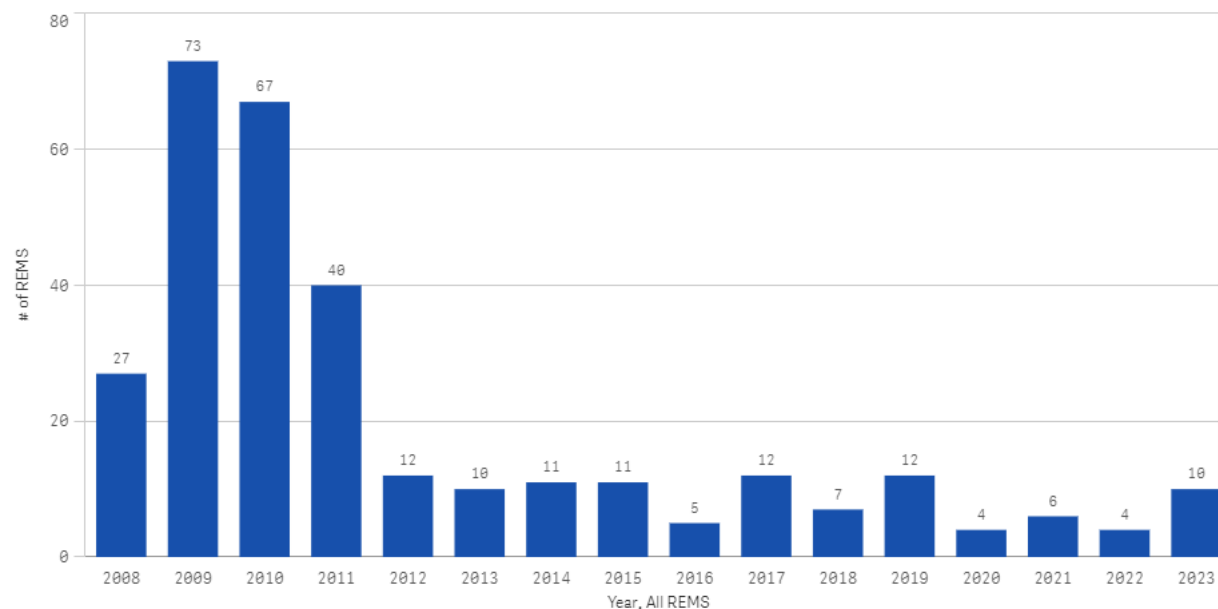
Quarterly

Monthly

Drop down selections

All REMS

REMS Approved



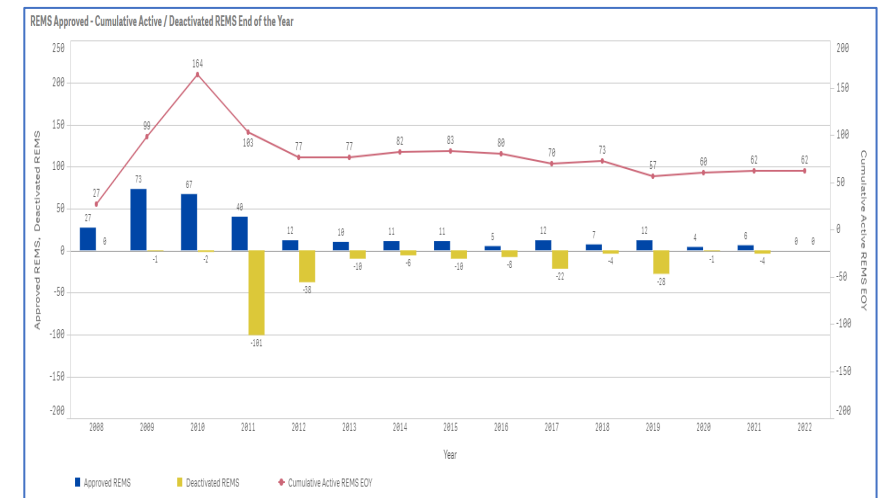
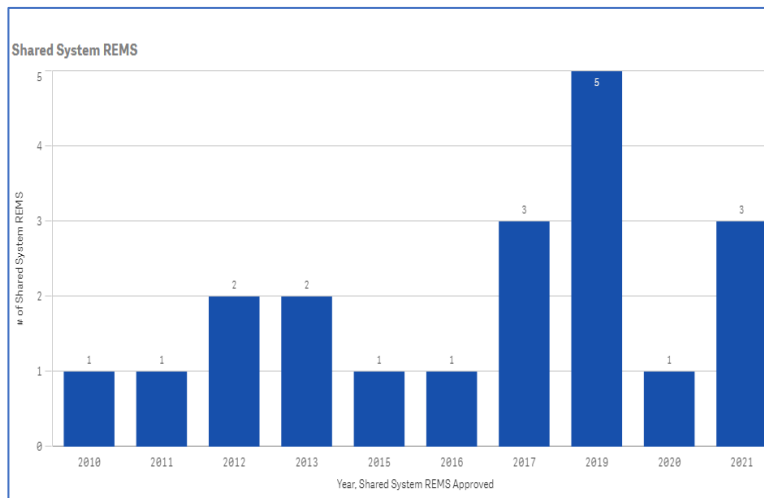
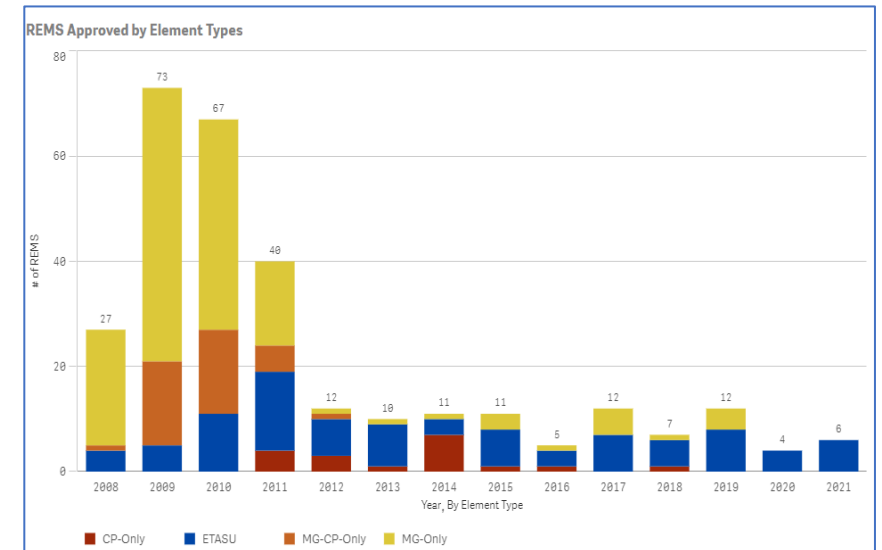
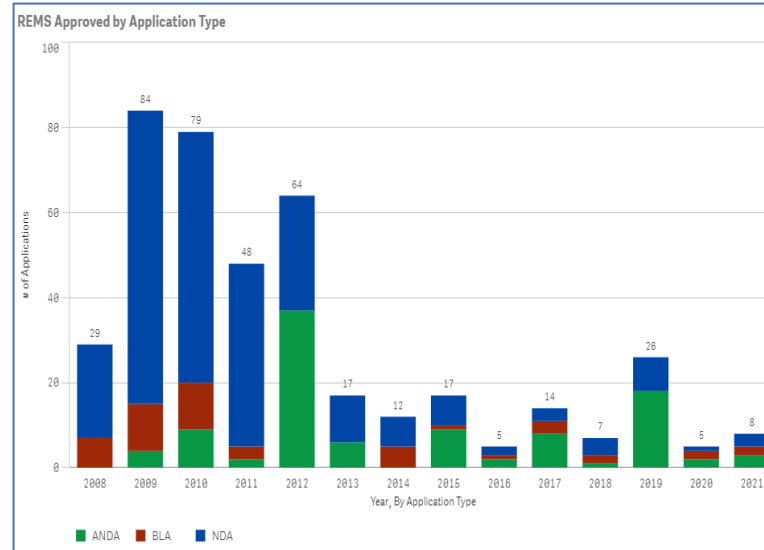
REMS Approved

| Name | Application N... | REMS App... | Elemen... | Comm... | Medic... | Active |
|----------------------|-----------------------|-------------|-----------|---------|----------|--------|
| Abecma | BLA #125736 | 03/26/2021 | Yes | No | Yes | Yes |
| Abstral | NDA #022510 | 01/07/2011 | Yes | No | Yes | No |
| Actemra | Multiple Applications | 01/08/2010 | No | Yes | Yes | No |
| Actiq | NDA #020747 | 07/20/2011 | Yes | No | Yes | No |
| Actonel | NDA #020835 | 01/25/2011 | No | No | Yes | No |
| Actonel with calcium | NDA #021823 | 01/25/2011 | No | No | Yes | No |
| Actoplus Met | NDA #021842 | 09/14/2009 | No | No | Yes | No |
| Actoplus Met XR | NDA #022024 | 05/12/2009 | No | No | Yes | No |
| Actos | NDA #021073 | 09/09/2009 | No | No | Yes | No |
| Adasuve | NDA #022549 | 12/21/2012 | Yes | Yes | No | Yes |
| Addyi | NDA #022526 | 08/18/2015 | Yes | No | No | Yes |
| Adempas | NDA #204819 | 10/08/2013 | Yes | No | Yes | No |
| Advair Diskus | NDA #021077 | 04/30/2008 | No | No | Yes | No |
| Advair HFA | NDA #021254 | 07/31/2008 | No | No | Yes | No |

Data as of October 30, 2023

This page displays the REMS approved for a selected time period. The elements of the REMS reflected in the table are the elements with which the REMS was initially approved.

Different REMS Data Views





FDA REMS Dashboard

The REMS Public Dashboard is a new interactive web-based platform that allows for user friendly query functionality to search for REMS related information. This platform is intended to provide improved access of [REMS@FDA](#) data to the general public and to other stakeholders with the data available in an analytic visual format for efficient data manipulation and functionality to meaningfully interpret the REMS data.

After reviewing the User Manual and Frequently Asked Questions, if you have additional questions or feedback, please contact FDA's Division of Drug Information at 301-796-3400 or druginfo@fda.hhs.gov

Frequently Asked Questions (FAQs)

[Expand all](#) | [Collapse all](#)

General Questions

- + [What is REMS?](#)
- + [What is REMS@ FDA?](#)
- + [What is REMS Dashboard ?](#)
- + [What information is available in the REMS Public Dashboard?](#)
- + [What is the data source for the dashboard?](#)
- + [What are the benefits of the REMS Public Dashboard?](#)
- + [Are there some limitations to the REMS dashboard?](#)
- + [How often will the REMS Public Dashboard be updated?](#)

[Back to Top](#)

Technical Questions

- + [What is the optimal internet browser to access the dashboard?](#)
- + [I am a new user, is there any user manual so I can learn how to use the database?](#)
- + [Can I view charts and tables in full screen mode? How do I exit from full screen mode?](#)
- + [Can I filter data in charts and tables?](#)
- + [How do I reset selected search criteria and remove all filters?](#)
- + [How I can download or export the results?](#)
- + [What do the acronyms stand for?](#)

[Back to Top](#)

REMS Dashboard FAQ Page

New Features since the Launch

- As of January 2023, data refresh is automated and updated weekly
- Hyperlink for direct access to REMS Materials is included in the dashboard on the currently “Active REMS” page



REMS Dashboard | Basic User Interface

1. Navigational bar

- Left side - page names
- Right side - aggregation type

2. Selection from bar chart and tables

- Single value
- Multiple values
- Click and drag

3. Search using filter panes in tables

4. Selection bar

- Add or remove selections from here
- Go back and forward in selections
- Reset selections

5. Other important features

- Fullscreen for better view
- Data export (limitations)
- For original data, export using tables
- Drop downs to change views
- When you move between pages, selections are reset
- Combo chart dual axis
- Mini chart – users must scroll

REMS Dashboard link: [REMS Public Dashboard](#)

REMS DASHBOARD DEMO

References

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Questions?

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