GUDID User Group Session

Unlocking (DI) Records for Edits

Monday, May 14, 2018

UDI Program Focus: WHAT

- Ensure data in GUDID is of **acceptable quality** to realize public health benefits and a return on investment across the entire health care ecosystem.

- Work to achieve **sufficient confidence** in the accuracy and completeness of the data to ensure UDI integration from manufacturing through supply chain to patients, electronic health records (EHRs), and registries.

UDI Program Focus: HOW

- Facilitate submission and maintenance of high-quality data in GUDID
- Develop an actionable Data Quality (DQ) plan that defines and targets completeness and accuracy of device information; initial focus on key fields and high risk devices
- Engage with stakeholders to address challenges and optimize data quality and utility for higher-risk devices

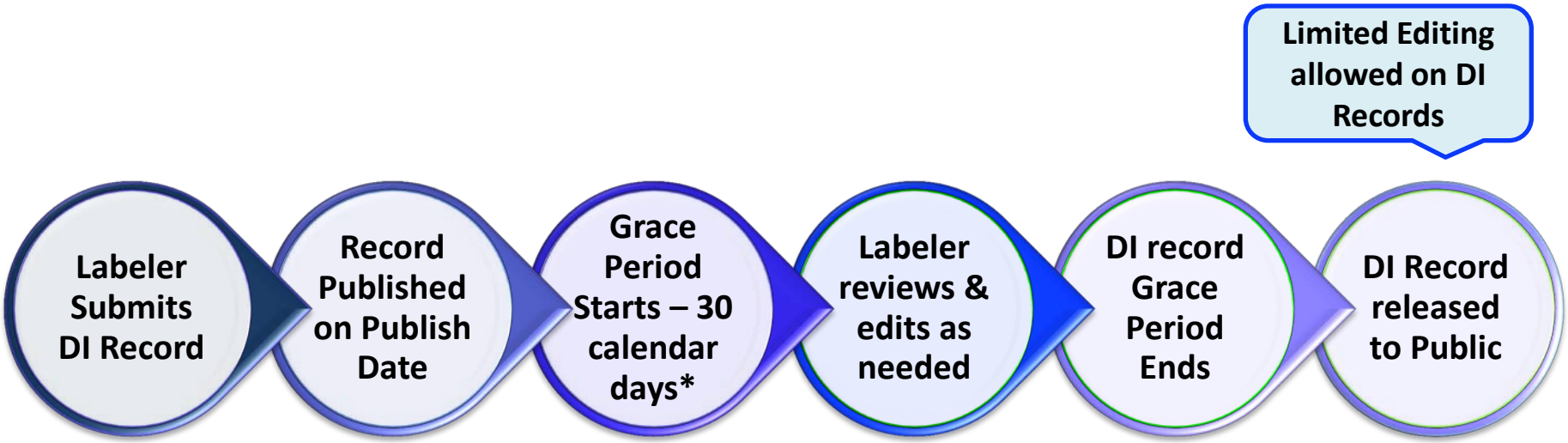
Facilitate submission and maintenance of high- quality data in GUDID

- Submission: Enhance business rule validations to improve data quality during initial submission processing
- Maintenance: Improve the DI record edit process to make error corrections after grace period

Today's Agenda

- Unlocking DI records for Edits After Grace Period
- Walk through the new unlock process
- Update on upcoming enhancements
- Q&A

DI Record Submission & Release Process

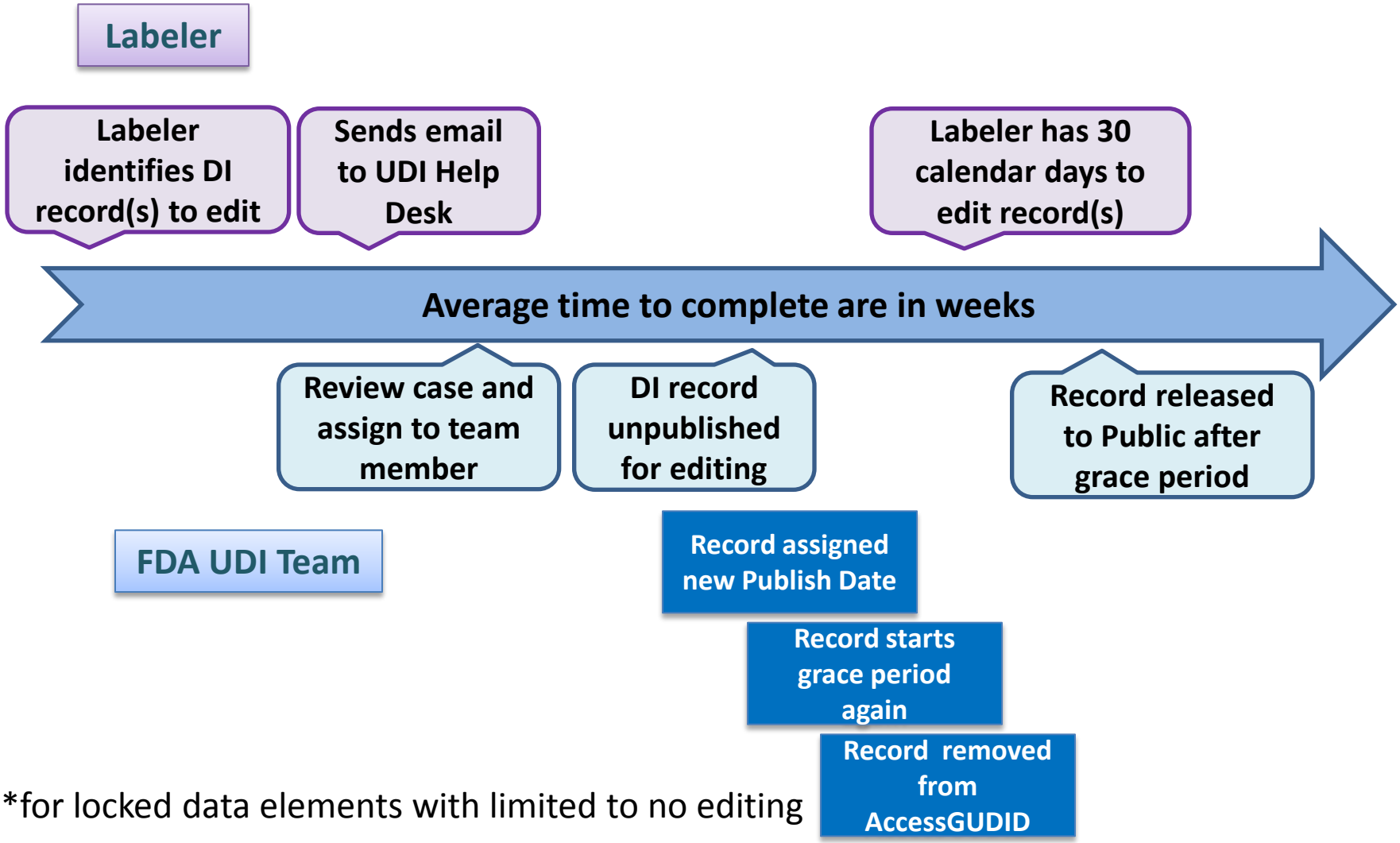


*grace period duration subject to change

Issue: Changes After Grace Period

- Grace period not used for record review and edits
- Data entry/submission errors identified after grace period; corrections needed
- Labelers need to request assistance via UDI Help Desk to unlock records for editing

Issue: Burdensome Process for Corrections*

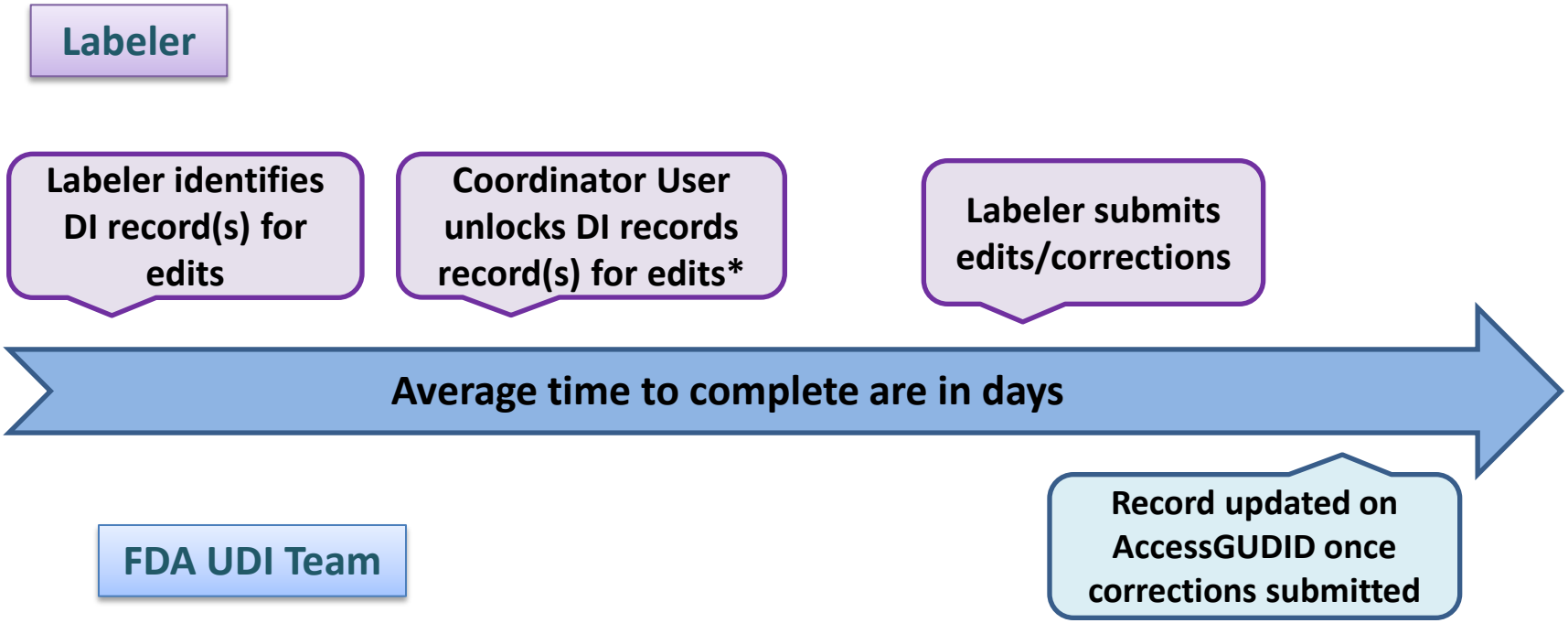


*for locked data elements with limited to no editing

FDA U.S. FOOD & DRUG ADMINISTRATION

To the Rescue: Unlocking DI Records For Editing

Less Burdensome Process for Corrections*



*for locked data elements with limited to no editing

Unlock DI Record Functionality – WHAT IT IS

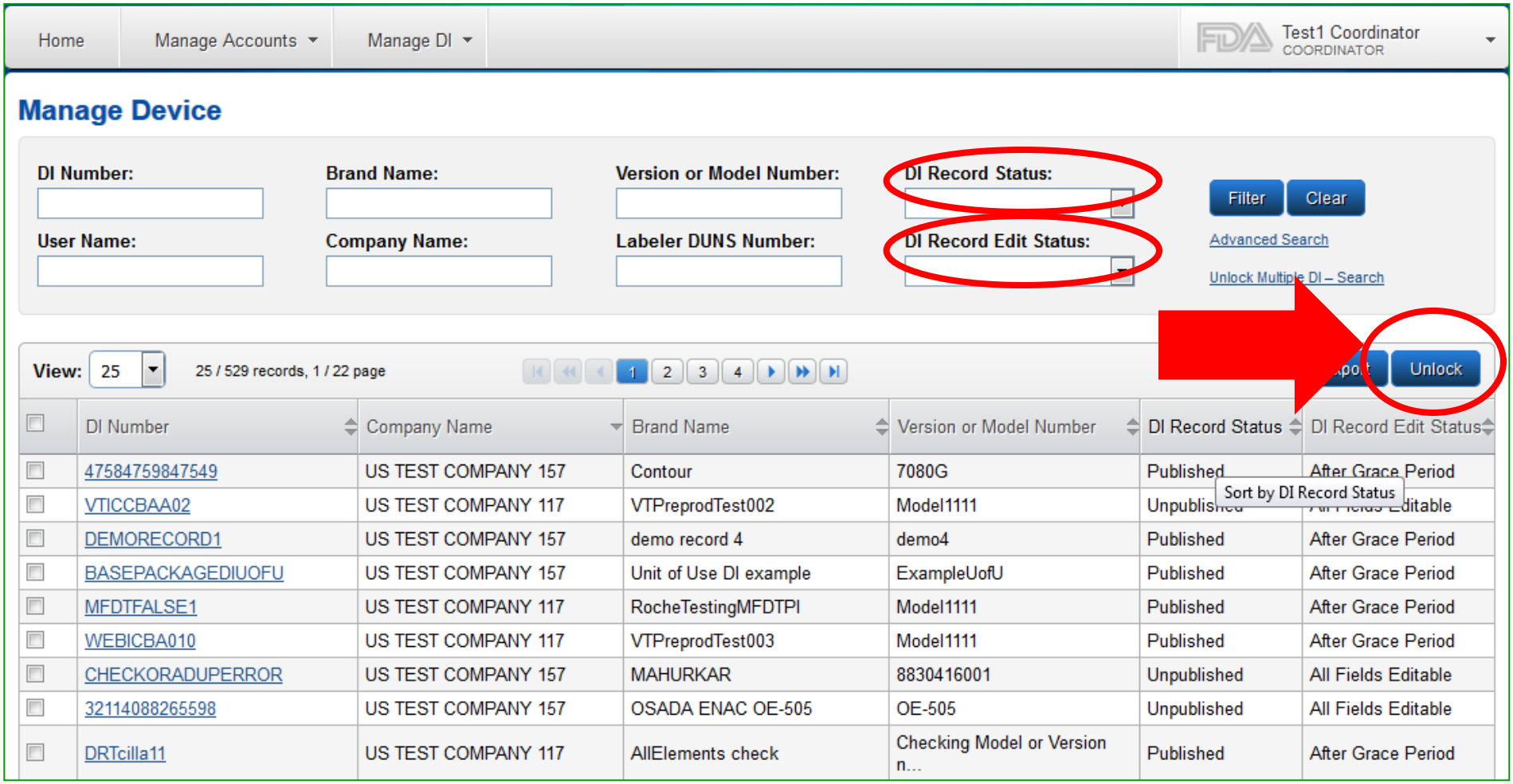
- For Labelers
  - More control over DI record management
  - Ability to edit records after grace period
    - For correction of data entry/submission/data quality errors
  - No changes to new DI trigger business rules
  - Retain original DI Record Publish Date
  - No IT system changes necessary; no change to HL7 SPL submission process/schema
  - Labelers need to establish training/procedures to manage unlock functionality

Unlock DI Record Functionality – WHAT IT IS

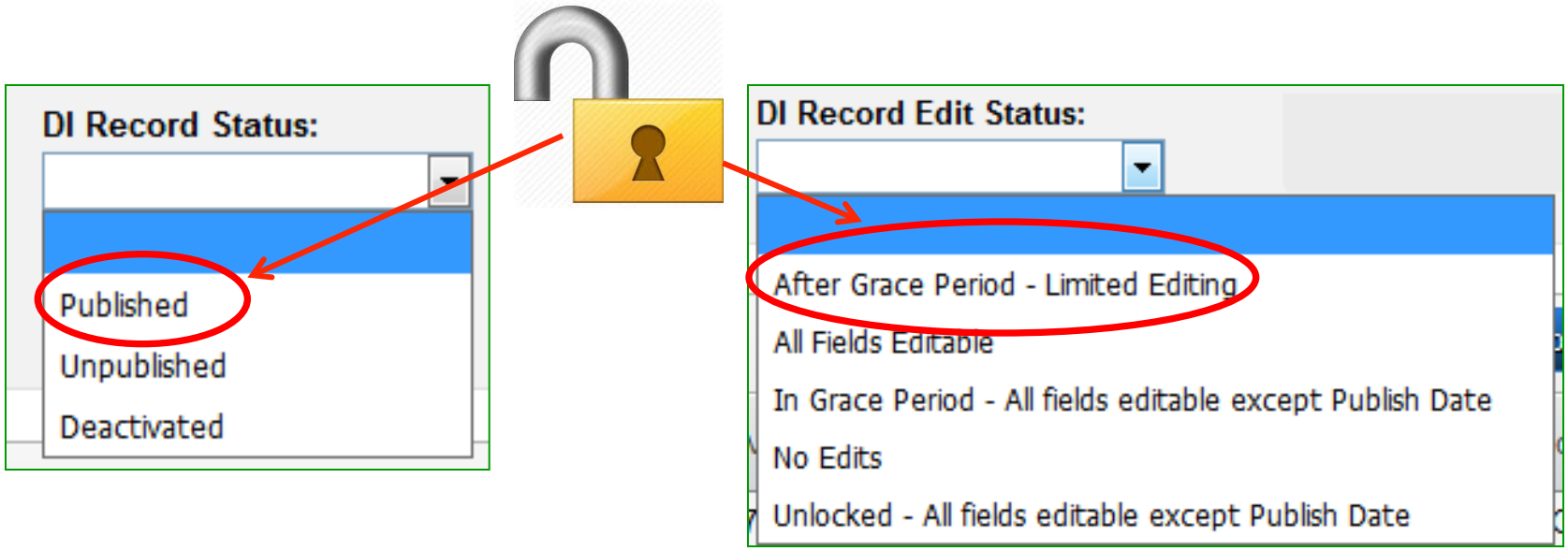
- For Public Data Users
  - Records do not ‘disappear’ while unlocked
  - Updates publicly available after corrections are submitted
  - Addition of FDA assigned data elements to allow for easier tracking of updates
    - Public Device Record Key, Public Version Number, Public Version Date, Public Version Status
  - Availability of DI record edit history

Unlocking DI Records: Walk-Thru

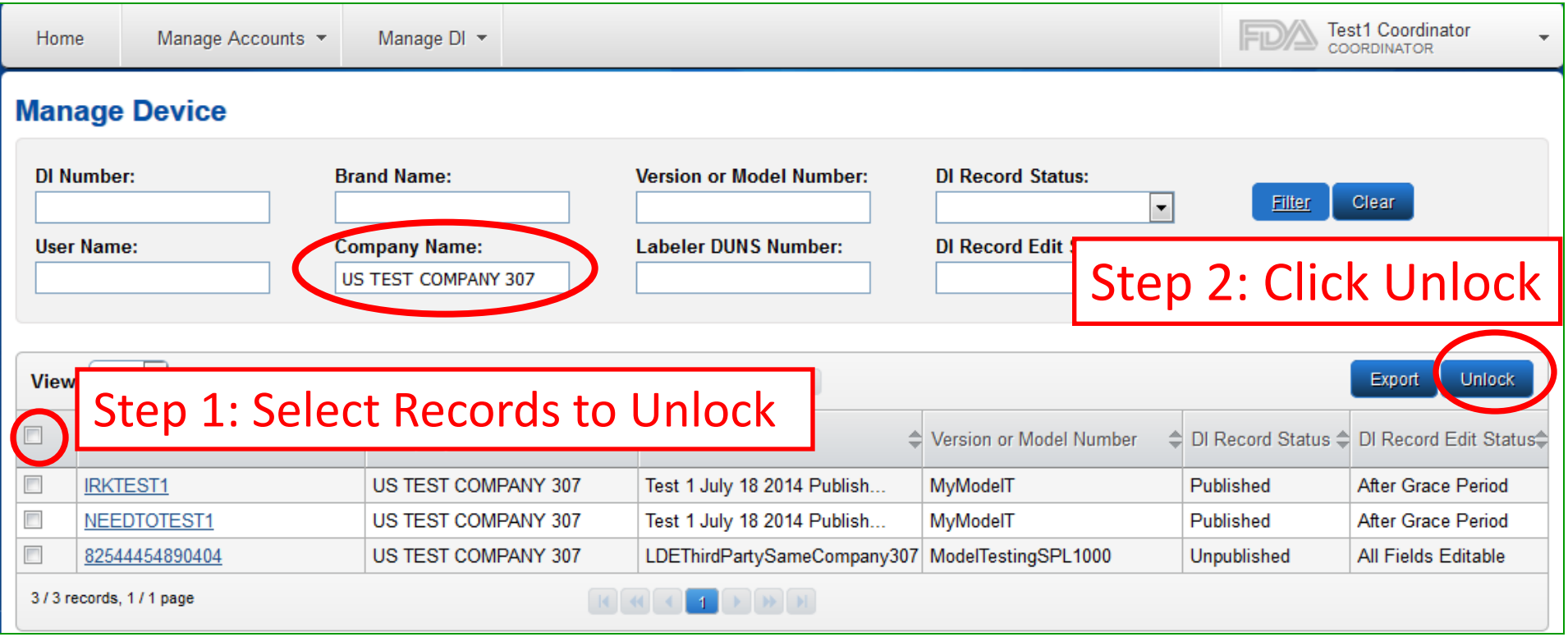
Coordinator User Logs-in



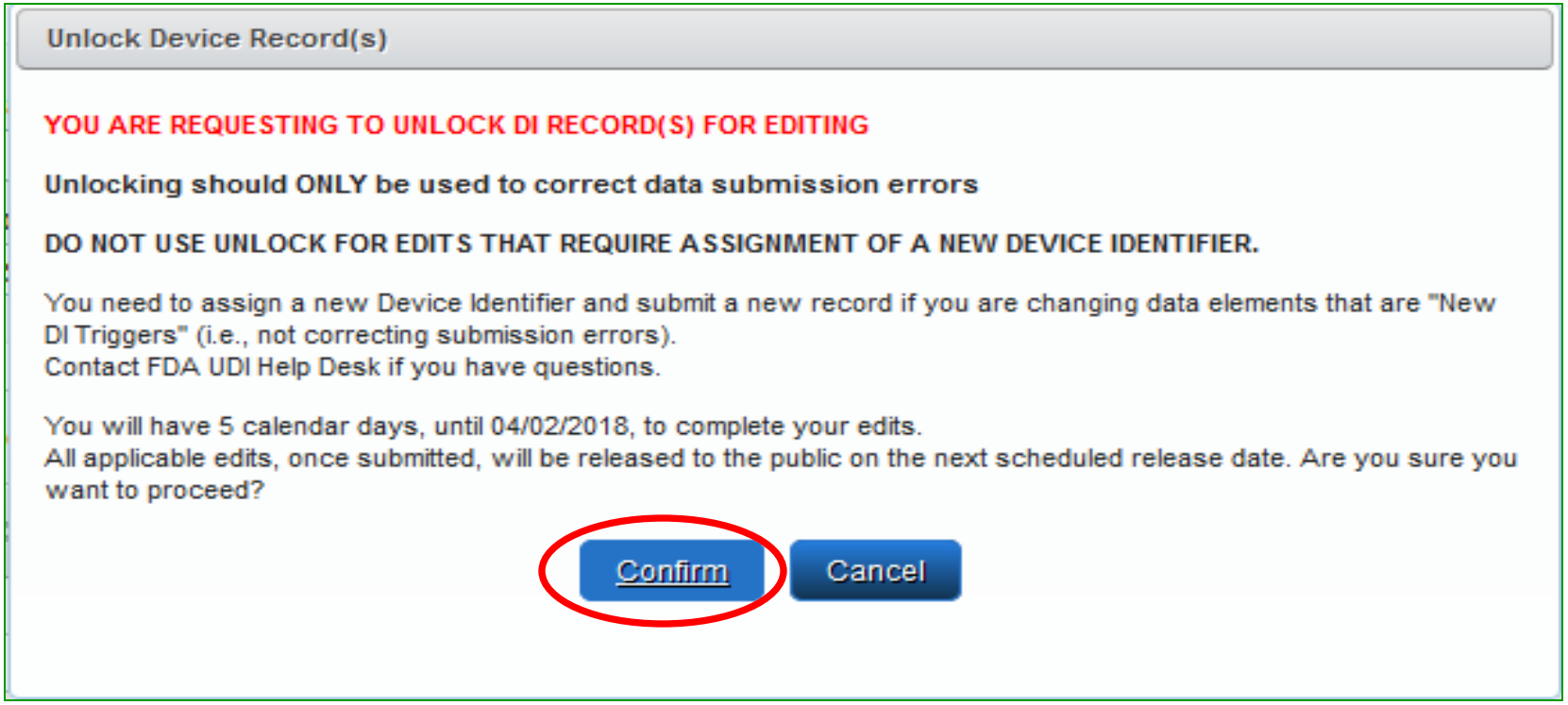
Ability to Filter Records



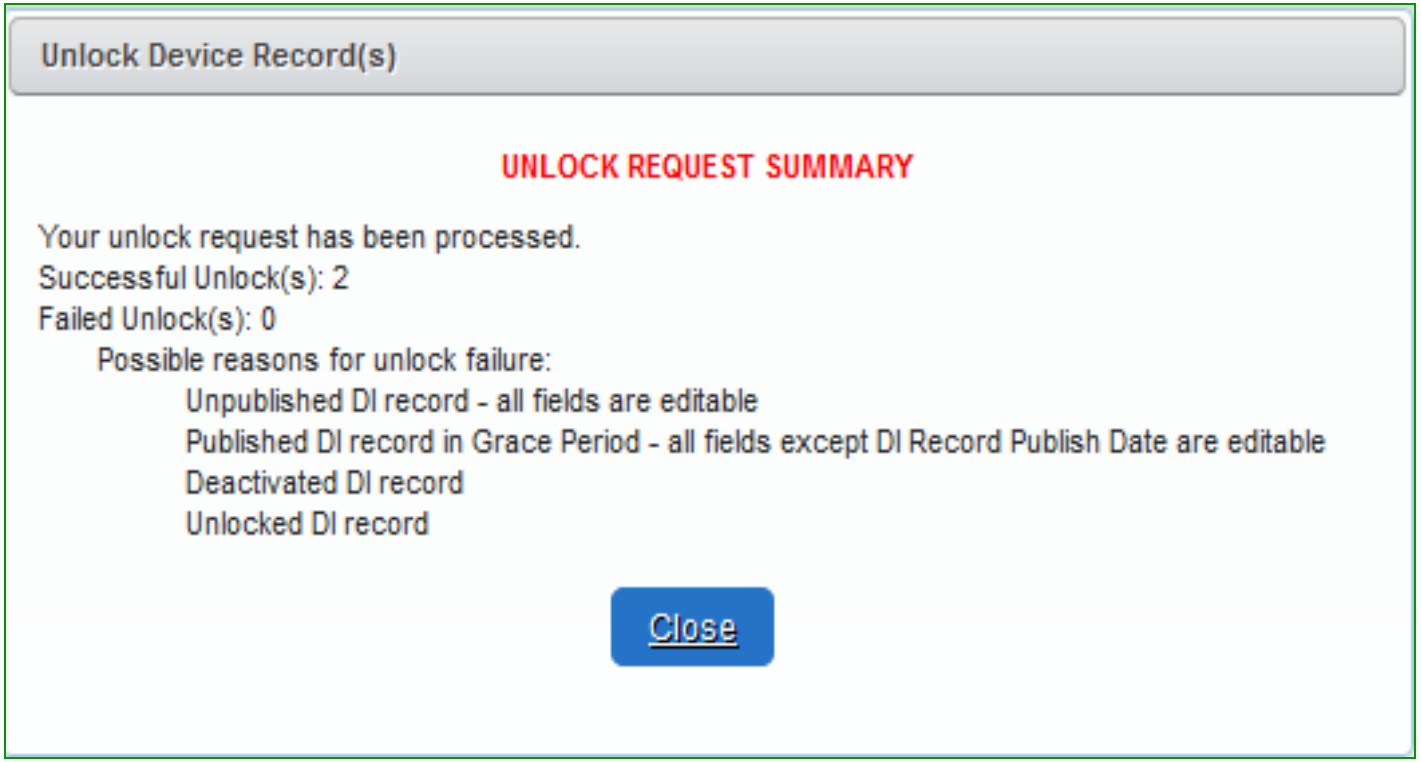
Unlocking Records



Reminder -- When to Use Unlock



Unlock Request Summary



System Sends an Email Confirmation

-----Original Message-----
From: GUDIDSystem@fda.hhs.gov [mailto:GUDIDSystem@fda.hhs.gov]
Subject: FDA GUDID - DI Unlock Process Report

Food and Drug Administration
Global Unique Device Identification Database

Dear Test1 Coordinator,

This email is to notify you that on Apr 18, 2018 11:58:37 AM you requested to unlock the following Primary Device Identifier(s) for editing.
Please note that Unlocking should ONLY be used to correct data submission errors. DO NOT USE UNLOCK TO SUBMIT EDITS THAT REQUIRE ASSIGNMENT OF A NEW DEVICE IDENTIFIER.
You need to assign a new Device Identifier and submit a new record if you are changing data elements that are "New DI Triggers" (i.e., not correcting submission errors).

GUDID Account Labeler Organization DUNS Number: 162773790
Labeler Organization Name: Safeway Inc.
Total Unlock Requested: 1

Successful Unlock(s): 1

Labeler DUNS Number	Primary Device Identifier
362151552	NEWTESTREC1

You have until 04/23/2018 to update all data elements except for the DI Record Publish Date, which cannot be changed.

Failed Unlock(s): 0

Records Unlocked – what next?

Records remain unlocked for 5 calendar days

DI Record Unlock Date	Unlock Period Start	Unlock Period Ends
Monday, May 7, 2018	Tuesday, May 8, 2018	Saturday, May 12, 2018

Records NOT removed from AccessGUDID & OpenFDA

Editing Unlocked Records

- All data elements editable except DI Record Publish Date
- No changes to how edits are submitted to GUDID

Edits may be submitted via either Submission Option

Initial Submission Option	Change of Submission Option prior to unlock?	After Unlock Edit Option
GUDID Web Manual Entry	No	GUDID Web Manual Entry
GUDID Web Manual Entry	Yes – updates via HL7 SPL	Web or HL7 SPL
GUDID HL7 SPL Submission	N/A	Web or HL7 SPL

Please make sure source system data is in sync with GUDID data

Records are locked…

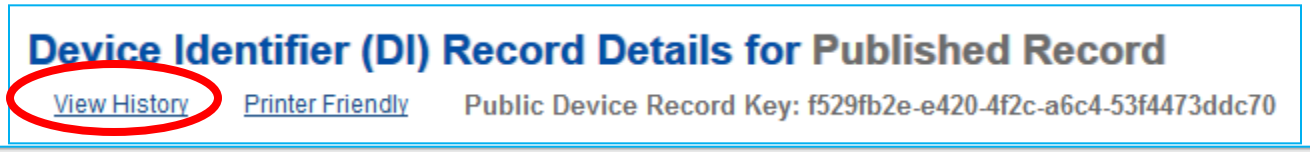
…. after successful submission of edits

OR

completion of the 5-calendar-day unlock period

Submitted updates released to public next scheduled release date

More Details Added to 'View History'



Device Identifier Record History

Public Device Record Key: 9720cbb1-64bc-417f-a41d-692cddae7c8b

Modified Date *	DI Number	DI Record Status	DI Record Edit Status	Modified By	Public Version Date	Public Version Number
2018-04-05 12:31 AM	REL22HTREC3	Published	After Grace Period - Limited Editing	System Process - Public Release	2018-04-05	3
2018-04-04 9:38 AM	REL22HTREC3	Published	After Grace Period - Limited Editing	Labeler Data Entry User - HT Lde1		
2018-03-12 10:20 AM	REL22HTREC3	Published	After Grace Period - Limited Editing	System Process - Public Release	2018-03-12	2
2018-03-09 3:33 PM	REL22HTREC3	Published	After Grace Period - Limited Editing	Labeler Data Entry User - HT Lde1		
2018-03-09 9:10 AM	REL22HTREC3	Published	Unlocked - All fields editable except Publish Date	Coordinator - HT cord1		
2018-02-27 12:30 AM	REL22HTREC3	Published	After Grace Period - Limited Editing	System Process - After Grace Period, Public Release	2018-02-27	1
2018-02-16 12:31 AM	REL22HTREC3	Published	In Grace Period - All fields editable except Publish Date	System Process - Record Published, Package Status Update - Active		
2018-02-14 11:48 AM	REL22HTREC3	Unpublished	All Fields Editable	Labeler Data Entry User - HT Lde1		

Version & History Information on AccessGUDID

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

DEVICE CHARACTERISTICS

DEVICE RECORD STATUS

Public Device Record Key: e6e6f600-5e0d-4f08-845a-9d875ee38483

Public Version Date: April 11, 2018

Public Version Number: 2

DI Record Publish Date: March 02, 2018

CLOSE

ALTERNATIVE AND ADDITIONAL IDENTIFIERS

CUSTOMER CONTACT [?]

DEVICE RECORD HISTORY | DOWNLOAD: XML | JSON | PRINT

Device Record History (e6e6f600-5e0d-4f08-845a-9d875ee38483)

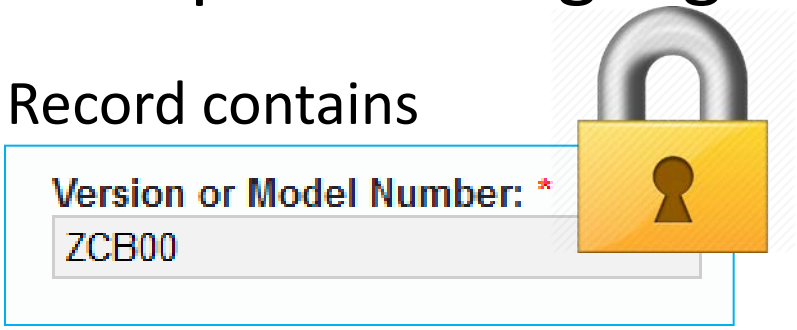
Primary DI Number	Public Version Date	Public Version Number	Public Version Status	Download
[redacted]	Apr 11, 2018	2 (current)	Update	XML
[redacted]	Apr 02, 2018	1	New	XML

Unlocking DI Record for Edits - WHEN TO USE

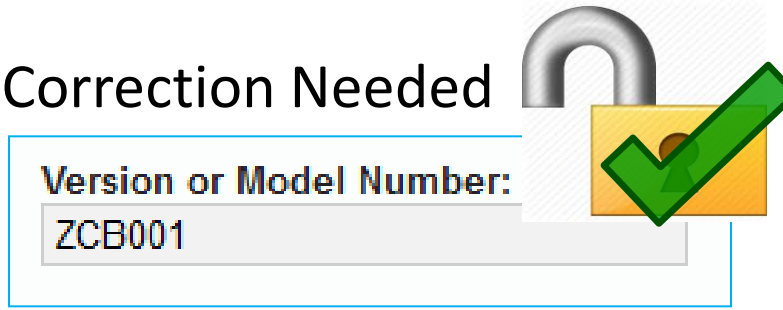
- Use for data corrections to existing records
  - Record publicly released, after-grace-period
  - Data elements with limited/no editing

Example: missing digit in Version or Model

Record contains



Correction Needed



Use Unlock for Corrections to Data Elements with Limited/No Editing After Grace Period

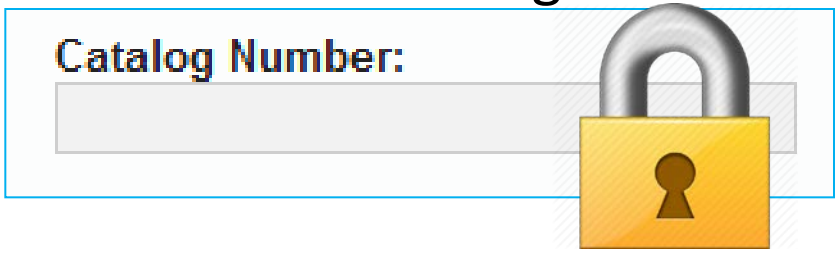
Issuing Agency	Device Identifiers - Primary, Secondary, Unit of Use, Previous, Package	Kit?
Brand Name	Device Count	Combination Product?
Version or Model	MRI Information	For Single Use?
Sterility Information	Latex Information	Size Information
Listing Number	Premarket Submission Information	

Unlocking DI Record for Edits - WHEN NOT NEEDED

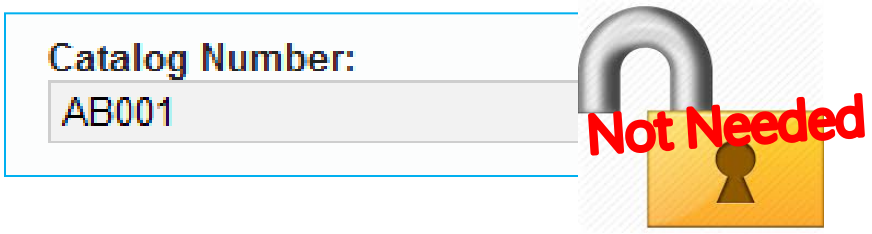
- Unlocking not needed to edit data elements with no edit restrictions after grace period

Example: Adding catalog number to a device record

Record has no catalog number



Need to add Catalog Number



Unlock NOT Needed for Correction to Data Elements with No Edit Restrictions After Grace Period

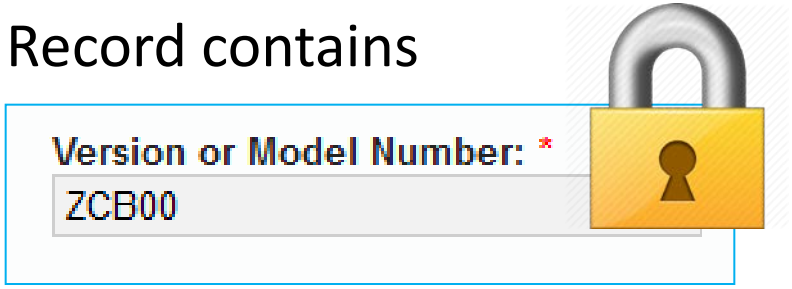
Catalog Number	Device Description	Direct Mark DI
FDA Product Code	Commercial Distribution End Date	HCT/P Product?
GMDN Code	Customer Contact Phone & Email	Prescription Use?
Sterilization Method	Production Identifier Information	OTC Use?
Storage & Handling Information		

Unlocking DI Record for Edits - WHEN NOT TO USE

- Do **NOT** use when new Device Identifier assignment is needed
  - Changes to DI Trigger elements that are not corrections
  - Issuing Agency guidelines for new DI assignment

Example: introduction of a new Version or Model

Record contains



New Version/Model

Unlock for Edits - Wrap-up

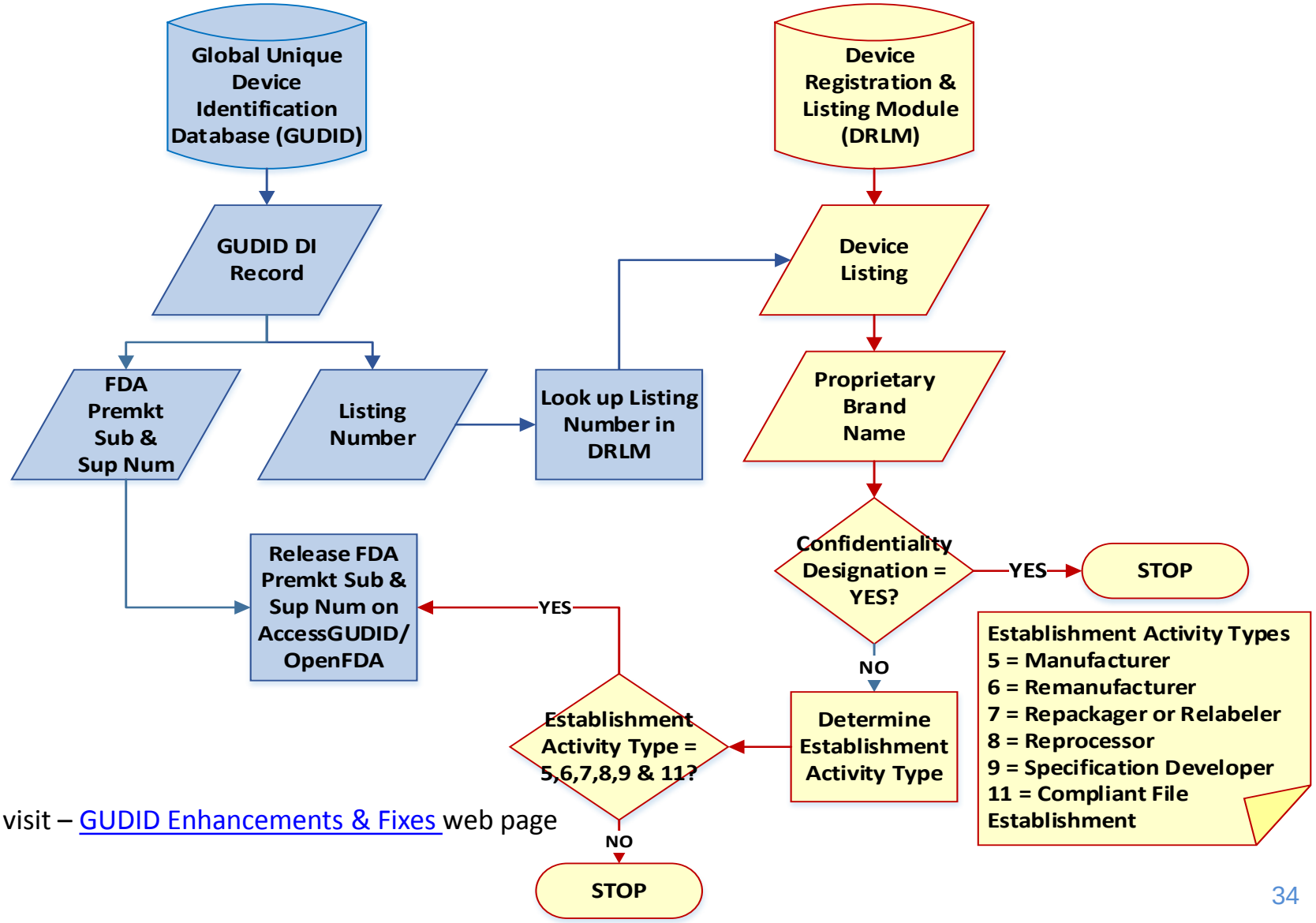
- Unlock functionality deployed and User Manual posted to website on March 30, 2018
- Use Unlock functionality for data corrections to existing records
- For new records, use the grace period for review and edits
- Remember that edit history is available to public users

Upcoming GUDID Enhancements

GUDID Release 2.3

- GS1 Check Digit validation for Device Identifiers
- Addition of Size List of Values
- Public release of DI Record Premarket Submission and Supplement Numbers

Logic to Determine Public Release of DI Record Premarket Submission Number*

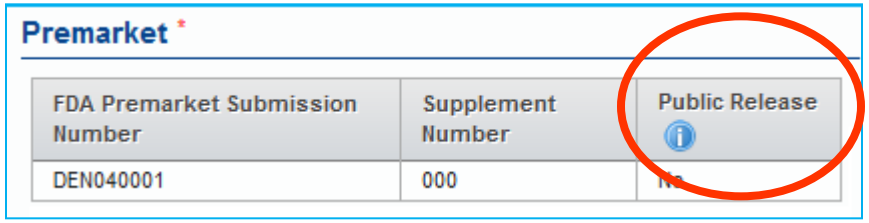


*For details visit – GUDID Enhancements & Fixes web page

Implementation in GUDID

- GUDID displays Public Release status for Unpublished & Published DI records

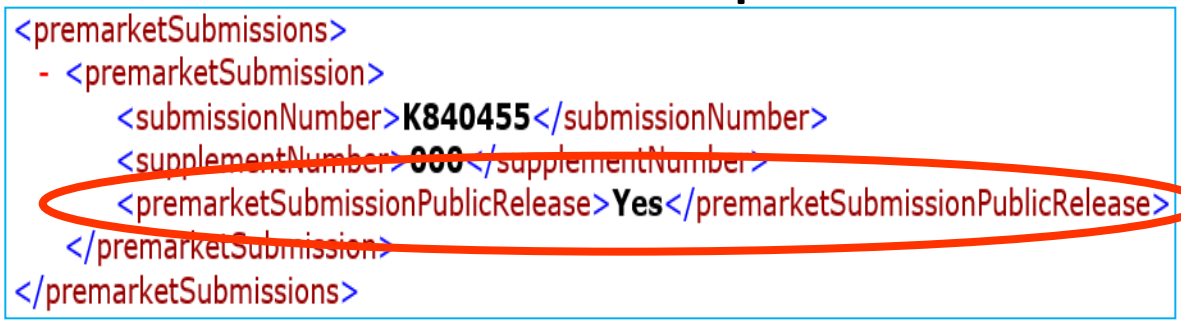
GUDID Web



Premarket *

FDA Premarket Submission Number	Supplement Number	Public Release
DEN040001	000	

GUDID Export

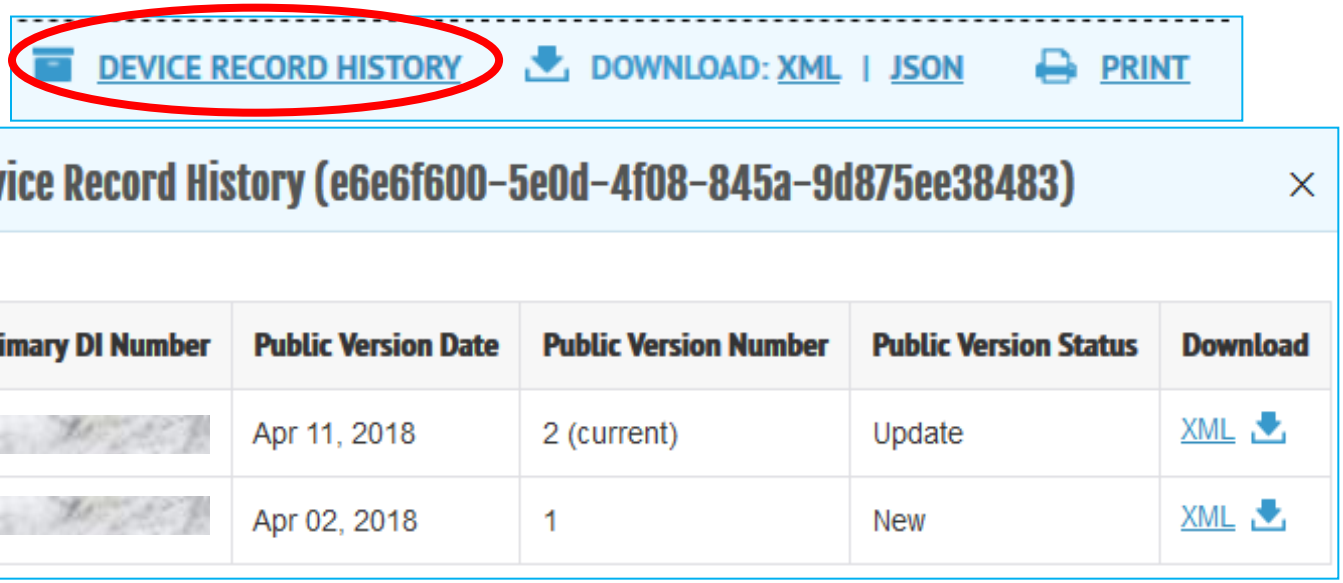


```
<premarketSubmissions>
  - <premarketSubmission>
        <submissionNumber>K840455</submissionNumber>
        <supplementNumber>000</supplementNumber>
        <premarketSubmissionPublicRelease>Yes</premarketSubmissionPublicRelease>
    </premarketSubmission>
</premarketSubmissions>
```

Making Changes to Public Release Status

- Public Release Status is derived from Device Registration & Listing (R&L) data
- To change Public Release Status, update data in R&L system
- Updates will take ~1 week to reflect in GUDID, refreshed every Sunday night

Once publicly released, data will continue to be available as part of 'Device History'



Best Practice: Check your data in Registration & Listing system BEFORE submission of GUDID DI Record

Communications on Public Release of Premarket Information

- September 2017: GUDID website updated with logic
- October 2017: Intent to release and logic information communicated via Annual Registration & Listing letter
- Feb & April 2018: reminder emails to review logic and data in R&L system

Tentative Release Schedule

- May 4, 2018
  - Logic implemented and deployed to GUDID
  - Labelers have ~8 weeks to review public release status
  - To change release status, update data in R&L system
  - Remember, changes take ~1 week to reflect in GUDID
- July 2, 2018
  - Public release of Premarket Numbers

Call for Action

- **Make 2018 the Year of GUDID Data Quality!!**
- Review all existing DI records in GUDID and make necessary corrections
- Tools available
  - Ability export all submitted records for review
  - Unlock functionality for correction of existing records

Call for Action

- Submit data that is accurate & complete
- Establish procedures to *review and edit* records during the DI record grace period
- Continue to maintain quality data


Q&A

Reminders

- Please sign up to receive email notifications
- Questions/Assistance – FDA UDI Help Desk, www.fda.gov/udi

Thank you!