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

- Labeler Submits DI Record
- Record Published on Publish Date
- Grace Period Starts – 30 calendar days*
- Labeler reviews & edits as needed
- DI record Grace Period Ends
- DI Record released to Public

*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*

Labeler identifies DI record(s) to edit
Sends email to UDI Help Desk
Labeler has 30 calendar days to edit record(s)

Average time to complete are in weeks

Review case and assign to team member
DI record unpublished for editing
Record assigned new Publish Date
Record starts grace period again
Record removed from AccessGUDID
Record released to Public after grace period

*for locked data elements with limited to no editing
To the Rescue: Unlocking DI Records For Editing
Less Burdensome Process for Corrections*

- Labeler identifies DI record(s) for edits
- Coordinator User unlocks DI records record(s) for edits*
- Labeler submits edits/corrections

Average time to complete are in days

- Record updated on AccessGUDID once corrections submitted

*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
    o 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

Manage Device

<table>
<thead>
<tr>
<th>DI Number</th>
<th>Brand Name</th>
<th>Version or Model Number</th>
<th>DI Record Status</th>
<th>DI Record Edit Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>47584759847549</td>
<td>US TEST COMPANY 157</td>
<td>Contour</td>
<td>Published</td>
<td></td>
</tr>
<tr>
<td>VTICCBA02</td>
<td>US TEST COMPANY 117</td>
<td>VTPreprodTest002</td>
<td>Unpublished</td>
<td></td>
</tr>
<tr>
<td>DEMORECORD1</td>
<td>US TEST COMPANY 157</td>
<td>demo record 4</td>
<td>Published</td>
<td>After Grace Period</td>
</tr>
<tr>
<td>BASEPACKAGEDIUOFU</td>
<td>US TEST COMPANY 157</td>
<td>Unit of Use DI example</td>
<td>Published</td>
<td>After Grace Period</td>
</tr>
<tr>
<td>MFDTFALSE1</td>
<td>US TEST COMPANY 117</td>
<td>RocheTestingMFDTPI</td>
<td>Published</td>
<td>After Grace Period</td>
</tr>
<tr>
<td>WEBICBA010</td>
<td>US TEST COMPANY 117</td>
<td>VTPreprodTest003</td>
<td>Published</td>
<td>After Grace Period</td>
</tr>
<tr>
<td>CHECKORADUPERROR</td>
<td>US TEST COMPANY 157</td>
<td>MAHURKAR</td>
<td>Unpublished</td>
<td>All Fields Editable</td>
</tr>
<tr>
<td>3211408265598</td>
<td>US TEST COMPANY 157</td>
<td>OSADA ENAC OE-505</td>
<td>Unpublished</td>
<td>All Fields Editable</td>
</tr>
</tbody>
</table>

Unlock Multiple DI - Search

Unlock
Ability to Filter Records

- DI Record Status:
  - Published
  - Unpublished
  - Deactivated

- DI Record Edit Status:
  - After Grace Period - Limited Editing
  - All Fields Editable
  - In Grace Period - All fields editable except Publish Date
  - No Edits
  - Unlocked - All fields editable except Publish Date
Unlocking Records

**Step 1: Select Records to Unlock**

- Select the records you wish to unlock.

**Step 2: Click Unlock**

- Click the 'Unlock' button to unlock the selected records.
Reminder -- When to Use Unlock

YOU ARE REQUESTING TO UNLOCK DI RECORD(S) FOR EDITING

Unlocking should ONLY be used to correct data submission errors

DO NOT USE UNLOCK FOR 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).

Contact FDA UDI Help Desk if you have questions.

You will have 5 calendar days, until 04/02/2018, to complete your edits.
All applicable edits, once submitted, will be released to the public on the next scheduled release date. Are you sure you want to proceed?

Confirm Cancel
Unlock Request Summary

Your unlock request has been processed.
Successful Unlock(s): 2
Failed Unlock(s): 0

Possible reasons for unlock failure:
- Unpublished DI record - all fields are editable
- Published DI record in Grace Period - all fields except DI Record Publish Date are editable
- Deactivated DI record
- Unlocked DI record
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
352151552  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

<table>
<thead>
<tr>
<th>DI Record Unlock Date</th>
<th>Unlock Period Start</th>
<th>Unlock Period Ends</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday, May 7, 2018</td>
<td>Tuesday, May 8, 2018</td>
<td>Saturday, May 12, 2018</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Initial Submission Option</th>
<th>Change of Submission Option prior to unlock?</th>
<th>After Unlock Edit Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>GUDID Web Manual Entry</td>
<td>No</td>
<td>GUDID Web Manual Entry</td>
</tr>
<tr>
<td>GUDID Web Manual Entry</td>
<td>Yes – updates via HL7 SPL</td>
<td>Web or HL7 SPL</td>
</tr>
<tr>
<td>GUDID HL7 SPL Submission</td>
<td>N/A</td>
<td>Web or HL7 SPL</td>
</tr>
</tbody>
</table>

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’

```
<table>
<thead>
<tr>
<th>Modified Date</th>
<th>Device Identifier (DI) Number</th>
<th>DI Record Status</th>
<th>DI Record Edit Status</th>
<th>Modified By</th>
<th>Public Version Date</th>
<th>Public Version Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-04-04 9:30 AM</td>
<td>REL22HTREC3</td>
<td>Published</td>
<td>After Grace Period - Limited Editing</td>
<td>Labeler Data Entry User - HT Lde1</td>
<td>2016-03-12</td>
<td>2</td>
</tr>
<tr>
<td>2016-03-12 10:20 AM</td>
<td>REL22HTREC3</td>
<td>Published</td>
<td>After Grace Period - Limited Editing</td>
<td>System Process - Public Release</td>
<td>2016-03-12</td>
<td>2</td>
</tr>
<tr>
<td>2016-03-09 3:30 PM</td>
<td>REL22HTREC3</td>
<td>Published</td>
<td>After Grace Period - Limited Editing</td>
<td>Labeler Data Entry User - HT Lde1</td>
<td>2016-03-09</td>
<td>2</td>
</tr>
<tr>
<td>2016-03-09 9:10 AM</td>
<td>REL22HTREC3</td>
<td>Published</td>
<td>Unlocked - All fields editable except Publish Date</td>
<td>Coordinator - HT cord1</td>
<td>2016-03-09</td>
<td>2</td>
</tr>
<tr>
<td>2016-02-27 12:20 AM</td>
<td>REL22HTREC3</td>
<td>Published</td>
<td>After Grace Period - Limited Editing</td>
<td>System Process - After Grace Period, Public Release</td>
<td>2016-02-27</td>
<td>1</td>
</tr>
<tr>
<td>2016-02-16 12:31 AM</td>
<td>REL22HTREC3</td>
<td>Published</td>
<td>In Grace Period - All fields editable except Publish Date</td>
<td>System Process - Record Published, Package Status Update - Active</td>
<td>2016-02-16</td>
<td>1</td>
</tr>
<tr>
<td>2016-02-14 11:40 AM</td>
<td>REL22HTREC3</td>
<td>Unpublished</td>
<td>All Fields Editable</td>
<td>Labeler Data Entry User - HT Lde1</td>
<td>2016-02-14</td>
<td>1</td>
</tr>
</tbody>
</table>
```

Public Device Record Key: 9720cbb1-64bc-4171-a41d-992cddae7c6b
Version & History Information on AccessGUDID

**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

**ALTERNATIVE AND ADDITIONAL IDENTIFIERS**

**CUSTOMER CONTACT** [2]

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

<table>
<thead>
<tr>
<th>Primary DI Number</th>
<th>Public Version Date</th>
<th>Public Version Number</th>
<th>Public Version Status</th>
<th>Download</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Apr 11, 2018</td>
<td>2 (current)</td>
<td>Update</td>
<td>XML</td>
</tr>
<tr>
<td></td>
<td>Apr 02, 2018</td>
<td>1</td>
<td>New</td>
<td>XML</td>
</tr>
</tbody>
</table>
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

Version or Model Number: *
ZCB00

Version or Model Number: ZCB001
Use Unlock for Corrections to Data Elements with Limited/No Editing After Grace Period

<table>
<thead>
<tr>
<th>Issuing Agency</th>
<th>Device Identifiers - Primary, Secondary, Unit of Use, Previous, Package</th>
<th>Kit?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>Device Count</td>
<td>Combination Product?</td>
</tr>
<tr>
<td>Version or Model</td>
<td>MRI Information</td>
<td>For Single Use?</td>
</tr>
<tr>
<td>Sterility Information</td>
<td>Latex Information</td>
<td>Size Information</td>
</tr>
<tr>
<td>Listing Number</td>
<td>Premarket Submission Information</td>
<td></td>
</tr>
</tbody>
</table>
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

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

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Device Description</th>
<th>Direct Mark DI</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Product Code</td>
<td>Commercial Distribution End Date</td>
<td>HCT/P Product?</td>
</tr>
<tr>
<td>GMDN Code</td>
<td>Customer Contact Phone &amp; Email</td>
<td>Prescription Use?</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Production Identifier Information</td>
<td>OTC Use?</td>
</tr>
<tr>
<td>Storage &amp; Handling Information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
Assign a new DI and enter a new DI record
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

```
<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
  o Logic implemented and deployed to GUDID
  o Labelers have ~8 weeks to review public release status
  o To change release status, update data in R&L system
  o Remember, changes take ~1 week to reflect in GUDID

• July 2, 2018
  o 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
Reminders

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

Thank you!