US FDA UDI Implementation Update & Lessons Learned

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Long...and fruitful journey

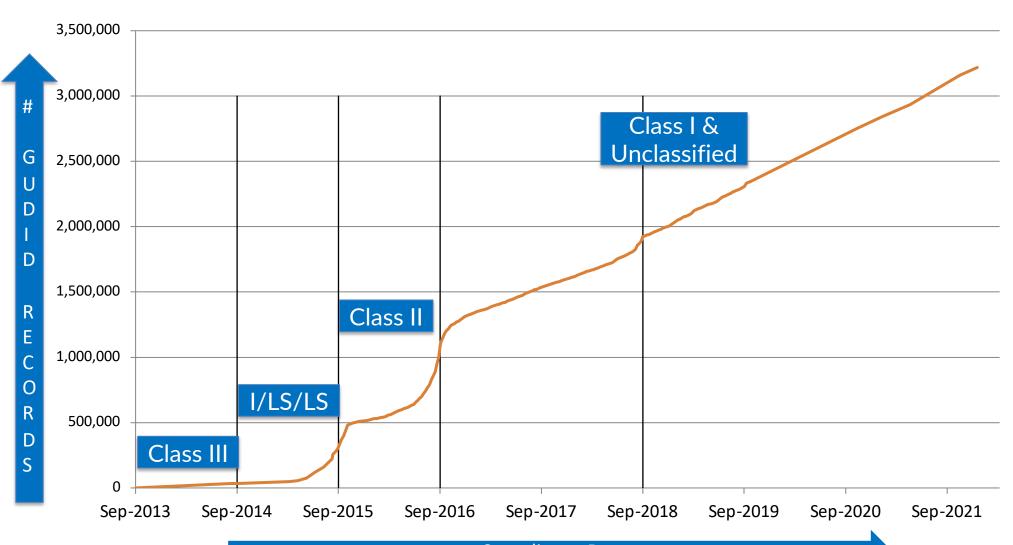
- September 2013: UDI Final Rule published
- September 2022: All applicable devices should have:
  - UDI on label &
  - Data in Global Unique Device Identification Database (GUDID)
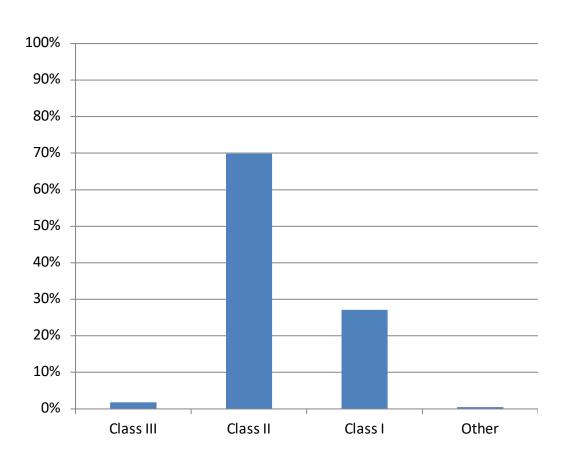
>3.2 million records in GUDID
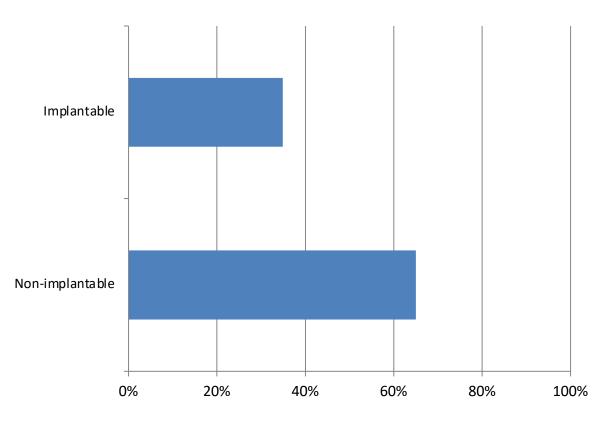## *Data Current as of January 10, 2022*

Most GUDID Records are Class II

~35% are Associated with Implantables
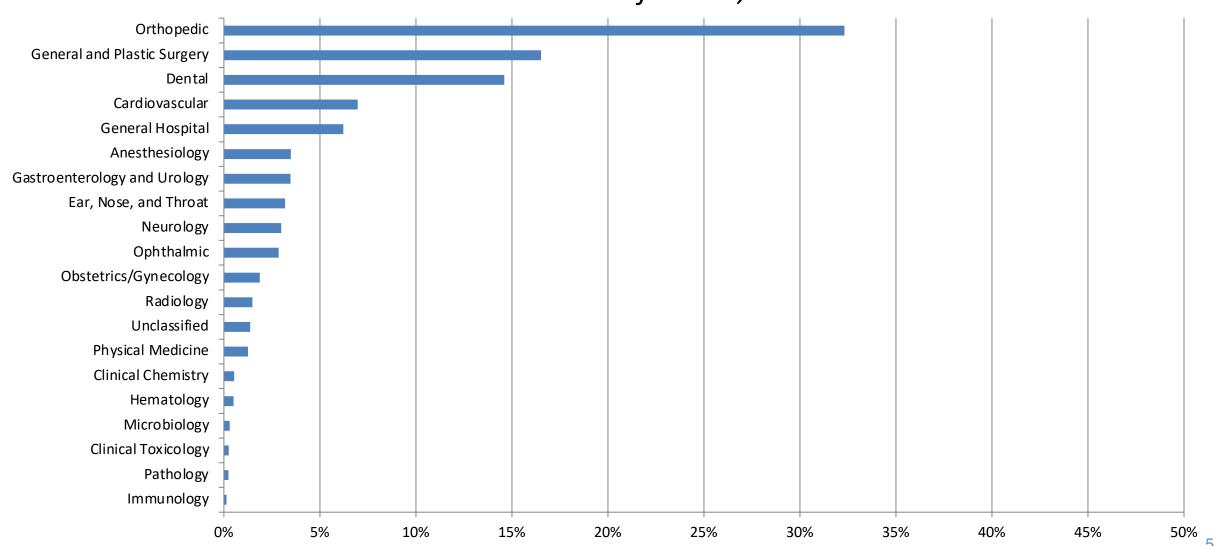*"Implantable" devices are those assigned FDA Product Codes associated with Implantable Devices, Systems and Accessories*

Data Current as of January 10, 2022

Medical Specialties in GUDID
Data Based on FDA Product Codes
Data Current as of Jan 10, 2022

Most Frequent FDA Product Code Terms in GUDID
Data Current as of January 10, 2022

AccessGUDID

- https://accessgudid.nlm.nih.gov/

- Public Access portal for GUDID data

- Managed by National Library of Medicine

- Daily data updates

- Search/Retrieval/Download of device data

- Useful APIs to query device information

Usage Data for December 2021

ACCESS GUDID

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Traffic Stats

Users	Sessions	Pageviews	Homepage Pageviews	Avg. Sessions per Day
45,439	131,777	976,788	57,410	4,250.87
↓ -5.6%	↓ -4.3%	↓ -6.5%	↓ -7.1%	↓ -7.4%

Location

1 — 83,706
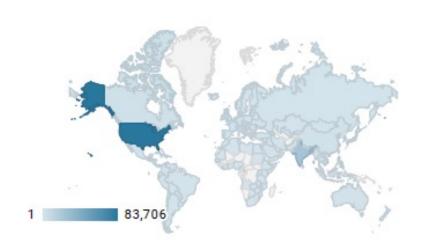
	Country	Sessions ▾
1.	United States	83.7K
2.	India	23.1K
3.	Canada	2.4K
4.	Philippines	2.4K
5.	China	1.7K
6.	Germany	1.4K
7.	Japan	1.3K
8.	United Kingdom	1.3K
9.	Vietnam	1K
10.	South Korea	828

United States Sessions	International Sessions
83.7K	48.1K
↓ -3.6%	↓ -5.6%

United States Pageviews	International Pageviews
521.1K	455.7K

8

Download & API Usage
December 2021

How many HTTP files were downloaded last month?
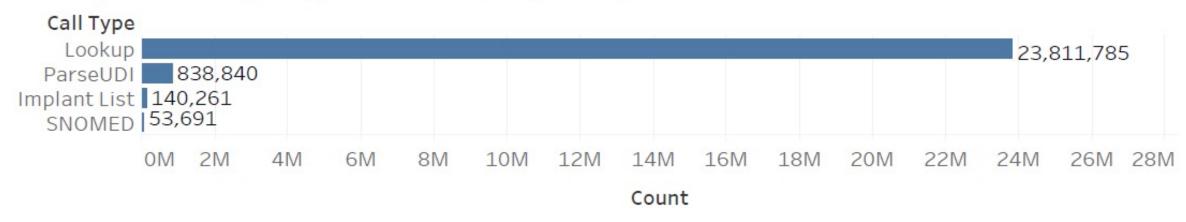
Total Events
1,466
▼ -10.8%

Unique Events
1,298
▼ -5.9%

API Request Analysis (Last month, Log data)

Call Type

Call Type	Count
Lookup	23,811,785
ParseUDI	838,840
Implant List	140,261
SNOMED	53,691

Count

Lessons Learned

UDI Policy

- Strive to Harmonize!! Leverage IMDRF work
- Establish realistic and achievable deadlines for industry & regulatory body
- Make policy & technical decisions based on real world use of UDI data
- Plan for challenging device types: kits, device systems, SaMD etc.
- Consider compliance policy for upkeep and maintenance of device identification data

Device Identification Database

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- Strive to Harmonize!! Leverage IMDRF work
- Spend time to establish clear definitions for data elements
- Use standard list of values
  - Consider values specific to each device area, e.g., Device Size
  - Yes/No drop downs vs. check boxes
- Consider how data will be used during system design
  - Begin pilot projects as data starts coming in
- Set up efficient and easy processes to enable data updates
- Establish strong data validation rules

Stakeholder Outreach & Education

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- Early & often: listening sessions, webinars, user-groups, FAQs etc.

- Leverage external stakeholders to multiply common messages

- Establish a help-desk for stakeholder inquiries

Adaptive

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- Initiate UDI-use/value demonstration projects throughout the supply chain and at point of care
  - Document & share demonstrated value & lessons learned
- Support & encourage learning communities and user-groups
- Establish processes to prioritize and take action on noted gaps

Moving Global UDI Efforts Forward

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Adequate identification through Distribution and use…

Centralized repository of device identification

UDI in Regulatory data (annual reports, adverse events, recalls, etc.)

UDI in Real World Data sources (EHRs, Registries)

Fully leverage UDI for patient safety

US FDA UDI Program Resources

- FDA UDI Website: www.fda.gov/udi
- Public access to GUDID data:
  - AccessGUDID: https://accessgudid.nlm.nih.gov/
  - Open FDA: https://open.fda.gov/apis/device/udi/

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It always seems impossible until it's done

-Nelson Mandela