UDI: RAPID

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March 20, 2019

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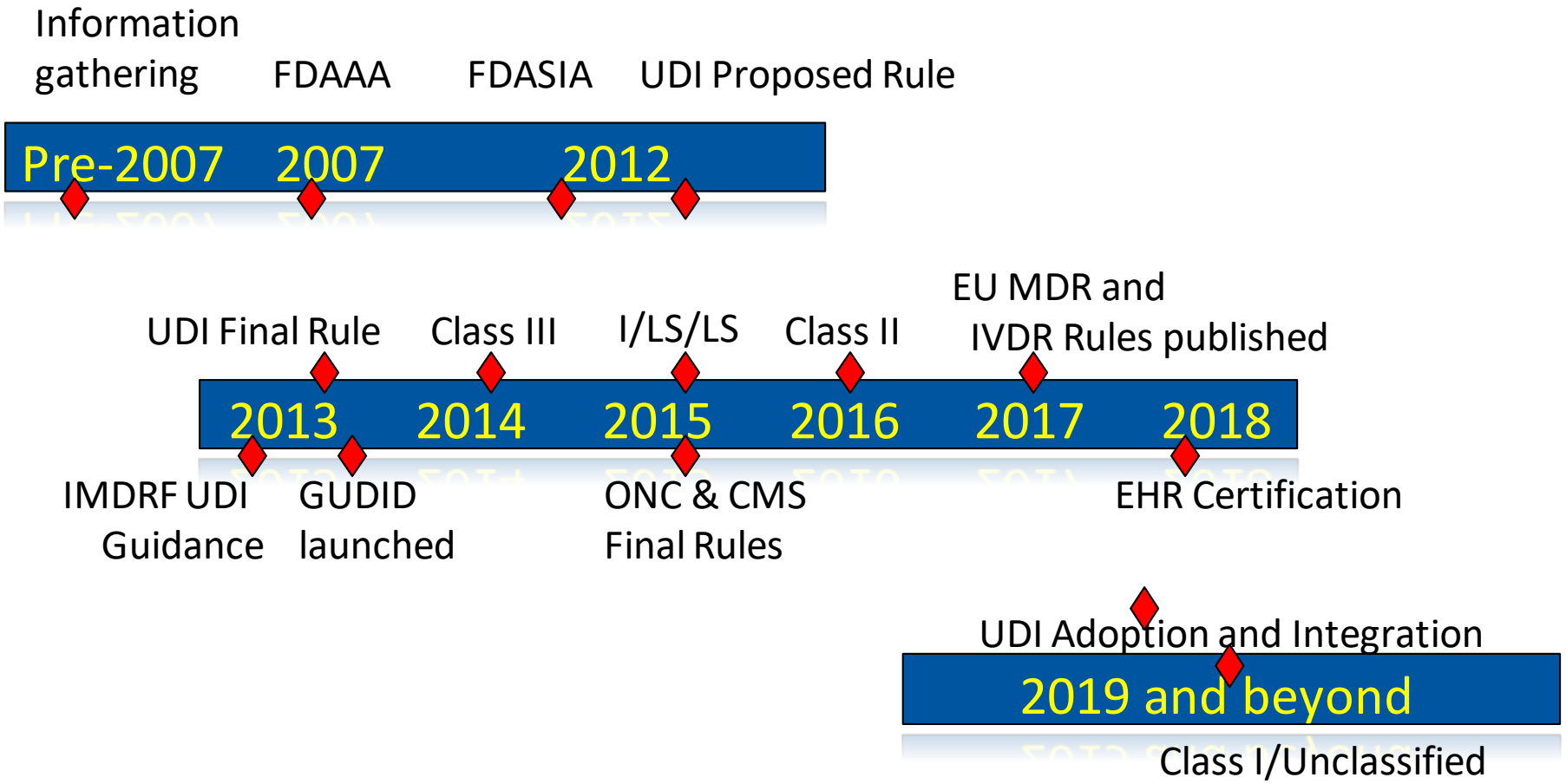
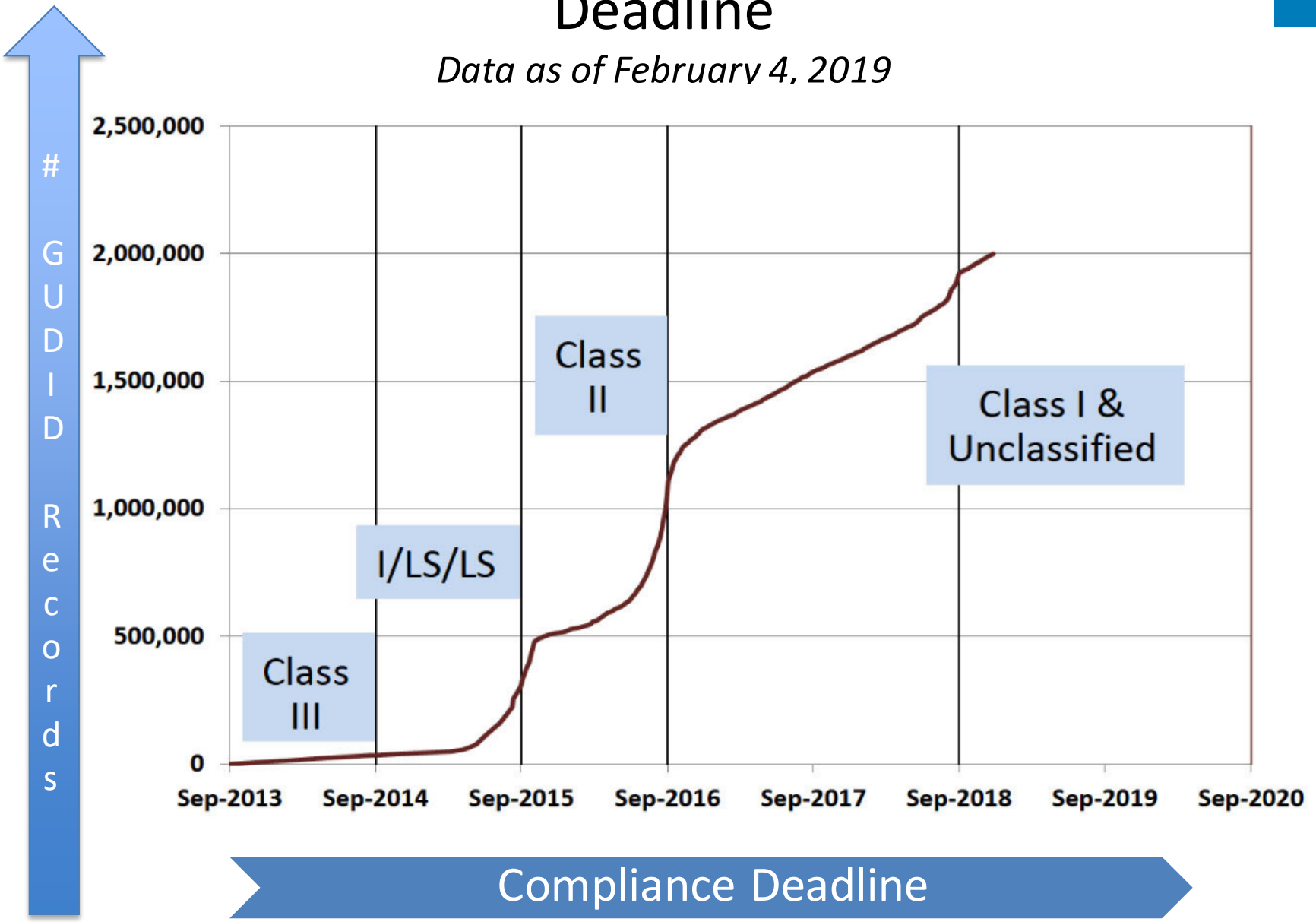
US FDA UDI System Timeline



GUDID Records and Submission Compliance Deadline

Data as of February 4, 2019



The Role of UDI in RWE

FDA Guidance August 31, 2017

Relevance

- UDI provides the necessary level of '*detail to capture the use of the device, exposures, and the outcome'*
- UDI contributes to '*the data elements available for analysis are capable of addressing the specified question*'

Reliability

- UDI and data in GUDID improve
  - *Data Accuracy*
- UDI DQ efforts assist with
  - *Data Assurance – Quality Control*

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Control over UDI quality - Barriers

Regulatory Data Submissions – multiple pathways

- Premarket application
- Data for label and labeling
- Data submitted to GUDID
- Data collected in health records and registries for use in regulatory decisions

Gap in incentives for consistent capture of UDI

- Lack of understanding of the 'Why of UDI' across the device lifecycle
- If you don't know 'Why of UDI', given low priority and seen as cost vs. benefit

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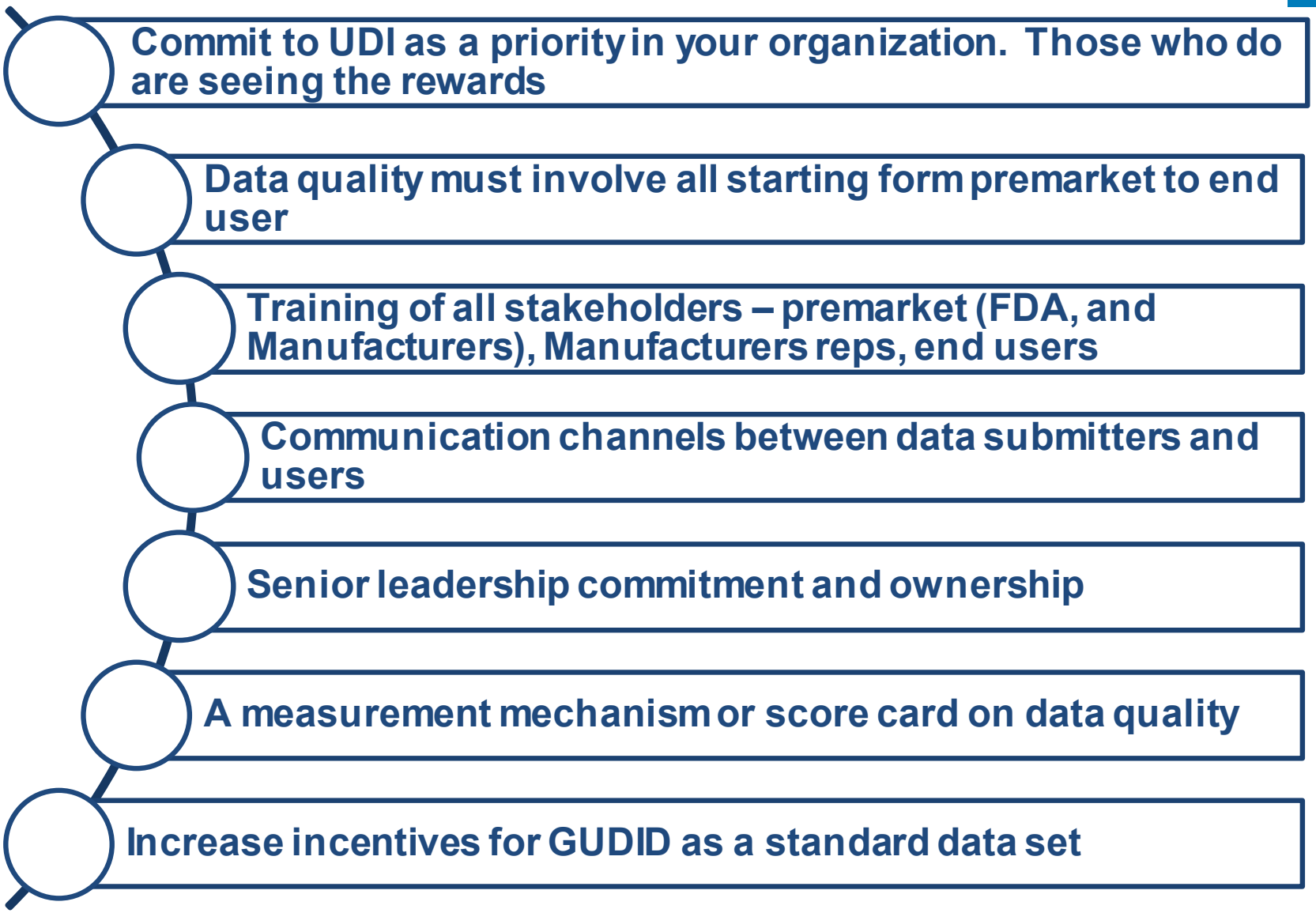
Control over UDI Quality - Solutions



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GUDID Data Analysis for RAPID
Find Peripheral Vascular Devices

Criteria to extract Peripheral Vascular Devices

By Product Code?

PROCODE	PREFERRED_NAME	DI count
MCW	Catheter, peripheral, atherectomy	**702**
NIO	STENT, ILIAC	**1,641**
NIP	STENT, SUPERFICIAL FEMORAL ARTERY	**2,554**
NIU	Stent, superficial femoral artery, drug-eluting	**60**
ONU	Drug-Eluting Peripheral Transluminal Angioplasty Catheter	**832**
PPN	Percutaneous [illegible] Ultrasound	**124**
[illegible]	[illegible]ered s arterial	[illegible]

By GMDN?

GMDN that are close to selected Product Code?

GMDN Type	DI Count
Catheter	**66**
Grafts	**142**
Guidewires	
Recanalization	**12,604**
Stents	**1,888**
	14,547

Categorization Challenges

- Categorization fit for purpose - Clinical care
- Consistency of assignment
- Regulatory data
- Multiple Nomenclatures
  - GMDN
  - SNOMED
  - CND (CLASSIFICAZIONE NAZIONALE DISPOSITIVI MEDICI)
- Additional challenges detailed in AHRMM LUC Device Categorization workgroup paper

Clinical Sizes Created by RAPID Informatics

Size Dimensions	# used in GUDID
Atherectomy Cutter Diameter	2
Balloon Diameter	15
Balloon Length	15
Balloon Nominal (Inflation) Pressure	12
Balloon Proximal Outer Diameter (OD)	12
Balloon Rated Burst Pressure	12
Catheter Inner Diameter	1
Catheter Length	34
Catheter Working Length	13
Guidewire Diameter	30
Guidewire Length	16
Introducer Sheath Compatibility	16
Shaft Length	3
Stent Diameter	61
Stent Length	59

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Shared Responsibility

Go beyond compliance with UDI regulation

Reduce gap between what UDI **users need** and what **manufacturers/third parties submit** and **what FDA monitors in AccessGUDID.**

- Improve the scan-ability of UDI at point of care
- Develop terminologies that allow standard clinically relevant data in GUDID
- Improve reliability of GUDID data to support the use of this data in real world evidence

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