



Catalog Number Work Group Charter

WORK GROUP TOPIC: Importance of Catalog Number in GUDID Information

WORK GROUP LEADERS:

Ricki Wilson, Vizient, Director of Standards Implementation

ricki.wilson@vizientinc.com 630-965-5236

Jim Booker, Stanford Health Care, Manager, Master Data Management, Supply Chain

JBooker@stanfordhealthcare.org 650-721-2166

PARTICIPATING MEMBERS:

Organization	Name	Title
Albany Medical Center	Bob Matthews	Assist VP Supply Chain
AORN	Denise Downing	Nurse Informaticist
BJC HealthCare	Tom Stenger	Manager MMIS and Analysis
Bon Secours Health System	Timothy Heist	Director, Supply Chain Data Management and Analytics
Champion Healthcare Technologies	Charity Carney	Senior Director of Software Development
Corning Life Sciences	Olga Stridiron	Quality Systems Specialist
Device Events	Madris Tomes	Founder and CEO
Geisinger Health System	Tasha Gowin	Contract Pricing Analyst II, SSS-Purchasing
Geisinger Health System	Dave Jurewicz	Supply Chain Information System Analyst
Genesis Automation USA	Guillermo Ramas	CEO
Infor	Chris Wiekert	Sr. Product Manager
Philips Healthcare	Mike Hudon	Director of Global Regulatory Affairs
Philips Healthcare	Zita Yurko	Director of Regulatory Affairs
Philips Healthcare	Jodi King	UDI Program Director
Procured Health	Anuj Kapoor	Director
Roche Diabetes Care	Joyce Trese	UDI Indianapolis Site Project Leader



Stanford Health Care	Jim Booker	Manager, Master Data Management, Supply Chain
Terumo Medical Corporation	Lauren Nitahara	Regulatory Affairs Specialist
The Franciscan Missionaries of Our Lady Health System	James Phillips	Consulting Manager DSI
University of Tennessee Medical Center	Becky Ashin	Vice President, Advanced Orthopaedic Center
USDM	Jean Sargent	
USDM Life Sciences	Jay Crowley	VP and Practice Lead – UDI Services and Solutions
VUEMED, Inc.	Lana Makhanik	Chief Operations Officer
Workday	Keith Lohkamp	Director, Industry Strategy
Cerner Corporation	Susan Morris	Supply Chain Healthcare Executive

CHARTER:

The mission of the Catalog Number workgroup is to provide the business case and industry value for requiring catalog number in GUDID submissions. In order to use the information in the GUDID, most stakeholders will need to match existing data sets to the GUDID, and manufacturer catalog number is the key data point that has been used historically for identifying product information.

BACKGROUND:

FDA Global Unique Device Identification Database (GUDID) compliance currently does not include Catalog Number as a required field when submitting unique device identifiers (UDI). If UDI is to replace Catalog Numbers in the healthcare industry, there will be a period of time when both must be available to assist with a cross-walk between the two data points.

The Version or Model number is required however it is not always a suitable substitute for a catalog number as it can be different from the catalog number, and in some instances, it only exists in the GUDID database and cannot be found on the supplier website or any other search engine. (example: AA14HS60NSC168N).

Please note, any examples used are not intended to highlight a particular supplier but rather highlight the issue.



Below is the definition of catalog number and model/version number per the FDA.

(Source: [FDA Data Element Reference Table](#)):

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period ¹	Required in Database? ²	Data Type & Length ³	Entry List of Values (LOV)	New DI Trigger
Version or Model	The version or model found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler.	Enter the Version or Model. Version/Model can be any distinguishing string of letters and/or numbers. Catalog Number can be entered if device does not currently have a Version or Model. If the device does not have a version, model or catalog number, enter a concept that can be used to identify all devices that have specifications, performance, size, and composition within limits set by the labeler.	None	Required	Type: Alphanu m. Length: 80	NA	YES
Catalog Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.	Enter the Catalog or Reference Number. Catalog/Reference number can also serve as Version/Model if it represents the devices that have specifications, performance, size, and composition within limits set by the labeler.	Add Delete Edit	Optional	Type: Alphanu m. Length: 80	NA	no

AFFECTED STAKEHOLDERS:

Manufacturers, distributors, providers, clinicians, solution companies, GPOs, etc. will be using GUDID data in the future.

Perspective of Data Users:

- Catalog number is most commonly used identifier of product in healthcare industry today
- Matching GUDID data to existing databases requires a cross-walk between Device Identifiers and Catalog Numbers
- Version or Model Number is not a reliable substitute for Catalog Number as a Version or Model Number can cover several different products. (i.e. Different sizes)



REQUIRED STAKEHOLDERS:

Stakeholder Breakout (as of 10/12/16):

- 7 Providers
- 5 Manufacturers
- 8 Solution Providers
- 1 Industry Organization
- 1 GPO

Potential recruiting needs:

- Distributor
- Additional GPOs

DELIVERABLES:

- Develop the business case and industry value for inclusion of catalog number in GUDID submissions to drive compliance and adoption within the industry, determine if FDA can change from optional to required and how existing records can be edited and updated.
- If GUDID requirements cannot be changed, develop guidance to be shared by FDA with suppliers on best practices when submitting new records, and to strongly recommend catalog number be included.
- Develop recommendations to be shared in various communities for suppliers to submit catalog number in GUDID.

COMMUNICATION PLAN

- Review and dissemination
 - Submission of recommendations to FDA and NLM
 - Posting to Learning UDI Community web page
 - Posting via FDA channels
 - White Paper/Manuscript opportunity
- Identify meetings and media for specific messaging

Meetings	Media Outlets
<ul style="list-style-type: none"> • ARHMM • HIDA • HIMSS • HDMA • HSCA • SMI • GHX Summit 	<ul style="list-style-type: none"> • HPN • HHN • Beckers • Fierce Health • Modern Healthcare