GMDN

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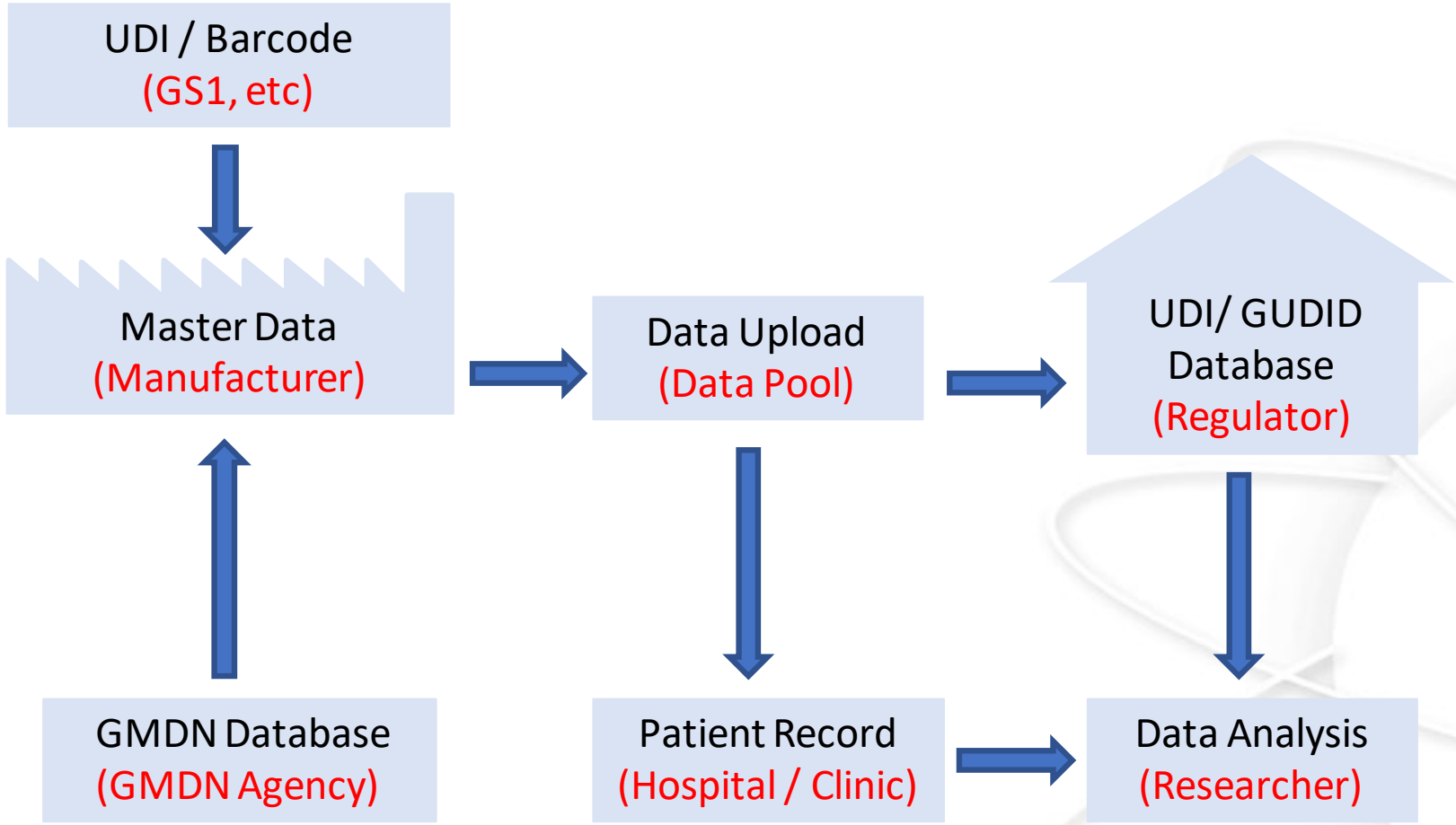
Who is GMDN ?

- The Global Medical Device Nomenclature (GMDN) is a system of internationally agreed generic descriptors used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.
- The main purpose of the GMDN is to provide health authorities and regulators, health care providers, medical device manufacturers and suppliers, conformity assessment bodies and others with a single generic naming system that will support patient safety.

- The GMDN is used for:
  - Data exchange between manufacturers, regulators and healthcare authorities
  - Exchange of post-market vigilance information
  - Supporting inventory control in hospitals
  - Purchasing and supply chain management

Provides a consistent and accurate data classification for Manufacturer, Regulatory, Clinical, & Post Market Surveillance



Who uses the GMDN

- US FDA requires GMDN in their national regulation of Unique Device Identification (UDI Rule)
- European Commission uses the GMDN for their current market surveillance database (EUDAMED) and are evaluating use for their new regulation (MDR & IVDR)
- The UK Regulator (MHRA) requires the use of GMDN by the UK NHS
- Used by 90 other countries to regulate medical devices
- Widely supported by device Trade Associations (GMTA, DITTA, Advamed, MedTech Europe, etc) in promoting global harmonization & reducing costs of compliance

The GMDN is the global standard

Use of GMDN in the USA

- The FDA is updated every 2 weeks with GMDN data in GUDID
- NLM provide GMDN Terms within SNOMED dataset every 6 months
- FDA GUDID will include GMDN Codes in future development
- The GUDID database provides basic information on all devices
- The GMDN Agency are willing support data for AUDI and NEST
- As UDI data is collected by other countries (i.e. EU, NHS), this can also be used to increase the bank of information for anaysis

How can *we use* GMDN to increase data interoperability and support analysis & post-market follow-up?

- What Projects would you like to see?
- Is this a classification database that can be enhanced?
- Data exchange project for common core data elements with GMDN globally?
- Consistent regulatory exchange language?
- AUDI - Augmented Unique Device Identifier information?
- Analysis of claims data to identify safety signals in post-market surveillance datasets?