RAPID toward NEST: Lessons learned, common themes and potential opportunities

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RAPID: Basic Principles for Success

- **Develop uniform, harmonized definitions specific to a particular area**
- **Establish quality by design principles to ensure data quality and ability of registry to withstand audit**
- Leverage existing data standards including the implant data in the Global Unique Device identification Database (GUDID) to increase efficiency and reduce errors in key device information
- Collaborate and coordinate across RAPID and other initiatives to address common identified gaps and share lessons learned
- Solving common issues supports infrastructure of National Evaluation System

RAPID Insights

Important: Linking data sources using the Device Identifier (DI) of UDI and other data in GUDID

- DI – model level identification captured in all sources; validated in GUDID
- Since DI is new, need to include additional GUDID attributes to integrate into existing sources – e.g. item master, registry
- GUDID data attributes that can be used to match to existing data:
  - Catalog Number
  - Device categorization - GMDN/SNOMED
  - Clinically relevant size
- Need for cross-stakeholder workgroup to evaluate and define progressive practices for collection and use of key attributes

RAPID Insights

Device Categorization

- GMDN – assigned and required in GUDID
- SNOMED – recognized clinical standard
- Other categorizations exist

- Current GMDN/SNOMED term assignment, governance, maintenance and costs/access to current code sets
- Purpose and use across device ecosystem
- Further work and broader stakeholder representation

RAPID Insights

Clinically Relevant Size

- Current GUDID capture of this data
  - Need for enhancement of existing controlled vocabulary
  - Need for complete data for implants
- Purpose and use across device ecosystem
- Further work and broader stakeholder representation

RAPID Insights

Additional UDI data attributes

- GUDID data is core for device identification
- Barriers to ad hoc additions to existing data attributes
- Clinical and registry requirements to collect more data associated with a device
- Need for a clinical workgroup to define data elements by device category
- BUILD and MDEpiNet co-sponsoring the AUDI work

Opportunities for Coordination & Collaboration

- MDEpiNet RAPID
- Learning UDI Community
- Sentinel
- BUILD Consortia
- HSPC

AHRMM – Leading a Learning UDI Community

FDA ⟺ **Device Labelers**

- Healthcare supply chain
- Distributors
- Value Analysis Professionals

- Device users
- Care providers
- Patients
- Device Surveillance

Learning UDI Community

Active Work Groups

- Unit of Use
- Recognition of AIDC
- ***Clinically Relevant Size***
- ***Device Categorization***