Unique Device Identification (UDI) in Administrative Transactions

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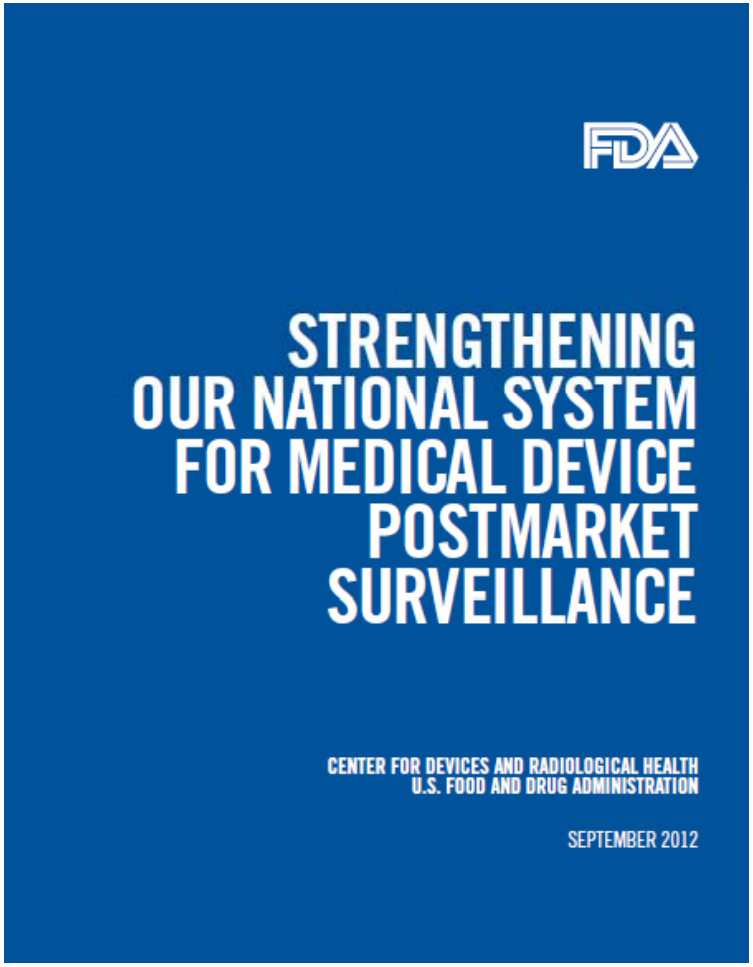
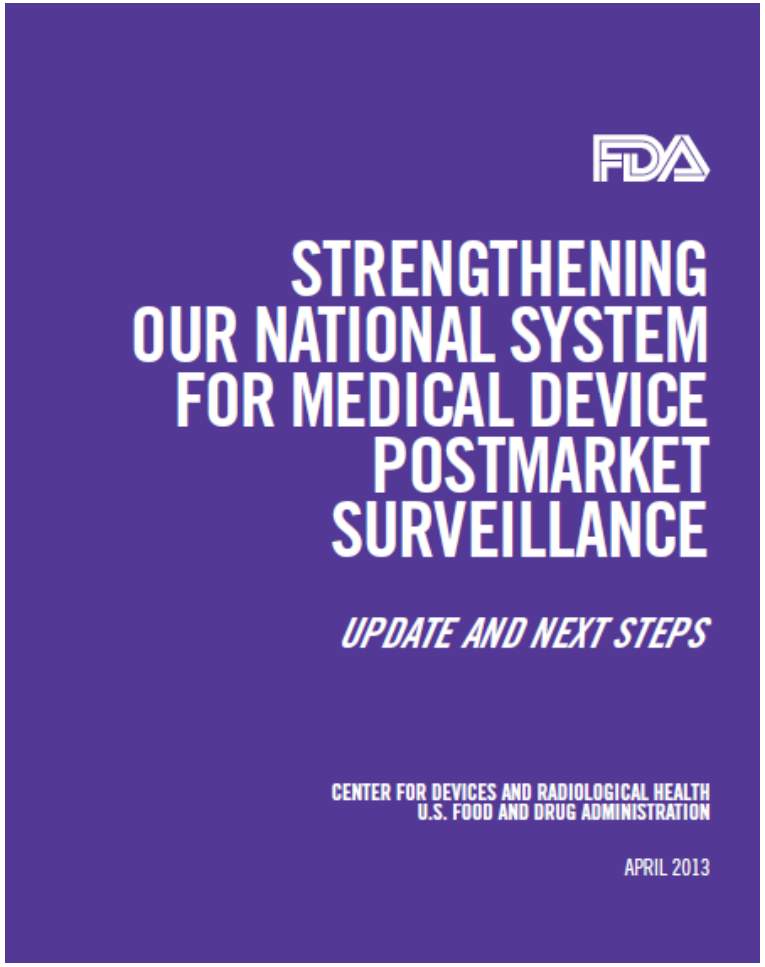
Center for Devices and Radiological Health
CDRH

Strengthening Our National System

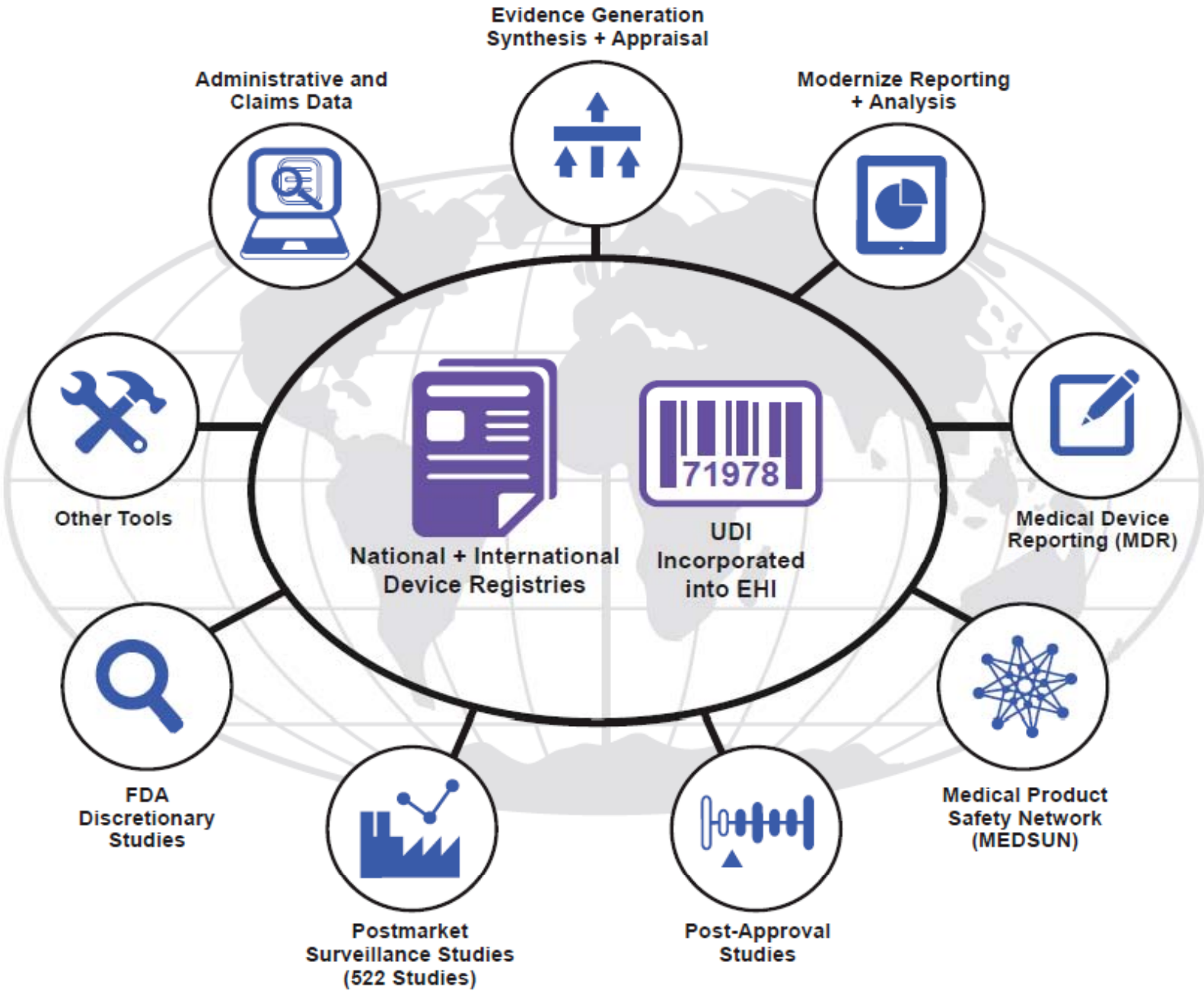
Taking the Next Steps





Proposed Specific Actions to Strengthen Device Postmarket Surveillance

1) Establish a UDI System and Promote the Incorporation of UDI into Electronic Health Information (EHI)
2) Promote the Development of National and International Device Registries for Selected Products
3) Modernize Adverse Event Reporting and Analysis
4) Develop and Use New Methods for Evidence Generation, Synthesis, and Appraisal


Evidence Generation
Synthesis + Appraisal
Administrative and
Claims Data
Modernize Reporting
+ Analysis
Other Tools
National + International
Device Registries
71978
UDI
Incorporated
into EHI
Medical Device
Reporting (MDR)
FDA
Discretionary
Studies
Medical Product
Safety Network
(MEDSUN)
Postmarket
Surveillance Studies
(522 Studies)
Post-Approval
Studies

Purpose, Value, Benefits

- UDI provides standard, unambiguous means to document device use in various EHI
- UDI in claims provides a complementary data source
  - Can generate population-based data on device exposures
    - Useful for assessing public health and/or regulatory planning, impact
  - Can generate population-based data on health outcomes of interest (related to specific device exposures)
    - Useful for assessing device benefit/risk in real-world setting
  - Can provide longitudinal profile of patient experience
    - Potentially useful for baseline active surveillance (e.g., implant revision rates)
    - Useful for easier and more accurate linkage across data sources
- UDI in claims may facilitate recall effectiveness

Steps Taken to Implement UDI

- Implemented a fully functional global UDI (GUDID) database
- Advocated for incorporation of UDI into EHRs as part of EHR certification (technical specifications and meaningful use)
- Completed a pilot demonstrating challenges in incorporating UDI into hospital information systems
- Completed Brookings-convened thinktanks to inform UDI "roadmap" on challenges in incorporating UDI into claims, EHRs, and providing patient and provider access
- Participated in WEDI/Pew stakeholder meetings on facilitating capture and transmission of UDI

CDRH Use of Claims Data

- Multi-Payer Claims Database
  - Pilot under auspices of ASPE and CMS
  - CMS and commercial payer data
- SafeRx
  - CMS initiative launched with Part D
  - Medicare and Medicaid data
- Registry Linkage
  - FDA in collaboration with professional societies

Sentinel Initiative and Devices

- Sentinel focused on drugs/biologics
- Expansion of Sentinel to include devices required under FDA Safety and Innovation Act of 2012
- Current records accessible to Sentinel lack manufacturer or brand-specific device identifiers
- Device Uses
  - utilization of hip arthroplasty devices by articulating surface
  - safety evaluation of robotically-assisted surgery

Additional Considerations

- Ability to assess real world benefit/risk of devices anticipated to have positive impact on healthcare costs and inefficiencies
- Need to identify specific versions of device to understand public health impact of that version
- Absent UDI, payers are limited in ability to reimburse for specific devices based on value

Conclusions

- UDI in claims provides a complementary data source to strengthen national postmarket surveillance
- UDI is a key data element that can transform claims data and its impact on public health
- FDA recognizes the challenges faced by multiple stakeholders in incorporating UDI into claims
- Question is what is the appropriate path forward to make it happen in pragmatic and cost-effective manner?