Registry Assessment of Peripheral Interventional Devices (RAPID)
Phase II Global Unique Device Identification (GUDID)/
Informatics Work Group Summary

Introduction

The Registry Assessment of Peripheral Interventional Devices (RAPID)[1] project was initiated as part of the PASSION program in MDEpiNet[2] to create and demonstrate a practical framework for the capture of real-world data (RWD) for evidence generation. The approach focused on addressing inconsistencies in nomenclature and data infrastructure (including device identification) in the treatment of peripheral artery disease (PAD via peripheral vascular intervention (PVI)). The RAPID project team is comprised of partners from three medical professional societies, seven US Regulatory agencies, twelve medical device manufacturers, and more than a dozen other entities representing both National and International organizations. RAPID has recently been recognized as a demonstration project for the National Evaluation System for Health Technology (NEST) [3,4].

RAPID includes three phases:
- Phase I – Identification and clinical definition of core PAD / PVI concepts (including the Unique Device Identifier (UDI) and associated data from AccessGUDID, the public portal for data from the Global Unique Device Identification System (GUDID)), and standardization of the core concepts as common data elements to facilitate utilization of data from multiple sources in both pre- and post-market assessment of PAD interventional devices.
- Phase II – Incorporation of the standardized data elements into two major registries (Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and American College of Cardiology National Cardiovascular Disease Registry – Catheterization: Peripheral Vascular Intervention (ACC NCDR CathPVI), as well as into the procedure documentation systems of at least one health information technology vendor.
- Phase III – Establishment of a device evaluation project (e.g. randomized clinical trial, device surveillance registry) using these data sources to demonstrate the benefit of interoperable device data collection for academia, clinicians, industry, payors, CMS, FDA, and other global regulatory agencies.

Phase I has been completed, including the use of UDIs and data from AccessGUDID as part of a defined set of core data collected and used for pre- and post-market assessment of PAD interventional devices. Refer to (http://mdepinet.org/rapid/) for more details including Phase I Working Group members and work products. **Phase II** was modified from the original plan because Phase I core data elements were only included in records specific to certain device types in the SVS VQI not allowing for sufficient analysis across data types; in addition, incorporation of data from the ACC CathPVI registry is still pending. The alternative to Phase II included creation of the SFA-Popliteal EvidencE Development (SPEED) statistical analysis that created contemporary Objective Performance Goals for SFA and Popliteal interventions using real-world data available from the SVS VQI registry to support regulatory decision-making for new devices. It also included the creation of an outreach webinar aimed to raise awareness for this project

[1] MDEpiNet RAPID website. http://mdpinet.org/rapid. Last accessed 10/29/2018.
[2] MDEpiNet website. https://nestcc.org/demonstration-projects/. Last accessed 10/29/2018.
[3] National Evaluation System for health Technology coordinating Center. https://nestcc.org/. Last accessed 10/29/2018.
[4] Shuren, J, Califf, R. Need for a National Evaluation System for Health Technology, JAMA. 21016; 316(11):1153-1154. https://jamanetwork.com/journals/jama/fullarticle/2533407. Last accessed on 10/29/2018

and continued exploration about challenges and opportunities related to linkage to GUDID by registries and health care providers. **Phase III** efforts are currently being planned to build upon the lessons learned and relationships developed in RAPID Phases I and II to further explore workflow, data and communication optimization strategies that would increase the likelihood of incorporating Phase I core data elements (including UDI) into all applicable registries so that they can be used as additional sources of improved device evaluation data. Phase III will incorporate independent development of Augmented Unique Device Identifier (AUDI) data elements and AUDI repository for PAD devices and creation of data standards that support documentation of clinically precise anatomic locations where devices are implanted/used in the peripheral anatomy. The purpose of this paper is to describe the RAPID Phase II GUDID/Informatics workgroup findings that will inform these specific Phase III initiatives.

Background

UDI has been prioritized and prominently featured in the RAPID project because of its importance in advancing the global harmonization of device identification and the significant foundational role it plays in FDA strategic priorities. The U.S. FDA, as mandated by federal law and using principles agreed to by the International Medical Device Regulators Forum (IMDRF)[5], has led global efforts to establish a Unique Device Identification (UDI) system. Implementation of the UDI System will facilitate the unambiguous identification of medical devices through distribution and use by providing a single global identifier that can be used to link and integrate existing government, clinical, hospital, and industry databases. Use of the UDI allows for improved procurement, inventory management, and accounting throughout the supply chain. The UDI consists of a UDI-DI (device identifier) for each model/version of a device and UDI-PI (production identifier) that include information such as lot, serial number, expiration date, manufacturer date, and distinct identification code. The existence of a single UDI-DI to link disparate data bases allows creative new medical and business applications, and synergy among those applications.

By 2020, it is expected that most devices sold in the U.S. will contain a UDI on their label. In addition to applying UDI on the device label, those devices subject to the UDI requirements must also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID). In partnership with the National Library of Medicine, FDA provides public, searchable and downloadable access to data in the GUDID via a portal named AccessGUDID. The availability of UDIs in both human-readable and machine-readable format on medical device labels has opened up opportunities to unambiguously distinguish one device from another for supply chain, clinical, regulatory and research purposes. Building on this, the 2018 FDA Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health[6] is aimed at improving patient safety, detecting safety risks earlier, and keeping doctors and patients better informed by integrating UDI in electronic health information (e.g. EHRs, registries) and implementing UDI use across the healthcare enterprise to more efficiently capture and search for specific device attributes captured in UDI.

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[5] IMDRF UDI Working Group. IMDRF UDI Guidance, December 9, 2013. See: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf (last accessed 22Jul2018).

[6] Medical Device Safety Action Plan: Promoting Patients: Protecting Public health. See https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf (last accessed 23Aug2018).

In RAPID Phase I, the Informatics and GUDID Workgroups met RAPID project goals by using MDEpiNet, a multi-stakeholder public-private partnership as the governance structure for establishing key data elements (including UDI) to be incorporated into the target PAD PVI registries. During Phase I, the Informatics and GUDID workgroups independently created two related deliverables to support improved consistency and capture of relevant data in registries: the RAPID Core Data Elements and the GUDID Integration Workgroup Project Summary, an analysis highlighting the challenges to GUDID integration among RAPID stakeholders. The Informatics workgroup engaged key clinical and informatics stakeholders who came to consensus on a set of 100 core data elements specific to peripheral vascular registry requirements. These elements were further defined and documented in standard templates. The Informatics methods and templates developed in Phase I provide the foundation for RAPID Phase II analytics and have also been made available for use as a model for other coordinated registry networks (CRNs) across the device ecosystem[7]. The GUDID Integration analysis highlighted the value of UDI capture in health systems and registries and the need to overcome initial integration challenges. The goal of both the Informatics and GUDID workgroups was to promote knowledge sharing that would increase the likelihood that regulatory authorities, device manufacturers, clinicians, and researchers could rely on core data (including UDI) pulled from standard repositories like AccessGUDID and the NLM Common Data Element (CDE) repository to populate registry data sources, rather than inconsistent device identification and clinical data manually abstracted from clinical documentation. The core data supports the exact identification of a device, patient, procedure or assessment and the linkages between device use and the patient receiving treatment.

As Phase II was launched, the GUDID and Informatics workgroups realized shared similarities in purpose and membership interest and expertise. These two workgroups joined together to accomplish their collective goals of establishing a method to integrate interoperable common data elements into registries, exploring opportunities and challenges with GUDID implementation in EHR systems and registries, and further developing the AUDI data elements.

The first major Phase II accomplishment was the inclusion of the Informatics core data elements (including UDI-DI and key GUDID data into the SVS VQI registry for device types of interest to RAPID. SVS VQI initially pulled all Global Medical Device Nomenclature (GMDN) terms associated with stent or stent graft treatment for lower extremity PAD. They narrowed their search on devices indicated for occlusive or aneurysmal disease. After a year of collecting device information, SVQ VQI analyzed the devices that their members entered as "other" as these were not included in the initial download from GUDID. SVS VQI discovered many devices were being used off-label for PAD treatment (e.g., coronary stents), so they expanded the GMDN term search to include these devices. SVS VQI continues to monitor devices that are not part of their query on a quarterly basis to assess the need to pull any further GMDN terms to adequately capture the list of devices use in PAD treatment. This integration provided specific use cases wherein real-world issues could be addressed via use of the core data concepts defined in Phase I.

The experiences in GUDID adoption shared by the SVS VQI provided real-world applications that informed:
- The critical fields needed to support use of UDI.

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[7] Jones WS, Krucoff MW, Morales P, Wilgus RW, Heath AH, Williams MF, Tcheng JE, Marinac-Dabic JD, Malone ML, Reed TL, Fukaya R, Lookstein R, Handa N, Aronow HD, Bertges DJ, Jaff MR, Tsai TT, Smale JA, Zaugg MJ, Thatcher RJ, Cronenwett JL, Nc D, Md SS, Japan. Registry Assessment of Peripheral Interventional Devices (RAPID)- Registry Assessment of Peripheral Interventional Devices Core Data Elements. Circ J. 2018 Jan 25;82(2):316-322. doi: 10.1253/circj.CJ-17-1156. Epub 2018 Jan 23. PM:29367497

- Development and actualization of Association for Healthcare Resources and Materials Management Learning UDI Community (AHRMM LUC) workgroups focused on gaps or issues related to the following:
    - Device categorization as related to the RAPID project;
    - Clinically-relevant device dimensions, from the RAPID PVI device perspective;
    - Multiple device identifiers being assigned to the same device model;
    - The need for Catalog number to be captured in the GUDID.

The SFA-Popliteal EvidencE Development (SPEED) project

The SPEED project is a component of RAPID Phase II and operates in parallel but separate from the activities of the GUDID/Informatics workgroup. The analyses of SPEED OPGs utilize the VQI registry of real-world data for elective/urgent superficial femoral (SFA) and popliteal artery endovascular interventions for chronic arterial occlusive disease but do not include the core data elements (including UDI) of Phase I. The study population includes patients who have had percutaneous transluminal angioplasty (PTA), stent and/or atherectomy treatments with index and follow-up procedures from January 2010 to September 2016. The study evaluates for the endpoints of mortality, major amputation of index limb, target lesion revascularization (TLR), target vessel revascularization (TVR), target lesion occlusion and technical failure/inability to cross lesion.

SPEED is designed to demonstrate the feasibility of data extraction from a registry and to lay the groundwork for a coordinated registry network (CRN). This type of framework could potentially be used for designing registry-embedded clinical trials in the future. Since the CDEs and GUDID were not actively collected during the period selected for the analysis, these data were not included as part of the SPEED analysis dataset. However, in future efforts, relying on the CDEs and high-quality GUDID data will enhance the accuracy of registry information by (1) offering assurance on the correctness of the registry data and (2) providing an avenue for validation.

Advantages realized by incorporating RAPID Phase 1 CDEs (including UDI) across clinical documentation systems and registry databases are better data consistency, quality, and validity. Examples of data concerns that could have been addressed more effectively by collecting well-defined core and UDI-related data include the lack of a standardized approach to describing lesion length and device classification.. Examples of data concerns that could have been addressed more effectively by collecting core and UDI-related data include issues with lesion length and device subtypes. More specifically, lesion length data such as a total treated lesion length may have been inappropriately excluded because the entries were in millimeters rather than centimeters. With robust GUDID information (i.e., lengths of the stents used), the actual total treated length can be identified, verified, and corrected. Similarly, lack of specificity of stent type (bare metal versus drug eluting stent and balloon-expandable versus self-expanding stent) and balloon type (plain versus drug coated balloon) may lead to further patient exclusions from the analyses. Improving device categorization terms in GMDN and linking to records in

the GUDID will close gaps in structured data capture, improve efficiency, and ensure the validity of the SPEED analysis.

Ultimately, it is anticipated that the SPEED dataset will support pre- and post- market analysis, quality improvement initiatives, and safety surveillance of PVI devices. The SPEED approach set the paradigm for a CRN of the future that includes structured, interoperable data collected at the point of care, available for use by patient registries, clinical research and medical device evaluation initiatives and will facilitate peripheral interventional device development, address regulatory needs and create efficiencies reducing time, costs and quality improvement efforts across the medical device lifecycle.

Addressing Gaps: GUDID and structured data to support RAPID SPEED

As might be expected with any complex new system, implementation and use of the GUDID by RAPID data partners has revealed several challenges. Device data and meta-data submitted to the GUDID for the PIV device type has proven inconsistent and variable due to incomplete clarity in some requirements, variations across individual company IT structures, and the enormous amount of work for manufacturers to organize, collect and submit data to GUDID as the device ecosystem transitions from text-based representations of devices to standardized structured data. Efforts by registry partners (e.g. SVS/VQI and ACC/NCDR) to match their medical device data elements to the GUDID has demonstrated some of the practical challenges. In particular, since the UDI-DI is a new field for registries, a pre-requisite for matching GUDID data to existing device registry data is that one or more data fields be successfully used to consistently match data between the registries and GUDID. As SVS VQI attempted to match GUDID data to their data they found matching to be challenging due to variations in how manufacturers populated the "Version or Model" and "Catalog Number" fields in the GUDID—due at least in part to different understandings of how these terms should map to internal corporate nomenclature. A lower level cause was inconsistent data entry of the formatting of these fields (e.g. use of '-'or ',' or no delimiter to separate parts of the product number). The mapping work also identified records in the registries for devices that were not actually available from the designated manufacturer, indicating that there may have been errors in manual entry of these data into the registry data libraries. SVS VQI no longer matches against their master device library for devices that use UDI-DI and GUDID. The current challenge is if a manufacturer does not consistently enter, clean or update information in GUDID as new devices enter the market.

The approach of some manufacturers to populate clinically relevant size (CRS) data elements in the GUDID has been especially challenging. Analyses of the GUDID records for the currently-marketed coronary drug-eluting stents revealed that stent dimensions were embedded within the device description (rather than in discrete data fields) for all three manufacturers. Device size fields were not populated at all for one manufacturer, and for the other two, the information was populated as free-form data entries. In all cases, the data was present in an unstructured format, rendering it non-interoperable. The diverse causes for these variations include: 1) unavailability of complete value set

selection lists (e.g., the term "Length" could be applied to stent length or to delivery catheter length, with no specific term available for either size parameter); 2) difficulty in understanding the process and securing the necessary clinical input for determining which parameters are clinically relevant (e.g., the Mercy demonstration project [Tcheng AmJHeart2014 http://dx.doi.org/10.1016/j.ahj.2014.07.001] reported that more than a full day of effort was needed to define the CRS for only a single device type); and 3) practical choices in finding resources to populate the optional CRS data fields within the broader context of hundreds of required data elements for thousands to tens of thousands of devices for each manufacturer.

Addressing Gaps: Device Categorization

In RAPID Phase II, the GUDID/Informatics Workgroup identified devices by their UDI-DIs, which could then be linked to GUDID device attributes. The WG identified a limitation of GUDID as the lack of categorization of devices as they are used clinically. Categories of devices with shared attributes, e.g. peripheral arterial stents, are needed, along with identification of devices (with their associated UDI-DIs) belonging to those categories. A preliminary analysis of the challenges in creating such categories in the GUDID is being addressed by the AHRMM LUC Device Categorization Workgroup, which is made up of clinicians, researchers, manufacturers, an FDA representative, and representatives of the two device categorization systems being evaluated by the group – Global Medical Device Nomenclature (GMDN) and Systemized Nomenclature of Medicine Clinical Terms (SNOMED CT).

GMDN and SNOMED CT are terminologies that have differing purposes and emphases. Although GMDN originated for regulatory purposes (i.e., to support implementation of the original Medical Device Directive in the European Union) and is still principally employed for post-market surveillance by regulators, it is not formally restricted to regulatory use. SNOMED CT's primary focus is clinical documentation and clinical care. Manufacturers are required to include a GMDN term in GUDID submissions, but the codes associated with the term are not available in AccessGUDID. SNOMED CT codes had originally been mapped in a one-to-one relationship to GMDN terms but are now diverging due to variability in the approach to term generation between the two organizations. In addition, due to access restrictions on GMDN codes and required, but free licensing for access to SNOMED codes, neither terminology offers unrestricted access to their code sets. Because of GMDN's large manufacturer customer base, GMDN names and definitions are changed as technology evolves but associated codes may or may not remain the same at the discretion of the GMDN Agency. SNOMED CT, as a controlled vocabulary, may not always agree with the logic the GMDN Agency applies in creating new terms based upon an internal need of SNOMED for consistency in meaning of its codes and concepts. So, when GMDN terms are updated, the one-to-one mapping with SNOMED CT may become broken due to differences in coding assignment methodology between the two terminologies. An additional challenge is that neither GMDN codes nor the SNOMED CT/GMDN mapping table are available to AccessGUDID users without GMDN licenses.

An analysis of the utility of GMDN terms for creating clinically useful device categories was carried out for the Device Categorization Workgroup by one of the GUDID Informatics Workgroup Chairs (JT). [Reference] The analysis was performed using a clinical categorization and subcategorization of devices

commonly used in peripheral artery intervention with the categories being atherectomy devices, stents, and balloons. The GMDN ontology did not discriminate among primary clinical device categories. Further, out of the 10 device subcategories, there were only 3 explicit matches at the Final Term level. For each of the remaining 7 subcategories, no directly matching, single / unique, clinical category specific term was identified.

GMDN, then, does not appear useful for capturing all devices as clinically used; such would have to be identified from other sources. For instance, a category of all stents used in the treatment of SFA disease could be created by clinical experts and all such devices could be identified in the VQI Registry or another source. The associated GMDN codes/SNOMED terms for the identified devices could then be obtained and used to extract GUDID device data including UDI-DIs. Further, the user-defined category could be updated on a regular basis and mapped to GMDN codes as one method to identify newly marketed devices from GUDID. There is also a possibility that the clinical categories created in this way might be housed in GMDN where they would be available for use by others. This approach has the advantage of including devices that may be used off-label but is predicated on the availability of GMDN codes to the user. Additionally, if GMDN is unable to house these categories, other options would have to be explored. For instance, the World Health Organization is funding a demonstration project that would test the potential of building clinical categories using their existing controlled terminology expertise.

If device categories such as those created to support the RAPID analyses are to be maintained beyond the time of the initial RAPID projects, questions of system governance and maintenance will need to be resolved. These issues were also addressed with respect to supplemental device data by the MDEpiNet Augmented UDI (AUDI) Workgroup, which made specific recommendations regarding them (insert reference for the final AUDI recommendations – unpublished; not sure of citation format – check w/ Jonathan McCall or one of the Writers in Communications). Having the same multi-stakeholder group provide governance both for AUDI data and for the related device categories is an approach to be considered along with the AUDI Workgroup proposed formal link to the NEST Coordinating Center and international efforts to create clinical device nomenclatures by organizations such as the World Health Organization[8].

Addressing Gaps: Clinically Relevant Size

A series of GUDID/Informatics workgroup sessions focused on identifying (size) dimensions of the PAD PVI devices in RAPID Phase II. Due to varying interpretations of the term 'clinically relevant size' and the lack of a workable device categorization schema, there was no a priori consensus regarding the clinically relevant size parameters. To address the need, an AHRMM LUC workgroup, the Clinically Relevant Size Workgroup was convened. Key principles identified by the WG included the need for device size data to

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[8] World Health Organization Request for input and collaboration towards international 2 classification, coding and nomenclature of medical devices:
http://www.who.int/medical_devices/priority/ConceptNoteNomenclaturemedicaldevicesv13forconsultation.pdf?ua=1)

be captured consistently and as discrete data, and the dependency of size data on a clinically oriented device categorization schema (reference – CRS WG report).

Of note, other groups have compiled resources for managing clinically relevant size for PVI devices, particularly the Endovascular Today (ET) Device Guide[9]. The GUDID/Informatics WG intends to use this published resource as a baseline for establishing a set of consensus-based sizes. The ET staff joined the GUDID/Informatics workgroup, providing expertise and background on how their clinically relevant size dimensions had been developed, the extent of their use in clinical settings and their willingness to include the data set as part of publicly available data in GUDID. Subsequently, the GUDID/Informatics workgroup selected candidate dimensions for the stent device type and developed a consensus on dimensions that would provide value if available in the GUDID data set. The FDA UDI team worked with the National Cancer Institute to create new size dimensions and relevant C-codes for these new terms, terms which are now available in the NCI EVS (see Appendix 1). All C-codes created for GUDID including the size dimension are listed at https://evs.nci.nih.gov/ftp1/FDA/CDRH/GUDID/About.html. In addition, the FDA UDI program has incorporated this new set of size dimensions as a code set available for use by GUDID submitters.

While this set of clinically relevant size dimensions for stents has expanded the number of size dimensions available to GUDID submitters, the extent of structured size dimensions still remains limited. We expect to generalize the process for defining clinically relevant size dimensions developed in RAPID Phase II across device types, resulting in more choices for submission of clinically relevant size dimensions by manufacturers.

Summary and Conclusions

The work of the GUDID/Informatics workgroup in Phase II of the RAPID project envisioned a healthcare system where device management (with the UDI as the index or key), clinical care (featuring interoperable clinical data – not just documents), and the processes and the systems thereof are orchestrated, coordinated, and efficient from manufacturer to supply chain management to clinical application, documentation, and care and on to the use of that data in analytics and electronic data transfer to registries. Advancing the concept of the integrated system was approached by selecting a complex, real-world clinical care context – the interventional treatment of peripheral arterial disease (PAD). The MDEpiNet RAPID group has succeeded in creating an end-to-end environment featuring data ability for data to flow between the systems , where use of real-world data by device manufacturers, healthcare systems, clinicians, regulatory authorities, and researchers is enabled, while identifying the limitations (i.e., opportunities) of the current environment that need to be collectively addressed. These opportunities can be logically grouped into the following categories.

1. Logistics of utilizing the UDI by healthcare systems. This includes both physical implementations (bar code scanners, software, hardware, database structures, interfaces between systems) along with transformed workflows that handle the UDI integrated into healthcare processes.

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[9] Endovascular Today Device Guide https://evtoday.com/device-guide/

2. Capture of device meta-data. For the GUDID to be of optimal use to healthcare systems, clinicians, researchers, registries, and regulators, device meta-data (e.g., clinically relevant parameters such as size, composition, performance characteristics) must be categorically managed (i.e., as discrete data – not text). This requires further evolution of the database structures housing device meta-data, extension of reference management systems for device categorization (organized by the clinical perspective), refinement of the management of meta-data coordinated between FDA and the manufacturing community, and governance thereof.

3. Use of device meta-data. Opportunities for use of device meta-data are numerous, starting with clinical care and documentation and extending through comparative effective analysis, safety surveillance, analysis that supports regulatory decision-making, registry submission, and research analytics. Optimal approaches will likely need to consider RESTful views of device meta-data[10], in addition to asynchronous database download and application. Real-time data will be optimal for use by the clinical community, while analytics may be better accomplished via database snapshots.

4. Registry engagement. A key contribution of professional societies to healthcare is the use of registries in the assessment and improvement of healthcare process, performance, and quality. The critical position of registries – from data elements through analytics – requires deep engagement with the society leadership and the clinicians they represent, particularly since subject matter expertise in the interpretation of aggregated data rests largely within those societies. Registries operated by other stakeholders (e.g., medical device developers) will likewise benefit from the processes being piloted in the RAPID project.

5. Extending the findings of RAPID. With the work of RAPID advancing the paradigm of UDI integrated into clinical care, expansion to encompass the multitude of disciplines that utilize medical devices looms on the horizon. The Coordinated Registry Networks approach – leveraging the registry environment spanning multiple medical disciplines – will further identify and develop the paradigm of real-world data captured at the point-of-care to prove useful and usable in the generation of real-world evidence.

Next steps - Phase III Informatics/GUDID Workgroup

Project participants will use knowledge gained and relationships built during RAPID Phase I and II as the basis for Phase III activity applying quality improvement principles to address workflow and data issues related to the auto-capture of UDI and use of GUDID data to link device identification information with patient care and outcomes. Participants are expected to have experience or training in LEAN Six Sigma or other quality improvement principles and have the ability to apply those principles and make recommendations on the workflows involved in the capture, reuse and analysis of structured UDI and other device data. Specific information about methods, proposed partners and expected outcomes are listed in the Phase III proposal located in Appendix 2.

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[10] Fielding, Roy Thomas (2000). "Chapter 5: Representational State Transfer (REST)". Architectural Styles and the Design of Network-based Software Architectures(Ph.D.). University of California, Irvine.

	Appendix 1		

NCIt Concept Code	FDA Source PT	FDA Source Synonyms(s)	FDA Source Definition
C150142	Shaft length		The length of the balloon catheter tube that extends from the catheter handle to the distal end of the catheter.
C150144	Introducer Sheath Compatibility	Introducer Size|Sheath Compatibility|Sheath Size	The size of the device that would fit through an introducer sheath.
C150145	Balloon Diameter	Nominal Diameter	The nominal diameter of the balloon per manufacturer specification.
C150146	Balloon Length	Nominal Diameter	The nominal length of the balloon per manufacturer specification.
C150147	Nominal (Inflation) Pressure		Balloon pressure at balloon nominal diameter condition.
C150161	Outer Diameter (OD)	Crossing Profile|Distal Outer Diameter (OD)|Proximal Outer Diameter (OD)	The nominal measure of the outer diameter of the balloon.
C150163	Balloon Catheter Tip Length		The length of the distal end of the catheter to the distal end of the balloon.
C150164	Rated Burst Pressure	RBP	Calculated pressure at which a balloon would not be expected to burst. Based on an appropriate confidence and reliability from measured burst pressures. (ISO 25539-2)
C150184	Catheter Length		The length of the catheter.
C150185	Guidewire Compatibility	Inner Lumen Dimension|Maximum Guidewire Size	The size of the guidewires that will fit through the inner lumen of the device.
C150186	Catheter Working Length	Effective Length|Working Length	The length of the catheter that can be inserted into the body or the working/functional measurement from the beginning to the end of delivery system.
C150187	Tip Bend Radius		The radius of an imaginary circle drawn inside of a curve of a curved catheter or guidewire.
C150189	Nominal Stent Diameter	Stent Diameter	Deployed stent diameter, as marked on packaging.
C150190	Nominal Stent Length	Stent Length	Deployed stent length, as marked on the packaging.
C150192	Tapered Stent Smaller Diameter	Distal Stent|Tapered Stent Smallest Diameter	The diameter of the portion of the tapered end of the stent that is the smaller of the two tapered ends.
C150194	Tapered Stent Larger Diameter		The diameter of the portion of the tapered end of the stent that is the larger of the two tapered ends.
C150196	Tapered Stent Length		The length of the tapered portion of the stent.
C150197	Maximum Stent Diameter		Maximum diameter to which a stent can be distended.

C150200	Atherectomy Device Tip Length		The length of the tip of the atherectomy device, if present.
C150226	Inner Diameter		The measurement of the diameter of the inner catheter tubing which goes over the guidewire.
C150229	Crossing Profile	Catheter Gauge|Catheter Size	The maximum diameter of the entire device entering the patient. ASTM F2081 definition: A linear measure of the maximum breadth of the stent/delivery system over the distal most region of the delivery system.
C150230	Cutter Length		The length of the cutter component for atherectomy devices that are used to cut plaque/thrombus.
C150233	Cutter Diameter		The diameter of the cutter component for atherectomy devices that is used to cut the plaque/thrombus.
C150243	Rotating Component Length		The length of the rotating component of an atherectomy device.
C150244	Rotating Component Diameter		The diameter of the rotating component of an atherectomy device.
C150371	Guidewire Length		The length of the guidewire.
C150372	Guidewire Diameter		The diameter of the guidewire.

National Evaluation System for health Technology Coordinating Center (NESTcc)

Second Round of Call for Concepts: An Invitation to Submit Concepts for Real-World Evidence Test-Cases

Concept Proposal

A. Test-Case Description

☒ *Yes, this is a project extension.*	The proposed project draws on and links lessons learned from selected key current real world evidence (RWE) efforts, being in particular an extension of RAPID. It would also align with related efforts in BUILD, SVS/VQI, AHRMM's Learning UDI Community (LUC), etc.

- The proposed RWE test case would aim to improve UDI capture/utilization in electronic health record (EHR) systems and registries, and broaden its impact, especially in support of the Total Product Life Cycle of peripheral vascular products that are commercialized globally. By developing best practices for UDI adoption, these data sources may be easier to link which contributes to building NESTcc operational processes. Many manufacturers commercialize products worldwide and anticipate a dramatic increase in the European Union (EU) requirements for clinical evidence. The NESTcc partners are uniquely positioned to collect RWE on commercially available products (e.g., guidewires). By implementing UDI within the NESTcc network, manufacturers could tap in to this rich data source to fulfill post-market regulatory requirements in multiple geographies. This will allow manufacturers to focus clinical study resources to support premarket studies of new, novel devices.
  - *Medical technology of interest*: Electronic health information systems (Interventional radiology, vascular, EHRs, quality system registries, mobile applications) and interventional devices used in the treatment of peripheral arterial disease (PAD).
  - *Population of interest*: Patients with claudication or critical ischemia of lower limbs who are having or have had endovascular treatment to alleviate their symptoms.
- The specific methodology would comprise two aspects:
  - Data Science component: FDA, manufacturers, quality program owners, software vendors, and researchers conduct a partner-based quality improvement study of UDI workflow by:
    - Clarifying structured data values to be assigned by manufacturers to improve quality of clinically relevant size and device categorization values in GUDID;
    - Assessing existing workflows at NESTcc data partners who are committed and show high level of UDI adoption maturity;
    - Assisting implementation of core RAPID phase I data attributes (including UDI)[1] into EHR or other point of care systems;
    - Exploring mechanism for transfer of UDI and other data into a PAD registry; and
    - Evaluating impact on data partner workflows and reductions in data capture, data transfer, and feedback to improve value of UDI to multi-stakeholders across the PAD lifecycle.
  - Applied component:
    - Capture of RWE from selected data partners for worldwide (WW) support of device total product life cycle (TPLC).
    - This component would also be a practical vehicle for assessing function of the improved processes and data available for decision making as a result of the data science component.

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[1] Jones, W. Schuyler et al. Registry Assessment of Peripheral Interventional Devices (RAPID): Registry assessment of peripheral interventional devices core data elements. *J Vasc Surgery*. 2018; 67(2); 637 – 644.

- <u>Data sources</u> would include:
    - o Results from RAPID (and related) projects to date, including:
        - Findings from an SVS/VQI survey of data managers in NESTcc (and other) data partners identifying opportunities to improve current workflows and potential pilot partners;
        - Findings of AUDI, CRS, and Device Categorization work
        - FDA instruction for participating manufacturers on specific requirements for updating UDI data.
    - o The EHR systems/registry databases of suitable data partners (e.g., SVS/VQI, EPIC, Cerner, other) as well as other willing and committed organizations who can add value by their participation.
- The project would capture de-identified/anonymized data, so patient participation barriers should be minimal.
- The project would be retrospective insofar as it begins with existing EHR workflows, with the intention of transitioning to retrospective, contemporaneous, or prospective as the workflows are optimized and data capture is initiated.
    - o The proposed use case would support product TPLC device evaluation by capture of RWE to support WW registrations (e.g., serving as postmarket clinical follow up (PMCF) confirmation of device safety and performance in CE mark maintenance in the EU).

B. Alignment

- The proposed test case aligns with NESTcc initiative goals to:
    - (1) Better understand the feasibility of practical use of real world data (RWD) sources (i.e., EHRs and registries) that are of value to industry.
    - (2) Use the learnings from initial workflow analysis to enable short-term and strategize on long-term efforts that contribute to a UDI Implementation Guide for those involved with device data capture and analysis.
    - (3) Contribute development of operational processes in terms of best practices for UDI implementation within healthcare systems—ideally extending to their processes of data submission to registries.
- The proposed test-case aligns to NESTcc's strategic priority to advance regulatory science by contributing to knowledge of UDI use and to the TPLC by development of efficient processes for generating medical device PMCF.
- It is expected that working with NESTcc to execute this test-case would facilitate development of UDI workflow processes that could be leveraged by other healthcare systems, as well as evidence generation processes that could be utilized across the medical device industry.

C. Other Information to Include

- Preliminary high level discussions have occurred with multiple NESTcc and non-NESTcc healthcare facilities using SVS/VQI regarding the applied component of this proposal. Initial steps in the data science component include a survey of data partners undertaken by the SVS/VQI. Initial pilot sites will be selected to represent different workflow types, to make the conclusions broadly applicable.
- FDA has been highly involved in identifying and addressing challenges in the GUDID. It is anticipated that FDA experts would be fully engaged contributors and leaders in the data science component of the proposal.

Attachments

None