Registry Assessment of Peripheral Interventional Devices (RAPID)

The RAPID program has been recognized for its collaborative, cutting edge leadership developing enhanced efficiencies in regulatory science for medical devices by the National Evaluation System for health Technologies (NEST) Coordinating Center (cc). The NEST cc formally named the RAPID program a NESTcc Demonstration Pilot in early February 2018 (https://nestcc.org/demonstration-projects/).

RAPID Phase I: Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used. Completed: J Vasc Surg. 2018 Feb;67(2):637-644 and Circ J 2018 Feb;82(2):316-322.

RAPID Phase II: Demonstrate the ability to extract registry or EMR data that provide patient-level data for RAPID core data elements. Phase II of RAPID also includes continued optimization of device identification protocols, including recommendations for incorporating supplemental device characteristics that are important for clinical purposes (but not contained in the generic Access GUDID database), as well as recommendations for core data elements required for RAPID that are not specific to PAD but are important to control as co-variates when evaluating patient outcome.

RAPID Phase III: Use a coordinated registries network (CRN) for studies supporting a regulatory decision.

Superficial femoral and Popliteal artery EvidencE Development (SPEED): RAPID's 1st Phase II Project

The goal of SPEED for RAPID Phase II is to extract de-identified patient level data from the Vascular Quality Initiative (VQI) registry for creation of objective performance criteria (OPC) for contemporary interventional treatment of occlusive disease in the superficial femoral artery (SFA) and the popliteal (POP) artery. Data will be extracted for analysis by FDA statisticians using a statistical analysis plan developed **by RAPID's Protocol Development Stakeholder Working Group**. SPEED was selected as the first Phase II RAPID project because many devices are currently being used "off-label" in these arteries under the practice of medicine and the published OPC being used to evaluate such devices were based on only 1000 patients and are over 10 years old, so do not reflect contemporary practice. The VQI registry have determined that ~20,000 peripheral vascular intervention (PVI) procedures with follow-up (average 1 year) treating the superficial femoral artery (SFA) and popliteal artery (POP) are available from years 2014-2016. This data contain most RAPID core data elements, and will allow creation of OPCs for all treatments combined, and for plain balloon, stent, atherectomy or combination treatments. Multiple covariates that may affect outcome (such as lesion length, symptom severity) will be analyzed to identify significant factors that should be considered and matched in future device comparison trials. The resulting OPC can be used by manufacturers to more accurately compare performance of their current devices than existing but outdated OPC, to estimate sample sizes needed for future device comparisons, and in some cases, to meet regulatory requirements as the control group for device approval or labeling expansion. The OPC will be published and the underlying patient/lesion characteristics provided, for general use. In addition, the multivariable models developed in this analysis can be made available to individual manufacturers by VQI if a more specific OPC is required (tailored to specific patient or lesion characteristics), as can line-by-line patient data be provided if required for certain regulatory applications.

Phase III of RAPID will extract data from sources other than VQI, such as the NCDR registry when the core data elements are available in these registries. The VQI registry has incorporated RAPID core data elements since September, 2016, so one-year follow-up data, with specific devices specified by unique device identifier, are becoming available for many devices being used on and off-label. Manufacturers can acquire data from VQI for

their device and potentially combine it with the OPC of SPEED to obtain expanded indications if warranted by such comparisons. It is critical that manufacturers insure the accuracy of their device data in the Access GUDID database in order to correctly identify their devices in registries such as VQI that have incorporated this method for device identification.