



Registry Assessment of Peripheral Arterial Devices (RAPID) Phase III

Face to Face Meeting Executive Summary March 20, 2019

FDA Headquarters

Executive Summary:

The RAPID F2F meeting brought together regulators, industry professionals, analysts and clinicians in common cause furthering our mission to develop a sustainable national medical device evaluation system for cardiovascular devices throughout the total product life cycle. The following summarizes the highlights of the meeting.

The evolving regulatory universe and place for real world evidence was discussed by leaders from FDA, NESTcc and industry. The international response to the impending EU MDR was a topic of discussion with the welcome involvement of notifying bodies and the International Consortium of Vascular Registries.

SPEED OPGs

One of RAPID Phase II aims is close to completion with the development of objective performance goals (OPG) for superficial femoral and popliteal artery intervention. RAPID chose this ambitious project because many existing devices are being used “off-label” with new drug-coated balloons and stents in use or in development. In addition the existing OPGs are based on data more than 10 years old that is not reflective of contemporary practice. For the first time the Superficial Femoral Artery Evidence Development (SPEED) Objective Performance Goals (OPG) were presented by our team of three analysts. Multivariable models for the three OPGs (Mortality, Major Amputation and TLR) stratified by artery and four treatment types (PTA, stenting, atherectomy and all treatments) were presented to the RAPID community. While there is additional work to be done we anticipate submission for peer review in the coming months. We hope the SPEED OPGs can inform practice guidelines adding to the limited available comparative effectiveness data, serve as new benchmarks and establish appropriate controls for future device trials. SPEED is a testament of RAPID's ability to bring together the necessary stakeholders and analytical power. The open discussion about lessons learned from the SPEED experience will be important for our future projects.

GUDID issues

Experts discussed the great potential and current limitations of the global universal device identifier. Barriers include multiple pathways of data submission, inconsistency of assignment, and multiple nomenclatures (GMDN, SNOMED, CND). Dr. James Tchong discussed the AUDI project aims to introduce the necessary clinical data elements. . Future success will be driven by the need for a unified system of device identification and is dependent on cooperation between industry, government and contributions from subject matter experts. The principle of “label once” would benefit everyone involved.

Paclitaxel mortality signal

Significant time was noted to discussion about the reported increase in late mortality after femoral popliteal intervention with paclitaxel coated balloons and stents. A range of perspectives were presented with consensus that the RAPID community should work to contribute to the evidence in a way that is additive to other ongoing analysis. The leadership decided to devote time on upcoming conference calls to develop a strategy that might be of interest to FDA and industry.

Leadership in transition

We thanked the original RAPID core leadership team of Dr. Jack Cronenwett, Dr. Pablo Morales and Robert Thatcher as they bring on new members Dr. Bertges, Dr. Misti Malone and Melanie Raska. Their visionary idea, dedication toward improving the system for device evaluation and hard work put the RAPID community in position to carry out its mission.

Finally, time was devoted to discussion of RAPID phase III-IV to support prospective studies and randomized controlled clinical trials (RCT) within coordinated registry networks. We hope to bring RAPIDs concept of “better, faster, cheaper” to fruition once an opportunity is identified. In the meantime we can seize upon opportunities to operationalize the SPEED OPGs and utilize Medicare claims matching while we work to improve GUDID and integrate with registries such as NCDR PVI.