



CDRH Post- Approval Update

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Circulatory Devices Advisory Panel,
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Post Approval Studies

- The new Center for Devices and Radiological Health (CDRH) Post-Approval Studies Program encompasses design, tracking, oversight, and review responsibilities for studies mandated as a condition of approval of a premarket approval (PMA) application. The program helps ensure that well-designed post-approval studies (PAS) are conducted effectively and efficiently and in the least burdensome manner.
- On January 1, 2005, the oversight responsibility was transferred to CDRH's Office of Surveillance and Biometrics (OSB) and the PAS review functions were integrated into the medical device epidemiology program. Guidance on report format and content was developed to ensure optimal PAS reporting and review. <http://www.fda.gov/cdrh/osb/guidance/1561.html>.
- CDRH has established a new automated tracking system that efficiently identifies the reporting status of active PAS studies ordered since January 1, 2005. This system represents CDRH's effort to ensure that all PAS commitments are fulfilled in a timely manner. The effective tracking system is based on study timelines incorporated in study protocols and agreed upon by the CDRH and manufacturer.
- In addition to this internal tracking system, CDRH launched this publicly available webpage to keep all stakeholders informed of their progress. It displays not only the report status, but also study status (based on protocol-driven timelines) of each PAS.

A B C D E M O P S T U V W Z

63 records

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Application Number	Applicant Name	Device Name	Medical Specialty	Date PMA Approved	Post-Approval Study Commitment	Study Name	Protocol Approved	Study Population	Stu Sta
P040038	ABBOTT VASCULAR DEVICES	XACT CAROTID STENT SYSTEM	Cardiovascular	09/06/2005	1. YOU HAVE AGREED TO CONDUCT THE FOLLOWING STUDIES AND TO REPORT ON THESE STUDIES EVERY ☒	PROTECT Study	02/05/2007	Transitional Adolescent B: 18-21 yrs, Adult: >21	Stud time
						EXACT Study	10/12/2005	Transitional Adolescent B: 18-21 yrs, Adult: >21	Stud time
H040006	ABIOMED, INC.	ABIOCOR	Cardiovascular	09/05/2006		Abiocor Artificial Heart	09/05/2006	Transitional Adolescent B: 18-21 yrs, Adult: >21	Stud time



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Focus on Infrastructure



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Focus on Methods





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Make better use of existing pre & post approval data

Integrate/combine when appropriate!

Use Simultaneous:

- **Meta-analysis**
- **Network meta-analysis**
- **Cross-design synthesis**

- **Bayes factors**

**Methods
of
Data
Integration**

**Direct
measure
of evidence**



Rethinking Analytical Strategies for Surveillance of Medical Devices

The Case of Hip Arthroplasty

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and Ronald Kaczmarek, MD, MPH†*

Background: Randomized trials that sometimes serve as the basis for device approval are small, short term, and generalizable to an increasingly smaller percentage of patients. Some of the most common and challenging devices are those used in hip replacement. Artificial hips are implanted in thousands to alleviate pain caused by noninflammatory joint disease and to restore patient mobility. During 2004 in the United States, although 68% of hospital stays for partial or total hip replacements were for those aged 65 years and older, younger patients will account for 52% by 2030.

Methods: Using hierarchical modeling, we propose a framework for combining information from premarket and postmarket settings. Our key assumption is that device performance characteristics and outcomes obtained from 1 cohort are related to device characteristics and outcomes of the same or similar devices observed in other cohorts. We illustrate methods by jointly modeling Harris Hip Scores (HHSs) and revision-success data from 1851 subjects who participated in 3 pivotal randomized or observational studies of artificial hips.

Results and Conclusions: Subjects participating in randomized studies had better 2-year HHS than those in observational studies (posterior mean increase in HHS = 4.1, posterior standard deviation = 0.6). Patients implanted with ceramic-on-polyethylene hip used in 1 study had higher 2-year HHS than those implanted with a different ceramic-on-polyethylene hip in another study (mean difference = 4.2, standard deviation = 0.6). Our approach is feasible and will advance regulatory science using a transparent and dynamic new paradigm for knowledge management throughout the total product life cycle.

Key Words: crossdesign synthesis, network meta-analysis, Bayesian hierarchical models, posterior distributions

(Med Care 2010;48: S58–S67)

Current approaches for integrating clinical information in clinical trials and real-world settings of medical devices require updating. This need arises due to the recognition of at least 2 facts. First, randomized controlled trials (RCTs), when serving as the basis for new device approval, are small, short term,¹ and are generalizable to an increasingly smaller percentage of patients. The reasons for decreased generalizability is 2-fold: (1) the population is aging, having more chronic diseases, and comprising a larger portion of routine practice yet are often excluded from trials and (2) the increasing inclusion of less sick patients who are less likely to benefit.²

Second, postmarket studies are often voluntary, have design limitations, and are difficult to execute.³ Although these problems are not new, they have become increasingly important during the last decade because device technology is changing at a rapid pace, therapies are used outside their intended populations, and more representative groups of patients are likely to have differential responses to the same therapy.⁴ A broader more inclusive group of patients means wider ranges of disease severity, of sociodemographic characteristics, of genetic characteristics, and of health-related behaviors. Consequently, the device effectiveness will be more heterogeneous.

Some of the most common and challenging devices are those used in hip replacement. A total hip replacement involves cutting off the top of the femur, inserting a stem (with a femoral ball) into the femur, and replacing the hip's socket, which will articulate with the femoral ball. Patient enrollment and retention in the pre or postapproval study setting pose unique problems in assessing hip replacement systems because long-term follow-up, generally 10 years postimplantation, is required. Blinding and allocation concealment in RCTs are difficult, and the numerous potential comparators requires very large numbers of patients to be studied. Device



Focus on Strategic Partnership



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MDEpiNet





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Thank you!

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