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# Postapproval Needs Reassessed

## Real-world data demands place Phase IV studies in spotlight.

Physicians, payers, and patients all want evidence of the real-world results of medical products, therapies, and services. And they want those results for larger and more diverse populations than are typically studied before approval to enable them to judge whether such products and services are safe and effective and how quality of care might be improved.

Recognizing and planning for postapproval research imperatives will be a differentiator for companies and their products—and the need for safety and effectiveness data postapproval should be considered in the context of a potential sea change in health care.

Much of the recent attention to the need for postapproval surveillance comes from heightened consumer anxiety over drug and device recalls. This anxiety has led to congressional hearings, the creation of the FDA's Drug Safety Oversight Board, a call for more postmarketing study commitments and possible "report cards," new initiatives from the Center for Devices and Radiological Health—and will potentially lead to further changes.

As I described in a previous article,<sup>1</sup> from a scientific perspective, it is simply not possible to predict all potential safety issues prior to approval.

### An effectiveness imperative

Safety grabs headlines, but it will be data on effectiveness (outcomes produced in the real world) that sells products. There is growing scrutiny by providers and payers of the effectiveness and cost-effectiveness of products in real clinical practice.

At the payer level, recent guidance by the Centers for Medicare and Medicaid Services on national coverage determinations with data collection<sup>2</sup> and coverage decisions by other payers make it very clear that evidentiary data, collected with appropriate rigor (i.e., not just claims data) on the populations who are to be treated, will increasingly be sought.

At the prescriber level, there is increasing interest in understanding the benefit of new products and therapies in the types of patients they see (ideally in their own practices). At the same time, there are increasing efforts to define methodological rigor for evaluating outcomes data derived in the postapproval phase from approaches such as observational studies and patient registries.<sup>3</sup>



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### A quality imperative

As clinicians, hospitals, and health care systems are increasingly being evaluated and paid on the basis of "quality," and as health care reorganizes along the lines Harvard Business School Professor Michael Porter calls "value-based competition," the focus turns to outcomes that depend on the combination of the product and its delivery, the provider, and patient.

This shift in focus is important for two reasons. First, providers will be collecting more data for their own purposes. Second, providers will be even more focused on postapproval data since their outcomes (and their livelihoods) may depend on the choices they make.

Ironically, the postapproval research imperative actually aligns the goals of patients, providers, industry, and regulators. There are already influential recommendations that the drug approval process consider "conditional" approvals.<sup>4</sup> Another trend that we are seeing is provider, payer, and industry partnerships in collecting postapproval data. Regardless of the ultimate model, a significantly expanded program of postapproval studies and registries is destined to be part of the cost, and opportunity, of doing business. Manufacturers who figure it out early are going to have a competitive advantage and ultimately improve both product and patient outcomes.

At the 2006 Post-Approval Summit at Harvard ([www.postapproval.org](http://www.postapproval.org)), Dr. Steven Galson, director of CDER, described the challenges for a regulatory agency in ensuring postapproval safety. Dr. Michael Panzara of Biogen Idec recalled the "stop and go" saga of Tysabri, and Professor Regina Herzlinger of the Harvard Business School called this real-world information the vital component for competition in health care. What these industry leaders all have in common is a shared notion that more—a lot more—Phase IV data is needed. □

### References

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