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Tufts Center for the Study of Drug Development

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ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Challenges loom for postmarketing study commitments; benefits unclear

Sponsors face delays, variable costs, but little improvement in product profile

- More than half of the studies were completed by the date expected.
- When studies were delayed, problems included slow enrollment, technical difficulties, and the need to satisfy additional requirements.
- Clinical studies, on average, took 10 months longer to complete and cost nearly nine times more than non-clinical studies.
- A majority of drug sponsors say study results contributed little to their understanding of the safety, efficacy, or quality of their product.
- Three-quarters of all postmarketing studies were conducted in-house; most of the outsourced studies were handled by contract research organizations.