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The Emerging Role of Postmarketing Clinical Research: Regulatory issues, strategic drivers and overall trends

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Report Summary

Post-marketing studies are undertaken to delineate additional clinical information concerning a drug's risks, benefits, and optimal use. Industry stakeholders acknowledge that research undertaken in order to obtain marketing authorization (MA) does not always coincide with initiatives to ensure that the product is subsequently placed in its ideal or intended market context. Such postmarketing data can therefore prove invaluable to governing bodies like the FDA and EMEA, institutional payors and health authorities, and also to the pharmaceutical companies themselves for strategic purposes.

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