



GOVERNANCE

BASEL INSTITUTE ON GOVERNANCE

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Self-Regulation vs. Regulation: Application of Genetics in Clinical Development (ABSTRACT)

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Pharmacogenetic studies, i.e. testing whether variants of certain genes may affect the response to therapeutic agents, have become an important and routinely conducted practice during and before clinical development. Public perception of the implications of genetic testing have made it important to introduce a set of guidelines and best practices to protect subject confidentiality that go beyond what is routinely practiced in clinical trials. A number of approaches have been developed by the pharmaceutical industry to ensure these heightened standards. In addition, the industry has made efforts to contribute to the dialogue among stakeholders by providing information and education.