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Sommario/riassunto	The idea of combining drugs and diagnostics in oncology is not new. When the selective estrogen receptor modulator tamoxifen was developed in the 1970's for the treatment of breast cancer a positive correlation between receptor status and treatment outcome was found. As a result of this research, it was suggested to use the estrogen-receptor assay as a diagnostic test for selection of patients for tamoxifen treatment. Despite this suggestion was put forward nearly 40 years ago the adaptation of the drug-diagnostic co-development model has been relatively slow and it is only within the last decade that it has gained more widespread acceptance. The parallel development of the monoclonal antibody trastuzumab (Herceptin®, Roche/Genentech) and the immunohistochemistry assay for HER2 protein overexpression (HercepTest™, Dako) seems to have served as an inspiration to a number of stakeholders such as pharma and diagnostic companies, regulatory agencies, and academia. In recent years we have seen an increasing number of oncology drug development projects that have taken advantage of the drug-diagnostic co-development model, as outline below. Most of the new targeted anti-cancer drugs that have been introduced in recent years, such as BRAF-, ALK-, EGFR- and HER2-inhibitors, are more or less all a product of the drugdiagnostic co-development model. These drugs have shown remarkable high

response rates in selected groups of patients within cancer diseases with great unmet medical needs.