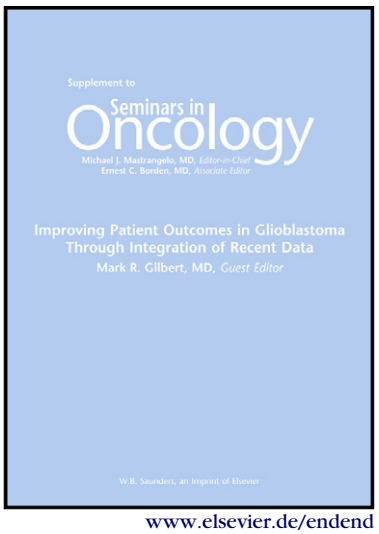

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Looking to the Future in an Unprecedented Time for Cancer Drug Development

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Looking to the future in an unprecedented time for cancer drug development

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Over the past several years sustained commitment to cancer research has been translated into therapeutic advances across a broad range of drug and biologic products. The magnitude of benefit observed with many of these cancer therapies has enabled the Office of Hematology and Oncology Products at the FDA to proactively utilize regulatory programs to expedite the delivery of safe and effective therapies to patients. How did we get here, and what can the cancer drug development community do to continue to bring tangible benefit to cancer patients?

In 2001 investigators published results of imatinib, an oral therapy that resulted in 53 of 54 interferon-refractory chronic myelogenous leukemia patients achieving durable complete hematologic response. The authors concluded their manuscript with the prescient statement that their results "demonstrate the potential for the development of anticancer drugs based on the specific molecular abnormality present in human cancer".[1] This marked a beginning for rationally developed cancer drugs based on identification and targeting of oncogenic pathways driving tumor growth, and we continue to see impressive durable response rates with other therapies directed at mutations across a range of targets and histologies.