Classical immunohistochemical parameters (IHC) are useful in the prognostication of the risk of distant relapse of early breast cancer patients. However, its performance is suboptimal due to the limitations of the techniques (non-automatized process, issues with tissue simple fixation, deparaffinization, etc). These techniques are semiquantitative and have somewhat artificial cut-offs of positivity. Besides, although IHC parameters are moderately accurate in predicting benefit with hormonal treatment, they are poor predictors of response to chemotherapy. Genomics platforms are automatized multigene profiles, based on the RNA expression of 12 to 70 genes.

Oncotype Dx is a 21-gene assay that classifies ER-positive breast cancers in three categories of risk of relapse (low, intermediate, and high); there is level IB evidence (evidence based on retrospective analysis of at least two prospective trials) that Oncotype Dx provides relevant prognostic information beyond classical clinicopathological parameters and predicts response to chemotherapy in ER-positive early breast cancer. Two prospective trials (TAYLOR-X and RxPONDER) are validating the clinical utility of Oncotype Dx in patients with intermediate recurrence score. Mammaprint is a 70-gene platform that classifies early breast tumors in two prognostic subgroups with different outcomes in absence of treatment. Patients whose tumors belong to the high-risk group seem to obtain significant benefit with chemotherapy. The MINDACT trial is prospectively validating the clinical utility of Mammaprint in early breast cancer. Endopredict is a decentralized assay, currently performed in 16 molecular labs in Germany, Switzerland and Austria, that provides the expression of 8 tumor genes and 3 normalization genes. It classifies tumors in two risk groups (low vs. high). Prosigna (PAM-50) is a 46-gene platform that provides the risk of recurrence of ER-positive early breast cancers. The test also identifies the breast cancer intrinsic subtypes (LumA, LumB, Basal-like, HER2-E). Prosigna is performed in local laboratories with the help of the nCOUNTER technology.

Disclosure: Dr Martin has served as an advisor of Genomic Health, and Agendia. He has been involved in the clinical development of Oncotype Dx, Endopredict and Prosigna. He is inventor of a patent related to PAM-50.