



2018 Translational Medicine Symposium

Translating the PAM50 Gene Expression Assay from LDT to FDA-cleared Test

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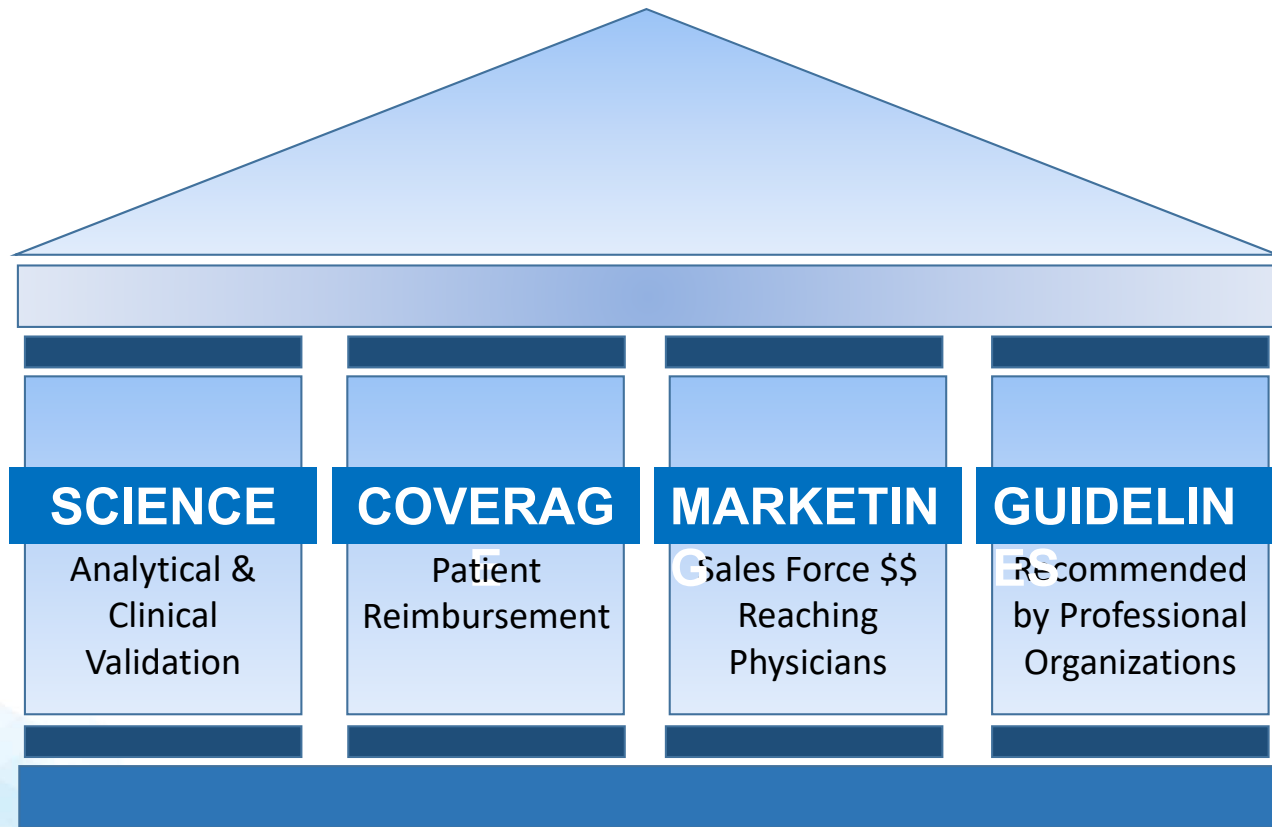
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Huntsman Investigator
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Conflict of Interest

I'm an inventor of the PAM50 signature and a stakeholder in BioClassifier LLC, a company that licensed the PAM50 know-how to Nanostring Inc. for commercialization of Prosigna[®]

The Four Pillars of a Successful Diagnostic Test



NIH “Strategic Partnering to Evaluate Cancer Signatures”

the four institution team funded by the NCI to develop a breast cancer test ...

Phil Bernard
University of Utah

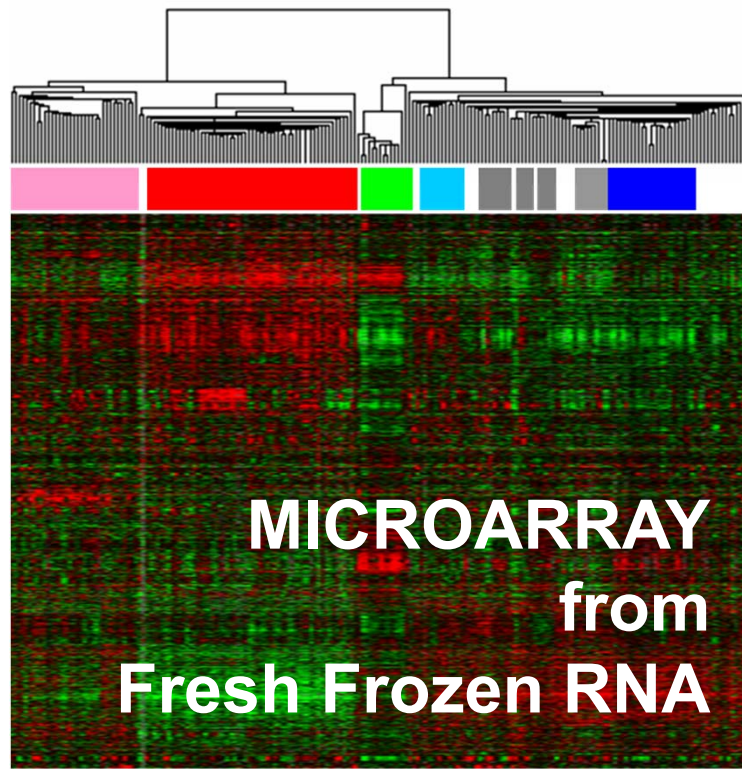
Chuck Perou
UNC-Chapel Hill

Torsten Nielsen
University of British
Columbia

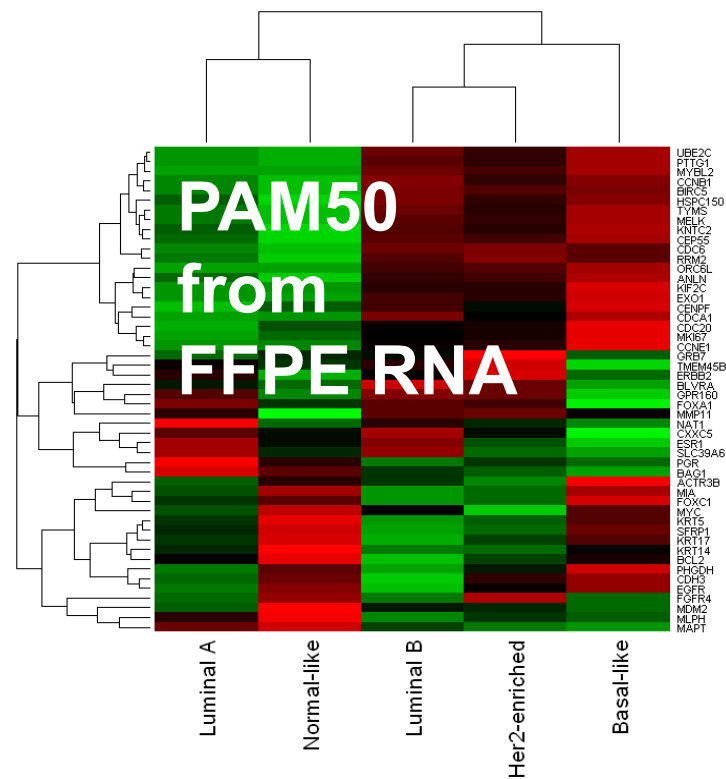
Matthew Ellis
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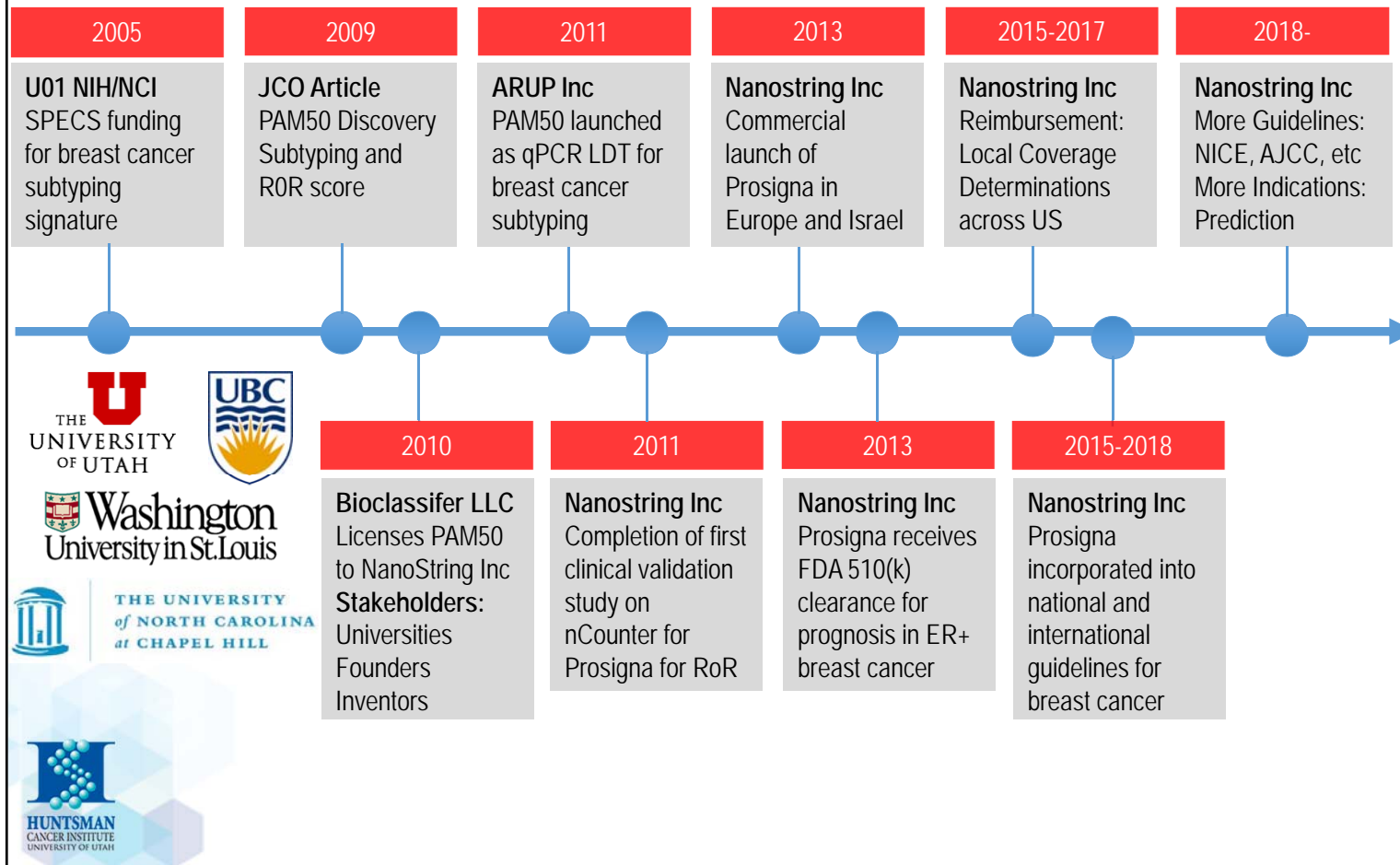
Parker JS et al. J Clin Oncol 2009



1. Took prototypical samples and subtype assignments from microarray
2. Used qRT-PCR data for 160 genes
3. Selected optimal gene subset for subtype classifications using 10-fold CV
4. Identified 50 optimal genes, and samples, giving a robust training set (PAM50)



MILESTONES: PAM50 Discovery to Commercialization



COMMERCIALIZING PAM50

Do DIFFERENT

- May not have spent effort and money on the qPCR LDT platform at ARUP
- May not have gone to the FDA with Prosigna due to claim restrictions and marketing disadvantage

Do the SAME

- Establish a strong scientific foundation for the signature beyond the initial offering
- License technology from the Universities
- Seek a platform that could be de-centralized allowing worldwide distribution