Case Study

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Prognostic (Predictive?) Breast Cancer Testing

- Not a CDx but…
- A case study in MAAA* access and reimbursement in the EU

*Multianalyte Assay with Algorithmic Analysis

Genomic Health, Paving the Way

- Oncotype Dx launched in the US in 2004 and established an EU commercial presence in 2009
- Positive guidance achieved with NICE DG10 (UK) in 2013
- Some regional reimbursement achieved throughout Europe supported by Guidelines
- Significant investment in clinical trials & commercial infrastructure with low early returns (<10% of global sales)

Barriers to Success

- Delays in TAT limited utility
  - All testing conducted in Redwood City, CA
  - Test frequently reported as taking ~4 weeks to result
- High perceived cost a barrier to entry
  - Early reluctance to compromise on price delayed adoption
  - Undisclosed discount schemes eventually implemented

Competitive Pressure

- MammaPrint (Agendia, Amsterdam)
  - Launched in 2004 but sample limited to fresh-frozen tissue, increased logistical challenges and hindered broad adoption
  - European testing conducted in centralized lab
  - Achieved FDA clearance in 2007 with limited impact on adoption
  - Perceived as lagging behind ODx in evidence generation while similarly priced
  - FFPE testing available in 2012 but limited impact due to ODx foothold

More Competition

- EndoPredict (Sividon, Cologne) launched in 2011
  - Aggressive pricing strategy drove local adoption in Germany and highly price-sensitive tender based markets (Spain)
  - Acquired by Myriad in 2016, plans to kit and seek FDA clearance, decentralize testing in EU

- Prosigna (NanoString, Seattle) launched in 2013
  - Decentralized option for local labs
  - Adoption initially hindered by up-front cost of instrument acquisition but test "naturalization" very attractive for European payors
  - Kit based model and local testing reducing TAT driving adoption throughout Europe

Where are we now?

- 2004 – 2018, still limited adoption overall despite high demand and Guideline inclusion
  - EU prognostic breast cancer testing market is still approximately 10% the size of the US
  - Only National reimbursement in 5EU is through NICE
    - DG10 due to be revised this year
    - GBA has been delaying a decision for several years pending further data
    - Regional, tender based access in France and Spain
    - Very limited access in Italy
    - Good adoption in certain regions (Nordics, Portugal)

What are the Barriers?

- Unrealistic expectations of LoE for Dx testing
  - Drug-like, multi-centre prospective studies expected with high risk of never reaching RoI for Dx companies with very limited resources
  - TAILORx reported (after ~10yrs) having some impact
  - GHI working on decentralizing Oncotype into Europe
- Lack of consistent HTA process across Europe
  - "If you've seen one country, you've seen one country"
  - Significant investment required to navigate the Payor landscape in each country
  - Reluctance to reward innovation with value-based pricing

What Does this Mean for a MAAA CDx Access?

- There are several MAAA CDx tests in development
  - (e.g. Lymph2CX/LST with lenalidomide for DLBCL in Phase III, clinicaltrials.gov NCT02285062)
  - Access will be challenging unless EU-wide solutions are found
- But, Pharma continues to be cautious about embarking on a CDx path with MAAAs
  - Sacrificing a better test for a tried and trusted approach with a single analyte
- Logistical solutions are key for centralized labs to maintain required TAT for a CDx, but this is possible!
- Value-based pricing needs to become the standard for novel CDx testing, and stand-alone diagnostics that bring value and utility to the clinic