

# **State of Molecular Diagnostics Industry and the LDTs**

*The role of biomarkers in medicine*

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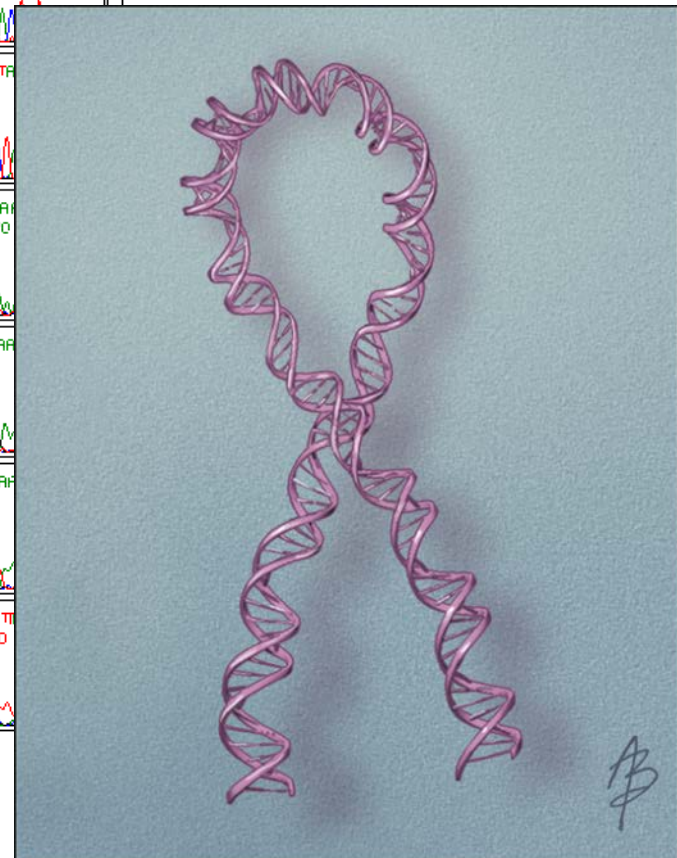
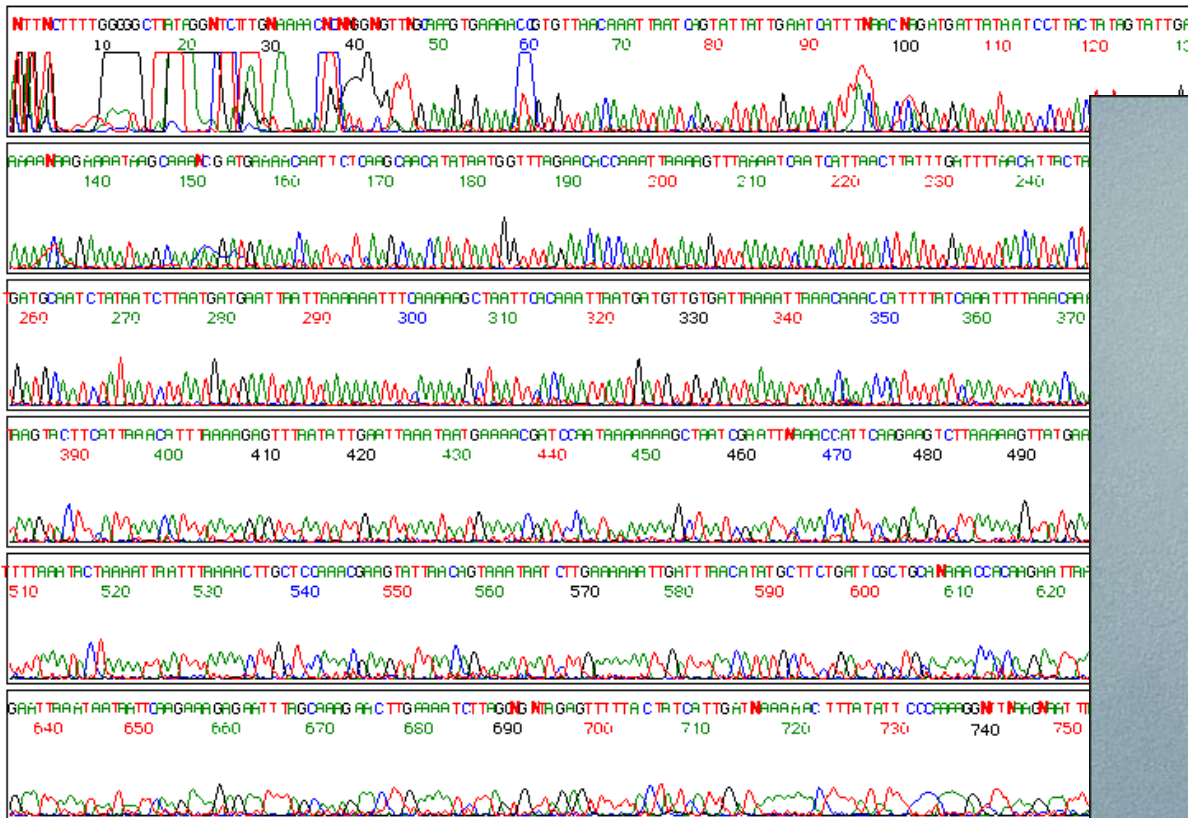
# What are biomarkers?

- A biomarker is anything that can be measured and tells you about a biological system
- Understanding based on biomarker measurements is used with other clinical information to personalize treatments

# Molecular biomarkers

- When we talk about biomarkers this is what most people think about, the most common use of the term
- Different markers are measured in different ways

# DNA: BRCA -1 and -2





## What can you do with biomarkers?

- Diagnostic
  - Prognostic
  - Predictive
- 
- Many biomarkers cross some or all of these lines!

# NGS in Oncology: An Estimated \$2B Market Within 5 Years

## Relative penetration of next generation sequencing in Oncology in the future

Types of markers likely tested

Driver mutation/variations

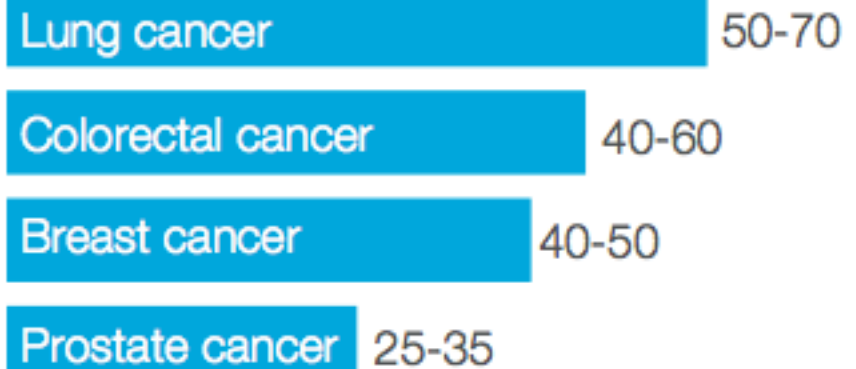
Other response markers

Drug metabolism markers

Resistance markers

Drug safety markers

Expected percentage of incident patients where NGS used for initial diagnosis in U.S. by 2018<sup>1</sup>



<sup>1</sup> Based on expert interviews and McKinsey analysis; both adjuvant and metastatic patients

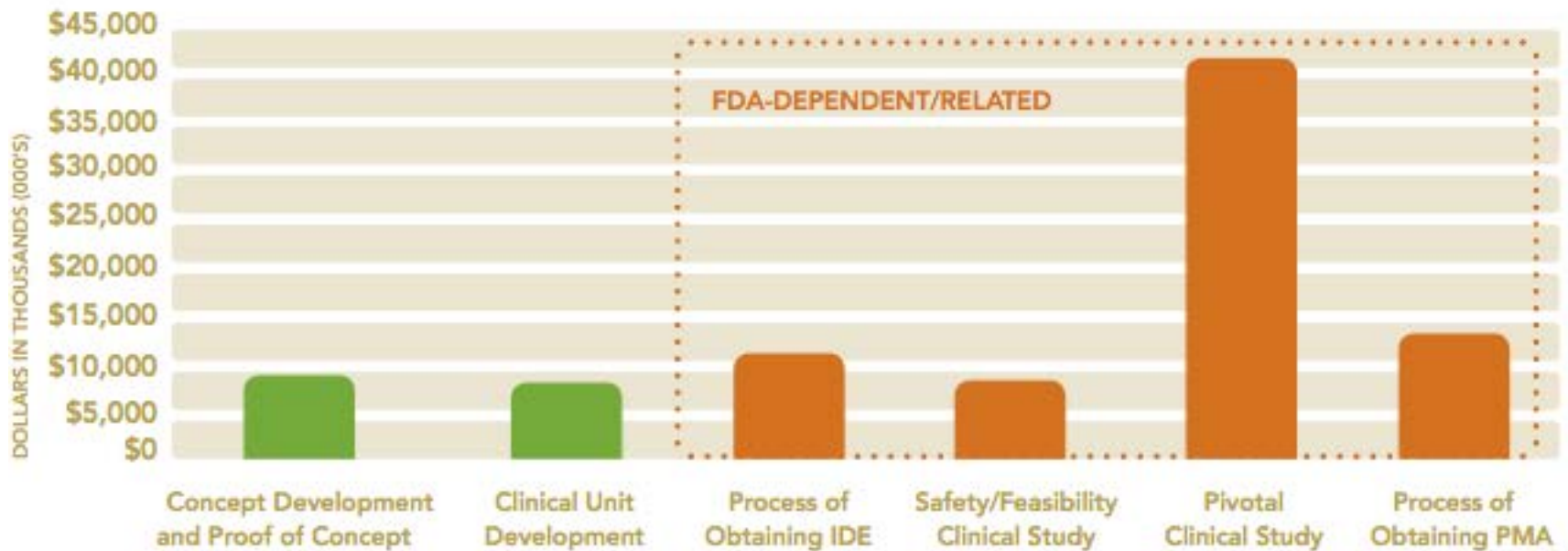
# Time to Obtain a PMA

FIGURE 3 – PMA AND CE MARK REGULATORY TIMELINES



## Cost of a PMA

FIGURE 13 – AVERAGE TOTAL EXPENDITURE BY STAGE FOR PMA PRODUCT



Average cost of obtaining a PMA approval is \$94M before marketing/reimbursement

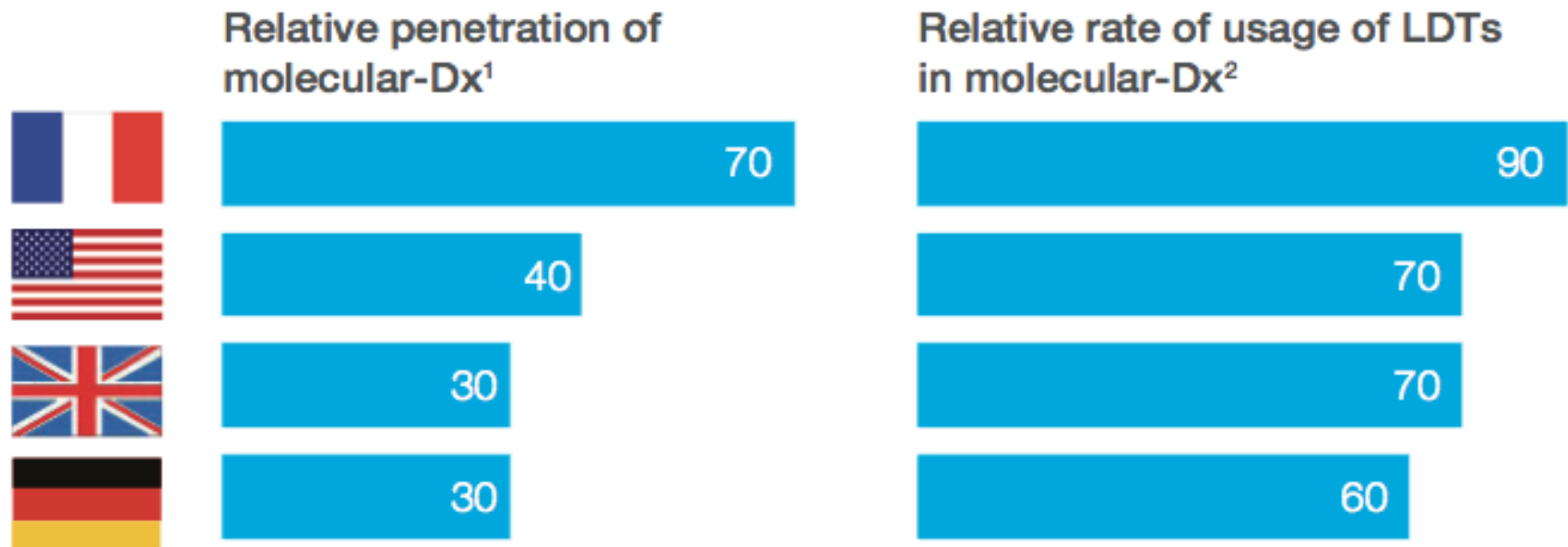


# Variation in payment

Innovative Test Examples	FDA Cleared	Positive Coverage Policies			
		Aetna	Regional CMS	Cigna	Regional BCBS
AlloMap	Yes		✓		
Oncotype DX (breast cancer)	No	✓	✓	✓	✓
MammaPrint	Yes		✓		
Pathwork Tissue of Origin	Yes				
BRACAnalysis	No	✓	✓	✓	✓
OVA1	Yes		✓		~
KRAS (colorectal cancer)	No	✓	✓	✓	✓

## Use of LDTs Instead of FDA/EMA Approved Tests

Relative penetration of molecular-based companion diagnostics and level of usage of lab-developed tests



<sup>1</sup> Based on customer interviews/survey; penetration defined as percent of biopsies tested across 3 different companion diagnostics

<sup>2</sup> Based on customer interviews; LDTs in U.S. defined as non-FDA approved but CLIA waived, in EU and APAC defined as tests without clinical validation

# Questions?

