

# WHY DO MEDTECH COMPANIES FALL INTO THE VALLEY OF DEATH?

## How medtech companies find themselves in the valley of death

### FDA Strategy is Not Favorable for Reimbursement

The diagnostic device's regulatory classification may not be favorable for reimbursement.

### Lack of Stakeholder Support

- Lack of support from professional societies for coding, coverage, and payment initiatives
- Payer non-coverage for new diagnostics
- Lack of patient education can result in a significant slowdown of market adoption

### No Early Stage Reimbursement Planning

- Not identifying the key payer markets for their diagnostic
- Not considering the coding, coverage and payment implications
- Not researching the clinical outcomes requirements by those payers.
- This can result in many surprises after product launch including provider push back and delay of market adoption.

### Lack of Payer - Desired Clinical Data

If the clinical study design and outcomes do not meet payer needs, the new diagnostic may not be covered and paid.



## How GIRS can help get you out of the valley of reimbursement death

We can assist you to:

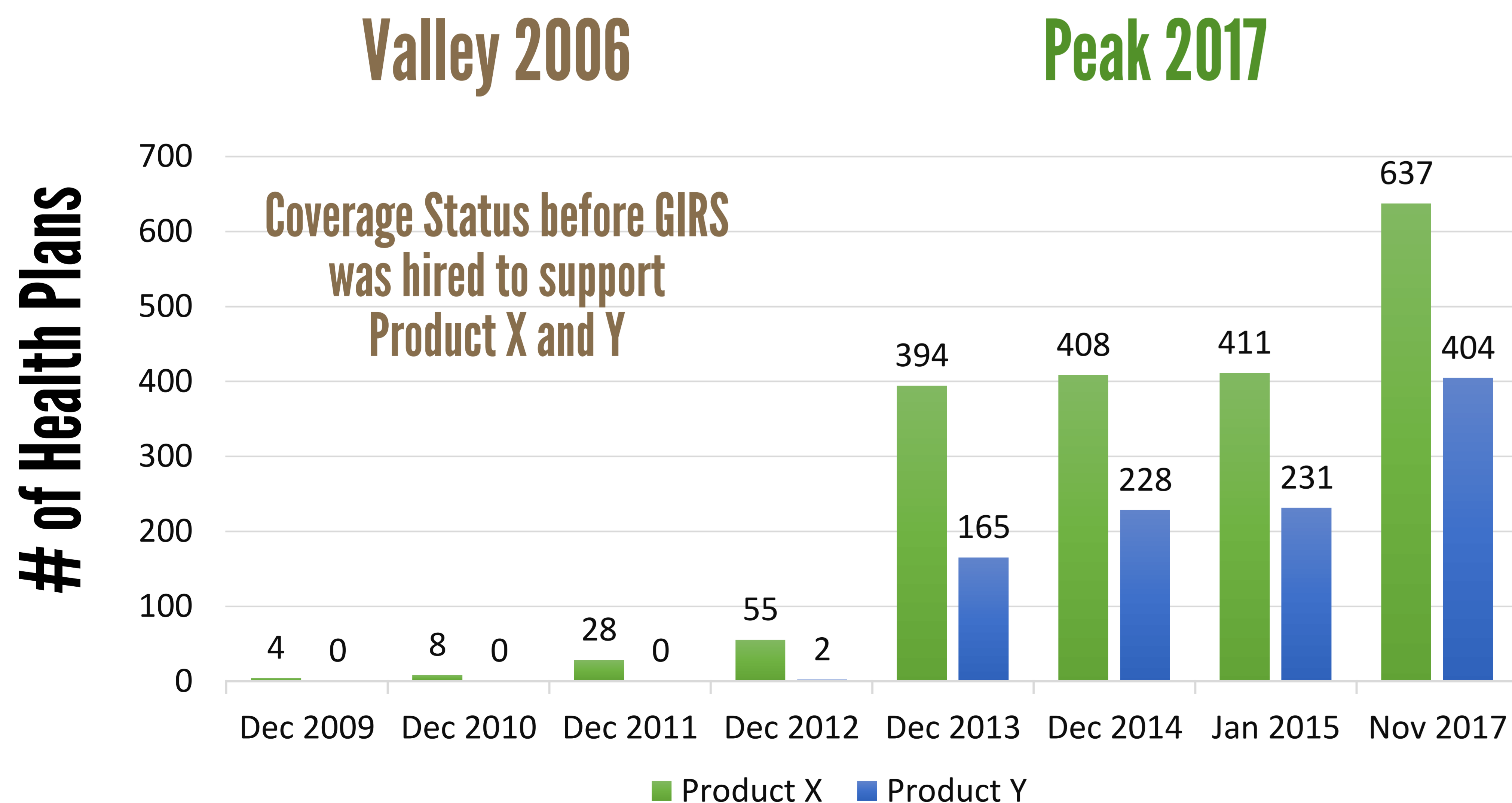
**Coordinate FDA Strategies with Reimbursement Strategies**

**Conduct Early Stage Reimbursement Strategies parallel with Clinical, Regulatory, Sales and Marketing Planning**

**Identify Payer Desired Clinical Outcomes Strategies so that you don't have to conduct multiple inadequate studies**

**Educate payers and other stakeholders of the value proposition for your diagnostic**

Commercial Payer Coverage Outcomes, Dec 2009 - Nov 2017



Case Study of Successful Medicaid Coverage, Sept 2017

