



# Case study: Clinical Implementation of HER-2 and TPMT testing in Europe

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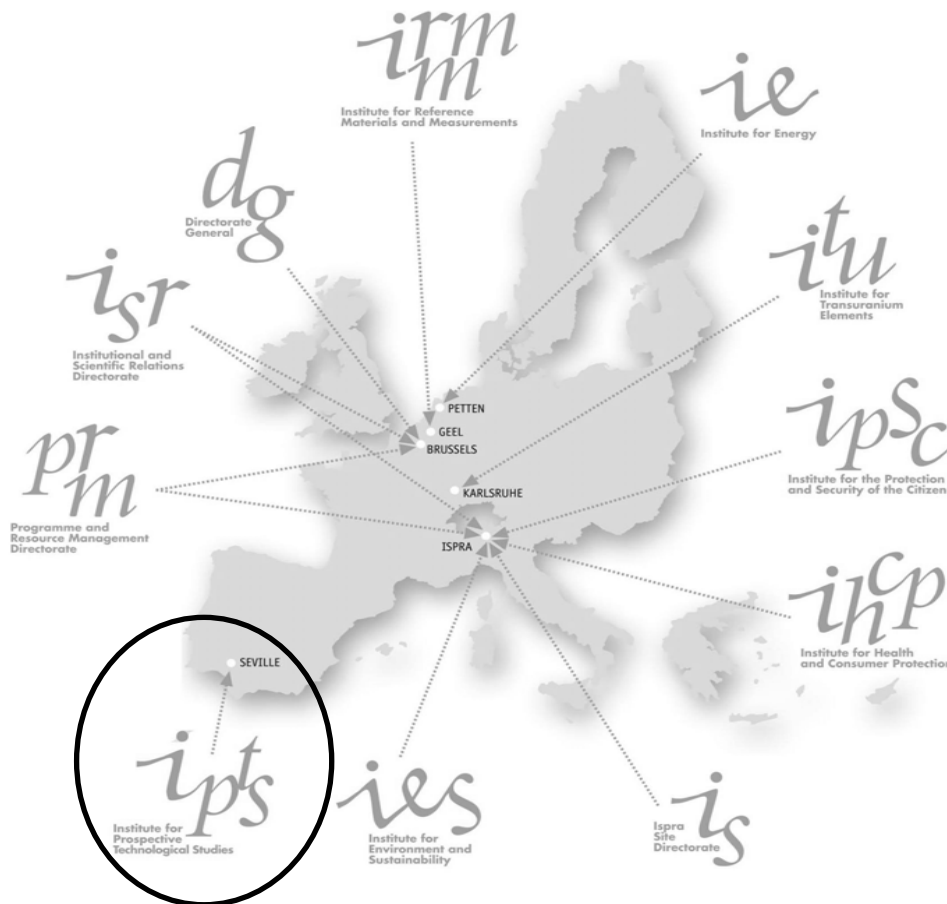
## *Presentation Outline*

### *Clinical implementation of Pharmacogenomics in Europe*

- Background
- Study design and Methodology
- Results
- Conclusions



# *Institute for Prospective Technological Studies*



## **IPTS:**

- one of the seven institutes of DG JRC of the European Commission
- provides customer-driven support to the EU policy-making process
- monitors and analyses S&T developments, their cross-sectorial impact and their policy implications

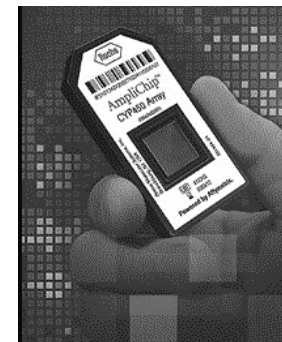


## Background

### Pharmacogenomics (PGx)

- Drug development
- Personalised medical care

PGx application in the clinic is still missing



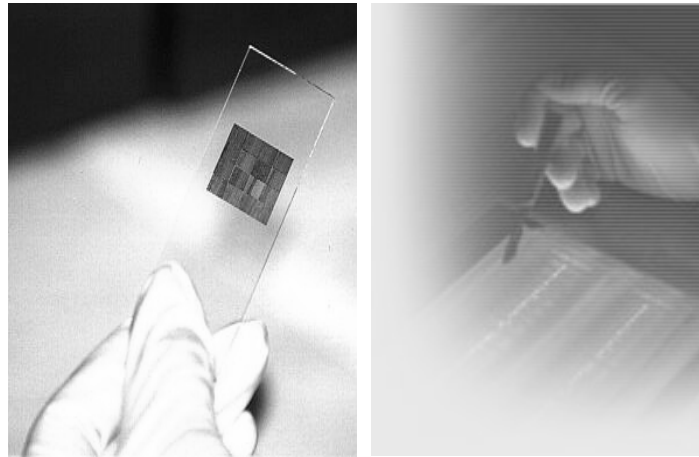


## *IPTS prospective study*

- Mapping current R&D status
- Assessing clinical impact
- Comparing regulatory and quality assurance frameworks



## Mapping current R&D



## Current R&D status (1)

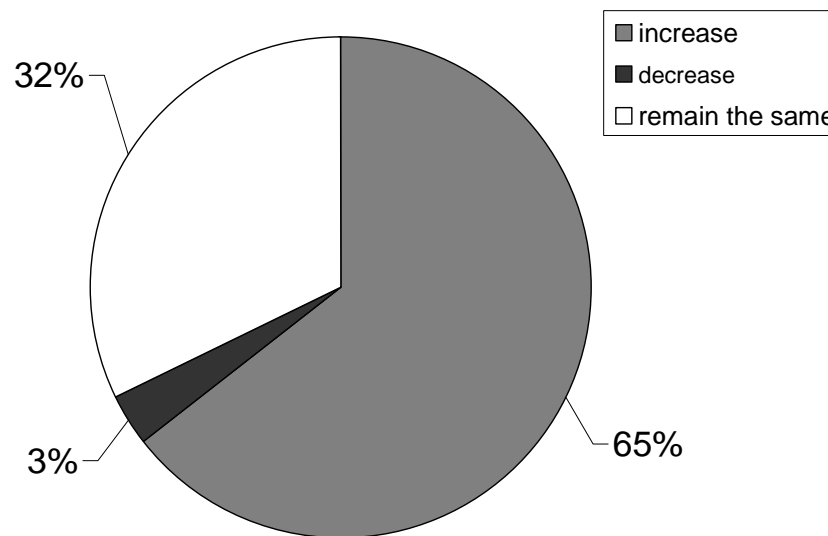
### Public Sector

- Europe counts 142 public research groups
- Pharmacogenetics Networks are established in the US and Japan

### Private Sector

- 47 SMEs make up the core of the PGx sector (60% of these are based in USA)
- High turn over – most see PGx as a drug development tool

Development of research staff in the last 5 years





## Current R&D status (2)

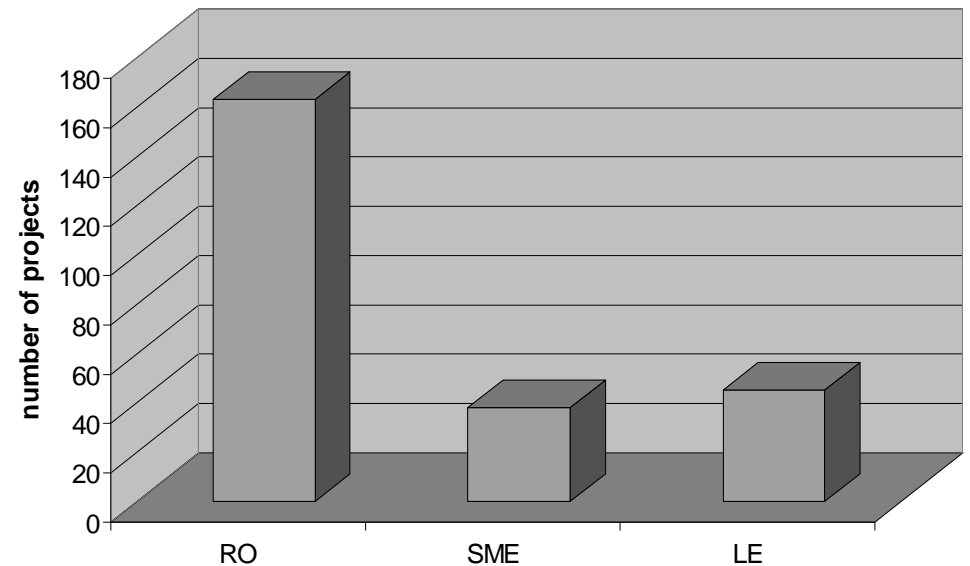
### Interaction of Academia and Industry

- Collaboration is limited
- Experts from academia complain about the lack of access to data

### Barriers to research

- Availability of samples and data protection requirements
- High cost of PGx work

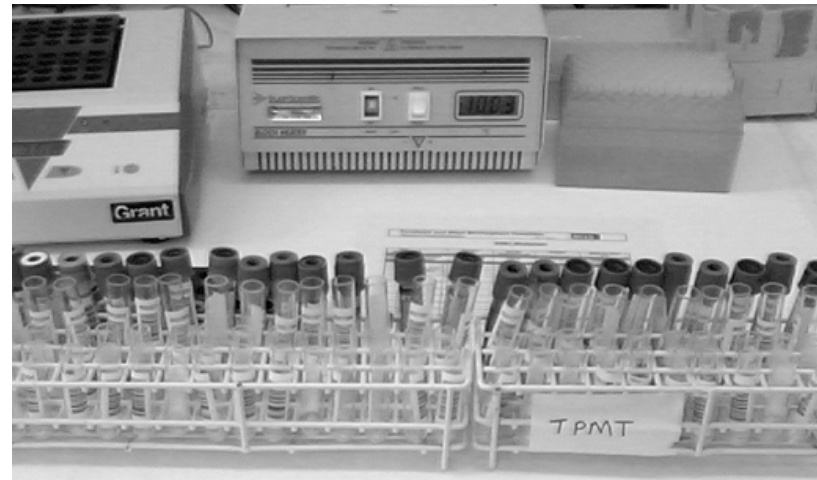
Number of co-operation projects in 2003







# Assessing clinical implementation





## *Study Design: 2 cases – 4 countries*

- HER2
  - efficacy of trastuzumab-Herceptin
- TPMT
  - safety of thiopurine drugs
- 4 EU countries
  - Germany
  - UK
  - Ireland
  - Netherlands



## Methodology

- Desk research
- Survey
- Interviews





## Implementation Levels are Low

Case	Treatment with NO prior testing	Treatment without testing all patients	Consistent Use
HER2	8%	8%	84%
Total number of respondents: 77			
TPMT	53%	35%	12%
Total number of respondents: 34			



## Main Factors Influencing Clinical Uptake (1)

- The role of industry
  - Market-size
  - Roche-HER2 example vs TPMT
- Education
  - Use and interpretation



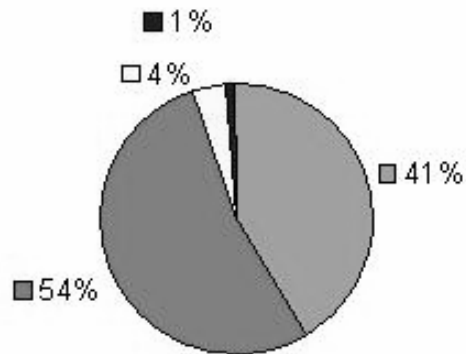
## Main Factors Influencing Clinical Uptake (2)

- Reimbursement
  - Difficult or unclear
- Liability
  - TPMT example

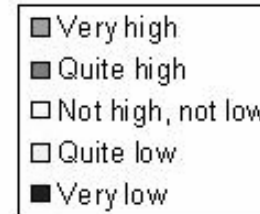
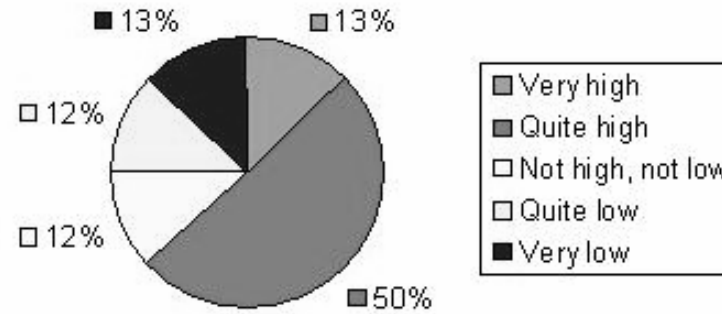
# Other Factors Influencing Clinical Uptake (1)

- Clinical utility/validity

a) Perceived clinical utility (HER2)



b) Perceived clinical utility (TPMT)





## *Other Factors Influencing Clinical Uptake (2)*

- Infrastructural
  - Communication with lab (varies by country)
  - Sample handling (sending, storage etc.)
- Social
  - No major social barriers for the two case studies investigated





## *Cost-effectiveness of PGx in clinical practice*

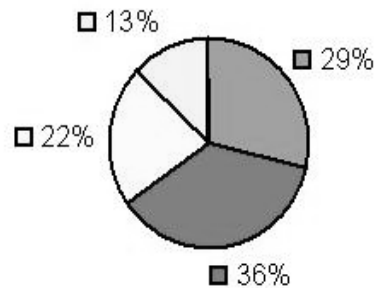
- Important for levelling off barriers
- Economic implications of PGx are less studied
- Cost-effectiveness review was performed
- Both tests were proven cost-effective



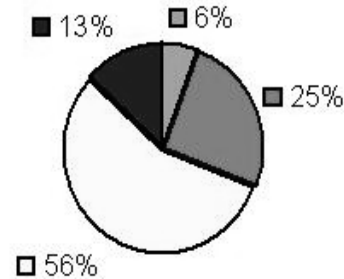


# Perceived vs. Calculated Cost/Benefit

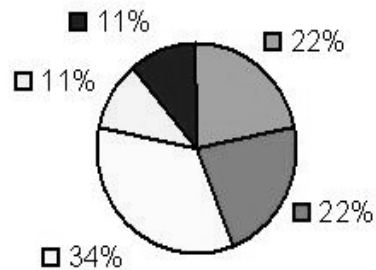
**a) Perceived CB (HER2)**



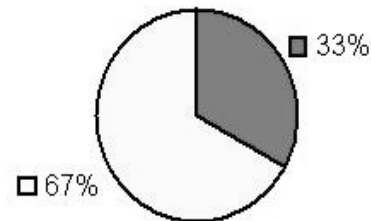
**b) Perceived CB (TPMT)**



**c) Calculated CB (HER2)**



**d) Calculated CB (TPMT)**



- Benefits much higher than costs
- Benefits a little higher than costs
- Benefits and costs equal
- Costs a little higher than benefits
- Costs much higher than benefits



## Regulatory Frameworks

- Interviews conducted in 4 countries studied
- New capabilities are being developed at regulatory agencies (EMA and FDA) to address PGx related needs
- Currently there is no regulatory framework imposing consistency of testing in Europe
- Challenges include biomarker validation and use of PGx data



## Summary

- Clinical implementation of HER2/TPMT testing is incomplete in spite of cost-effectiveness.
- Main influencing factors include:
  - industry
  - lack of training
  - reimbursement procedures
  - liability issues
- Additional work is required to extend findings to other PGx cases.



## Acknowledgements

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