

About the author

Disclaimer

## EXECUTIVE SUMMARY

The personalized medicine paradigm

Co-development partnerships

Retrospective development alliances

Alternative partnership models

Best practices in RxDx partnering

Future trends influencing RxDx partnerships

The personalized medicine paradigm

Summary

Introduction

Drivers of Rx/Dx partnerships

Regulatory drivers

EU regulatory initiatives

A convergence of different industry sectors

Partnership trends

Scope of report

Co-development partnerships

Summary

Introduction

Genentech/Dako: Herceptin/HercepTest

The partnership

The results

Observations

Pfizer/Monogram Biosciences: Selzentry/Trofile

The partnership

Results

Observations

Plexxikon/Roche: Zelboraf/BRAF test

The partnership

Results

Observations

Bayer Schering/Prometheus

The partnership

Observations

Novartis/Invivoscribe: midostaurin/FLT3

The partnership

Observations

Retrospective development alliances

Summary

Introduction

Vectibix/Erbitux:KRAS

The partnerships

Observations

Iressa (AstraZeneca)/Qiagen

- The partnership
- Observations
- Alternative partnership models
  - Summary
  - Introduction
  - Prometheus/Entocort
    - The partnership
    - The results
    - Observations
  - Takeda/Zinfandel: pioglitazone/TOMM40 assay
    - Background
    - The partnership
    - Observations
  - GSK/Enigma Diagnostics
    - The partnership
    - Observations
  - Dako/Quintiles
    - Background
    - The partnership
    - Observations
  - Medco/MolecularMD
    - The partnership
    - Observations
- Best practices in RxDx partnering
  - Summary
  - Introduction
  - What are pharma companies looking for?
  - What are Dx companies looking for?
  - Negotiating the deal
  - Ingredients of a successful relationship
    - Start early
    - Sharing a common goal
    - Mutual understanding of different business models
    - Understanding risks
    - Good working processes
  - Reimbursement
  - Commercialization
- Future trends influencing RxDx partnerships
  - Summary
  - Introduction
  - Industry dynamics
  - Regulators take proactive role
  - Pricing and reimbursement environment
    - UK Stratified Medicine initiative
  - Appendix
  - Bibliography/References

Abbreviations

TABLES

Table: Scope of Rx-Dx partnership deals in Jan-August 2011

FIGURES

Figure: Therapeutic categories of drugs with pharmacogenomic biomarkers in US label

Figure: Ideal Rx-Dx co-development scenario

Figure: Rx-Dx partnership deals 2007-2011

Figure: Zelboraf & CDx – From discovery to approval

Figure: KRAS timeline

Figure: Percentage of mCRC patients tested for KRAS

Figure: Sales of Entocort EC, 2005-2010, \$m

Figure: Key considerations when choosing a Dx partner

Figure: Key considerations when choosing a Rx partner