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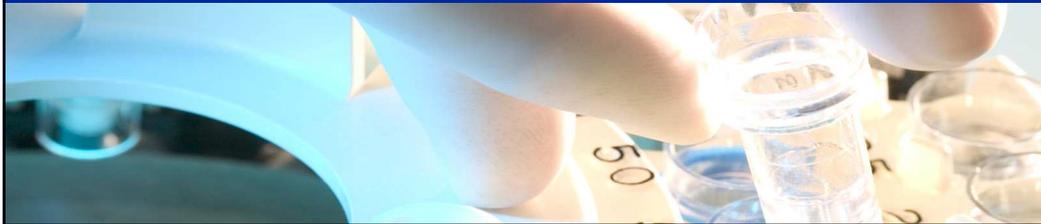
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Roche Diagnostics Driving Personalized Healthcare

*Robert Yates, Head Business Development, Diagnostics
Natixis Diagnostics Seminar, Paris, 3 April 2008*



Introduction

Personalized Healthcare

Biomarker Development

PHC in Roche Oncology

Closing

Introduction – Roche Group

Two Divisions focused on high-value healthcare



Diagnostics



Pharmaceuticals



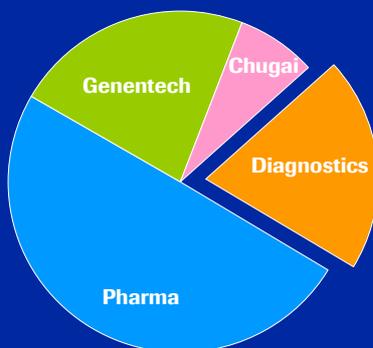
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Introduction – Roche Group

Diagnostics represents 20 % of group sales



Roche Group Sales 2007
CHF 46 bn



Roche Diagnostics 2007

Sales	CHF 9,350 m
R&D spend	CHF 787 m
<i>% of sales</i>	8.4 %
EBITDA	CHF 2,580 m
<i>% of sales</i>	27.6 %
Operating profit	CHF 1,648 m
<i>% of sales</i>	17.6 %
No. employees	23,062

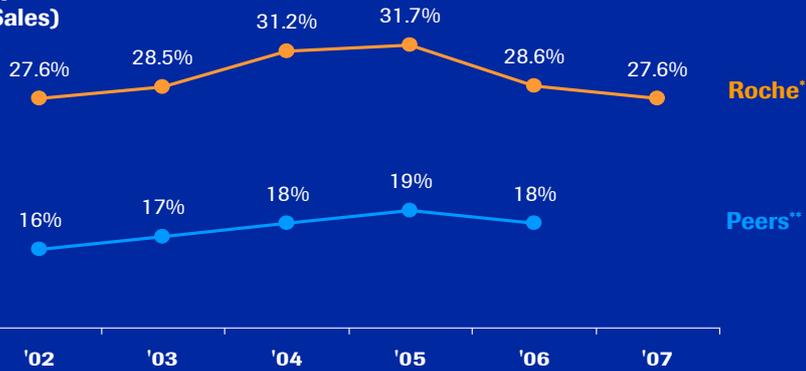
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Introduction – Roche Diagnostics



Strong cash generation! High margins relative to peers

EBITDA (% of Sales)



*Before exceptional items

**peer group: Abbott Dx., Bayer Dx., Beckman Coulter, Becton Dickinson, Dade Behring, JNJ

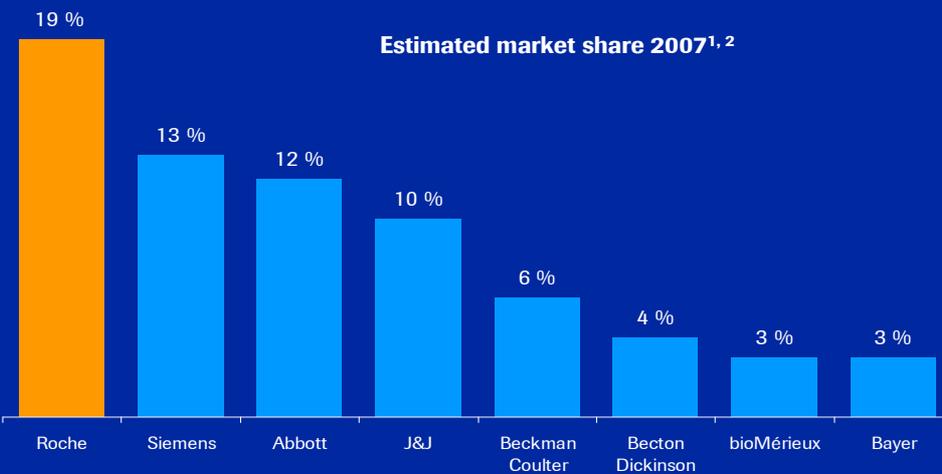
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Introduction – Roche Diagnostics



#1 in-vitro diagnostics company

Estimated market share 2007^{1, 2}



¹ Source: company reports, Boston Biomedical Consultants and Roche analysis

² in vitro diagnostics market; excludes Life Science research market

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Introduction

Personalized Healthcare

Biomarker Development

PHC in Roche Oncology

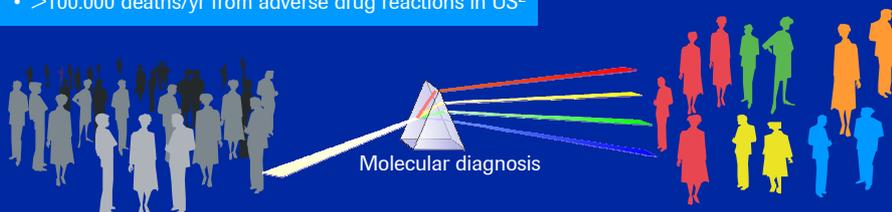
Closing

Personalized Healthcare

Use of molecular insights and diagnostic tests to better tailor medicines and manage a patient's disease

Today most patients are treated the same

- 25-80 % of patients receive effective treatment¹
- >100.000 deaths/yr from adverse drug reactions in US²

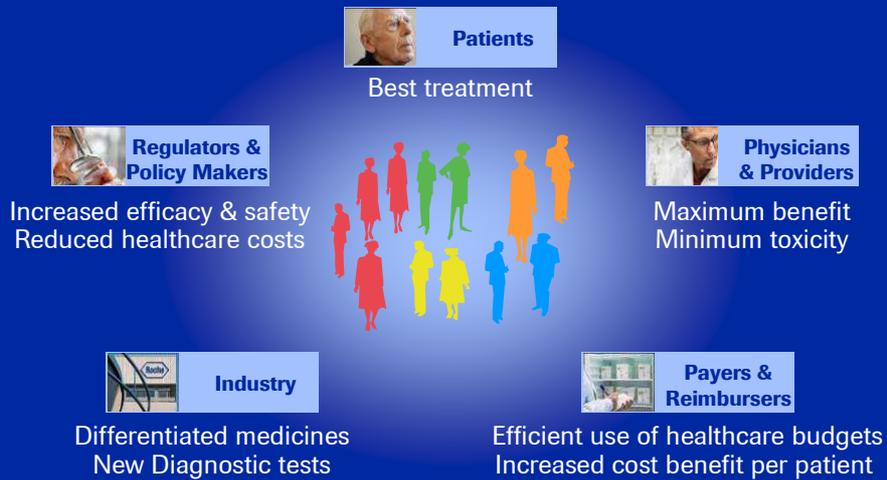


Increasingly, treatment will be tailored to **selected patient groups** defined by **molecular markers**

¹ Spears et al., Trends Mol Med, 2001
² Lazarou et al., JAMA, 1998

Personalized Healthcare

Provides benefits for all key stakeholders



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Personalized Healthcare

Dispelling the myths



Myth #1

- Pharma companies are not interested in pursuing PHC because it will reduce eligible patient populations

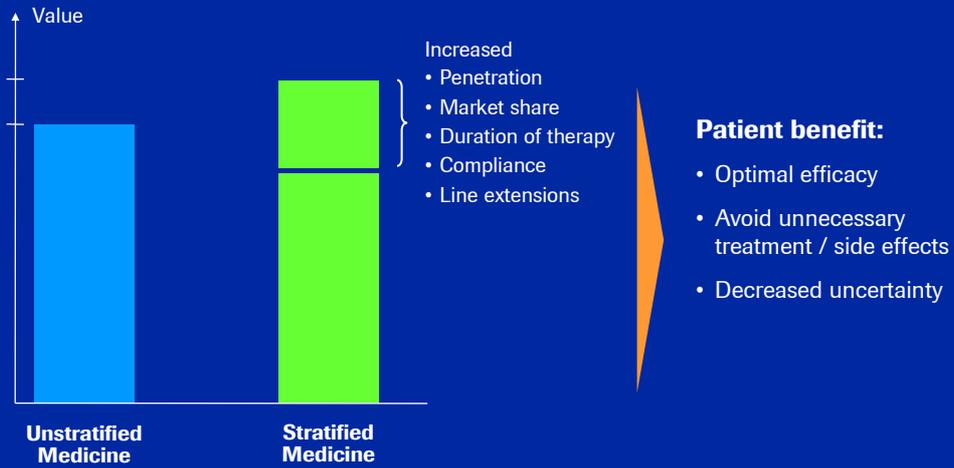
Myth #2

- Identifying viable Biomarkers is easy

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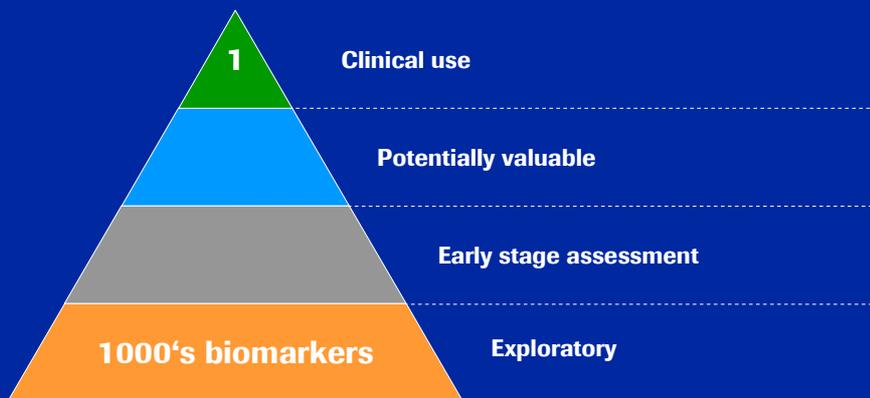
Personalized Healthcare

Creates patient benefits and commercial incentives



Personalized Healthcare – The complexity of science

A biomarker might be more difficult to find than a drug



Biomarker = Any biological parameter used as indicator of disease process or drug response

Introduction

Personalized Healthcare

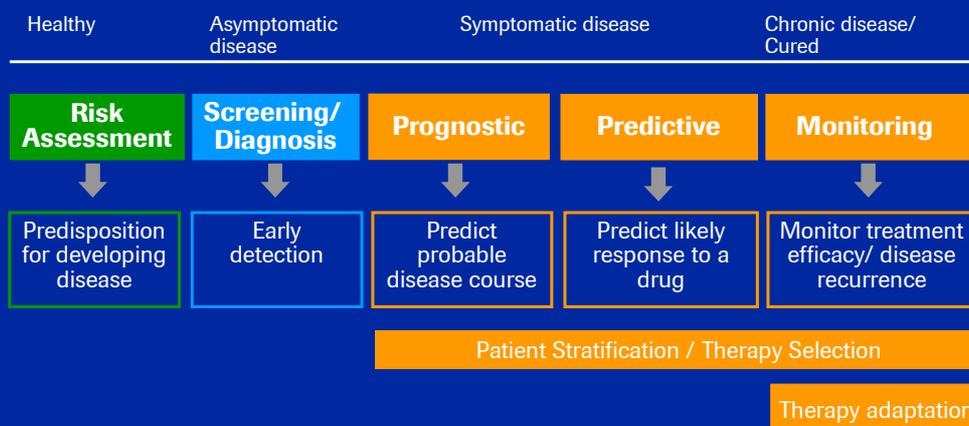
Biomarker Development

PHC in Roche Oncology

Closing

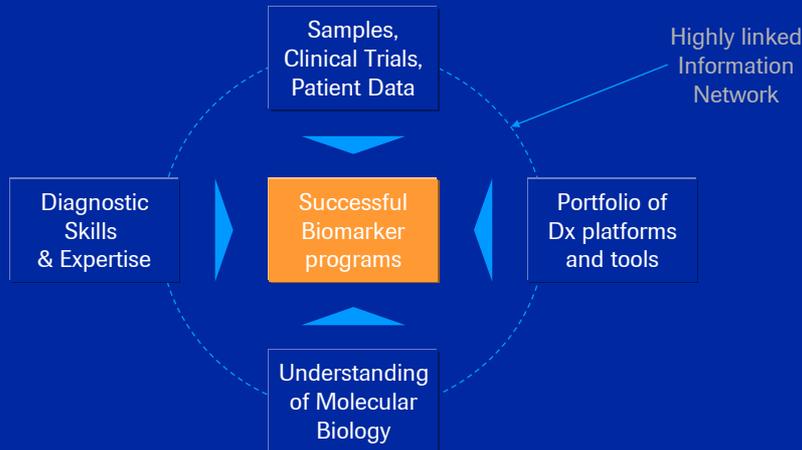
Biomarker Development – Why?

Identify patients most likely to benefit / most effective treatment



Biomarker Development – What it Takes

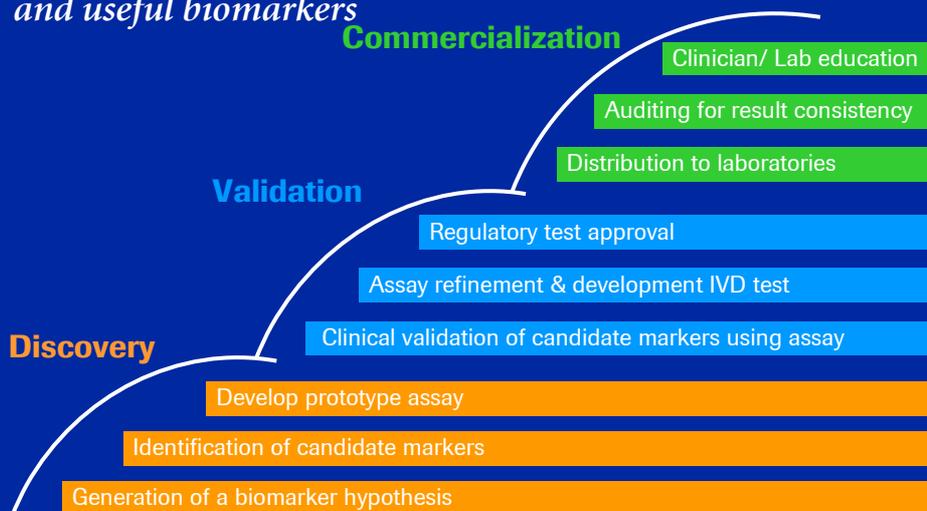
A plethora of tools, skills and capabilities



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Biomarker Development – Capabilities

Significant hurdles to establishing clinically viable and useful biomarkers



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Biomarker Development – Technology

Variety testing methods for biomarkers



- Protein expression
 - immunohistochemistry (IHC)
 - enzyme-linked immunosorbent assay (ELISA)



- Gene expression
 - assessed by microarray technology or reverse transcription-polymerase chain reaction (RT-PCR)



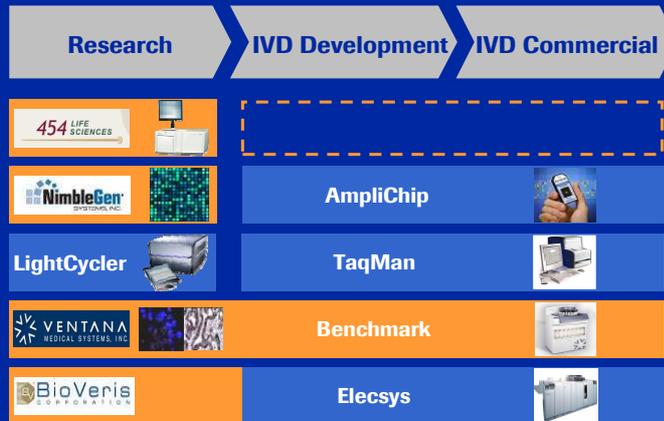
- Gene copy number
 - fluorescent/ chromogenic in-situ hybridisation (FISH/CISH)



- Gene sequence
 - DNA sequencing (other methods possible for known mutations)

Biomarker Development – Roche Technology

Full range of Diagnostic capabilities required; one-stop-shop greatly improves flexibility and speed



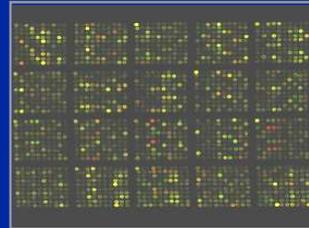
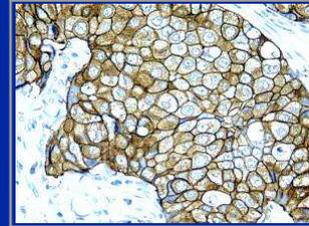
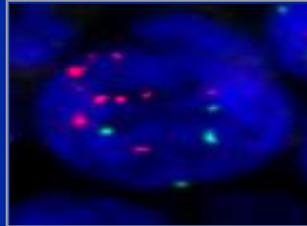
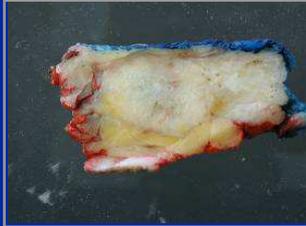
*Immunohistochemistry / In Situ Hybridization

** enzyme-linked immunosorbent assay

Biomarker Development – Challenges



Numerous challenges associated with biomarker testing

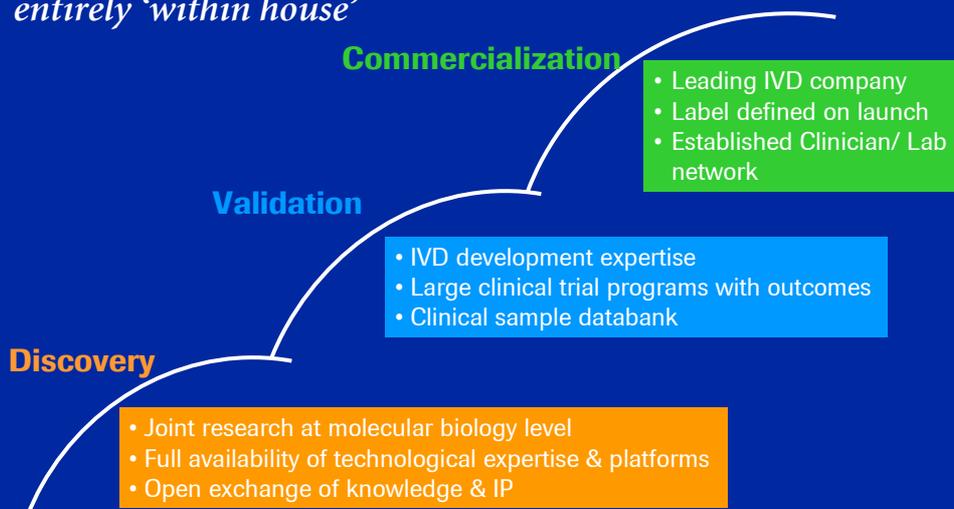


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Biomarker Development – Roche Distinctiveness



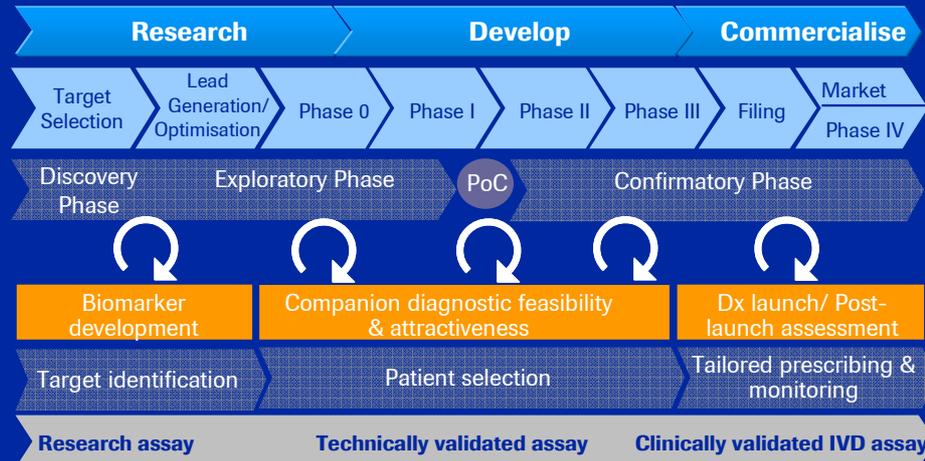
Roche's competitive edge is driving Personalized healthcare entirely 'within house'



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Biomarker Development

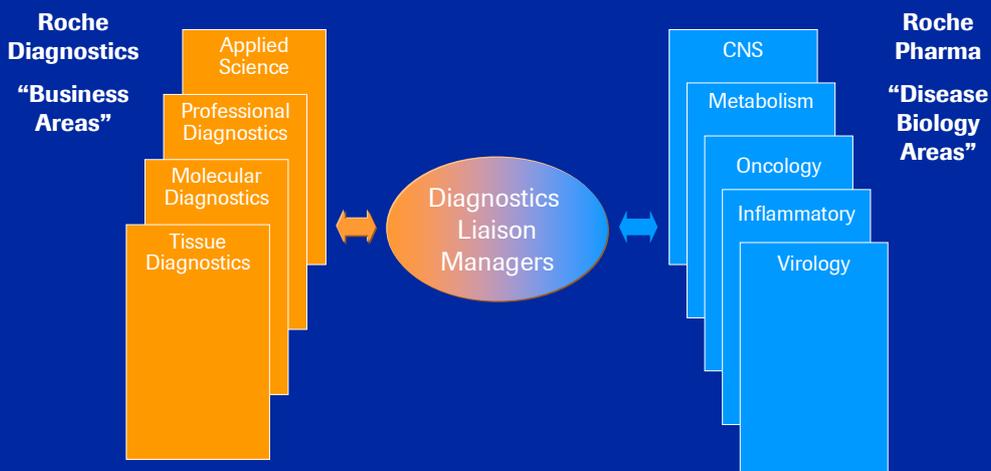
Diagnostics input for all Pharma projects - from discovery to market



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Biomarker Development – Roche Distinctiveness

Align Diagnostics to Pharma Disease Biology Areas



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Introduction

Personalized Healthcare

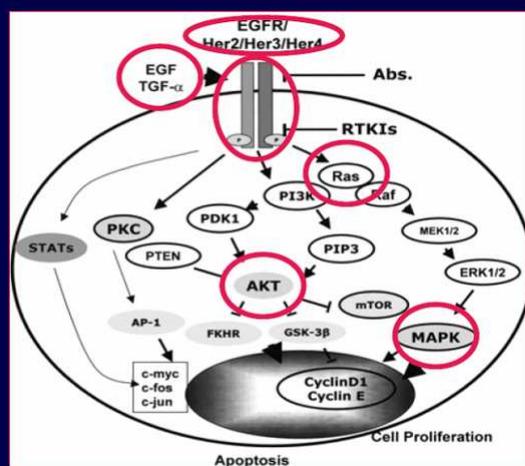
Biomarker Development

PHC in Roche Oncology

Closing

PHC in Roche Oncology – HER Family

Fertile ground for new drugs and biomarkers



Abnormalities in important genes/proteins

Potential predictive biomarkers

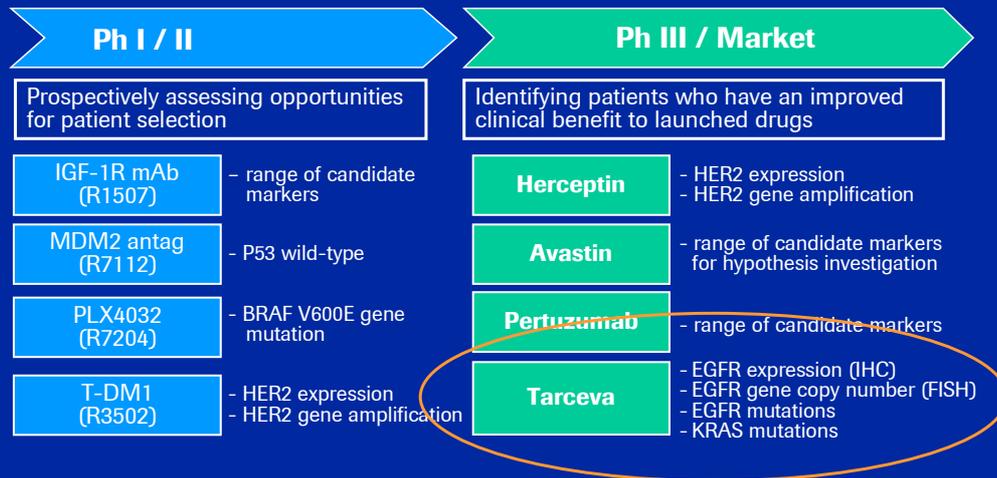
Clinical Cancer Research Vol. 10, 4227S-4232S, June 15, 2004



PHC in Roche Oncology – Overview



Biomarker programs for all pharma projects

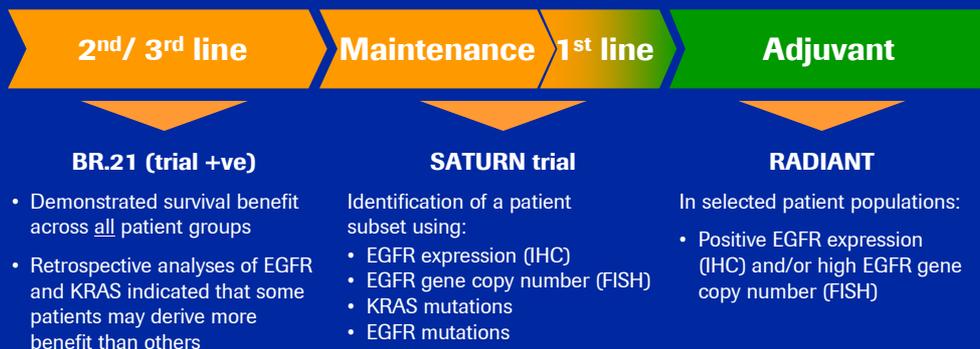


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PHC in Roche Oncology – Tarceva



Predictive biomarkers may enable expansion into earlier lines of treatment for NSCLC

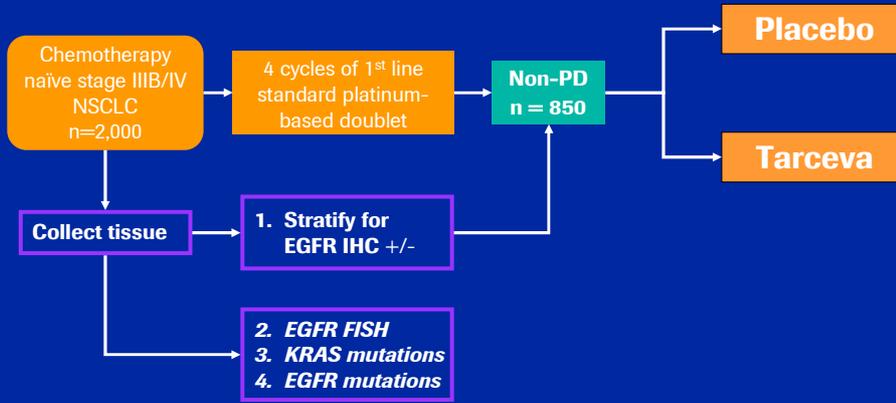


Analysis of completed trials indicated a number of promising predictive biomarkers
Biomarkers being assessed in large prospective trials to understand predictive power

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PHC in Roche Oncology – Tarceva

SATURN - phase III 1st line maintenance



Largest randomized trial to prospectively address relationship between biomarkers & clinical outcome – due to report in H2 2008

PHC in Roche Oncology – Tarceva

Assessing biomarkers in large prospective trials to understand their predictive power

Biomarker	Completed Clinical trials					Ongoing or planned clinical trials							
	B.R. 21	MERIT	TRIBUTE	TALENT	TRUST 1	SATURN	TITAN	TRUST 2	Betalung	ATLAS	Bunn	TASK	RADIANT
EGFR IHC													
EGFR FISH													
EGFR Mutations													
KRAS Mutations													

Introduction

Personalized Healthcare

Biomarker Development

PHC in Roche Oncology

Closing

Closing – Roche Group

Differentiation through Personalized Healthcare

- Personalized Healthcare is here to stay!
- Many hurdles to overcome in biomarker discovery, validation and commercialization
- Diagnostics capabilities and technologies play a crucial role in discovering & harvesting biomarkers
- Having Diagnostics intertwined throughout all stages of drug development is a significant competitive advantage

Our strategy provides Roche with a competitive edge in developing innovative products and services

Closing – Roche Group



Embracing Personalized Healthcare creates competitive advantage on three dimensions

Develop a pipeline of clinically differentiated medicines

Produce safer, more efficacious and cost-effective medicines

Ensure the full value of products in the market

Understand post-launch stratification via better lifecycle management

Launch more companion diagnostics

Opportunities for companion diagnostics – although these will only occasionally be required

**Better understand the complexity of disease and treat accordingly
More integrated and adjusted therapies**

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Closing – Roche's Distinctiveness



Driving Personalized Healthcare through medically differentiated medicines and tests

Life Sciences



In Vitro Diagnostics



Pharma



Increasing medical value to patients & physicians

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We Innovate Healthcare