
Personalised Healthcare Making it happen

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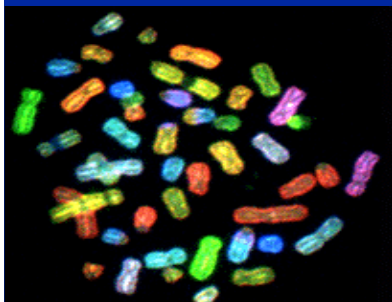


Agenda

- Personalised Healthcare is getting closer
- Why is Personalised Healthcare so complex?
- How we make Personalised Healthcare happen
- Remaining challenges
- Summary

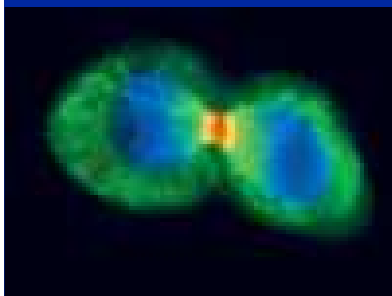
Progress in science and medicine

From macroscopic to cellular to subcellular level



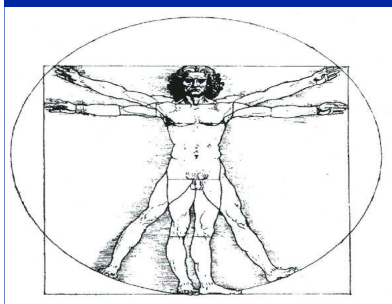
Today

Diagnosis and treatment increasingly based on rapidly growing insights into molecular processes and variations in our genes



The last 100 years

Diagnosis and treatment based on increasing knowledge about biochemistry and cellular processes



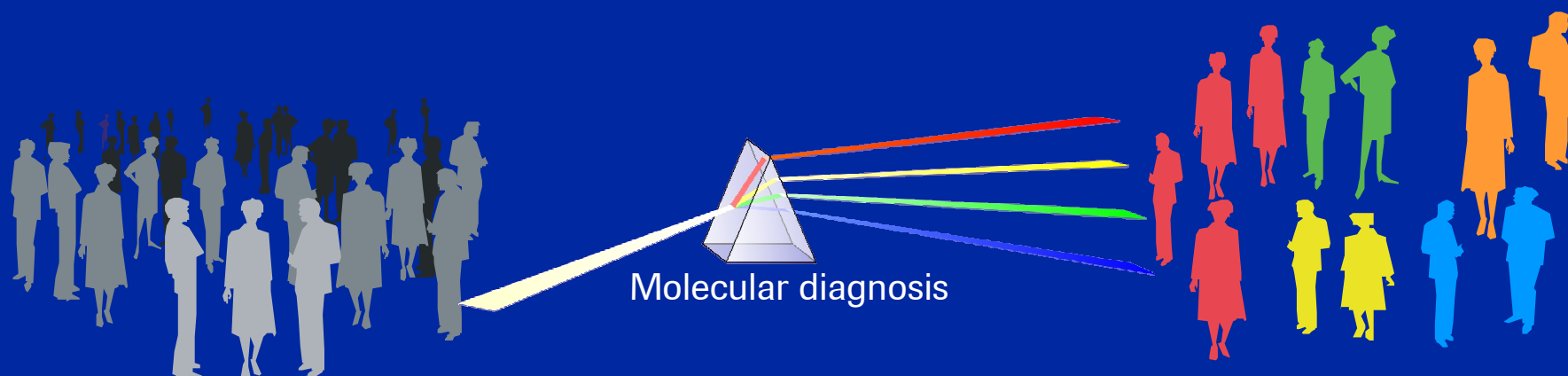
For more than 10, 000 years

Diagnosis and treatment based on what could be seen, smelled, tasted, palpated or intuited

The advent of Personalised Healthcare

Every good therapy starts with a good diagnosis

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



Still today, almost all patients are treated in a few similar ways

- Only 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**

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

Personalised Healthcare will become a necessity

Benefits for all key stakeholders



Patients

- Welcome any better medicine
- Influence payment and prescribing



Regulators & Policy Makers

- Reduce toxicity, increase efficacy
- Control healthcare costs



Physicians & Providers

- Provide best care for patient
- Reduce toxicity, increase efficacy



Industry

- Rx: Clinically differentiated medicines
- Dx: Biomarkers to develop & choose therapies



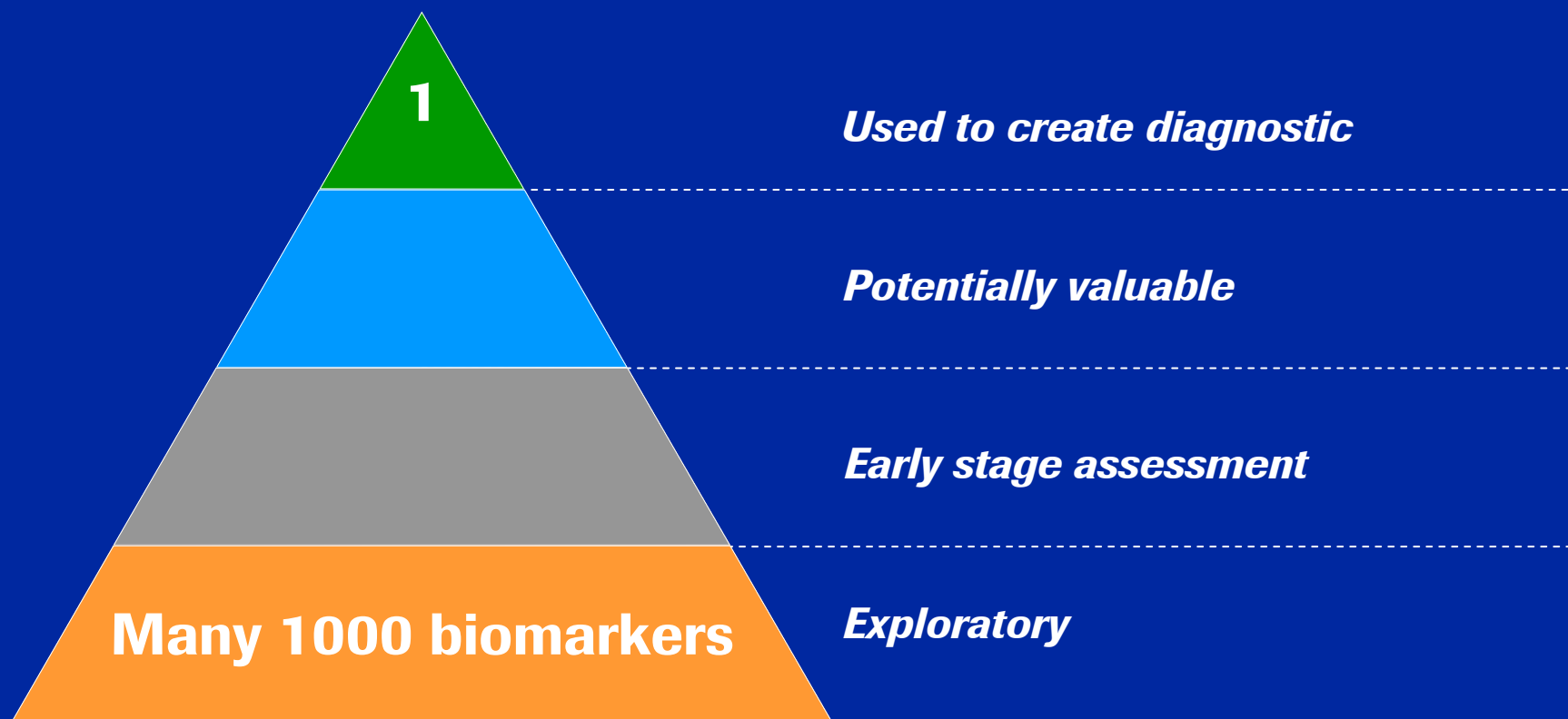
Payers & Reimbersers

- More cost-effective healthcare



The complexity of science

A biomarker might be more difficult to find than a drug

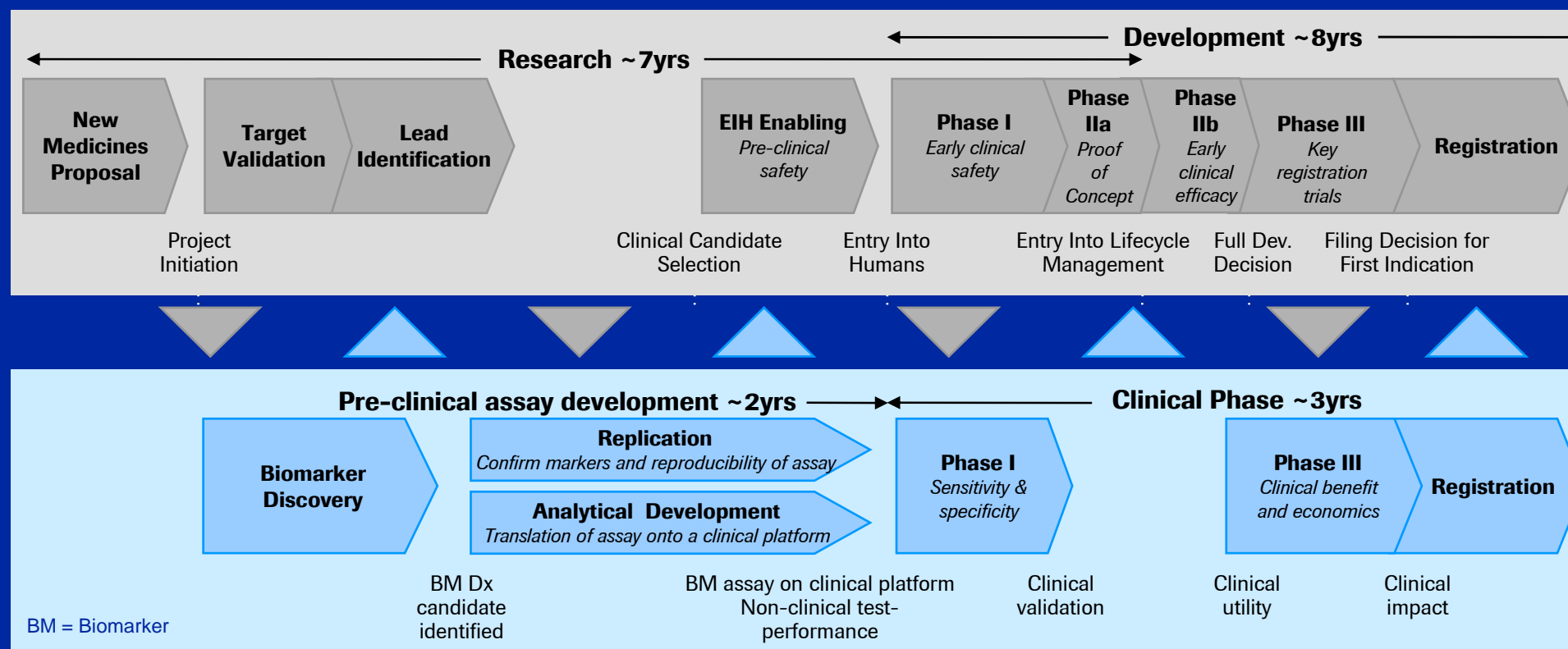


Biomarker = Any biological parameter used as indicator of disease process or drug response



The complexity of Pharma and Diagnostics workflows

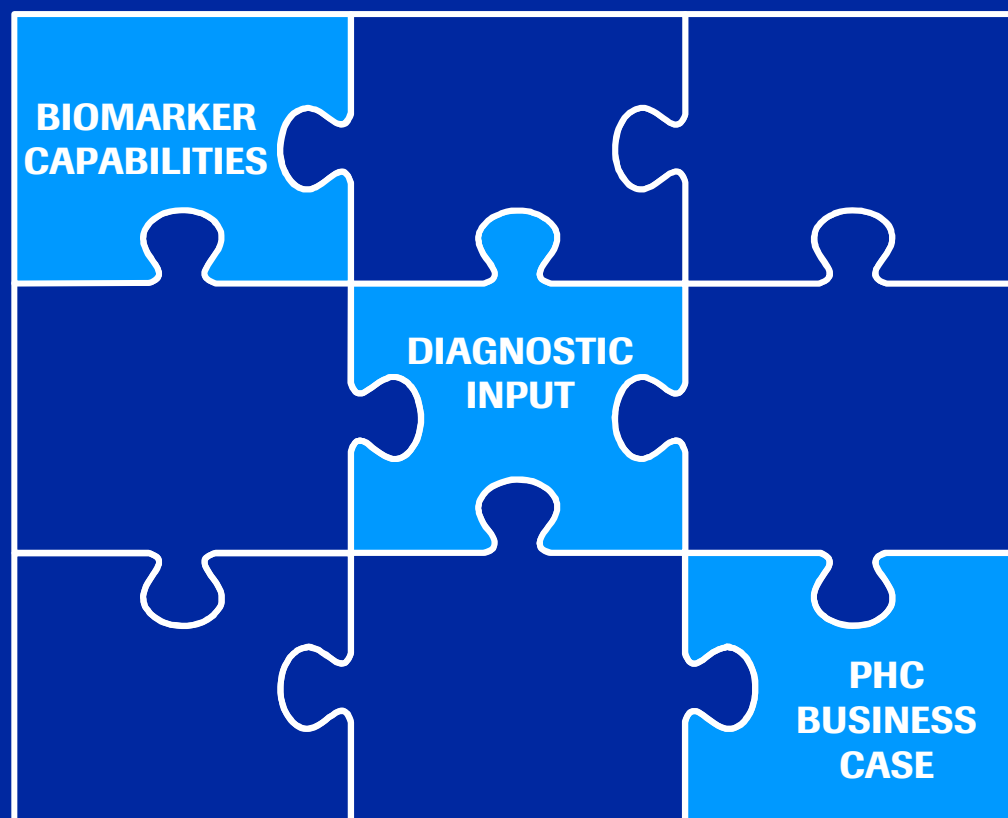
Synchronize and integrate across the value chains



- 1) Coordinate joint launch (where feasible / sensible)
- 2) Manage interdependencies between Rx and Dx workflows

Critical success factors for PHC

Key enablers for a fully integrated PHC company



World-class biomarker expertise for every project team

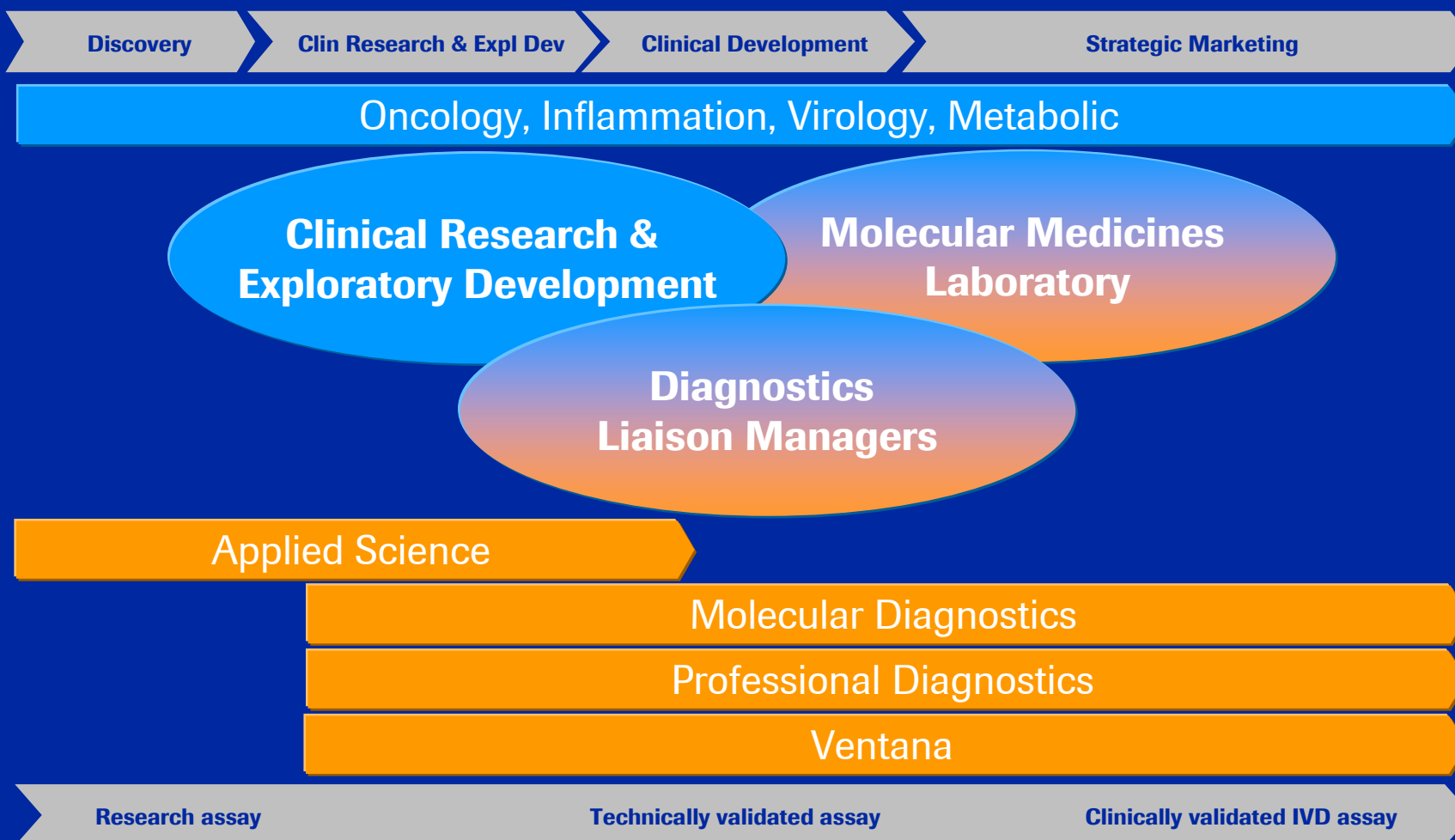
Full range diagnostic services from discovery to the market

Market-driven view of the product along the lifecycle



PHC is at the core of our organisation

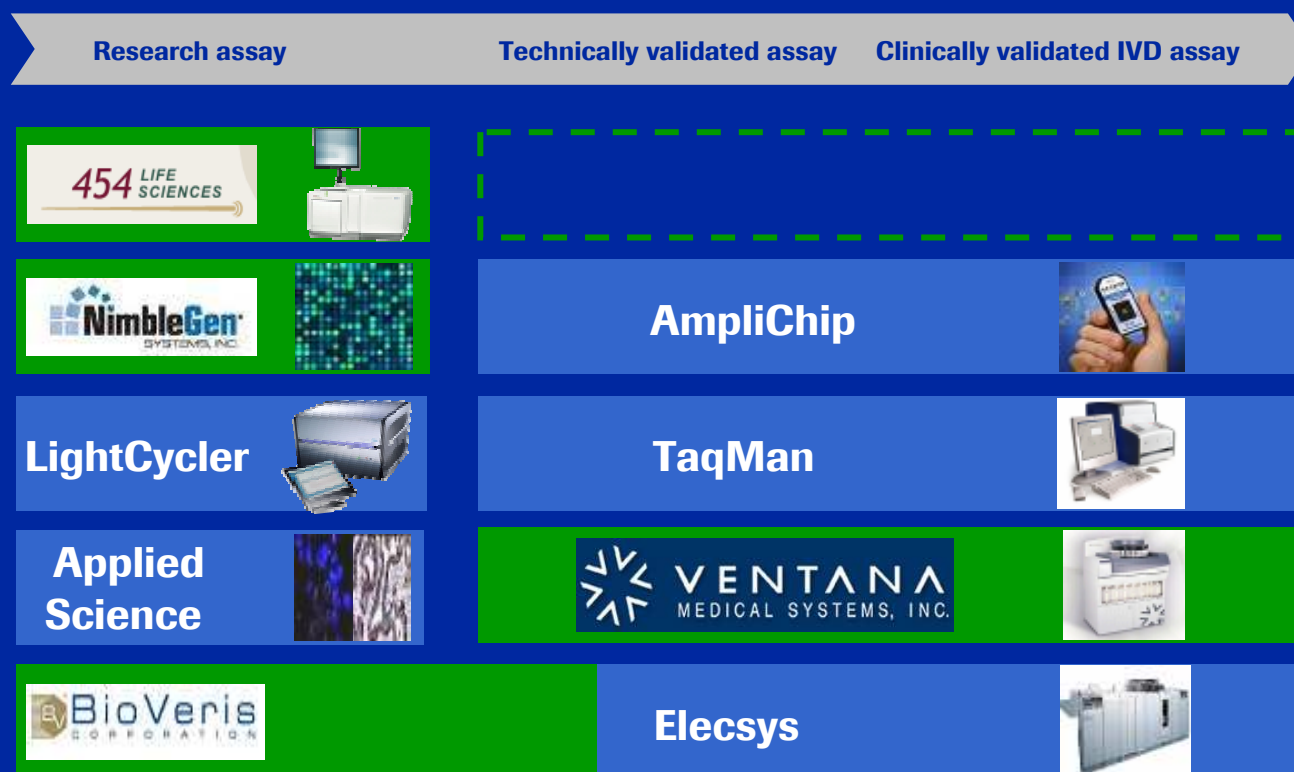
Key interfaces between Pharma and Diagnostics





Full range of Dx capabilities required

One-stop-shop improves flexibility and speed



* ImmunoHistoChemistry/In Situ Hybridisation

** ElectroChemiluminescent Label ImmunoAssay



Personalised Healthcare for good drug development

Competitive advantage on three dimensions

Develop a pipeline of clinically differentiated medicines

Produce safer, more efficacious and cost-effective medicines

Improve lifecycle management of medicines

Identifying patients who have an improved response to launched drugs

Launch more companion diagnostics

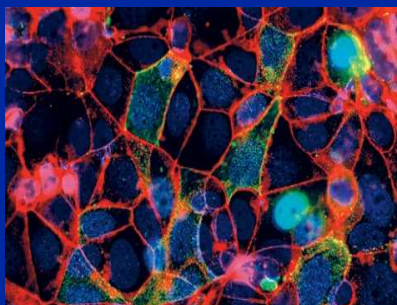
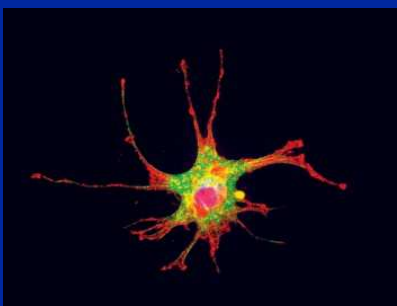
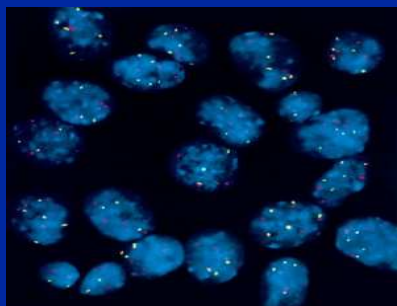
Opportunities for companion diagnostics – although these will only occasionally be required

Better understand the complexity of disease and treat accordingly

More integrated and adjusted therapies

Current PHC examples in oncology

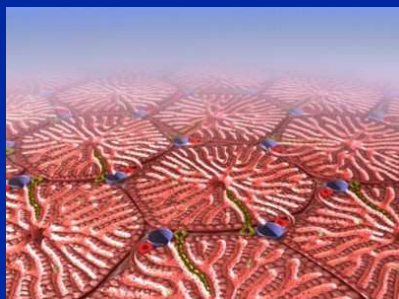
Broad approach to leverage stratification opportunities



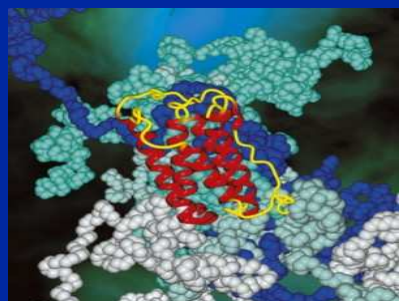
- Implementing biomarker strategy for all pipeline drugs
- Assessing opportunities for companion diagnostics
 - *Pertuzumab / HER dimerization inhibitors*: Expression of Her-2 etc.
 - *IGF-1R inhibitor*: Expression of IGF-1R
 - *MDM2*: Active only in p53 wild-type patients
 - *PLX4032*: Presence of BRAF V600E gene mutation
- Identifying patients who have an improved response to launched drugs
 - *E.g. Tarceva in 1st line NSCLC / SATURN trial*

Current PHC examples in virology

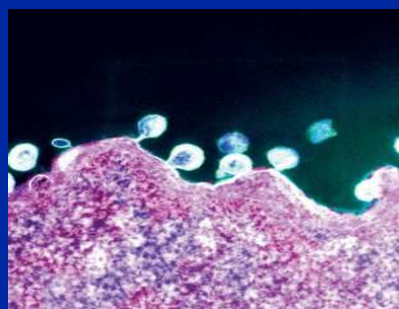
Targeted activities to improve care in HCV and HPV



- **Detecting Hepatitis C virus subtype / Pegasys response**
 - Identify carriers of virus
 - Identify patients most likely to respond to Pegasys
 - Monitor viral load (response / compliance)



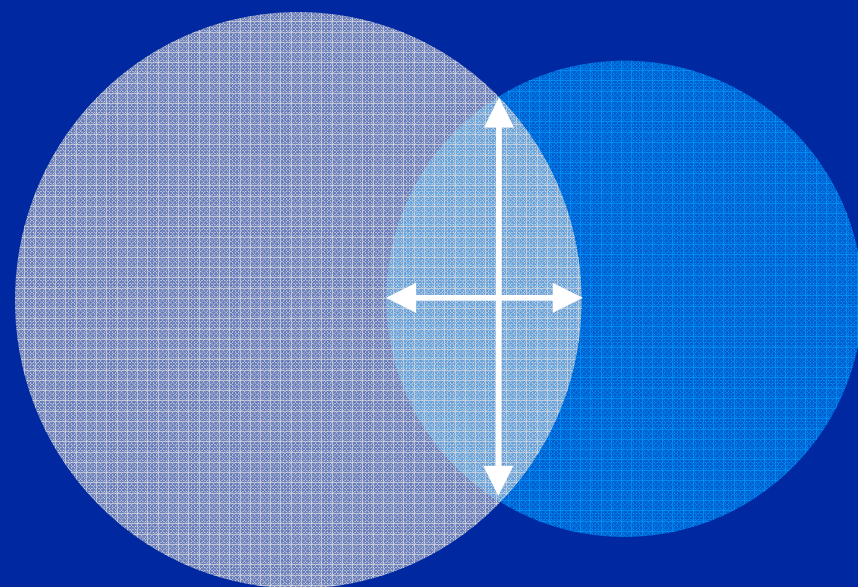
- **Determining genotype 16 Human Papilloma Virus**
 - Reduce risk of cervical cancer by closer monitoring
 - Support Roche Pharma studies on therapeutic vaccines



The significance of PHC for Roche

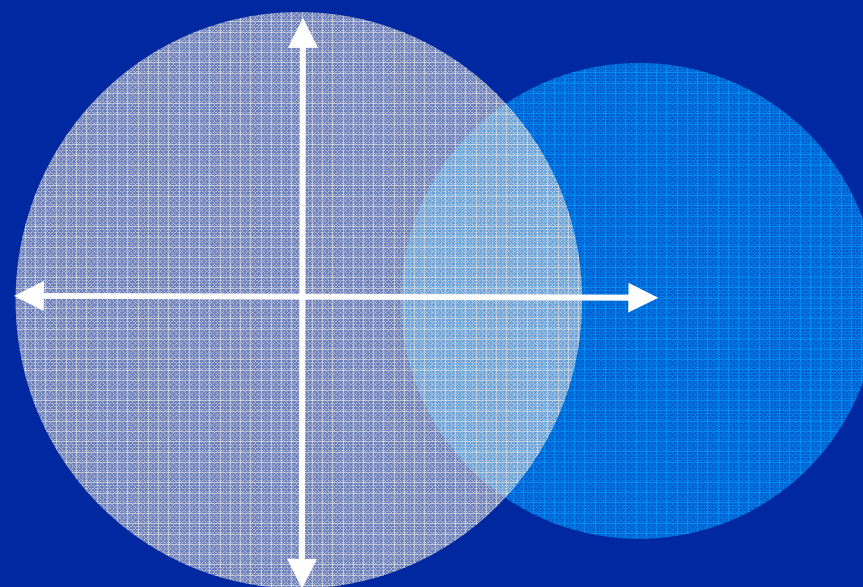
Systematically applied PHC drives value for Rx and Dx

Not „just“ companion diagnostics... ...but value creation for Pharma and beyond



Pharma

Diagnostics

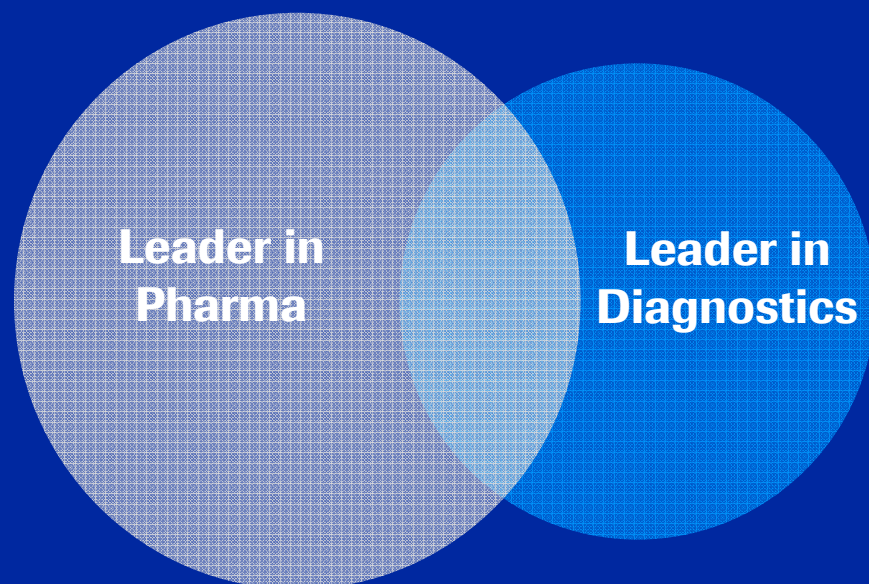


Pharma

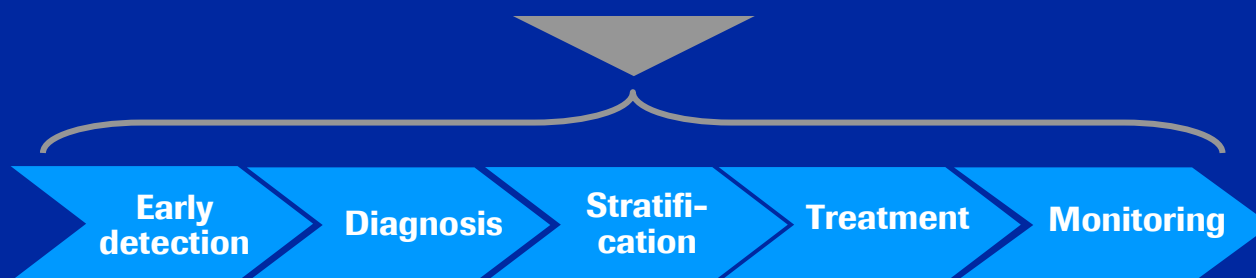
Diagnostics

Strategic acquisitions and portfolio enhancements

Advance PHC through technology leadership



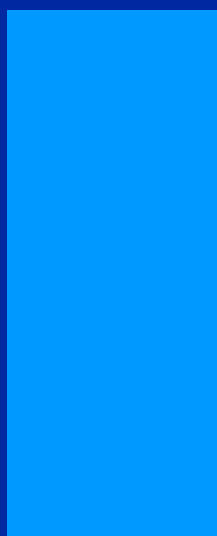
- **THP** (therapeutic antibody technology)
- **Alnylam** (RNA interference technology)
- **Transgene** (therapeutic HPV vaccine)
- **BioVeris** (electrochemiluminescence)
- **454 Life Sciences** (ultra fast gene sequencing)
- **NimbleGen** (high-density DNA microarrays)
- **Ventana** (tissue-based diagnostics)



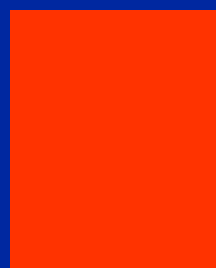
Economics of stratification drive PHC

Creating patient benefits and commercial incentives

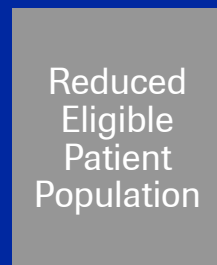
**Not targeted
Medicine**



**Targeted
Medicine**



Reduced
Eligible
Patient
Population



- Penetration
- Market share
- Duration of therapy
- Compliance
- Line extensions

Patient benefit:

- **Optimal efficacy**
- **Avoid unnecessary treatment / side effects**
- **Decreased uncertainty**

Rewarding innovation to unlock the value of PHC

PHC benefits patients, society and industry



Challenge for Diagnostics

Protecting intellectual property
Cost of demonstrating clinical utility



Patent protection
Support for clinical development



Challenge for Pharma

No pricing flexibility in
postapproval stratification



Pricing flexibility linked to
demonstrable value



Public-private research partnerships to establish clinical utility and new approaches to regulatory dialogue



Summary

Roche is the first fully integrated PHC company

- Understanding of therapeutic stratification is complex and specialised but integral to business planning and the realisation of optimal healthcare
- At Roche each project team has access to biomarker capabilities and diagnostic science which allows identification of mechanism for therapeutic stratification
- Devising new incentives for Pharma and Diagnostics will be critical to help reap the full potential of PHC for patients
- The patient benefits of more precise diagnoses and better targeted treatments are already evident – particularly in oncology



We Innovate Healthcare