
Current and future trends in Personalised Healthcare

*Bruce Jordan, International Business Leader
Companion Diagnostics (CDx)*



Why Personalised Healthcare (PHC)?

PHC is the central pillar to Roche's strategy

Success stories to date – life-changing improvements

Future examples highlighting Asthma and Alzheimer's

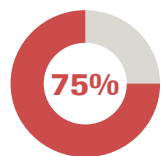
Summary

PHC is about addressing unmet need

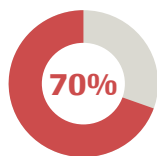
Give patients a treatment that works!

Today's Medical need

Non-responders to current therapy*



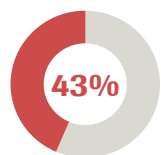
Cancer



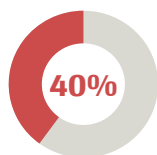
Alzheimer's



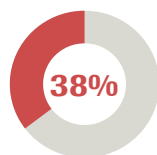
Arthritis



Diabetes



Asthma



Depression

Personalised Healthcare

The right therapy for the right group of patients



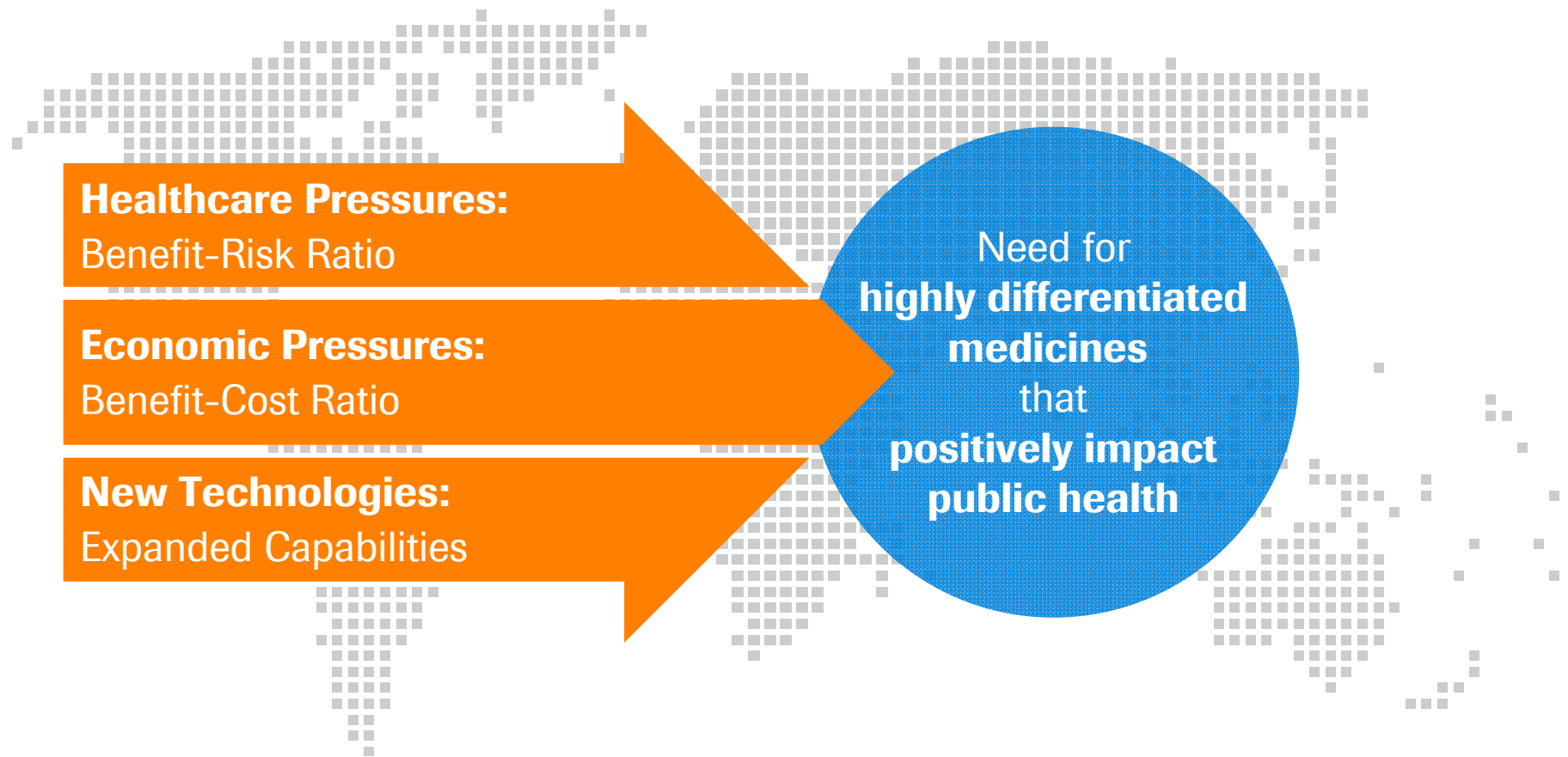
1998-2014:
1% of NDAs with CDx⁺

By 2030: up to 80% of NDAs with CDx[#]

*Clinical Trends in Molecular Medicine," Volume 7, Issue 5, 1 May 2001, pages 201-204: + <http://www.personalizedmedicinecoalition.org/> #=extrapolation of +

PHC – driver of change

Key to enabling highly differentiated medicines



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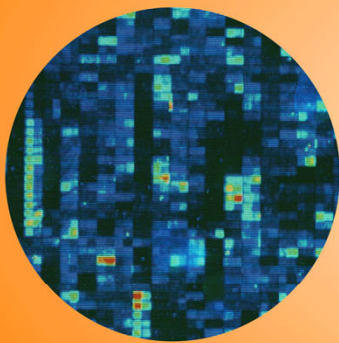
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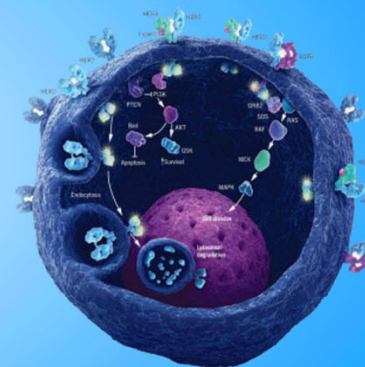
Roche uniquely positioned to drive PHC

Translating excellence in science into effective treatments

Diagnostics



Pharmaceuticals



→ Combine expertise in molecular biology and technologies to benefit patient



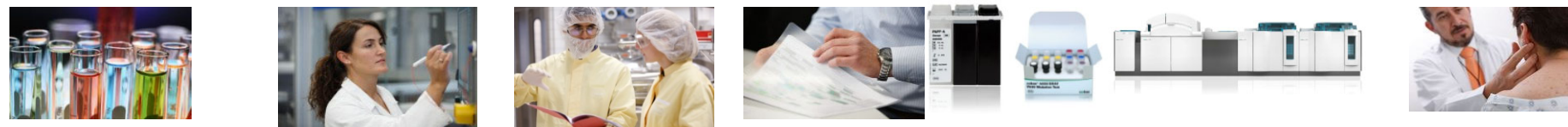
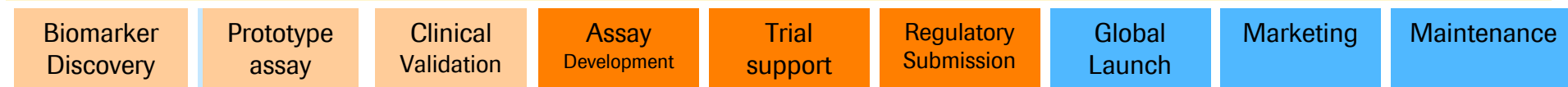
PHC requires collaboration across the value chain

Bringing together the right capabilities at the right time

Pharma



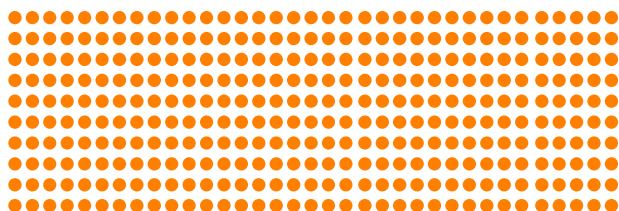
Diagnostics



PHC at Roche – an integral part of our business

Results of sustained efforts

Research



>350

Internal collaborations on biomarker and/or companion diagnostic programs

Development



8/10

New Phase III molecules have companion diagnostics and/or biomarker program

On-market



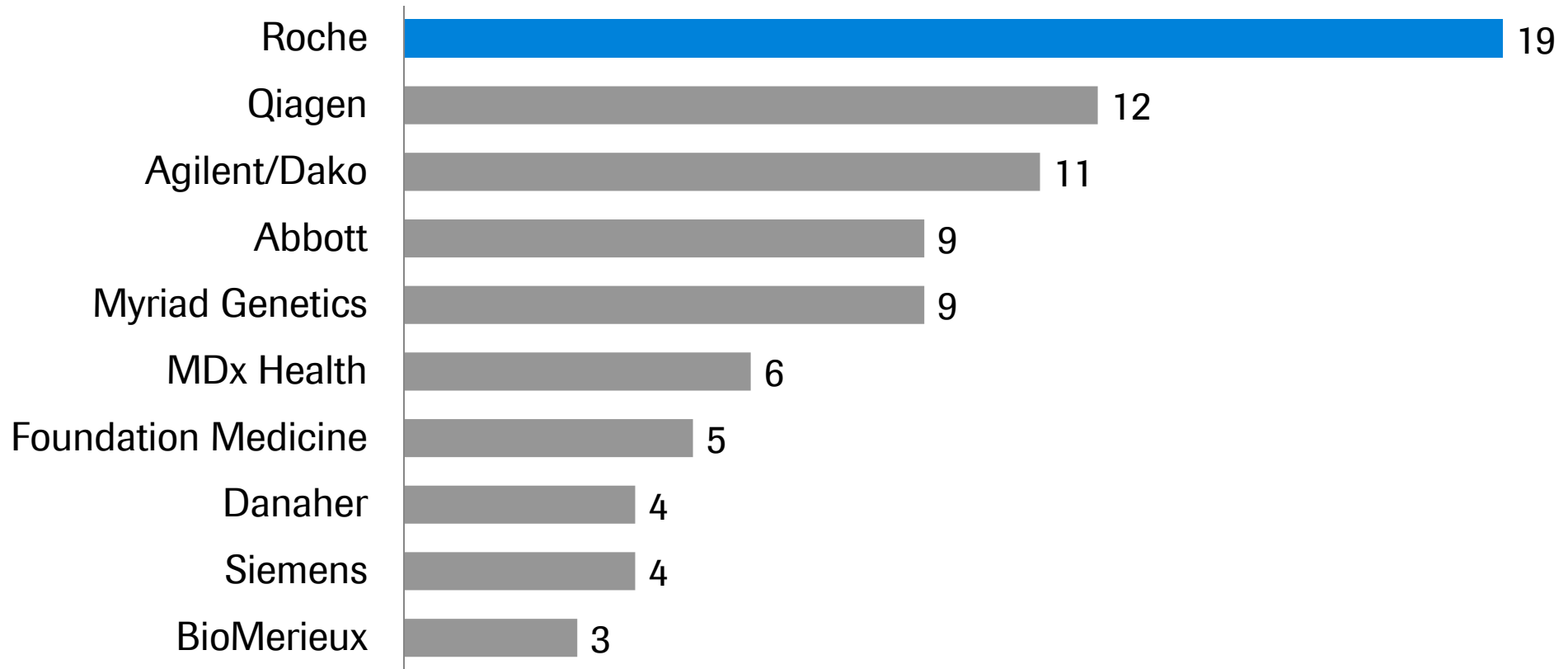
5/24

FDA-approved oncology drugs requiring a companion diagnostic



PHC with 3rd parties- Leading with companion deals

Roche works with many pharma companies





PHC is a strategic choice of Roche

At Roche, PHC is a reality now



“We see an enormous potential and huge opportunities in PHC. Targeted therapies and diagnostic tests that help to improve medical decision-making not only offer clinical benefits for patients but are also attractive through health economic benefits to regulatory authorities and payers.”

“At Roche Personalised Healthcare is a reality now!”

Severin Schwan, CEO Roche

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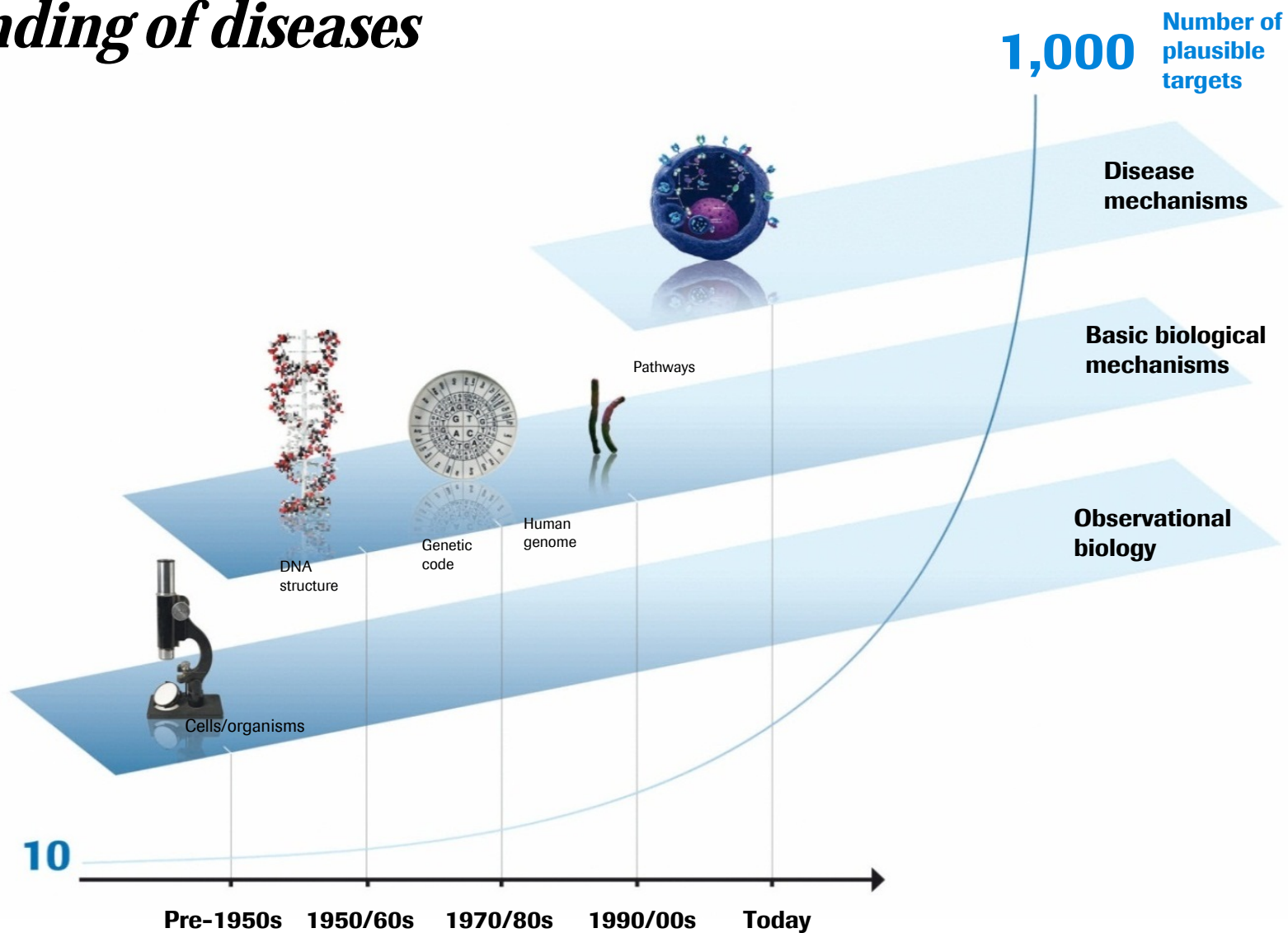
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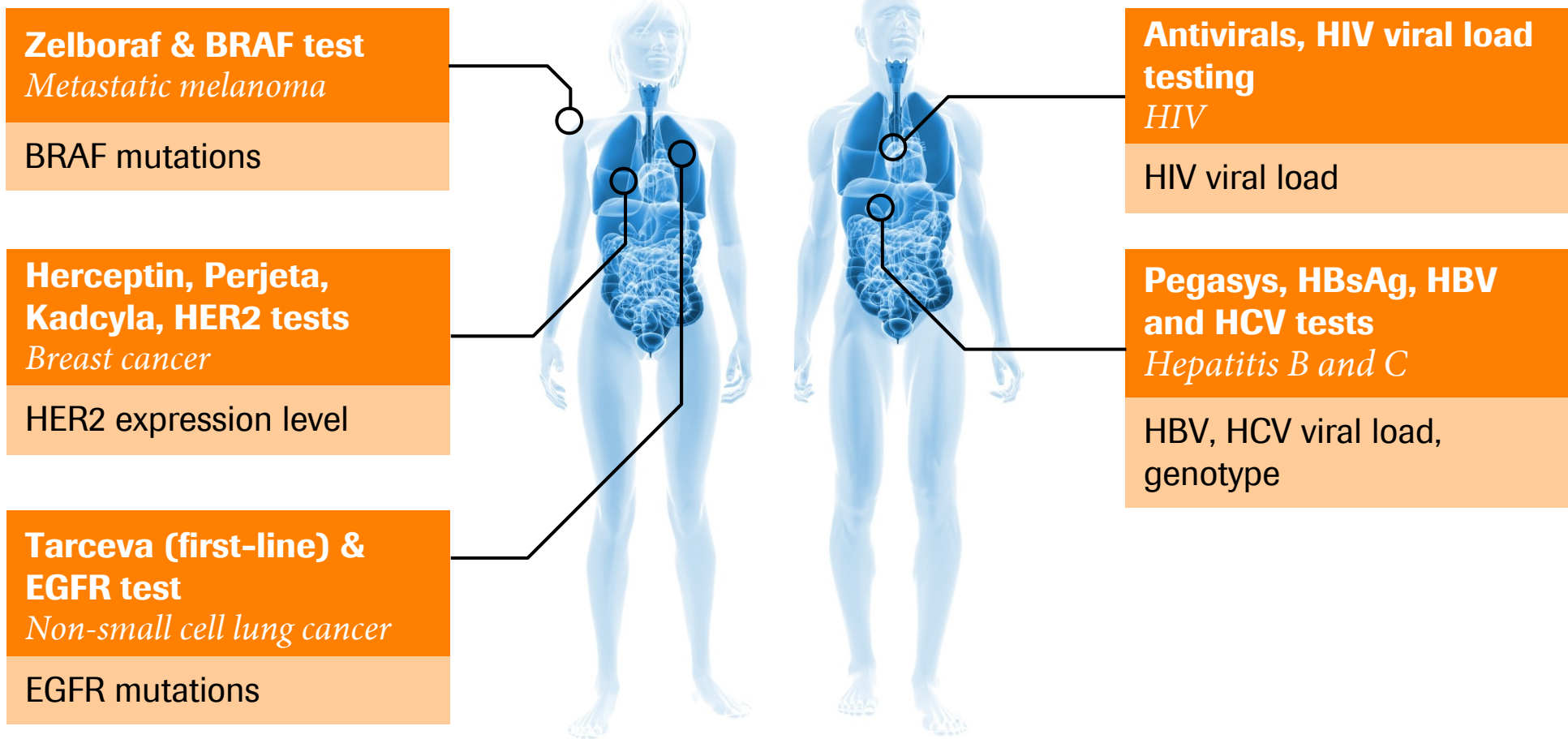
Understanding disease mechanisms

New technologies allow better insights and deeper understanding of diseases



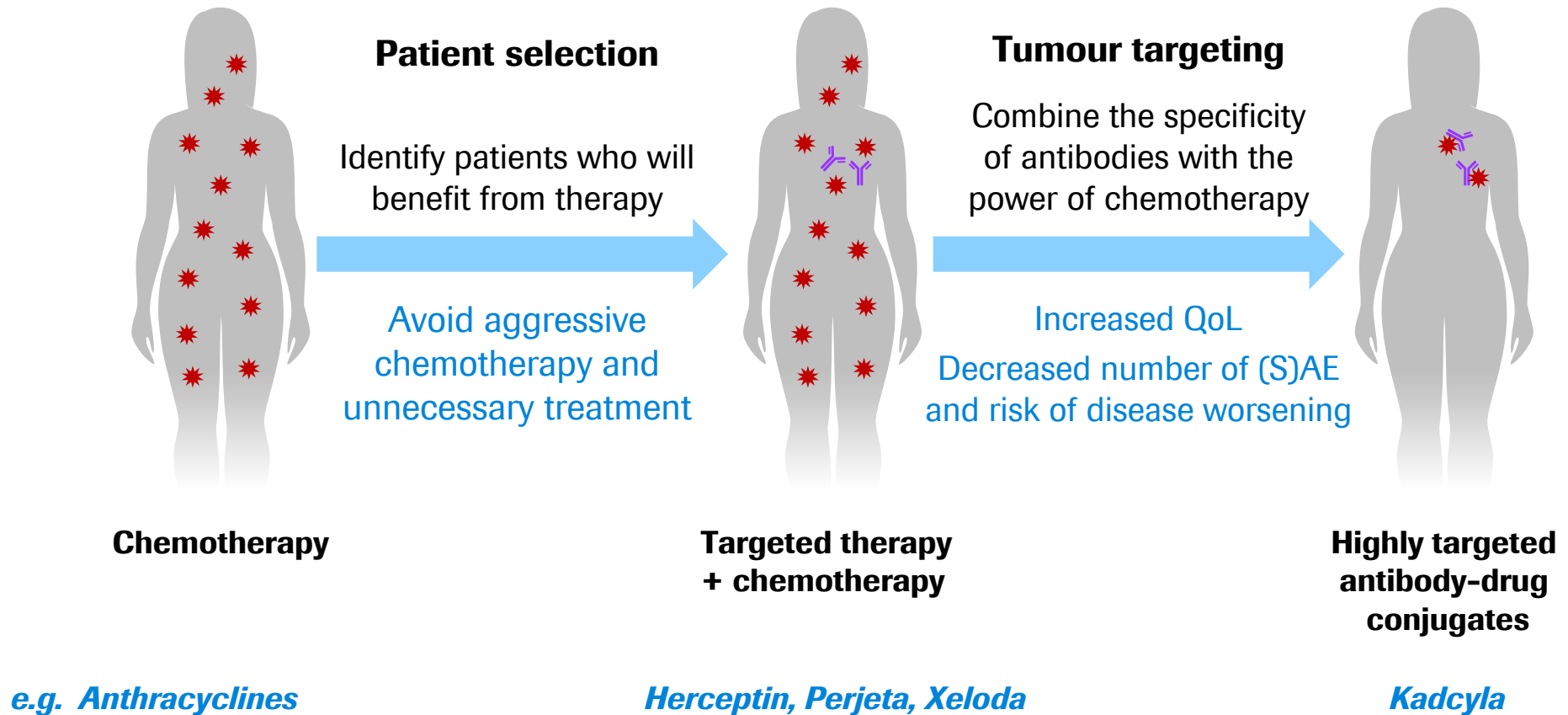
Enabling targeted therapies with diagnostic tools

Targeted therapies - approved



Evolution of HER2 overexpressing cancer therapy

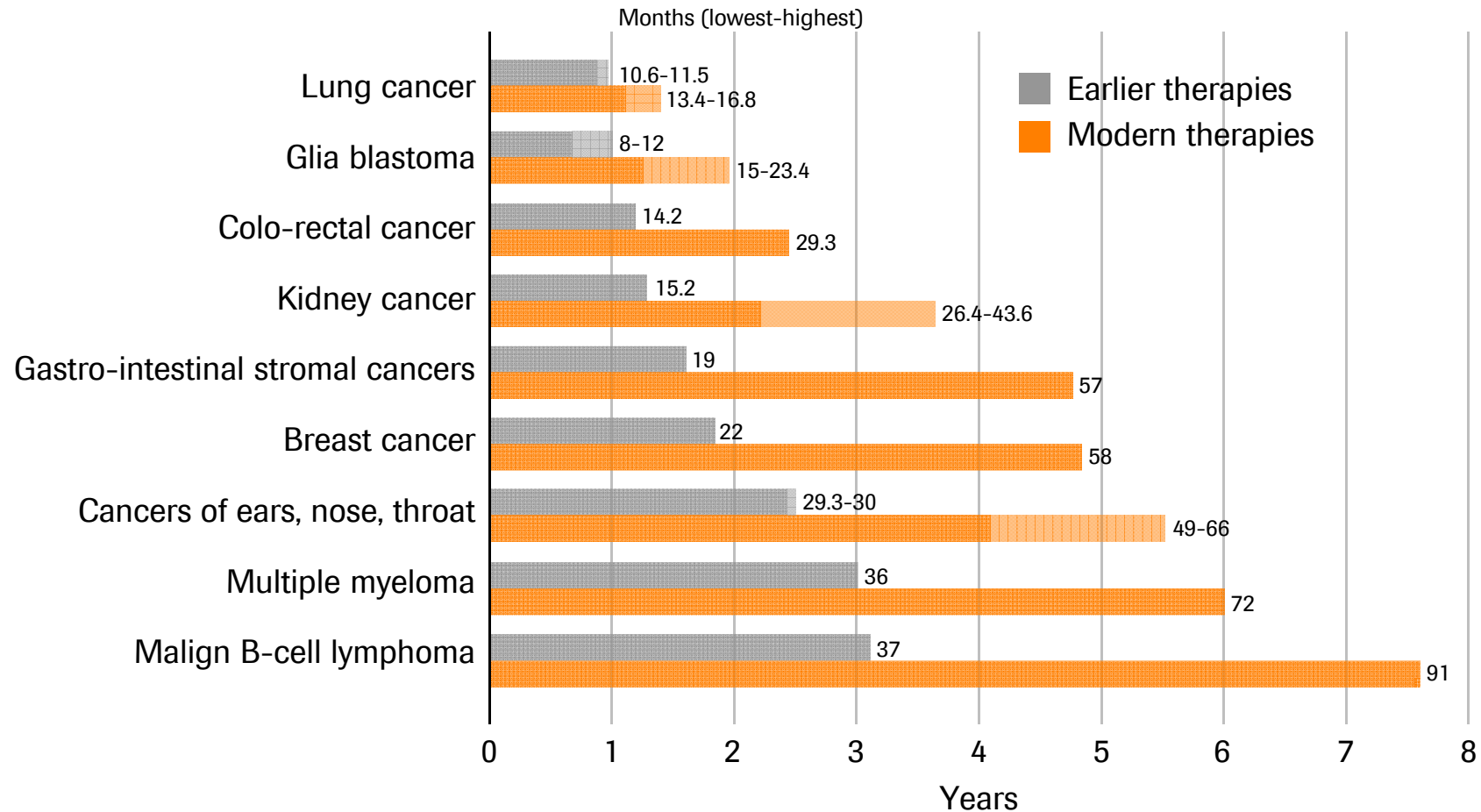
Targeted therapy enabled by advances in Pathology



(S)AE: (serious) adverse event; QoL: quality of life.

PHC delivering game-changing improvements

Advanced cancer – progress seen in 2000 - 2010



Source: Prof. Ch. Zielinski, University Vienna, Austria, March 2010, „Ergebnisoptimierung in der Therapie maligner Erkrankungen durch moderne Behandlungsstrategien: Einfluss auf die Überlebensdauer von PatientInnen mit Krebserkrankungen, <http://www.onkologie-wien.at/forschung-und-lehre/positionspapier/>;

* average data, in months

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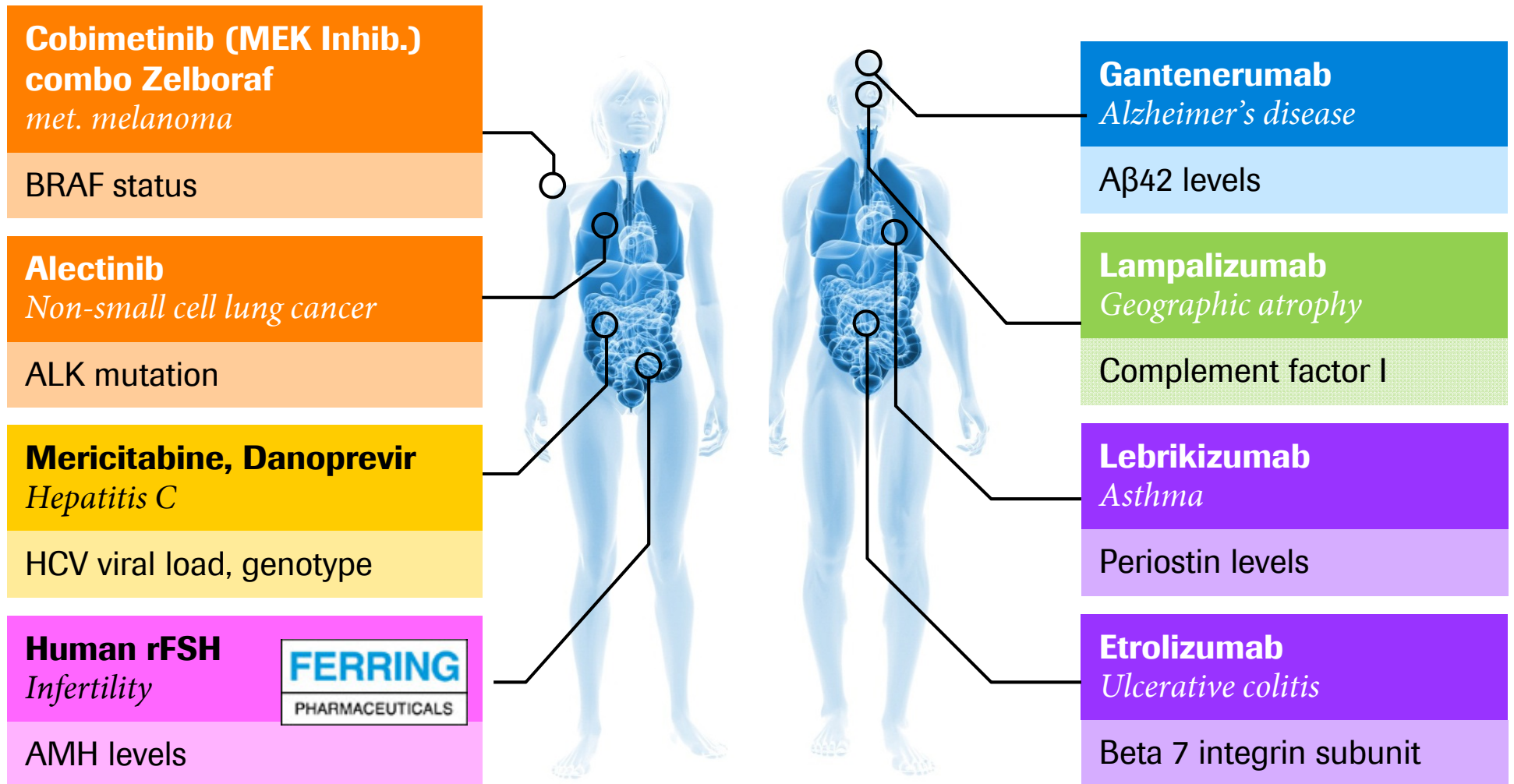
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New treatments to be enabled by diagnostic tests

Improved targeting through diagnostic tools



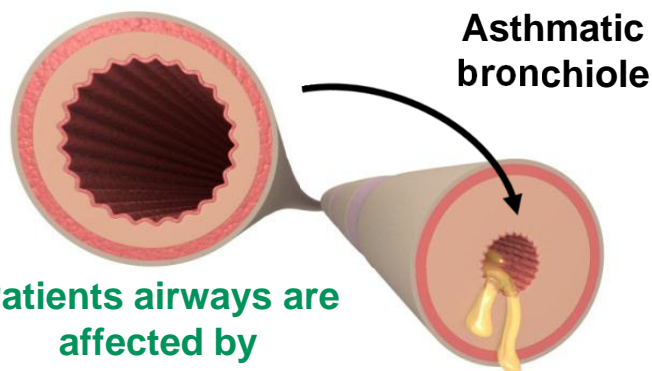
Note: All in development, not commercially available

Asthma – heterogeneous disease

Potential for targeted treatment paradigms in asthma



Normal
bronchiole



Patients airways are
affected by
inflammation

- **Asthma**
- 235 million asthma patients worldwide, and more than 200.000 deaths per year
- Asthma complex disease with marked heterogeneity
- Over-expression of IL13 is a critical mediator of airway inflammation¹
- Different mechanisms lead to symptoms clinically called ‘asthma’
- Patients move up/down treatment steps (ICS/OCS) until control is achieved and maintained
- Asthma treatment so far has been a one-size-fits-most approach



Global Initiative for Asthma (GINA). 2011. Available at:
http://www.ginasthma.org/uploads/users/files/GINA_Report_2011.pdf

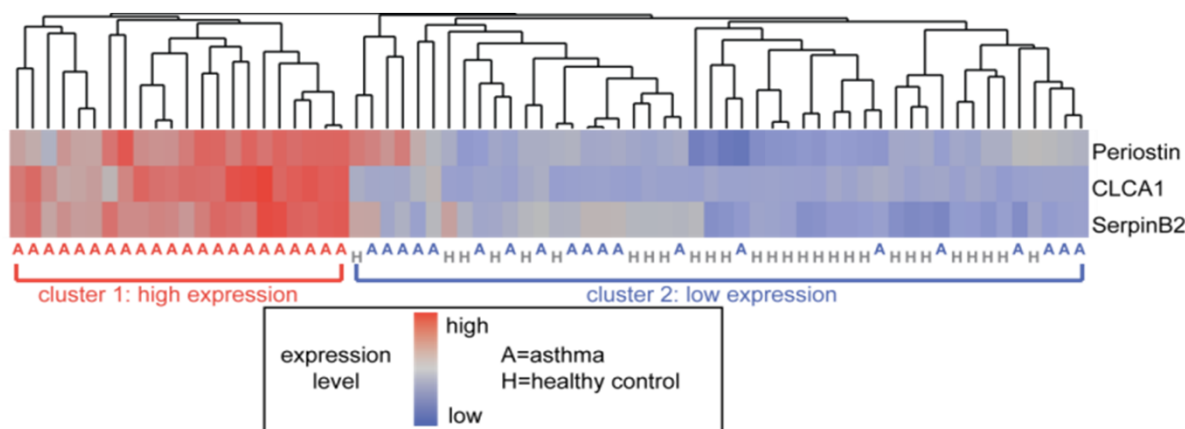
1. Wills-Karp M et al. *Science*, 2001: **282**:2258-60

cobas[®]

Life needs answers

IL-13 is a significant player in severe asthma

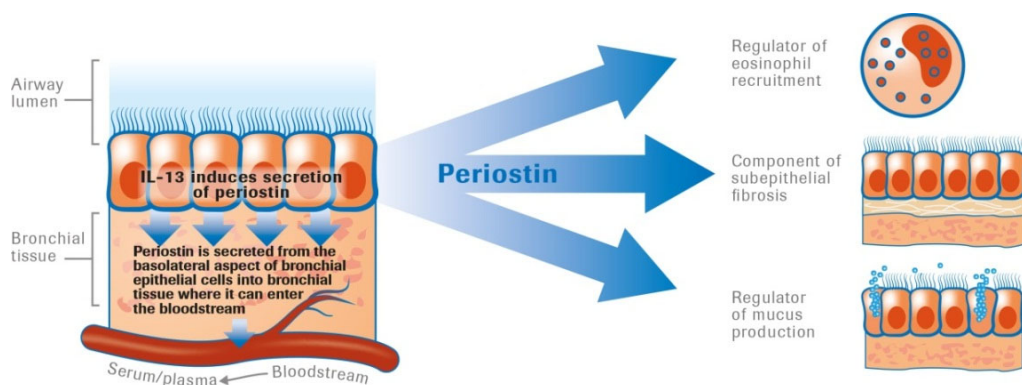
Periostin is a surrogate blood biomarker for high lung IL-13



- The **periostin** gene, together with **CLCA1** and **serpinB2**, were found to be co-upregulated with IL-13 in epithelial cells of subjects with asthma²

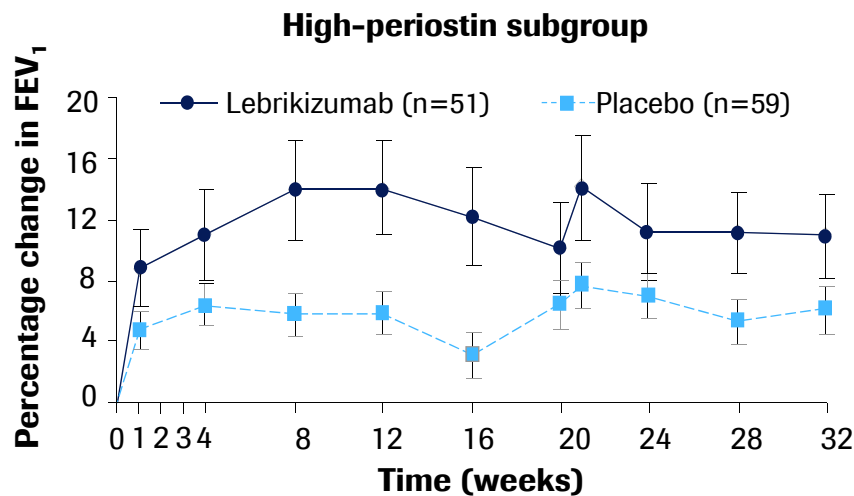
- Only Periostin was detectable in blood

- Periostin is known to play a role in eosinophil recruitment, subepithelial fibrosis, and mucus production



Lebrikizumab (aIL-13) Phase II study data

Improvement in lung function greater in periostin high

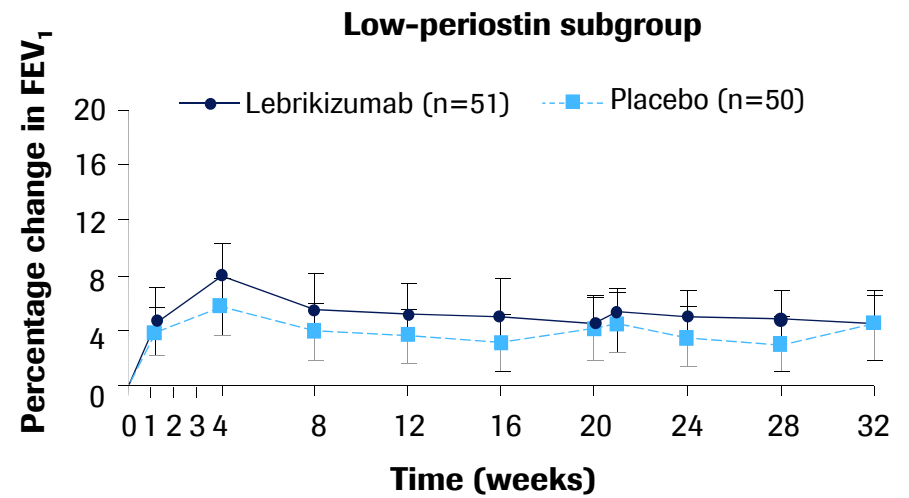


Mean change at Week 12

Lebrikizumab 14.0%, placebo 5.8% (p=0.03)

Difference 8.2%

180 ml



Mean change at Week 12

Lebrikizumab 5.1%, placebo 3.5% (p=0.61)

Difference 1.6%

30 ml

Error bars correspond to mean \pm 1 SD



*Corren J, et al. *N Engl J Med.* 2011; **365**:1088–98
In Development. Not commercially available



Life needs answers

Moving towards greater biomarker driven care in asthma

- In 2 phase IIb studies, Lebrikizumab* significantly improved lung function in severe asthma patients+
- Periostin is a potential biomarker to identify patients more likely to benefit from lebrikizumab*+
- A periostin immunoassay development was initiated in time to enable it's use in phase III studies


Lebrikizumab *+ Cobas® Periostin immunoassay* = Identify most likely responders



*In development, not available in the USA
+ Corren J, *et al. N Engl J Med.* 2011; **365**:1088–98

Alzheimer's Disease is a complex and debilitating

Current diagnoses and therapies are very limited

2013  48 million people

2030  76 million people

2050  130 million people

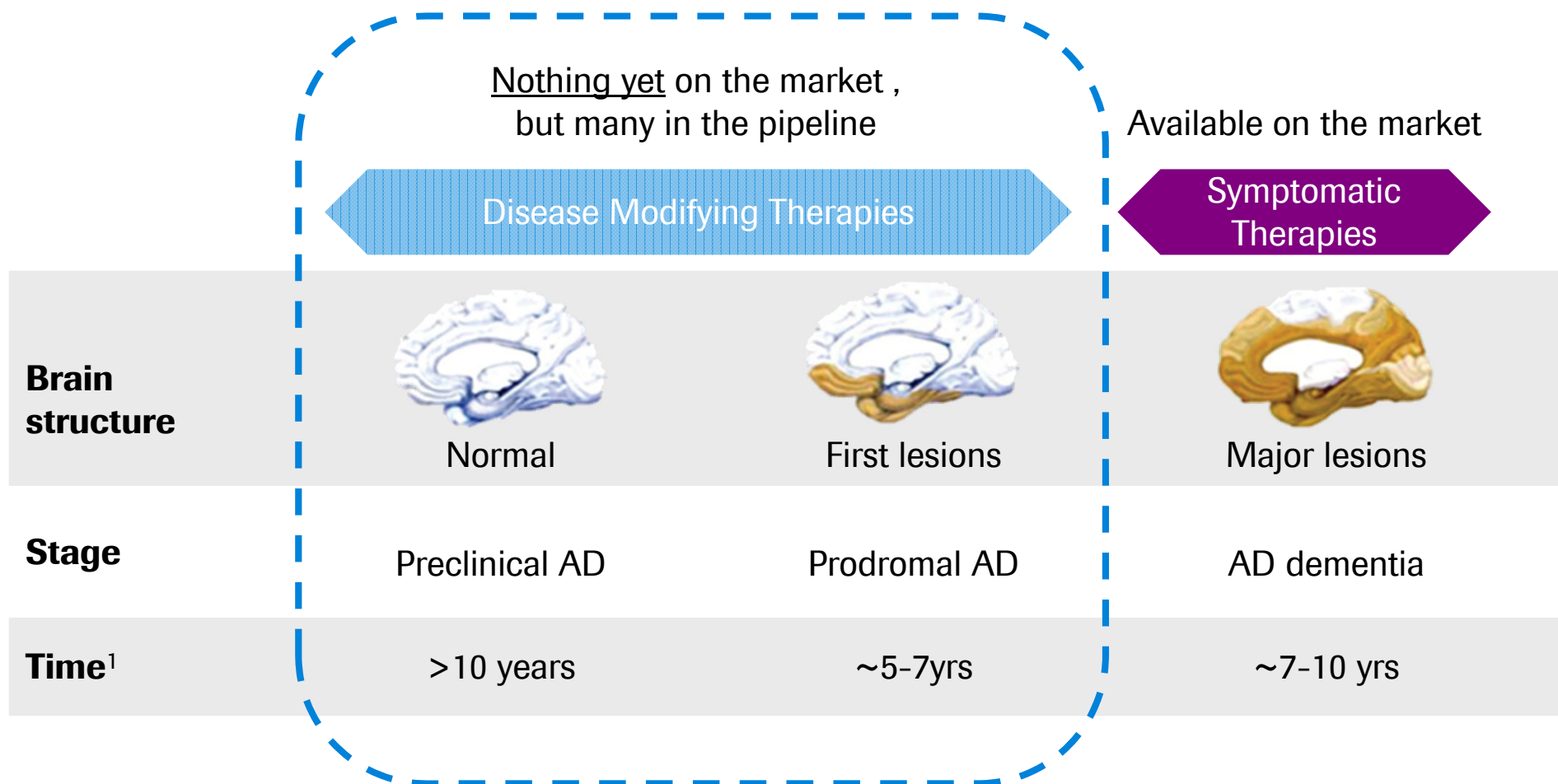


The field is desperate for advancements to alleviate the heavy burden on **patients, caregivers, and healthcare** systems.



Early treatment is the key to fighting the disease

Current treatments address symptoms and not disease

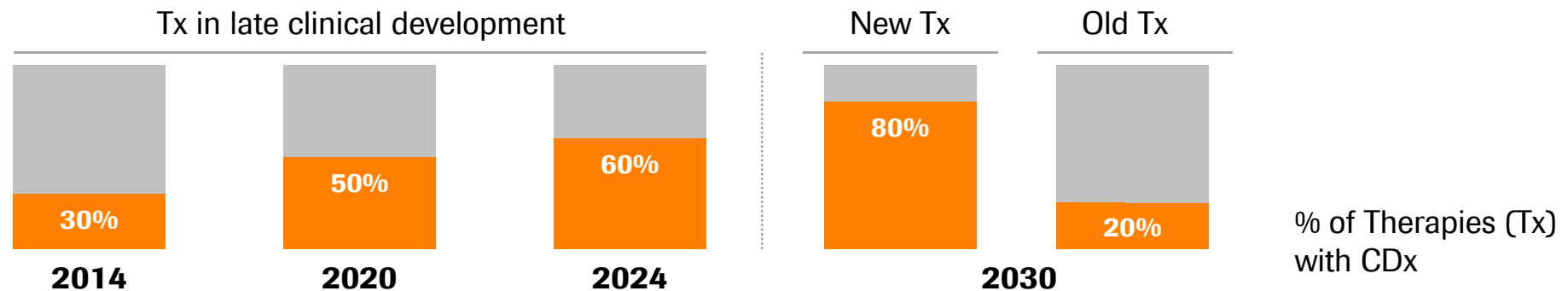


1. Adapted from Herbert LE et al. Arch Neurol 2003, preventAD.com; Average duration per disease stage:
>10 yrs pre-clinical, 5-7 yrs pAD, 2-4 yrs mild, 2-4 yrs moderate, 3-4 yrs severe 2. Mueller SG et al. Alzheimers Dement. 2005

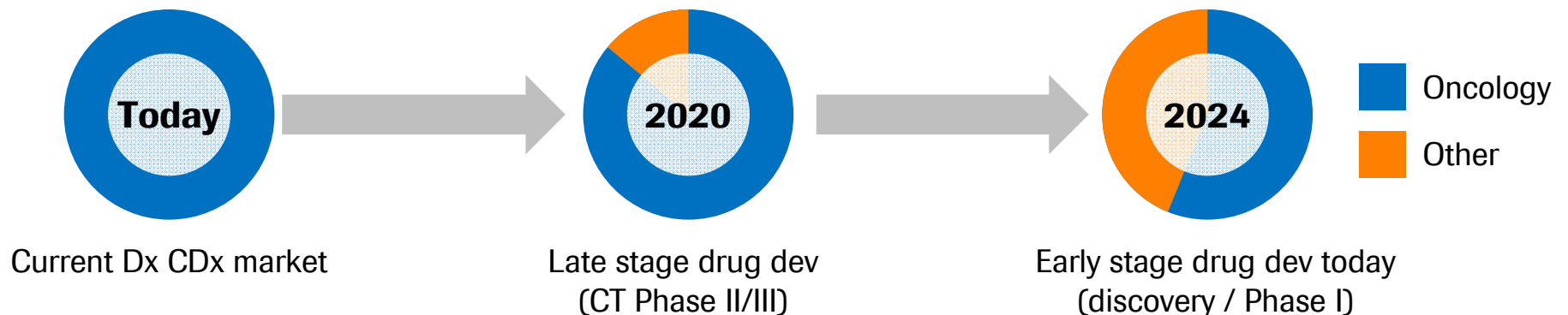
PHC is the future of medicine

What is today exceptional will be routine in 2030

Estimated that up to 80% new drugs will come with a CDx in the 2030



Shift from Oncology to other Disease Areas create more opportunities for RPD



Personalized Medicine by the Numbers (<http://www.personalizedmedicinecoalition.org/>)

Tufts Center for the Study of Drug Development. Personalized Medicine Is Playing a Growing Role in Development Pipelines. Impact Report, 12 (November/December 2010)

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- There is a significant unmet need to improve treatment response rates
- Roche addresses this by making PHC central to the strategy of the company
- PHC has the potential to significantly improve delivery of healthcare, bringing benefits to patients, and society
- There are exciting developments that will hopefully bring advancements to patients in many new areas of medicine



Doing now what patients need next