

# Doing Now What Patients Need Next

*Teppo Hyytiä*

*Roche Diagnostics Oy*

*21 May 2015*

*Future Diagnostics Symposium*



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# **The Roche Group**

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**Our Company Strategy**

**Our Innovation**

**Pharmaceuticals**

**Diagnostics**

# Basic facts at a glance



- Founded 1896 in Basel, Switzerland
- Founding families still hold majority stake
- Employing 88,500 people
- Currently active in 150 countries on all continents
- 2014 – sales of 47.5 billion Swiss francs
- 2014 – 19 million patients treated with one of Roche's top 25 selling medicines
- 2014 – **3 billion diagnostic tests** performed
- Clear focus on healthcare
- **Leadership in pharmaceuticals (#3)\***
- **World's largest biotech company** (position #1)\* with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS
- **Leadership in *in vitro* diagnostics (#1)** and pioneer in diabetes management
- Unique innovation model

# Basic facts at a glance

*Focusing on innovative pharmaceuticals drugs and diagnostic tests*

- Our aim is to discover, develop and market **innovative solutions that bring clear medical benefit** in disease areas with high unmet medical need
  - Oncology (e.g. breast, cervical, colon cancer)
  - Virology (e.g. hepatitis, HIV)
  - Inflammation and autoimmune disorders (e.g. rheumatoid arthritis, asthma)
  - Cardiovascular and metabolic disorders (e.g. diabetes)
  - Central Nervous System (e.g. Alzheimer's)
- Our products and services help to **prevent, diagnose and treat diseases**, thus enhancing people's health and quality of life



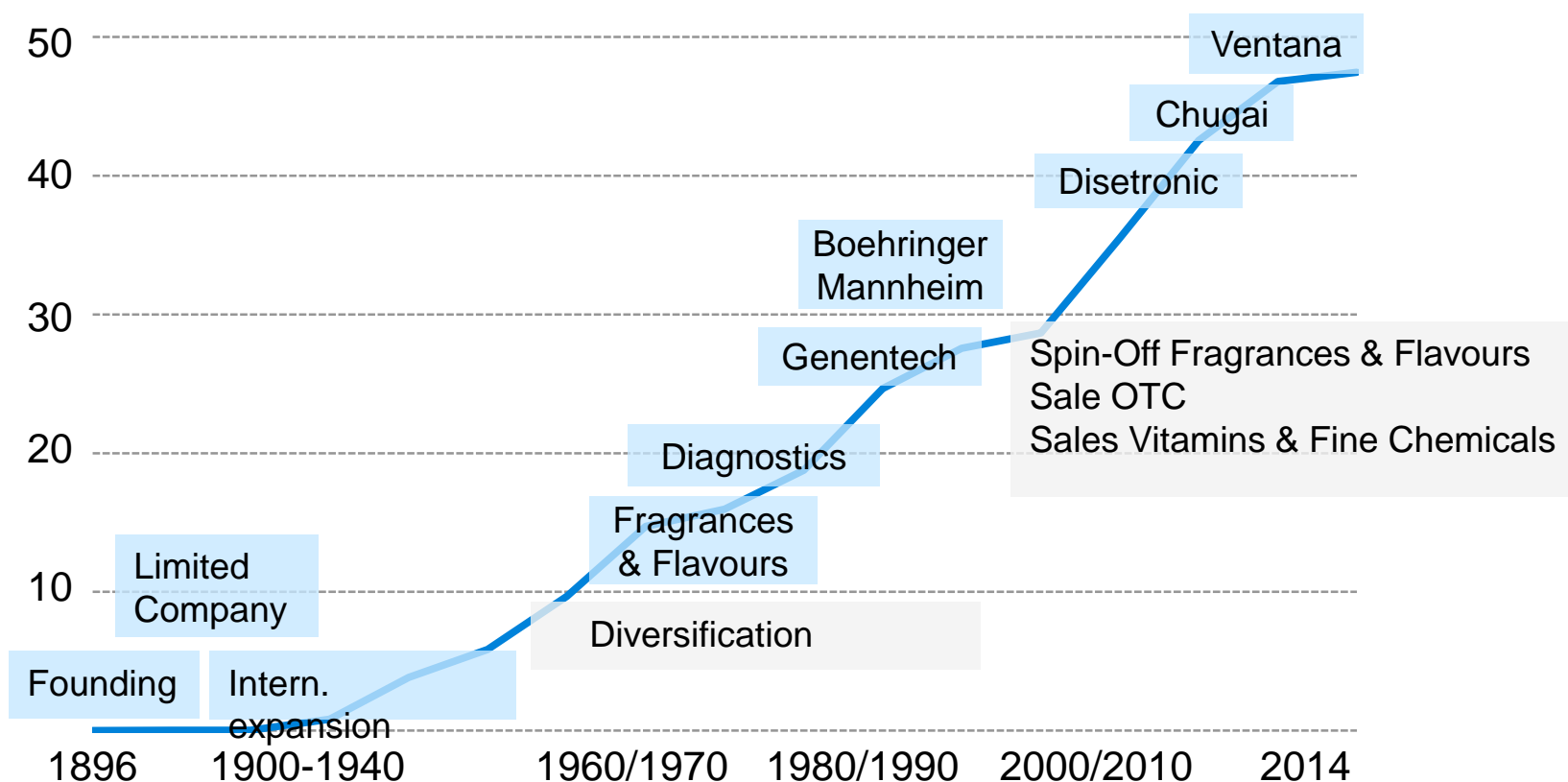
# 118 years of Roche

## *Historical timeline*

### *Personalised Medicine*

Sales 2014: 47,462 million CHF

Strategic Transition –  
Focus on Pharma & Diagnostics



# Innovative since 1896 ...

## Sirup



1896/98

Founding

## Vitamins



1940/50

Expansion

- Vitamin C
- Vitamin A
- Vitamin B1, B2, ...

## CNS



1960/70

Diversification

## Clinical Diagnostics



- Enterotube
- CEA-RIA

## Anti-infectives



1980/90

Genentec

## Automation



- Cobas Bio
- Cobas Mira
- Cobas Core

## Oncology



2000/10

Disetroni

Chugai

Ventan

## Molecular Diagnostics/ Biomarker



- PCR (HIV, HXV)
- Elecsys
- ImmunDx
- Accu-Chek (Diabetes)



- Histology
- Sequencing
- cobas 6000 (SWA)

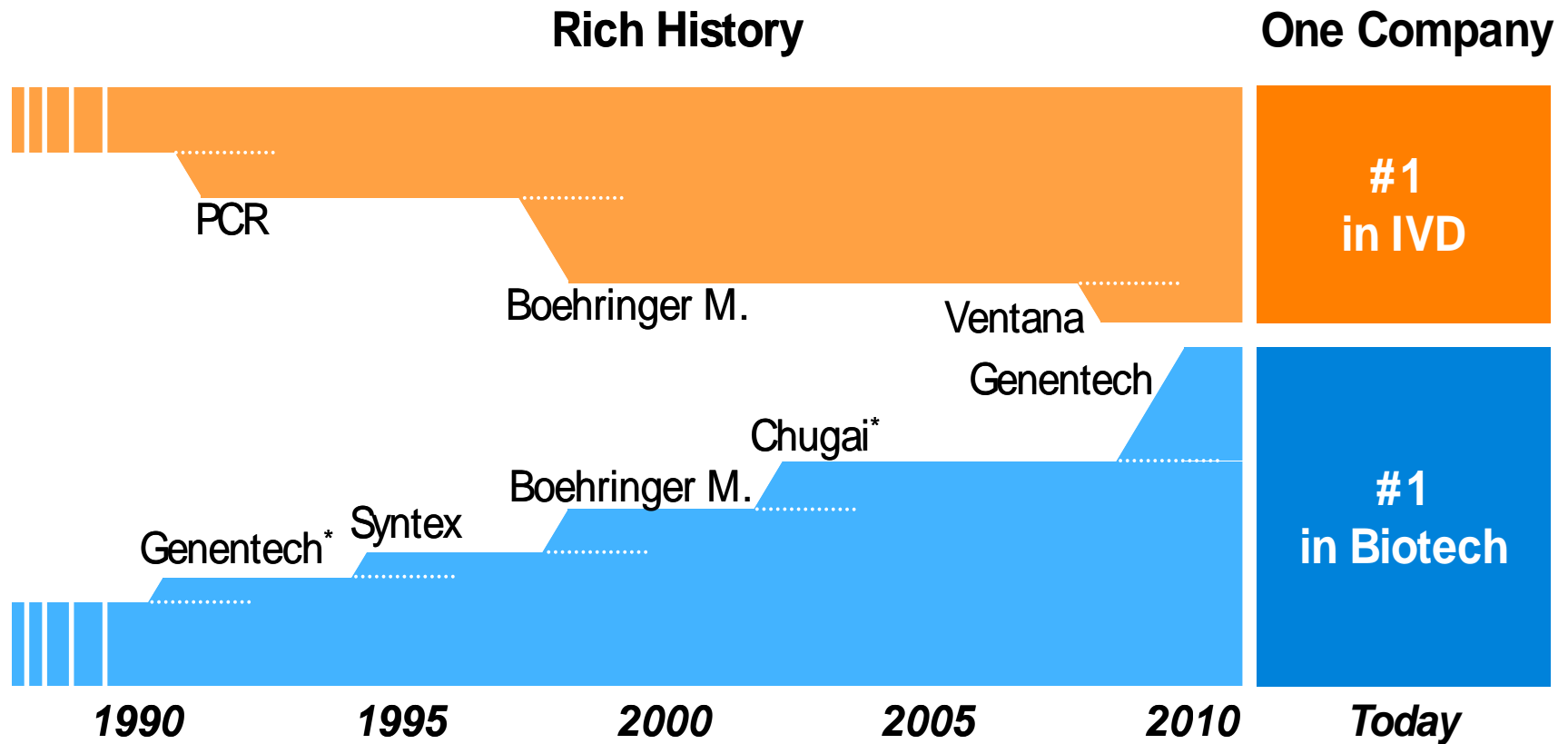
## PHC

2020/30

Differentiating molecular medicines and diagnostics

# Strengthening Pharma and Diagnostics

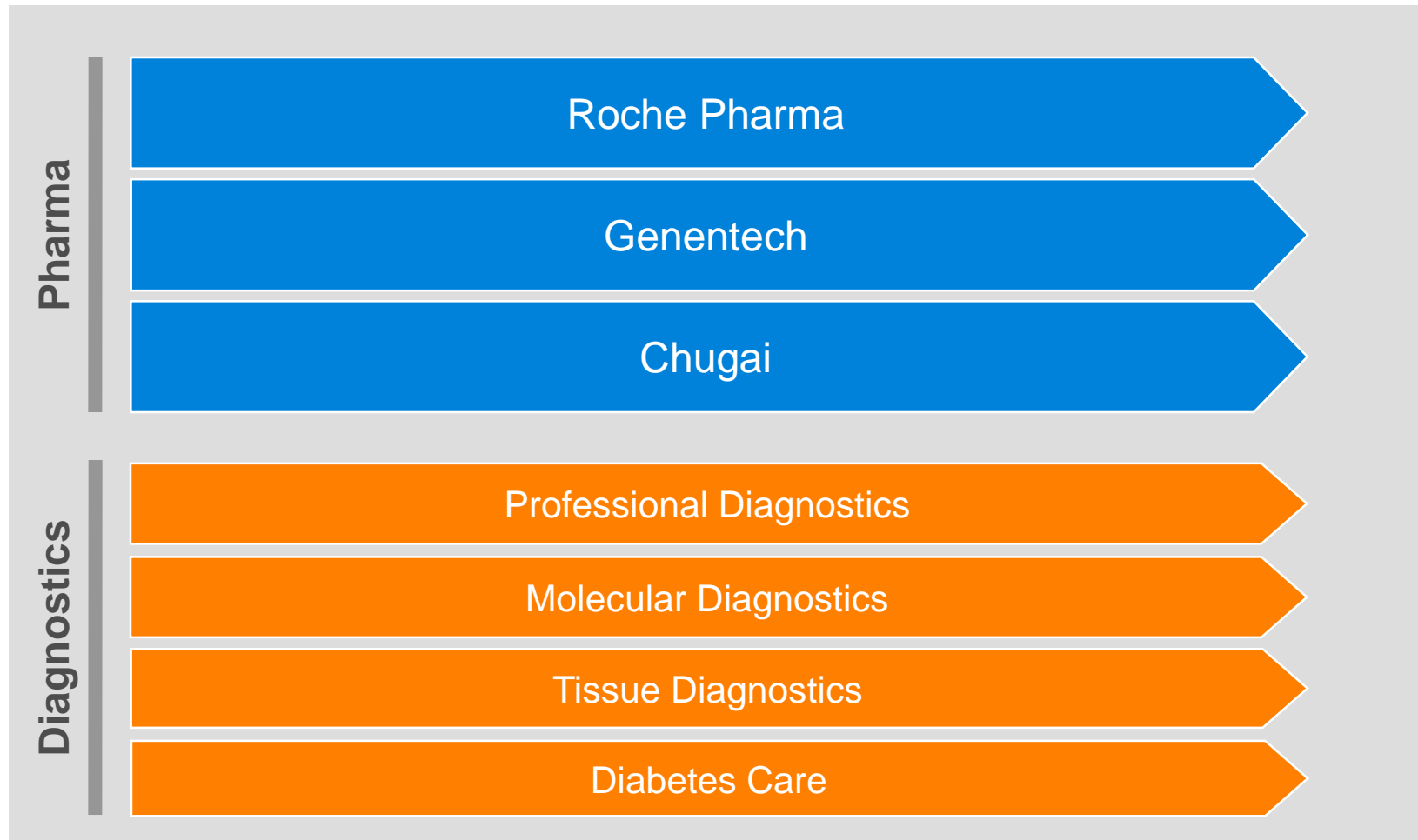
*Building biotech expertise*



\*majority ownership

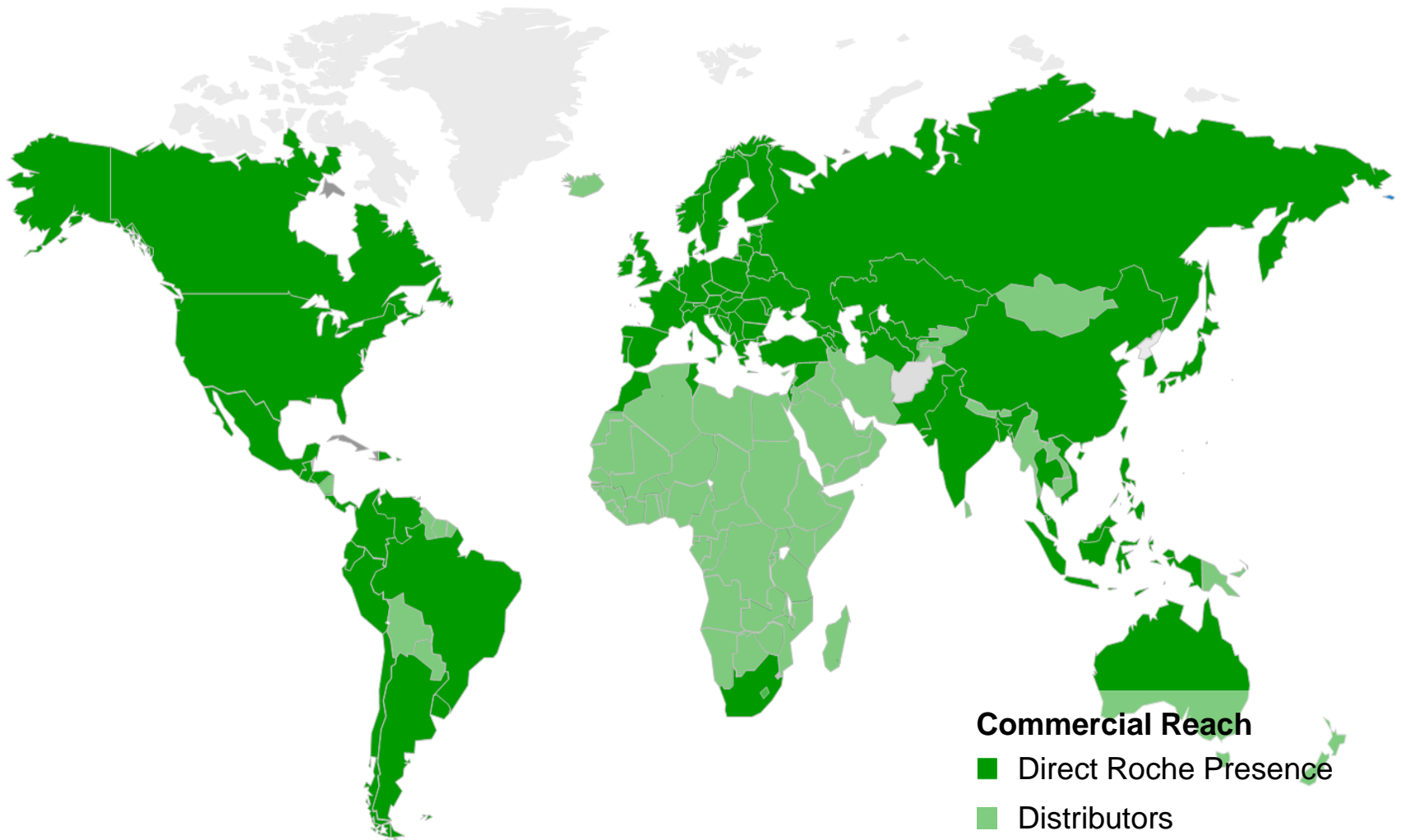
# Roche Group

## *Our Structure*



# Roche Group

*Structure with global reach*



# Value for patients

## *Roche products in a nutshell*

Growth-driving products 2014 in millions of Swiss francs

### Pharmaceuticals



**Avastin**  
Oncology

**6,417** +6%



**Herceptin**  
Oncology

**6,275** +7%



**Actemra/RoActemra**  
Immunology

**1,224** +23%



**Perjeta**  
Oncology

**918**



**Kadcyla**  
Oncology

**536**

Top-selling diagnostics in millions of Swiss francs

### Diagnostics



**cobas e602**  
Immunodiagnosics

**2,797** +13%



**Accu-Chek Aviva Nano**  
Blood glucose meters

**2,159** +1%



**cobas c502**  
Clinical chemistry

**1,626** +7%



**BenchMark Ultra**  
Tissue diagnostics

**716** +10%



**cobas 6800**  
Virology

**530** +7%

# **The Roche Group**

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## **Our Company Strategy**

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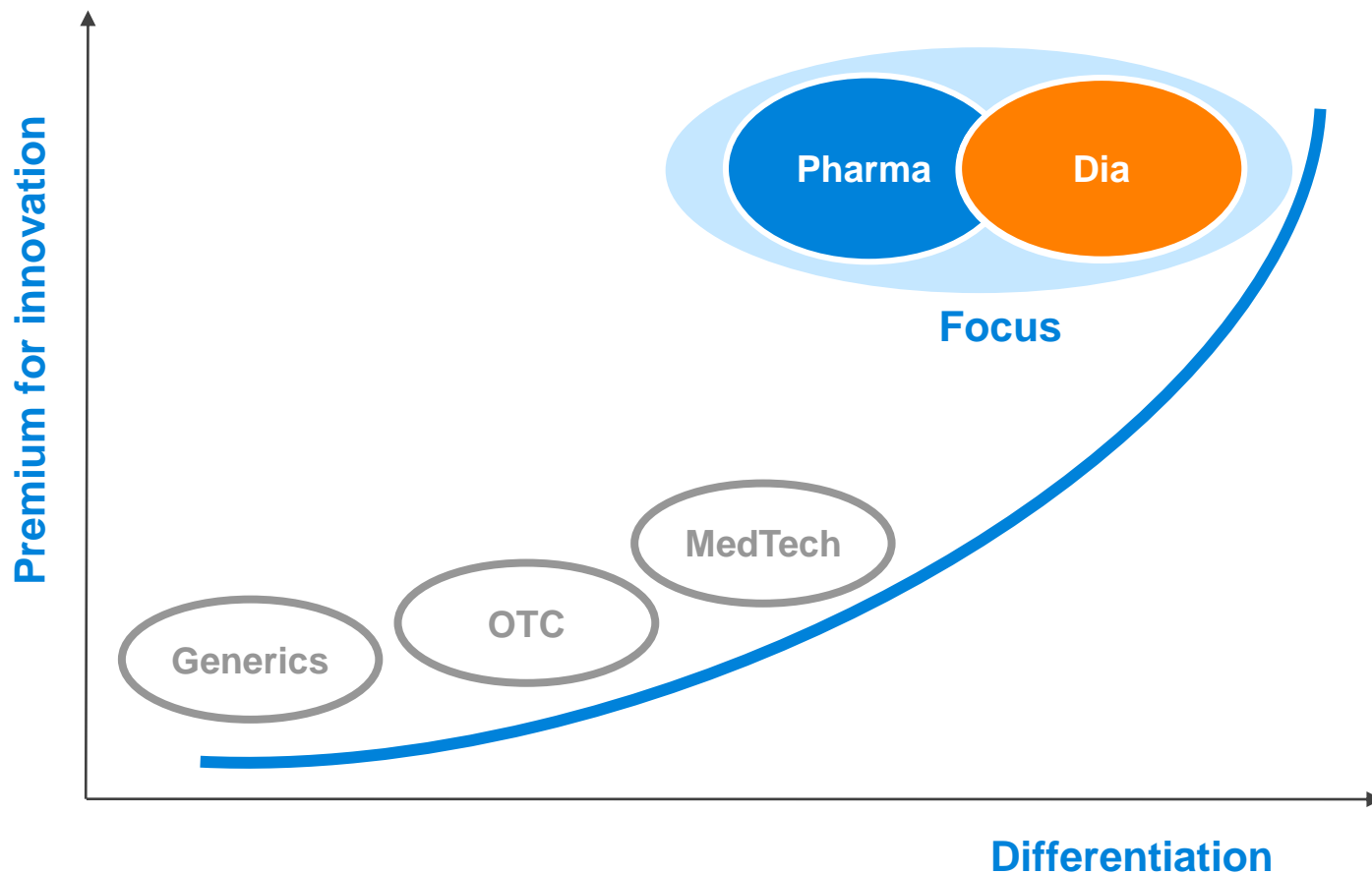
### **Our Innovation**

### **Pharmaceuticals**

### **Diagnostics**

# Roche Strategy

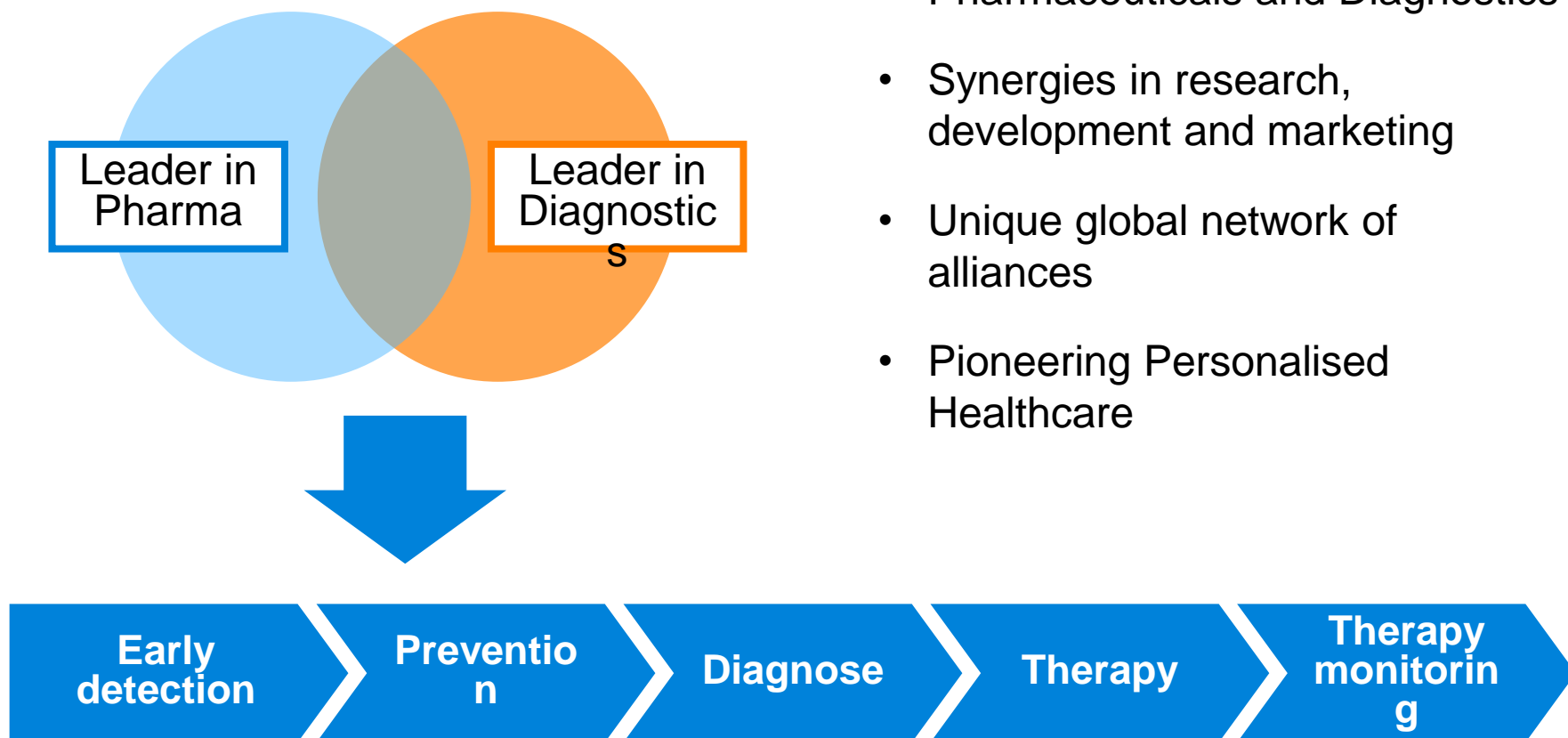
*Focused on medically differentiated therapies*



# Roche Group — what makes us distinctive

*Optimally positioned for the future*

- Combined strengths of Pharmaceuticals and Diagnostics
- Synergies in research, development and marketing
- Unique global network of alliances
- Pioneering Personalised Healthcare



# Personalised Healthcare (PHC) - driver of change

*Key to enabling highly differentiated medicines*

A diagram illustrating the drivers of change for Personalised Healthcare (PHC). On the left, three orange chevron-shaped boxes point towards a central grey circle. The first box is labeled "Healthcare Pressures: Benefit-Risk Ratio", the second "Economic Pressures: Benefit-Cost Ratio", and the third "New Technologies: Expanded Capabilities". The central grey circle contains the text "Need for highly differentiated medicines that positively impact public health". The background features a light grey world map.

## Healthcare Pressures:

Benefit-Risk Ratio

## Economic Pressures:

Benefit-Cost Ratio

## New Technologies:

Expanded  
Capabilities

Need for  
highly  
differentiated  
medicines  
that positively  
impact  
public health

# PHC - Fitting the treatment to the patients

*Delivering better, safer and more efficacious treatments*

## Roche Personalised Healthcare means:

- To better understand disease diversity or subtypes
- To identify the differences between patients
- To identify the best drug targets
- To improve the quality and efficiency of R&D results
- To provide biomarkers and diagnostic tests

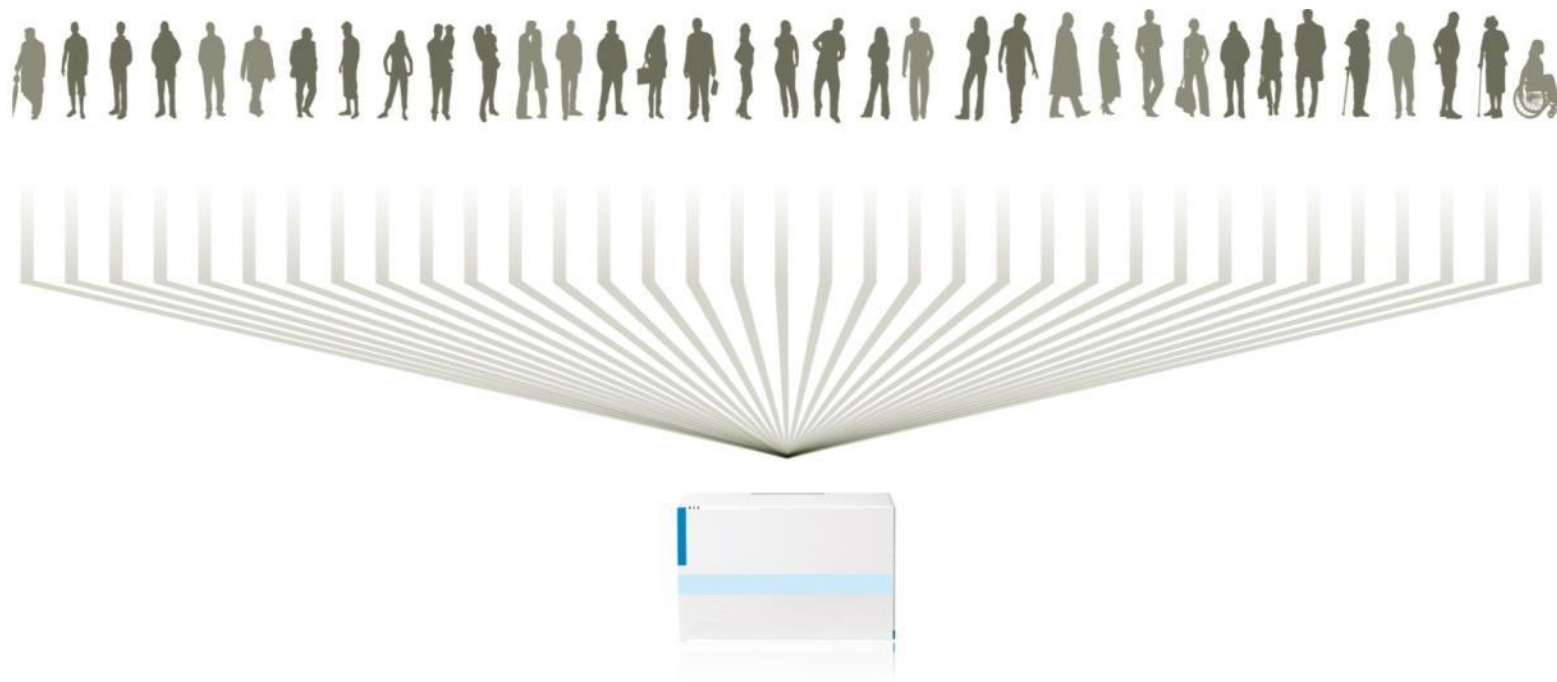


**Optimising patient care**

**Making development of new tests and drugs more efficient**

# Personalised Healthcare versus standard treatment

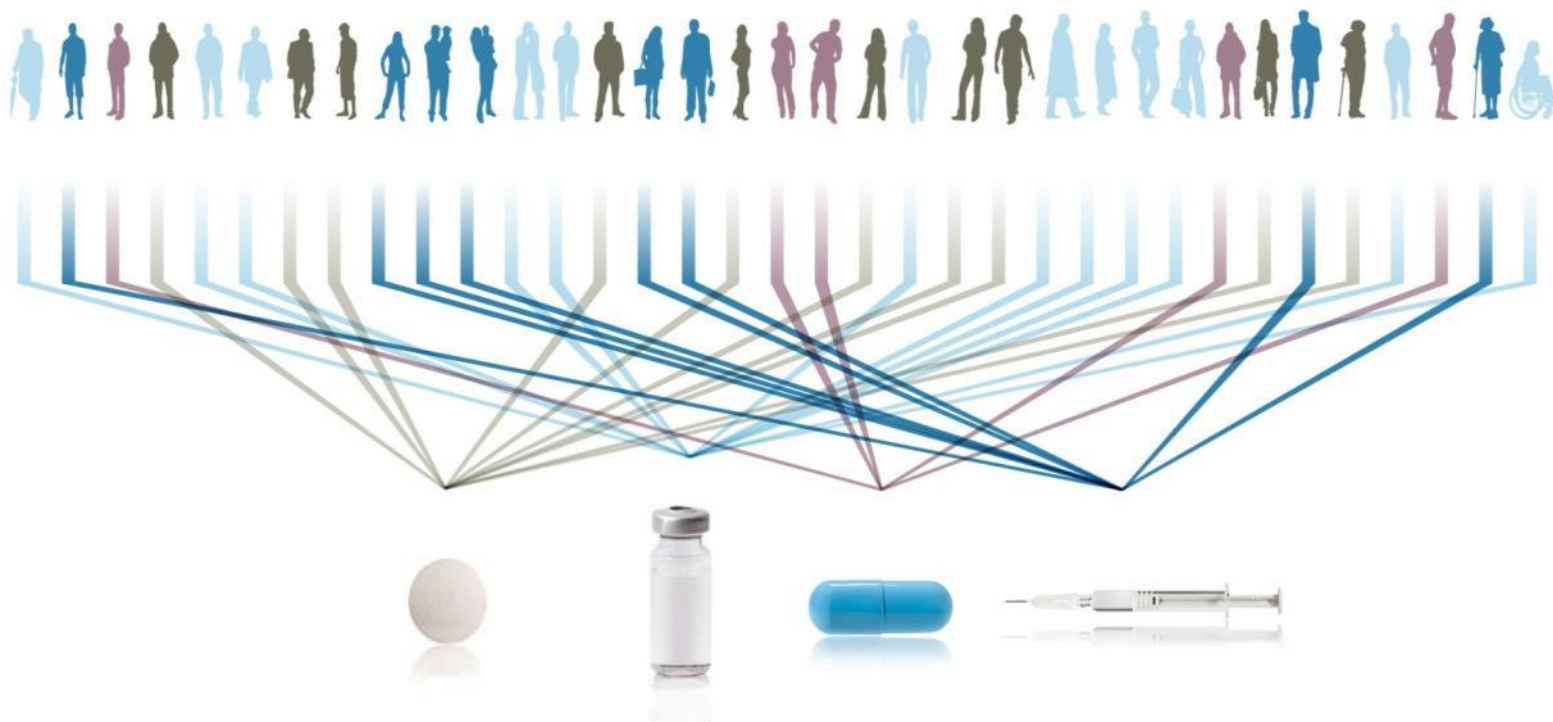
## Patients with same syndrome



**One-size-fits-all approach**

# Personalised Healthcare versus standard treatment

Group of patients with the same syndrome



Targeted therapy

# Roche already offers a range of examples

*Targeted therapies - approved*



## Oncology

- Breast- and stomach cancer: Herceptin for patients with HER2-positive cancer
- Metastatic melanoma (skin cancer): Zelboraf for patients with BRAF-positive metastatic melanoma
- Lung cancer: Tarceva first-line treatment for patients with EGFR-positive non-small lung cancer

## Virology

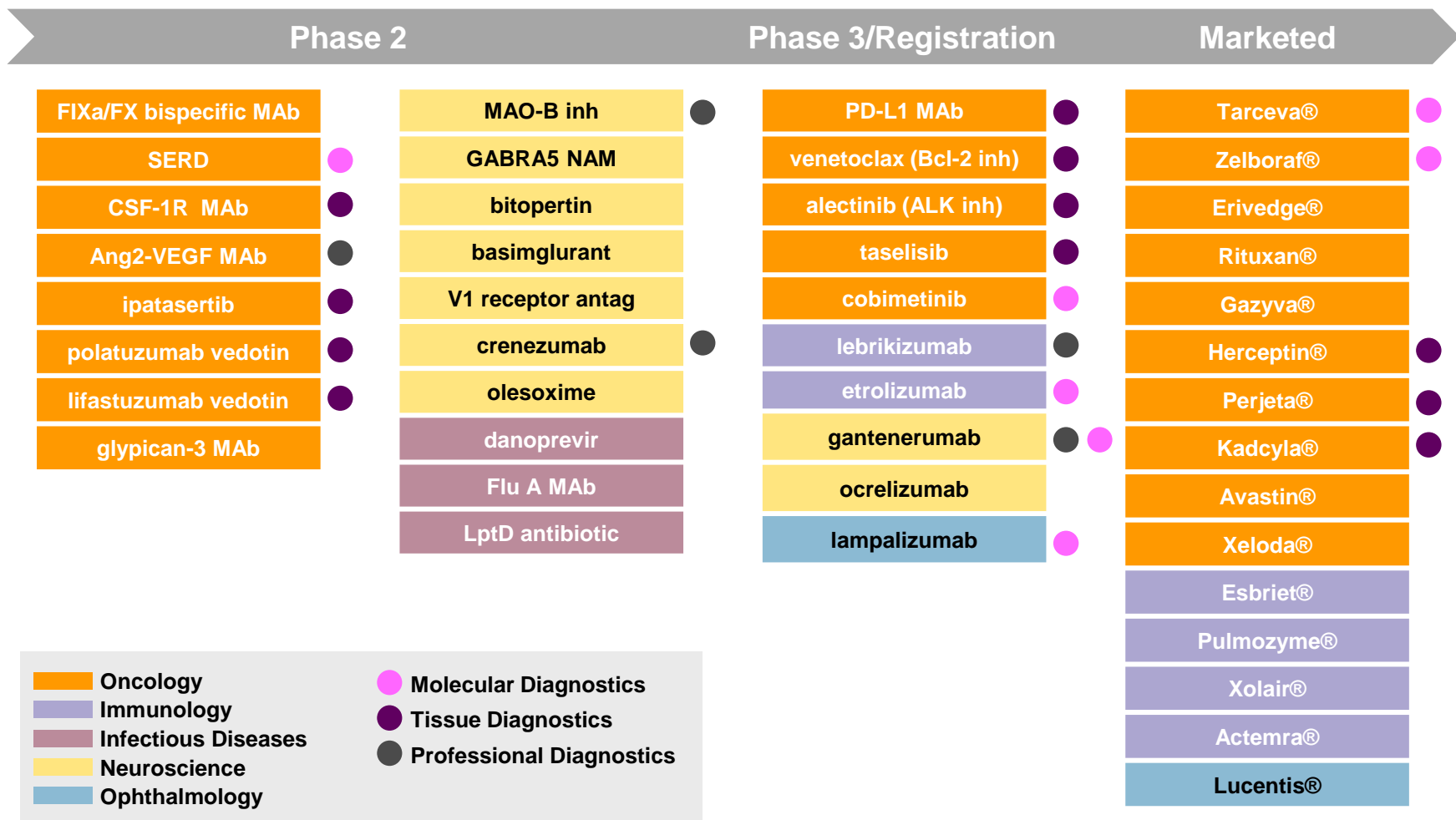
- Hepatitis B and C infections: Pegasys (HBV) and Pegasys/Copegus (HCV), genotype and viral load testing
- HIV: Invirase/ Viracept/ Fuzeon, viral load testing

## Diagnosis

- Providing biomarkers and diagnostic tests

# Progressing in Personalised Healthcare

*60% of phase 2 & 3 products have PHC component*



**The Roche Group**

**Our Company Strategy**

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**Our Innovation**

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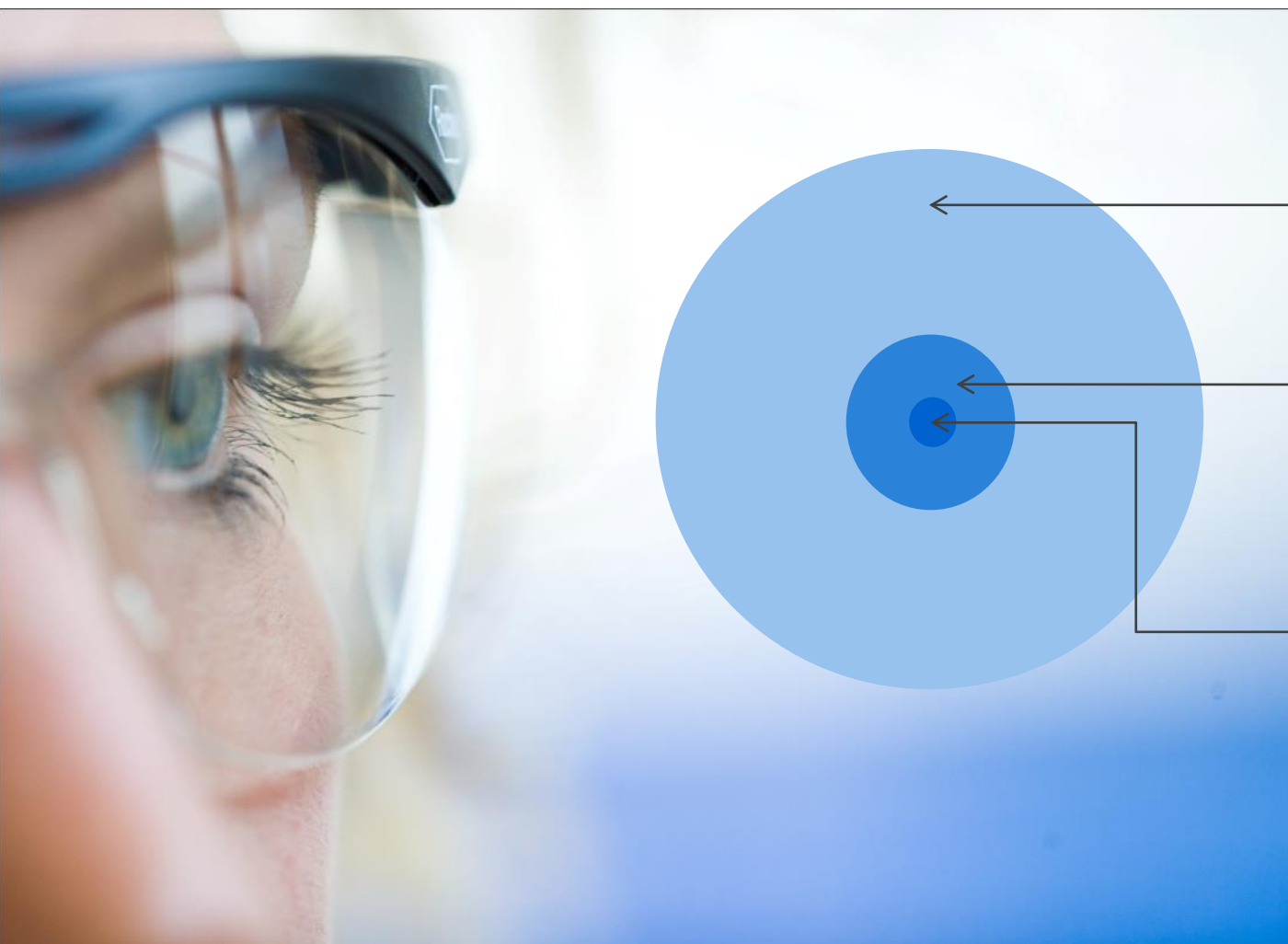
**Pharmaceuticals**

**Diagnostics**

# R&D innovation springs from diverse sources



*Wealth of scientific pool*



**5.8 mio**

Science & engineering  
Researchers in the world

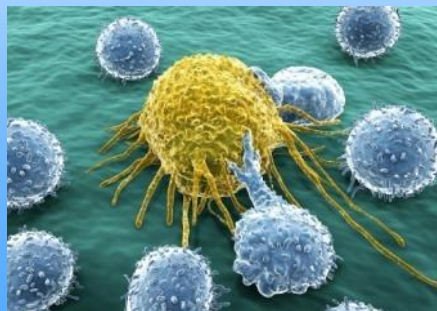
**388 000**

Scientists in Pharma  
R&D in US & Europe

**15 500**

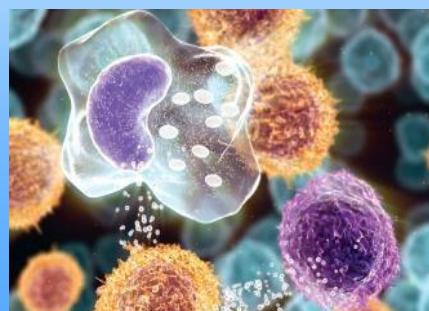
Scientists in Roche  
Pharma R&D

# What We Work On



## Oncology

*Developing effective cancer therapies*

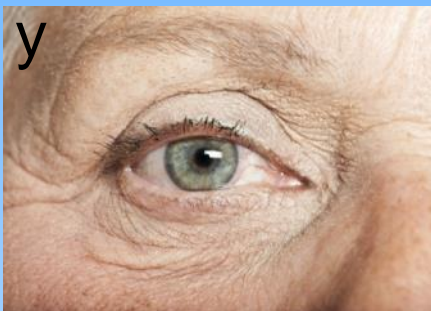


## Infectious Diseases

*Developing effective treatments for life-threatening infectious diseases*

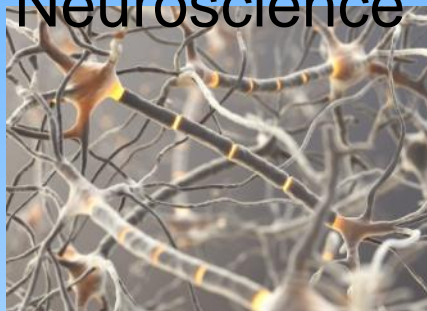
*Restoring sight*

## Ophthalmology



*Developing medicines for serious brain diseases*

## Neuroscience



*Tackling rare genetic disorders*

## Rare Diseases



**The Roche Group**

**Our Company Strategy**

**Our Innovation**

---

**Pharmaceuticals**

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**Diagnostics**

# Roche Group

*Structure – Pharmaceuticals*



# Pharmaceuticals businesses

*Driving excellence in innovation in therapeutic areas*

## Oncology



## Transplantation



## Virology



## Metabolism Bone, Anemia



## Inflammation Autoimmune



# Roche Group development pipeline

## Phase II (22 NMEs + 14 AIs)

RG435	Avastin+Tarceva	EGFR mut+ NSCLC
RG3502	Kadcyla	HER2+ NSCLC
RG6013	FIXa/FX bispecific MAb	hemophilia A
RG6046	SERD	ER+(HER2-neg) mBC
RG7155	emactuzumab (CSF-1R)	PVNS/s. tumors
RG7221	vanucizumab (Ang2-VEGF MAb)	mCRC
RG7421	cobimetinib+paclitaxel	TNBC
RG7440	ipatasertib	solid tumors
RG7446	PD-L1 MAb	NSCLC 2/3
RG7446	PD-L1 MAb	bladder cancer 1/2
RG7446	PD-L1 MAb +Avastin	RC
RG7596	polatuzumab vedotin	hem tumors
RG7599	lifastuzumab vedotin	Pt-resist. OC
RG7601	venetoclax	17p del CLL rel/ref
RG7601	venetoclax	DLBC
RG7601	venetoclax+Rituxan	FL rel/ref
RG7604	taselisib	NSCLC sq
RG7604	taselisib	ER+(HER2-neg) BC neo
RG7686	glypican-3 MAb	liver cancer
RG7853	alectinib	ALK+ NSCLC 2L
RG1569	Actemra	systemic sclerosis
RG3637	lebrikizumab	IF
RG6062	Esbriet	SSc-interstitial lung disease
CHU	IL-31R MAb	atopic dermatitis
RG7227	danoprevir	HCV
RG7745	Flu A MAb	influenza
RG7929	LptD antibiotic	antibacterial
RG7697	GIP/GLP-1 dual ago	type 2 diabetes
CHU	URAT 1 inh	gout
RG1577	sembragiline (MAO-B inh)	Alzheimer's
RG1662	GABRA5 NAM	Down Syndrome
RG1678	bitopertin	obsessive compulsive dis.
RG6083	olesoxime	spinal muscular atrophy
RG7090	basinglurant	TRD
RG7314	V1 receptor antag	autism
RG7412	crenezumab	Alzheimer's

## Phase III (9 NMEs + 27 AIs)

RG435	Avastin	glioblastoma
RG435 <sup>1</sup>	Avastin	ovarian cancer
RG435 <sup>1</sup>	Avastin	rel. ovarian ca. Pt-sensit
RG1273	Perjeta+Herceptin	HER2+ mBC 2
RG1273	Perjeta+Herceptin	HER2+ BC a
RG1273	Perjeta+Herceptin	HER2+gastric ca
RG3502	Kadcyla	HER2+ gastric cancer
RG3502	Kadcyla +/- Perjeta	HER2+ mBC 1
RG3502	Kadcyla	HER2+ BC a
RG3502	Kadcyla + Perjeta	HER2+ BC a
RG3502	Kadcyla + Perjeta	HER2+ BC neo
RG7159	Gazyva	DLBC
RG7159	Gazyva	iNHL rituximab-r
RG7159	Gazyva	follicular lymphoma
RG7204	Zelboraf	melanoma a
RG7446	PD-L1 MAb	NSCLC 2L
RG7446	PD-L1+chemo	NSCLC non-sq
RG7446	PD-L1+chemo+Avastin	NSCLC non-sq
RG7446*	PD-L1+chemo	NSCLC sq
RG7446*	PD-L1 MAb Dx+	NSCLC sq
RG7446*	PD-L1 MAb Dx+	NSCLC non-sq
RG7446	PD-L1 MAb	bladder cancer
RG7601	venetoclax+Rituxan	CLL rel/ref
RG7601	venetoclax+Gazyva	CLL
RG7604	taselisib	ER+(HER2-neg) mBC
RG7853	alectinib	ALK+ NSCLC
RG1569	Actemra	giant cell arteriti
RG3637	lebrikizumab	severe asthma
RG7413	etrolizumab	ulcerative colitis
RG7413	etrolizumab	Crohn's disea
CHU	Actemra	large-vessel vasculit
CHU	IL-6R MAb	neuromyelitis optica
RG1450	gantenerumab	Alzheimer's
RG1594	ocrelizumab	RMS
RG1594	ocrelizumab	PPM
RG7417	lampalizumab	geographic atrophy

## Registration (1 NME + 2

RG105	MabThera SC	CLL
RG1273 <sup>2</sup>	Perjeta	HER2+ BC neo
RG7421	cobimetinib + Zelboraf	m. melanoma

- 1 US only : FDA submission decision pending
  - 2 Approved in US, submitted in EU
- \* FPI imminent

	New Molecular Entity (NME)
	Additional Indication (AI)
	Oncology
	Immunology
	Infectious Diseases
	CardioMetabolism
	Neuroscience
	Ophthalmology
	Other
RG-No	Roche Genentech managed
CHU	Chugai managed
RG105	MabThera is branded as Rituxan in US and Japan
RG1569	Actemra is branded as RoActemra in EU
RG7159	Gazyva is branded as Gazyvaro in EU

Status as of April 22, 2015

**The Roche Group**

**Our Company Strategy**

**Our Innovation**

**Pharmaceuticals**

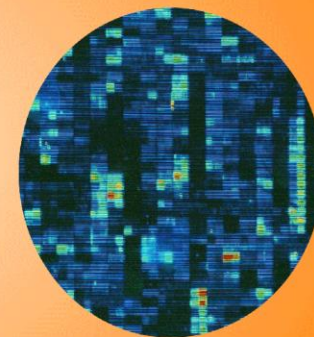
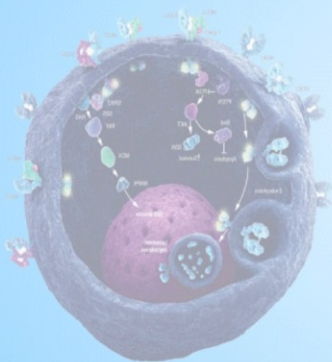
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**Diagnostics**

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# Roche Group

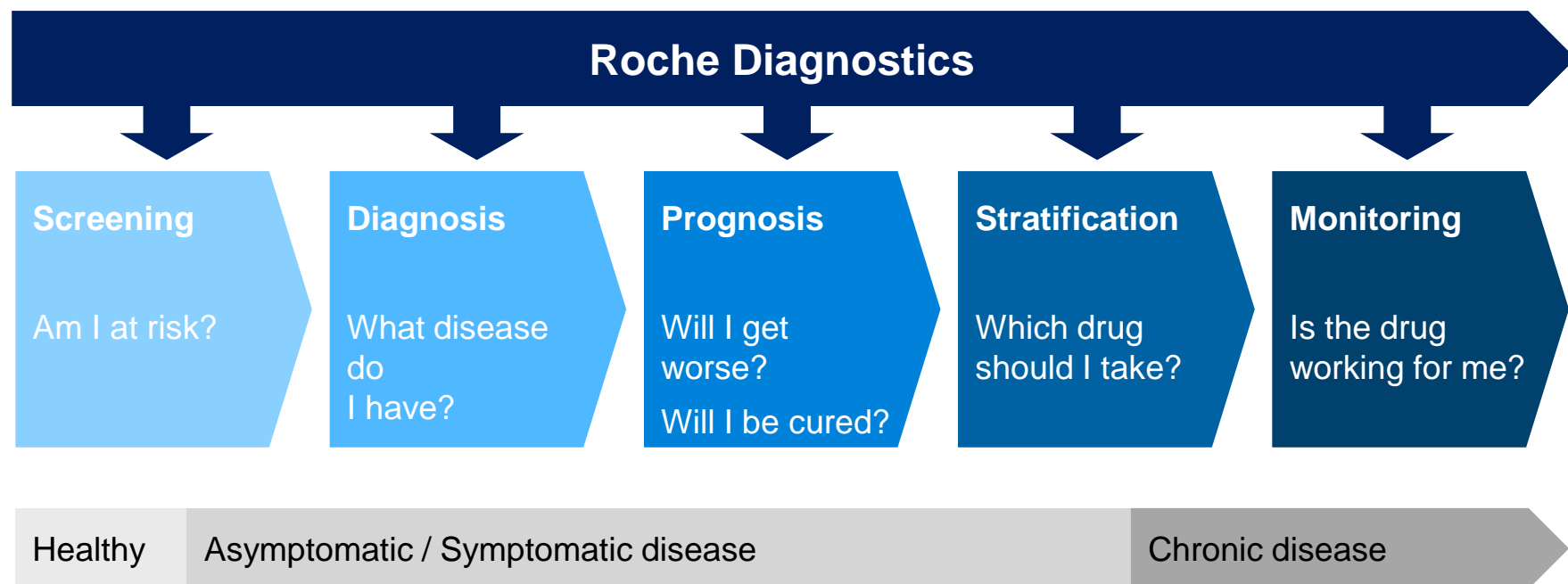
*Structure - Diagnostics*



# The diagnostics value chain

*An integral part of treatment decision making*

Roche Diagnostics is offering diagnostic tests along the entire healthcare chain:



# Revaluing Diagnostics

**In vitro diagnostics testing has long been a silent champion of healthcare:**

IVD accounts for  
**~2%**  
of worldwide healthcare spending







IVD influences  
**>60%**  
of clinical decision-making



# Roche Diagnostics Division



*Serving both clinical and life sciences segments*

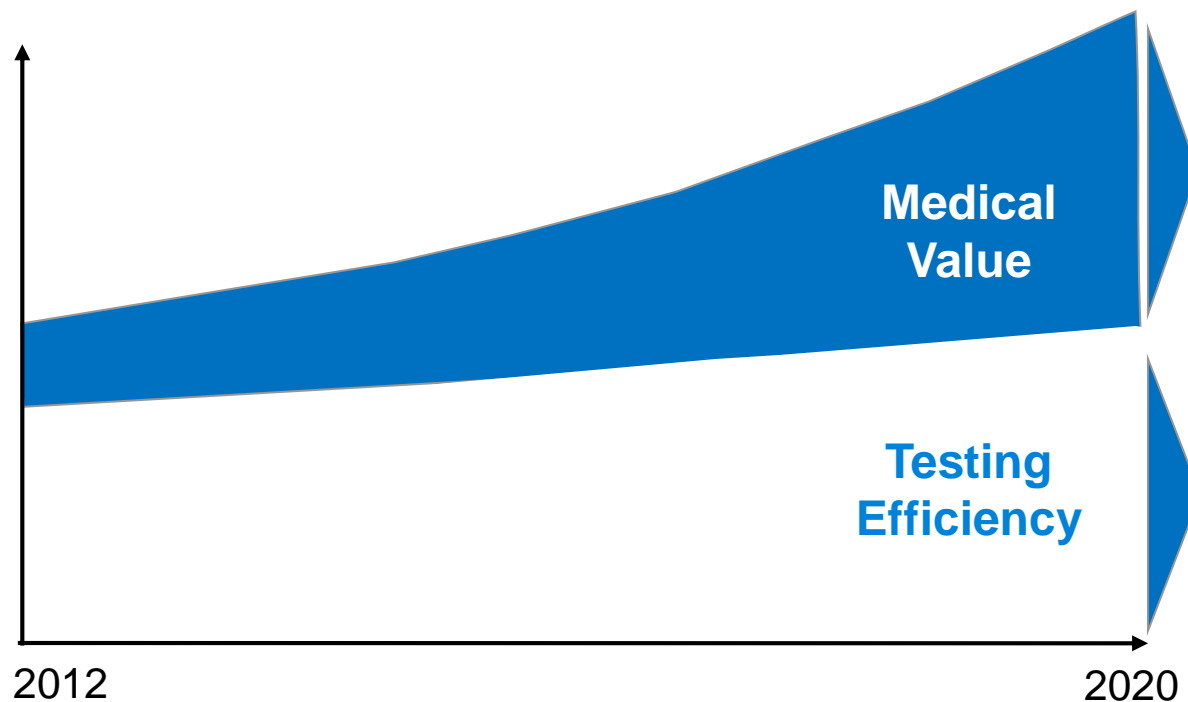
Professional Diagnostics Business Area	Molecular Diagnostics Business Area	Tissue Diagnostics Business Area	Diabetes Care Business Unit
			
<ul style="list-style-type: none"><li>• Serum work area/immunoassays and clinical chemistry</li><li>• Point-of-care testing</li><li>• Coagulation and specialty testing</li><li>• Workflow management</li><li>• Custom Biotech</li></ul>	<ul style="list-style-type: none"><li>• Virology</li><li>• Blood screening</li><li>• Genomics/oncology</li><li>• Microbiology</li><li>• Women's health</li><li>• Biochemical reagents</li><li>• Nucleic acid DNA purification and real-time PCR</li></ul>	<ul style="list-style-type: none"><li>• Primary staining</li><li>• Advanced staining</li><li>• Workflow management</li><li>• Digital pathology</li></ul>	<ul style="list-style-type: none"><li>• Blood glucose monitoring</li><li>• Insulin delivery</li><li>• Diabetes management systems</li></ul>
Sequencing Unit	offering sequencing solutions for both clinical and life science segments		

# Roche Diagnostics

## *Business strategy*

Roche Diagnostics differentiates itself in the marketplace through:

- continuously increasing **testing efficiency**
- developing novel tests with **high medical value**



- Revaluing diagnostics
- Unmet needs
- Access & create IP
- Clinical evidence

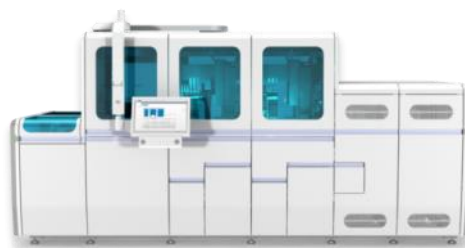
- Total lab solutions
- Modular offering
- Complete menus
- Lab IT and workflow

# Molecular Diagnostics

*Launch of cobas 6800/8800 & test menu expansion*

High Throughput

Reference Labs



**cobas® 8800**

Large Hospitals



**cobas® 6800**

Medium Hospitals



**cobas® 4800**

Low Throughput

- Advanced PCR automation
- Highest throughput (3x above closest competitor)
- CE launch of blood screening and virology assays

- Low to middle volume throughput
- Broadest menu incl HPV testing

# Entering Molecular Point of Care Diagnostics

*Acquisition of IQum - testing close to the patient*

## Liat™ Analyzer



### Target market:

- ~CHF 350m, growing ~20% p.a.

### Laboratory in a tube technology:

- Fast and easy to use
- CLIA waiver expected in 2015

### Portfolio:

- Influenza A/B and Strep A test, CE marked and FDA cleared
- Plans to extend menu in:
  - Respiratory Syncytial Virus tests
  - MRSA and C-difficile

# Sequencing strategy

*Building a leading sequencing solution*

## Developing complete innovative sequencing solutions

Sample  
preparation

Testing Platform

Menu of  
assays

Data analysis

Reporting

AbVITRO

genia

Ariosas  
DIAGNOSTICS

bina

PB  
PACIFIC  
BIOSCIENCES\*

FOUNDATION  
MEDICINE\*





*I'm great because I don't play the game where it is,  
but where it's going to be!"*

**-Wayne Gretzky**



*Doing now what patients need next*