Roche Diagnostics Investor Day 2021

23rd March 2021

Roche Diagnostics Investor Day 2021

Welcome

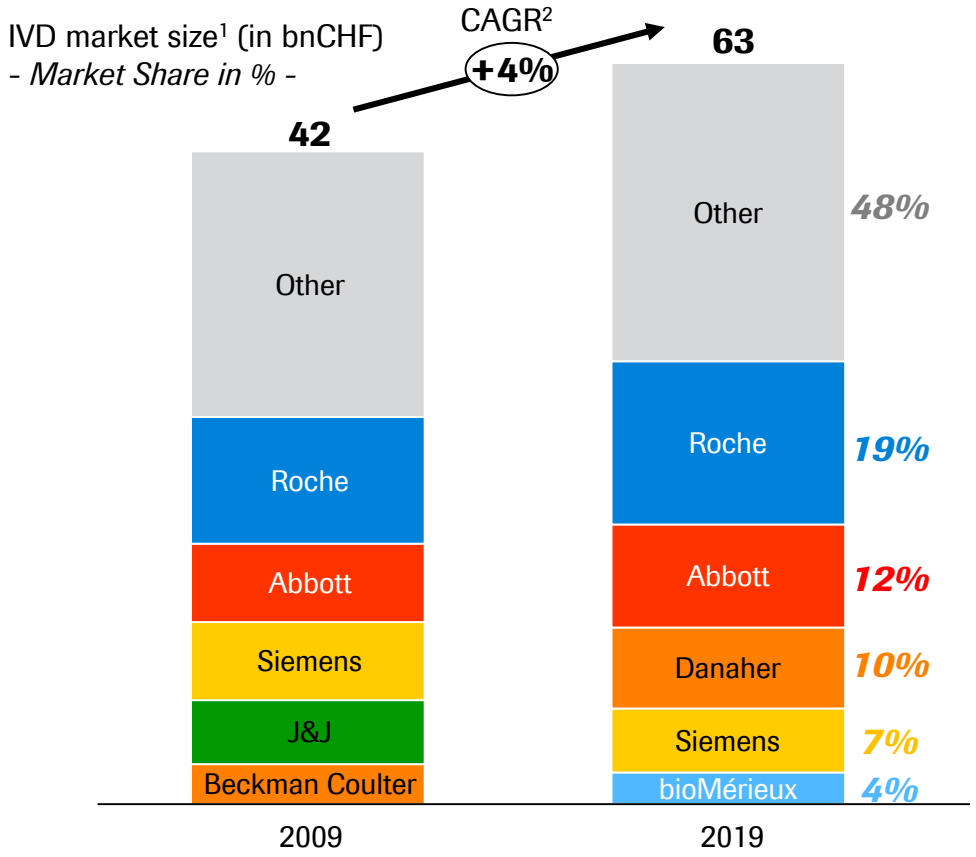
Karl Mahler | Head of Investor Relations and Roche Group Planning

Agenda

Welcome Karl Mahler, *Head of investor Relations and Roche Group Planning*	**2.00–2.40pm**
Strategy & Organization Thomas Schinecker, *CEO Diagnostics*	
Diagnostics Solutions & Customer Areas Ann Costello, *Global Head Roche Diagnostics Solutions*	
Research & Development Palani Kumaresan, *Head of Research & Development*	
Q&A Birgit Masjost, *Investor Relations Officer,* & speaker panel	**2.40–3.05pm**
Break	**3.05–3.10pm**
Systems Benjamin Lilienfield, *Life Cycle Leader Systems*	**3.10–3.35pm**
Infectious Diseases Michael Hombach, *Global Clinical Leader Infectious Diseases*	
Cardiology Andre Ziegler, *Global Clinical Leader Cardiology*	
Oncology Jill German, *Global Head of Pathology Lab*	
Q&A	**3.35–3.55pm**
Closing Thomas Schinecker, *CEO Diagnostics*	**3.55–4.00pm**

IVD Market has seen consolidation

Roche staying in the lead



Insights

- Roche staying in the lead with 4% growth (CAGR 2009- 2019)
  - broadest menu, highest automation
- Significant M&A activities / consolidation with Abbott (Alere), Danaher (Radiometer, Leica, Beckman Coulter, Cepheid), bioMérieux (BioFire) etc.
- «Other» category has expanded driven by specialty players like Sysmex or low-cost entrants like Mindray (China based)

Source: Divisional MCI, IVD Market Books 2009-2019; CAGR: Compound Annual Growth Rate; [1] Market size accounts for IVD incl. Blood Glucose Monitoring; [2] Growth in constant exchange rate adjusting for currency fluctuations

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Strategy & Organization

Thomas Schinecker | CEO Diagnostics

Roche clear leader in growing IVD market

14 billion CHF revenue in 2020[1]

19% share as IVD market leader[1]

23.4 billion tests[1]

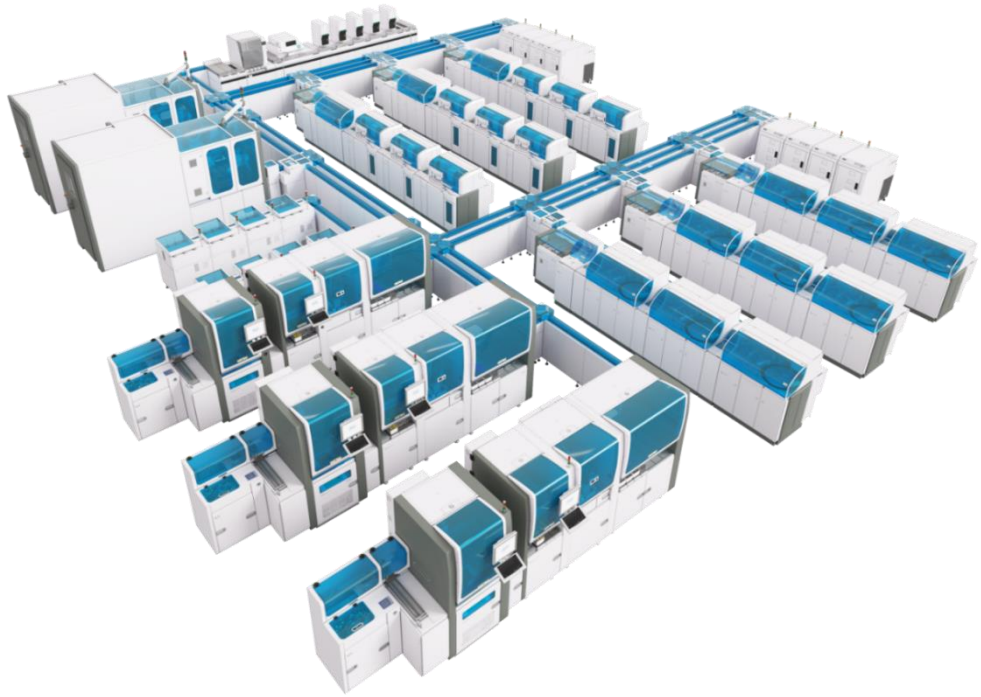
#1 in Clinical Chemistry & Immunodiagnostics

#1 in Molecular Diagnostics

#1 in Tissue Diagnostics

#3 in Point-of-Care Diagnostics

#1 in Workflow & IT



IVD: In-Vitro Diagnostics; [1] Incl. Diabetes Care

Global transformation exercise

Develop strategic options and recommendations

Strategic topics ...

1	Customers & value pools
2	Diagnostics portfolio segments
3	Digital solutions
4	Geographical focus
5	People & culture
6	Customer centricity & customer experience
7	Fuel innovation engine

... addressed by cross-functional teams of experts

15+	Workshops
40+	Customers
200+	Experts and leaders
30+	Coaching sessions
400+	Internal & external expert interviews

Healthcare objectives

Improve patient outcomes and reduce costs

Healthcare systems aim to…

Improve outcomes

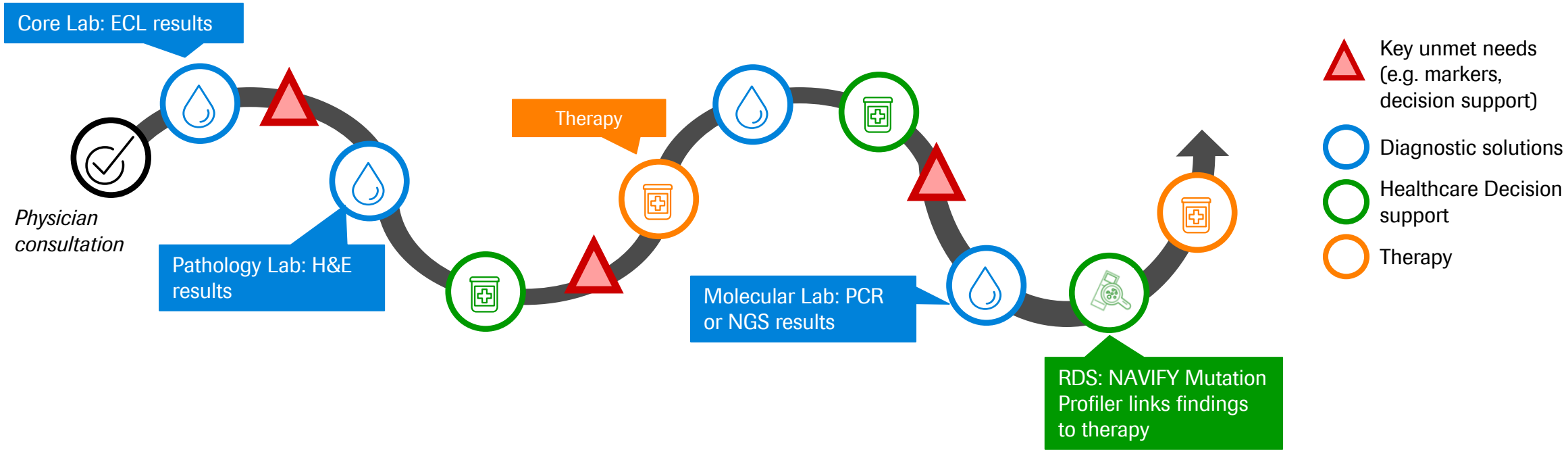
Better outcomes and better social and economic benefits for patients, healthcare providers and the healthcare system as a whole

Reduce costs

Lower total care delivery costs with more effective prevention, diagnosis, treatments and care along patient journey

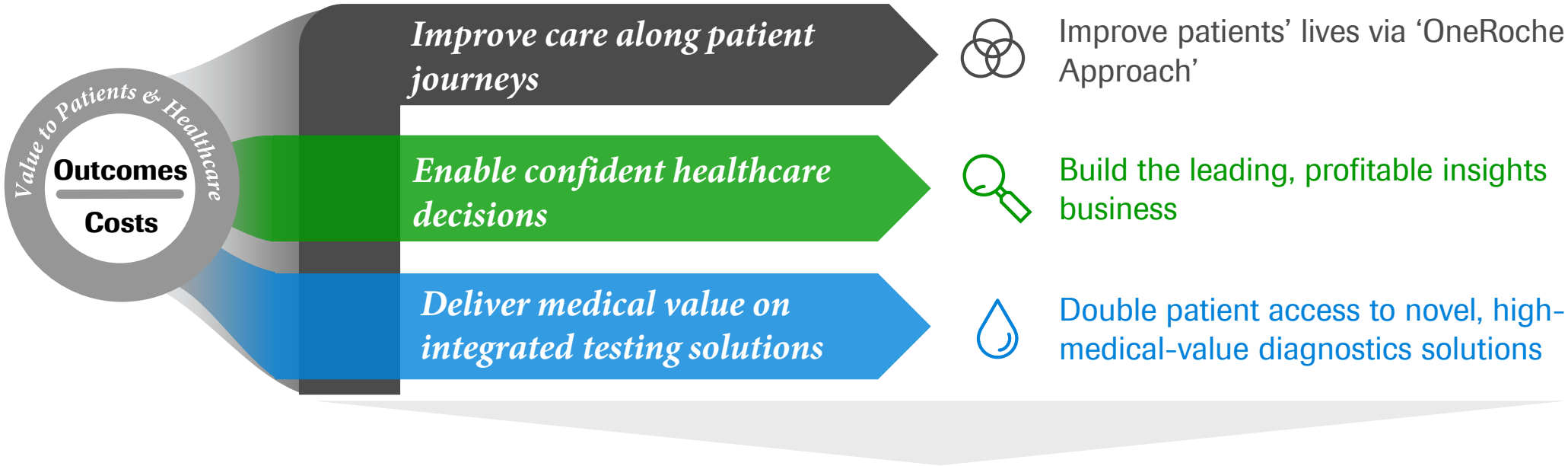
Patient journey

Optimising care along the patient journey



Patient journey: sequence of care events (e.g. diagnosis steps, medical procedures, medicines) which a patient has to go through for a specific disease from the point where the patient enters the healthcare systems to the point of exit due to any cause; ECL: Electrochemiluminescence; RDS: Roche Diagnostics Solutions; NGS: Next Generation Sequencing; PCR: Polymerase chain reaction; H&E: Hematoxylin & Eosin

Strategy and financial ambitions



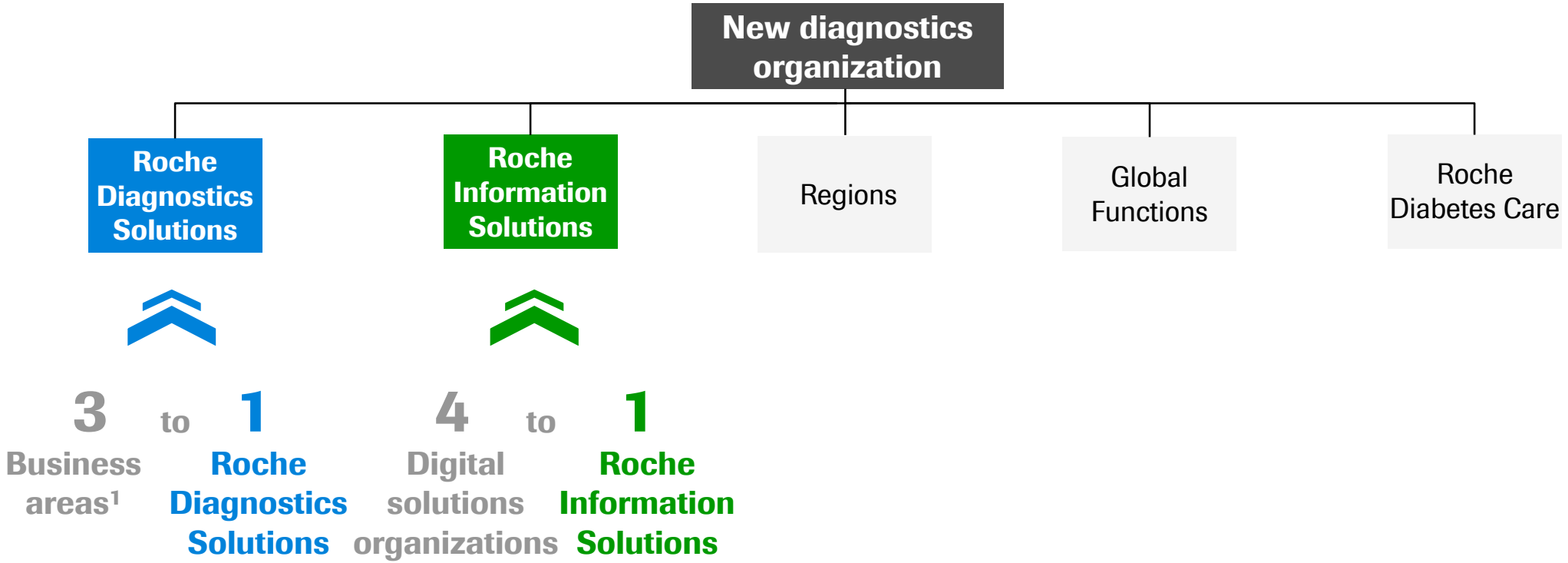
Grow **talent**

Invest in **strategic priorities**

Grow **market share**

Organizational transformation enabling new strategic priorities

Simplification and focus through customer & function centricity



[1] Roche Diabetes Care excluded based on previous transformation

Diagnostics reporting 2021 onwards

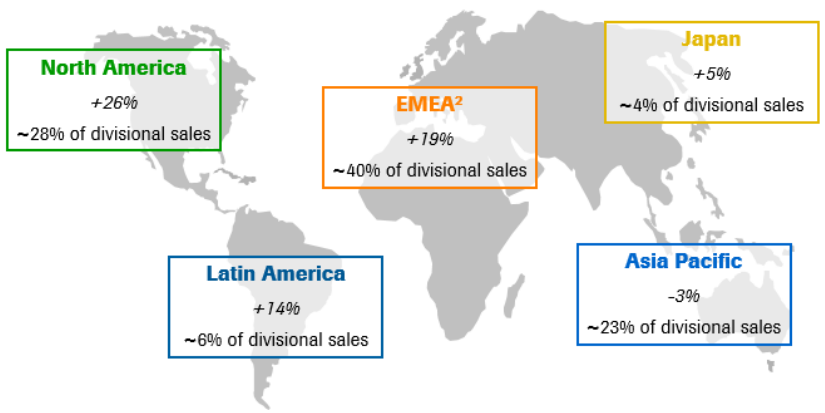
Moving from business to customer areas and adjusting regions

Old

Changes in customer areas reporting

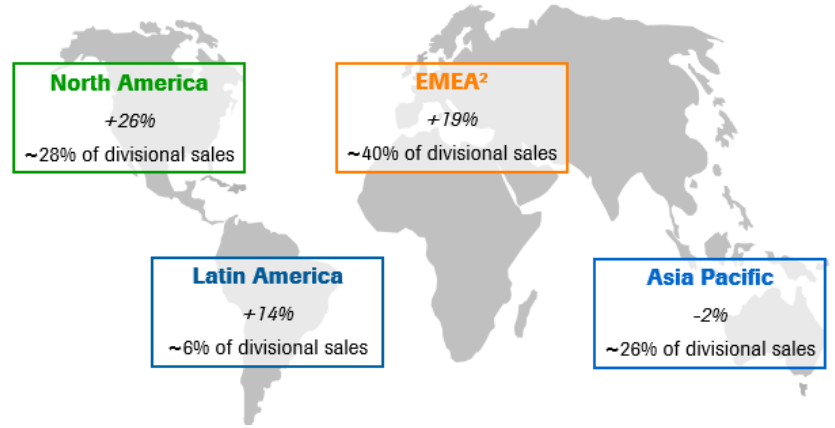
	2020 CHFm	2019 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**13,791**	**12,950**	**6**	**14**
Centralised and Point of Care Solutions	7,273	7,819	-7	-1
Molecular Diagnostics	3,760	2,109	78	90
Diabetes Care	1,670	1,918	-13	-5
Tissue Diagnostics	1,088	1,104	-1	5

Changes in regional reporting



New

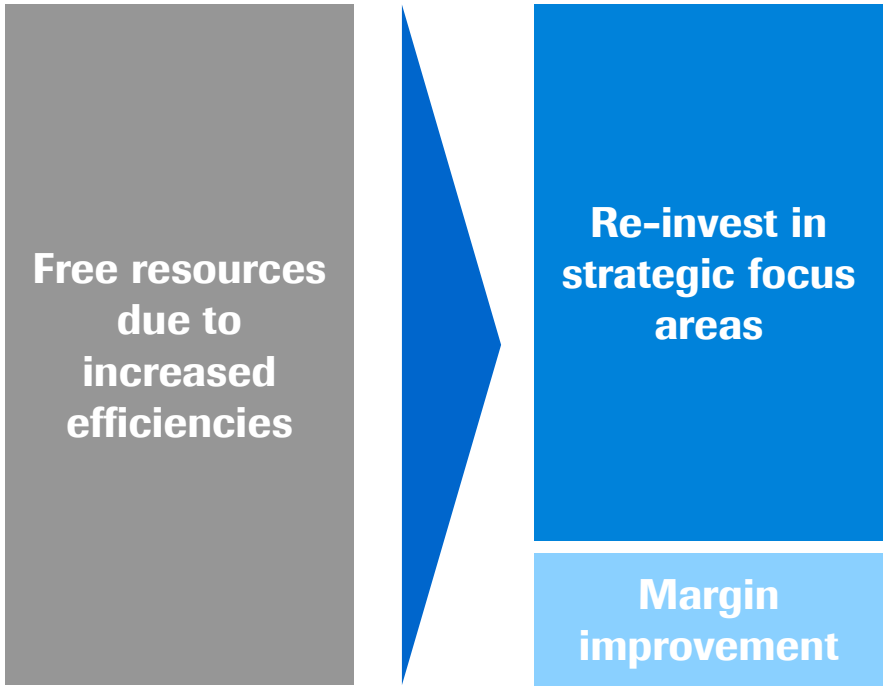
	2020 CHFm	2019 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**13,791**	**12,950**	**6**	**14**
Core Lab[1]	6,194	7,078	-12	-6
Molecular Lab	3,760	2,109	78	90
Point of Care	1,079	741	46	54
Pathology Lab	1,088	1,104	-1	5
Diabetes Care	1,670	1,918	-13	-5



CER: Constant Exchange Rates; [1] Includes Roche Information Solutions sales; [2] Europe, Middle East and Africa

Funding the Strategy

Shifting investments into strategic priorities

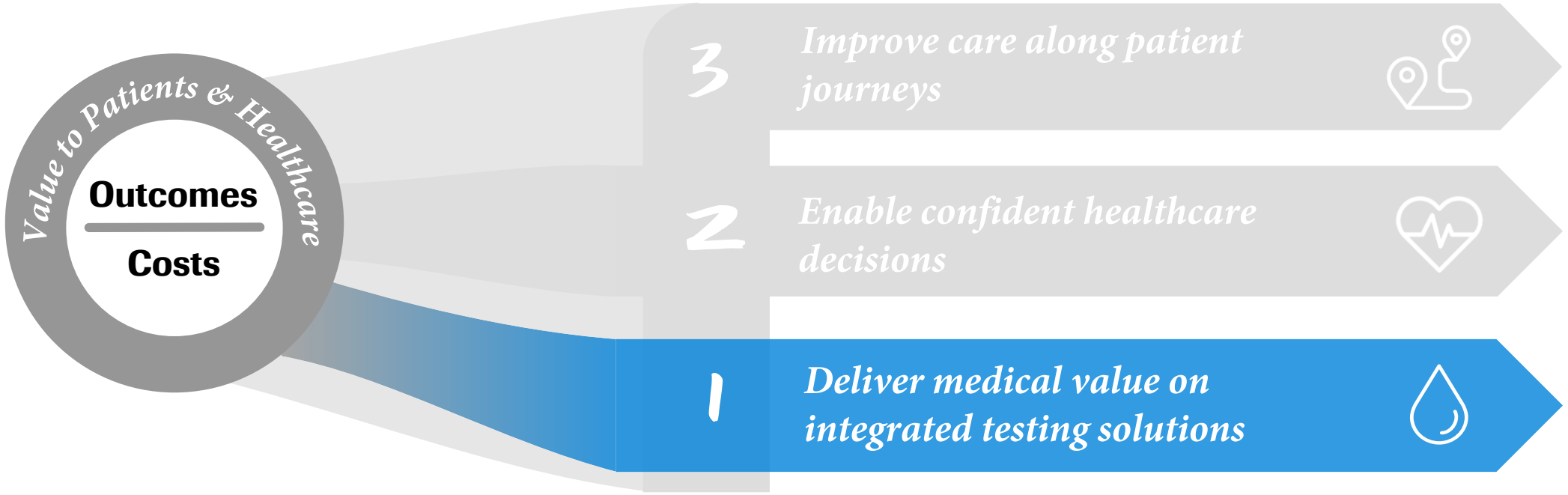


Fund strategic priorities:

- Medical value solutions
- Digital solutions & insight generation
- Disease management
- Access capabilities

Diagnostics solutions

Deliver medical value on integrated testing solutions



Diagnostics Solutions strategic priorities

Developing comprehensive solutions for our customers

Focus on customer solution and experience

Core Labs

Molecular Labs[1]

Pathology Labs[1]

Points of Care

Systems & assays

Digital & IT

Services

Differentiators

Medical value

Efficiency

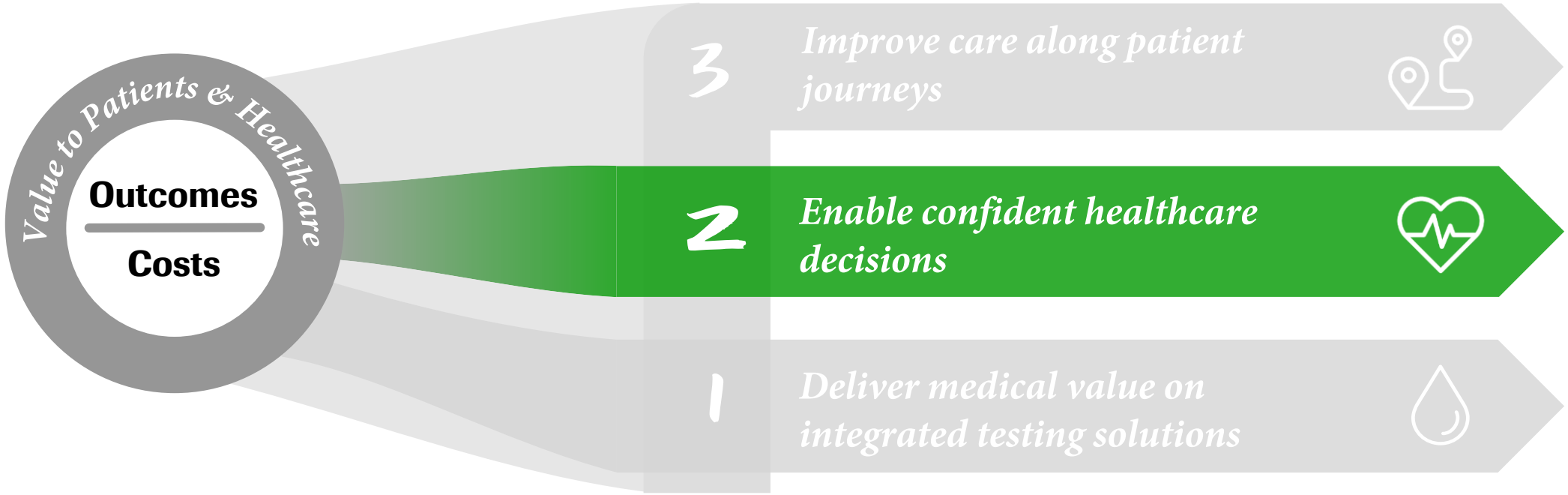
Digitalisation

Access

[1] Sequencing as key technology to address needs of molecular and pathology labs customer segments

Healthcare decision support solutions

Enable confident healthcare decisions



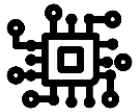
Roche Information Solutions strategic priorities

Supporting healthcare decisions

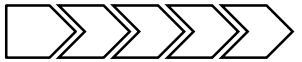
Focus on customer solutions and experience

Lab Insights	Platforms, applications, marketplace
Provider Insights	Lab and clinical workflow
Patient Insights	Clinical decision support
	Disease management

Differentiators



Platform



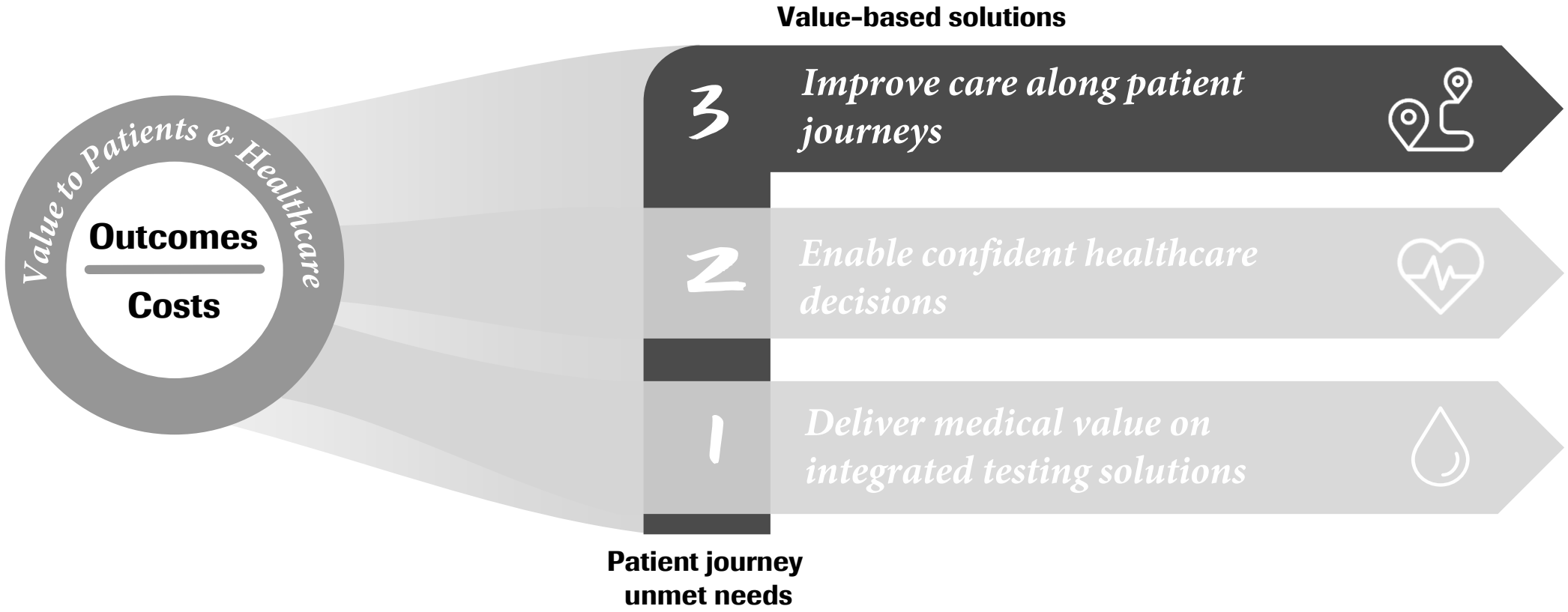
Efficiency

Medical Value

Insight generation

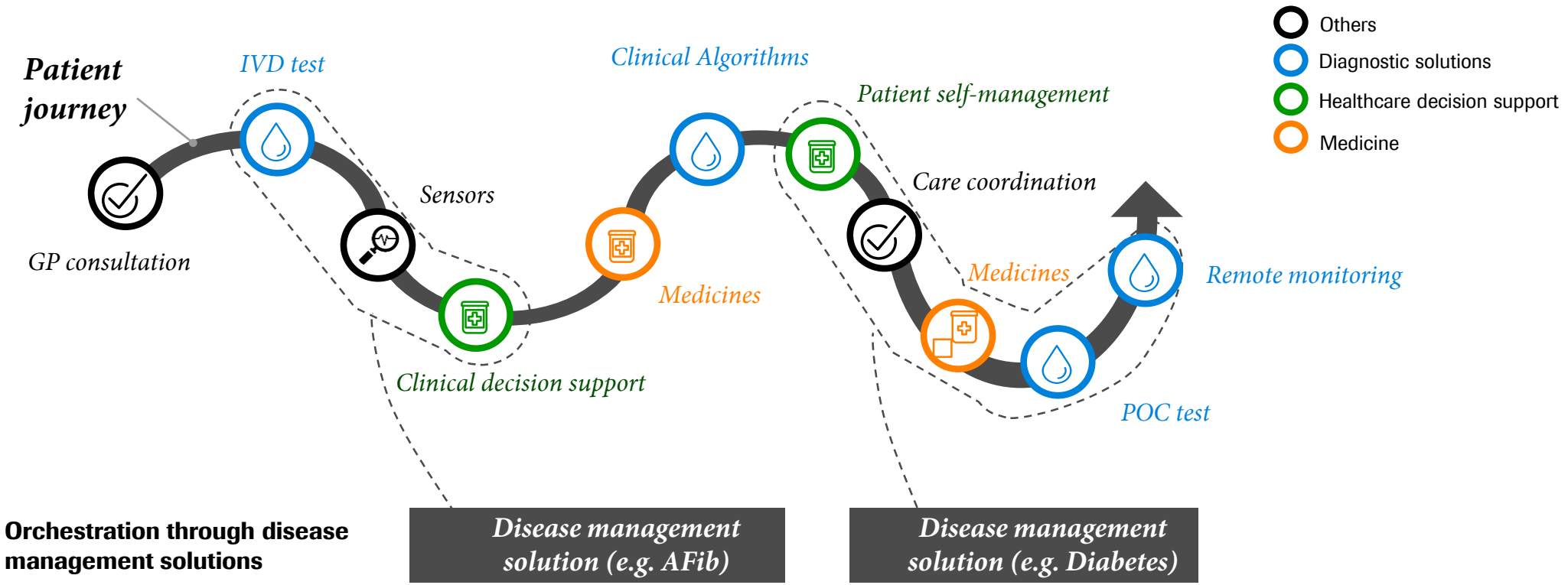
Disease management solutions

Improve care along patient journeys



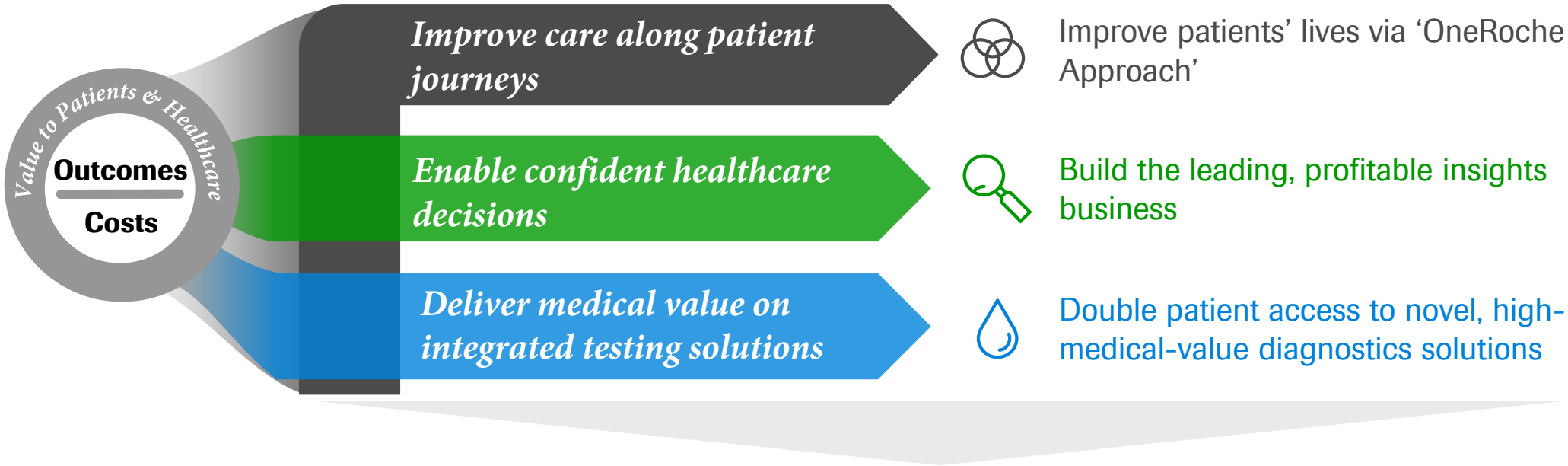
Disease management solutions

Unlocking value through orchestration along patient journey



AFib: Atrial Fibrillation; GP: General Practitioners; IVD: In-Vitro Diagnostics; POC: Point Of Care

Strategy and financial ambitions



Grow **talent**

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Grow **market share**

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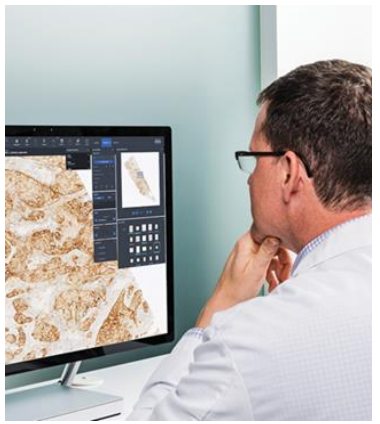
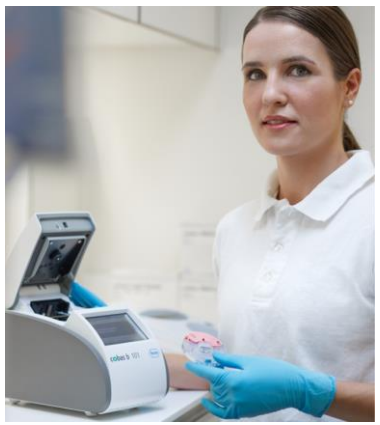
Diagnostics Solutions & Customer Areas

Ann Costello | Global Head Roche Diagnostics Solutions

Diagnostics solutions: Strategic priorities

Providing comprehensive solutions for our key customer segments

Customer area	Core Lab	Molecular Lab[1]	Pathology Lab[1]	Point of Care
				
Customer segments	**Central Labs** **Molecular Labs** **Blood Banks**		**Pathology Labs**	**Satellite Labs** **ERs/ICUs** **GPs / Specialists** **Patients** **Pharmacies**
Solution components	**Systems & assays**		**+ Digital & IT**	**+ Services**

[1] Sequencing as key technology to address needs of molecular and pathology labs customer segments

Diagnostics solutions: Strategic priorities

Achieving differentiation based on four distinct pillars

Medical value	Diagnostics efficiency	Digitalization	Market access
Address **top disease areas** and unmet clinical needs	Drive **integration & connectivity** from labs to patients	Digitalize **lab operations and test interpretation**	Ensure **access to novel diagnostics**

Examples of success

Molecular Lab & Core Lab, Point of Care:
9 FDA Breakthrough Device Designations since 2018

Molecular Lab: cobas® prime

Point of Care: cobas® pulse[1]

Pathology Lab: uPath Software

Point of Care: v-TAC Software

Molecular & Pathology Lab: Cervical Cancer Screening

Core Lab: Pre-eclampsia in guidelines

[1] Product to be launched in 2021

SARS-CoV-2 diagnostics portfolio[1]

Comprehensive portfolio of tests and digital solutions

	Clinical Labs		Near Patient	
Molecular solutions	• **cobas®** SARS-CoV-2	*Launched*	• **cobas®** SARS-CoV-2 & Influenza A/B	*Launched*
	• **cobas®** SARS-CoV-2 Variant	*Launched*	• **cobas®** SARS-CoV-2	*In-development*
	• **cobas®** SARS-CoV-2 & Influenza A/B	*Launched*		
	• TIB MOLBIOL LightMix® Modular SARS-CoV-2	*Launched*		
Immunology solutions	• Elecsys® Anti-SARS-CoV-2	*Launched*	• SARS-CoV-2 rapid antibody	*Launched*[3,4]
	• Elecsys® Anti-SARS-CoV-2 S[2]	*Launched*	• SARS-CoV-2 rapid antigen	*Launched*[3,4]
	• Elecsys® SARS-CoV-2 antigen	*Launched*[4]	• SARS-CoV-2 rapid antigen nasal	*Launched*[3,4]
	• Elecsys® IL-6 Test to diagnose cytokine release syndrome	*Launched*	• SARS-CoV-2 rapid antigen nasal self-testing	*Launched*[3,4,5]
			• SARS-CoV-2 & Influenza A/B rapid antigen	*In-development*[3,4]
Digital solutions	• Viewics LabOps COVID-19 for efficiency improvements	*Launched*	• NAVIFY Remote Monitor[6]	*Launched*
			• v-TAC[7] digital algorithm for blood-gas	*Launched*
			• iThemba Life COVID-19	*Launched*
			• cobas Infinity POC COVID-19	*Launched*
			• NAVIFY Pass	*Launched*

CER: Constant Exchange Rates (avg FY 2020); [1] Not all products are available in all countries; [2] Spike protein; [3] External distribution partnership; [4] Not yet approved in the U.S; [5] Germany only; [6] US only; [7] v-TAC: venous to arterial conversion

Investing CHF >600m to increase supply chain capacities

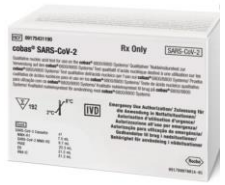
Driving to unprecedented volume in record time

Consumables

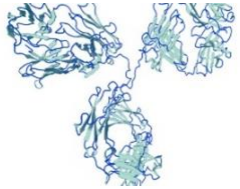
- **60** new manufacturing lines
- **17** locations with 5 new partners

Reagents

- **20** new manufacturing lines
- **4** major facility expansions



- **CHF >600m** investment
- **>1,200** new employees



- **8** new manufacturing lines
- **1** new biotech facility

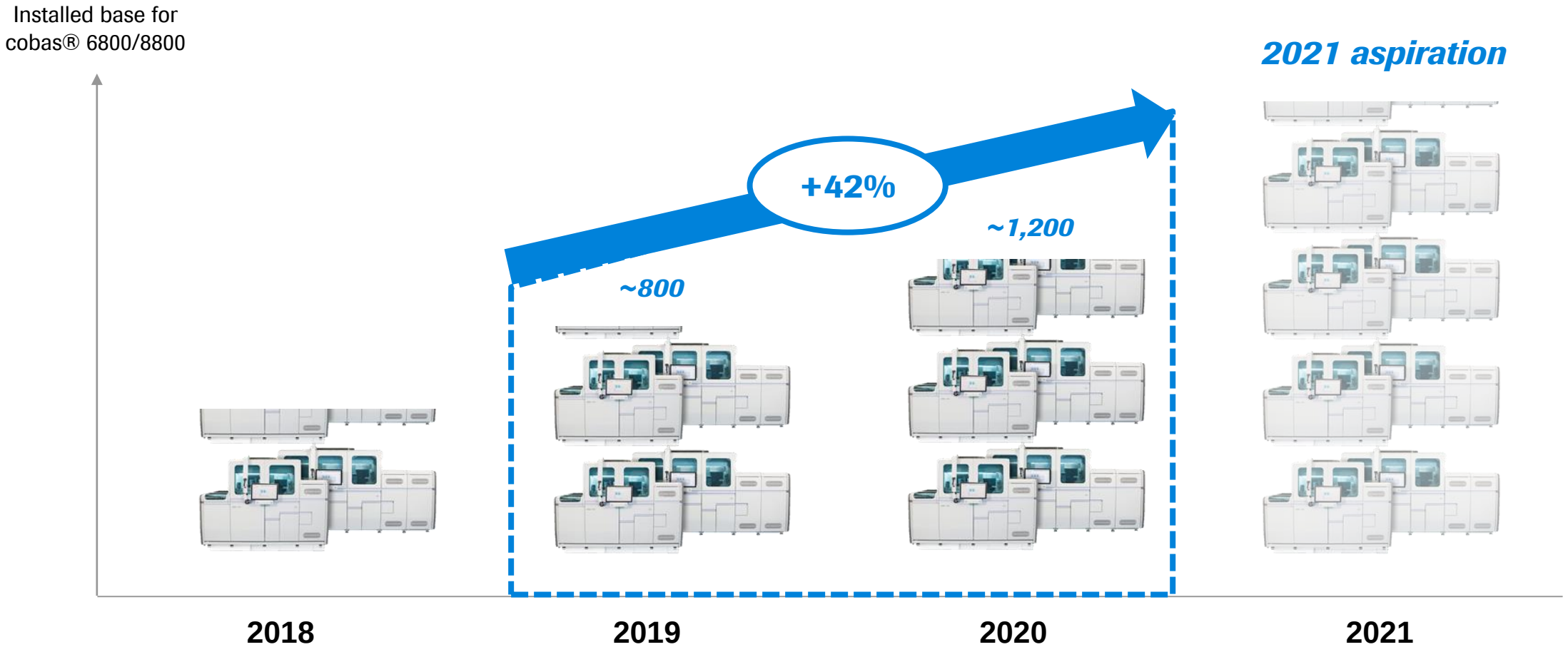
- **1** new manufacturing space

Raw materials

Instruments

Molecular Lab installed base

We significantly increased our footprint in the market



Levering our installed base in the future

Enabler to sell high medical value biomarkers

Further consolidation of labs & customer preference for fully automated solutions

+42%

Increase of installed base for cobas® 6800/8800 in 2020

Our aim to bring more menu to installed base focusing on medical value

We built a strong position for sustainable performance

Roche molecular solutions portfolio

GenMark[1] Diagnostics fills the portfolio gap in molecular multiplexing

Throughput

cobas® Liat®	GenMark	cobas® 5800[2]	cobas® 6800	cobas® 8800
		2021		
Molecular point-of-care	**Molecular multiplexing**	**Molecular medium throughput**	**Molecular high throughput**	

[1] GenMark Diagnostics offering is subject to successful closing of the merger agreement dated March 12, 2021; [2] Currently in development and not commercially available

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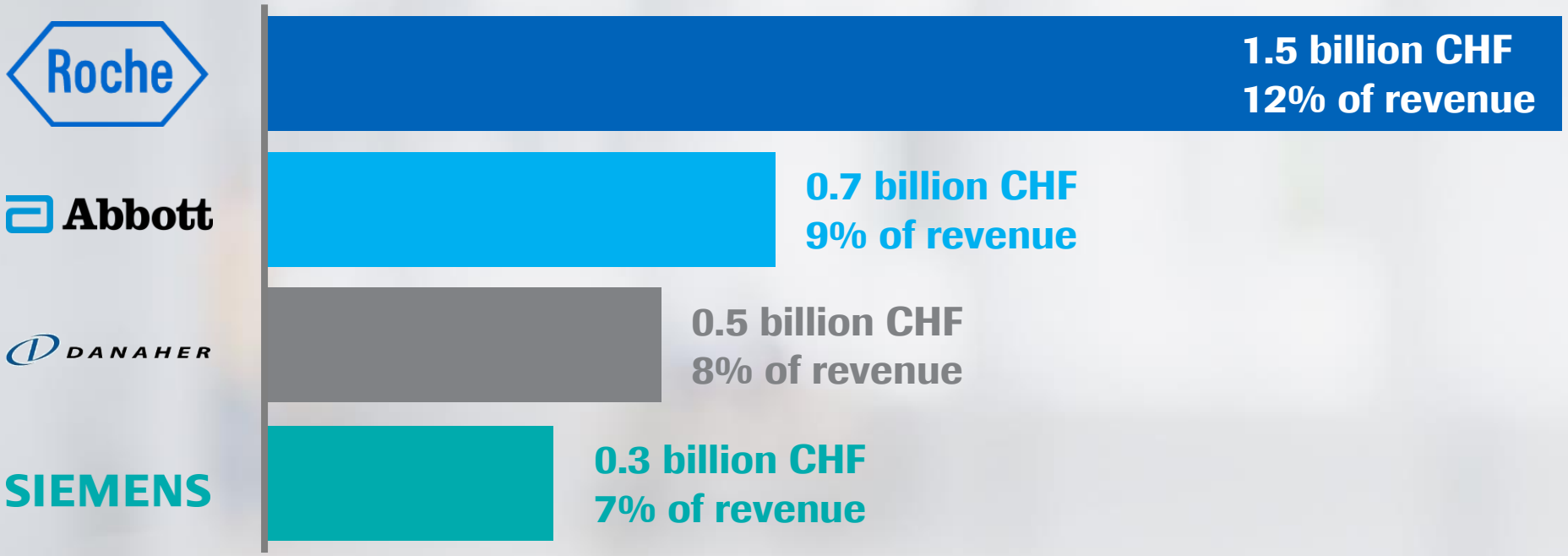
Research & Development

Palani Kumaresan | Head of Research & Development

Our commitment to innovation

We invest more in our IVD portfolio than other companies

125 CHF million per month



R&D investments as percentage of revenue for 2019

Ref: Roche estimates for IVD portfolio based on annual reports together with independent 3rd parties (including diabetes care); Product names and trademarks are the property of their respective owners.

R&D efficiencies

Implementing our new strategy will improve productivity

Increase organizational effectiveness

- Improved standardization and cross-pollination of best practices
- Greater shift of funds to projects versus non-project activities

Improve project delivery

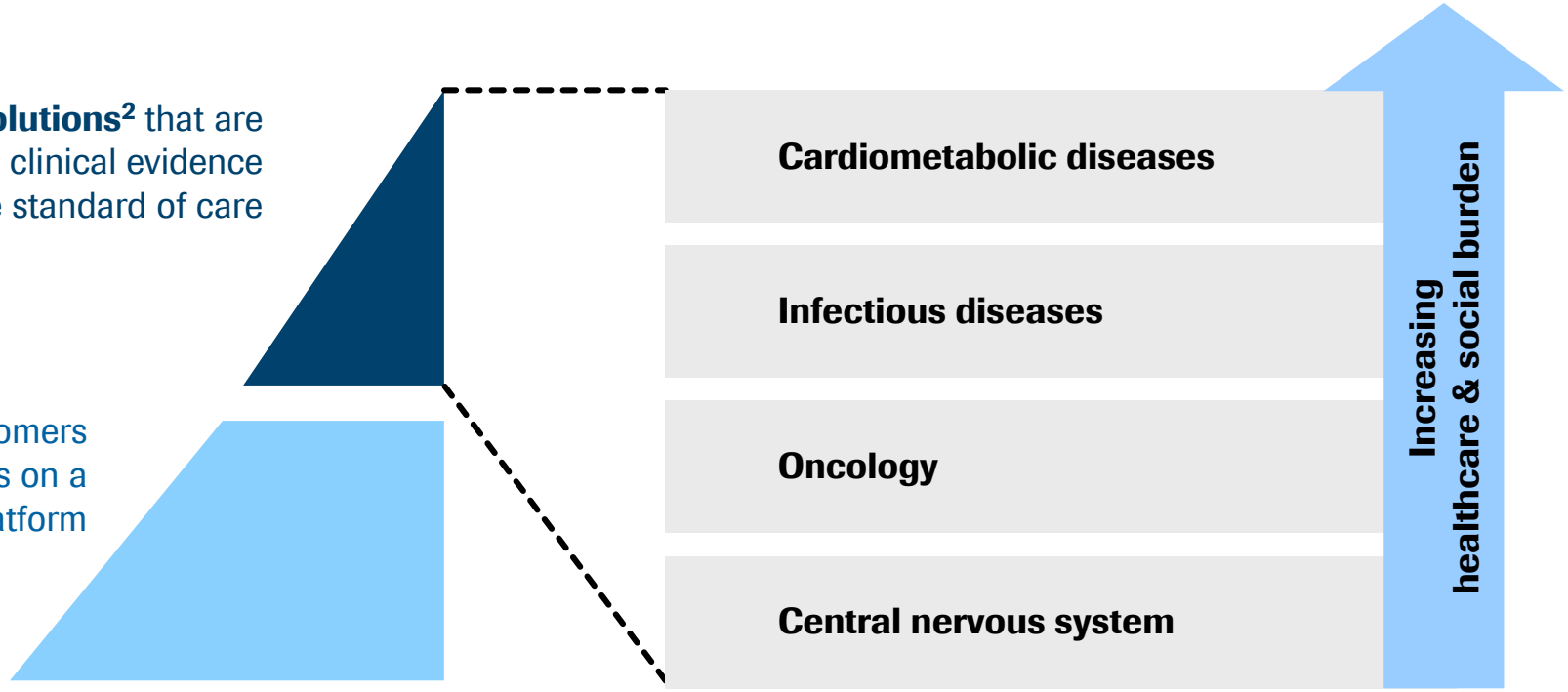
- More rigorous portfolio prioritization
- Internalize learnings from unprecedented development timelines of COVID solutions

Strategy around menu expansion

Broadest menu and most differentiated medical value solutions

Medical value solutions[2] that are **differentiated**, based on clinical evidence and improve the standard of care

Broad menu that allow customers to **consolidate** various tests on a single platform

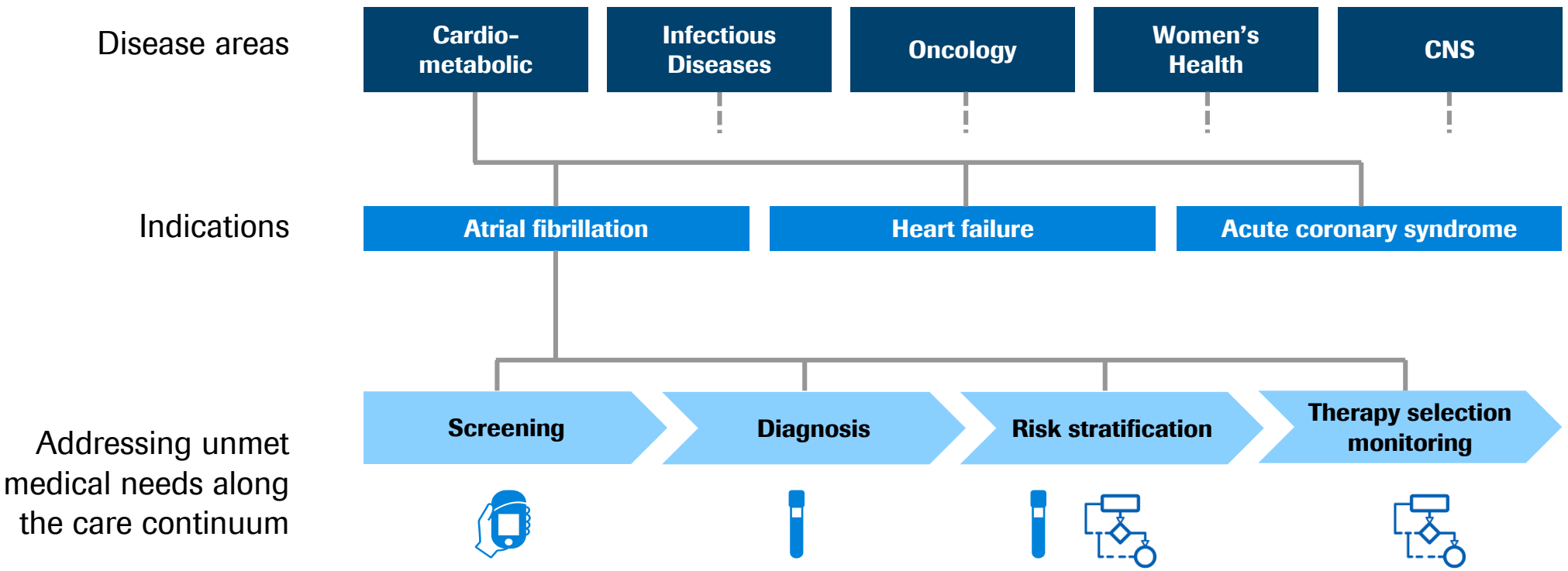


With medical value solutions & broad menu we address top healthcare burdens[1]

[1] Based on Divisional Medical & Scientific Affairs definitions and disease burden; [2] Including both top disease burden areas and other disease areas

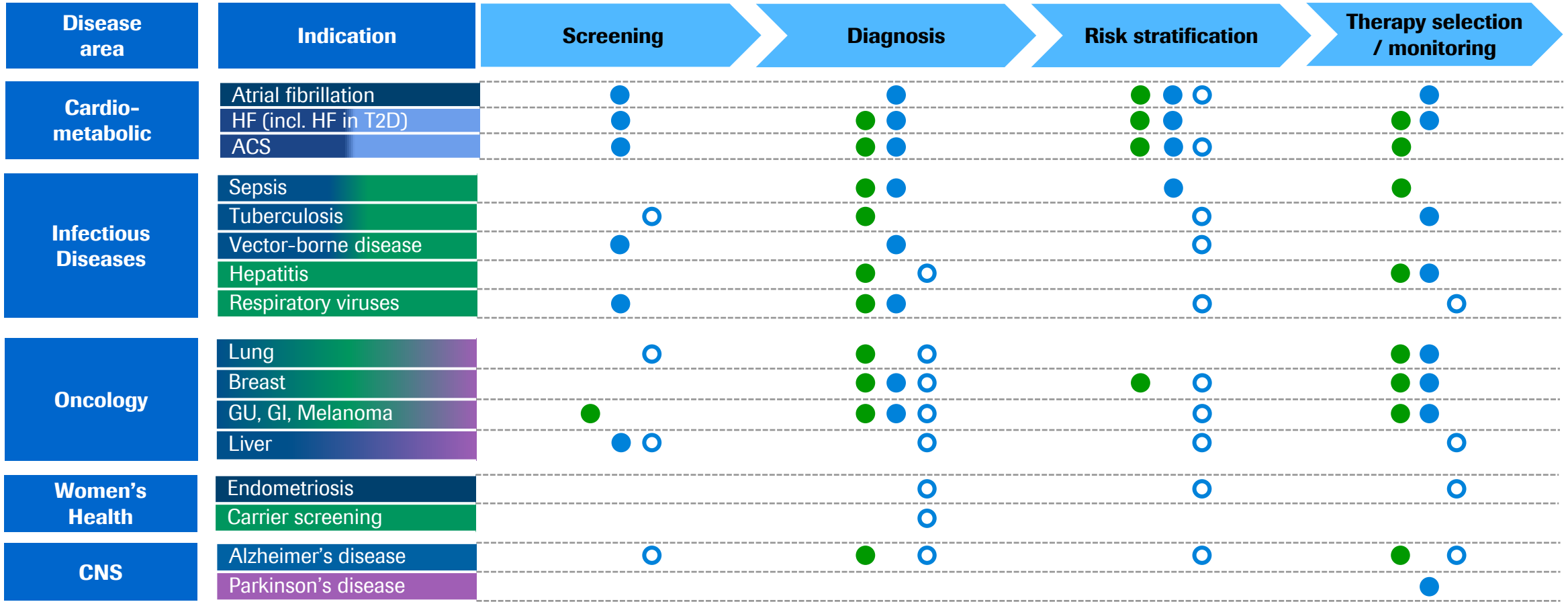
Approach to medical value solutions

Multi-modal, multi-parametric approach along continuum of care



Digital Solution | Biomarker | Clinical Algorithms

A broad portfolio of solutions across the care continuum



ACS: Acute Coronary Syndrome
HF: Heart failure; T2D: Type 2 Diabetes;
GU: genitourinary; GI: Gastrointestinal;
CNS: Central nervous system

Core Lab | Molecular Lab | Pathology Lab | Point of Care

On market
In development
Under evaluation

Recent Breakthrough Device Designations (BDDs)

Leading innovation recognized by the FDA

FDA BDD

Infectious diseases

cobas® EBV: EBV in transplant patients

cobas® BKV: BKV in transplant patients

Oncology

FACT CDx (liquid biopsy assay): 70 oncogenes + MSI + bTMB

Elecsys® GALAD score: Diagnosis of early stage hepatocellular carcinoma

Elecsys® GDF-15: GDF-15 in cachectic patients with solid tumors[1]

Women's health

Elecsys® sFlt-1/PlGF: rule-out of Preeclampsia within 1 week

CNS

Elecsys® ß-Amyloid and Elecsys® p-Tau in Cerebro Spinal Fluid assays: PET concordance and progression in Alzheimer's Disease

Others

CoaguCheck® Direct-X: Patients on Factor Xa

EBV: Epstein-Barr virus; BKV: BK virus; FDA: Food & Drug Administration; CDx: Companion Diagnostics; CNS: Central nervous system; [1] Treated with Pfizer Inc.'s investigational drug PF-06946860

Key launches 2021

	Area	Product	Description	Market[1]
Instruments	Core Lab	**cobas**® pure integrated solutions	Low-to-medium volume SWA	CE
		cobas® pro integrated solutions	New high throughput configurations of the cobas pro instrument	US & CE
	Point of Care	**cobas**® pulse	Successor of Accu-Chek® Inform II	CE
	Molecular Lab	**cobas**® 5800	Fully automated low throughput PCR system	CE
		AVENIO Edge System	Automated sequencing library preparation and target enrichment instrument	WW
	Diabetes Care	Accu-Chek Instant	New features for the monitoring system to increase performance and user experience	WW
Tests	Core Lab	Elecsys® SARS-CoV-2 Antigen	Automated laboratory assay intended as an aid in the diagnosis of SARS-CoV-2 infection	US
		Elecsys® NT-proBNP IU • extensions in Heart Failure • extension for Atrial Fibrillation Elecsys® TnT–hs 3 claim extensions in Coronary Arterial Disease	A set of 5 intended use extensions in the Coronary Arterial Disease, Atrial Fibrillation and Heart Failure Space	CE
	Molecular Lab	AVENIO FoundationOne kit (RUO)	Decentralized kit of the FoundationOne test	WW
		KAPA HyperPETE kit	New targeted sequencing portfolio using primer extension for small targets	WW
Digital Solutions	Pathology Lab	uPath 2.0	First IVD release and version of Open API of the clinical pathologist workflow module for NAVIFY Digital Pathology & on-premise uPath	WW
		RUO Algorithms	Whole slide image analysis algorithms (ER (SP1), Ki-67 (30-9), and PR (1E2))	WW
	Insights	NAVIFY Oncology 1.0	Modular Oncology decision support solution	WW[3]
		NAVIFY Pass 1.0	Solution for providers to communicate SARS-CoV-2 rapid antigen test results to a mobile app	US & CE[3]
	Core Lab	Elecsys® GAAD Algorithm	Algorithm for early detection of HCC in patients with chronic liver disease.	CE
	Diabetes Care	RocheDiabetes RemoteCare	Module within the RocheDiabetes Care Platform enabling remote interactions between HCPs and patients, including a patient dashboard, check-in and chat functionality	WW[3]
		Accu-Chek SugarView	Meter-free blood glucose testing using a smartphone app and test strips	OUS[3]

RDCP: Roche Diabetes Care Platform; [1] CE: European Conformity, US: FDA approval, WW: Worldwide, OUS: Outside the US; [2] Research Use Only; [3] Only a few selected countries

Q&A

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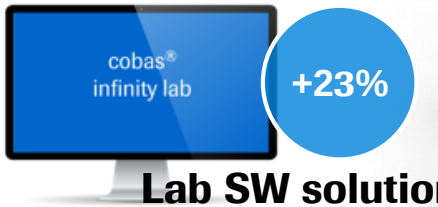
Systems

Benjamin Lilienfield | Life Cycle Leader Systems

Largest installed base worldwide with significant growth in 2020

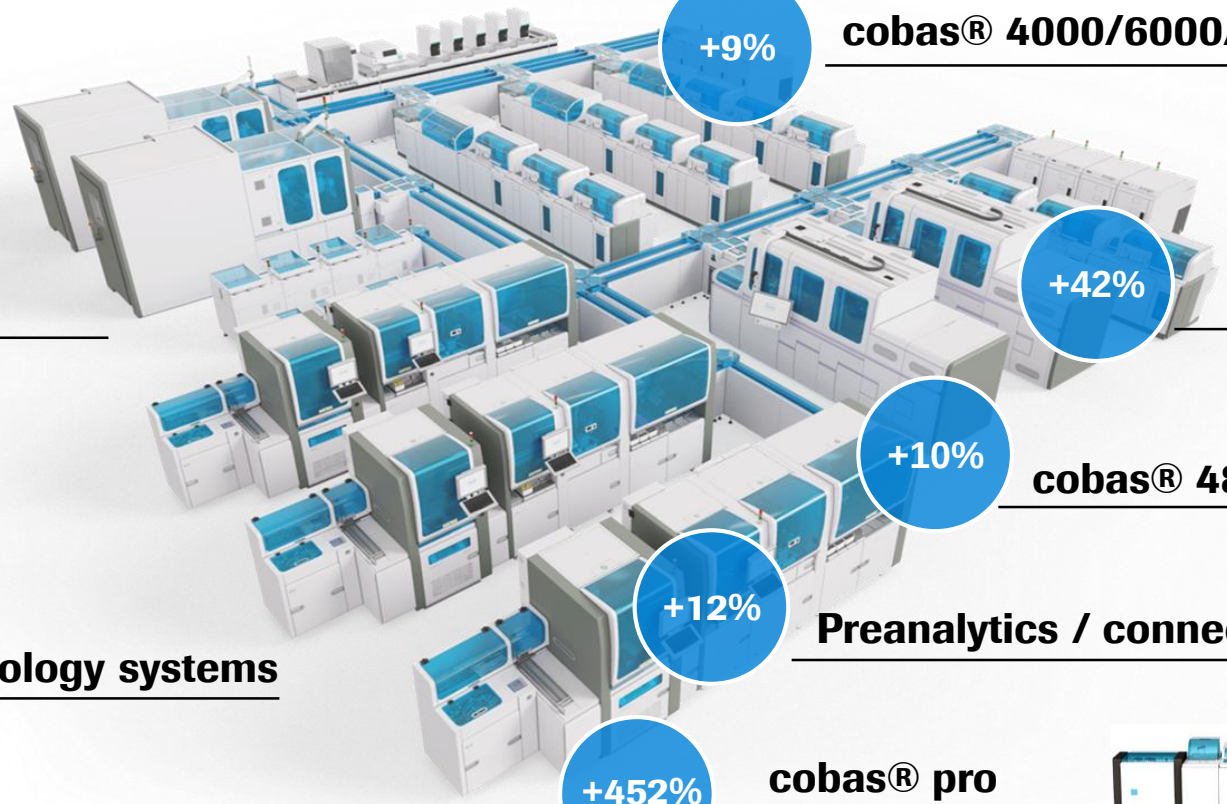


+23%

Lab SW solutions

+10%

Histopathology systems



+9%

cobas® 4000/6000/8000

+42%

cobas® 6800/8800

+10%

cobas® 4800

+12%

Preanalytics / connectivity

+452%

cobas® pro

cobas® 6800/8800 menu expansion driving growth in molecular

Further growing the installed base in 2021

Donor Screening	Blood Borne Disease	Sexual Health	Transplant	Respiratory	Antimicrobial Stewardship
MPX ✓	HIV-1 ✓	HPV ✓	CMV ✓	Flu A/B & RSV ✓ Not available in the US	MTB-RIF/INH ✓ Not available in the US
WNV ✓	HBV ✓	CT/NG ✓	EBV ✓	MTB ✓ Not available in the US	C.diff ✓ Not available in the US
DPX ✓	HCV ✓	TV/MG ✓	BKV ✓	MAI ✓ Not available in the US	MG Resistance CE-IVD in 2022
HEV ✓ Not available in the US	HIV-1/2 Qual ✓	PivNG ✓	ADV Quant ✓ Not available in the US	SARS-CoV-2 ✓ EUA & CE-mark	GC Resistance CE-IVD in 2022
CHIKV/DENV ✓ Not available in the US	HSV-1/2/VZV ✓	HPV Self-sampling CE-IVD in 2022	HSV-1/2/VZV ✓ Not available in the US	SARS-CoV-2 & Flu A/B ✓ EUA & CE-mark	
Zika ✓	HBV RNA (IA) ✓			SARS-CoV-2 Variant (RUO in 2021)	
Babesia ✓				Influenza A/B & RSV (CE-IVD in 2021)	
Malaria Global launch in 2023				AMER (CE-IVD in 2021)	
				Parainfluenza 1-4 (CE-IVD in 2021)	
				MPLX Respiratory (CE-IVD in 2022, US-IVD in 2023)	

Installed instrument base >1,200

~400 new placements in 2020

Launched in 2020

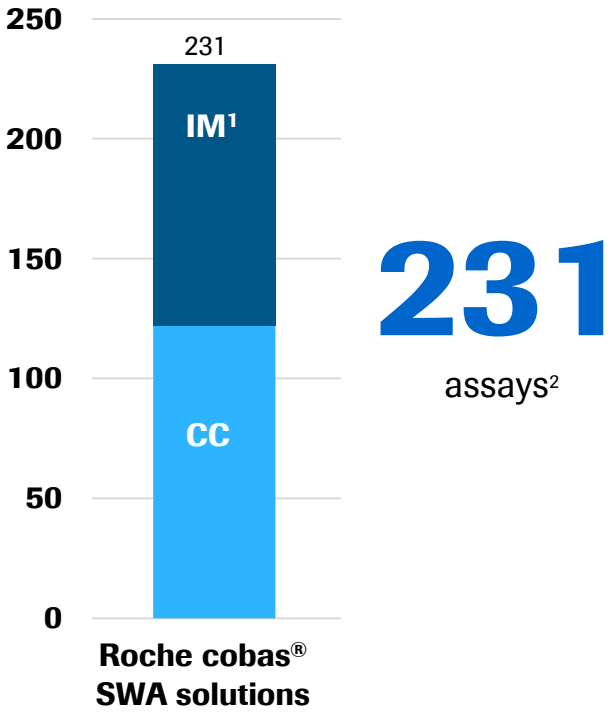
In development

MPX=multiplex detection of HIV-1, HIV-2, HCV and HBV; WNV=West Nile virus; DPX=duplex detection of parvovirus B19 and HAV; HEV=Hepatitis E virus; CHIKV=chikungunya virus; DENV=Dengue virus; CMV=Cytomegalovirus; MTB=Mycobacterium tuberculosis; MAI=Mycobacterium avium-intracellulare infection; RIF=rifampicin; INH=isoniazid (detection of RIF/INH resistance in MTB positive samples); TV=trichomonas vaginalis; MG=mycoplasma genitalium; Babesia=detection of babesiosis caused by tick-born parasites; EBV=Epstein-Barr virus post-transplant monitoring; BKV=BK virus post-transplant monitoring; ADV=Adenovirus post-transplant monitoring; HSV-1/2/VZV=multiplex detection of Herpes simplex virus 1 and 2 and Varicella-zoster virus; MPLX=detect and discriminate multiple (up to 14) pathogens associated with a clinical syndrome, including SARS-CoV-2; Malaria=mosquito-borne infectious disease; SARS-CoV-2=2019 novel coronavirus; HSV=Herpes Simplex Virus; VZV=Varicella-zoster virus, the cause of chickenpox and herpes zoster (also called shingles); PivNG=Neisseria Gonorrhoeae Piv Gene Target; CG=Neisseria gonorrhea (NG)--aka Gonococcus (GC); ADV=Adenovirus; AMER=ADV (Adenovirus), hMPV (Human metapneumovirus), EV/RV (Enterovirus/Rhi

Roche Serum Work Area menu

Broadest menu on one integrated platform

Breadth of assay menu



Launched in 2020 & upcoming launches in 2021

Immuno chemistry assays

HBsAg II Auto Conf	EBV EBNA IgG
Androstenedione	EBV VCA IgG
Anti-SARS-CoV-2	EBV IgM
Anti-SARS-CoV-2 S	Anti-p53
SARS-CoV-2 Ag	HCV Duo
IL6 (EUA)	GAAD
HIV Duo	NT-proBNP claim extension[4]
	TnT–hs claim extension[4]
	PCT CE claim extension[4]
	Vit D total III[4]
	Preeclampsia
	Anti-HBe
	Alzh CSF biomarkers
	PIVKA II

Clinical chemistry assays

Kappa FLC[3]	ASTP2[4]
Lambda FLC[3]	ALTP2[4]
sdLDL[3]	Fentanyl[3]
fCal[3]	Ethyl Glucuronide[3]
CRP4	sTfR Gen 2[4]
A1MG[3,4]	Benz 2[4]
	Sirolimus

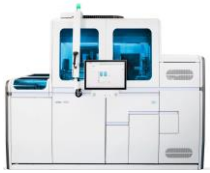
On market (Launched in 2020) | **In development** (to be launched in 2021)

IM: Immunochemistry; CC: Clinical chemistry; [1] Not including confirmatory tests, stat tests and special assays in the allergy panel. Variants of the same assay (e.g. for HIV AG/Ab, different kit sizes) are counted once; [2] Core unit| ISE |c 702 | c 702 | e 801 | e 801; [3] Partner Channel; [4] Product update

New systems launches in 2021

Enabling comparable results in different size laboratories

Throughput

Serum Work Area solutions	**cobas® pure**[1] 2021	**cobas® pro**	**cobas® pro (high throughput)** 2021
Molecular solutions	**cobas® 5800**[1] 2021	**cobas® 6800** 	**cobas® 8800**

Improved outcomes

Family concept addressing needs of all lab sizes to increase access

Increased profitability

Up to 50% lower SMCs per test and 20% lower service cost

More sustainable

Up to 80% less plastic waste per test

[1] Currently in development and not commercially available

Live Stream Demo

New innovations driving market access

Mass Spectrometry

First fully integrated mass spectrometry

- **Integration** of mass spec into the Core Lab
- Sample in – result out
- **Increase patient access** to mass spec technology
- Promising new **high medical value** biomarkers

CHF 2.1 billion accessible market

Emerging Market Analyzer

Routing testing in remote areas

- Designed for the **specific needs of emerging markets**
- **Compact, easy-to-operate** benchtop analyzer
- Combines **immunochemistry and clinical chemistry** into one box

CHF 2 billion accessible market

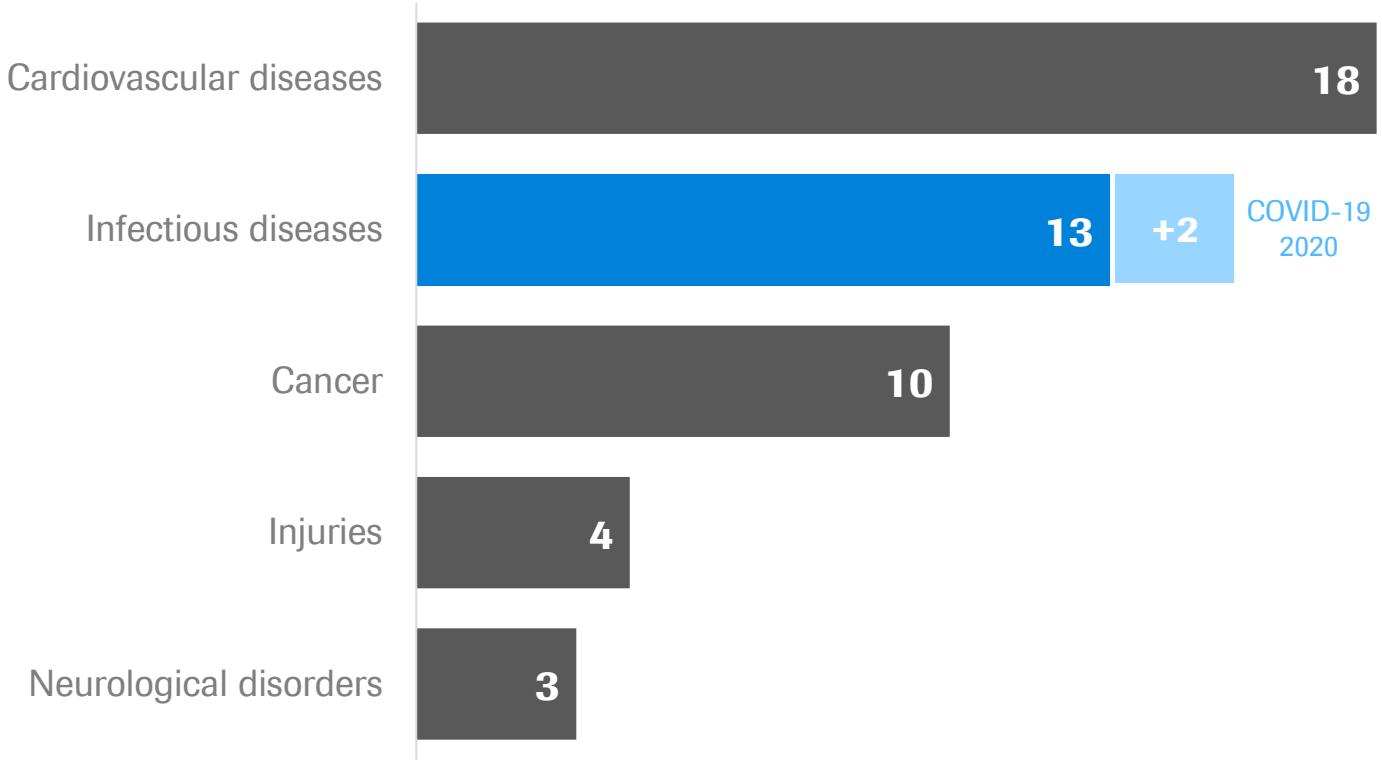
Roche Diagnostics Investor Day 2021

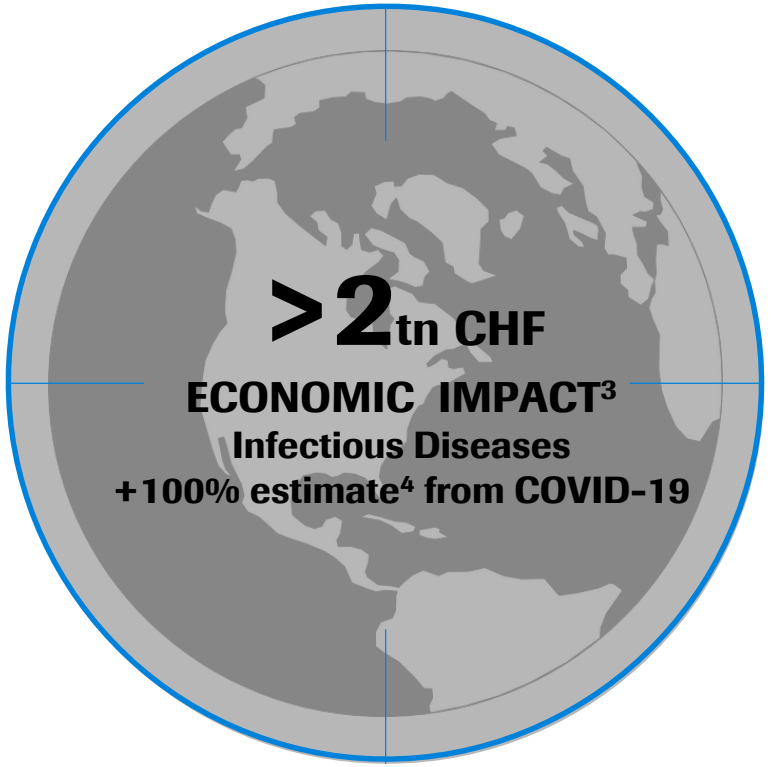
Infectious Diseases

Michael Hombach | Global Clinical Leader Infectious Diseases

Infectious Diseases are still causing global harm

Cause of death globally (millions per year)[1,2]

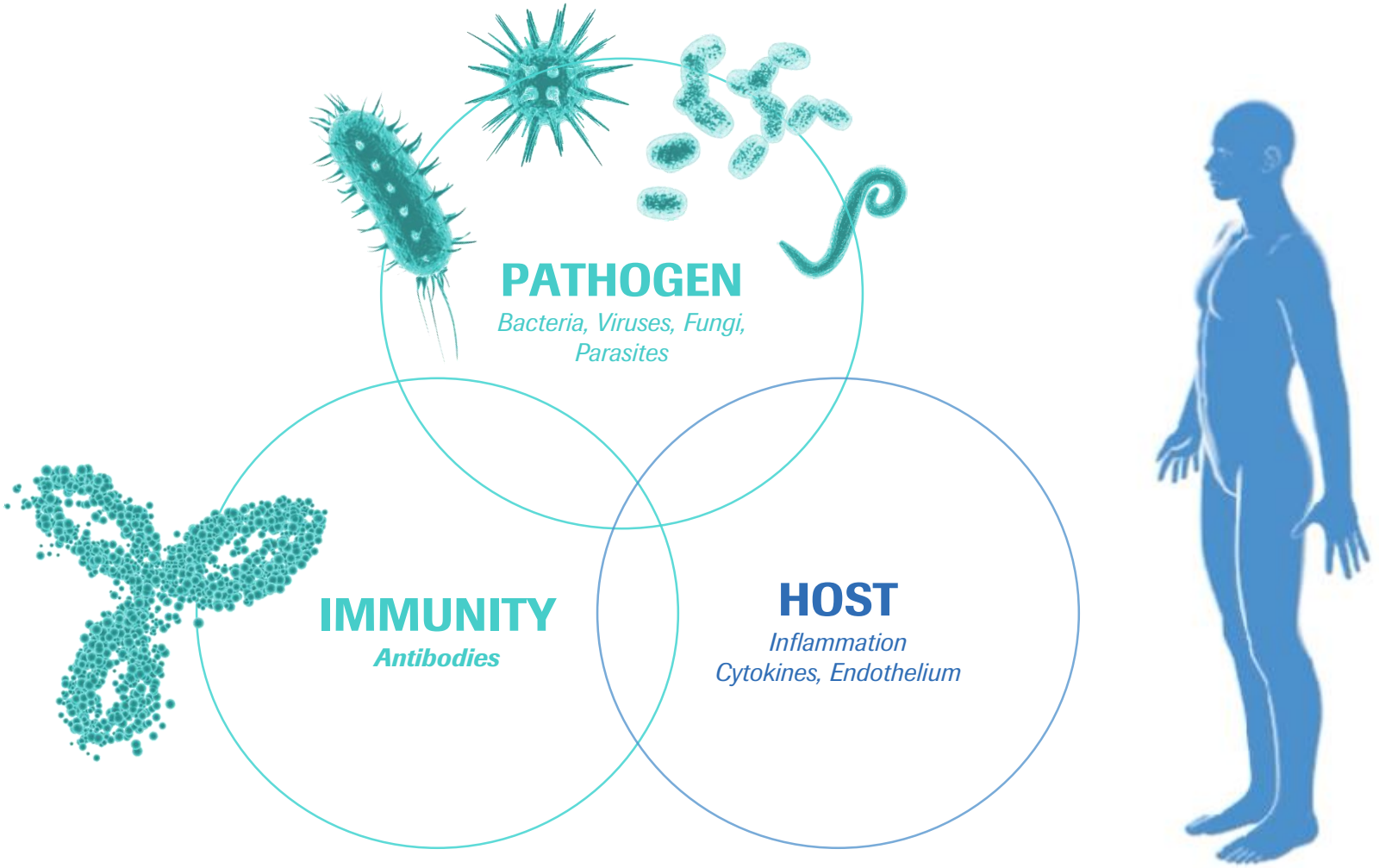




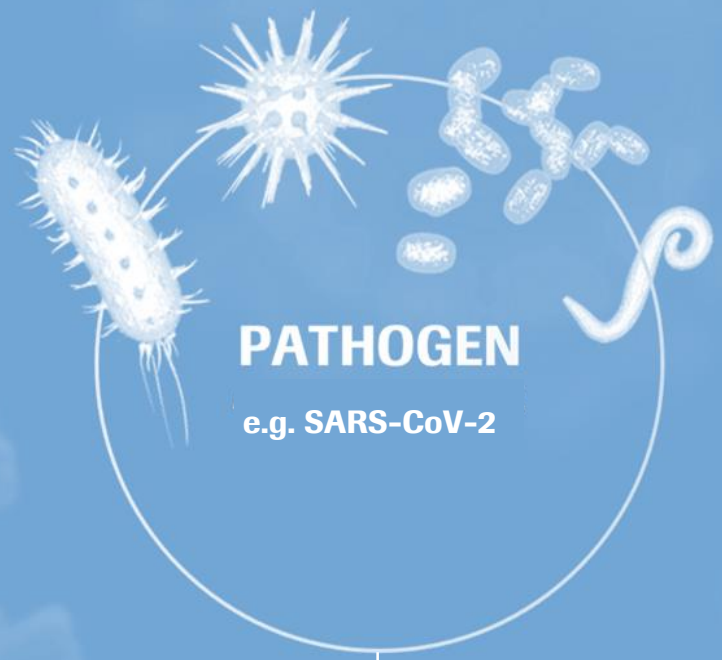
[1] GBD 2017 Causes of Death Collaborators. Global, regional, and national age-sex-specific mortality for 282 causes of death in 195 countries and territories, 1980-2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018 Nov 10;392(10159):1736-1788. doi: 10.1016/S0140-6736(18)32203-7. Epub 2018 Nov 8; [2] Sung S., Ferlay J., Siegel R., et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2021;0:1-41; [3] Bloom DE et al. National Bureau of Economic Research Working Paper 7757; [4] Prediction United Nations (March 9, 2020)

Pathogen, immunity and host belong together

Developing comprehensive disease-based solutions for patients



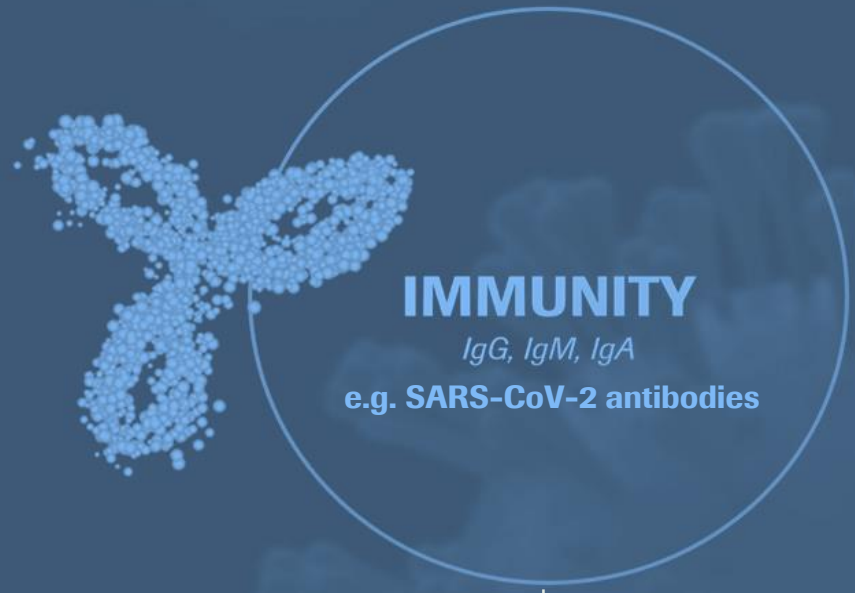
What are the medical use cases across the patient journey ?



PCR and Antigen assays:

e.g. cobas® SARS-CoV-2 or Elecsys® SARS-CoV-2 Antigen

Is someone actively infected?

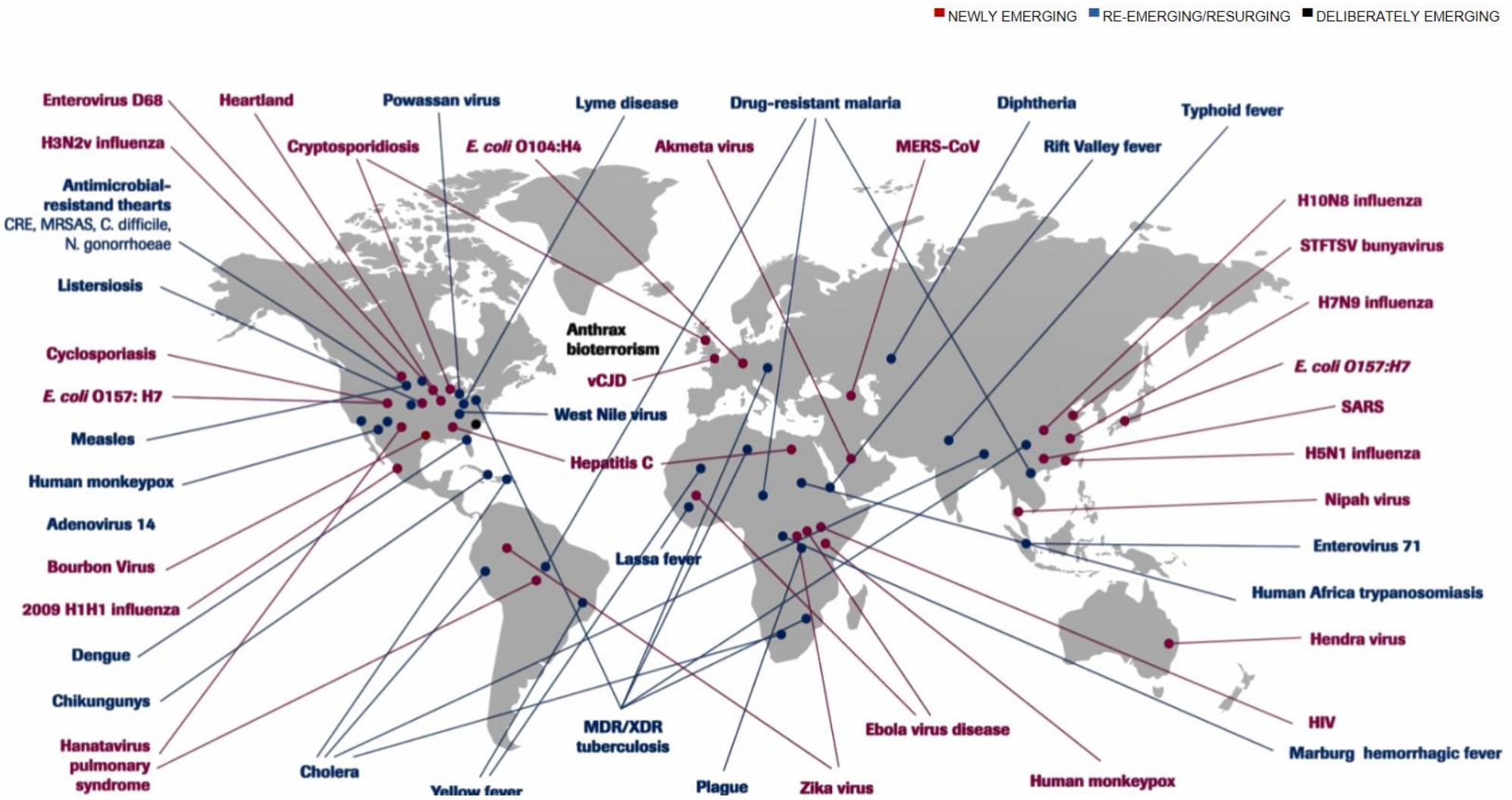


Antibody assays:

e.g. Elecsys® Anti-SARS-CoV-2 Antibody

Has someone recovered?

Global emerging and re-emerging infectious diseases



Source: National Institute of Allergy and Infectious Diseases (NAID) 2017

Roche infectious diseases pipeline

Holistic portfolio coverage is a key medical value

Viral Hepatitis + STDs

- HIV-1
- HBV
- HCV
- HIV-1/2 Qual
- Anti-HAV
- Anti-HAV IgM
- HBsAg
- HBsAg confirmatory
- HBsAg quant
- Anti-HBs
- Anti-HBc
- Anti-HBc IgM
- Anti-HBe
- HBeAg
- Anti-HCV
- HIV combi PT
- HIV DUO
- HIV confirmatory
- HTLV I/II
- Syphilis
- RPR
- HSV-1 IgG
- HSV-2 IgG
- CT/NG
- TV/MG
- HPV
- HCV DUO
- Anti-HEV IgG
- Anti-HEV IgM
- Genital Ulcer Panel
- Vaginal Discharge Panel
- Mycoplasma Panel
- HBeAg quant
- Anti-HBc quant
- **>10** more medical value solutions

Pregnancy + Transplant

- CMV
- HSV-1/2/VZV
- EBV
- BKV
- CMV IgG
- CMV IgM
- CMV Avidity
- Toxo IgG
- Toxo IgM
- Toxo Avidity
- EBV EBNA IgG
- EBV VCA IgG
- EBV IgM
- Adeno Quant
- HSV-1/2/VZV
- **>3** more medical value solutions

Respiratory

- Flu A/B/RSV
- MTB
- MAI
- MPLX Respiratory
- **>5** more high medical value solutions

Vector Borne

- Zika IgG
- Zika IgM
- Dengue IgG
- Dengue IgM
- Dengue Ag
- Chik IgG
- Chik IgM
- Lyme IgG
- Lyme IgM
- **>2** more medical value solutions

Donor Screening

- Anti-HCV
- HBsAg
- Anti-HBc
- HIV combi PT
- HIV Duo
- Syphilis
- Chagas
- HTLV I/II
- CMV IgG
- MPX
- WNV
- DPX
- HEV
- CHIKV/DENV
- Zika (US-IVD)
- Babesia
- Zika (CE-IVD)
- **>2** more medical value solutions

Vaccination Panel

- Anti-HBs
- Rubella IgG
- Anti-HAV
- **>6** more medical value solutions

Gastrointestinal

- cDiff
- **>3** more medical value solutions

Antimicrobial Stewardship

- MTB-RIF/INH
- **>6** more medical value solutions

Sepsis

- PCT
- IL-6
- IL-6 US neonatal & adult
- New Early Sepsis Marker
- Digital Decision Support

On market | **In development** | **Considered**

IA: Investigational Assay, US-IVD: Exclusive to US

Roche infectious diseases pipeline

Systematically addressing areas of unmet medical needs

Tuberculosis

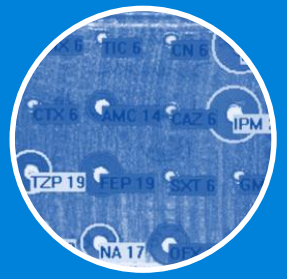
10m new cases p. a.
1.4m death p.a.[1]

Sepsis

50m new cases p. a.
11m death p.a.[2]

Dengue Fever

400m new cases p. a.
4bn people at risk[1]



Antimicrobial Resistance

1m death p.a. 2020
10m death p.a. in 2050[3]

Lyme Disease

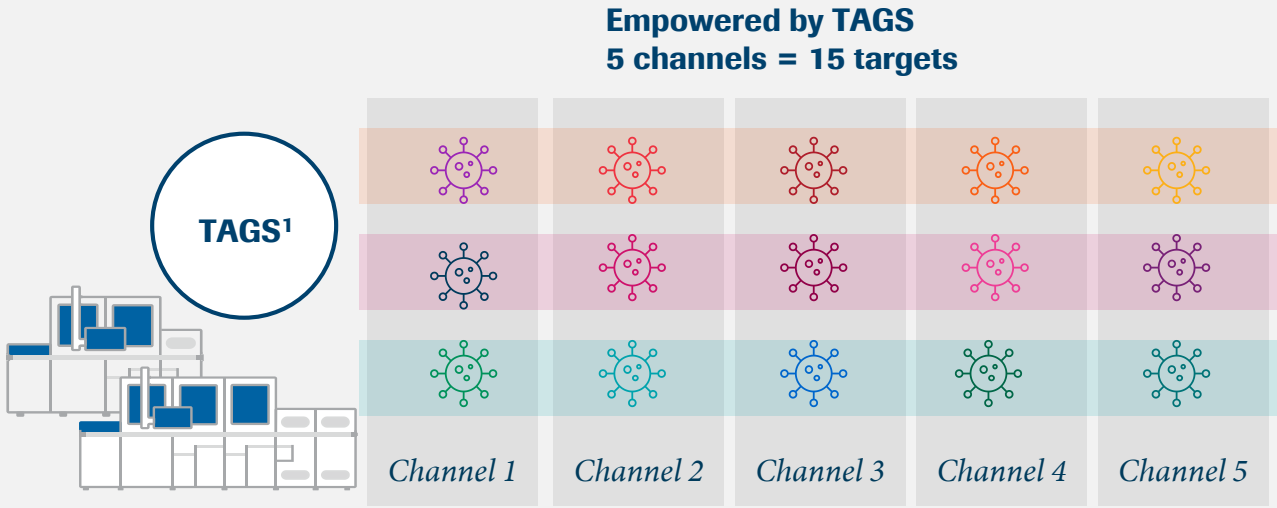
1.1m new cases p. a.
Rapidly increasing[4,5]

Adressing >CHF 100bn total healthcare costs per year[1-4]

[1] WHO 2020; [2] Rudd KE, et al. Lancet. 2020; [3] Dadgostar P. Infect Drug Resist. 2019; [4] CDC 2020; [5] ECDC 2020.

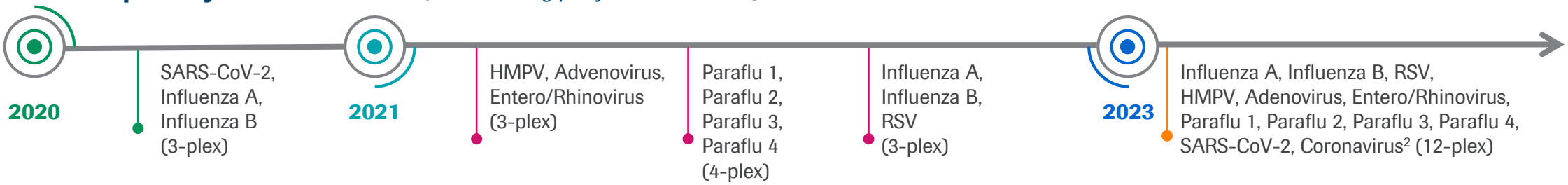
Molecular Diagnostics respiratory multiplex panel

Breaking the barriers of syndromic testing



- High unmet medical need: differential diagnosis between viruses
- Cost-efficient approach
- Fully automated high throughput
- Utilizes the **cobas®** 6800/8800 install base

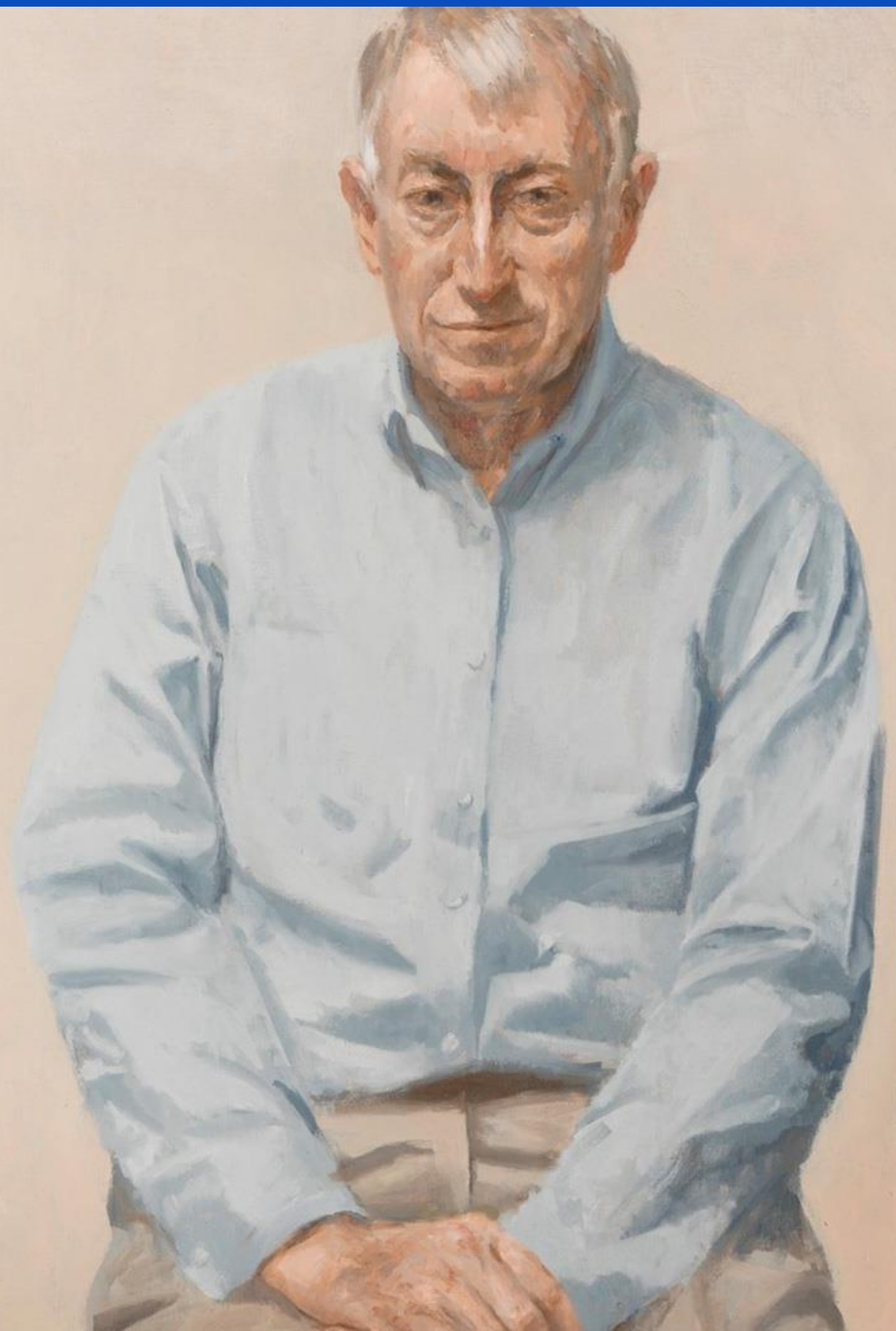
Respiratory Panels Timeline (*launch timing per year is illustrative):*



[1] TAGS: Temperature Activated Generation of Signal; [2] Common cold coronaviruses including HKU1, OC43, NL63, 229E

"I share Alfred Nobel's conviction that war is the greatest of all human disasters. Infectious disease runs a good second."

Peter C. Doherty, 1996 Nobel Prize Laureate in Physiology or Medicine



Roche Diagnostics Investor Day 2021

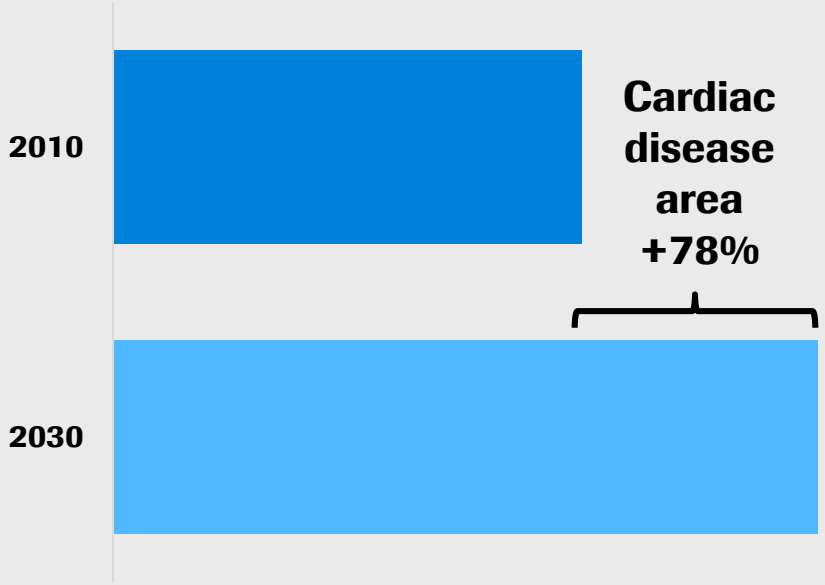
Cardiology

Andre Ziegler | Global Clinical Leader Cardiology

Cardiovascular disease is #1 killer in the world

Cause of 18 million deaths globally per year[1]

Disease Burden Index



Cardiovascular disease major cost driver for healthcare systems[5]

Prevalence (per million)

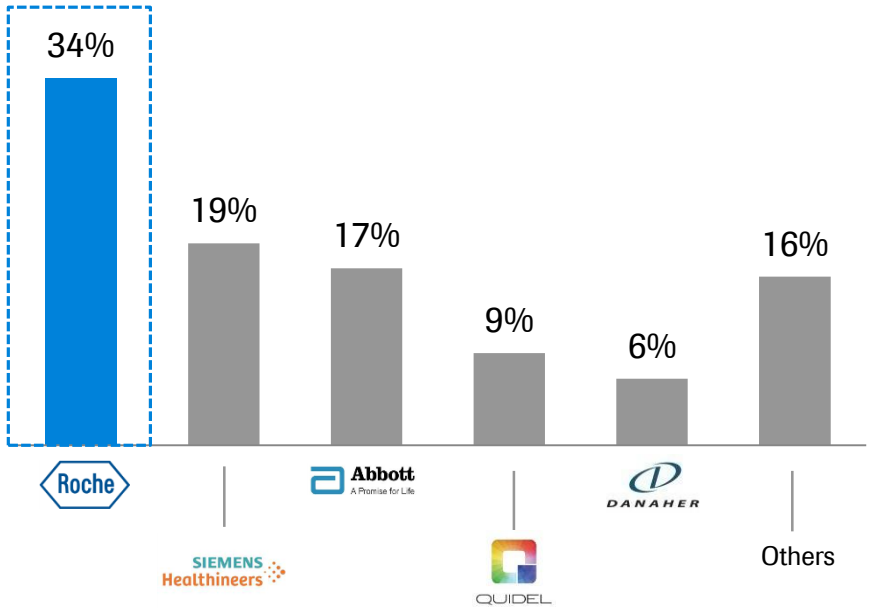
Coronary Artery Disease[3]	197
Strokes[3]	101
Heart Failure[4]	64
AFib[3]	60

Disease burden: Impact of a health problem as measured by mortality, prevalence, quality of life and economic costs; [1] Roth GA et al., Lancet. 2018;392:1736-1788; [2] Mendoza-Herrera K et al., Int J Environ Res Public Health. 2019; 16: 4041; [3] Roth GA et al., JACC 2020; 76: 2982. [4] Groenewegen A et al, Eur J Heart Failure 2020;22: 1342; [5] Timmis A et al., Eur Heart J 2020;41:12-85

Roche is an IVD market leader in cardiovascular diseases

Highest benefit class and evidence level in major cardiac guidelines

Core Lab cardiovascular market share in 2019[1]



Clinical practice guidelines[8]

"Redefining the gold standard of myocardial infarction using Troponin T"[4]

- Diagnosis[2,3]
- Risk prediction[2,3]
- Early invasive strategy[2]

"NT-proBNP: The gold standard biomarker in heart failure"[7]

- Diagnosis[5,6]
- Prognosis[6]

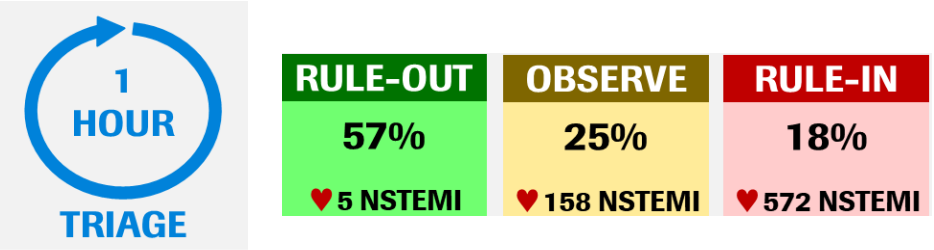
[1] Source – Roche Diagnostics with BBC; [2] Roff M et al, Eur Heart J 2016; 37: 267; [3] Amsterdam EA et al., Circulation 2014;130:2354; [4] Ohman EM. Clin Chem 2017; 63: 429; [5] Ponikowski P et al., Eur Heart J 2016; 37:2129; [6] Yancy CW et al, Circulation. 2017;136:e137; [7] McKie PM et al, J Am Coll Cardiol 2016;68:2437; [8] American College of Cardiology / American Heart Association

Leading coronary artery disease

Setting new standards of care in diagnosing heart attacks

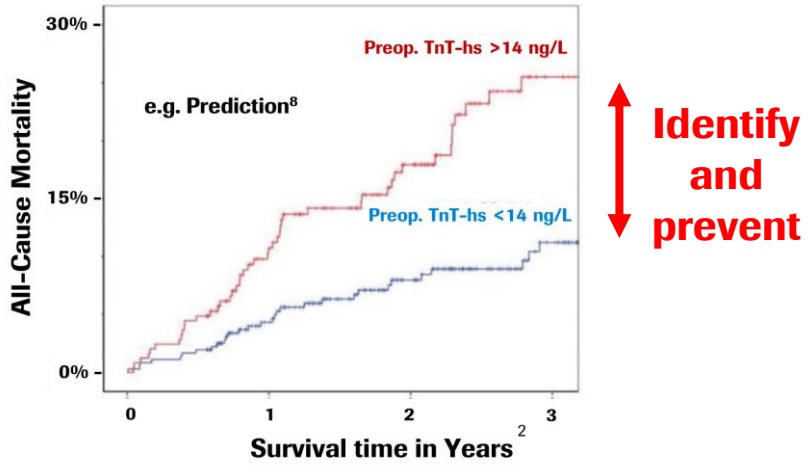
Elecsys® Troponin T-high sensitive (TnT-hs) test

1 hour decision algorithm



- Shortened hospital stay in suspected heart attack leading to reduced clinical costs[1,2]
- Algorithm confirmed in interventional studies and included in treatment guidelines[3,4,5,6]
- 100 million chest pain patients treated globally

New data on cardiac risk in non-cardiac surgery



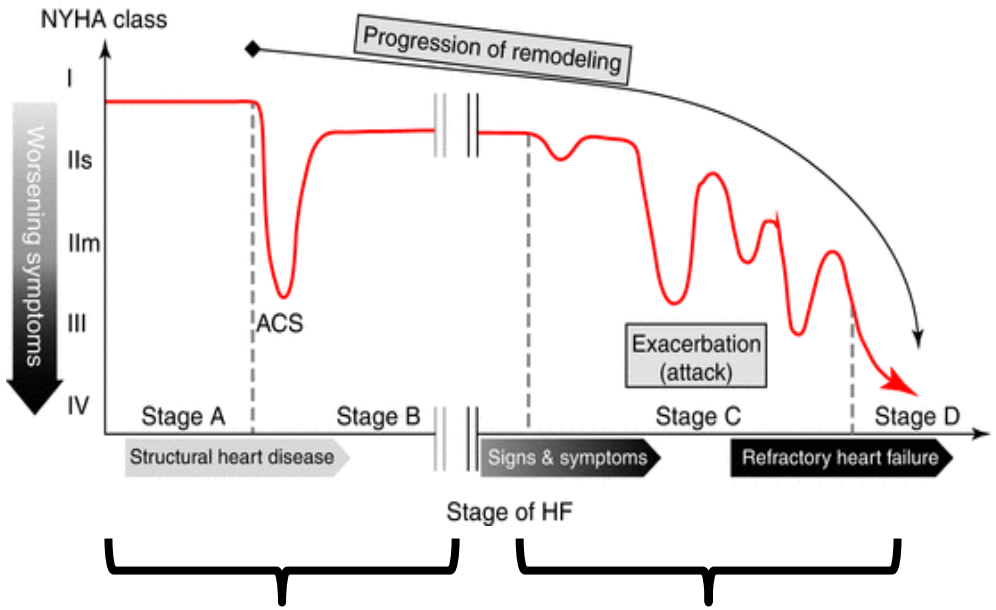
- TnT-hs test able to predict heart attack risk and mortality in non-cardiac surgeries
- > 80% of myocardial injuries after non-cardiac surgery are clinically asymptomatic
- 300 million non-cardiac surgeries globally[6,7]

[1] Twerenbold, R et al. J Am Coll Cardiol. 2018, 72: 620; [2] Ambavane A et al., PLoS One. 2017; 12(11): e0187662; [3] Chew D et al, Circulation. 2019,140:1543; [4] Stoyanov KM et al, Eur Heart J Acute Cardiovasc Care. 2020, 9:39; [5] Puelacher C et al. Circulation. 2018, 137:1221; [6] Devereaux PJ et al. JAMA 2017, 317:1642; [7] Nagele P et al, Am Heart J. 2013, 166: 325

Transforming diagnostics in heart failure

Type-2 diabetes: Identifying heart failure early to improve outcome

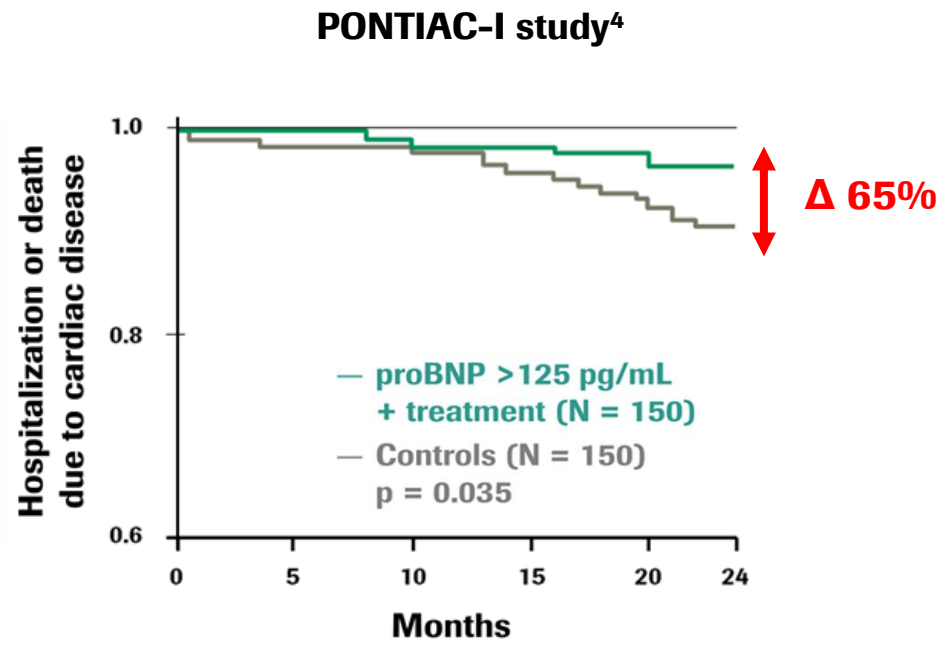
Stages of heart failure[1]



Tomorrow's focus:
463 million
type-2 diabetes patients[2]

Today's focus:
64 million
patients[3]

New NT-proBNP intended use (IU) to be launched in 2021



- Identify type-2 diabetes patients with high cardiovascular risk to start effective drug treatment

[1] Kato M. The Concept of Heart Failure. 2018 (doi.org/10.1007/978-4-431-56065-4_1); [2] Saeedi P et al., Diabetes Res Clin Pract 2019; 157: 107843; [3] Groenewegen A et al, Eur J Heart Failure 2020; 22: 1342;
[4] Huelsmann M. et al. JACC. 2013, 62:1365, confirmatory clinical trials (RCTs) running both in Europe (NCT02817360, PONTIAC-II) and Asia (NCT04286399, ADOPT).

Improving disease management to reduce strokes

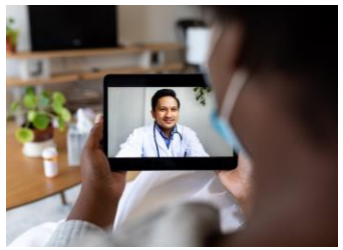
Innovation on-market and pipeline for atrial fibrillation

Screening	Diagnosis	Risk stratification	Therapy selection
NT-proBNP[1] and handheld ECG	**ECG & new biomarkers[3]**	**ABC risk scores with GDF-15 and clinical information**	**Integrated digital solutions; ABC scores**
Launch in 2021[2]	Research ongoing[3]	On-market[4]	Clinical trials (RCT)[5,6]
+29% AFib patients identified	Identify patients at high risk for Afib and recurrence of AFib[3]	Best available predictors of stroke and bleeding risk[4]	Personalised risk assessment for better outcomes: Reduce stroke risk[5,6] Increase therapy adherence[5]

AFib: Atrial Fibrillation; ECG: Electrocardiogram; (N)OAC: (Novel) Oral Anticoagulant ; [1] Article: Gudmundsdottir KK et al, EP Europace 2020, 22: 24; [2] Launch new intended use planned for 2021; [3] New biomarker research projects: Chua W et al., Lancet 2021 (1-Feb-2021, http://dx.doi.org/10.2139/ssrn.3777185), Reyat JS et al, JCI Insight 2020,15: e139179 (and 7 new Roche patents in 2020); [4] Hijazi Z et al, Lancet. 2016; 387: 2302; [5] Clinical outcome trial ongoing (NCT03753490, ABC-AF); [6] Clinical outcome trial ongoing (NCT02743416, STROKESTOP-II)

Cardiovascular disease solutions

New solutions to impact medical practice

	Launch new intended uses in 2021	New patient population
Coronary artery disease	• TnT-hs in non-cardiac surgeries. Diagnosis of peri-operative myocardial infarction (MI) • TnT-hs in asymptomatic population. Long-term risk stratification of cardiovascular events	300 million surgeries[1,2] 457 million at age 70+
Heart failure	• Heart Failure prevention in diabetes. Identify patients at high CV risk and start protective therapy	463 million with diabetes[3]
 **Stroke prevention in atrial fibrillation**	• NT-proBNP + ECG for atrial fibrillation screening in the elderly	457 million at age 70+

[1] Puelacher C et al. Circulation. 2018;137:1221; [2] Devereaux PJ et al. JAMA 2017;317:1642; [3] Saeedi P et al., Diabetes Res Clin Pract 2019; [4] World Data Atlas. https://knoema.com/atlas/topics/Demographics/Age/Population-aged-70-years

Roche Diagnostics Investor Day 2021

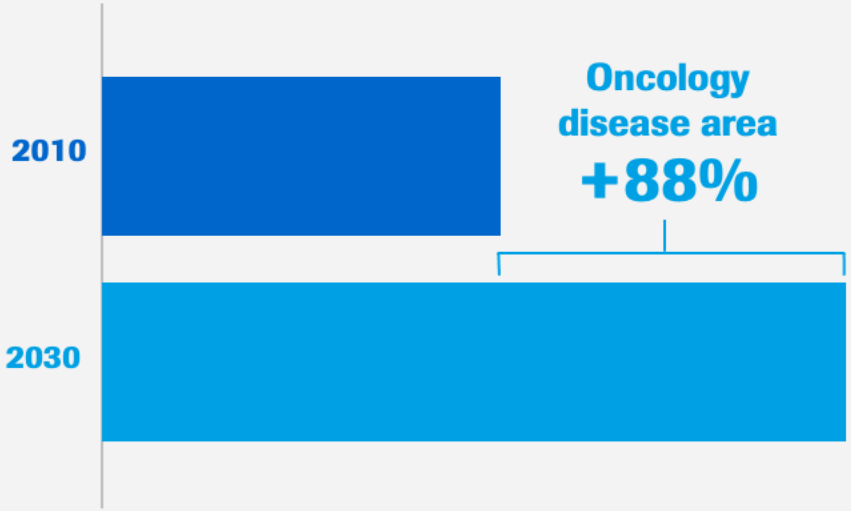
Oncology

Jill German | Global Head of Pathology Lab

Global cancer burden projected to increase

Significant impact to both human lives and world economy

Disease Burden Index[1]



1.7tn CHF
ECONOMIC IMPACT[2]

Global cancer impact 2020[3]

19.3 million
new cancer incidences

10 million
cancer mortalities

It is estimated that **1 in 10 women** and **1 in 8 men** will be diagnosed with cancer during their lifetime

[1] Disease burden: Impact of a health problem as measured by mortality, prevalence, quality of life and economic costs; [2] Global economic impact of Oncology estimated at more than 2% of GDP (WHO); [3] Sung S., Ferlay J., Siegel R., et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2021;0:1-41

The field of oncology is evolving and increasing in complexity

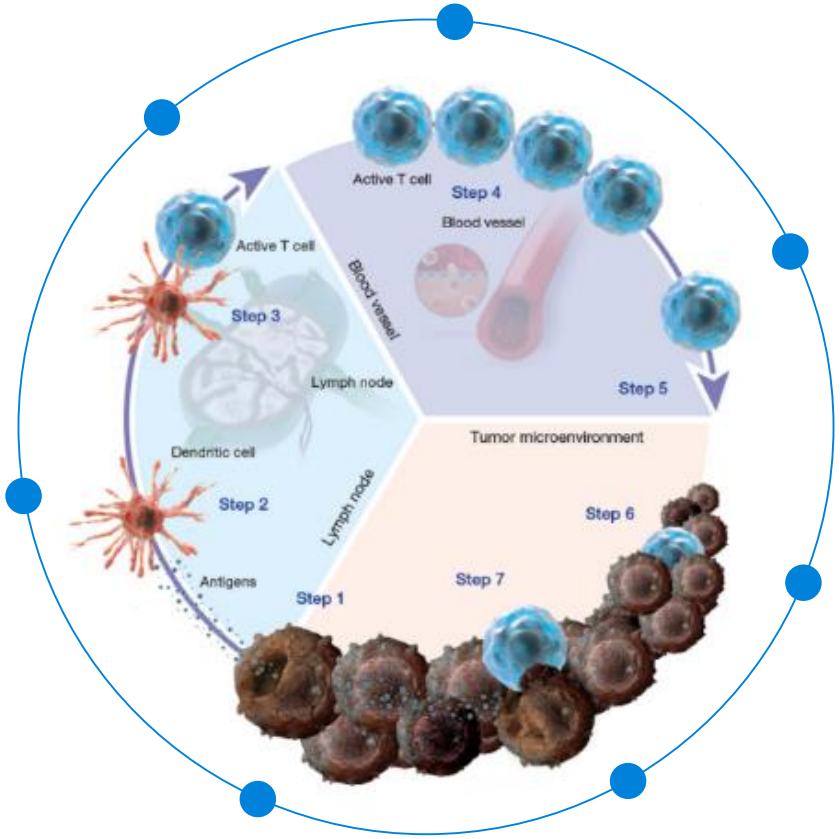
Driving the need for novel diagnostic solutions

Oncology market is rapidly evolving

New therapies and therapy combinations emerging to prolong patients' lives

5,000+ clinical trials

are now exploring the utility of cancer immunotherapy

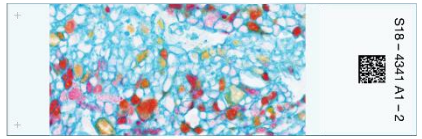


Growing understanding of the biological complexity of immune oncology

New diagnostics and digital tools are required

Innovation is needed to identify optimal therapies for individual patients

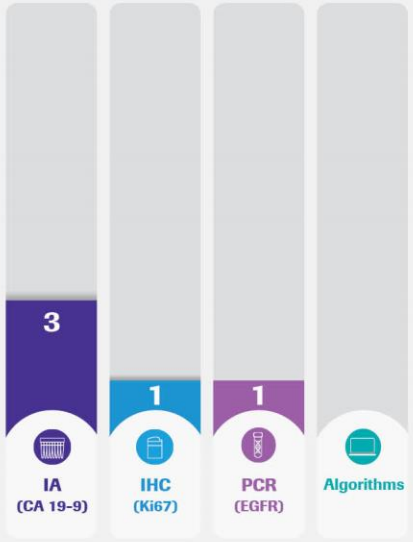
- Multi-modal diagnostics
- Clinical decision support



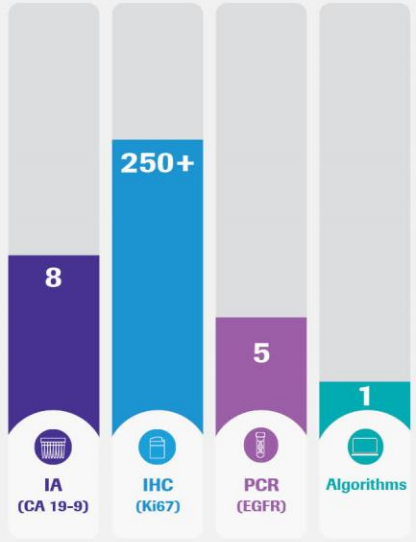
Supporting patient journeys with our oncology portfolio

Sales of oncology reagents surpassing CHF 1.8 bn in 2020

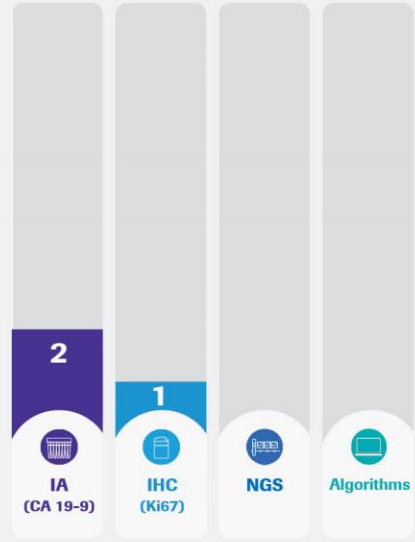
Screening



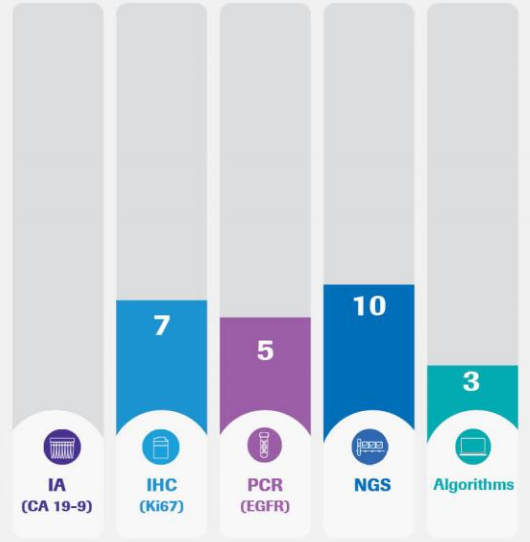
Diagnosis & Classification



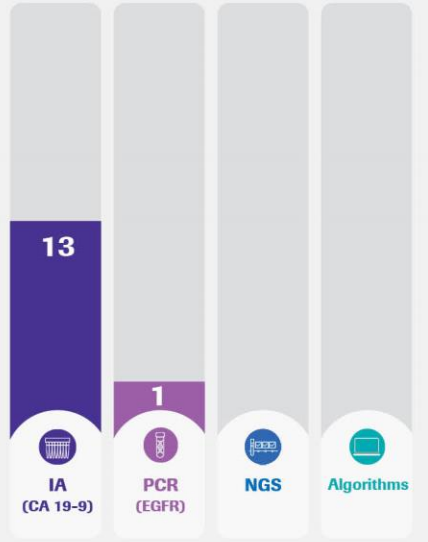
Prognosis[1]



Therapy selection[2]



Monitoring/Surveillance



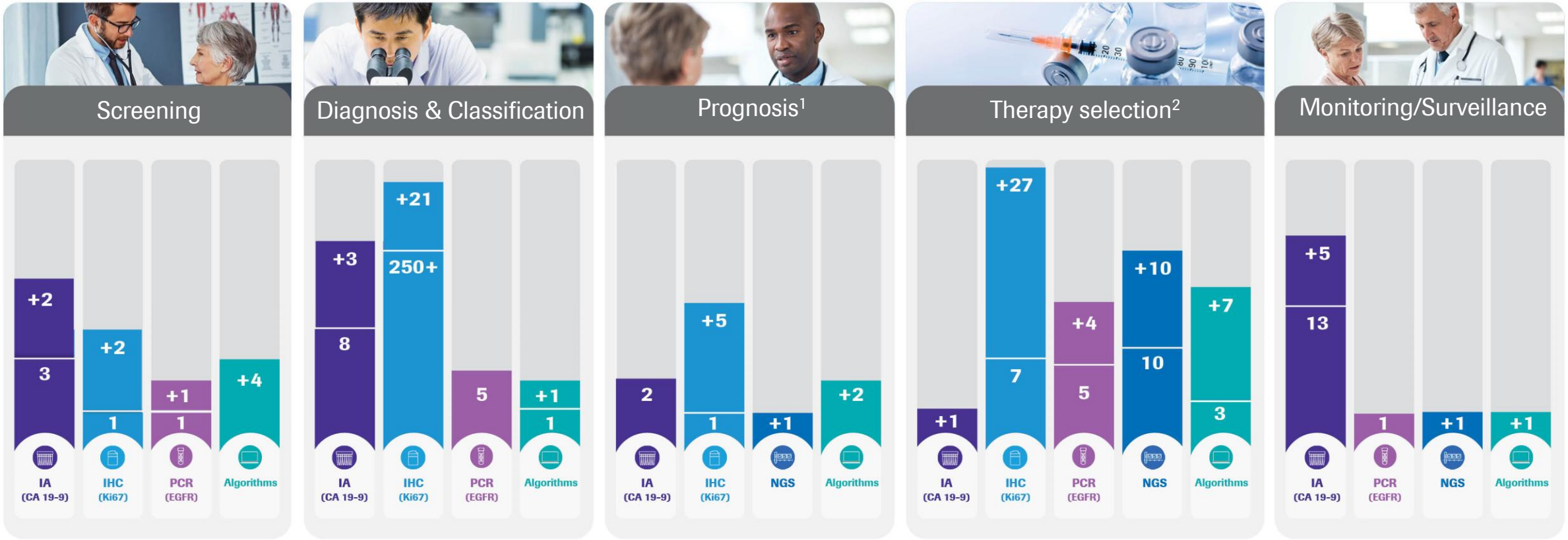
[1] Predicting the likely or expected development of a disease [2] On-label CDx indications

Decision support: NAVIFY Mutation Profiler, NAVIFY Tumor Board, NAVIFY guidelines

Immunoassay (IA) | Immunohistochemistry (IHC) | Next Gen Sequencing (NGS) | Polymerase Chain Reaction (PCR) | Algorithms

Supporting patient journeys with our oncology pipeline

Pharma partner of choice, driving personalised healthcare



[1] Predicting the likely or expected development of a disease [2] On-label CDx indications

Decision support: NAVIFY Mutation Profiler, NAVIFY Tumor Board, NAVIFY guidelines
+ Patient Journey, Guidelines adherence tracking, quality reporting, therapy matching

Immunoassay (IA) | Immunohistochemistry (IHC) | Next Gen Sequencing (NGS) | Polymerase Chain Reaction (PCR) | Algorithms

Example: Our comprehensive solution for lung cancer

Innovating clinical decision making and improving patient care

Diagnosis & Classification

IA

ProGRP

IHC

Napsin A, TTF1, CK5/6, p63, p40, ROS1, pan-TRK

Therapy selection

PCR

EGFR, KRAS, BRAF

IHC

ALK, PD-L1

PD-L1 Algorithm

NGS

Foundation One CDx

Monitoring/Surveillance

IA

CYFRA 21-1, ProGRP, NSE, SCC

PCR

EGFR

Decision Support: NAVIFY Tumor Board, NAVIFY Mutation Profiler

Integrated oncology decision support

AI-enabled digital solutions for informed, efficient patient management

NAVIFY® Digital Pathology PD-L1 Algorithm

Interpretation of biomarker

NAVIFY® Mutation Profiler

Therapy options & clinical trials

NAVIFY® Tumor Board

Radiology, pathology & clinical data together

Flatiron and Foundation Medicine

Access to clinico-genomics database

Quick, accurate answers for patients

Confident decisions & standardized care

Q&A

Roche Diagnostics Investor Day 2021

Closing

Thomas Schinecker | CEO Diagnostics

Setting up Diagnostics for a sustainable and successful future

Point of departure	Healthcare is shifting to reward improved patient outcomes at reduced cost of care Roche as a market leader is uniquely positioned to address the evolving healthcare needs
Strategy	Expand the business model from diagnostics solutions to healthcare decision support and disease management to improve patient outcomes Invest in innovation, access and partnering
Implications	The new Diagnostics strategy will contribute to the Roche strategic ambitions Shift investments and realign the operating model to implement the strategy

Diagnostics investor day summary

Grow our market share

- Larger installed base and new systems launches fueling growth
- Differentiation through medical value
- Broad and innovative testing pipeline portfolio

Invest in strategic priorities

- Increase productivity by simplifying the organization
- Reallocate investments to drive innovations

Doing now what patients need next