



## Broadening access for innovative diagnostic solutions

CENTIVIS AG, Norbert Farkas – Founder & Managing Partner  
Barcelona, 21. May 2019

# Agenda

- 1 Why access is a relevant diagnostics topic?
- 2 How to make it happen?
- 3 What can we learn from a few cases?
- 4 Summary, Q&A

# Introducing CENTIVIS, Norbert Farkas

## Solving diagnostics access and health policy challenges

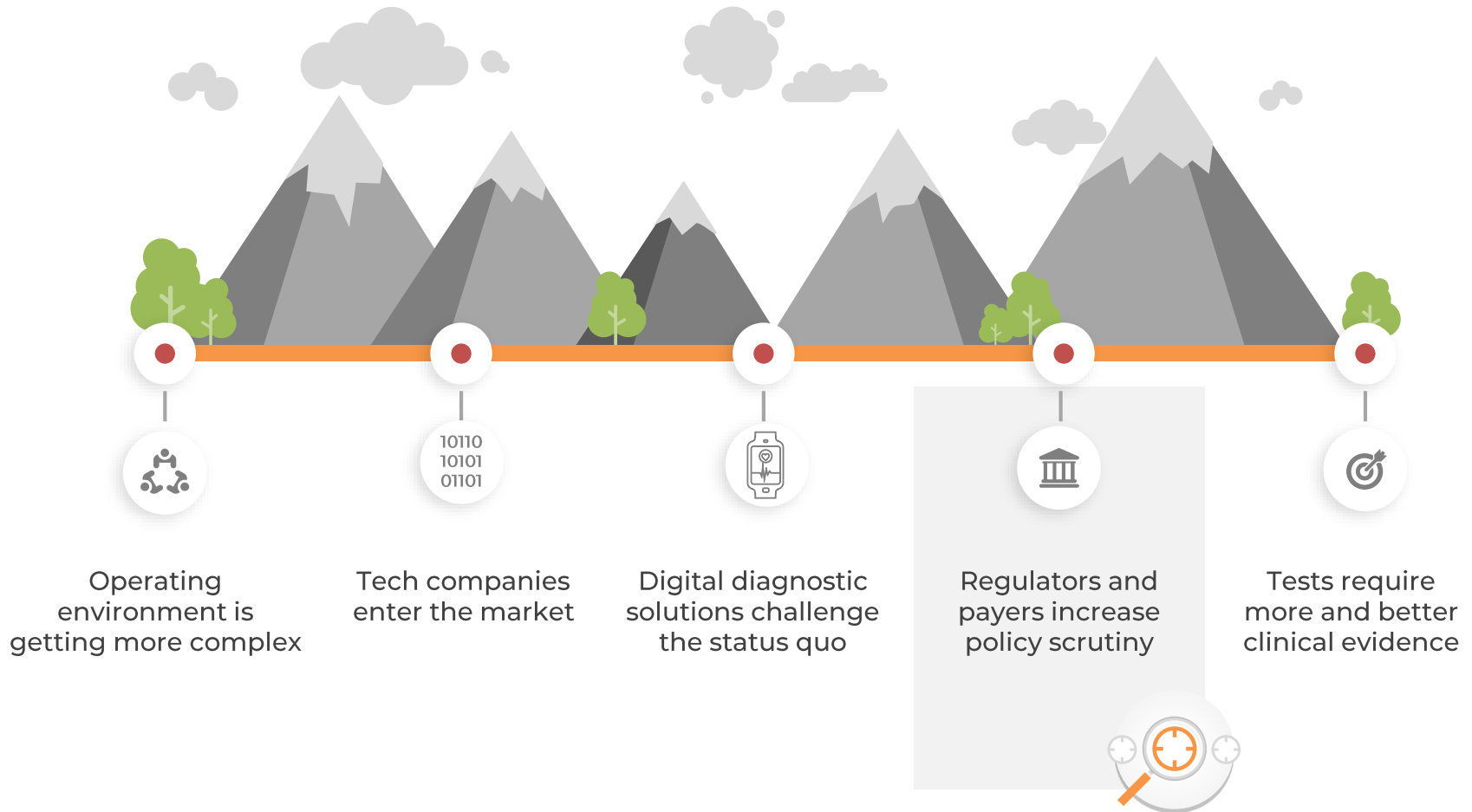


Norbert Farkas  
Founder and Managing Partner

- Market Access, Policy Consulting
- Diagnostics and Digital Health
- based in Switzerland
- Former Head – Market Access & Health Policy @ Roche Diagnostics (CPS)
- Novartis Pharma, Vaccines
- Start-up coach, part-time university lecturer

# Diagnosics industry is full of challenges

## Industry is changing: more Payer, Policy attention



# Policy initiatives have impact on diagnostics access... ...in emerging economies, in clinical evidence generation & HTA

## 1. Essential Diagnostics List (EDL)

- 100+ in vitro tests mostly in “priority” diseases
- evidence-based guidance to develop national lists
- updated on regular basis
- India has already drafted its local EDL



## 2. In-Vitro Diagnostics Regulation (IVDR)

- Currently in transition stage until 2022
- Reclassification and reregistration of all on market products
- More stringent clinical evidence requirements



1. broadening global access in emerging economies
2. increasing clinical evidence requirements
3. comprehensive value frameworks, broader HTA



## 3. EU-Health Technology Assessment (EU-HTA)

- Not yet approved, might change
- EU-wide, joint/coordinated clinical, HTA in Pharma & MedTech
- Diagnostics scope is open

## 4. Value Frameworks

- VODI: Value of Diagnostics Information (MedTechEurope)
- Comprehensive framework that captures the entire value of complex diagnostic solutions
- Frameworks for Assessing Value of MedTech and Diagnostics (AdvaMed)



Sources:  
[https://www.who.int/medical\\_devices/diagnostics/WHO\\_EDL\\_2018.pdf?us=1](https://www.who.int/medical_devices/diagnostics/WHO_EDL_2018.pdf?us=1)  
[https://ec.europa.eu/health/technology\\_assessment/eu\\_cooperation\\_en](https://ec.europa.eu/health/technology_assessment/eu_cooperation_en)

Sources:  
Matthias Havenaar, The in-vitro diagnostics regulation (IVDR): From oversight to overhead, Researchgate.net, 2018 September  
<https://www.medtecheurope.org/access-to-medical-technology/value-of-diagnostic-information-vodi/>  
<https://www.advamed.org/newsroom/press-releases/advamed-unveils-frameworks-assessing-value-medtech-and-diagnostics>

# Payers have closer eye on (digital) diagnostics

## More HTA, joint evidence reviews, digital health



### Growing appetite for diagnostics health technology assessment in Europe

- EUnetHTA: 4 diagnostics assessments in colorectal cancer, diabetes, antibiotic prescribing and in early breast cancer
- NICE: evidence-based diagnostics guidance on Tumor profiling tests to guide adjuvant chemotherapy decisions in early breast cancer



### Joint (regulator-payer) evidence reviews and scientific advice gain momentum in the US

- After the Parallel Review Program, the voluntary Private Payor Program was launched
- Manufacturers can receive joint feedback from the regulator, private payers and health technology assessors to develop a more efficient evidence generation plan



### Payers start to embrace Digital Health

- NICE: Framework on Digital Health Technologies from the required clinical evidence perspective
- Health insurer Cigna Corp. committed \$250 million to invest in promising start-ups
- Centres for Medicare and Medicaid Services (CMS) issued three new CPT codes to reimburse remote patient monitoring, embracing telehealth

# How to ensure broad diagnostics access? And also...



# Follow the 5-steps framework

## Pathways, evidence, health economics, tariff, coverage



5

**Coverage / reimbursement**  
How to ensure successful coverage?

4

**Price/tariff**  
What is the likely price/tariff based on comparators, value drivers and willingness to pay?

3

**Health Economics**  
How does the medical value translate into economic benefits?

2

**Clinical evidence**  
What clinical evidence is necessary to prove diagnostics medical value?

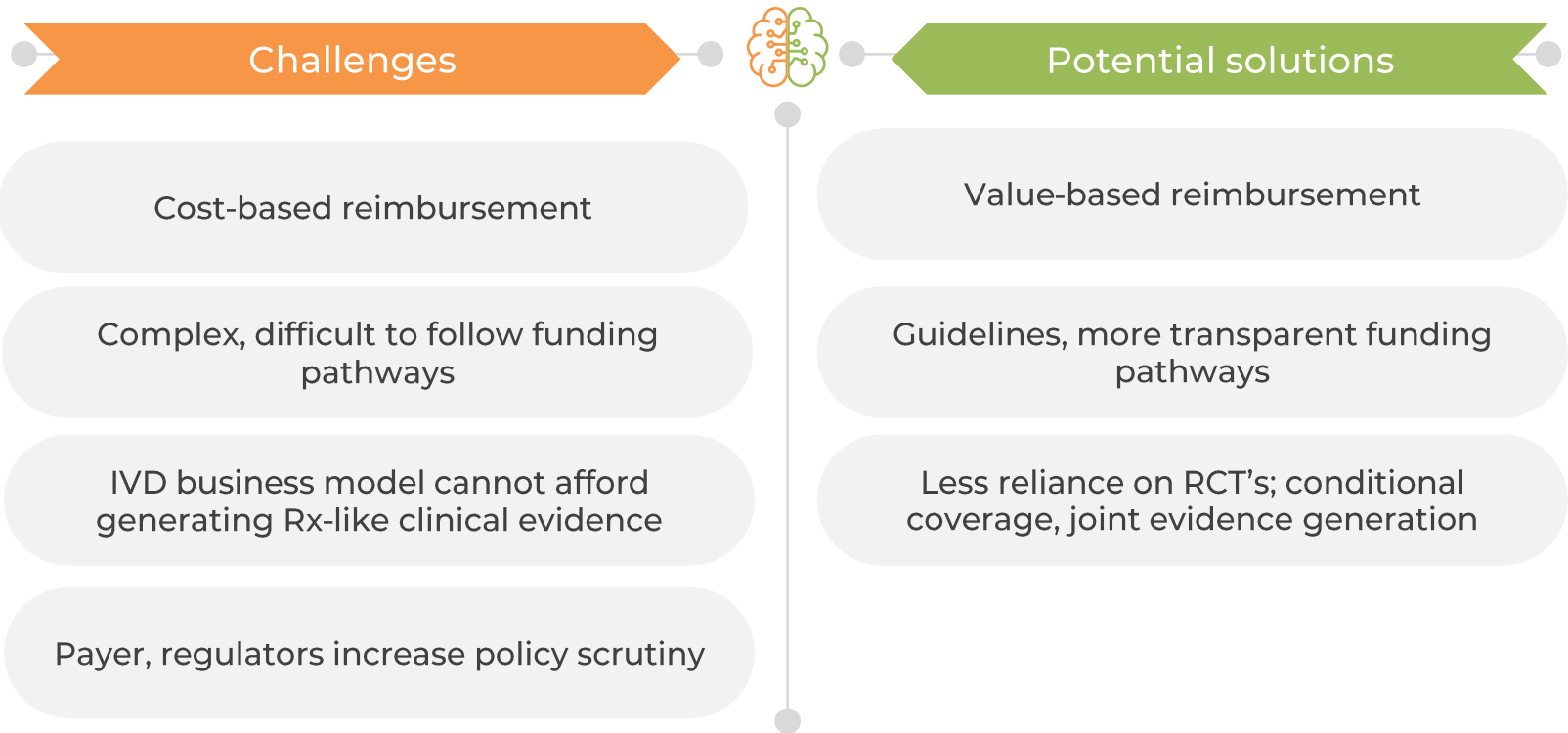
1

**Reimbursement Pathway**  
What are the available funding pathways and how to get there?



# The road is not easy to travel, but not impossible

## 5 step framework has challenges in real life practice...



What examples can we learn from?

# Oncotype Dx – Genomic Health

## From cost-based to value-based tariff

**Case:** Through systematic evidence generation oncotypeDX breast cancer score secured reimbursement tariff that reflects its medical, economic value and diligently worked with Payers to ensure coverage



### Challenge

1. Innovative **breast cancer score identifies low/high risk patients** where chemotherapy does/does not work
2. Score has **high medical, economic value** and favourable budget impact
3. Initial **reimbursement tariff does not reflect the true value** of the score



### Solution

1. Request new **reimbursement code**, reflecting health economic value
2. **Convince Payers one by one to secure coverage**
3. **Continue generating clinical evidence** and aim for guideline inclusion



### Key success factors

1. Consider **launching a diagnostic solution as an innovative medicine**
2. Favour **value vs. volume approach**
3. Keep **investing in medical and economic evidence**

Sources: Cronin et al. Clin Chem. 2007;53:1084-91, Paik et al. N Engl J Med. 2004;351:2817-2826, Habel et al, Breast Cancer Res. 2006;8:R25, Paik S, et al. J Clin Oncol. 2006;24:3726-3734. \*Lyman et al, Cancer. 2007;109:1011-1018, CLIA: Clinical Laboratory Improvements Amendments, Gustavsen et al, Health Advances, 2010, p11

# Pre-eclampsia – Roche / Alere / NICE

## Positive recommendation from NICE

**Case:** After systematic clinical and economic assessment, NICE recommends Alere's & Roche's pre-eclampsia tests to help rule-out pre-eclampsia in pregnant women



**NICE** National Institute for Health and Care Excellence



Key success factors



Challenge



Solution

1. Systematic health technology assessment (HTA) (clinical, economic) is **not yet broadly applied** in diagnostics
2. How can healthcare systems **decide** what novel **diagnostics** solutions should get **access** and (funding)?

1. National Institute for Health and Care Excellence (NICE) in the UK runs **Diagnostics Assessment Programme** (DAP) – systematic HTA
2. **Participate** in DAP and learn from the process

1. Significant amount of **quality clinical evidence** generated before the assessment
2. **Health economic evaluations**, publications performed
3. Have **market access**, **medical teams in place** to answer NICE's questions

# NIPT – Illumina / Harvard Pilgrim

## Value based contracting & joint evidence generation

**Case:** Pharma-like, value-based contract between Illumina and Harvard Pilgrim (Payer) in non-invasive prenatal testing



### Challenge

1. Clinical **evidence** generation **takes long time** and high investment
2. Securing **reimbursement** for novel diagnostics **needs solid evidence** in place
3. Many **payers limit NIPT coverage** to pregnant women of advanced maternal age



### Solution

1. Set-up **value based manufacturer – payer contract**
2. Provide **market access** of NIPT for average-risk pregnancies
3. **Create real world data** to demonstrate the clinical and economic value of NIPT for detecting births genetic anomalies



### Key success factors

1. Be open for **novel solutions** (value based contracting)
2. **Collaborate** for joint success
3. Be willing to **share the risk**

Sources: <https://www.illumina.com/company/news-center/feature-articles/illumina-harvard-pilgrim-health-care-partner-on-value-based-con.html>

# Summary

- 1 Diagnostics industry is **complex and changing**...
- 2 ...and **facing** more **policy** and **payer attention**
- 3 **Market access** is getting a more **relevant** topic
- 4 There is a simple, **5-step framework** to follow
- 5 We can **learn from** great **examples**
- 6 and **CENTIVIS** is here to support

Questions?

# Thank you for your attention

## Do you want to know more? Watch, read, subscribe, call



Watch video



Read blog



Join mailing list



Schedule a call

