IVD industry perspective on HTA

DG SANTE meeting with MTE members

Brussels, Sept. 22, 2016

What we would like to share today

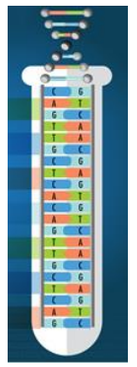
- Thank you for being here with us!
- How valuable and diverse IVDs are and how innovative and supportive of European economy the IVD industry is
- That 99 % of IVDs don’t have HTA in their access pathways to patients and that works well to ensure timely patient access
- That when Assessments are done on IVDs they are rarely informing access decisions at national level. Examples show that patient have more difficulties to gain access to novel IVDs when HTA is present.
- That Experience is lacking on how a European HTA model focusing on IVDs can support patient access, sustainable health systems or industry
- We have proposals we would like to share and continue to think together

Getting to know IVDs

IVDs are non invasive tests done on samples

Provide information of key value for patients, society, economy, and health systems

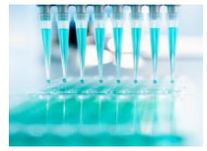
Influence 70% of healthcare decisions[1]



Diagnosis:
Diabetes
Infectious diseases
Cholesterol
Heart Disease
Pregnancy
Allergy
Immunology
Renal disease

Prognosis
Cancer
HIV
Heart disease
Immunology
Sepsis

Prediction
Select patients likely to respond to treatment:
CDx for
Cancer
AMR
Cystic Fibrosis
HIV
Growth failure



Monitor
Treatment performance:
diabetes,
anticoagulation
Antibiotics
Viral load

Screening-Prevention-early detection:
Cancer
Infectious diseases
HAI-AMR
Diabetes
Genetic conditions
Rare diseases

Produce **information**

Know and change to healthier habits and more effective treatments

Make plans: Genetic conditions counseling, allocation of patients in hospitals

Keep people healthy, active, out of hospitals

Guide the use of other techs, and avoid waste of resources

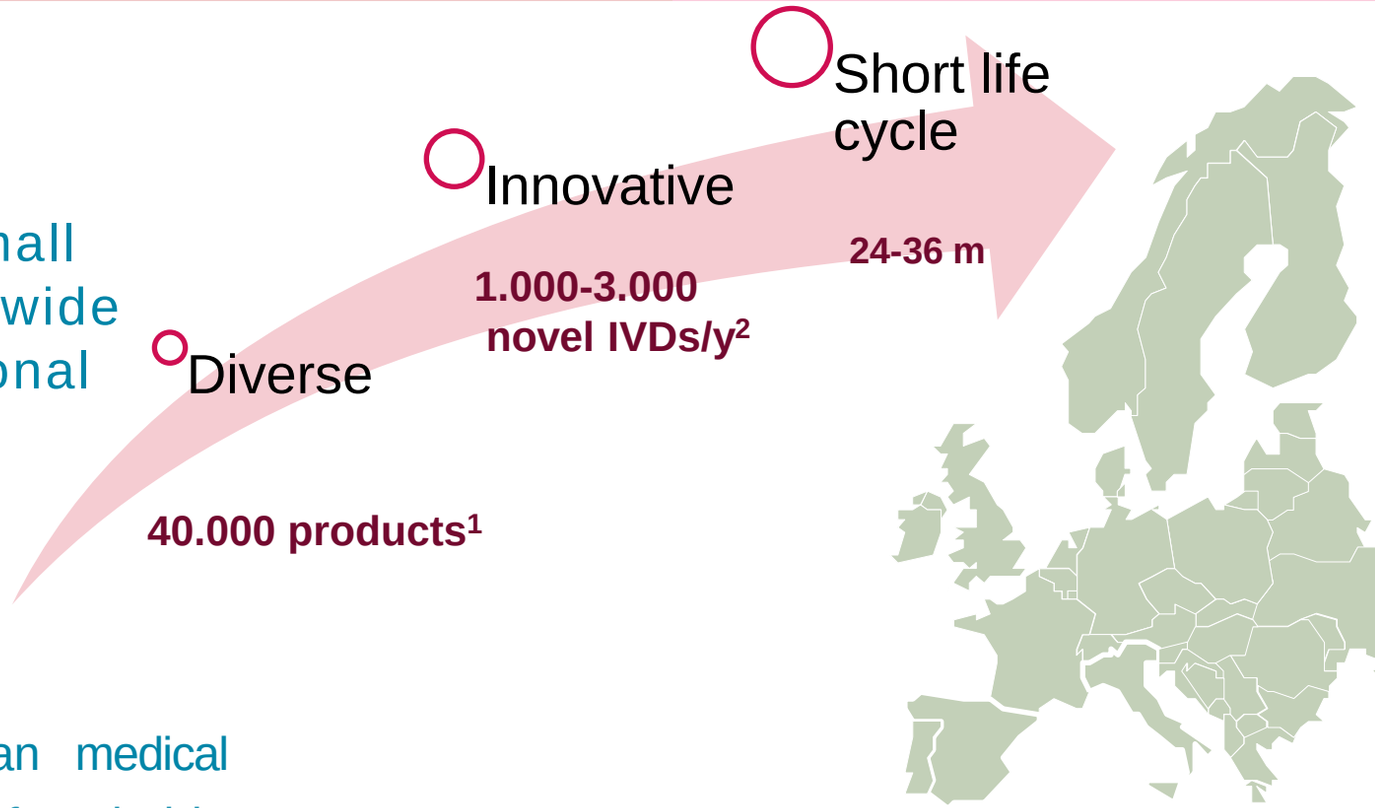
1.Rohr, U. (2016). The Value of *In Vitro* Diagnostic Testing in Medical Practice: A Status Report. *PLoS*

The IVD industry is highly innovative and supports regional and national economies in Europe

75.000 people employed in Europe

12-15% of the €11 billion revenue is reinvested in R&D[1]

EDMA represents the in vitro diagnostic companies, ranging from innovative small and medium-sized enterprises to worldwide leading manufacturers, as well as national IVD associations from across Europe.

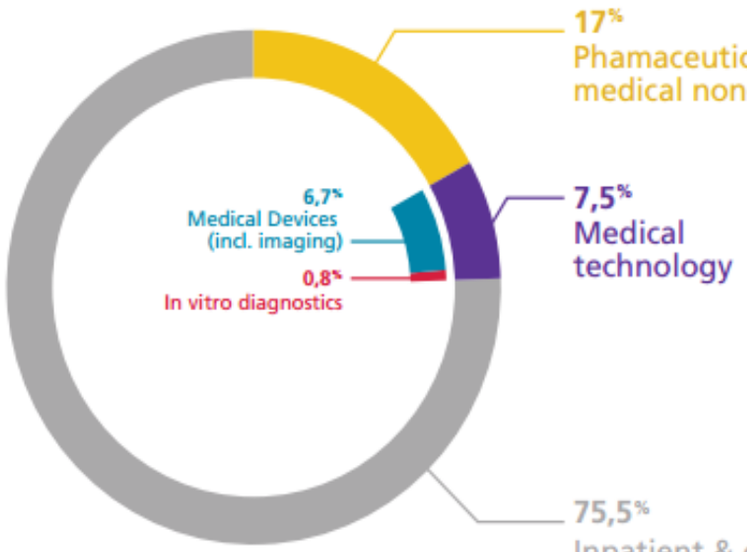


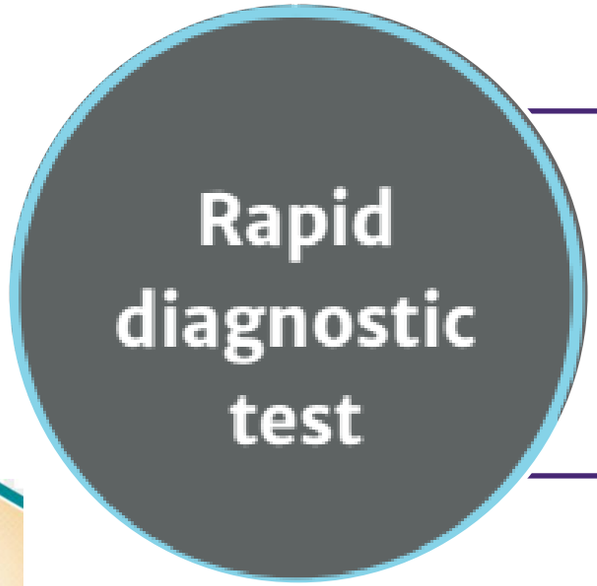
MedTech Europe is an Alliance of European medical technology industry associations. The Alliance was founded in October 2012 and currently has two members: EDMA and Eucomed.

1.In vitro diagnostics Fact Sheet
2.EDMA calc. based on survey to manufact. 2016

With less than 1% of total healthcare expenditure in IVDs, they are key to sustainable healthcare systems

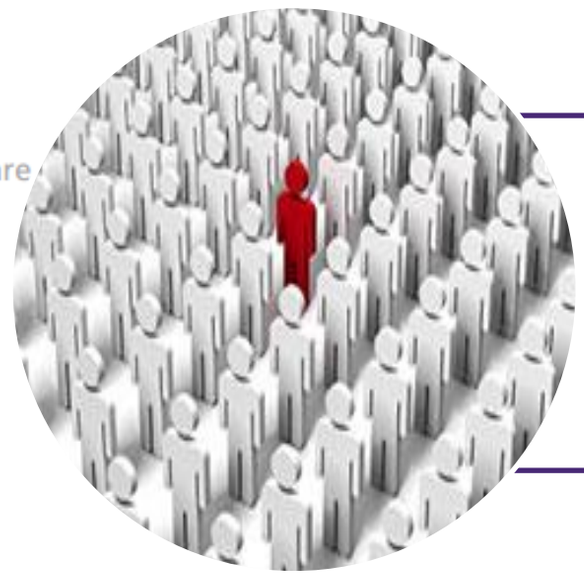
Total healthcare expenditure in Europe[1] , breakdown





Sexually Transmitted Diseases: £11.7 million./a can be saved[2] (ATB + in patient care)

Infections resistant to antibiotics (AMR): US 20 billion direct med cost & US 35 billion prod. Loss could be saved[3]



Cervical cancer screening: 230 mill. y. of life free of disability or U$1 trillion could be saved globally[4]

Molecular Diagnostics for cancer: Cancer expenditure. increased from £3.19 bill. (2003) to £5.68 bill. (2012)[5] in UK while provision of lung, colorectal, and melanoma diagnostics costs £ 13.32 million[6]

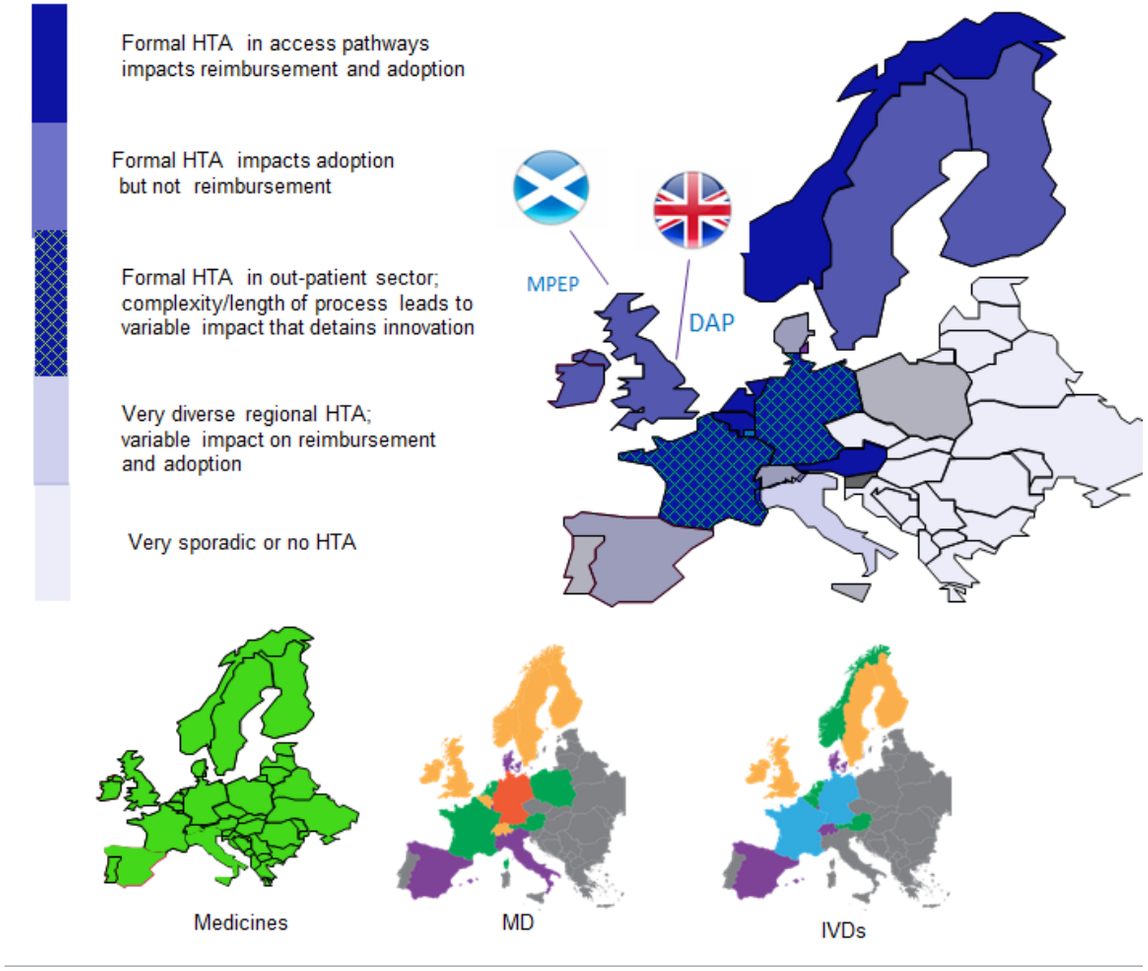
IVDs expenditure is **less than 1%** of total EU HC expenditure

1.MTE 2015.The European MT ind. in figures; 2.Turner 2013 *Sex Transm Infect; 3 Invest.in research 2015; 4.ASCO 2015;5.* NHS England 2014;6 Concentra, NHS 2015.

How do IVDs reach patients in Europe?

The majority of IVDs (incremental innovation) are purchased by hospitals and/or labs in a decentralized way and that is working well to ensure timely access to valuable IVDs

Authorities in different countries, regions, hospitals, in -patient and out -patient sectors can decide differently according to their context and priorities



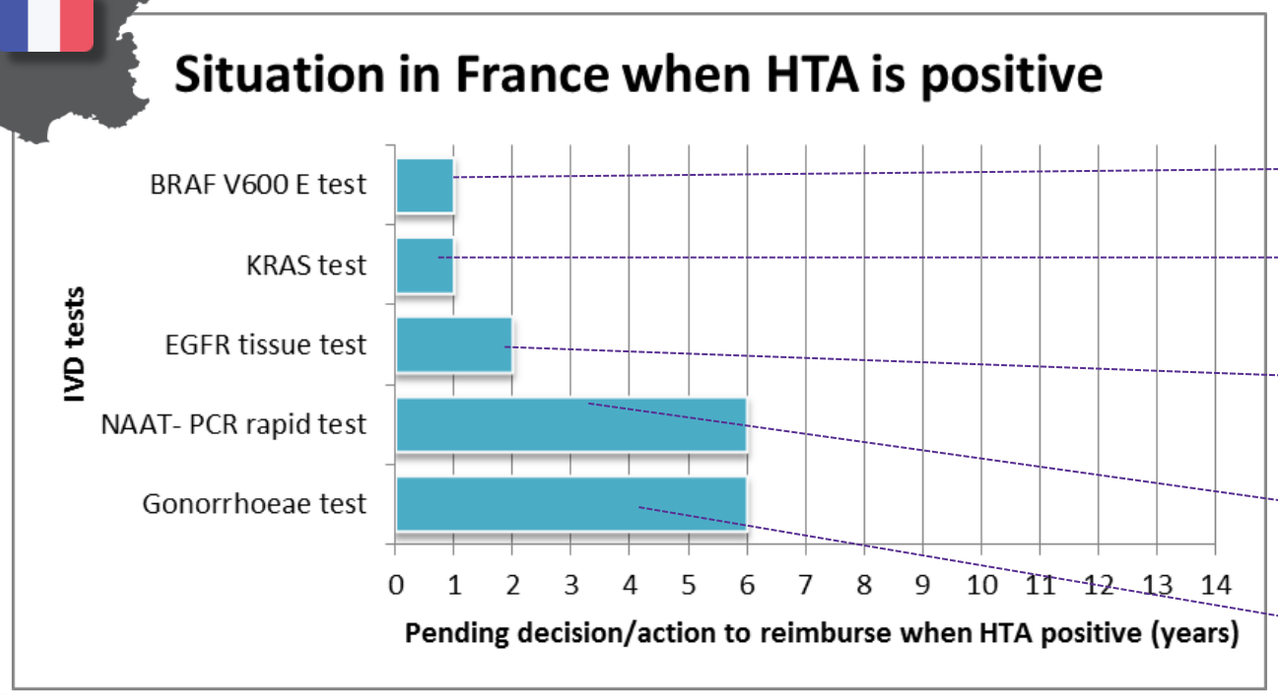
HTA is done for less than 1% of IVDs, very differently across countries, with low impact on reimbursement or adoption

Current HTA processes are designed to inform centralized decisions and not decentralized like IVDs'

The access pathways are different for IVDs than for medical devices and medicines; the role of HTA is also different for IVDs

What happens when HTA is applied to novel IVDs in two of the larger IVD markets?

Patients face difficulties to access valuable innovative IVD tests (and subsequent treatment and care) when they need them if HTA is done



CDx test to aid in selecting **melanoma** patients who may respond to specific **treatment**

CDx test to identify patients with **advanced lung or colon cancer** who will not respond to **specific therapy**

CDx test to identify patients with **advanced lung cancer** who may respond to **specific treatment**

Rapid near patient test to confirm **viral infection** and reduce unnecessary antibiotic therapy and **AMR**

Rapid diagnostic test for **Sexually Transmitted Disease** allows fast treatment and preventts complications - spread of disease

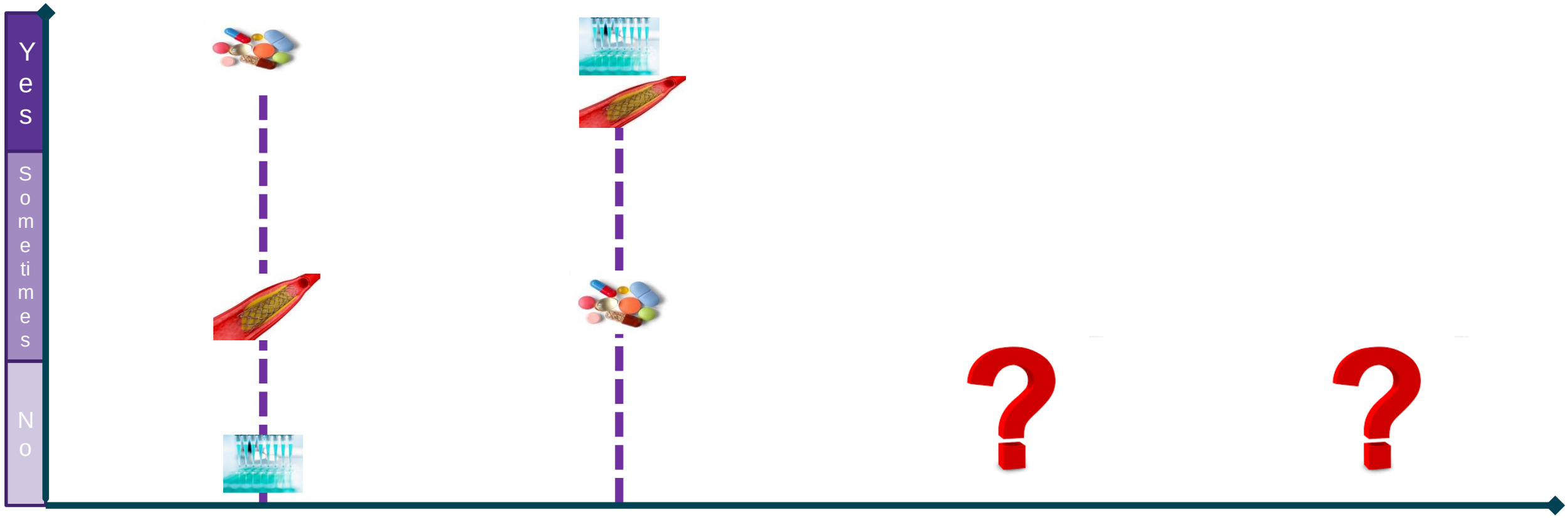
Test to rule out and predict course of **life-threatening condition in pregnant women**(preeclampsia)

Screening test to diagnose **Infection in pregnant women** to prevent neonatal infection

Test to evaluate the **risk** that a seriously ill person develops a **generalised bacterial infection** (sepsis)

Screening test for HPV infection to identify women at risk of **cervical cancer**

What challenges do we see ahead on HTA and EU HTA?



It will be important to **assess the effects that a mandatory EU HTA system would have on IVD industry** such as :

.Increased demand of EU HTAs and data generation while no ROI expected as HTA not informing decisions at national level

.Increased time to patient access

.Decrease external funding for SMEs if highly regulated environment

.Rate of innovation in Europe

.Possible market concentration, impact on prices and adoption of novel IVDs

The IVD industry is willing to collaborate with the European Commission on the assessment of these effects

How do we see the way forward?

Evolution to value based assessment needed

- Fit-for-purpose methods and tailored outcomes to unfold the wide value of IVD information
- IVDs assessed at the ‘right time’ in the technology lifecycle[1]
- HTA responding to the needs of patients and decision makers
- Increasing predictability of evidence requirements within and across agencies

Voluntary application of HTA to transformative IVDs[2]

- *This is true only if the d*emand comes from multiple MS or is initiated by manufacturers AND health *systems commit to adopt the valuable IVD innovation picked up by fit-for-purpose joint/collaborative HTA [3]*

Appropriate methods, capacity and structure IVD focused at national and EU level

Stakeholder dialogue will enable this evolution of HTA

1.It **may vary for different IVD types** but it’s **not at market launch**, it’s predictable and **agreed with manufacturers**.
2. *They can **solve** high clinical, social and health systems **unmet needs and for that require structural, organizational, health services or business changes**.*
3. **Upfront adoption plan** (e.g. innovation fund) in place **from EU countries before the Joint assessment is initiated**. **EU** could help MS transition through **innovation funds**, or becoming an **evidence incubator** (e.g. supporting evidence generation that should be accepted at MS level, facilitating development of conditional access schemes at nat. level, real world evidence (RWE) data collection systems, among others)

What key points we hope we were able to share

99 % of IVDs don’t have HTA in their access pathways to patients

The majority are purchased by hospitals and/or labs in a decentralized way and that is working well to ensure timely access to valuable IVDs

Assessments of IVDs are rarely associated with appraisals

Improved uptake of a joint EU assessment by a national HTA agency would not necessarily relate to efficiencies or predictability for manufacturers, as the national HTA agency rarely informs reimbursement, funding or adoption of IVDs

Experience is lacking on how a European HTA model focusing on IVDs should look like to support patient access and sustainable health systems

We believe it should be voluntary, at the ‘right time’ in the technology lifecycle, with tailored methods, specifically focused capacity and organizational structures,and responding to the needs of patients and decision makers

European HTA needs to focus on detecting and supporting the adoption of transformative IVDs that can solve high unmet clinical, social or health system’s needs across Europe

We believe EU HTA topics should be driven by common MS needs and EU HTA initiatives supporting evidence generation for IVDs and the set-up of national adoption plans for novel IVDs would be needed.

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Back-up information on IVDs

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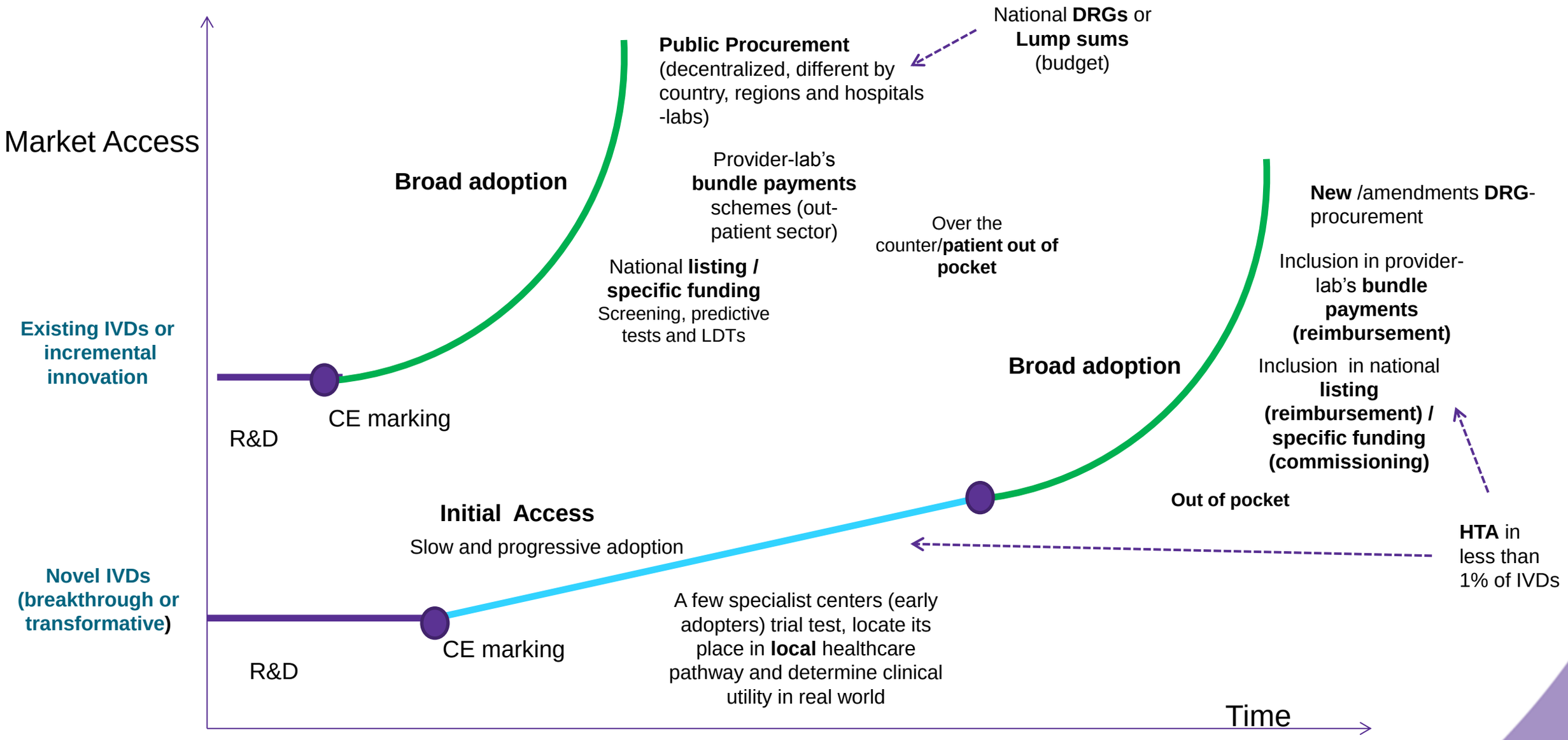


Authorities in different countries, regions, hospitals, in -patient and out -patient sectors can decide differently according to their context and priorities

What are the specificities of IVDs that relate to HTA?

Medicine

MD

IVD

Yes

Sometimes

No

Direct Clinical Effect
Contact with human body
Added therapeutic benefit
Clinical Effectiveness

Clinical utility context dependent (learning curve, use of information)

Clinical utility affected by healthcare pathway, availability and effectiveness of downstream treatment/care, sequence of testing, prevalence and stage of disease

Wide range of outcomes beyond clinical ones
Novel specific methods needed to unfold full value incl. socio-econ value and value of diagnostic information

High methodological complexity of assessment
Resource intensive

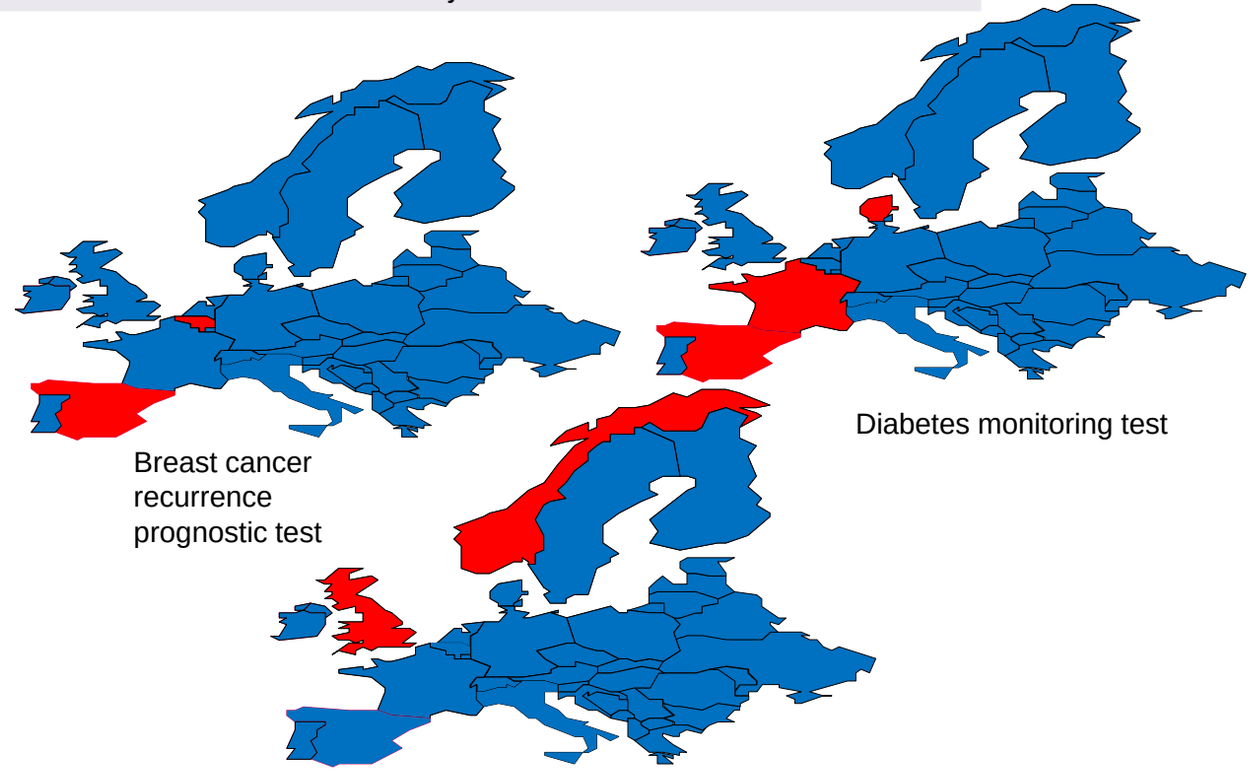
Direct effect is to produce information
Change management and value of knowing
Clinical effect /utility linked to subsequent treatment or care
One test can influence multiple treatments / multiple conditions

What national decisions could EU HTA for IVDs inform?

Very few countries are performing HTA for IVDs
Very few countries are asking the same question on IVDs at the same time
What could be the benefit of assessing jointly?

	2014	2015
Total HTA reports MedTech	372	372
Total HTA reports IVDs	28	16
80% of all IVD reports published in	**3 countries:** UK, Spain, Norway	
43 % of all report published in	**1 country:** UK	

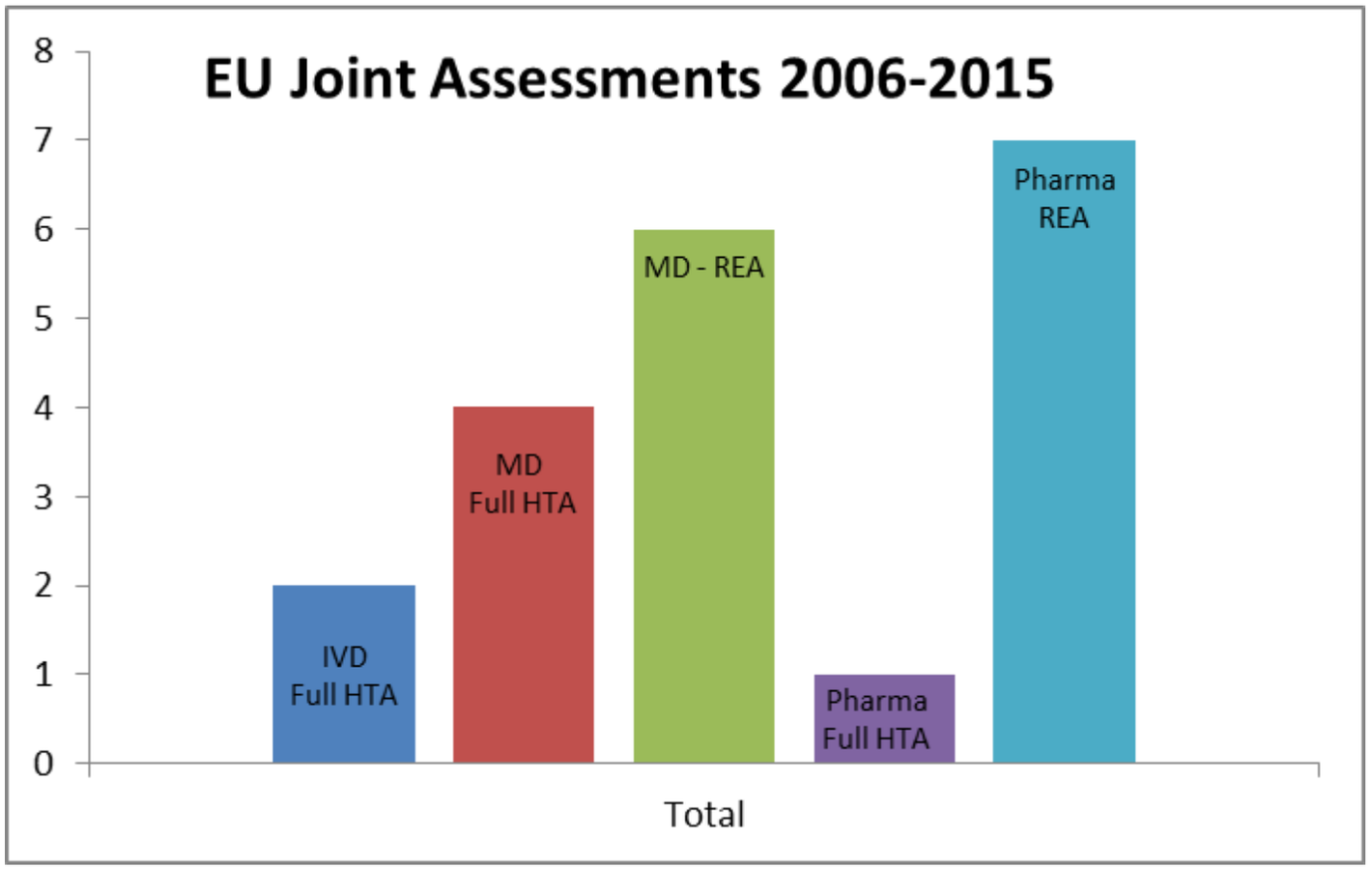
- **Common topics assessed in 2014**



- **No common topics assessed in 2015**

Statistic based on Synergus database (link)
* EU28 + Switzerland + Norway

What experience EU HTA and manufacturers have developed on Joint Assessments for IVDs?



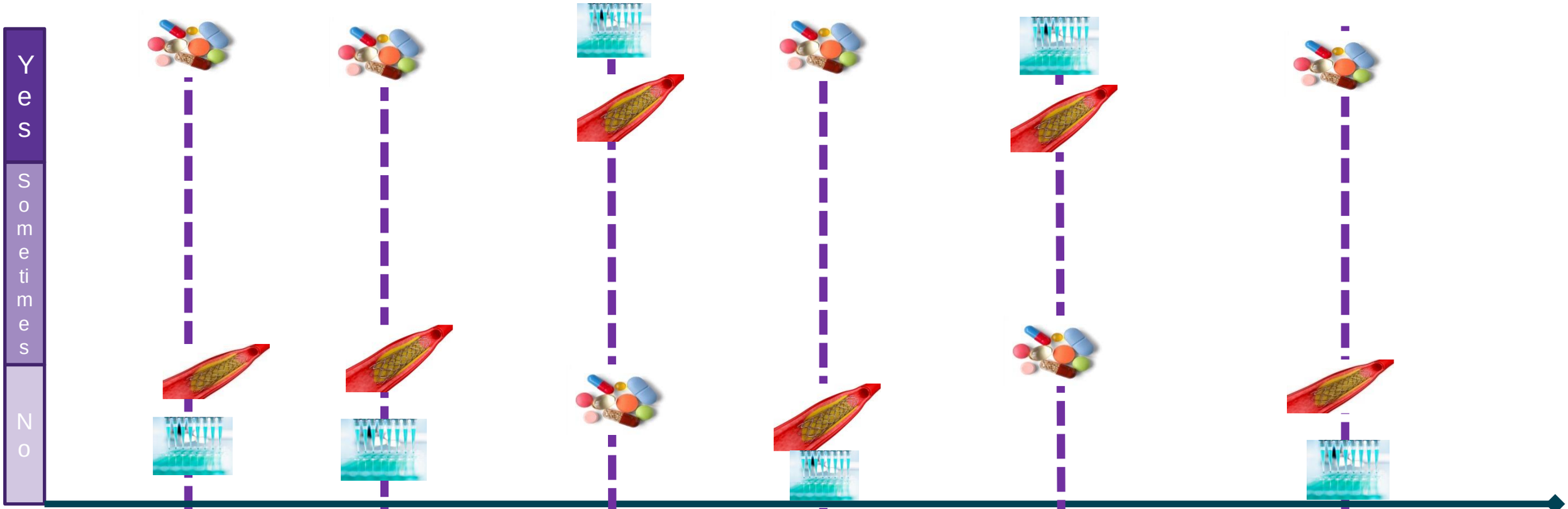
- ❑ No REAs have been conducted on IVDs (no experience from EU HTA or manufacturers)
- ❑ 2 Full HTAs have been conducted on IVDs

1 in JA-1 without participation of manufacturers

1 in JA-2 without direct participation of manufacturers, with feedback from EDMA.

- ❑ 6 countries used the JA-2 Full HTA report as input for their national report (Au,Ro,Esl,Est,Sp,Sw).
- ❑ Only 1 (Spain) used it to inform decision making.

What challenges do we see ahead on HTA and EU HTA?



Enough expertise/capacity specific units/programmes at national level

Are tailored methods to account for the full tech. value ready

Enough experience at EU HTA level (pilots)

EU REA /Full HTA face challenges to be transferable and inform the national level as is context dependent.

Are countries asking the same question at the same time so an EU HTA can bring efficiencies at national level

Are MS doing HTA differently (dif. methods, results they consider important, dif. evidence requirements, processes)

Are reimbursement systems rewarding evidence of value

It’s difficult to understand what decisions can EU HTA inform for IVDs at the national level