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# DIAGNOSTIC INFORMATION: AN UNPOLISHED JEWEL

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—  
The EGG  
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A MedTech Europe event

## The MedTech Forum

bringing HealthTech stakeholders together

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# DIAGNOSTIC INFORMATION: AN UNPOLISHED JEWEL

## Socio-economic aspects of Value of Knowing

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# Motivation

- Concern that traditional health technology assessment (HTA) does not appropriately recognize or reward the value of diagnostics
- Need to broaden the concept of diagnostics beyond companion diagnostics:

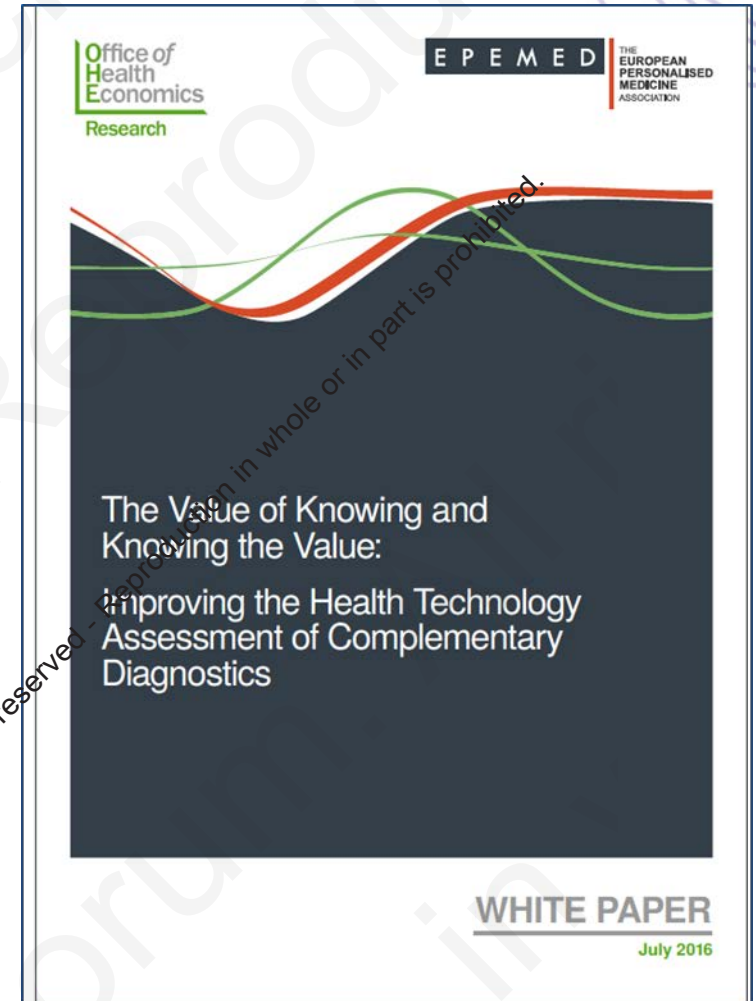
→ **“Complementary diagnostics”**

- Diagnostics provide value to patients beyond health gain and cost-saving: they can reduce uncertainty about benefit:

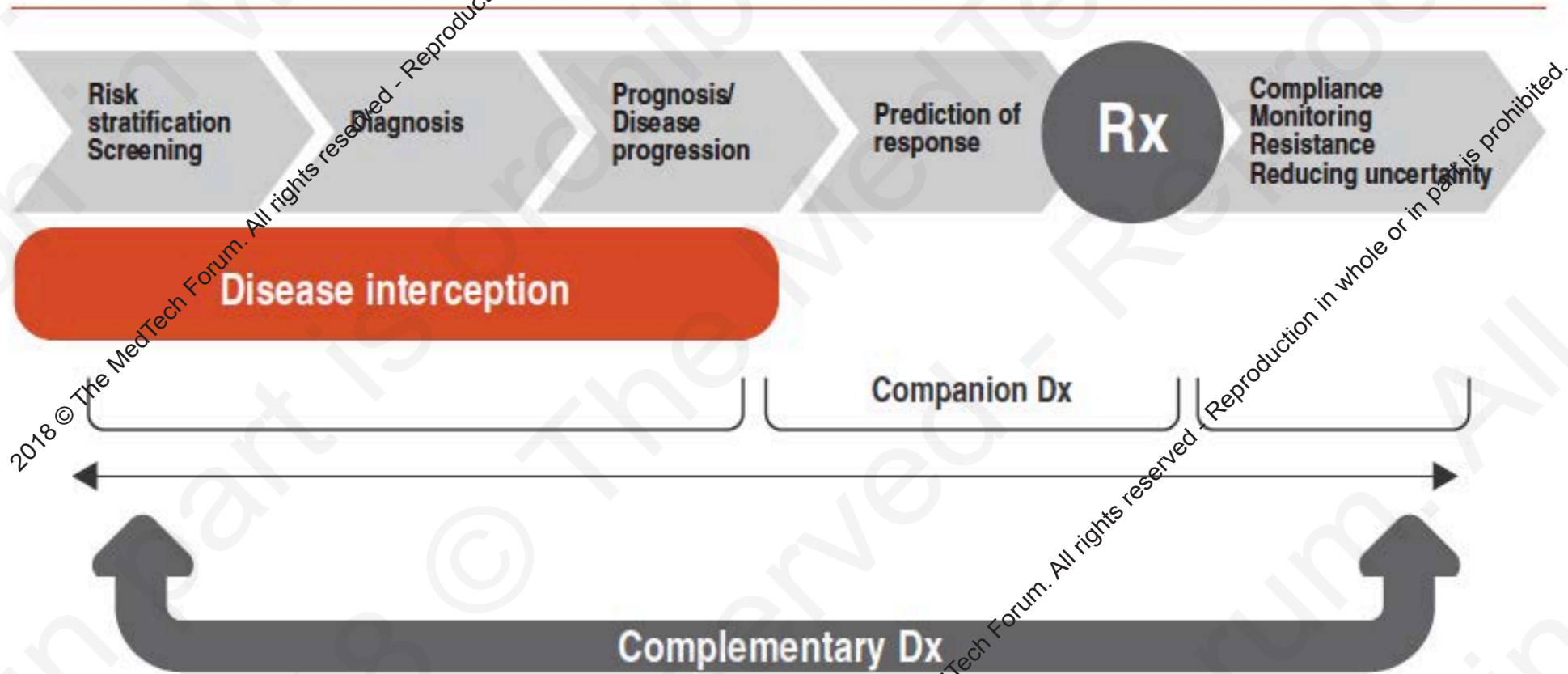
→ **“Value of knowing”**

# OHE/EPEMED White Paper

- To identify key issues facing the HTA of complementary diagnostics in Europe
- To provide coherent and consistent terminology for the definition of diagnostics and the elements of value
- To define options for addressing challenges and barriers
- To recommend approaches for dealing with them



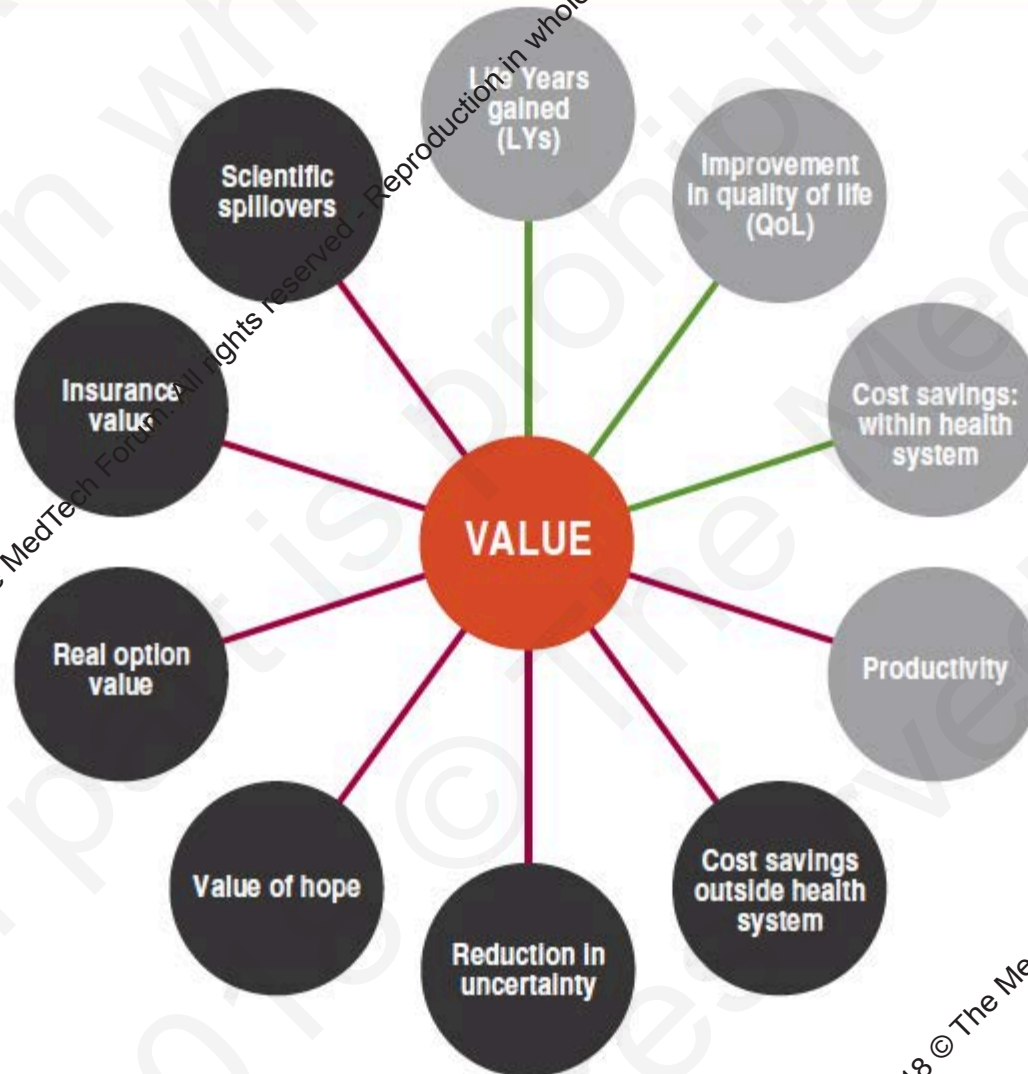
# Definition of Complementary Diagnostics



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# Elements of Value



Light grey circle: traditional elements of value as considered by HTA

Dark grey circle: expanded value framework: elements not traditionally considered/measured

Green line: value from health system perspective

Red line: value also included in societal perspective

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# Five additional elements

- **Reduction in uncertainty**—additional value from knowing a technology is more likely to work
- **Value of hope**—willingness to accept greater risk given a chance for a cure
- **Real option value**—the value of benefiting from future technologies due to life extension
- **Insurance value**—physical risk protection value provided by invention of an innovative medical product and by the accompanying financial risk protection afforded by a new treatment
- **Scientific spillovers**—value due to other innovations that become possible once a new technology has been proven to work.

# Elements of value included in ISPOR Initiative on US Value Assessment Frameworks

Elements of Value	Type of Element	Features of Medical Technologies where Element is Relevant in Value Assessment	Consideration under Healthcare perspective	Consideration under Societal perspective
Net Costs	Core	All	Y	Y
QALY	Core	All	Y	Y
Productivity	Common but inconsistently included	Relevant where treatment has an impact on productivity		Y
Adherence-Improving Factors	Common but inconsistently included	Relevant where features of the treatment itself improves adherence with the treatment	Y	Y
Value of Reduction of Uncertainty due to a New Diagnostic	Novel	Relevant when the treatment is accompanied by a companion diagnostic test	Y	Y
Fear of Contagion Risk of Contagion	Fear-Novel Risk- Common	Relevant when dealing with treatments for infectious diseases	Y	Y
Insurance Value	Novel	Relevant when baseline health status is particularly poor.	N	Y
Severity of Disease	Novel	Relevant when considering treatments for end-of-life care or high severity conditions		Y
Value of Hope	Novel	Relevant where therapies have uncertain effects that cannot be predicted beforehand by a diagnostic	N	Y
Real Option Value	Novel	Relevant where technology extends the life of patient	N	Y
Equity	Novel	All	N	Y
Scientific Spillovers	Novel	Relevant where technology identifies a new mechanism of action or mode of delivery	N	Y

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# ISPOR Initiative on US Value Assessment Frameworks

## **Recommendation 3.1: Apply cost-effectiveness analysis to inform public and private coverage and reimbursement decision making**

The cost-per-QALY metric derived from cost-effectiveness analysis serves as the core component of value assessments that should inform public and private coverage and reimbursement decisions in the US.

## **Recommendation 3.2: Support additional research that enhances the applicability, scope, and relevance of cost-effectiveness analysis for decision making**

In the spirit of the Second Panel's Impact Inventory, we strongly encourage development of a more comprehensive CEA that could potentially include novel elements of value—such as insurance value, real option value, value of hope, scientific spillovers, and others—that could ultimately provide for more efficient resource allocation within the health sector and between health and non-health spending.

# Conclusions

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# Application of Extended CEA

- Align static and dynamic efficiency: achieving maximum health gain for a fixed budget and the optimal rate of innovation
- Align budgets and thresholds when considering adding coverage of diagnostics according to new elements of value
- Align payer's decisions with value perceived by insurance enrollees or taxpayers
- Consider patients' perspectives when making choices between covered technologies or treatment options

# Thank you

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