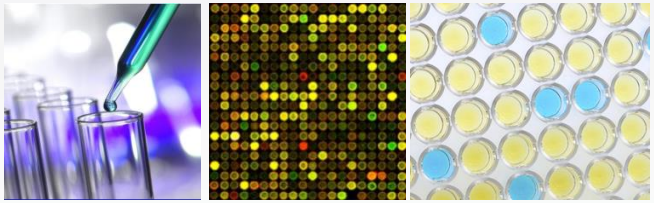


Views on successes, value and impact of JA2 collaboration for IVDs

Victoria Wurcel,
HTA & Economic Policies Manager, EDMA

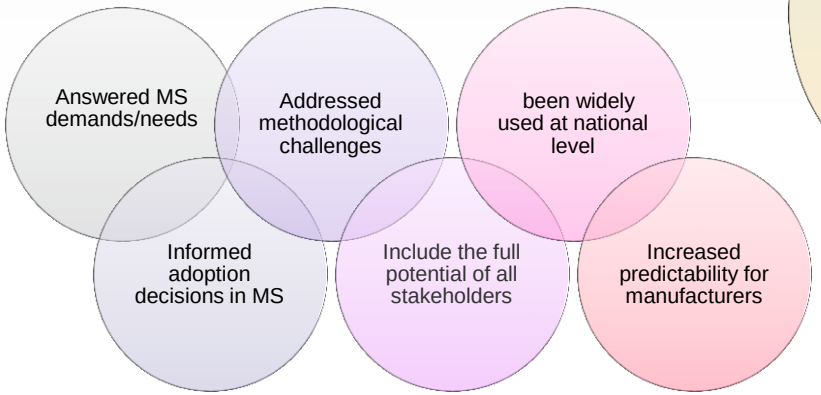
edma
DIAGNOSTICS FOR HEALTH

JA-2 & IVDs

HTA sould be specific for IVDs

It has not

JA-2 has not recognised IVDs specificities from therapeutic devices and drugs



Answer relevant questions from decision makers across MS

Specific methodologies for value demonstration

Linked to decision making - specificities of the patient access pathway and model of access

Specific framework, programme, methods, approaches to HTA for IVDs exist


NZHTA*


MPEP*


CADTH-H TERP**


MSAC*

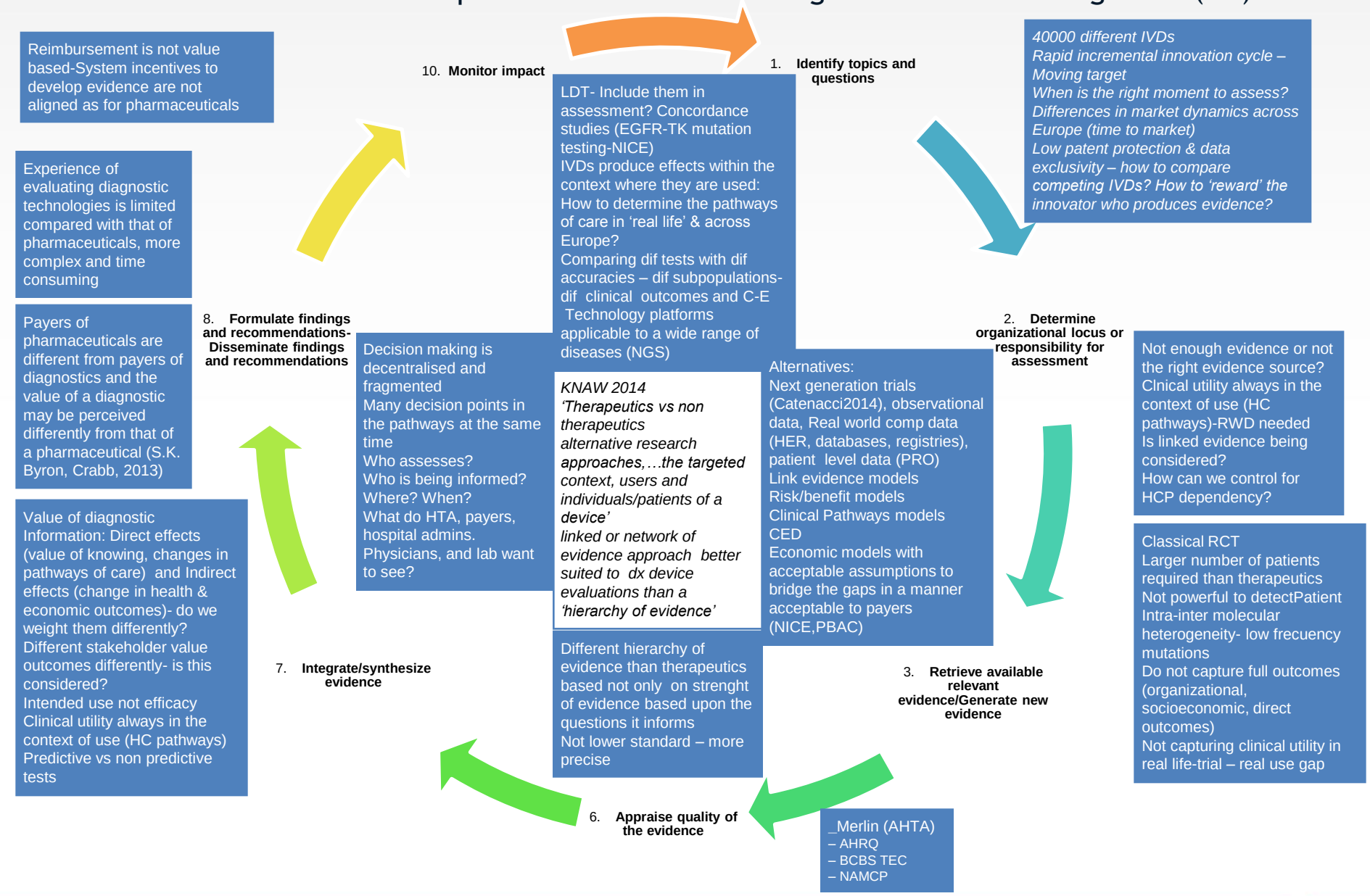

PALMETTO*
EGAPP**


DAP**

Variable HTA requirements & link to reimbursement across health care systems in Europe

*HTA linked to reimbursement ** Optional reimbursement

One-size-does not fits-all: specificities of in vitro diagnostics and challenges for (EU) HTA



JA-2 & IVDs

Pilots

HTA Core Model: CRC screening

- Are decision makers asking for this?
- Lengthy & complex process.

How to…

- choose assessment elements? assure consistency and quality when adapting?
- incorporate new evidence?
- Limited adaptation at national level
- A more flexible and pragmatic approach to evidence requirements suited to IVD specificities

Guidelines

- ✓ Are decision makers asking for this?
- ✓ Guidelines not sufficiently addressing the specific methodological challenges for IVDs HTA assessors will encounter
- ✓ Evidence generation requirements generate complexities for manufacturers:

Are they possible to achieve for the IVD technologies ?

Are they realistic?

Is the effort proportionate to the benefit achieved for manufacturers?

Are there incentives?

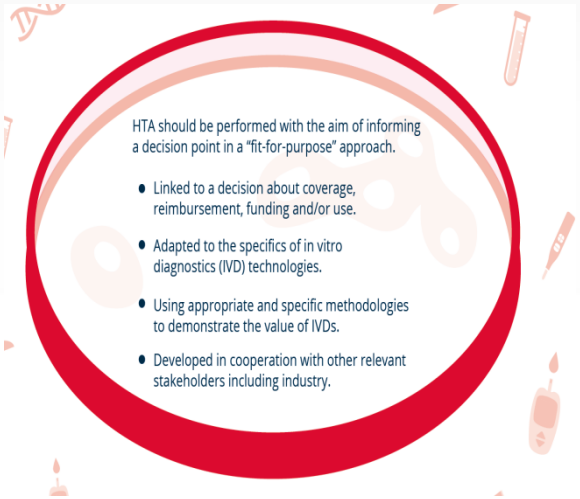
Do they lead to predictability ?

Involvement of stakeholders

- Consultative late phase
- Feedback generally not taken into account
- Resource intensive requirements
- Not enough time to respond
- Direct contact over written consultations would be favoured
- Full potential of the expertise and experience from industry not included

Non pharma is not sensitive enough for IVDs= patient pathways are different = specificities need to be recognized
IVDs are non therapeutics AND they reach patients in a different way
IVDs are a wide variety of diagnostics that **do not touch the body** , they **produce information with direct and indirect effects depending on its use, and** have **specific applications** (diagnosis, prognostic, predictive, monitoring, screening) and with many **other specificities (stand alone genetic testing vs companion diagnostics, point of care testing vs central lab testing**, etc)

Need for Fit for Purpose HTA for IVDs



Dedicated multi-stakeholder dialogue platform for medical technologies at HTA-N and specific activities/WP for IVDs in JA-3 are needed

HTA FIT FOR PURPOSE would contain following points:

1. Acknowledges **specificities of IVDs from other technologies**
2. **Links assessment to decision** making ,taking into account the specific access pathways for IVDs
3. **Develops and uses specific methods to bring out the full value of IVDs,** that are widely acknowledged and **applied in a consistent way**
4. Involves all stakeholders – patients, decision makers, healthcare professionals and manufacturers **-as partners all throughout the process**
5. Identifies **right timing** for assessment in the life-cycle of the technology

THANK YOU