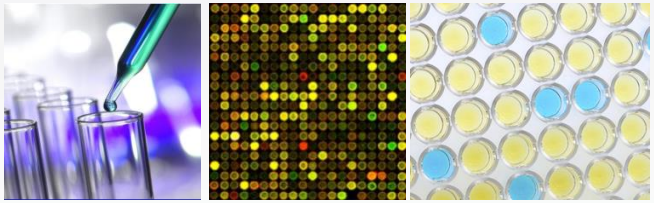

Teaming up for value
How can HTA cooperation be valuable and impactful in the next JA3 and beyond

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European Joint HTA can become valuable if it enables patient´s access to valuable IVD innovation across Europe

Fit-for-purpose EU HTA that effectively takes into account the specificities of IVDs, performed in partnership with decision makers and the IVD industry, will increase its value to inform access decisions across European Member States

Fit-for-purpose EU HTA for IVDs should be:

- ❑ Based on a defined policy and access-related demand of Member States
- ❑ Use of appropriate & specific methodologies that comprehensively demonstrate their value
- ❑ Have an impact on national decision making, considering the specific and varying patient access pathways and acknowledging the value of the European access model for IVDs

We have shared with the EC and MS that JA-3 activities should focus on the following success factors

- Acknowledge IVDs demonstrated **value** → **by applying it for real decision making** (informing funding, reimbursement and **adoption** decisions on IVDs)
- Lead to **increase patient access** → of valued IVD innovation in Europe
- Lead to **predictability for IVD manufacturers** → on topic selection, timing of assessment in the IVD life cycle and evidence requirements (outcomes, comparators)
- Be performed in a **collaborative multi-stakeholder partnership*** of **relevant/impacted** stakeholders → including IVD-specific reflections (HTA-N) and joint work within EUnetHTA´s dedicated Work Packages.
- **Be actionable** → **HTA agencies acknowledge joint work** on IVDs has been performed on their behalf in the EU collaboration and is valid as evidence submission in their national processes
- Be performed within a **clear quality framework** → to ensure consistency and relevance **and ultimately reuse** of joint work for decision making.

*A collaboration of patients, decision makers, experienced HTA agencies on IVD assessment and IVD manufacturers jointly defining: areas of priority to focus, addressing common EU MS unmet health needs , pragmatic evidence requirements (predictable, relevant, proportional) incorporating decision maker's values in a transparent way ,adequate methodologies for value based assessment of IVDs ,adequate timing of assessment.

Teaming up for value

Team up to define what European HTA joint work will inform for IVDs before discussing how it will do it

EU cooperation valuable for IVDs

❑ Establish a **multi-stakeholder dialogue platform on medical technologies including IVDs at HTA-N, implemented through dedicated meetings and reflections, to exchange knowledge, to** establish common grounds and build trust, key steps towards a valuable cooperation for all partners.

❑ **Build up European HTA expertise** to define and implement the most appropriate methodologies for HTA on IVDs, certification, and quality assurance mechanisms.

❑ **Account for the specificities of IVDs in all EUnetHTA guidelines, pilots and tools**, to avoid negative impact of non-specific / not fit-for-purpose assessments (in the **reuse** and value of joint work for patients and national level decision making, ability to reveal the true value of a technology, and patient access to new technologies)

❑ **IVD manufacturers would engage as collaborating stakeholders in certain EUnetHTA JA -3 scientific technical activities and observe in others, provided that a dedicated dialogue on IVDs at the strategic level is in place, and JA-3 activities shift to a collaborative work mode at the WP level**.

❑ **The stakeholder forum, as a way of information exchange** could add value if shifts to a collaborative mode

THANK YOU