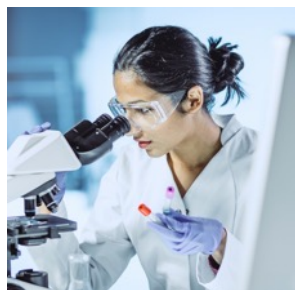
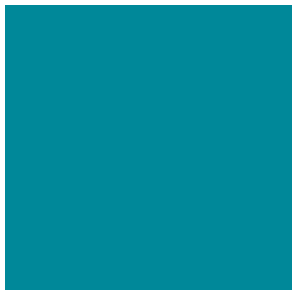
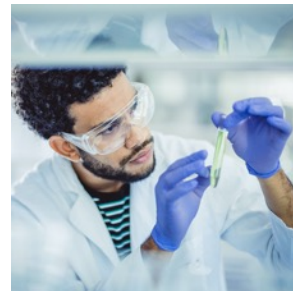




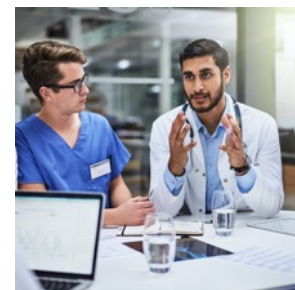
European Federation of Pharmaceutical
Industries and Associations



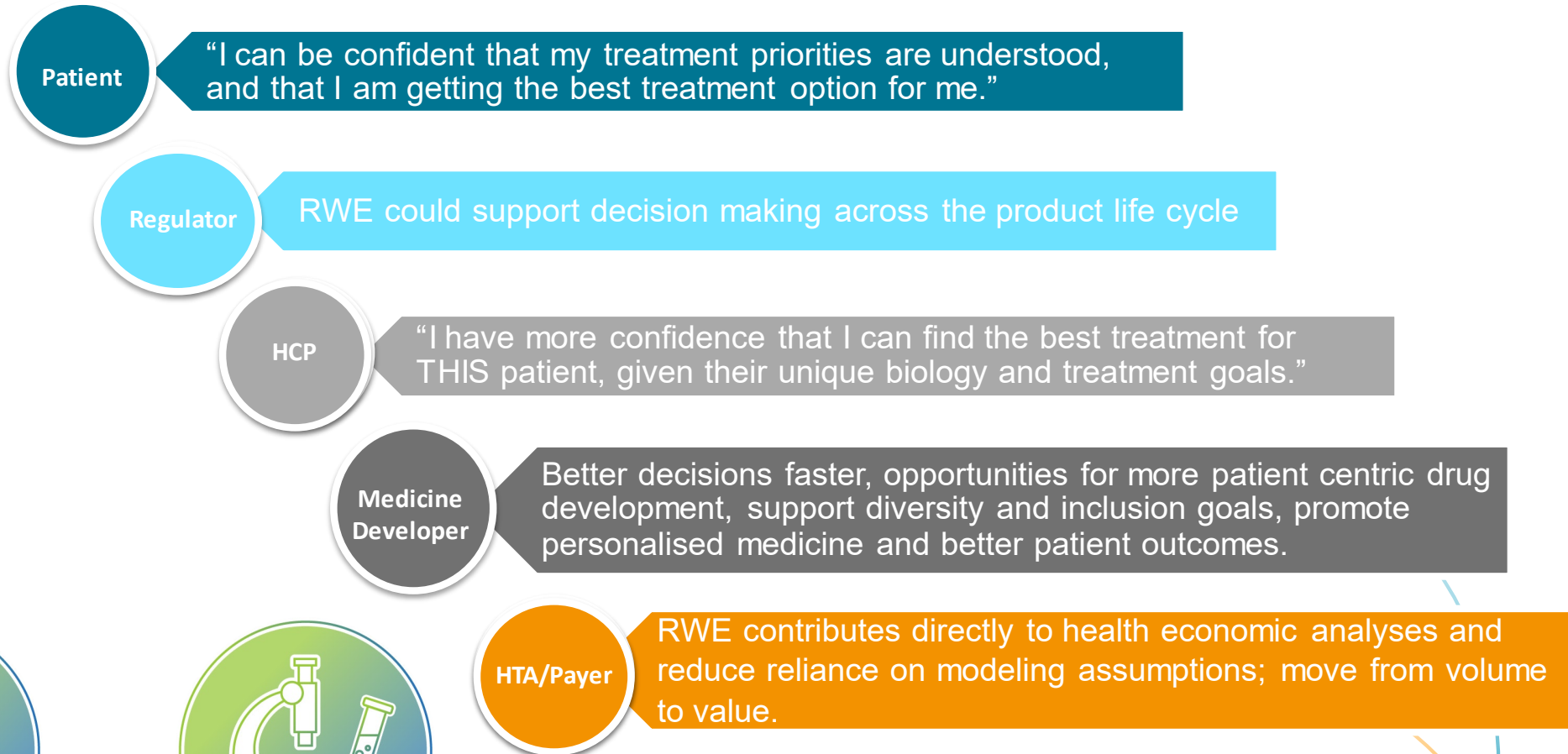
Breakout session 2: Platform for stakeholders' consultation



Learnings initiative workshop, 30 November 2021



RWE - A multistakeholder conversation.



HEALTHCARE
SYSTEM

2



RESEARCHERS

Concept of a Learning Healthcare System

General principles to guide stakeholder engagement

Dialogue to inform and accelerate “guidance” development - more predictability to the outcome of submissions

Platform /forum with sufficient agility to allow for sustained scientific dialogue recognising emergent area.

Facilitate process development and improvement.

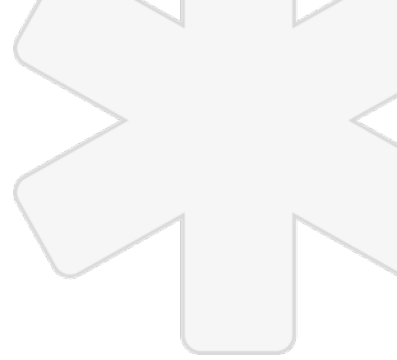


Build on contribution of existing international discussion forums – ISPE, ISPOR etc.

Supported by learnings initiatives - focus on less well established use cases.

Collaboration on data governance/secondary use of data.

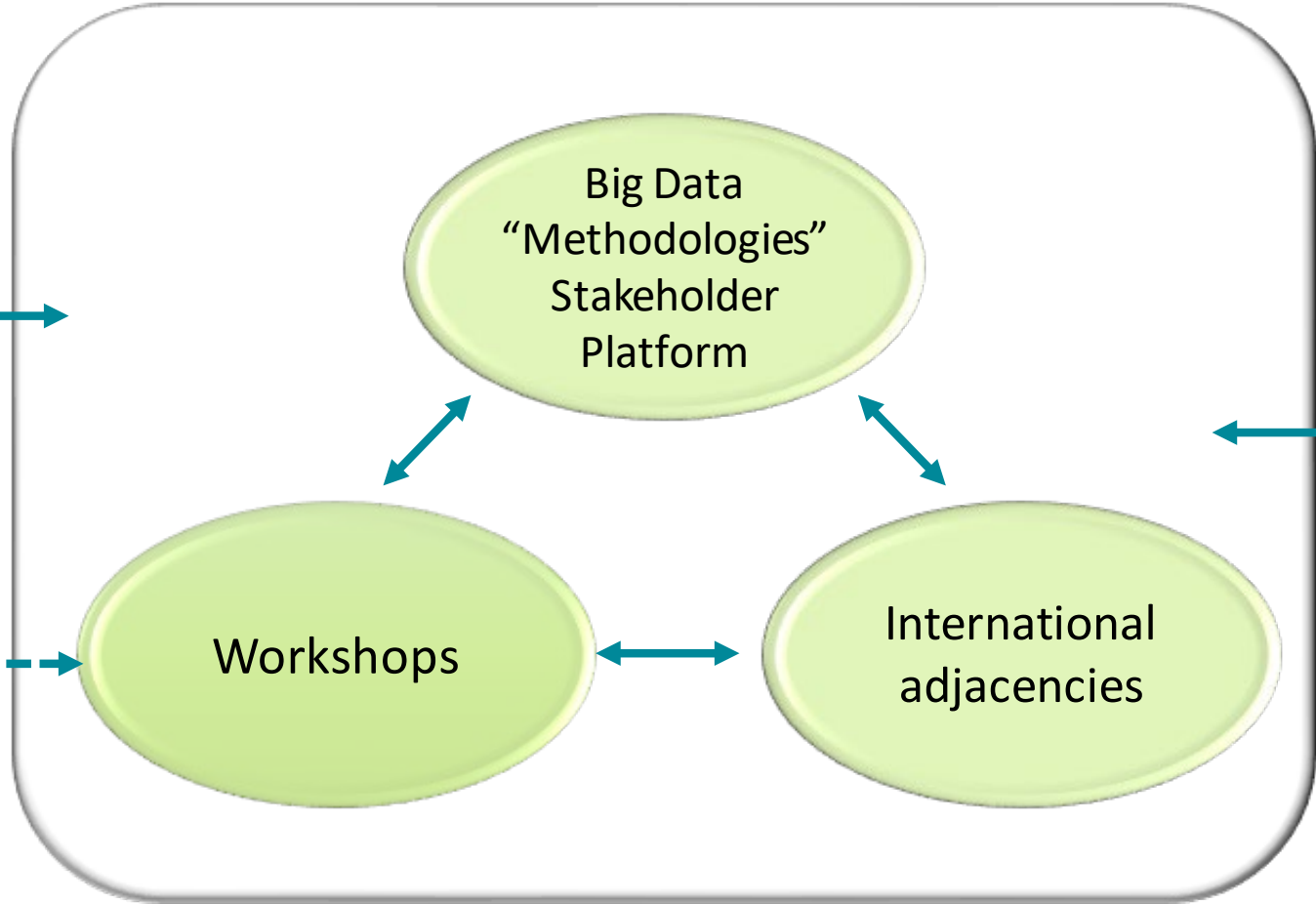
Stakeholder Engagement



Ecosystem of exportable knowledge

Learnings Initiatives

Evolving regulatory, healthcare and research environment



Integrate into guidelines/Q&A

Increasing capacity for generation and use of RWE.



Examples of areas for stakeholder input.

- Consultation process for meta data and quality framework.
- Interaction with Methodologies Working Group(s) on methodologies.
- Consultation on DARWIN EU start-up methods, templates for protocols and analyses that could be used for similar studies.
- Policy development/pilots on submission of patient level clinical trial data and/or RWD – example of insightful pilot with Danish Data Analytics Centre (DAC).
- Qualification procedures (for registries).
- Artificial intelligence: Scope of application and evaluation
- Procedural guidance associated with the use of DARWIN EU findings.
- International adjacencies.