Methodological Guidance for the Life Science Industry

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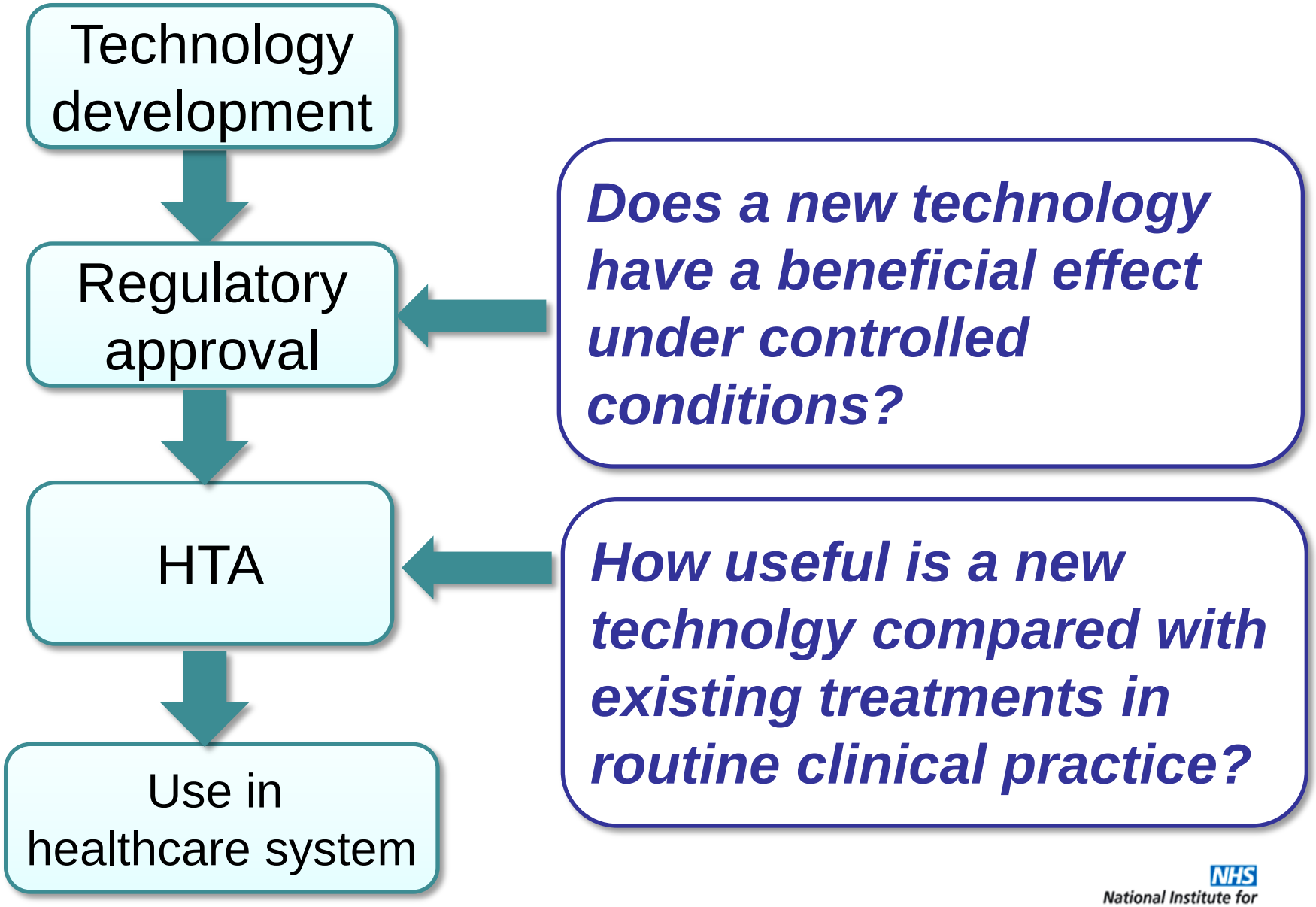
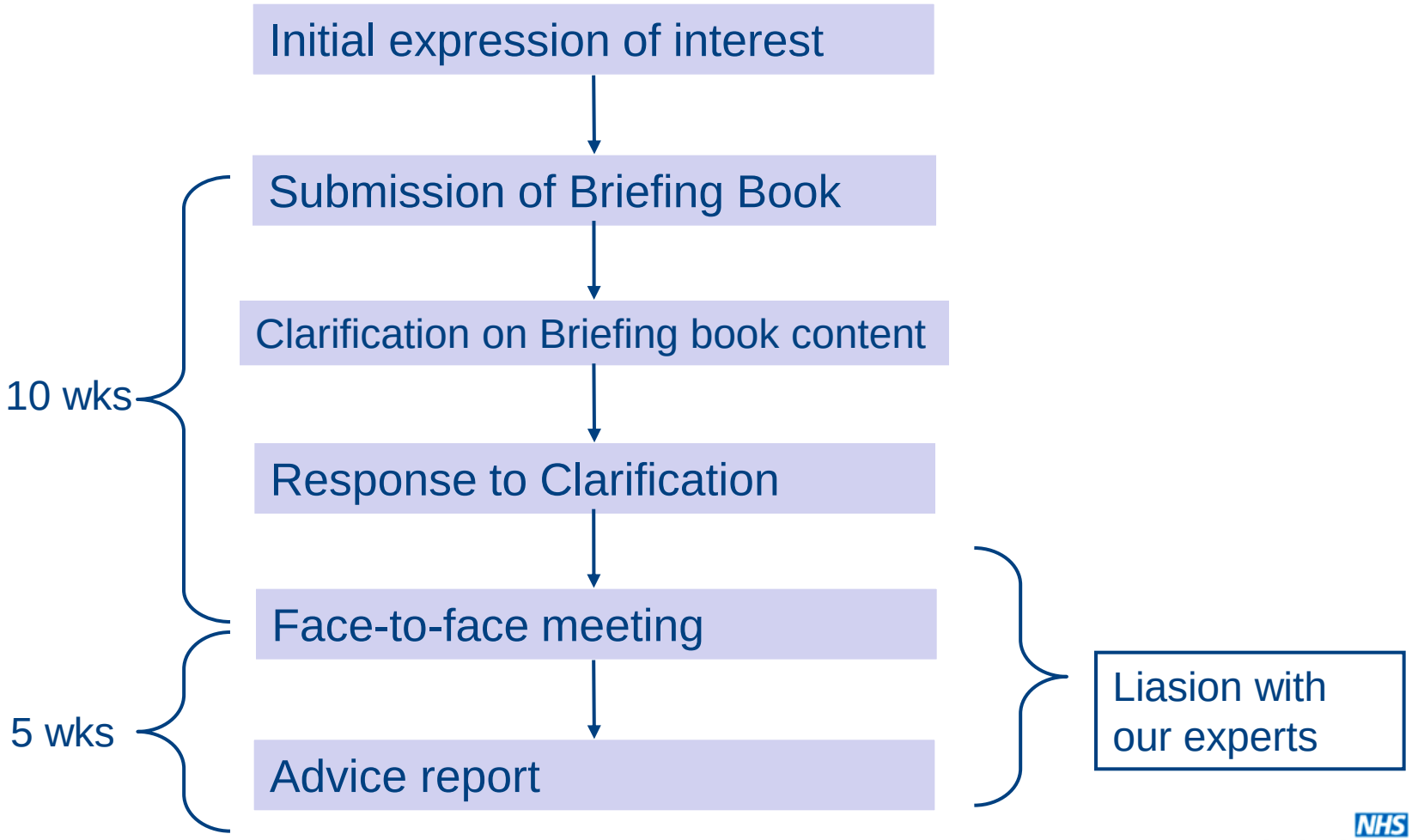
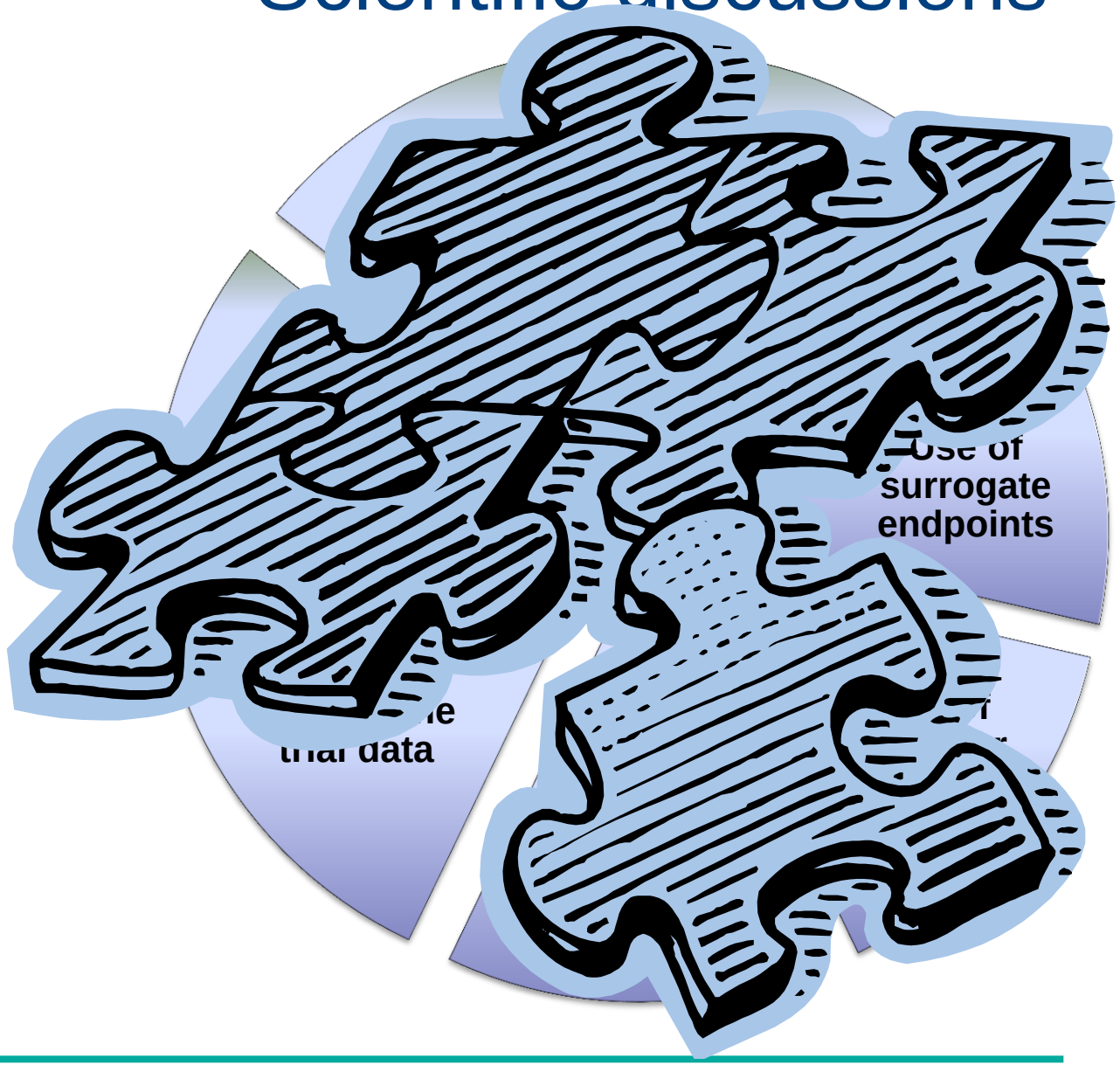
NICE


Technology development
Regulatory approval
HTA
Use in healthcare system
Does a new technology have a beneficial effect under controlled conditions?
How useful is a new technolgy compared with existing treatments in routine clinical practice?

NICE Scientific Advice

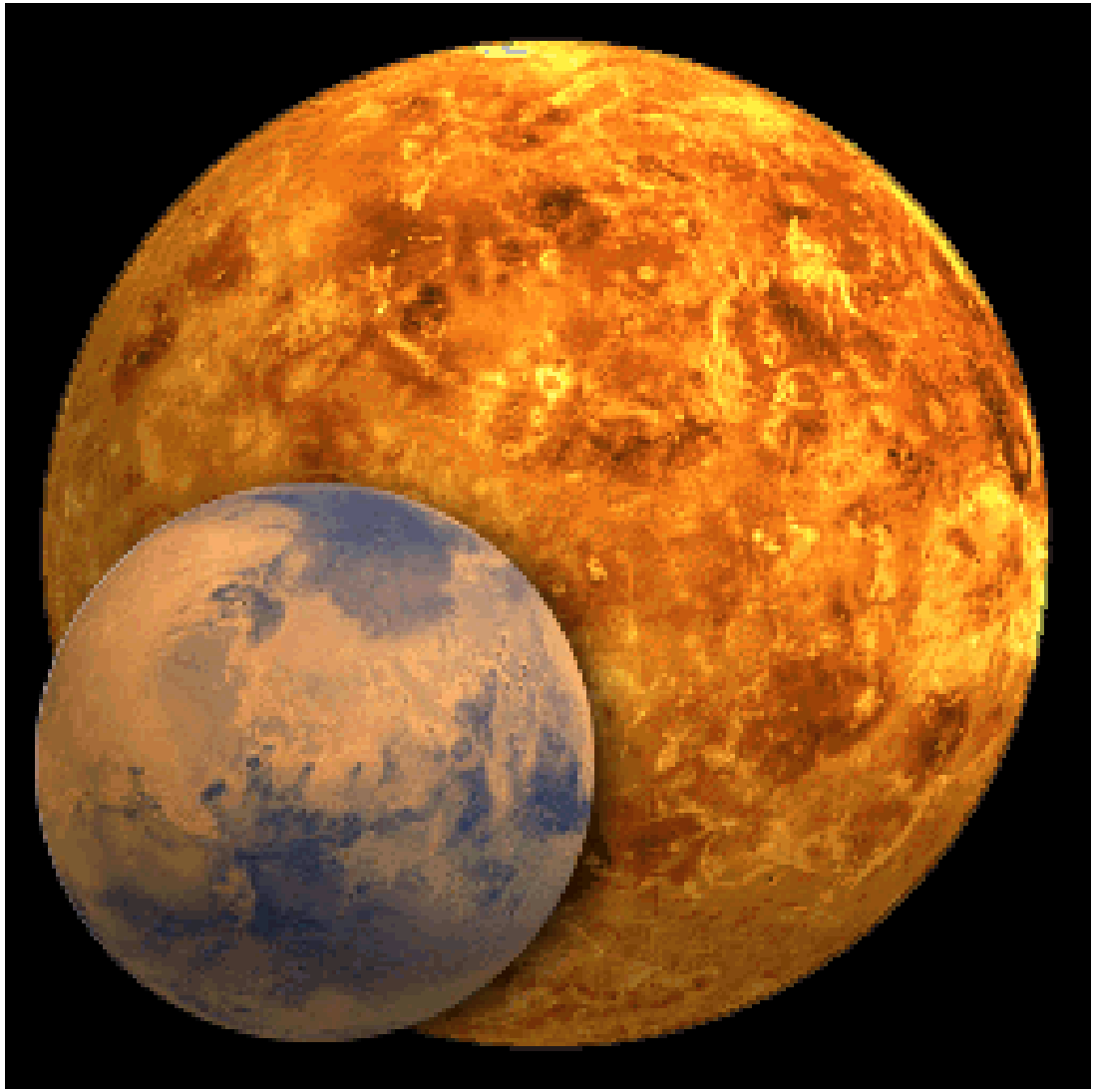


Scientific discussions

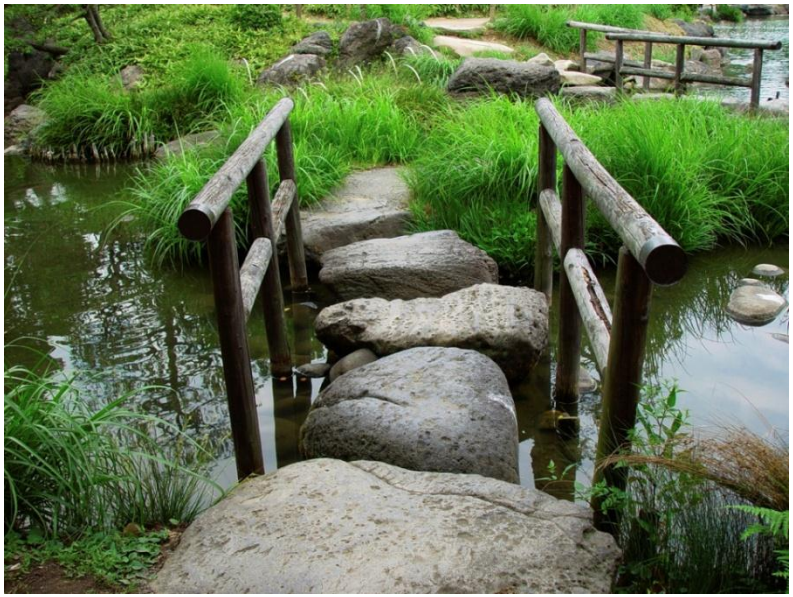


HTA scientific advice – how does it relate to the regulatory process?

- Key difference is that HTA requires quantification of the magnitude of difference in health outcomes
- Perspective is different but experience to date suggests that the issues are not necessarily incompatible
- Useful for both HTA and regulators to better understand each others perspectives



Building bridges



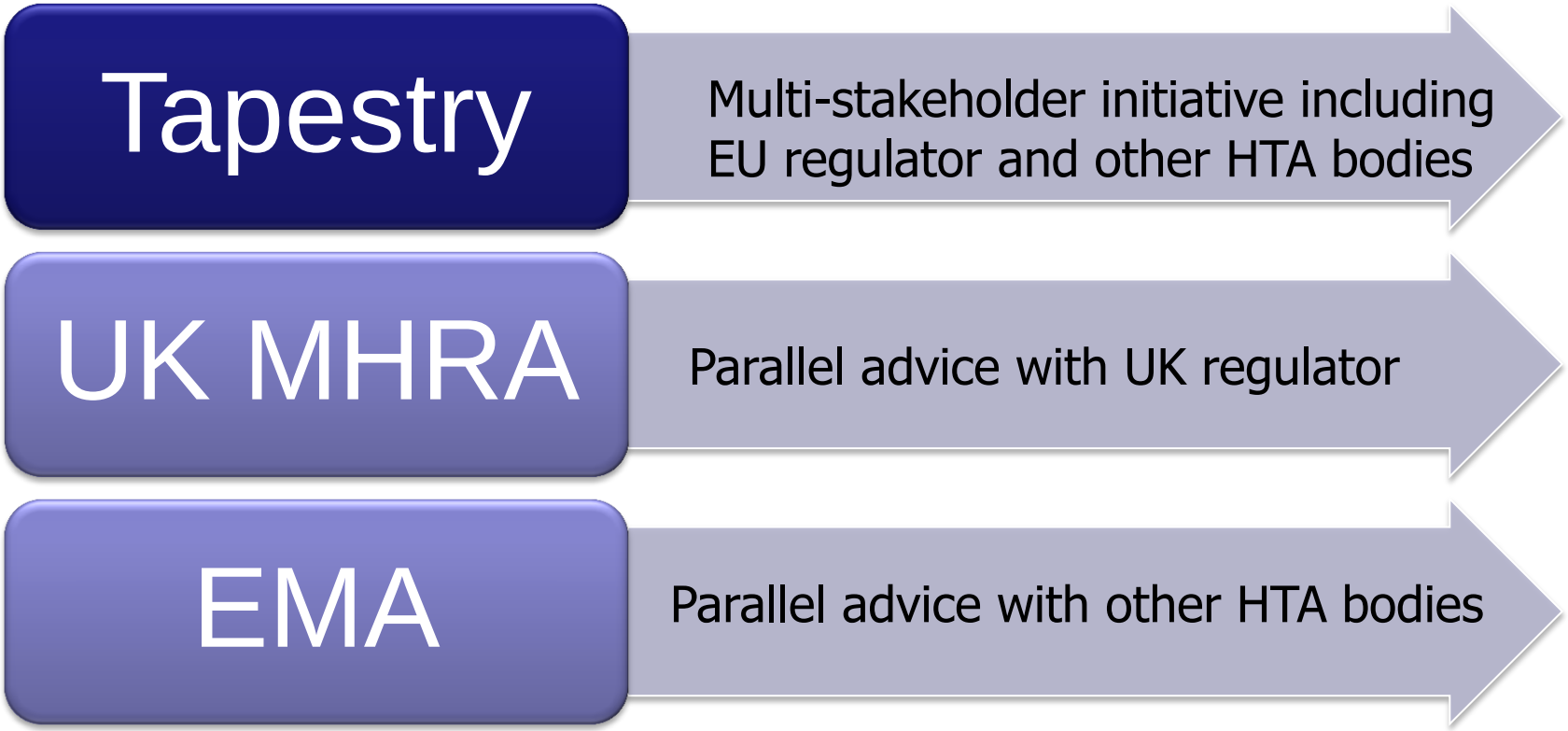
- Talking to each other
- Being clear about roles and boundaries
- Understanding what is common and what is different
- Developing similar approaches to common problems
- Being prepared to adapt

2011 HTAi Policy Forum meeting

HTA, Coverage and Regulatory Processes

1. **Build on current work to develop joint scientific advice from regulatory/HTA/coverage bodies for manufacturers on the design of pre-market evaluations (e.g., phase II/III trials) for specific products….**
2. **Develop joint scientific advice from regulatory/HTA/ coverage bodies for industry on the design of pre- and post-market evaluations (e.g., phase II/III/IV studies) for specific conditions…**
3. **In parallel with condition-specific advice develop joint scientific advice from regulatory/HTA/coverage bodies for the general design of pre- and post-marketing evaluations (e.g., phase II/III/IV studies)…**

NICE and parallel HTA-regulatory product specific advice



What’s next