Methodological Guidance for the Life Science Industry

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NICE
Does a new technology have a beneficial effect under controlled conditions?

How useful is a new technology compared with existing treatments in routine clinical practice?
NICE Scientific Advice

1. Initial expression of interest
2. Submission of Briefing Book
3. Clarification on Briefing book content
4. Response to Clarification
5. Face-to-face meeting
6. Advice report

Liaison with our experts

10 wks

5 wks
Scientific discussions

- Usefulness of primary clinical endpoint
- Use of surrogate endpoints
- Choice of comparator
- Place in clinical practice
- Modelling beyond the trial data
- Specification of subgroups
- Measure of health-related QoL
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

- **Tapestry**: Multi-stakeholder initiative including EU regulator and other HTA bodies
- **UK MHRA**: Parallel advice with UK regulator
- **EMA**: Parallel advice with other HTA bodies
What’s next