# Principles and approaches: Eliciting Values for Risk Management choices

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# Main message

- Eliciting values for risk management choices involves structured common sense
- It also relies on concepts of decision making under deep uncertainty
- I will refer to the FDA Tysabri example to set the context

# Tysabri case study

- **This case shows FDA already does much of what is covered in this talk.**
- Approval decisions consider the available alternatives to the proposed drug and the consequences of not approving it
- The Tysabri case shows willingness to monitor and create an improved (less burdensome) alternative over time

# Case study continued

- Tysabri case also shows reliance on the views of affected parties who are bearing the risk and getting the benefits

- Hearing from these parties may often be important in these individual risk/risk tradeoffs

# What should valuation entail for risk decisions?

- Eliciting values for risk choices makes most sense within the context of a specific *regulatory decision process* (values are context dependent). This fits with the Benefit-Risk Framework
- The *ideal* : legitimate, transparent governance processes make informed choices among alternatives within an insightful, well-structured framework. *FDA has that advantage.*
- This requires *technical (scientific) information* and *value-based information* (preferences) to clarify and examine tradeoffs, addressed explicitly and distinctly
- Decisions for risk management are *always required* before uncertainties are resolved. *Surprises* are potential part of any risk decision process.

# Pharmaceutical Risk Governance

- FDA is in an enviable position relative to many risk governance bodies: clear authority, domain expertise, respect, abundant data,  flexibility, monitoring
- The patient/physician context is unusual: patient takes the risk and obtains the benefits, with expert guidance.
- The FDA panel structure as an forum for combining analysis and reflection on values is also a strong feature

# Key themes in risk decisions

- The *acceptable level of risk in a given decision context* should be a function of the *available alternatives*, not just a single scientific threshold. Thresholds simplify (but mask, or leave out) tradeoffs.

- Managing in order to improve (build less undesirable) alternatives is one key to achieving better risk management outcomes.

- When faced with *deep* uncertainties: *learning* over time and *flexibility* for adaptation (to address different contexts differently) are fundamental. These are the components for robust and resilient alternatives (that work better over a wide range of uncertainties and cope with surprise)

- The Tysabri example show FDA follows these themes.

# Some initial generic objectives

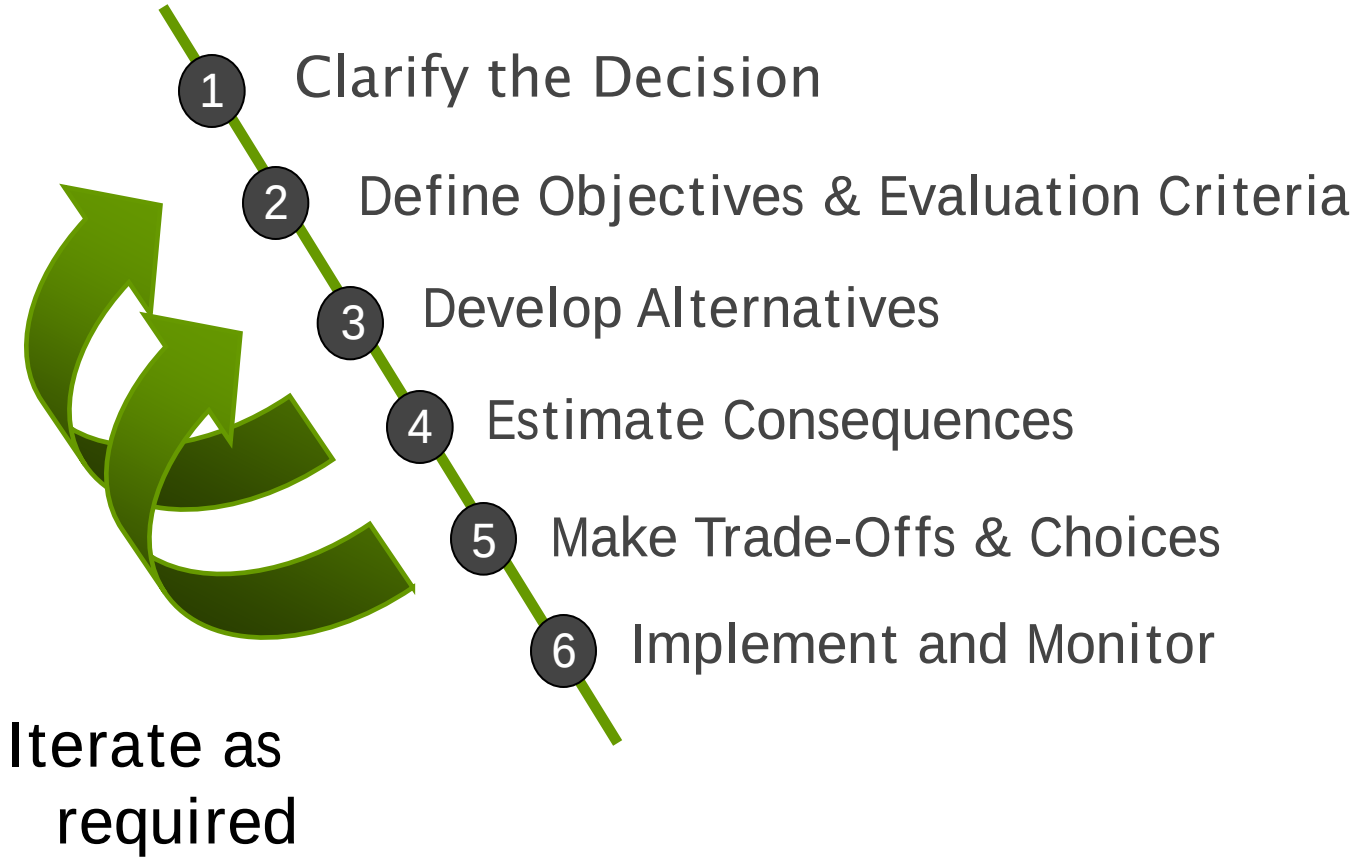
- A view of basic objectives for pharma regulatory decisions:
  - *Enhance human health* through new drugs
  - *Avoid adverse health effects* from new drugs
  - *Learning and flexibility* are important means to those long term ends, and so can be treated as objectives for designing alternatives in initial approvals
- These all need to be specified further and measured

# A multiple objective view

- Multiple conflicting objectives are best addressed by keeping the dimensions and valuation judgments separate, *in natural units*.

- This is directly in keeping with the Benefit-Risk Framework

# Structured decision making



# Valuation Questions

- Given the estimated impacts of the alternatives on these objectives, *is it worthwhile for society to accept the tradeoffs in going from "do not approve" to "approve" for one of the alternatives?*
- The alternatives could include "approve as proposed", "approve with modifications" (e.g, different doses) "approve with more testing and monitoring"