Health Technology Assessment

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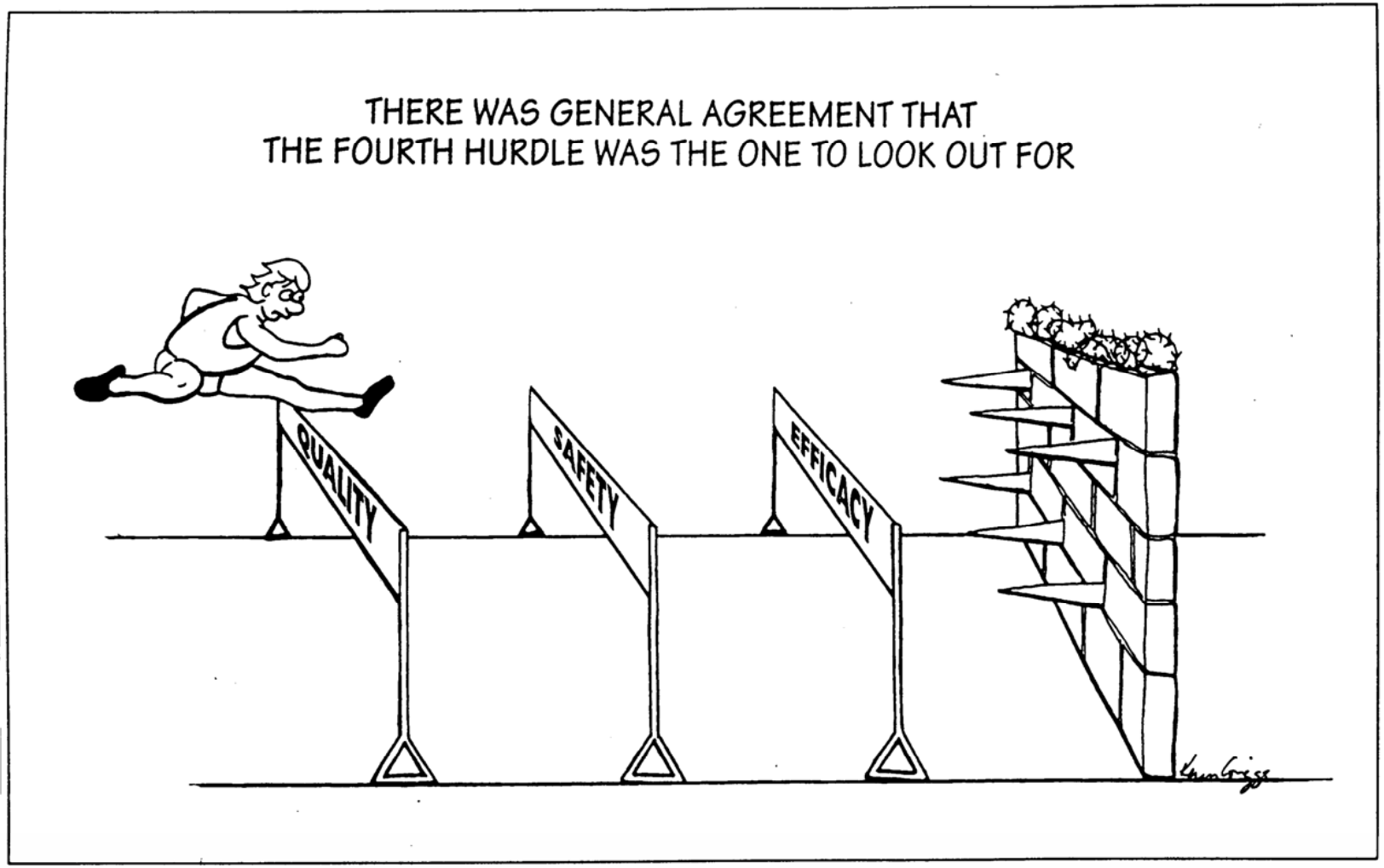
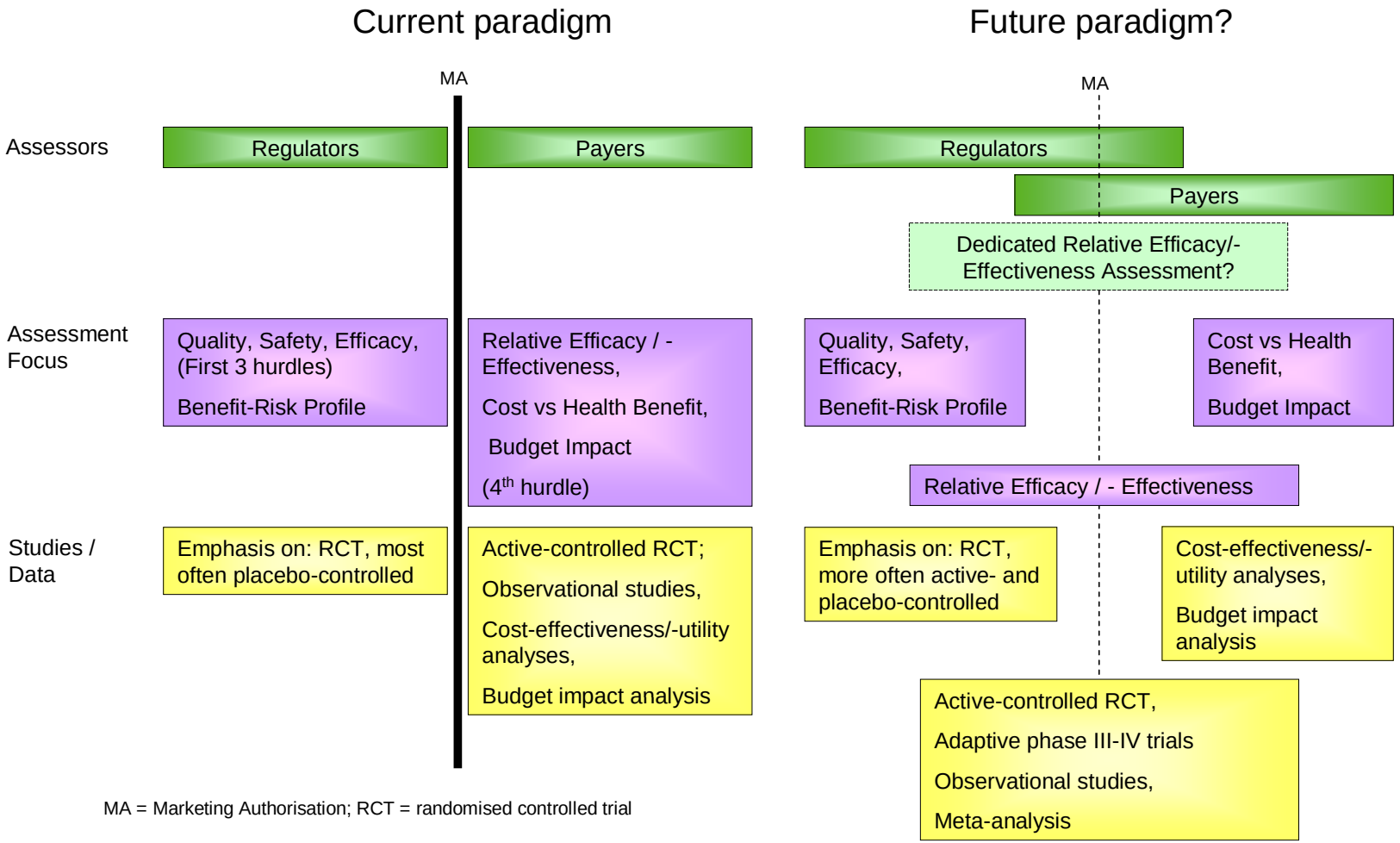
The Fourth Hurdle



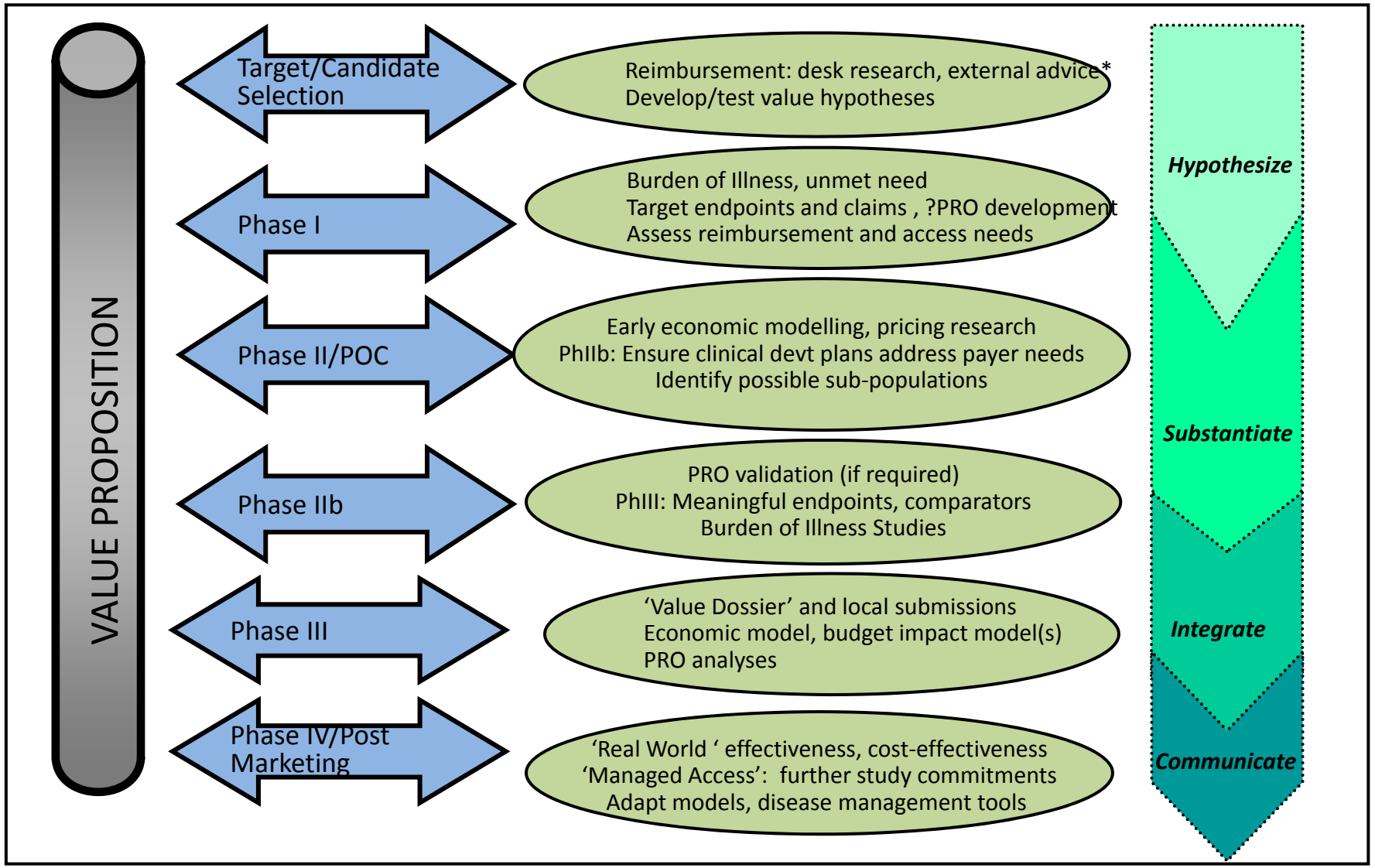
What the Regulatory/HTA Interface might look like in the future – EMA Perspective*



MA = Marketing Authorisation; RCT = randomised controlled trial

* How Regulatory Agencies could interact with Health Technology Bodies, Presentation at DIA, Berlin, March 2009, by Thomas Lonngren, EMA

Health Outcomes in Product Development



Based on: Sollano JA, Kirsch J, Bala MV, Chambers MG et. al. Clinical Pharmacology & Therapeutics (2008); 84, 2, 263–26

**External advisors/payer input obtained iteratively throughout product development*

Relationship clinical development – HEOR/HTA

- In the past: work in parallel w/o much interaction
  - HEOR/HTA „recycled“ the clinical study data
- Today & future:
  - Incorporation of HTA data needs into planning of clincial development programme
  - Joint PRO validation activities
  - Partnership between statisticians and 4th hurdle collagues, e.g. Health Economics, HTA Policy/Corporate Affairs, Pricing

Skills sets in HTA

- Observational research versus interventional research
  - Linking “efficacy” with “effectiveness”
- Economic related outcomes
  - Health resource utilisation measures
- Evidence synthesis
  - indirect/mixed treatment comparisons
  - Subgroups/subpopulations of interest
- Modelling life-time clinical and cost outcomes
  - use of surrogate endpoints

Suggested points for discussion

- **Is the HTA area seen as an area where statisticians should be involved?**
- **If yes,**
  - **Are statisticians in the industry sufficiently equipped to deal with the statistical challenges faced in HTA research?**
  - **How can EFPSI promote the statistical profession in the HTA area?**