

NICE National Institute for
Health and Care Excellence

Real- world data deployment

Professor Sarah Garner

Associate Director NICE – Science Policy and Research

sarah.garner@nice.org.uk

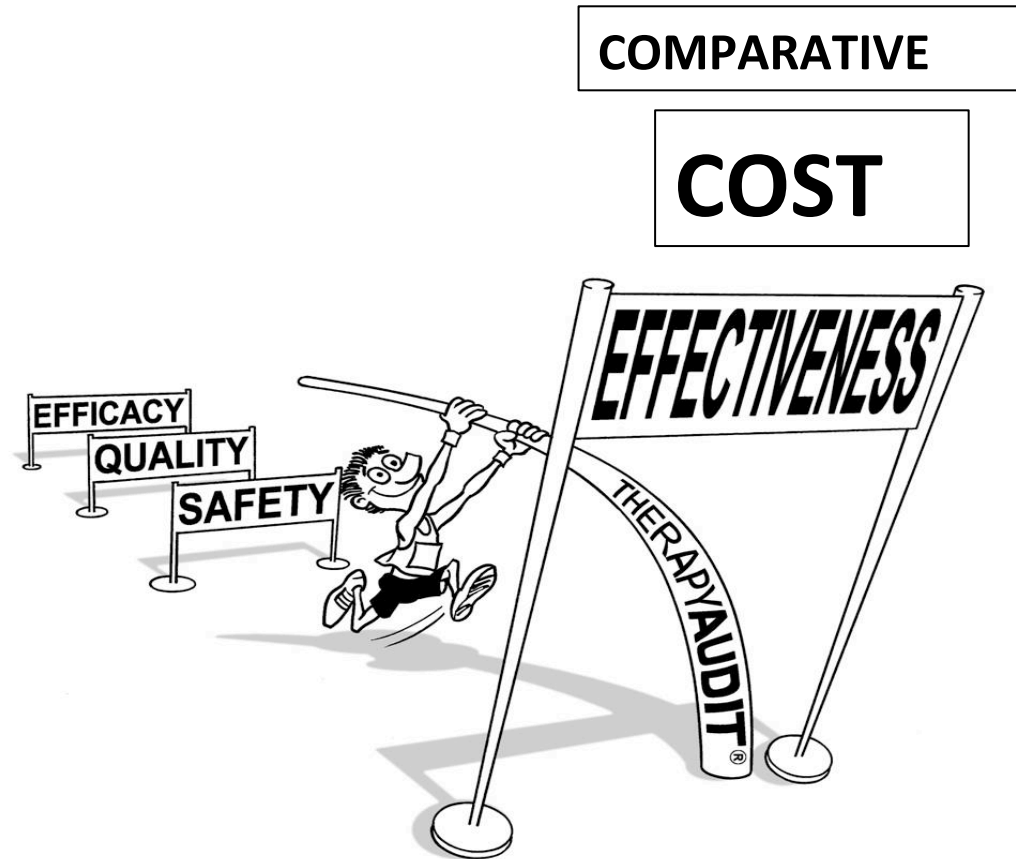
Existing 'fixed menu' of drug development

Phase I/II

Phase III/
Regulation

HTA/Reimbursement

Post market



The MAPPS menu

Using the same menu ingredients to create new combinations tailored to the drug and patient group

Safe harbour

(Co-design the evidence development and access strategy)

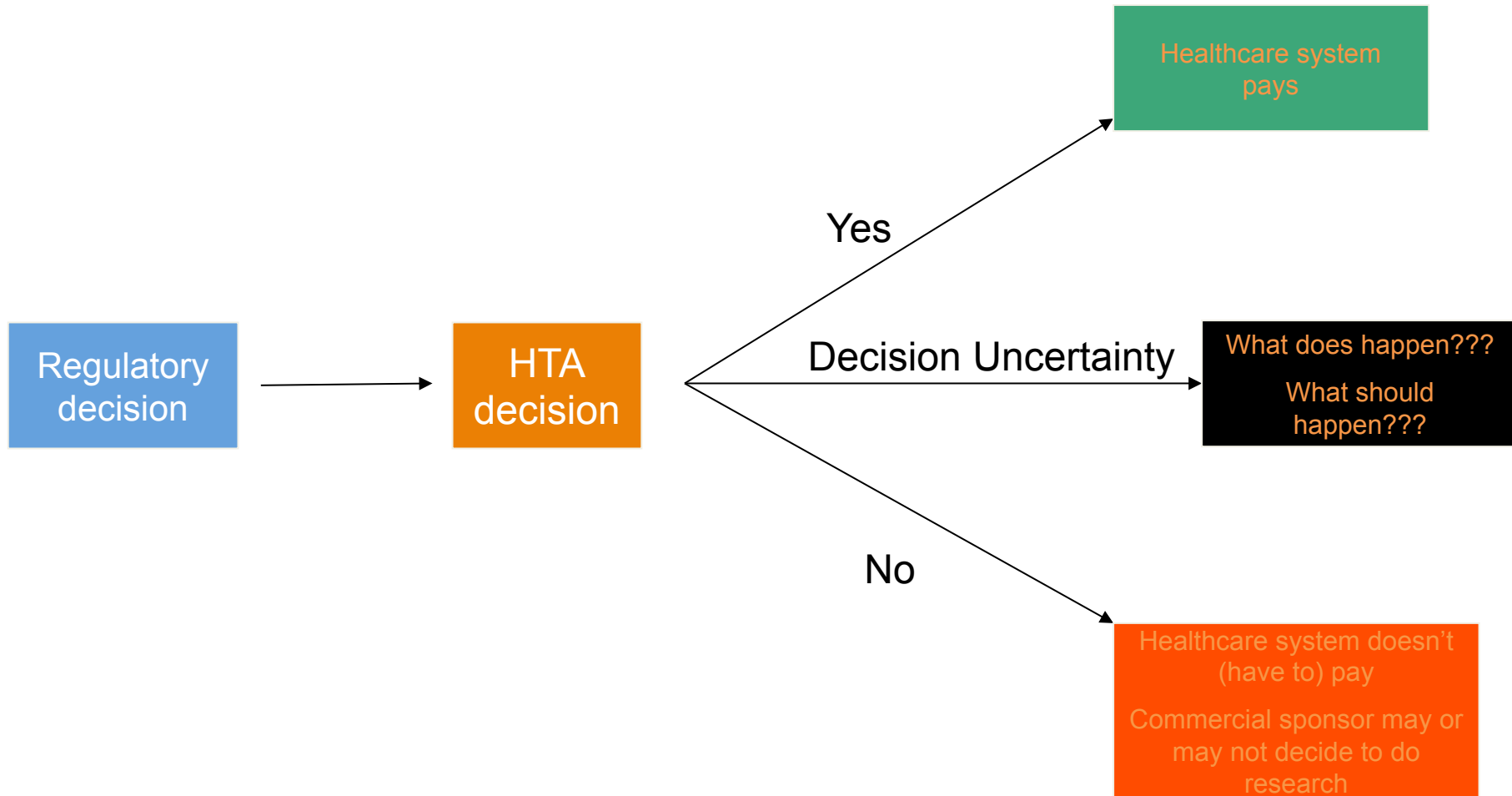
Early evidence development

Patient access

Conditional license and reimbursement

Confirmatory evidence and review

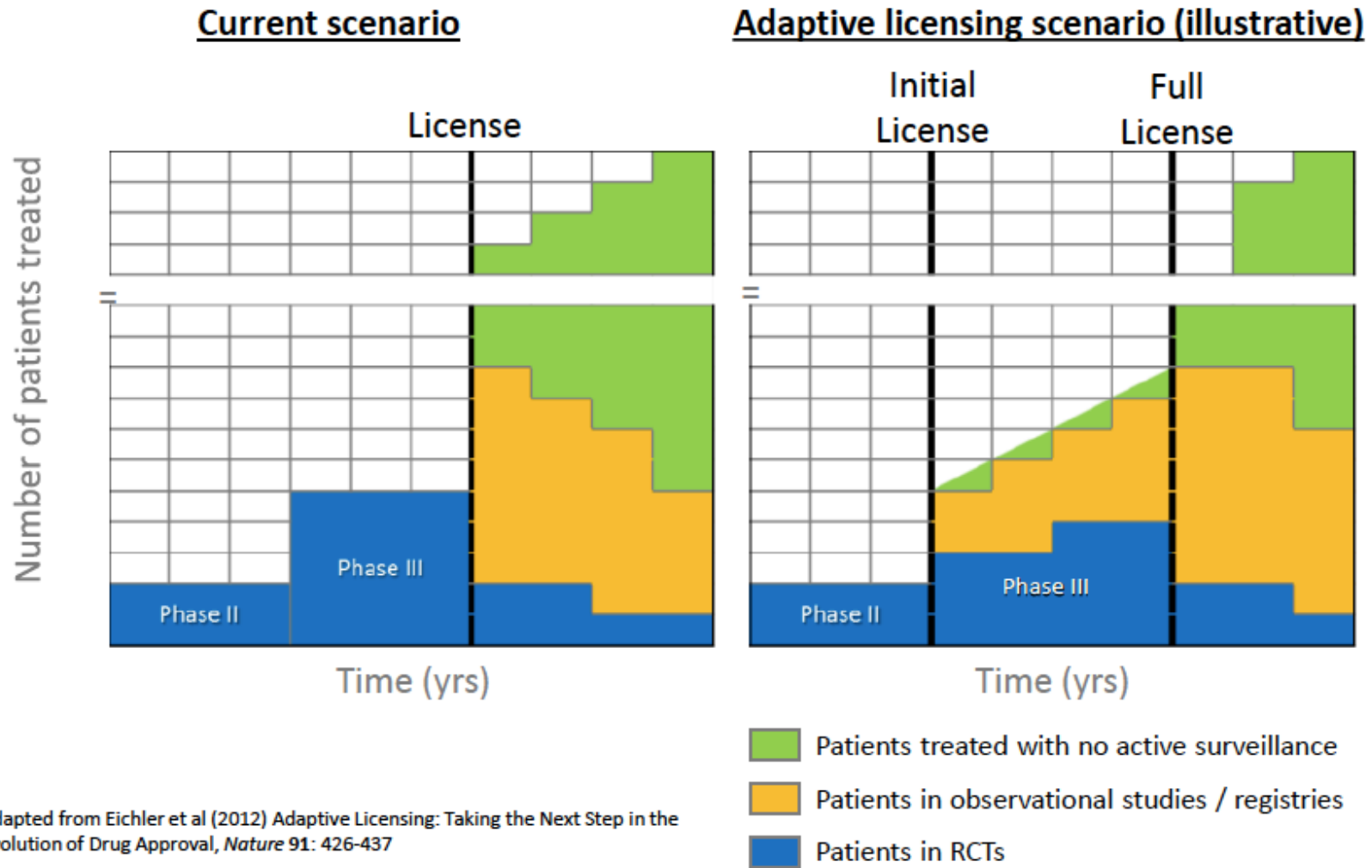
Current framework



Adaptive framework



AL shifts the way evidence is used



Adapted from Eichler et al (2012) Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval, *Nature* 91: 426-437

Real world data challenges

- Culture change
- Understanding of potential impact
- Skill development and capacity
- Concerns over confidentiality
- Research or care?
- Ethical issues: coercion
- Terminology
- Methods - data science
- How to define best practice
 - Critical appraisal tools?