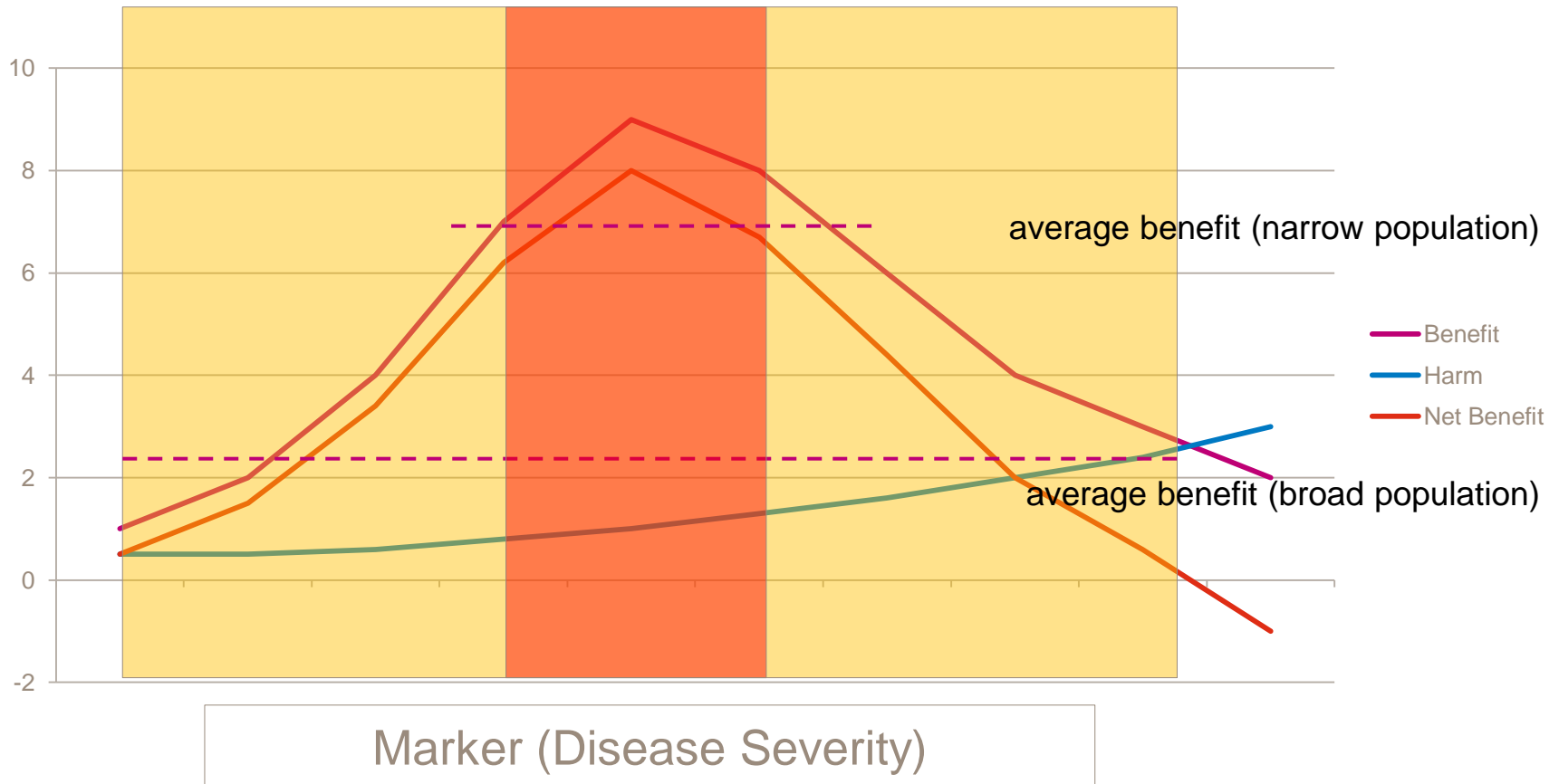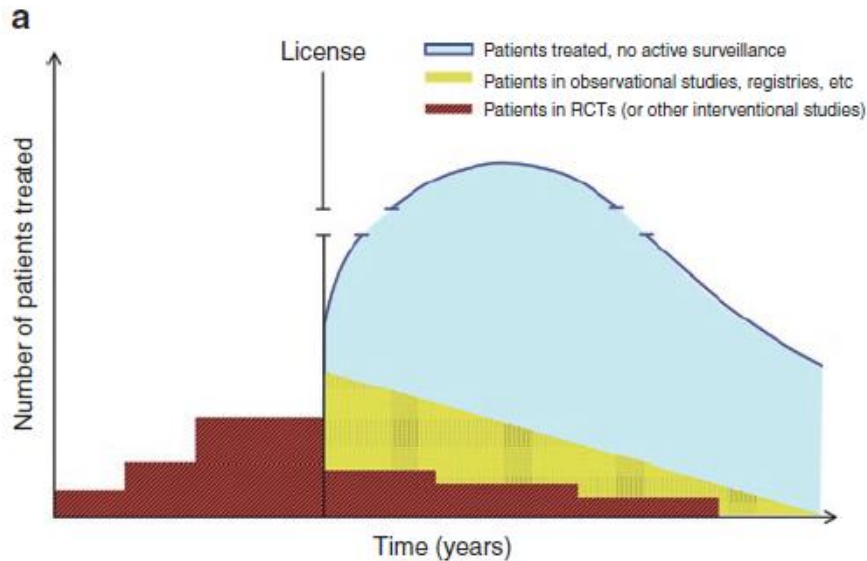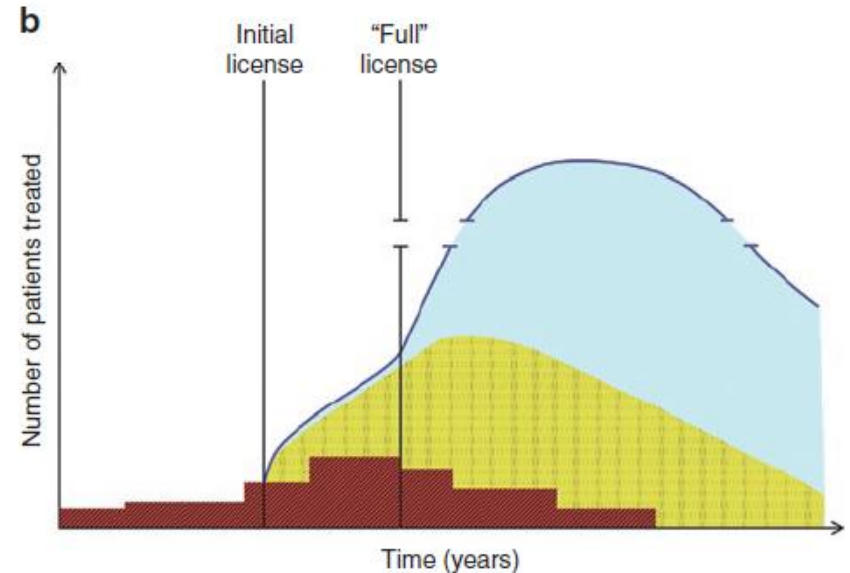# GSK's approach to MAPPs

21st October 2014

Identify Patients with highest Net Benefit

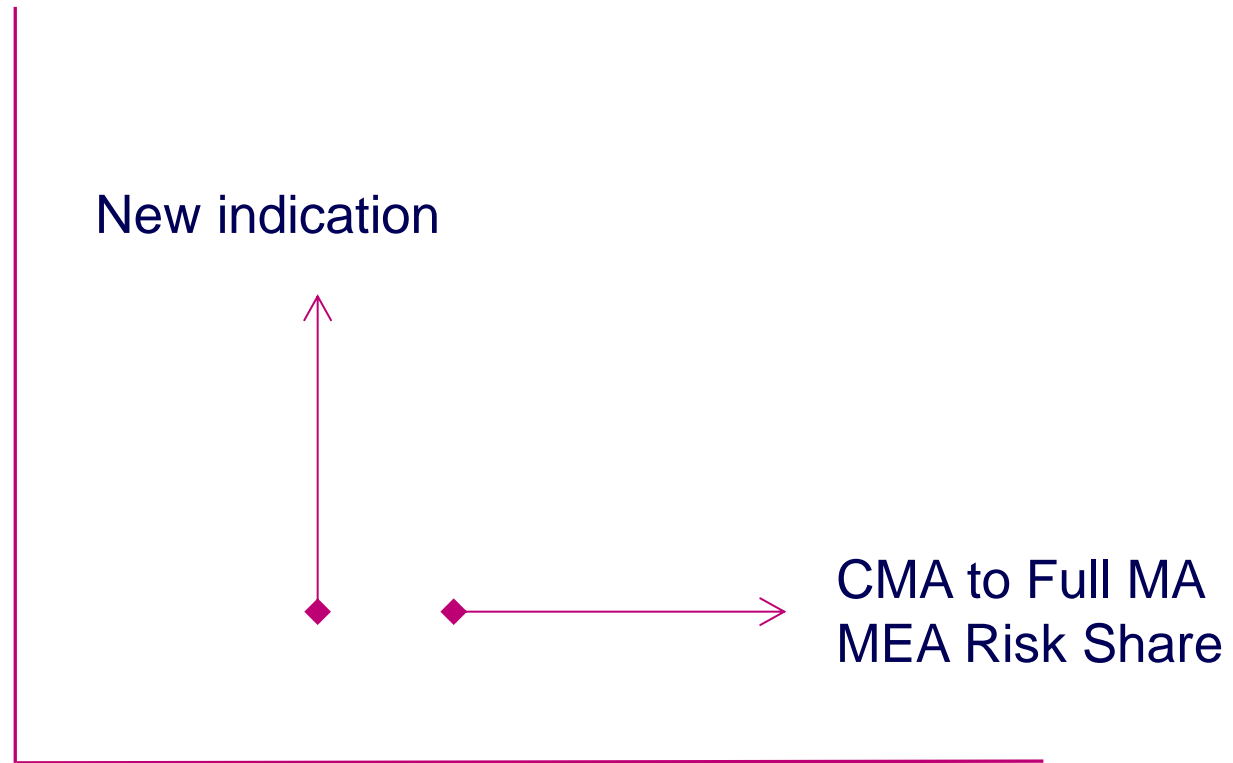# Comparison of Traditional Model with Adaptive Pathway

- Current model (a):
  - Single authorisation decision point
  - Pre-authorisation focus on RCTs
  - Rapid expansion of treated population after MA
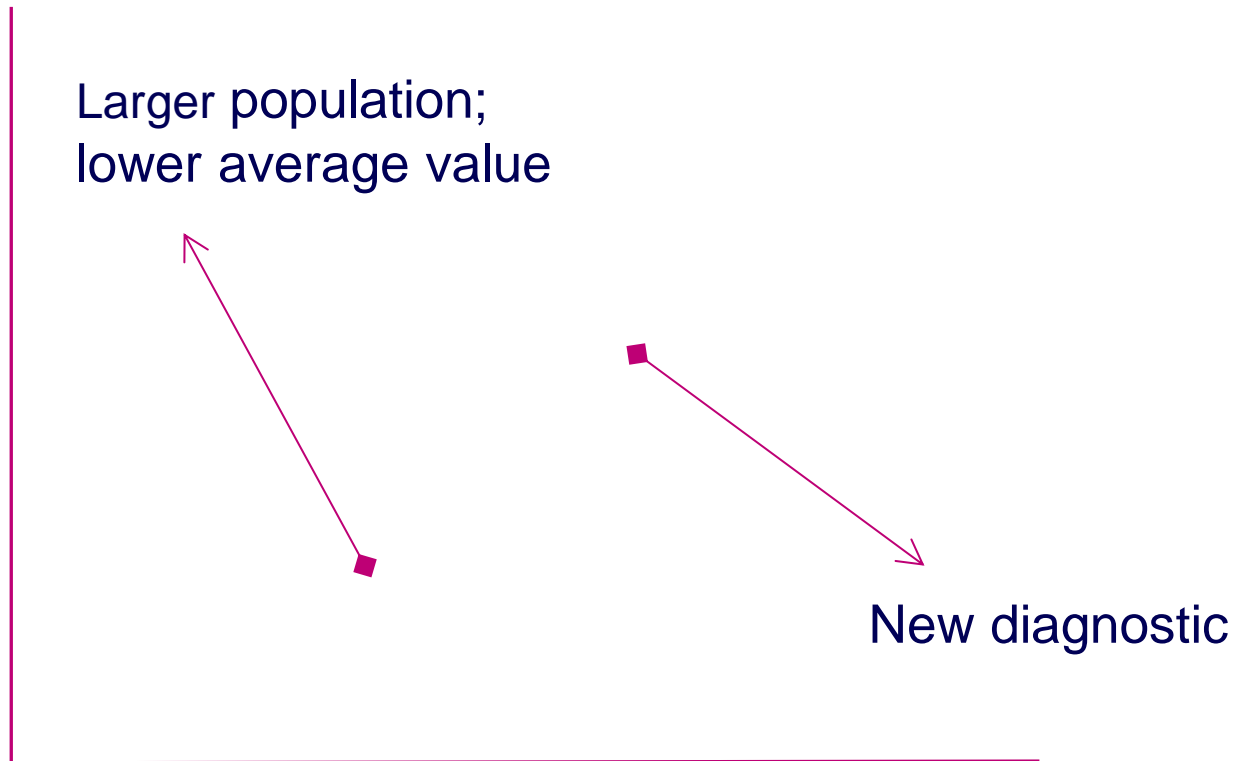 - Treatment experience contributes little to evidence generation

- Adaptive licensing (b):
  - Earlier "initial" MA and/or MA based on fewer patients
  - Prescribing restrictions slow expansion of treated population
  - Greater use of observational studies to capture "effectiveness" data
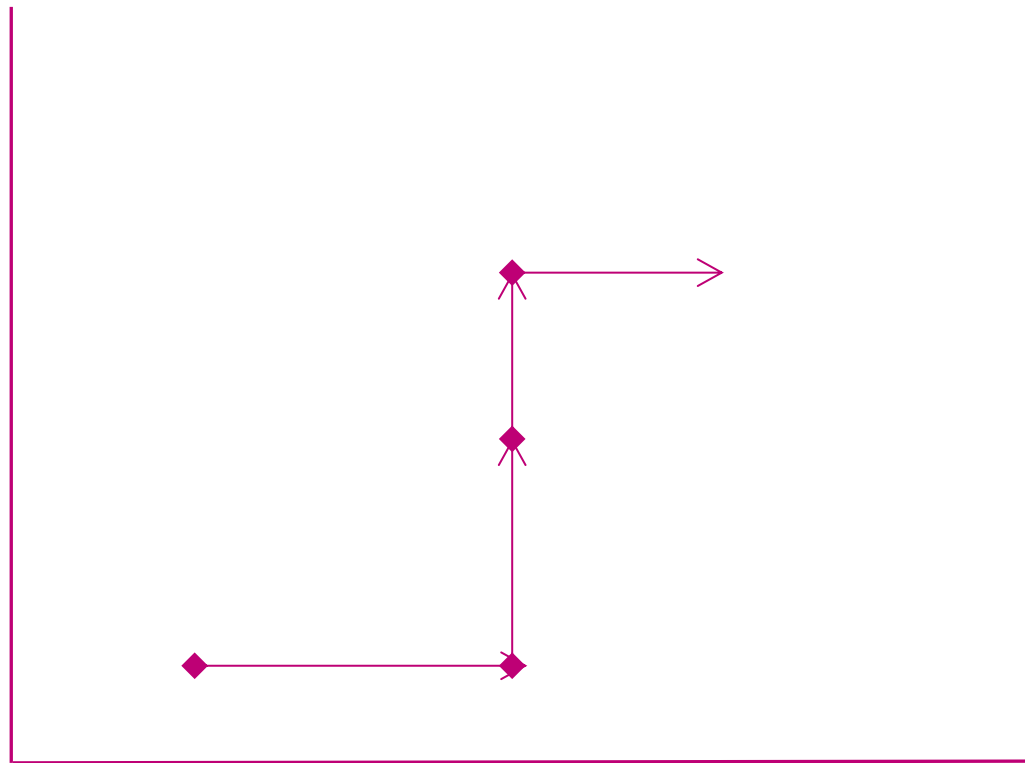 - Cycles of evaluation and label modification

Adaptive Pathways – a Framework & EMA pilot

Indicated
Population

New indication

CMA to Full MA
MEA Risk Share

Value: (Regulator = better benefit/risk)
(HTA/Payer = value for money)

Adaptive Pathways – a Framework & EMA pilot

Indicated
Population

Larger population;
lower average value

New diagnostic

Value: (Regulator = better benefit/risk)
(HTA/Payer = value for money)

Adaptive Pathways – a Framework & EMA pilot

Indicated
Population

Value: (Regulator = better benefit/risk)
(HTA/Payer = value for money)