Opportunities from Adaptive Pathways

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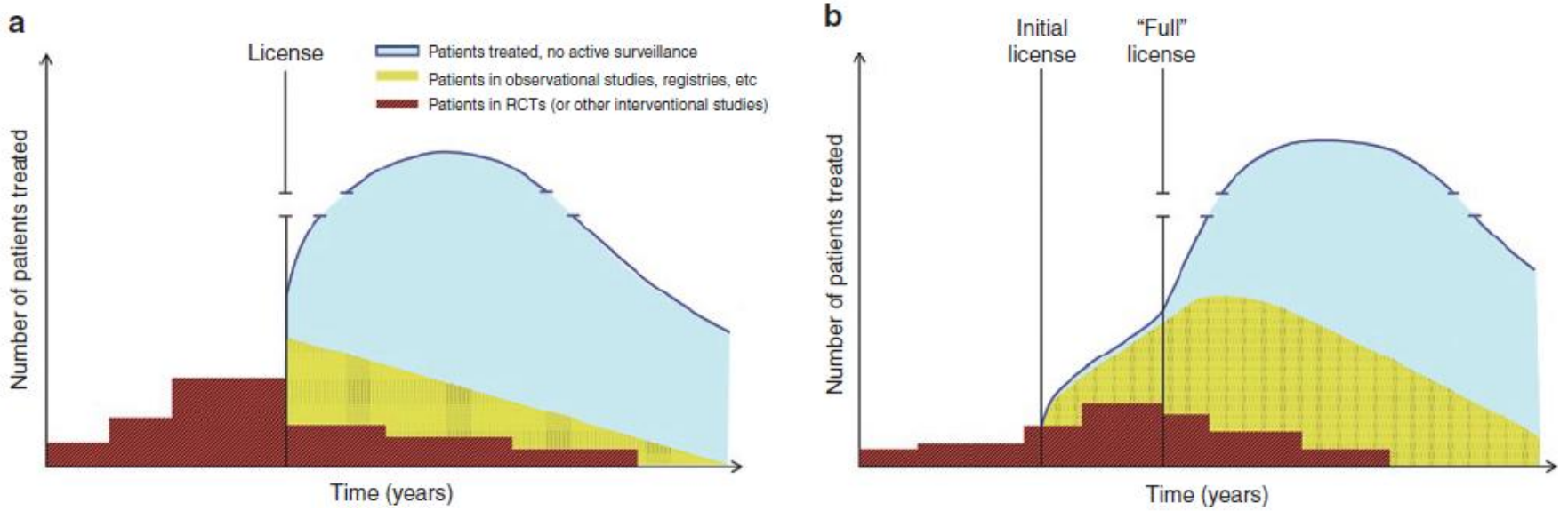
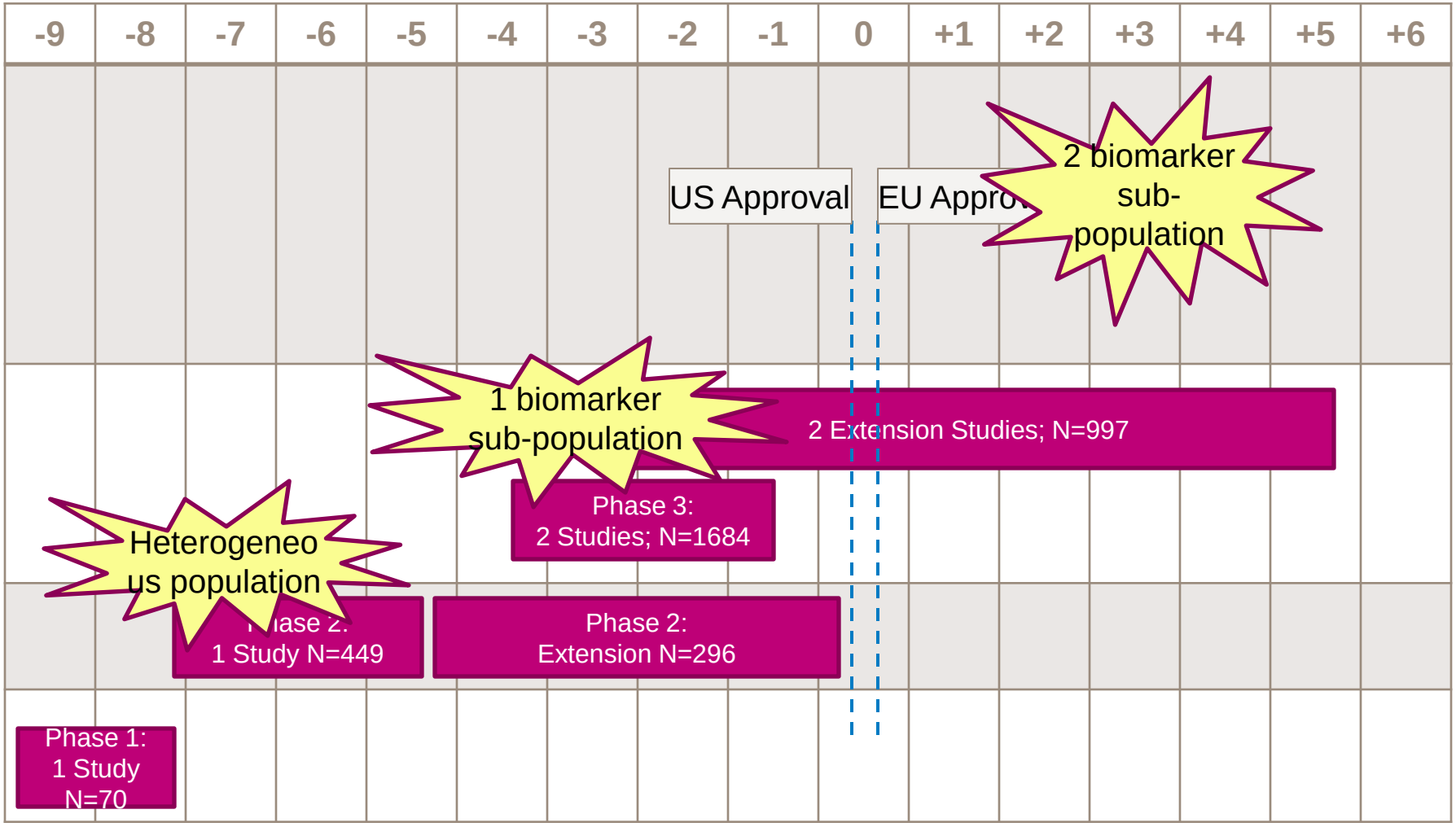
Which paradigm are we in today?



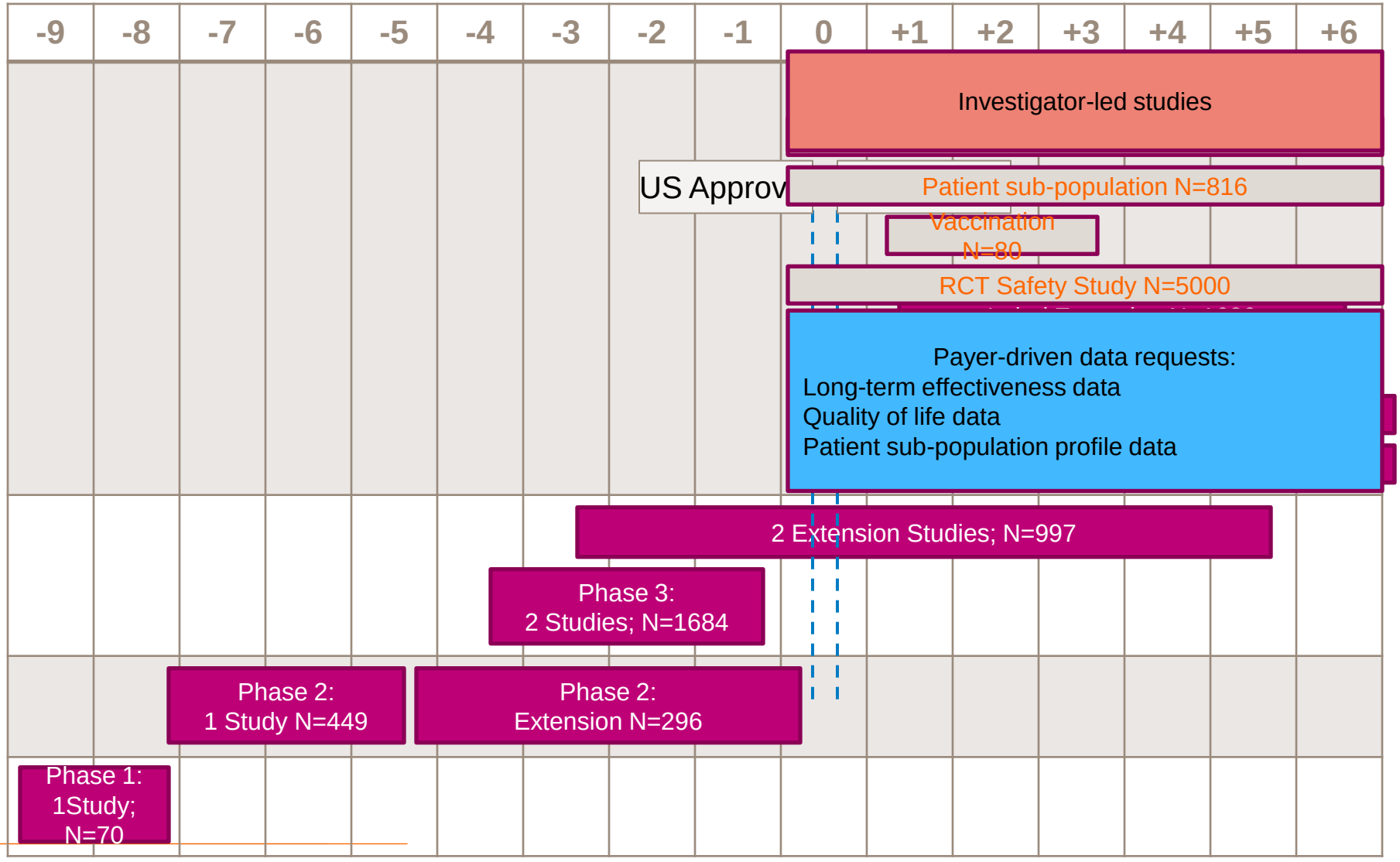
- Current model (a):
  - Single authorisation decision point
  - Pre-authorisation focus on RCTs
  - Rapid expansion of treated population after MA
  - Treatment experience contributes little to evidence generation
- Adaptive licensing (b):
  - Potentially earlier "initial" MA and/or MA based on fewer patients
  - Prescribing restrictions slow expansion of treated population
  - Greater use of observational studies to capture "effectiveness" data
  - Cycles of evaluation and label modification

Adapted from: Eichler et al – Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval. Clin Pharm & Ther (2012) 91 (3), 426-437

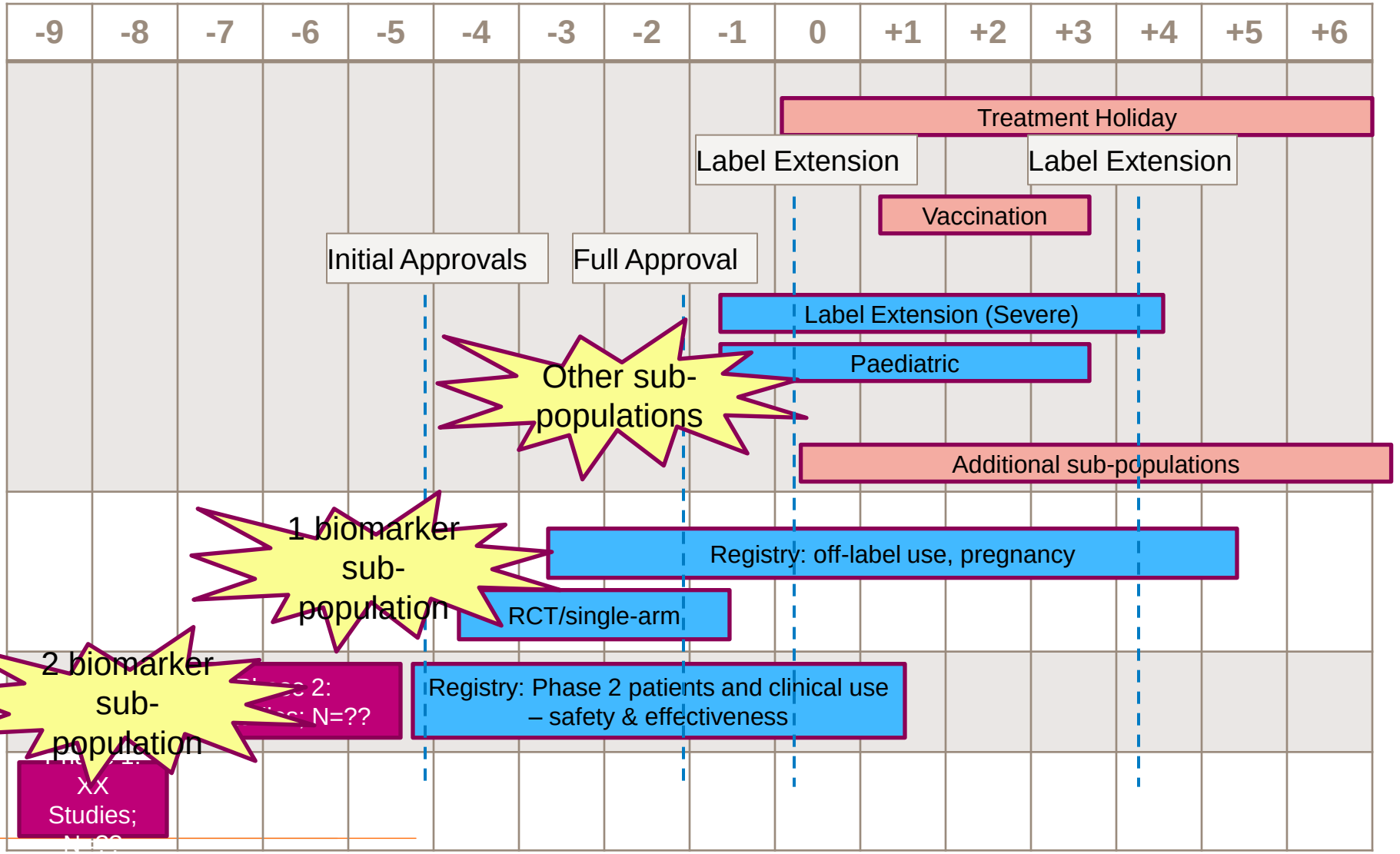
GSK Case Study: Clinical Development



Post-Approval Studies: Regulators, Physicians & Payers



What could AL have looked like?



EMA Safe Harbour Platform and Adaptive Pathways

Remaining Challenges

- Will payers pay and how much?
- How to manage use before full approval?
- How to manage withdrawal/ reduce patient populations?
- Ability to conduct studies after initial approval

Characteristics of Suitable Medicines

- Identifiable sub populations with high unmet needs
- Reasonable chance of meaning-ful clinical benefit
- Challenges for traditional development pathways

But NOT a ‘short-cut’ for development
NOT only for rare diseases
NOT a new Regulatory pathway or Legal framework


gsk
do more
feel better
live longer
Thankyou