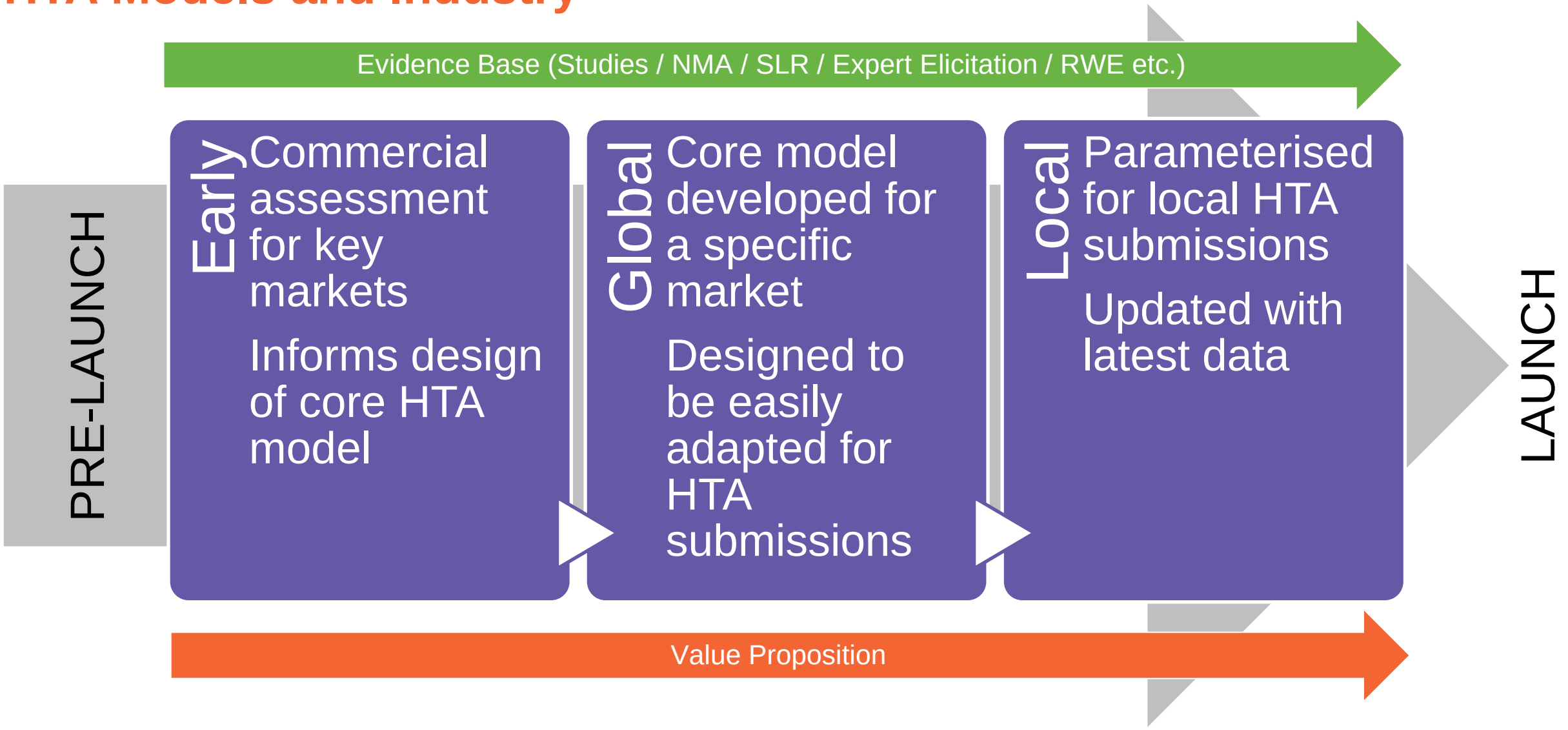
Disease-Specific Reference Models for Health Technology Assessment: Necessity or Nice-to-Have?

Jon Tosh, PhD
GSK

HTA Models and Industry



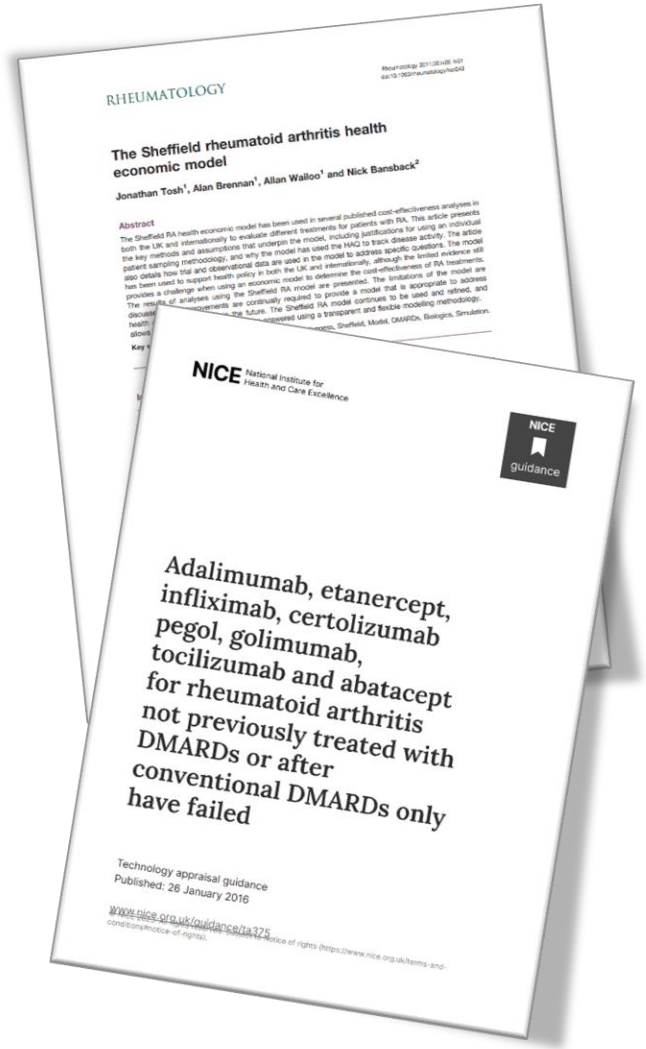
Industry Perspective

- Supportive of streamlining HTA processes
  - Efficiency
  - Earlier access for patients
- Reducing modelling burden
  - Could enable time and resource to focus on other evidence generation activities (e.g. RWE)
- More predictable decision-making could result in greater certainty in HTA outcome
  - Potentially reducing futile submissions and speeding up the HTA process

Examples of Disease-Specific Reference Models

Sheffield model for Rheumatoid Arthritis in UK

- Model used for two NICE multiple technology appraisals, and a NICE clinical guideline
  - Informed NICE guidance for 7 biologics
  - Also contributed to US Medicare guidelines
- Model evolved over time
  - Utilised innovative RWE analysis
  - Multiple decision-nodes in treatment sequence
- Did not streamline the evidence submission process
- Very complex decision-making, taking a long time



Tosh, J., Brennan, A., Wailoo, A., & Bansback, N. (2011). The Sheffield rheumatoid arthritis health economic model. *Rheumatology*, *50*(suppl_4), iv26-iv31.
Stevenson, M., Archer, R., Tosh, J., Simpson, E., Everson-Hock, E., Stevens, J., ... & Wailoo, A. (2016). Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for the treatment of rheumatoid arthritis not previously treated with disease-modifying antirheumatic drugs and after the failure of conventional disease-modifying antirheumatic drugs only: systematic review and economic evaluation. Health technology assessment (Winchester, England), 20(35), 1-610.

Examples of Disease-Specific Reference Models

NICE COVID-19 Multiple Technology Appraisal (TA878)

- Evidence Assessment Group developed a model to inform guidance for several COVID-19 therapeutics
- Bespoke process with streamlined evidence submission
  - Did not reduce timelines compared to standard process
  - Model development was challenging
  - Not clear if more efficient for NICE or companies
- Multiple appeal points upheld with ongoing assessments for several treatments

https://www.nice.org.uk/guidance/ta878

Challenges

May not enable companies to fully demonstrate value proposition for a health technology

Model reliant on studies/RWE to inform it

- Who will be responsible for this?

Complex modelling may not capture innovation/value of a health technology

- Structural changes?
- Is it ‘future proofed’?
- Intensive processes to engage stakeholders

Risk of an unfair situation

- Difference in different disease areas?

Open Source Models

- Standard HTA process where company still presents value proposition
  - Chooses whether to use open source model
- Lighter-touch HTA review/streamlined evidence submission
  - Key assumptions and data sources have been validated
  - Model code has been validated
- Reduces burden for HTA agency and company
  - Opportunity for faster access

Conclusions

Will it improve patient access and what are the potential unintended consequences?

Modelling approach may be desirable and potentially feasible, but is not without challenges

Open-source modelling may be a suitable first step