

Breakout session on complex clinical trials, platform trials – a HTA perspective

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ACT EU PA08 multi-stakeholder workshop on methodology guidance:
collaborating across the regulatory network

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Context of health technology assessment

- Our question: comparative effectiveness (is there any difference between a new intervention and the current standard of care/best available treatment?)
- => inform treatment decisions, inform pricing and reimbursement decisions

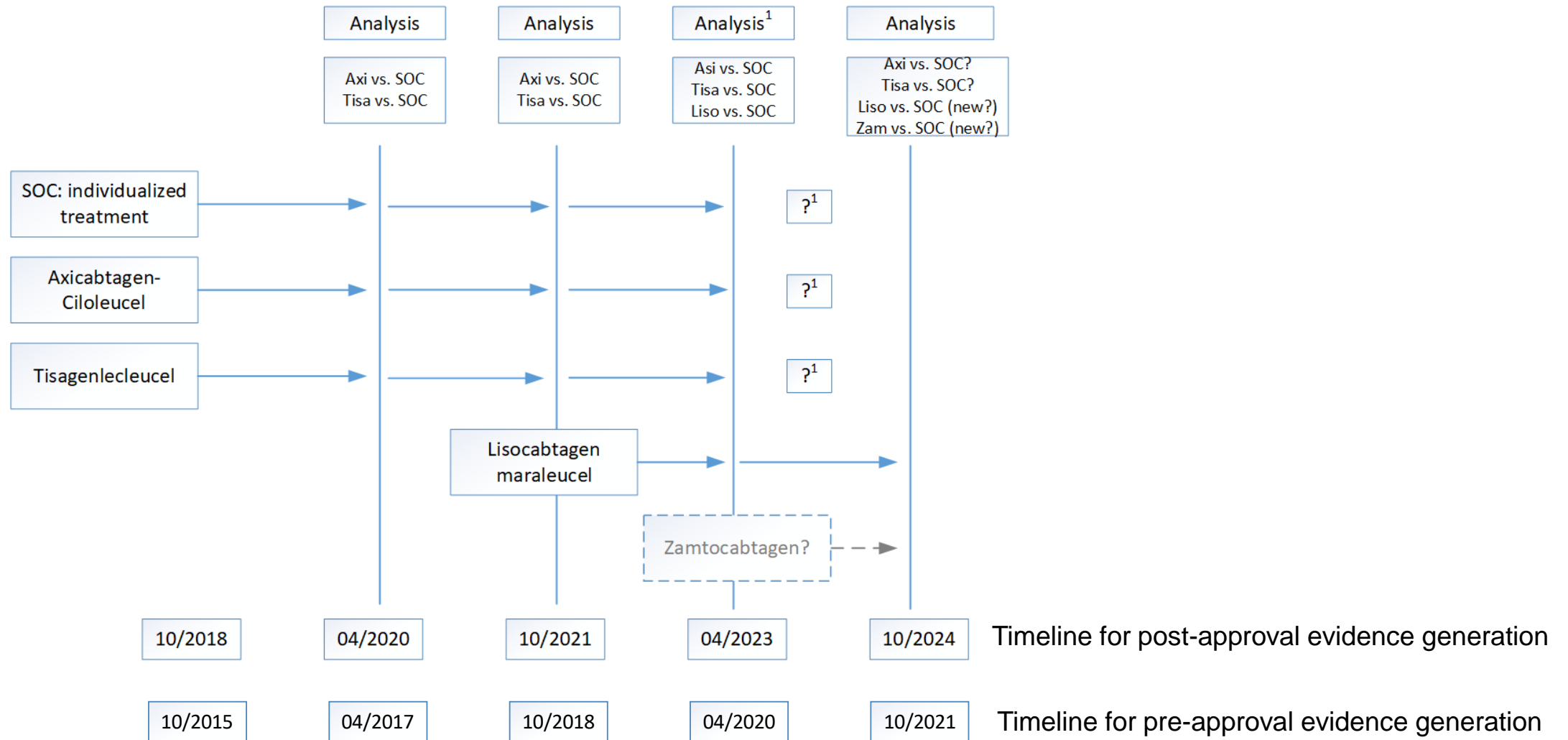


- We often lack data to answer our question
- We need more and other studies to enable a description of comparative effectiveness

Why (randomised, adaptive) platform trials?

- We need comparative data also in small populations
- Randomised trials provide more robust results, non-randomised treatment comparisons (including indirect comparisons of single arm trials) require huge efforts to overcome confounding
- We need adaptive designs to react to changes in health care systems, i.e. new treatment options

Randomised adaptive platform trial for CAR-T cells in r/r DLBCL



1: change comparator?

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