



TANDVÅRDS- OCH

LÄKEMEDELSFÖRMÅNSVERKET

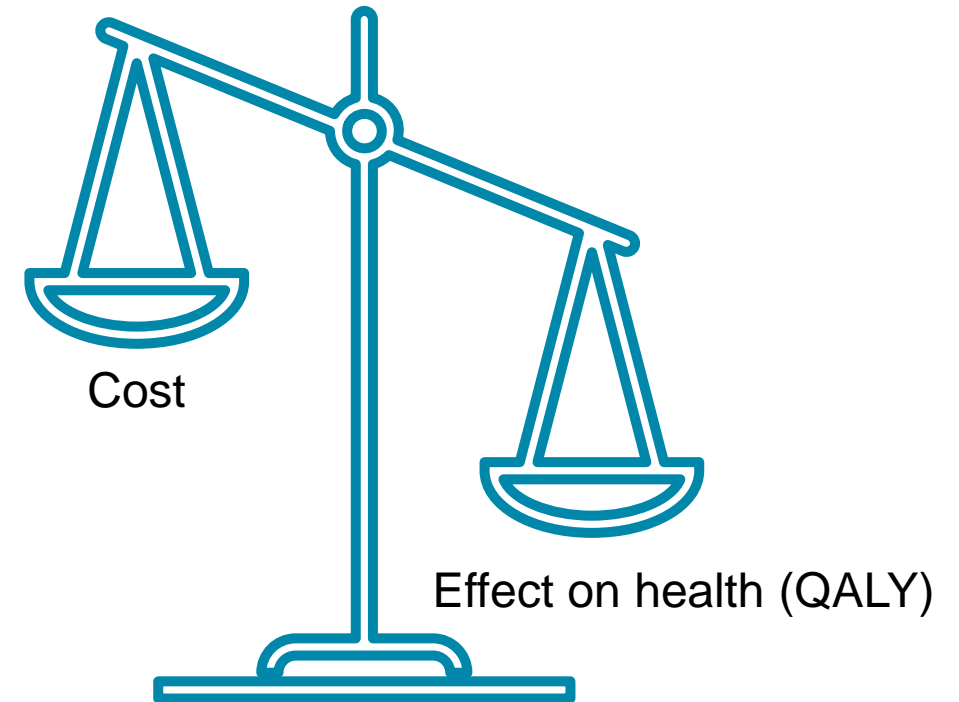
HTA's view on complex innovative designs

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Health Technology Assessment (HTA)

- ❖ Evaluates the magnitude of effect in relation to the cost of a product
- ❖ Involves the health economy of the product
- ❖ Might determine whether a pharmaceutical product or medical device shall be subsidized



$$\text{Incremental Cost Effectiveness Ratio (ICER)} = \frac{\text{Cost}_A - \text{Cost}_B}{\text{QALY}_A - \text{QALY}_B}$$

Regulatory vs HTA evaluation

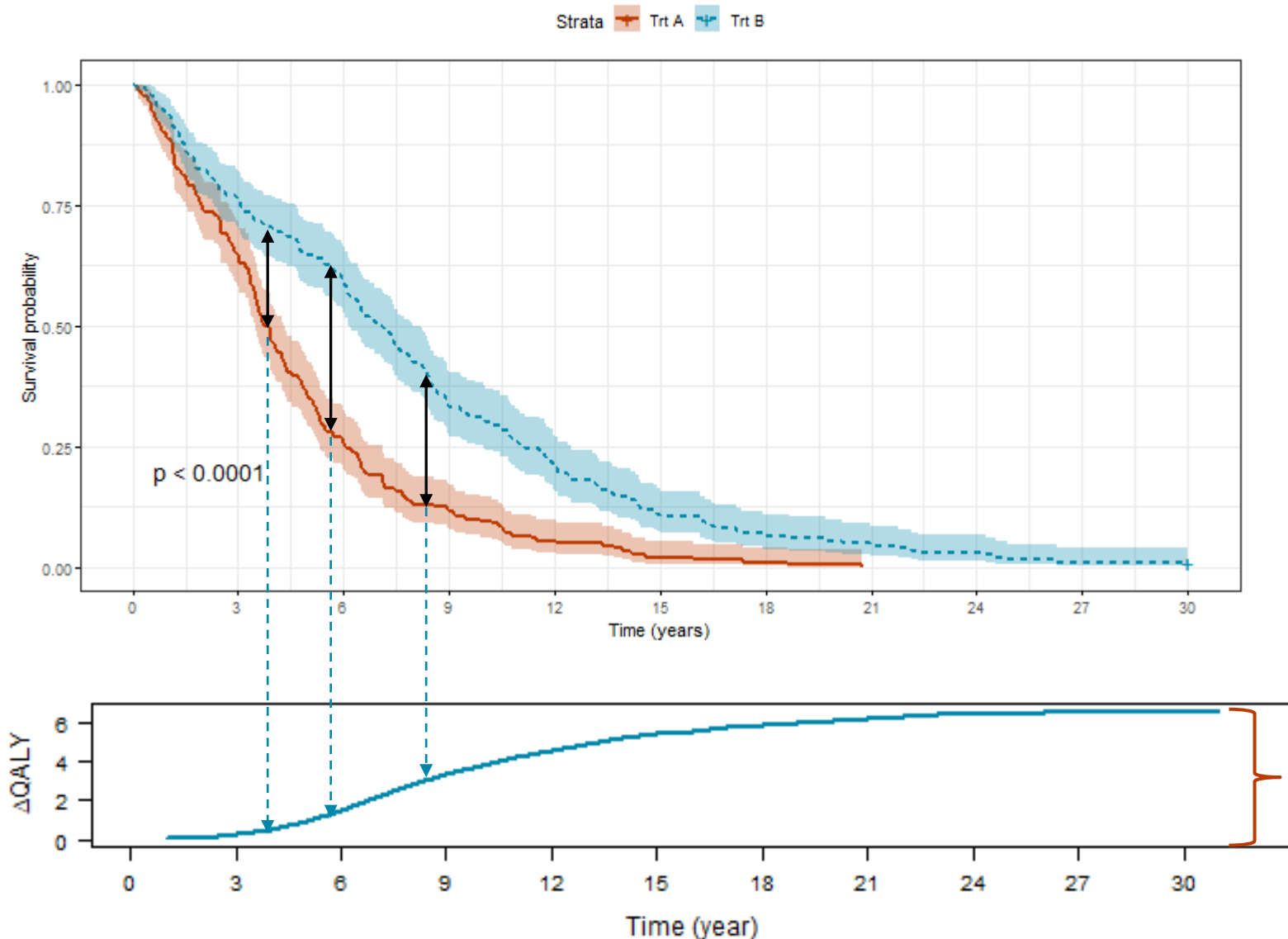
Regulatory evaluation

- ❖ Evaluates risk-benefit of a product
- ❖ Often based on several clinical studies
- ❖ Is the product safe to use?

HTA evaluation

- ❖ Evaluates the cost-effectiveness of a product
- ❖ Often based on the same clinical data as regulatory evaluation
- ❖ Is the product worth the money?

How do we evaluate cost-effectiveness?

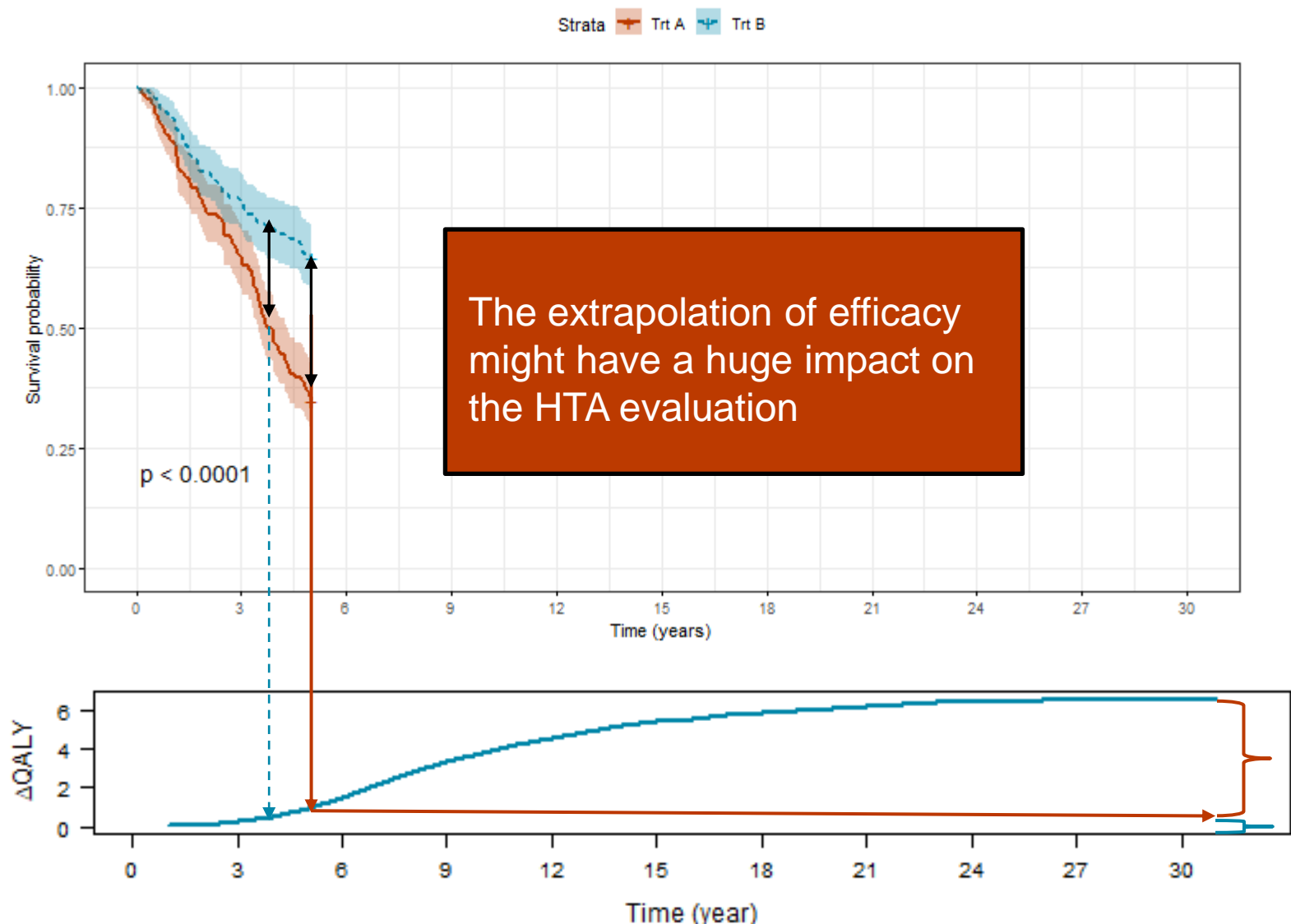


Price of product

$$ICER = \frac{\Delta Cost}{\Delta QALY}$$

Cumulative health gain

How do we evaluate cost-effectiveness? cont.



Price of product

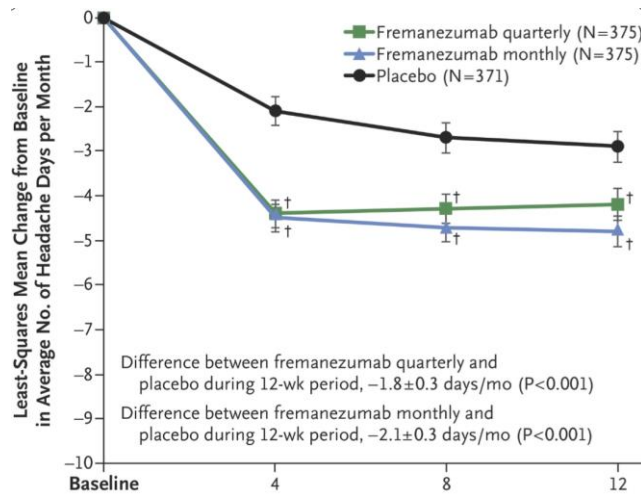
$$ICER = \frac{\Delta Cost}{\Delta QALY}$$

Cumulative health gain

80% of ΔQALY extrapolated

The indication is of importance for HTA evaluation

Chronic migraine

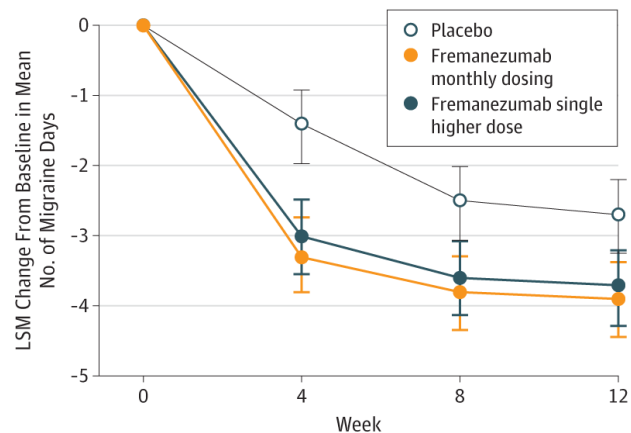


$$ICER = \frac{\Delta Cost}{\Delta QALY}$$

$\Delta QALY$

Episodic migraine

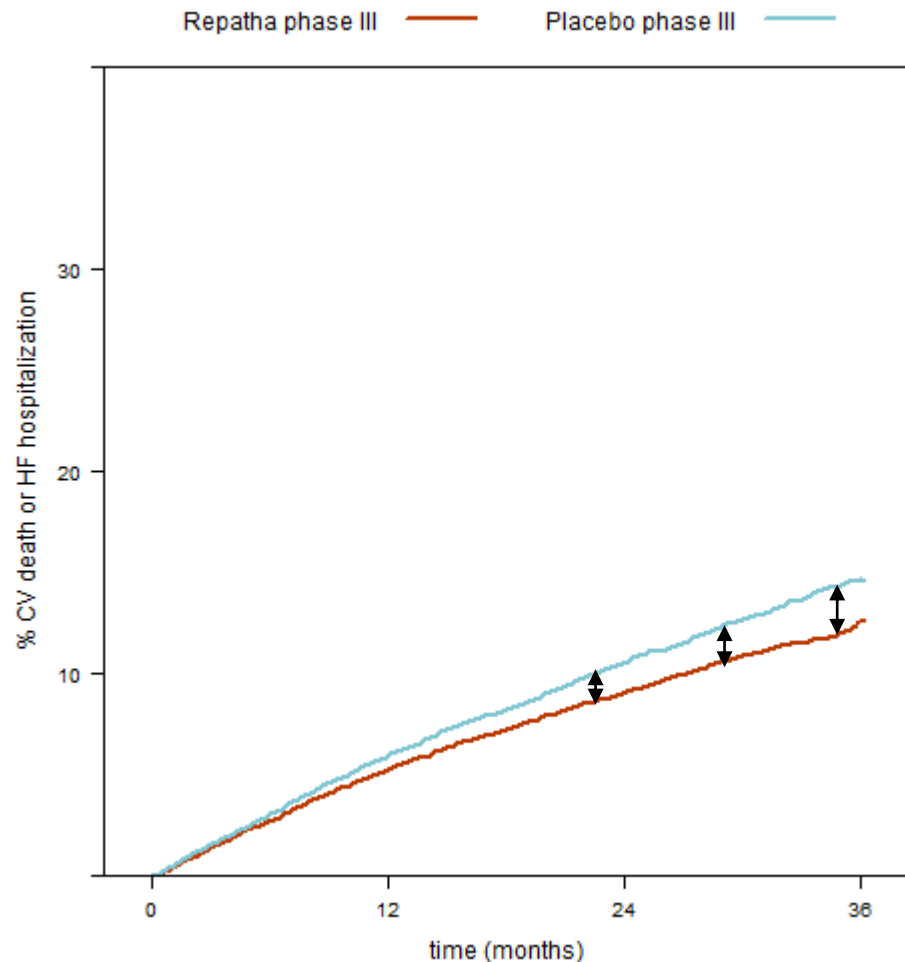
Change from baseline in mean monthly migraine days



$\Delta QALY$

- ❖ The different indications have the same relative reduction in days with headache
- ❖ Patients with chronic migraine have more days of headache at baseline -> number of days with reduced headache is larger
- ❖ Pricing is based on $\Delta QALY$ for chronic migraine

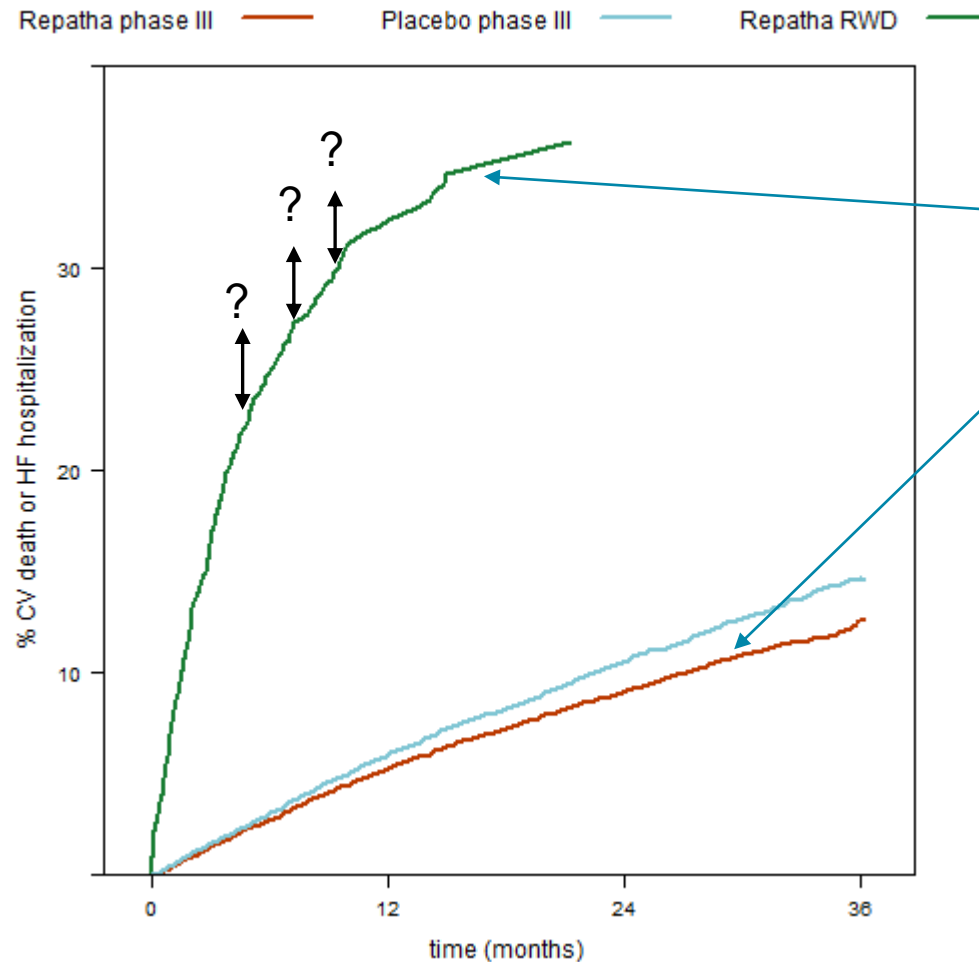
The intended population might impact the evaluation



Repatha significantly reduces the risk of CV death or heart failure hospitalisation

$$ICER = \frac{\Delta Cost}{\Delta QALY}$$

How do we predict the patient population?



- ❖ Observed data from clinical practice does not look like phase III results
- ❖ Does not necessarily indicate lack of efficacy
- ❖ Might depend on different population in real life compared to clinical study
- ❖ How a product is used in clinical practice might have impact on health economy

Take home message



Regulatory and HTA evaluations are not the same things



Cost effectiveness depends on both efficacy and price



An innovative design supporting a regulatory decision does not necessarily support the HTA evaluation