

# Risk Benefit Assessment

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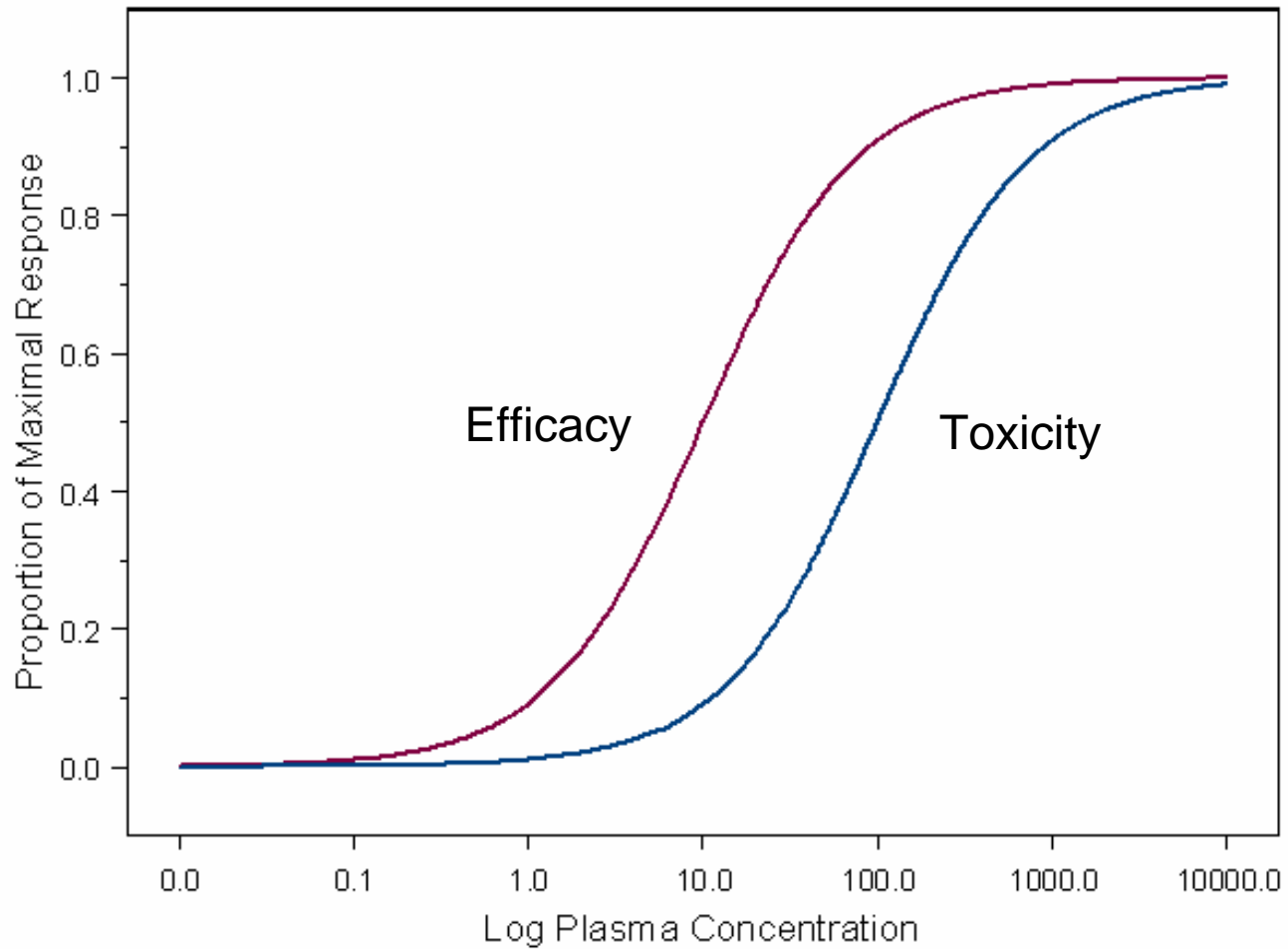
# Efficacy

- Has efficacy been demonstrated in the target population?
- Efficacy in comparison with placebo?
- Efficacy in comparison with active comparator?
- Alternative treatments?

# Safety

- Adverse event profile in the target population
- SAEs
- Tolerability: withdrawal from treatment because of AEs

# Therapeutic Index



# Risk Benefit Profile

- Benefit
  - Efficacy
  - Disease burden/natural history
  - NNT
- Risk
  - AEs
  - Tolerability
  - NNH
- Value judgment