

# Retinopathy of Prematurity

- ROP – exclusively neonatal condition
  - highest incidence in neonates < 28 weeks GA
  - incidence and severity increases by increasing the degree of prematurity
- Non-medicinal treatment
- Medicinal treatment
  - treatment of the disease /anti-VEGF agents/
  - prevention – scientific and regulatory challenges

# Research challenges

- New trend – prevention of ROP by substitution of hormones dropping after premature birth
- Design of CTs for ROP prevention:
  - not all preterm neonates develop ROP
  - Type 1 ROP incidence in neonates < 25 w approx. 25%, while in neonates with the GA between 25 and 28 weeks only 2 – 3%
  - multifactorial condition /degree of prematurity, i/u growth retardation, oxygen supply, gender, concurrent illness, hypoxia/
  - validated prediction tool for development of severe ROP not available

## Research challenges – points for discussion

- Inclusion criteria
- Selection of the target population – universal administration vs population at highest risk
- Sample size- sufficient and realistic?
- Study endpoints - ‘qualitative’ vs ‘quantitative’
- Safety follow-up – how long?
- Dose calculation – substitution? Intrauterine levels?
- Ethical considerations
  - universal administration- unnecessary exposure?
  - risk/ benefit assessment