# Regulatory Panel

Joint EIP / ABIRISK Scientific Symposium

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Panel members:

- Dr Amy Rosenberg (Division Director, OBP, CDER, FDA)
- Dr Joao Pedras-Vasconcelos (Biotech Quality and Immunogenicity Reviewer, OBP, CDER, FDA)
- Prof Pekka Kurki (Finnish Medicines Agency)

Theme:

# Regulator's priorities for assessment of immunogenicity-related risks

1. Early risk assessment / pre-Phase 1
2. Mid-stream (Phase 1 & 2 Clinical studies)
3. EOP2 to Marketing Authorization Application
4. Post-approval / Life-cycle management