



# Non-clinical development checklist

- Perform a risk based approach
- Conduct safety and toxicity studies
- Address safety concerns from previous trials
- Conduct proof-of-concept studies
- Investigate pharmacokinetics
- Have a clear rationale for the tissues selection in the pharmacokinetics studies
- Determine intended patient population
- Assess relevance and suitability of animal model
- Use the same administration route as will be used in clinical studies
- Identify the role and added value of each of the separate components of the cell product
- Apply the same manufacturing process to the materials used in pivotal studies as will be used in clinical studies
- Ask for Scientific Advice

