

**Decisions in a Proof of Concept Strategy ? A union between pharmacology and statistics**  
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Proof of Concept (PoC) is the decision point to promote a candidate beyond a development milestone or not. A good decision requires a quantitative definition of the criteria and optimal information to support it. Achieving this goal efficiently requires that all exploratory activities supporting PoC must be planned so as to optimally support this decision. Statistical approaches which set a Level of Proof by balancing risk in terms of probability of success and level of current investment, given clinically relevant decision criteria, provide an elegant framework for making PoC related decisions. Given clearly defined quantitative criteria, it is then possible to define information needs required to support this decision. Model based approaches which take into account the underlying pharmacology are the most efficient means of generating quantitative information on drug candidates in an exploratory setting. Thus, the aim of a PoC strategy becomes one of designing studies to provide data, which is in turn transformed into model based information and fed into the pre-defined decision making process. Achieving this goal requires an integration of Pharmacology and Statistical modeling skills to provide a clear well-defined process to clinical development teams.