Executive Summary

This document describes the proof-of-concept trial design skeleton. The goal of this document is to create an overall structure of the PoC trial to allow further investigation and optimization of the trial through the simulation process. The skeleton typically provides the overall structure of randomization, modelling, and adaptive features of the trial.

This document will allow progress to be made on the simulations and trial optimization. In addition this will allow initial drafts of synopses and protocols to be progressed.

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