Optimising First In Human (FIH) Studies

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The Problem

Question

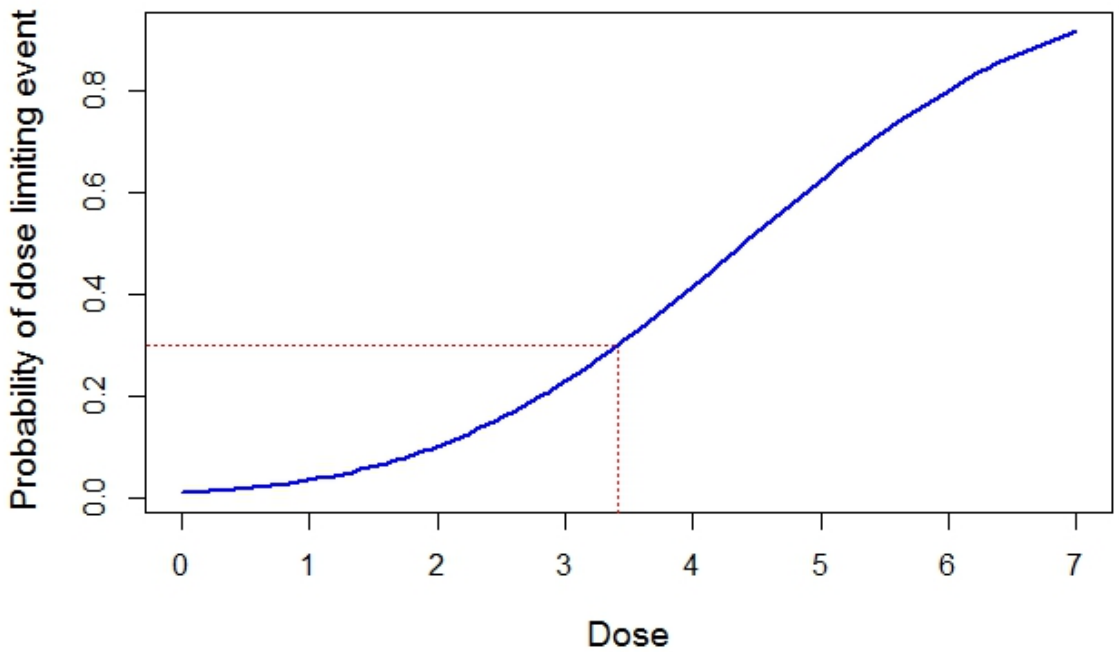
How can we optimise First In Human studies?

Aims

- SAD: Optimise the dosing scheme based on safety endpoints
- MAD: Incorporate efficacy endpoints

Optimising Single Ascending Dose (SAD) Studies

- Study aim: find the Maximum Tolerated Dose (MTD)



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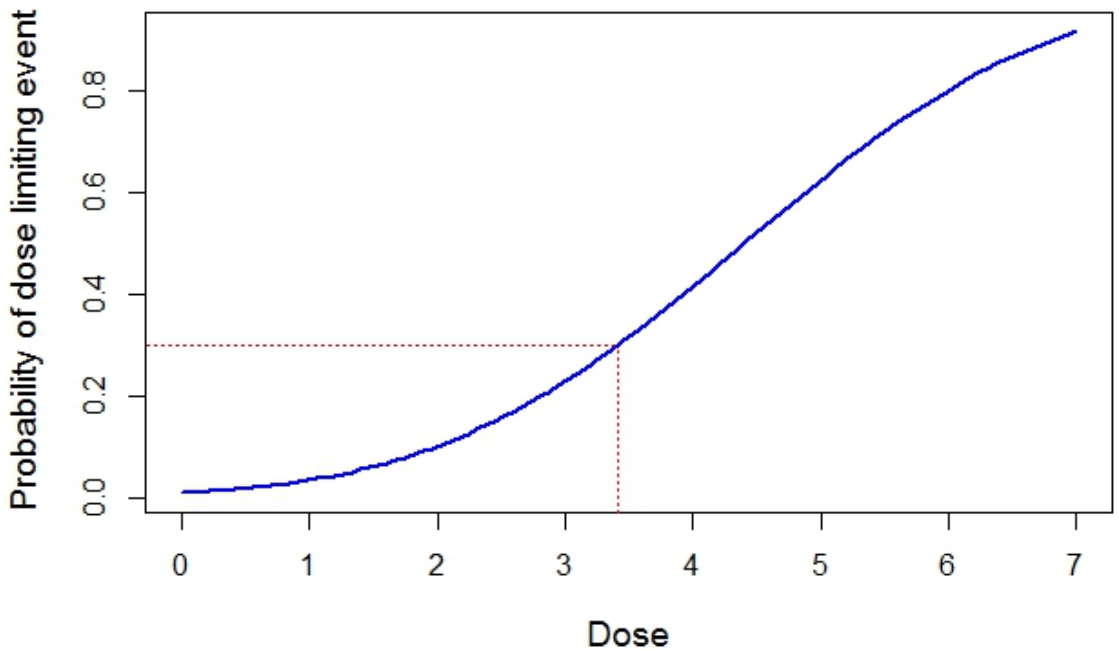

Measure of success

$$|p-\gamma|\ \beta_1 \mathbb{I}\{p>\gamma\} + |p-\gamma|\ \beta_2 \mathbb{I}\{p<\gamma\}$$

Optimising Multiple Ascending Dose (MAD) Studies

- Study Aim: Assess safety when dosed multiple times
- Can we see an early signal of efficacy using a biomarker endpoint?
- Improve the information carried forward to Phase II