

Human dose prediction approach for a therapeutic monoclonal antibody for a CNS indication inferred using preclinical data including target occupancy

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Introduction

Providing a prediction of the efficacious dose needed to treat patients is a key element to support the developability of a mAb¹ and design the initial clinical trial.

This case study presents our approach to provide a human dose prediction for a mAb which targets an extracellular protein within the CNS². It uses target engagement characterization and leverages the preclinical data from human *ex vivo* model and NHP³ *in vivo* target occupancy studies.

Methods

