

Using the MBAOD package

Andrew C. Hooker

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1 Introduction

The MBAOD (Model Based Adaptive Optimal Design) package can be used to simulate clinical trials using predefined adaptive and optimization rules. In addition the package can be used to optimize any specific cohort of an actual study using MBAOD.

Adaptive designs (AD), in general, are a way to adapt experiments as your understanding of the system you are studying improves through intermediate analyses of the experimental data. Adaptive **optimal** design (AOD) uses optimal design theory as a way to design the next stage of your study. In this package we are assuming the use of **population** models for both the estimation of parameters (analysis of data) as well as for the optimization of the various cohorts of our experiment (see figure 1).

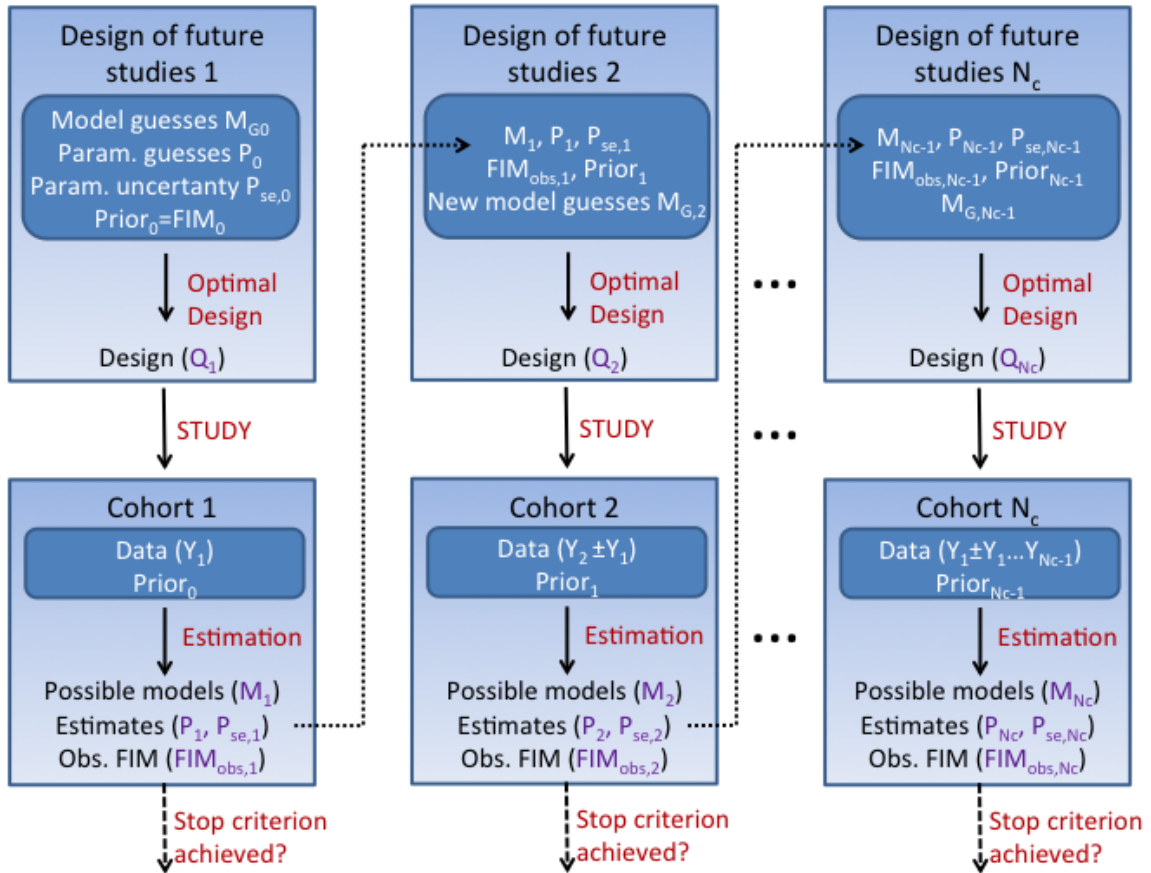


Figure 1: General schematic of a model based adaptive optimal design.

This package currently uses PopED, NONMEM, PsN and R to handle the various tasks inherent to simulating and evaluating an MBAOD experiment (see figure 2). The code has been written to be (hopefully) quite

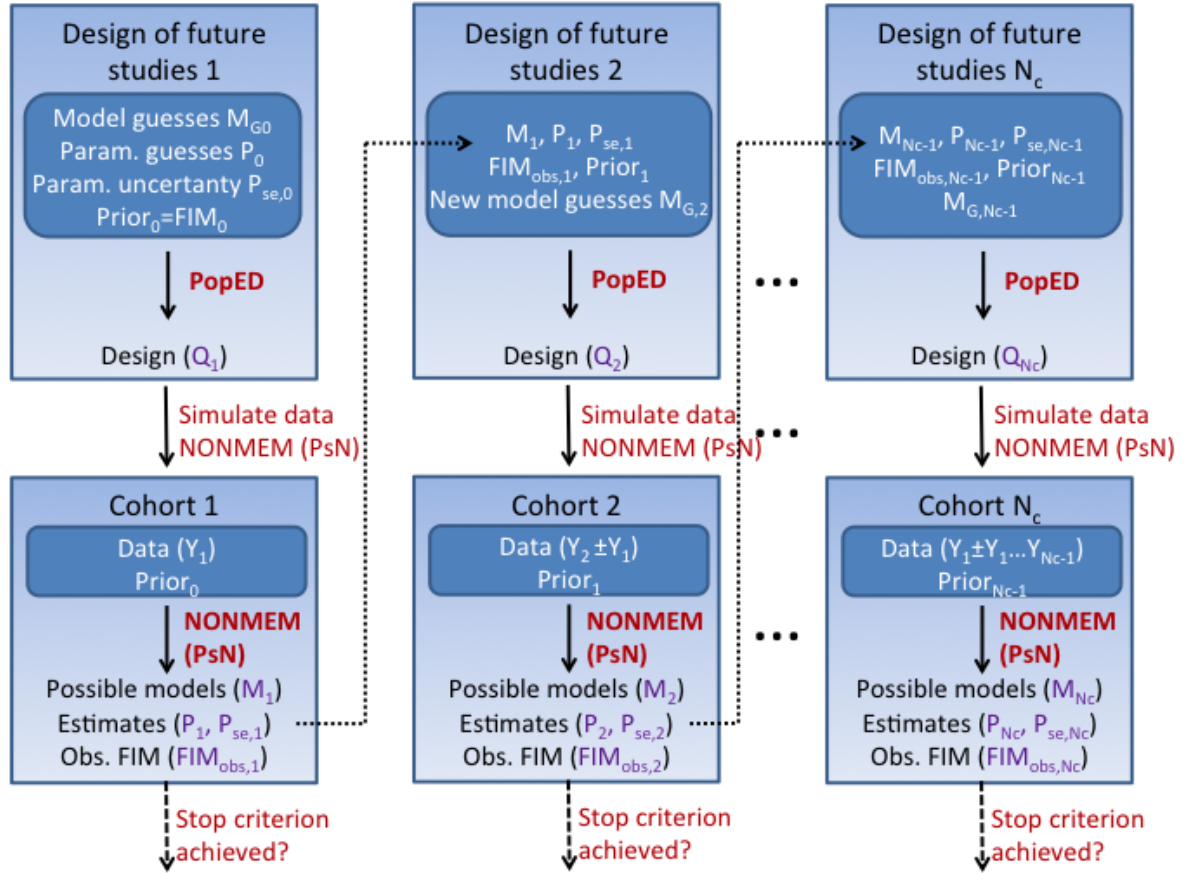


Figure 2: Specific schematic of MBAOD implemented in the MBAOD package. The entire process can be repeated multiple times and then the results of those repeated simulations can be summarized using R.

modular, so that other tools can easily be switched in place of the current tool set (e.g. PFIM instead of PopED).

This document describes how to install and use the MBAOD (Model Based Adaptive Optimal Design) package.

2 Installation

- You need to have R installed. Download the latest version of R from <http://www.r-project.org>.
- Install PopED for R. To install the latest stable release from CRAN, write at the R command line:

```
install.packages("PopED")
```

- NONMEM and PsN (<http://psn.sf.net>) should be installed. Cluster installations accessible via ssh should be ok.

3 An example