

Assignment 1 solutions for m2001207

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This document is not designed to be a perfect example of what you should have done in the assignment, it simply provides some example text alongside tables and figures.

In this study, 50 mg of drug ND42 was given to 8 participants. Table 1 summarises the characteristics of the study participants. The median weight was 67kg (range 48.8 to 78.5kg). Fourteen samples were taken from each participant over a 24 hour period. Figures 1 & 2 show the time concentration profile for individuals and a mean profile respectively.

Tables 2 and 3 show a summary of the non-compartmental analysis of these data. Mean $AUC_{0-\tau}$ was 11.5 mg.h/L. C_{max} was 1.11 mg/L, which was reached in a median time of 4 hours (median) with a range of 1.5 to 6 hours. Mean CL/F was 4.18 L/hr and V/F was 27.1 L. The drug had a mean elimination half life of 4.42 hours.

Table 1: Summary of participant characteristics

| Characteristic | N = 8 |
|----------------|-------------------|
| Weight (kg) | 67.0 (60.0, 71.7) |
| Height (m) | 1.66 (1.55, 1.73) |
| Female | 4 (50%) |

¹ Median (IQR); n (%)

Table 2: Standard pharmacokinetic analysis using PKNCA

| $AUC_{0-\tau}$ (h.mg/L) | C max (mg/L) | T max (hours) | Half life (hours) | $AUC_{0-\infty}$ (h.mg/L) |
|-------------------------|--------------|-------------------|-------------------|---------------------------|
| 11.5 [17.8] | . | . | . | . |
| . | 1.11 [12.9] | 4.00 [1.50, 6.00] | 4.56 [0.783] | 12.0 [19.3] |

Tmax: median [range], half-life: arithmetic mean [standard deviation]. Other parameters are presented as geometric mean [coefficient of variation]

Table 3: k_e , CL/F and Vd/F estimates using a non-compartmental approach

| Elimination rate constant (k_e) | Clearance/F (L/hr) | Volume of distribution/F (L) |
|-------------------------------------|--------------------|------------------------------|
| 0.131 [10.3] | 4.18 [19.3] | 27.1 [14.6] |

Parameters are presented as geometric mean [coefficient of variation]

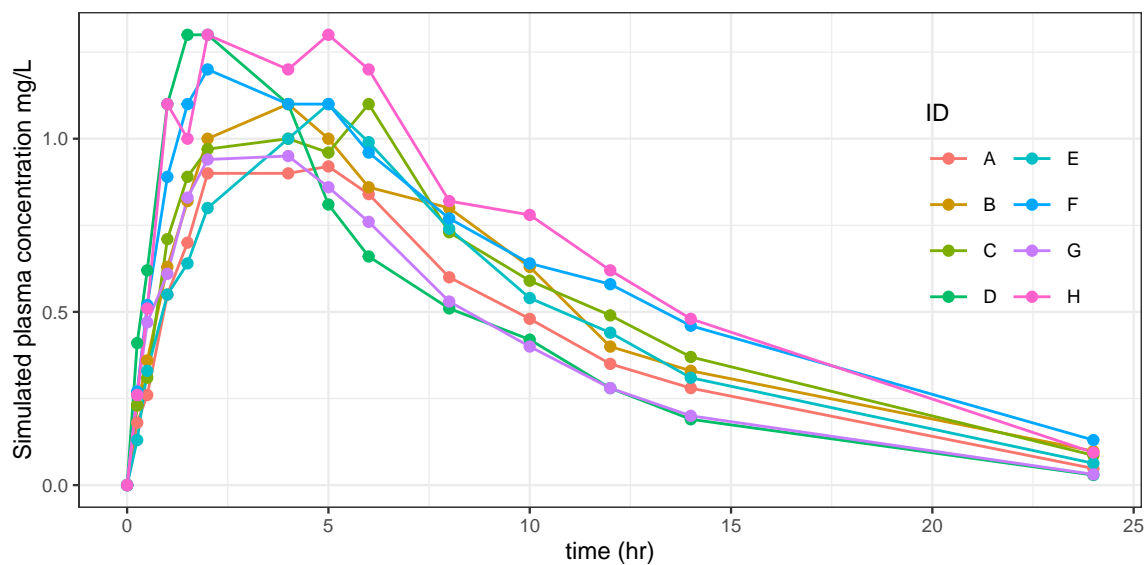


Figure 1: Concentration-time plot for drug ND42

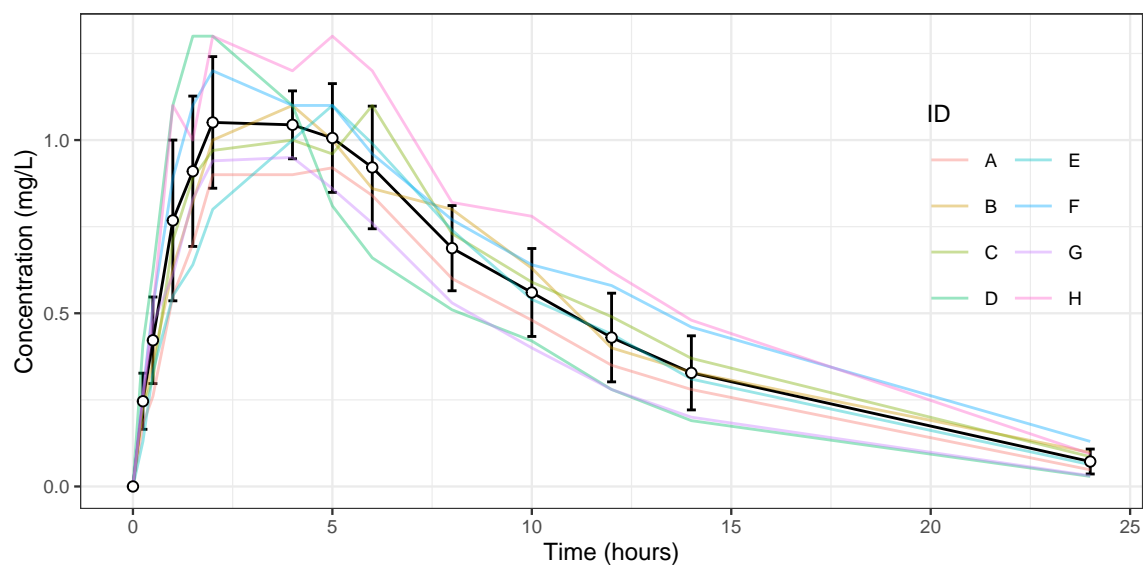


Figure 2: Concentration-time plot for drug ND42, showing individual plots in colour and mean concentration with standard deviation superimposed (black line)