



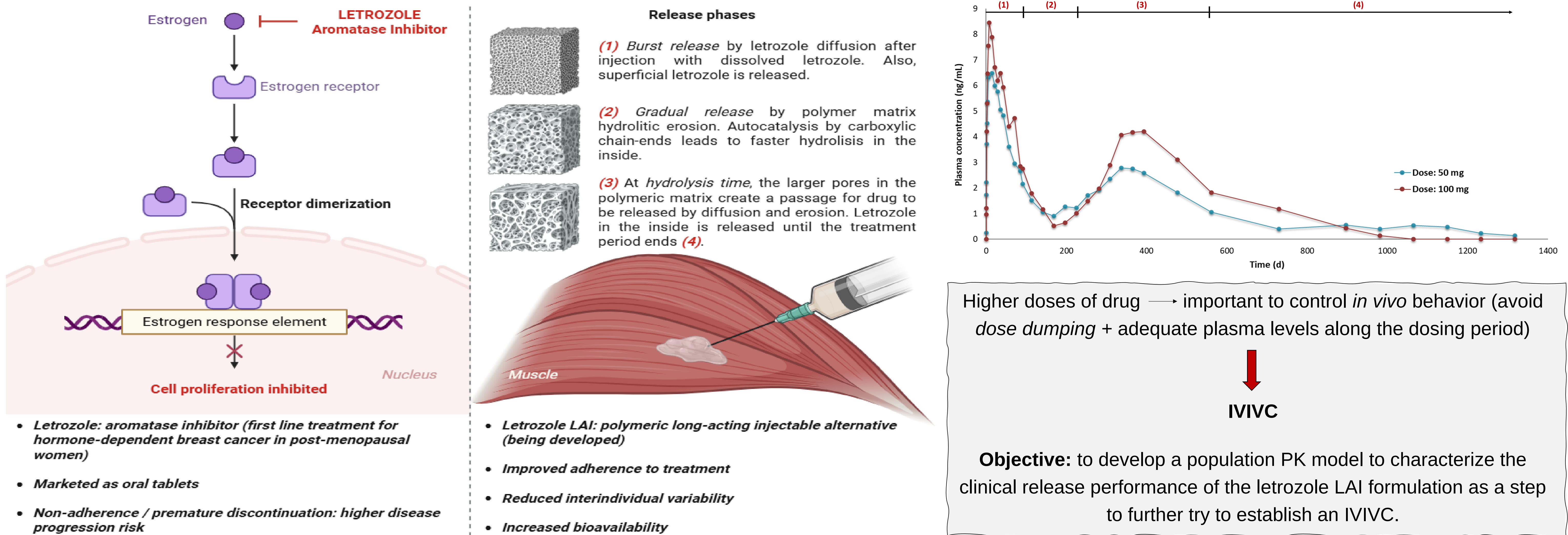
Population analysis of the clinical pharmacokinetic characteristics of a letrozole long-acting injectable formulation

Castiñeiras, Adriana^{1,4}; López Ginés, Gema⁴; Trocóniz, Iñaki^{1,2,3}



(1) Department of Pharmaceutical Sciences, School of Pharmacy and Nutrition, University of Navarra, Spain. (2) IdISNA, Navarra Institute for Health Research, Pamplona, Spain. (3) Institute of Data Science and Artificial Intelligence, DATAI, University of Navarra, Pamplona, Spain. (4) Laboratorios Farmacéuticos Rovi, Spain.

INTRODUCTION AND OBJECTIVE



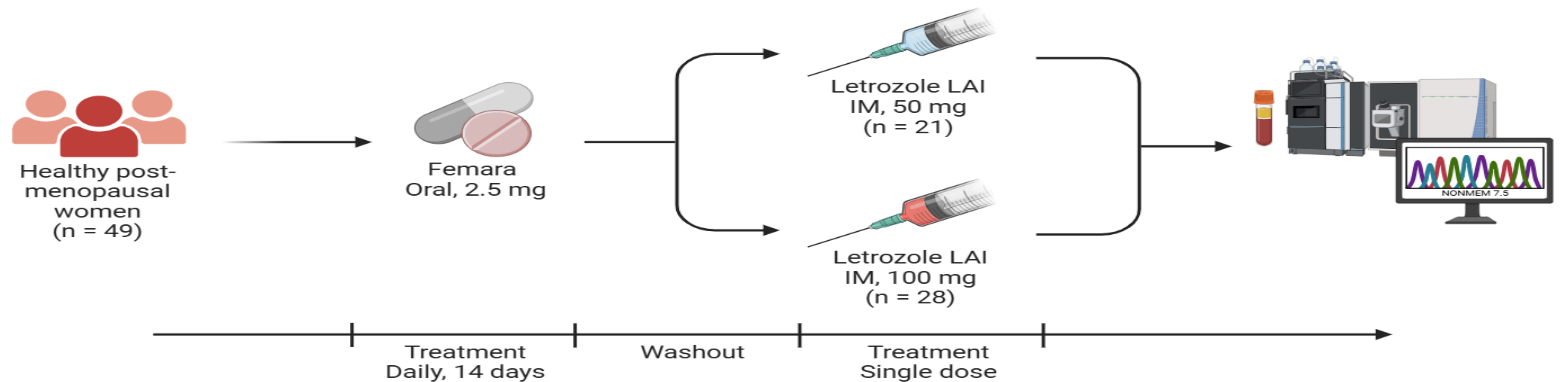
STUDY DESIGN AND METHODOLOGY

Sample analysis:

- UPLC-MS/MS

Data analysis:

- NONMEM 7.4
- PsN 5.3
- R statistical software 4.0.2



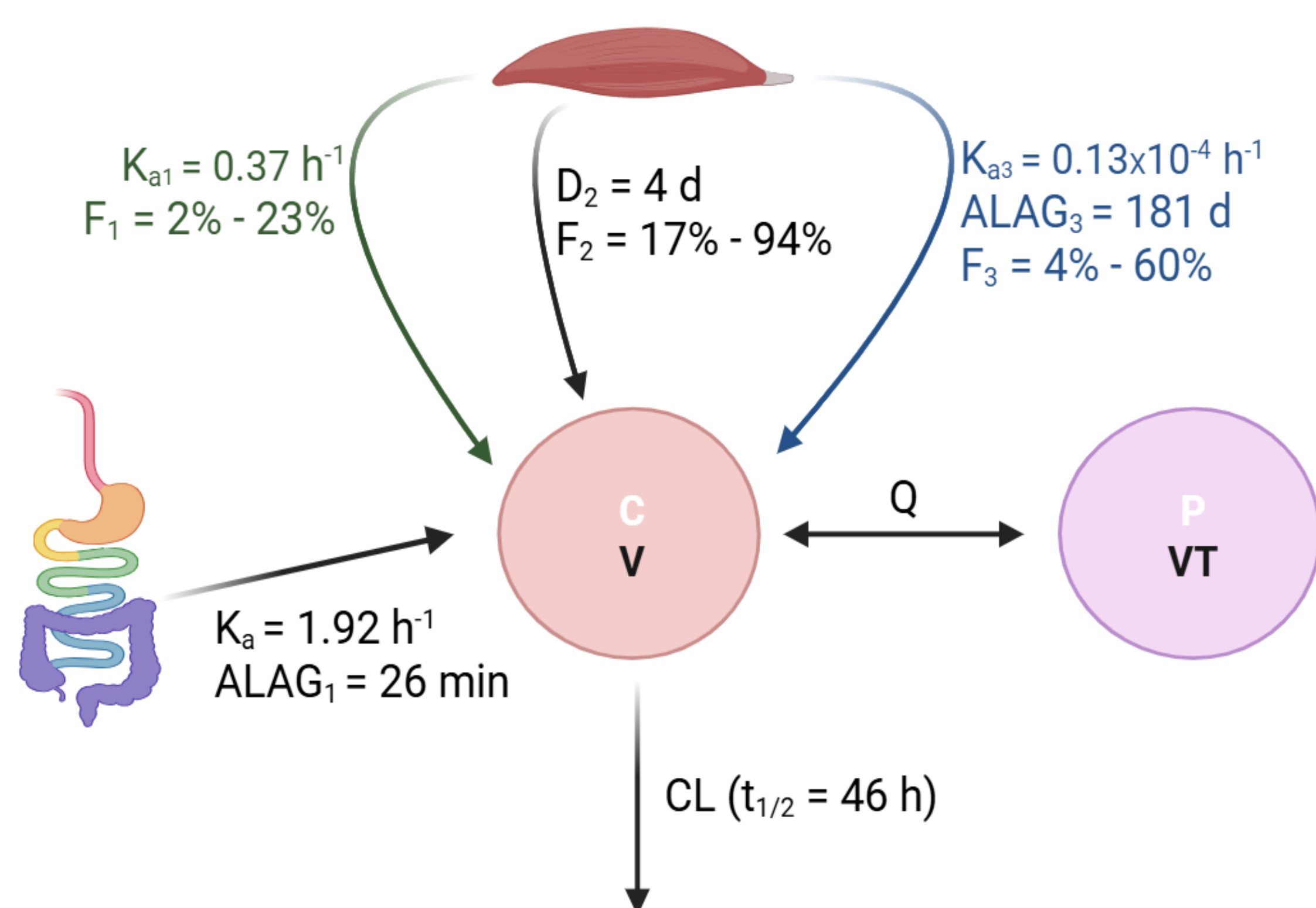
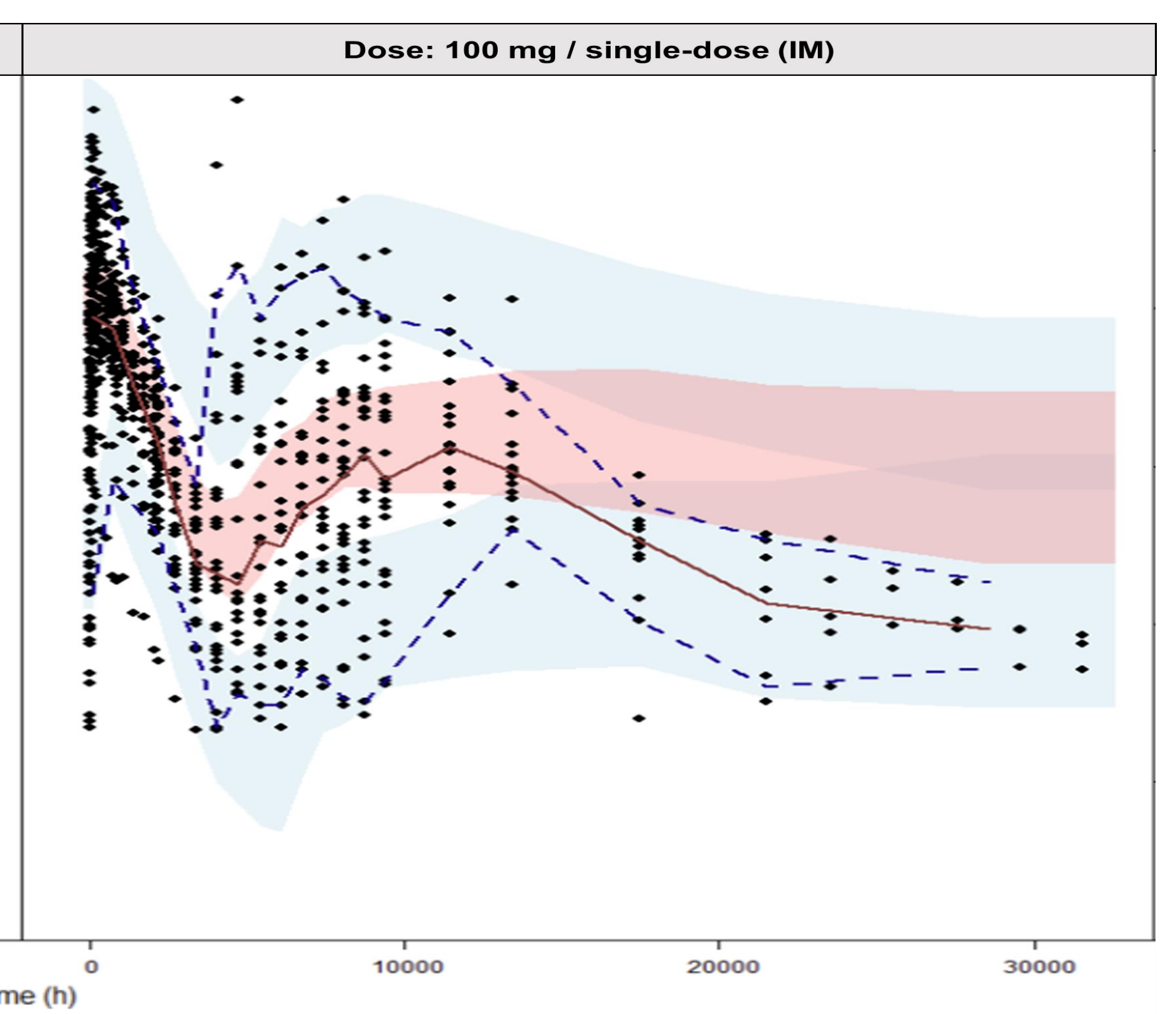
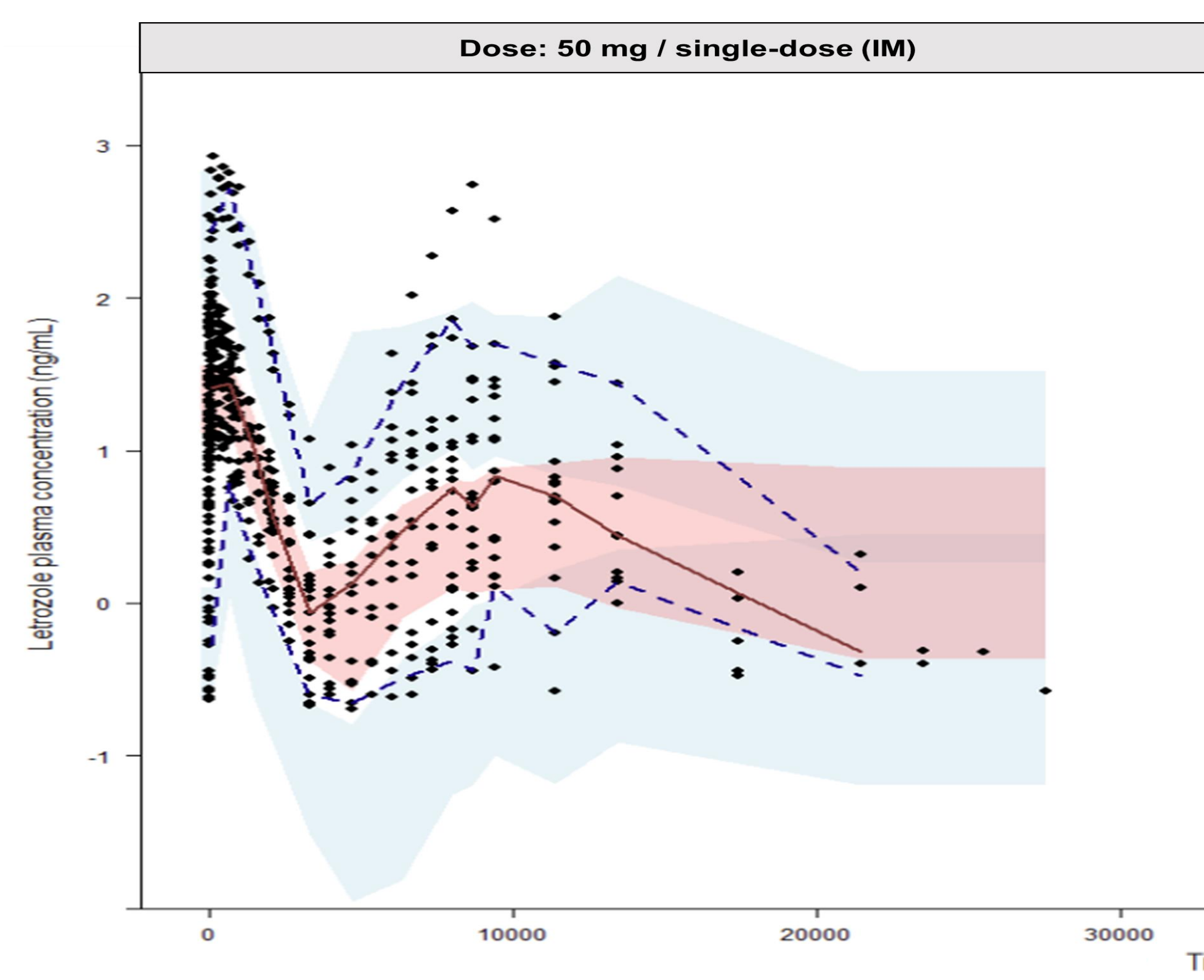
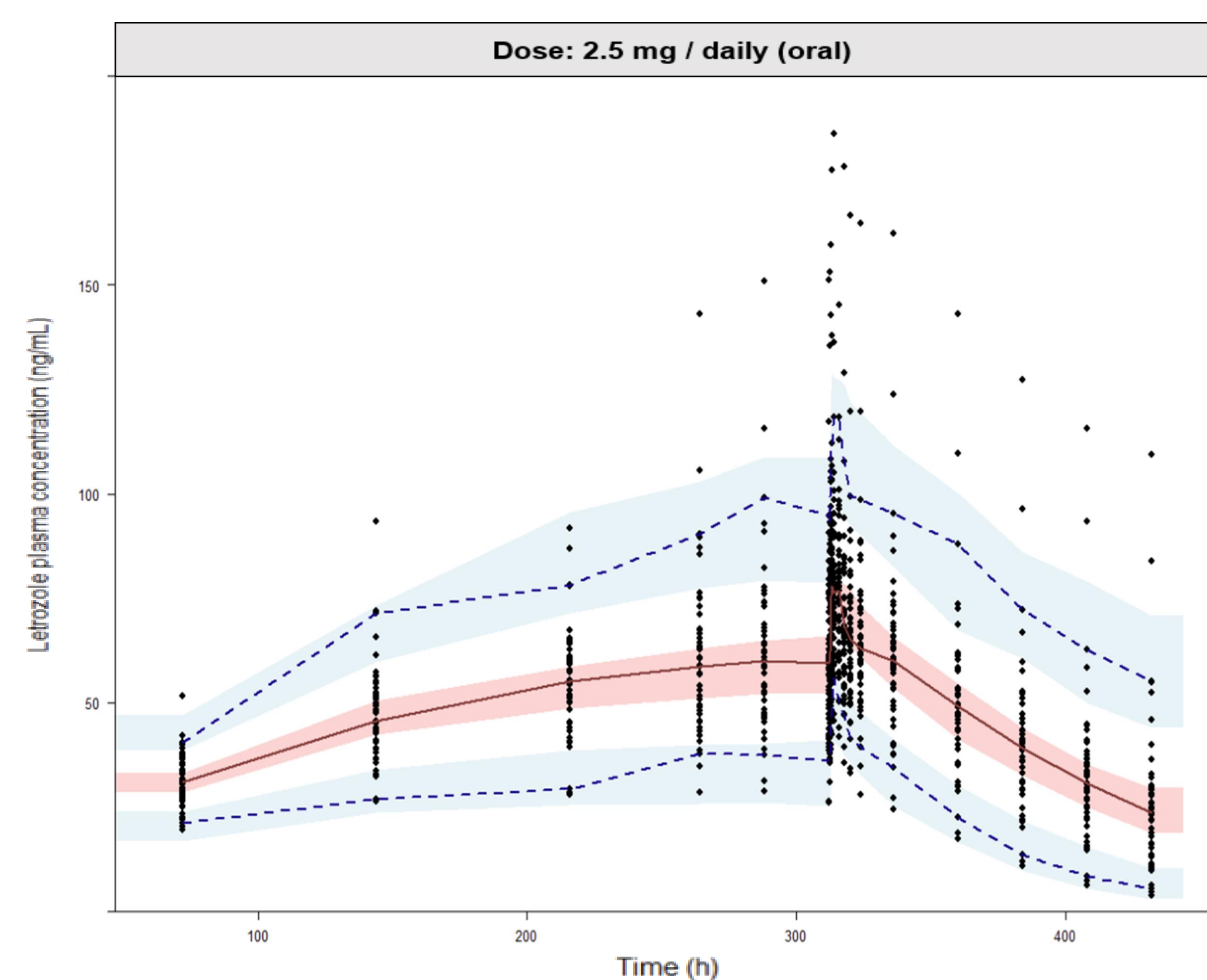
RESULTS

LETROZOLE ORAL ADMINISTRATION

- 16-20 samples / volunteer
- Relative bioavailability IIV: negligible
- IIV ranged from 35% to 55%

LETROZOLE LAI IM ADMINISTRATION

- 19-37 samples / volunteer
- 3 absorption processes:
 - 1 zero-order + 2 first order



CONCLUSIONS

The nlme approach was successfully applied to clinical pharmacokinetic data obtained after intramuscular administration of the letrozole LAI formulation, allowing the characterization of the letrozole absorption process. This constitutes a further step to potentially establish an IVIVC with previously obtained *in vitro* dissolution data.

REFERENCES

- [1] Subramani, R. et al. (2017).
- [2] SEOM clinical guidelines in advanced and recurrent breast cancer (2018).
- [3] Vademecum Letrozole.
- [4] Yusuf, M. et al. (2021).
- [5] Chaudhary, K. et al. (2019).
- [6] Bao, Q. et al. (2022).
- [7] Mast, M. et al. (2021).
- [8] Alimpertis, N. et al. (2024).

Email : acastineiras@rovi.es
Website: <http://rovi.es> ; <http://unav.edu/psp>