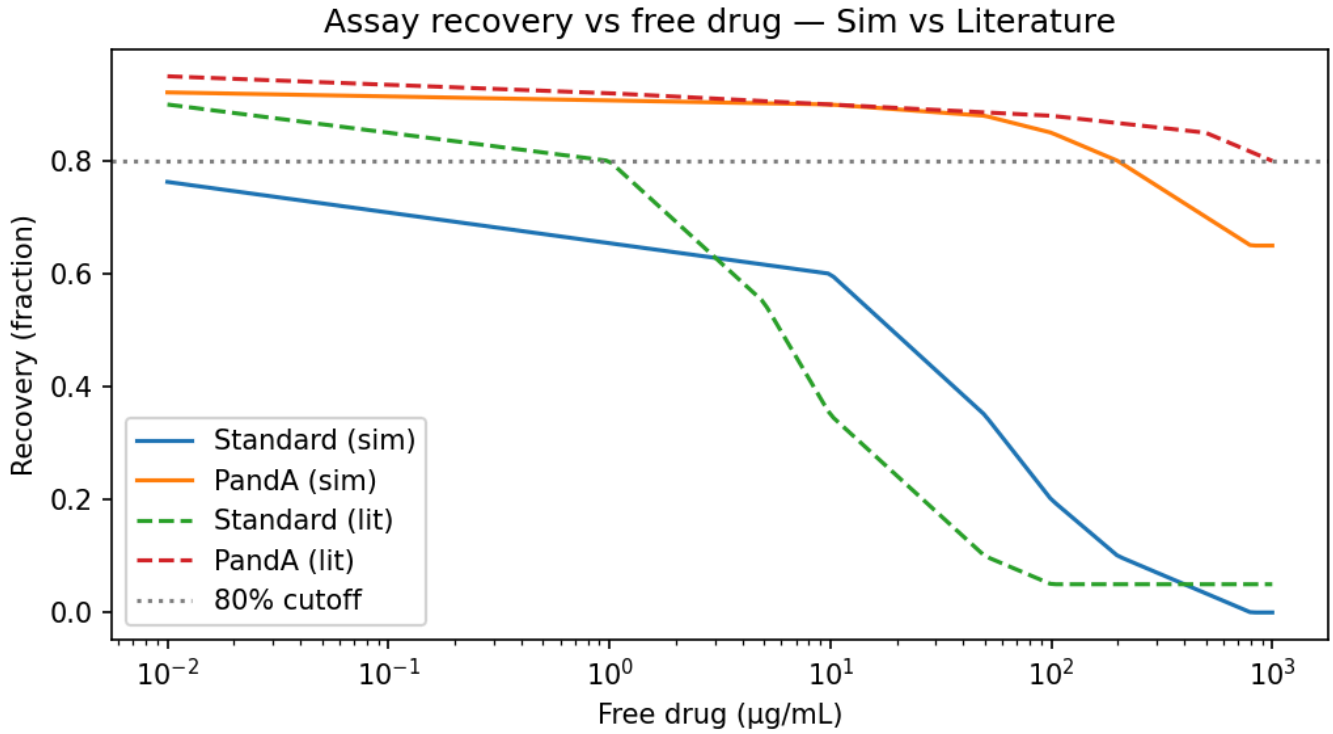
Clinical Pharmacology Summary – ADA Drug Interference & PandA Correction

Product: Monoclonal X • **Sponsor:** Demo Biotech • **Date:** 2025-10-25

1. Bioanalytical Methods & Interference

PandA (PEG + Acid) improves drug tolerance vs standard bridging (≥80% recovery up to ≥100 μg/mL).

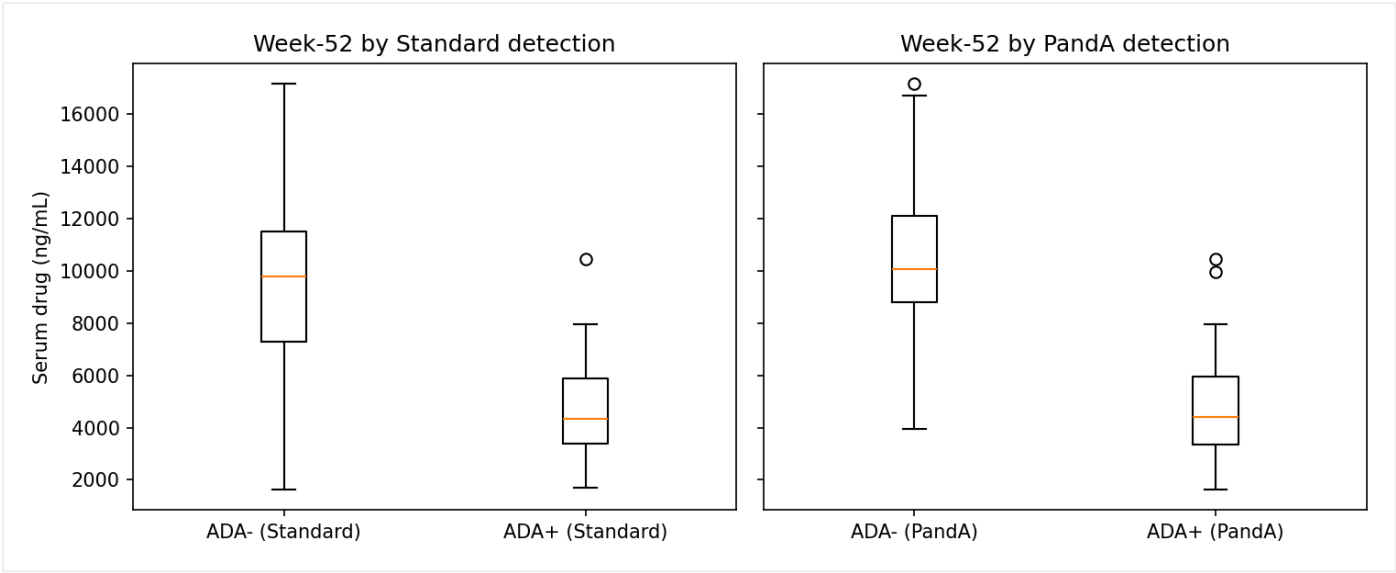


PASS/ALERT summary

Method	Cutoff	Req tol (μg/mL)	Obs tol (μg/mL)	Flag
Standard (sim)	0.8	100.0	0.0	ALERT
PandA (sim)	0.8	100.0	197.92	PASS
Standard (lit)	0.8	100.0	0.97	ALERT
PandA (lit)	0.8	100.0	1000.0	PASS

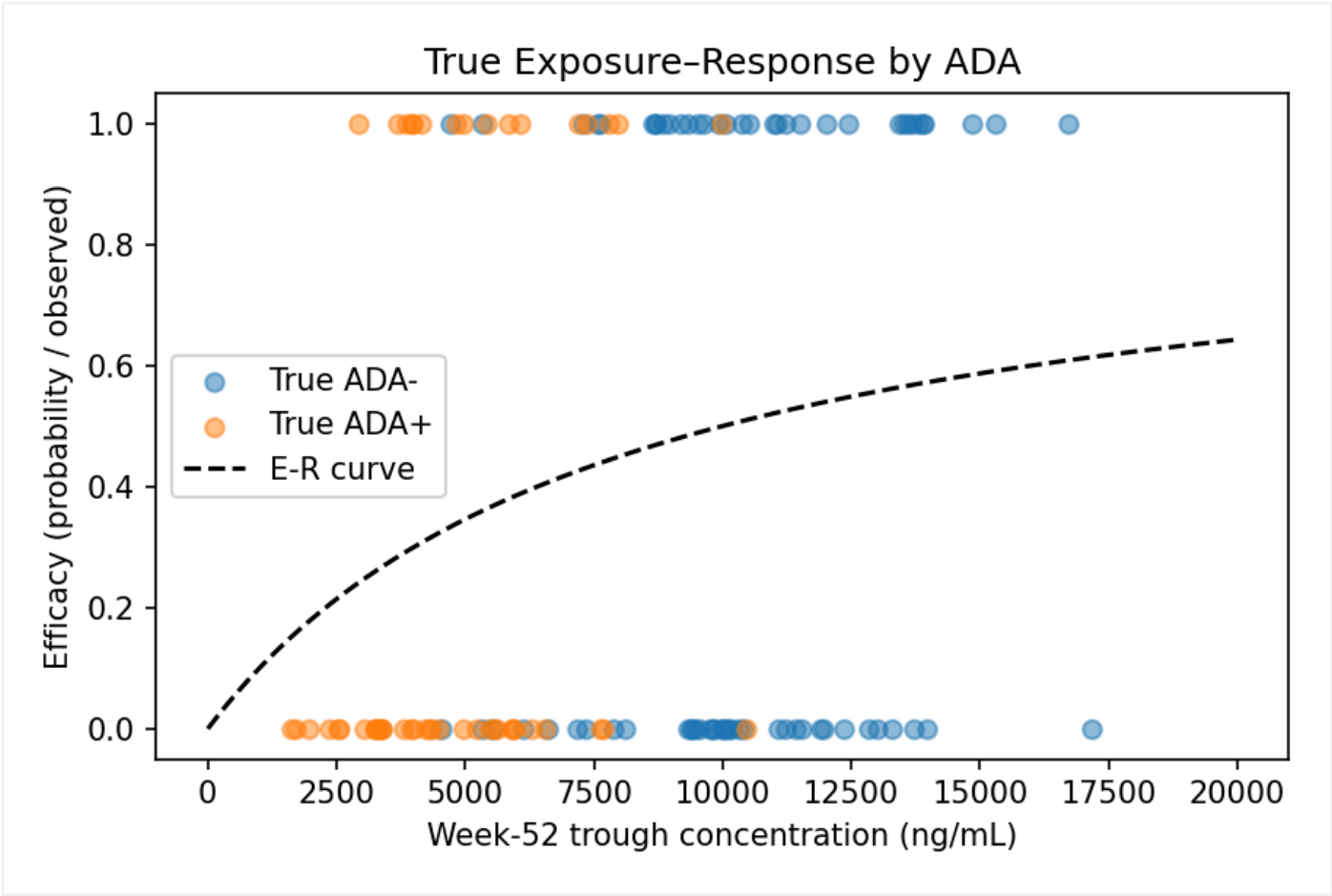
2. Population PK & Variability (brief)

At Week 52, ADA⁺ subjects show reduced troughs.



3. Exposure–Response & Target Attainment

True exposure–response shows reduced efficacy at low troughs.



Target attainment table (CSV): `/Users/cmontefusco/Coding projects/regulatory-style-clinpharm-report/output/TLG_target_attainment.csv`

4. Dose Recommendation (draft)

Use **PandA-based immunogenicity** for PK/E–R decisions at therapeutic drug levels. If program requires ≥X% target attainment, consider dose adjustment **only if** safety margin allows.

5. Conclusions

- Standard bridging fails tolerance benchmark; PandA passes.
- Bioanalytical method selection materially changes PK/E–R interpretation and dose justification.