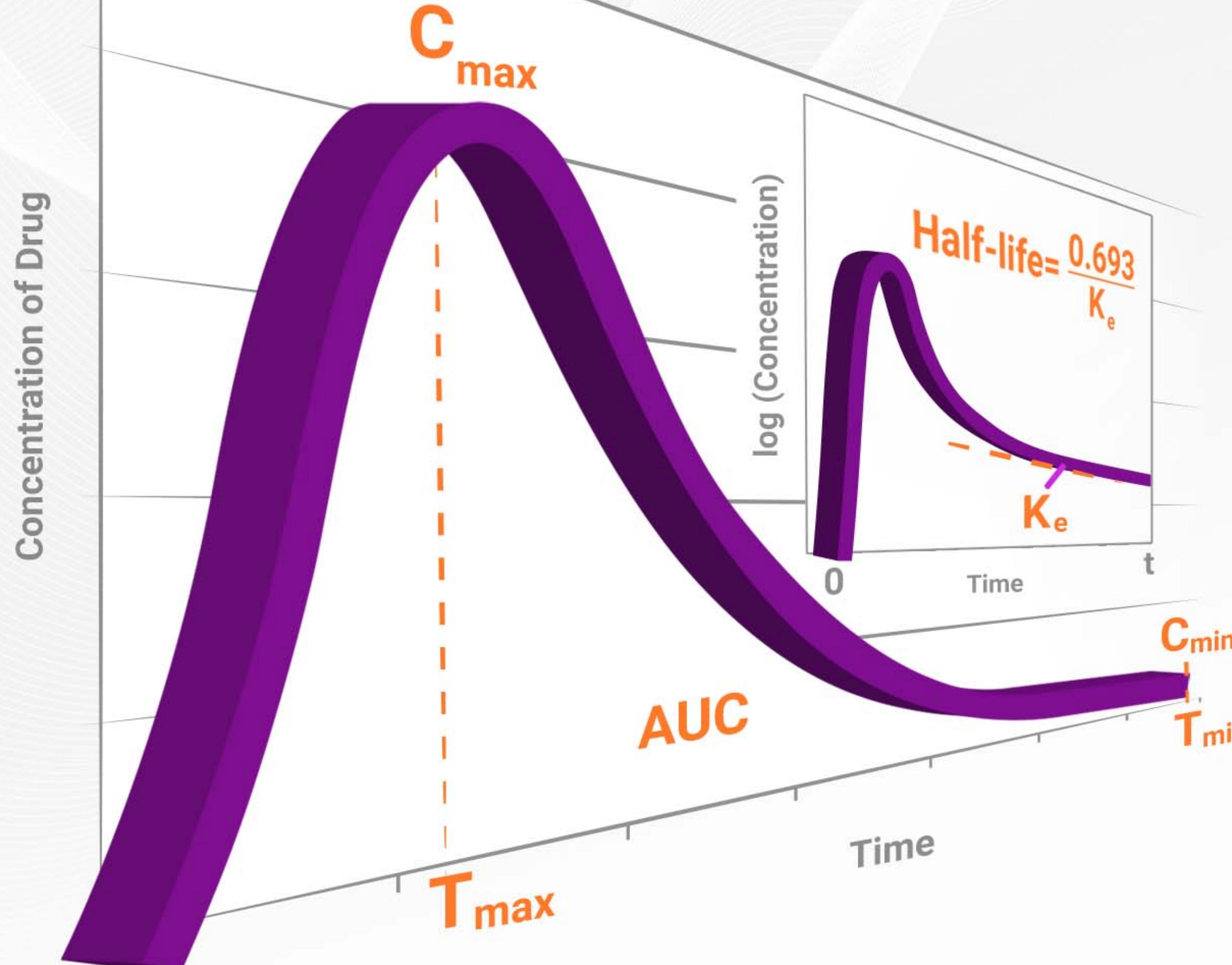


NCA powered by Cognigen®



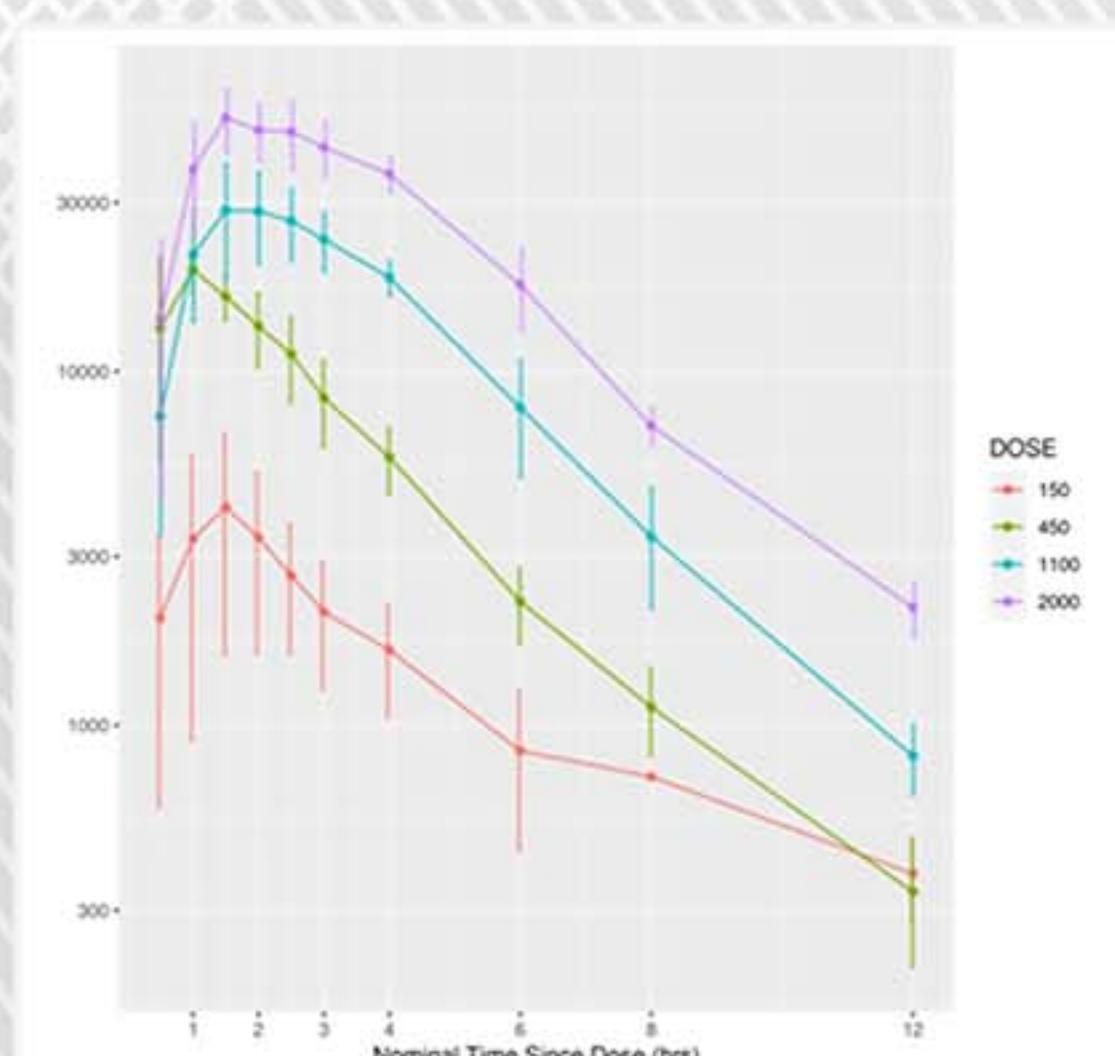
Cognigen® has a long-standing reputation for accuracy and integrity

- All analyses are performed in a validated environment and undergo senior scientific QC to ensure accurate and reliable results
- Data formatted for NCA and further pharmacometric analysis, saving time and money on future modeling work
- **First in human studies, especially SAD/MAD, and other Clinical Pharmacology Studies**
 - Clinical Bioequivalence
 - Dose-proportionality
 - Drug-Drug interactions
- Preclinical Pharmacokinetics (PK) and Toxicokinetics (TK)

	Cost Effective	Timely	Senior Scientific Review	Cognigen Quality Management	Validated Workflows	Seamless Follow-on Modeling
Cognigen NCA Services	✓	✓	✓	✓	✓	✓
The Other Guys	Sometimes	Sometimes	Sometimes	✗	Sometimes	✗

We Deliver!

- Blazing-fast turnaround of preliminary interim results
- Submission-ready full report or CSR sections
- Complete set of tables, figures, and listings (TFLs)
- All transport files (CDISC SDTM or SEND format)
 - SUPPPP
 - PP
 - PC
- Pharmacometric PK analysis-ready dataset



Parameter (units)	MINIMUM	Q1	MEDIAN	Q3	MAXIMUM	MEAN	SD	SE	CV	NTOT	NOBS	NMISS	GEO MEAN	GEO SD
AUC ₀₋₈ _D_obs ($\mu\text{g} \cdot \text{L}^{-1} \cdot \text{h}$)	0.0079	0.11	0.13	0.14	0.45	0.13	0.044	0.0036	34.25	233	144	89	0.12	1.56
AUC ₀₋₈ _obs ($\text{ng} \cdot \text{L}^{-1} \cdot \text{h}$)	1533.66	29800.6	64513.55	86028.95	288853	68372.73	51876.82	4523.07	73.87	233	144	89	51443.79	2.3
AUC ₀₋₈ ($\text{h} \times \text{ng} \cdot \text{L}^{-1}$)	666.52	27860.15	36749.1	77730.85	264520	60425.24	45781.35	3763.2	75.77	233	148	85	44087.34	2.54
AUC ₀₋₈ _D ($\text{ng} \cdot \text{L}^{-1}$)	0.0033	0.098	0.12	0.13	0.18	0.11	0.035	0.0029	30.89	233	148	85	0.1	1.78
AUC %Extrap_obs (%)	0.22	1.82	4.01	5.96	65.65	53.3	7.3	0.61	136.86	233	144	89	3.26	2.78
AUClast ($\text{h} \times \text{ng} \cdot \text{L}^{-1}$)	52.5	8808.75	27596.25	69171.7	288221	44426.94	48888.52	3252.02	110.04	233	226	7	21904.99	4.07
Clav_0-8 ($\text{L} \cdot \text{h}^{-1}$)	83.32	3450.03	7099.64	9716.36	33064.9	7353.15	5722.66	470.4	75.77	233	148	85	5510.92	2.54
Cl_F_obs ($\text{ng} \cdot \text{L}^{-1}$)	2.22	6.91	7.91	9.41	126.29	101	12.77	1.06	126.42	233	144	89	8.44	1.56
Clast ($\text{ng} \cdot \text{L}^{-1}$)	103	400	780	1930	13700	1421.3	1712.87	113.94	120.51	233	226	7	808.35	3
Cmax ($\text{ng} \cdot \text{L}^{-1}$)	105	2250	9440	19900	64800	12224.42	11921.06	792.98	97.52	233	226	7	6216.8	4.02



Cognigen

PHARMACOKINETIC REPORT
A Phase 1, Double-blinded, Placebo-controlled, Sequential Cohort, Multiple-Dose Escalation Study to Evaluate the Safety and Multiple Dose Pharmacokinetics of Drug-X in Healthy Human Volunteers

FINAL

FINAL TECHNICAL REPORT

April 30, 2021

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