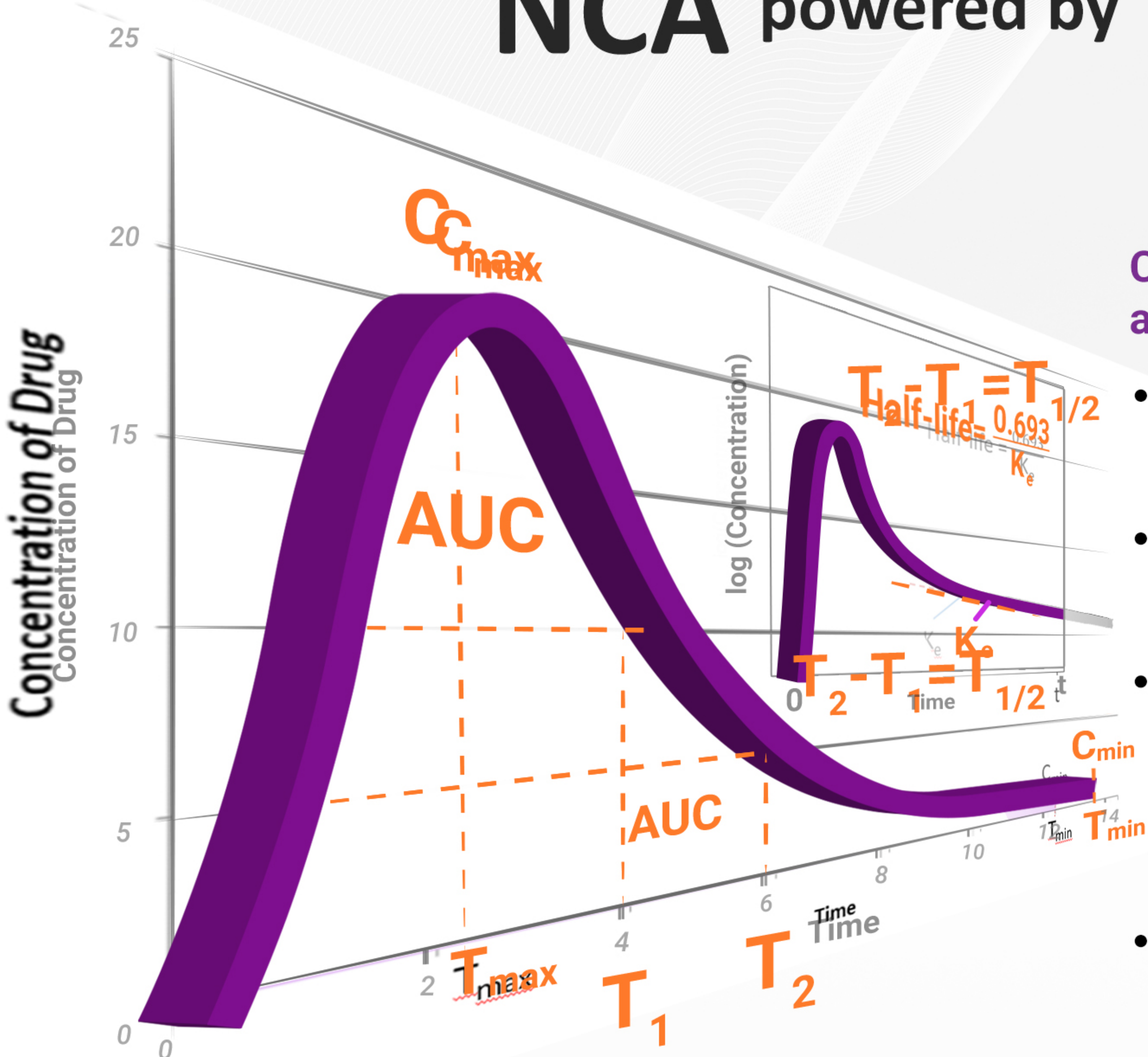


# NCA powered by *Cognigen*<sup>®</sup>



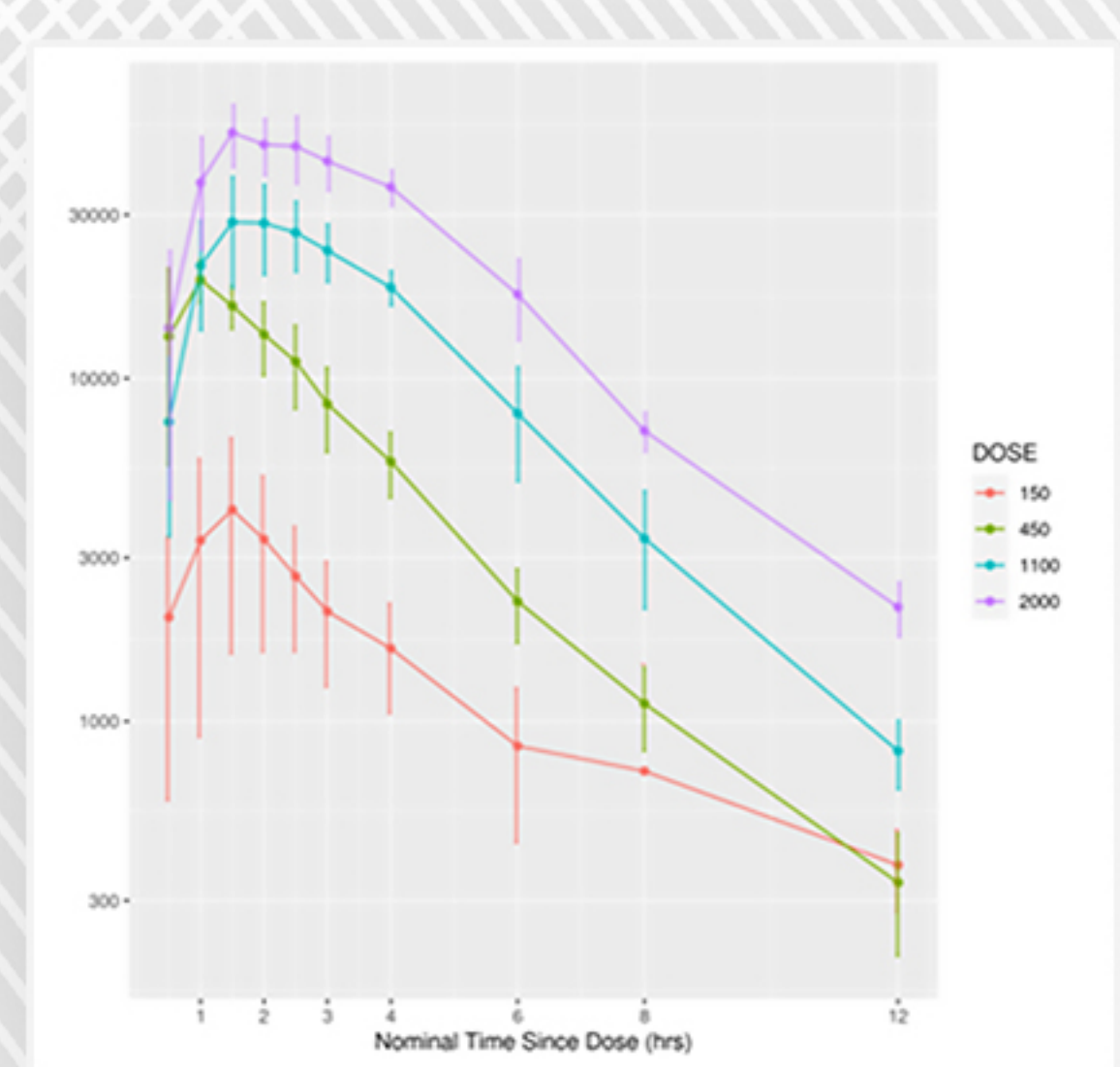
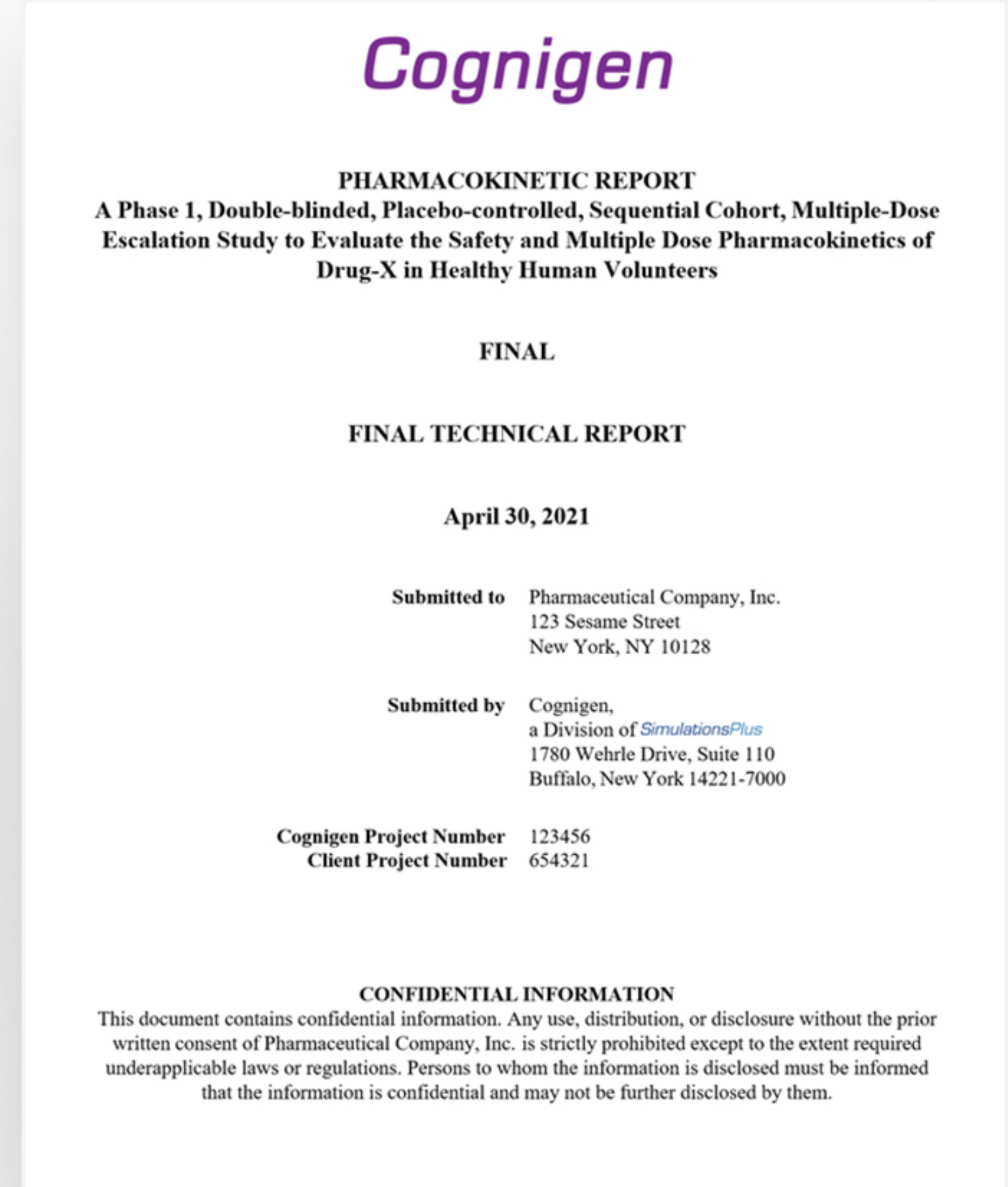
Cognigen<sup>®</sup> has a long-standing reputation for accuracy and integrity

- 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
  - Food effects
  - Drug accumulation
- 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	GEOMEAN	GEOSD
AUCINF_obs (µg × L <sup>-1</sup> )	0.0079	0.11	0.13	0.14	0.45	0.13	0.044	0.0036	34.25	233	144	89	0.12	1.36
AUCINF_obs (h × µg × L <sup>-1</sup> )	1583.66	29800.6	64513.55	86028.95	288853	68372.73	51876.82	4323.07	75.87	233	144	89	51443.79	2.3
AUC_0-8 (h × µg × L <sup>-1</sup> )	666.52	27800.15	56749.1	77730.85	264520	60425.24	45781.35	3765.2	75.77	233	148	85	44087.34	2.54
AUC_0-8_D (µg × L <sup>-1</sup> )	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_0-8Emp_obs (%)	0.22	1.82	4.01	5.96	63.65	5.33	7.3	0.61	136.86	233	144	89	3.26	2.78
AUClast (h × µg × L <sup>-1</sup> )	52.5	8808.75	27596.25	69171.7	388221	44426.94	48888.52	3252.02	110.04	233	226	7	21904.99	4.07
Cavg_0-8 (L × h <sup>-1</sup> )	83.32	3450.03	7093.64	9716.36	33064.9	7353.15	5722.66	470.4	75.77	233	148	85	5510.92	2.54
Cl_F_obs (µg × L <sup>-1</sup> )	2.22	6.91	7.91	9.41	126.29	10.1	12.77	1.06	126.42	233	144	89	8.44	1.56
Clast (µg × L <sup>-1</sup> )	103	400	780	1950	13700	1421.3	1712.87	113.94	120.51	233	226	7	808.35	3
Cmax (µg × L <sup>-1</sup> )	105	2250	9440	19900	64800	12224.42	11921.06	792.98	97.52	233	226	7	6216.8	4.02