

# Phase 1 SAD of Drug Y

Study ID: STUDY-001

Sponsor: PumasAI

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## **1 Summary Observations vs. Time**

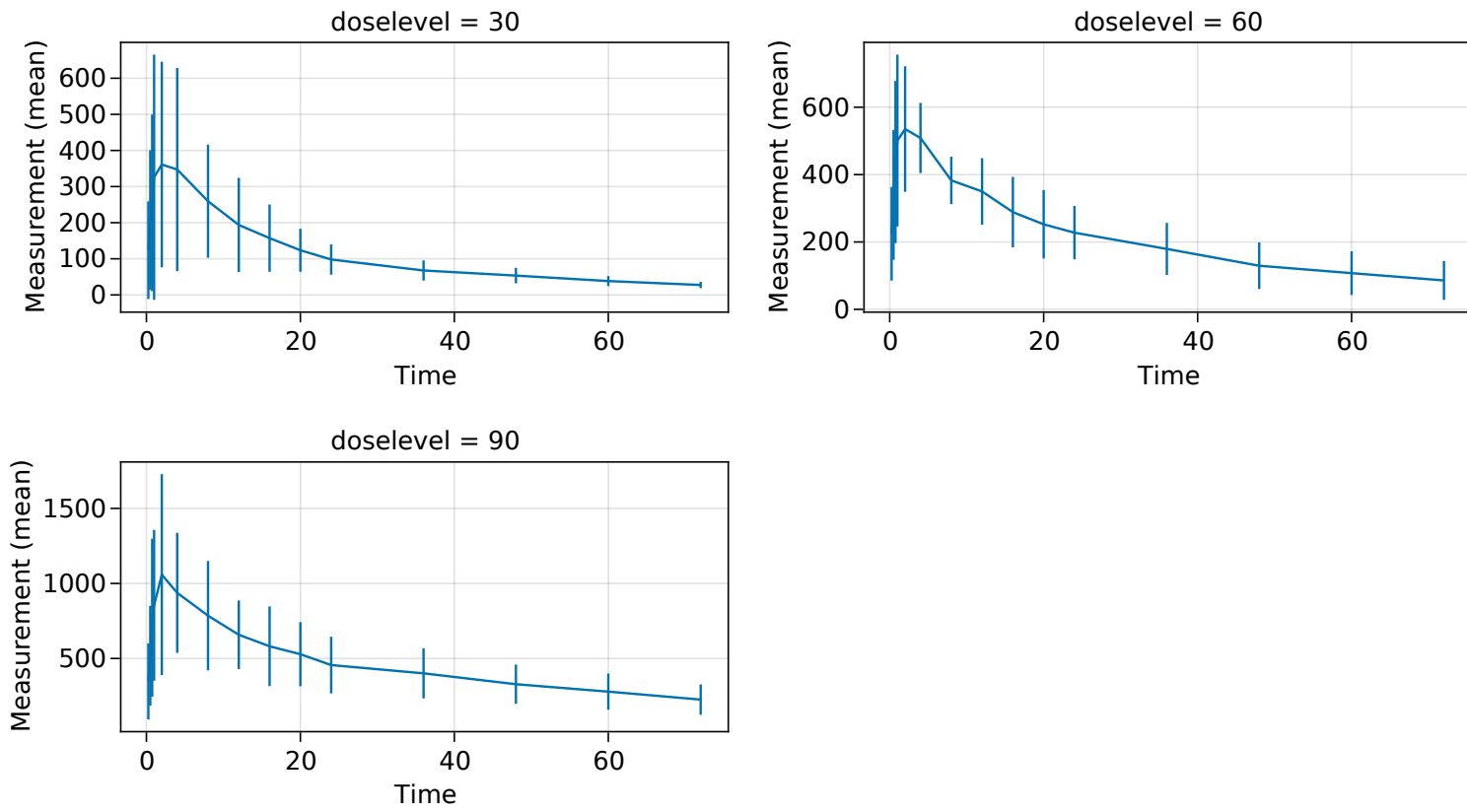


Figure 1: Summary of Observations vs Time

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## **2 NCA Summary**

Table 1: NCA Summary.

parameters	extrema	geomean	geomeanCV	geostd	mean	numsamples	std
cmax	(141.561, 2232.39)	567.0	0.344	1.95	696.0	18	495.0
aucinf_obs	(5600.54, 75366.4)	18900.0	0.0123	2.33	26100.0	18	21100.0

---

### **3 NCA parameters**

Table 2: NCA parameters (doseamt to aucinf\_obs)

id	doselevel	doseamt	tlag	tmax	cmax	tlast	clast	clast_pred	auclast	kel	half_life	aucinf_obs
1	30	30.0	0.0	8.0	201.0	72.0	17.9	17.8	4990.0	0.0292	23.8	5600.0
2	30	30.0	0.0	2.0	516.0	72.0	22.0	21.5	6980.0	0.0261	26.6	7830.0
3	30	30.0	0.0	2.0	275.0	72.0	24.5	23.5	5730.0	0.0253	27.4	6700.0
4	30	30.0	0.0	8.0	142.0	72.0	30.1	29.1	4680.0	0.0221	31.3	6040.0
5	30	30.0	0.0	1.0	961.0	72.0	43.3	42.9	16300.0	0.0321	21.6	17600.0
6	30	30.0	0.0	4.0	296.0	72.0	27.0	28.1	7750.0	0.0321	21.6	8590.0
7	60	60.0	0.0	1.0	826.0	72.0	45.4	38.1	14300.0	0.0374	18.5	15500.0
8	60	60.0	0.0	2.0	587.0	72.0	54.2	55.6	11500.0	0.0215	32.3	14100.0
9	60	60.0	0.0	2.0	526.0	72.0	38.4	35.3	9410.0	0.0272	25.4	10800.0
10	60	60.0	0.0	4.0	508.0	72.0	167.0	166.0	21000.0	0.0134	51.8	33500.0
11	60	60.0	0.0	1.0	752.0	72.0	58.2	56.0	17200.0	0.0327	21.2	18900.0
12	60	60.0	0.0	4.0	432.0	72.0	152.0	155.0	18400.0	0.0131	53.0	30100.0
13	90	90.0	0.0	4.0	597.0	72.0	205.0	204.0	23600.0	0.00872	79.5	47100.0
14	90	90.0	0.0	2.0	918.0	72.0	253.0	252.0	37000.0	0.0249	27.9	47200.0
15	90	90.0	0.0	2.0	2230.0	72.0	225.0	230.0	48300.0	0.0255	27.2	57100.0
16	90	90.0	0.0	4.0	700.0	72.0	258.0	258.0	29100.0	0.0113	61.3	51900.0
17	90	90.0	0.0	2.0	1450.0	72.0	363.0	347.0	44500.0	0.0117	59.0	75400.0
18	90	90.0	0.0	4.0	611.0	72.0	52.4	49.9	13500.0	0.0279	24.9	15300.0



Table 3: NCA parameters (aucinf\_pred to auclast\_dn)

id	doselevel	aucinf_pred	vz_f_obs	cl_f_obs	vz_f_pred	cl_f_pred	n_samples	cmax_dn	auclast_dn
1	30	5600.0	0.184	0.00536	0.184	0.00536	15	6.7	166.0
2	30	7810.0	0.147	0.00383	0.147	0.00384	15	17.2	233.0
3	30	6660.0	0.177	0.00448	0.178	0.00451	15	9.17	191.0
4	30	5990.0	0.224	0.00497	0.226	0.005	15	4.72	156.0
5	30	17600.0	0.053	0.0017	0.0531	0.0017	15	32.0	542.0
6	30	8630.0	0.109	0.00349	0.108	0.00348	15	9.87	258.0
7	60	15400.0	0.103	0.00386	0.105	0.00391	15	13.8	239.0
8	60	14100.0	0.199	0.00427	0.198	0.00425	15	9.79	192.0
9	60	10700.0	0.204	0.00554	0.206	0.0056	15	8.76	157.0
10	60	33400.0	0.134	0.00179	0.134	0.0018	15	8.46	351.0
11	60	18900.0	0.0969	0.00317	0.0972	0.00318	15	12.5	286.0
12	60	30300.0	0.152	0.00199	0.152	0.00198	15	7.21	307.0
13	90	47000.0	0.219	0.00191	0.219	0.00191	15	6.63	262.0
14	90	47100.0	0.0767	0.00191	0.0768	0.00191	15	10.2	411.0
15	90	57400.0	0.0618	0.00158	0.0616	0.00157	15	24.8	537.0
16	90	51800.0	0.153	0.00173	0.154	0.00174	15	7.78	323.0
17	90	74000.0	0.102	0.00119	0.104	0.00122	15	16.1	494.0
18	90	15200.0	0.211	0.00587	0.212	0.0059	15	6.79	149.0

Table 4: NCA parameters (aucinf\_dn\_obs to aumcinf\_obs)

id	doselevel	aucinf_dn_obs	auc_extrap_obs	aucinf_dn_pred	auc_extrap_pred	aumclast	aumcinf_obs
1	30	187.0	10.9	187.0	10.9	109000.0	174000.0
2	30	261.0	10.8	260.0	10.6	127000.0	220000.0
3	30	223.0	14.5	222.0	14.0	129000.0	237000.0
4	30	201.0	22.5	200.0	21.9	126000.0	285000.0
5	30	587.0	7.66	587.0	7.59	296000.0	435000.0
6	30	286.0	9.79	288.0	10.1	183000.0	270000.0
7	60	259.0	7.81	256.0	6.63	284000.0	404000.0
8	60	234.0	18.0	235.0	18.4	270000.0	569000.0
9	60	180.0	13.0	179.0	12.1	198000.0	351000.0
10	60	558.0	37.2	557.0	37.0	625000.0	2.45e6
11	60	316.0	9.4	315.0	9.08	376000.0	559000.0
12	60	502.0	38.7	505.0	39.1	563000.0	2.29e6
13	90	523.0	49.9	523.0	49.8	703000.0	5.09e6
14	90	524.0	21.6	524.0	21.5	1.09e6	2.23e6
15	90	635.0	15.4	637.0	15.8	1.18e6	2.16e6
16	90	576.0	44.0	576.0	43.9	890000.0	4.55e6
17	90	837.0	41.0	823.0	39.9	1.24e6	6.09e6
18	90	170.0	12.3	169.0	11.7	293000.0	495000.0

Table 5: NCA parameters (aumc\_extrap\_obs to rsq\_adj\_kel)

id	doselevel	aumc_extrap_obs	aumcinf_pred	aumc_extrap_pred	n_samples_kel	rsq_kel	rsq_adj_kel
1	30	37.5	174000.0	37.4	3	1.0	1.0
2	30	42.3	218000.0	41.7	5	0.994	0.993
3	30	45.6	233000.0	44.6	5	0.982	0.976
4	30	55.9	280000.0	55.0	3	0.953	0.907
5	30	32.0	433000.0	31.8	3	0.998	0.996
6	30	32.2	273000.0	33.0	9	0.983	0.981
7	60	29.7	385000.0	26.1	10	0.969	0.965
8	60	52.6	577000.0	53.3	7	0.976	0.971
9	60	43.7	339000.0	41.6	5	0.98	0.974
10	60	74.5	2.44e6	74.4	4	0.999	0.998
11	60	32.7	552000.0	31.9	9	0.991	0.989
12	60	75.4	2.32e6	75.7	5	0.953	0.938
13	90	86.2	5.08e6	86.1	3	0.998	0.997
14	90	51.1	2.23e6	51.0	3	0.999	0.998
15	90	45.3	2.19e6	45.9	4	0.978	0.966
16	90	80.4	4.54e6	80.4	9	0.904	0.891
17	90	79.7	5.88e6	79.0	6	0.955	0.944
18	90	40.9	486000.0	39.7	7	0.97	0.964

Table 6: NCA parameters (corr\_kel to run\_status)

id	doselevel	corr_kel	intercept_kel	kel_t_low	kel_t_high	span	route	run_status
1	30	1.0	4.98	48.0	72.0	1.01	EV	Success
2	30	0.997	4.95	24.0	72.0	1.81	EV	Success
3	30	0.991	4.98	24.0	72.0	1.75	EV	Success
4	30	0.976	4.96	48.0	72.0	0.766	EV	Success
5	30	0.999	6.07	48.0	72.0	1.11	EV	Success
6	30	0.992	5.65	8.0	72.0	2.96	EV	Success
7	60	0.984	6.33	4.0	72.0	3.67	EV	Success
8	60	0.988	5.56	16.0	72.0	1.73	EV	Success
9	60	0.99	5.53	24.0	72.0	1.89	EV	Success
10	60	0.999	6.07	36.0	72.0	0.695	EV	Success
11	60	0.995	6.38	8.0	72.0	3.02	EV	Success
12	60	0.976	5.98	24.0	72.0	0.906	EV	Success
13	90	0.999	5.95	48.0	72.0	0.302	EV	Success
14	90	0.999	7.32	48.0	72.0	0.861	EV	Success
15	90	0.989	7.27	36.0	72.0	1.32	EV	Success
16	90	0.951	6.37	8.0	72.0	1.04	EV	Success
17	90	0.977	6.69	20.0	72.0	0.881	EV	Success
18	90	0.985	5.92	16.0	72.0	2.25	EV	Success

---

## **4 Parameter Distribution**

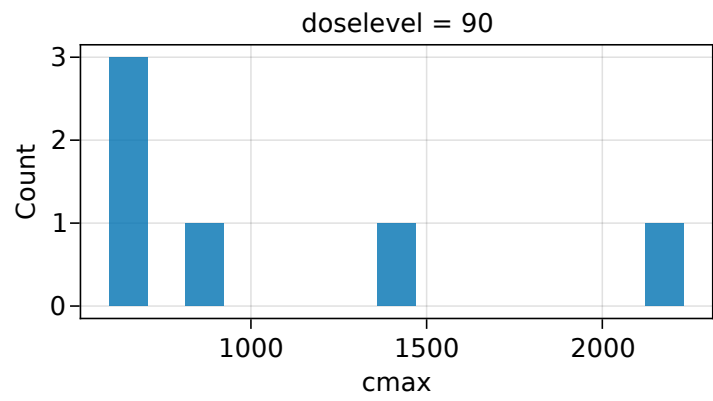
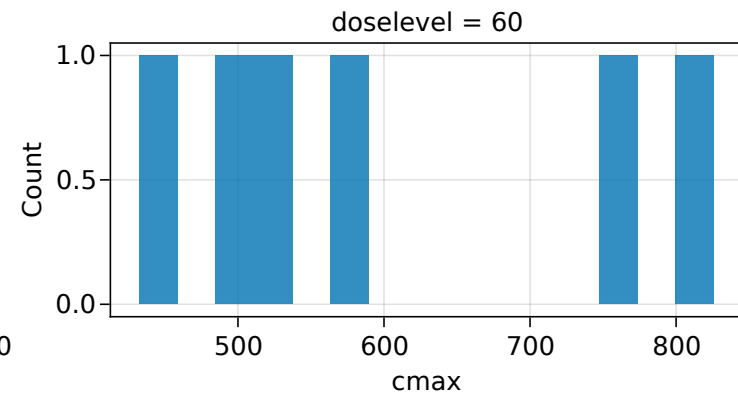
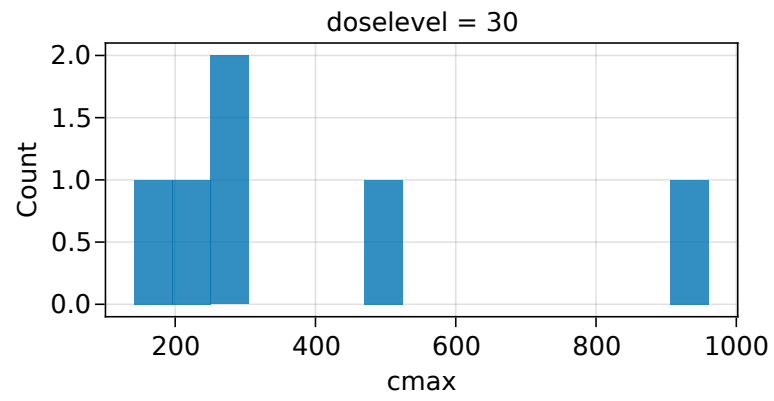


Figure 2: Parameter (cmax) Distribution

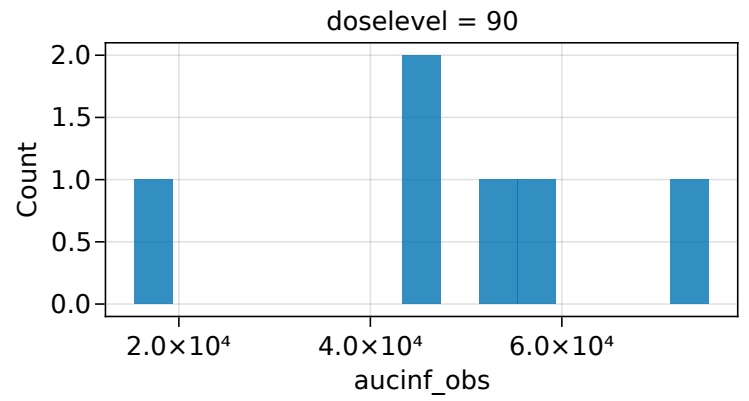
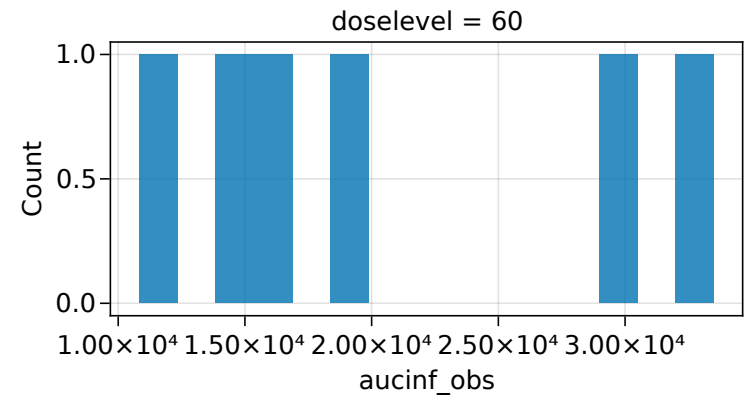
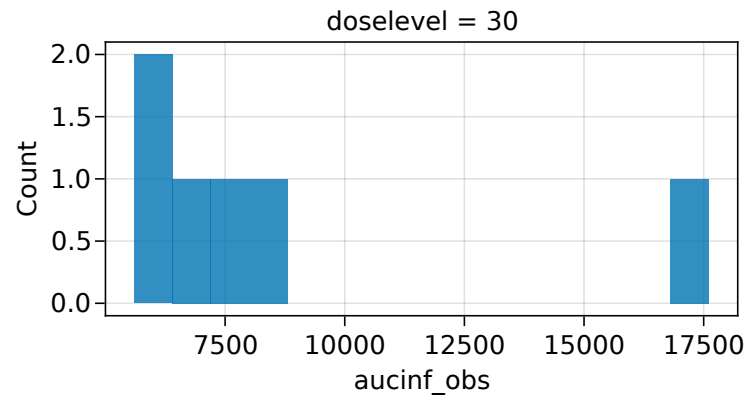


Figure 3: Parameter (aucinf\_obs) Distribution

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## **5 Parameters vs Group**



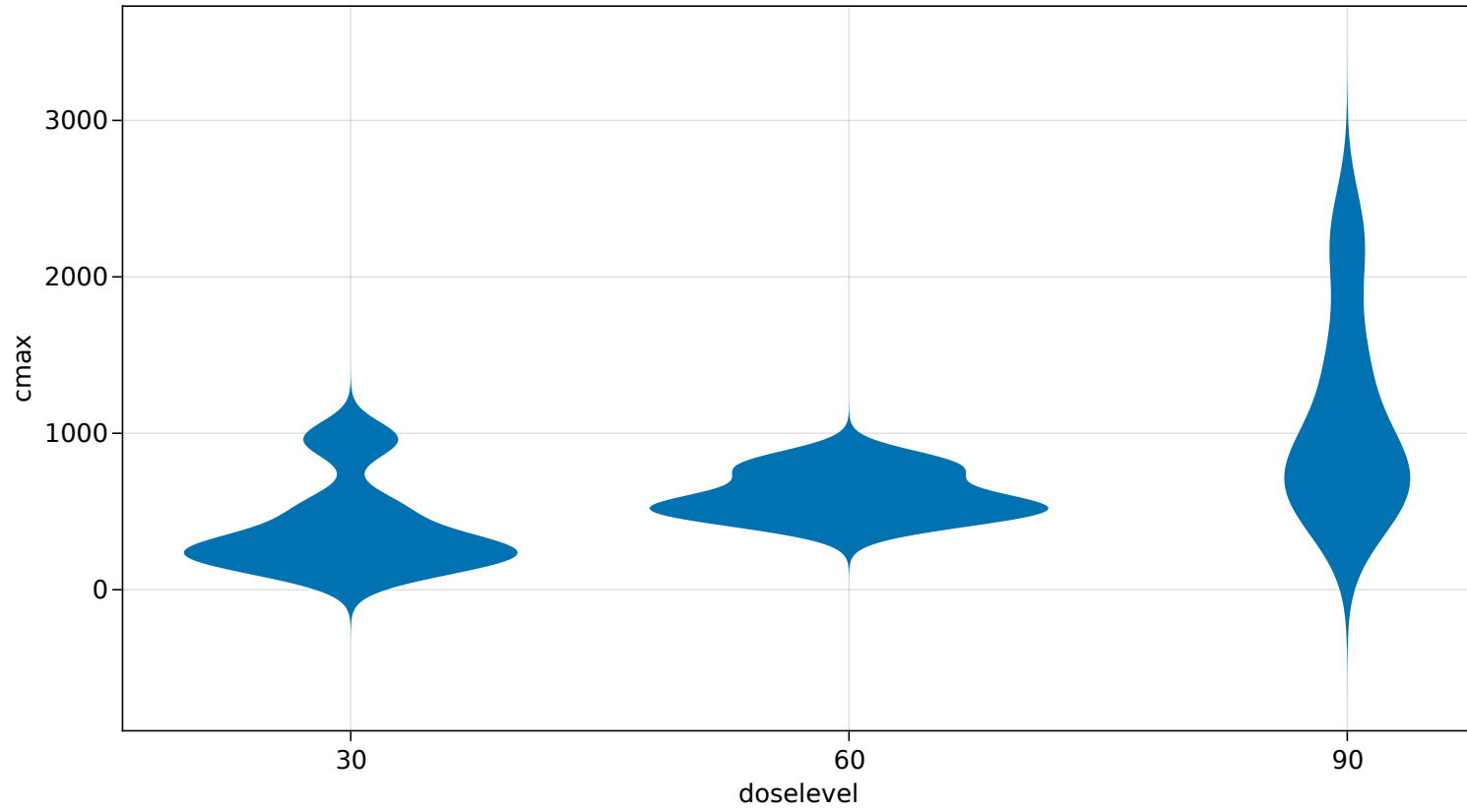


Figure 4: Parameter ( $c_{max}$ ) vs Group

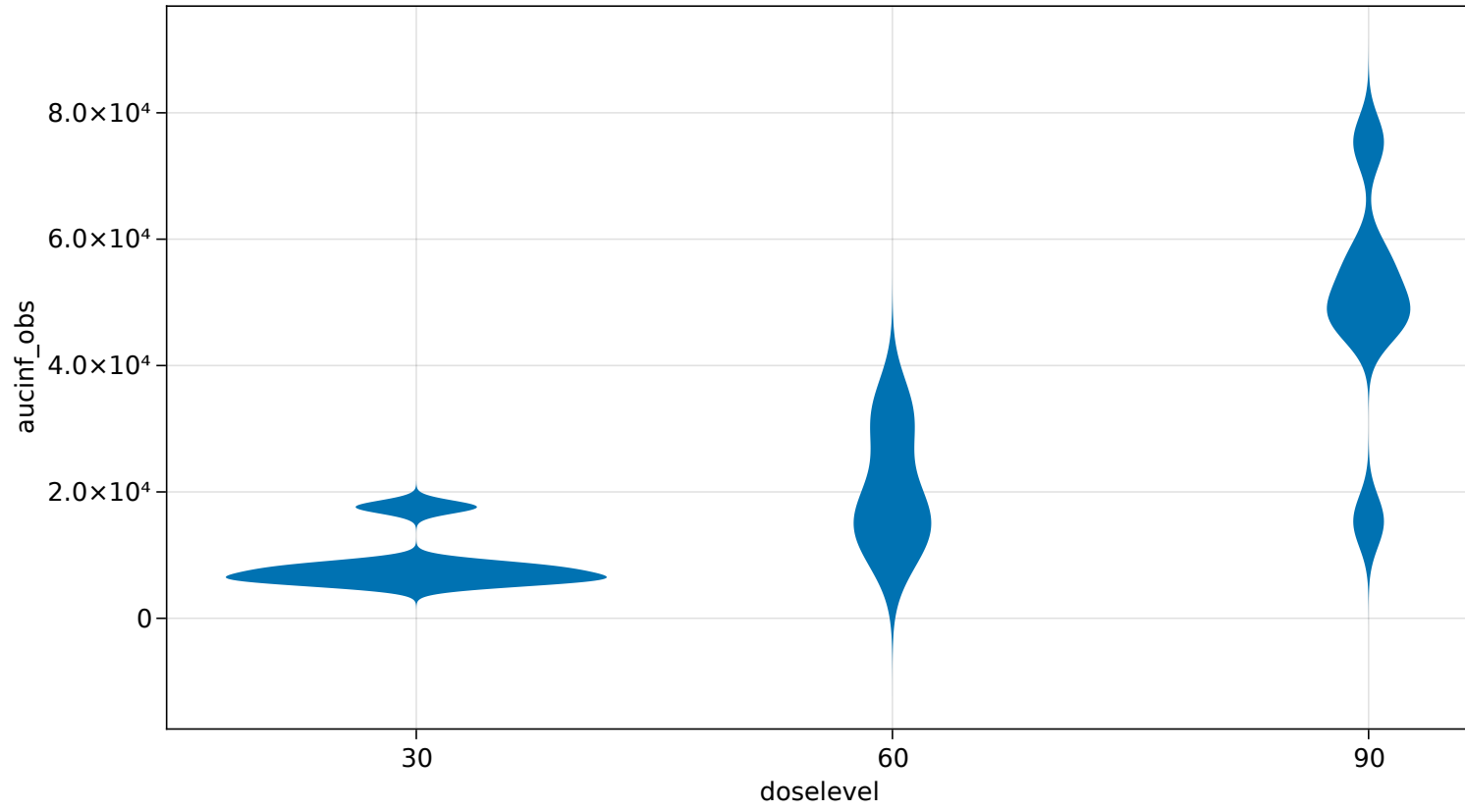


Figure 5: Parameter (`aucinf_obs`) vs Group

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## **A Subject Fits**

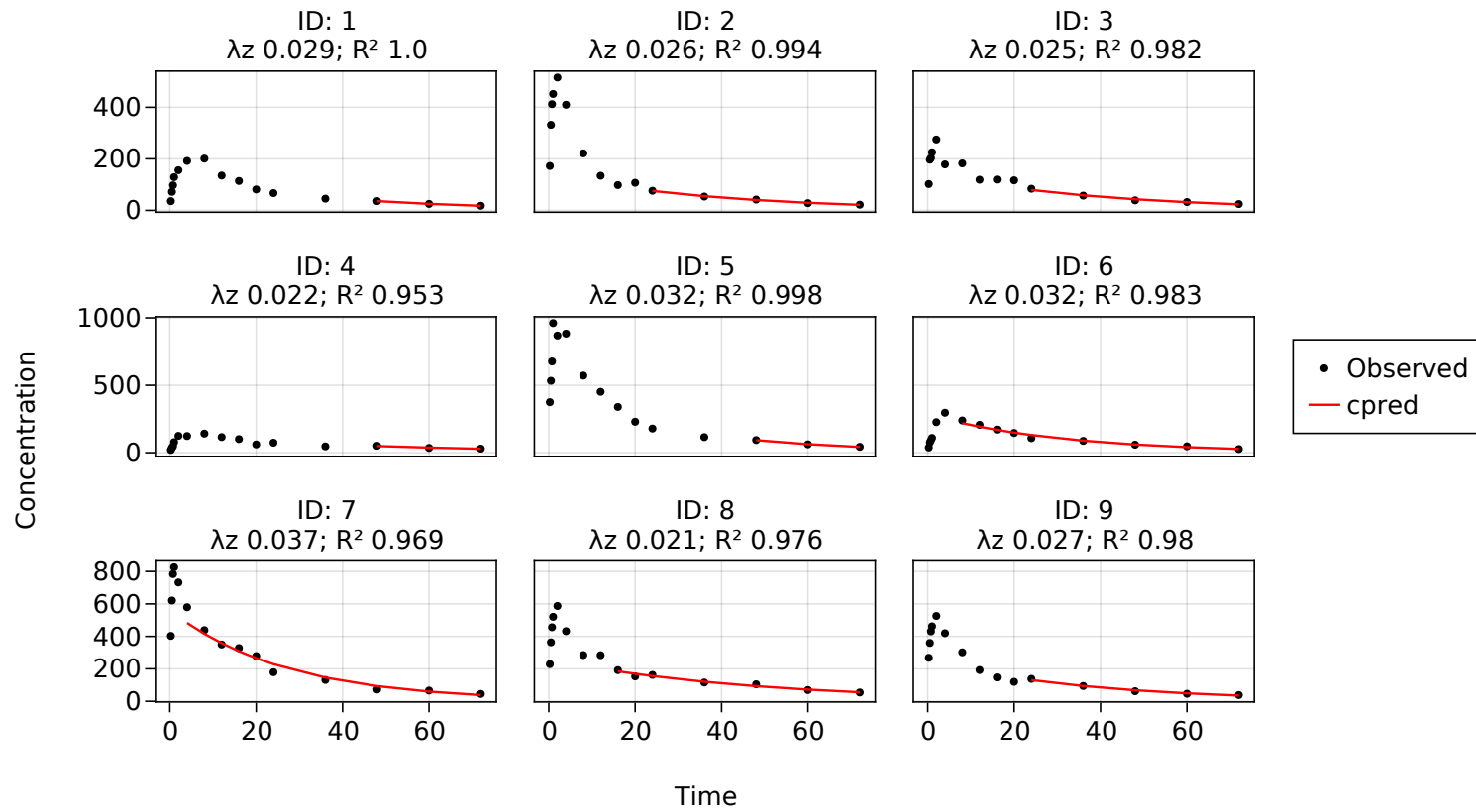


Figure 6: Subject Fits (1 of 2).

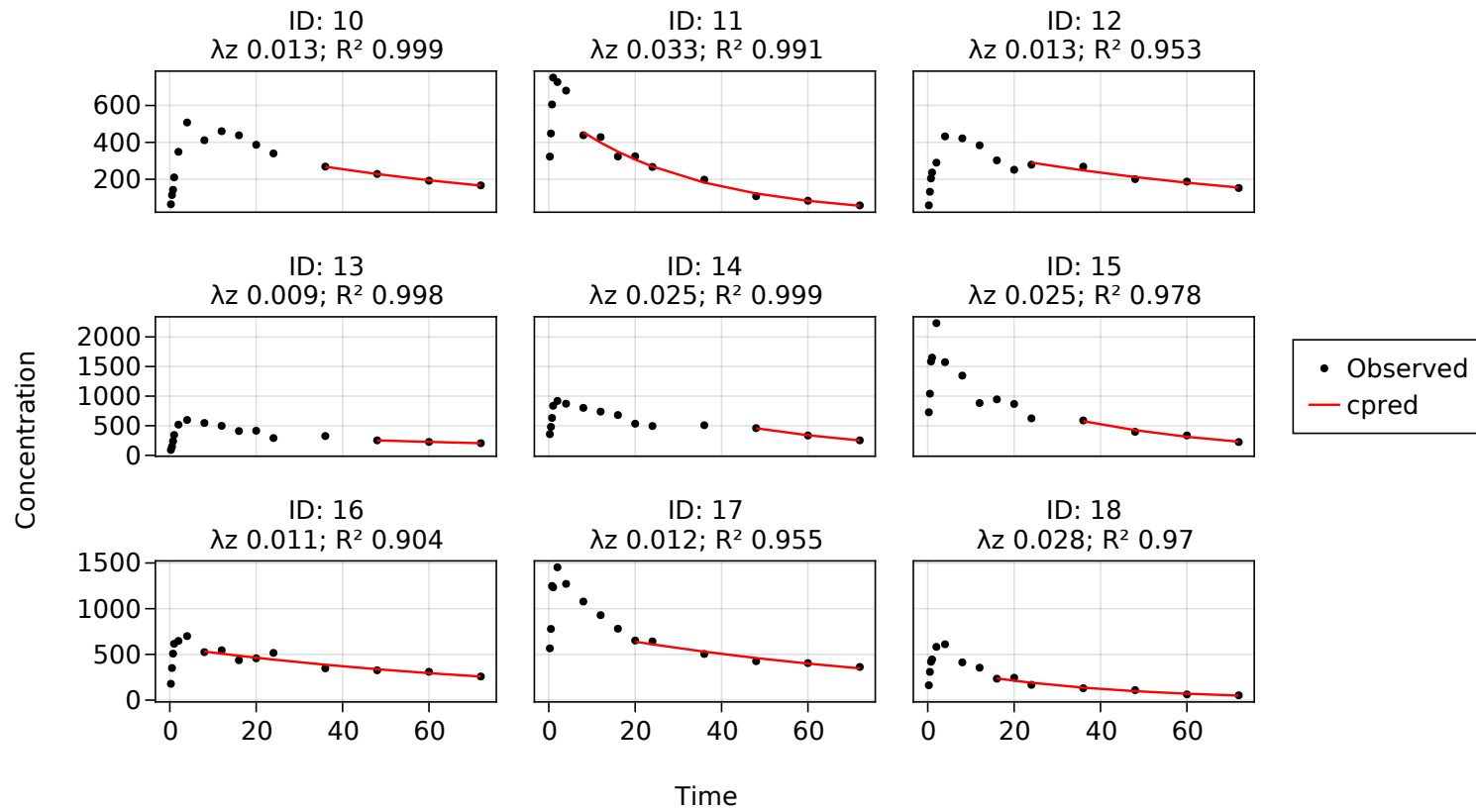


Figure 7: Subject Fits (2 of 2).

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## B System Information

```
Julia Version 1.6.1
Commit 6aaedecc44 (2021-04-23 05:59 UTC)
Platform Info:
  OS: Linux (x86_64-pc-linux-gnu)
  uname: Linux 4.14.209-160.339.amzn2.x86_64 #1 SMP Wed Dec 16 22:44:04 UTC 2020 x86_64
         ↪ x86_64
  CPU: Intel(R) Xeon(R) Platinum 8175M CPU @ 2.50GHz:
           speed      user      nice      sys      idle      irq
        #1  3089 MHz   5600 s   1015 s    854 s   25759 s    0 s
        #2  3098 MHz   4108 s   564 s    887 s   27590 s    0 s

  Memory: 7.500556945800781 GB (708.09375 MB free)
  Uptime: 3376.0 sec
  Load Avg: 0.2 0.15 0.18
  WORD_SIZE: 64
  LIBM: libopenlibm
  LLVM: libLLVM-11.0.1 (ORCJIT, skylake-avx512)
Environment:
  JULIAHUB_USEREMAIL = patrick.mogensen@gmail.com
  JULIAHUB_HOME = /opt/juliahub
  JULIARUN_DATA_FOLDER = 11711238891753218815
  JULIARUN_JOB_ID = gtewu5qzr2
  JULIA_GR_PROVIDER = BinaryBuilder
  JULIA_LOAD_PATH = @:@v#.#:@stdlib:/opt/juliahub/projects/default:/opt/juliahub/projects/
                  ↪ default
  JULIAHUB_NAMESPACE = 11711238891753218815
  JULIA_NEW_PKG_SERVER = https://pumasai.juliahub.com/
  JULIA_DATASETS_PATH = /var/run/secrets/jr-gtewu5qzr2secret/DATA_TOML:/opt/juliahub/
                  ↪ JuliaHubDataDriver.toml:@:
  JULIAHUB_USERNAME = Patrick Kofod Mogensen
  JULIA_DEPOT_PATH = /home/jrun/.julia
  JULIARUN_RUN_MODE = script
  JULIA_HOME = /home/jrun/.julia
  JULIATEAM_HOSTNAME = pumasai.juliahub.com
  JULIARUN_RESTART_POLICY = Never
  JULIA_PKG_SERVER = pumasai.juliahub.com
  JULIA_NUM_THREADS = 2
  JULIA_EDITOR = "/opt/codeserver/lib/code-server/lib/node"
  JULIAHUB_HOME = /opt/juliahub
  FONTCONFIG_PATH = /home/jrun/.julia/artifacts/69ab5e1318fa87cac480350ccc9faffff3b00c5b/etc
                  ↪ /fonts
  JULIA_LOAD_PATH = @:@v#.#:@stdlib:/opt/juliahub/projects/default:/opt/juliahub/projects/
                  ↪ default
  HOME = /home/jrun
  JULIA_DATASETS_PATH = /var/run/secrets/jr-gtewu5qzr2secret/DATA_TOML:/opt/juliahub/
                  ↪ JuliaHubDataDriver.toml:@:
  TERM = xterm-256color
  JULIA_DEPOT_PATH = /home/jrun/.julia
  LD_LIBRARY_PATH = :/opt/julia-1.6.1/bin/./lib/julia:/home/jrun/.julia/artifacts/04
                  ↪ cddd7adc69260fa855b10afdbfbc8c244c7862/lib:/opt/codeserver/lib:/opt/julia-1.6.1/
                  ↪ bin/./lib/julia:/home/jrun/.julia/artifacts/04
                  ↪ cddd7adc69260fa855b10afdbfbc8c244c7862/lib
  JULIA_HOME = /home/jrun/.julia
  JRUN_APP_BASE_PATH = /
  PATH = /opt/PsN/4.9.3/bin:/usr/local/sbin:/usr/local/bin:/usr/sbin:/usr/bin:/sbin:/bin
```

---

## B.1 NCA Version

```
Status `~/julia/environments/v1.6/Manifest.toml`  
[29142fd5] NCA v2.1.1 ☐  
[b07d0016] NCAUtilities v0.4.1 ☐
```

## B.2 Project Manifest

```
Status `~/julia/environments/v1.6/Manifest.toml`  
[c3fe647b] AbstractAlgebra v0.16.0 ☐  
[621f4979] AbstractFFTs v1.0.1 ☐  
[80f14c24] AbstractMCMC v3.2.1 ☐  
[1520ce14] AbstractTrees v0.3.4 ☐  
[79e6a3ab] Adapt v3.3.1 ☐  
[0bf59076] AdvancedHMC v0.2.27 ☐  
[cbdf2221] AlgebraOfGraphics v0.4.9 ☐  
[27a7e980] Animations v0.4.1 ☐→  
[197a6dec] AppServer v0.1.2 ☐  
[dce04be8] ArgCheck v1.1.0 ☐  
[ec485272] ArnoldiMethod v0.1.0 ☐  
[4fba245c] ArrayInterface v3.1.17 ☐  
[69666777] Arrow v1.6.2 ☐  
[31f734f8] ArrowTypes v1.2.0 ☐  
[67c07d97] Automa v0.8.2 ☐  
[13072b0f] AxisAlgorithms v1.0.0 ☐  
[39de3d68] AxisArrays v0.4.4 ☐  
[198e06fe] BangBang v0.3.31 ☐  
[9718e550] Baselet v0.1.1 ☐  
[6e4b80f9] BenchmarkTools v1.1.1 ☐  
[b99e7846] BinaryProvider v0.5.10 ☐  
[c3b6d118] BitIntegers v0.2.4 ☐  
[8e7c35d0] BlockArrays v0.11.2 ☐  
[fa961155] CEnum v0.4.1 ☐  
[336ed68f] CSV v0.8.5 ☐  
[159f3aea] Cairo v1.0.5 ☐  
[13f3f980] CairoMakie v0.6.3 ☐  
[49dc2e85] Calculus v0.5.1 ☐  
[479239e8] Catalyst v6.12.1 ☐  
[324d7699] CategoricalArrays v0.10.0 ☐  
[9961bab8] Cbc v0.7.1 ☐  
[8be319e6] Chain v0.4.7 ☐  
[082447d4] ChainRules v0.7.70 ☐  
[d360d2e6] ChainRulesCore v0.9.45 ☐  
[523fee87] CodecBzip2 v0.7.2 ☐  
[5ba52731] CodecLz4 v0.4.0 ☐  
[944b1d66] CodecZlib v0.7.0 ☐  
[6b39b394] CodecZstd v0.7.0 ☐  
[a2cac450] ColorBrewer v0.4.0 ☐  
[35d6a980] ColorSchemes v3.13.0 ☐  
[3da002f7] ColorTypes v0.11.0 ☐  
[c3611d14] ColorVectorSpace v0.9.5 ☐  
[5ae59095] Colors v0.12.8 ☐  
[861a8166] Combinatorics v1.0.2 ☐  
[a80b9123] CommonMark v0.8.2 ☐  
[38540f10] CommonSolve v0.2.0 ☐  
[bbf7d656] CommonSubexpressions v0.3.0 ☐  
[34da2185] Compat v3.31.0 ☐  
[a33af91c] CompositionsBase v0.1.1 ☐
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---

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[88cd18e8] ConsoleProgressMonitor v0.1.2 ♡
[187b0558] ConstructionBase v1.3.0 ♡
[d38c429a] Contour v0.5.7 ♡
[a8cc5b0e] Crayons v4.0.4 ♡
[d58978e5] Dagger v0.11.7 ♡
[9a962f9c] DataAPI v1.7.0 ♡
[75880514] DataFrameMacros v0.1.0 ♡
[a93c6f00] DataFrames v1.1.1 ♡
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[82cc6244] DataInterpolations v3.5.0 ♡
[864edb3b] DataStructures v0.18.9 ♡
[e2d170a0] DataValueInterfaces v1.0.0 ♡
[e7dc6d0d] DataValues v0.4.13 ♡
[244e2a9f] DefineSingletons v0.1.1 ♡
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[3f19e933] p7zip_jll
Info packages marked with → not downloaded, use `instantiate` to download
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