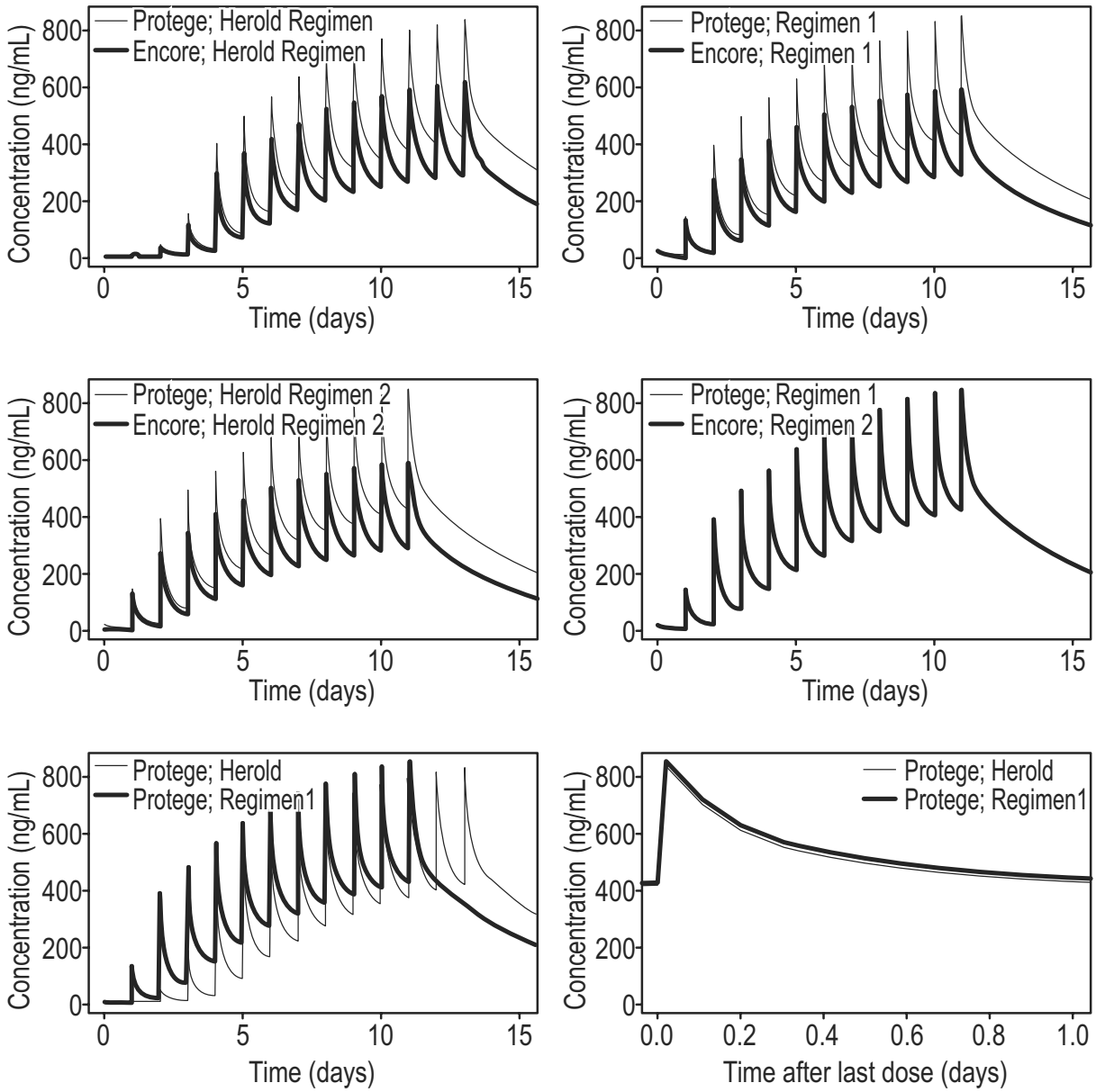
FIG. 1


Protege; Herold Regimen
Encore; Herold Regimen
Concentration (ng/mL)
Time (days)
Protege; Regimen 1
Encore; Regimen 1
Concentration (ng/mL)
Time (days)
Protege; Herold Regimen 2
Encore; Herold Regimen 2
Concentration (ng/mL)
Time (days)
Protege; Regimen 1
Encore; Regimen 2
Concentration (ng/mL)
Time (days)
Protege; Herold
Protege; Regimen1
Concentration (ng/mL)
Time (days)
Protege; Herold
Protege; Regimen1
Concentration (ng/mL)
Time after last dose (days)

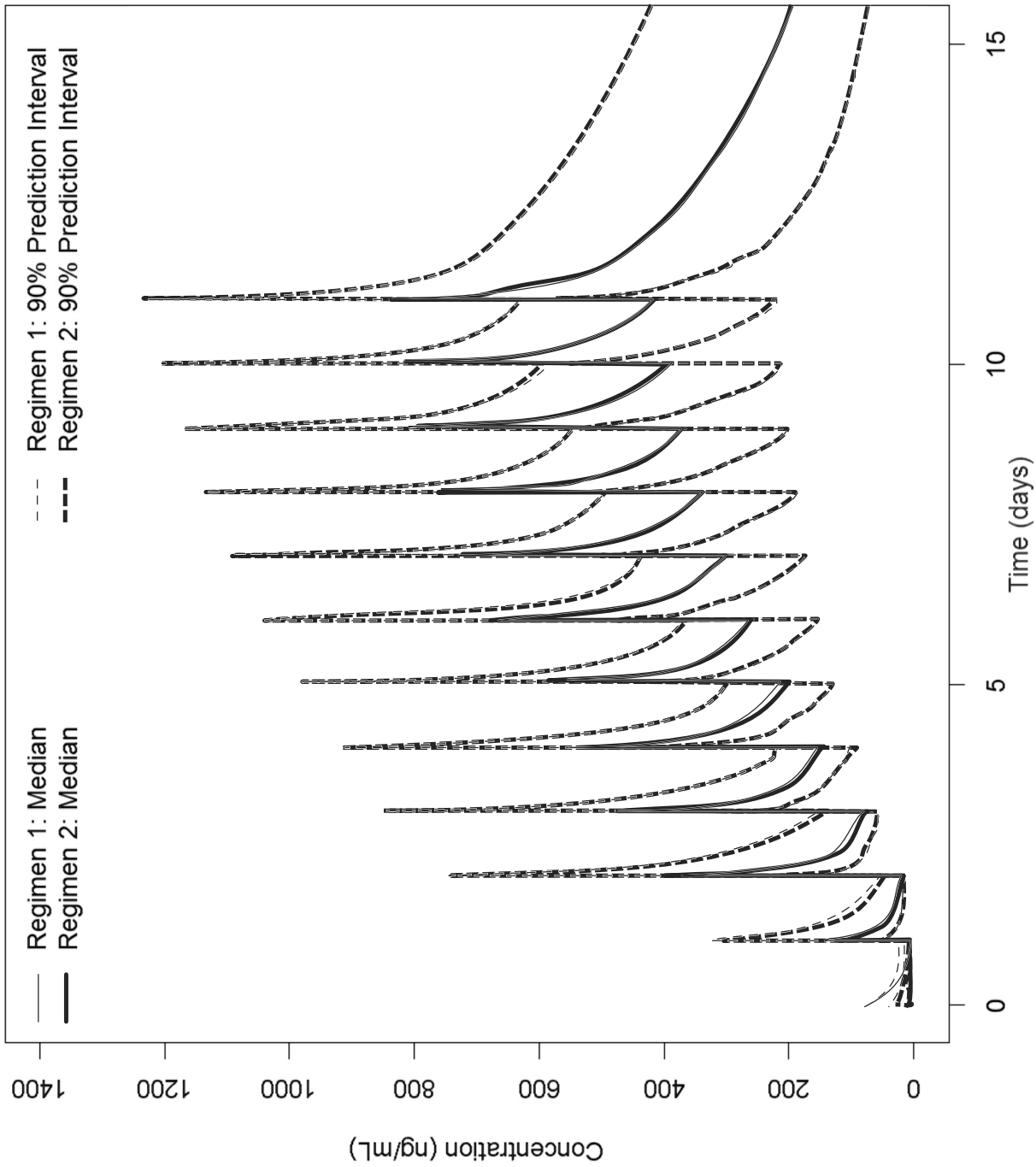

Regimen 1: Median
Regimen 2: Median
Regimen 1: 90% Prediction Interval
Regimen 2: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
Time (days)
0
5
10
15

FIG. 2

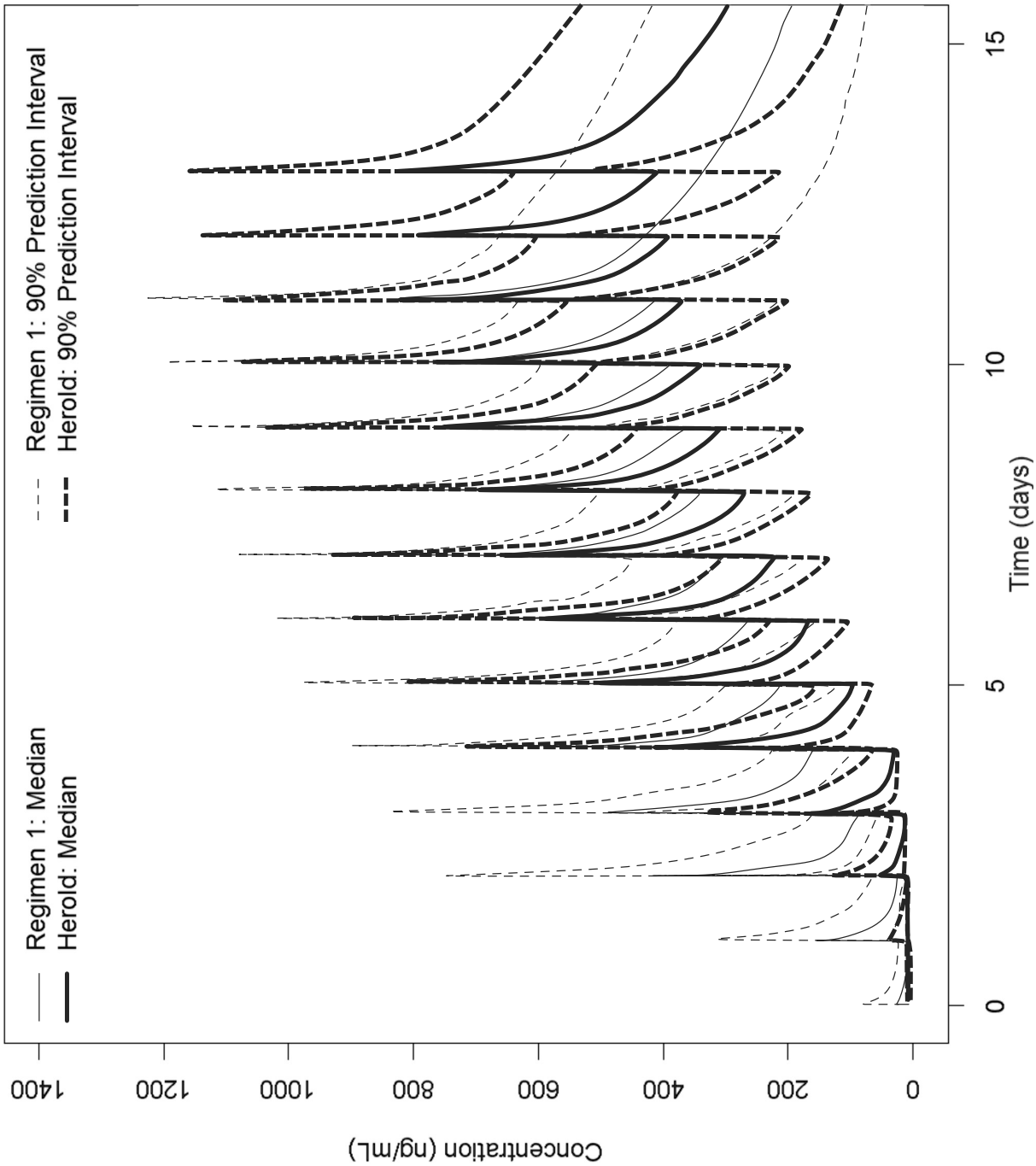

Regimen 1: Median
Herold: Median
Regimen 1: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
Time (days)
0
5
10
15

FIG. 3

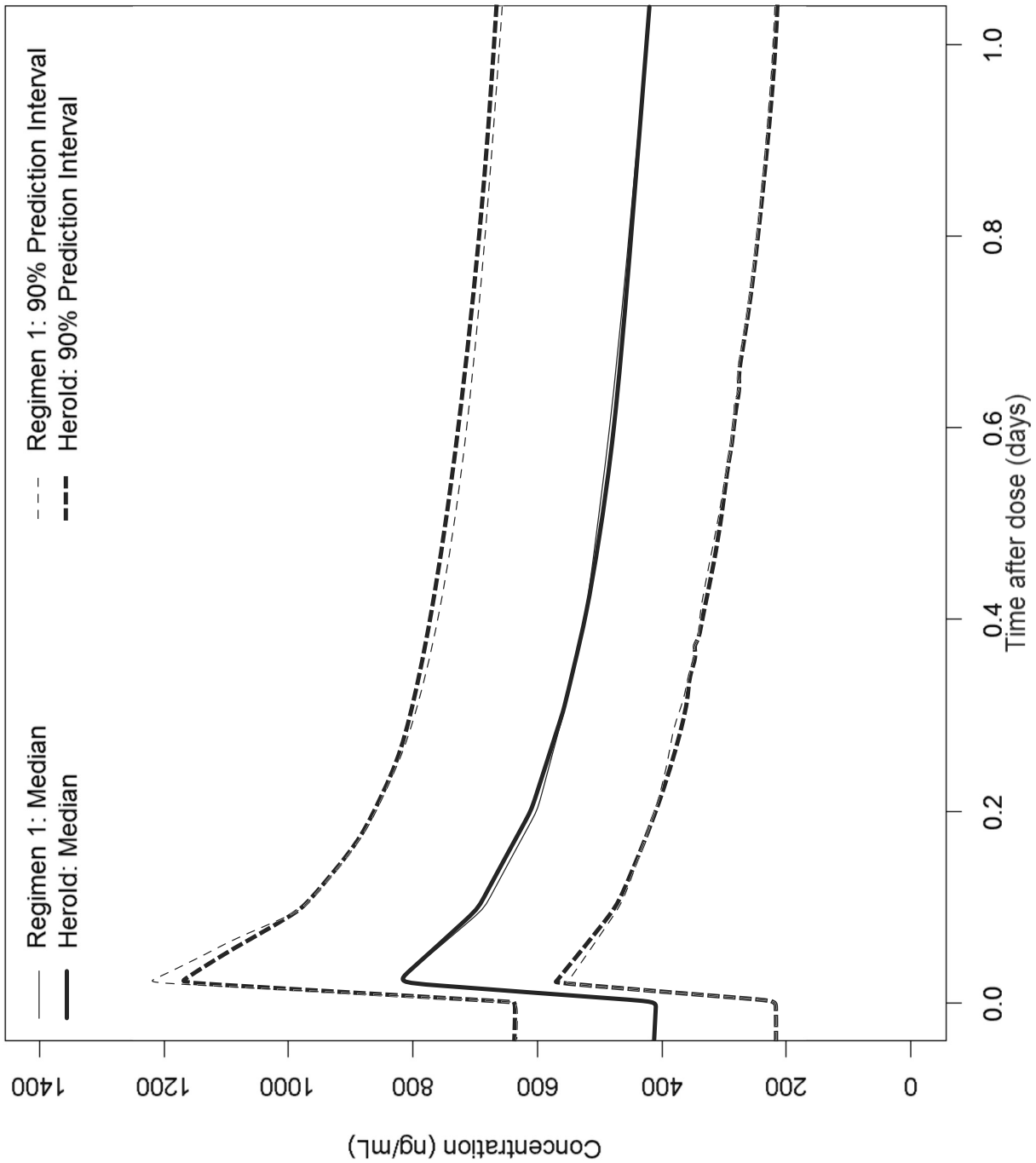
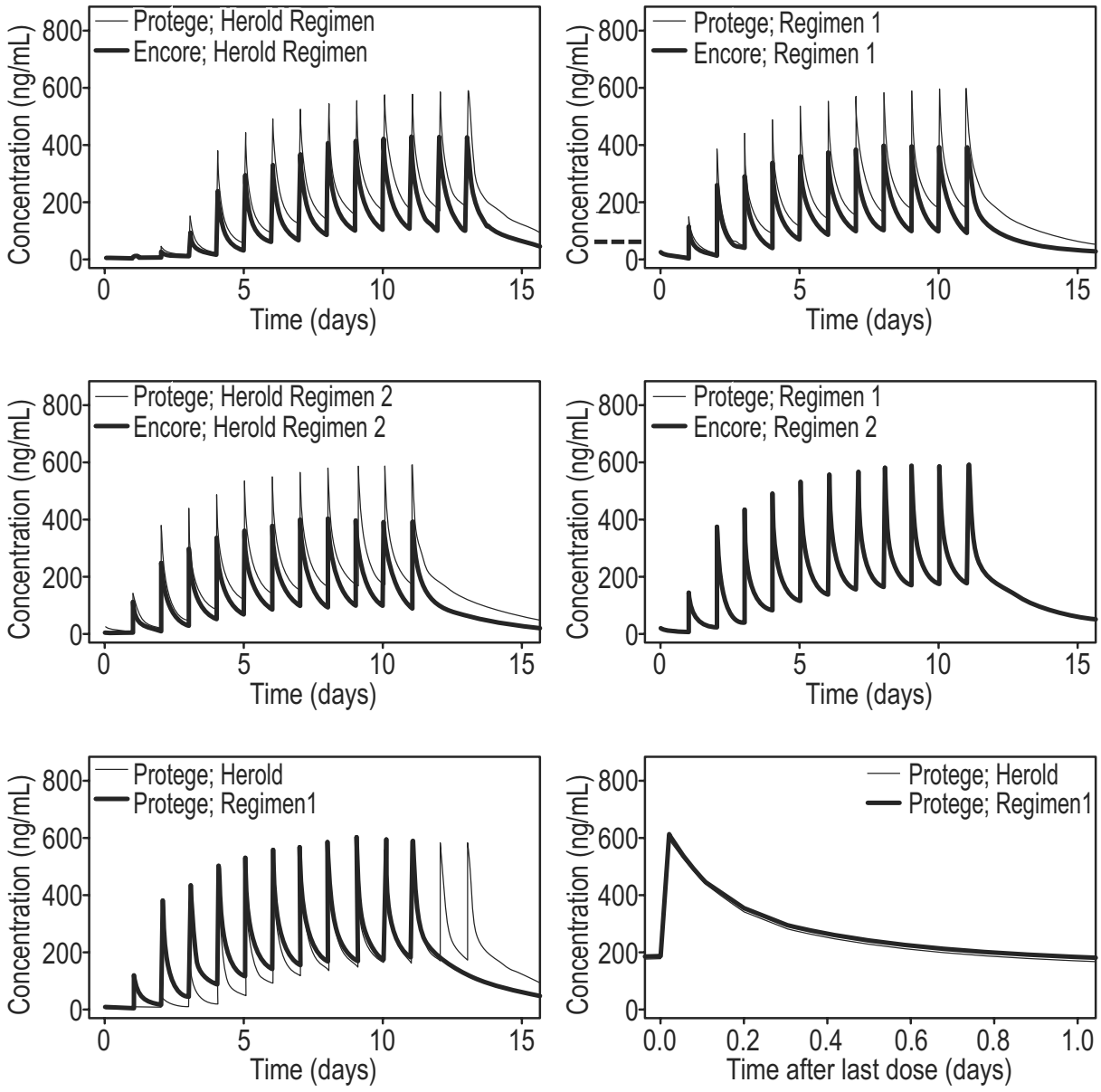

Regimen 1: Median
Herold: Median
Regimen 1: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
0.0
0.2
0.4
0.6
0.8
1.0
Time after dose (days)

FIG. 4

FIG. 5


Protege; Herold Regimen
Encore; Herold Regimen
Protege; Regimen 1
Encore; Regimen 1
Protege; Herold Regimen 2
Encore; Herold Regimen 2
Protege; Regimen 1
Encore; Regimen 2
Protege; Herold
Protege; Regimen1
Protege; Herold
Protege; Regimen1
Concentration (ng/mL)
Time (days)
Time after last dose (days)
0
200
400
600
800
0
5
10
15
0.0
0.2
0.4
0.6
0.8
1.0

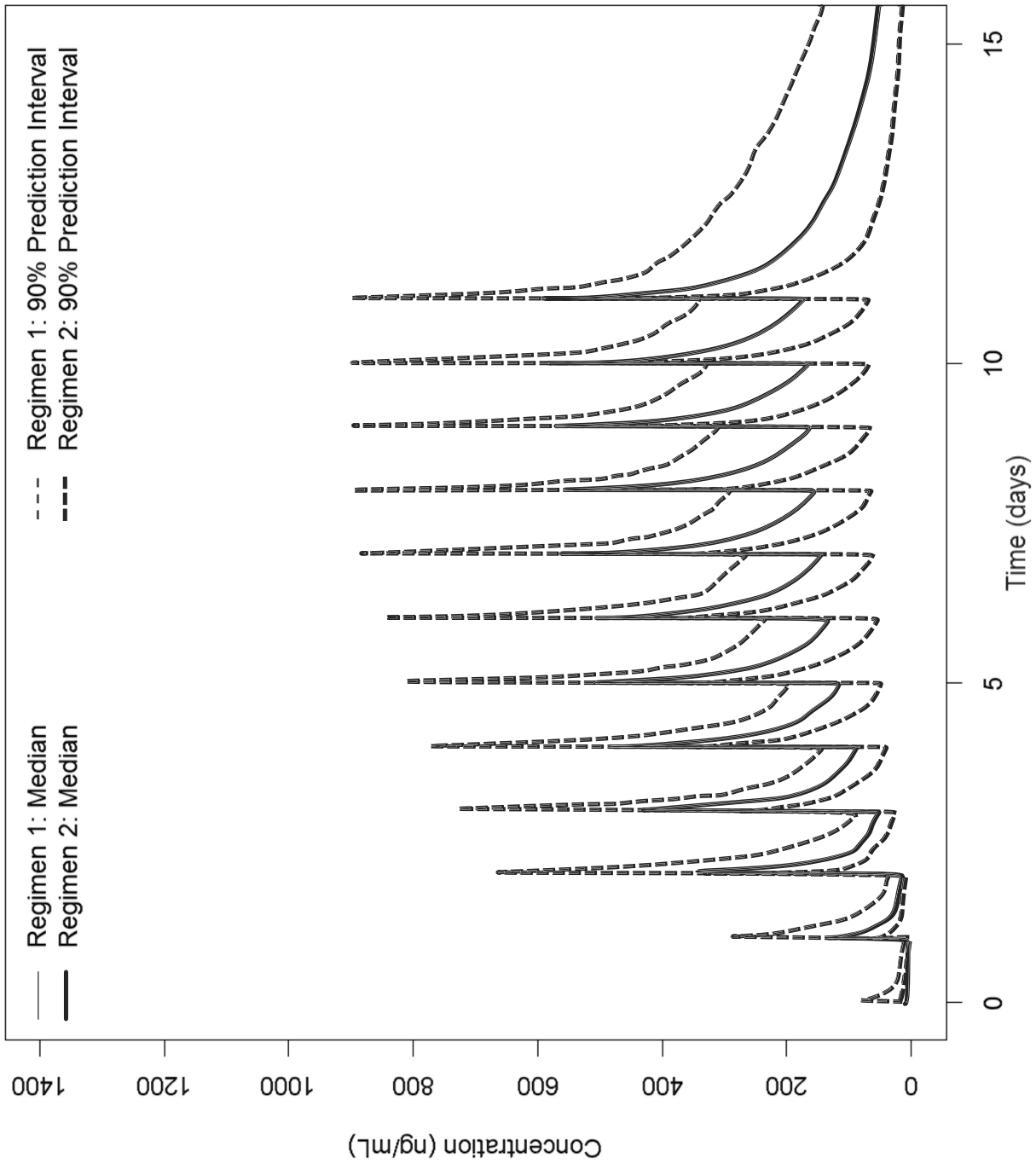

Regimen 1: Median
Regimen 2: Median
Regimen 1: 90% Prediction Interval
Regimen 2: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
0
5
10
15
Time (days)

FIG. 6

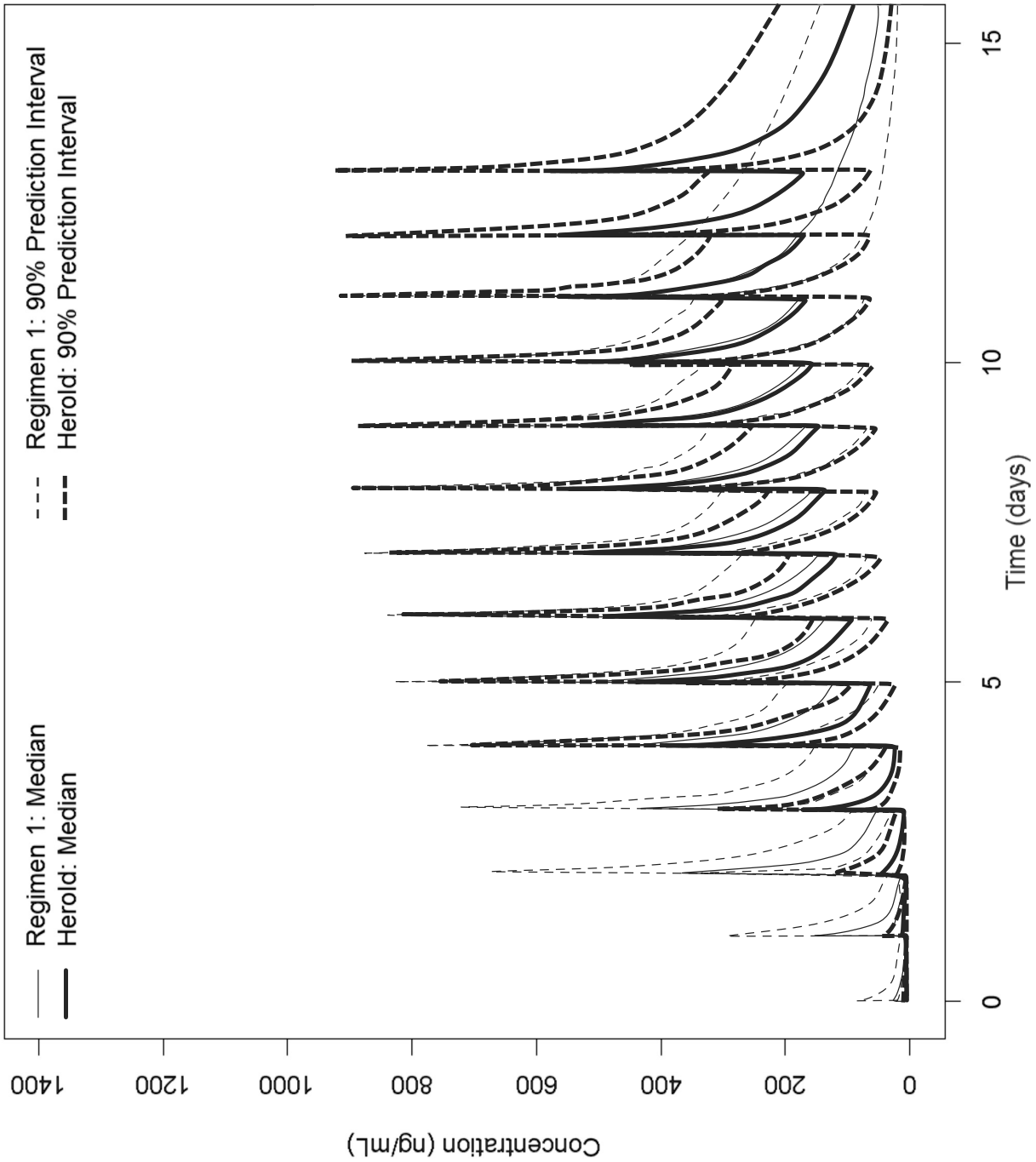

Regimen 1: Median
Herold: Median
Regimen 1: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
Time (days)
0
5
10
15

FIG. 7

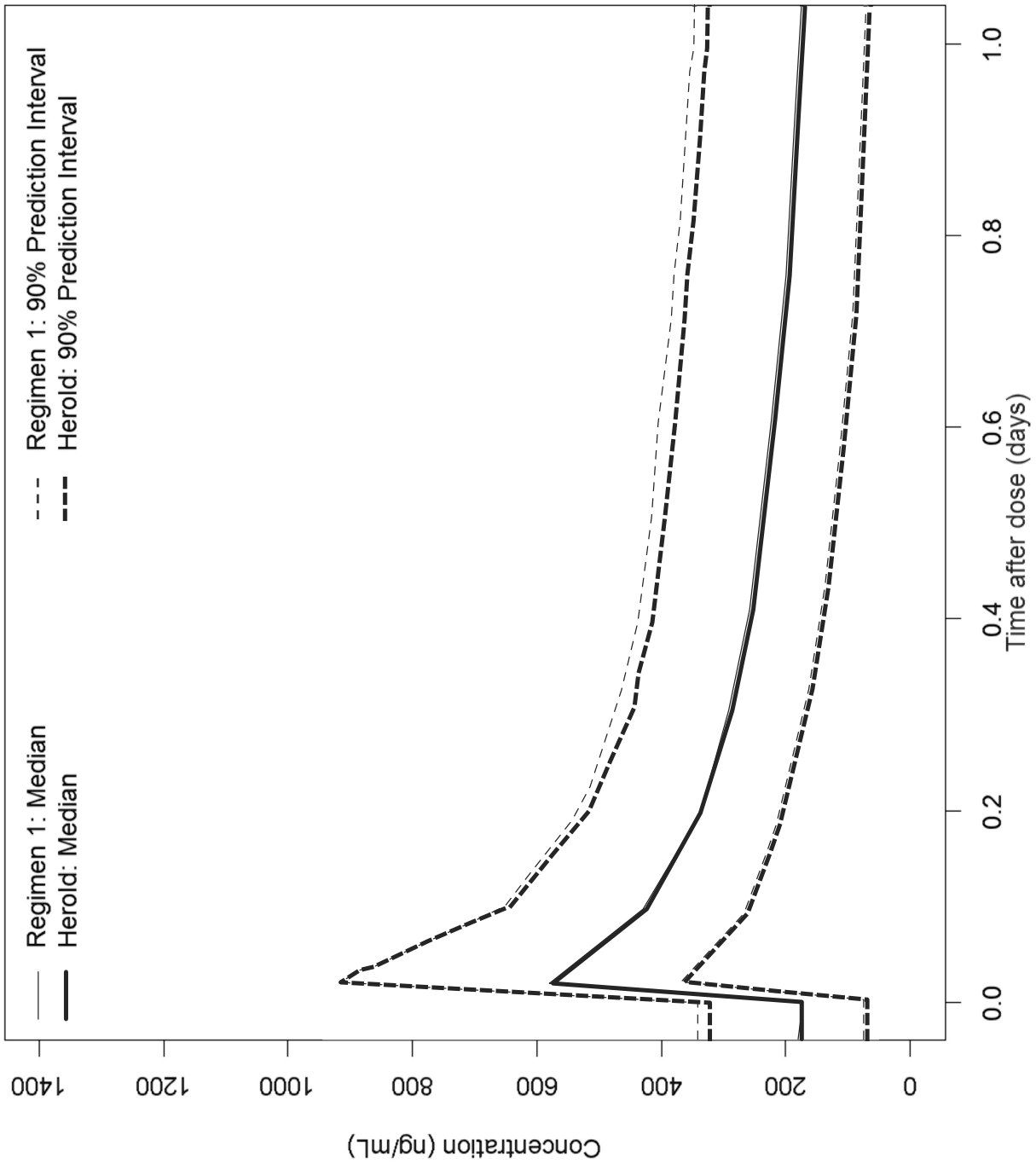
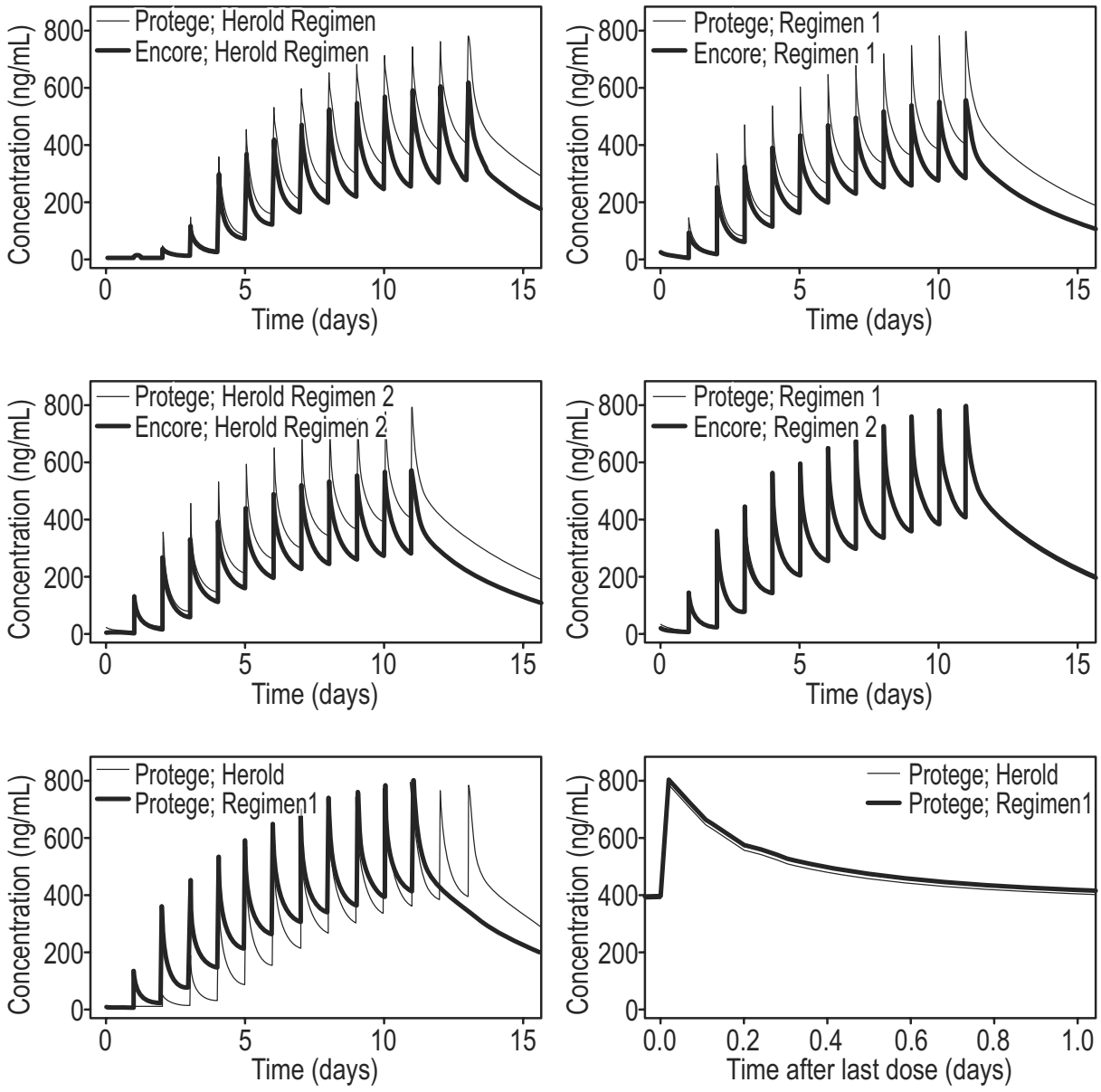

Regimen 1: Median
Herold: Median
Regimen 1: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
0.0
0.2
0.4
0.6
0.8
1.0
Time after dose (days)

FIG. 8

FIG. 9


Protege; Herold Regimen
Encore; Herold Regimen
Concentration (ng/mL)
Time (days)
Protege; Regimen 1
Encore; Regimen 1
Concentration (ng/mL)
Time (days)
Protege; Herold Regimen 2
Encore; Herold Regimen 2
Concentration (ng/mL)
Time (days)
Protege; Regimen 1
Encore; Regimen 2
Concentration (ng/mL)
Time (days)
Protege; Herold
Protege; Regimen1
Concentration (ng/mL)
Time (days)
Protege; Herold
Protege; Regimen1
Concentration (ng/mL)
Time after last dose (days)

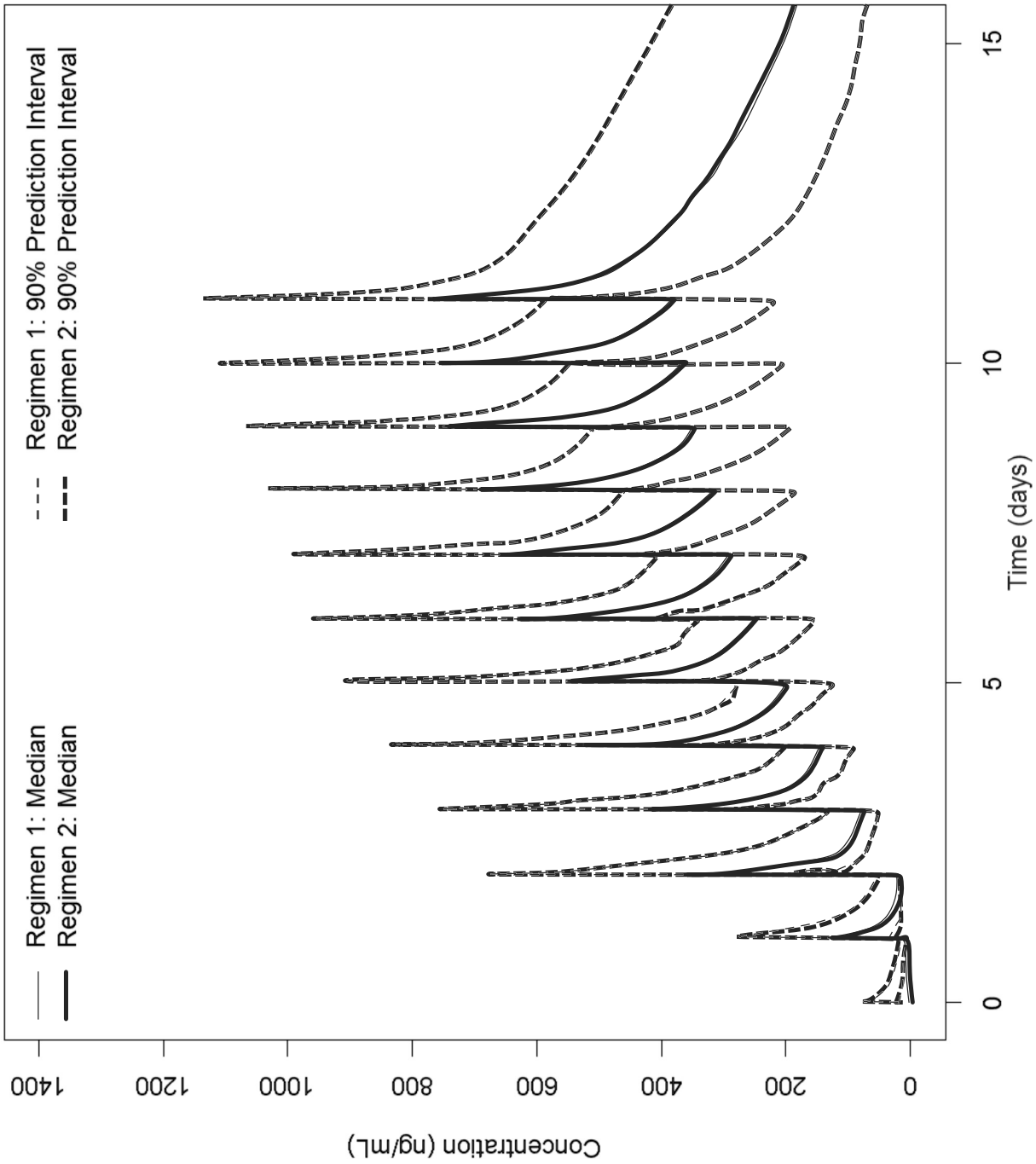

Regimen 1: Median
Regimen 2: Median
Regimen 1: 90% Prediction Interval
Regimen 2: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
0
5
10
15
Time (days)

FIG. 10

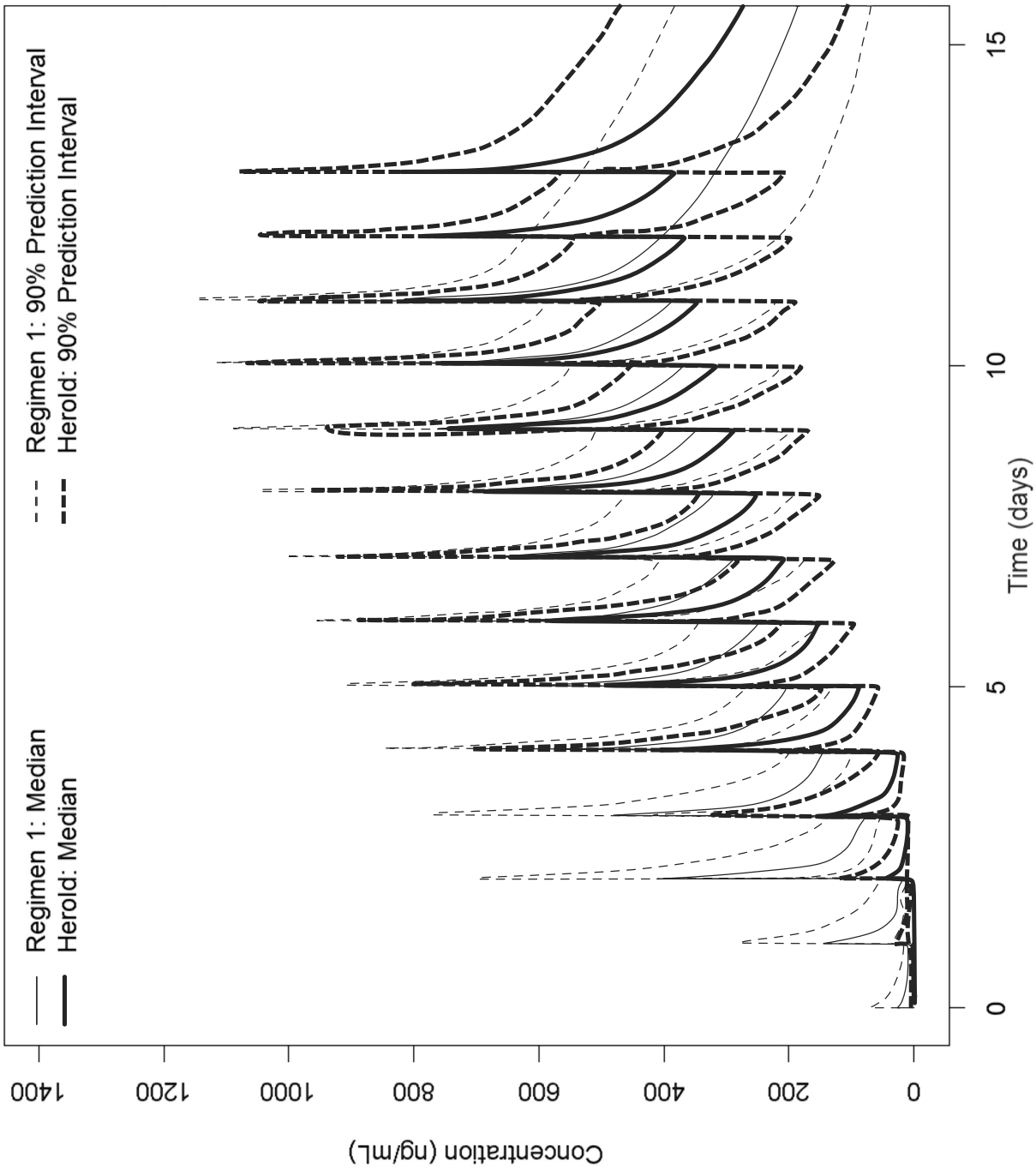

Regimen 1: Median
Herold: Median
Regimen 1: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
Time (days)
0
5
10
15

FIG. 11

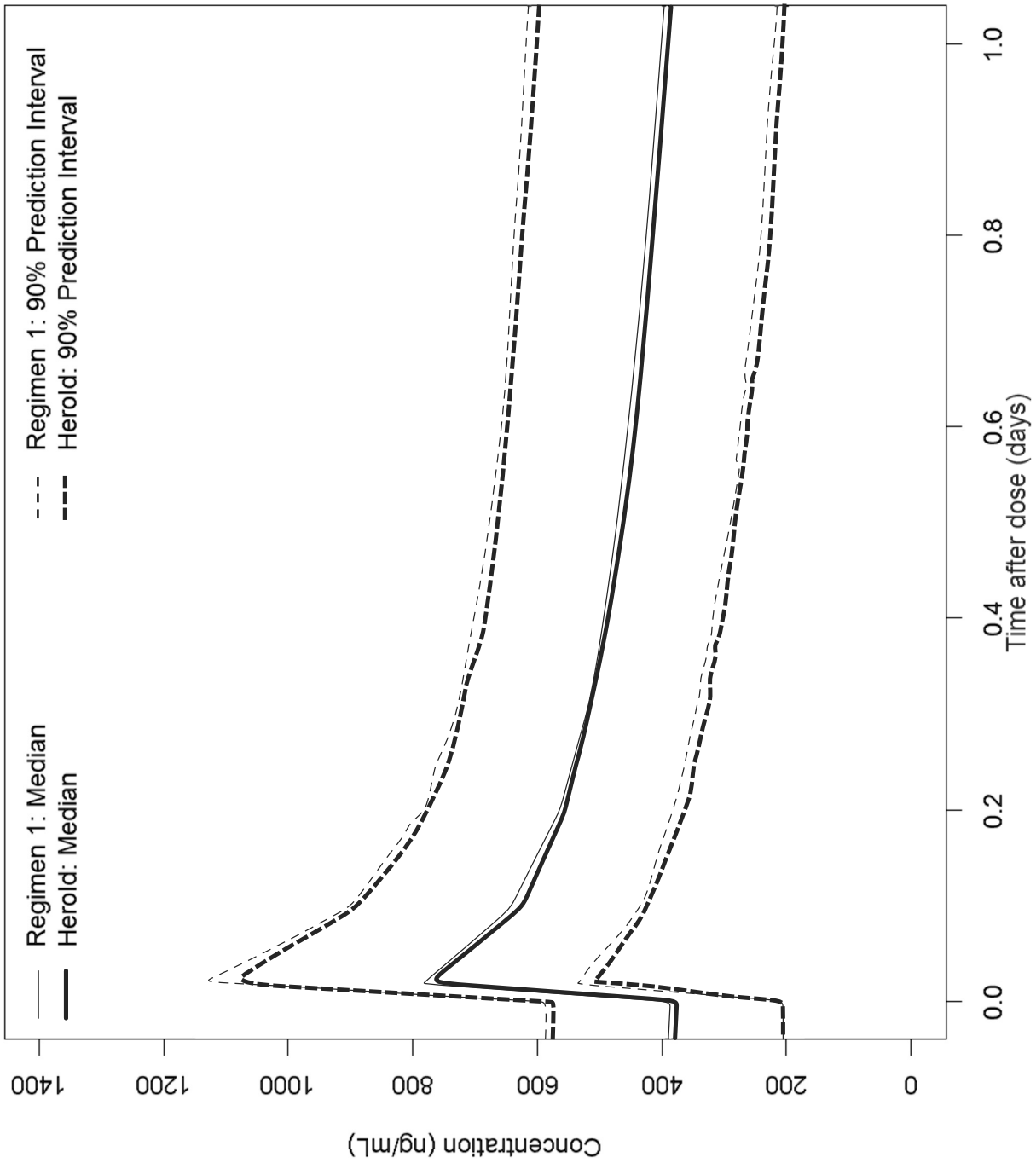
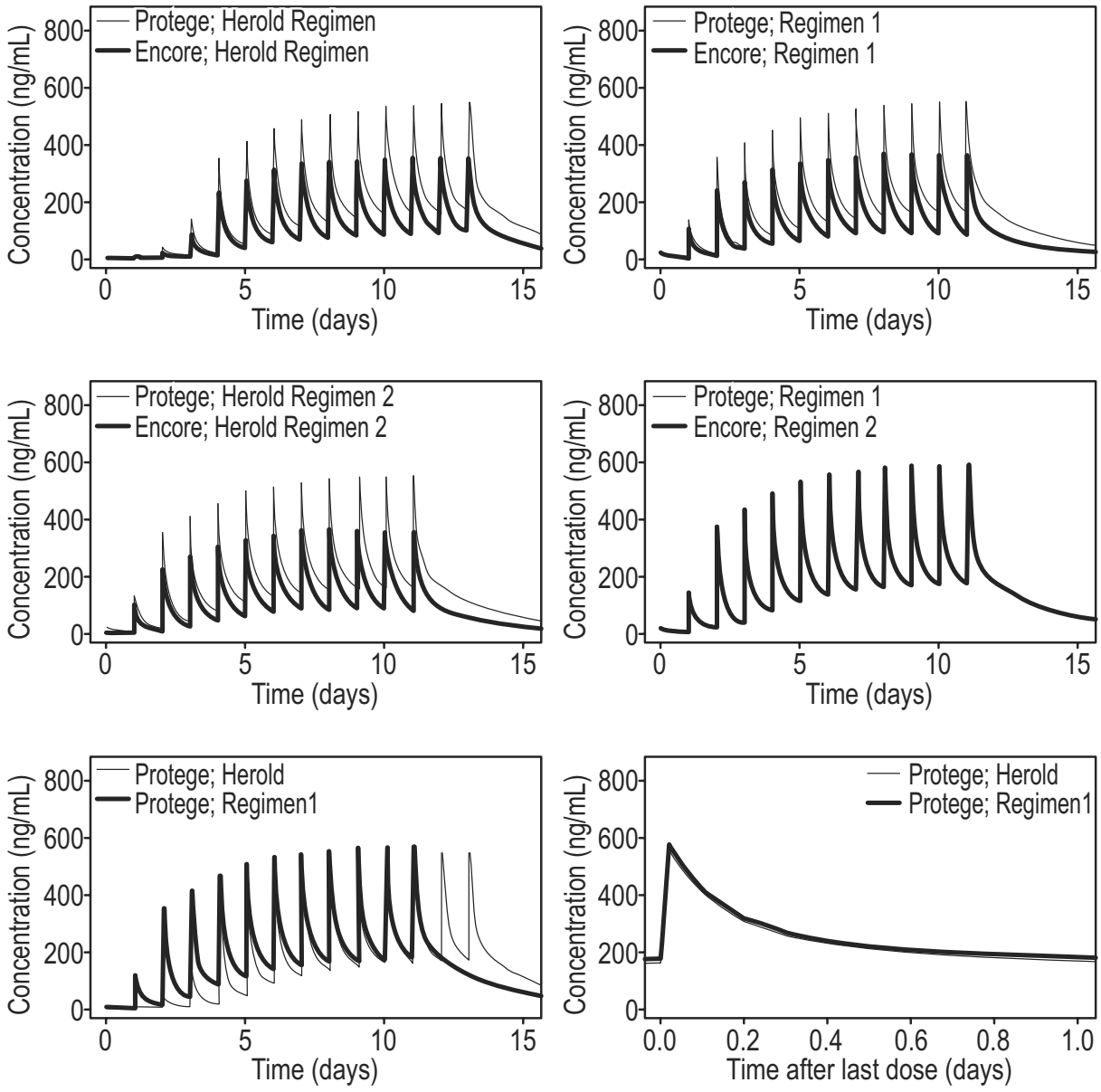

Regimen 1: Median
Herold: Median
Regimen 1: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
0.0
0.2
0.4
0.6
0.8
1.0
Time after dose (days)

FIG. 12

FIG. 13


Protege; Herold Regimen
Encore; Herold Regimen
Protege; Regimen 1
Encore; Regimen 1
Protege; Herold Regimen 2
Encore; Herold Regimen 2
Protege; Regimen 1
Encore; Regimen 2
Protege; Herold
Protege; Regimen1
Protege; Herold
Protege; Regimen1
Concentration (ng/mL)
Time (days)
Time after last dose (days)
0
200
400
600
800
0
5
10
15
0.0
0.2
0.4
0.6
0.8
1.0

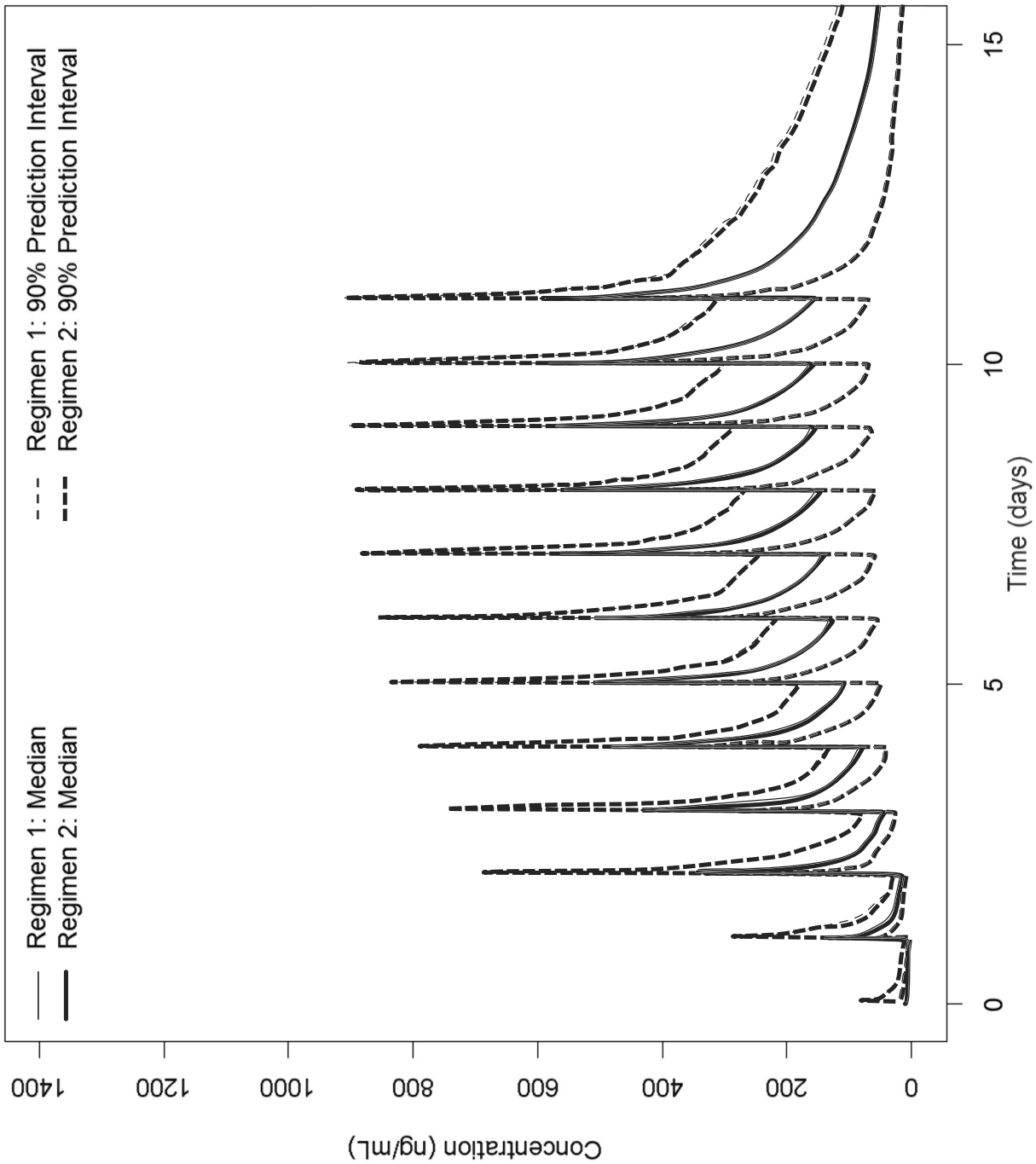

Regimen 1: Median
Regimen 2: Median
Regimen 1: 90% Prediction Interval
Regimen 2: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
0
5
10
15
Time (days)

FIG. 14

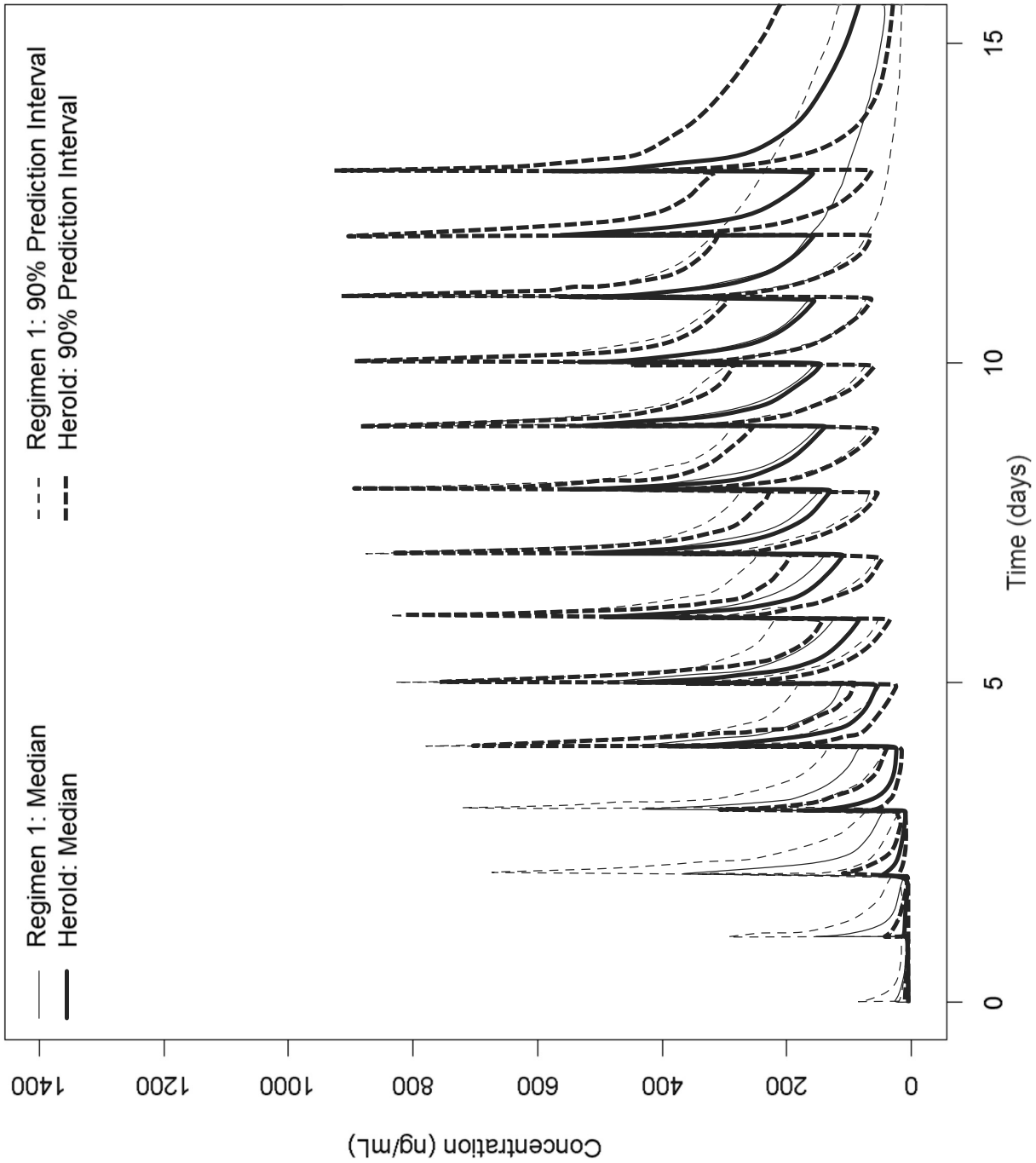

Regimen 1: Median
Herold: Median
Regimen 1: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
Time (days)
0
5
10
15

FIG. 15

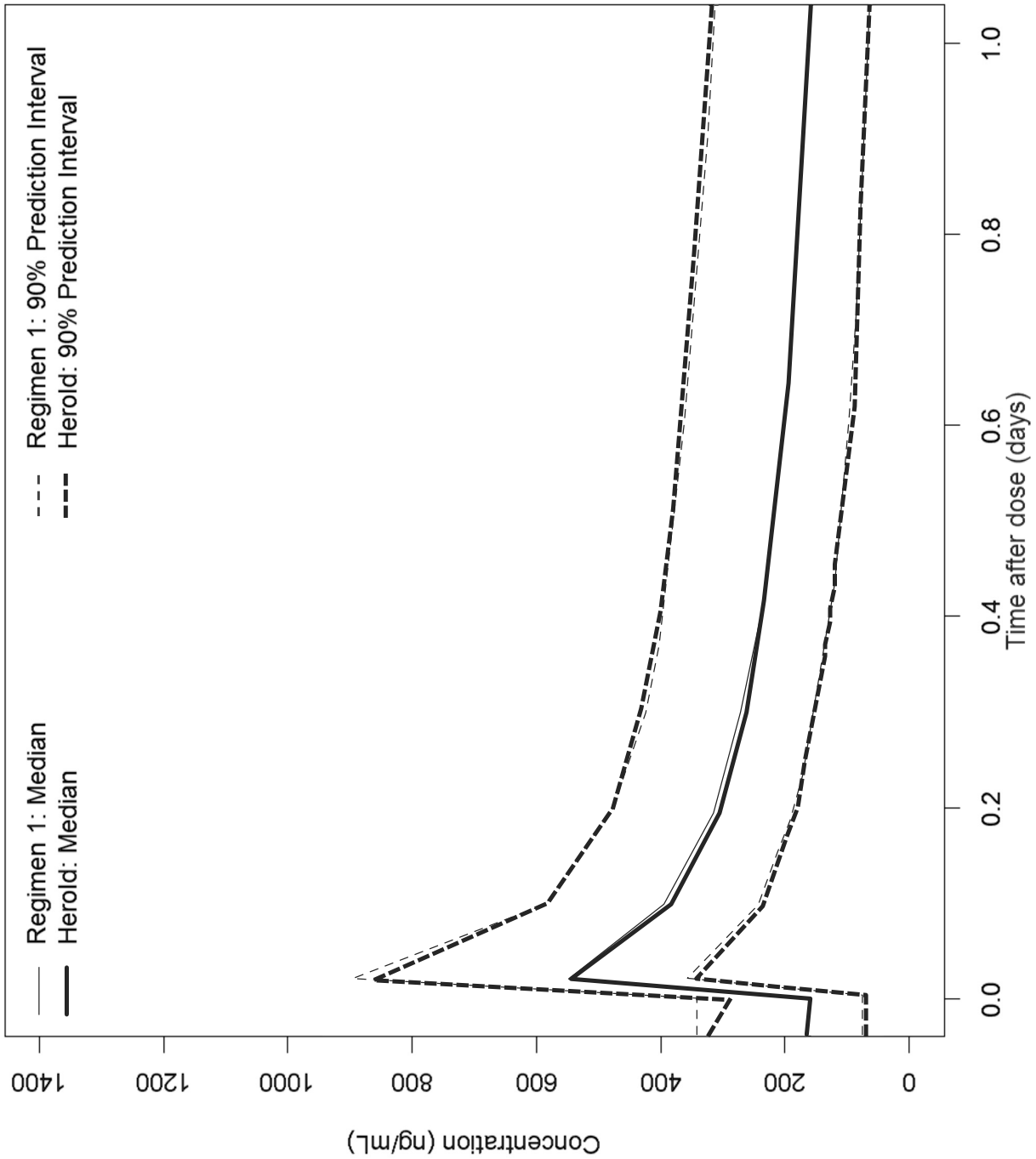

Regimen 1: Median
Herold: Median
Regimen 1: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
1400
0.0
0.2
0.4
0.6
0.8
1.0
Time after dose (days)

FIG. 16

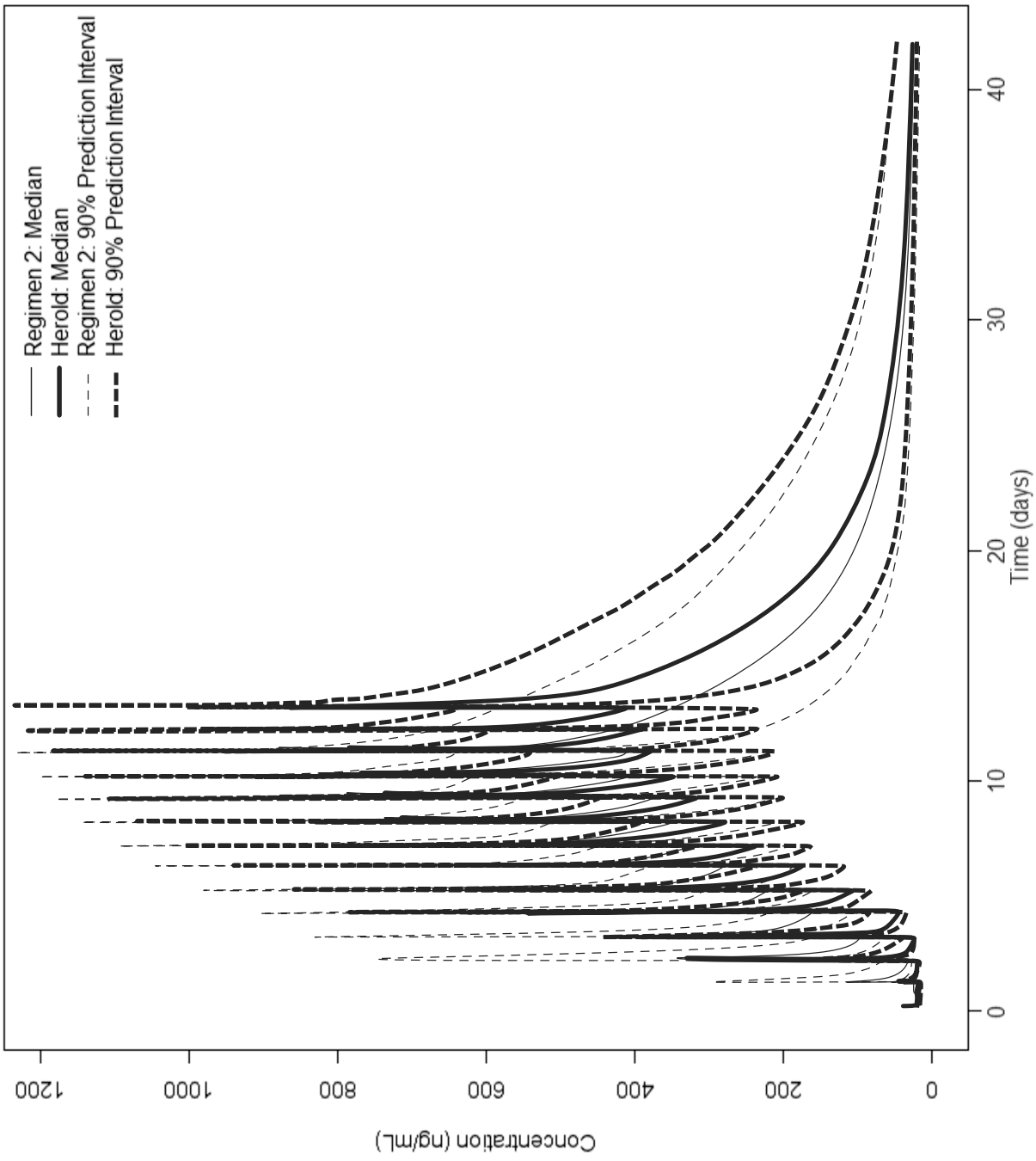

Regimen 2: Median
Herold: Median
Regimen 2: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
Time (days)
0
10
20
30
40

FIG. 17

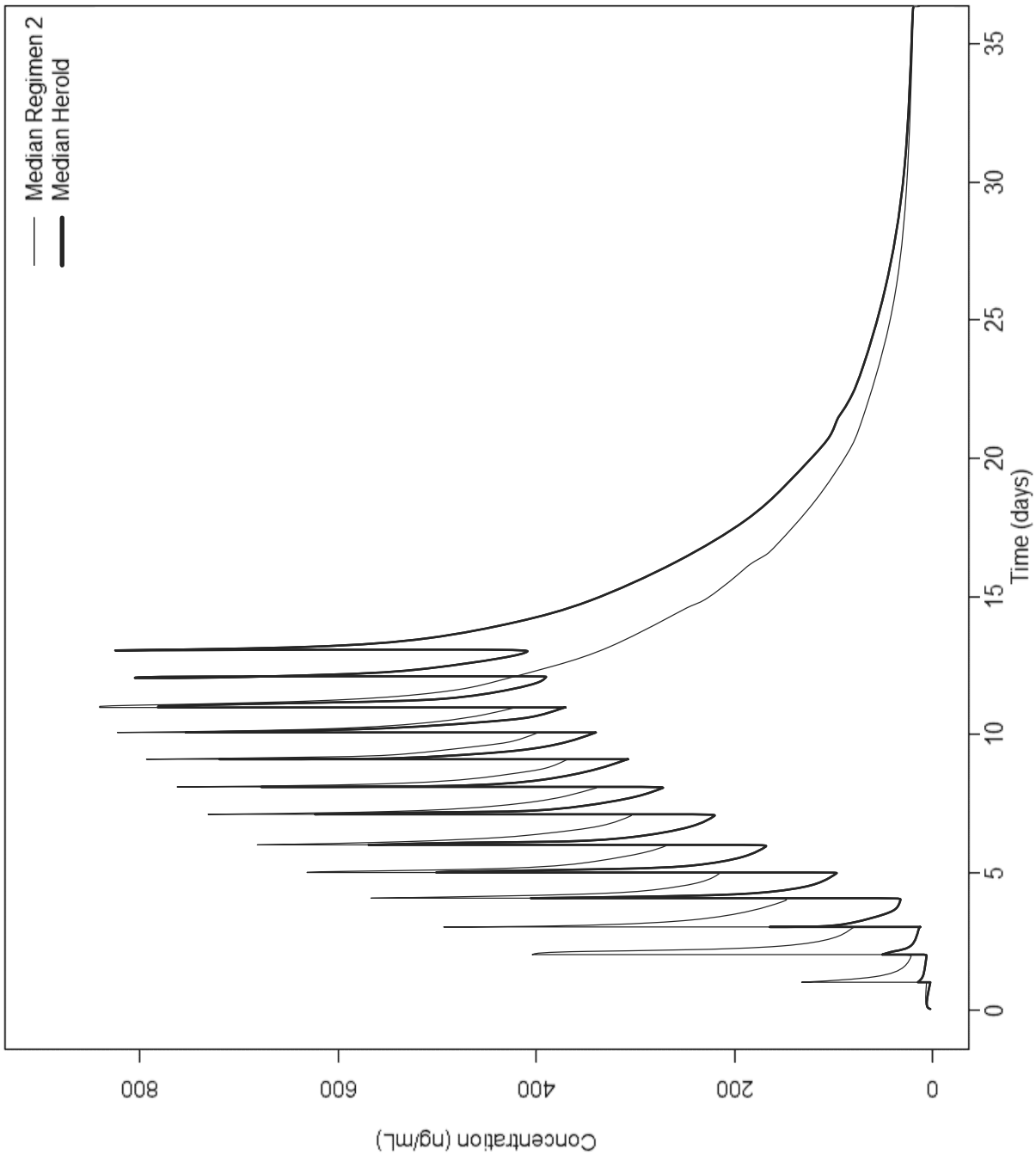

Median Regimen 2
Median Herold
Concentration (ng/mL)
0
200
400
600
800
Time (days)
0
5
10
15
20
25
30
35

FIG. 18

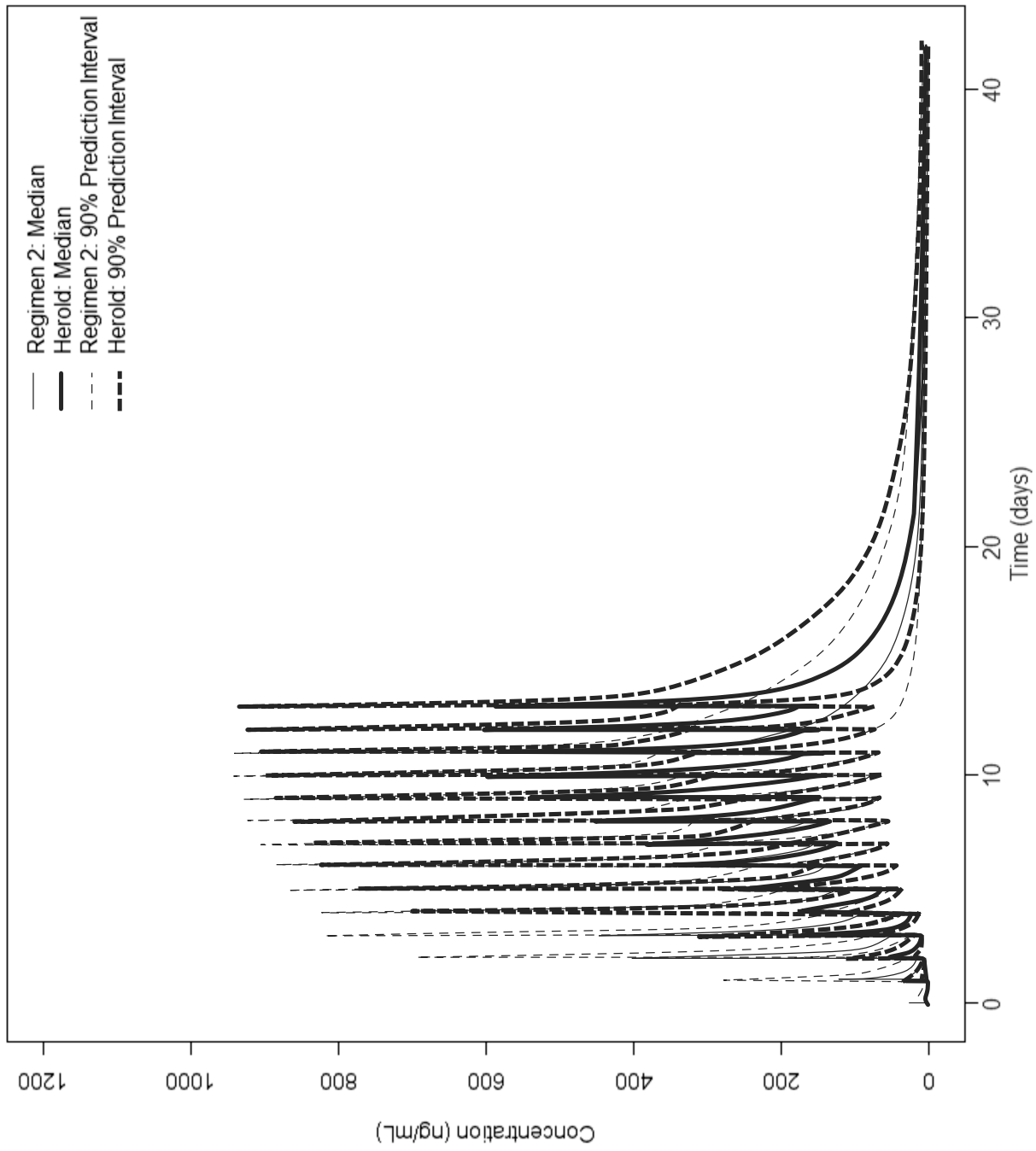

Regimen 2: Median
Herold: Median
Regimen 2: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
Time (days)
0
10
20
30
40

FIG. 19

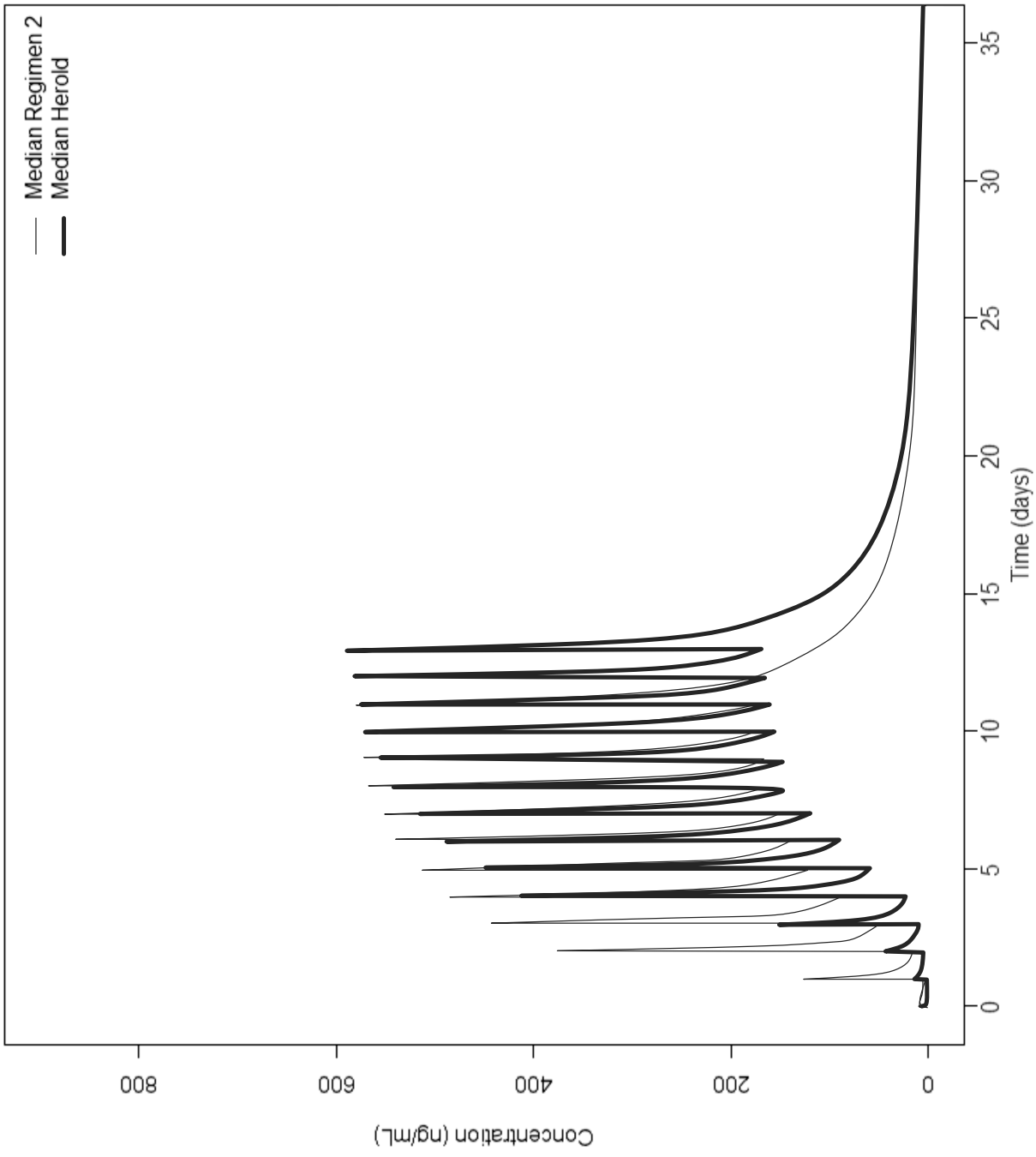

Median Regimen 2
Median Herold
Concentration (ng/mL)
0
200
400
600
800
Time (days)
0
5
10
15
20
25
30
35

FIG. 20

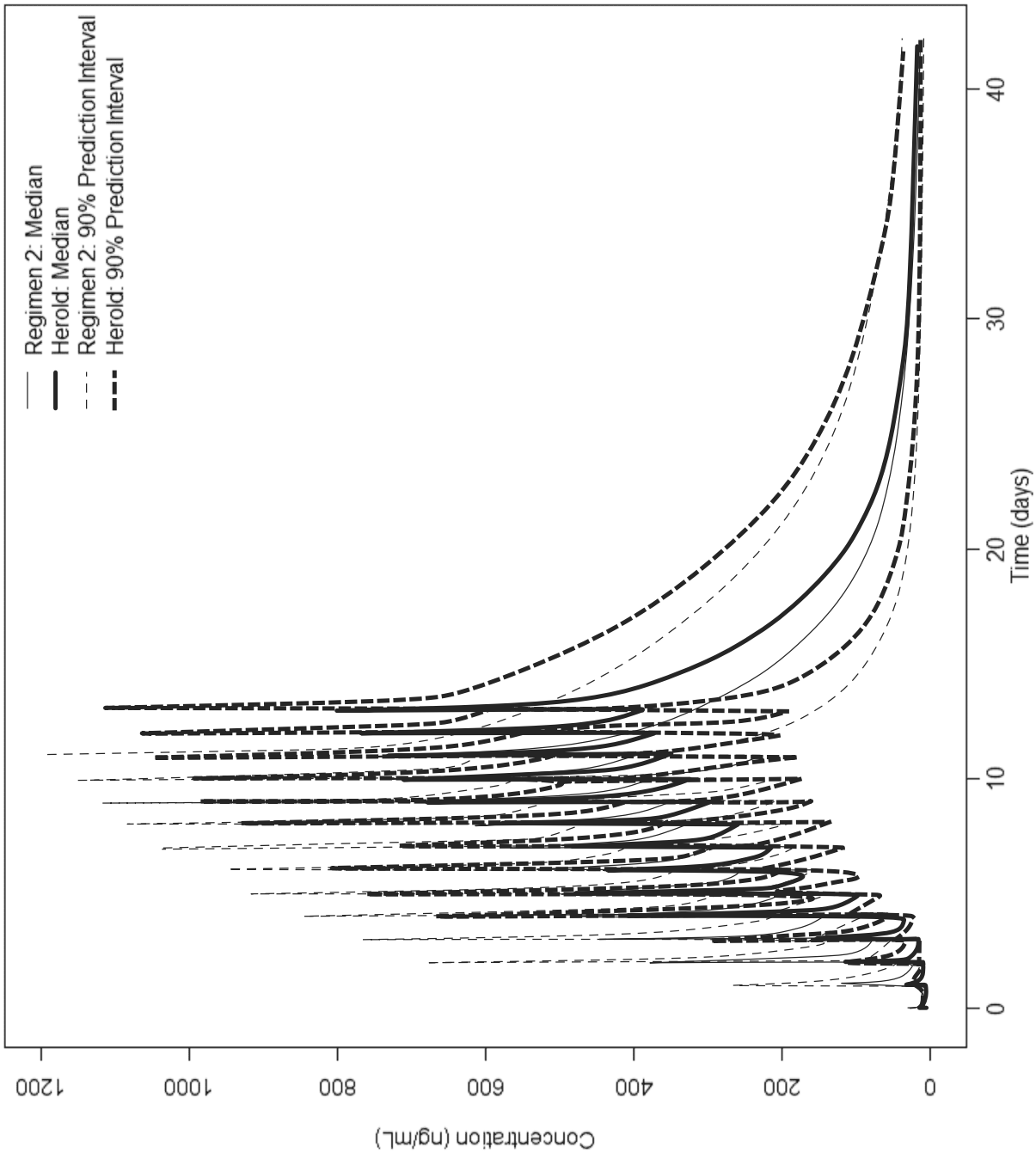

Regimen 2: Median
Herold: Median
Regimen 2: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
Time (days)
0
10
20
30
40

FIG. 21

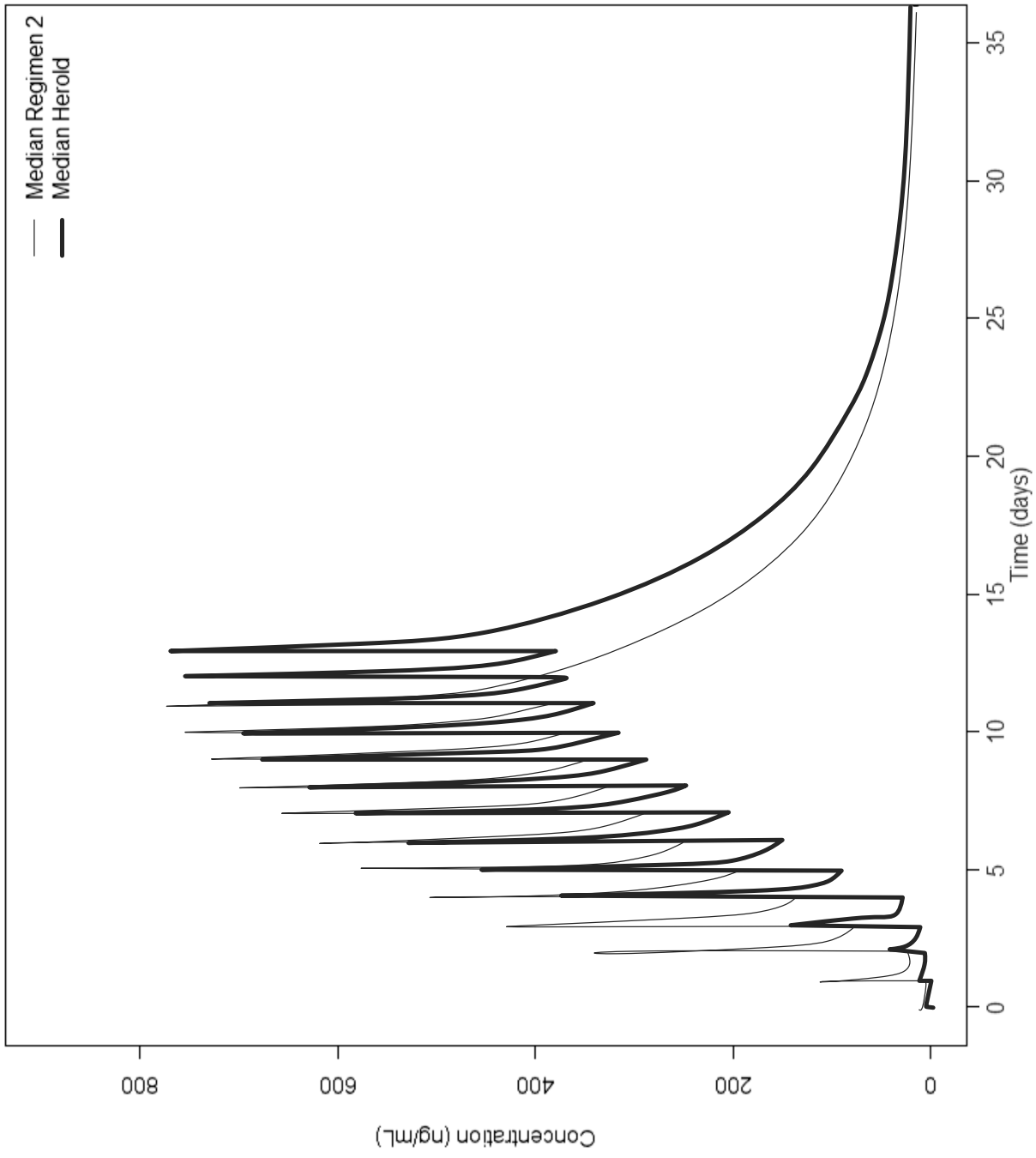

Median Regimen 2
Median Herold
Concentration (ng/mL)
0
200
400
600
800
0
5
10
15
20
25
30
35
Time (days)

FIG. 22

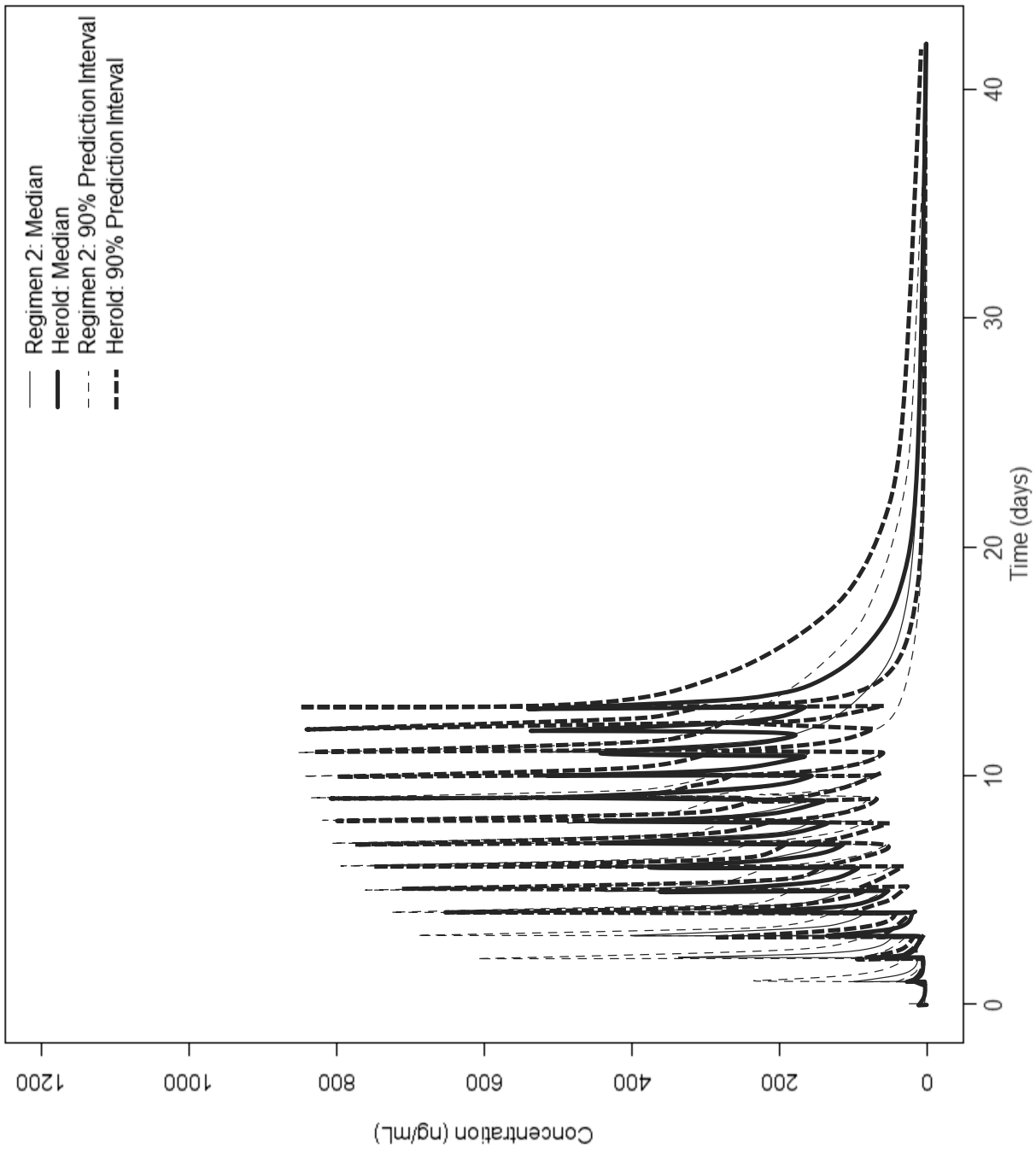

Regimen 2: Median
Herold: Median
Regimen 2: 90% Prediction Interval
Herold: 90% Prediction Interval
Concentration (ng/mL)
0
200
400
600
800
1000
1200
Time (days)
0
10
20
30
40

FIG. 23

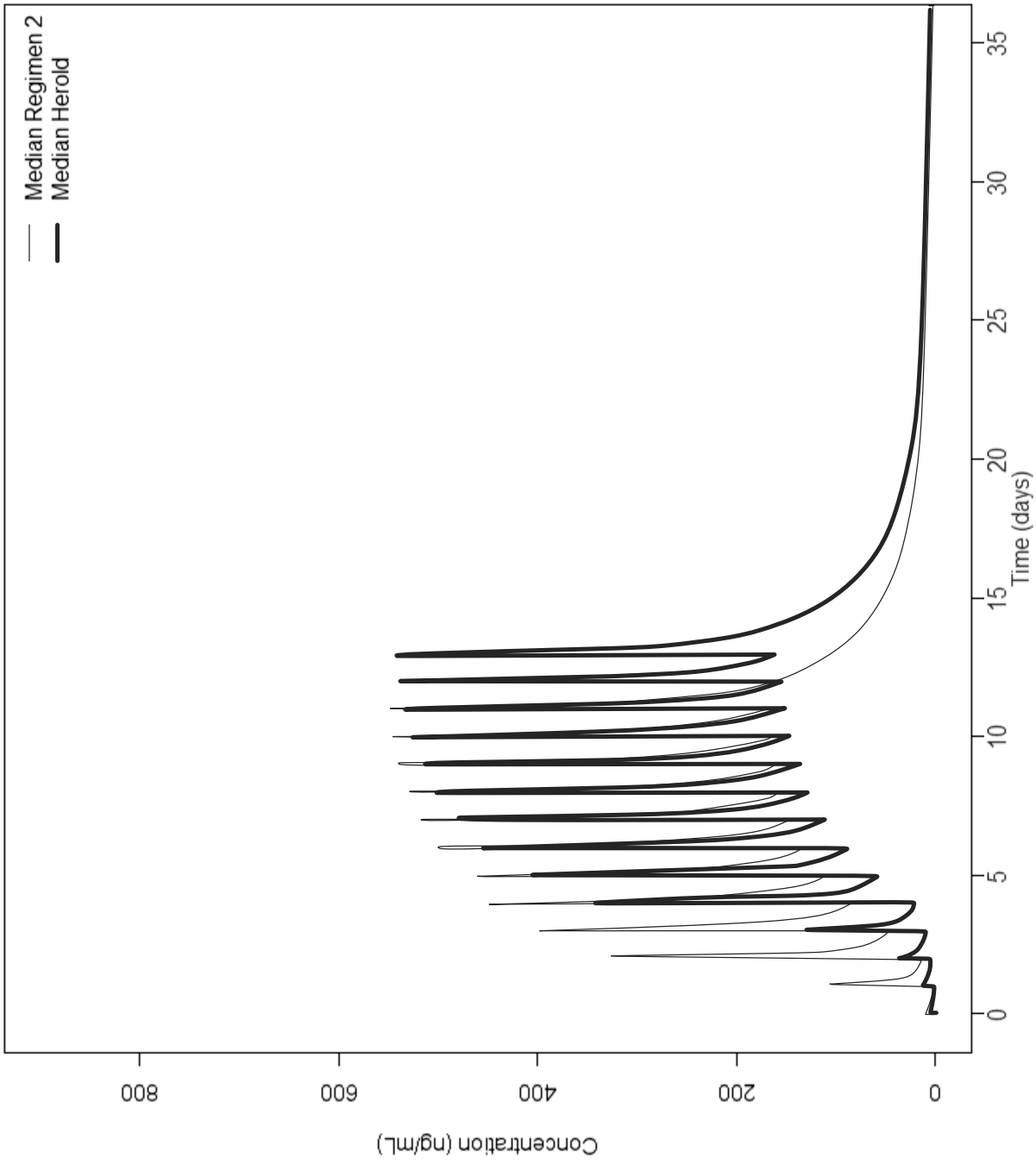

Median Regimen 2
Median Herold
Concentration (ng/mL)
0
200
400
600
800
0
5
10
15
20
25
30
35
Time (days)

FIG. 24

FIG. 25

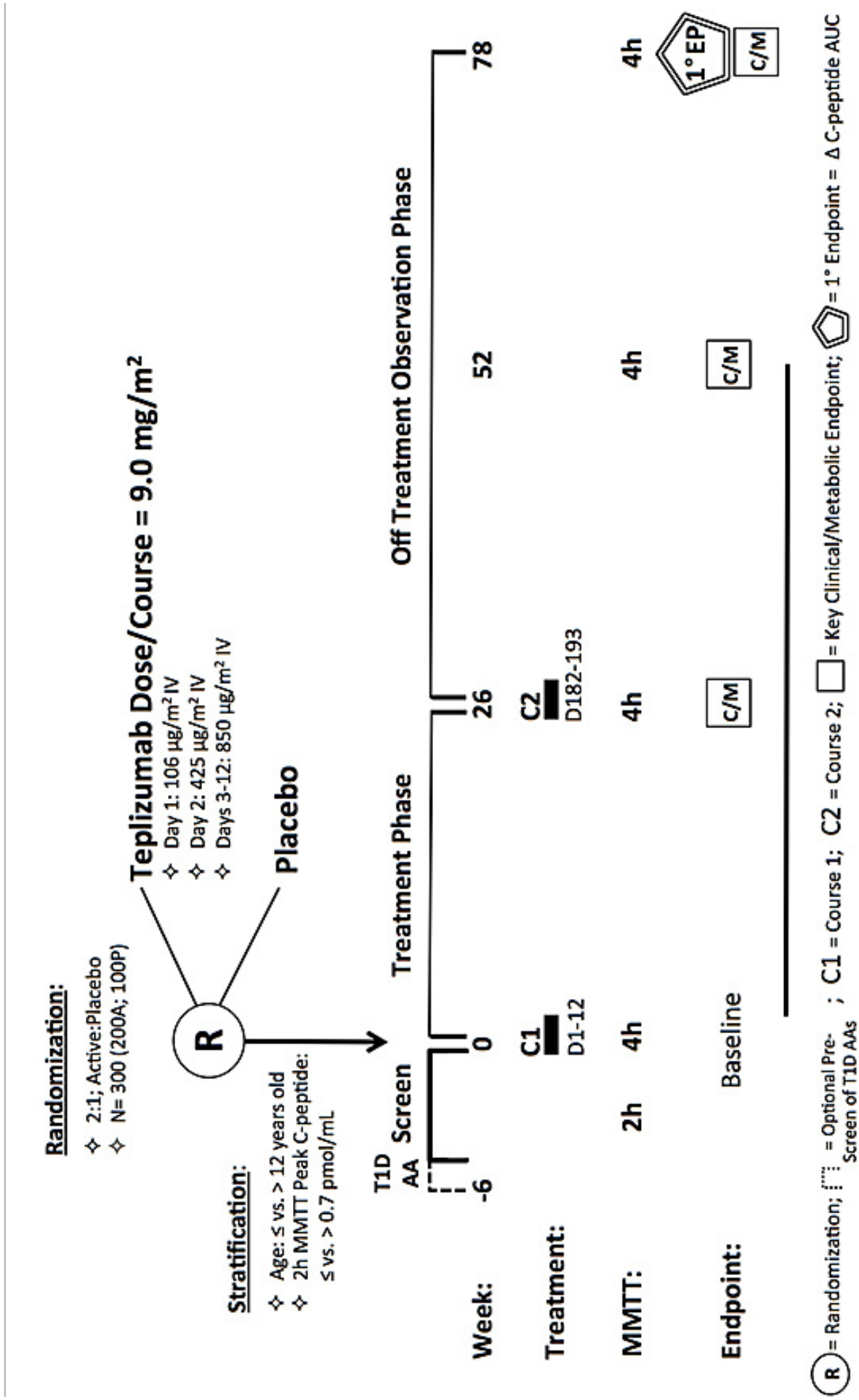

Randomization:
2:1; Active:Placebo
N= 300 (200A; 100P)
Stratification:
Age: ≤ vs. > 12 years old
2h MMTT Peak C-peptide: ≤ vs. > 0.7 pmol/mL
R
Teplizumab Dose/Course = 9.0 mg/m²
Day 1: 106 µg/m² IV
Day 2: 425 µg/m² IV
Days 3-12: 850 µg/m² IV
Placebo
T1D AA Screen
Treatment Phase
Off Treatment Observation Phase
Week: -6 0 26 52 78
Treatment: C1 D1-12 C2 D182-193
MMTT: 2h 4h 4h 4h 4h
Endpoint: Baseline C/M C/M 1° EP C/M
R = Randomization; = Optional Pre-Screen of T1D AAs ; C1 = Course 1; C2 = Course 2; = Key Clinical/Metabolic Endpoint; = 1° Endpoint = Δ C-peptide AUC

FIG. 26

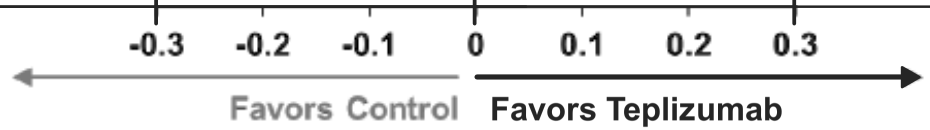
	N		LSM Difference Between Teplizumab and Control in Change from Baseline	LSM (95% CI)
	Teplizumab	Control		
Overall Observed	**306**	**179**		**0.08** (0.04, 0.12)
Overall Imputed	**375**	**234**		**0.09** (0.05, 0.13)
Protégé Observed	**188**	**91**		**0.04** (-0.002, 0.08)
Protégé Imputed	**207**	**98**		**0.03** (-0.01, 0.08)
Encore Observed	**17**	**17**		**0.002** (-0.11, 0.12)
Encore Imputed	**63**	**62**		**0.05** (-0.06, 0.15)
AbATE Observed	**50**	**22**		**0.15** (0.06, 0.23)
AbATE Imputed	**52**	**35**		**0.15** (0.06, 0.24)
Delay Observed	**30**	**28**		**0.06** (-0.03, 0.15)
Delay Imputed	**32**	**28**		**0.06** (-0.03, 0.15)
Study 1 Observed	**21**	**21**		**0.16** (0.05, 0.26)
Study 1 Imputed	**21**	**21**		**0.1**6 (0.05, 0.26)



Note: Analysis conducted and results presented for ln(AUC+1)
Abbreviations: AUC=area under the concentration-time curve, CI=confidence interval, LSM=least squares mean
N=number with 1-year data included in the meta-analysis

FIG. 27

	N		LSM Difference Between Teplizumab and Control in Change from Baseline	LSM (95% CI)
	Teplizumab	Control		
Observed	**199**	**99**		**0.12** (0.07, 0.17)
Imputed	**280**	**144**		**0.10** (0.05, 0.16)
Protégé Observed	**131**	**64**		**0.06** (0.004, 0.11)
Protégé Imputed	**207**	**98**		**0.06** (0.01, 0.10)
AbATE Observed	**49**	**21**		**0.14** (0.05, 0.23)
AbATE Imputed	**52**	**25**		**0.14** (0.05, 0.23)
Study 1 Observed	**19**	**14**		**0.16** (0.04, 0.28)
Study 1 Imputed	**21**	**21**		**0.12** (0.001, 0.24)



Note: Analysis conducted and results presented for ln(AUC+1)
AUC=area under the concentration-time curve, CI=confidence interval, LSM=least squares mean, N=number with 2-year data included in the meta-analysis

FIG. 28

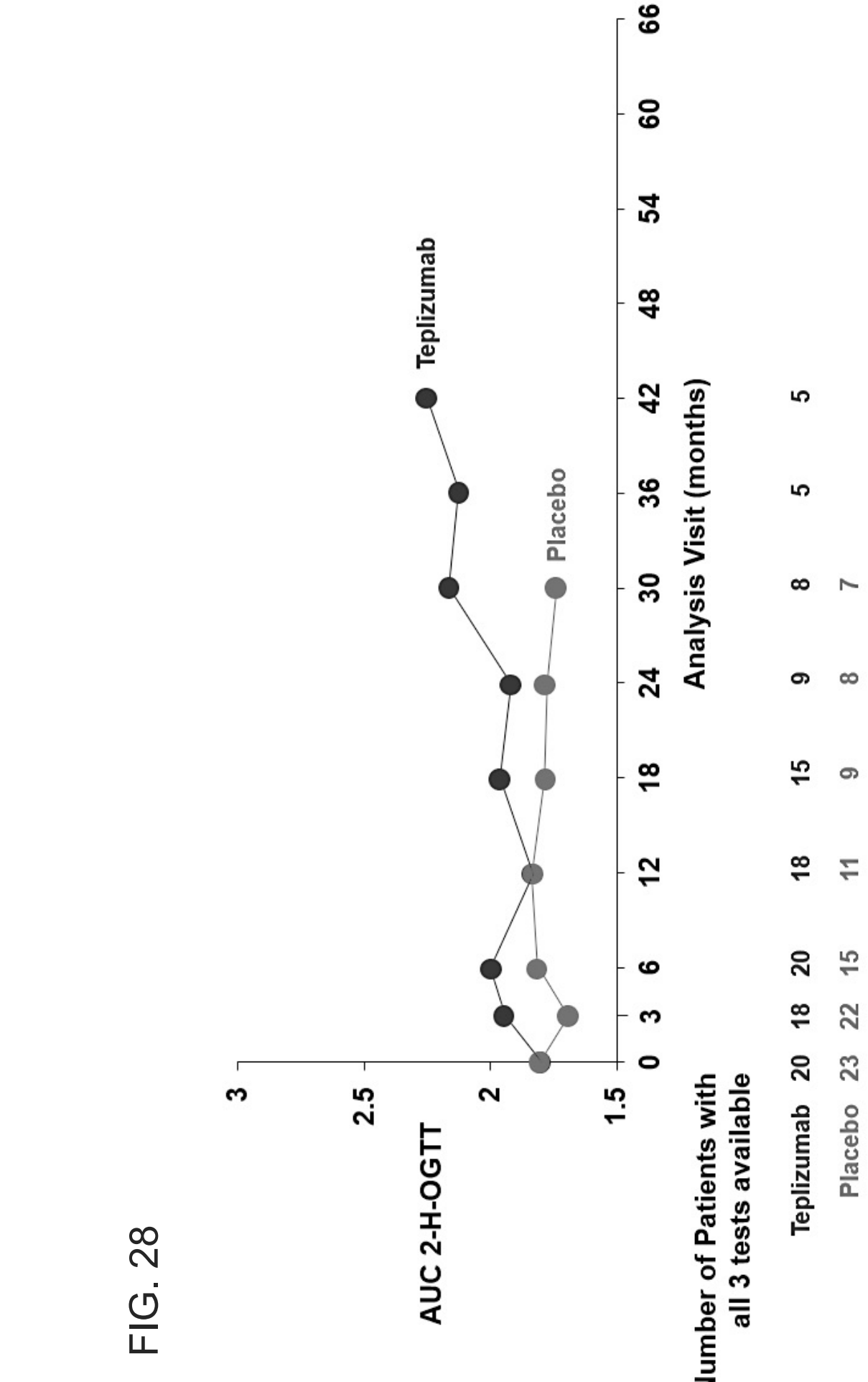

AUC 2-H-OGTT
3
2.5
2
1.5
Teplizumab
Placebo
0 3 6 12 18 24 30 36 42 48 54 60 66
Analysis Visit (months)
Number of Patients with all 3 tests available
Teplizumab 20 18 20 18 15 9 8 5 5
Placebo 23 22 15 11 9 8 7

FIG. 29

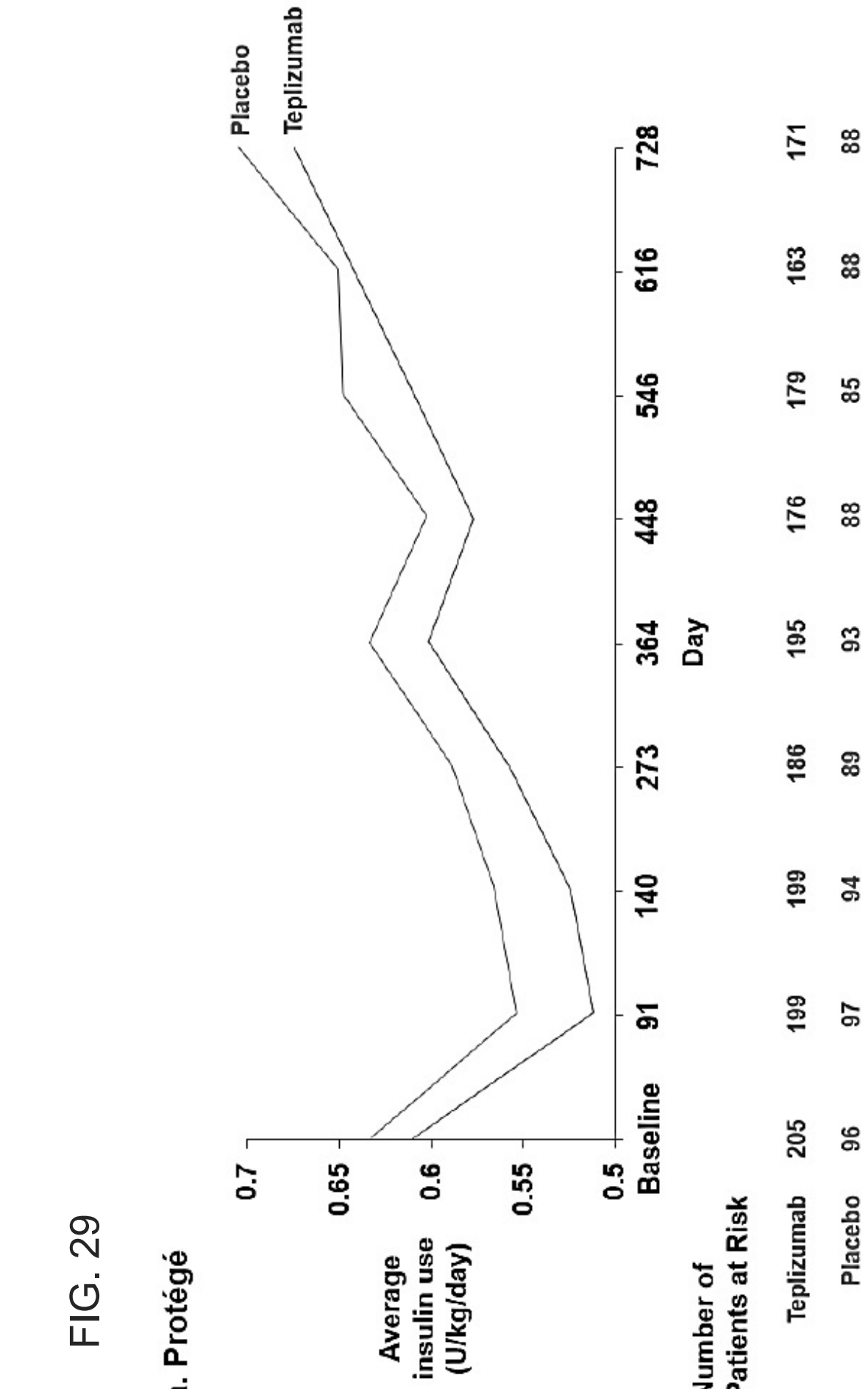

a. Protégé
Placebo
Teplizumab
Average insulin use (U/kg/day)
0.7
0.65
0.6
0.55
0.5
Baseline
91
140
273
364
448
546
616
728
Day
Number of Patients at Risk
Teplizumab 205 199 199 186 195 176 179 163 171
Placebo 96 97 94 89 93 88 85 88 88

FIG. 29 (cont.)

b. Encore

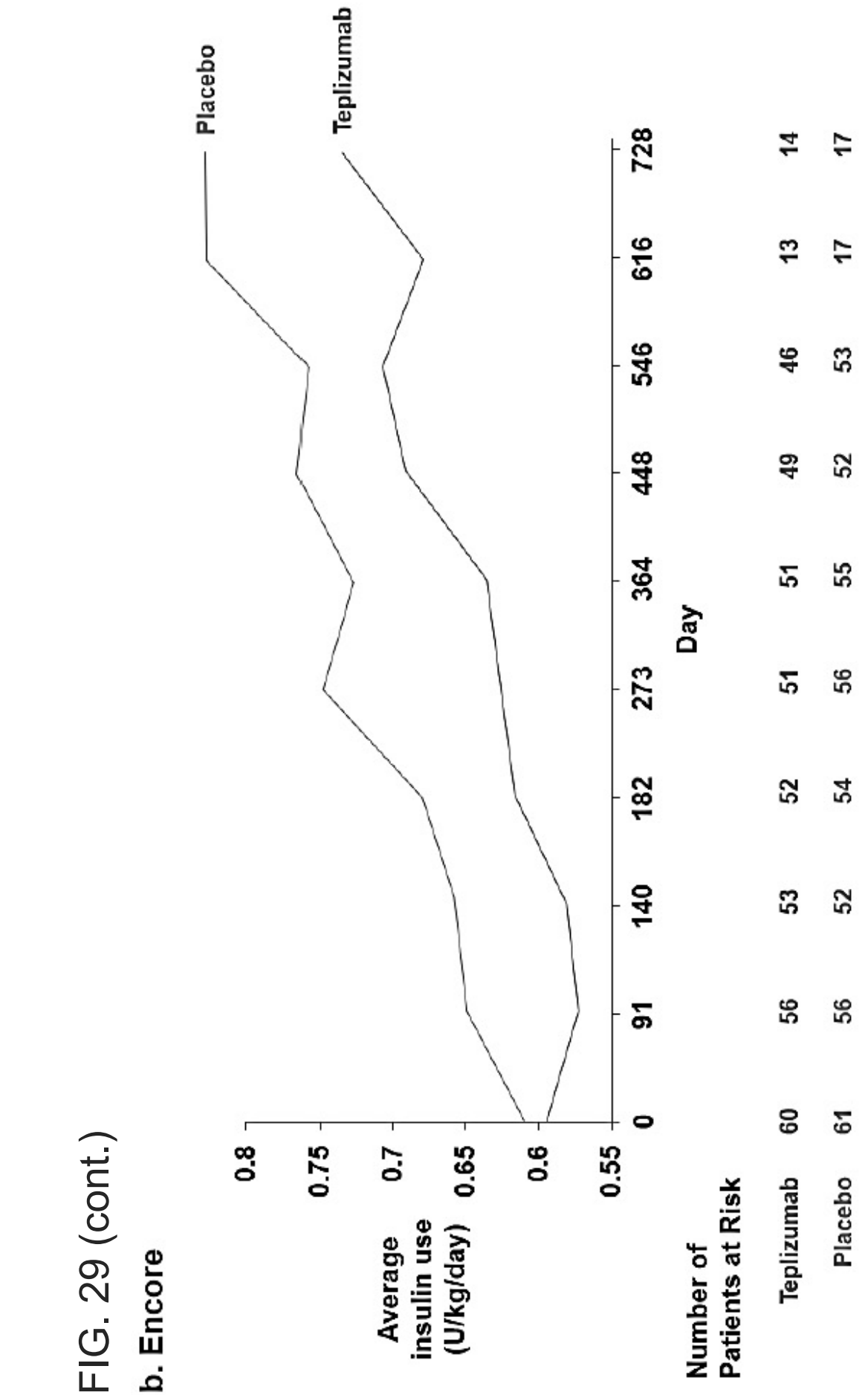


FIG. 29 (cont.)

c. Study 1

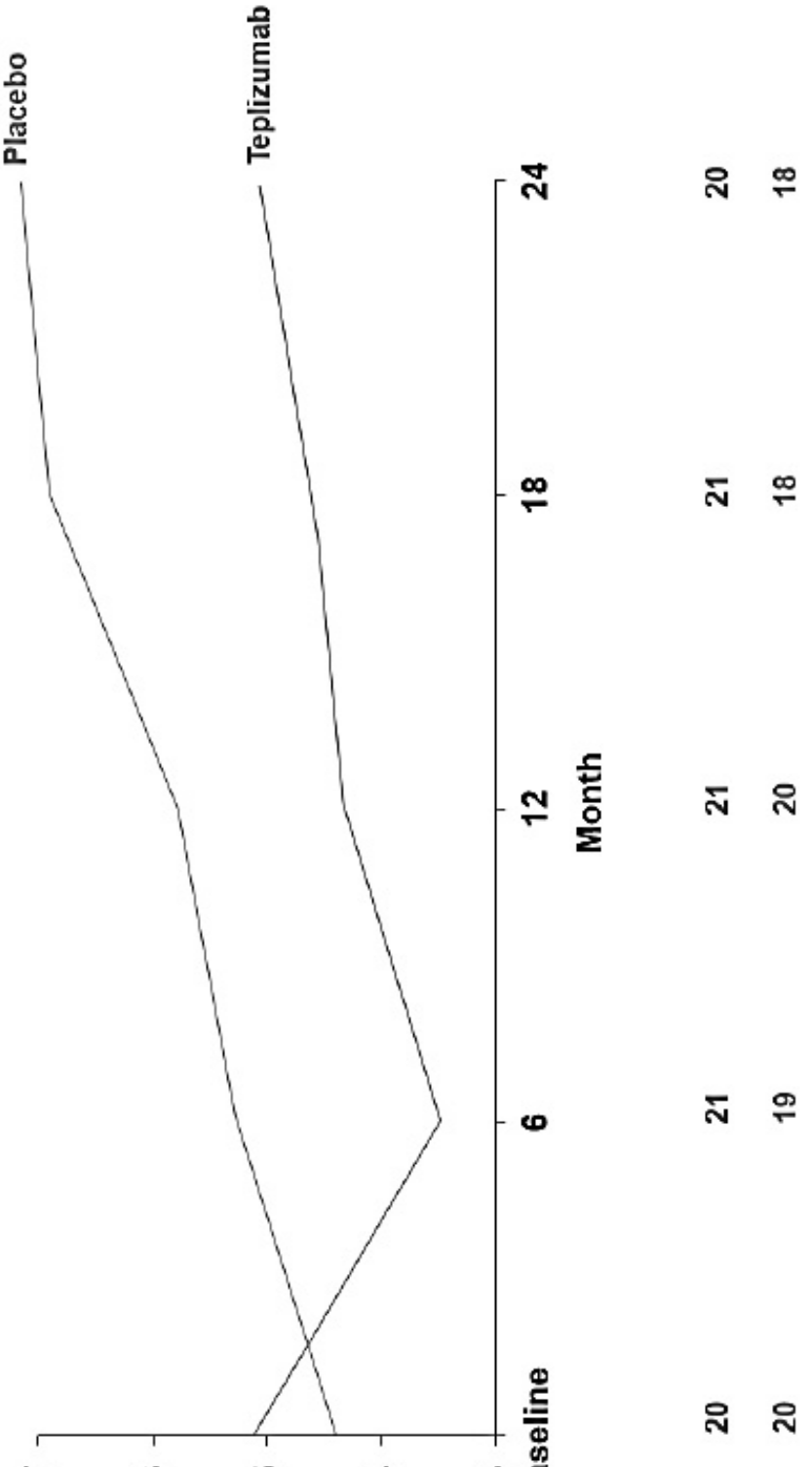


FIG. 29 (cont.)

d. AbATE

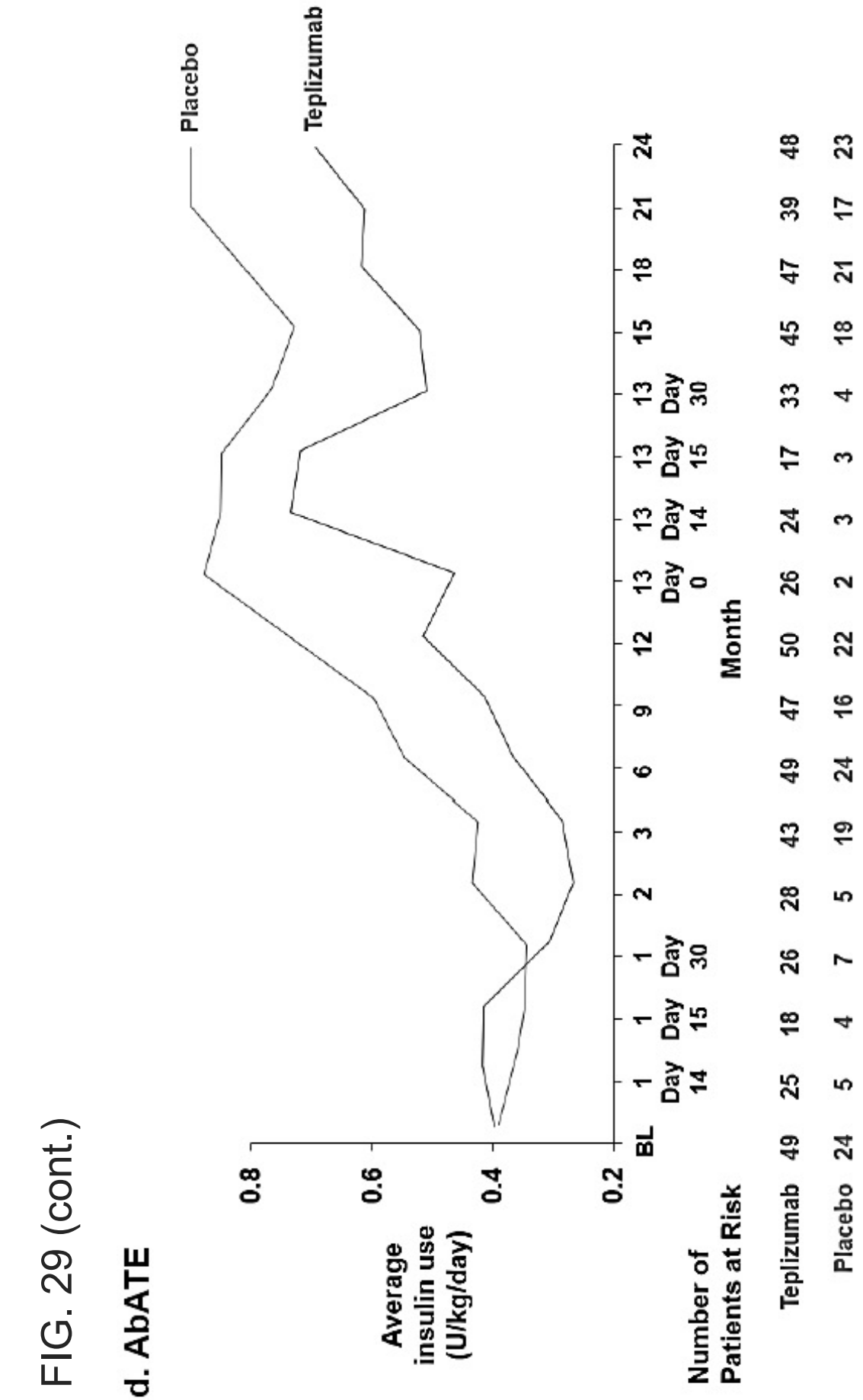


FIG. 29 (cont.)

e. Delay

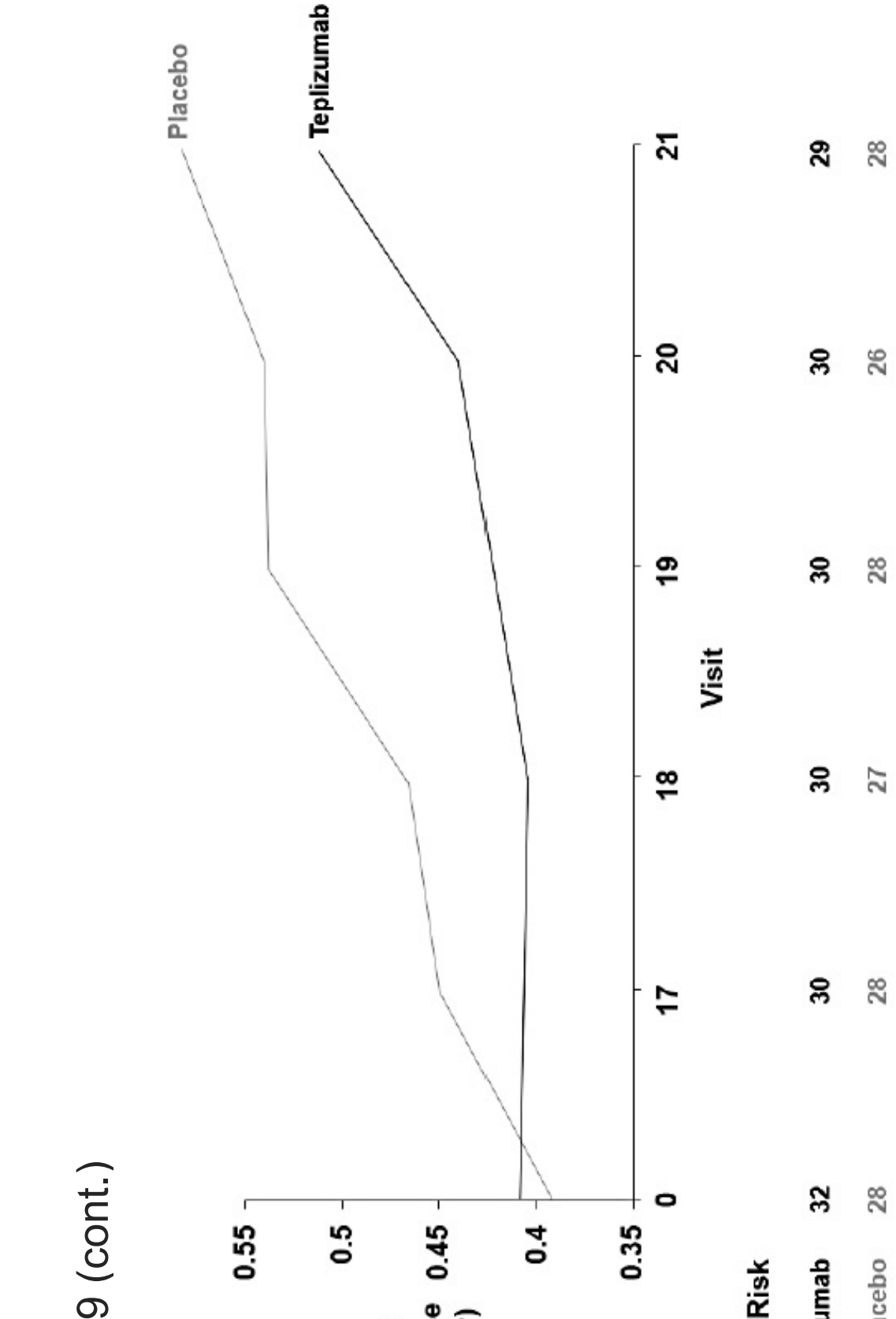
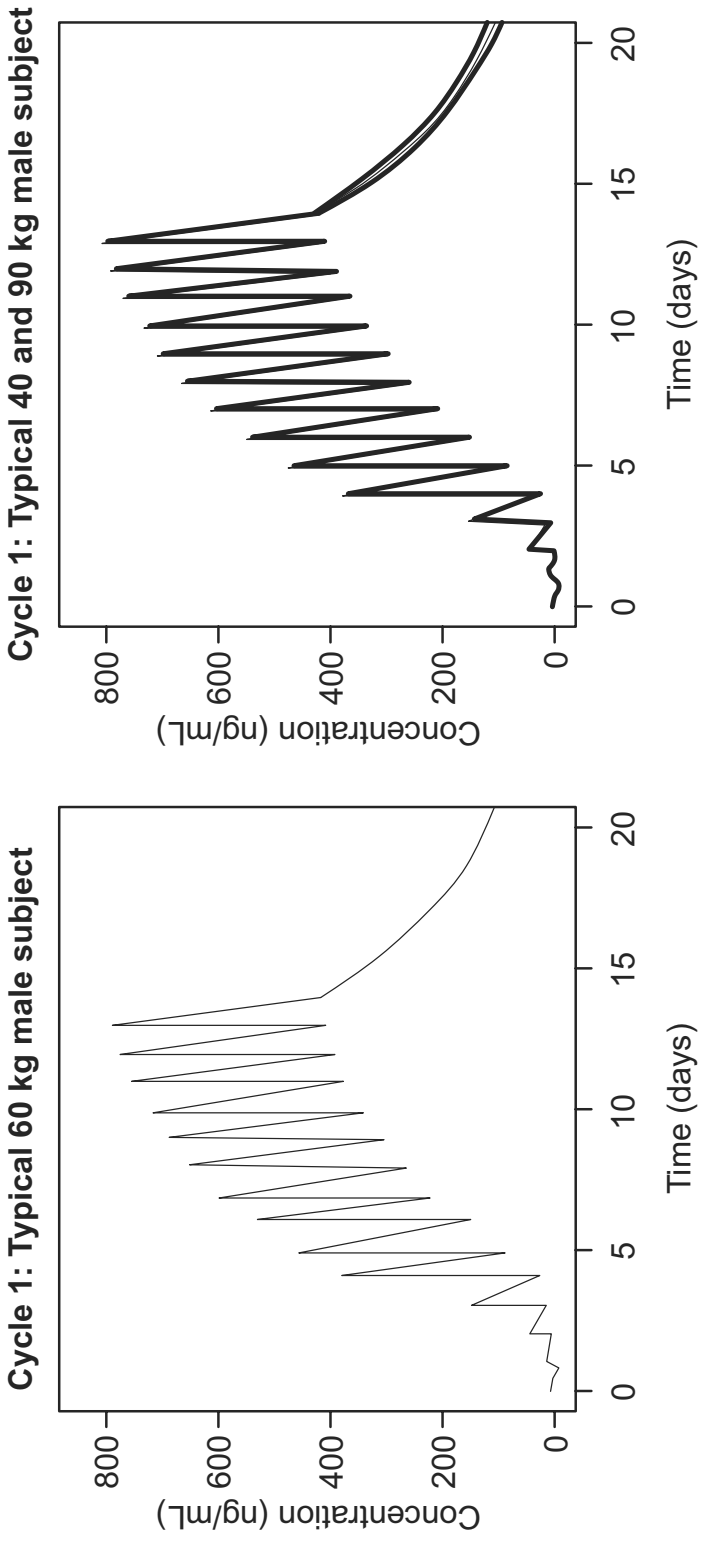


FIG. 30


Cycle 1: Typical 40 and 90 kg male subject
Concentration (ng/mL)
0
200
400
600
800
0
5
10
15
20
Time (days)
Cycle 1: Typical 60 kg male subject
Concentration (ng/mL)
0
200
400
600
800
0
5
10
15
20
Time (days)