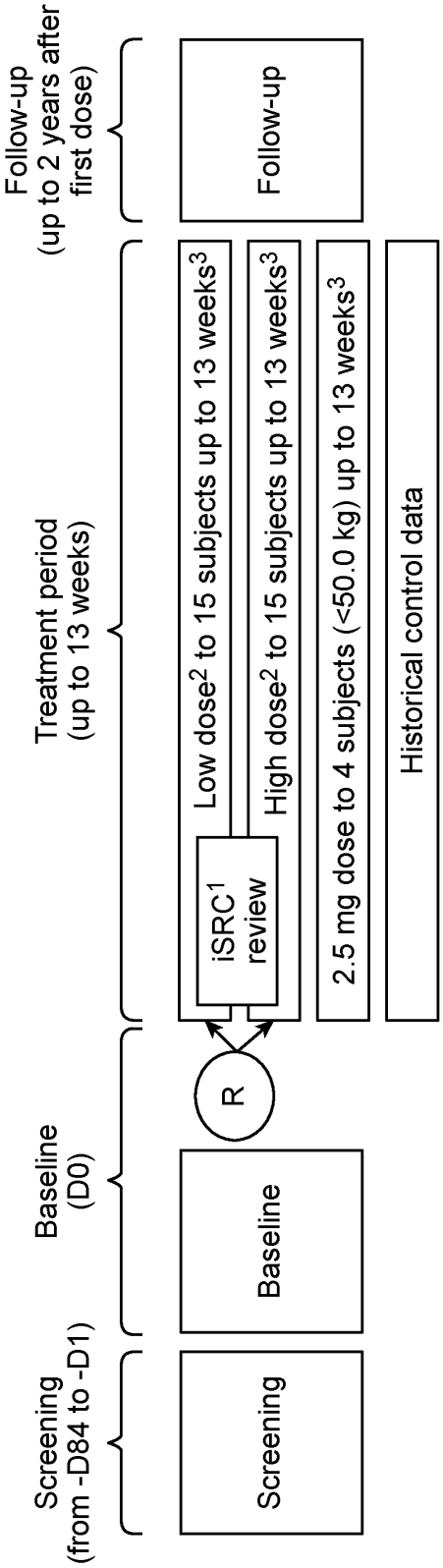

Screening
(from -D84 to -D1)
Baseline
(D0)
Treatment period
(up to 13 weeks)
Follow-up
(up to 2 years after
first dose)
Screening
Baseline
R
iSRC1
review
Low dose2 to 15 subjects up to 13 weeks3
High dose2 to 15 subjects up to 13 weeks3
2.5 mg dose to 4 subjects (<50.0 kg) up to 13 weeks3
Historical control data
Follow-up

FIG. 1

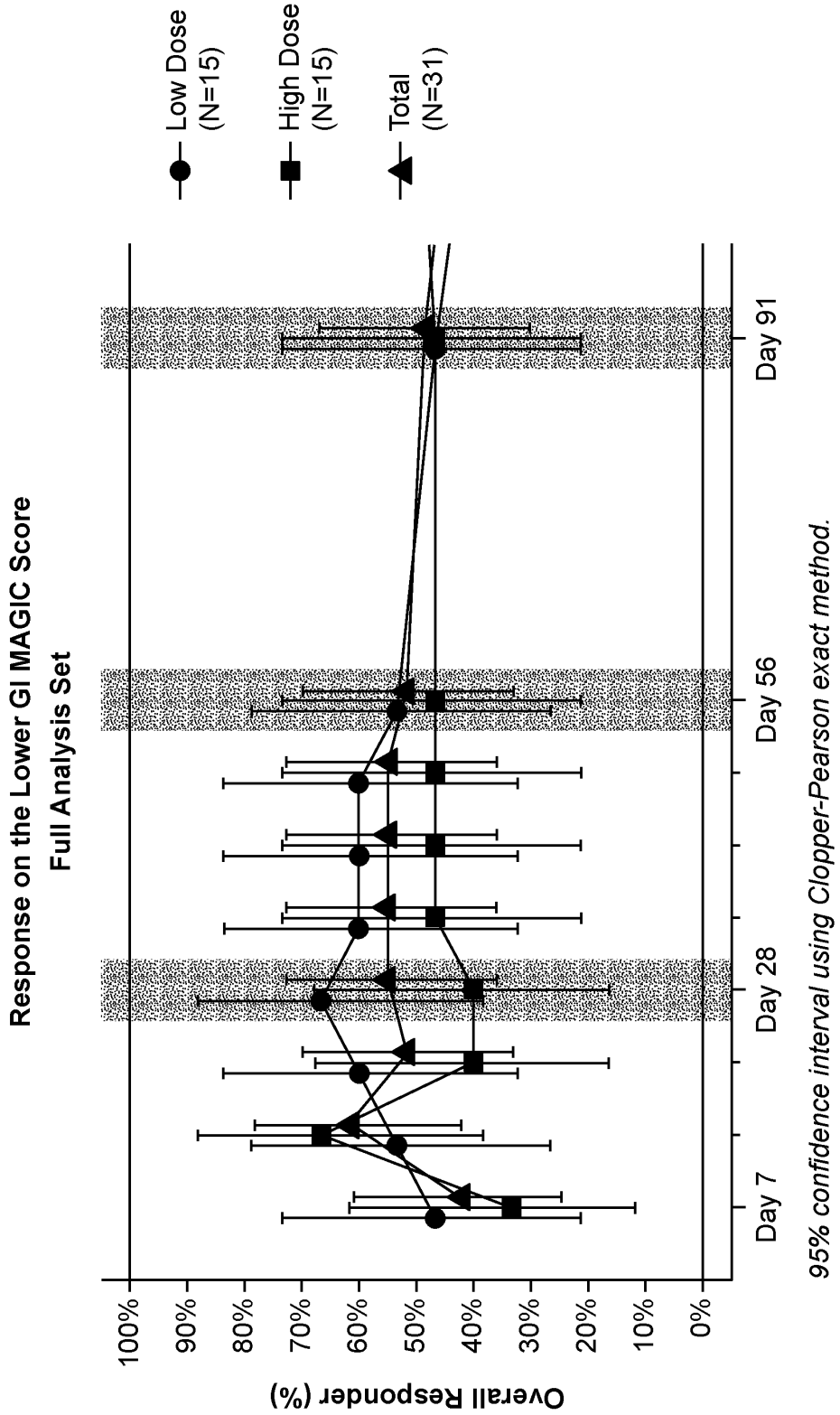

Response on the Lower GI MAGIC Score
Full Analysis Set
Low Dose (N=15)
High Dose (N=15)
Total (N=31)
Overall Responder (%)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Day 7
Day 28
Day 56
Day 91
95% confidence interval using Clopper-Pearson exact method.

FIG. 2A

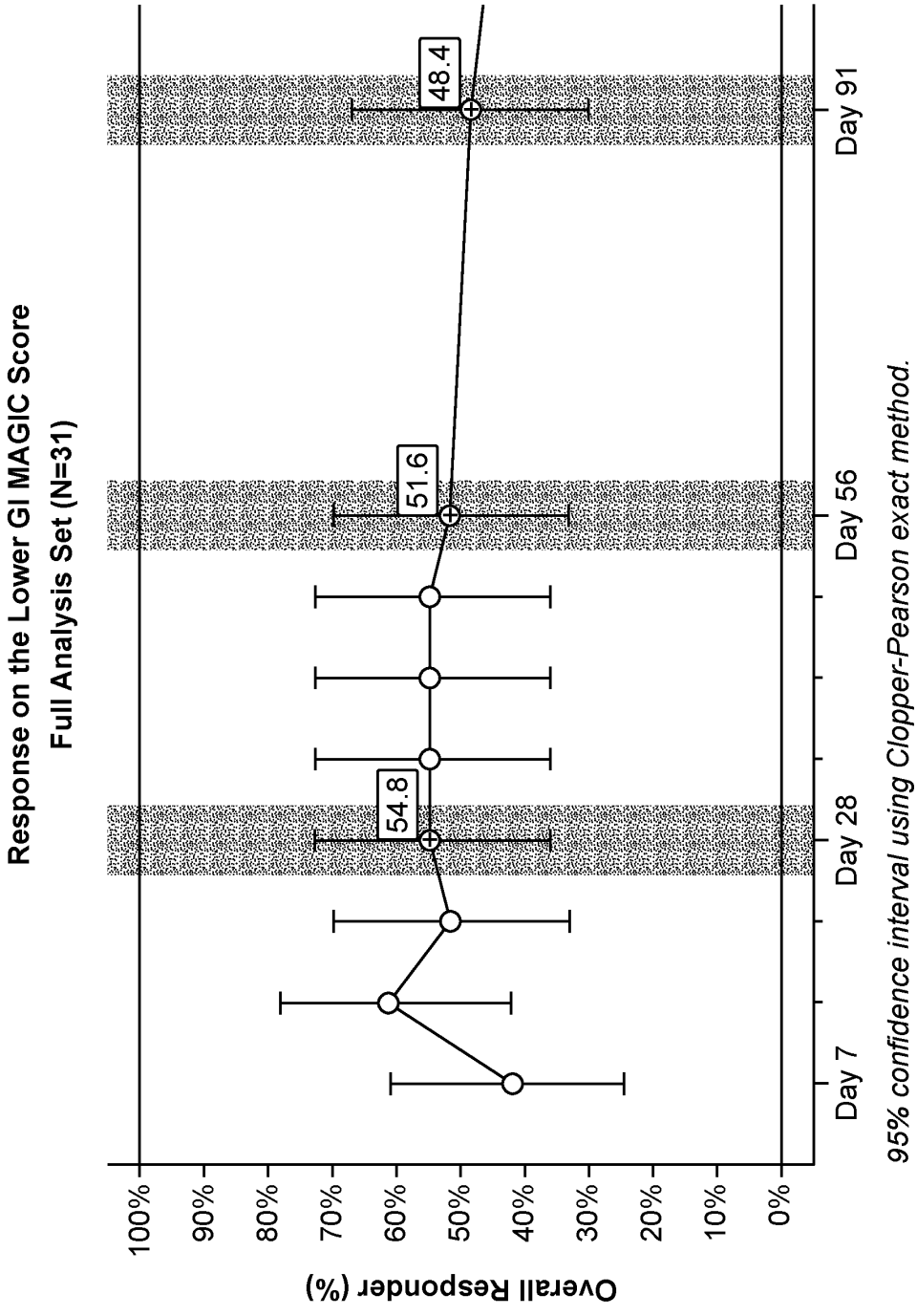

Response on the Lower GI MAGIC Score
Full Analysis Set (N=31)
Overall Responder (%)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Day 7
Day 28
Day 56
Day 91
54.8
51.6
48.4
95% confidence interval using Clopper-Pearson exact method.

FIG. 2B

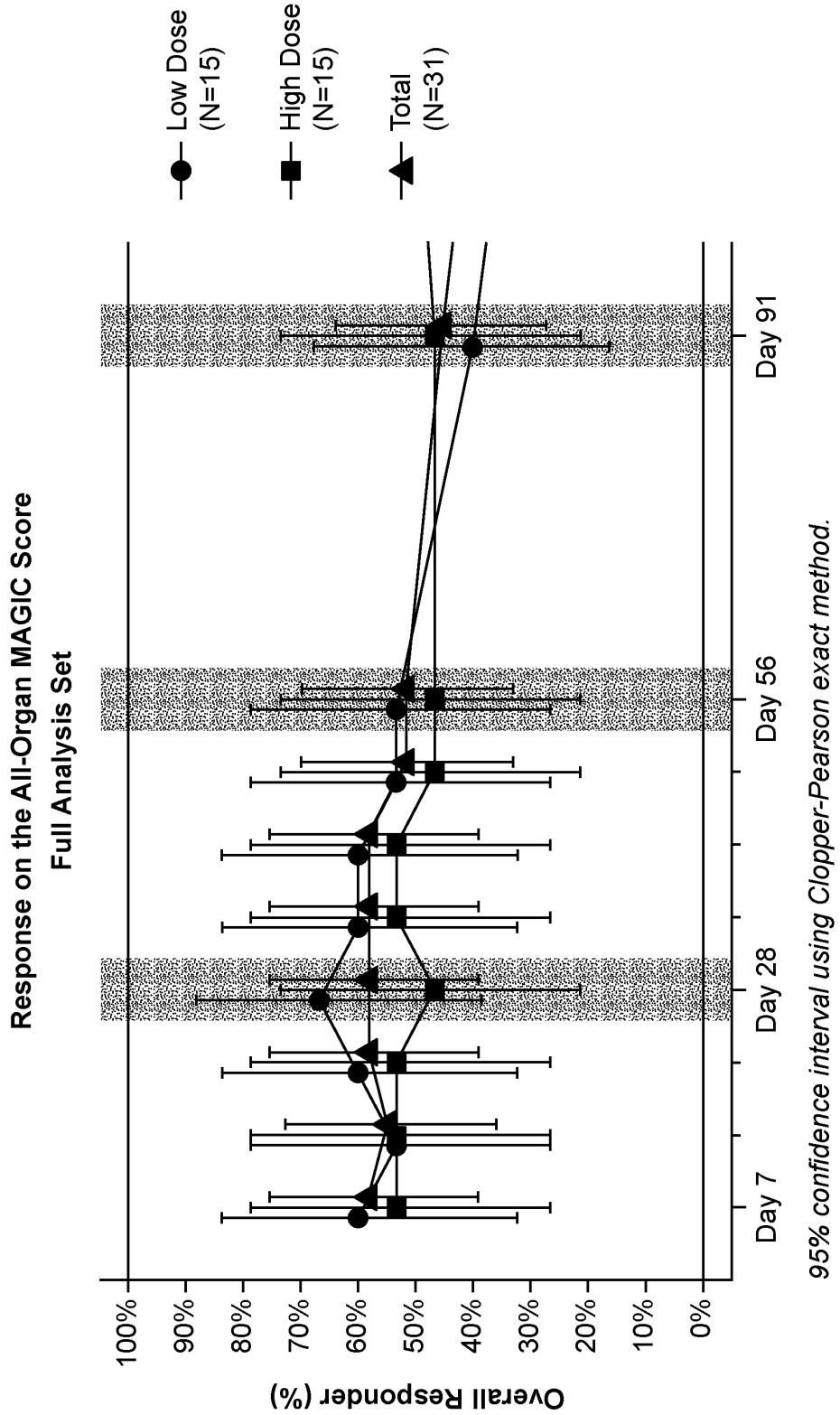

Response on the All-Organ MAGIC Score
Full Analysis Set
Low Dose (N=15)
High Dose (N=15)
Total (N=31)
Overall Responder (%)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Day 7
Day 28
Day 56
Day 91
95% confidence interval using Clopper-Pearson exact method.

FIG. 3

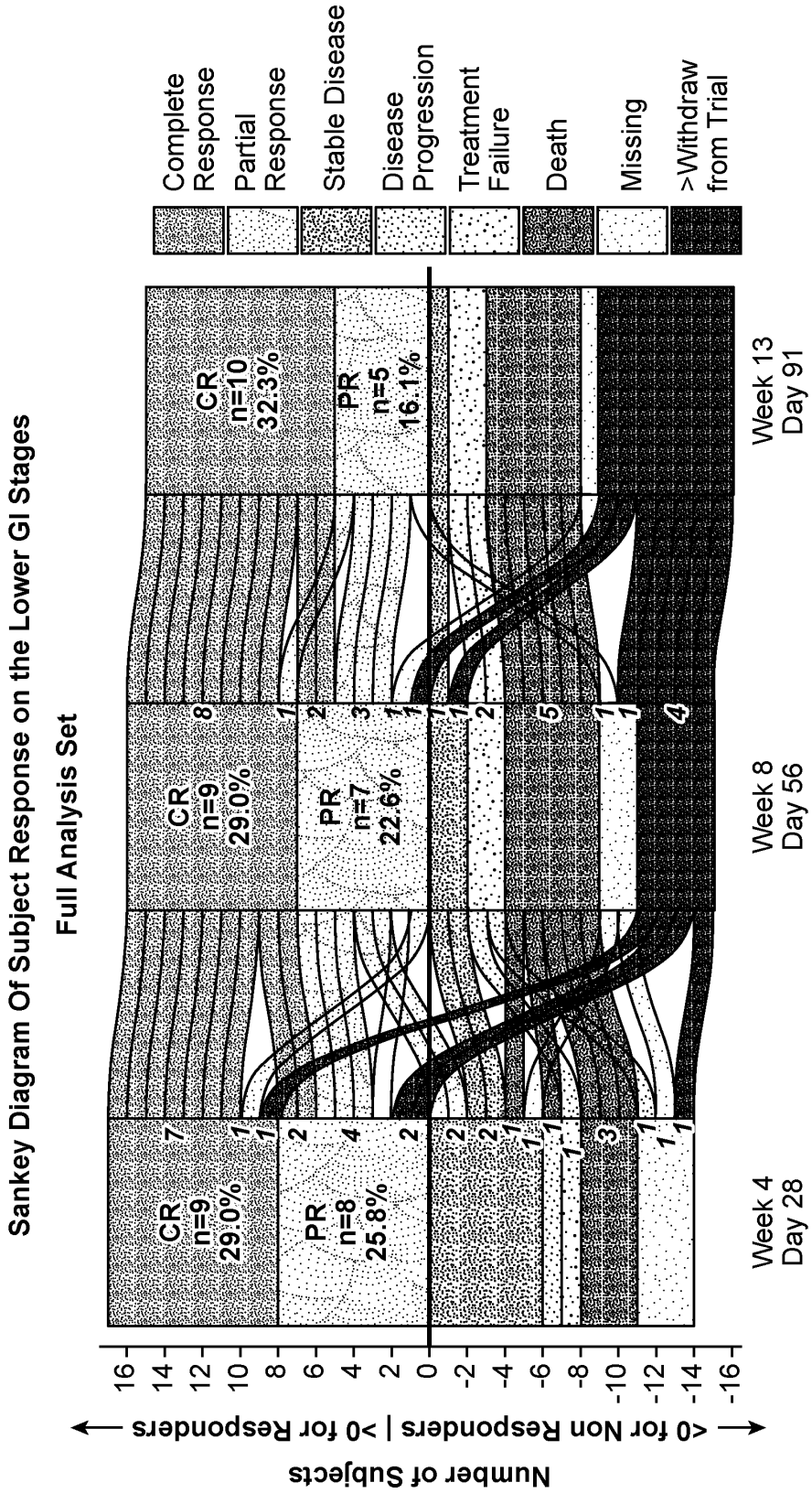
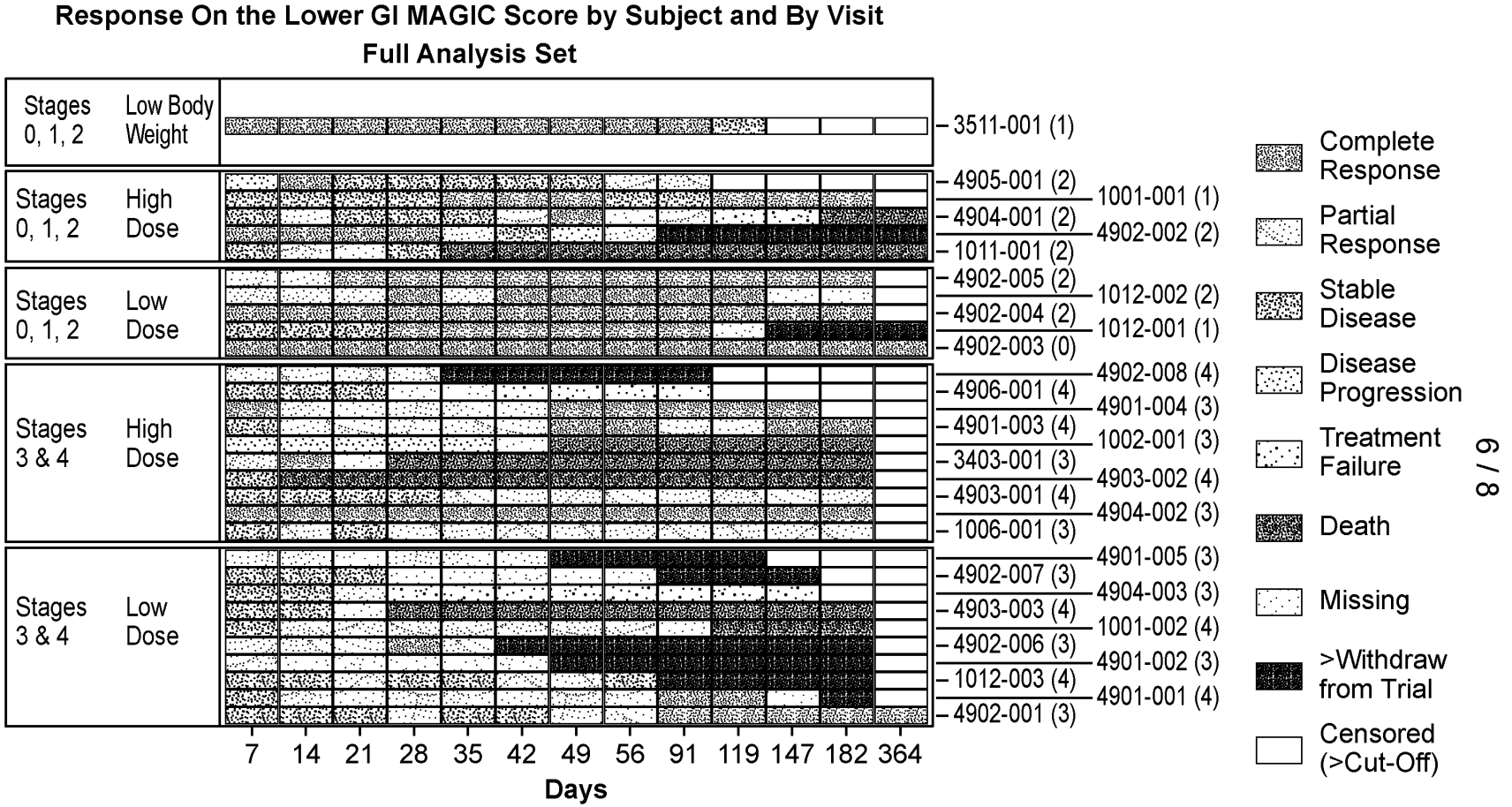
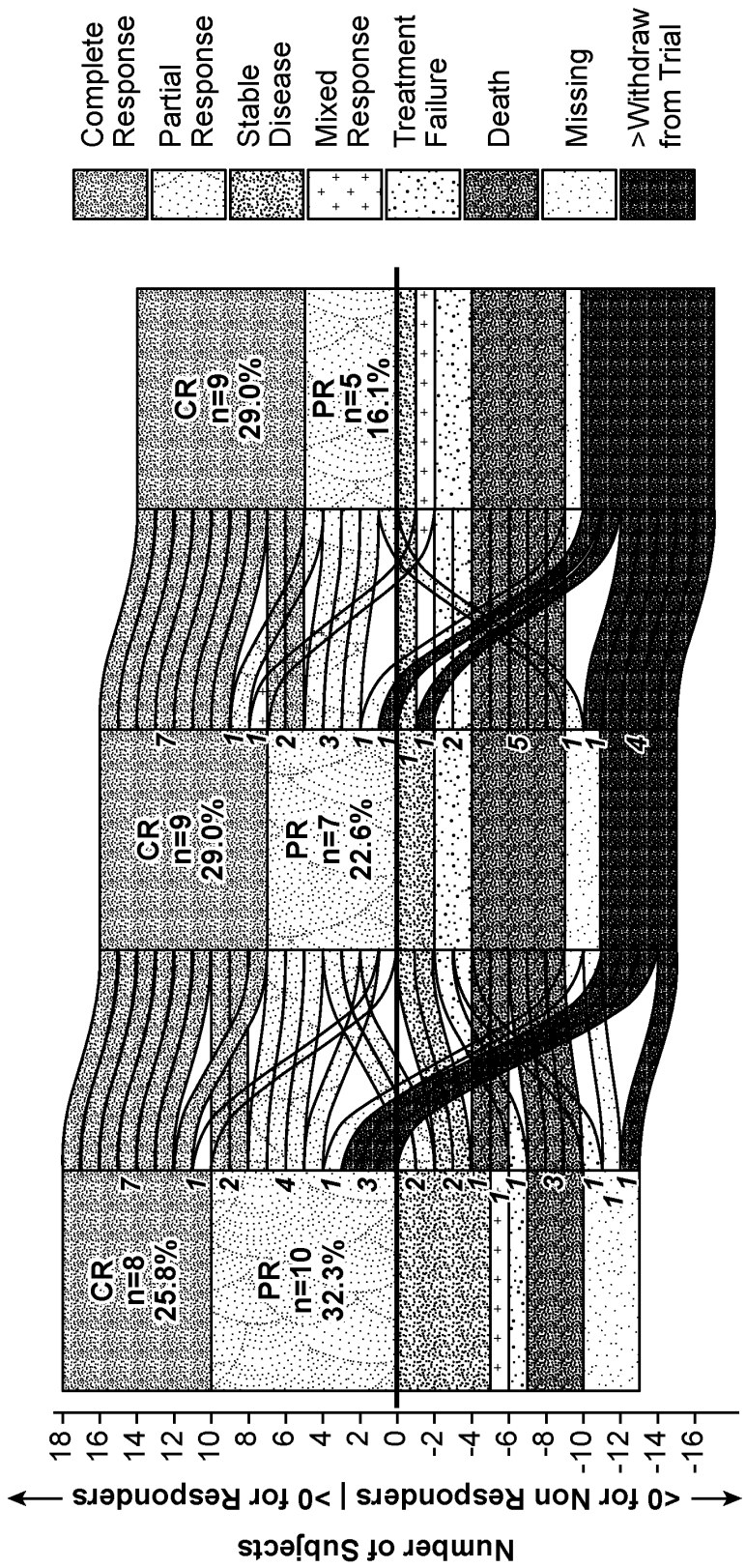

Sankey Diagram Of Subject Response on the Lower GI Stages
Full Analysis Set
Complete Response
Partial Response
Stable Disease
Disease Progression
Treatment Failure
Death
Missing
>Withdraw from Trial
CR n=9 29.0%
PR n=8 25.8%
CR n=9 29.0%
PR n=7 22.6%
CR n=10 32.3%
PR n=5 16.1%
Week 4 Day 28
Week 8 Day 56
Week 13 Day 91
Number of Subjects
<0 for Non Responders | >0 for Responders
Every subject "flows" between visits from the previous to the next.

FIG. 4A



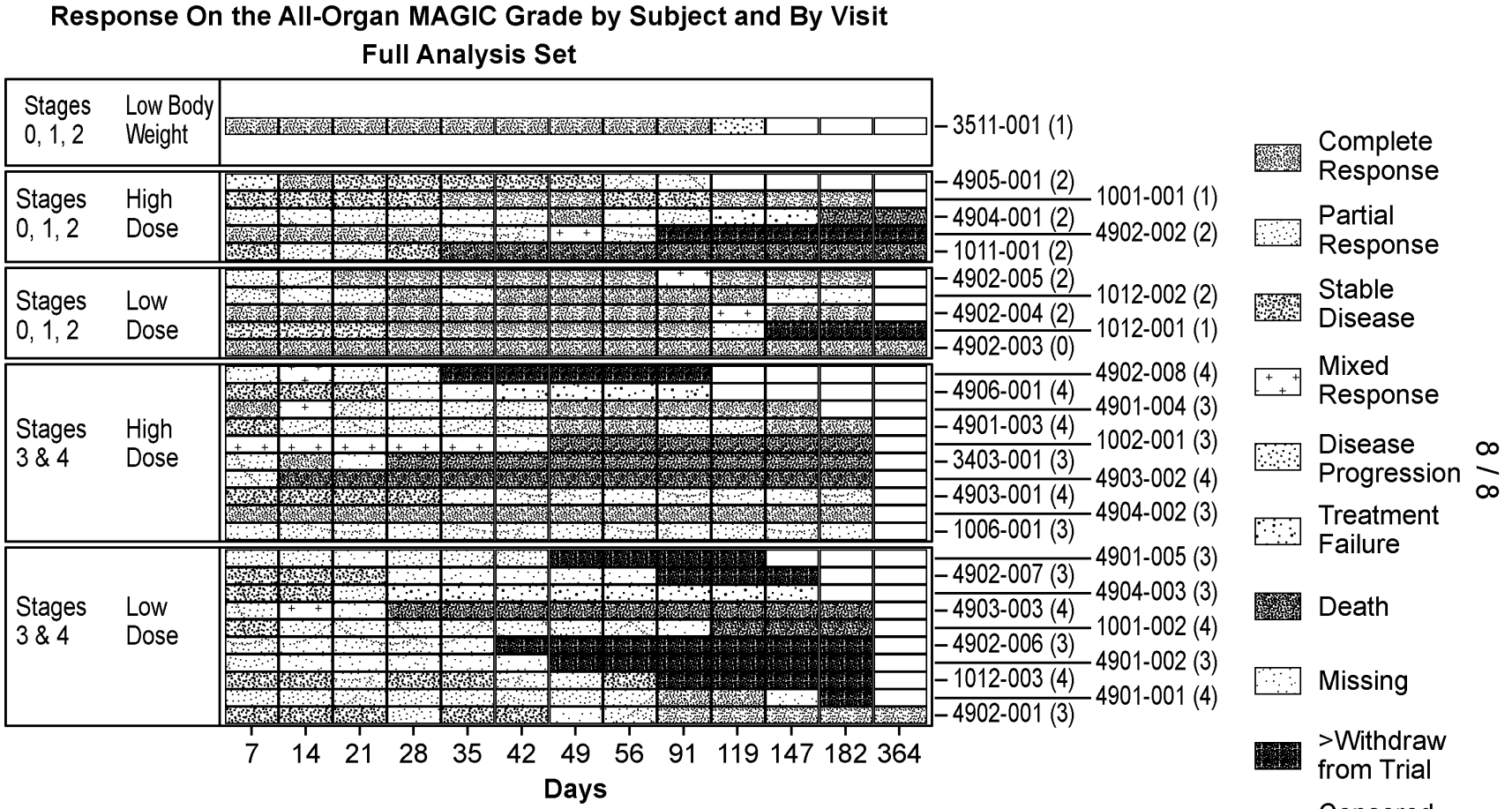

*Note: Subjects (followed by Lower GI MAGIC Stage at baseline) are grouped by Lower GI Stage at baseline and treatment group, ordered by treatment start date.*

FIG. 4B




*Every subject "flows" between visits from the previous to the next.*

FIG. 4C




*Note: Subjects (followed by Lower GI MAGIC Stage at baseline) are grouped by Lower GI Stage at baseline and treatment group, ordered by treatment start date.*

FIG. 4D