Randomized to study formula (n = 335)

INTACT (n = 167)

Withdrawn:
2 Received no study formula

INTACT (n = 165)
D-II dataset

(n = 44)
9 Lost to follow-up
18 Other reasons (not study physician-assessed)

INTACT Completed (n = 121)

INTACT (n = 138)
D-I dataset

PH (n = 168)

D-II dataset

(n = 42)
5 Lost to follow-up
17 Other reasons (not study physician-assessed)

PH (n = 168)
Completed (n = 126)

17 Formula intolerance (study physician-assessed)

PH (n = 146)
D-I dataset

Figure 1