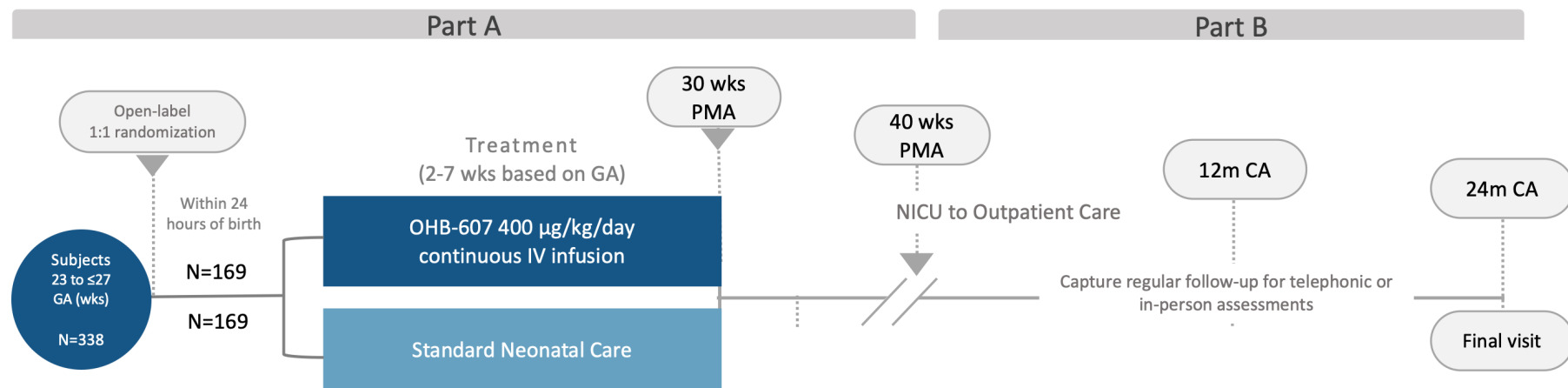




Part A:

Use the NAESS Terms and AE-Specific Severity Grading

- If the subject's condition is diagnosed/developed while in the NICU or other hospital ward
- If the subject's condition continues after discharge

*If the subject's condition is not among the 35 predefined NAESS terms, then must use the MedDRA term with the NAESS "generic" severity grading**

Part B:

- NAESS Terms and AE-Specific Severity Grading will continue for conditions that developed in the NICU or other hospital wards
- Non-NAESS MedDRA terms will be used for conditions developed post-NICU or hospital discharge, but severity grading must use the NAESS "generic" scale*

*** Important:** CTCAE or other common grading scales are not appropriate for this study.