NAESS is the 1st neonatal-specific AE severity grading instrument

- Infant SAFETY is important to all stakeholders in clinical research
- Developed with input from parents, nurses, physicians, & representatives from industry and regulatory agencies
- Parents and nurses offer unique insight into infant’s change in baseline
- Can be used by local investigators, sponsors, and regulatory groups
- Mapping to MedDRA and standard terminology supports regulatory processes
- Can help inform pharmacovigilance reviews, pediatric safety reports, & benefit/risk assessment
- Validation is ongoing. Education is needed for ALL stakeholders.

NEONATAL ADVERSE EVENT SEVERITY SCALE (NAESS)