

# NEONATAL ADVERSE EVENT SEVERITY SCALE (NAESS)



## 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



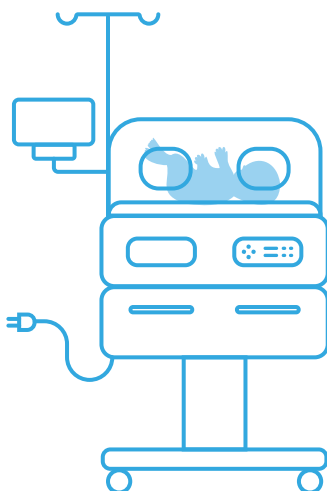
Can be used by local investigators, sponsors, and regulatory groups



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.