

Supplemental Table: Summary of Adverse Events

Summary of Trial Adverse Events: all subjects, all sites.				
Event Category (MedDRA)	# of Events	Unexpected and Harm and Related*	Fatal	Comments
Upper Respiratory Tract Infection	68	0	No	Coincidental common infections in study age group.
Diarrhea, infectious	51	0	No	Condition under study, and very common in study age group
Dermatitis, not allergic	23	0	No	No allergic type rash. Majority diaper dermatitis, others non-specific and self-resolving
Otitis media NOS	7	0	No	Coincidental common infection in study age group.
Pneumonia	5	0	No	All clearly unrelated to study procedures
Insect bite NOS	5	0	No	All clearly unrelated to study procedures
Oral ulceration	3	0	No	All clearly unrelated to study procedures
Tonsillitis NOS	3	0	No	Coincidental common infection in study age group.
Vaccine site swelling	3	0	No	All clearly unrelated to study procedures
Conjunctivitis	2	0	No	
Fall	2	0	No	Subject had brief seizure day 29 of study (4 weeks after last test dose). No sequelae.
Fever	2	0	No	All clearly unrelated to study procedures
Cyanosis	1	0	No	Self-resolving episode clearly unrelated to study procedures
Hordeolum	1	0	No	Coincidental common infection in study age group.
Septic Shock	1	0	Yes	
Urinary tract infection	1	0	No	Coincidental common infection in study age group.
Vomiting	1	0	No	All clearly unrelated to study procedures

* No adverse event was attributed to study product, placebo or study procedure