

TOLSURF Data Collection Frequency

Form #	Form name	Study Hospital				Post Discharge					
		Pre-Dosing		Dosing	Post-Dosing	Follow-up visits					
		SV	RV	Dosing + 7 days	Dosing+8 days - Discharge	3 mon	6 mon	9 mon	12 mon	18 mon	24 mon
1A	Screening	X	X								
1B	Documentation of Eligibility		X								
2	Perinatal Demographics		X								
3	Infant Delivery		X								
4	Pre-Enrollment Co-Morbidities of Prematurity		X								
5	Pre-Enrollment Respiratory Parameters		X								
6	Inhaled Nitric Oxide Delivery		X								
7A	Initial Study Drug Delivery			X							
7B	Subsequent Study Drug Delivery			X							
8	Study Day 0-31 Respiratory Parameters	X	X								
9A	Study Day 32-120 Respiratory Parameters			X	X						
9B	Study Day 121-Discharge Respiratory Parameters			X	X						
10A	Extubation Data			X	X						
10B	Additional Extubation Data			X	X						
11A	Co-Morbidities of Prematurity Enrollment-Final Dose + 7 Days			X							
11B	Co-Morbidities of Prematurity Final dose + 8 days - Discharge				X						
12A	BPD Outcomes - 36 Weeks PMA				X						
12B	BPD Outcomes - 40 Weeks PMA				X						
13A	Adverse Events Dosing Period			X							
13B	Adverse Events Discharge Period				X						
14A	Hospital Course While at Study Hospital			X	X						
14B	Additional Transfusions			X	X						
14C	Additional Surgeries While at Study Hospital			X	X						
15	Medications While at Study Hospital			X	X						
16A	Discharge Report				X						
16B	Hospital Discharge Breathing Outcome Questionnaire				X						
17	Death Report			X	X						
18	Protocol Deviations	X	X	X	X						
19	Protocol Violations	X	X	X	X						
20	Early Termination/Permanent Discontinuation of Medication			X	X						
21	Serious Adverse Events			X							
23	Breathing Outcomes Interval Questionnaire					X	X	X	X	X	
24	Neurodevelopmental Follow-up Exam								X		X
25	Comments	X	X	X	X	X	X	X	X	X	X
DTF	Dose Tolerance Form			X							