

# A BLINDED EVALUATION OF THE CONNECTION STUDY

## SUSTAINED FEEDING TOLERANCE (SFT) CORRELATES TO CLINICAL OUTCOMES

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### OBJECTIVE

Consolidate clinical outcomes (see table) from patients enrolled in the Connection Study IBP-9414-020 with respect to the Primary Endpoint 'Time to SFT

### METHODS

Use regression models to evaluate the impact of a 1-day reduction in time to SFT in 439 randomized preterm neonates <32 weeks gestation. 248 (77.7%) of randomized patients reported time to SFT defined as the combination of

1. Enteral feeding at  $\geq 120$  ml/kg/day for 10 consecutive days.
2. No use of parenteral nutrition for 10 consecutive days.
3. Average body weight gain is  $\geq 10$ g/kg/day during these days.

	Regression model	Mean/N events	Estimate	95 % CI	p-value	R-square
Confirmed NEC Events	Logistic regression	20	1.0765	(1.0357-1.1189)	0.0002	5.9
Days with Clinical Signs of Feeding Intolerance	Negative binomial regression	5.2	1.0029	(0.9791-1.0272)	0.8155	0.0
Relevant Gastrointestinal AEs	Logistic regression	55	1.0586	(1.0293-1.0887)	0.0001	6.0
Late Onset Sepsis	Logistic regression	29	1.0671	(1.0326-1.1028)	0.0001	5.8
Weight Gain (g/day)	Linear regression	21.2	-0.0831	(-0.1333--0.0328)	0.0014	5.2
Clinically Suspected Sepsis	Logistic regression	18	1.0531	(1.0108-1.0972)	0.0133	2.8
Bronchopulmonary Dysplasia	Logistic regression	85	1.0275	(1.0018-1.0539)	0.0360	1.9
Retinopathy of Prematurity	Logistic regression	65	1.0500	(1.0221-1.0786)	0.0004	5.6
Number of Respiratory AEs	Negative binomial regression	1.2	1.0331	(1.0214-1.0449)	<0.0001	11.1
Number of Days of Hospitalisation	Linear regression	75.8	0.7710	(0.5086-1.0335)	<0.0001	13.9
Number of SAEs	Negative binomial regression	0.4	1.0420	(1.0076-1.0776)	0.0162	2.8
Days with Antibiotic Use	Negative binomial regression	15.4	1.0585	(1.0353-1.0821)	<0.0001	7.6
Concurrent Respiratory and Cardiac AEs	Logistic regression	9	1.0392	(0.9848-1.0967)	0.1611	0.6

**INTERPRETATION:** Several clinically meaningful adverse outcomes correlate to a reduction in time to SFT. This infers that even a brief time to SFT may be used as a predictor for adverse outcomes in the Connection Study, a prospective randomized trial of *L. reuteri* administration in very low birthweight preterm infants.