Infant Bacterial Therapeutics

Staffan Strömberg, CEO

January 24, 2019

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Infant Bacterial Therapeutics AB

Corporate overview

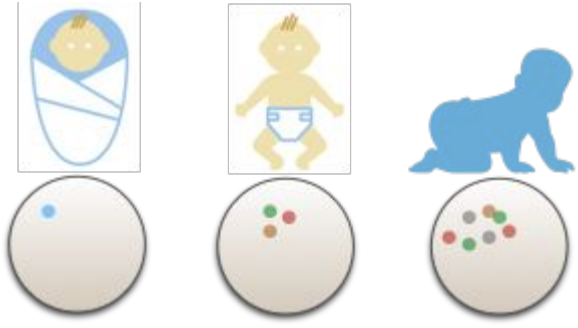
- Founded in 2013 in Stockholm, Sweden as a subsidiary of BioGaia
- IPO in 2016, listed on Nasdaq Stockholm Mid-Cap
- Institutional shareholders and specialist investors e.g. AP4, AP3, AMF, Swedbank Robur, Sectoral
- Cash end of Q3 2018: 62 MUSD, sufficient to fund IBP-9414 development
- Initiation of Phase III during H1 2019
- Market cap: USD 190m

Stock price development since IPO

The IBT concept

Altering the human microbiome to prevent or treat diseases

Newborn infant microbiome is dynamic



Human bacterial strains derived from human breast milk

Published proof-of-concept clinical signal

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

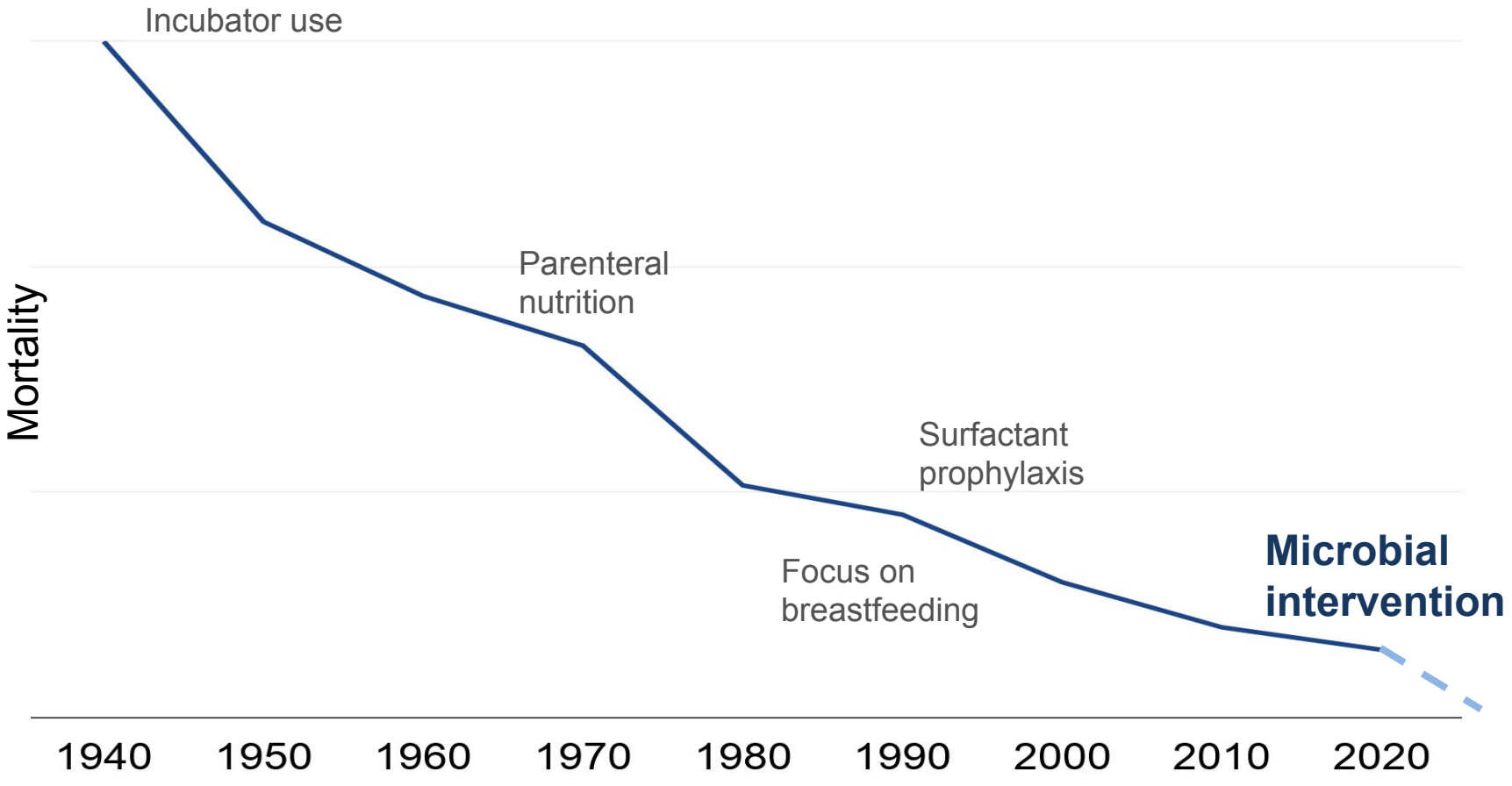
Prophylactic Probiotics to Prevent Death and Nosocomial Infection in Preterm Infants

Mario A. Rojas, Juan M. Lozano, Maria X. Rojas, Viviana A. Rodriguez, Martin A. Rondon, Jaime A. Bastidas, Luis A. Perez, Catherine Rojas, Oscar Ovalle, Jorge E. Garcia-Harker, Maria E. Tamayo, Gloria C. Ruiz, Adriana Ballesteros, Maria M. Archila and Mauricio Arevalo

Pediatrics 2012;130;e1113; originally published online October 15, 2012; DOI: 10.1542/peds.2011-3584

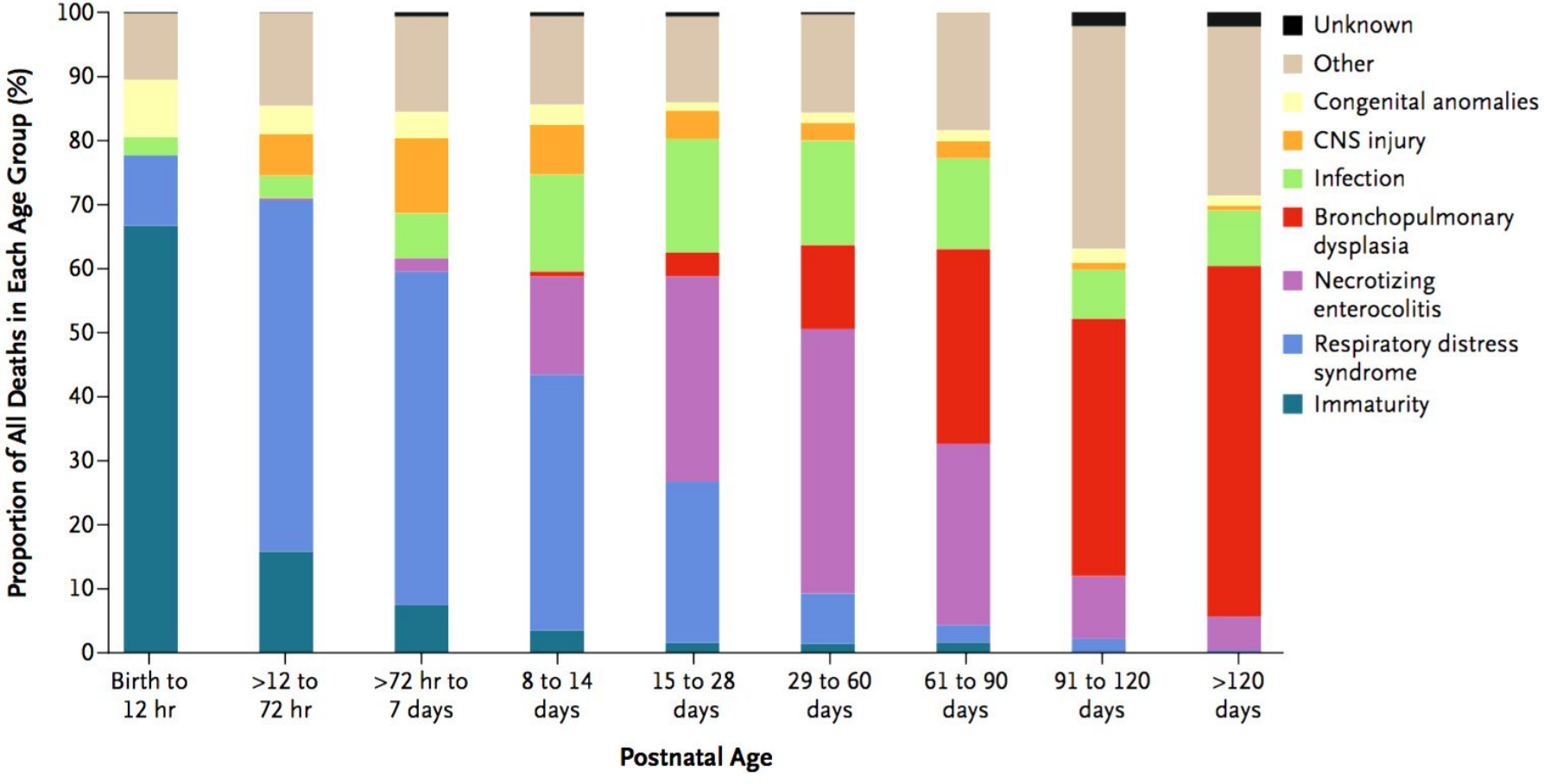
Our patients

GI tract left untreated in preterm infants



CDC/NCHS, National Vital Statistics System

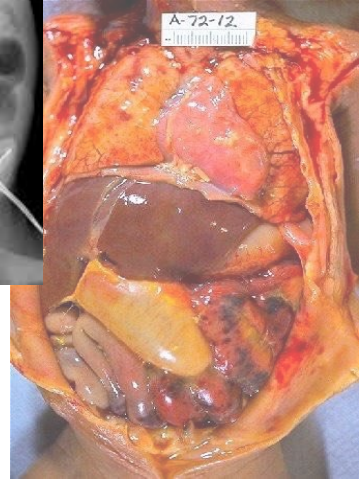
Causes of death



Patel 2015

Necrotizing enterocolitis (NEC)

- NEC is severe inflammation of the bowel in preterm infant where 20-40% need complicated and costly surgery
- Survivors have long-term consequences such as short-bowel syndrome, abnormal growth, cognitive, visual and hearing impairments
- There is no therapy available today
- **NEC is one of the leading causes of death in the Neonatal intensive care unit (NICU) with up to 40% morbidity rate killing 1500 US and 3700 EU infants each year**



Simpson 2010, Clark 2012

Feeding the preterm infant

Prolonged parenteral (needle feeding) nutrition increases cost and causes complications: cholestasis, increased risk of BPD, pulmonary vascular resistance, infections and sepsis.

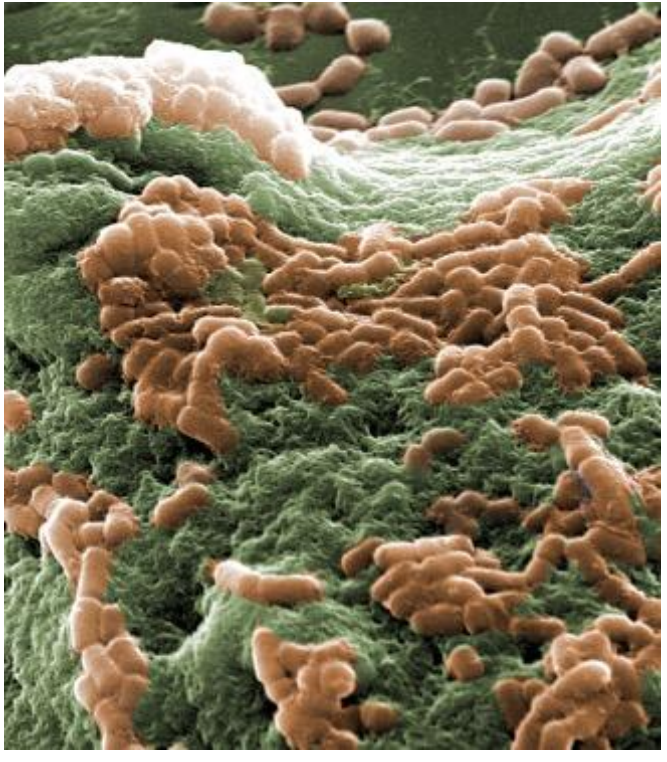
Establishing enteral (mouth) feeding is one important goal in preterm infants for “catch up growth”, for development and to combat intestinal damage.

Murgas-Torrazza, 2013; Agostoni, 2010

Lactobacillus reuteri

Active pharmaceutical ingredient of IBP-9414

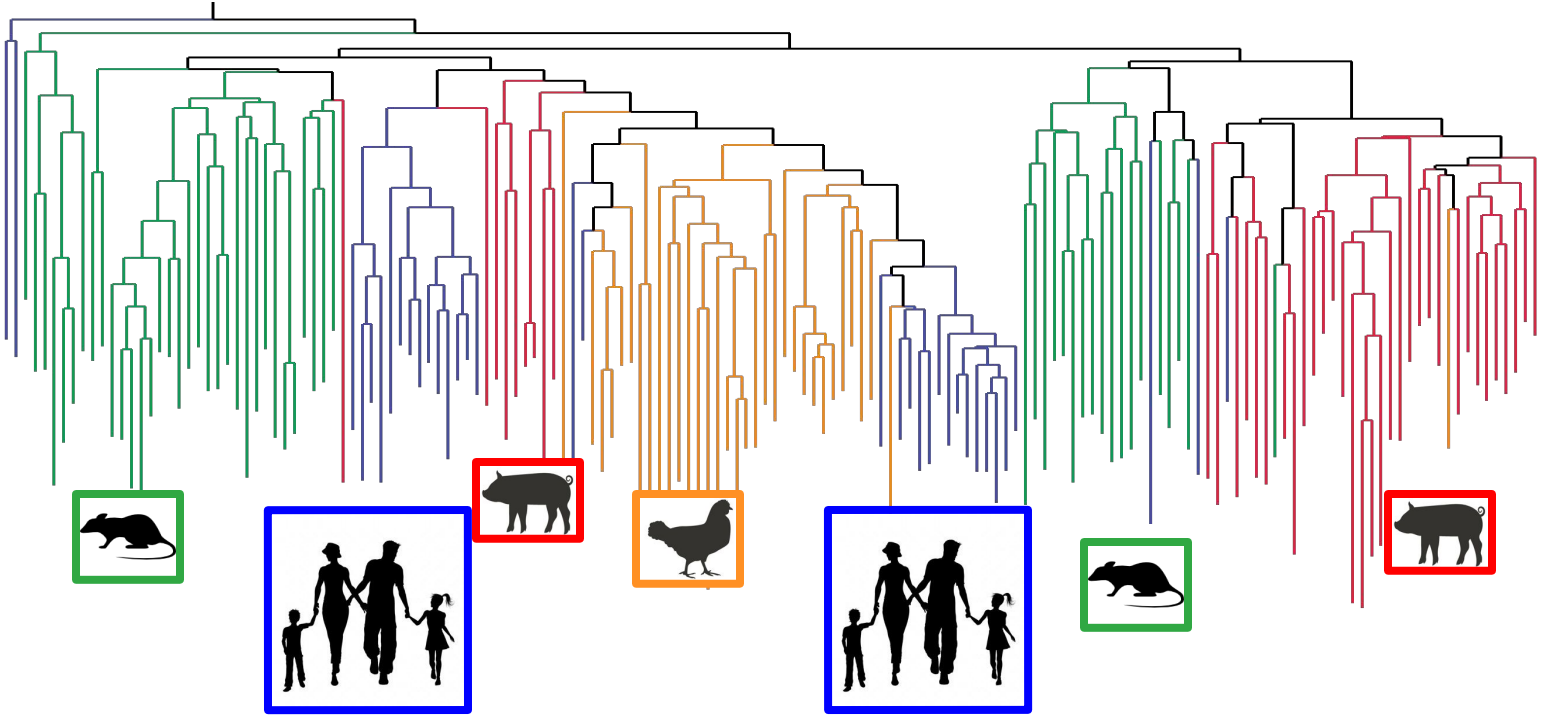
Lactobacillus reuteri present on women's breasts



Lactobacillus reuteri (orange) adhering to intestinal mucus

Evolutionary adaptation of *L. reuteri* to the human gut

Genetic relatedness of global *L. reuteri* genomes

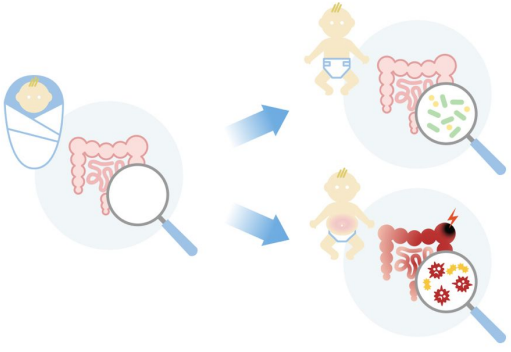


L. reuteri shares a long evolutionary history in the human gut and in human breast milk

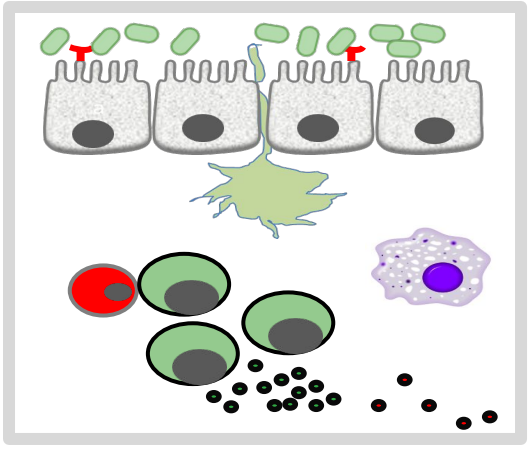
L. reuteri is a true human gut symbiont with mutual benefit to both human host and bacterium

Oh 2010, Walter 2011

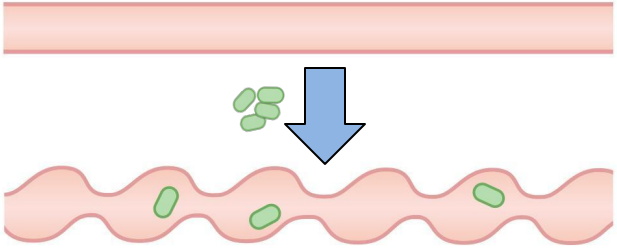
L. reuteri mechanisms of action



Combats dysbiosis



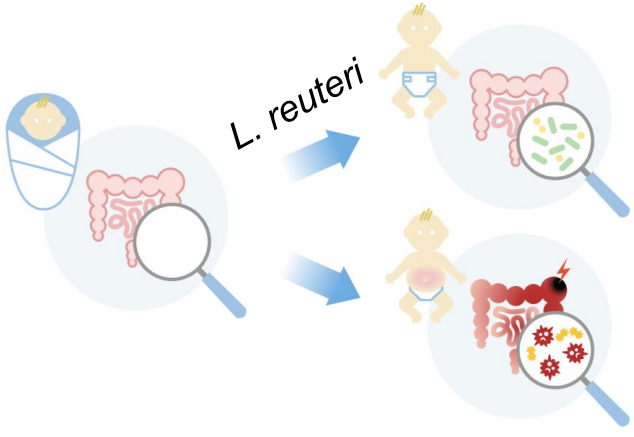
Reduces inflammation

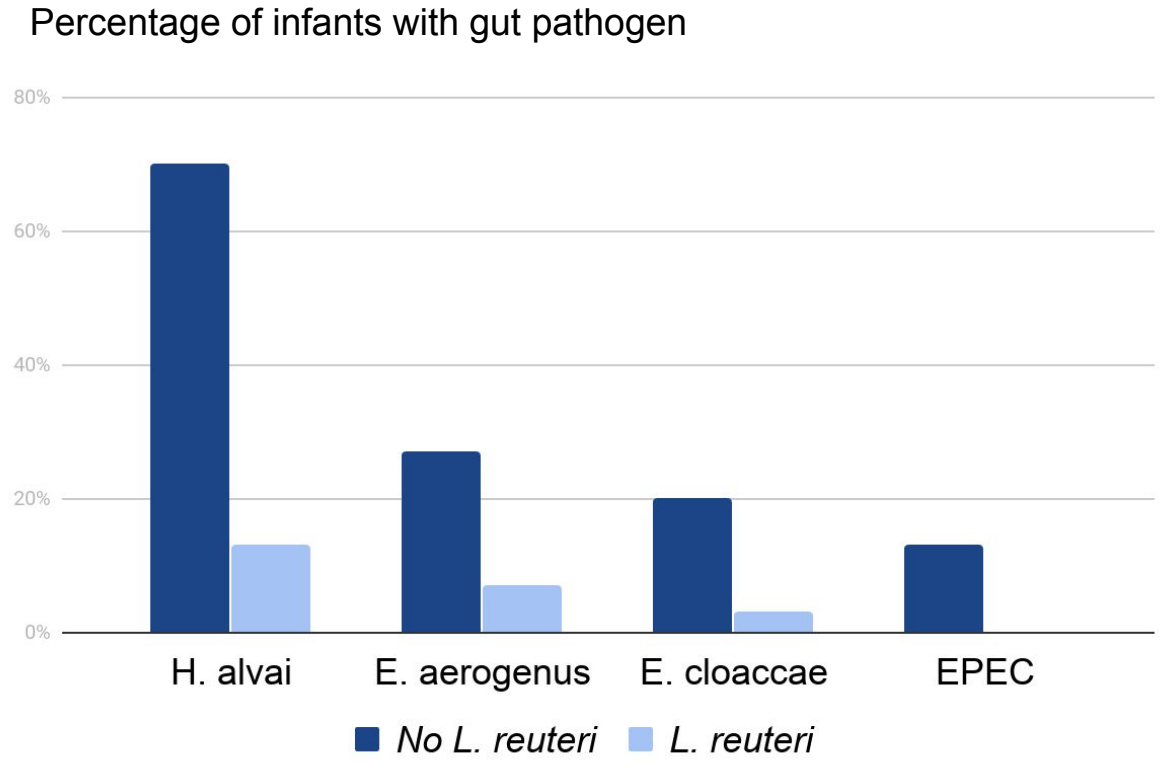


Improves gut motility

Improved feeding tolerance and reduction of NEC

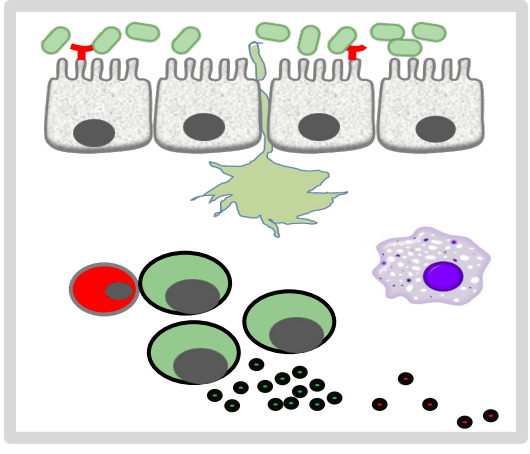
L. reuteri combats dysbiosis



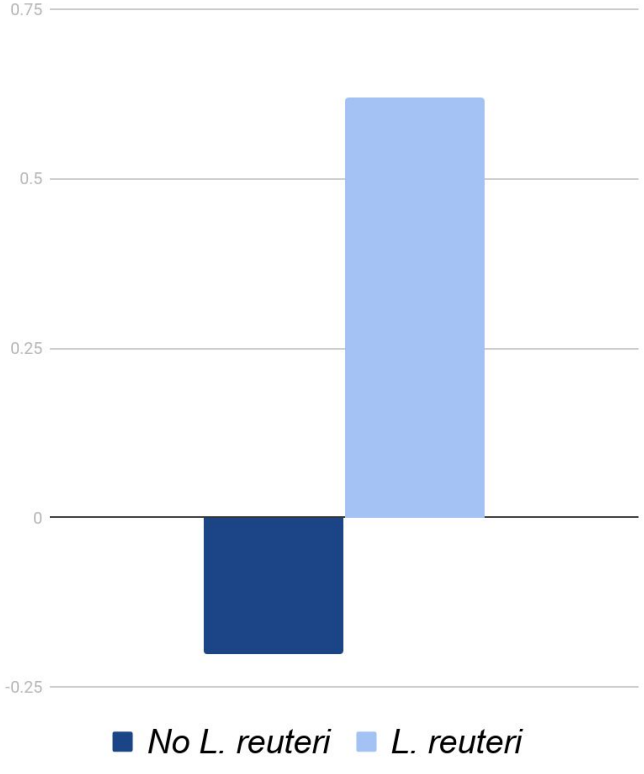


Savino 2015

L. reuteri reduces inflammation

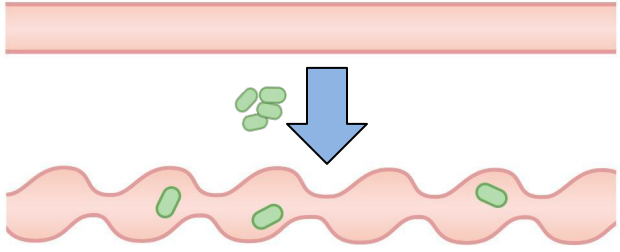


Change in T-regulatory cells (m-RNA) in blood of infants after 30 days with or without *L. reuteri*

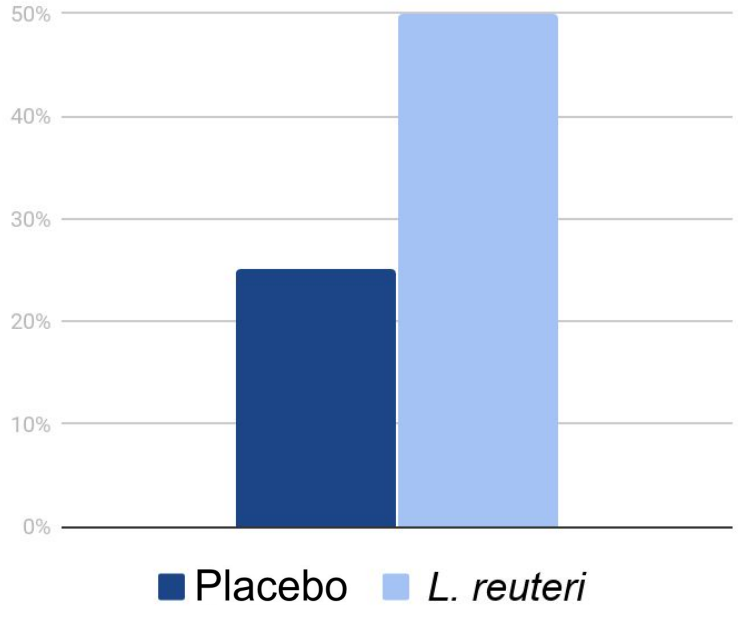


Savino 2017

L. reuteri improves feeding tolerance



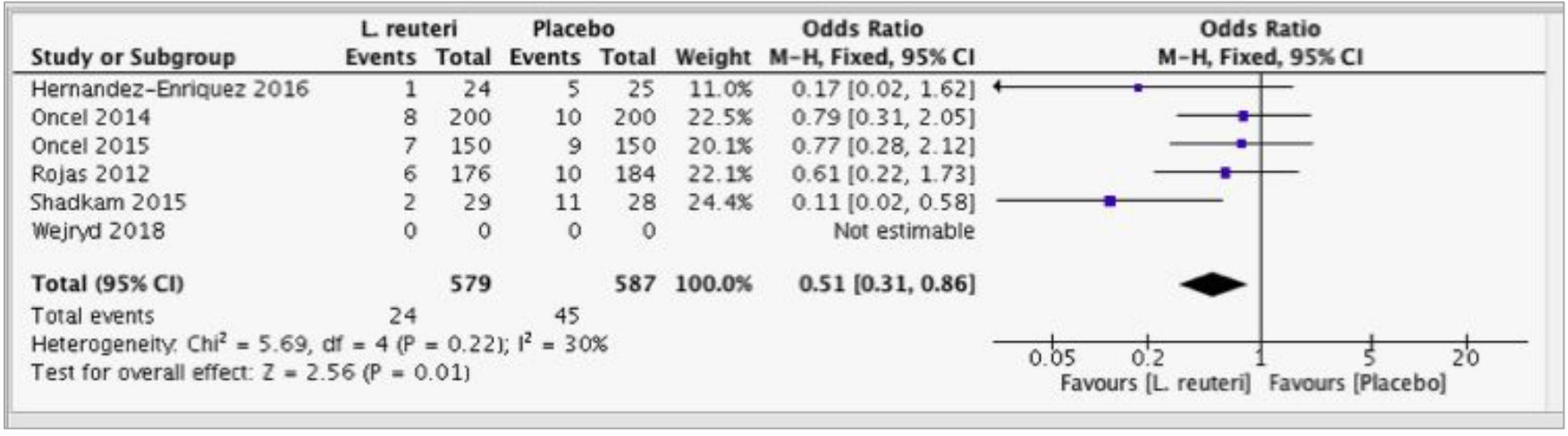
Gastric emptying rate preterm infants after 30 days feeding with placebo or with *L. reuteri*



Indrio 2008

NEC clinical signals

Incidence of NEC



Study or Subgroup	L. reuteri Events	L. reuteri Total	Placebo Events	Placebo Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Hernandez-Enriquez 2016	1	24	5	25	11.0%	0.17 [0.02, 1.62]
Oncel 2014	8	200	10	200	22.5%	0.79 [0.31, 2.05]
Oncel 2015	7	150	9	150	20.1%	0.77 [0.28, 2.12]
Rojas 2012	6	176	10	184	22.1%	0.61 [0.22, 1.73]
Shadkam 2015	2	29	11	28	24.4%	0.11 [0.02, 0.58]
Wejryd 2018	0	0	0	0		Not estimable
Total (95% CI)		**579**		**587**	**100.0%**	**0.51 [0.31, 0.86]**
Total events	24		45			

Heterogeneity: Chi² = 5.69, df = 4 (P = 0.22); I² = 30%
Test for overall effect: Z = 2.56 (P = 0.01)

Meta-analysis: NEC <1500g all randomized controlled trials gives an Odds Ratio of 0.51

Economic burden associated with NEC

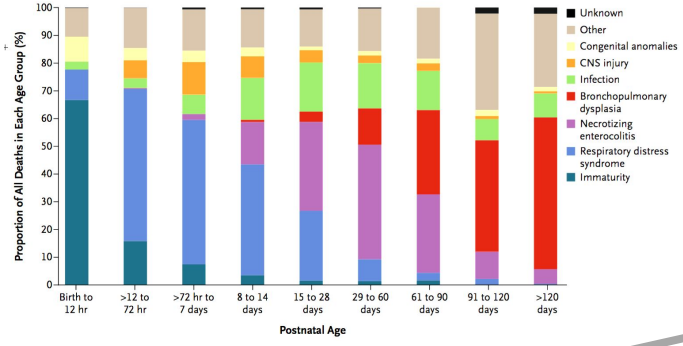
- NEC economic burden is estimated to be 20% of the total cost of initial care and USD 5B spent annually on NEC in the US

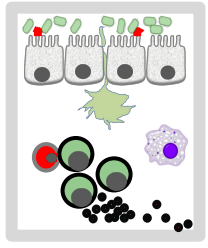
- Market research annual revenue potential of **USD 360m in US** ClearView Healthcare Partners

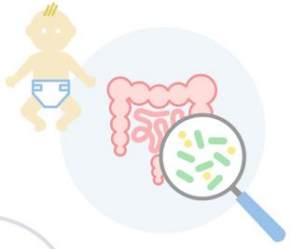
- Long term costs associated with sequelae

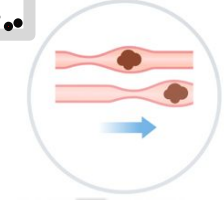
Ganapathy 2011, 2013

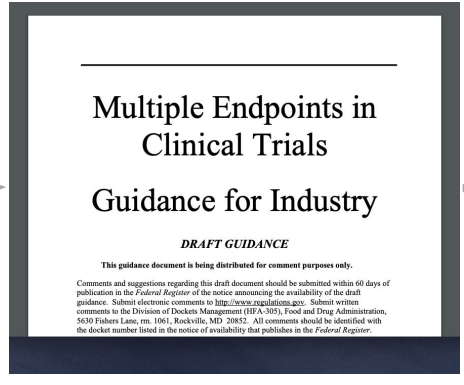
FDA meeting - November 20










Multiple Endpoints in Clinical Trials

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

COMPOSITE Primary Endpoint

"NEC or Feeding tolerance"

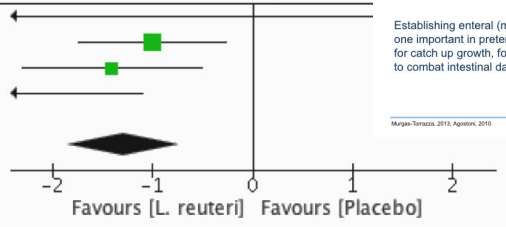
Additional Endpoints	Additional Endpoints
NEC	**Feeding**
Medical NEC Surgical NEC	Time to full feed
etc	Hospital days
	etc

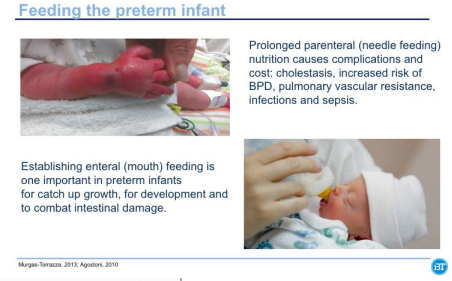
Feeding tolerance – clinical signals

Time to full enteral feeding

Study or Subgroup	L. reuteri Mean	L. reuteri SD	L. reuteri Total	Placebo Mean	Placebo SD	Placebo Total	Weight	Mean Difference IV, Fixed, 95% CI
Hernandez-Enriquez 2016	23.5	12.6	24	28.2	14.6	20	0.5%	-4.70 [-12.85, 3.45]
Oncel 2014	9.1	3.2	200	10.1	4.3	200	57.0%	-1.00 [-1.74, -0.26]
Oncel 2015	9	3.1	150	10.4	4.7	150	38.8%	-1.40 [-2.30, -0.50]
Shadkam 2015	12.8	4.3	29	16.8	6.6	28	3.7%	-4.00 [-6.90, -1.10]
Total (95% CI)			**403**			**398**	**100.0%**	**-1.28 [-1.85, -0.72]**

Heterogeneity: Chi² = 4.66, df = 3 (P = 0.20); I² = 36%
Test for overall effect: Z = 4.49 (P < 0.00001)

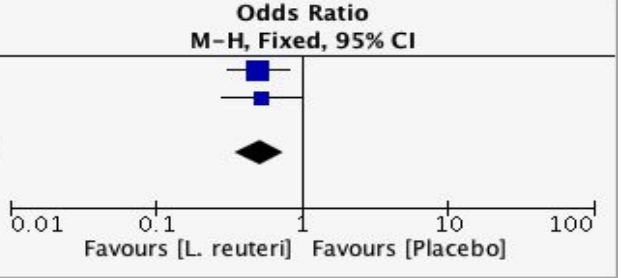




Reported feeding intolerance events

Study or Subgroup	L. reuteri Events	L. reuteri Total	Placebo Events	Placebo Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Oncel 2015	41	150	64	150	62.9%	0.51 [0.31, 0.82]
Rojas 2012	17	176	31	184	37.1%	0.53 [0.28, 0.99]
Total (95% CI)		**326**		**334**	**100.0%**	**0.51 [0.35, 0.75]**
Total events	58		95			

Heterogeneity: Chi² = 0.01, df = 1 (P = 0.92); I² = 0%
Test for overall effect: Z = 3.40 (P = 0.0007)

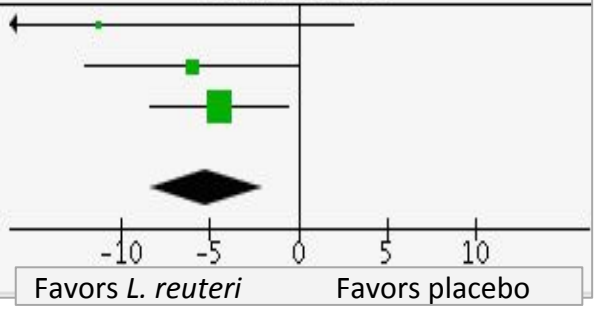


Hospital stay – clinical signals

Study or Subgroup	L. reuteri Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Hernandez-Enriquez 2016	39.3	22.8	24	50.6	25.4	20	4.9%	-11.30 [-25.69, 3.09]
Oncel 2015	42.4	24.1	150	48.4	29.2	150	27.9%	-6.00 [-12.06, 0.06]
Rojas 2012	32.5	17	176	37	20.7	184	67.2%	-4.50 [-8.41, -0.59]
Total (95% CI)			**350**			**354**	**100.0%**	**-5.25 [-8.46, -2.05]**

Heterogeneity: $Chi^2 = 0.88$, $df = 2$ ($P = 0.64$); $I^2 = 0\%$

Test for overall effect: $Z = 3.22$ ($P = 0.001$)



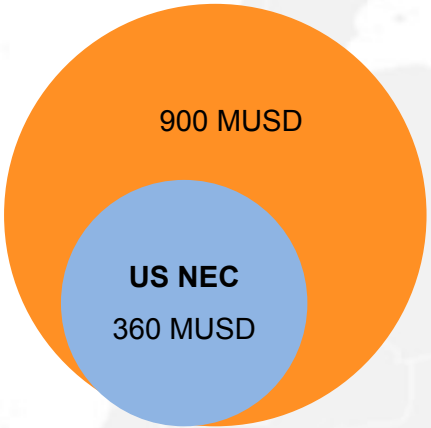
Assuming $16,000* cost of 5 hospital days

56,000 Infants ≤ 1500 g in US /year

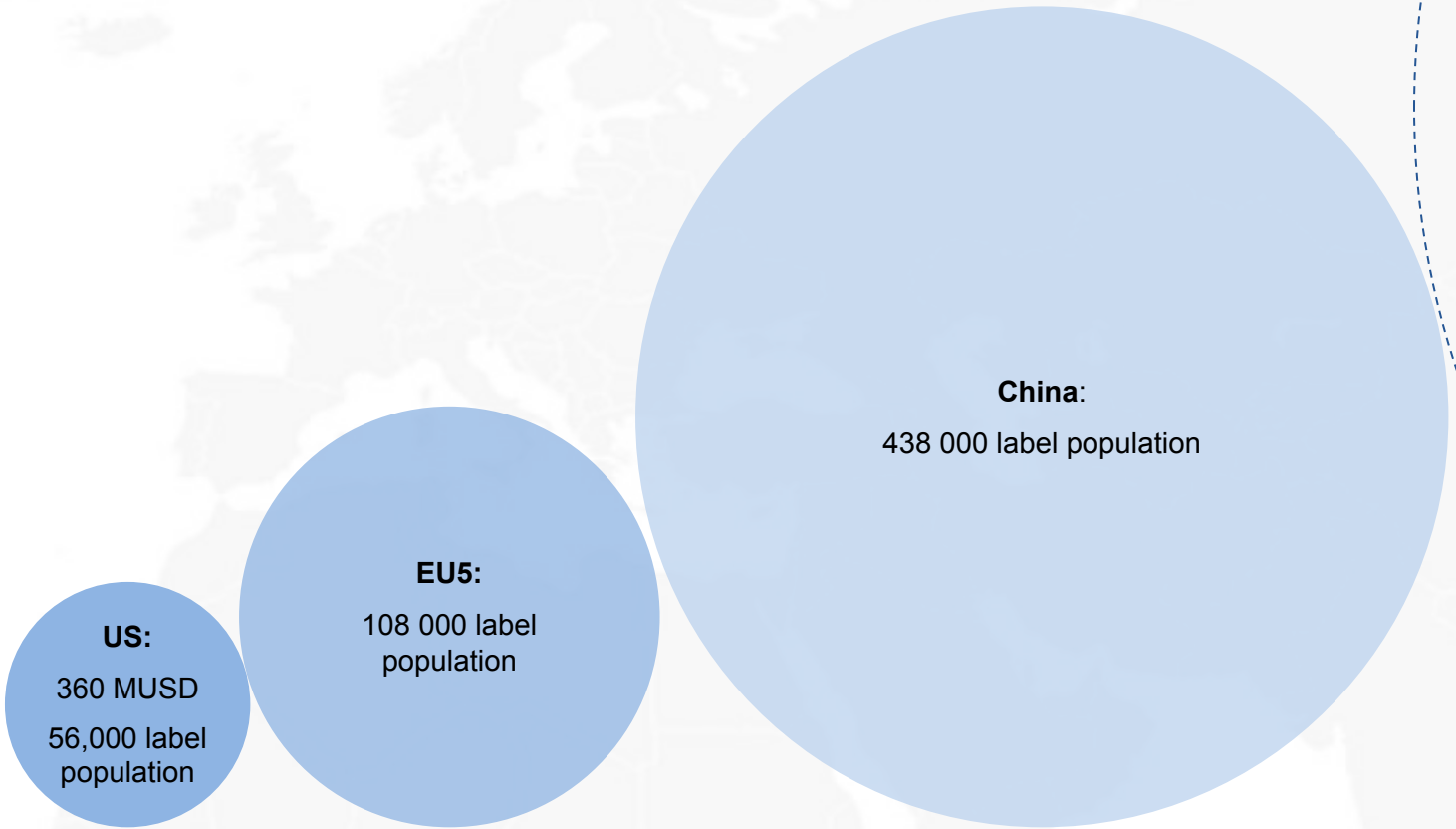
USD 900m / year in US

*Ganapathy, 2011

Annual sales potential of pharmaceutical product



A global NEC pharmaceutical



Roadmap

- Start Phase III - “The Connection Study”
- Explore strategic deals to create awareness and regulatory preparations for launch
- Prepare the EU and US markets through medical communication
- Secure commercial production

- Get Gastroschisis into clinic
- Explore new NCE programs for preterm babies and/or bacterial therapies


ROTHSCHILD