



Infant Bacterial Therapeutics

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Infant Bacterial Therapeutics AB

Founded in 2013 in Stockholm, Sweden

IPO in 2016, listed on Nasdaq Stockholm

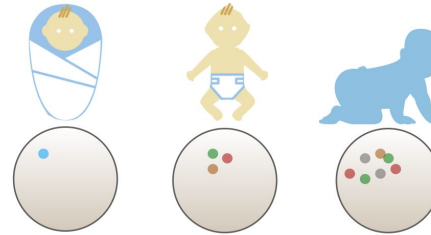
- Market cap SEK 1 700 M (\$175 M)
- Cash position as of September 30, 2019 SEK 511 M (\$53 M) sufficient to fund IBP-9414 development to market

Pivotal Phase III Trial for lead development program IBP-9414

- Patients recruited in EU and US
- Orphan Drug Designation in EU and US
- Rare Pediatric Disease Designation

The IBT concept

- Establish the human microbiome to treat diseases related to poor gut function
- Newborn infant microbiome is dynamic
- Human bacterial strains derived from human breast milk
- Published clinical proof-of-concept signal



PEDIATRICS
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

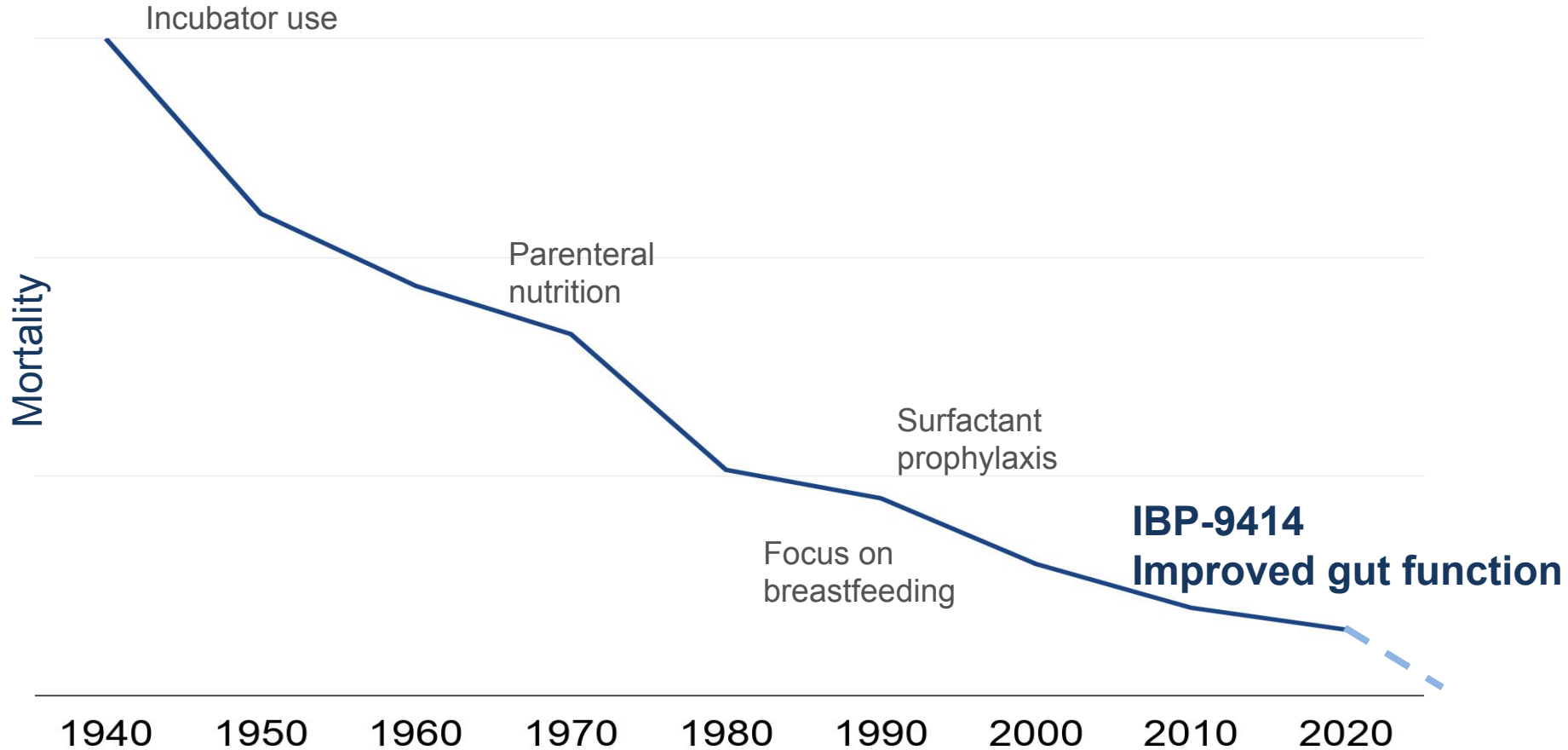
Prophylactic Probiotics to Prevent Death and Nosocomial Infection in Preterm Infants
Mario A. Rojas, Juan M. Lozano, Maria X. Rojas, Viviana A. Rodriguez, Martin A. Rendon, Jaime A. Bastidas, Luis A. Perez, Catherine Rojas, Oscar Ovalle, Jorge E. Garcia-Harker, Maria E. Tamayo, Gloria C. Ruiz, Adriana Ballesteros, Maria M. Archila and Mauricio Arevalo
Pediatrics 2012;130:e1113, originally published online October 15, 2012;
DOI: 10.1542/peds.2011-3584



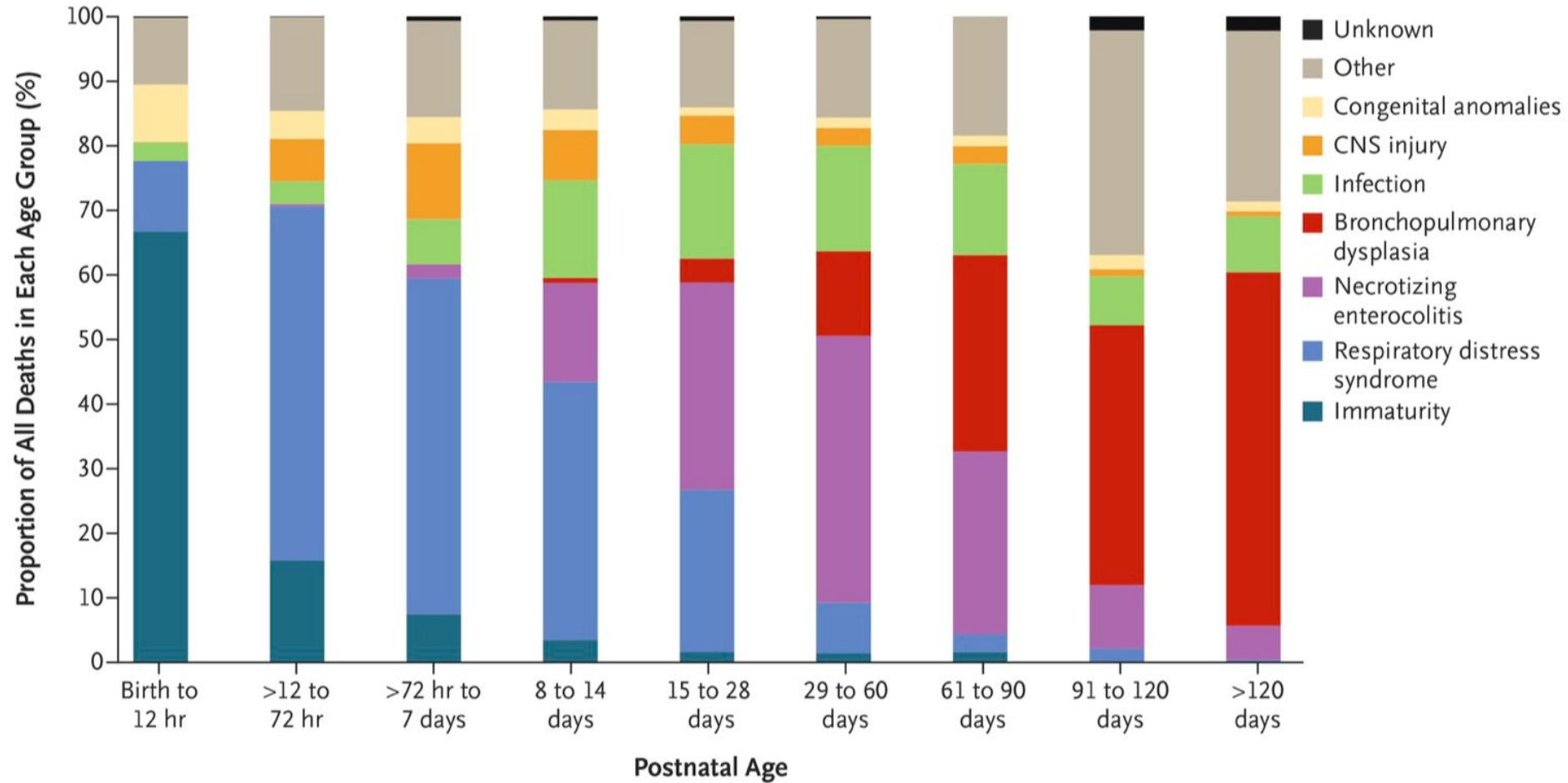
High unmet medical need



Breakthroughs in preterm infant care



Causes of death



Feeding the preterm infant



Establishing enteral (mouth) feeding in preterm infants is a primary clinical goal to **attain normal growth**, important for e.g. cognitive development.



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

Economics of NICU stay



Overall cost of of preterm births in the US is estimated at \$26 Billion

More than 65% of NICU admissions have an average LOS of about 20 days

Average NICU cost per day is \$3,000

Cost of average NICU admission is similar to that of patients admitted for spinal cord injury and heart valve disorders

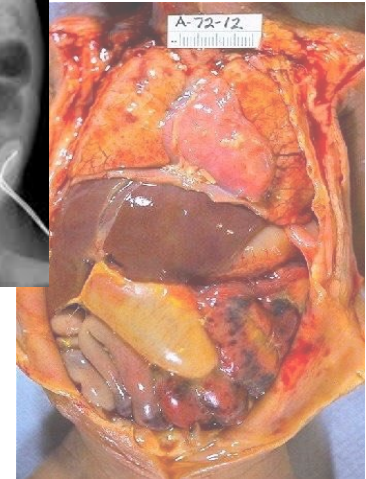


$5 \text{ days} * \$3,000 * 65\% (\text{LOS } 20 \text{ days}) * 56,000 (\text{VLBW US/year}) = 546 \text{ MUSD}$

Necrotizing enterocolitis (NEC)

- NEC is severe inflammation of the bowel in preterm infants 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% mortality rate killing 1500 US and 3700 EU infants each year

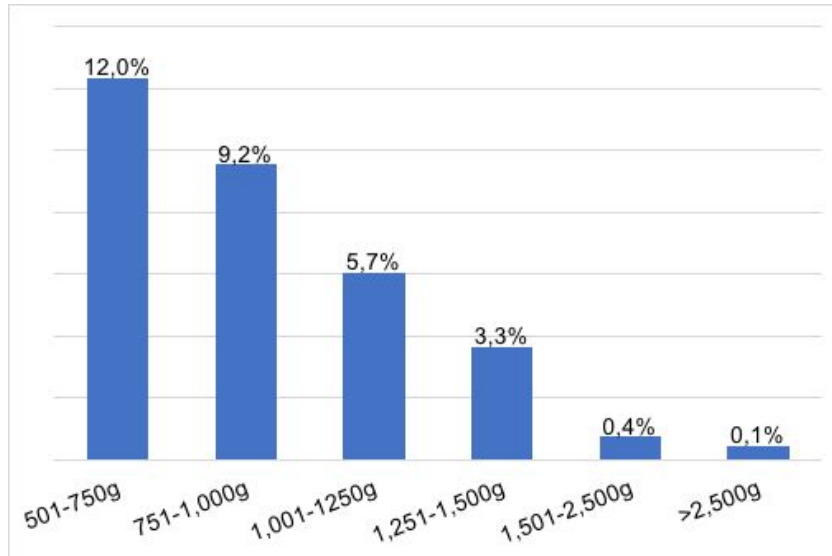


NEC – a devastating disease



The smaller the premature infant is at birth, the more likely he/she will die

NEC incidence rate



NEC mortality rate

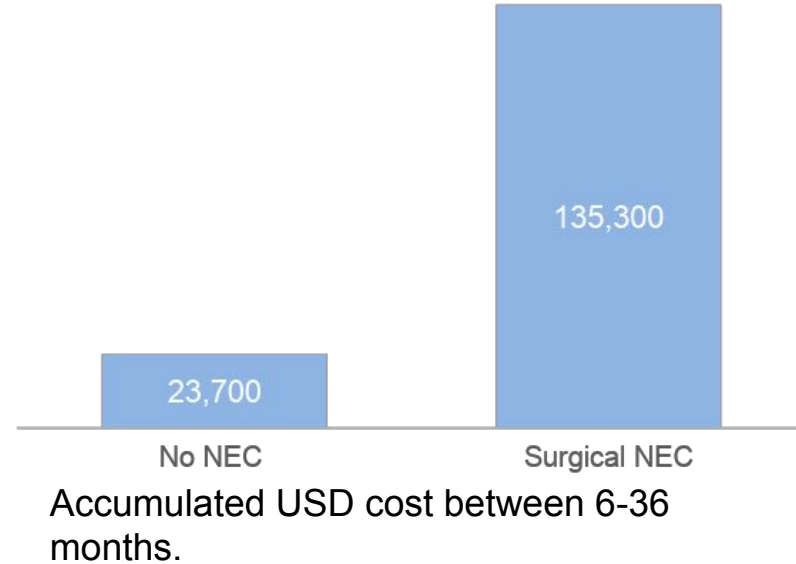
501-750g	42.0%
751-1,000g	29.4%
1,001-1,250g	21.3%
1,251-1,500g	15.9%
1,501-2,500g	12.7%

Economic burden of NEC



Average total treatment cost of NEC is USD 500,000 per patient in the USA

Costs continue after NICU discharge



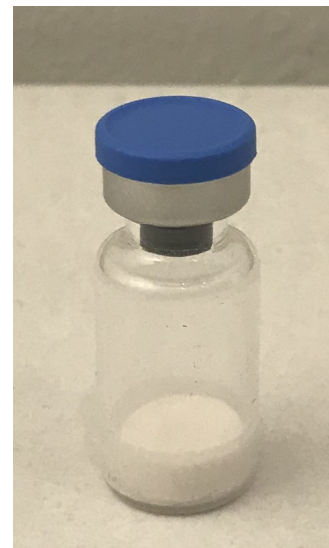
NEC Economic Burden is estimated to be 20% of the total cost of initial care and USD 5 Billion spent annually on NEC in the US.



The product

Pharmaceutical drug candidate IBP-9414

- ◆ Rigorous pharmaceutical Chemistry-
Manufacturing-Control standards in all steps with GMP
according to 21 CFR Part 210
- ◆ Developed under IND
- ◆ Single dose vial with dose accuracy following ICH
Guidelines for Pharmaceuticals
- ◆ Stringent control of bioburden and
microbial purity on final product analysis according to
US and Eur Pharmacopeia

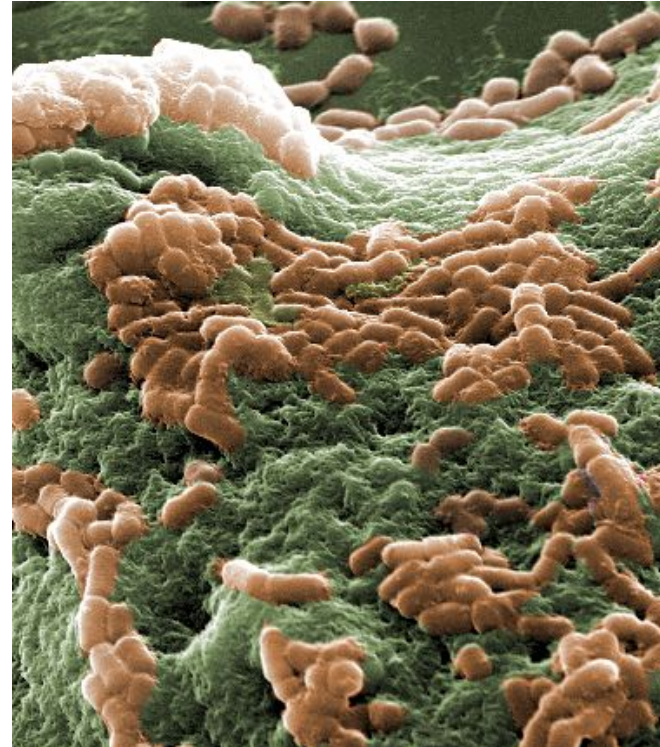


Lactobacillus reuteri

Active substance of IBP-9414

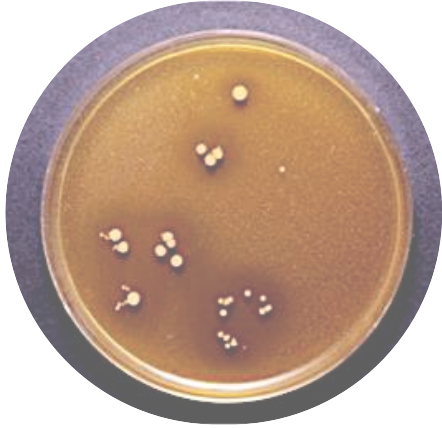


Lactobacillus reuteri present
on women's breasts



Lactobacillus reuteri (orange)
adhering to intestinal mucus

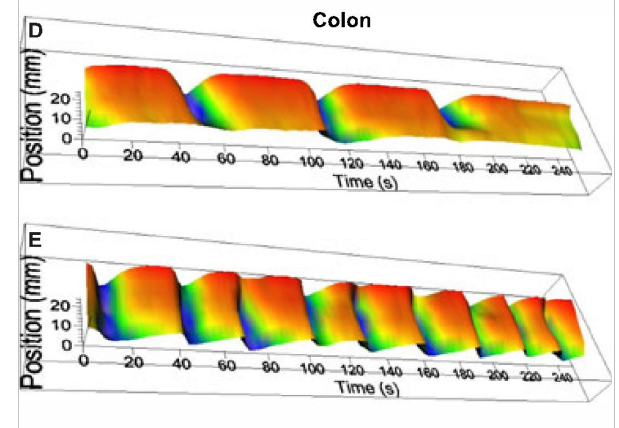
L. reuteri - mechanisms of action



Combats dysbiosis



Reduces inflammation

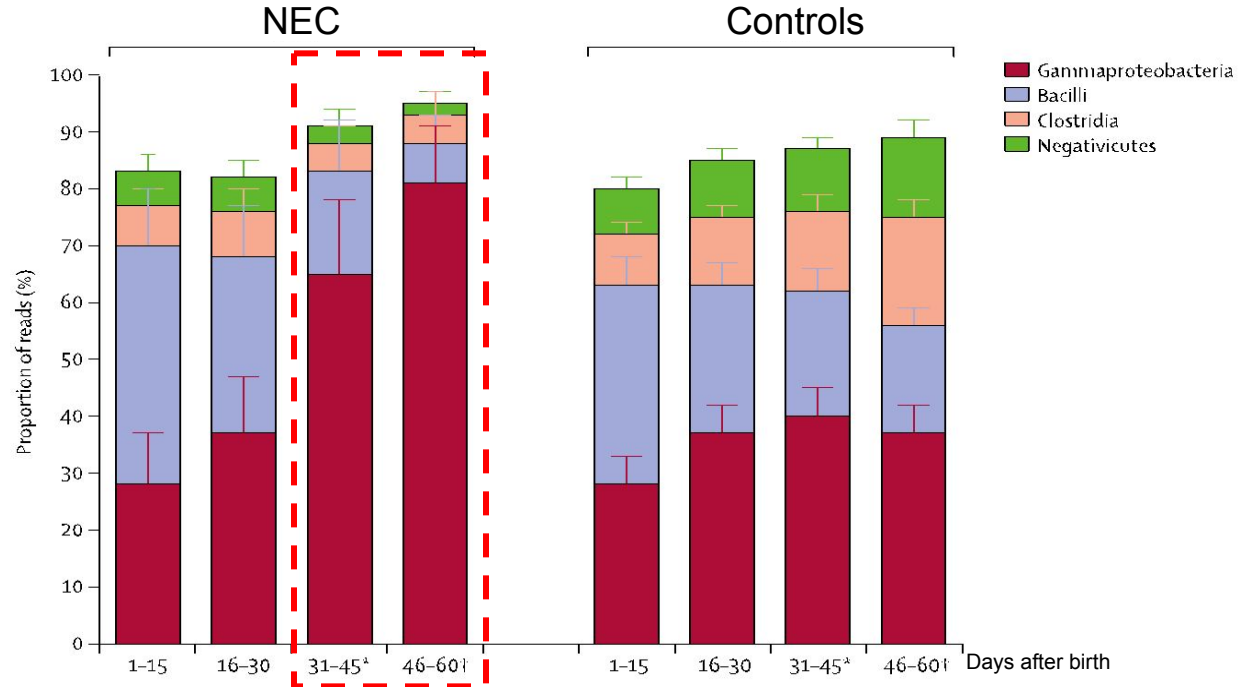


Improves gut motility

Improved gut function including prevention of NEC

Clinical Signal - Dysbiosis

Dysbiosis with pathogen blooms in the microbiota can contribute to necrotizing enterocolitis in preterm infants



Bloom of pathogen-rich gamma proteobacteria prior to onset of NEC

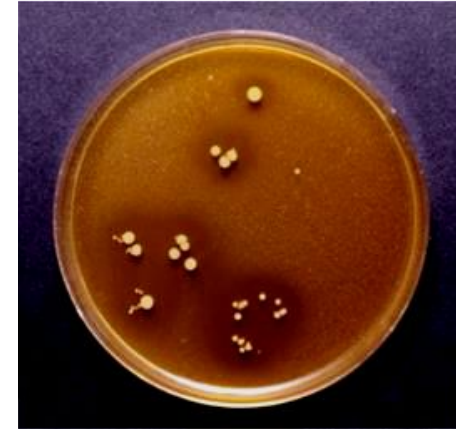
Microbiome optimization may provide a novel strategy for preventing NEC

Combats dysbiosis

***L. reuteri* produces species-specific antimicrobial substance called reuterin**

Bacteria

- | | |
|-----------------------------------|--------------------------------------|
| ▪ <i>Bacillus subtilis</i> | ▪ <i>Escherichia coli</i> (patogena) |
| ▪ <i>Listeria monocytogenes</i> | ▪ <i>Salmonella typhimurium</i> |
| ▪ <i>Campylobacter jejuni</i> | ▪ <i>Enterobacter sakazakii</i> |
| ▪ <i>Porphyromonas gingivalis</i> | ▪ <i>Shigella</i> spp |
| ▪ <i>Clostridium perfringens</i> | ▪ <i>Fusobacterium nucleatum</i> |
| ▪ <i>Prevotella intermedia</i> | ▪ <i>Staphylococcus aureus</i> |
| ▪ <i>Clostridium difficile</i> | ▪ <i>Helicobacter pylori</i> |
| ▪ <i>Pseudomonas fluorescens</i> | ▪ <i>Streptococcus mutans</i> |



L. reuteri* inhibits *S. aureus

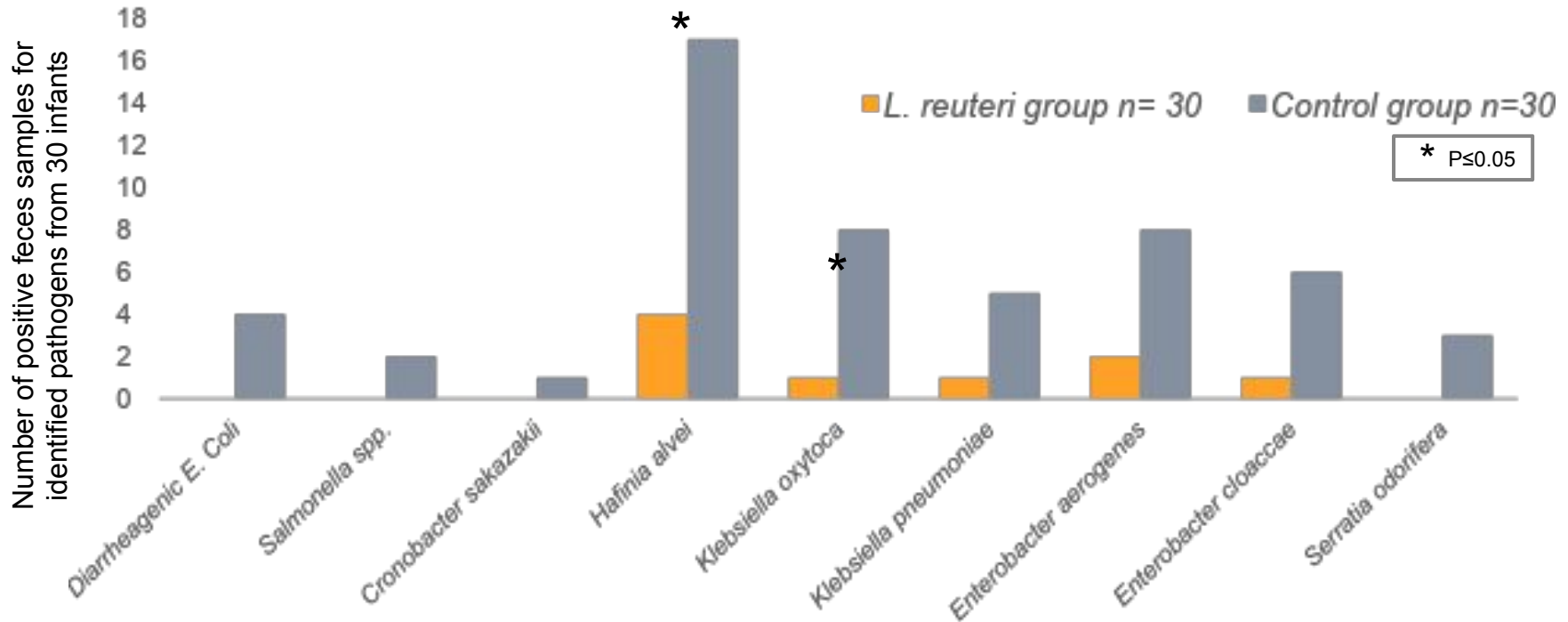
Yeast and fungi

- *Candida albicans*
- *Aspergillus flavus*
- *Fusarium samiciensis*

***L. reuteri* inhibits the growth of pathogens**

Clinical data - Combats dysbiosis

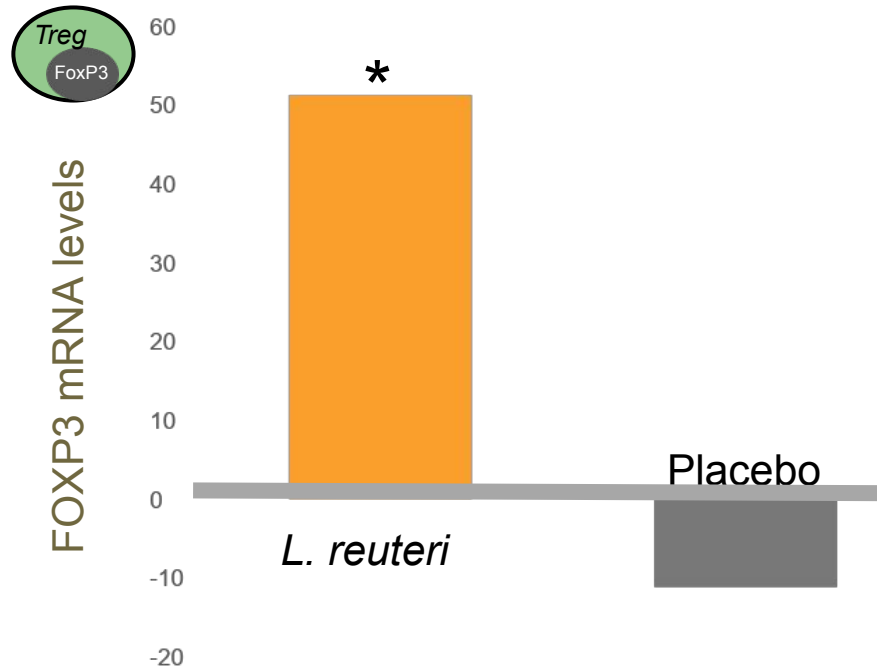
Infant fecal pathogens after 1 month *L. reuteri* treatment



***L. reuteri* decreased gut pathogen colonization in infants**

Clinical - Anti-inflammatory

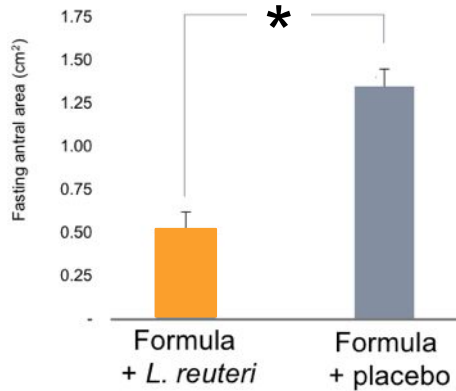
Treg cells increase in infant blood after *L. reuteri* administration



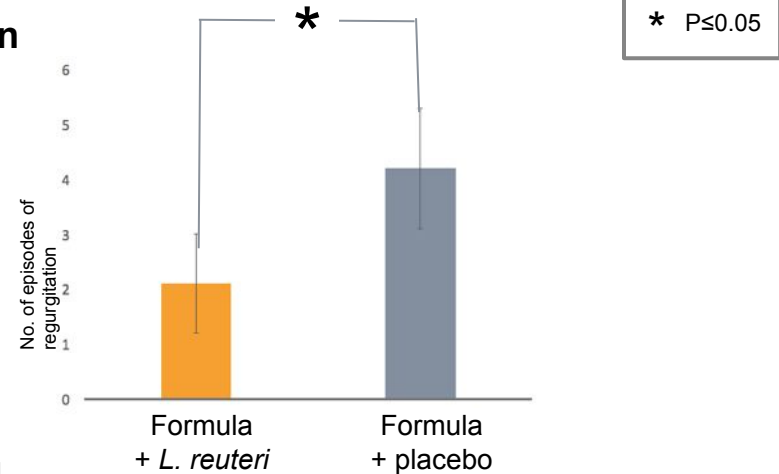
L. reuteri recruitment of Treg cells now shown in infants

Clinical data - Modulation of gut motility

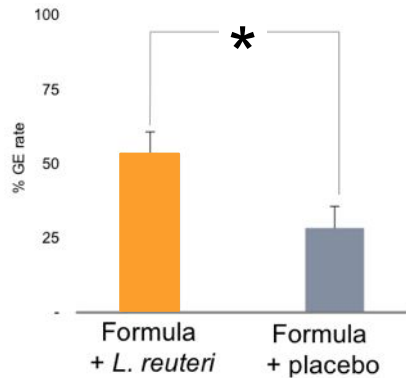
Fasting antral area



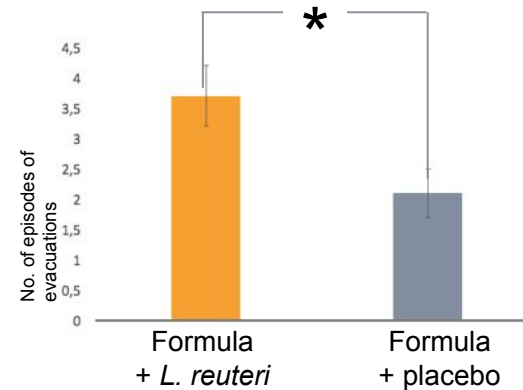
Regurgitation



Gastric emptying

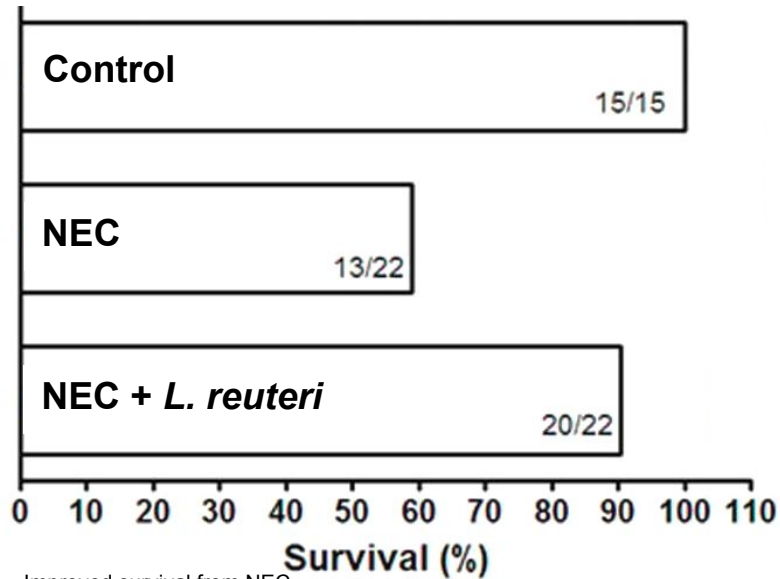


Stooling



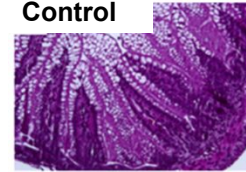
Preterm infants given *L. reuteri* show improved gut emptying

L. reuteri protects from NEC in animal models

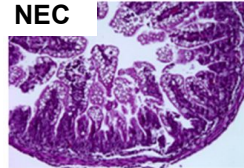


Improved survival from NEC

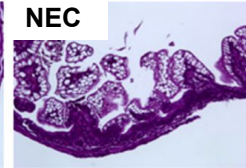
Control



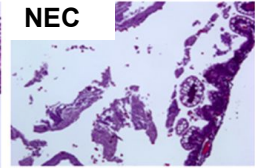
NEC



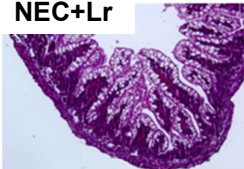
NEC



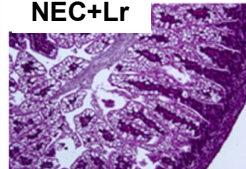
NEC



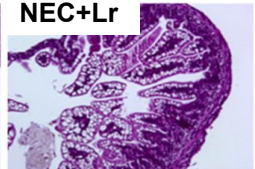
NEC+Lr



NEC+Lr



NEC+Lr



Reduced intestinal damage

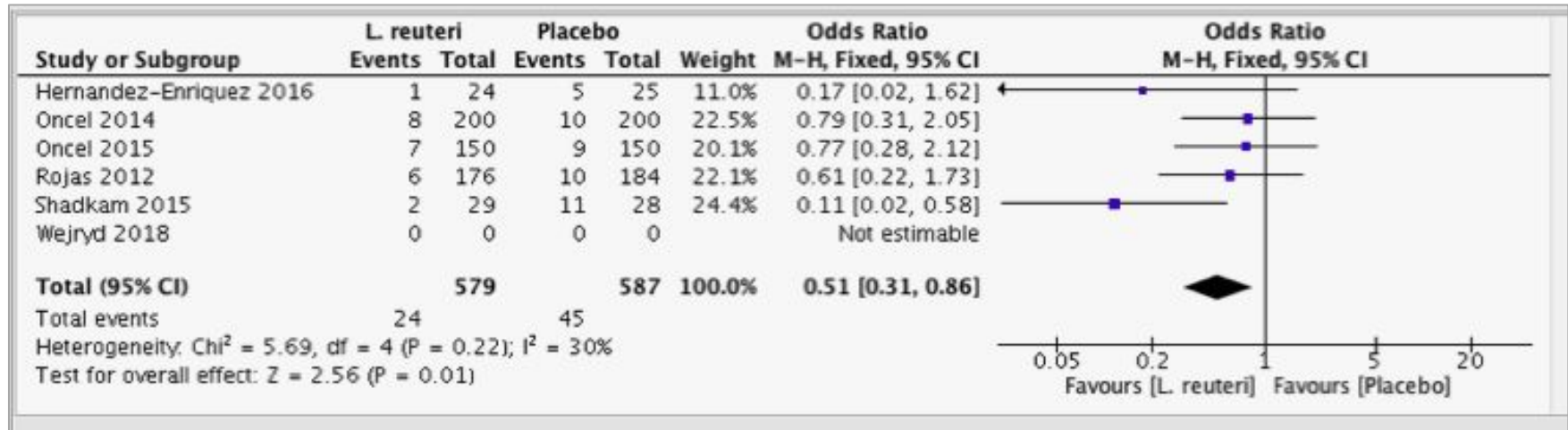


Clinical signal

Publications with clinical signal of NEC reduction



	Number of Infants	NEC incidence	
		Control	With <i>L. reuteri</i>
Rojas et al. 2012	750	5,4 %	↘ 3,4 %
Oncel et al. 2014	400	5,0 %	↘ 4,0 %
Oncel et al. 2015	300	6,0 %	↘ 4,7 %
Shadkam et al. 2015	60	36,7 %	↘ 6,7 %
Hernandez-Enriquez et al. 2016	44	25,0 %	↘ 4,2 %
Spreckels et al. 2018	104	9,0 %	↘ 4,0 %
Wejryd et al. 2019	134	12,0 %	↘ 10,0 %
Hunter et al. 2012/Dimaguila et al. 2013	354	15,1 %	↘ 1,6 %
Sanchez-Alvarado 2017	225	14,6 %	↘ 5,3 %
Rolnitsky et al. 2017	937	6,0 %	↘ 2,9 %
Jerkovic-Raguz et al. 2016	100	8,0 %	↘ 4,0 %

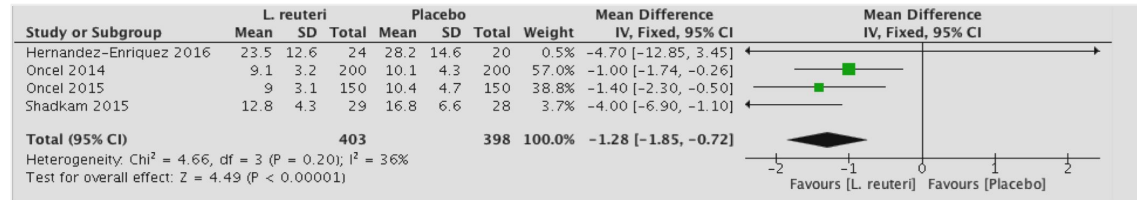


Meta-analysis of 1166 patients <1500g all randomized controlled trials gives an Odds Ratio of 0.51

Feeding Tolerance - clinical signals and consequences

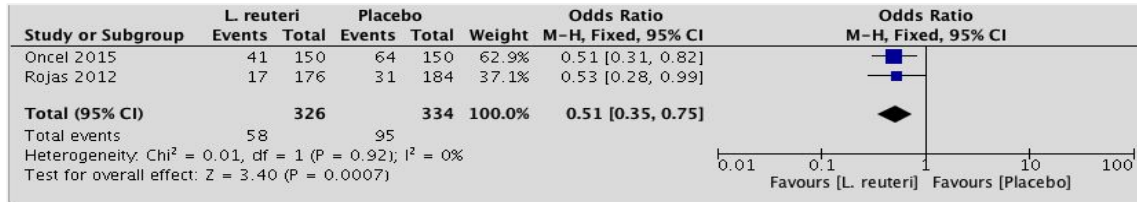
Time to full enteral feeding

-1.28 days [-1.85, -0.72]



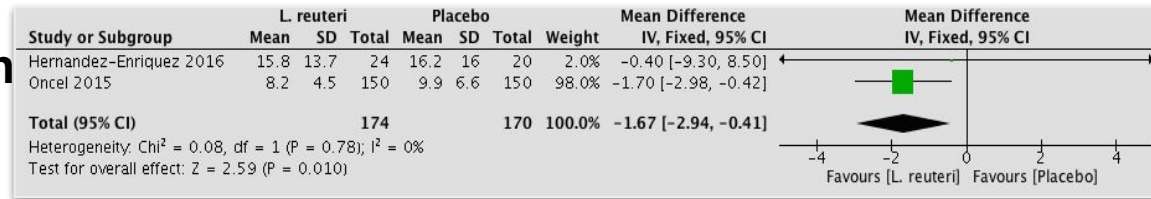
Feeding intolerance events

OR 0.51 [0.35, 0.75]



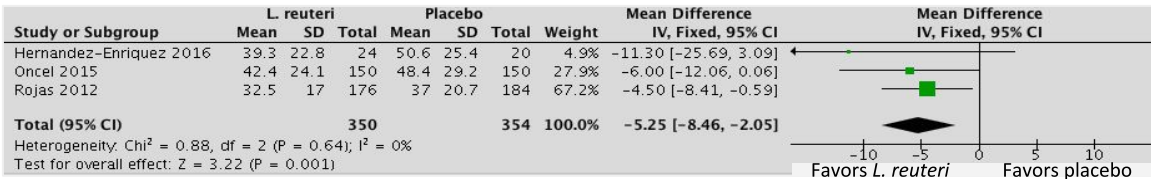
Days on Parenteral Nutrition

-1.67 days [-2.94, -0.41]



Days in hospital

-5.25 days [-8.46, -2.05]





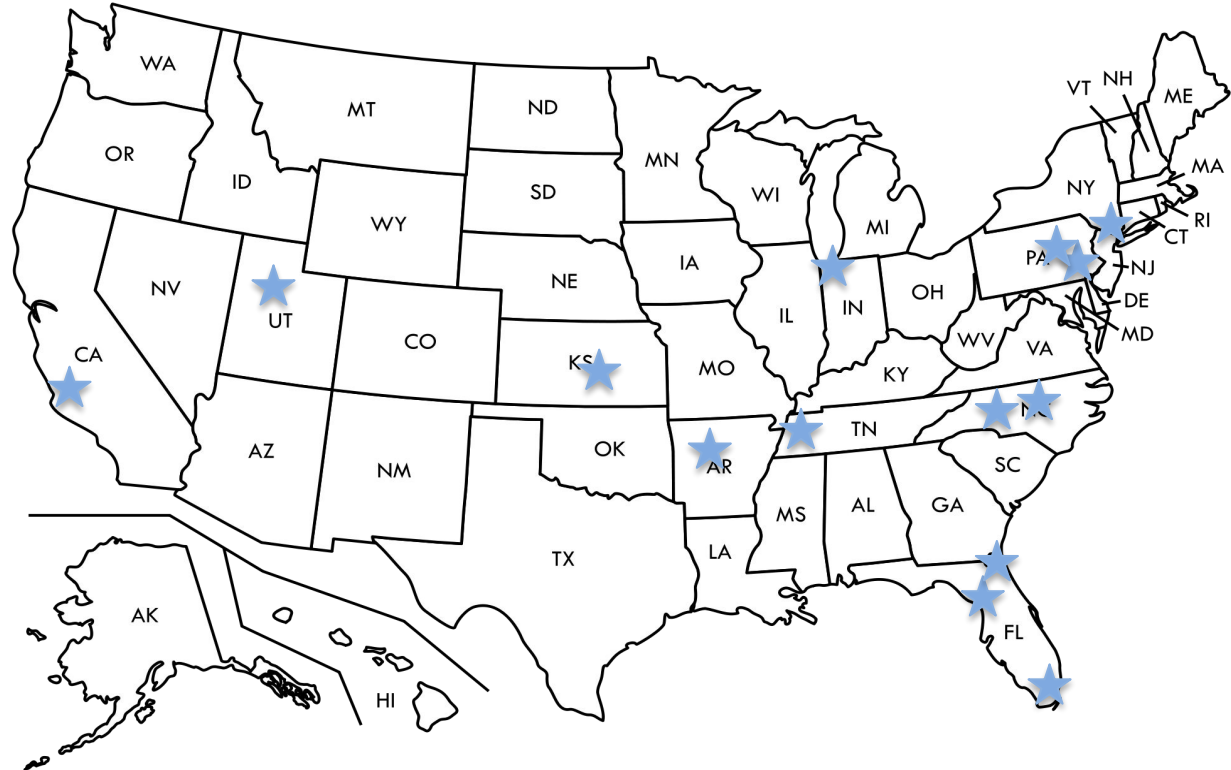
Clinical Development Program

IBP-9414 Phase II: Safety & Tolerability Study

RCT; 120 infants 500g - 2000g; 14 days daily dosing from 48h;
dose 10^8 or 10^9 CFU or placebo; follow up 1 & 6 months

Dr. Neu, Gainesville FL, PI

Dr. Ashley, Durham NC
Dr. Bloom, Wichita KS
Dr. Del Moral, Miami FL
Dr. Garg, Los Angeles CA
Dr. Gerstmann, Orem UT
Dr. Guthrie, Jackson TN
Dr. Hand, Brooklyn NY
Dr. Hirsch, Philadelphia PA
Dr. Hudak, Jacksonville FL
Dr. Kehinde, Philadelphia PA
Dr. Kona, Little Rock AR
Dr. Porcelli, Wake Forest NC
Dr. White, South Bend IN



IBP-9414 Phase II Safety & Tolerability Study

- Similar AE and SAE profile in active and placebo groups
- No SAE related to study drug
- No evidence of cross-contamination with IBP-9414 in placebo treated infants
- Executed according to timeplan

Key conclusion: Safe and well-tolerated



Endorsed Phase III Pivotal Trial

- IBT has developed the IBP-9414 program in cooperation with the regulators and with considerations of KOLs experience and clinical practice
- CTX/IND approval received in UK, Spain, Hungary, France and USA, application filed in Israel



IBP-9414 Clinical Development Plan

Phase 2

Safety and Tolerability Trial

- ◆ Randomized, double blind, dose escalation, placebo-controlled
- ◆ Multicenter study
- ◆ Safety and tolerability of IBP-9414 in premature infants $\leq 2,000$ g birth weight
- ◆ 120 infants
- ◆ 15 sites in the US

Phase 3

Efficacy and Safety Trial – Connection Study

- ◆ Randomized, double blind, placebo-controlled
- ◆ Multicenter study
- ◆ Efficacy and safety of IBP-9414 in premature infants 500-1500g birth weight for the prevention of necrotizing enterocolitis and time to sustained feeding tolerance
- ◆ 2158 infants
- ◆ 100 sites in the US, UK, Spain, France, Hungary, Israel

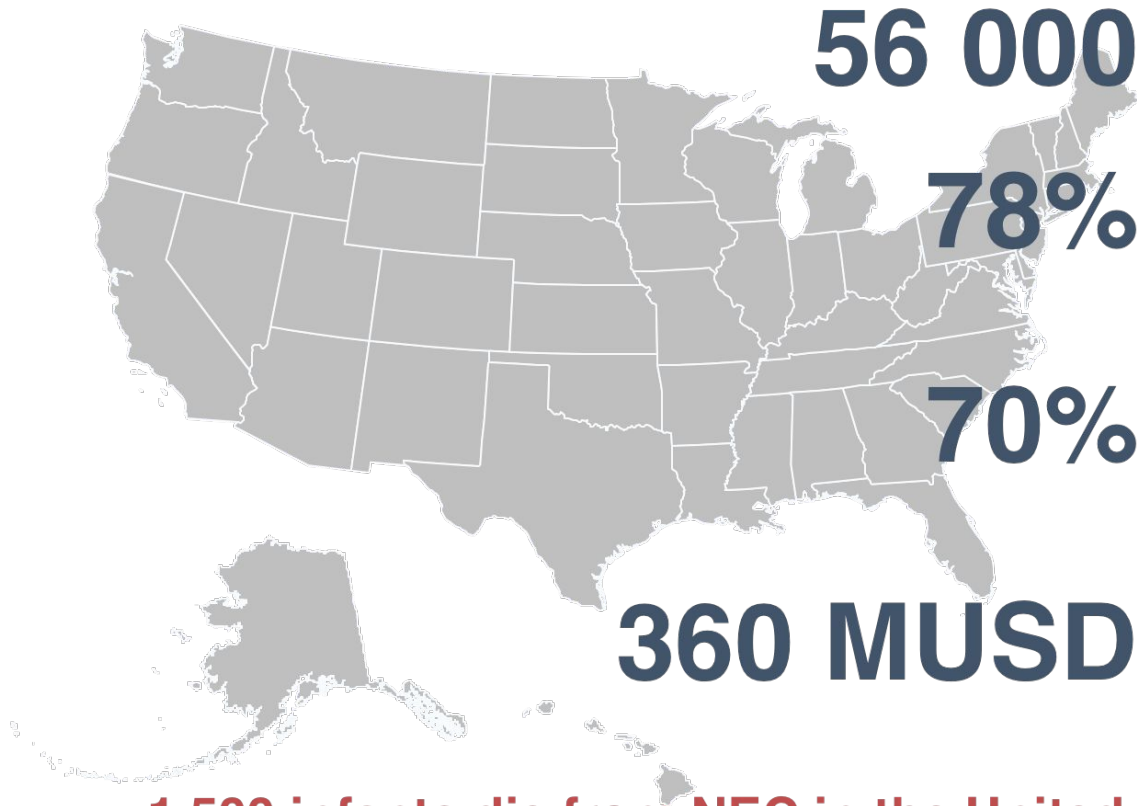


STRONG INTEREST FROM THE MARKET

A valuable pharmaceutical



Results of NEC market analysis by ClearView Healthcare Partners



Number of infants born under 1,500 grams in the United States annually

Physician preference share demonstrates neonatologists show high willingness to prescribe IBP-9414

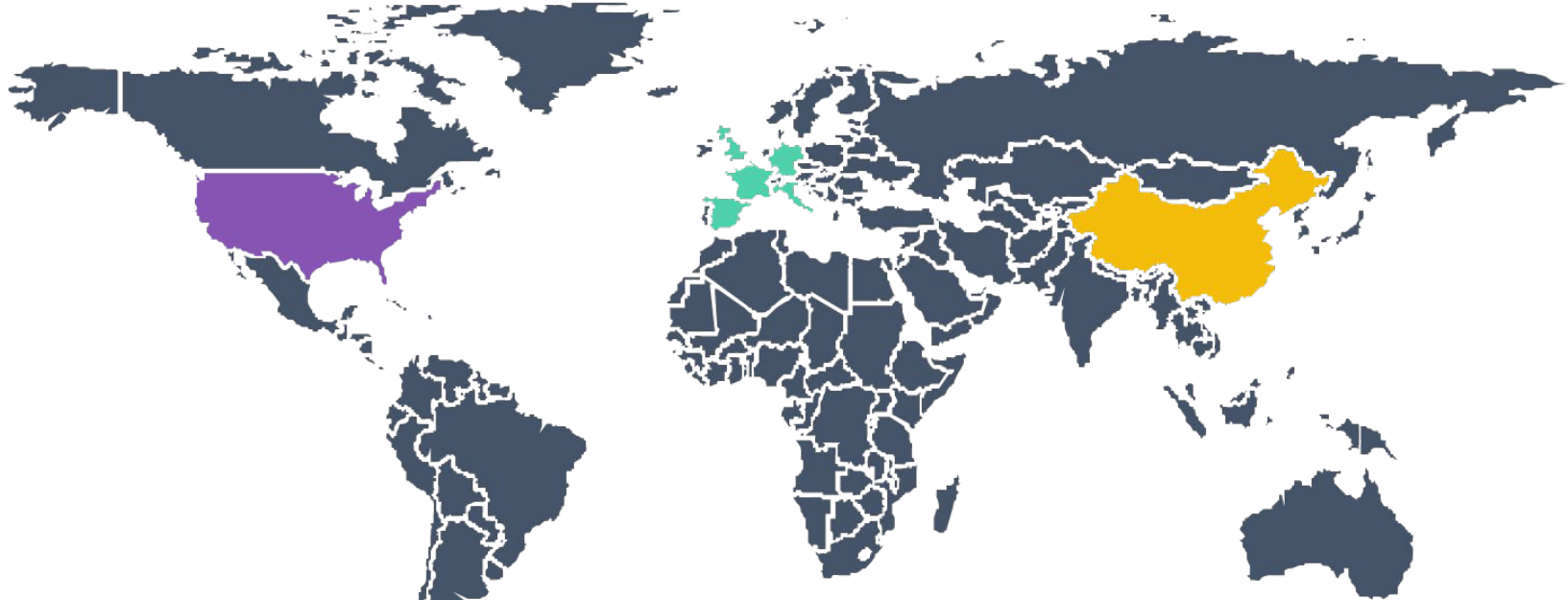
Of addressable patients are anticipated to receive care at an institution that includes IBP-9414 on formulary

Estimated annual revenue potential in US based on ClearView market research

1 500 infants die from NEC in the United States each year

A global need

15 Million Pre-term births annually



● US

56 000 label
population = 360
MUSD annual sales
for NEC prevention

● EU5

108 000 label
population

● China

408 000 label
population

IBP-9414 our lead Phase III program

Ticks all relevant pillars for the development of a successful drug

Medical need



Mechanism of action



Clinical data



Safe



Aligned regulatory agencies



GMP manufacture



Market exclusivity



Aligned payers



Orphan Drug and Rare Pediatric Disease designations



Thank you



INFANT BACTERIAL THERAPEUTICS