Infant Bacterial Therapeutics

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IBT Overview

1. Necrotizing enterocolitis (NEC) and poor gut function are major causes of death among premature infants

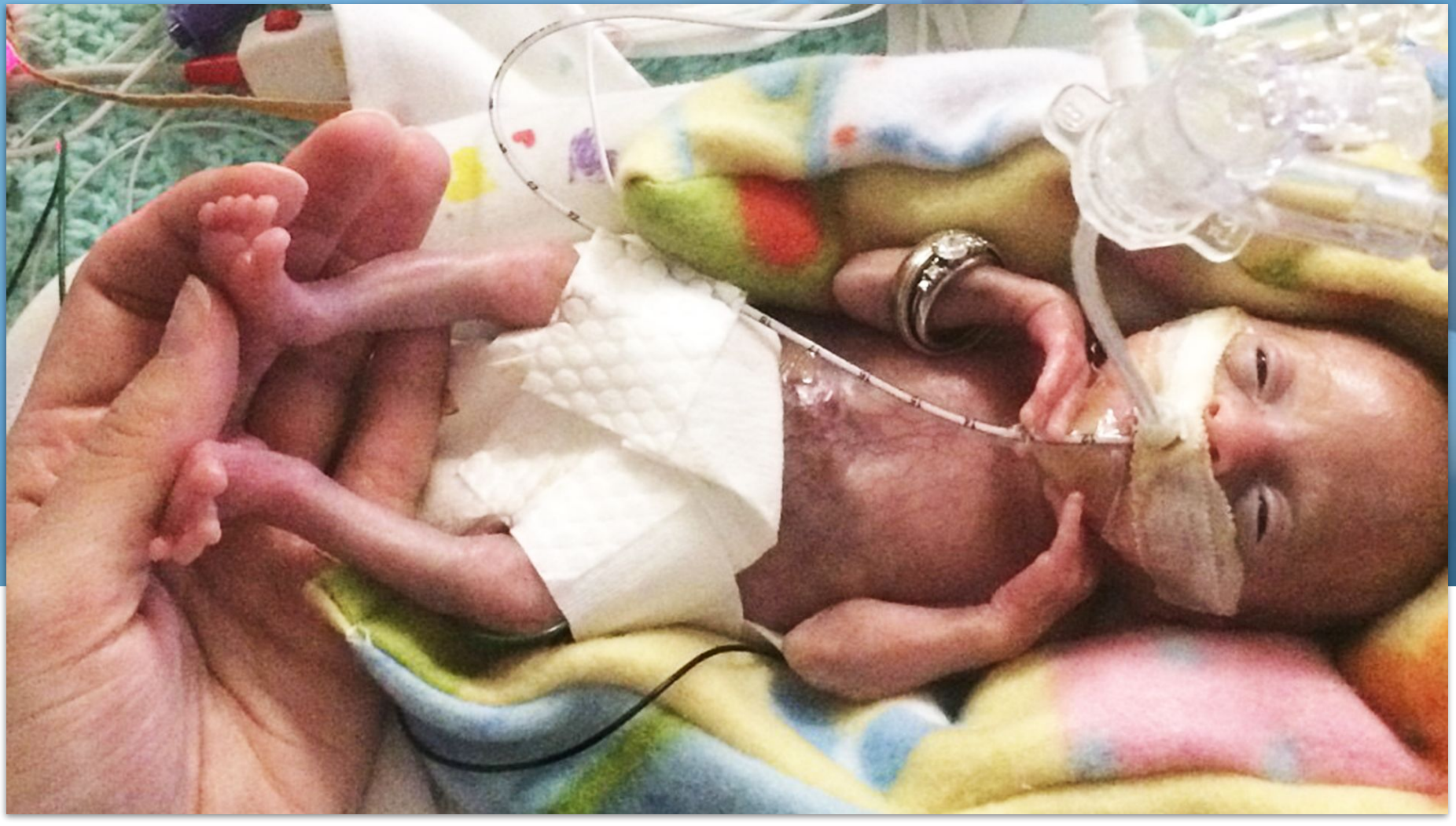
2. IBP-9414 is a unique GI bacteria altering the microbiome with market blockbuster potential (>$1B)

3. Safety and Proof of concept are established - published clinical studies

4. Final formulation set, four years stability on file, scalable production in place for launch

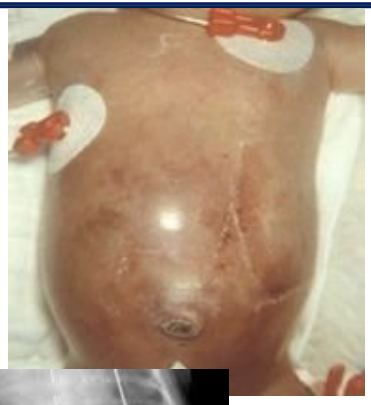
5. Clinical program to be completed in 2022, Marketing Application to follow

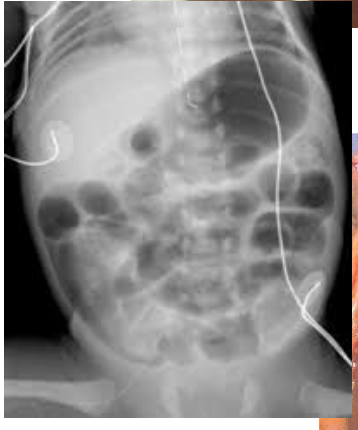
1 Necrotizing enterocolitis (NEC) and poor gut function are major causes of death among premature infants

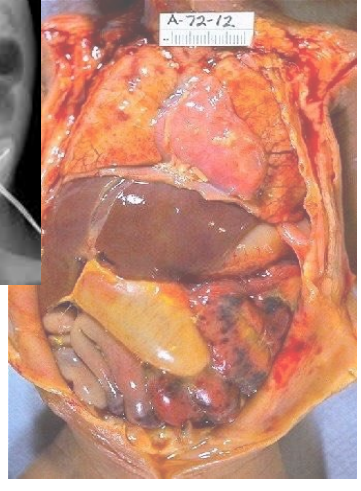


Necrotizing enterocolitis (NEC)

- NEC is severe inflammation of the bowel in the preterm infant where 20-40% of those diagnosed 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**







Source: Simpson 2010, Clark 2012

Who gets NEC?

	Infants birth weight	NEC incidence rate (%)	NEC mortality rate (%)	Mortality (% of weight cohort)
High incidence and mortality	501-750g	12.0%	42.0%	5.0%
	751-1,000g	9.2%	29.4%	2.7%
	1,001-1250g	5.7%	21.3%	1.2%
	1,251-1,500g	3.3%	15.9%	0.5%
	1,501-2,500g	0.4%	8.2-17%	0.03-0.06%
	>2,500g	0.1%	0-20%	0-0.02%

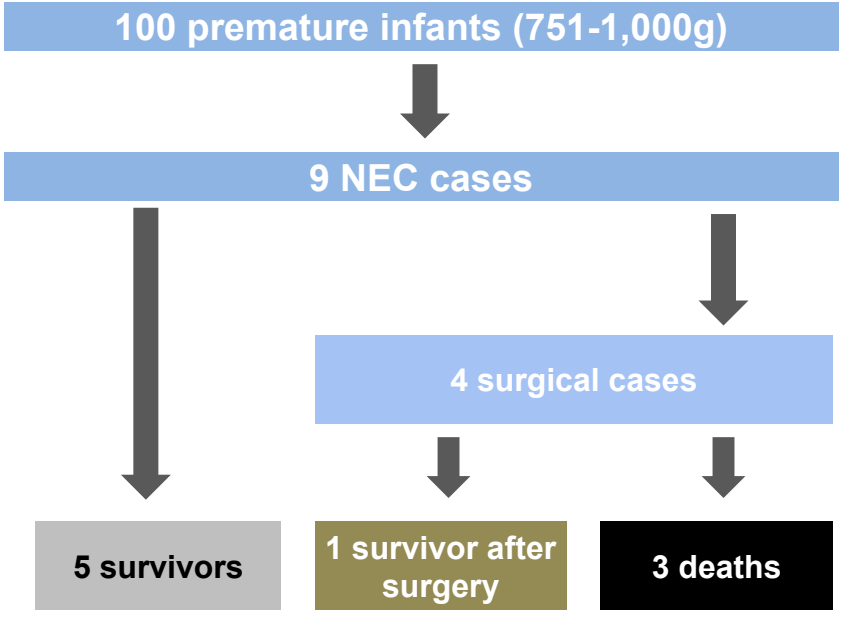
The smaller the premature infant is at birth, the more likely he/she will get NEC and die.

Source Shelley 2012, Bolisetty 2000, Llanos 2002, Fitzgibbons 2009, Fizan 2010, Christensen 2010

Target population

A preventive therapy for all preterm infants at risk of NEC

Current clinical NEC progression



Target label population

Based on the expected IBP-9414 drug label, the targeted annual label population is:

- **US:** 56,000 premature infants (≤1500 gram)
- **EU5:** 108,000 premature infants (≤ 34 weeks)

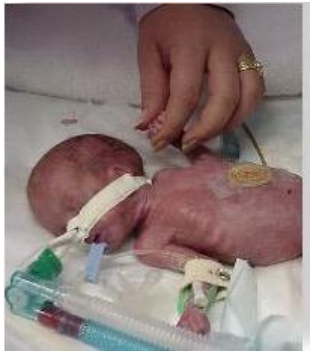
Approximately 162,000 premature infants at risk of NEC are born each year in US and EU5

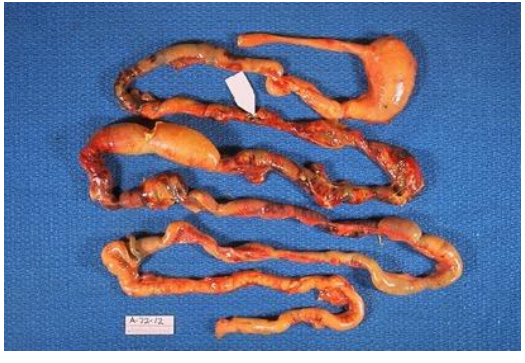
Short and long term burden of NEC

NEC exposes the infant to severe consequences

NEC short term consequences

- Highly complicated and intensive medical management
- Risk of emergency surgery
- Extended hospitalization
- Increased risk of comorbidities
- High mortality





NEC long term consequences

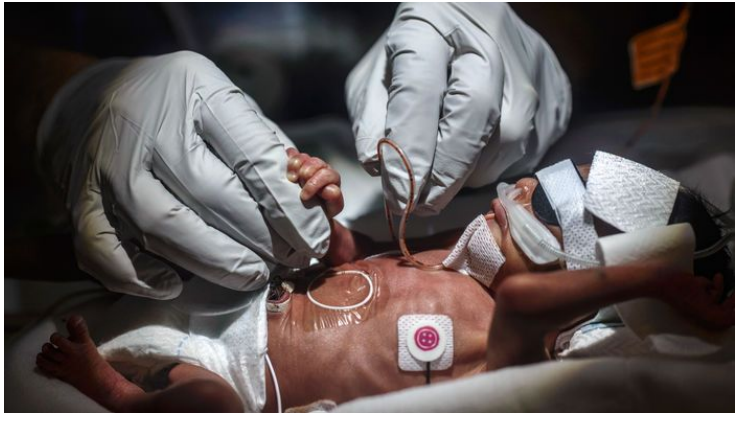
- Number one cause of short-bowel syndrome
- Prolonged parenteral nutrition with increased risk cholestasis
- Abnormal growth
- Adverse neurodevelopmental outcomes, including cerebral palsy, cognitive impairment, visual impairment, and hearing impairment

Source Ganapathy 2011, 2013, pictures from Dr Josef Neu and Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities

Neurodevelopmental outcomes and NEC

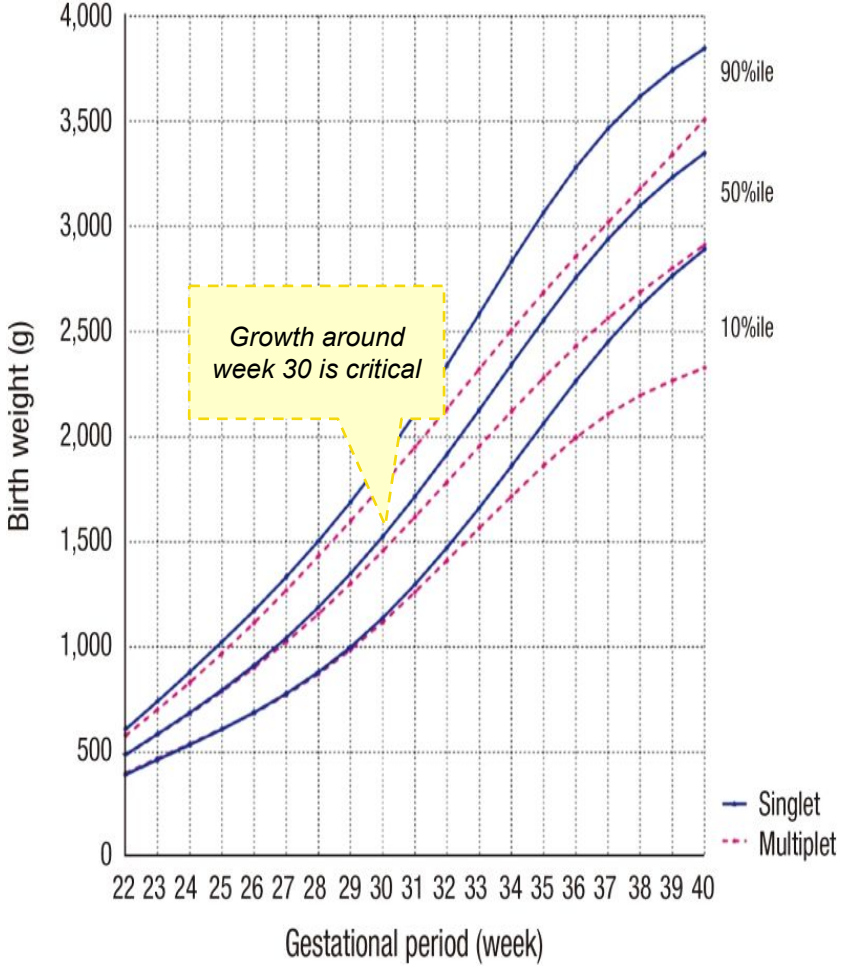
- **Neurodevelopmental Impairment**
  40% of NEC infants
  vs.
  29% of infants without NEC
  1.6-fold increased risk of NDI

- **Cerebral Palsy outcome**
  17% of NEC infants
  vs.
  7% of infants without NEC
  1.8-fold increased risk of CP



Source: Matei 2020

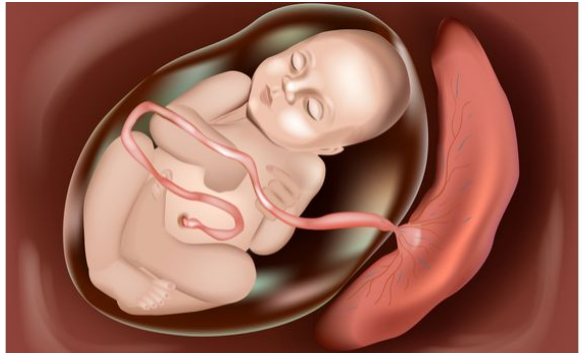
Feeding the preterm infant

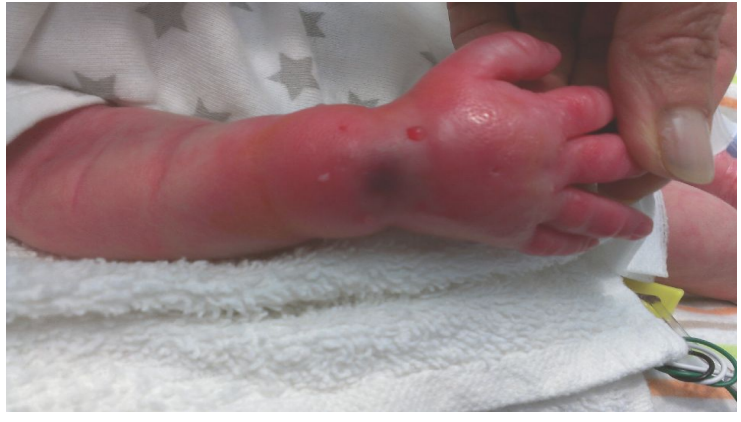


Weight gain as a 30 weeker corresponds to 27 kg/week weight gain for me

Importance of feeding

- Born too soon means that placental food supply is terminated

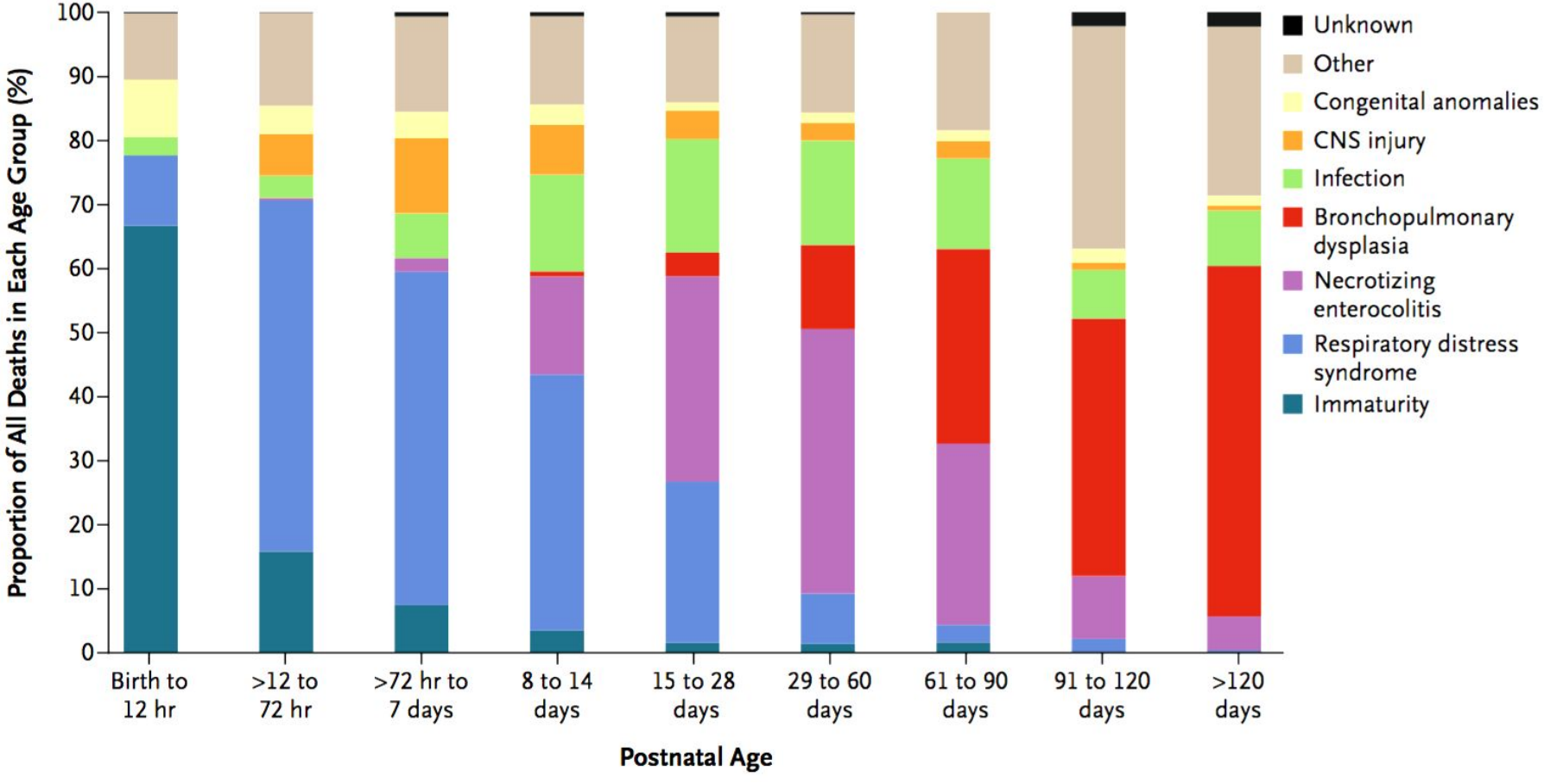




- The preterm infant needs food to continue to grow and develop
- Improved growth velocity improves neurodevelopmental outcomes
- Prolonged parenteral increased risk of e.g. BPD, infections and sepsis

Source: Lee 2016

Causes of death



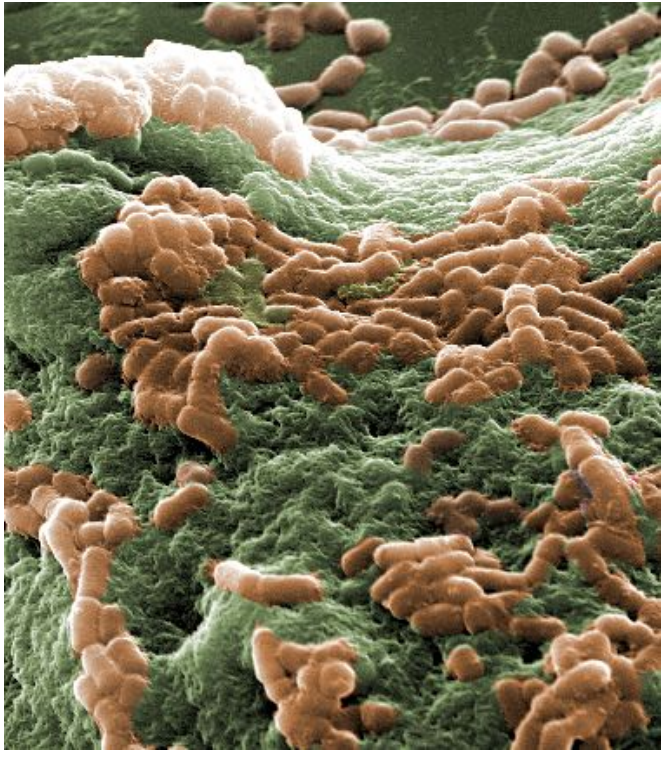
Source: Patel 2015

2 IBP-9414 is a unique GI bacteria altering the microbiome with market blockbuster potential (>$1B)

Lactobacillus reuteri

Active substance of IBP-9414

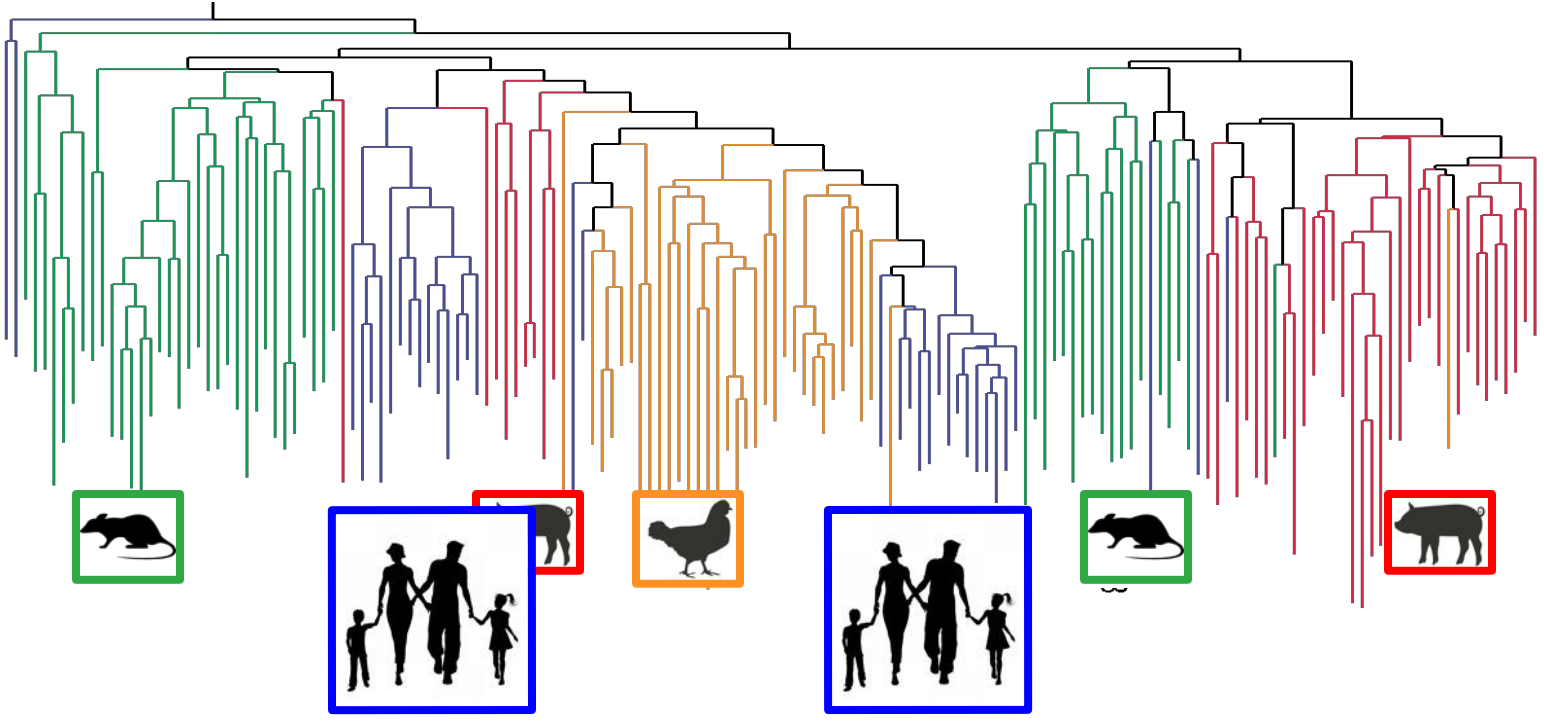
Lactobacillus reuteri present on women's breasts



Lactobacillus reuteri (orange) adhering to intestinal mucus

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

Genetic relatedness of global *L. reuteri* genomes

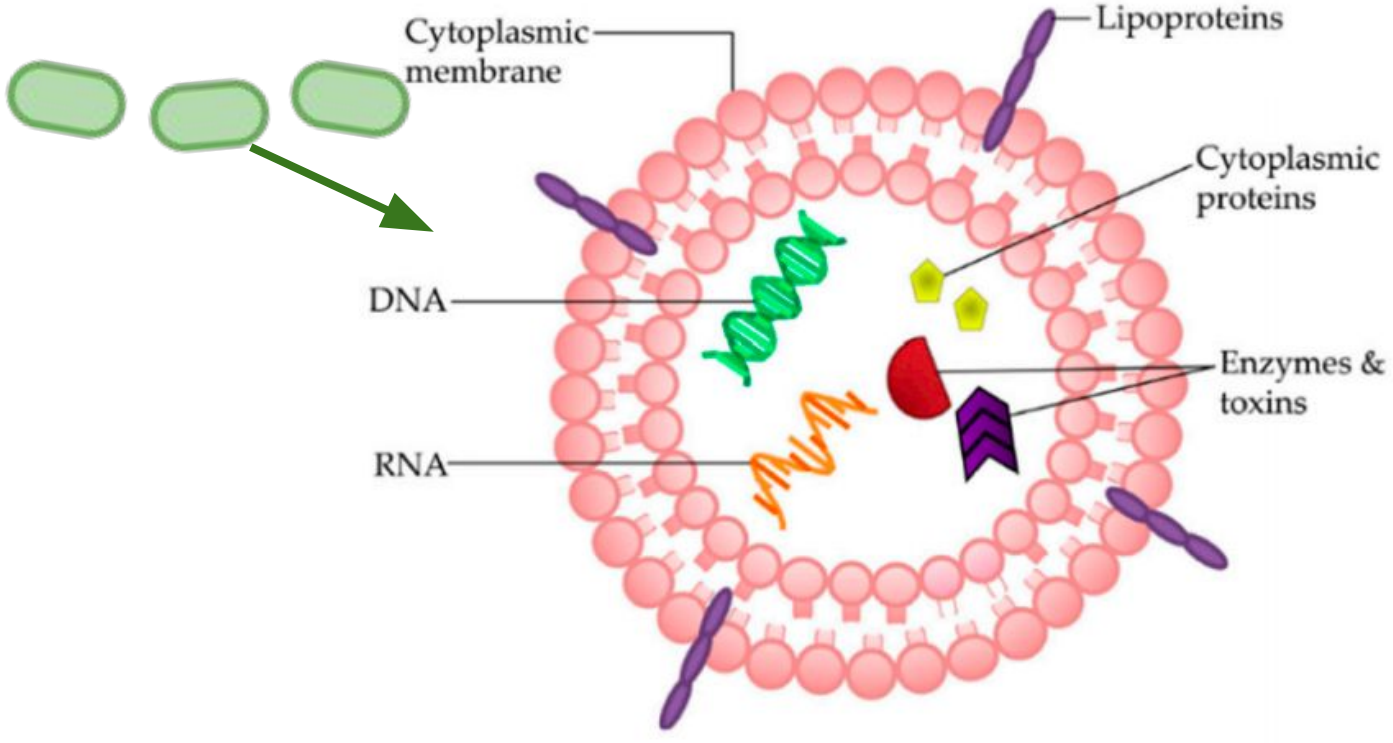


L. reuteri shares a long evolutionary history in the human gut and in human breast milk

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

Source Oh 2010, Walter 2011

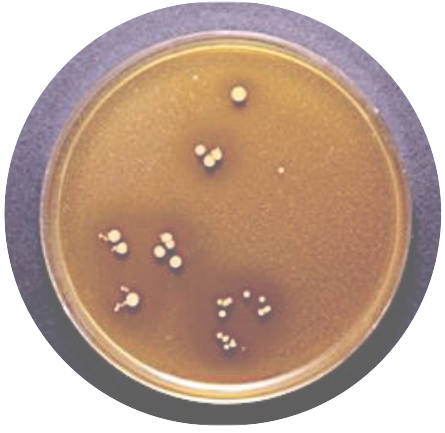
Microvesicles from L. reuteri

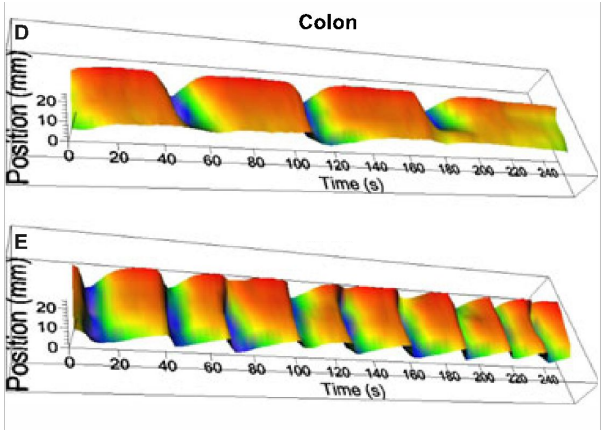


Bacterial membrane vesicles produced by *L. reuteri*

Source: West 2020

L. reuteri - mechanisms of action





Combats dysbiosis

Reduces inflammation

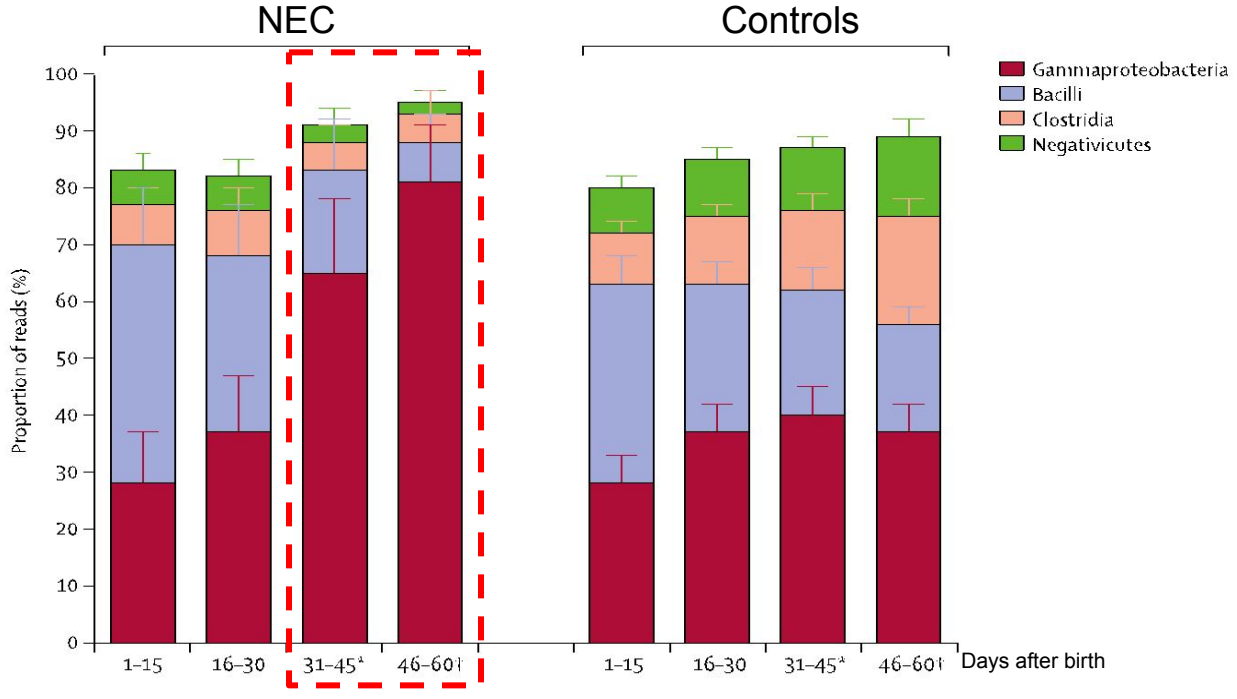
Improves gut motility

Improved gut function including prevention of NEC

Source: Schaefer 2010, Walter 2011, Wu 2013, West 2020

Clinical Signal - Dysbiosis

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



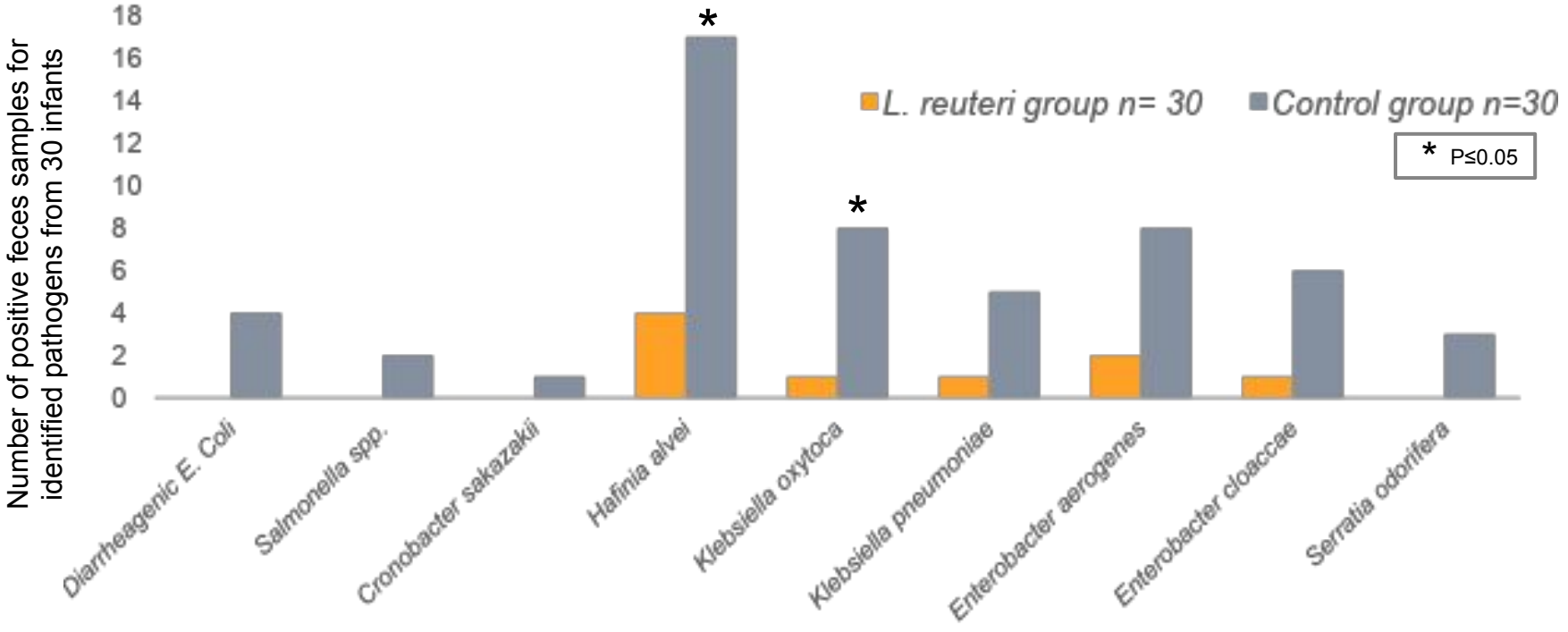
Bloom of pathogen-rich gamma proteobacteria prior to onset of NEC

Microbiome optimization may provide a novel strategy for preventing NEC

Source: Warner et al, 2016, Pammi et al. 2017

Clinical data - Anti-pathogen effects

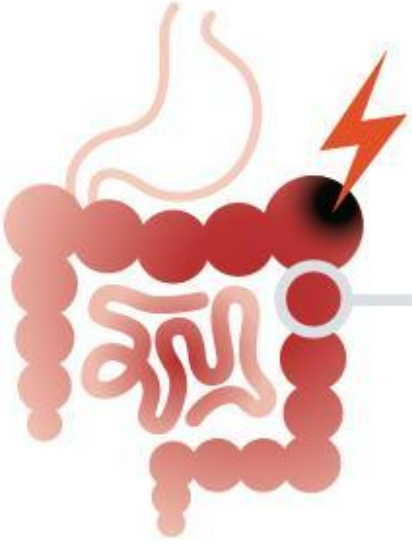
Infant fecal pathogens after 1 month *L. reuteri* treatment

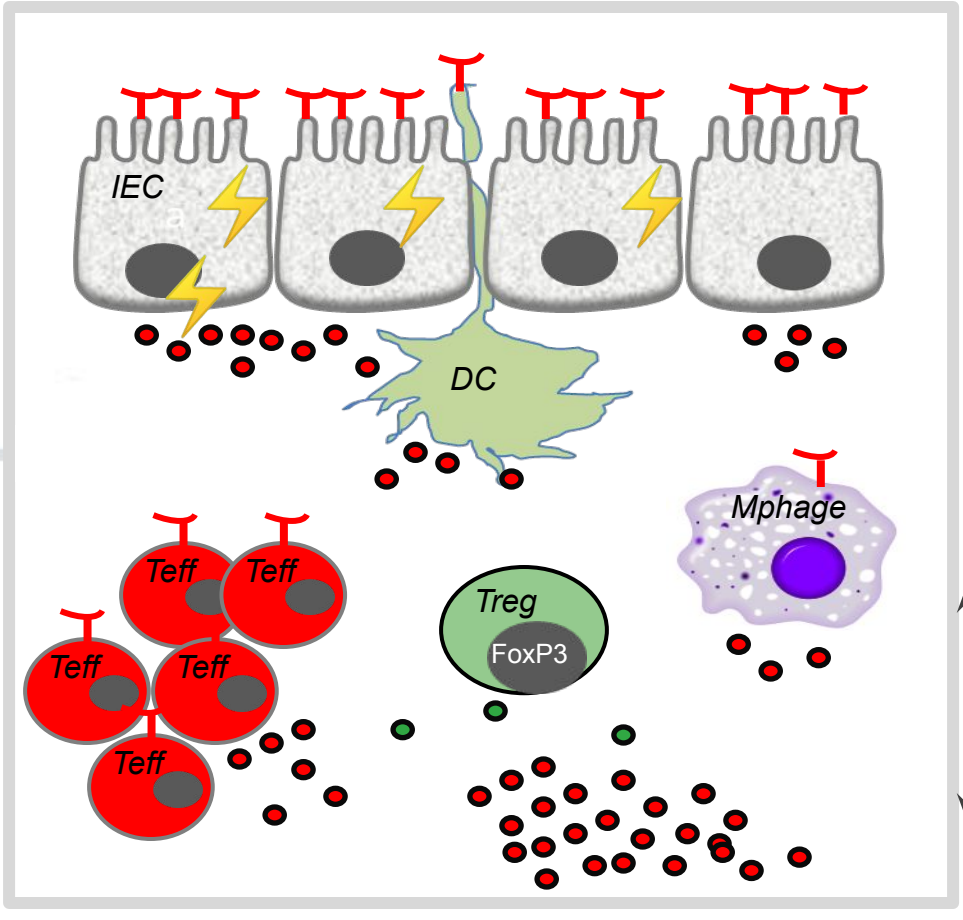


***L. reuteri* decreased gut pathogen colonization in infants**

Source: Savino 2015

Excessive inflammation in NEC





Toll-like receptors (TLR4)

Teff cells

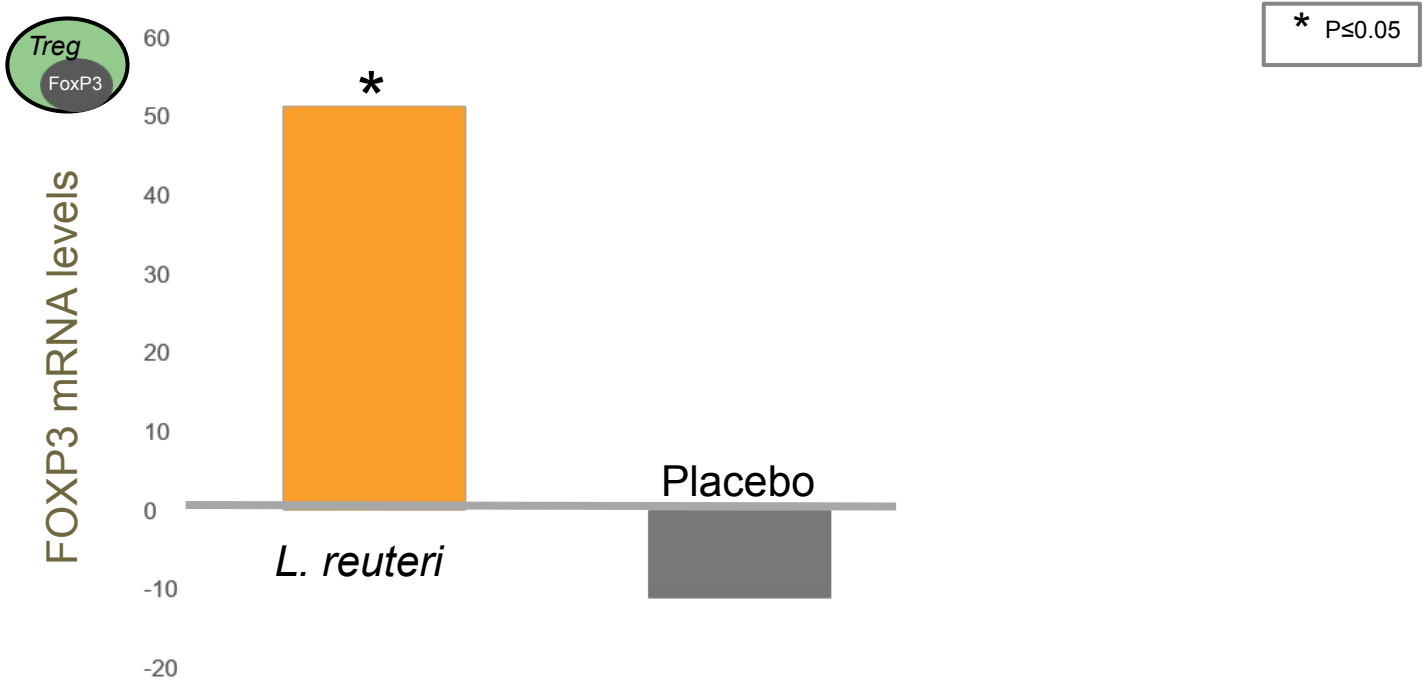
Treg cells

Inflammatory cytokines

Anti-inflammatory cytokines

Clinical - Anti-inflammatory

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

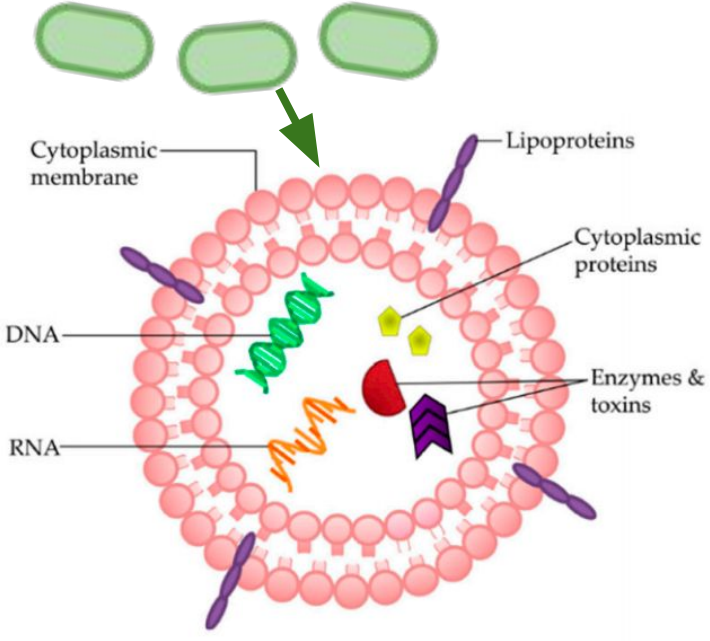


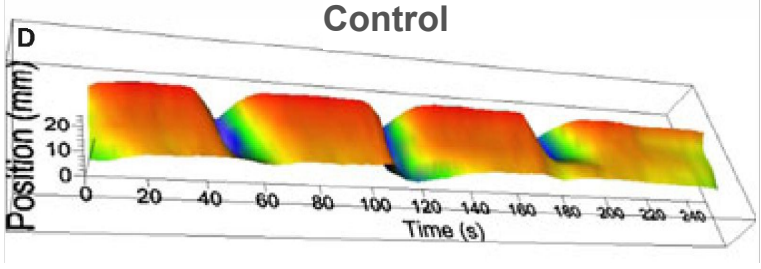
***L. reuteri* recruitment of Treg cells now shown in infants**

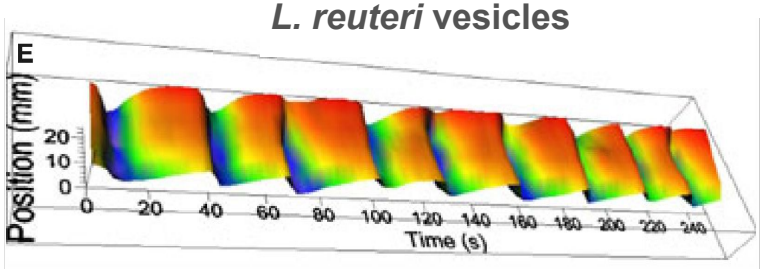
Source: Savino 2017

Pre-clinical data - improved gut motility

Microvesicles from *L. reuteri* completely reproduce gut motility modulation of the intact bacteria in mouse







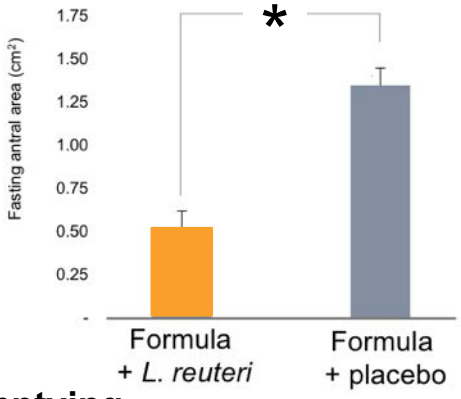
Bacterial membrane vesicles produced by *L. reuteri*

Propagating contractile clusters in the colon

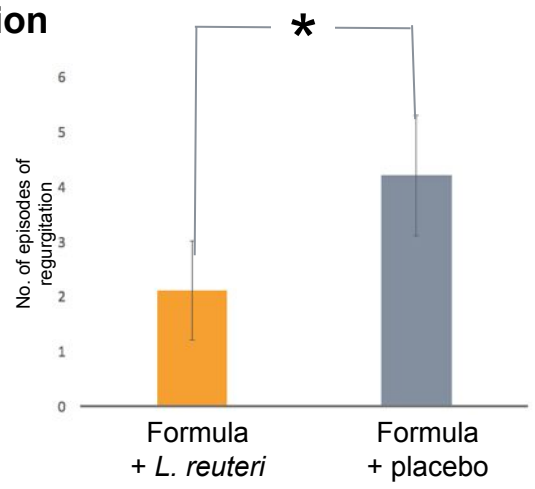
Source: Wu 2013, West 2020

Clinical data - Modulation of gut motility

Fasting antral area

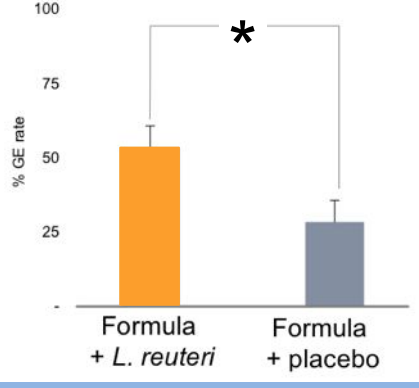


Regurgitation

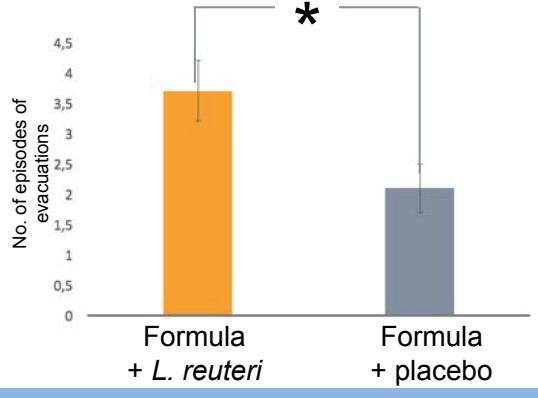


* P≤0.05

Gastric emptying



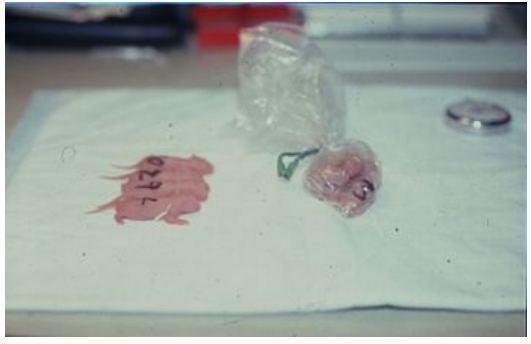
Stooling

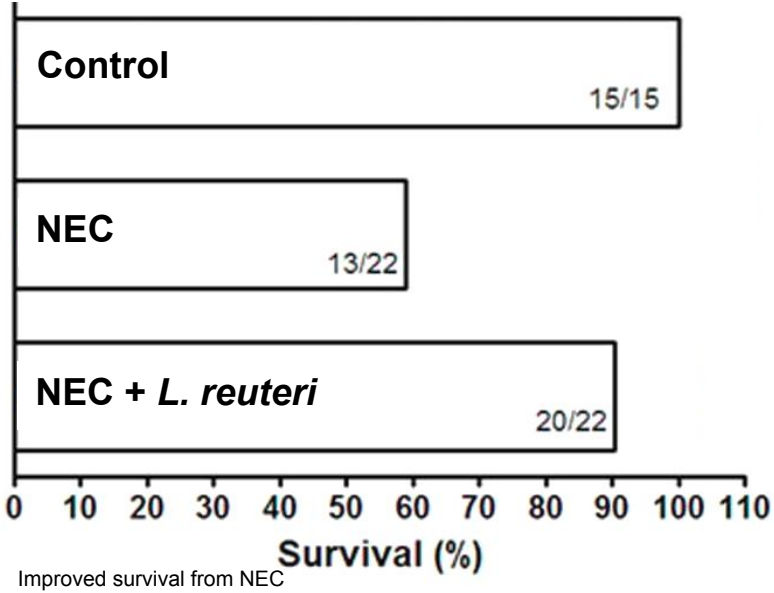


Preterm infants given *L. reuteri* show improved gut emptying

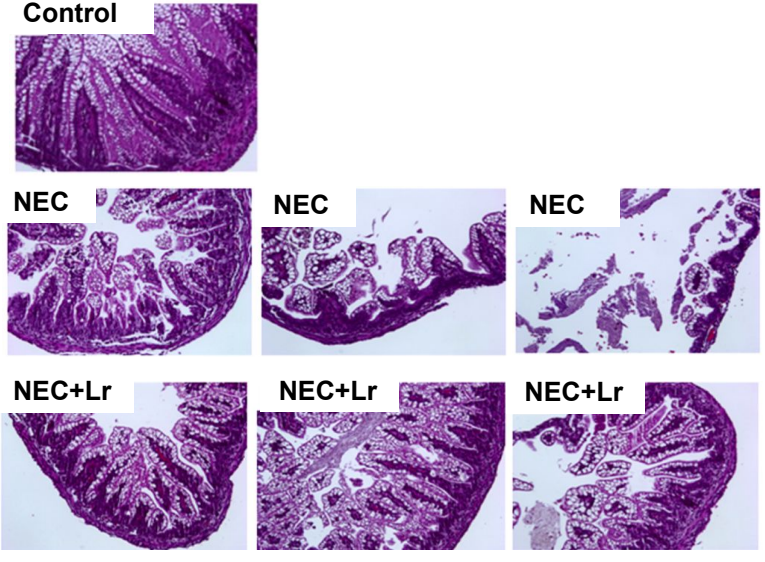
Source: Indrio 2008

L. reuteri protects from NEC in animal models





Improved survival from NEC

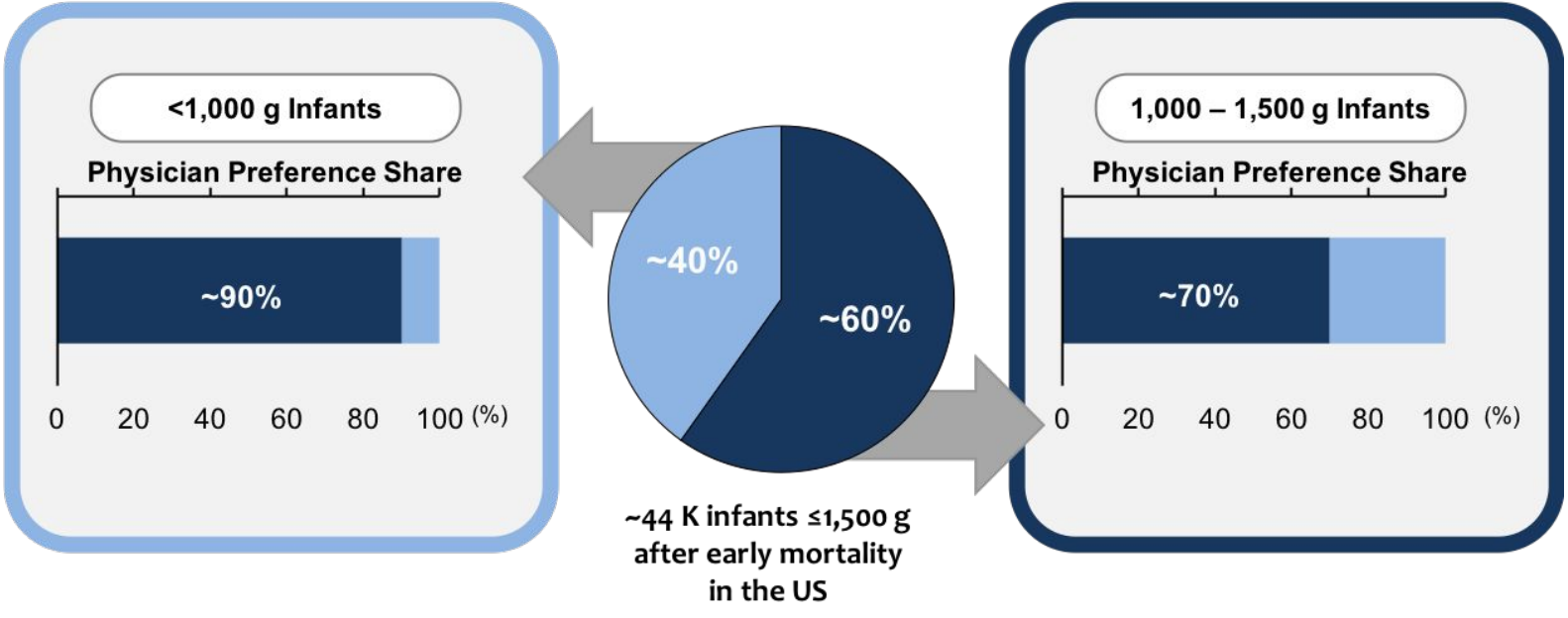


Reduced intestinal damage

Source: Liu, 2012, 2013, 2014

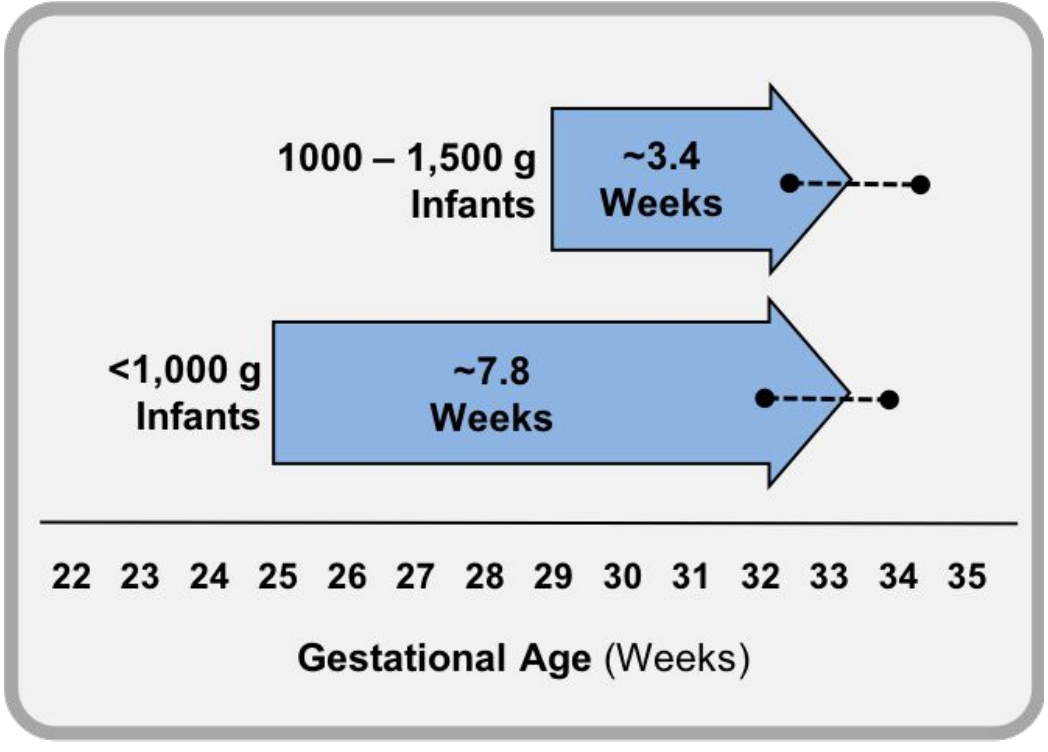
Neonatologists show high willingness to prescribe IBP-9414

Clearview US market research indicates an overall 78% physician preference share reflecting a high unmet medical need



ClearView Healthcare Partners

Treatment up to 34 weeks

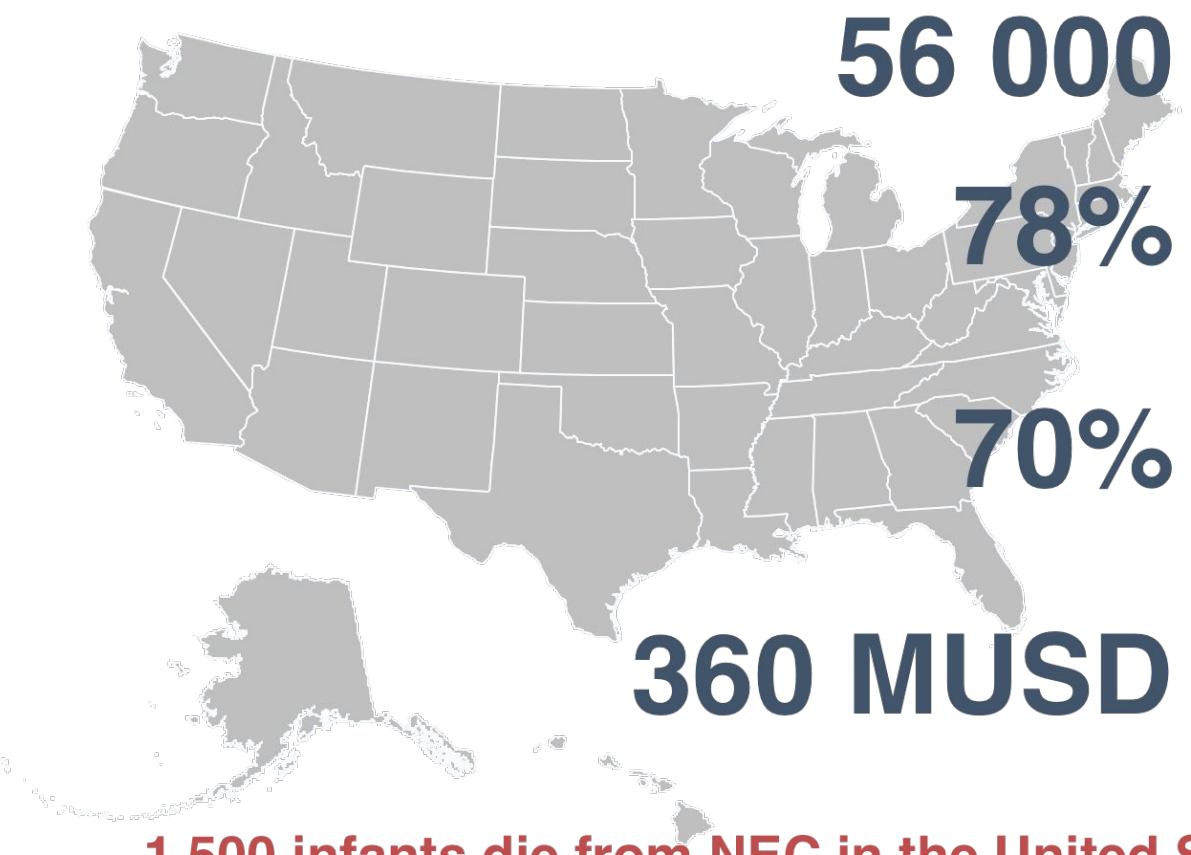


●------● ***Physicians expected to halt IBP-9414 treatment once infants had reached 32 to 34 weeks postmenstrual age***

ClearView Healthcare Partners

A valuable pharmaceutical

Results of market analysis by ClearView Healthcare Partners



56 000

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

78%

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

70%

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

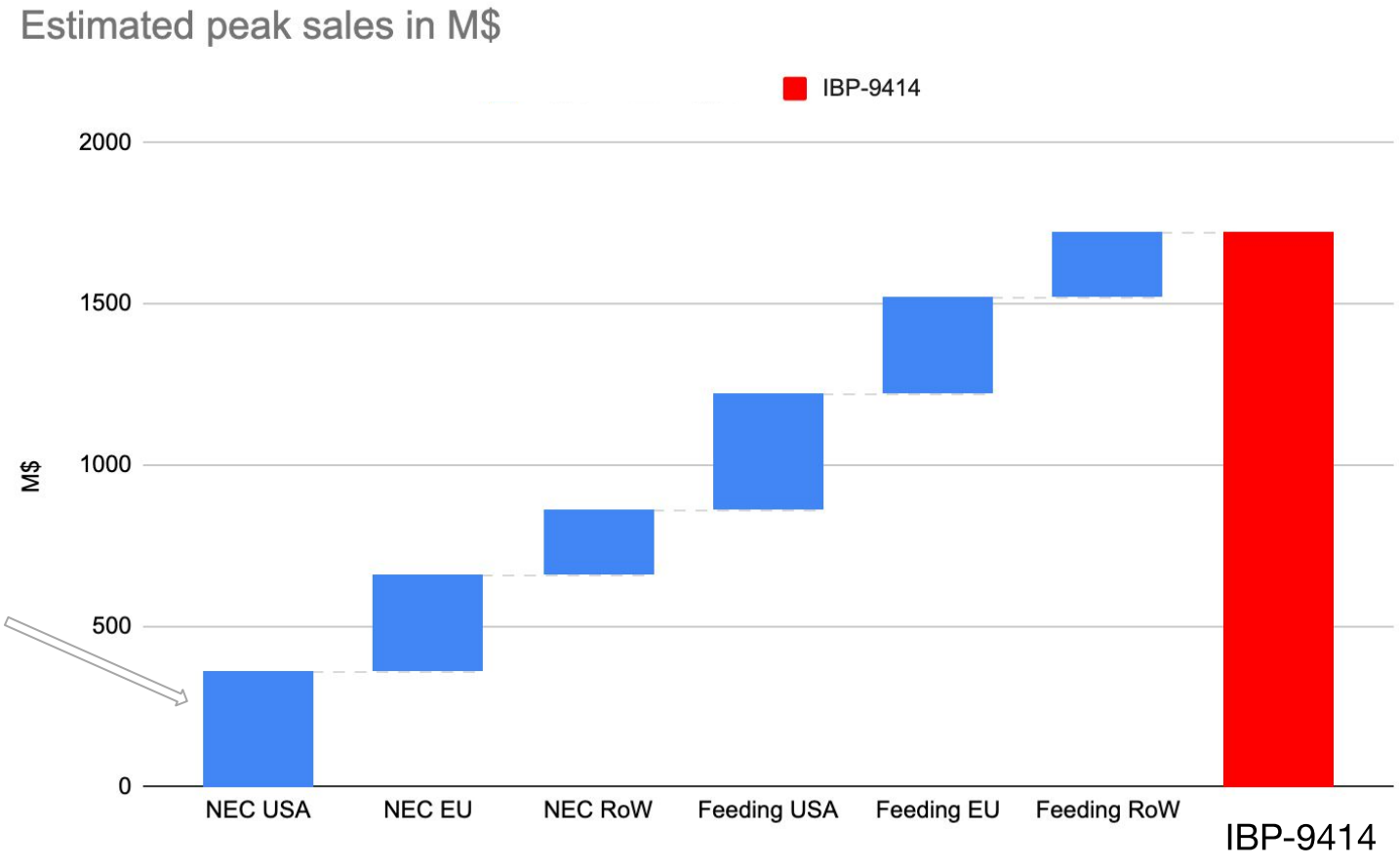
360 MUSD

Estimated annual revenue potential in US based on ClearView market research

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

Megabrand potential

Clearview
360 M$/year



IBP-9414 Exclusivity starts from approval!

Three layers of protection

1	**Orphan Drug Designation**	• Granted Orphan Status • Provides Orphan Drug Exclusivity in EU 12.5 years and US 7.5 years
2	**Data Exclusivity**	• EU and US • Provides protection for 10 years in EU and 12 years in US
3	**Patent Protection**	• Granted in EU and US • SPC 5 Year + .5 year Pedia extensions in EU • Patent Term extensions possible

Pending formulation patent application could extend Patent Protection

Total existing potential protection of 12 years in EU and 12.5 years in US after approval.

Additional patent protection existing in all important markets, including China and Japan.

3 Proof of concept established - published clinical studies

Phase II Completed, a Safety and Tolerability Study

- Recruitment rate was higher than estimated without a difference between larger and smaller infants
- Similar Adverse Event and Serious Adverse Event profile between active and placebo groups
- No evidence of cross-contamination with IBP-9414 in placebo treated infants
- Treatment with IBP-9414 leads to presence of bacterium in the feces
- Smaller infants needed the higher dose to display IBP-9414 in the feces
- 30 days after last dose, the bacteria have been washed out

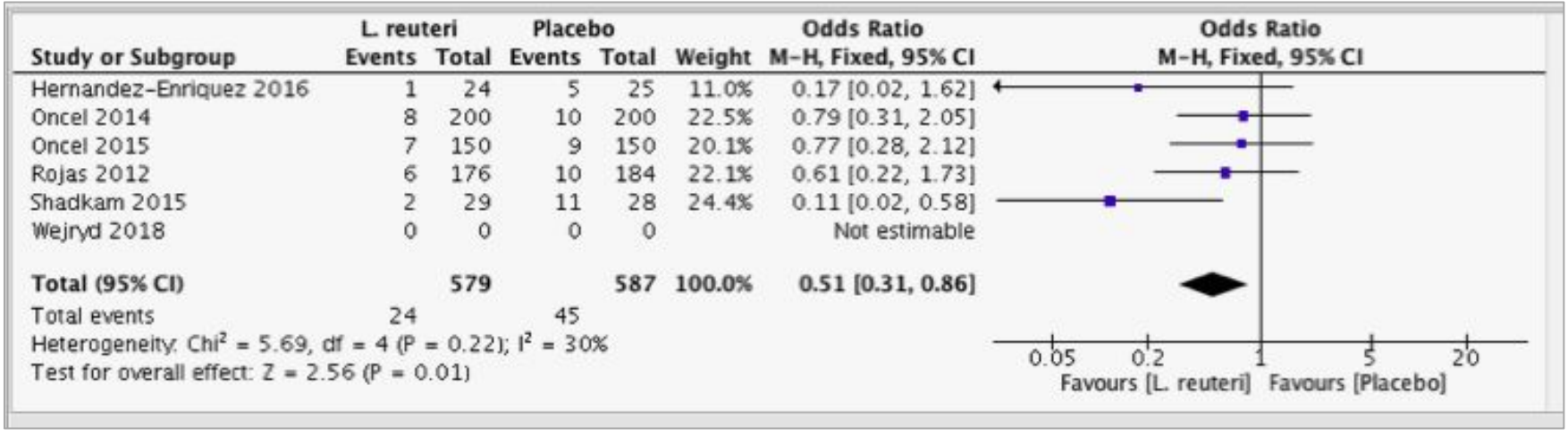
The study shows that IBP9414 was safe and well tolerated

Clinical signal on clinically meaningful endpoints

NICU Study	Number of Patients	Reduction of NEC incidence	Reduction in episodes of feeding intolerance *or* reduction in time to full enteral feeding
Rojas et al. 2012	750	**37 %**	**43 %**
Oncel et al. 2014	400	**20 %**	**33 %**
Oncel et al. 2015	300	**22 %**	**36 %**
Shadkam et al. 2015	60	**82 %**	**24 %**
Hernandez-Enriquez et al. 2016	44	**83 %**	**17 %**
Indrio et al. 2017	60		**44 %**
Spreckels et al. 2018	104	**55 %**	
Wejryd et al. 2019	134	**17 %**	**0 %**
Hunter et al. 2012/Dimaguila et al. 2013	354	**89 %**	
Jerkovic-Raguz et al. 2016	100	**50 %**	
Sanchez-Alvarado 2017	225	**64 %**	
Kaban et al. 2019	94	**100 %**	**67 %**
Rolnitsky et al. 2019	1,357	**55 %**	**52 %**
Cui 2019	93	**75 %**	**18 %**

NEC clinical signals

Incidence of NEC



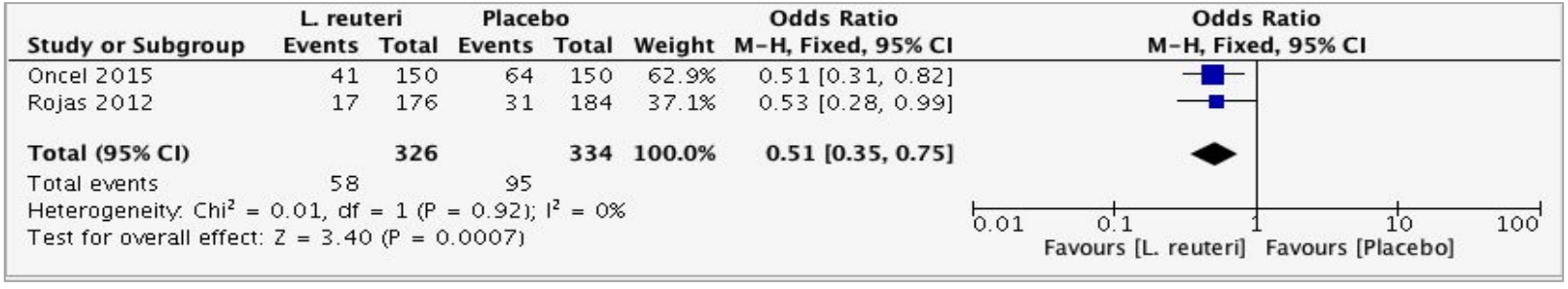
Study or Subgroup	L. reuteri Events	L. reuteri Total	Placebo Events	Placebo Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Hernandez-Enriquez 2016	1	24	5	25	11.0%	0.17 [0.02, 1.62]
Oncel 2014	8	200	10	200	22.5%	0.79 [0.31, 2.05]
Oncel 2015	7	150	9	150	20.1%	0.77 [0.28, 2.12]
Rojas 2012	6	176	10	184	22.1%	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)

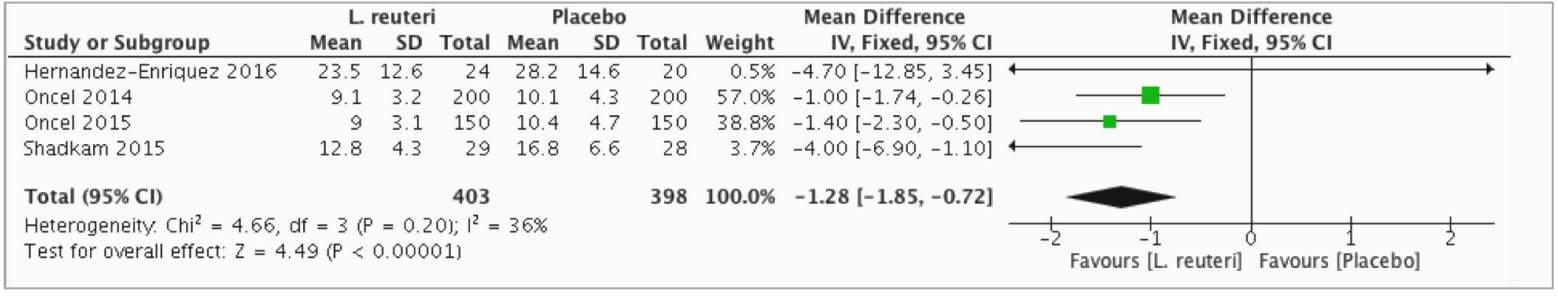
Meta-analysis:
-NEC <1500g all randomized controlled trials gives an Odds Ratio of 0.51

Feeding tolerance – clinical signals

Reported feeding intolerance events

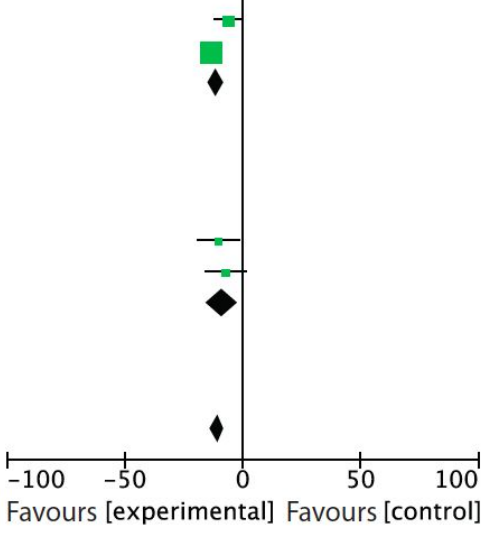


Time to full enteral feeding



Hospital stay – clinical signal

Study or Subgroup	L.reuteri DSM 17938 Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.5.1 Birth weight<2500g								
Oncel A 2014	42.4	24.1	150	48.4	29.2	150	23.0%	-6.00 [-12.06, 0.06]
Romeo 2011	17.8	7.9	83	31.3	16.3	83	55.7%	-13.50 [-17.40, -9.60]
Subtotal (95% CI)			**233**			**233**	**78.7%**	**-11.31 [-14.58, -8.03]**
Heterogeneity: $Chi^2 = 4.16$, df = 1 (P = 0.04); $I^2 = 76\%$								
Test for overall effect: Z = 6.76 (P < 0.00001)								
1.5.2 Birth weight<1000g								
Oncel A 2014	44.4	27.7	83	54.7	33	92	10.4%	-10.30 [-19.30, -1.30]
Oncel B 2014	46	30.7	93	53.3	32.3	103	10.9%	-7.30 [-16.12, 1.52]
Subtotal (95% CI)			**176**			**195**	**21.3%**	**-8.77 [-15.07, -2.47]**
Heterogeneity: $Chi^2 = 0.22$, df = 1 (P = 0.64); $I^2 = 0\%$								
Test for overall effect: Z = 2.73 (P = 0.006)								
Total (95% CI)			**409**			**428**	**100.0%**	**-10.77 [-13.67, -7.86]**
Heterogeneity: $Chi^2 = 4.87$, df = 3 (P = 0.18); $I^2 = 38\%$								
Test for overall effect: Z = 7.26 (P < 0.00001)								
Test for subgroup differences: $Chi^2 = 0.49$, df = 1 (P = 0.48), $I^2 = 0\%$								



-HOSPITAL DAYS REDUCED BY 8.77 DAYS

Source: Athalye-Jape et al 2015

Regulatory achievements

IBT has had close interaction with regulatory agencies on the IBP-9414 development program

FDA

- ✓ Sep-13: pre-IND type B FDA meeting
- ✓ Aug-13: FDA approval of Orphan Drug Designation
- ✓ Dec-15: IND becomes effective
- ✓ Mar-16: FDA grants Rare Pediatric Disease product status
- ✓ May-19 FDA and IBT agree design of Phase III study

EMA

- ✓ Dec-14: Scientific Advice issued by CHMP
- ✓ Feb-15: EU Orphan Drug Designation
- ✓ Sept-17: PDCO adopts a positive opinion on the PIP

National Medical Products Agencies

- ✓ e.g. Dec-15: Clinical Trial Application approved in Sweden

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 **Final formulation established, four years stability on file, scalable production in place for launch**

Pharmaceutical drug candidate IBP-9414

Developed under IND and CTX in contrast to food supplements

- Rigorous pharmaceutical Chemistry-Manufacturing-Control standards in all steps with GMP according to 21 CFR Part 210
- Single dose vial with dose accuracy following ICH Guidelines for Pharmaceuticals
- Stringent control of bioburden and microbial purity on final product analysis according to USA and Eur Pharmacopoeia
- Four years stability on file
- Scalable production in place for launch

Why product quality is important

The Solgar incident

October 2014	November 2014	December 2014	Consequences

- A premature infant given a Solgar product (ABC Dophilus Powder) died from gastro-intestinal fungal infection

- Solgar issued a voluntary recall of the product
- Investigators from the CDC identified the infecting fungus (Rhizopus oryzae) in unopened bottles of ABC Dophilus Powder
- **FDA/CDC warning letter issued**
- Healthcare providers encouraged to submit an Investigational New Drug Application for FDA review
- **Pressure to conform to FDA's rigorous standards due to risk of contamination**
- **Increased awareness of risk amongst healthcare providers**

FDA – US Food and Drug Administration
CDC – Centers for Disease Control and Prevention

Source http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a6.htm?s_cid=mm6406a6_x

Manufacturing Process of IBP-9414

Stringent control of manufacturing environment

Cell Bank

Pre-culture

Fermentation

Filtration

Mixing

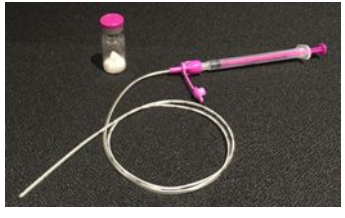
Formulated Cell Suspension

Filling

Freeze-drying

Packaging & Labelling

IBP-9414
powder for oral suspension

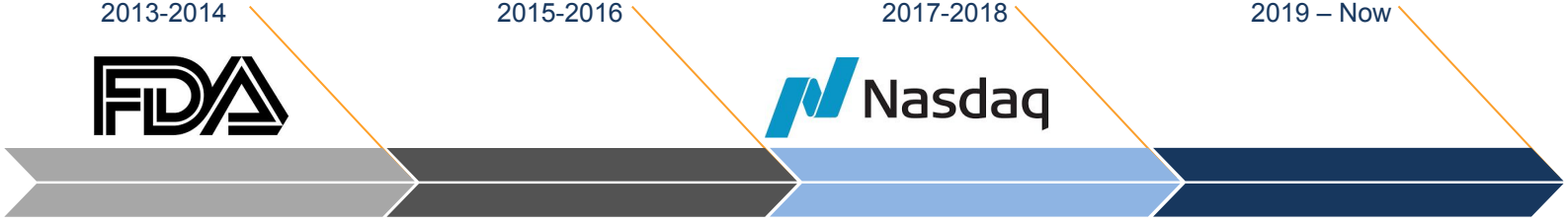


5 Clinical program to be completed in 2022, Marketing Application to follow in US and EU

Phase III Pivotal Trial - The Connection Study

- Connection Study started July 2019
- 2158 patient study of the prevention of NEC and improvement of feeding tolerance in premature infants 500 to 1500 grams
- Regulatory approvals in Bulgaria, Hungary, France, Spain, Israel, Poland, UK and USA. Waiting on Romania and Serbia.
- Cash position sufficient for the completion of the ongoing Phase III study

IBT's Timeline



2013-2014

IBT Founded as a subsidiary of BioGaia

Pharmaceutical / CMC Development

Orphan Drug Designation by FDA

2015-2016

IBTs stock is listed on Nasdaq First North

Capital Raise of 100 MSEK to fund Phase II program

IND open FDA

Phase II Study commences

Rare Pediatric Disease Designation from FDA for IBP-9414

2017-2018

IBTs stock is approved for listing on Nasdaq Stockholm Main List

Capital raise of 545 MSEK to fund Phase III Trial completed

Phase II Study completed

EMA adopts positive opinion of PIP

2019 – Now

IND updated with FDA input with Phase III protocol

Commencement of Phase III

First distribution agreement in place

Line Extension: Gastroschisis

Supply Chain

Market Preparation

First distribution deal for IBP-9414 in place

With Megapharm for IBP-9414 for the Israeli market and the Palestinian Authority's territories.

- Megapharm responsible for local registration, price negotiation and marketing
- IBT will receive 70% of revenue after an initial period
- Potential to include Israeli medical centers in Phase III trial

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	✓
Cash position sufficient to fund IBP-9414 development	✓

Thank you

Infant Bacterial Therapeutics AB

www.ibtherapeutics.com