Infant Bacterial Therapeutics

Capital Markets Day 2017

INFANT BACTERIAL THERAPEUTICS

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Agenda

Introduction

Peter Rothschild, Chairman of the Board, IBT

Staffan Strömberg PhD, Chief Executive Officer, IBT

What is Necrotizing Enterocolitis

Professor Josef Neu MD, Department of Pediatrics, Division of Neonatology, Univ. Florida, Gainesville

Break

Why IBP-9414 for Necrotizing Enterocolitis Gastroschisis and IBP-1016 – A New Opportunity

Eamonn Connolly PhD, Chief Scientific Officer, IBT

Pharmaceutical Development of IBP-9414 – Breaking New Ground

Agneta Heierson PhD, Vice President, Clinical Development, IBT

Anders Kronström M.Sc., M.B.A., Chief Technical Officer, IBT

A Globally Valuable Pharmaceutical

Daniel Mackey, Chief Financial Officer, IBT

Closing Remarks

Staffan Strömberg PhD, Chief Executive Officer, IBT

Infant Bacterial Therapeutics

Rare Pediatric Disease Status, Priority review voucher possibility

Orphan Drug Designation US/EU

IBT's lists Nasdaq First North Premier

Founded in 2013

IBT listed Nasdaq First North

SEK100m (approx. €10m) rights issue

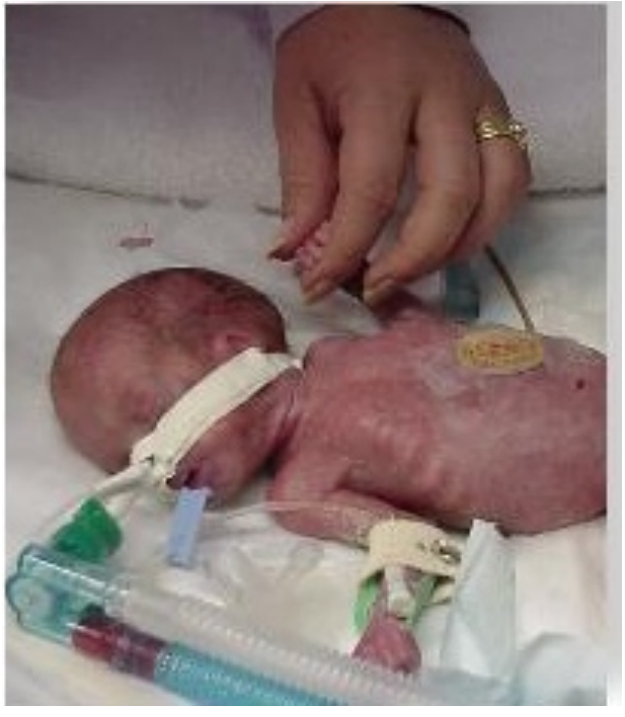
IBT announced that the last premature infant was enrolled in the Phase II study

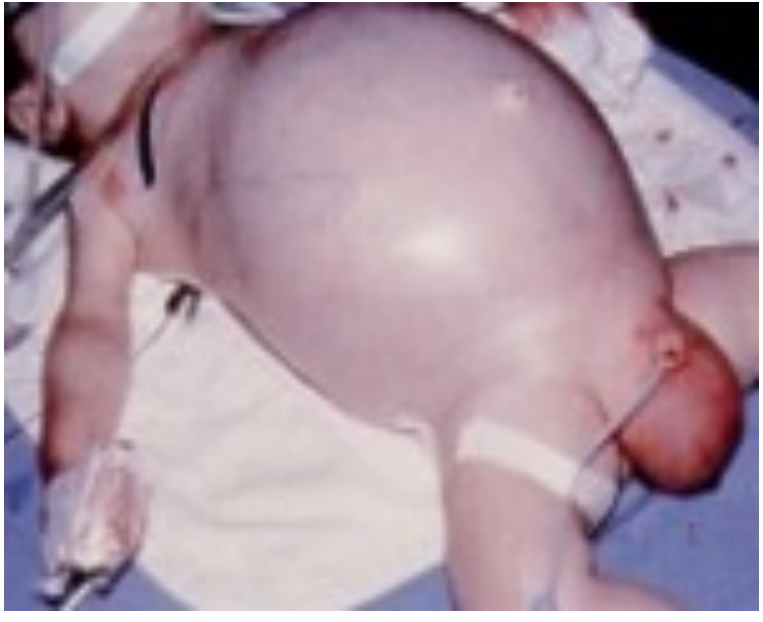
Necrotizing Enterocolitis: An Update

Josef Neu, M.D.

Neonatal Biochemistry, Nutritional and Gastrointestinal Development Laboratory

University of Florida





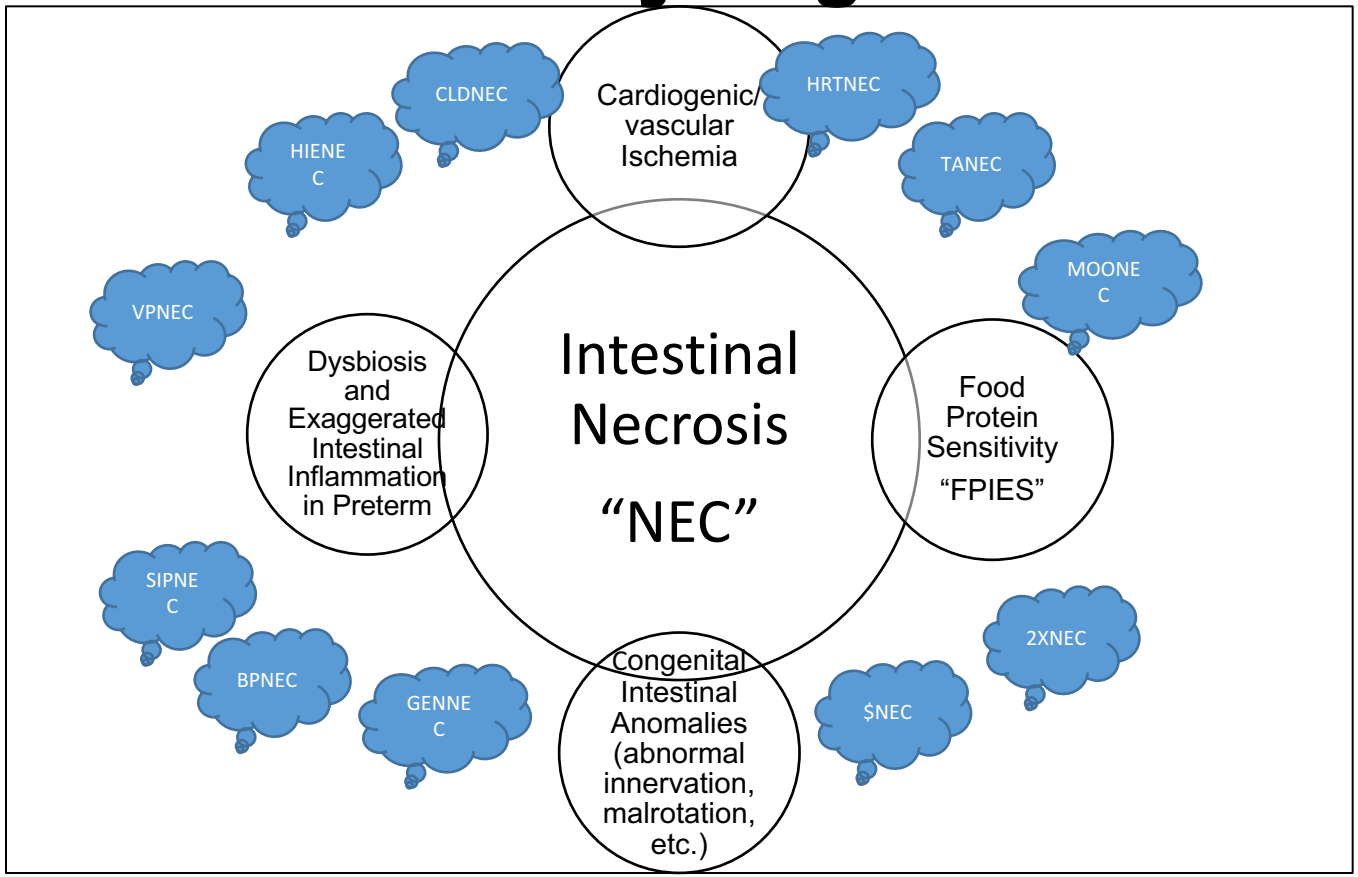
Agenda

- Definition of “NEC”: Can we focus on a “Classic NEC”?
- Dysbiosis and NEC
- Are neonatologists causing dysbiosis in preterms?
- The Future

Historical Perspective: Being led astray: 50 years---not much progress

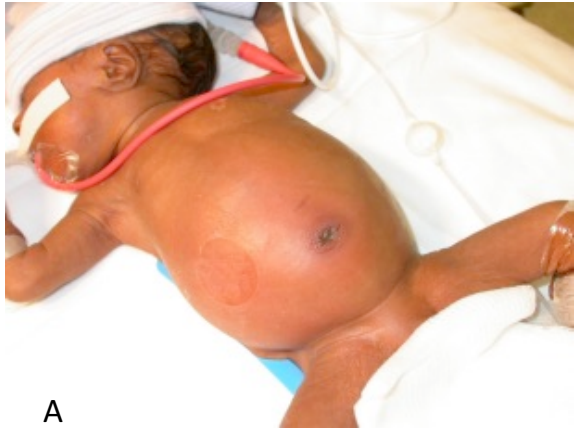
- Lumping of several diseases called “NEC” into the same data set.
- Animal models that do not represent the disease we see in human preterms.
- Narrow focus on individual pathways rather than systems.

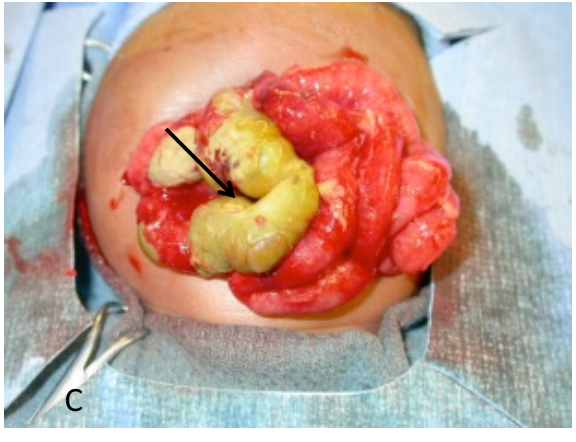
More than one disease or one disease with many origins?

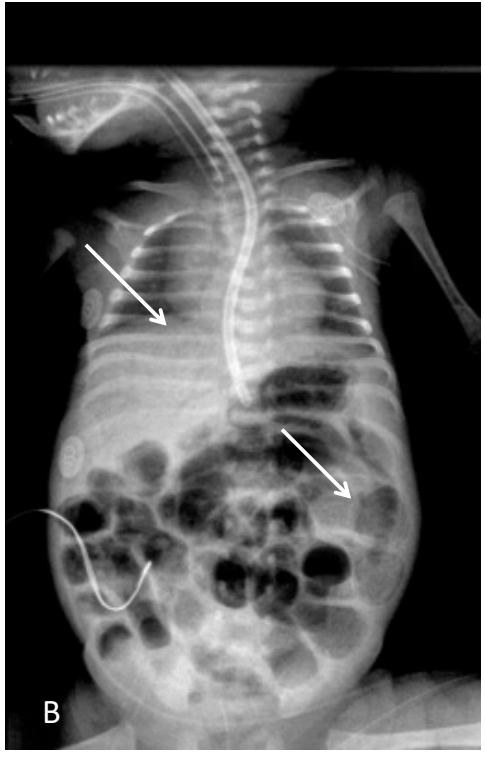


Adapted from Gordon, PV. Et al.Seminars in Perinatology, 2017

“Classic” NEC

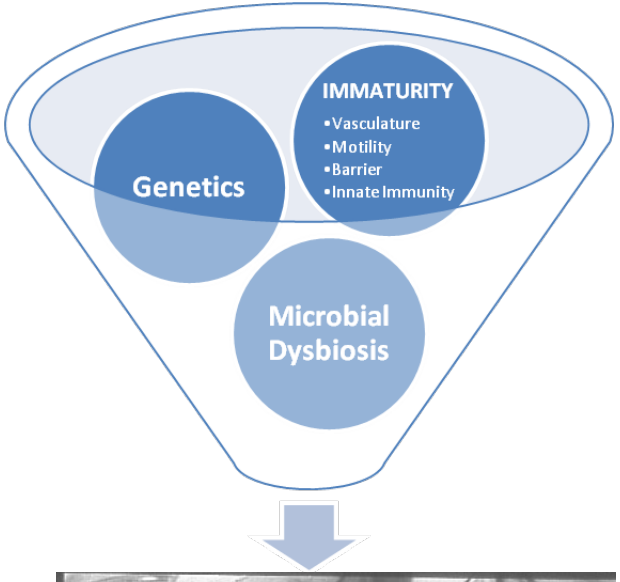


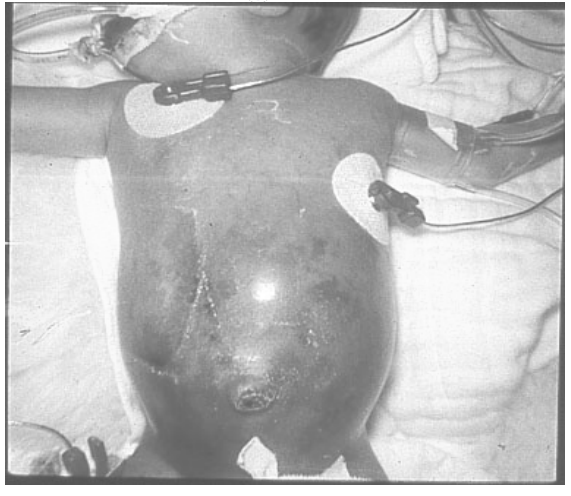




Neu, J. and Walker , W. A. New England Journal of Medicine, Jan. 2011

What Causes Classic "NEC"? Some Factors

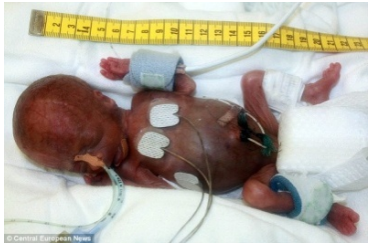




Where's Hypoxia-Ischemia and Feeding?

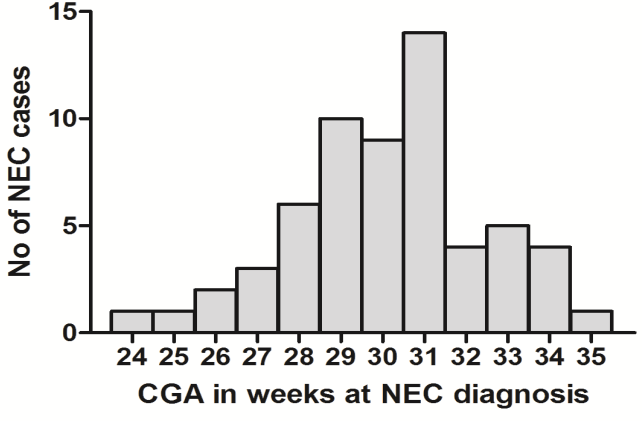
Rat model of "NEC".

Mean Gestational Age at NEC Diagnosis



23 week preterm

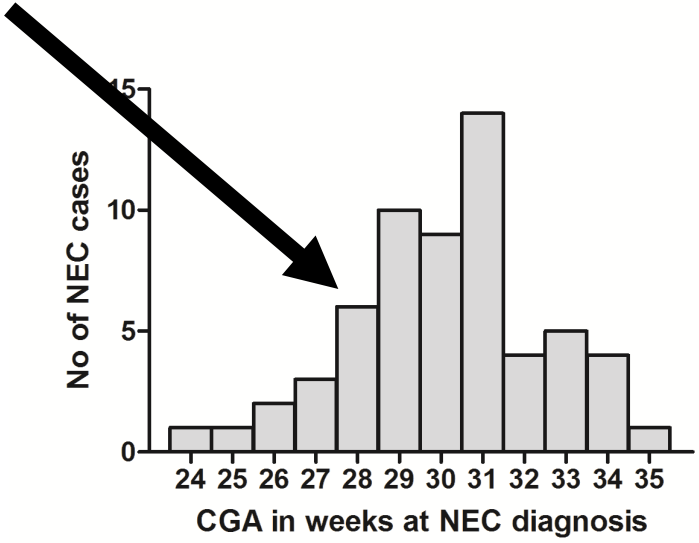
29 week preterm



Pammi, M. et al. Microbiome, 2017

Mean Gestational Age at NEC Diagnosis

- Microvasculature Changes?
- TLR Developmental Pattern?
- Microbiota changes?

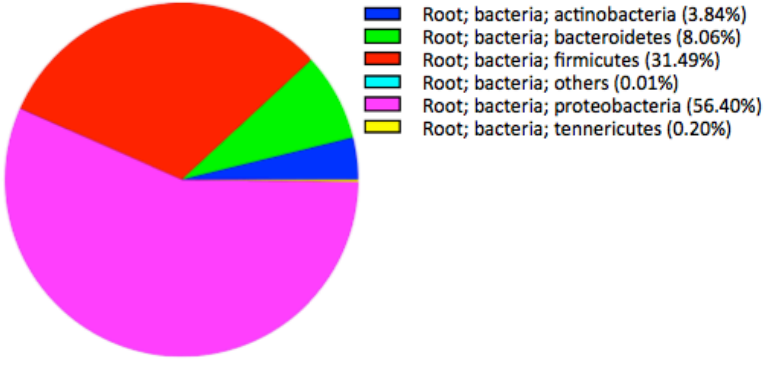


Pammi, M. et al. Microbiome. 2017 Mar 9;5(1):31

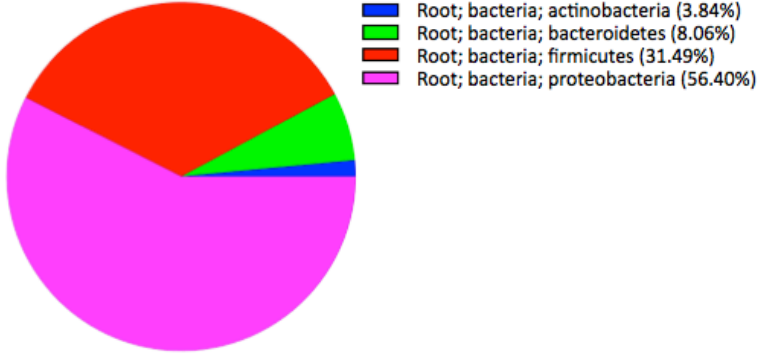
FECAL MICROBIOTA: NEC

Mai V, Young C. PLOS One, May 2011

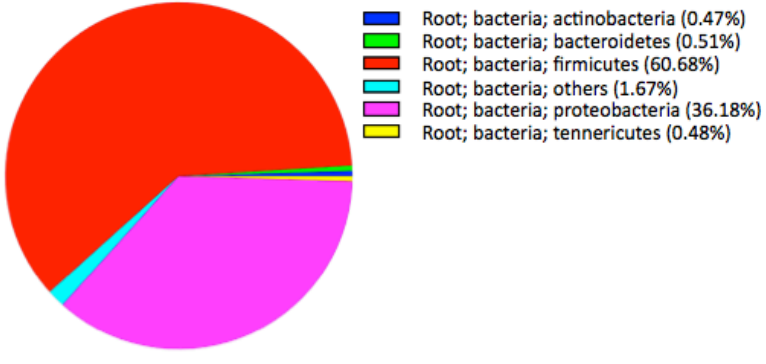
Controls, one week before diagnosis



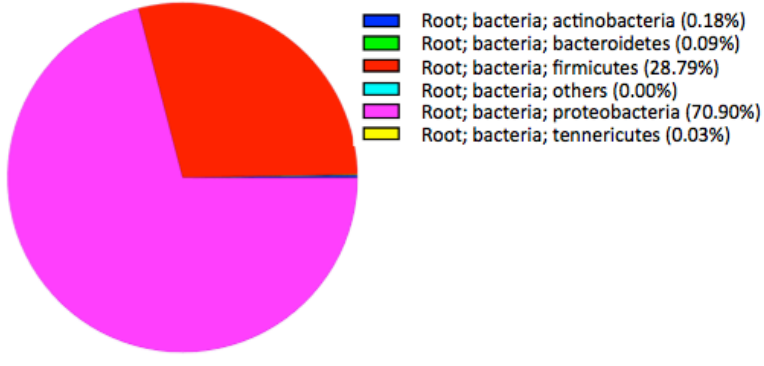
Controls, <72h of diagnosis



Cases, one week before diagnosis



Cases, <72h of diagnosis



Microbial Shift Prior to NEC

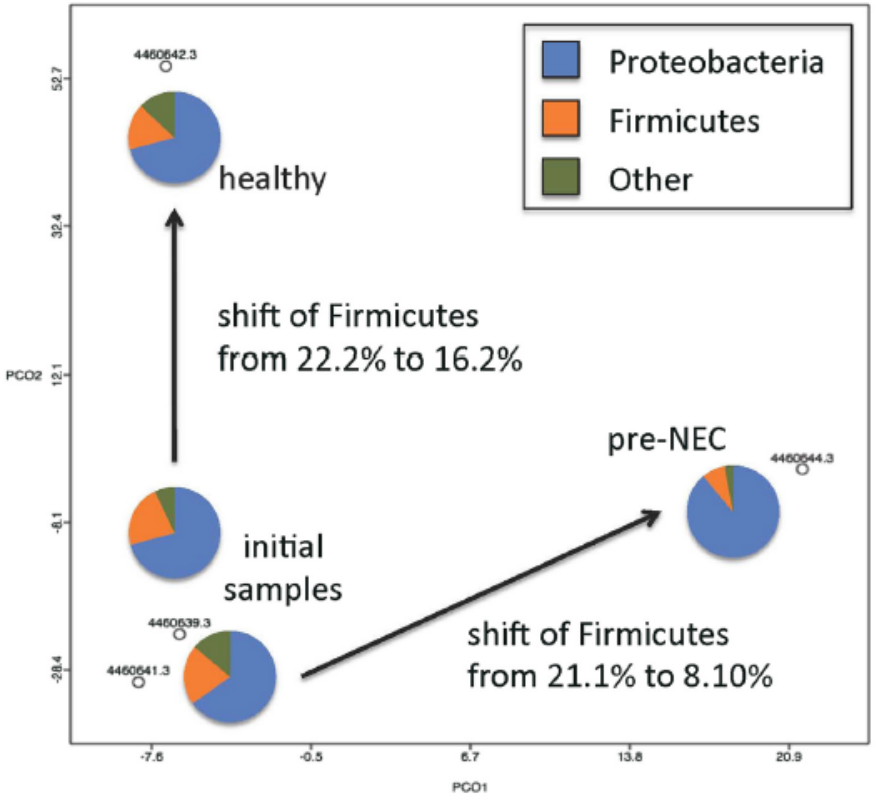
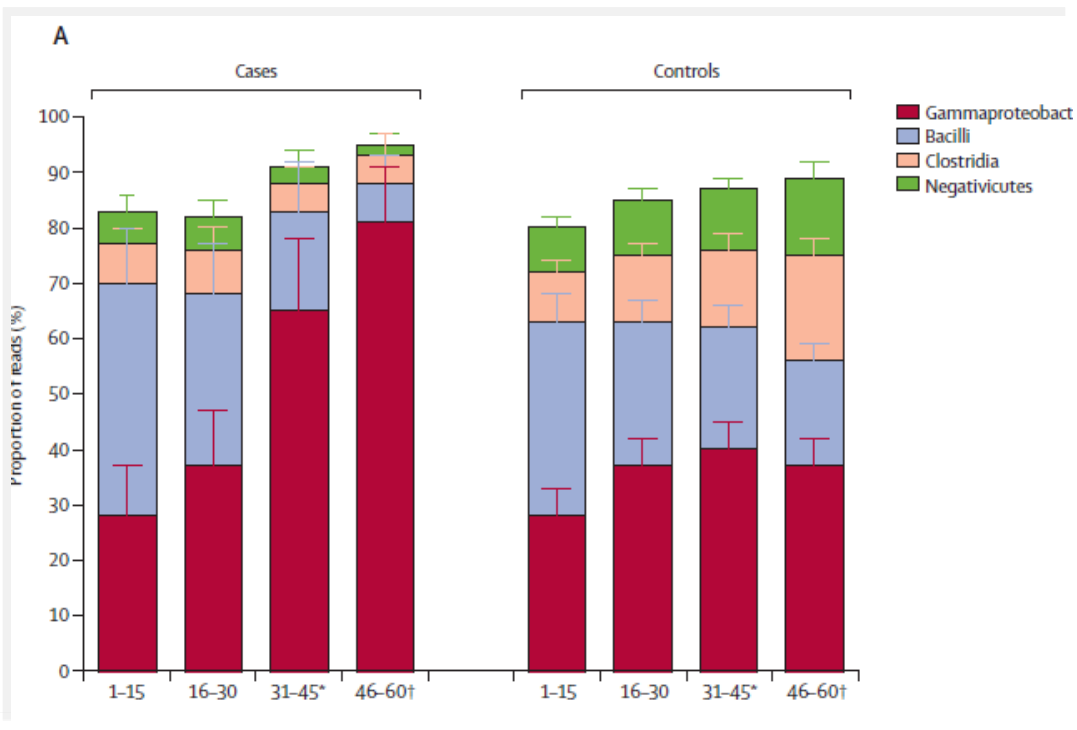


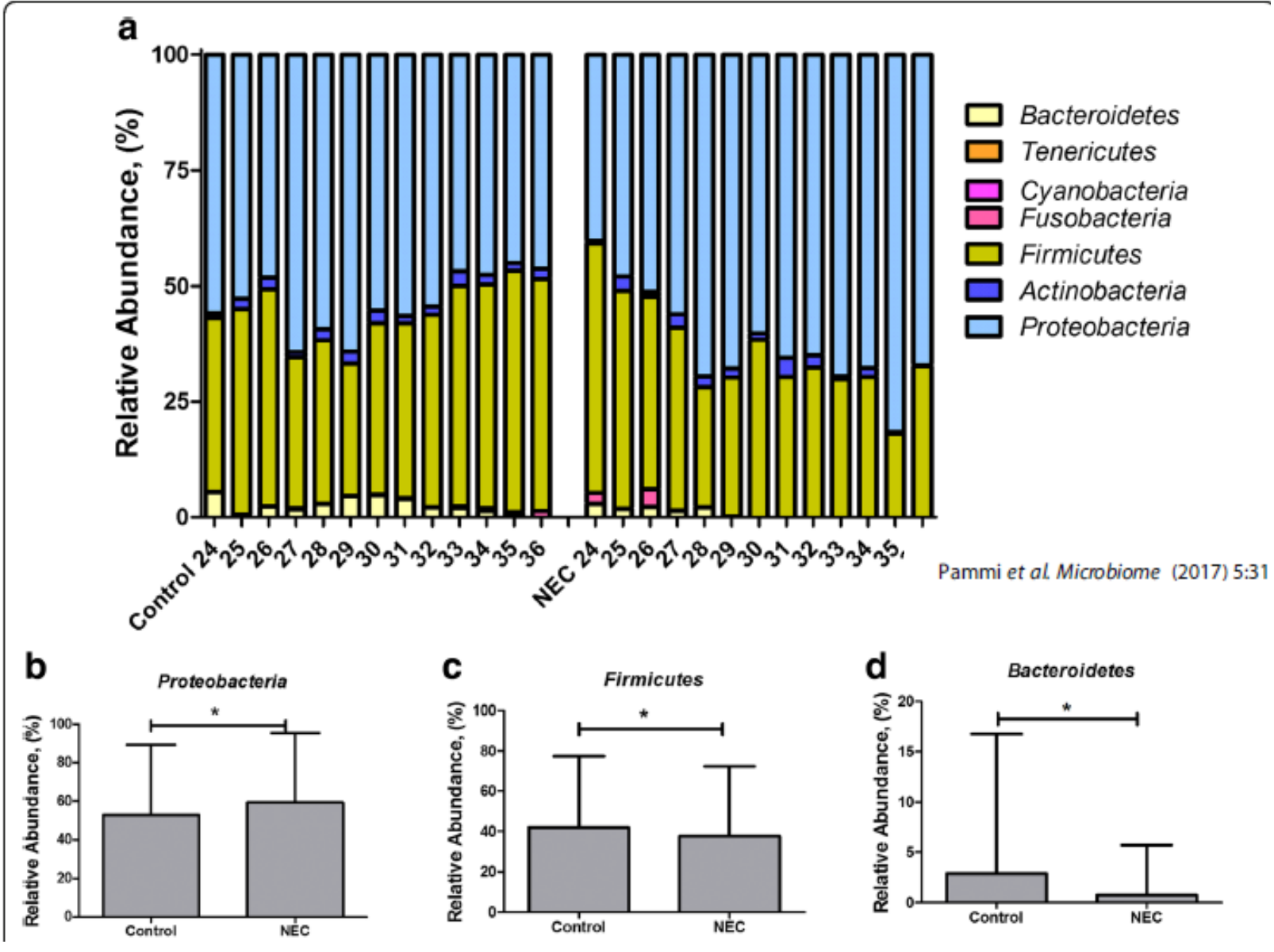
Figure 4 Analysis of microbial communities by shotgun metagenomics between two weeks of life and NEC diagnosis demonstrate functional distinction. Shotgun metagenomes generated from twin patients at times prior to NEC diagnosis (only one of the twins went on to be diagnosed with NEC; labeled 'pre-NEC'). An expansion of the Proteobacteria is noted in the patient that went on to develop NEC.

From Claud, E. et al . Microbiome, 2013

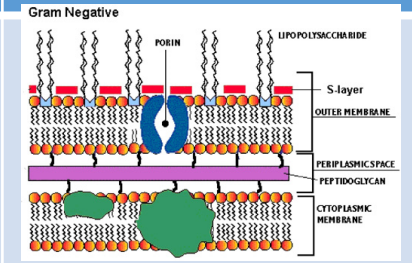
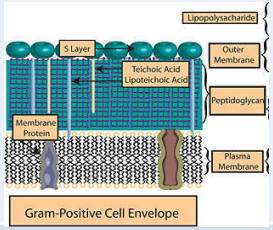
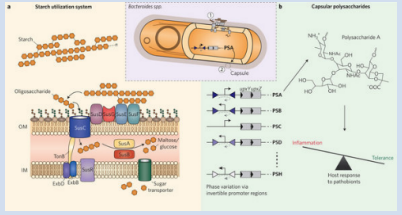
Abundance of Gamma-Proteobacteria



Warner, B. et al. Lancet March 8,2016


a
Relative Abundance, (%)
100
75
50
25
0
Control 24 25 26 27 28 29 30 31 32 33 34 35 36
NEC 24 25 26 27 28 29 30 31 32 33 34 35
Bacteroidetes
Tenericutes
Cyanobacteria
Fusobacteria
Firmicutes
Actinobacteria
Proteobacteria
Pammi et al. Microbiome (2017) 5:31
b
Proteobacteria
Relative Abundance, (%)
Control
NEC
c
Firmicutes
Relative Abundance, (%)
Control
NEC
d
Bacteroidetes
Relative Abundance, (%)
Control
NEC

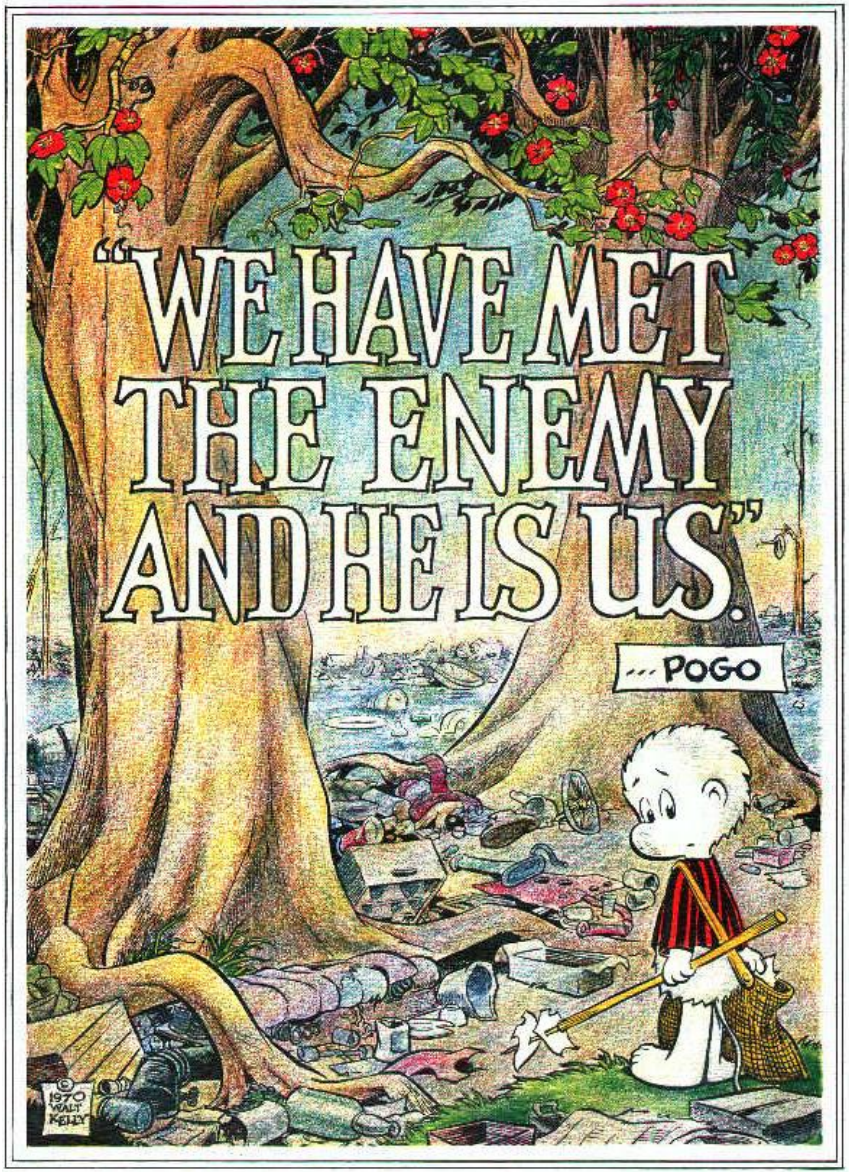
Comparison of three major phyla: Proteobacteria, Firmicutes and Bacteroidetes

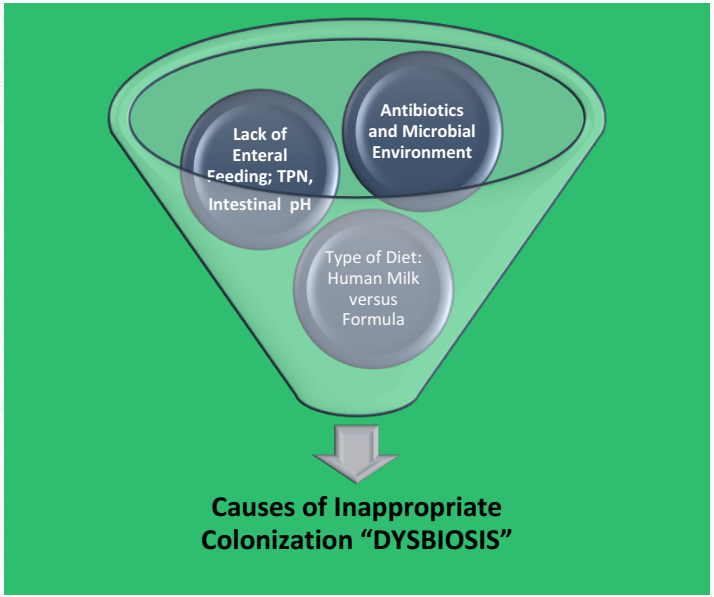
Phylum	Gram Staining	Functional Relationship	Comment
Proteobacteria	Gram negative	High Lipopolysaccharide (LPS) content in cell wall. Abundance of Proteobacteria increased prior to exacerbations of inflammatory bowel diesease. Strong stimulator of TLR4. E. Coli, Klebsiella and Pseudomonas are representatives.	
Firmicutes	Gram positive	Lactobacilli are a common class of the Firmicutes phylum. Have high lipoteichoic acid in the cell wall, but low LPS. Have excellent capacity for energy harvest. Produce butyrate in high quantities. Butyrate is a major fuel for colonocytes and important for maintenance of tight junctions.	
Bacteroidetes	Gram negative, anaerobic, rod shaped bacteria.	Involved in fermentation of carbohydrates (propionate and acetate producers), utilization of nitrogenous substances, and biotransformation of bile acids. Bacteroides fragilis is a representative. The immunomodulatory molecule, polysaccharide A (PSA), of *B. fragilis* mediates the conversion of $CD4^+$ T cells into $Foxp3^+$ Treg cells that produce IL-10 during commensal colonization. PSA is not only able to prevent, but also cure experimental colitis in animals. Propionic acid is also a strong inducer of the Foxp3+ R regulatory pathway.	

Pathways hypothesized to be involved in the etiology of NEC

- Microbial Mucosal Interactions
- Toll Like receptor activation primarily TLR-4
- Modulation of anti-inflammatory pathways (IL-10, TGF Beta) via macrophages
- Regulation of Protective Th17 Cells
- Paneth cell protective mechanisms
- VEGF maturation pathways
- ER Stress Pathways
- Oxidation Pathways

Best to aim for proximal components of pathophysiologic cascade---these can be utilized for prevention. <u>It is unlikely that we find a treatment for this disease.</u>


"WE HAVE MET THE ENEMY AND HE IS US."
...POGO
© 1970 WALT KELLY


Lack of Enteral Feeding; TPN, Intestinal pH
Antibiotics and Microbial Environment
Type of Diet: Human Milk versus Formula
Causes of Inappropriate Colonization "DYSBIOSIS"

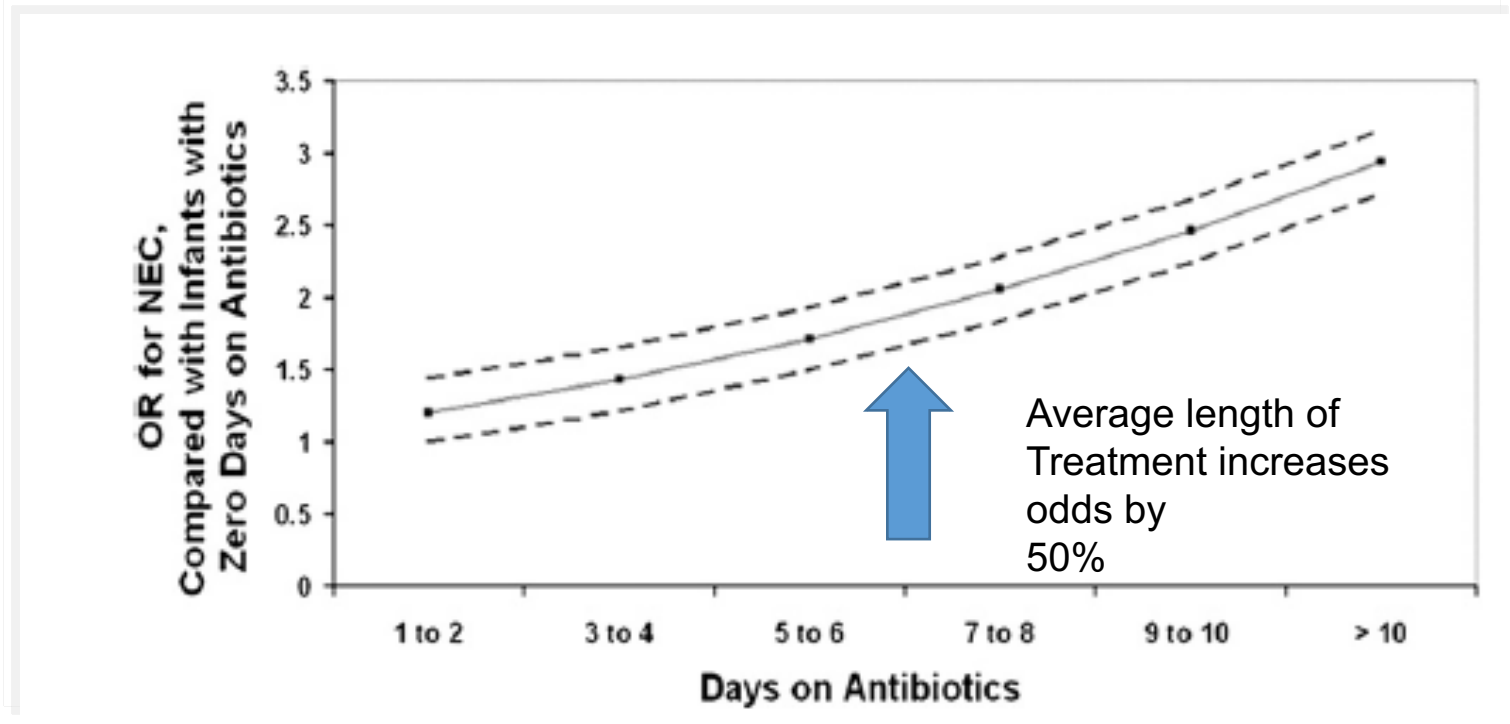
Most Commonly used Drugs in the NICU: Majority of VLBW infants are Exposed to Antibiotics

Top 10 Medications Prescribed in the NICU

Medication Name	Frequency, *A*
Ampicillin	186 799
Gentamicin	171 388
Ferrous sulfate	90 152
Vitamin (multivitamin)	64 329
Cefotaxime	55 455
Caffeine citrate	48 814
Furosemide	47 278
Vancomycin	44 218
Beractant (Survanta)	36 410
Metoclopramide	27 541

Odds Ratio of NEC with Increased Days on Antibiotics

Alexander, V.N. J. Pediatrics, Sept. 2011



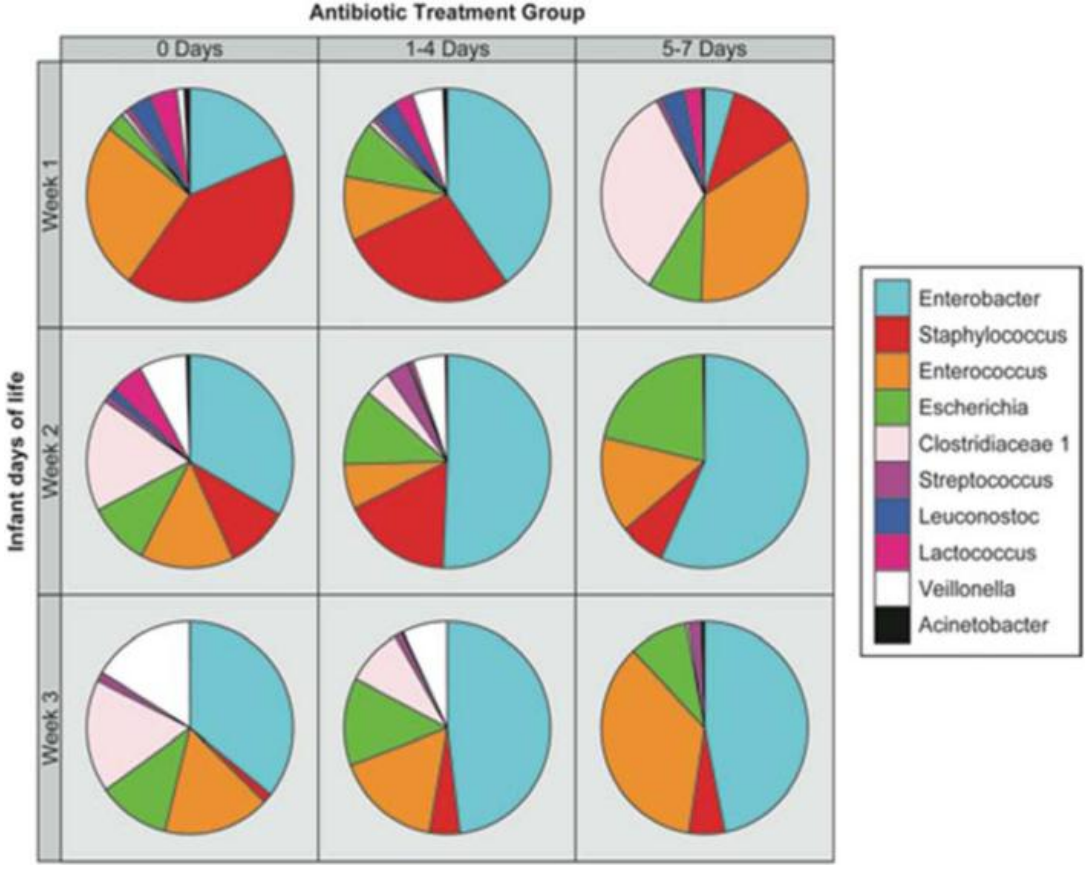
Initial Antibiotics, Total Antibiotic Exposure and Select Adverse Outcomes

	Description	Initial Empirical Antibiotic Therapy			p-value
		0 days 60 (16.4%)	1–4 days 175 (48%)	≥5 days 130 (35.6%)	
Total days treated with antibiotics during hospital course	Median (range) [IQR]	0 (0–21) [0–0]	3 (1–55) [3–8])	14* (5–84) [8–27]	<.0001
Composite[+]	No. (%)	7 (11.7%)	31 (17.7%)	53 (40.8%)*	<.0001
Late onset sepsis	No. (%)	7 (11.7%)	23 (13.1%)	46 (35.4%)*	<.0001
NEC	No. (%)	0	8 (4.6%)	9 (6.9%)	0.11
Death	No. (%)	0	8 (4.6%)	12 (9.2%)	0.03

[+] Any outcome of death, sepsis, or NEC after 7 days of life

Kuppala, et al. J. Pediatrics, 2011

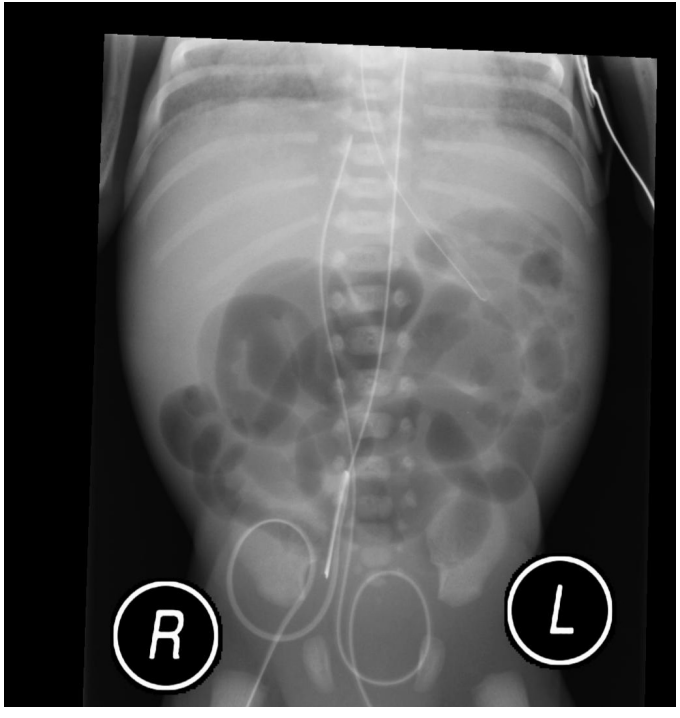
Antibiotics and the Microbiome

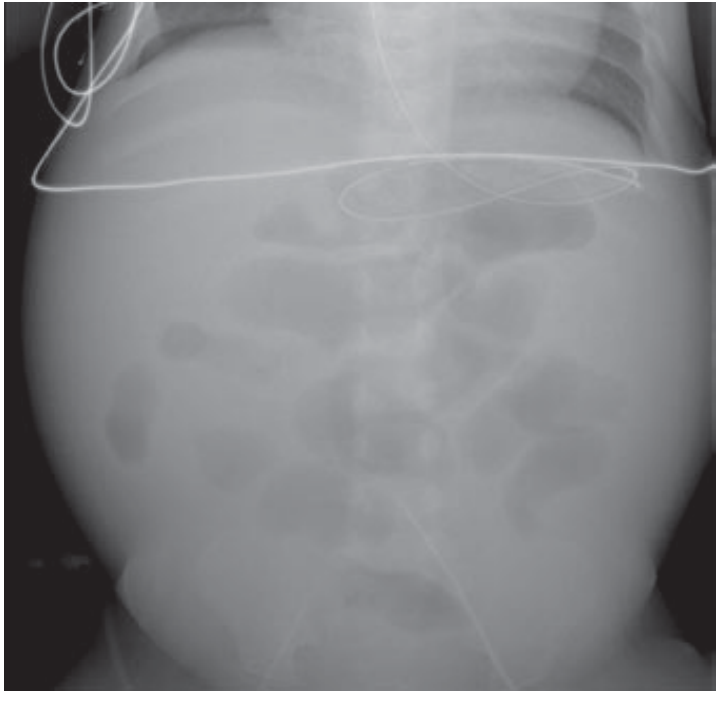


Greenwood C, Morrow AL, Lagomarcino AJ, et al. J Pediatr 2014.

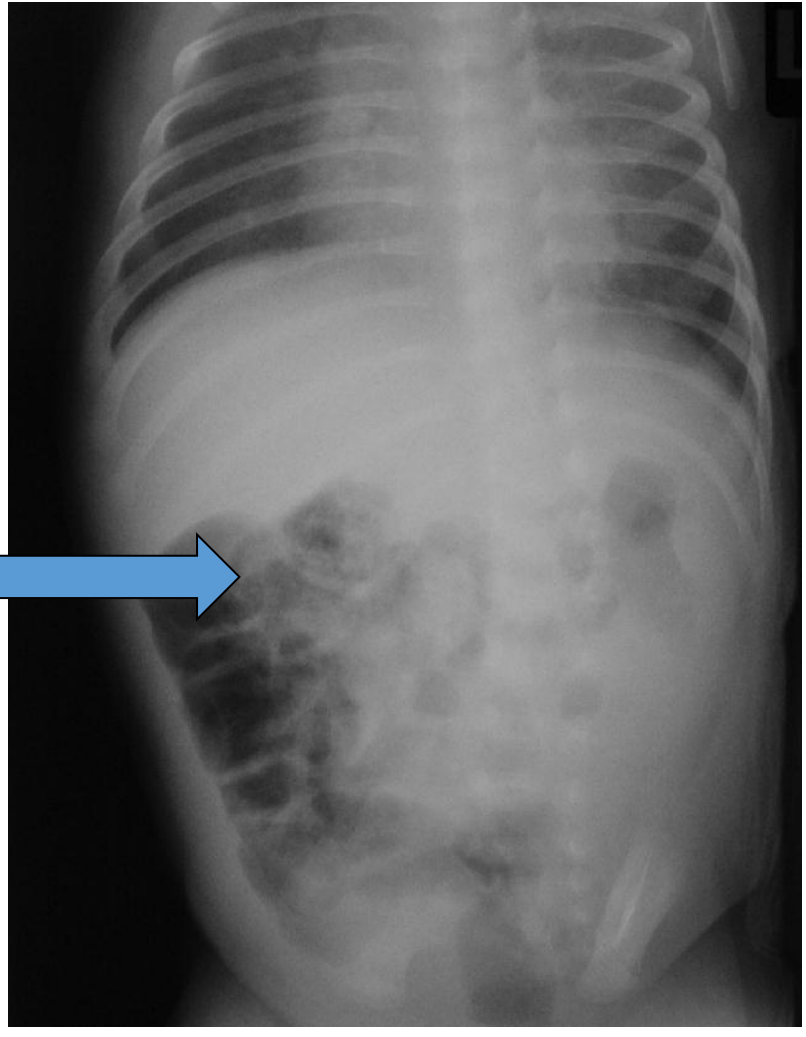

The Future
NEXT EXIT

NEC: A Diagnostic Dilemma





“Poopatosis”



NEC versus Non NEC Differentiation

Thuijls, et al. Annals of Surgery, 251 (6), June 2010

Marker	Cutoff Point	Sensitivity	Specificity	LR+	LR-	AUC (95%CI)	P
I-FABP	2.25 pg/mmole creatinine	0.93	0.90	9.3	0.08	0.98 (0.94-1.0)	<0.001
Claudin-3	8OO.8 INT	0.71	0.81	3.74	0.36	0.76 (0.59-0.94)	0.016
Calprotectin	286.2 microgram/gram feces	0.86	0.93	12.29	0.15	0.94 (0.85-1.0)	0.001

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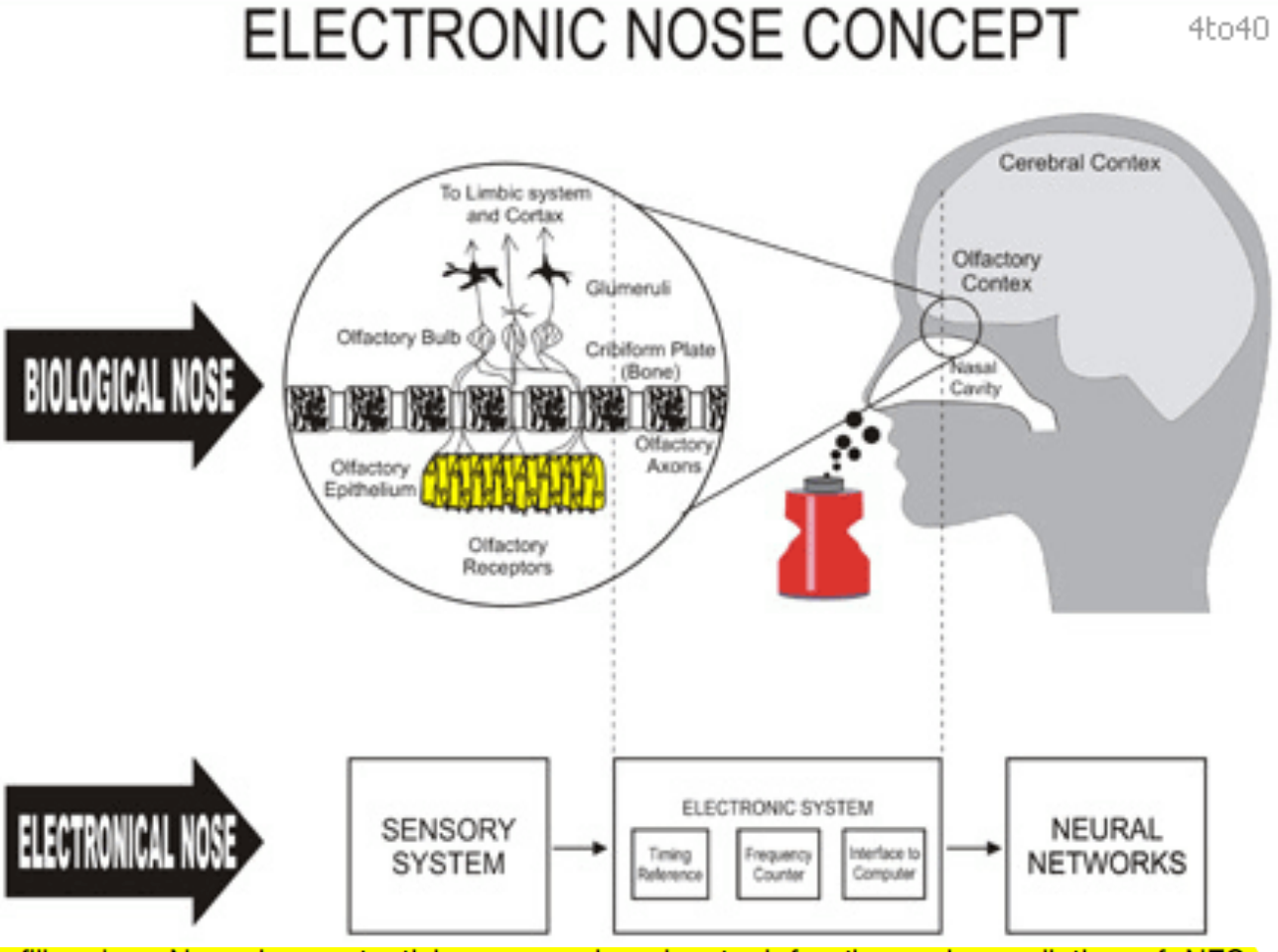
VOC-profiling by eNose has potential as a noninvasive tool for the early prediction of NEC. *(J Pediatr 2015;167:562-7)*.



Summary and the Future

- Treatment of NEC once the process begins is extremely difficult and prevention based on a better understanding of the causes will be critical.
- NEC Pathogenesis is Multifactorial. However, there is strong evidence that a microbial “dysbiosis” constitutes an important component of the pathophysiology of the “classic” form of NEC.
- We need to have better systems (enteroids, animal models) to evaluate mechanisms that fulfill criteria for causality derived from strong associations found in humans.
- Microbial based strategies are promising.

Acknowledgments

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  - Joseph Larkin
  - Catalina Bazacliu
  - Jessica Lauren Walker Ruoss
  - Ana Conessa –Cegarra
  - Rob Lawrence
  - Darlene Kertes
  - Michelle Cardel
  - Mark Hudak (Jacksonville)
  - Renu Sharma (Jacksonville)

Special thank you to Nursing Staff , Families and Babies at UF Health NICU

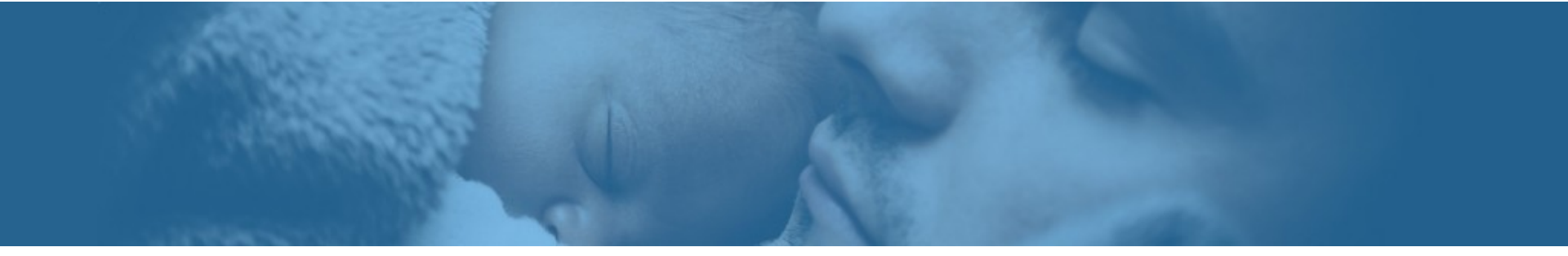
- **Recent Fellows**
  - Nicole Cacho (currently faculty at UF)
  - Diomel De la Cruz (currently faculty at UF)
  - Oleksandr (Sasha) Kudin
  - Sarah Bajorek
  - Mary Lenfestey (UF GI)
  - Desiree Rivera-Nieves (Peds GI-Orlando)
  - Lily Chang
  - Roberto Torrazza Murgas (Neonatologist Panama City, Panama)
  - Lexi Ardissone (graduate student—microbiology and cell sciences)
- **Visiting Scholars**
  - Maka Mshvildadze (Tbilisi, Georgia)
  - Ma Liya (Boan Hospital, Shenzhen, China)
  - Terrence Ma (Chinese University, Hong Kong)
  - Liyan Zhang (Fujyan, China)
  - Huang Ying (Director of Pediatric GI, Fudan University, Shanghai, China)
  - EK Kim (Chairman of Korean Society of Neonatology, Seoul, Korea)
  - Kellym Liboni (Sao Paulo, Brazil)
  - LiLuquan (neonatologist currently here from Chongqing, China)
- **Non-UF Faculty, Fellows and Grad Students**
  - Richard Polin (Columbia University)
  - Sharon Donovan (U. of Illinois—Nutrition)
  - Rob Chapkin (Texas A and M, cell transcriptomics)
  - Dominique Darmaun (Nantes, France)
  - Jean-Christophe Roze (Nantes, France)
  - MCarmen Collado (Valencia, Spain—human milk studies)
  - Anthony Fodor (U. North Carolina, Charlotte---bioinformatics)
  - Kathryn Winglee (Graduate Student, U. North Carolina, Charlotte)
  - W. Allan Walker (Harvard)
  - Mohan Pammi (Baylor)
  - Rob Knight (Bioinformatics UCSD)
  - Flavia Indrio (Bari, Italy)
  - Mike Cotten (Duke)
  - Bill Benitz (Stanford)

RECENT FUNDING SOURCES

NIH RO1, R21, RO3, CMN, Medela, Infant Bacterial Therapeutics

Why IBP-9414 for Necrotizing Enterocolitis Gastroschisis and IBP-1016 – A New Opportunity

Eamonn Connolly PhD, Chief Scientific Officer

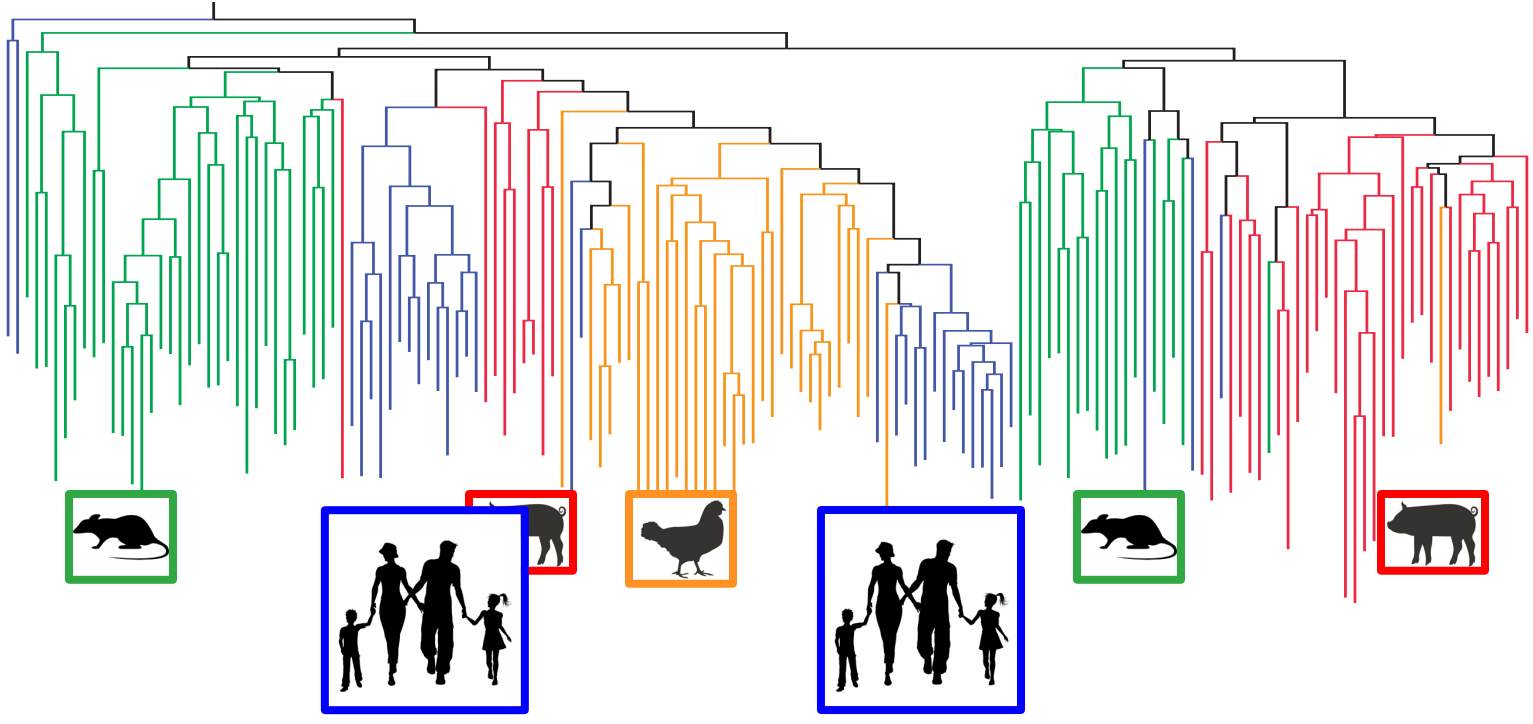


Why is *Lactobacillus reuteri* so unique?

Source: www.vectortemplates.com/raster/globes-022.png

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

Genetic relatedness of global *L. reuteri* genomes



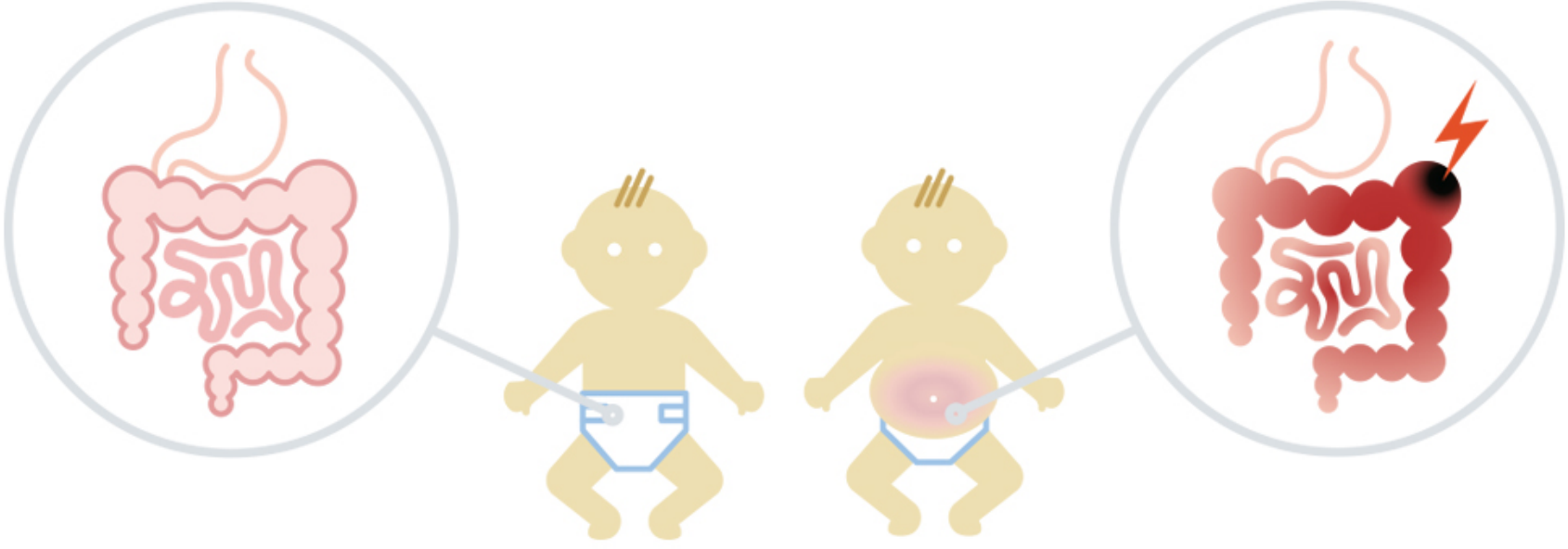
L. reuteri shares a long evolutionary history in the human gut and in human breast milk

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

Source: Oh 2010, Walter 2011

IBP-9414 for the prevention of necrotizing enterocolitis

Necrotizing Enterocolitis (NEC)



NEC is severe inflammation of the bowel in preterm infant bowel which can lead to death of the baby

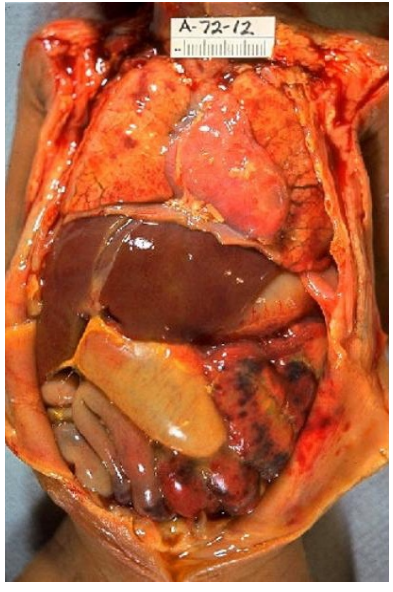
Major surgery required in 20-40% of NEC cases at cost of 300 kUSD or more

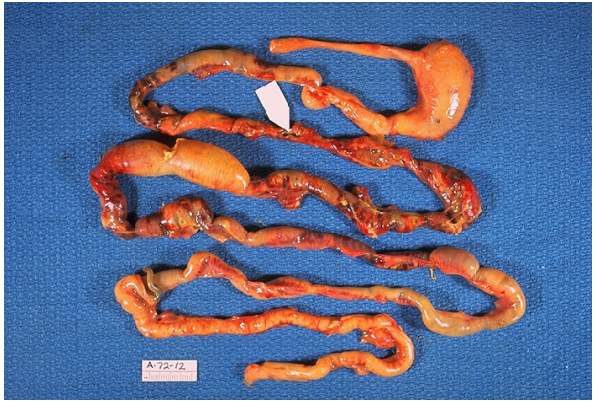
Survivors have long-term consequences: short-bowel syndrome, abnormal growth, cognitive, visual and hearing impairments

There is no preventive treatment for NEC

Necrotizing Enterocolitis (NEC)

NEC kills 1500 US och 3700 EU infants every year





Source: Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities

Who gets NEC?

Premature infants

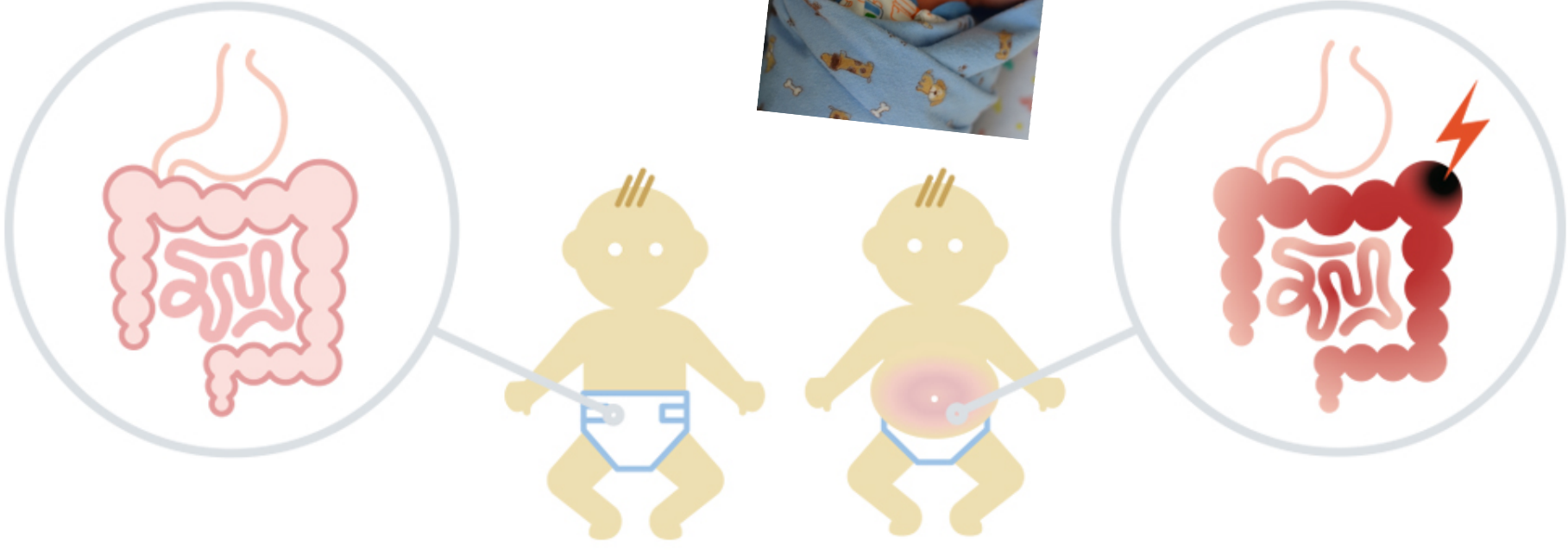
	Infants birth weight	NEC incidence rate (%)	NEC mortality rate (%)	Mortality (% of weight cohort)
High incidence and mortality	501-750g	12.0%	42.0%	5.0%
	751-1,000g	9.2%	29.4%	2.7%
	1,001-1250g	5.7%	21.3%	1.2%
	1,251-1,500g	3.3%	15.9%	0.5%
	1,501-2,500g	0.4%	8.2-17%	0.03-0.06%
	>2,500g	0.1%	0-20%	0-0.02%

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

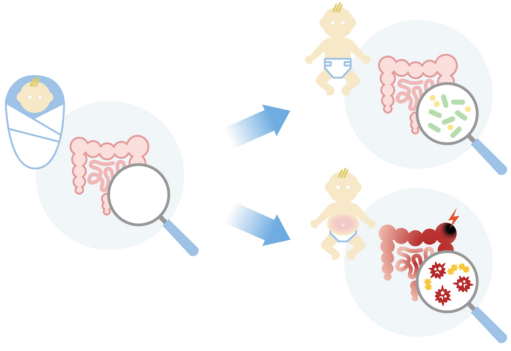
Source: Clark et al, 2012

What causes NEC?

What happened to Micah?

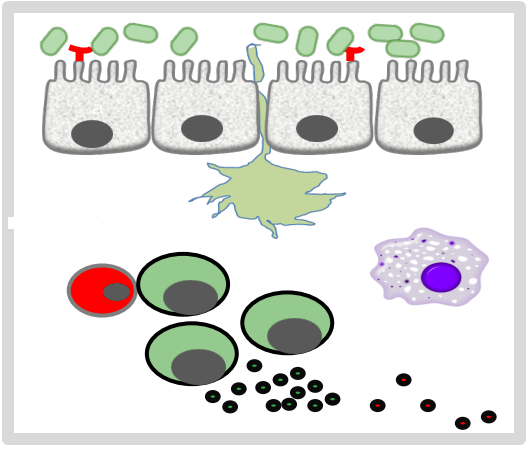


What causes NEC?



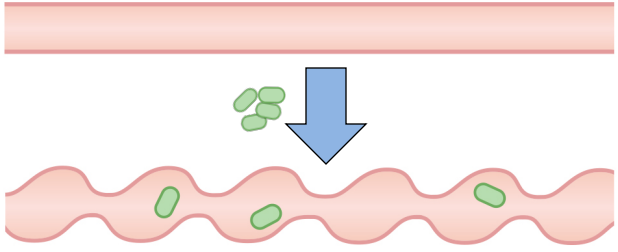
Dysbiosis

Over representation of pathogens in the gut of the gastroschisis infant



Inflammation

Intestinal inflammation is known to have negative effects on gastrointestinal function

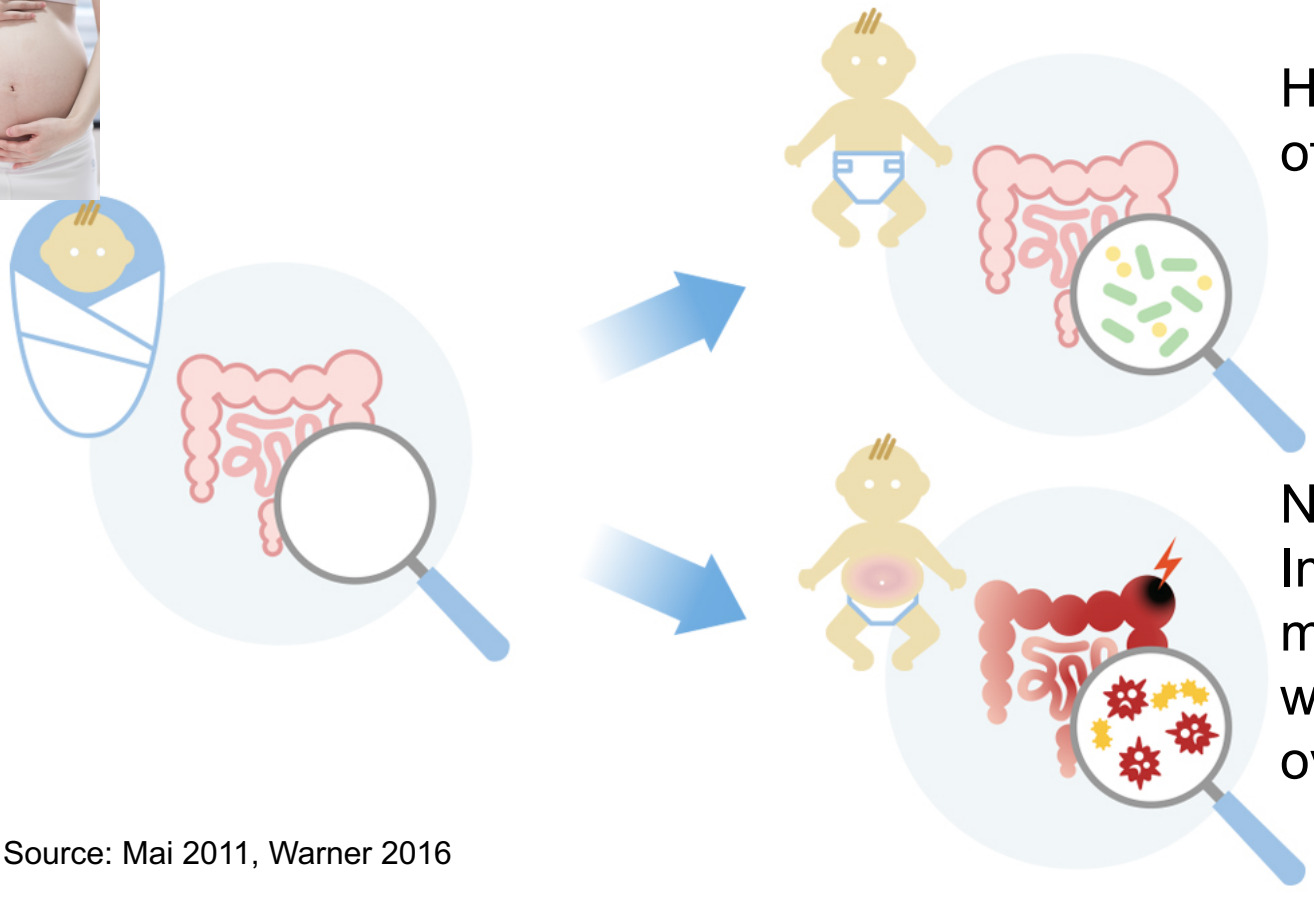


Gut motility

Severe impairment of gut motility is the unmet medical need of the gastroschisis infant

What causes NEC? – Dysbiosis in the gut

Growth of pathogens



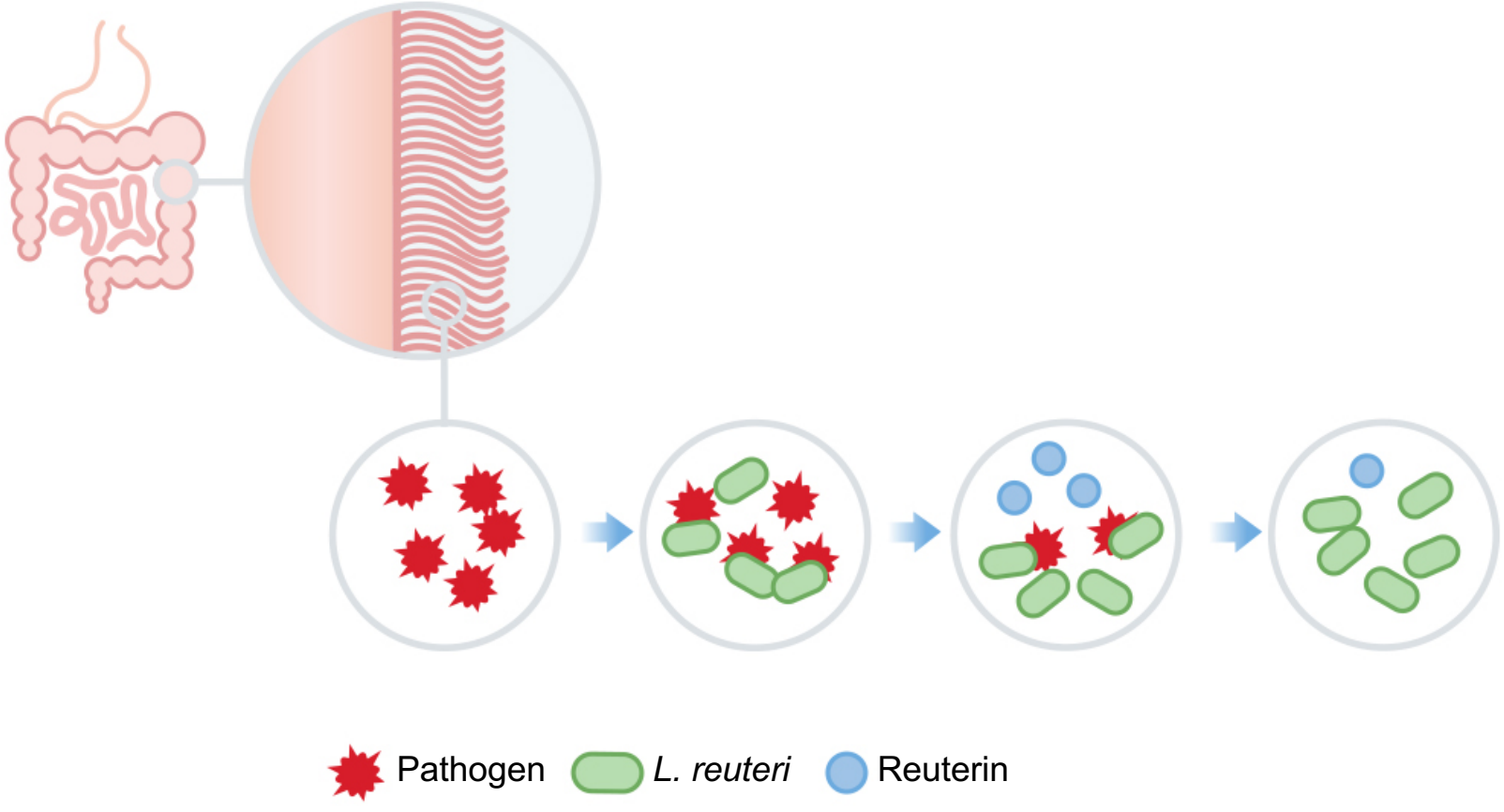
Healthy development of gut microbiota

NEC
Imbalanced gut microbiota (dysbiosis) with pathogen overgrowth

Source: Mai 2011, Warner 2016

What does *L. reuteri* do?

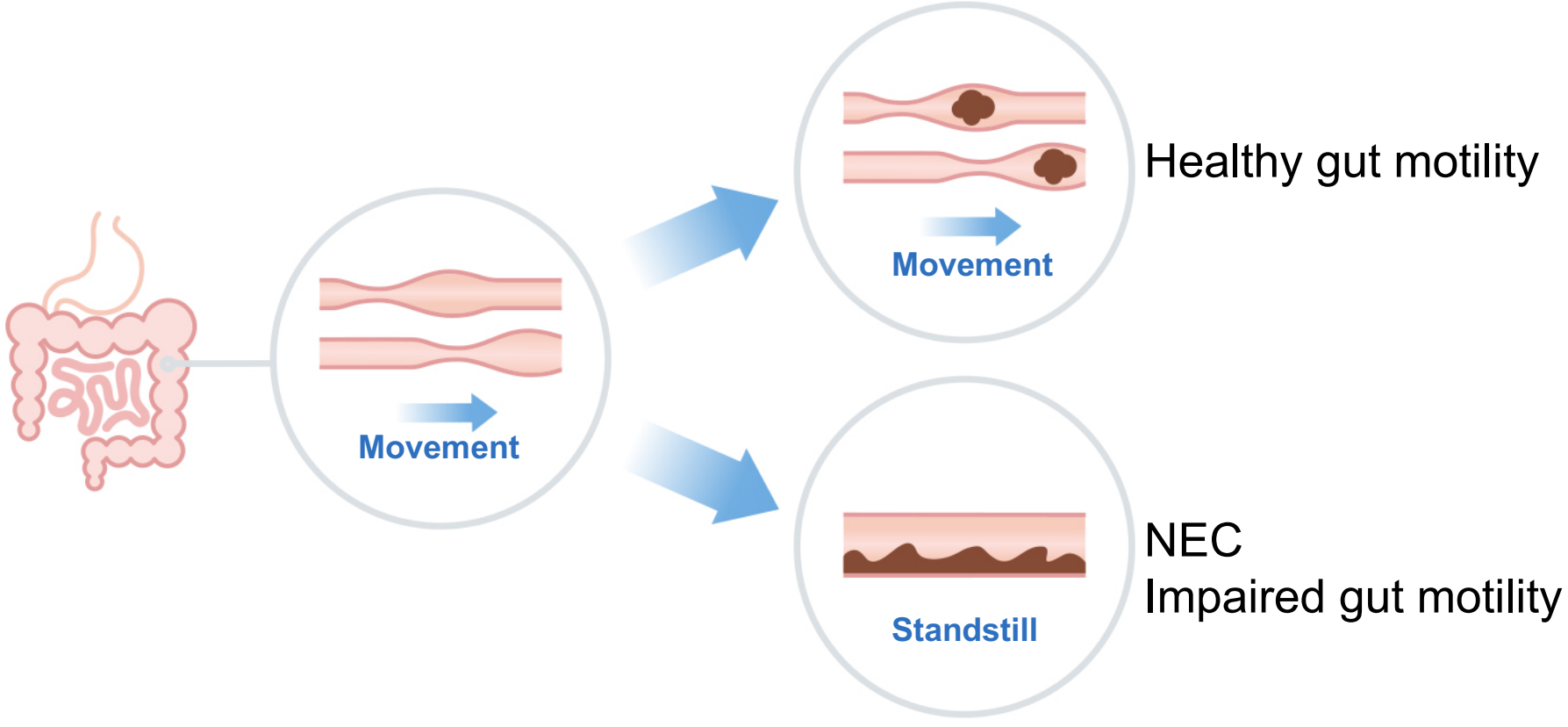
Fights pathogen growth in gut



Source: Talarico 1988, Axelsson 1989 Morita 2008, Spinler 2008, Schaefer 2010, Savino 2015

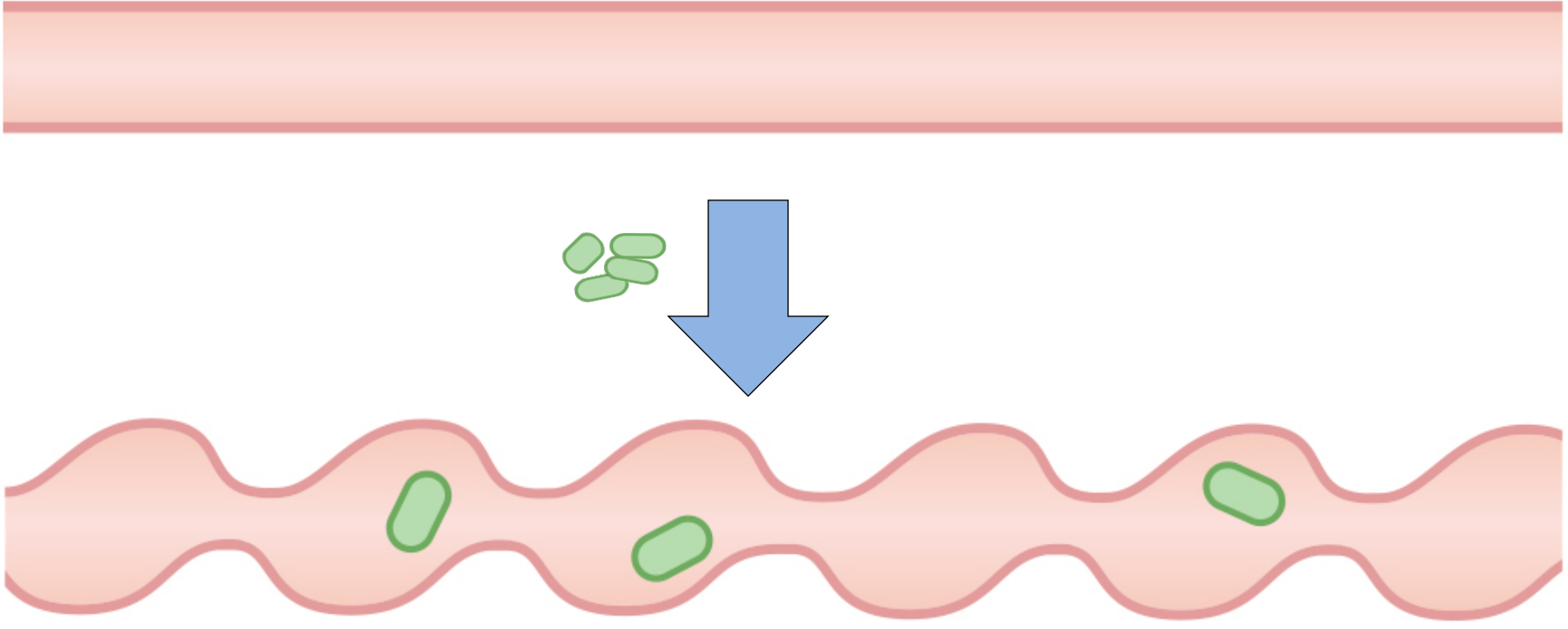
What causes NEC? Gut motility

The baby´s gut movements stop



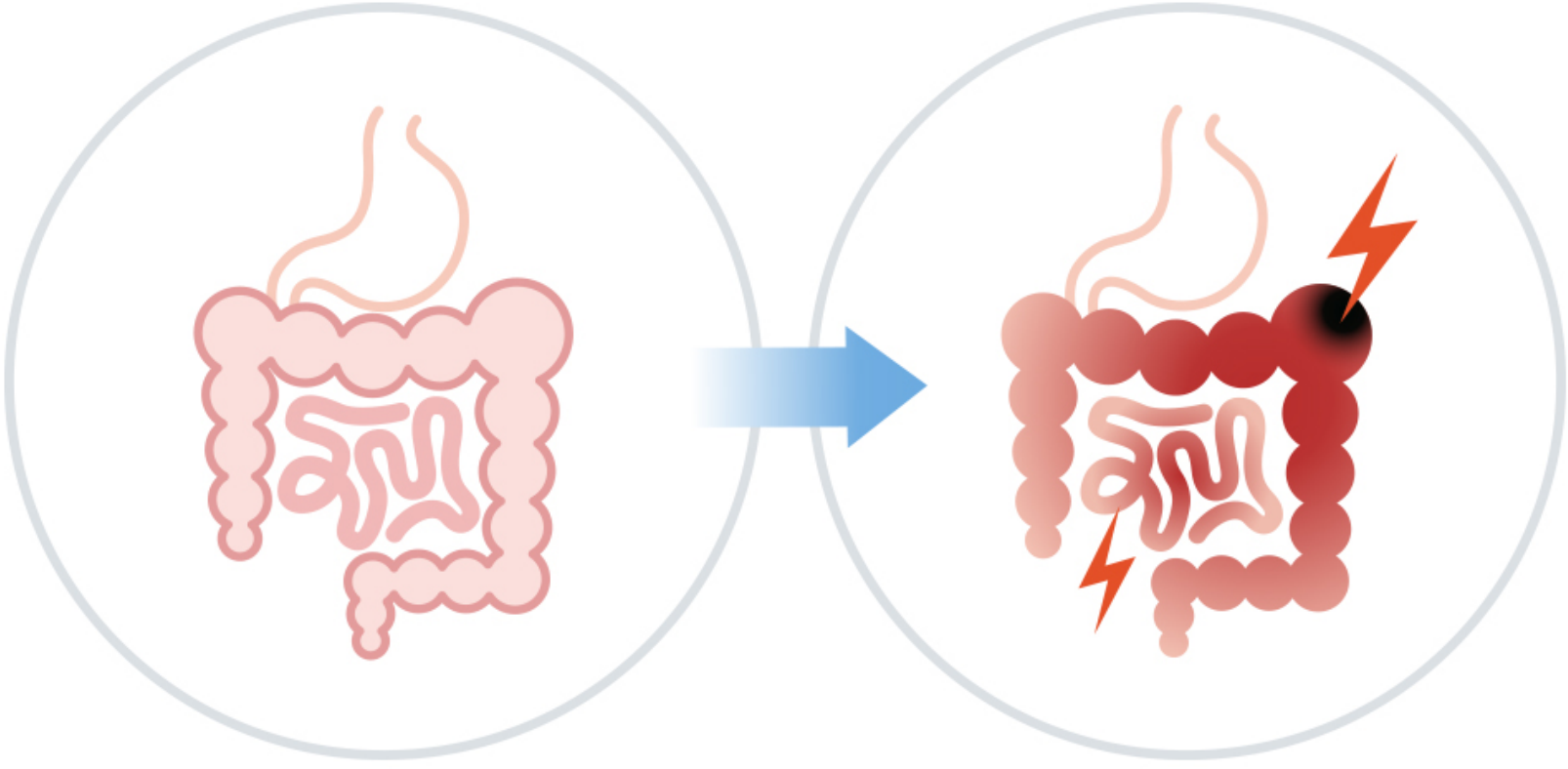
What does *L. reuteri* do? Gut motility

L. reuteri improves gut motility

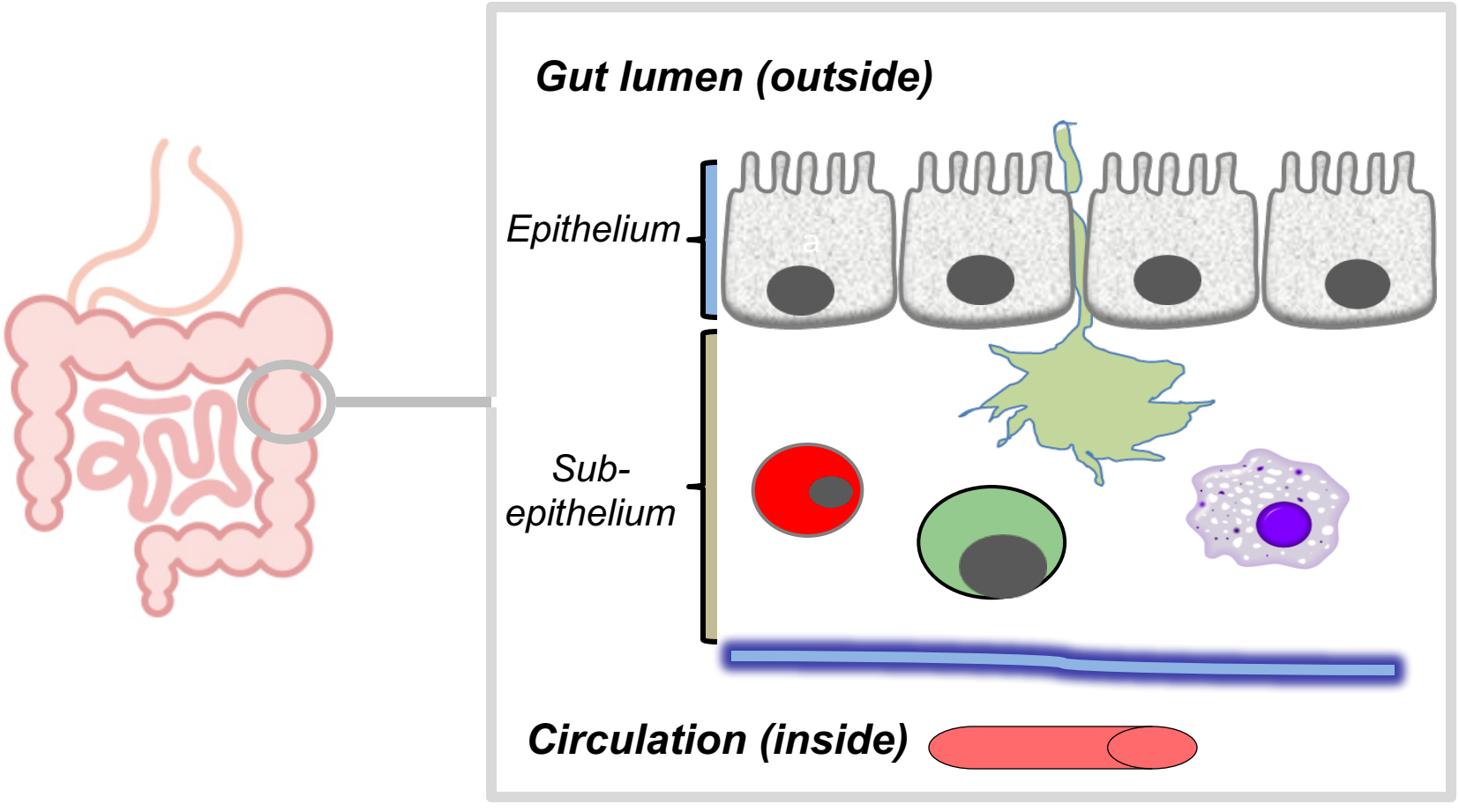


Source: Wu 2013

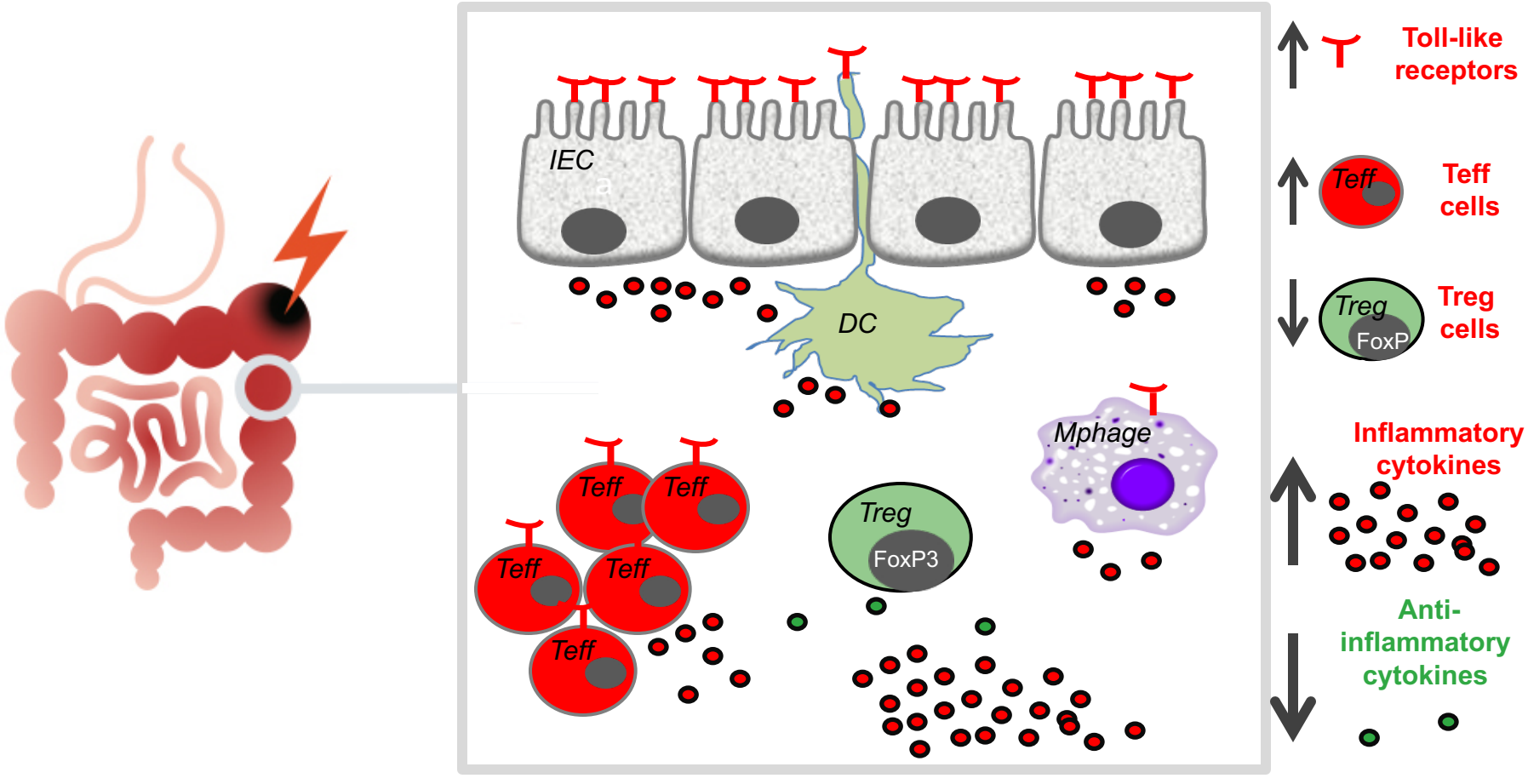
What causes NEC? – Inflammation in the gut



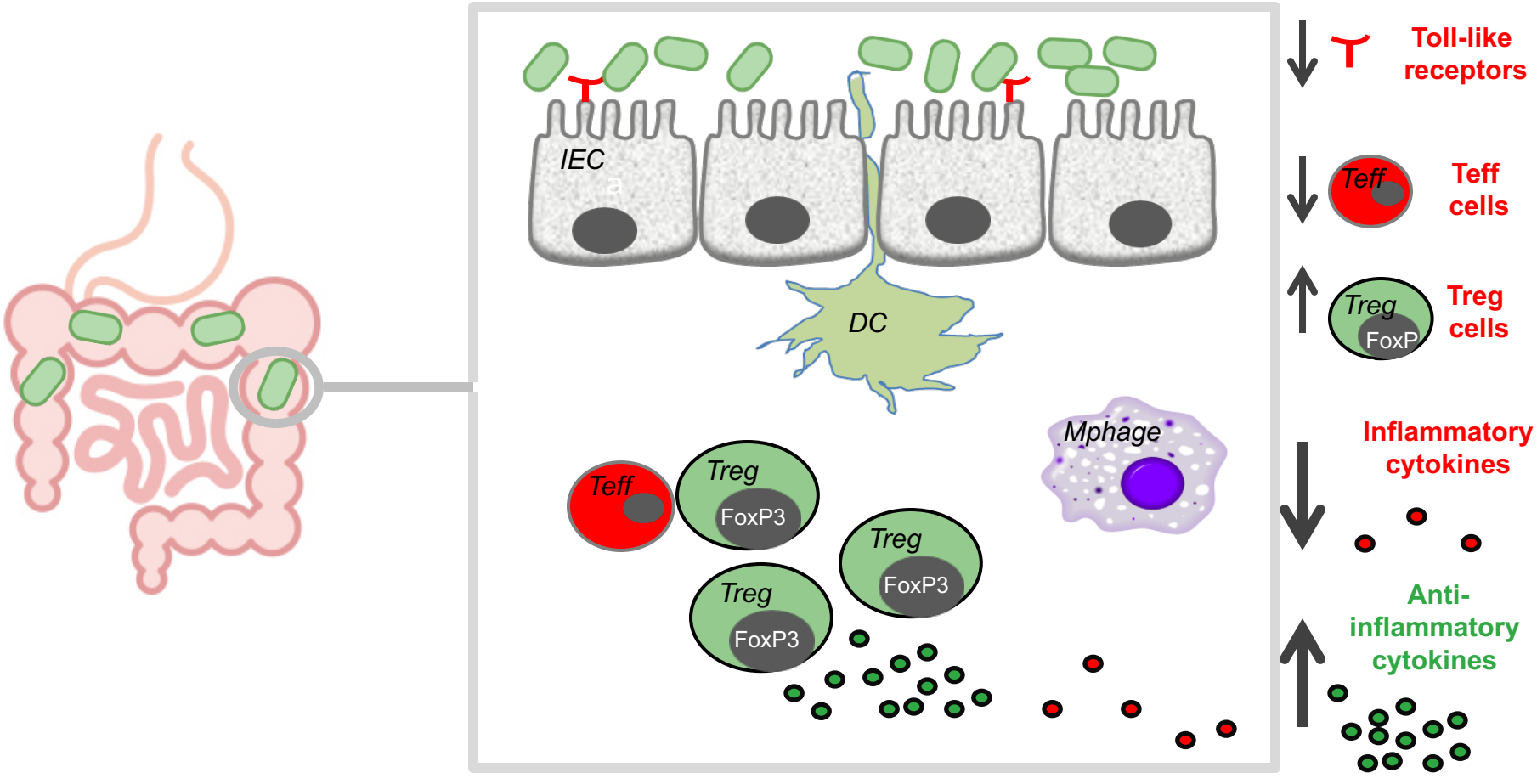
Normal gut


Gut lumen (outside)
Epithelium
Sub-
epithelium
Circulation (inside)

What causes NEC? – Inflammation in the gut



What causes NEC? – Inflammation in the gut



Source: Liu 2010, Liu 2012, Liu 2014

Independent clinical studies

Documented signal of Lactobacillus Reuteri in infants

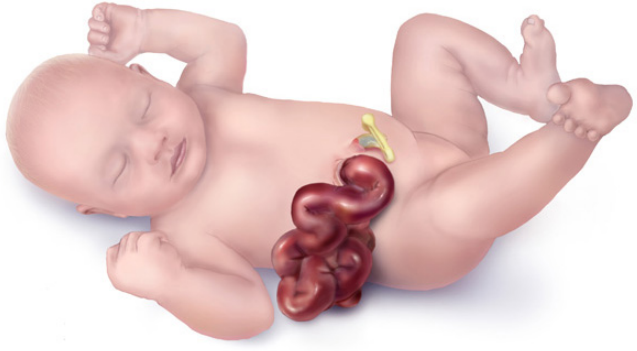
Clear clinical signal

All studies show clinically significant reduction of NEC

Study	Number of patients	Reduction in NEC incidence
Rojas et al. (2012)	▪ 750 patients	▪ 40% in the total study population with *L. reuteri* ▪ 37% in infants ≤1,500g with *L. reuteri*
Oncel et. al (2014)	▪ 400 patients	▪ 20% in the total study population with *L. reuteri* ▪ 38% in infants ≤1,000g with *L. reuteri*
Hunter et al. (2012) & Dimaguila et al. (2013)	▪ 354 patients	▪ 89% in the total study population with *L. reuteri*
Jerkovic Raguz et al. (2016)	▪ 100 patients	▪ 50% in the total study population with *L. reuteri*
Shadkam et al. (2015)	▪ 60 patients	▪ 82% in the total study population with *L. reuteri*
Hernandez-Enriquez et al. (2016)	▪ 44 patients	▪ 92% in the total study population with *L. reuteri*

IBP-1016 for the treatment of gastroschisis

Gastroschisis



Gastroschisis is a severe birth defect where the baby's intestines are external to the baby's body, through a hole beside the belly button

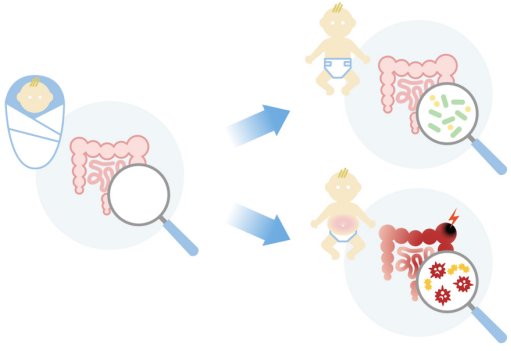
Afflicts approximately 2,000 late preterm Infants per year in the US, of average gestational age 36 weeks and birth weight 2.4kg

After surgical repair, the main complication is severe impairment of gut motility and there is no safe treatment to promote gut motility in gastroschisis infants

1-5 months in NICU with heavy costs incurred until baby can feed freely.
Fed parenterally, with increased risk of liver disease, infection and NEC.

Picture sourced from Centers for Disease Control and Prevention

Treating gastroschisis with IBP-1016



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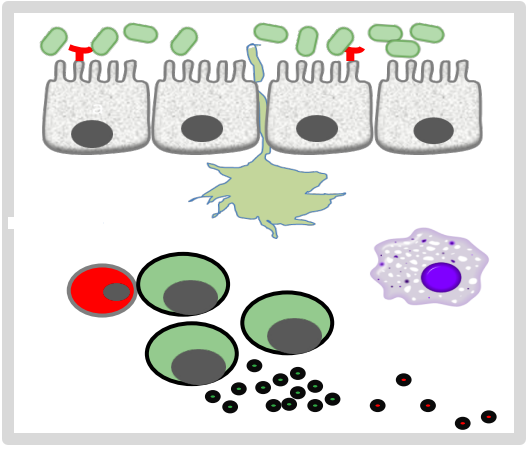
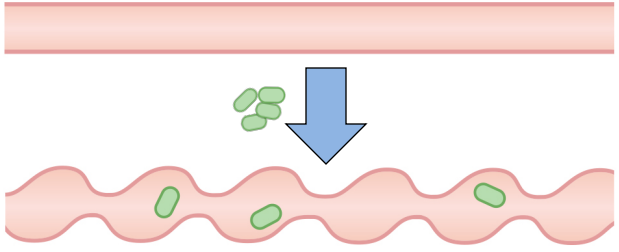


Inflammation

Intestinal inflammation is known to have negative effects on gastrointestinal function



Gut motility

Severe impairment of gut motility is the unmet medical need of the gastroschisis infant

Improved gut function

Source: Powell 2016, Peuhkuri et al, 2010, Wu 2013

Independent clinical studies

Documented signal of Lactobacillus Reuteri in infants

Clear signal on improved gut motility

5 studies

	Study	Number of patients	Results
Improved gut motility in term and preterm infants	Indrio et al. (2008)	■ 30 patients	■ 85% increase in gastric emptying rate with *L. reuteri* (p<0.001)
	Indrio et al. (2011)	■ 34 infants	■ 39% increase in gastric emptying rate with *L. reuteri* (p=0.01)
Improved feeding tolerance in preterm infants	Rojas et al. (2012)	■ 750 patients	■ 34% reduction in episodes of feeding intolerance with interruption of feeding (p=0.08)
	Oncel, Sari et. al (2014)	■ 400 patients	■ 29% reduction in episodes of feeding intolerance with interruption of feeding (p=0.015) ■ 10% reduction in time to full enteral feeding (p=0.006)
	Oncel, Arayici et al. (2014)	■ 300 patients	■ 36% reduction in episodes of feeding intolerance with interruption of feeding (p=0.004)

Gastroschisis – next steps

During the summer of 2017 we have interacted with a Regulatory Agency

IBT is planning for next steps based on agency feedback

Clinical Development of IBP-9414 for NEC

Agneta Heierson PhD, Vice President, Clinical Development

Study design considerations

IBP-9414 clinical program

- A live bacterial drug
- Not systemically absorbed from the GI tract
- Local effect in the gut
- Restrictions in blood sampling in the premature baby

No PK or PD studies
No interaction studies

After interactions with regulatory authorities, the clinical program consists of two studies:

- **Phase 2 safety and tolerability**
- **Phase 3 efficacy**

Phase 2 safety & tolerability study *

Careful design

Scientific advice by FDA and EMA

- Double-blind, randomised, placebo controlled
- 2 dose levels
- 2 weight groups

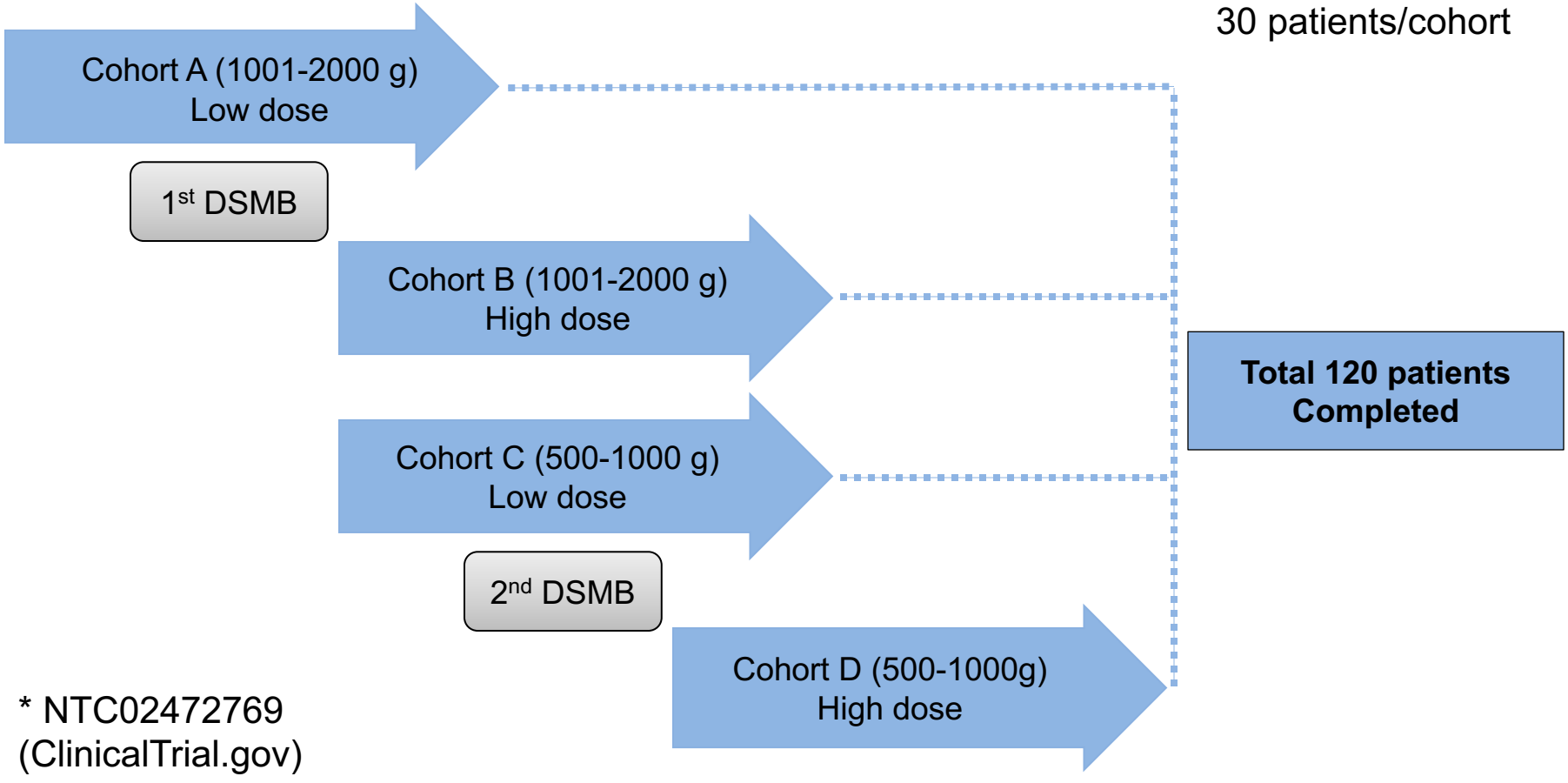
Minimal disturbance to the vulnerable patient group

Data Safety Monitoring Board (DSMB)

* NTC02472769 (ClinicalTrial.gov)

Phase 2 safety & tolerability study*

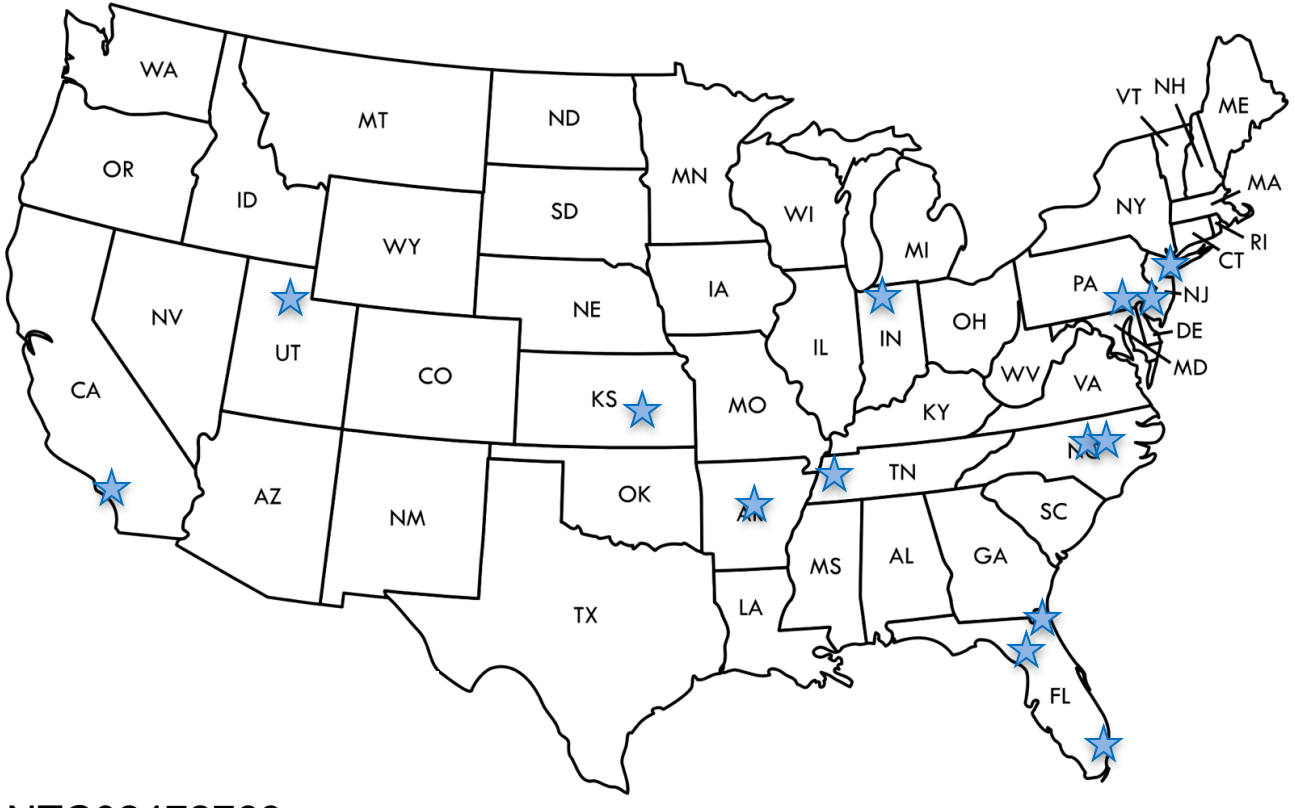
With interim safety evaluations



* NTC02472769
(ClinicalTrial.gov)

Phase 2 safety & tolerability study*

Performed in the USA



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

* NTC02472769 (ClinicalTrial.gov)

Confidence for Phase 3 study

With IBT's clinical experience

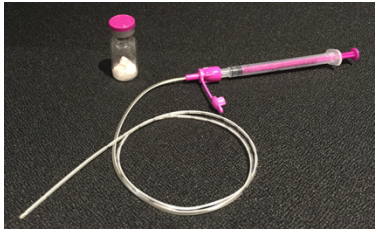
- Careful selection and identification of suitable sites in the USA, characterized by dedicated and focused study teams
- The smaller babies can be recruited at similar pace as the larger ones
- Parental consent did not restrict recruitment
- The phase 2 study has been delivered according to time line and with no major issues

Chemistry, Manufacturing and Controls (CMC)

Anders Kronström M.Sc., M.B.A., Chief Technical Officer

IBP-9414 Drug Product

- Freeze-dried powder for oral suspension
- *Lactobacillus reuteri*
- Excipients for ensuring product stability and quality
- Reconstitution with sterile water before use
- Careful consideration of the vulnerable preterm infant

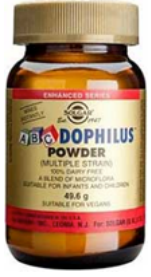


Why product quality is important

The Solgar incident

October 2014

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



November 2014

- 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

December 2014

- **FDA/CDC warning letter issued**
- Healthcare providers encouraged to submit an Investigational New Drug Application for FDA review

Consequences

- **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

We are serious about product quality

- IBP-9414 is an oral drug with exceptional quality demand due to the vulnerability of the patient population

- IBT is in close dialogue with regulators and healthcare providers to ensure product quality aspects are appropriately addressed

➢ **IBT is in the forefront**

Manufacturing Process of IBP-9414

Stringent control of manufacturing environment

Cell Bank

Pre-culture

Fermentation

Filtration

Mixing

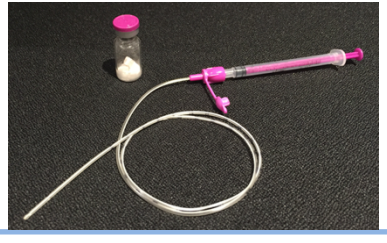
Formulated Cell Suspension

Filling

Freeze-drying

Packaging & Labelling

IBP-9414
powder for oral suspension



Conclusions

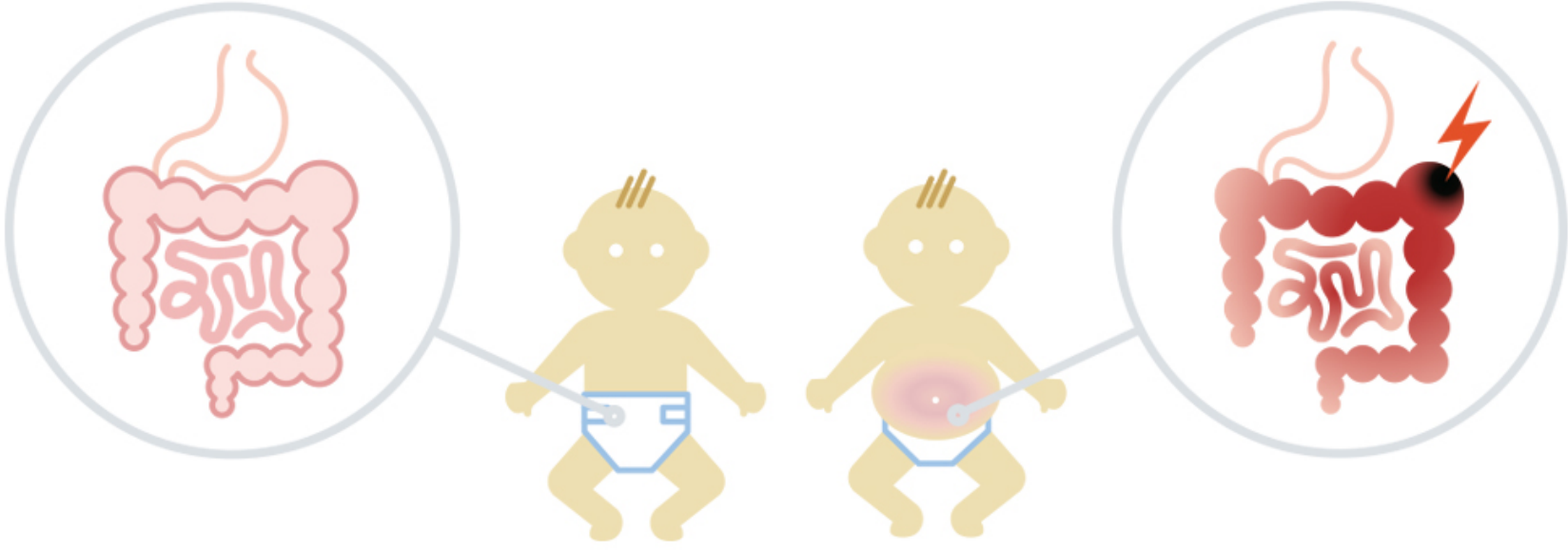
- We have successfully developed a live bacterial drug that is suitable for treating preterm infants
- We are confident in our ability to supply the future program with a high quality product
- We have an experienced team of scientists leading the development

➢ **IBT is the pioneer in the new field of live bacterial drugs**

A Globally Valuable Pharmaceutical

Daniel Mackey, Chief Financial Officer

Economic burden of NEC



Major surgery required in 20-40% of NEC cases at cost of 300 kUSD or more

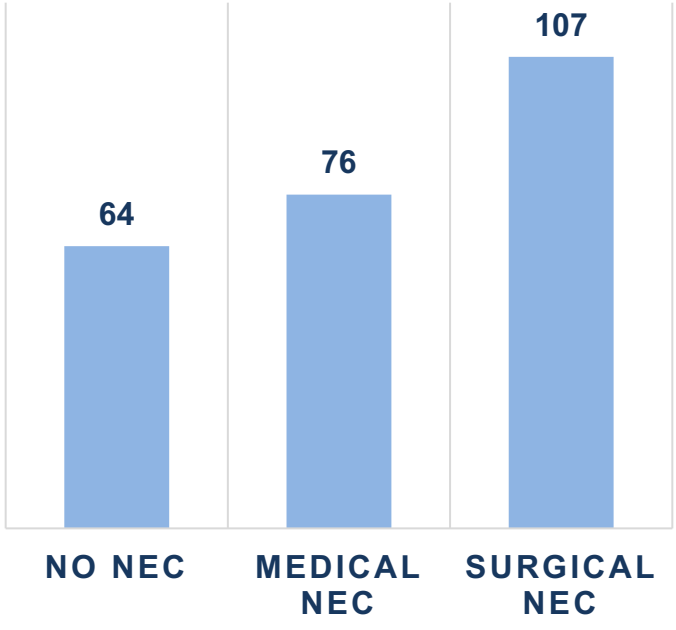
Survivors have long-term consequences: short-bowel syndrome, abnormal growth, cognitive, visual and hearing impairments

The economic cost of NEC is estimated to be USD 5 Billion for hospitalization in the US*

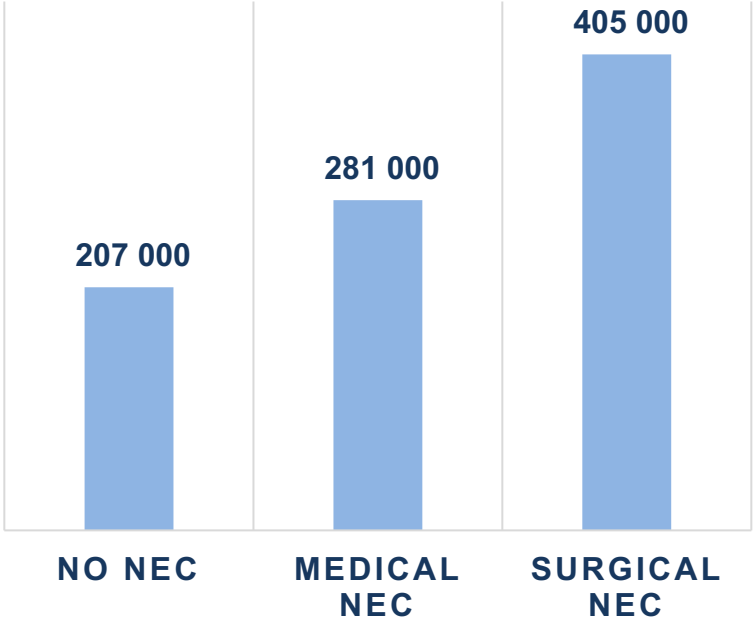
* Sheila M. Gephart et al, 2012

Economic burden of NEC

Prolonged days of hospital stay*

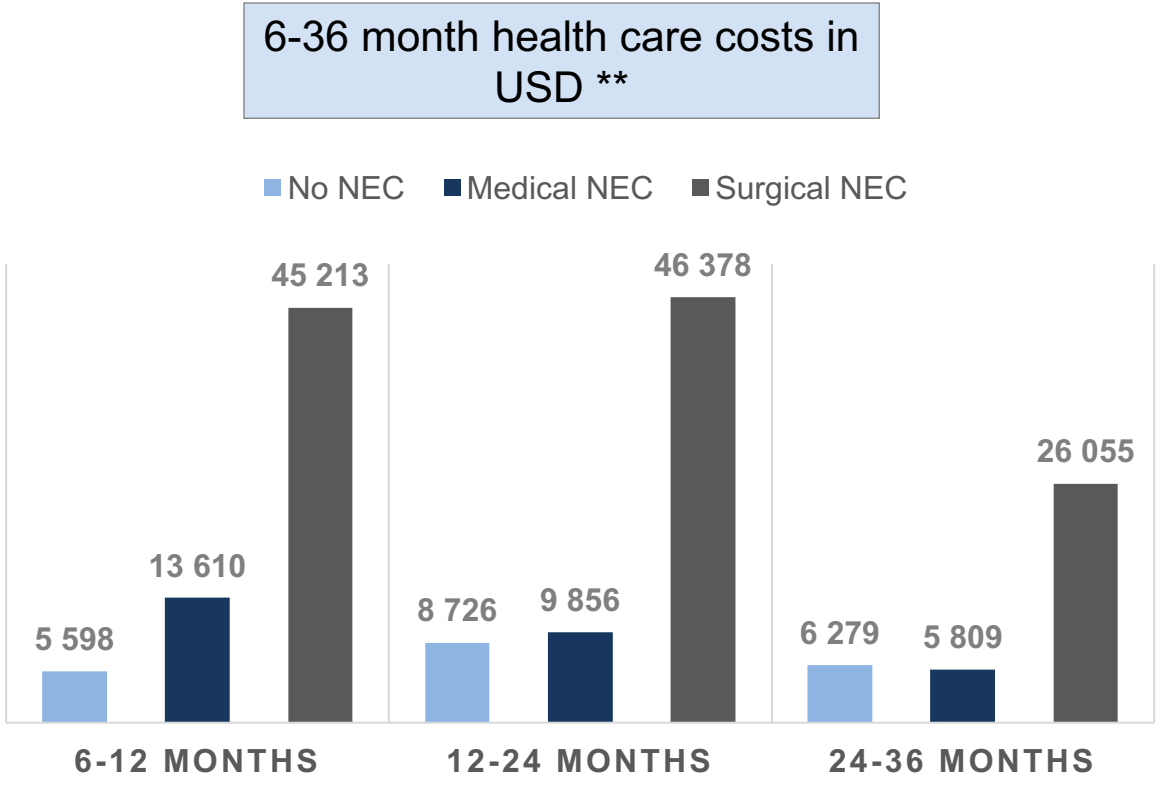


Initial hospitalization costs in USD*



*Ganapathy et al, 2011; For infants ≤ 28 weeks of gestational age

Extended economic burden of NEC



And long term costs associated with sequelae such as impaired growth, short bowel syndrome, poor long-term neurodevelopment

** Ganapathy et al, 2013

IBP-9414 Target Product Profile

For the prevention of necrotizing enterocolitis

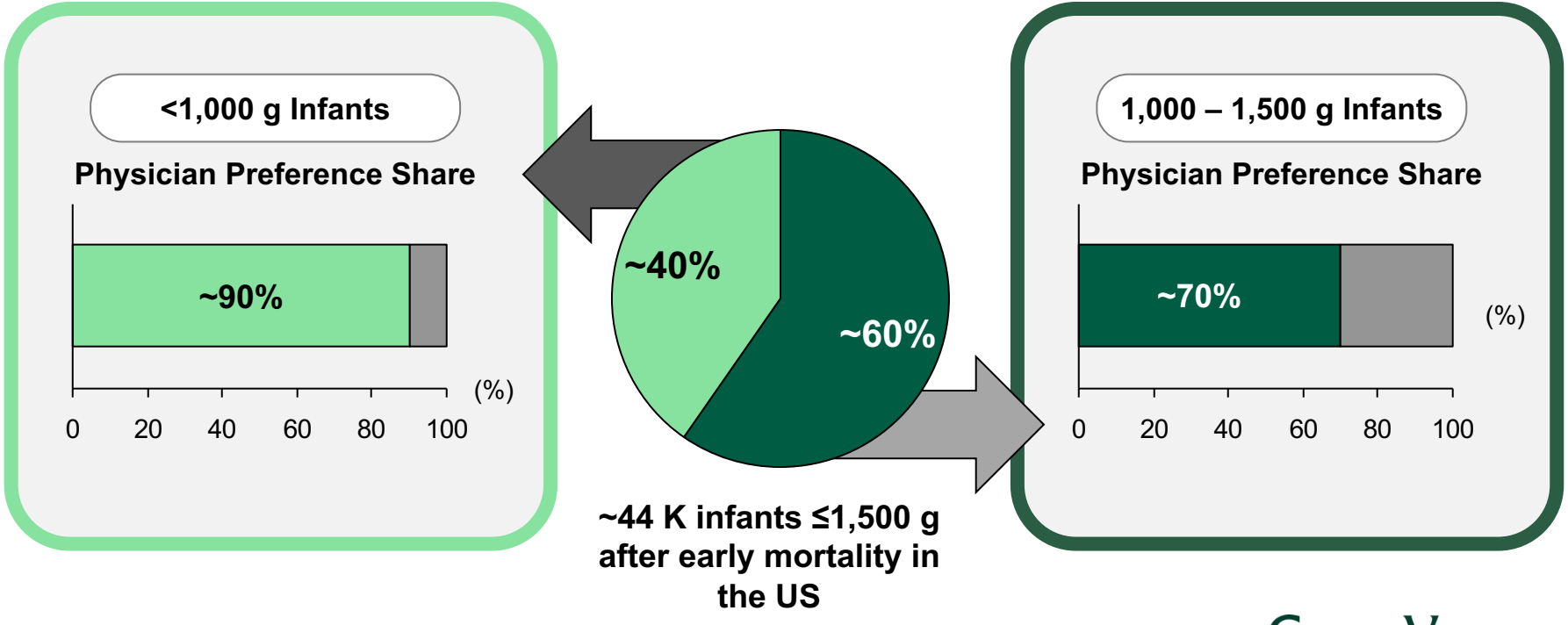
Product description	▪ Pharmaceutical therapy approved as Orphan Drug in EU and US to prevent NEC ▪ The first FDA and EMA-approved drug product to prevent NEC
Patient population	▪ Premature infants ≤1,500g (US) ca 56,000 ▪ Premature infants ≤ 34 weeks gestational age (EU5) ca 108,000
Route of Administration	▪ Oral / enteral
Product efficacy	▪ Demonstrates 33% reduction in the incidence of NEC compared to standard of care alone
Safety profile	▪ Well tolerated with no known side effects ▪ No increase in risk of sepsis or multi-resistance to antibiotics ▪ No known contraindications

Market potential for IBP-9414 assessment

IBT has mandated consultants to assess the market opportunity…	APEX HEALTHCARE CONSULTING CLEARVIEW Healthcare Partners
…who have interviewed the relevant key stakeholders across US and Europe…	▪ Including 60 Neonatology Key Opinion Leaders interviews ▪ 15 Pharmacy and Therapeutics neonatologists and pharmacists (P&T members) ▪ Payers

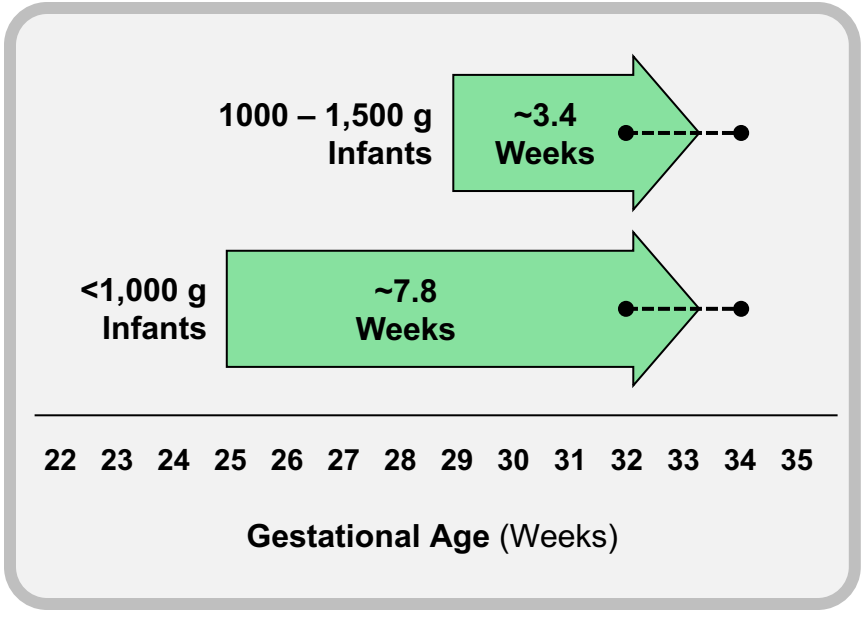
Neonatologists show high willingness to prescribe IBP-9414

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

Expected Formulary Inclusion by Institution Type



Institution Type	Major Medical Centers	Medium Hospitals	Small Community Hospitals
Share of Premature Infants	~60%	~30%	~10%
Estimated Formulary Adoption	~85%	~60%	~0%

Overall Formulary Inclusion	Approximately 70% of addressable patients are anticipated to receive care at an institution that includes IBP-9414 on formulary

ClearView Healthcare Partners

Significant market potential for IBP-9414

IBT has mandated consultants to assess the market opportunity…

APEX HEALTHCARE CONSULTING

CLEARVIEW Healthcare Partners

…who have strongly engaged and favorably reacted to IBP-9414's targeted profile…

- KOLs recognized NEC as a high unmet need with high mortality rates and lack of any medical preventive treatment
- NEC economic cost is estimated to be USD 5 Billion for hospitalization in the US*
- Highly positive reaction towards clinically proven safety and efficacy due to safety concerns
- Based on target profile, interviewees would expect IBP-9414 to be included on formulary

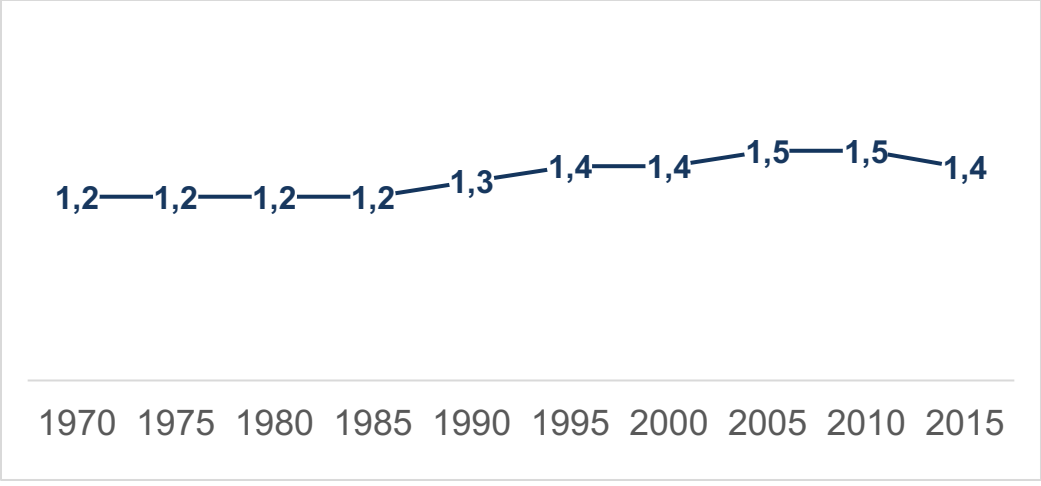
…resulting in significant market opportunity

- Estimated annual revenue potential of **USD 200m – USD 350m in US**

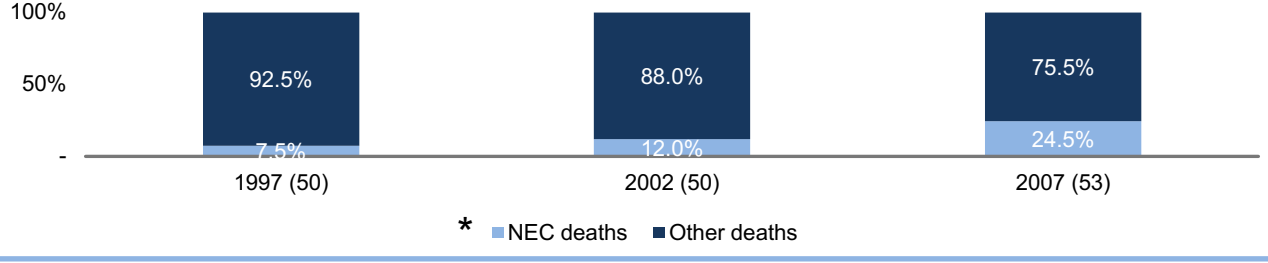
*Sheila M. Gephart et al, 2012

Urgent medical need

1,4 % of infants born in the US are under 1500 grams



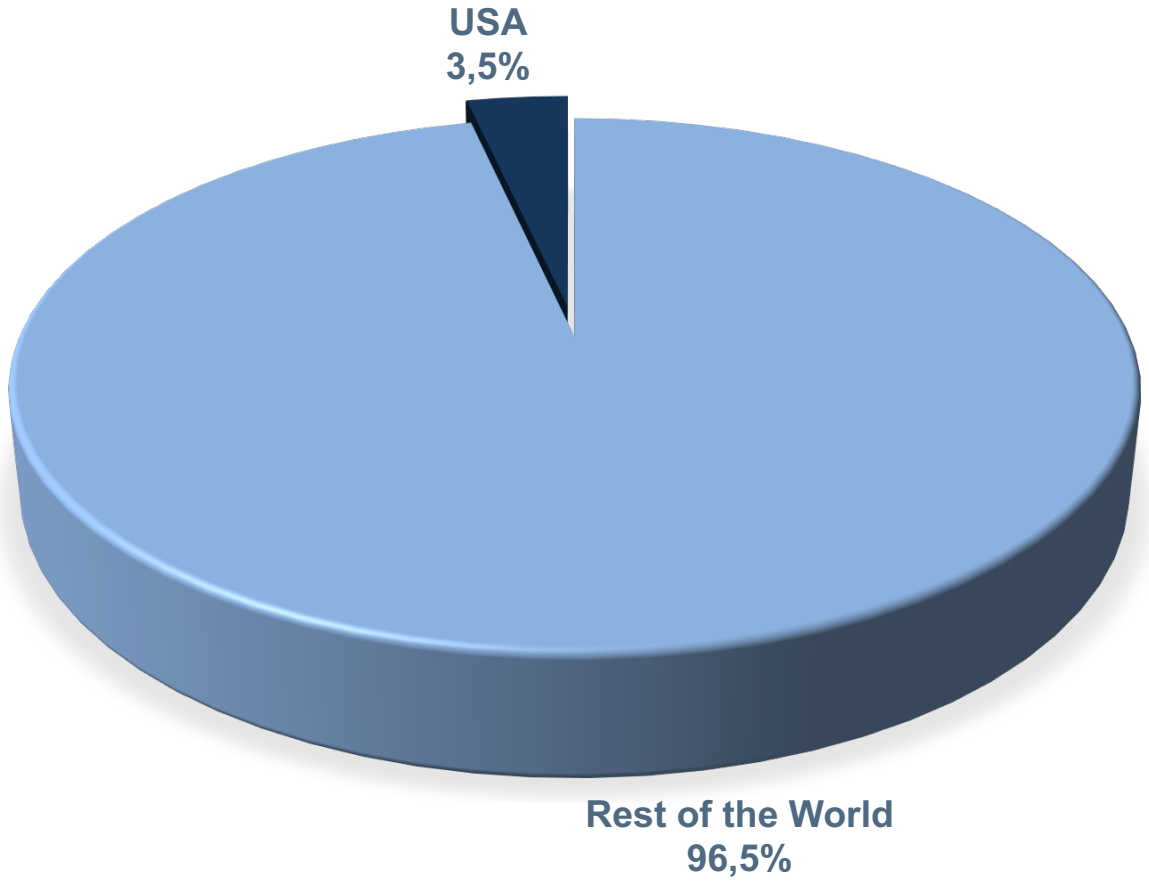
NEC treatments have not improved over the years



*Clark et al, 2012

Global preterm births

15 Million preterm births annually



H. Blencowe et al. 2012

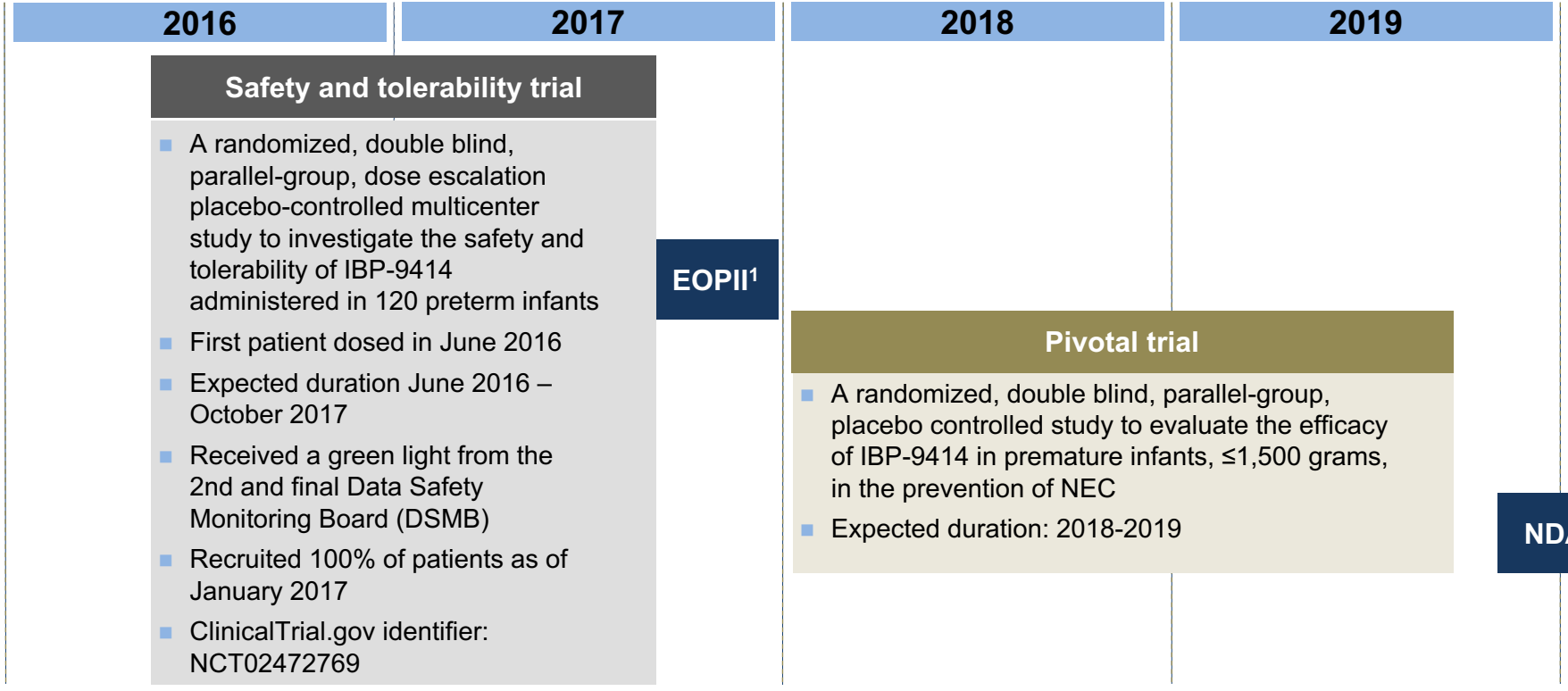
Closing Remarks

Staffan Strömberg PhD, Chief Executive Officer

IBP-9414 – development plan

A development program consisting of two clinical trials

Drug development plan



Notes

1 End of Phase II

2 New Drug Application

Infant Bacterial Therapeutics

Summary

- Pharmaceutical microbiome company focused on areas of unmet medical need
- Experienced team supported by a well established network of Key Opinion Leaders
- Clear clinical signal and safety profile of *Lactobacillus Reuteri*
- Strong Intellectual Property protection of *Lactobacillus Reuteri*
- Main project, IBP-9414 for the prevention of NEC, is in Phase 2 in the US and has received:
  - Orphan Drug Designation from the FDA and EU
  - Rare Pediatric Disease designation from the FDA, Priority review voucher may be awarded by the FDA
- Annual revenue potential for IBP-9414 estimated to be USD 200-350m by third-party in the US alone

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