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IBT Corporate Facts



Founded 2013

Founded in Sweden as a subsidiary of BioGaia



Unique Asset

Lactobacillus reuteri - unique GI bacteria leading to improved gut function and reduction of NEC*



IPO 2016

Nasdaq main market Stockholm



First in Class

IBT is the only company in the world dosing bacteria to preterm infants under US IND



Well Funded

Cash on hand sufficient for development through approval (Q3 21 SEK 390M)



Scalable

Final formulation established, four years stability on file, phase III underway, scalable production in place for launch.



Mega Potential

Breakthrough potential as first and only therapy to prevent NEC, a leading cause of death among premature infants.

* Necrotizing enterocolitis

Major Unresolved Medical Need in Preterm Babies



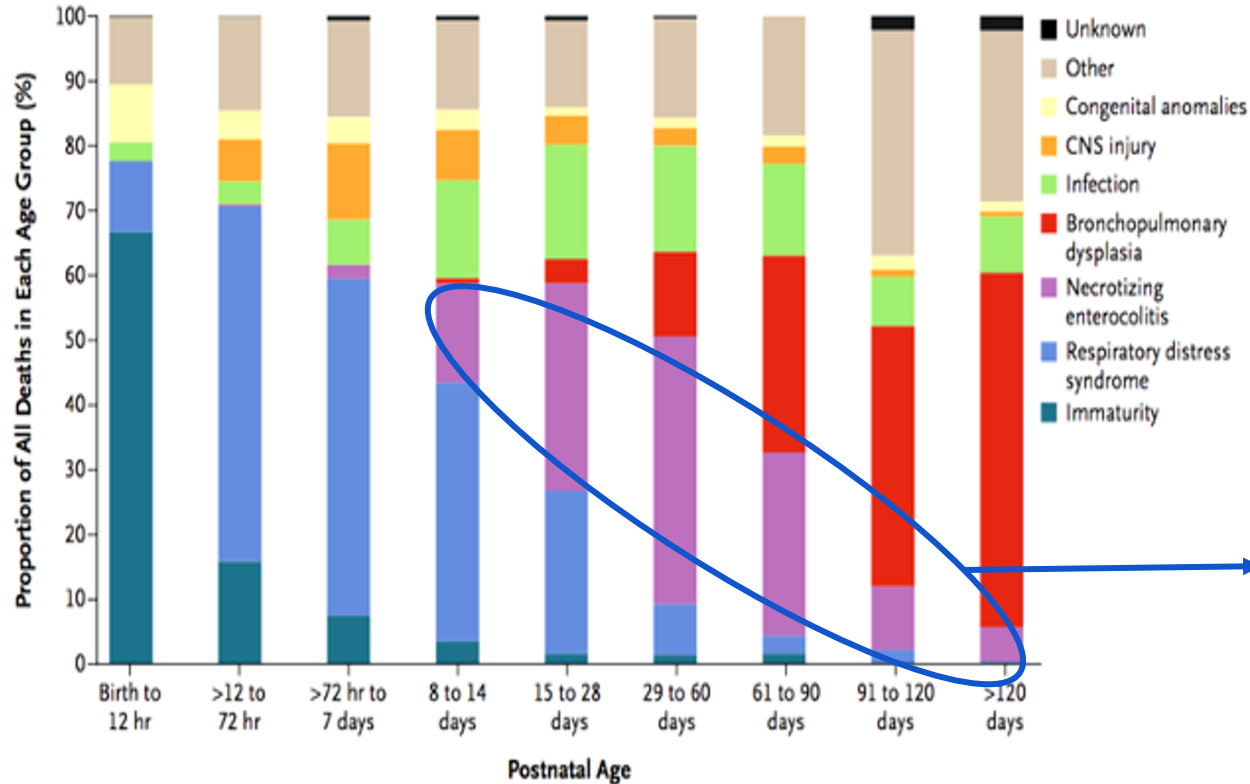
- **NEC:** leading cause of death in NICU* with 5000 deaths annually
- **SFT** (Sustained Feeding Tolerance) critical to avoid serious complications

- **No predictors,** biomarkers or available therapy
- **Need for preventive treatment**



* Neonatal Intensive Care Unit

NEC Clinical Relevance



NEC

- 5,000 die each year (1,500 US and 3,700 EU)
- Severe inflammation of the gut / invasive surgery
- Survivors suffer long-term consequences e.g.:
 - Short-bowel syndrome
 - Abnormal growth
 - Cognitive, visual and hearing impairments

SFT Clinical Relevance presented at Hot Topic Dec 2021

Data from the Connection study validate the Primary SFT Endpoint

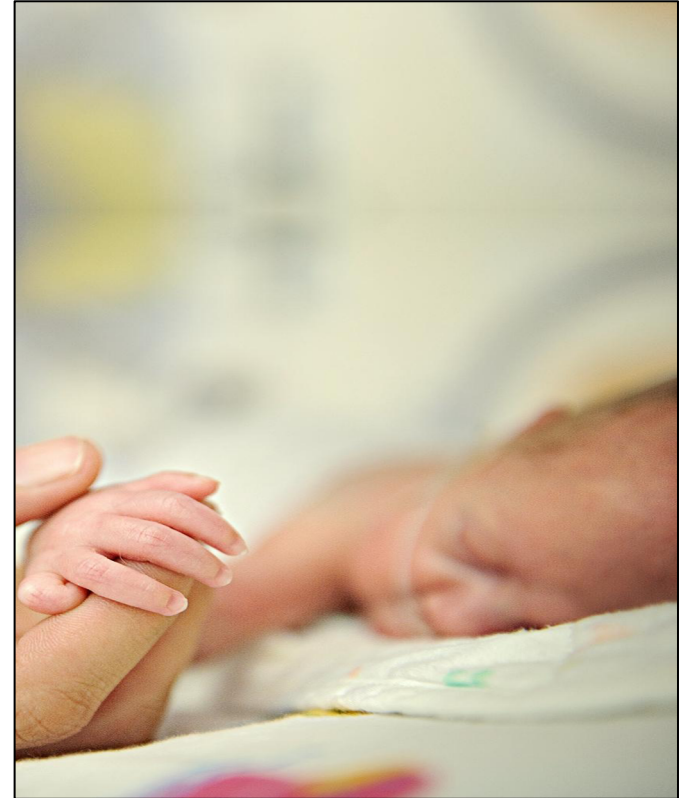
If time to SFT is increased by 1 day we observe a 7.65% increase in the risk of getting NEC

	Estimate	P-Value
Confirmed NEC Events	1.0765	0.0002
Late Onset Sepsis	1.0671	0.0001
Bronchopulmonary Dysplasia	1.0275	0.0360
Days with Antibiotic Use	1.0585	<0.0001

- Well functioning GI tract is essential for growth and development of the baby
- A shortening of time to SFT reduces the risk of serious complications

First Pharmaceutical Grade Probiotic

IBP-9414 on a mission to become the
first pharma grade probiotic to
prevent life threatening infant
diseases including NEC and sepsis
by promoting healthy GI development



Pharma Grade - for Most Vulnerable Patient Population

Different Burden of Proof

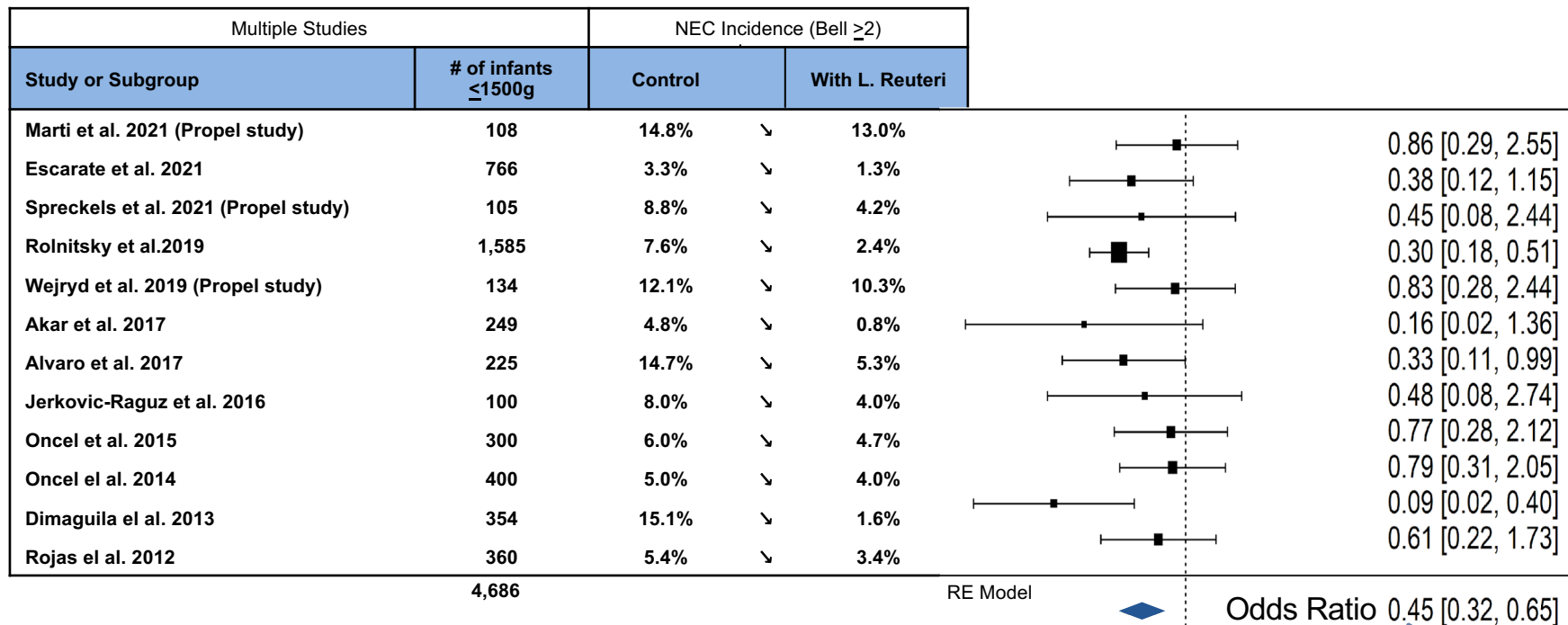
	Drugs	Supplements
Proof of Safety	Required	Not Required
Proof of Effectiveness	Required	Not Required
Good Manufacturing Practices (GMPs)	Pharmaceutical GMPs	Food GMPs
Post-Marketing Surveillance	Required	Not Required
Payer Reimbursable	Yes	No
Disease Treatment Claims	Yes	No

Drugs: considered unsafe until proven safe.

vs

Supplements: considered safe until proven unsafe.

Phase III Probability of Success - NEC



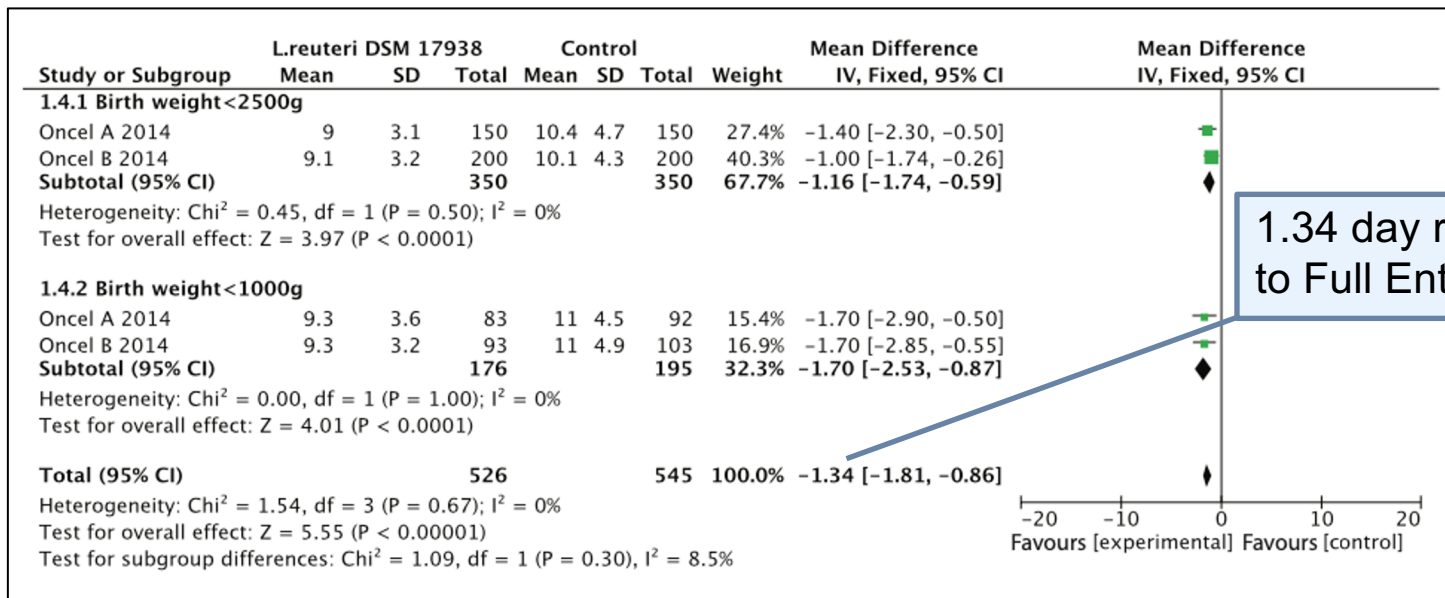
IBP-9414 phase III is powered for a smaller effect size, a 40% reduction of NEC.



55% of NEC cases prevented

* 90% Power

Phase III Probability of Success - SFT



IBP-9414 powered to demonstrate as little as a 1.00 day reduction

HCP Interest in Live Bacteria growing

While concerns remain around regulation



Increasing Data and Clinical Experience Suggesting Benefit of Live Bacterial Tx



Broadening Interest Given Inclusion in Society Guidelines and Conferences

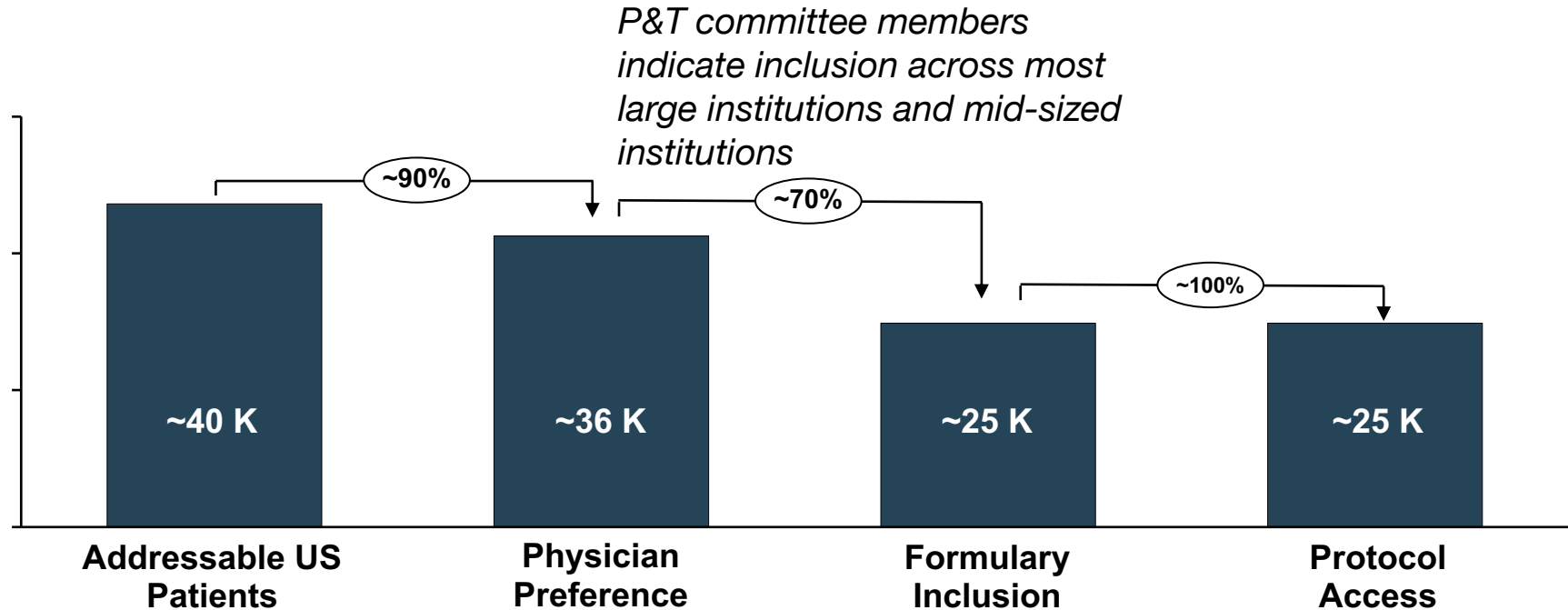


Higher Comfort Given Broad Live Bacterial Tx Use in the EU



Desire for FDA Regulation and RCT Data

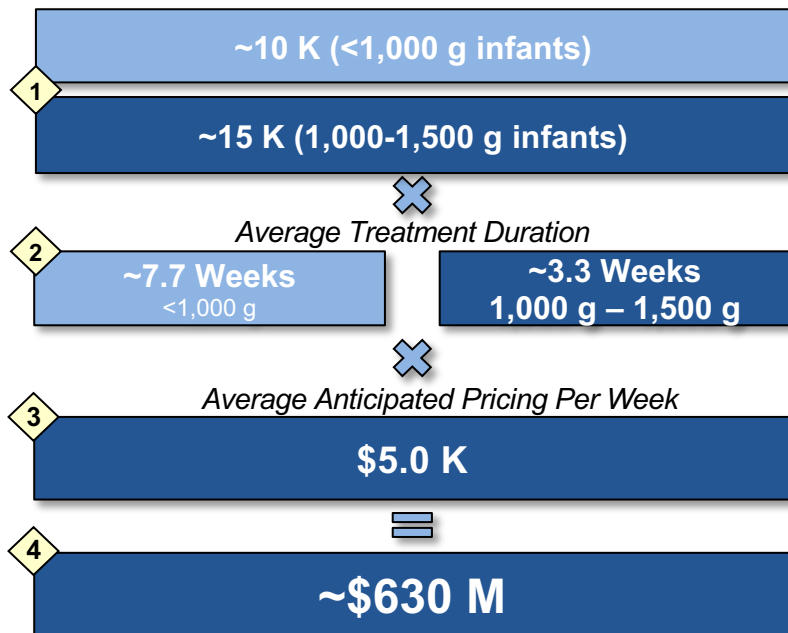
Broad Utilization of IBP-9414



25K Treated US Patients Expected to Generate \$630M Peak Sales

IBP9414 Commercial Opportunity

Patients Treated with IBP-9414



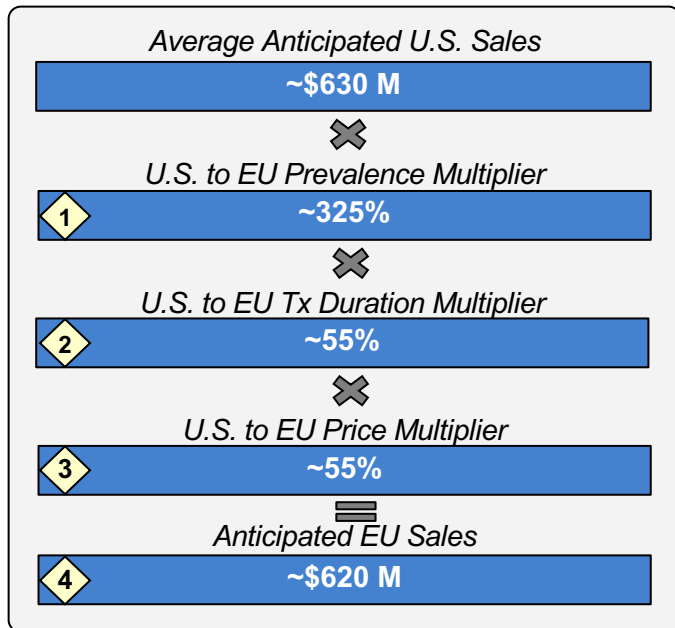
Key Considerations

- 1 25K patients treated with full access in two weight cohorts
- 2 Treatment durations of ~7.7 and ~3.3 weeks expected (overall 5.6 weeks average), based on physician preference
- 3 Anticipated pricing of \$3K was thought to be acceptable for the NEC alone. Now price sensitivity for a + SFT profile was performed
- 4 US Sales estimated to be ~\$630M

Overall EU Revenue Potential Similar to the US

EU label broader than US; <34Weeks babies in EU vs. $\leq 1500g$ in the USA

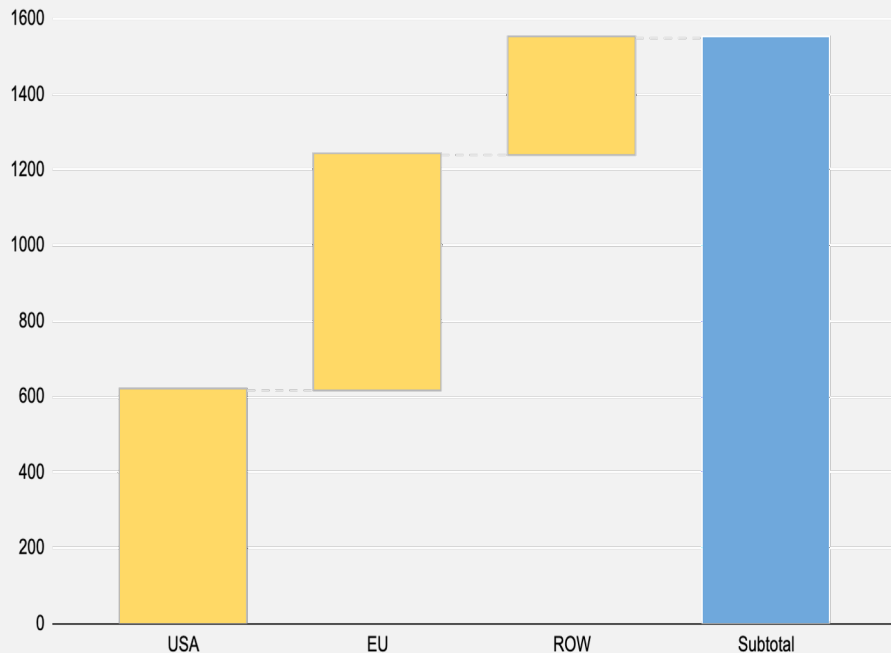
Projected EU Revenue Potential



Key Considerations

- 1 EU preterm prevalence of 2.8% of 4.7M births = 130K treatable patients, ~325% multiplier vs 40K in the US
- 2 EU average treatment duration is 3.1 weeks compared to US 5.6 weeks, ~55% multiplier
- 3 Evaluation of EU to US pricing analogues (e.g. surfactants) motivates a ~55% multiplier
- 4 EU Sales estimated to be ~\$620M

Megabrand Potential >\$1.5B Peak Sales*



→ Triple layer IP protection

1) data exclusivity

2) patent protection

3) orphan drug status

→ ≥12 years exclusivity
across EU, US, Japan and
China

* New market research conducted 2021. ROW estimated at 50% of EU

IBP Development Progress

CMC Established

Phase II
Completed

Phase III
Underway

Stringent
manufacturing
requirements

Specifications
include test for 27
pathogens in line
with US and EU
pharmacopeia

Safety and
tolerability
demonstrated in
2017

Progressing in 10
countries to demonstrate
efficacy

NEC
prevention

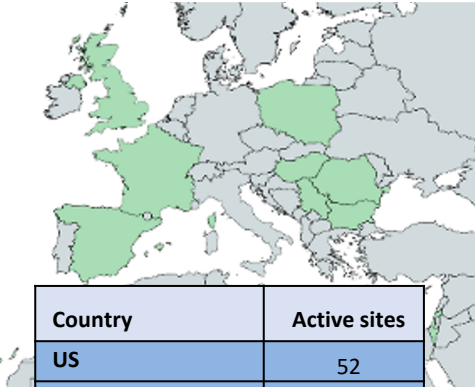
Shortening
of time to
SFT

Randomization milestone >750 subjects



Top 10 recruiters

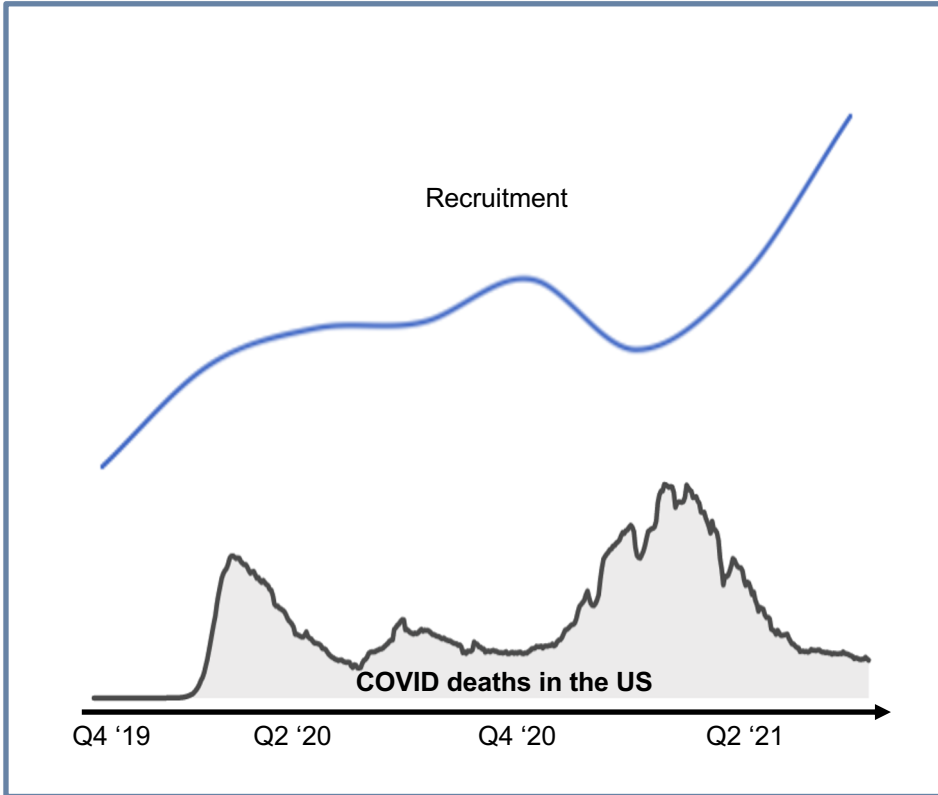
Site	Team
St. Joseph's Womens Hosp.	Ferry
Univ. Miami Holy Cross Hospital	Del Moral
Univ. Tennessee Health Science CTR	Talati
Debrecen Univ. Clinic center	Nagy
Jackson Madison CTY Gen. Hosp.	Guthrie
Univ. Mississippi Medical CTR	Famuyide
Wake Forest Baptist Health	Porcelli
Beth Israel Deaconess Med. CTR	Frantz
Helen Devos Children's Hosp.	Doctor
Univ. Arkansas for Med. Services	Chowdhary



Country	Active sites
US	52
Hungary	7
Bulgaria	4
Spain	6
Romania	5
France	3
Poland	4
Israel	2
UK	2
Serbia	0
Total	85

Correlation between Recruitment Speed and Covid Progress

Covid has had a demonstrated impact – Omicron mutation impacts the recruitment



-Scenario 1!

Covid goes away quickly, recruitment increases and recruitment completes in 2022

-Scenario 2!

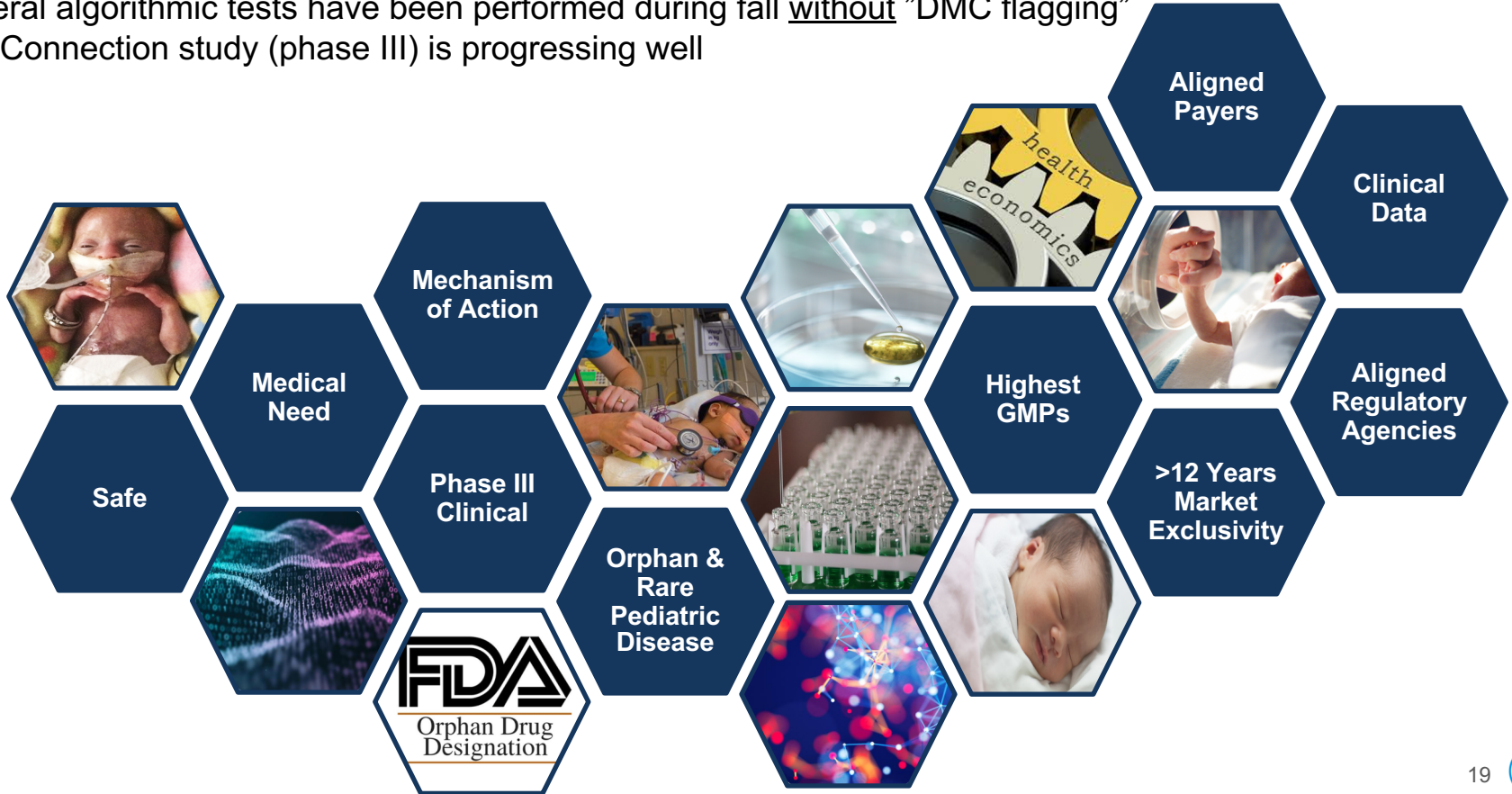
Current Covid disruptions go away slowly and come back after summer with fear for mutations....as a result recruitment picks up but is then reduced again in fall, recruitment completes in 2023

-Scenario 3!

Covid impacts the healthcare systems for extended period, resulting in recruitment through 2023 into 2024

IBP-9414 our lead Phase III program

- Validation of our SFT endpoint finished
- Several algorithmic tests have been performed during fall without "DMC flagging"
- The Connection study (phase III) is progressing well



Gastroschisis IBP-1016: A Potential New Indication

Significant unmet need

- 2,000 diagnosed US infants per year
- Post surgery: gut motility is absent, and oral feeding not tolerated for extensive period
- Serious comorbidities including growth retardation, sepsis (31%), NEC (5%) and in hospital mortality (3.6%)
- High economic burden with hospital stay estimated at \$200-\$300M (20-30 days at \$5K per day for 2,000 infants)



Synergies with IBP-9414

- Same API (Lactobacillus reuteri)
- Both conditions in need of gut moving and functioning more quickly
- Adjacent patient target population
 - IBP-9414 targets <1500g Bwt / GA 23-32 weeks
 - IBP-1016 targets ~2500g Bwt / GA ~35 weeks
- Orphan drug potential
- Potential additional IP protection / biologics

Key Future Milestones



2022-2023

- Identify partnering distribution
- Prepare the market and key influencers
- Complete plan for production and distribution

- Validate manufacturing process
- Complete Phase III clinical results
- Build launch team and organization

- Validate commercial IBP-1016 commercial and regulatory pathway
- Launch IBP-9414 following regulatory approval



Thank you

Infant Bacterial Therapeutics AB

www.ibtherapeutics.com