



## Australian Biologics Festival 2024

Melbourne, Australia, February 21, 2024: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to advise our Research & Development Manager, Joanne Casey, PhD will be presenting at the Australian Biologics Festival 2024 on Wednesday, 21<sup>st</sup> February in Melbourne, Australia.

A copy of the presentation being made is included below.

Authorised for release by the Board of Immuron Limited.

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### COMPANY CONTACT:

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### About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting traveller's diarrhoea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tabletised preparation of hyperimmune bovine antibodies and other factors, which when taken with meals bind to diarrhoea-causing bacteria and prevent colonisation and the pathology associated with traveller's diarrhoea. In Australia, Travelan® is a listed medicine on the Australian Register for Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Traveller's Diarrhoea, reduce the risk of minor gastrointestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Traveller's Diarrhoea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

### About Traveller's Diarrhoea

Traveller's Diarrhoea is a gastrointestinal infection with symptoms that include loose, watery (and occasionally bloody) stools, abdominal cramping, bloating, and fever. Enteropathogenic bacteria are responsible for most cases, with enterotoxigenic *Escherichia coli* (ETEC) playing a dominant causative role. *Campylobacter* spp. are also responsible for a significant proportion of cases. The more serious infections with *Salmonella* spp. the bacillary dysentery organisms belonging to *Shigella* spp. and *Vibrio* spp. (the causative agent of cholera) are often confused with Traveller's Diarrhoea as they may be contracted while travelling and initial symptoms are often indistinguishable.

### About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian biopharmaceutical company focused on developing and commercialising orally delivered targeted polyclonal antibodies for the treatment of infectious diseases.

For more information visit: <http://www.immuron.com>

### FORWARD-LOOKING STATEMENTS:

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to



risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.



## 2<sup>ND</sup> AUSTRALIAN BIOLOGICS FESTIVAL 2024

### NAVIGATING NEW HORIZONS: TRAVELAN<sup>®</sup> MARKET EXPANSION INTO THE USA

STRATEGIC COLLABORATIONS, PARTNERSHIPS  
AND CLINICAL TRIALS

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JERRY KANELLOS, PhD  
Chief Scientific Officer

Presented by:  
JOANNE CASEY, PhD  
R&D Manager

NASDAQ: IMRN  
ASX: IMC



# SAFE HARBOR STATEMENT

Certain statements made in this presentation are forward-looking statements and are based on Immuron's current expectations, estimates and projections. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward-looking statements.

Although Immuron believes the forward-looking statements are based on reasonable assumptions, they are subject to certain risks and uncertainties, some of which are beyond Immuron's control, including those risks or uncertainties inherent in the process of both developing and commercializing technology. As a result, actual results could materially differ from those expressed or forecasted in the forward-looking statements.

The forward-looking statements made in this presentation relate only to events as of the date on which the statements are made. Immuron will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.

FY2024 results in this presentation are subject to audit review.





# TOPICS

## Introduction

- Immuron's Pipeline Technology
- Travelan – commercial product

## Partnering with US Department of Defense (DoD)

- History of collaborations
- DoD funding

## Commercial pathway of Travelan® in the US

- FDA clinical pathway to BLA
- Scale-up Product Development
- Current status and future

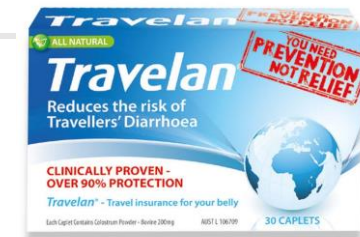


*Immuron Ltd is a globally integrated biopharmaceutical company focused on developing, and commercialising, oral immunotherapeutics for the treatment of gut mediated diseases*

Dual listed (ASX:IMC) (NASDAQ:IMRN)

## Company Overview

- Platform Technology: capable of producing highly specific **orally active immunoglobulins** to any enteric pathogen
- Two commercially available oral immunotherapeutic products – **Travelan®** and Protectyn®
- Three pipeline assets in four clinical programs

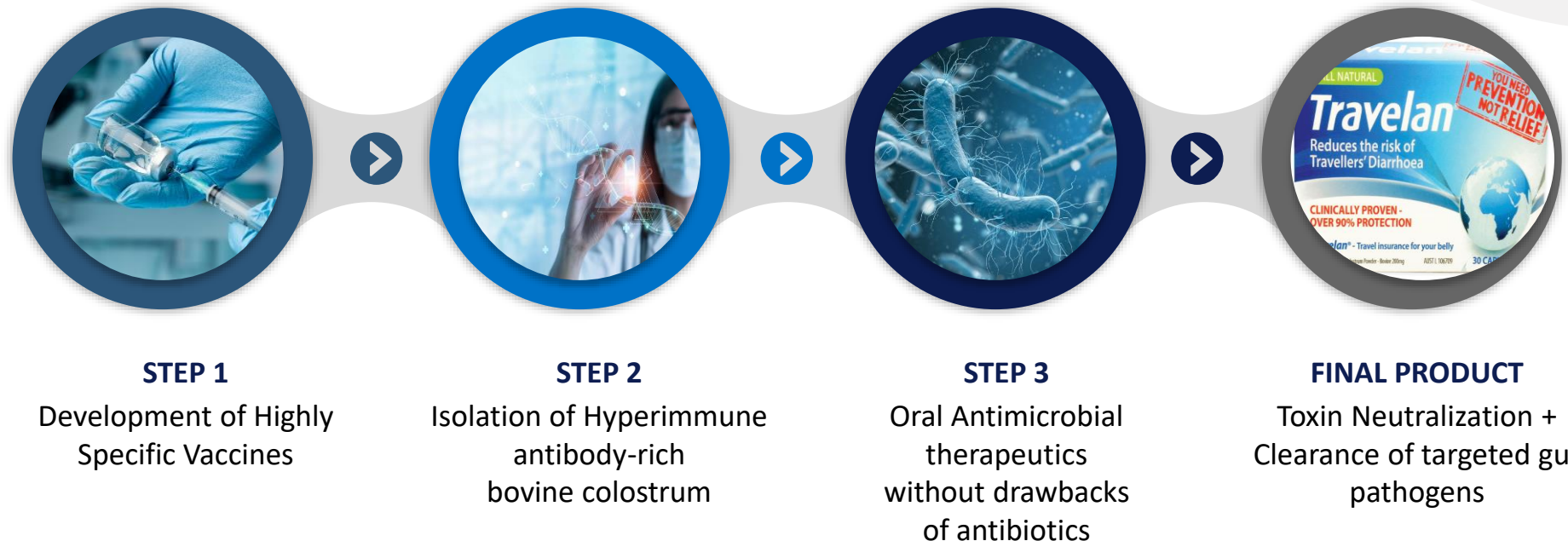




# PLATFORM TECHNOLOGY

Bovine colostrum is the first milk of cows after calving. It is rich in immunoglobulins, lactoferrin, lysozyme, lactoperoxidase, growth factors and bioactive peptides. Colostrum has higher levels of protein, fat, vitamins, and minerals when compared to milk. This enables full development of the newborn calf in addition to immunity against several pathogens.\*

Immuron's proprietary technology platform ***combines the natural human nutrition & health benefits of bovine colostrum with a novel class of specifically targeted oral polyclonal antibodies*** that offer delivery within the gastrointestinal ("GI") tract and can be used to target viruses or bacteria and neutralize the toxins they produce at mucosal surfaces.





# INTELLECTUAL PROPERTY

Due to the practical nature of the technology used to produce our products, the company retains a significant amount of know-how and other unregistered intellectual property which presents significant hurdles to competitors in producing the same products. The company has a policy of actively in-licensing and filing upon new technology that relates to all relevant business objectives.

Immuron currently has a suite of patents either approved or pending that cover the full spectrum of its Technology Platform.

## METHODS AND COMPOSITIONS FOR THE TREATMENT AND/OR PROPHYLAXIS OF CLOSTRIDIUM DIFFICILE ASSOCIATED DISEASE

Granted (Expiry: April 17, 2034): Australia, New Zealand, Canada, USA, Belgium, France, Germany, Italy, Netherlands, Spain, Switzerland, United Kingdom

Pending: China

## COMPOSITION AND METHOD FOR THE TREATMENT AND PREVENTION OF ENTERIC BACTERIAL INFECTIONS

Granted (Expiry: February 25, 2028): USA

Granted (Expiry: March 4, 2024): Australia, Canada, India, New Zealand, Austria, Denmark, Finland, France, Germany, Greece, Spain, Sweden, United Kingdom



# BILLION DOLLAR MARKET - INDUSTRY OVERVIEW



## Billion Dollar Market

Travellers' diarrhoea treatment market is large and growing at a CAGR of ~7%



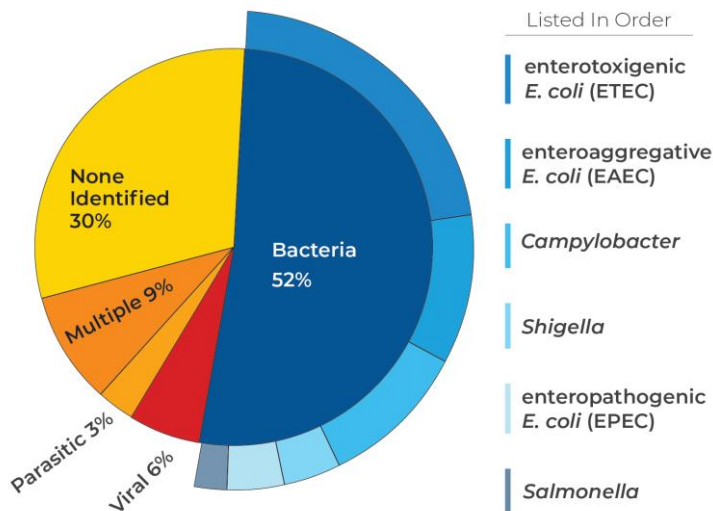
## Industry tailwinds

Travel picking up significantly following COVID lockdowns



## Frequent Symptoms

30% - 70% of travelers experience travellers' diarrhoea<sup>1</sup>



- There are no current reliable vaccines for prevention of Travellers' diarrhoea<sup>1</sup>
- Enterotoxigenic *Escherichia coli* (ETEC) is the leading cause of Travellers' diarrhoea<sup>1</sup>
- Travelan® is a hyperimmune bovine colostrum produced by immunization of cows during gestation with a vaccine consisting of antigens derived from 13 different ETEC strains known to cause Travelers' diarrhea
- Travelan® is broadly cross-reactive with other ETEC strains not included in the vaccine and other gram-negative bacteria (*Shigella*, *Vibrio cholera*, *Campylobacter spp.*)<sup>2,3</sup>



# Bioactivity and efficacy of a hyperimmune bovine colostrum product - Travelan, against shigellosis in a non-Human primate model (*Macaca mulatta*).

## Abstract

Infectious diarrhea is a World Health Organization public health priority area due to the lack of effective vaccines and an accelerating global antimicrobial resistance crisis. New strategies are urgently needed such as immunoprophylactic for prevention of diarrheal diseases. Hyperimmune bovine colostrum (HBC) is an established and effective prophylactic for infectious diarrhea. The commercial HBC product, Travelan® (Immuron Ltd, Australia) targets multiple strains of enterotoxigenic *Escherichia coli* (ETEC) is highly effective in preventing diarrhea in human clinical studies. Although Travelan® targets ETEC, preliminary studies suggested cross-reactivity with other Gram-negative enteric pathogens including *Shigella* and *Salmonella* species. For this study we selected an invasive diarrheal/dysentery-causing enteric pathogen, *Shigella*, to evaluate the effectiveness of Travelan®, both *in vitro* and *in vivo*. **Here we demonstrate broad cross-reactivity of Travelan® with all four *Shigella* spp. (*S. flexneri*, *S. sonnei*, *S. dysenteriae* and *S. boydii*) and important virulence factor *Shigella* antigens.** Naïve juvenile rhesus macaques (NJRM) were randomized, 8 dosed with Travelan® and 4 with a placebo intragastrically twice daily over 6 days. All NJRM were challenged with *S. flexneri* 2a strain 2457T on the 4th day of treatment and monitored for diarrheal symptoms. All placebo-treated NJRM displayed acute dysentery symptoms within 24–36 hours of challenge. Two Travelan®-treated NJRM displayed dysentery symptoms and six animals remained healthy and symptom-free post challenge; resulting in **75% efficacy of prevention of shigellosis (p = 0.014).**

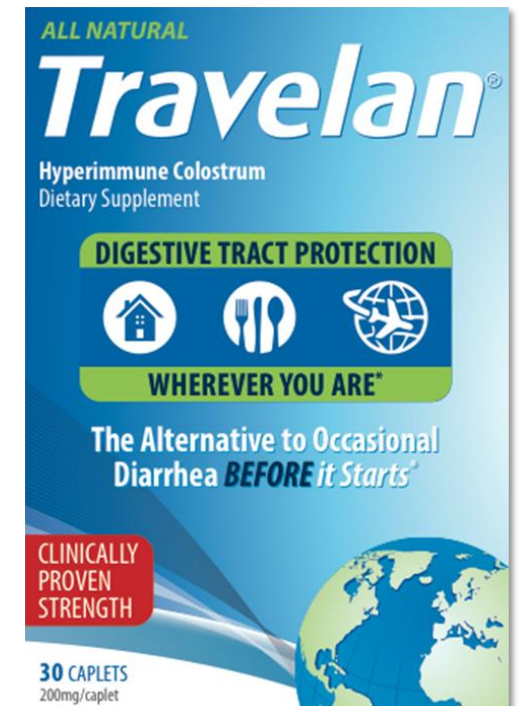
These results strongly indicate that Travelan® is functionally cross-reactive and an effective prophylactic for shigellosis. This has positive implications for the prophylactic use of Travelan® for protection against both ETEC and *Shigella* spp. diarrheal infections. Future refinement and expansion of pathogens recognized by HBC including Travelan® could revolutionize current management of gastrointestinal infections and outbreaks in travelers' including military, peacekeepers, humanitarian workers and in populations living in endemic regions of the world.

# TRAVELAN®

- Travelan® is a pasteurized, lactose-reduced, low-fat, high-protein colostrum powder which contains over 80% proteins by weight.
- Travelan® is enriched with anti-Enterotoxigenic *E.coli* (ETEC) antibodies (35-45% w/w), which target ETEC in the gastrointestinal tract
- Travelan® is a biological product intended to **prevent** Travellers' Diarrhoea without major alterations to the microbiome, unlike antibiotics
- Travelan® is the **world's first** listed medicine (2004) on the Australian Register for Therapeutic goods (TGA) indicated to **reduce the risk of Travellers' Diarrhoea** (AUST L 106709)
- Travelan® has been marketed in Canada since 2013 as a natural health product (NPN 80046016) indicated to reduce the risk of TD
- Travelan® has been marketed since 2015 in the US as a dietary supplement for digestive tract protection



Australian Packaging



USA Packaging

# TRAVELAN DISTRIBUTION CAPABILITY



	Australia	USA	Canada	
Retail Pharmacy	✓		✓	
B2B	✓	✓	✓	✓ Established
E-commerce	✓	✓	✓	✓ Developing

## Key Commentary

### Australia

- Retail network includes over 3,500 pharmacies
- Online sales of both [Travelan®](#) and [Protectyn®](#)
- Protectyn® is distributed by [Osborne Health Supplies](#)

### USA

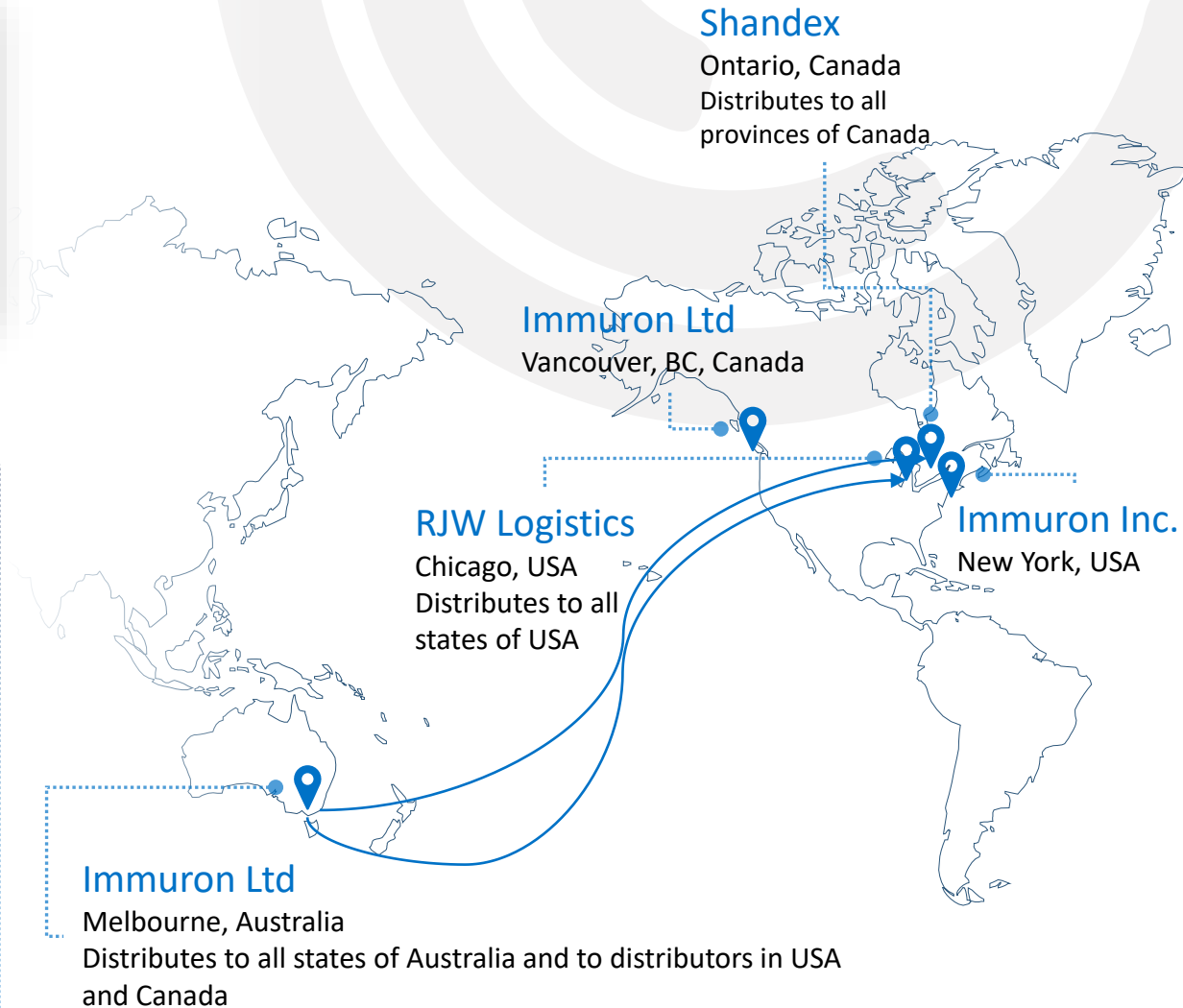
- Travelan® is sold to travel medicine clinics and on our own [amazon.com](#) shopfront (launched July 2023)

### Canada

- We re-launched in January 2024

### International

- We are evaluating options to enter international markets through distributors





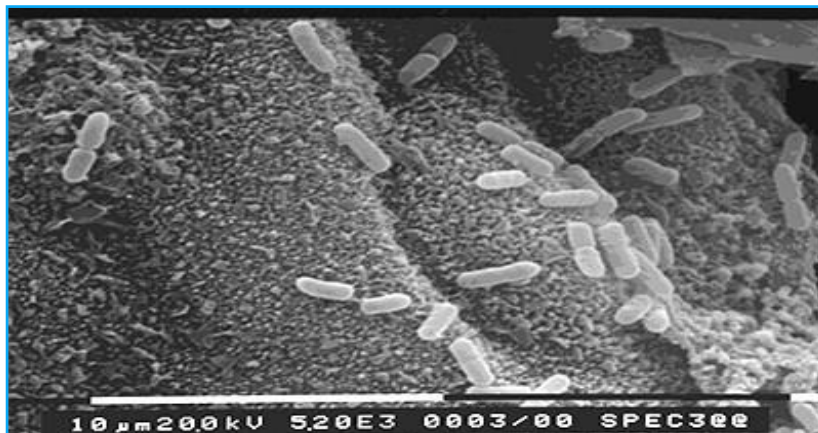


# TRAVELAN – MECHANISM OF ACTION

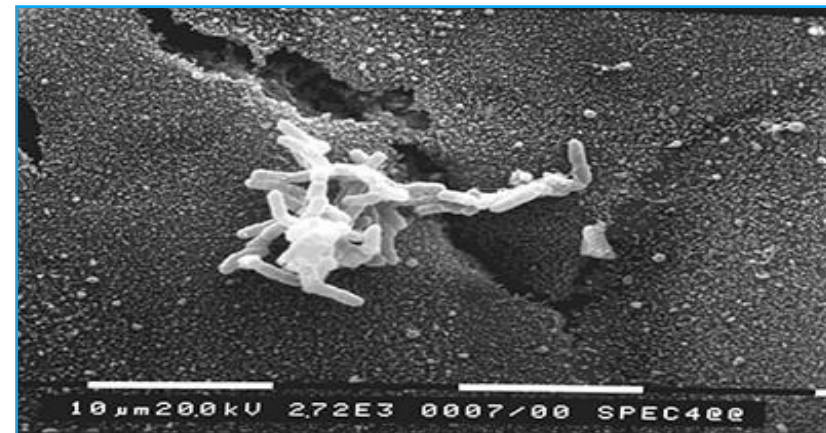
## Pre-Clinical Studies

- Broad spectrum antimicrobial (gram negative bacteria)
- Protects against bacterial adhesion to host cell intestinal epithelia
- Caesin and other colostrum proteins are known to protect the antibodies from the acid environment of the stomach
- Binds to surface layer proteins preventing bacterial colonization and motility
- Toxin neutralization and clearance of targeted gut pathogens

**Without Travelan®:** Bacteria attach to gut wall and infect



**With Travelan®:** Bacteria neutralized by Travelan® antibodies





# TRAVELAN® MANUFACTURING



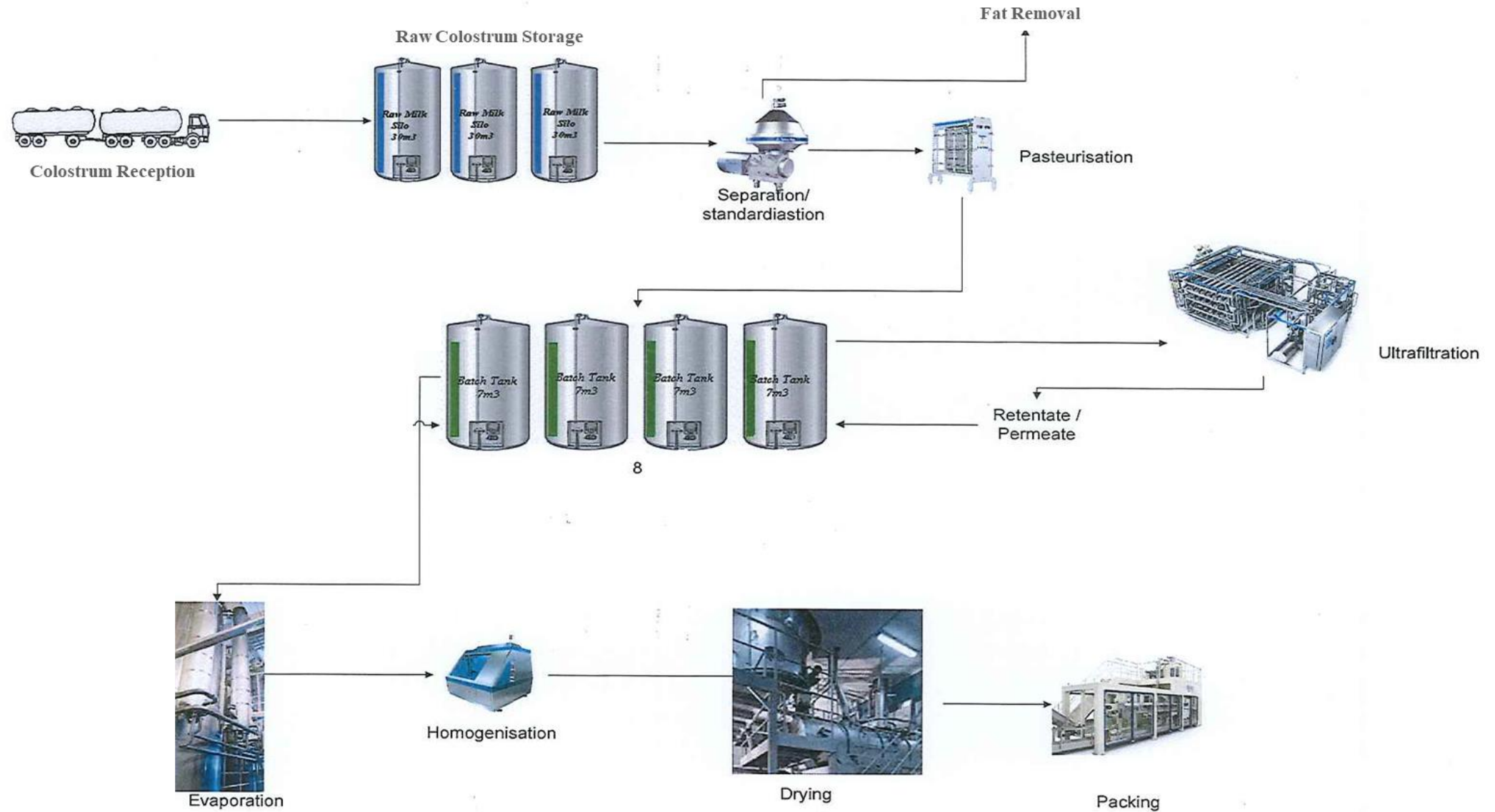
## Vaccine

- Manufacture involves proprietary shearing technology developed to harvest cell surface antigens from 13 Enterotoxigenic *E. coli* (ETEC) strains known to cause Travelers' diarrhea
- Approved by performing a risk assessment for use in food-producing animals with the Australian Pesticides and Veterinary Medicines Authority (APVMA)
- Manufactured under Good Manufacturing Practice (GMP) in a facility licensed by the APVMA

## Colostrum

- Colostrum is collected from cattle on dairy farms using GMP-compliant collection and Manufacturing methods, using Australian Dairy Industry approved procedures and FDA guidelines
- Manufacturing Process: i) pasteurization, ii) separation of fat, iii) ultrafiltration to reduce lactose and concentrate the product, and iv) spray-drying to produce a stable colostrum powder milled to 100 microns
- No chemical additives are used in the manufacturing process
- Colostrum Product analyzed for safety under Codex Alimentarius and FDA regulations for human consumption

# MANUFACTURING TRAVELAN® - DRUG SUBSTANCE





# MANUFACTURING – TRAVELAN® DRUG PRODUCT

- Tablets packaged in unit-dose blister packs containing 200 mg of bovine colostrum formulated as a 700 mg solid oral dose tablet with non-novel excipients
- All excipients are within regulations of United States Pharmacopeia and National Formulary
- Product specifications include i) IgG content, ii) antibody ETEC titer, iii) metal content iv) microbiological sterility analysis
- Current FDA CMC requirements for Phase 2 Biologics (CBER)

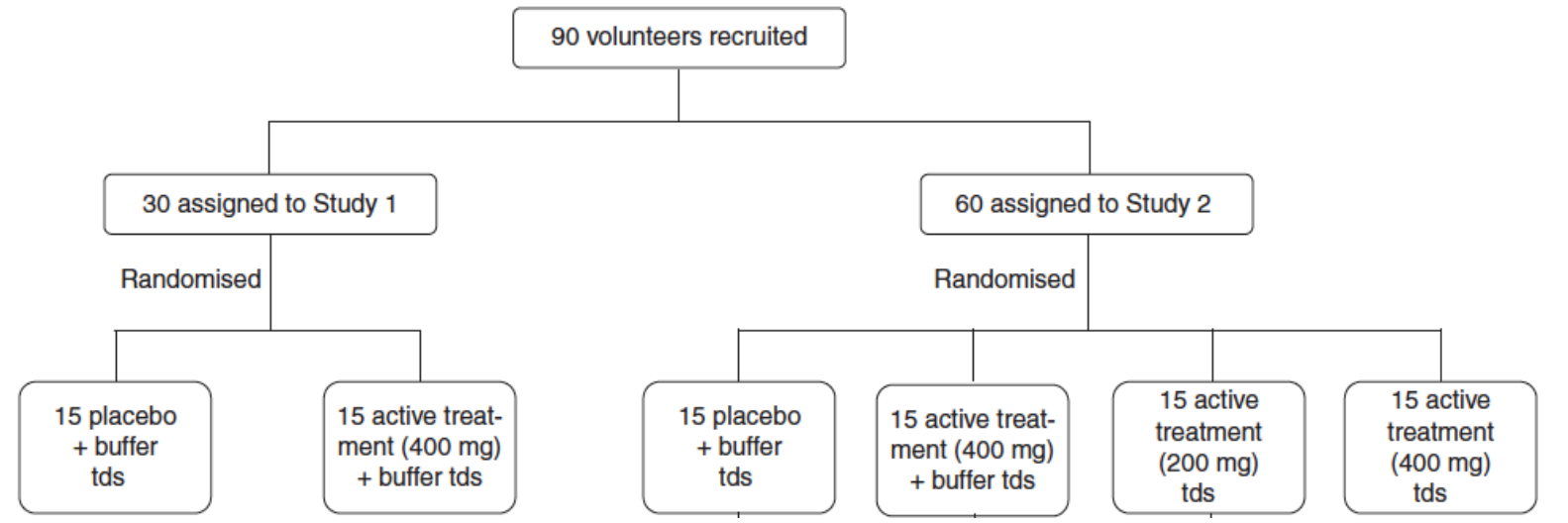
## Stability data

- 25°C - 48 month (real-time)
- 40°C / 75% RH – 12 month (real-time)
- Long term -20°C/4°C (real-time)



# TRAVELAN® SAFETY AND EFFICACY

- Randomised, double-blind, placebo-controlled human infection model studies
- Travelan or placebo 200-400mg 3 times daily for 7 days
- Challenge with ETEC 2 days after dosing



	Treatment Group		
	Placebo	Colostrum	p
Number of volunteers	15	15	
Number of volunteers with diarrhea	11 (73%)	1 (7%)	0.0005
Number of diarrheal stools/volunteer (mean ± SEM)	4.4 ± 0.9	0.4 ± 0.4	0.0004
Mean number of diarrheal stools per volunteer with diarrhea (mean and range)	6 (2 – 8)	6 (6)	NS
Abdominal pain	5 (33%)	0 (0%)	0.04
ETEC H10407 isolated from feces after challenge	15 (100%)	12 (80%)	NS

\*Fisher's exact test or Student's t-test (two-tailed) as appropriate. NS, not significant.

	Treatment group			
	Group 1: Placebo tid	Group 2: Colostrum 400 mg tid + buffer	Group 3: Colostrum 200 mg tid	Group 4: Colostrum 400 mg tid
Number of volunteers	14	14	14	15
Number of volunteers with diarrhea	12 (86%)	2 (14%), $p = 0.0004^*$	5 (36%), $p = 0.02$	3 (20%), $p = 0.007$
Number of diarrheal stools/volunteer (mean ± SEM)	3.9 ± 0.8	0.5 ± 0.3, $p = 0.0005$	1.8 ± 0.8, $p = 0.07$	0.9 ± 0.5, $p = 0.003$
Mean number of diarrheal stools per volunteer with diarrhea (mean and range)	5 (3–10)	3.5 (3–4)	5 (2–7)	4.7 (2–7)
Abdominal pain	5 (36%)	0 (0%), $p = 0.04$	2 (14%), $p = 0.04$	0 (0%), $p = 0.02$
ETEC H10407 isolated from feces after challenge	12 (86%)	14 (100%)	14 (100%)	12 (80%)

\*All tests of significance compared the results of active treatment with the placebo group and were calculated by using Fisher's exact test or Student's t-test (two-tailed) as appropriate.

**84% to over 90% prophylactic efficacy in the Travelan® treatment arm**



# TRAVELAN® SAFETY

- Travelan® is well tolerated and has been administered orally in over 500 subjects in clinical trials with doses up to 4.8 g per day for 28 days with no treatment related Serious adverse events (SAEs)
- Clinically evaluated in Children (6 to 19 years of age)
- Pharmacovigilance has reported no product related SAEs to date
- Reported Adverse Events (AEs) are mild in severity (abdominal discomfort, bloating, constipation, flatulence, nausea and occasionally diarrhea (usually related to lactose intolerance)

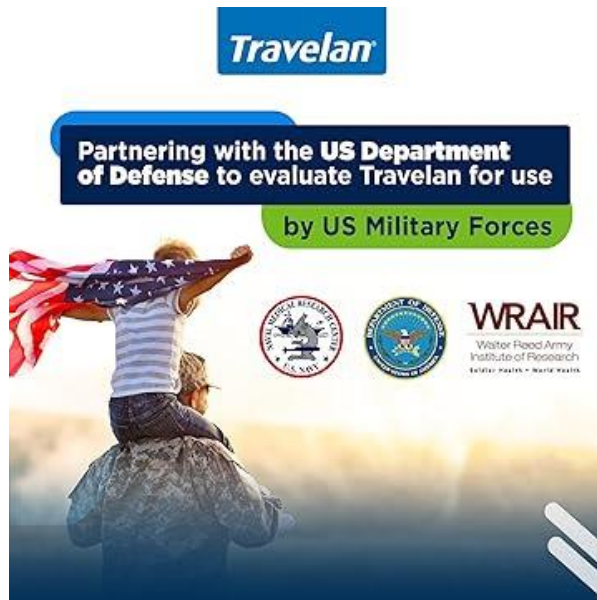


# NEW HORIZONS EXPANSION INTO THE US

1. Collaboration with the US Department of Defense (DOD)
2. FDA Clinical Pathway to approval of a listed medicine
3. Immuron distribution and expansion plans



# TRAVELERS' DIARRRHEA AND THE US MILITARY



**Diarrhea ranked 1<sup>st</sup> among 57** infectious disease threats by the 2019 Military Infectious Disease Research Program's Infectious Disease Threat Prioritization Panel based on its impact to readiness.

Bacterial pathogens are the predominant risk, thought to account for the majority of traveler's diarrhea.

76% of Soldiers in OIF and OEF experienced traveler's diarrhea early in their deployment.

The threat of diarrhea will only grow as the effectiveness of antibiotics continues to diminish.

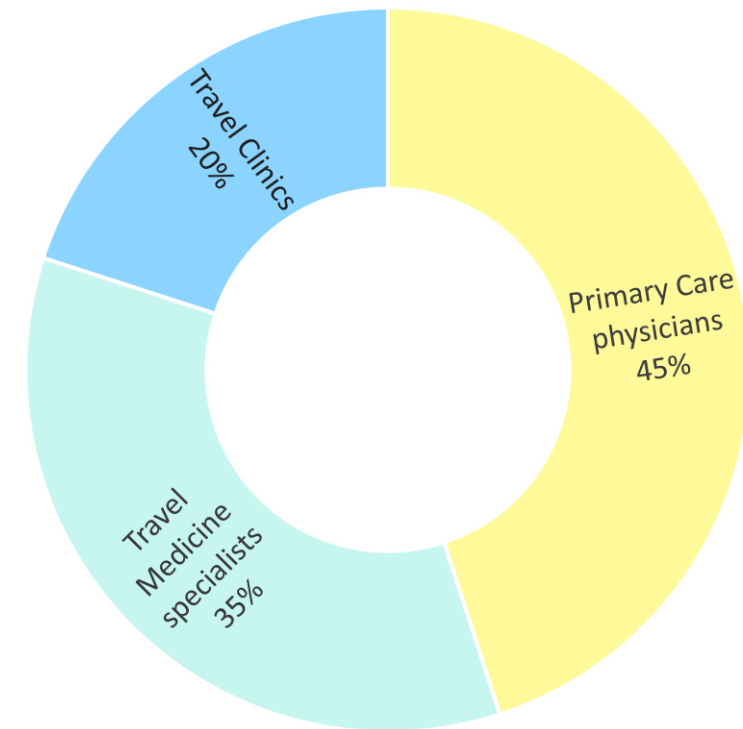
Olson et al. "Tropical Diseases, Travel Medicine and Vaccines, 2019, 5:1-15 Page 3



# TRAVELERS' DIARRHEA – CURRENT MANAGEMENT IN THE US

- The literature indicates that overall, ~50% of US travelers to remote or less developed countries seek pre-travel guidance. Advice from physicians, travel clinics, pharmacists, or other source.
- Physicians' **standard protocol** for a patient traveling to a high-risk area is the **prescription of a 5-day course of an antibiotic** (typically ciprofloxacin or azithromycin) for the patient to fill and take if symptoms develop (e.g., diarrhea, fever).
- Concerned travelers are prescribed antibiotics to be taken prophylactically

Resources for Travelers Seeking Advice





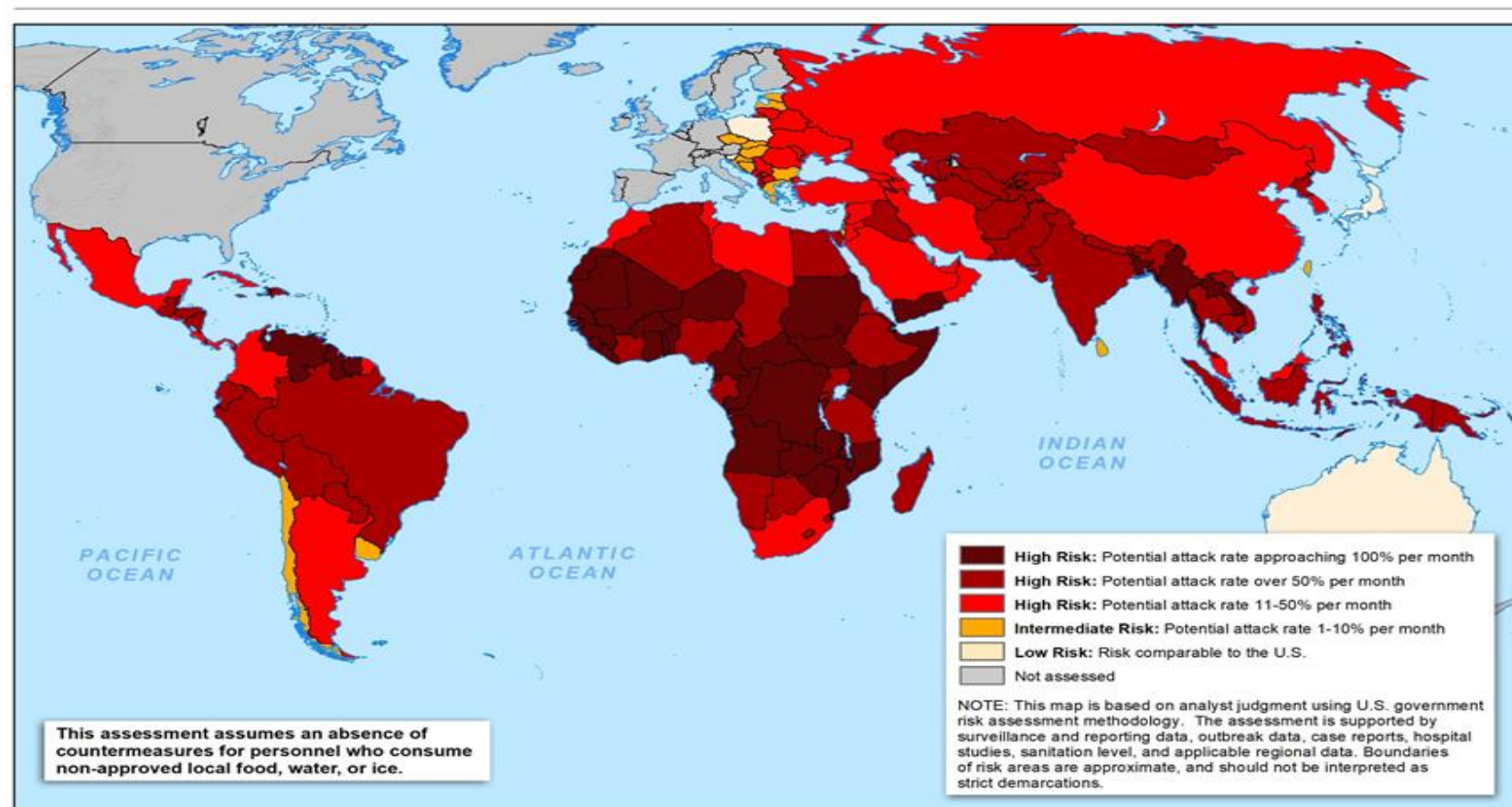
# US MILITARY – TRAVEL AND RISK



## Key Commentary

- **US Military Infectious Diseases Research Program (MIDRP)**
- The mission of the MIDRP is to plan, coordinate and oversee for the US DOD requirements-driven medical solutions that **PREVENT, PREDICT, and TREAT** infectious diseases threats
- Diarrheal disease is the leading infectious threat facing deployed U.S. Military
- Effective vaccines are the most suitable preventive measure for infectious diarrheal diseases but there are no licensed products available
- Enteric countermeasure products need to provide protection against military-relevant enteric pathogens

Worldwide: Bacterial Diarrhea Risk to U.S. Forces



UNCLASSIFIED

Boundary representation is not necessarily authoritative

17 May 19

US Military Map – worldwide risk to US forces, APIS/I-92 MONITOR data (trade.gov)



# US DOD R&D COLLABORATIVE AGREEMENTS



	NMRC	AFRIMS	WRAIR	
Travelan® (ETEC)	✓	✓	✓	✓ Established
Campylobacter	✓			
Shigella	✓		✓	✓ Developing



## Key Commentary

- Immuron history of collaboration with NMRC **since 2015**
- R&D focused on diarrheal infectious agents: *Campylobacter*, enterotoxigenic *Escherichia coli* (ETEC) and *Shigella*
- Historically focused on human vaccine development
- Several vaccines are in clinical evaluation
- No licensed vaccine products currently available
- US DoD R&D efforts diversified to evaluate prophylaxis products



ARMED FORCES RESEARCH INSTITUTE OF  
MEDICAL SCIENCES (AFRIMS)



NAVAL MEDICAL RESEARCH COMMAND  
(NMRC)



UNIFORMED SERVICES UNIVERSITY  
(USU)





# US DOD R&D COLLABORATIONS



	NMRC	AFRIMS	WRAIR
Travelan® (ETEC)	✓	✓	✓
Campylobacter	✓		
Shigella	✓		✓



## Current clinical programs

✓ **Travelan® MTEC military grant (USD\$3.4M) phase 2 clinical study**  
[NCT05933525](#)

✓ **Travelan® - Uniformed Services University** field study 868 participants including deployed military [NCT04605783](#)

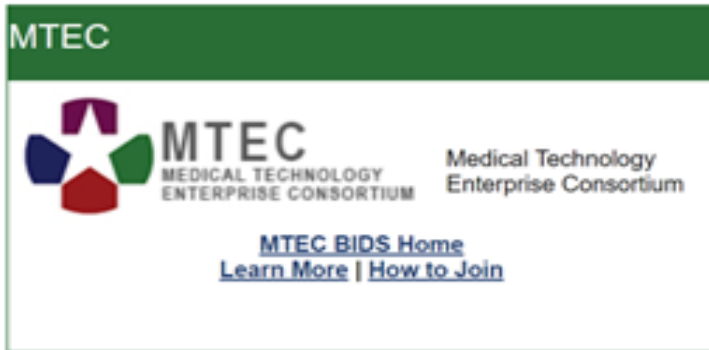
✓ **CampETEC (NMRC)** – clinical phase 2 *Campylobacter* challenge study  
[NCT06122870](#)



## Key Highlights

- Immuron partnered with AFRIMS, NMRC & WRAIR to analyze Travelan® specificity against Campylobacter, ETEC, Shigella and Vibrio cholera field samples (2016)
- Travelan® reacts with 180 pathogenic strains of bacteria from infected personnel deployed in Bhutan, Cambodia, Nepal and Thailand (ETEC, Shigella, Campylobacter)
- Travelan® binds to 71 different pathogenic strains of Vibrio cholera from infected personnel in Bangladesh, Cambodia, and Thailand
- Travelan® prevented the development of Shigellosis in 75% of non-human primates receiving therapy

# PARTNERING WITH US DEPARTMENT OF DEFENSE



## MTEC Membership

**Note: In order to respond to any solicitation on this site, you must be a member of the MTEC Consortium.**

Solicitations include awards from:

Military Infectious Diseases Research Program (MIDRP)  
Combat Casualty Care Research Program (CCCRP)  
Military Operational Medicine Research Program (MOMRP)  
Clinical and Rehabilitative Medicine Research Program (CRM RP)  
Medical Simulation and Information Sciences Research Program (MSISRP)

- **Join funding consortiums like MTEC** which the U.S. Army Medical Research and Development Command (USAMRDC) and other DoD agencies offer funding opportunities to members through solicitations called Requests for Prototype Proposals (RPPs): <https://mtec-sc.org/how-to-join/>
- **Register on the various U.S. Government / DoD grant funding platforms as a Nontraditional Defense Contractor:**  
<http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title10-section3014&num=0&edition=prelim>
- **The System for Award Management (SAM.gov) is an official website of the U.S. Government.** <https://sam.gov/content/home>
- There is no cost to use SAM.gov. You can use this site to:
  - Register to do business with the U.S. Government
  - Search for contract opportunities
  - Access publicly available awards
- **Understand the terms and processes, e.g.**
  - Technology Readiness Levels: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>
  - **Grant application and approval process:**  
<https://research.uga.edu/docs/units/dsc/MTEC-Proposal-Preparation-Guide.pdf>
- **Connect with DOD leadership** at USAMRDC and others like the US Military Infectious Diseases Research Program (MIDRP); key decision-making bodies for future solicitations; membership of MTEC facilitates this



# TRAVELAN<sup>®</sup>: MARKET EXPANSION IN THE US

Supported (in part) by MTEC

- Immuron is pursuing a regulatory pathway to license Travelan<sup>®</sup> with the FDA via a Biologics License Application (BLA) with a proposed indication to prevent TD induced by ETEC
- US DOD financial support (US\$3.4M) to fund part of this initiative and develop a dosing regimen acceptable for use by the military



**DRUG CANDIDATE**

**TRAVELAN<sup>®</sup>**

**Status with FDA:**

**IND 14933**

**IND 15675 / IND 17066**

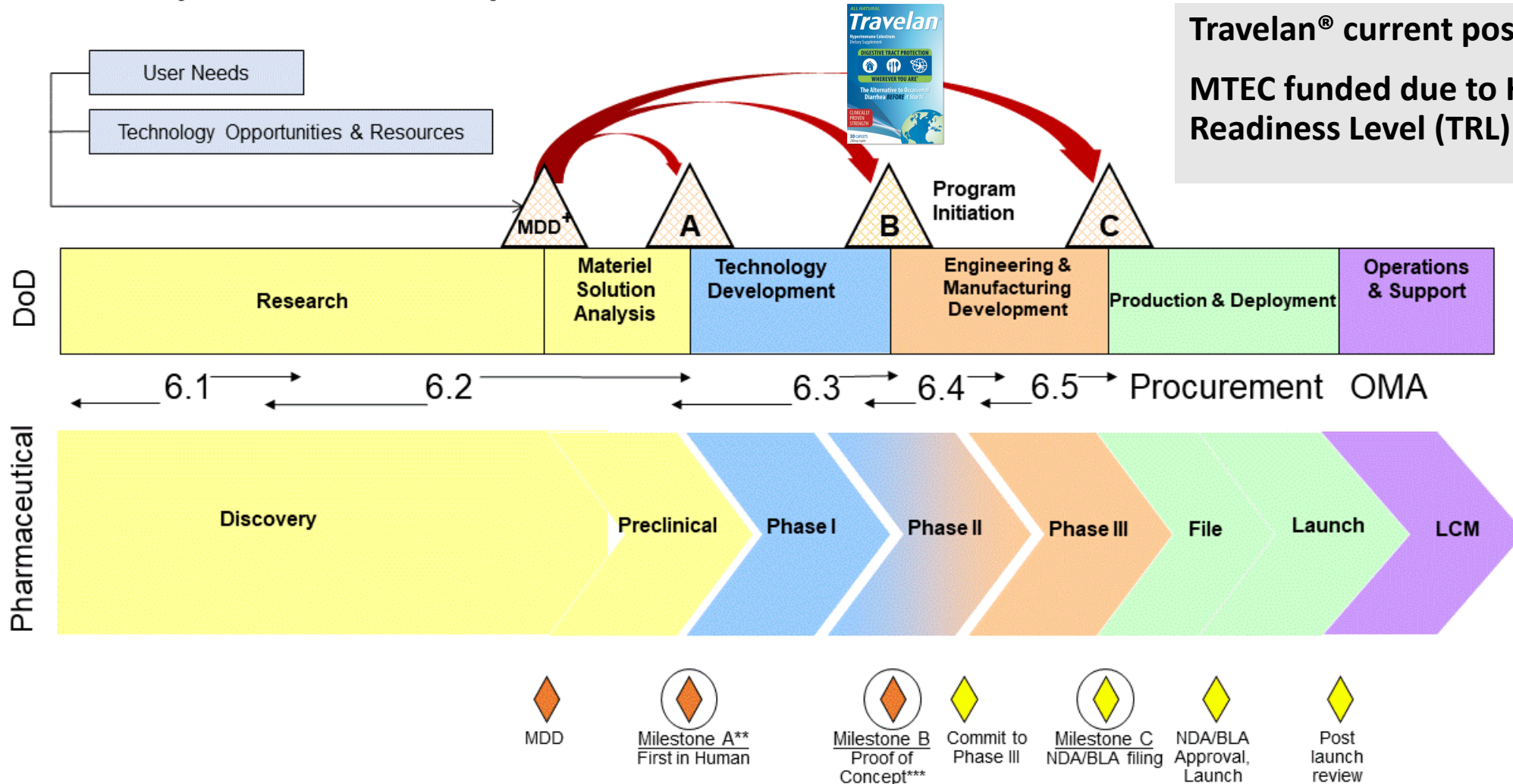


Plan to develop Travelan as an approved biologic in the US targeting travelers' diarrhea

# TRAVELAN® DRUG DEVELOPMENT PLAN

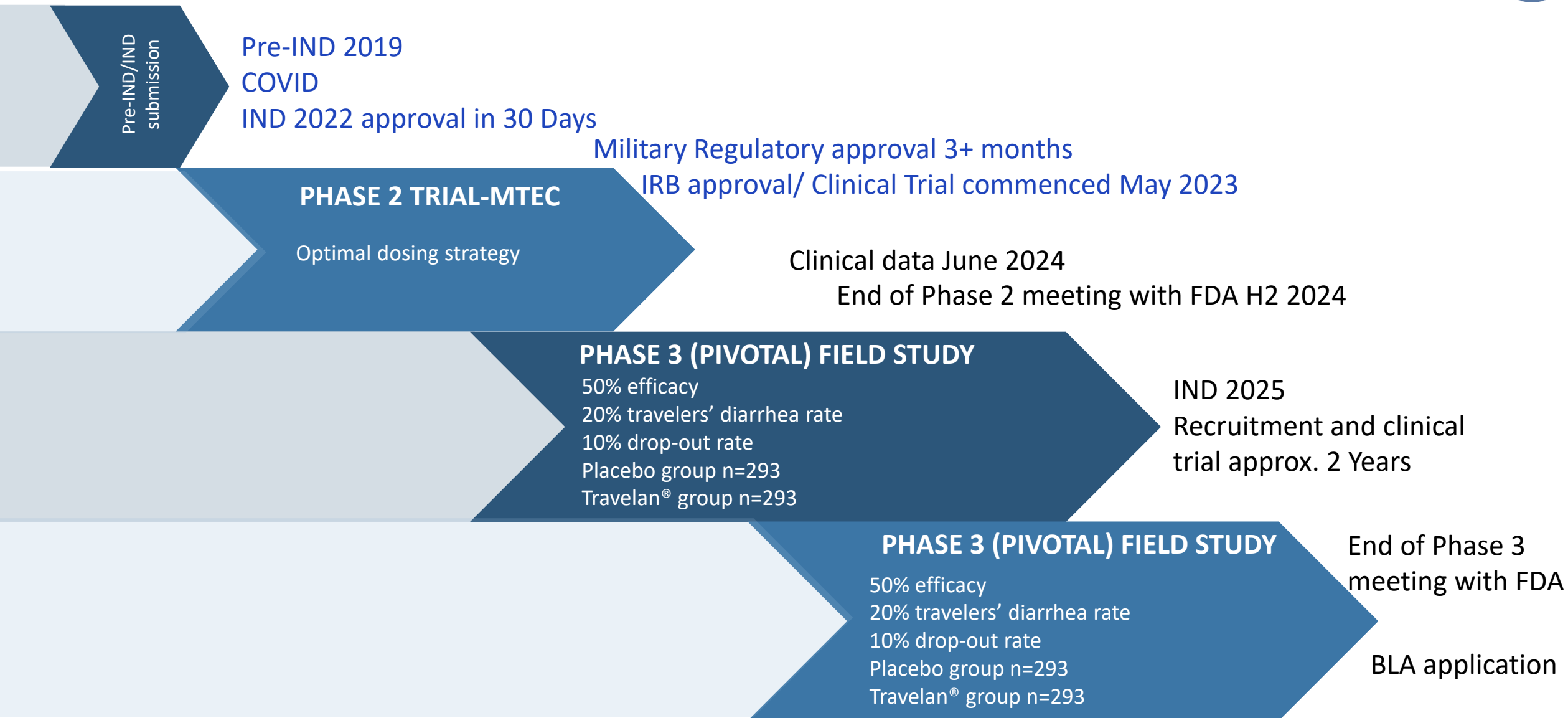


## Development Lifecycle - Overview



Travelan® current position Milestone B.  
MTEC funded due to High Technology  
Readiness Level (TRL) rating.

# OVERVIEW OF FDA LICENSURE PATHWAY







# COMPANY COMPETENCIES & MANUFACTURING AND DISTRIBUTION EXPANSION PLANS

- ✓ Immuron is the sole proprietary of the Travelan® product and associated intellectual property
- ✓ Strong US DoD collaboration
- ✓ Immuron has an international distribution network to ensure prompt delivery to deployed US military if necessary
- ✓ All Immuron's commercial operations involve suitably, qualified cGMP service providers that meet the regulatory requirements of the company's Quality Management Systems



# COMPETITOR MARKET ANALYSIS (US)

Drug	Indication	Dosing	Average cost: 2-week trip
PRESENTLY, THERE IS NO FDA-APPROVED DRUG TO <u>PREVENT</u> TRAVELERS' DIARRHEA			
TRAVELAN®	Dietary supplement	3 caps (200 mg) TID	\$29.57 – 30 caplets <sup>5</sup>
FDA-APPROVED DRUG TREATMENTS FOR DIARRHEA			
PEPTO BISMOL	Relief for heartburn, nausea, indigestion, upset stomach, and diarrhea	2 tabs QID	\$20.94 <sup>1</sup>
IMMODIUM	Decrease the frequency of diarrhea in TD, gastroenteritis, inflammatory bowel disease, and short bowel syndrome	2 tabs (2 mg)	\$22.00 <sup>2</sup> (2x24 caplets)
CIPROFLOXACIN	Bacterial infections	500 mg	\$59.92 <sup>3</sup> (2x 5-day supply)
RIFAXIMIN	Treatment of travelers' diarrhea	3 caps (200 mg) TID	\$778.10 <sup>4</sup> (without insurance)

International Society of Travel Medicine, 2017 guidelines for treating travelers' diarrhea included:

- Antibiotics should **NOT** be used routinely, except in patients at high risk of complications
- Rifaximin recommended when antibiotic prophylaxis is indicated
- Fluoroquinolones not recommended for prophylaxis
- Insufficient evidence to recommend prebiotics or probiotics

1. Amazon.com
2. Amazon.com
3. Amazon.com (Cipro)
4. Amazon.com (Xifaxan)
5. Amazon.com

# US SALES FORECAST FOR TRAVELAN®:

IF FDA APPROVED



## MARKET POTENTIAL FOR TRAVELAN® SALES:

USD >\$100 MILLION

### Market potential figure derived from:

November 2023 figures of US citizens traveling to high-risk destinations for TD (60 million)<sup>1</sup> and obtaining pre-travel advice (24 million)<sup>2</sup>. Sources of pre-travel advice include primary care providers, travel medicine specialists, company doctors, pharmacists, and travel agencies<sup>2</sup>. Our forecast utilizes a conservative estimate for % of US citizens purchasing Travelan® after seeking pre-travel advice.

1. U.S. Department of Commerce, International Trade Administration: U.S. International Air Travel Statistics (I-92 data), Monthly U.S. Outbound Data, U.S. Outbound Travel to World Regions. Available at: <https://www.trade.gov/us-international-air-travel-statistics-i-92-data>

2. Mathyas Wang , MD , Thomas D. Szucs , MD, MBA, MPH, LLM , and Robert Steffen , MD. Economic Aspects of Travelers ' Diarrhea. Journal of Travel Medicine, Volume 15, Issue 2, 2008, 110–118

Regulatory Authority	Regulatory Pathway	Indications
Australia Therapeutic Goods Administration (TGA)	Australian Register for Therapeutic Goods (ARTG)  Listed Oral Medicine (2004) <b>AUST L 106709</b>	<ul style="list-style-type: none"><li>• Reduces the risk of travelers' diarrhea</li><li>• Reduces the symptoms of minor gastrointestinal disorders</li></ul>
Health Canada	Oral Natural Health Product (2013) <b>NPN 80046016</b>	<ul style="list-style-type: none"><li>• Helps reduce the risk of travelers' diarrhea</li></ul>
Food and Drug Administration FDA (US)	Dietary Supplement (2015)	Helps reduce the risk of Travelers' diarrhea
FDA (US)	Biologics License Application  (on completion of Phase 3 field studies)	<ul style="list-style-type: none"><li>• Reduces the risk of travelers' diarrhea</li><li>• Reduces the symptoms of minor gastrointestinal disorders</li></ul>

# THANK YOU



Immuron team



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Collaborators:



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# SCIENTIFIC REFERENCES



## Travelan® (IMM-124E)

Travelan® has been shown to reduce both the incidence and severity of ETEC-induced diarrhea in up to 90% of volunteers	<a href="#">Scandinavian Journal of Gastroenterology, 46:7-8, 862-868, DOI: 10.3109/00365521.2011.574726</a>
Clinical Evaluation of Travelan® an Oral Prophylactic for Prevention of Travelers' Diarrhea in Active Duty Military Service Assigned Abroad.	<a href="#">Military Health System Research Symposium 14-17 Aug 2023 Abstract 1</a>
Travelan as a broad Spectrum anti-bacterial	<a href="#">Immuron Limited, 29 April, 2011</a>
Travelan® demonstrates broad reactivity to Vibrio cholera strains from Southeast Asia indicating broad potential for prevention of traveler's diarrhea	<a href="#">US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 4 September, 2019</a>
Travelan® prevented clinical shigellosis (bacillary dysentery) in 75% of Travelan® treated animals compared to placebo and demonstrated a significant clinical benefit	<a href="#">US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 5 September, 2018</a>
Travelan® able to bind and was reactive to 60 clinical isolates of each bacteria, Campylobacter, ETEC, and Shigella	<a href="#">US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 30 January, 2017</a>
Bioactivity and efficacy of a hyperimmune bovine colostrum product- Travelan, against shigellosis in a non-Human primate model (Macaca mulatta)	<a href="#">Islam D, Ruamsap N, Imerbsin R, Khanijou P, Gonwong S, Wegner MD, et al. (2023) Bioactivity and efficacy of a hyperimmune bovine colostrum product- Travelan, against shigellosis in a non-Human primate model (Macaca mulatta). PLoS ONE 18(12): e0294021.</a>
Bioactive Immune Components of Travelan®	<a href="#">Clin Vaccine Immunol 24:e00186-16. <u><a href="https://doi.org/10.1128/CVI.00186-16">https://doi.org/10.1128/CVI.00186-16</a></u></a>
Hyperimmune bovine colostrum containing lipopolysaccharide antibodies (IMM-124E) has a non-detrimental effect on gut microbial communities in unchallenged mice	<a href="#">Infect Immun. 2023 Nov; 91(11): e00097-23.</a>
Administration of the Hyper-immune Bovine Colostrum Extract IMM-124E Ameliorates Experimental Murine Colitis	<a href="#">Journal of Crohn's and Colitis, Volume 13, Issue 6, June 2019, Pages 785–797, <u><a href="https://doi.org/10.1093/ecco-jcc/ijy213">https://doi.org/10.1093/ecco-jcc/ijy213</a></u></a>

## IMM-529

Bovine antibodies targeting primary and recurrent Clostridium difficile disease are a potent antibiotic alternative	<a href="#">Sci Rep 7, 3665 (2017). <u><a href="https://doi.org/10.1038/s41598-017-03982-5">https://doi.org/10.1038/s41598-017-03982-5</a></u></a>
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