



# FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL  
IMMUNOTHERAPIES – OCTOBER, 2020

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**ASX: IMC**

# DEVELOPMENT PIPELINE



PRE-CLINICAL    PHASE I    PHASE II    PHASE III    MARKET

1

Commercial Products

Travelan® - commercial product Australia

Protectyn® - commercial product Australia

Travelan® - commercial product Canada

Travelan® - commercial product USA

2

IMM-124E

i) Travelers' Diarrhea FDA drug registration USA

ii) P4TD Travelers' Diarrhea Efficacy Field Trial

iii) COVID-19 research

3

IMM-529

Recurrent *C. difficile* infections

4

Naval Medical Research Center

Moderate to severe *Campylobacteriosis* infections

*ETEC* infections

5

Walter Reed Army Institute of Research

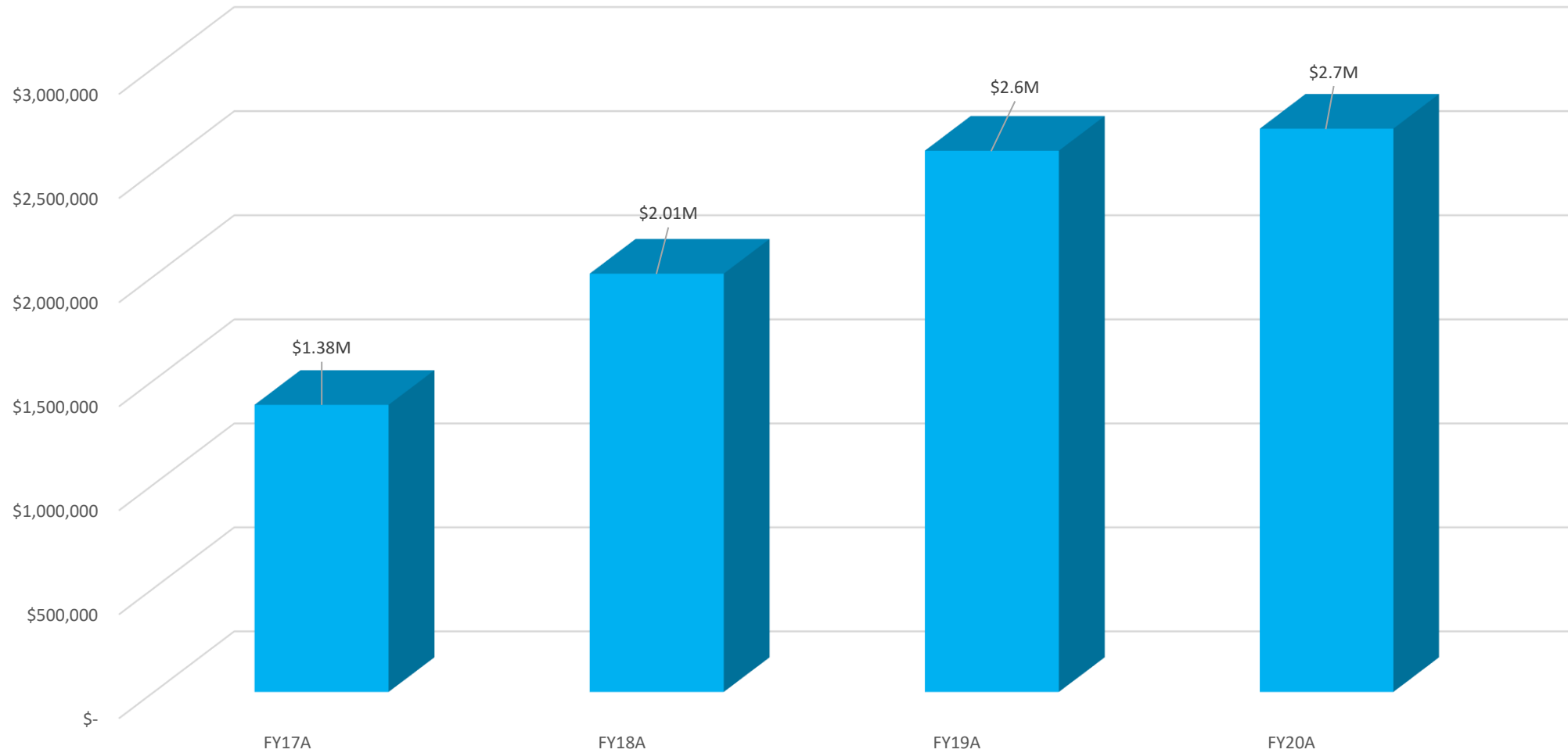
Evaluation of *Shigella* specific therapeutic drug candidates

Personal use only

# TRAVELAN® COMMERCIAL PROFILE:



Global Immuron Sales (Gross) - AUD



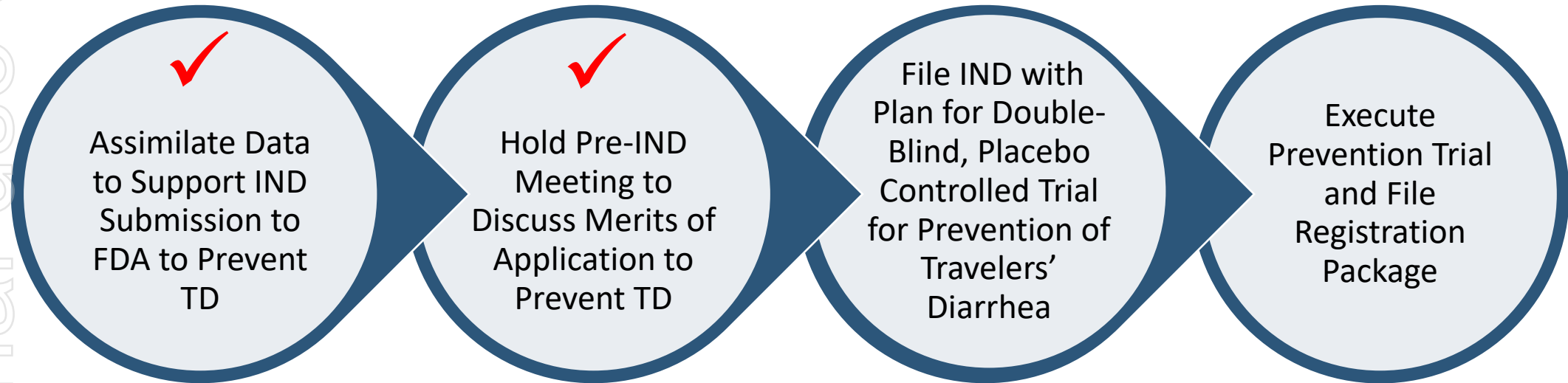
AUD

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# IMM-124E DRUG DEVELOPMENT PLAN

Plan to register Travelan<sup>®</sup> as a drug in the USA with the FDA to reduce the risk of Travelers' Diarrhea (TD) in travelers to endemic areas:



# US SALES FORECAST FOR TRAVELAN<sup>®</sup>: IF APPROVED AS DRUG



## MARKET POTENTIAL FOR TRAVELAN<sup>®</sup> SALES:

USD >\$100 MILLION

### Market potential figure derived from:

2014 figures of US citizens traveling to high risk destinations for TD (44.3 million)<sup>1</sup> and obtaining pretravel advice (22.2 million)<sup>2</sup>. Sources of pre-travel advice include primary care provider, travel medicine specialist, company doctors, pharmacist, and travel agencies<sup>2</sup>. Our forecast utilizes a very conservative estimate for % of US citizens purchasing Travelan<sup>®</sup> after seeking pre-travel advice.



1. U.S. Department of Commerce, International Trade Administration, National Travel and Tourism Office. U.S. Citizen Traffic to Overseas Regions, Canada & Mexico 2014. Monthly Statistics, U.S.Outbound Travel by World Regions. 2014. Available at: <http://travel.trade.gov/view/m-2014-O-001/index.html>. Accessed June 26, 2015.
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



# A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL EVALUATING THE EFFICACY OF NON-ANTIBIOTIC OTC PRODUCTS IN TRAVELERS' DIARRHEA (TD) PREVENTION (P4TD)

**CURRENT STATUS – PLAN TO COMMENCE ENROLMENT JUNE 2021**

## *Primary Objective:*

To evaluate the clinical efficacy of Travelan®, Florastor® and Bimuno® vs. placebo for maintenance of Gastrointestinal Health (GH) focusing on a 10 day window of prophylaxis during travel.

## **STUDY DESIGN**

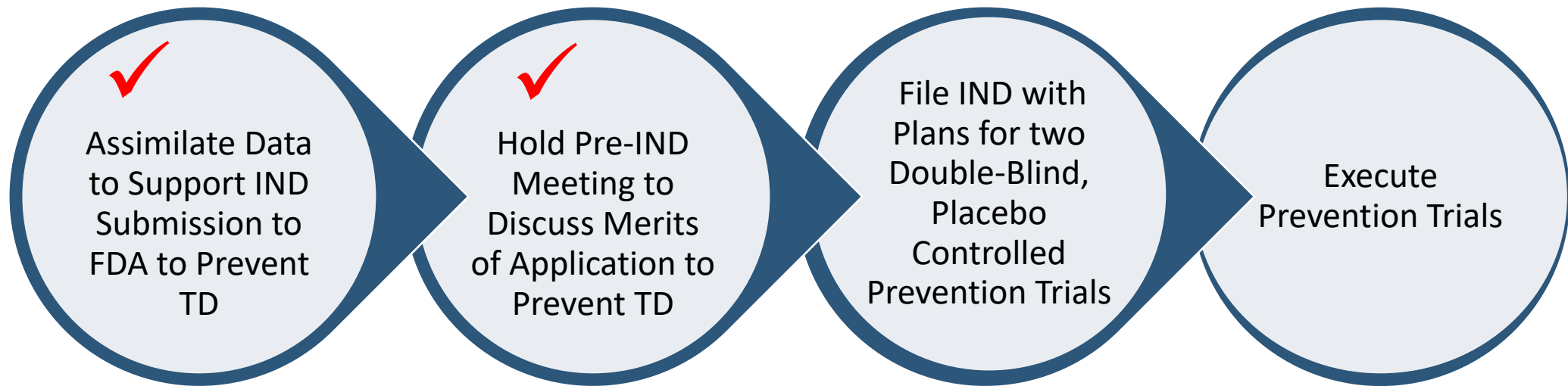
This is a randomized (1:1:1:1 allocation), double-blind, placebo controlled multicenter clinical trial comparing three dietary supplements, Travelan®, Florastor® and Bimuno®, individually against placebo to determine efficacy for maintenance of GH.

**A total of 1320 subjects (330/arm)** will be enrolled from the following populations: active duty US and UK military personnel, US DoD beneficiaries and **US civilians** deploying or traveling to intermediate or high GH disruption risk destinations.

# US NAVEL MEDICAL RESEARCH CENTRE DRUG DEVELOPMENT PLAN



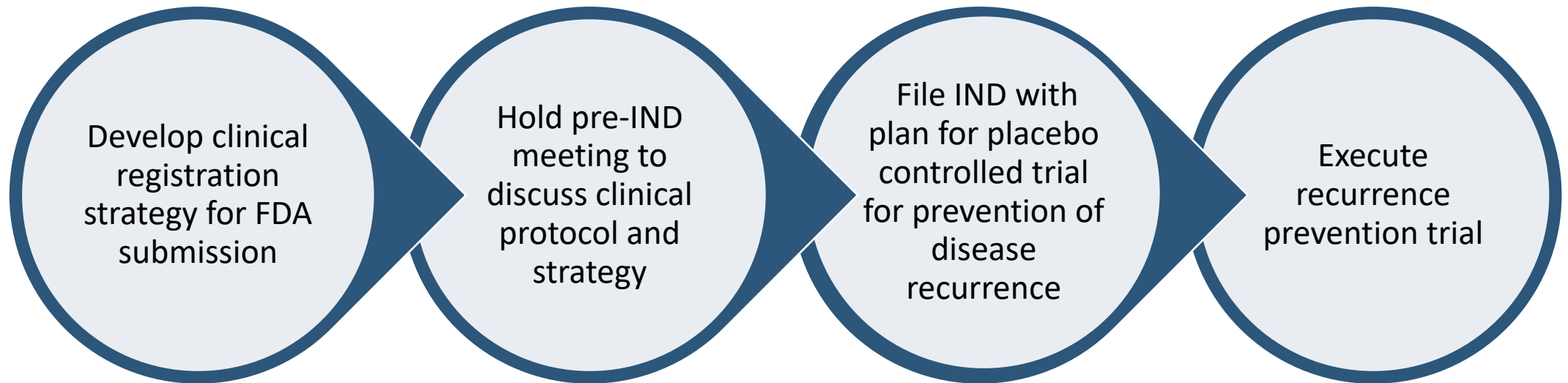
Two Human Clinical Trials Planned: New Drug to Reduce the risk of Infectious Diarrhea Caused by Campylobacter and by ETEC





# IMM-529 DRUG DEVELOPMENT PLAN

Develop clinical protocol for FDA approval as drug to prevent recurrent *Clostridioides difficile* Infection:



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# Immuron Reports Neutralizing activity Against SARS-CoV-2

## Key Points

- Immuron's Hyper-immune Bovine Colostrum used to manufacture Travelan® and Protectyn® demonstrates antiviral activity against the COVID-19 virus in laboratory studies
- Immuron's technology platform offers a potential new oral therapeutic approach to target SARS-CoV-2 in the GI Tract

Melbourne, Australia, July 21, 2020: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, today is pleased to announce that the hyper-immune bovine colostrum used to manufacture the company's flag ship commercially available and over-the-counter gastrointestinal and digestive health immune supplements Travelan® and Protectyn® has demonstrated neutralizing activity against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus that causes COVID-19.

# IMM-124E SARS-COV-2 RESEARCH & DEVELOPMENT PROPOSAL



## CURRENT STATUS

### RESEARCH & DEVELOPMENT

Reached out to local, national, and international potential research collaborators to advance this work and assist in the further characterization of the neutralization activity of SARS-CoV-2 observed with IMM-124E

- **Research Services Agreements**
  - To identify the inhibitory substance/s in IMM-124E
- **Preclinical Development**
  - Access application form for a contract research project – submitted
  - The project aims to assess the effect of IMM-124E in ex-vivo and animal models infected with SARS-CoV-2

# IMM-124E SARS-COV-2 RESEARCH & DEVELOPMENT PROPOSAL



## CURRENT STATUS

### CLINICAL PROPOSALS

- **Consultancy agreement** executed with Professor Teena Chopra, Professor of Medicine Wayne State University School of Medicine, Detroit
  - Professor Chopra is building a registry of the patients presenting with gastrointestinal events to better understand this cohort and the unique medical challenges they present
- **Clinical protocol development**
  - Reviewing several proposals to assess the efficacy of IMM-124E to treat patients with COVID-19