# Drug Discovery Alliances Expert Working Group (DA-EWG)

# Our Journey: Comprehensive Review and Strategic Outlook

Megumi Ikemori

Eisai Co., Ltd.
JPMA APAC DA-EWG Leader

Jun Terauchi

Japan Microbiome
Consortium/Metagen Therapeutics Inc.
DA-EWG member

# Drug Alliances Expert Working Group (DA-EWG)

APAC
Asia Partnership Conference of Pharmaceutical Associations

◆ **Mission**

- *"Promote cross-border open innovation to develop innovative medicines for patients in Asia "*

◆ **The DA-EWG will be dissolved in a forward-looking manner following its 15th conference.**

◆ **At the 15th conference, we review and summarize our history and achievements.**

# Contents

APAC
Asia Partnership Conference of Pharmaceutical Associations

1. Introduction
   Our Journey, Comprehensive Review and Strategic Outlook

2. Topics
   1) Asia Natural Compounds Consortium (ANPDC)
   2) Drug Seeds Alliance Network Asia (DSANA)
   3) New modality / Microbiome

3. Closing

# DA-EWG

APAC
Asia Partnership Conference of Pharmaceutical Associations

## Established in 2012 as a Team Responsible for Drug Discovery Collaboration

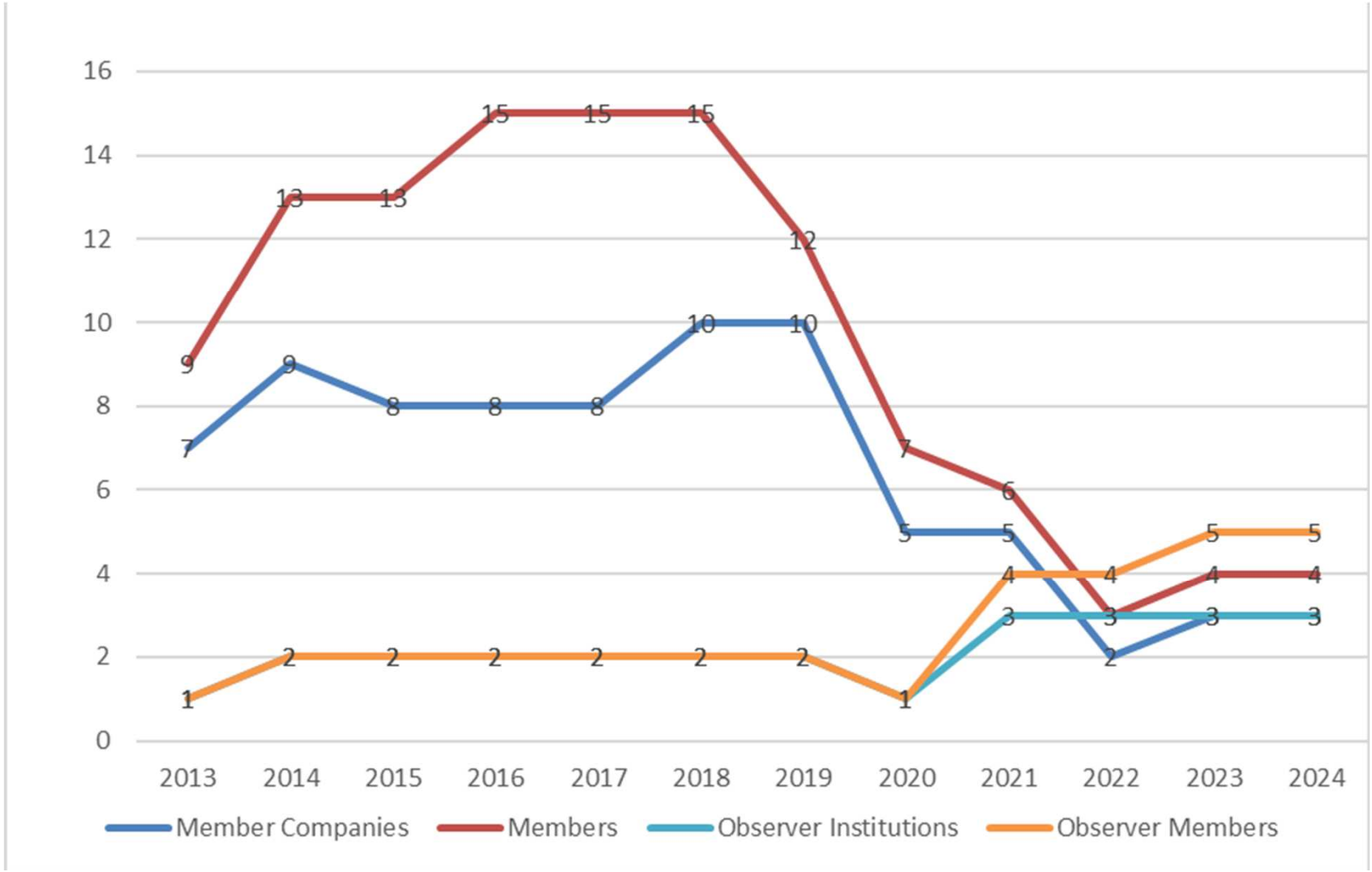
- ✓ The team was established in 2012 to promote drug discovery collaboration across the Asia-Pacific (APAC) region.
- ✓ At the time, Asian countries were recognized as important partners from the perspectives of the future pharmaceutical market and drug discovery collaboration; however, only a limited number of pharmaceutical companies were actively engaged in collaborative drug discovery with Asian countries.

## Needs for DA-EWG

- ✓ Activities aimed at building relationships with government and industry stakeholders in each Asian country, with a view to future drug discovery collaboration, and at creating opportunities for collaborative drug discovery.

**Activities were carried out based on five defined themes.**

# Membership History



# Member Countries and Economies : Peak vs Recent

APAC
Asia Partnership Conference of Pharmaceutical Associations

**Peak Era (2018)**


**2021~2023**


**2024~**

1. Introduction

# Mission and 5 Pillars

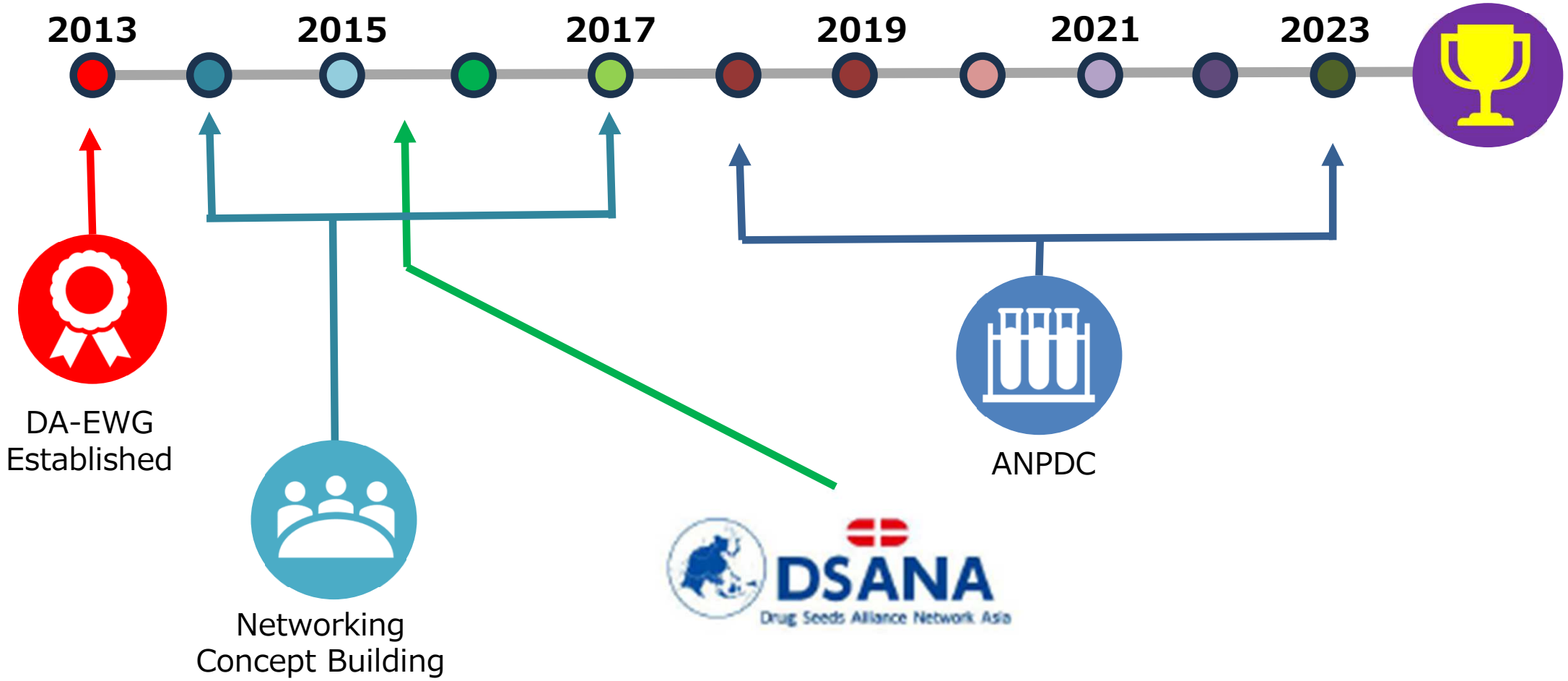
APAC
Asia Partnership Conference of Pharmaceutical Associations

| | Mission | Mission /Explanation |
|---|---|---|
| 1 | Establish an **"Information-Sharing System** | Establish an "Information-Sharing System" to promote the exchange of drug seeds between academia and research alliance representatives in pharma companies, based on the Drug Seeds Alliance Network Japan (DSANJ) program. **DSANA** |
| 2 | Promote a "**Networking Opportunity**" | Promote a "**Networking Opportunity**" at Asian bio-conferences between ventures and business development representatives in pharma companies, focusing on compounds in the development stage. |
| 3 | Support "**Capacity Building**" to foster young scientists | Support "**Capacity Building**" to foster young scientists working in the drug discovery field at Asian Bio-conferences and promote governmental programs when available. |
| 4 | Identify "**Asia-specific diseases**" targeted by cross-border collaboration. | Identify "Asia-specific diseases" targeted by cross-border collaboration. As the first step, we will collect and share information of human biobanks useful for international genomic research to find Asia-common genetic background. |
| 5 | Make the best use of vast **natural resources** | Make the best use of vast natural resources for the drug discovery aiming for the **"natural product drug discovery ecosystem"** in Asia. |

水色カラム：APAC HP記載内容 DA-EWG Introduction | APAC (apac-asia.com)

# Our History

APAC
Asia Partnership Conference of Pharmaceutical Associations



1. Introduction

# All missions have been successfully accomplished.

APAC Asia Partnership Conference of Pharmaceutical Associations

| | Mission | Situation | Background Explanation |
|---|---|---|---|
| 1 | Establish an **"Information-Sharing System** | **Done**/On-going | **DSANA system,** Activities were conducted over approximately ten years, with Taiwan as the primary partner. |
| 2 | Promote a "**Networking Opportunity**" | On-going | Taiwan: Close collaboration was maintained, with Taiwanese government agencies serving as the primary point of contact. Thailand: Strong collaboration was established through the **ANPDC** and networking events. |
| 3 | Support "**Capacity Building**" to foster young scientists | **Done** | **APAC Natural Product Drug Discovery Consortium (ANPDC)** 2018-2023 (Thailand) |
| 4 | Identify "**Asia-specific diseases**" targeted by cross-border collaboration. | Terminate/ On-going | The initial drug discovery approach focused on Asia-specific diseases was discontinued because appropriate themes could not be identified and members withdrew. Recently, attention has shifted to **a new modality, microbiome**. |
| 5 | Make the best use of vast **natural resources** | **Done** | **APAC Natural Product Drug Discovery Consortium (ANPDC)** 2018-2023 |

2. Topics

**1) Asia Natural Compounds Consortium (ANPDC)**

2) Drug Seeds Alliance Network Asia (DSANA)

3) New modality / Microbiome

ANPDC

# New opportunity for NP drug discovery

## Natural product meets new demands and technologies

APAC Asia Partnership Conference of Pharmaceutical Associations

**Mid-size molecules**

Targeting protein complex as well as **protein-protein interaction**

**Assay technology**

Phenotypic screening system such as **iPS cell-derived human disease models**

**Synthetic biology**

Natural products are **“Genetic products”** that can be modified by genetic manipulation

**New era of “NP” Drug Discovery**

ANPDC

# Reasons for Focusing on Natural Products

APAC Asia Partnership Conference of Pharmaceutical Associations

## Asia has advantages to drug discovery using natural compounds

**Natural products useful for drug discovery**

- Natural compound/product library

**Geographical proximity**

- enables close collaboration between researchers in Asian countries

**Scientific expertise and know-hows for drug discovery**

①Organic synthesis ②Structural analysis ③iPS derived disease models

**Japanese pharma's strategy to leverage open innovation**

ANPDC

# Discover new NPs through APAC NPDD Consortium

## Constructing unique and sustainable collaboration mechanism in Asia

APAC Asia Partnership Conference of Pharmaceutical Associations

**Japan**

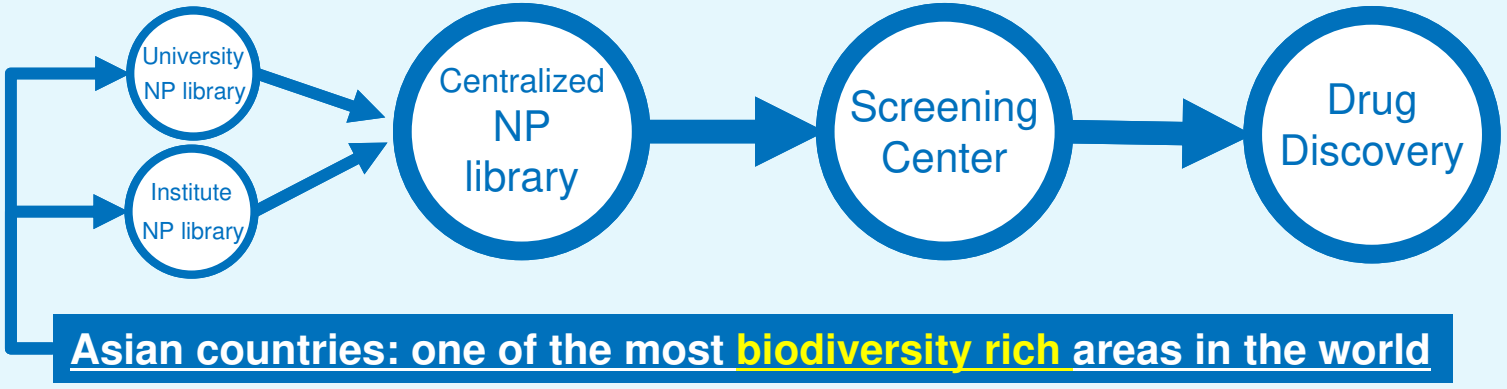
**JPMA members with N²PC and IMC**

- Technology transfer
- Technical support
- Consultation

1. **Capacity building** of young researchers in Asian countries

2. **Drug discovery** using natural products in Asian countries

**each Asian country**



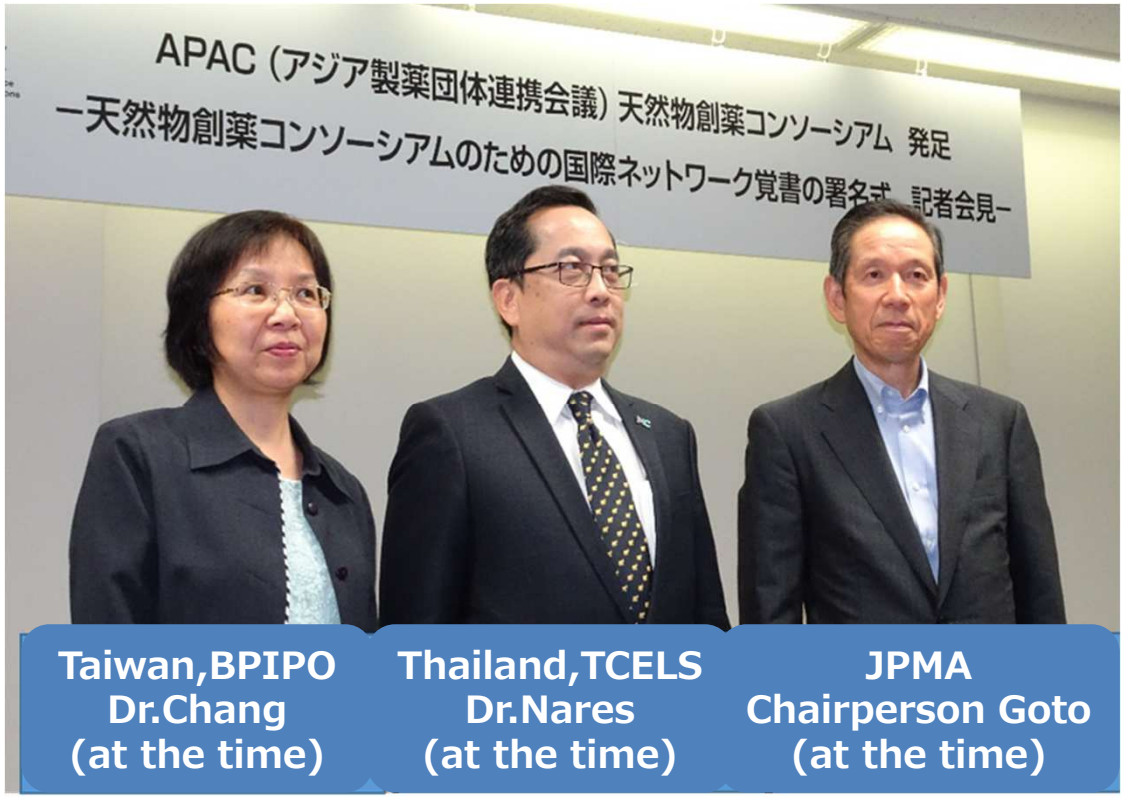

**Asian countries: one of the most biodiversity rich areas in the world**

N²PC: Technology Research Association for Next generation natural products chemistry

IMC: Institute of Microbial Chemistry

ANPDC

# ANPDC Signing Ceremony




Signing Ceremony of Representatives from Consortium Member Countries, held on October 12, 2018

ANPDC

# Member of ANPDC

APAC
Asia Partnership Conference of Pharmaceutical Associations

## Aggregate Access Service Point

Thailand Center of Excellence for Life Sciences

Japan Pharmaceutical Manufactures Association

Biotechnology and Pharmaceutical Industries Promotion Office

## Research Organization

**Takeda Pharmaceutical Company** : Provided screening technology training to researchers dispatched from Thailand at the Shonan Research Center.

**Eisai Co., Ltd.** : Provided support for compound design and transferred screening technologies.

ANPDC

# Section Summary

APAC Asia Partnership Conference of Pharmaceutical Associations

- The Natural Products Drug Discovery Consortium was established with two primary objectives:
  - ✓ to promote the use of natural products in drug discovery
  - ✓ to foster the development of young researchers

- The consortium included participation from academia and public institutions in Thailand, as well as Takeda Pharmaceutical Company and Eisai in Japan.

- Despite the need to revise plans due to the COVID-19 pandemic, the consortium successfully delivered meaningful outcomes.

## 2. Topics

1) Asia Natural Compounds Consortium (ANPDC)

**2) Drug Seeds Alliance Network Asia (DSANA)**

3) New modality / Microbiome

# Creation of DSANA Platform, Present Status and Future Directions

April 21, 2026

Jun Terauchi（JPMA）

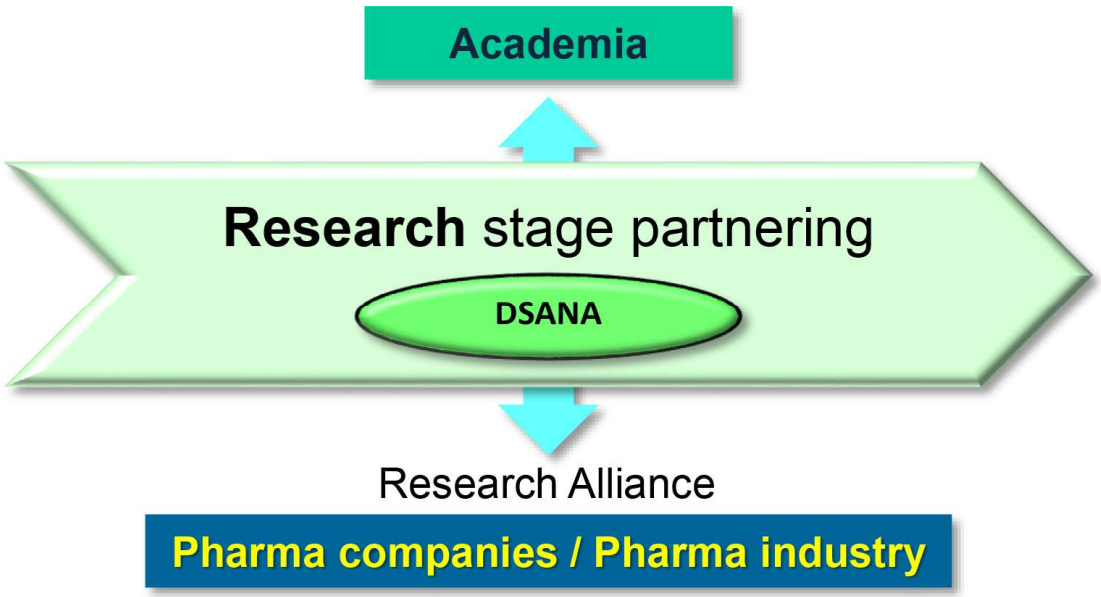
# Mission and 5 Pillars

| | Mission | Mission /Explanation |
|---|---|---|
| 1 | Establish an **"Information-Sharing System** | Establish an "Information-Sharing System" to promote the exchange of drug seeds between academia and research alliance representatives in pharma companies, based on the Drug Seeds Alliance Network Japan (DSANJ) program. **DSANA** |
| 2 | Promote a "**Networking Opportunity**" | Promote a "**Networking Opportunity**" at Asian bio-conferences between ventures and business development representatives in pharma companies, focusing on compounds in the development stage. |
| 3 | Support "**Capacity Building**" to foster young scientists | Support "**Capacity Building**" to foster young scientists working in the drug discovery field at Asian Bio-conferences and promote governmental programs when available. |
| 4 | Identify "**Asia-specific diseases**" targeted by cross-border collaboration. | Identify "Asia-specific diseases" targeted by cross-border collaboration. As the first step, we will collect and share information of human biobanks useful for international genomic research to find Asia-common genetic background. |
| 5 | Make the best use of vast **natural resources** | Make the best use of vast natural resources for the drug discovery aiming for the **"natural product drug discovery ecosystem"** in Asia. |

水色カラム：APAC HP記載内容 DA-EWG Introduction | APAC (apac-asia.com)

DSANA

# Initial Concept of "DSANA"




- DSANA stands for "**Drug Seeds Alliance Network in Asia**" generated from DSANJ established and operated in Japan.
- DSANA is ideally considered to contain attractive and innovative new drug seeds and new technologies for drug discovery from Asian countries.
- DSANA also offers system to introduce seeds and technologies from producers/originators to pharma/biotech companies, such as Business meetings.

**Purpose: Promotion of Cross Boader Open Innovation in Asia**

DSANA

# Evolution of DSANA with event-based matching

APAC Asia Partnership Conference of Pharmaceutical Associations

February to December 2016 in Osaka, etc.

Japan Academia
(Novel Recombinant Proteins
for Treatment of Intractable Liver Diseases)
vs
Biotech Company
(Biopharmaceutical development
and manufacturing platform Company)

July 2015 in Taipei

*DSANA partnering Conference*
9 TW Biotech and Academia
=> Total 11 proposal
6 JP pharmaceutical company
Total 21 matching

**45 Proposals, 112 Meetings have realized from 2019 to 2024**

**Issues to be resolved**

**Issue #1. Fright, Accommodation Fee**

**Issue #2. The criteria of invitees to the event must be strict to maintain invitees' satisfaction.**

**Issue #3. There are various intermediary costs to DSANA organizer.**

**DSANA moved to Web-based match-up**

**To Solve the issue #1 - #3**

January 2019 in Osaka

*DSANA partnering Conference*
3 TW Biotech and Academia
=> Total 3 proposal
11 JP pharmaceutical company
Total 18 matching

January 2020 in Osaka

*DSANA partnering Conference*
4 TW Biotech and Academia
=> Total 4 proposal
11 JP pharmaceutical company
Total 17 matching

**Event-based matching**

DSANA

# Achievement through DSANA

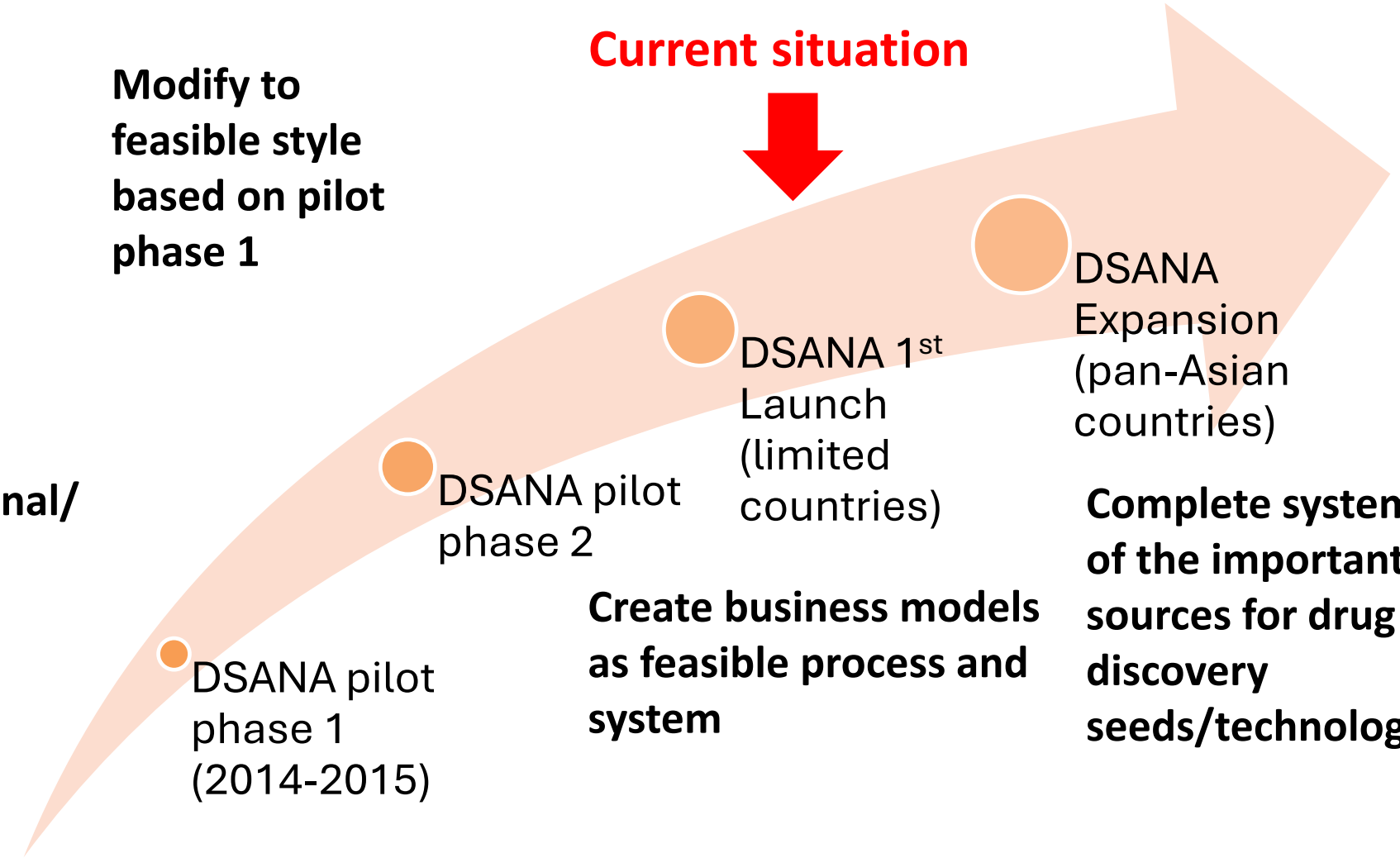
APAC Asia Partnership Conference of Pharmaceutical Associations

- We have created DSANA process based on existing DSANJ system.
- To understand hurdles and issues for DSANA, we have pursued "Pilot" trials twice.
- After conducting Pilot trials, the DSANA Standard process for D-Bio meeting was launched in 2020.
- Under pandemic situation, we have successfully moved to virtual DSANA at D-Bio meeting from 2021.

DSANA

# Future Expectation for DSANA

APAC Asia Partnership Conference of Pharmaceutical Associations



DSANA

# Section Summary

- From concept to create information sharing platform to promote Cross Boarder Open Innovation for drug discovery, we have successfully launched DSANA by utilizing DSANJ system through continuous efforts and contributions by enthusiastic DA-EWG members as well as relevant stakeholders. DA-EWG expresses sincere appreciation for the efforts.
- Although regular process for D-Bio conference from selection of proposals to business meeting is completed, further enhancement and improvement, especially securing quality of proposals needs to be addressed.
- All team members believe this initiative contributes to achieve APAC mission.

APAC
Asia Partnership Conference of Pharmaceutical Associations

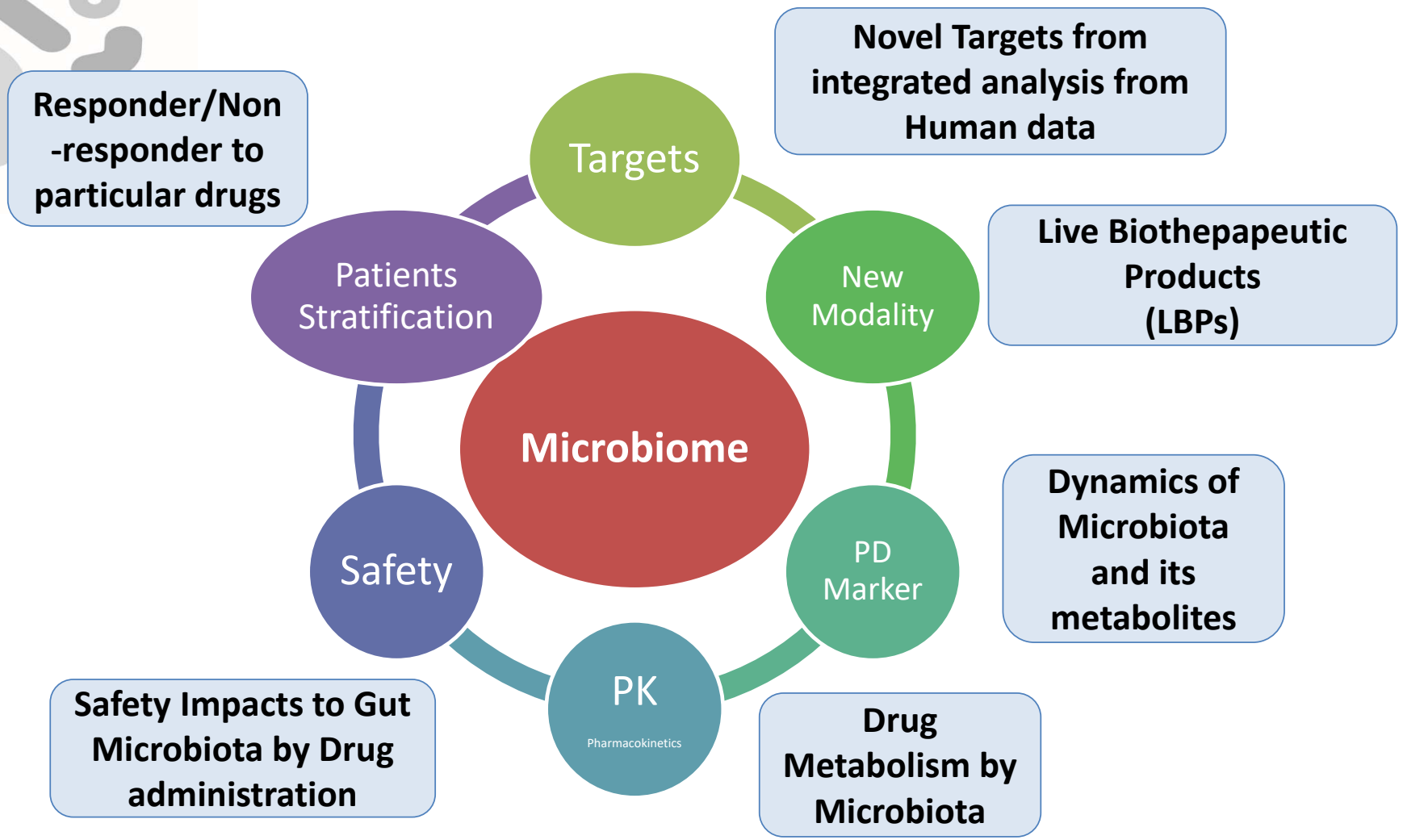
## 2. Topics

1) Asia Natural Compounds Consortium (ANPDC)

2) Drug Seeds Alliance Network Asia (DSANA)

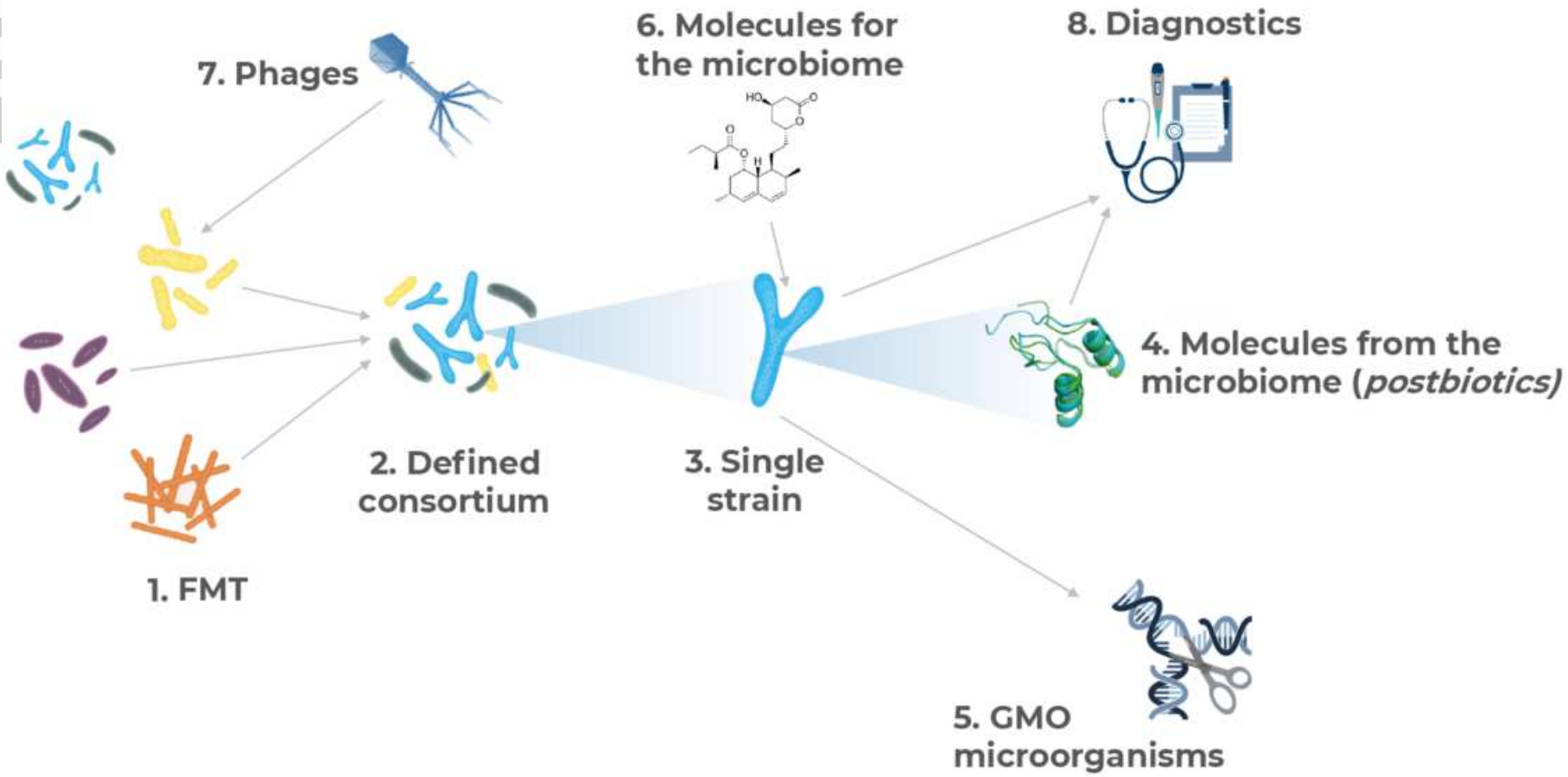
**3) New modality / Microbiome**

# Implications of microbiome for drug discovery




Japan Microbiome Consortium

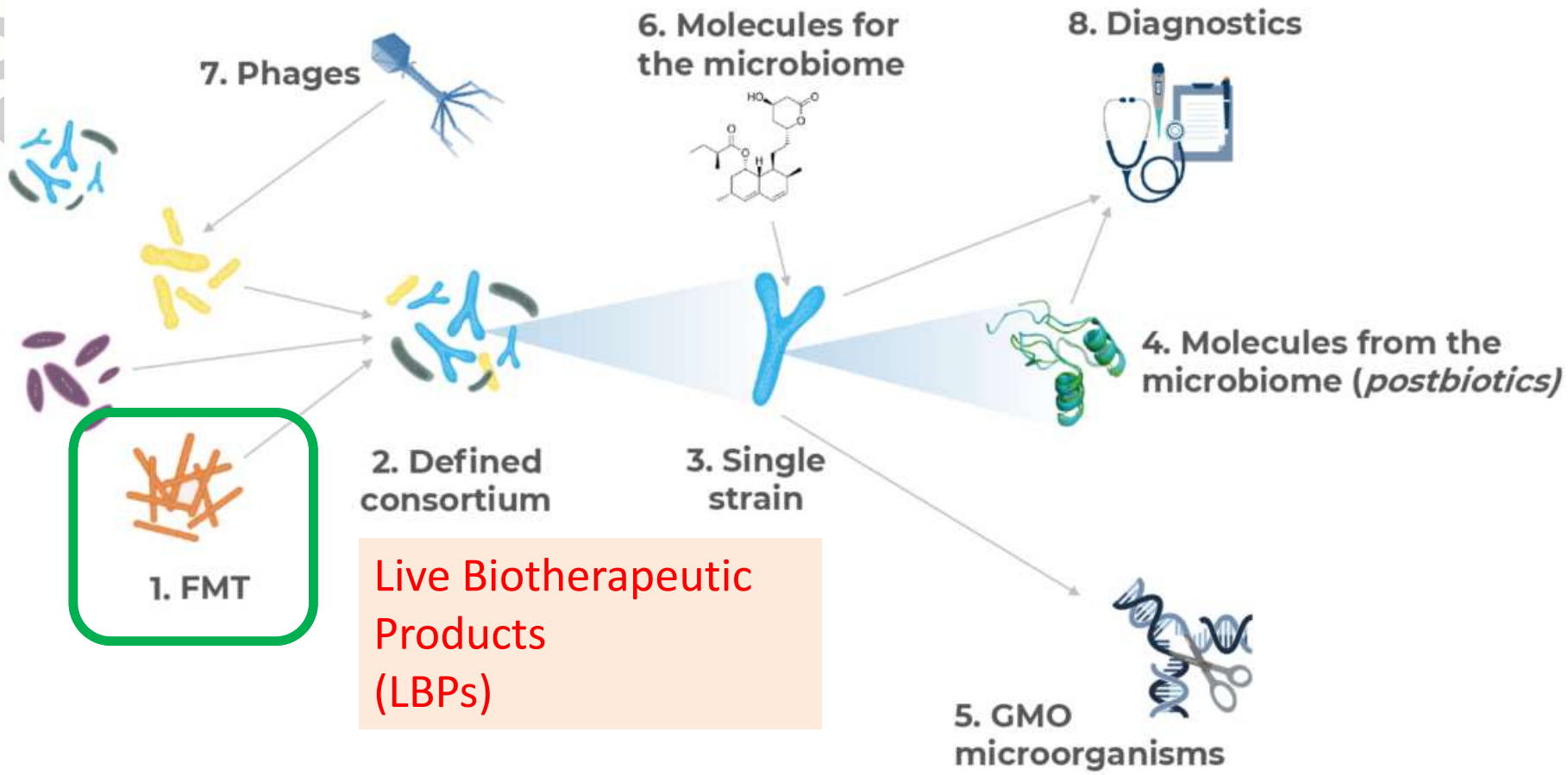
# Various Microbiome related drug discovery approach




Japan Microbiome Consortium

https://www.sandwalkbio.com/microbiome-drug-database

# Various Microbiome related drug discovery approach




Live Biotherapeutic Products (LBPs)

Japan Microbiome Consortium

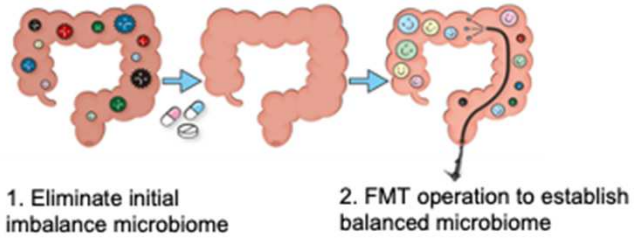
https://www.sandwalkbio.com/microbiome-drug-database

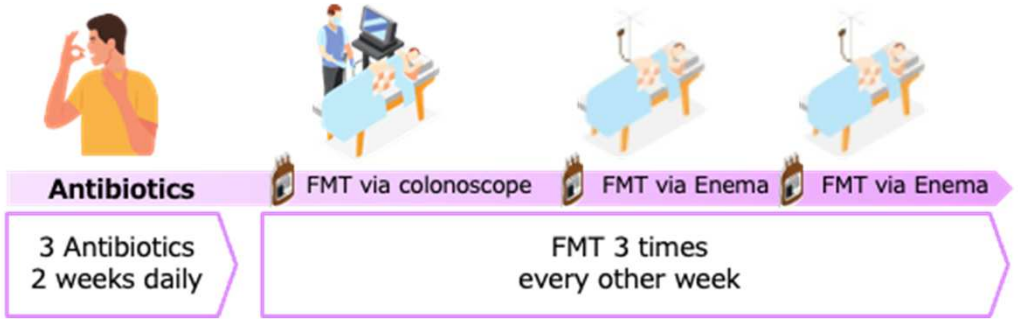
# Attractiveness of MBDD/FMT (Gut)

- FMT **starts from clinical studies** to obtain firm evidences for target diseases.
- **Drug action sites are "GUT",** not systemic sites.
- FMT can address **multiple pathway/MOA**.
- FMT clinical data delivers **new pathway/targets** with clinical intervention evidence.
- **Regulatory path for FMT products has been cleared** by multiple countries/authorities.

# A-FMT for Ulcerative Colitis (UC)

- **FMT method: A-FMT (Pretreatment with combination of three Antibiotics and FMT)**
  - Aiming to eliminate the initial imbalance in the microbiome and establish a balanced microbiome through FMT
- **Juntendo University and MGTx initiated pivotal study of A-FMT for UC from Jan. 2023 under the *Advanced Medical Care Program* authorized in Japan**
  - Advanced Medical Care Program offers an official approval path for medical treatments and potential reimbursement
  - **Remission rates: 45.9%, response rate: 70%, no serious side effects.**



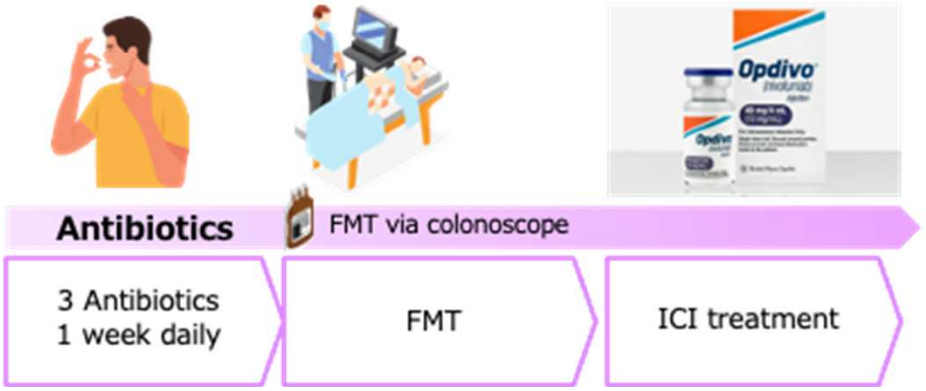

Japan Microbiome Consortium

# Indication Expansion

## A-FMT clinical study for cancer patients treated with immune checkpoint inhibitors (ICI) in collaboration with National Cancer Center Japan

- Safety study for up to 45 patients with esophageal and gastric cancer will begin soon ( jRCTs031240170, NCCH2308 )
- A-FMT aimed at improving the response rate to ICI

国立研究開発法人
国立がん研究センター
National Cancer Center Japan




## A-FMT clinical study for Parkinson's disease is scheduled to begin this year in collaboration with Juntendo University Hospital

- In an aging society, Parkinson's disease continues to increase
- Parkinson's disease has the highest number of patients among designated intractable diseases in Japan

JUNTENDO UNIVERSITY TOKYO 1838


Observational Study

Medicine

OPEN

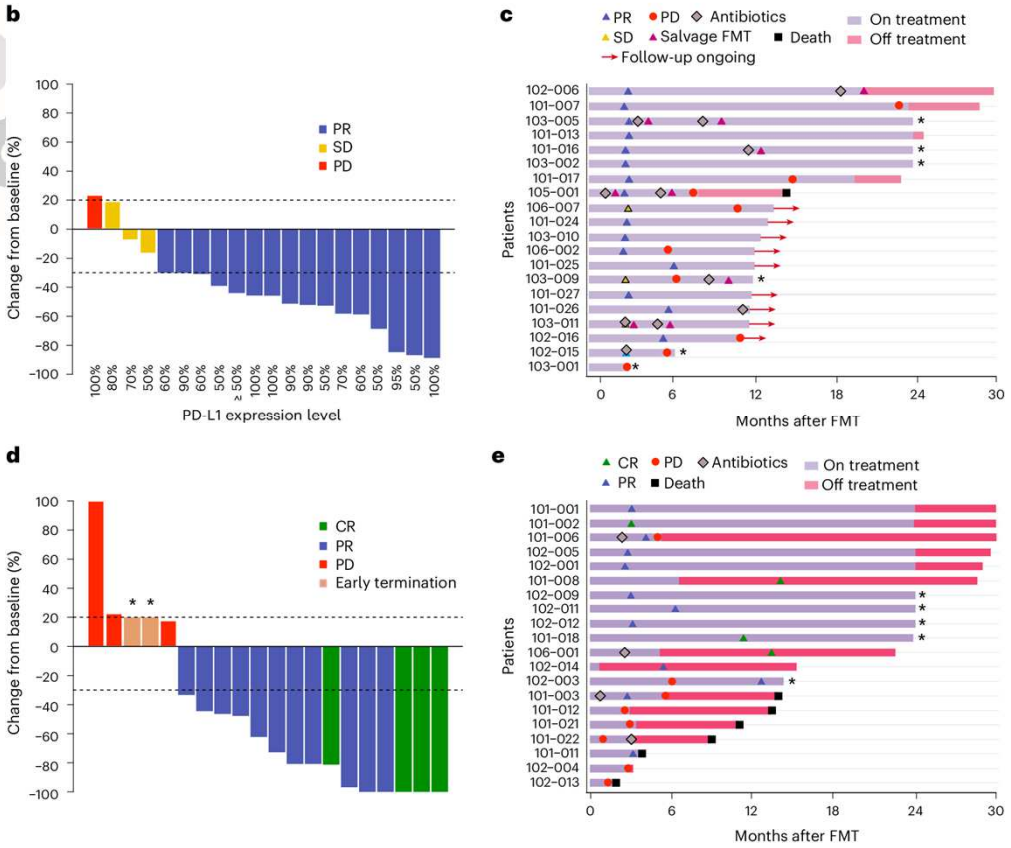
**Fecal microbiota transplantation therapy for Parkinson's disease**

**A preliminary study**

Liu-Jun Xia, MD[a], Xiao-Zhong Yang, MD, PhD[b], Qiang Tong, MD[a], Peng Shen, MD[b], Shi-Jie Ma, MD[b], Shang-Nong Wu, MD[b], Jin-Long Zhang, MD, PhD[a,*], Hong-Gang Wang, MD[a,*]

Japan Microbiome Consortium

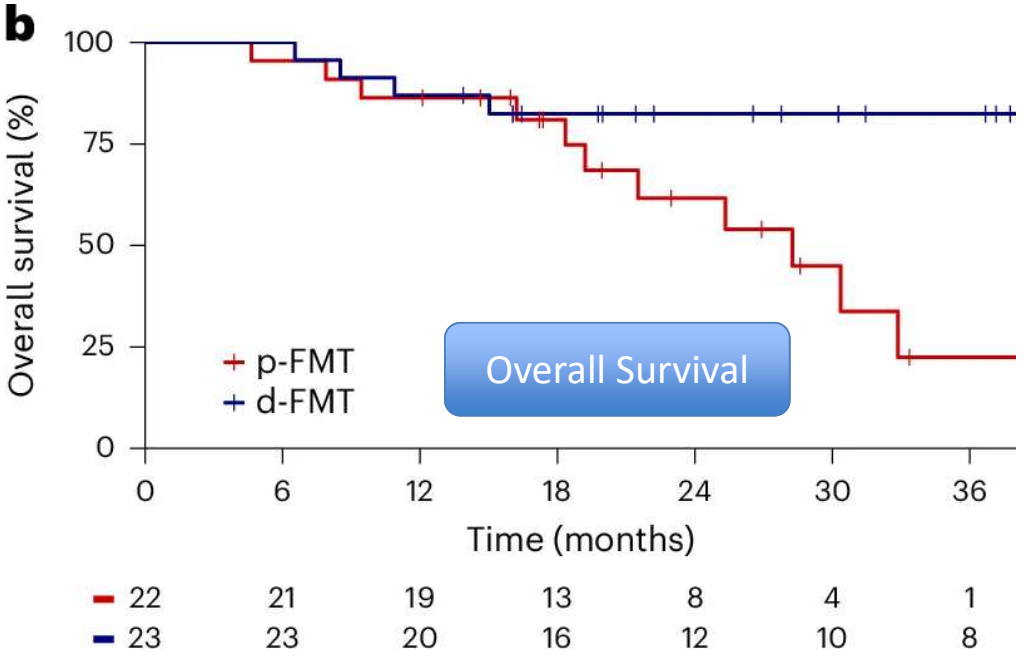
# ICI＋FMT showed promising outcome




NSCLC：ORR 80%

Melanoma: ORR 75%

https://www.nature.com/articles/s41591-025-04186-5




Metastatic Renal Cell carcinoma：
ORR52%(32% placebo)

https://www.nature.com/articles/s41591-025-04189-2

Japan Microbiome Consortium

# MBDD(FMT) : Recognized Globally

## Moving towards becoming standard of care

### Stool-derived product development accelerating in the U.S

- ✓ Nov. 2022, world's first FDA approval of REBYOTA for CDI *1

150 mL fecal microbiota suspension containing a consortia of $10^8$ to $10^{10}$ (CFU)/mL

- ✓ Apr. 2023, FDA approval of VOWST, as first oral treatment for CDI *2

### Australia leads in FMT regulations globally

- ✓ Nov 2022, BIOMICTRA, a FMT syringe formulation developed by BiomeBank, receives first-ever regulatory approval for CDI *3

### Dec. 2022, European Medicines Quality Directorate sets guidelines for FMT

### Aug. 2022, UK's NICE creates guideline for FMT for CDI

## Regulatory Status

- ❖ **FDA-approved FMT products available in the U.S. and EU**
- ❖ **Japan/Asia needs regulatory standards**

Japan Microbiome Consortium

*1:https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product
*2:https://www.fda.gov/news-events/press-announcements/fda-approves-first-orally-administered-fecal-microbiota-product-prevention-recurrence-clostridioides
*3:https://www.biomebank.com/news/biomebank-announces-world-first-regulatory-approval-for-donor-derived-microbiome-drug/

# A New Guideline by PMDA

PMDA published the first guideline for FMT product as one of the Early Considerations.


Provisional Translation (as of November 2025) *

Quality of Fecal Microbiota Transplantation (FMT) Products at the Initial Development Stage (Early Consideration)

October 31, 2025
Pharmaceuticals and Medical Devices Agency
Office of Cellular and Tissue-based Products

1. Introduction

Fecal microbiota transplantation (hereinafter referred to as "FMT") is a therapy in which enteric bacteria prepared from the feces of healthy human donors, but not specifically identified bacterial strains, are transplanted into patients with the aim of improving the gut microbiota and thereby exerting the expected effect.[1)] Outside Japan, FMT products derived from human feces have already been approved. In 2022, "BIOMICTRA" and "REBYOTA" were approved in Australia and the US, respectively, and in 2023, "VOWST" was approved in the US for the indication of refractory *Clostridioides difficile* infection, which is an intestinal infection.[2-4)]

For development of FMT products, how to assess the eligibility of fecal donors, including evaluation of infectious risks, is critical for ensuring product safety. In ensuring the safety of subjects, the most important action is to sort items for selecting eligible donors, such as screening by interview, stool test, and blood test.

Japan Microbiome Consortium

https://www.pmda.go.jp/files/000273117.pdf

# APMC Public Private Partnership outcome


Guideline

Development of live biotherapeutic products: a position statement of Asia-Pacific Microbiota Consortium

Ching-Hung Tseng [1], Sunny Wong [2], Jun Yu [3], Yeong Yeh Lee [4], Jun Terauchi [5], Hsin-Chih Lai [6], Jiing-Chyuan Luo [7], Cheng Yen Kao [8], Sung-Liang Yu [9], Jyh-Ming Liou [10], Deng-Chyang Wu [11], Ming-Chih Hou [7, 12], Ming-Shiang Wu [10], Jiunn-Jong Wu [13], Joseph J Y Sung [2], Emad M El-Omar [14], Chun-Ying Wu [15, 16, 17]

Correspondence to Professor Chun-Ying Wu; dr.wu.taiwan@gmail.com; Professor Emad M El-Omar; e.el-omar@unsw.edu.au; Professor Joseph J Y Sung; josephsung@ntu.edu.sg

https://gut.bmj.com/content/early/2025/02/26/gutjnl-2024-334501

Created LBP guideline under **Asia Pacific Microbiota Consortium(APMC)** discussion lead by Taiwan Microbiota Consortium(TMC)
**Member: Taiwan, Australia, Hong Kong, Japan, Malaysia, Singapore**

Japan Microbiome Consortium

# Section Summary

- Development of Microbiome Based Drug continues to deliver new drugs as one of the **promising new modalities**.
- Among Microbiome Based Drugs, FMT is the most promising approach with **firm evidence** and **clear regulatory path**.
- FMT can **target various indications**, such as oncology, immunology, infectious disease etc.
- More products expect to be launched from Asia.

# 3. Closing

# Summary of DA-EWG

APAC
Asia Partnership Conference of Pharmaceutical Associations

- DA-EWG was active for 12 years, from 2013 to 2024, with the objective of promoting drug discovery collaboration in Asia and the creation of innovative new medicines.

- During its activities, DA-EWG successfully achieved nearly all five missions established at its inception:

  - ✓ Establish an Information-Sharing System (DSANA)
  - ✓ Promote Networking Opportunities (ANPDC,DSANA)
  - ✓ Support Capacity Building to foster young scientists (ANPDC)
  - ✓ Identify Asia-specific diseases targeted by cross-border collaboration (information sharing and new modality Microbiome)
  - ✓ Make the best use of Asia's vast natural resources (ANPDC)

- As representative examples of these achievements, this session highlighted the Natural Products Drug Discovery Consortium, the Japan–Taiwan network system DSANA, and microbiome research.

# Conclusion and Future Perspectives

- During this period, the environment surrounding drug discovery research in Asia changed significantly, DA-EWG has concluded its activities in a forward-looking manner, building on its achievements and legacy.

- While industry-wide initiatives of this nature may become increasingly challenging, the importance of drug discovery collaboration in Asia continues to grow.

- Looking ahead, we encourage more practice-oriented efforts toward drug discovery innovation and collaboration in Asia.

# Acknowledgements

Throughout the activities of the DA-EWG, we received invaluable support and cooperation from many individuals and organizations.
We would like to express our deepest and most sincere gratitude to all who contributed to and supported these efforts.

Special thanks to DA-EWG leaders, members and the following organizations:

| | |
|---|---|
| **THAILAND** | Thailand Center of Excellence for Life Sciences (TCELS)<br>The National Research Council of Thailand (NRCT)<br>National Center for Genetic Engineering and Biotechnology (BIOTEC)<br>Thailand Bioresource Research Center (TBRC) |
| **TAIWAN** | Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO)<br>Development Center for Biotechnology (DCB)<br>Research Center for Natural Products & Drug Development,Kaohsiung Medical University (RCNPDD)<br>National Yang Ming University<br>Trade Wind Biotech Co. Ltd (TWBIO) |
| **JAPAN** | Microbial Chemistry (IMC)<br>Next-generation Natural Products Chemistry($N^2PC$) Osaka Chamber of Commerce and Industry (OCCI)<br>Japan Agency for Medical Research and Development (AMED)<br>Japan Pharmaceutical Manufacturers Association (JPMA) |

APAC
Asia Partnership Conference of Pharmaceutical Associations

We had a very fulfilling and rewarding time.


Thank you very much for your kind attention.