Strengthening Academic Researchers' Drug Discovery Capabilities through DSANJ Business Meeting

5th APAC

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Imperial Hotel, Tokyo

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Self-Introduction

大阪大学 OSAKA UNIVERSITY

➢ Brief Personal Record

1975: Starting work at the central research laboratory of Takeda Pharmaceutical Company Ltd: 1) researcher of cardiovascular group, 2) a research manager, 3) a director Pharmaceutical Research Division (1998 -).
2003: Senior manager at Strategic Product Planning Department; in charge of project evaluation.
2009: Mandatory retirement

➢ My Research Results

•Advanced 9 projects to clinical stages Most of them were dropped because of insufficient safety and efficacy in various clinical stages.

2012
One Project

AZILVA: 7th ARB*but in terms of drug price, it won usability addition class 2 (5%)

*ARB : Angiotensin Ⅱ Receptor Antagonist

➢ After Retirement

2009: Professor of industry-university cooperation at Osaka University(OU).
2012: Visiting professor at the Graduate School of Pharmaceutical Sciences at OU

http://pford.jp/

PDIS Platform for Drug Discovery, Informatics and Structural Life Science

AMED Japan Agency for Medical Research and Development

Need of systems to link academic drug discovery researches and pharmaceutical companies

Headquarters　Strategic Product Planning Department

- **Measure against off-patent main products**
  - ✓ Took charges of the search for promising drug seeds of bio-venture companies and universities, and attended to domestic and foreign bio-conferences

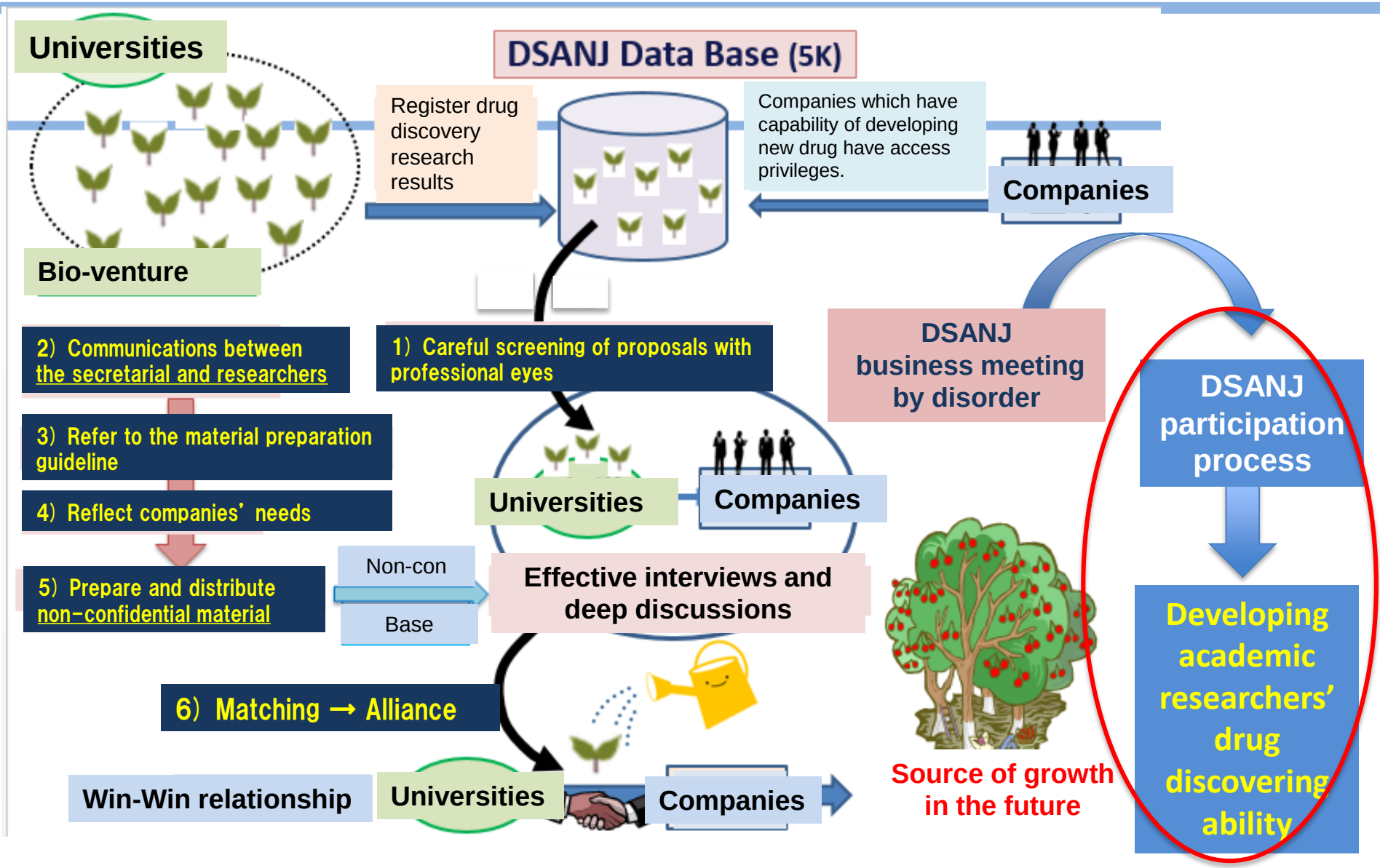
Western drug discovery alliances are large in size and quick to act

Nature Review Drug Discovery, 2010

- 60% of scientifically new drugs approved by FDA originated in universities and bio-venture companies

I felt keenly that in Japan it was necessary for us to have effective systems to link academic drug discovery researches and relevant companies.

Drug Seeds Alliance Network Japan



Mr. Yoshikawa's presentation at 4th APAC, Tokyo, 2015

Problems found in university researchers' drug discovery seeds original material

Attitudes of academic researcher

GAP

Needs of companies

Problems found in drug discovery seeds materials

1. Research titles : Inappropriate
2. Validation : Insufficient
3. Clinical Indication : Inappropriate
4. Differentiation data : Short

In order to fill the gaps, we prepared DSANJ material preparation guidelines, aimed at building a "Common Language" between academia and companies.

Problem：Title（Research's face）

Unkind and Unappealing Title

- Unclear Target：New drug for diabetes
- Unclear Clinical Indication：New xx（chemical name）derivative, or new biologics

Uninteresting➡Risk to loose interview chances

Title to sum up drug discovery research contents

- Drug discovery target and disease name（clinical indication）
  - ✓ New receptor ABC antagonist: Anti-diabetic drug
    - ・Nondisclosure of drug discovery target is acceptable.

Use of appealing title for your important research results

Problem：Validation of drug targets

New protein, new receptor, new mechanism of action・・・

- New drug targets alone are unappealing.

Data indicate prospects to lead to new drugs are important.

- Pathophysiological analysis：Relationship between the target and the disorder
- Validation as a drug discovery target is needed.
  - ✓Research tools：genome editing, knock-down, knock-out, antibodies, hit compound (specificity is important：➠hit validation)
- Experimental results：easy-to-understand descriptions for persons in charge are able to understand the merits of the research.
  - ✓Experimental title, animals/cells, dose/root, drug concentration, abbreviation should be in full spelling with footnote.

Problem : Clinical Indication

1st indication : The most promising disease name of the target

- Researchers are likely to list many diseases with hope.

→ **Difficult to set the direction of the joint research**

- We recommended to narrow down 1st indication, based on passion for drug discovery as a researcher and experimental data.
  - Companies participating in DSANJ business meetings are diverse covering from domestic medium-sized companies, major companies to global mega-pharmas.
    - ✓ Research strategies and portfolios are different by company.
      →There are diverse needs for clinical indication.

Data and scientific overviews → 2nd , 3rd indication should be listed.

Problem : Inappropriate clinical indications

In the case of the target related to immunity :
Overall immune diseases are pointed out.

Too wide clinical indication

It is difficult to determine the direction of the joint drug discovery research.

The most promising and specific disease name based on experimental data and logic

For example, 1st indication such as rheumatoid arthritis should be determined by the discernment of the researcher. Of course, 2nd and 3rd indications should also be noted.・・・・

Problem：Shortage of Differentiation from Gold Standard（GS：standard drug）

- Treatment algorithm（point to attack）
  - ➡Make the patient segment clear
  - ➡Identify GS and collect information
  - ➡Points of advantage/differentiation to over the GS

Stress the importance ⇔ Academic researchers' interest is not high.

Sun Tzu's Art of War 孫子の兵法

- To get GS data from the initial stage of drug discovery research
  - ➡To know strengths and weaknesses of yourself and competitors, GS

Research aiming for advantage against GS

◎ High clinical effects and safety

△ Others：a) Convenience（reduction of the number of doses）

b) biologics at high drug prices ⇛ low-molecular drug at low drug prices

Alliance (joint research) with companies toward practical application

To advance the project with Win-Win relationship

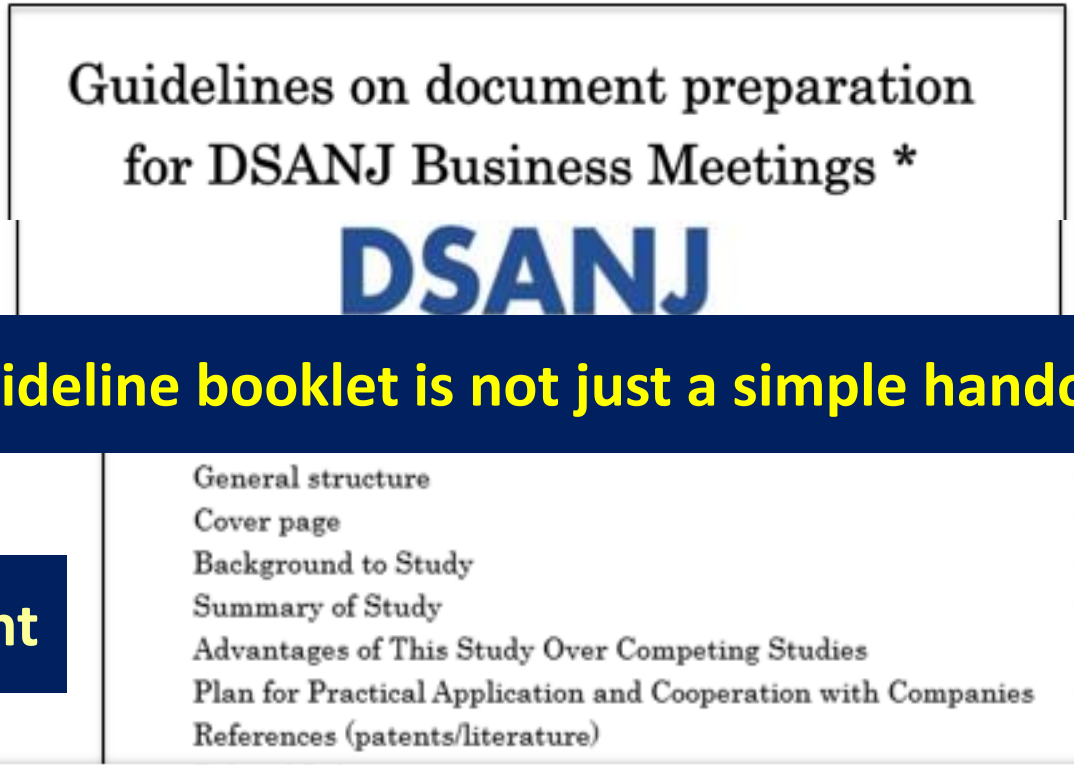
1. Have a sense of ownership
2. Share experimental plans, goals, milestones and risks

To make clear the task assignment between the university and the company with a view to advancing to clinical test

- **Assignment to university :**
  1. Provision of information of the role of target in pathogenesis of the disease
  2. Research of precise mechanism of action etc.

- **Task assignment to companies :**
  1. Provision of compound library
  2. Synthetic spread of compound
  3. In vivo pharmacological data
  4. Acquisition of ADME・Tox data
  5. Securing intellectual property

DSANJ guideline to bridge the gaps


Guidelines on document preparation
for DSANJ Business Meetings *

DSANJ

Guideline booklet is not just a simple handout .

Important

Close communication between DSAN secretariat & researchers

- **To build good human relationship**
- **Inform researchers of the objectives while interviewing**
  - ✓ **Explanations of companies' needs → Bridge the gaps**
  - ✓ **To find out potential clinical indications of researches**

Developing academic drug discovery researchers through DSAN Asia

DSAN Taiwan 2015～

Bilateral

DSAN X、Y・・ country

Multilateral

DSAN Asia

DSANJ

Guidelines on document preparation for DSANJ Business Meetings *

DSAN Japan 2010~

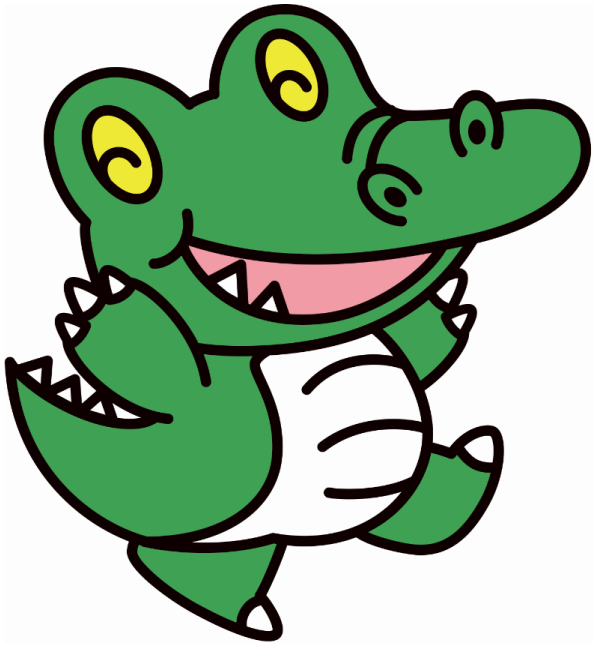
DSAN Business meeting

Strengthening drug discovery capabilities of academic researchers

Acceleration of academic drug discovery research in Asia

New drugs originated from academia in Asia

Thank you for your attention.



Part of contents of today's presentation has been published in the following journal.

Japanese Pharmacological Review Journal (Folia Pharmacologica Japonica) 144：257-258 (2014)　Academia drug discovery – with a view to inviting companies －

（In Japanese）