

「日本発のシーズを迅速に実用化する為にアカデミアが  
果たすべき役割」

## 早期臨床試験

**Collaboration with Academia  
-For early clinical development-**

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# Objective

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- **To propose a new collaboration model between academia and industry in drug development of academia discovered seeds.**

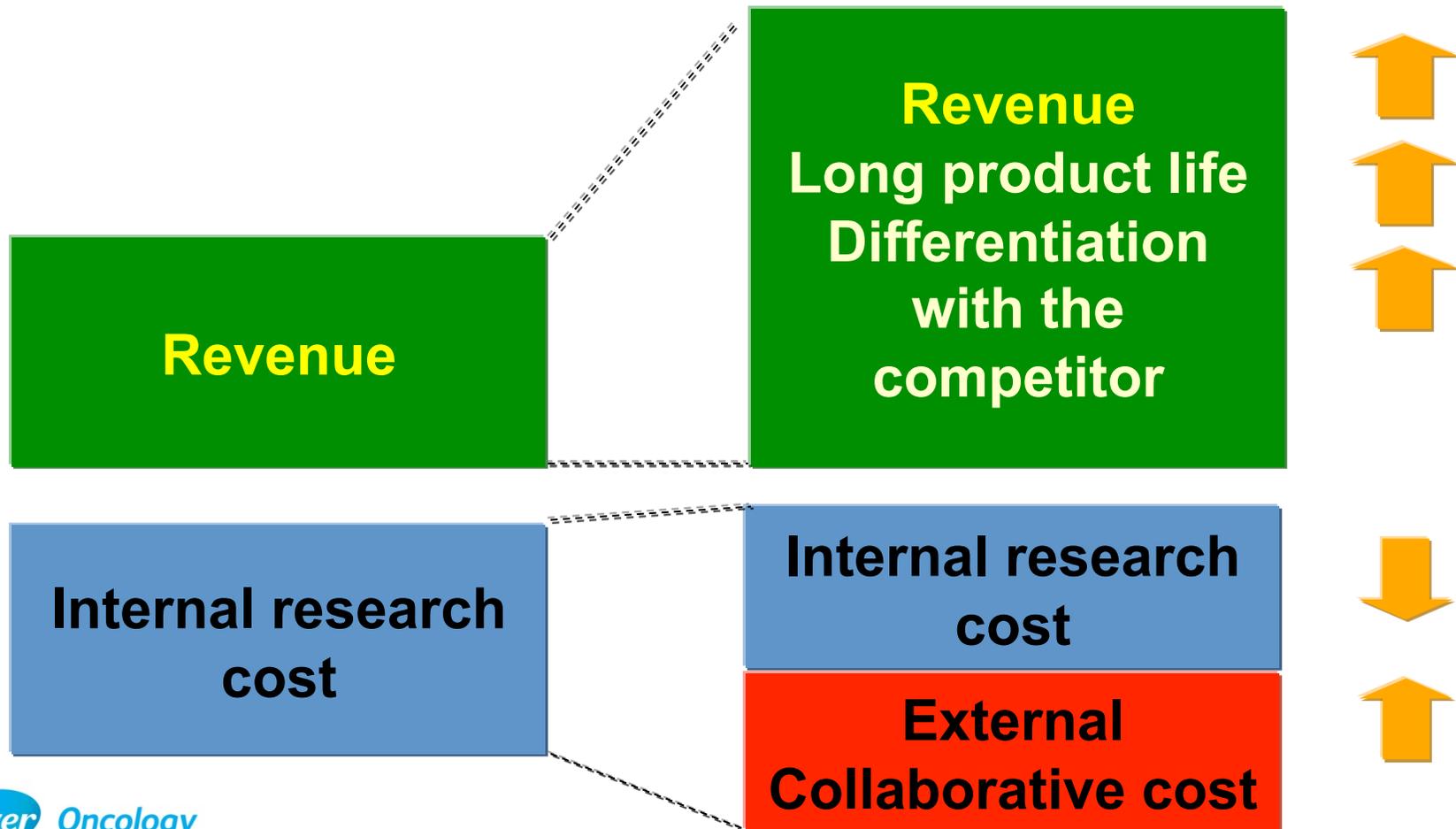
[NOTE: The content of my presentation comes from my personal experiences](#)

# Open innovation

ハーバード・ビジネス・スクール  
ヘンリー・チェスブロウ助教授 (2003)

## Closed innovation

## Open innovation



# Issues of open innovation in Japan

## For industry (esp. J-subsubsidiary of global com.)

- Less effort for collaboration with academia
  - Because HQ already has the function or system/process
  - **But open innovation is not a process, but comes from “WILL”**
- Lack of knowledge about basic science
- Less experiences to evaluate academia discovered seeds

## For academia (not only Japan, but also US)

- Little know-how about marketing strategy, clinical development strategy, regulatory strategy

## For academia and industry (not only Japan, but also US)

- Overly protective of their/our science
- Lack of relationship, reliance



\* Academia includes venture company

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# Solutions

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**New Role**

**New competency**

**New way of thinking**



# New Role

# The timing of hand-over from academia to industry

**Preclinical**



**Phase I**



**Phase II**



**Phase III**



**After POC is established**

**<Industry>**

**Demerit: Lots of competitors**

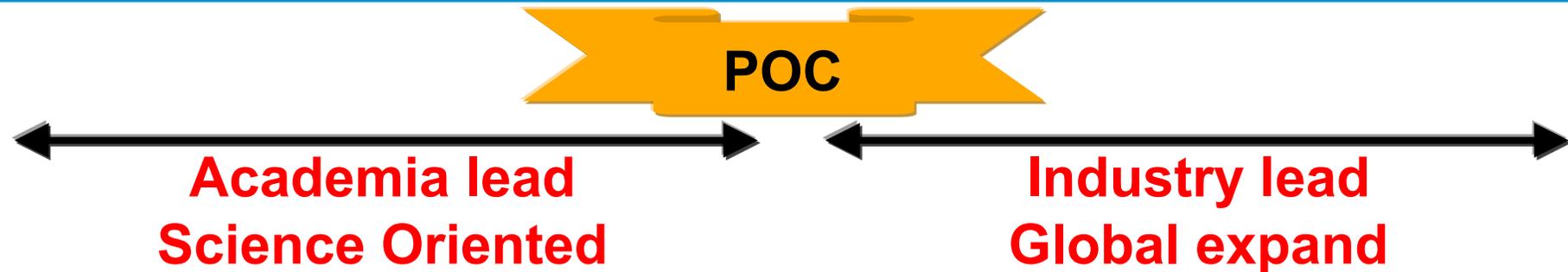
**Merit: High success rate of launching**

**<Academia>**

**Demerit: Need more resource and funds**

**Merit: Develop based on the founder's concept**

# New role of academia and industry in drug development of academia discovered seed



## -Role of Academia –

- Basic science
- Innovation
- Translational research
- Early development as investigator initiated trial

## - Role of Industry -

- World wide expansion
- Use internal network, experiences and knowledge
- Regulatory strategy
- Marketing strategy

# Expectations of academia driven clinical development

- Develop therapies for rare diseases
- **Leader of clinical development for next generation therapies**
  - New innovative technology
  - New therapeutic concept



# New competency



# Assessment points for buy-up of academia discovered seeds by industry

- Overall research/clinical development plan
  - POC data is reliable
  - No additional study/research is required
  - Any advantage over the competitors

- Intellectual Property

- Market

**Reliability of POC data**

- Enrich the pipeline
- Potential indication expansion
- No critical obstacle to expand to other countries

- Regulatory Strategy

**Pfizer Oncology**

- No critical regulatory issues

# What is reliable POC data?

- **No critical issues of CMC**
  - If there is, POC study should be repeated
- **Scientific rationale of POC establishment**
  - Adequacy of comparator
  - Adequacy of efficacy assessment method
    - RECIST or other appropriate criteria
- **Quality of data**
  - Data management concept/system is applied
- **No critical GCP issues**

**NOTE; These are not mandatory criteria.**

**Based on these points, the company will evaluate the seeds**



# Proposal of new competency for academia

## Adapt to an **industry-like approach** of drug development plan

- Research/clinical development plan
  - Market potential
  - Regulatory Strategy

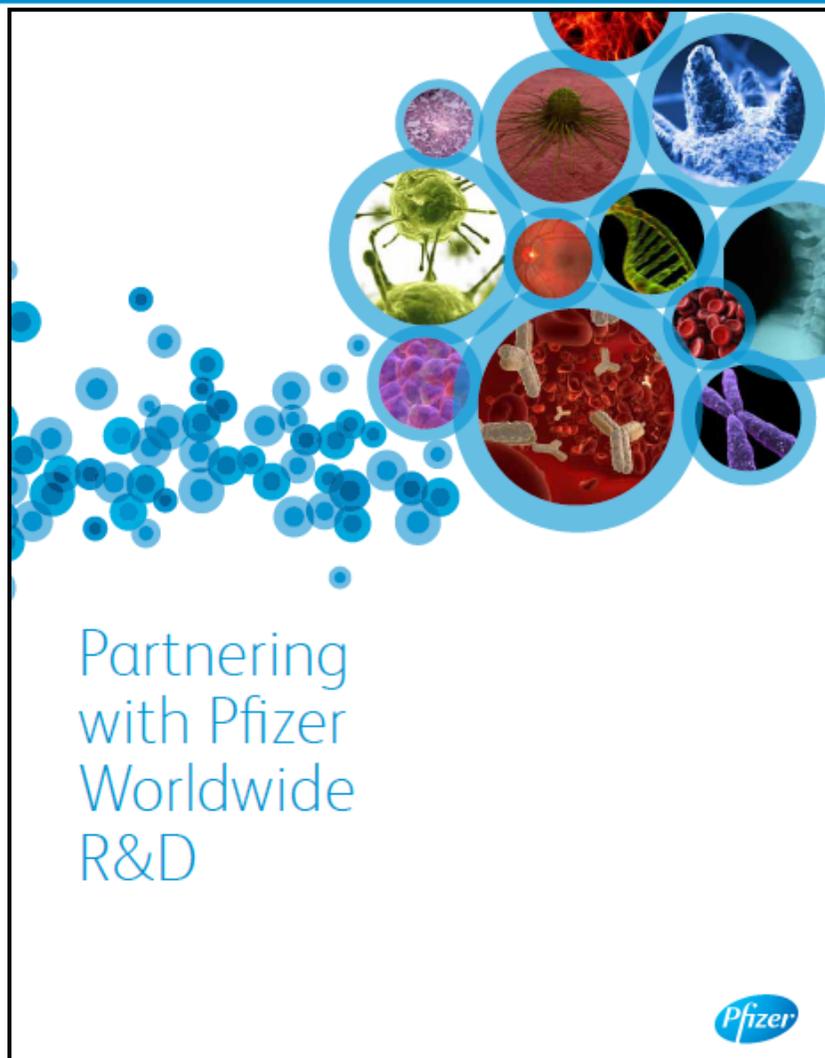
- The seeds from industry and academia will be reviewed based on the same review points.
- This competency will lead to **meaningful dialogue** with industry and to **successful partnership**

# Proposal of new competency for the company (Japan subsidiary)

- 1. Improve knowledge of basic science**
- 2. Understand the company policy**

- Capability of understanding the quality of the underlying hypothesis/discovery/science**
  - Discussion between Japan subsidiary and academia sometimes works effectively and leads to successful collaboration ( for global company)**
- Avoid unnecessary approach**

# Where company policy is written?



Each company may have particular areas of interest for collaboration with an external partner.

Approach to the appropriate partner is the fastest way.

Pfizer Oncology

[http://www.pfizer.com/partnering/areas\\_of\\_interest/research\\_and\\_development.jsp](http://www.pfizer.com/partnering/areas_of_interest/research_and_development.jsp)

Anti-Cancer Symposium Poster Nov 18, 2011

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**New way of thinking  
(new approach)**

# Proposal of new way of thinking (1)

## Knowledge transfer

- **Mini-trial inspection or site visit**
  - Regulatory strategy (CMC, GLP, GCP)
- **Mini-consultation**
  - IP assessment
- **Mini-consortium**
  - Lecture exchange
    - Development plan, market strategy
- **Routine interaction**

**Establish reliance**

# Proposal of new way of thinking (2)

## Resource sharing

- **Human resource sharing**
  - Academia-Industry
    - Company employee can be a member of academia project
  - Academia-Academia
    - Make up for deficient resources each other
- **Partnering/Team research (Function sharing)**
  - One company – multi sites of academia
  - Multi-company – multi sites of academia
  - Not much focus on who should do what,



**But “What skills should be brought to the table?”**

# Summary

## For a development of academia discovered drug

- **New role of academia**
  - Leader of basic science, translational research and early development
  - Develop therapy for rare disease
  - Leader of development for next generation therapies
- **New competency**
  - Academia: Adapt to an industry-like approach of drug development
  - Industry: Capability of basic science and review of seeds
- **New way of thinking**
  - Knowledge transfer
  - Resource sharing

**Develop new model from seeds to the market**

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Thank you for your attention !  
ご静聴ありがとうございました。