How clinical data packages in NDAs are constructed?

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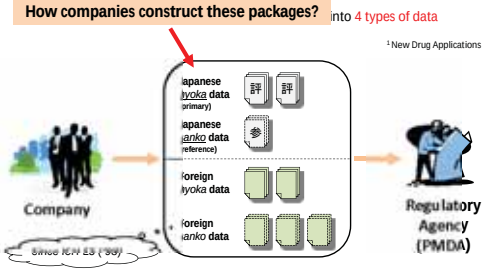
既に本学会利益相反委員会に申告しましたように、本演題発表に関連して、開示すべきCOI関係にある企業等はありません。

Background: Clinical Data Packages

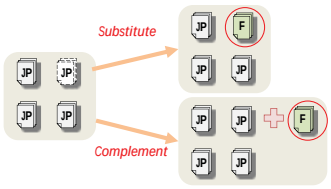
How companies construct these packages? into 4 types of data

[1] New Drug Applications



Objective

- **Investigate how pharmaceutical companies construct clinical data packages**
  - **Does foreign data "*substitute*" or "*complement*" for Japanese data?**



Methods

- Samples
  - 209 new drugs approved from 2001 to 2010 in Japan
- Regression analysis (Simultaneous equations model)
  - Dependent variables:
    Number of submitted JP *hyoka*/ JP *sanko*/ F *hyoka*/ F *sanko* data per NDA
  - Estimated by three-stage least squares (3SLS)

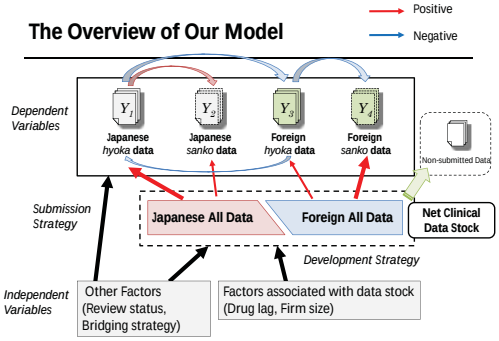
Japanese *hyoka* data: $Y_{1i} = \alpha_1 + \gamma_{12}Y_{2i} + \beta_{11}X_{11i} + \cdots + \varepsilon_{1i}$

Japanese *sanko* data: $Y_{2i} = \alpha_2 + \gamma_{21}Y_{1i} + \beta_{21}X_{21i} + \cdots + \varepsilon_{2i}$

Foreign *hyoka* data: $Y_{3i} = \alpha_3 + \gamma_{31}Y_{1i} + \beta_{31}X_{31i} + \cdots + \varepsilon_{3i}$

Foreign *sanko* data: $Y_{4i} = \alpha_4 + \gamma_{41}Y_{1i} + \beta_{41}X_{41i} + \cdots + \varepsilon_{4i}$

The Overview of Our Model

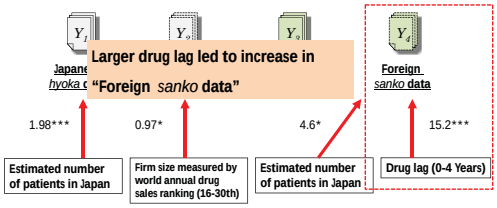


Results & Discussion

*p<0.1, **p<0.05, ***p<0.01

Factors associated with data stock

Larger data stock led to larger data submission

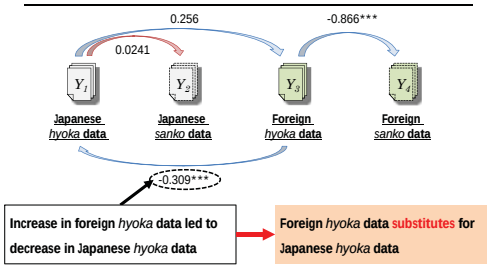


data: expressed as number of clinical trials per NDA

Results & Discussion

*p<0.1, **p<0.05, ***p<0.01

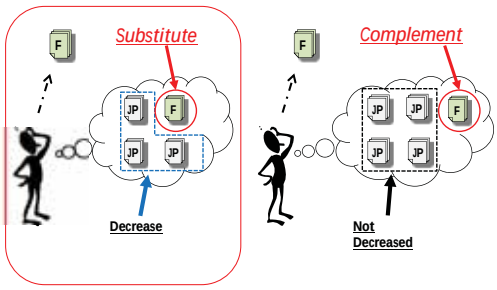
Relationship between dependent variables



data: expressed as number of clinical trials per NDA

Results & Discussion

Substitute or Complement?



Results & Discussion

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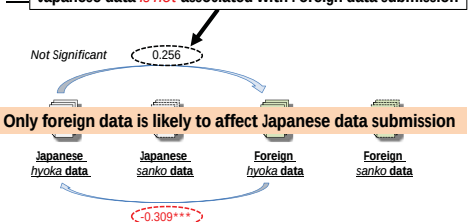
Japanese data *is not* associated with Foreign data submission

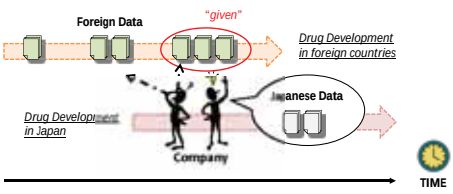


Foreign data *is* associated with Japanese data submission

data: expressed as number of clinical trials per NDA

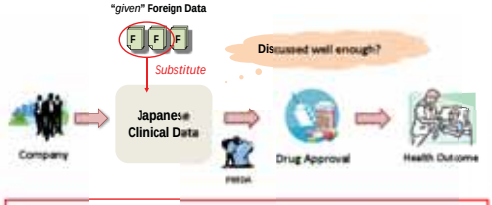
Results & Discussion

→ This result reconfirmed the common belief that companies decide Japanese data volume per NDA based on the "*given*" foreign data



Question Raised by Our Research

- **Most Japanese clinical data packages depend on the "*given*" foreign data**



What should the "*ideal clinical data package*" for Japanese people be like?