Overview of Consultation System in Japan

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Clinical trial consultation system

New Challenges

- Priority Assessment Consultation (July 2011～)
- Consultation on eligibility for priority review products (Oct 2011～)
- Pharmaceutical Affairs Consultation on R & D strategy (July 2011～)
Clinical trial consultation system
1. Reinforcement of consultation/guidance on clinical trials
2. Reinforcement of approval review
3. Strengthening of post-marketing measures
4. Others

October, 1994
Increase in the number of innovative drugs.
\to Needs for improvement of drug safety

- Strengthening the responsibility of pharmaceutical companies
- Taking comprehensive measure for pharmaceuticals

June, 1996 Publication of the revised Pharmaceutical Affairs Act
April, 1997 Enforcement of the revised Pharmaceutical Affairs Act
History of JP clinical trial consultation system

- 1980: Grant approval
- 1980: Approval review
- 1980: Clinical trial notifications
- 1980: Pharmaceutical consultations

- 1997: Establishment of PMDEC at NIHS
- 1997: Clinical Trial Consultation started on April 1997
- 1997: Equivalence review for generic drugs
- 1997: GCP Inspection
- 1997: Compliance audit

- 2001: Approval review
- 2001: Clinical trial notifications / review
- 2001: Clinical Trial Consultation

- 2004: Establishment of PMDA
- 2004: Approval review
- 2004: Clinical trial notifications / review

- 2009: Approval review
- 2009: Others
Purpose of clinical trial consultations

By implementation of consultation in development stage

- Secure the ethical and scientific appropriateness of clinical trials
- Share common views of the issues in clinical development between applicants and regulatory agency
  - Reduce application preparation time and cost
  - Avoid critical problems found during NDA review
Consultations tailored for a range of needs

1997 OPSR/Kiko

1. Consultation before IND
2. Consultation after completion of phase II study for drug
3. Pre-application consultations
4. Individual consultation

Expansion of the consultation category

2012 PMDA

1. Consultation Pre-phase I study for drugs
2. Consultation Pre-phase IIa study for drugs
3. Consultation Pre-phase IIb study for drugs
4. Consultation after End of phase II study for drugs
5. pre-application consultation
6. Additional consultation
7. Consultation on the protocols of clinical trials for reevaluation and re-examination of drugs
8. Consultation at completion of clinical trials for reevaluation and re-examination of drugs

Application procedure consultation
2. Quality consultation
3. Safety consultation
4. Consultation on bioequivalence testing, etc. for drugs
5. GLP/GCP compliance (for priority review)
6. Consultation on document maintenance of Cell- and-tissue-based products
7. Pharmacogenomics (PGs)/Biomarker consultation

Charged!
Clinical trial consultation System at PMDA

Pre-PI
Additional
Pre-PII
Additional
End-of-PII
Additional
Pre-Application
Additional

Safety
Additional
(Consultation only for Toxicity and Pharmacology)

Quality
Additional
(Consultation only for CMC)

Procedure
Procedure
(Consultation for Pharmaceutical Affairs Procedures)

GLP/GCP Compliance

Bioequivalence testing

Document maintenance of Cell-and tissue-based products

PGx/ Biomarker
# Implementation status of each consultation

Total number of each IND scientific consultation about the new medical products  

<table>
<thead>
<tr>
<th></th>
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<tr>
<td>Additional consultation</td>
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<td>2</td>
<td>2</td>
<td>2</td>
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<td>0</td>
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<td>17</td>
<td>16</td>
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<td>7</td>
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<tr>
<td>Quality consultation</td>
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<td>8</td>
<td>23</td>
<td>8</td>
<td>14</td>
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<td>13</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Consultation on bioequivalence testing, etc. for drugs</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>10</td>
<td>6</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Consultation on GLP/GCP compliance (for priority reviews)</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Consultation on document maintenance of Cell-and-tissue-based products</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pharmacogenomics (PGx)/ Biomarker consultation</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
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</table>

*: including a withdrawal
Consultation Pre-phase I study for drugs

Based on available data of non-clinical tests, approvals and experiences in other countries, information of similar drugs...

- The validity of applying the drug to a person for the first time
- Clinical study design of Phase I etc.

For example…

Q: Are non-clinical tests data sufficient at the beginning of a phase I trial?

Q: Are the initial safe dose and subsequent dose escalation schemes acceptable in a phase I trial?

Q: Are the safety parameters for clinical monitoring acceptable?
Consultation Pre-phase IIb study for drugs

Based on results from phase I trials, approvals and experiences in other countries, information of similar drugs:
- Clinical study design of phase II etc.

For example...
Q: Are the selection of doses in dose-finding study rationale?

Q: Are the selection of endpoints in dose-finding study acceptable?
Consultation End of phase II study for drugs

Based on available data of clinical trials...

- Clinical study design of phase III etc.

**For example…**

Q: Are dose-response assessment and recommended dose appropriate?

Q: Are the selection of control products and endpoints in the confirmatory clinical trials acceptable?

Q: Are the data analysis such as the method of sample size calculation suitable?

Q: Dose the design of long-duration trials meet the related GL?

Q: Can foreign clinical data be extrapolated?

Q: Is Japanese population in multi regional trials sufficient?
Pre-application consultation

Based on available data of clinical trials...
- The way for compiling the application document
- Sufficiency of the application document

*For example*...

Q: Are the non-clinical and clinical data sufficient for the application?

Q: Are Dosage & Administration, and Indication appropriate?

Q: Is it acceptable that the results of clinical studies in non-Japanese are treated as the evaluation data?

Q: Is the data package including foreign clinical data acceptable?
Trend of Clinical trial Consultation (FY2010)

### No. of Global Clinical Trial Consultations

- **No.**
- **%**

<table>
<thead>
<tr>
<th>Disease</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
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<td>Oncology</td>
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<td>10</td>
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<tr>
<td>Circulation</td>
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<td>14</td>
</tr>
<tr>
<td>Respiratory</td>
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<td>3</td>
</tr>
<tr>
<td>CNS</td>
<td>40</td>
<td>29</td>
</tr>
<tr>
<td>Anti-biotics</td>
<td>33</td>
<td>31</td>
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<tr>
<td>Urology</td>
<td>42</td>
<td>45</td>
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<tr>
<td>Raido-pharmaceuticals</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>10</td>
<td>1</td>
</tr>
</tbody>
</table>

### Global clinical trial consultations

- **FY2006**
- **FY2007**
- **FY2008**
- **FY2009**
- **FY2010**

- □ No. of Global Clinical Trial Consultations
- ■ % of Global Clinical Trial Consultations
Consultation for Global Clinical trials

For example...

Based on “Basic principles on Global Clinical Trials”,

Q: Is it appropriate to participate in the global trial based on intrinsic and extrinsic ethnic factors?

Q: Is a development program acceptable in which Japanese subjects are included only from a phase III trial without conducting any dose-finding study in Japan?

Q: How to determine a sample size and a proportion of Japanese subjects in global clinical trial?
Documents required for clinical trial consultation

① Background and concept of the IND development
   • Existing treatment for the disease
   • Problems of the existing treatments and expected benefits of the IND
② Draft of protocols
③ The latest Investigator’s Brochure
   • List of clinical trials
   • List of toxicity studies
④ Development status in other countries
⑤ References
⑥ Past consultation’s minutes  etc.
Composition of Consultation Team

Office Director*

Review Director

CMC
Pharmacology
ADME
Toxicology
Clinical
Biostatistics
Project Management

1~2
1~2
1~2
1~2
1

* PMDA has 5 offices for New Drug Review and 2 offices for Biologic product evaluation
Scene of Face-to-face Meeting

PMDA’s member

Consultant’s member
Prior Assessment Consultation
Why did we introduce “Prior Assessment Consultation”?

“How to eliminate drug lag?”

**Targets:** To reduce the “drug lag” by a total of 2.5 years

- **Development time**
  - **Expansion of the Consulting Service**
    - Increase the number of staff about 236 approximately in 3 years
    - Give adequate training
  - **Improve the quality and quantity of consultations**
    - Advise on overall development strategy to improve development time
    - Reduce the application preparation time through stepping up the pre-application consultations
  - **Clarify the review criteria**
    - Further promote Global Clinical Trials
    - Draft a guideline on cutting-edge technologies

- **Approval review time**
  - **Expansion of the Review System**
    - Increase the number of staff
    - Give adequate training
  - **Enhancement and improvement of the Review System**
    - Introduce a prior assessment, and reduce applicant workload.
    - Improve productivity of reviews through measures such as the standardization and Streamlining of the review process
  - **Liaise more closely with the FDA and other overseas regulatory authorities**

**Targets (by 2011)**
- 1.5 year reduction of development time
- 1.0 year reduction of approval review time
## Target review time (New Drugs)

<table>
<thead>
<tr>
<th></th>
<th>FY</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
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<td><strong>Standard review</strong></td>
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<tr>
<td><strong>Products (Median)</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total review time</td>
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<td>21</td>
<td>20</td>
<td>19</td>
<td>16</td>
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<tr>
<td>Regulatory review</td>
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<td>12</td>
<td>11</td>
<td>9</td>
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<tr>
<td>Applicant’s time</td>
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<td>8</td>
<td>8</td>
<td>7</td>
<td>5</td>
<td>3</td>
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<td><strong>Priority review</strong></td>
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<td><strong>Products (Median)</strong></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Total review time</td>
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<td>12</td>
<td>11</td>
<td>11</td>
<td>10</td>
<td>9</td>
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<tr>
<td>Regulatory review</td>
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<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
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<tr>
<td>Applicant’s time</td>
<td></td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>3</td>
</tr>
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</table>

**Regulatory and Applicant’s work in collaboration to tackle a goal!**
Purpose of prior assessment consultation

By implementation of consultation before formal NDA

- Shorten NDA review time
  - Identify major discussion points and tasks for NDA submission
  - Help applicants to prepare a good CTD with the inclusion of PMDA’s view points
Contents of prior assessment consultation

**Consultation contents**

- Quality
- Toxicity (non-clinical)、Pharmacology (non-clinical)、Pharmacokinetics (non-clinical)
- Phase I study、Phase II study、Phase II/III study

- Data evaluation before a formal NDA submission
- PMDA provides a prior-assessment report for the submitted data/study
Prior assessment consultation Flow

PMDA’s Action
- Accept tentative application
- Inform the availability
- pre-meeting (Informally)
- Accept application
- Review the documents
- Inquiry
- Review response
- Evaluation report writing
- Evaluation

Consulter’s Action
- Tentative application
- Application
- Submit documents
- Submit the response to inquiry
- Confirm the evaluation report
- Evaluation report

*working day

- 6 months rough standard
- 40 d*
- 30 d*
- 35 d*
- 15 d*
## Implementation status of prior-assessment consultation

<table>
<thead>
<tr>
<th>(FY)</th>
<th>Status of acceptance</th>
<th>Status of consultation (Numbers of category)</th>
<th>Status of review (Number of the ingredient)</th>
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<tbody>
<tr>
<td></td>
<td>Total of the ingredient</td>
<td>Total of the acceptance</td>
<td>Before consultation</td>
</tr>
<tr>
<td>2009</td>
<td>7</td>
<td>33</td>
<td>0</td>
</tr>
<tr>
<td>2010</td>
<td>9</td>
<td>30</td>
<td>0</td>
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<tr>
<td>2011</td>
<td></td>
<td></td>
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<tr>
<td>First half</td>
<td>3</td>
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<tr>
<td>Second half</td>
<td>7</td>
<td>24</td>
<td>8</td>
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※Data: the end of January 2012
Consultation User Survey Summary - I

Q: Consultation Items were resolved or cleared?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Resolved or Cleared</td>
<td>7</td>
</tr>
<tr>
<td>Relatively cleared</td>
<td>7</td>
</tr>
<tr>
<td>Neither</td>
<td>2</td>
</tr>
<tr>
<td>Relatively Not cleared</td>
<td>0</td>
</tr>
<tr>
<td>Not resolved or Not cleared</td>
<td>0</td>
</tr>
</tbody>
</table>

Q: How can you conclude a value of the consultations?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Very useful</td>
<td>5</td>
</tr>
<tr>
<td>Useful</td>
<td>9</td>
</tr>
<tr>
<td>Neither</td>
<td>2</td>
</tr>
<tr>
<td>Not useful</td>
<td>0</td>
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</table>

Q: Unexpected problems are found for application?

<p>| | |</p>
<table>
<thead>
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<th></th>
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<tbody>
<tr>
<td>Found</td>
<td>10</td>
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<tr>
<td>Not found</td>
<td>6</td>
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Thought of as advantages

Generally cleared

Generally found the value
Consultation User Survey Summary – II

<table>
<thead>
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<th>Q: Number of inquiries after the application will be decreased?</th>
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<tr>
<td>Clearly decreased</td>
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<tr>
<td>Perhaps decreased</td>
</tr>
<tr>
<td>No change</td>
</tr>
<tr>
<td>Perhaps increased</td>
</tr>
<tr>
<td>Clearly increased</td>
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<table>
<thead>
<tr>
<th>Q: Become helpful in submission data?</th>
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</thead>
<tbody>
<tr>
<td>Very helpful</td>
</tr>
<tr>
<td>Helpful</td>
</tr>
<tr>
<td>Neither</td>
</tr>
<tr>
<td>Not very helpful</td>
</tr>
<tr>
<td>Not helpful</td>
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</table>

Expect the decrease of inquiries

Generally helpful
## Consultation User Survey Summary – III

**Q: Review become more efficient?**

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<td>Very efficient</td>
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<tr>
<td>Efficient</td>
<td>4</td>
</tr>
<tr>
<td>Neither</td>
<td>0</td>
</tr>
<tr>
<td>Inefficient</td>
<td>0</td>
</tr>
<tr>
<td>Very inefficient</td>
<td>0</td>
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</table>

**Q: Shortened the review time?**

<table>
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<tr>
<th>Comment</th>
<th>Count</th>
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<tr>
<td>Considerably shortened</td>
<td>2</td>
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<tr>
<td>Shortened</td>
<td>3</td>
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<td>Neither</td>
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<td>Extended</td>
<td>0</td>
</tr>
<tr>
<td>Considerably extended</td>
<td>0</td>
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**Q: As at the application, remaining tasks resolved?**

<table>
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<th>Count</th>
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<tbody>
<tr>
<td>Resolved</td>
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<td>Nearly resolved</td>
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<td>Neither</td>
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<tr>
<td>Unresolved</td>
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**Q: Did you spend more time for a weighty discussion (dosage and administration, effect-efficacy etc.)?**

<table>
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<th>Count</th>
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<tr>
<td>Very fulfilling discussions</td>
<td>1</td>
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<tr>
<td>Spend more time for discussion</td>
<td>2</td>
</tr>
<tr>
<td>Neither</td>
<td>1</td>
</tr>
<tr>
<td>Conventional</td>
<td>2</td>
</tr>
<tr>
<td>Rather, non-fulfilled</td>
<td>0</td>
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</table>
Consultation on eligibility for priority review products
Priority review

Reviews of approval applications for orphan drugs and other drugs that are regarded as having particularly high medical need ※ were conducted on a priority basis as priority review products.
※ i.e., drugs for serious diseases with distinctly superior efficacy or safety to existing drugs or therapies
Purpose of consultation on eligibility for priority review products

By evaluating the eligibility for priority review products before formal NDA

- Expect to shorten the priority review time
  - Form a PMDA ‘s opinion immediately after formal NDA
  - Spend more time for NDA review
- For applicants, it is beneficial to be clear the product may be eligible for priority review products or not before formal NDA
Flow of consultation on eligibility for priority review products

**PMDA’s Action**
- Accept application
- Review the documents
- Inquiry
- Review the response
- Evaluation report (Draft)
- Expert Discussion
- Evaluation report

**Consulter’s Action**
- Application
- Submit documents
- Submit the response to inquiry
- Confirm the evaluation report

1.5 or 2 months (rough standard)
10 d*
15 d*
25 d*
40 d*

*working day
As the end of evaluation, we will start the form our opinion.

**Application:**
3 months to a day before NDA

**Pre-application consultation**
Consultation Fee (JPY): 168,700

**Assessment for designation of priority review products**
Consultation Fee (JPY): 823,300

**Assessment report**

**PMDA opinion**

**MHLW**

**Notification**

**Consultation on eligibility for priority review products** Consultation Fee (JPY): 823,300

**Assessment for designation of priority review products**

**PMDA opinion**

**MHLW**

**Notification**

**Consultation on eligibility for priority review products** Consultation Fee (JPY): 168,700

**Assessment for designation of priority review products**

**PMDA opinion**

**MHLW**

**Notification**
Pharmaceutical Affairs Consultation on R & D strategy
Policies

- New Growth Strategy (Cabinet decision in June 2010)
  (2) Health power strategy through “Life Innovation”

  *Promoting research and development of innovative pharmaceuticals and medical and nursing care technologies from Japan*

  We will promote research and development of highly safe, superior, and innovative pharmaceuticals and medical and nursing care technologies from Japan. We will promote unified approaches among industry, government, and academia, foster drug development ventures, and promote research, development, and application in a number of fields. These include new drugs, regenerative medicine and other state-of-the-art medical technologies, remote medical treatment systems making full use of information and communications technologies, use of manufacturing technologies to improve personal mobility for the elderly, and medical and nursing care robots. To this end, we will work to resolve the urgent drug and device lag issue, improve the clinical testing environment, and expedite drug approval decisions.
Current status in New Drug Research and Development Originated by Academia in Japan

Drug discovery by Academia

Target for Drug discovery
Seeds Discovery
Lead compounds Identification
Optimization
Non-clinical Trial
Clinical Trial
License out to Industry

Death valley

R & D by Industry

License
Efficacy
Marketability
Toxicity

Medicinal Chemistry

From Seed compounds to Lead compounds

Screening (HTS, etc)

- Target Evaluation
- Screening technology
- Increasing
- Cost Increasing
- Lack of facilities

IMP Production (GMP)
Drug Formulation (GMP)

- Cost burden
- Possible to outsource
- Production for anti-body drug

Pharmacology, Toxicity
ADME (non GLP)

- Planning
- Evaluation
→ Optimization
- Cost burden
- Possible to outsource

Pharmacology, Toxicity
ADME (GLP)

- Planning
- Cost burden
- Possible to outsource

Clinical Trial by Company

Investigator’s Initiate Trial

Clinical research

- Impossible to use NDA
- Site
- Quality

Intellectual property

Target Search

Increasing
- Cost burden
- Property, Manufacturing process
- Lack of Researchers

Increasing
- Cost  Increasing
- Lack of facilities

Cost
Speed
Quality
Global
Pharmaceutical Affairs Consultation on R&D Strategy

-To accelerate the development of Japan-originated medical products-

- Accelerating the development for Japan-originated medical products
  - Shorten duration of collecting data for application
  - Improve the success rate
  - Creation of innovative medical product

Pharmaceutical Affairs Consultation on R&D Strategy

PMDA consultations

- New
  - Consultation on conducting clinical trials (in operation)
  - Necessary CTs / Drug formulation / Efficacy / Validity
  - The consultation fee for ventures and academia can be reduced by subsidies from GoJ

Apply for product approval

Clinical Trial

Seeds Improvement

Seeds Search

Basic Research

Accelerate the development for Japan-originated medical products
Pharmaceutical Affairs Consultation Group on R&D Strategy

Academia Venture

Office of Review (New drugs and devices)

Application of *Pre-consultation
*Consultation

Follow Up

Enforcement of *Pre-consultation
*Consultation

Connection of Academia and PMDA offices

Technical Experts

Are experts for pharmaceutical affairs who had worked in companies

Mediate academia and PMDA offices

Coordinate and follow up before/after the consultations

July 2011 started
Scope of the Pharmaceutical Affairs Consultation on R&D Strategy

Innovative Products in following priority area

• Regenerative medicine (cell- and tissue-based products)
• Cancer
• Incurable disease and orphan disease
• Pediatrics
• Other area, products utilizing particularly innovative technologies

(Note) Regardless of the order among the areas.
### The number of each consultation

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<th>Medical device</th>
<th>Regenerative medicine</th>
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Summary

- Consultation system in Japan is the important tool to support and encourage drug development for regulatory approval.

- PMDA provides consultations tailored for a range of needs and challenges to make the better consultation systems for each other.
Thank you for your attention!