PMDA’s Efforts in Medical Innovation
- Regulatory Science & Science Board -

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Director General of the Office of Review Innovation
Pharmaceuticals and Medical Devices Agency (PMDA)
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Today’s Presentation

1. Current Status of Pharmaceutical Affairs Consultation on R&D Strategy
2. Advancing Regulatory Science and Collaboration with Academia
3. Establishment of the Science Board
Pharmaceutical Affairs Consultation on R&D Strategy

Valley of Death
- Short of funds, Knowledge on Regulation and development strategy

Basic Research
Pharmaceutical and Medical Devices candidates originating from Japan

Quality Study
Consultation on quality or toxicity study of biologics, cell-and tissue-based products

Non-Clinical Study

Clinical Trial
Up to the level of POC studies

Practical Use
Innovative Products originated from Japan

Strategic Consultation

Consultation on endpoints or sample size of early clinical trial

* Further studies are handled by the Regular Consultation
Flow of R&D Strategy Consultation

- Introductory Consultation (No Charge)
  - 120 Consultations

- Pre-Consultation (No Charge)
  - Not binding
  - 30 minutes

- Face-to-Face Consultation (charged)
  - Binding
  - Written record to Applicant
  - 2 hours

- Total Consultations:
  - 166 Consultations
  - Product Category:
    - Anti-neoplastic 56%
    - Cardiovascular 21%

- Final Consultations:
  - 36 Consultations
  - (7/1/2011 – 3/31/2012)
# Fees for Consultation

<table>
<thead>
<tr>
<th>Pharmaceuticals</th>
<th>Price per consultation</th>
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<tr>
<td></td>
<td>¥1,498,000 (US$ 19,000)</td>
</tr>
<tr>
<td></td>
<td>¥149,800*</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>¥849,700 (US$ 11,000)</td>
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<td></td>
<td>¥84,900*</td>
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*academia, start-ups
Today’s Presentation

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Regulatory Science is seen as “Science that adjusts science technology outcome to its most favorable shape in harmonization between human and society” that is an essential concept to prove risk/benefit and to ensure safety of pharmaceuticals and medical devices.
Program of Collaborative Graduate Schools

Agreement with 12 Universities
(as of June, 2012)

- Yamagata University
- Musashino University
- University of Tsukuba
- Kobe University
- Shujitsu University
- Osaka University
- Gifu Pharmaceutical University
- Gifu University
- Chiba University
- Teikyo University
- Yokohama City University
- Shizuoka Prefectural University
- Osaka University
Today’s Presentation

1. Current Status of Pharmaceutical Affairs Consultation on R&D Strategy
2. Advance of Regulatory Science and Collaborating with Academia
3. Establishment of the Science Board
Why “Science Board” now?

With Review Goal (Time) achieved and Staffers increasing, We at PMDA are required to:

① Provide review and consultation services with understanding of advanced technologies (antibody-based drugs, companion diagnostic drugs, ventricular assist devices, regenerative medicine, cancer vaccines, etc.).

② Provide consultation/advice on the advanced scientific technology from the early stage of development to deliver the medicinal products utilizing advanced technologies sooner to the medicinal scene.

③ Keep close relationship with the academia to have the PMDA reviewers updated to the accelerating innovation.
Science Board and Office of Review Innovation

- **Committee members**: External experts from Academia
- **Not involved in the Review Process of individual products**

**Committee**

- Review policy for innovative medical products
- Development of guidelines
- Regulatory Science Research
- Personnel exchanges
- Election of External review experts
- Improvements in the scientific aspects of review

**Subcommittee**

- Deliberation on problems in each field
- Collaboration with PMDA working team (RS research, guideline development, etc.)

**Mission**
Reform PMDA reviews and related services based on science with consideration for actual medical practices

**Office of Review Innovation**
- Director General
- Secretariat Director
- Associate Director General
- Secretariat Director’s office

**PMDA Offices**
- Review
- Safety
- RS
- SGD

**Science Board**

- RS: Office of Regulatory Science
- SGD: Office of Standards and Guidelines Development
Strengthen Review System in PMDA

- Enhance partnership with academia -

Set up Office of Review Innovation (April 2012) and the Science Board (May 2012)
<table>
<thead>
<tr>
<th>NAME</th>
<th>POSITION &amp; ORGANIZATION</th>
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<tbody>
<tr>
<td>Tatsuro Irimura</td>
<td>Professor, Faculty of Pharmaceutical Science, the University of Tokyo (CHAIRMAN)</td>
</tr>
<tr>
<td>Kazuhiko Yamamoto</td>
<td>Professor, Graduate School of Medicine and Faculty of Medicine, the University of Tokyo (CO-CHAIR)</td>
</tr>
<tr>
<td>Akinori Akaike</td>
<td>Professor, Graduate School of Pharmaceutical Sciences, Nagoya University</td>
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<tr>
<td>Yukihide Iwamoto</td>
<td>Professor, Orthopedic Surgery, Department of Clinical Medicine, Kyushu University</td>
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<tr>
<td>Hideuki Okano</td>
<td>Professor, Department of Physiology, School of Medicine, Keio University</td>
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<td>Chieko Kai</td>
<td>Professor, Institute of Medical Science, the University of Tokyo</td>
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<td>Hideo Kusuoka</td>
<td>President, Osaka National Hospital, National Hospital Organization</td>
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<td>Professor, Graduate School of Pharmaceutical Sciences, Kyoto University</td>
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<td>Toshiya Sato</td>
<td>Professor, Biostatistics, Public Health, Graduate School of Medicine, Kyoto University</td>
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<td>Yuichi Sugiyama</td>
<td>Invited Senior Scientist, Sugiyama Laboratory, RIKEN Innovation Center, RIKEN</td>
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<td>Tatsutoshi Nakahata</td>
<td>Deputy Director, Center for iPS Cell Research and Application, Kyoto University</td>
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<td>Masahiro Hayashi</td>
<td>Department of Pharmacy, Toranomon Hospital</td>
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<td>Akira Matsuda</td>
<td>Professor, Faculty of Pharmaceutical Sciences, Hokkaido University</td>
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<td>Yoichiro Matsumoto</td>
<td>Professor, Graduate School of Engineering, the University of Tokyo (Office of Medical Innovation, Cabinet Office)</td>
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<td>Masaki Mori</td>
<td>Professor, Department of Gastroenterological Surgery, Graduate School of Medicine, Osaka University</td>
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<tr>
<td>Nobuhiro Yamada</td>
<td>University president, the University of Tsukuba</td>
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<tr>
<td>Teruko Yamamoto</td>
<td>Professor, Graduate School of Dentistry, Tohoku University</td>
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Schedules of main meetings Ahead

Science Board

Sub Committees
Establishment of the Science Board

The Science Board was established in May 2012 to discuss how PMDA can better cope with products with advanced scientific technology, in each developmental stage such as basic research, development support, product review, and post market safety measures.

Board members

Academia
Thank you for your attention!

http://www.pmda.go.jp/