The 7.5th Kitasato University-Harvard School of Public Health Symposium

Expectations and Demands from Industry, Regulatory agencies and Academia —NPO Perspective—

Foundation of JCPM and Talent Development in Pharmaceutical Medicine

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Agenda

• Awareness of Professional Education/Training in Clinical Research/Clinical Trials
• Initiatives for Talent Development in Clinical Research
• Current status of Pharmaceutical Medicine Education in Japan
• Overview of JCPM
• 1st JCPM symposium
• Conclusion/Expectations
Awareness for Education/Training in Clinical Research

- **Physician Investigators**
  - Generally understand the importance of clinical research/drug development
  - Tend to accept clinical trials in their specialty therapeutic area
  - Recognize the Importance of Training/Education in clinical research
  - Recognize that most physicians have not received education/training in clinical research field

- **Urgent need for human resource development is recognized**
  - The need to develop expertise in clinical research/clinical trials
  - Incentives for investigators/supporting staffs including career path

「Report from the expert group to study human resource situation in the filed of clinical research/clinical trials 」(Oct.23, 06)
Initiatives for Talent Development in Clinical Research

- **Governmental Initiatives for talent development in the field of clinical research**
  - The new 5 yearly Clinical Trial Activation Plan (March, 2007)
  - Science and Technology Promotion Grand for Talent Development Program (MEXT)
- **On-going discussion efforts for education/training in clinical research in medical education**
  - Possible inclusion during undergraduate medical school education
  - Re-education of physician investigators
  - Accreditation as specialists
  - Training programs in Academic Institutes
Educational Activities of Pharmaceutical Medicine

Scientific Associations
The Japanese Society of Clinical Pharmacology and Therapeutics
The Japanese Society of Clinical Neuropsychopharmacology etc.

Academia
Tokyo U., Kyoto U., Oita U., Nagasaki U., Yokohama City U.,
Kitasato U., Juntendo U., Kurume U, Tokai U., Keio U.,
Kyoritsu U. of Pharmacy, International U. of Health and Welfare,
UHCT alliance etc.

Industry etc
JAPhMed (Japanese Society of Pharmaceutical Medicine)
1. Programs and courses are rather isolated and not comprehensive to cover diverse disciplines necessary for clinical research/clinical trials

2. No clear criteria agreed regarding the level of knowledge, skills and experience required for individuals to be accepted as experts in clinical research/clinical trial

3. Without standardized education, consistent development of high quality study and evaluation of associated trial results may be at risk
Pharmaceutical Medicine as a Solution

• To improve the situation:
  – We need to establish consensus and promote common standards of medical and operational expertise for clinical research/clinical trials

• Pharmaceutical Medicine
  – A new discipline in medicine that includes a broad spectrum of drug-related clinical sciences; including clinical pharmacology, epidemiology, toxicology, biostatistics, and regulatory science
  – This breadth of disciplines has been an important contributing factor in the development of consistent high quality of trial specialists and reviewers in Europe and the United States

• Promotion of Pharmaceutical Medicine could be a solution to improve the situation
Overview of JCPM (Japanese Center of Pharmaceutical Medicine)

Non-Profit Organization (NPO)
- Approved by Tokyo Metropolitan Office (12/7/2006)
- Chaired by Dr. Hiroo Imura

Purpose
- To promote the education in Pharmaceutical Medicine in Japan
- To develop experts in clinical research/trials in collaboration with relevant organizations

Target Audience
- Clinical Research Investigators in hospitals and academic facilities (mostly Physicians)
 japcenter.com-pharmaceutical-medicine\n
JCPM functions and Related Fields

① Facilitate information sharing among relevant groups shown in Green field

② Establish the minimum requirement of Pharmaceutical Medicine for clinical Research investigators
1st JCPM Symposium (1.19.2008)

- Lack of opportunity to share and actively exchange education/training activities among academic institute

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- To provide opportunities to share/exchange information of activities
- To facilitate collaboration/networking among relevant groups
- To help develop advanced and coordinated education/training system for clinical research/clinical trials in Japan
There are three ways to get qualification of pharmaceutical medicine professionals:

1. **Graduate Students + Company Employees + Physicians**
2. **Internet / Independent Courses**
   - 12 Sessions
   - Certificate
3. **Academia**
   - Tokyo Univ.
   - Kitasato Univ.
   - Other
   - Degree
4. **OJT, Conference, Symposium etc.**
   - JAPhMed Course
   - Tokyo Univ.

Examination for Qualification / executed by JCPM

Qualified Pharmaceutical Medicine Professional (TBD)
Conclusion/Expectation

1. Development of highly qualified specialists with global standard is absolutely necessary

2. It is critical to consolidate training/education to a highly organized, continuous, and comprehensive activity

3. Positive signs for significant future improvement in expertise are observed
   - Governmental Initiatives for talent development
   - Academic efforts to build education/training system
   - Industry contribution to these activities

4. JCPM will contribute for more organized and comprehensive education/training activity in Japan