Promoting Patient and Public Involvement in Japan

FUJIIWARA Yasuhiro, M.D., Ph.D.
Chief Executive, PMDA

Join us at the Crossroads of Healthcare:
Europe in the Fast Lane
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<td>☐ Grants/Research Funding</td>
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My Priorities at PMDA

Medical Oncologist, specializing in breast cancer.
—Chief Executive, PMDA (2019.4 -)
—Deputy Director, the Hospital (Research), National Cancer Center (2015 - 2019.3)
—Director-General, Strategic Planning Bureau of the National Cancer Center (2012 - 2019.3)
—Deputy Secretary General, Office of Medicinal Innovation, Cabinet Secretariat of Japan (2011 - 2013)
—Deputy Director of the Evaluation Division II, PMDEC (1997 - 2002)
My Priorities at PMDA

< 4Fs >

◆ Patient First
◆ Access First
◆ Safety First
◆ Asia First

by Fujiwara

The main priorities include putting patients first by promoting early access while ensuring safety, further strengthening pharmacovigilance and increasing collaboration with Asia.
My Priorities at PMDA

◆ Patient First

Improve patient satisfaction by learning what is happening around the clinical practice
Active patient involvement in planning, designing or evaluating clinical trials and relevant education are proposed in multiple government plans, e.g.,

- The Plan for Promotion of Medical Research and Development by the Headquarters for Healthcare Policy, July 22, 2014
- Basic Plan to Promote Cancer Control Programs, Oct 2017
- Health Science Council Clinical Research Division, Mar 2019
- and more.

Some patients participated in developing these plans.
PPI Activities in Japan - My Contribution as an Expert -

Definition, mission and basic principles of PPI were discussed and established by the committee chaired by Dr. Fujiwara.

7 committee meetings held during 2017.07-2019.03
• Report of the discussion on PPI in clinical trials was published

• PPI Guidebook was published in Apr, 2019
In May 2019, PMDA established Patient Centricity Working Group to:

- discuss how patients can be involved in PMDA’s overall activities
- develop and publish guidance / principles on PPI at PMDA (expected in 2021)
PPI Activities in Japan
- Other Actions-

PPI Consortium in Japan

- Established in July, 2019 as the open forum of patients, industry, academia and regulatory authority
- Partnering with EUPATI to introduce EUPATI tools to patient and public
How to Further Promote PPI in Japan?

Learn from others, e.g.,
- EUPATI Trainings
- Patients' and Consumers’ Working Party at EMA
- Patient Representative Program at US-FDA

Next steps:
- **Trainings** for patient, public and health care professionals (HCPs)
- **Coordinating person** for dialogue between patient, public and HCPs
- Disseminate **PPI information**
- Promote **opinion exchange**
Join the conversation #DIAEurope2020

Thank you.
Ask questions during the Q&A!!

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