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(Patient & Public Involvement) JAPAN

## Updates on PPI/PE activities in Japan & Challenges faced by the activities

# General Incorporated Association PPI JAPAN



**Dr. Masaru IWASAKI,**  
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<b>Board Member</b>	Masaru IWASAKI	Academia
	Shun EMOTO	Patient Advocate, Rare Disease
	Naomi SAKURAI	Patient Advocate, Cancer
	Naoko SO	HCP
	Satoshi MIKI	Pharma Industry
	Kazuhiko MORI	Former MHLW General Councilor for Pharmaceuticals
<b>Auditor</b>	Ikuko YAMAGUCHI	Patient Advocate

## **Membership**

45 regular members

3 associate member

8 corporate support members

*(As of Sep. 1, 2022)*

- Established as a legal entity in November 2019
- Joined in EUPATI National Platform representing Japan in April 2020 and the MOU with EUPATI signed in November 2020
- Promote mutual understanding and collaboration between patient groups, patient support groups, the general public, and industry-government-academia while digging up the needs of related parties through our policy based on careful communication
- Formulate our business plan and aim to become a parent body that realizes true "industry-patient-government-academia" collaboration

# Updates on PPI/PE activities in Japan

## Major activities at PPI JAPAN

### 1. Dialogue with PPI JAPAN members (quarterly web meeting)

- Exchange personal experience and history on PPI among members
- Brainstorming to co-create **“Desired Future State of PPI” in next 5 years** under planning

### 2. Hold PPI JAPAN seminar “Let’s Learn about PPI activities in Japan” (quarterly web-based seminar)

- 3<sup>rd</sup> seminar: April 18
- 4<sup>th</sup> seminar: Aug. 1
- 5<sup>th</sup> seminar: Oct. 31



### 3. “Connecting” event(s) under planning

- Event(s) to identify the needs of patients, patient groups, companies, etc., and to create a forum for exchanging ideas about fulfilling and effective “Connecting” activities

# Updates on PPI/PE activities in Japan

## A Working Group initiated at PPI JAPAN

- Draft model document for Lay Summary suitable for Japan
  - Prepare a draft model document that meets the needs and realities of Japanese patients after scrutinizing the European GLSP requirements
  - Propose a study on how to introduce and utilize the model document in Japan
    - Collaboration with regulatory authorities, patient groups and other stakeholders



### Good Lay Summary Practice

This guidance was developed in cooperation with the Roadmap Initiative to Good Lay Summary Practice and adopted by the Clinical Trials Expert Group (CTEG, a working group of the European Commission representing Ethics Committees and National Competent Authorities (NCA)).

#### Version 1

Document history:	
Date of adoption by the expert group on Clinical Trials	9 July 2021
Date of publication	4 October 2021

# Updates on PPI/PE activities in Japan

## Practical PPI/PE activities based on the available public information

**PMDA (Pharmaceuticals and Medical Devices Agency)** released “Cooperation with patient associations for the prompt and appropriate provision and collection of information for patients” on May 31, 2022

In collaboration with the Japanese Council of Lysosomal Disease Patient and Family Associations, the following are being implemented on a trial basis.

- Providing easy-to-understand information on the efficacy and safety of new drugs to be launched in the future.
- Collect safety information related to the use of therapeutic drugs using the patient association network.

Based on the results of the trial, consider whether the scope of cooperation should be expanded.

**JCOG (Japan Clinical Oncology Group):** the largest Japanese cooperative group with 190 active participating institutions, funded primarily by the National Cancer Center Research and Development Fund. It has been and is running “Patient and Public Involvement Committee” since 2018.

### JCOG Patient and Public Seminar

- From 2021, seminars will be held twice a year, with an **introductory session** and an **advanced session**.

**Introductory session:** Participants will attend basic lectures on clinical research and clinical trials conducted by the JCOG. And it will be held on the same theme each year.

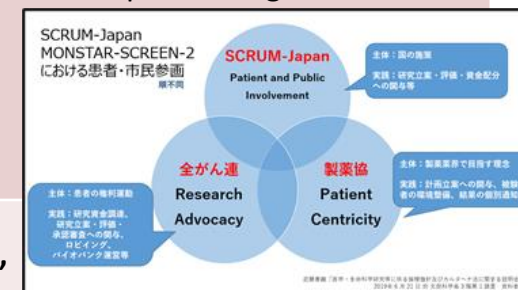
**Advanced session:** It is intended for participants who have attended a previous JCOG patient public seminar. And the topics of the Advanced Session vary each year.

### NCCHE (National Cancer Center Hospital East)

- **SCRUM-Japan** : an industry-academia collaborative project launched in 2015 with the aim of delivering the latest gene panel tests and the best treatments for cancer patients

From 2019, PPI activities have been incorporated and promoted together with patient organizations and pharmaceutical companies.

- **Opinion exchange meetings from 2020 onwards**
- **Review of Protocols and ICFs is also conducted**



### DIA Japan Pt. Engagement Community (PEC):

a learning community where companies, academia, regulators, providers and recipients of healthcare can exchange information, openly exchange opinions and learn from each other, transcending their positions, with the aim of realizing patient-initiated drug development

On-line Workshops held: May 28 and Sep. 3, 2022

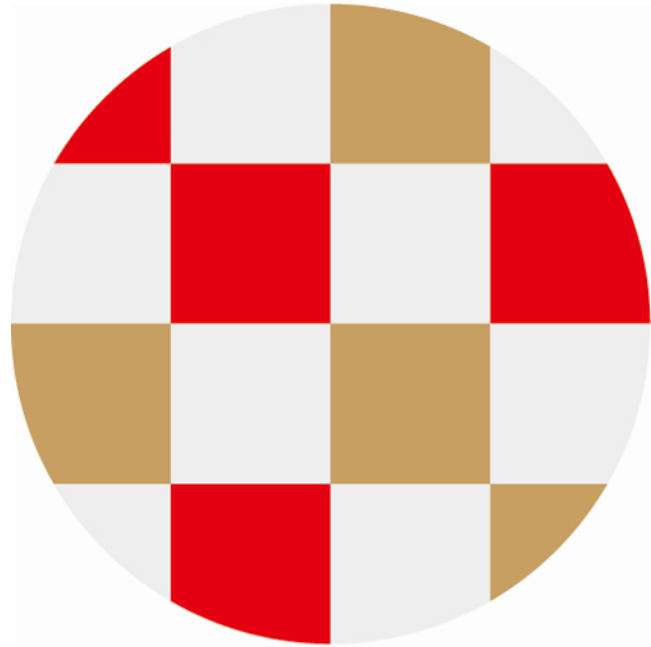
Theme: “**Break barriers to patient engagement in drug development**”

- On May 28: “What barriers to patient engagement exist?”
- On Sep. 3: “Think about actions to remove barriers and take action tomorrow”

# Challenges faced by the activities

- PPI/PE has become popular in different sectors over the past few years
  - Limited active members play major roles
  - Should not be a “buzzword” but should be sustainable and effective practice in Medicines Development in Japan
- PPI/PE needs to be penetrated in the wider audience in general public (including patients), while fostering active patients and their care-takers through well-developed education and training
  - “Gap” always exist between Information providers (speakers) and recipients (listeners)
  - “More Gaps” exist between HCPs (physicians) / Industry / Authorities and Patients
  - What to do about “communication gaps”
    - *Use easy-to-understand language (Lay Language) for general public*
    - *Respect diverse and different backgrounds and opinions: prepare safe space for pt. to talk and actively listen to pts. voice*
    - *Pts. to practice asking question(s): at least one question to your physician in charge*

**Thank you for your attention!**



**PPI JAPAN**