# Overview of PACMP* pilot program in Japan

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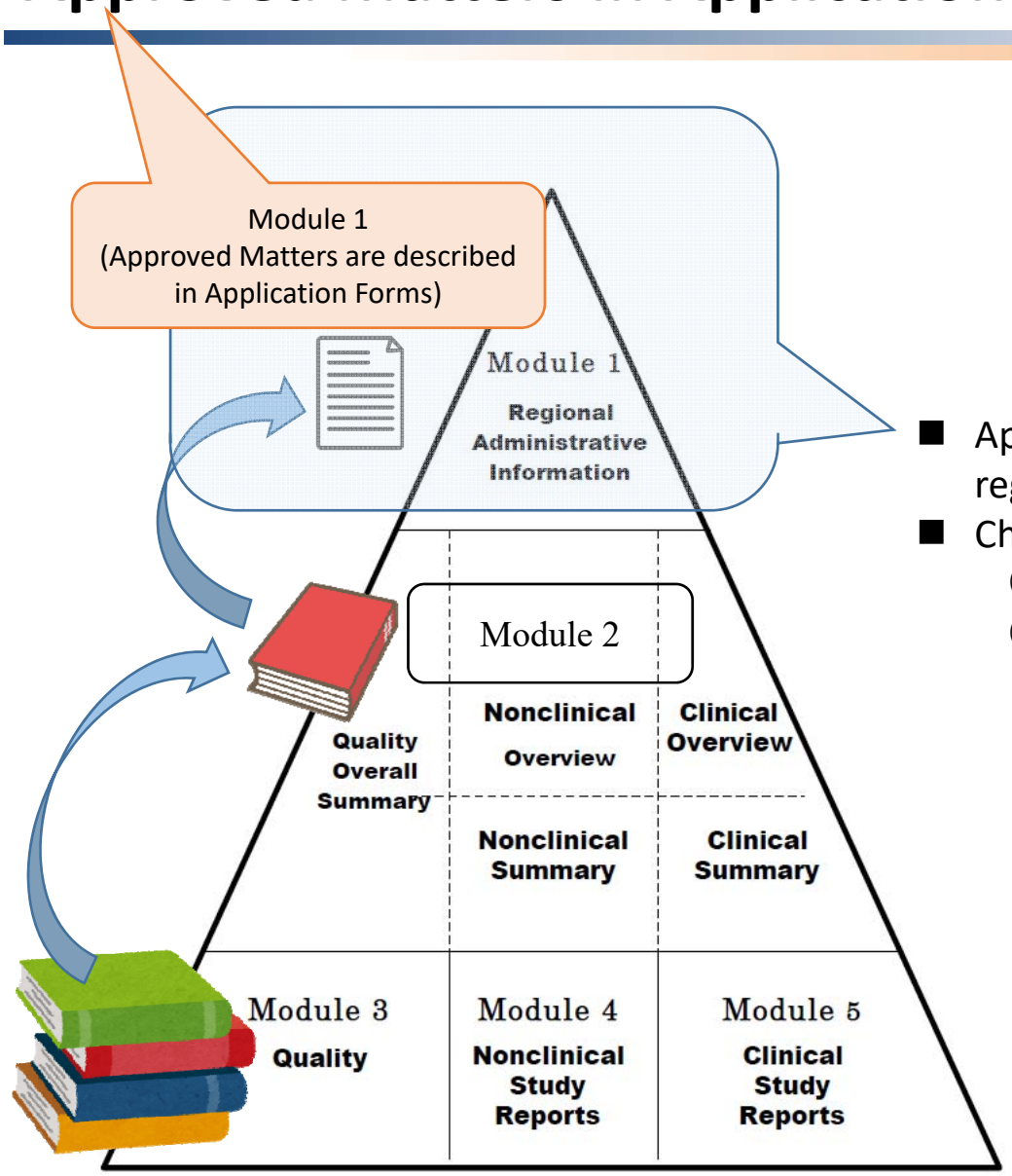
* Post-Approval Change Management Protocol

# Approved Matters in Application Forms in Japan




- Approved Matters in Module 1 is the target of regulatory process in Japan
- Change categories for approved matters:
  - ① Partial change Application
  - ② Minor change Notification

Reference: ICH M4

# Post-Approval Change Procedures

| Risk of Changes | Japan | US | EU |
|---|---|---|---|
| High | **Partial change Application** (Application for approval of variation) | Major change (Prior approval supplement) | Type II variation (Application for approval of variation) |
| Moderate | **Minor change Notification** (Notification within 30 days after implementation or shipping) | Moderate change 1)Supplement-changes being effected (CBE) in 30 days | Type IB variation (Notification before implementation and MAHs must wait a period of 30 days) |
| | | 2)Supplement-changes being effected (CBE) | Type $IA_{IN}$ variation (Immediate notification) |
| Low | **(Non-approved matters)** | Minor change (Annual report) | Type IA variation (Notification within 12 months after implementation) |

# PACMP in ICH Q12

This guideline provides a framework to facilitate the management of post-approval CMC changes in a more predictable and efficient manner.

**TECHNICAL AND REGULATORY CONSIDERATIONS FOR PHARMACEUTICAL PRODUCT LIFECYCLE MANAGEMENT**
**Q12**

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Definition of a PACMP:
A PACMP is a regulatory tool that provides predictability and transparency in terms of the requirements and studies needed to implement a change as the approved protocol provides an agreement between the MAH and the regulatory authority.

# Post-Approval Change Management Protocol

- Regulatory tool that provides predictability and transparency in terms of the requirements and studies needed to implement a CMC change as the approved protocol provides an agreement between the MAH and the regulatory authority.
- A protocol describes the CMC change an MAH intends to implement during the commercial phase of a product, how the change would be prepared and verified, including assessment of the impact of the proposed change, and the suggested reporting category in line with regional requirements, i.e., a lower reporting category and/or shortened review period.

- PACMP enables planning and implementation of future changes to approved matters in an efficient and predictable manner.
- Already implemented in US (2003-) and EU (2010-)

**In Japan, PACMP pilot program has started since April 2018**

# PACMP pilot program in Japan

- PACMP pilot program provides predictability and transparency of post-approval CMC change.
- PACMP pilot program provides the type of change categories (PCA / MCN) based on prior agreement between the MAH and PMDA.
- Conditions and acceptance criteria outlined in the PACMP must be met in order to implement the change(s).
- Partial Change Application ⇔ Approval : 3 months (median).

PACMP

【Prior Agreement】

- ✓ CMC Changes
- ✓ Evaluation methods
- ✓ Acceptance criteria
- ✓ Approved matters
- ✓ Change categories
- ✓ …….
- ✓ Necessity of PACMP GMP consultation
- ✓ Necessity of GMP inspection
- ✓ …….

User restrictions and general instructions:

- The MAH is responsible for ensuring that whenever a CMC change is to be introduced under a PACMP.
- The use of a PACMP is enabled through an effective PQS (ICH Q10).

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