Pivoting to Platform: A Case Study in Leveraging Reliance to Enable Fast Implementation of Platform Analytical Procedure for Commercial Products

WCBP January 28, 2026

Christine Wu, Pharma Technical Regulatory
Genentech, A Member of the Roche Group

Innovative Approach to Bring New Technology Globally Faster

-Implement across Roche biopharmaceutical portfolio in over 120 countries

Today

Multiple analytical procedures for Identity

Over 120 COUNTRIES

Multiple Biopharmaceutical Products

>2000 applications

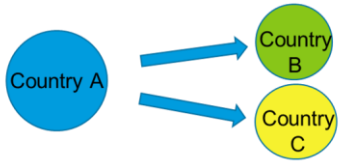
Up to 3 years to get approval for each product

5~6 years to implement for all the products

EMA OPEN Framework

Multi-product PACMP

Unilateral Reliance



Cloud based submission and Q&A

GOAL

Platform analytical procedure

< 1 year to get approval for each product

< 3 years to implement for all the products

Multi-product change to 1 platform analytical procedure

Consolidation of preceding technologies to a more sensitive, specific, and reliable procedure

- Meets demand for increasingly complex product portfolio
- Single analytical procedure

One Platform Analytical Procedure

- Suitable to all biopharmaceutical products in portfolio
- Same operating conditions, SST criteria and reporting structure

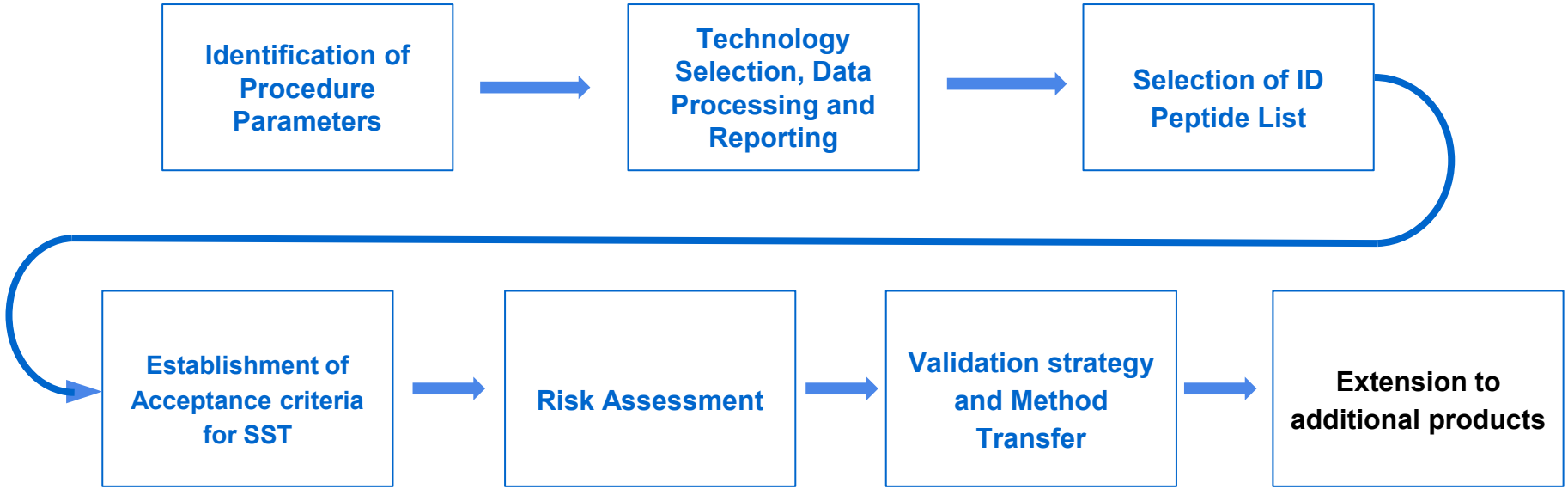
Health Authority Expectations

- Platform Analytical Procedure defined and validated in accordance with **ICH Q2 R2** principles
- Includes **ICH Q14** elements such as risk assessment driven robustness studies executed during development

Enhanced Supply Reliability

- Easy for health authorities to review and inspect
- Centralized lifecycle management of a single procedure at a Roche global level for new product introduction

Platform Analytical Procedure: ID by Lys-C Peptide Mapping

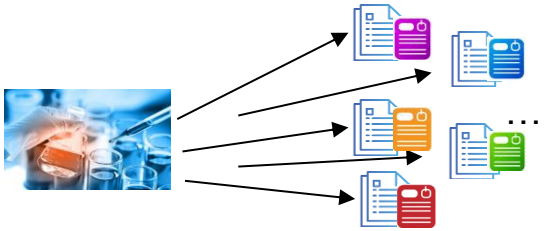


Leverage Multi-Product PACMP to Enable Faster Implementation of Platform Analytical Procedure

Step 1+2 (without PACMP)

Now

N independent dossier/submission of the same variation (Prior Approval or Notification Moderate)



N independent review and approval for each product

>3 years to get global approval for each product

Tomorrow

1 submission of common dossier **(multi-product PACMP)** via Type II variation/prior approval to cover N products

1 review to cover N products

Core validation data, common validation strategy & plan

N product specific package, submission via Notification low

Product specific data

Faster Implementation

Step 1 (worksharing procedure)

Step 2

→ Reduce regulatory review time and resources.

→ Flexible implementation per product with reduced reporting

Register ID Platform Analytical Procedure via a Multi-Product PACMP

Multi-Product PACMP Step 1

One common PACMP for all products submitted as prior approval (e.g., Type II, PAS)

- Description and rationale for the proposed changes
- Establishment of Platform Analytical Procedure
- Description of Platform Analytical Procedure
- Platform Analytical Procedure Validation
- Analytical Procedure transfer strategy
- Study design and acceptance criteria for product-specific partial re-validation and method transfer to extend to additional products and sites
- Proposed reduced reporting category

Multi-Product PACMP Step 2

One package for each product submitted in accordance to the agreed reporting category from Step 1 with the following data

- Product specific partial re-validation data
- Product specific verification data for method transfer

Ongoing challenges

- **Large amount of submissions to be submitted for most countries:**
  - No multi-product submission possible
  - Intermediates, DS, DP may require separate submissions
  - Each DP strength may require separate submissions…

- **Limiting Regulatory framework in several countries:**
  - No official variation pathways for PACMP assessment
  - No possibility to downgrade step 2
  - Specific PACMP restrictions (e.g., limited duration, not reusable, specific to a product)

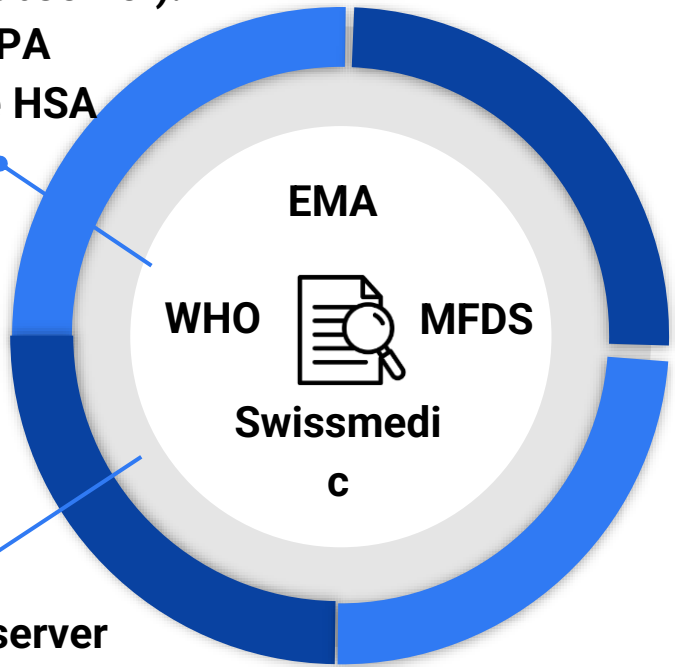
- **Minimization of double testing, registration testing, local requirements…**

EMA OPEN Framework

OPEN partners

EMA OPEN Framework

WHO experts (observer):
China NMPA
Singapore HSA



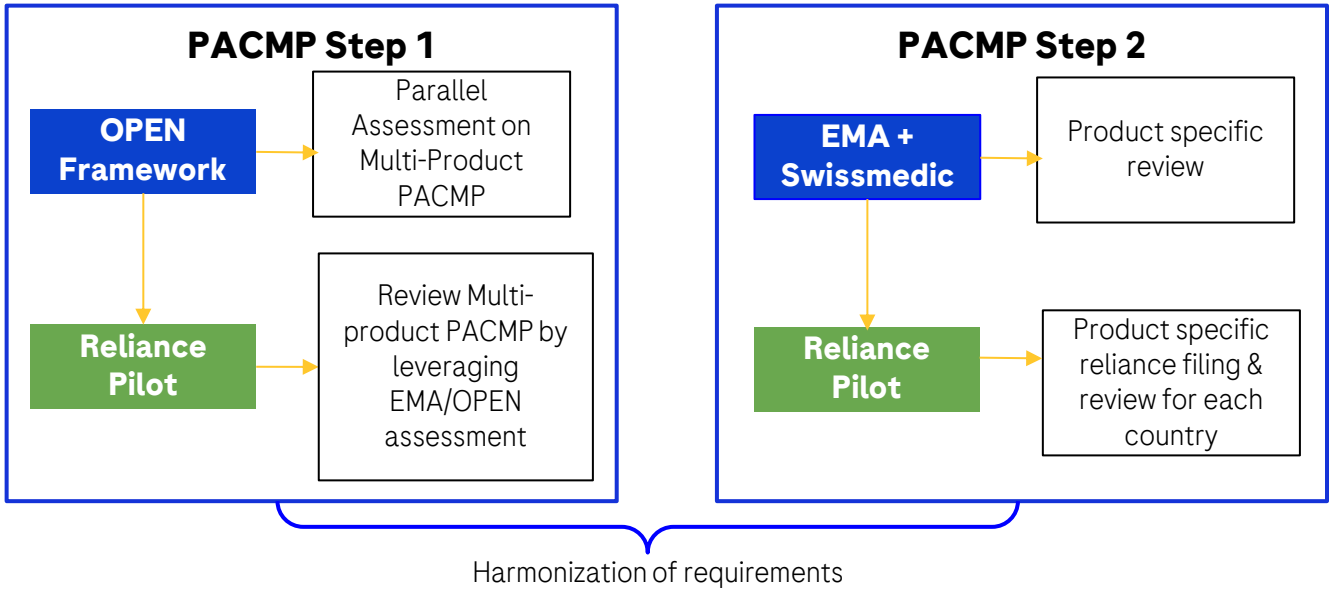
PMDA as observer

Benefit of OPEN parallel assessment

- Facilitate sharing of scientific expertise
- Facilitate alignment of regulatory approaches between regulatory authorities
- Enhance transparency on regulatory decisions
- Consolidated list of question from regulators

Reliance Strategy to accelerate global implementation

- Use OPEN framework Parallel Assessment to ideally have a harmonized assessment and list of questions
- Use unilateral Reliance to accelerate the global implementation of platform ID analytical procedure



PACMP Step 1: Unilateral Reliance Layout & Participation Criteria

One Standard Dossier

Submitted to all countries

Q&A Document

Reference agency's questions and Roche's responses document will be shared with the participating NRAs

Reference agency Assessment Report

Shared with participating NRAs

No Country Specific Requirements

Avoid submission of country specific requirements when justified by scientific rationale

No Registration Testing

For all participating NRAs

One Timeline for All

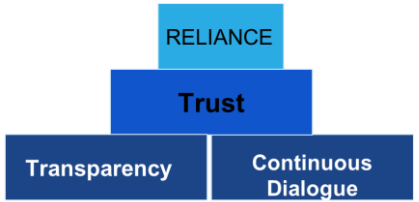
Same dossier and Q&A review timelines for all participating NRAs

PACMP Step 2: One downgrading principle

Use of cloud-based platform for sharing variation package and Q&As

- Use of **cloud-based data and information exchange platform** to support regulatory interactions between Company and Global Health Authorities
- To ensure **visibility and full transparency**:
  - A single, standardized variation package will be accessible to all participating National Regulatory Authorities (NRAs) in Accumulus*
  - All Q&As will also be shared online among the participating NRAs

*Simultaneous submission of the variation package will be performed via the standard local submission process



Project Summary

Innovative regulatory pathway using a two-step multi-product PACMP:

- Step 1: a common dossier for multiple products submitted via EMA worksharing and OPEN framework.
- Step 2: product-specific package, proposed with a reduced reporting category.

Unilateral reliance pathways will be used after EMA OPEN process to accelerate global implementation.

This approach is expected to achieve the following benefits:

- Reduce regulatory burden and increase efficiency as review of one PACMP will cover multiple products, thereby saving regulatory resources.
- Enable fast implementation of state-of-art platform analytical procedure across multiple products.
- Promote global use of PACMP and reliance pathways.
- Support convergence of global regulatory requirements, including change classification.

Acknowledgements

Technical Regulatory

Dulce Aldana Sanchez
Thomas Buckel
Kowid Ho
Suat Gnoh Por
Melly Lin
Elisa Strauss

Analytical Development and QC

Hilary Pallat
Thomas Chan
Sebastien Leibe
Milady Ninonuevo
Sebastien Violini
Moritz Vollrath

And many more …

Doing now what patients need next