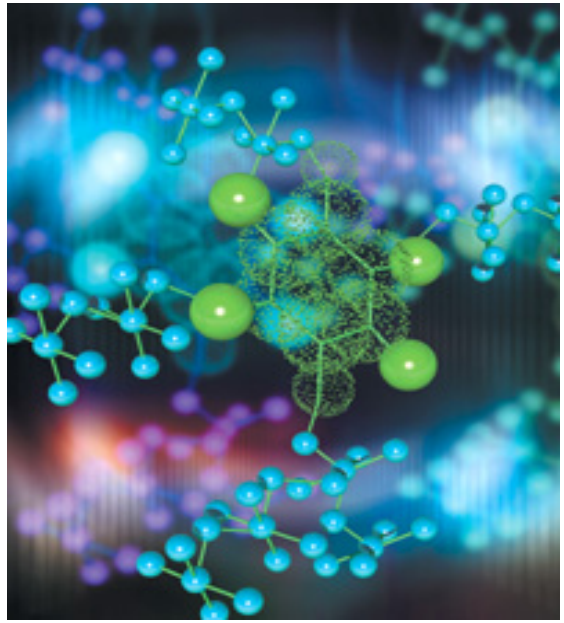
Summary Report on PMDA 3rd International Symposium on Biologics



Omnitrope

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PMDA (Japan)

The Purpose of this Symposium

- Form an international platform for quality, efficacy and safety of Follow-on biologics (Biosimilar).
- Offer an opportunity to exchange opinions on Follow-on biologics (Biosimilar) and to think a direction for the future among representatives from regulatory authorities and industry.
- Promote and advance the R&D activities and approval review on Follow-on biologics (Biosimilar).

Session 1:

Chair: Dr. Richardson, EMEA & Dr. Arato, PMDA

- Quality, Safety and Efficacy of Follow-on Biologics.
  Dr. Teruhide Yamaguchi, Division Head, Division of Biological Chemistry and Biologicals, NIHS

- Innovator's perspective of Follow-on Biologics.
  Mr. Hideaki Nomura, Manager, Strategic Product Planning Department, Kyowa Hakko Kirin Co., Ltd., JPMA

Japanese perspective of Follow-on Biologics

- **Name: Follow-on Biologics**

- **Guideline: Guideline on Follow-on Biologics: Quality, Safety and Efficacy Issues**
  Draft for public commet by MHLW; Sept. 17, 2008

- **Definition: a biotechnological product that is produced by a subsequent-entry manufacturer and claimed to be comparable to a biotechnological product already approved in Japan**

- **Scope: Well-characterized recombinant protein products**

Japanese perspective of Follow-on Biologics

- **Establishment of the well-defined manufacturing process, and extensive characterization studies of the follow-on biologics are required.**

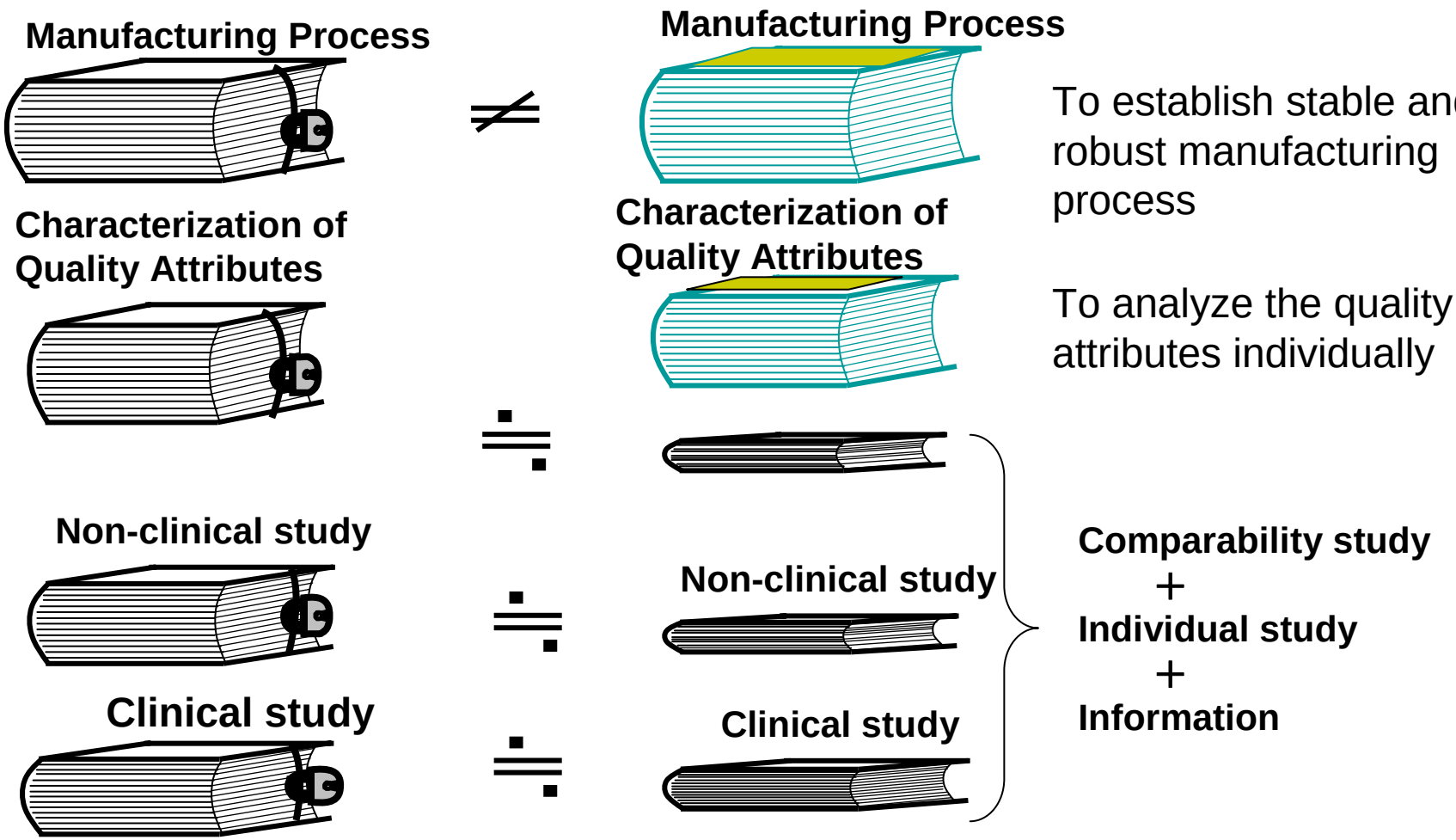
- **Demonstration of the similarity in quality attributes with the reference medicinal product is required.**

- **Comparability between the follow-on biologics and reference medicinal product should be evaluated based on the data from non-clinical and clinical studies.**

- **PMS**

Japanese perspective of Follow-on Biologics

Dossiers of the innovator product Dossiers of the biosimilar product



Session 2:

Chair: Dr. Yamaguchi, NIHS & Dr. Nyarko, HC

- Regulation of Biopharmaceuticals in the United States of America.
  Dr. Keith Webber, Deputy Director, Office of Pharmaceutical Science CDER, FDA

- PhRMA Perspective on Follow-on Biologics.
  Dr. Marie A. Vodicka, Assistant Vice President, Biologics & Biotechnology, PhRMA

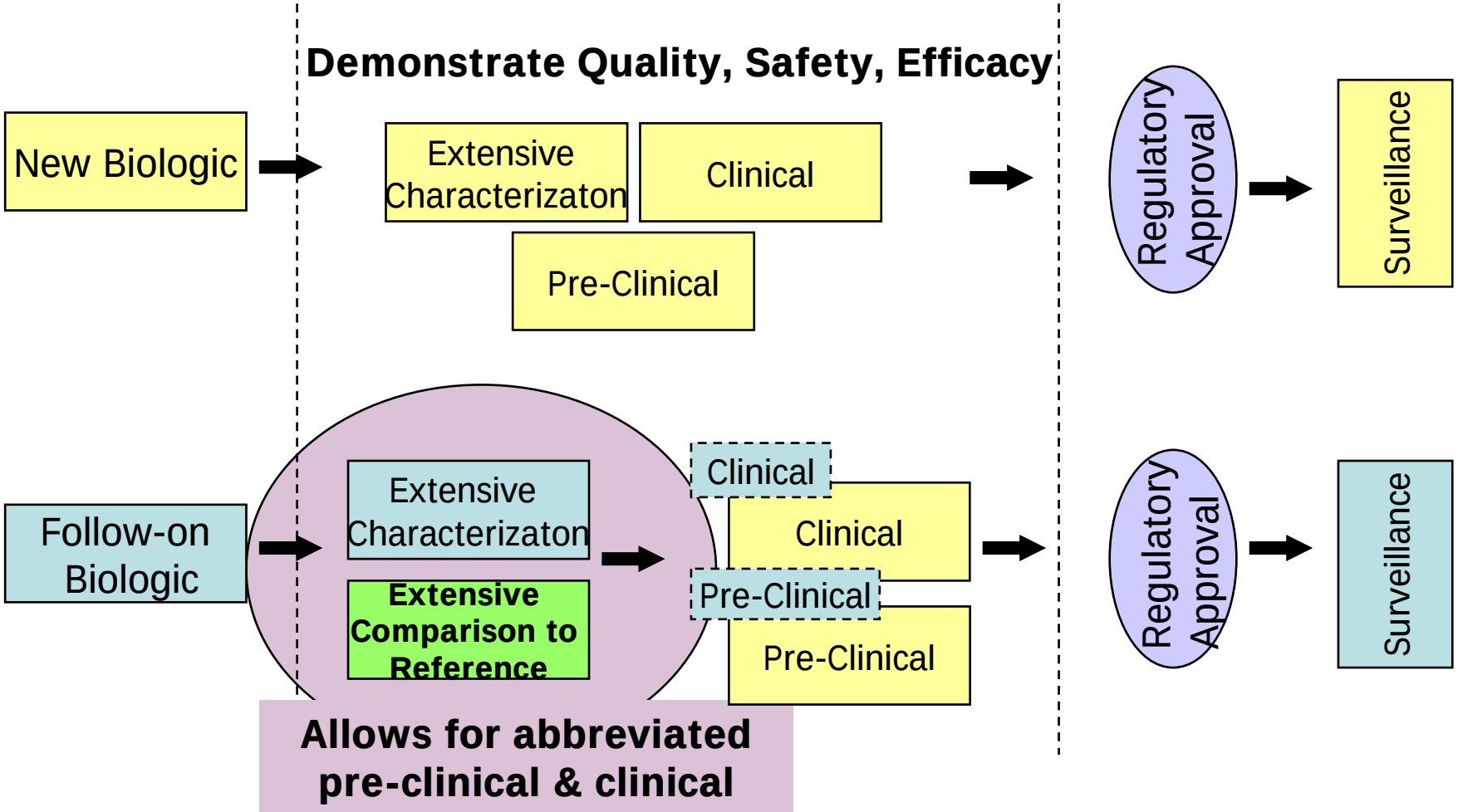
US perspective of Follow-on Biologics

- **Name: Follow-on Products (Follow-on Biologics)?**

- **Guideline: −**

- **Definition:**
  - **A product for which a sponsor relies to some extent on the finding of safety and efficacy of an approved reference product**
  - **Product intended to be interchangeable with comparator product**
  - **Product intended to be similar to comparator product**

US perspective of Follow-on Biologics



Session 3:

Chair: Dr. Webber, FDA & Dr. Shikano, PMDA

- Biosimilar Medicines in EU.

  Dr. Peter Richardson, Scientific Administrator, Quality of Medicines Sector Human Unit Pre-Authorisation, EMEA

- Scientific Aspects for the Establishment of Biosimilar Guidelines, the Perspective of EFPIA and EBE.

  Dr. Stephan Fischer, SVP Biologics Research and Strategy Pharma Research Penzberg, Roche Diagnostics GmbH, EBE-EFPIA

- EGA's perspective on Biosimilar Products.

  Dr. Martin Schiestl, Head, Analytics and Pharmaceutical Development Sandoz GmbH, EGA

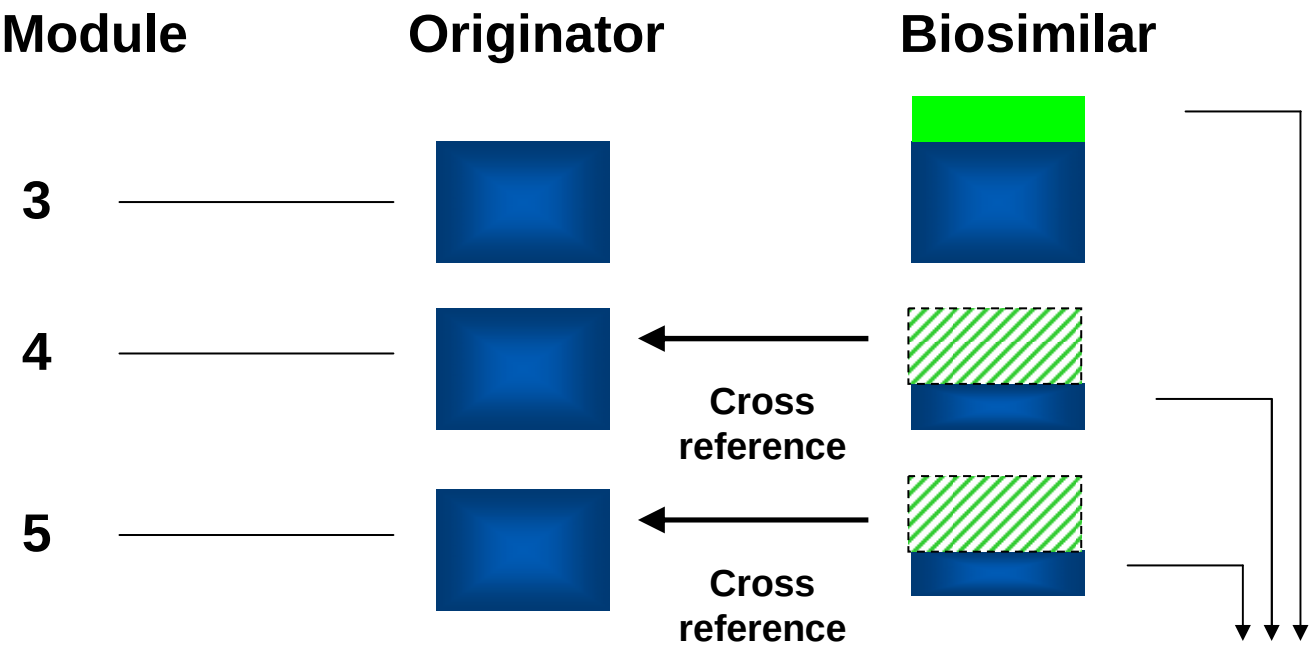
EU Perspective on Follow-on Biologics

- **Name**: **Biosimilar**

- **Definitaion: The provisions for generic medicinal products may not be sufficient in the case of biological medicinal products. If the information required in the case of essentially similar products (generics) does not permit the demonstration of the similar nature of two biological medicinal products, additional data, in particular, the toxicological and clinical profile shall be provided.**

- **Scope: rDNA derived proteins**

EU Perspective on Follow-on Biologics



Session 4:

Chair: Mr. Narita, PMDA & Mr. Sato, PMDA

- WHO's perspective on Biosimilar Products.

  Dr. Ivana Knezevic, Scientist, Quality, Safety and Standards Team, Immunizations, Vaccines and Biologicals, Department Family and Community Health Cluster WHO

- Canadian Approach to the Regulation of Subsequent Entry Biologics.

  Dr. Kwasi A. Nyarko, Manager - Special Projects Unit, Policy and Promotion Division, Center for Policy and Regulatory Affairs, Biologics and Genetic Therapies Directorate Health Canada

Canadian Perspective on Follow-on Biologics

- **Name**: **Subsequent Entry Biologics**
- **Guideline: Draft Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics**
- **SEB hinges on the ability to demonstrate similarity to a suitable reference biologic product.**

  SEBs are not “generic biologics”

WHO Perspective on Follow-on Biologics

- **Name**: **Similar Biotherapeutic Products**
- **Guideline: WHO Guidelines for Similar Biotherapeutic Products (Draft)**
- **Definition: a biological medicinal product developed to be “similar” in terms of quality, safety and efficacy to an already licensed, well established, reference medicinal product marketed by an independent applicant**

Common Perspective & key issues

- **NOT generic**
- **Guidelines have been developed**
- **Approach to evaluate the comparability between reference biomedical products and follow-on products**
- **Quality: the well-defined manufacturing process and extensive characterization studies + Comparability Exercise**
- **Non-clinical study & Clinical Study (PK/PD, efficacy, safety) are needed to evaluate the comparability**
- **PMS**

Conclusion

・Establishment of the well-defined manufacturing process, and extensive characterization studies of the follow-on biologics are required.

・Demonstration of the similarity in quality attributes with the reference medicinal product is required.

• Extensive Characterization and Extensive Comparison to Reference allows for abbreviated pre-clinical & clinical studies

The regulatory framework is flexible to enable the Regulator and sponsors adapt to the needs of the different classes of products and the changing legislative environment

Thank you for your attention!