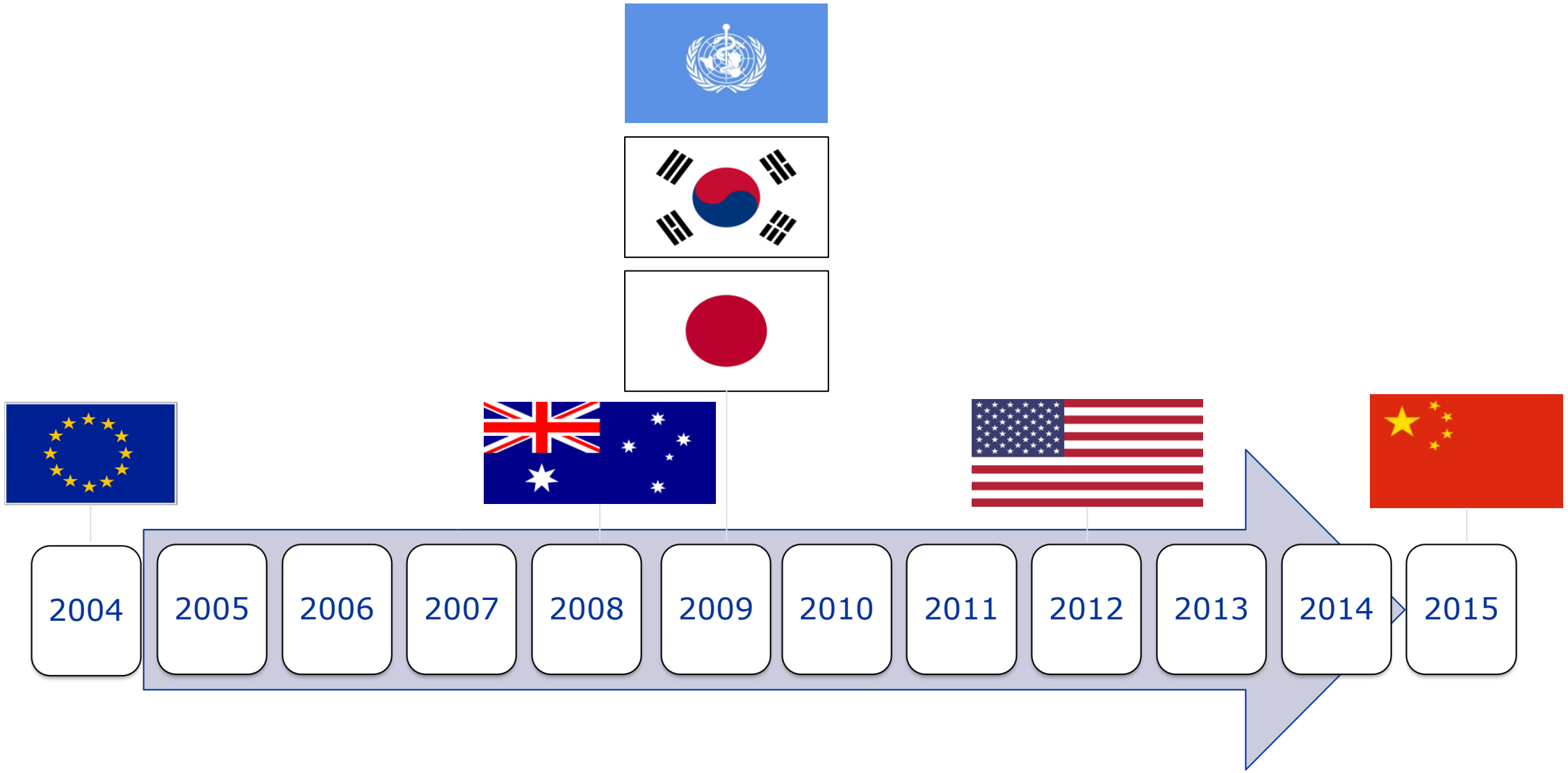
EMA
EUROPEAN MEDICINES AGENCY

Reflection Paper on Tailored Biosimilar development

Update at PCWP/HCPWP meeting

24 Sep 2025

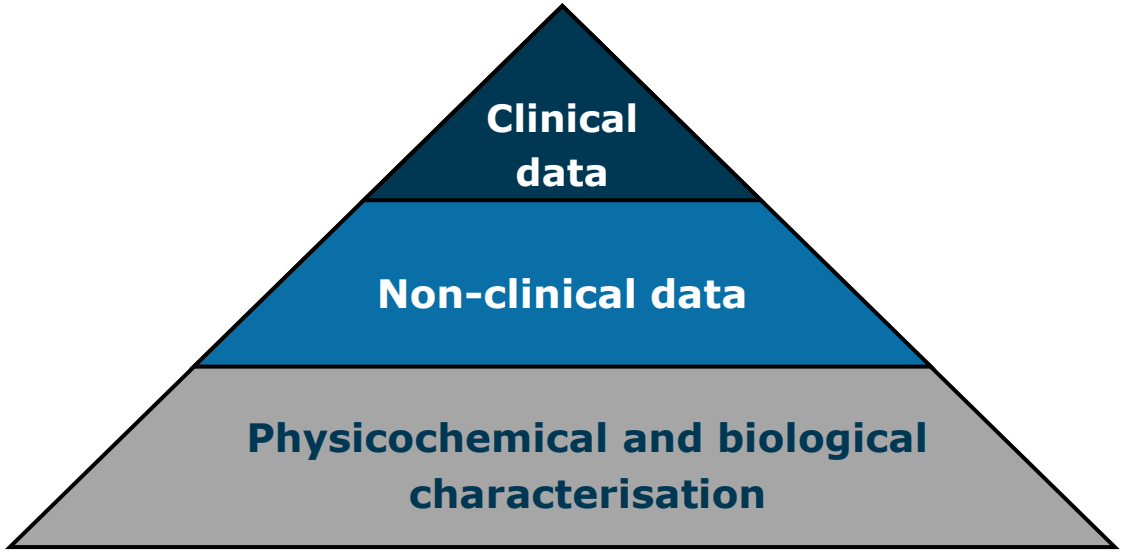
Steffen Thirstrup, CMO, EMA



Comparability Exercise

Scenario 1
(changes in manufacturing)

Scenario 2
(biosimilar development)



Comparability Exercise

Scenario 1
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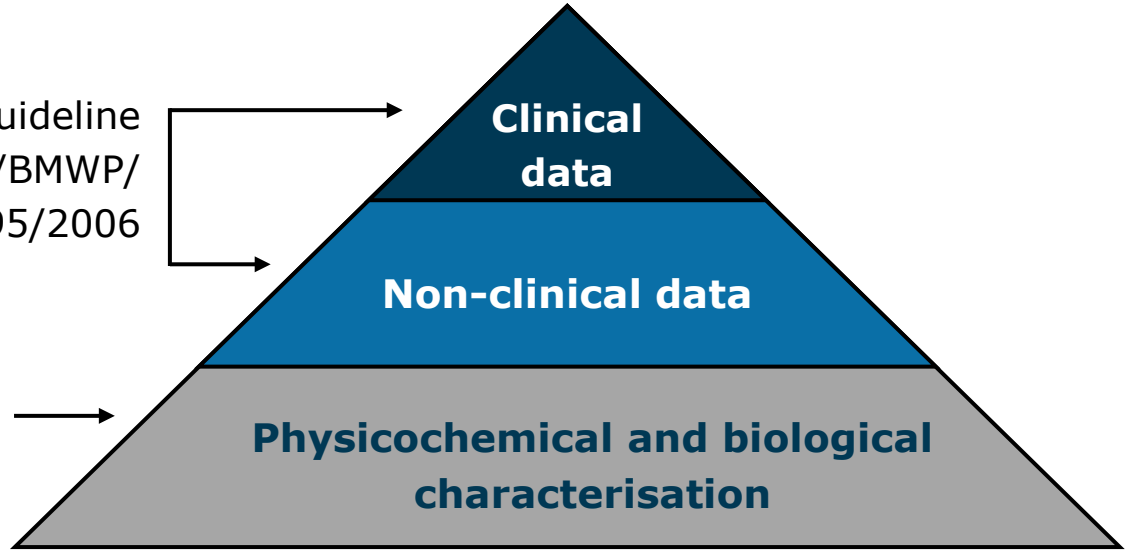
CHMP Comparability-Guideline EMEA/CHMP/BMWP/ 101695/2006

Guideline ICH Q5E



Comparability Exercise

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101695/2006

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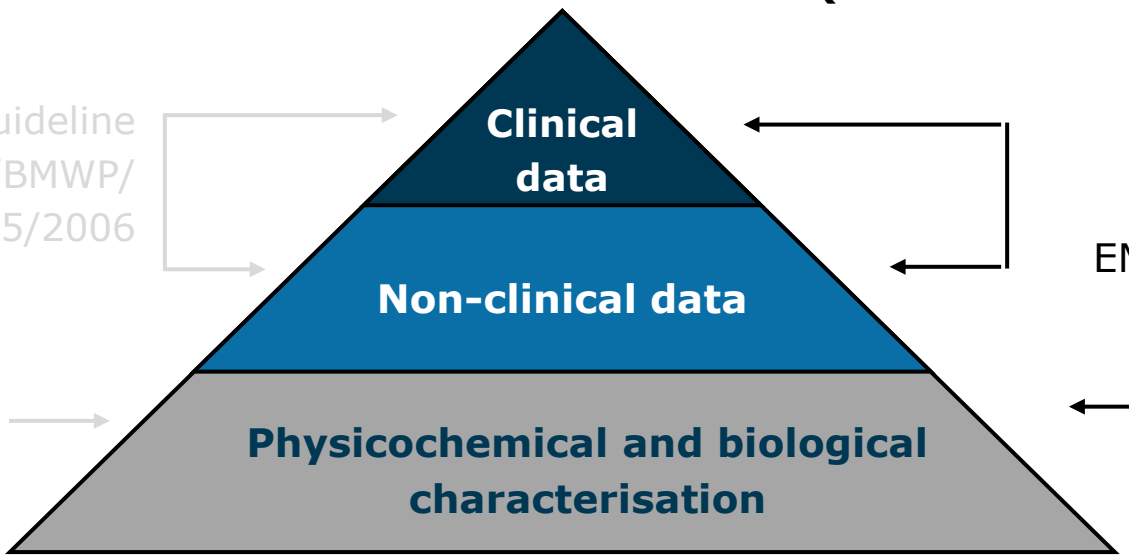


CHMP/BMWP Non-clinical/
clinical guideline
EMEA/CHMP/42832/2005 Rev1

CHMP/BMWP/BWP
Quality guideline
EMA/CHMP/BWP/
247713/2012

Evolving science and >20 years' experience

EUROPEAN MEDICINES AGENCY

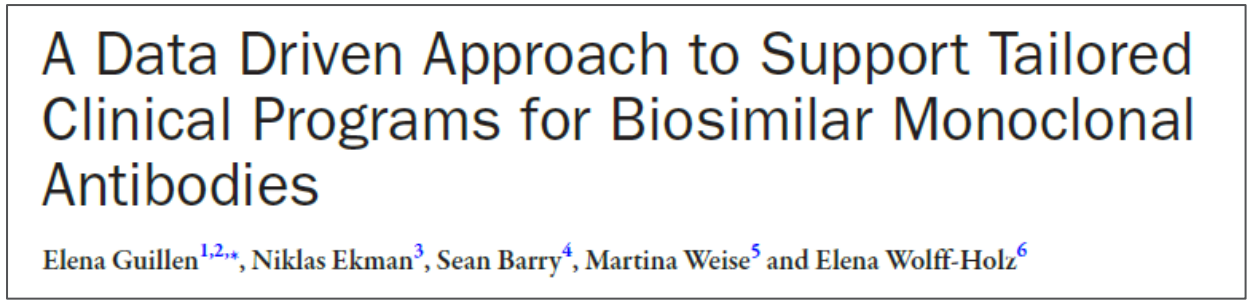
BioDrugs (2022) 36:359–371
https://doi.org/10.1007/s40259-022-00533-x

REVIEW ARTICLE

Check for updates

Regulatory Evaluation of Biosimilars: Refinement of Principles Based on the Scientific Evidence and Clinical Experience

Pekka Kurki[1] · Hye-Na Kang[2] · Niklas Ekman[3] · Ivana Knezevic[2] · Martina Weise[4] · Elena Wolff-Holz[5]



A Data Driven Approach to Support Tailored Clinical Programs for Biosimilar Monoclonal Antibodies

Elena Guillen[1,2,*], Niklas Ekman[3], Sean Barry[4], Martina Weise[5] and Elena Wolff-Holz[6]

BioDrugs
https://doi.org/10.1007/s40259-023-00631-4

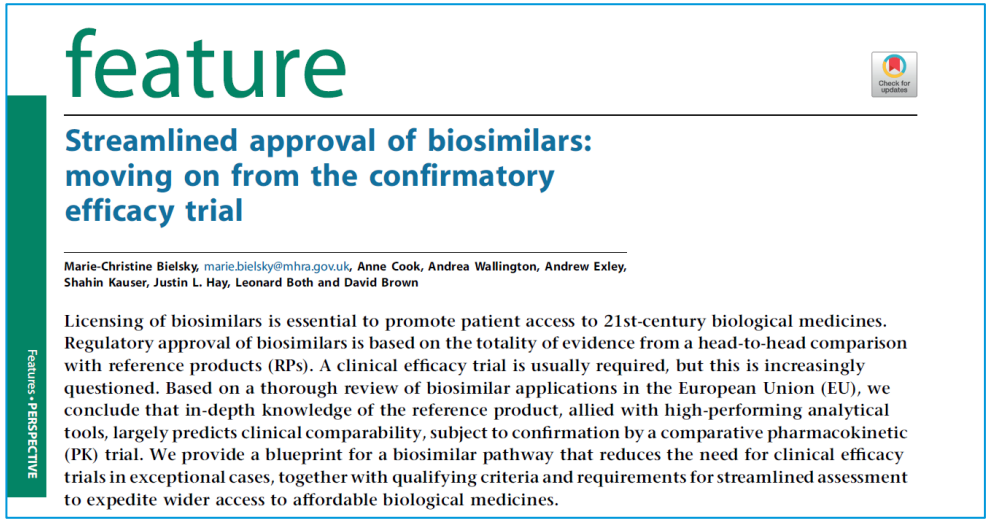
ORIGINAL RESEARCH ARTICLE

Check for updates

Do the Outcomes of Clinical Efficacy Trials Matter in Regulatory Decision-Making for Biosimilars?

Nadine Kirsch-Stefan[1] · Elena Guillen[2] · Niklas Ekman[3,7,8] · Sean Barry[4,8] · Verena Knippel[1] · Sheila Killalea[4,9] · Martina Weise[5,7,10] · Elena Wolff-Holz[6]

https://doi.org/10.1007/s40259-023-00631-4
https://doi.org/10.1002/cpt.2785
https://doi.org/10.1007/s40259-022-00533-x



feature

Features • PERSPECTIVE

Streamlined approval of biosimilars: moving on from the confirmatory efficacy trial

Marie-Christine Bielsky, marie.bielsky@mhra.gov.uk, Anne Cook, Andrea Wallington, Andrew Exley, Shahin Kauser, Justin L. Hay, Leonard Both and David Brown

Licensing of biosimilars is essential to promote patient access to 21st-century biological medicines. Regulatory approval of biosimilars is based on the totality of evidence from a head-to-head comparison with reference products (RPs). A clinical efficacy trial is usually required, but this is increasingly questioned. Based on a thorough review of biosimilar applications in the European Union (EU), we conclude that in-depth knowledge of the reference product, allied with high-performing analytical tools, largely predicts clinical comparability, subject to confirmation by a comparative pharmacokinetic (PK) trial. We provide a blueprint for a biosimilar pathway that reduces the need for clinical efficacy trials in exceptional cases, together with qualifying criteria and requirements for streamlined assessment to expedite wider access to affordable biological medicines.

Drug Discovery Today, 2020, 25(11), 1910-18

GOV.UK

Guidance

Guidance on the licensing of biosimilar products

Published 6 May 2021

Confirmatory efficacy trial

Although each biosimilar development needs to be evaluated on a case by case basis, it is considered that, in most cases, a comparative efficacy trial may not be necessary if sound scientific rationale supports this approach. Therefore, a well-argued justification for the absence of an efficacy trial should be appended to CTD Module 1 of the submitted application.

Applicants are encouraged to seek scientific advice to discuss this approach as soon as they have sufficient comparative analytical and functional data to support it. However final acceptance of this approach would only be considered after submission of the complete data package. The general principles to be used in this justification are summarised hereafter.

Guidance on the licensing of biosimilar products - GOV.UK (www.gov.uk)

Global collaboration and alignment

Key messages

- Need to reexamine the need for CES
- Global harmonisation
- Educations effort to increase awareness and understanding of the rigor and role of analytical studies
- Enhanced understanding of link between product quality assurance and clinical performance

Drugs
https://doi.org/10.1007/s40265-025-02168-y

CURRENT OPINION

The Tailored Biosimilar Approach: Expectations and Requirements

Elena Guillen[1] · Sean Barry[2,10] · Nils Jost[3,11] · Niklas Ekman[4,10,11] · Verena Knippel[3] · Johanna Kuhlmann-Gottke[3] · Julia Maier[3] · Martina Weise[5,11] · Andrea Laslop[6,12] · René Anour[6,11] · Ger van Zandbergen[3,7,8] · Nadine Kirsch-Stefan[9]

Accepted: 24 February 2025

Reflection paper on a tailored clinical approach in biosimilar development

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 March 2025
EMA/CHMP/BMWP/60916/2025
Committee for Medicinal Products for Human Use (CHMP)

Reflection paper on a tailored clinical approach in biosimilar development

Draft

Draft for internal consultation agreed by Biosimilar Medicines Working Party	21 October 2024
Consultation with MWP, BWP and SAWP	17 January 2025
Draft agreed by Biosimilar Medicinal Products Working Party	12 February 2025
Adopted by CHMP for release for consultation	17 March 2025
Start of public consultation	1 April 2025
End of consultation (deadline for comments)	30 September 2025

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Workshop on a tailored clinical approach in biosimilar development

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Event summary

Registration

Date: Monday, 22 September 2025, 09:00 - 16:00 Amsterdam time (CEST)

Location: Online

European Medicines Agency, Amsterdam, the Netherlands

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Thank you

Steffen.Thirstrup@ema.europa.eu

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