Learning Resources

General education:

1. **Fast Facts: Biosimilars in Hematology and Oncology: Biologics and biosimilars - getting decisions right eBook : Cornes, P., McBride, A.: Amazon.co.uk: Books** – link to FREE Kindle Edition

2. The US Medicines Regulator offers online courses, webinars, and presentations (US-FDA)
   a. For healthcare professionals: **Webinars, Presentations, and Articles | FDA**
   b. For patients: **Patient Materials | FDA**
   c. For healthcare providers, including sources of data and infographics that are copyright free to reuse: **Health Care Provider Materials | FDA**

3. The European Medicines Regulator (EMA)
   a. Information guide for healthcare professionals: **Biosimilars in the EU - Information guide for healthcare professionals (europa.eu)**
   b. And versions in 22 European languages: **Biosimilar medicines: Overview | European Medicines Agency (europa.eu)**
   c. Educational video for patients explaining key facts on biosimilars in 8 European languages: **(8) EMA Biosimilars - YouTube**
   d. An information guide for patients published by the European Commission in 23 official EU languages: **DocsRoom - European Commission (europa.eu)**

4. European Specialist Nurses Organisations (ESNO) – Switch Management between Similar Biological Medicines - A Communication and Information Guide for Nurses: **biosimilar-nurses-guideline-final_EN.cdr (esno.org)**

5. The UK Medicines regulator (MHRA) – document produced by the UK National Health Service in collaboration with the MHRA, NICE and industry bodies, entitled 'What is a biosimilar medicine?' and provides a detailed and reference guide, including links to information on biosimilar pharmacovigilance and commissioning biosimilar programmes: **NHS England Report Template 1 - long length title**

6. Key paper explaining the development and regulatory framework for biosimilars – written by a group of EU regulators: **Biosimilars: what clinicians should know - PubMed (nih.gov)**

7. A recent key paper on biosimilar **Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective - PubMed (nih.gov)**

8. Key paper which very clearly explains the concept of extrapolation of indication: **Biosimilars: the science of extrapolation - PubMed (nih.gov)**

9. Key paper on how biosimilars are made: **Worldwide experience with biosimilar development - PubMed (nih.gov)**

10. **Biosimilar Interchangeability Regulatory Practical Considerations (clinicalleader.com)**

11. **Interchangeability of Biosimilars: Overcoming the Final Hurdles - PMC (nih.gov)**

12. **Informing Patients about Biosimilar Medicines: The Role of European Patient Associations - PubMed (nih.gov)**

13. **Biosimilar-to-Biosimilar Switching: What is the Rationale and Current Experience? - PMC (nih.gov)**

For Oncologists:

14. ESMO position paper on biosimilars: **Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers - ESMO Open**

15. Paper written by ESMO and EMA regulators: **Preparing for the incoming wave of biosimilars in oncology - PubMed (nih.gov)**

16. Paper on the clinical development of biosimilars: **The arrival of biosimilar monoclonal antibodies in oncology: clinical studies for trastuzumab biosimilars - PubMed (nih.gov)**

17. **Global Acceptance of Biosimilars: Importance of Regulatory Consistency, Education, and Trust - PubMed (nih.gov)**