

Developing evidence for biosimilar: Current implications and future perspective

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In contrast to generic medicines, it is not possible to manufacture similar copy of an innovator product. Therefore, biosimilars are "similar but not the same" or in other words biosimilars are "the twin but not the clone" to the original biologic innovator product. Therefore the field of biosimilars presents several important challenges, including

- a) Verification of the similarity
- b) The interchangeability of biosimilars and innovator products
- c) Commercial opportunities as well as guidelines to assist manufacturers in product development
- d) Regulatory framework
- e) The possible need for unique naming to differentiate the various biopharmaceutical products
- f) Intellectual property rights and
- g) Public safety