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Biosimilars, Challenges and Developments

Samer M. Al-Hulu

Al-Qasim Green University / Iraq

alhulusamer@ymail.com

Abstract

Biosimilars are "similar but not the same" to the original biologic innovator product. Some of challenges that effect on biosimilars development such as Verification of similarity, not having of Unique name, Findings of biosimilars guidelines, safety and others. Development of Biosimilars achieved by finding of Unique name, Using of powerful analytical tools for comparability to the reference, Quality by Design studies, Using of statistical method reducing of simple size of biosimalir clinical trail and post-marketing surveillance studies to establish biosimilar safety.

Background

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

Methods

Challenges

1. **Verification of Similarity** for biosimilars with reference must be provided.
2. Finding of **biosimilars substitution** with reference product
3. Finding of **Unique name** to differentiate of biosimilars from other product.
4. The needing for **guidelines** for helping of manufacturers in developing of biosimilars.
5. **Public safety** of biosimilars should be achieved.
6. Biosimilar must be **approved .**
7. Needing for **Close definition** for biosimilar.
8. Biosimilars must be provide **cost savings** and greater accessibility to biopharmaceuticals.
9. **Non-clinical data** :type and amount of non-clinical data (including data comparing a biosimilar to its reference product) are needed, to support biosimilar authorization.
10. **Labeling** of biosimilar , what information which appear on biosmilar labeling.
11. **Regulatory framework** for assessing of biosimlar

Development:

1. Needing for **Unique naming** to differentiate of biosimilars from other biopharmaceutical products.
2. Developing **new generation of biosimilar** such as biobetters, monoclonal antibody and others.
3. Using of **Powerful analytical tools** the need to prove comparability to the reference product
4. **Clinical studies** with biosimilars are made on a case-by-case basis for more safety product.
5. Finding of new methods for increasing of **potency** of biosimlar
6. **Quality by Design** (QbD), will provide products with defined specifications in relation to quality, purity, safety, and efficacy that were not possible when the reference product was developed.
7. Using of **Statistical method** which helping in reducing of simple size of biosimalir clinical trail.
8- **Post-marketing surveillance** studies are likely to establish biosimilar safety.
9- **Pharmacovigilance programs** is important for establishing clinical databases.
10- **Immunogenicity** is a major factor in biosimlar developing.
11- **Single use bioprocessing system (single use bioreactor)** for biosimliar production to meet their clinical manufactures.

Results

1- Unique name is important for developing of biosimliras.
2- Guidelines for helping of manufacturers in developing of biosimilars.
3- Increasing of Potency and Public Safety for developing of biosimilars
4- Planning for Pharmacovigilance, post marketing , risk management should be provided.

Conclusions

Biosimliars is a new jump for developing in the field of pharmaceutics.

References

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