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Current Challenges and Future Opportunities
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Abstract

The role of International Standards for Monoclonal Antibodies in supporting bioassay data harmonisation: perspectives from the human biotherapeutics field

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Biotherapeutic monoclonal antibodies provide treatment to many oncological, immunological, and infectious diseases. A robust regulatory framework, facilitated by state-of-the-art analytical methodologies and the improved understanding of product heterogeneities, has enabled the approval of more than 30 biosimilar monoclonal antibodies in the last few years, increasing global patient accessibility to these medicines. Although analytical development and increased knowledge have leveraged their successful regulatory approval and control, ensuring consistency in a rapidly expanding and complex marketplace emerges as a new regulatory challenge. Further, various mechanisms of action typically contribute to the clinical therapeutic effects of monoclonal antibodies, but often in ways not fully understood. Therefore, there is a clear need to develop tools to assess the potential drift and divergence in the various biological activities for different monoclonal antibody products overtime and across jurisdictions.

International Standards have contributed to the harmonization of biological medicines for over a century. The development of International Standards for monoclonal antibodies represents a significant milestone as a new type of international standard and an addition to the tools available to ensure consistency in the potency of different versions of the same product. However, understanding their unique role is essential to fully realize their potential in supporting bioactivity traceability horizontally (across different products) and longitudinally (over the products' life cycle). Appreciating the differences between the international standard and the reference medicinal product that is required for biosimilar approval and breaking through common misconceptions are key discussions.