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Case Study: Regulatory Timeline for a Rare Cancer Clinical Research in Brazil

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ABSTRACT

The period for regulatory analysis and approval is a critical factor for pharmaceutical laboratories and global CROs in choosing countries to participate in a clinical trial. Most of the companies that develop new medical products are from the USA and Europe, therefore, they have less experience, knowledge, visibility of process details and timelines in other regions, such as Asia, Africa and Latin America.

In Brazil, ANVISA has been developing internally to update itself on medical innovations, harmonize with the ICH (in 2019 became part of the Steering Committee), in order to improve the processes analysis and streamline their approvals, thus making, Brazil an increasingly attractive country for the conduction of clinical studies. Specifically with regards to Rare Diseases, the absence of different expedited processes in Brazil meant that many studies were not approved on time, since other countries in the world have specific legislation for this. In December 2017, ANVISA published RDC 205, which establishes better timelines for reviewing and responding to submissions of new studies to be conducted in the country for rare diseases. This study presents a review of historical data and a critical discussion based on a case report referring to a Phase 2 clinical study of an immunotherapy for a cancer classified as rare. The expedited review process under the new regulation allowed Brazil to have the same opportunity to participate in the research as other countries in the world. Based on this analysis, additionally, we collected historical data from the agency (ANVISA), confirming the effectiveness of the new legislation, where studies approval average time was really reduced. This reflected in a great benefit, observed by an increase in the amount of rare disease studies submitted and approved for conduction in Brazil.

BIOGRAPHY

Thiago Favano, PharmD has over 10 years of experience within the pharmaceutical industry, dealing with clinical research, patient advocacy, access management, diagnostics programs, business development and business operations. Has occupied technical and operational positions at Alexion and Sanofi-Aventis. Thiago is OrphanDC's Alliance & Project Management Lead, being responsible for the strategic conduction of Clinical Research and Business operations in Latin America for Rare Disease projects. Thiago has a Pharmacy and Biochemistry educational background, having obtained a PharmD at the University of São Paulo.

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