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FAIR Data, Clear Insights: Enhanced PRO Analysis

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ABSTRACT

Roche's application of FAIR (Findable, Accessible, Interoperable, and Reusable) data principles facilitated secondary data usage and big data analytics, including the creation of indication-specific data marts under the EDIS (Enhanced Data and Insights Sharing) initiative. This project utilizes the data mart created for Non-Hodgkin Lymphoma to analyze patient-reported outcomes (PRO), demonstrating the prognostic and psychometric value of key PRO scales. We developed a new risk index that incorporates the NHL International Prognostic Index (IPI) and identified subgroups of patients with advanced DLBCL and high unmet medical needs. Currently we are analyzing all studies in the EDIS NHL data mart to inform future Target Product Profiles (TPPs) with PRO endpoints using statistical evaluations of PRO scales through change from baseline and time to deterioration analyses. This work highlights how FAIR data and robust statistical analysis drive innovation and improve patient care.

INTRODUCTION

BACKGROUND

The importance of patient-centered care in modern healthcare has led to the increased use of Patient Reported Outcomes (PROs) in clinical evaluation and drug development. The EDIS initiative by Roche aims to integrate FAIR principles into data management to maximize the utility of secondary data and support advanced analytics.

OBJECTIVES

This paper aims to demonstrate the application of FAIR data principles in creating and leveraging the EDIS data marts, with a focus on the specific data mart for Non-Hodgkin Lymphoma (NHL). We will explore the prognostic and psychometric value of key PRO scales, describe the newly developed risk index for DLBCL patients, and discuss how this data informs future Target Product Profiles (TPPs).

FAIR DATA PRINCIPLES

FAIR data principles ensure that data is Findable, Accessible, Interoperable, and Reusable. The EDIS initiative is built on these principles to enhance data sharing and insights generation, thereby fostering innovative solutions for patient care.

DATA MART OVERVIEW

The EDIS data mart integrates comprehensive clinical and patient-reported data, structured to adhere to FAIR principles. This infrastructure supports advanced big data analytics and secondary usage of existing datasets to deepen our understanding of disease biology and inform clinical development.

USE CASE: PRO SCALES FOR DLBCL PATIENTS

OVERVIEW

This case study investigates the use of PRO scales for patients with Diffuse Large B-Cell Lymphoma (DLBCL). We developed a risk index incorporating the NHL International Prognostic Index (IPI) to identify high-risk subgroups with unmet medical needs.

PATIENT REPORTED OUTCOMES (PROS) DATA

Patient-Reported Outcomes (PRO) capture patients' perspectives on their symptoms, functional status, and overall well-being, providing valuable insights beyond clinical measures. For this analysis, we focused on five key PRO scales with high prognostic and psychometric value: physical functioning, fatigue, global health score, pain, and role functioning. By analyzing PRO data within the EDIS NHL data mart, we aim to uncover valuable prognostic and psychometric insights specific to Non-Hodgkin Lymphoma patients.

ENHANCED PRO ANALYSIS

The development and validation of the new risk index have improved the stratification of DLBCL patients, allowing for better identification of those with advanced disease and high unmet medical needs. These insights contribute to more targeted and effective therapeutic approaches.

CHALLENGES AND VARIABILITY

Interpreting endpoints from PRO data can be challenging due to high variability. Addressing this variability is critical for the reliability of Target Product Profile (TPP) development and ensuring robust statistical evaluations.

FUTURE WORK

This analysis involves evaluating changes from baseline and time to deterioration to inform future TPP development. Future work will focus on enhancing the robustness of PRO scale evaluations, particularly addressing the variability in change from baseline and time to deterioration analyses. This ongoing research aims to continuously improve patient-centered care and the development of therapeutic strategies.

CONCLUSION

The EDIS data mart effectively demonstrates the application of FAIR principles, significantly enhancing the utility of secondary data and supporting advanced analytics. By developing and validating a new risk index, we have improved the stratification and management of DLBCL patients, identifying patient subgroups with significant unmet needs. This work illustrates the potential of integrating PRO data with robust statistical analysis to drive innovation and improve patient care. Despite challenges related to high variability in PRO data, addressing these issues is crucial for the reliability of Target Product Profile (TPP) development. Ongoing analysis of studies within the EDIS NHL data mart will continue to refine PRO endpoints and support the development of impactful TPPs, ultimately contributing to more targeted and effective therapeutic strategies.

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