RWD- Enbrel Safety Elderly

Brief Project Overview/Project Goals

The goal of this project was to enhance an existing analysis, "Safety of Etanercept in Elderly Patients with Rheumatoid Arthritis: A Pooled Analysis", that used clinical data to examine Enbrel (Etanercept) safety in RA patients that were less than 65 years old versus those that were greater than 65.

The hypothesis for the real world data (RWD) analysis was that Enbrel does not modify the risk of certain Adverse Events (AEs) in RA patients that are ≤65 years old versus those that are >65.

Scope

In Scope: Indications Research, RWD	Out of Scope:

Team Membership	Timeline and High Level Milestones/Deliverables	

Sponsor: Heather Jones
PI Lead: Sara Burns
PI Team members: Joan Sopczynski
External Team members: Heather Jones,
               Lisa Marshall,
               Katherine Roshak
	Milestone	**Person Responsible**

	Identify key questions	Team
	Identify approach to answering key questions	Team
	Complete charter, DAP and build project inventory	Sara Burns
	Visualize findings with data visualization software	Sara Burns
	Data profiling, analysis and internal review	PI Team
	Extract datasets and generate metrics	PI Team
	Publish all findings in summary report	Sara Burns
	Present to team members	PI Team

Data Analysis Plan

Questions to be Answered/Purpose of Evaluation

Is Enbrel safe for patients >65 with RA?

Does Enbrel increase the risk of adverse events (AEs) in patients over 65?
- AEs chosen for the analysis using Real World Data (RWD) data were based upon those examined previously in the clinical data analysis and consisted of:
  - Serious Infection (SI)
  - Congestive Heart Failure (CHF)
  - Non-Melanoma Skin Cancer (NMSC)
  - Interstitial Lung Disease (ILD)

What Project Team Hopes to Learn

- Discover any potential association between Enbrel and adverse events for patients >65 with RA.
- Compare RWD to clinical data results

Analysis Technique/Method

Data from 2013 to 2018 were analyzed from the IBM Watson Health MarketScan Database which contains information on 104.5 million distinct patients, including 531,996 with RA.

Patients were required to be enrolled ≥1 yr prior to RA diagnosis; the first exposure to ETN was after RA diagnosis and before the AE of interest.

Proportion of patients experiencing each AE was determined for patients ≤65 yr and >65 yr receiving and not receiving ETN and differences were evaluated using Fisher's Exact test.

Logistic regression models assessed the interaction between ETN and age group. Propensity matching was performed, and logistic regression was applied using the propensity-score-matched cohort. Patients receiving and not receiving ETN were matched by age, age >65 yr, gender, and geographical region.

Limitations / Risks of approach

- Potentially small sample sizes
- Composite outcomes may be difficult to create

Discuss how data will be presented

- Tables, Visualizations
- Slides
- Written abstract