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Product traceability of US adverse event reports in Med-Watch for multisource biologics prior to introduction of biosimilars

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Biologics differ from small molecule drugs in that the structure of the active ingredient in addition to the entire compound can vary with changes in manufacturing procedures. The possibility that these differences in structure could result in variable adverse events (AEs) increases the need for accurate and complete adverse event reports including unique brand name, lot number and manufacturer identification. The introduction of biosimilars into the US market may create an even stronger demand for improved pharmacovigilance to ensure proper attribution of AEs. To explore the traceability of biologics in the FDA's current adverse event reporting system (FAERS), all primary suspect US reports from Q4 2005 – Q3 2013 for two classes of multi-sourced biologics, Insulin and Human Growth Hormone (HGH), were analyzed. The rate of identifiable names was 92% for HGH drugs and 84% for insulin drugs. Lot number completion rates were lower, with a higher prevalence for insulin drugs (32%) than for HGH drugs (13%). Additional trends, such as NDA number as an identifier, and accuracy of reports by reporter, were identified. Results suggest that recognizable brand names can result in high name attribution. However, significant number of reports can go unattributed even with no biosimilar on market. Additionally, lot number completions were low. These findings highlight the need for improving how AEs are reported to FAERS, such as increased education and system improvements to encourage use of identifiable names and lot numbers for proper drug attributably, especially as biosimilars are introduced into the US.

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Immunosenescence in rheumatoid arthritis: Use of CD28 negative T cells to predict treatment response

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Recent data tend to suggest that immune system in Rheumatoid Arthritis (RA) might be in a state of decline and this weakened state results in demise of the tolerance mechanisms. Expansion of CD28-ve T cells is characteristically seen in RA; infact it precedes development of RA. Rising count of CD28-ve T Cells is a hallmark of immune-senescence. With successful management of RA, CD28-ve T cells count falls. Not many years ago achieving remission in rheumatoid arthritis was difficult due to lack of effective treatment. With the advent of biologics, remission is very much within reach. But biologics are expensive. And not all patients respond adequately to biologics. Hence it will be useful if we have a marker which predicts response to any disease modifying anti-rheumatic drug (DMARD), whether conventional or biologic. Newer biomarkers are constantly being looked at and CD28-ve T cells is one of them.

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