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Case Study: Evaluation of Data Sources for FDA's Blood & Tissue Product Safety Surveillance – Sentinel

Evaluation of Data Sources for Blood & Tissue Product Safety Surveillance

Business Need

At a time when patients and caregivers are demanding more information about the associated benefits and potential risks of the products they use, 21st century technology has opened up innovative methods of monitoring FDA-regulated products to enhance public health safety in ways previously unachievable. Thus, FDA wanted to leverage this latest technology, together with emerging automated healthcare data sources, to build and implement a new active surveillance system, Sentinel, to transform its ability to track all regulated blood and tissue products. Biovalorem supported and partnered to help the FDA by identifying, evaluating and prioritizing the available data sources for blood and tissue products.

Innovative Solution

A method was devised to identify, prioritize, evaluate and review the potential data sources and provide useful recommendations to the FDA. This was achieved in the following steps:

- An extensive research was performed **to identify** as many U.S. healthcare networks and institutes, commercial data brokers and other types of organizations, which could provide the richest data sources and/or environments: close to primary patient specific data for the blood and tissue products in terms of use/procedure/diagnostic codes/events; had a diverse and large patient population; had a national geographic footprint or differed geographically from each other; and agreed to participate.
- The team prepared and utilized a detailed questionnaire to evaluate various key attributes of the identified organizations' potential data sources and environments. Over 25 organizations were identified with attributes of particular interest. The organizations were further distilled to a short list and graciously took part in the detailed questionnaire for further assessment. The responses to the detailed questionnaire were amalgamated **to evaluate** and contrast each data source's capability and capacity to support the Sentinel system in terms of blood and tissue product data. The breakdown of the questionnaire was designed to better understand the opportunities and limitations of the responding organizations' data sources and environments using six main categories: General Information, Population, Product, Adverse Events, Experience and Participation.
- After a detailed review of the completed questionnaires, discussions with representatives from relevant associations [AATB (American Association of Tissue Banks) and AABB (American Association Blood Bank)] were held to finalize and **to recommend** actions for the FDA. These included: establishing leadership with strong governance using an informed approach along with a dynamic communication strategy; investigating the possibility of establishing a common or shared infrastructure with the relevant associations (AABB and AATB) surveillance efforts; planning, designing and implementing a motivational reward system and required technologies; and finally, prioritizing on key characteristics that are required per type and within the various regulated products.

Benefits

Biovalorem's approach helped in understanding the interested potential data sources' capabilities and capacities in integrating into the national electronic surveillance system from a blood and tissue product safety perspective. The outcome was a step forward in developing a linked sustainable system of active risk identification using health care data.