Provision of Publicly Available FAERs Data for SAVAYSA® (*Edoxaban*)

You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and streamline post-market drug adverse event data collection and assessment.

The FDA's Adverse Event Reporting System (FDA AERS or FAERs), is a publicly available database which contains more than 28 million deidentified reports of AEs. Information from the FAERs public dashboard has been ***pre-filtered to Savaysa® (Edoxaban) and bleeding events,*** with data as of 31 December 2022.

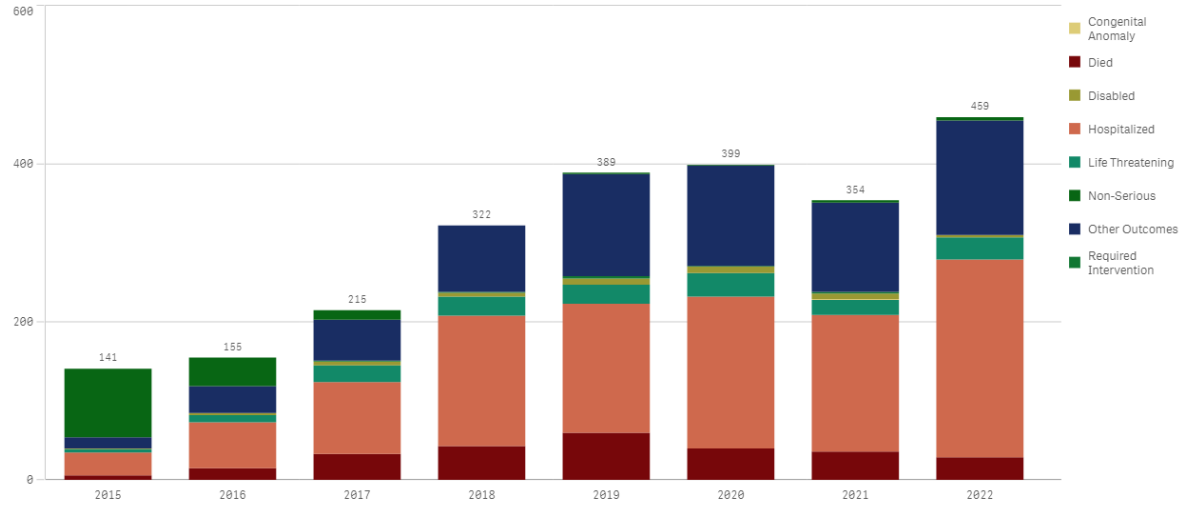
Bleeding events were taken from a comprehensive list of bleeding events used by Joos C et al 2019[1], to determine accuracy of ICD-10 code for bleeding events in anticoagulated patients admitted to the hospital.

The information provided below is for **information purposes only**, when using this data, you should be aware that there are a number of limitations, these are described in detail in this document and available on the FAERs public dashboard website. If you have any questions related to Savaysa please contact the manufacturer Daiichi Sankyo on 1-877-437-7763.

[1] Joos C, Lawrence K, Jones AE, Johnson SA, Witt DM. Accuracy of ICD-10 codes for identifying hospitalizations for acute anticoagulation therapy-related bleeding events. Thromb Res. 2019 Sep;181:71

Pre-filtered to SAVAYSA® (Edoxaban) and Bleeding events, with data as of 31 December 2022.

Outcome counts by Received Year



Case counts by Age Group and Sex

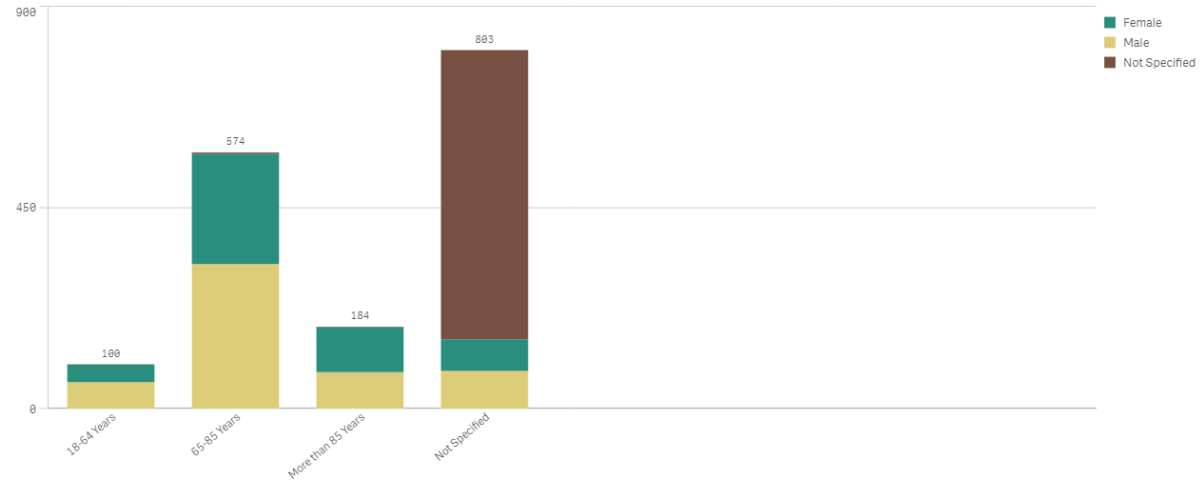


Table of Adverse Events of Bleeding *(SAVAYSA® (Edoxaban)* with data as of 31 December 2022

Reaction Term	Count	Reaction Term	Count
Gastrointestinal Haemorrhage	284	Gastric Ulcer Haemorrhage	14
Haematuria	231	Heavy Menstrual Bleeding	14
Melaena	205	Pulmonary Haemorrhage	8
Epistaxis	181	Subdural Haemorrhage	8
Haemorrhage	180	Haemoperitoneum	6
Cerebral Haemorrhage	147	Retinal Haemorrhage	6
Haematoma	87	Gastritis Haemorrhagic	5
Rectal Haemorrhage	87	Pharyngeal Haemorrhage	4
Upper Gastrointestinal Haemorrhage	82	Oesophageal Varices Haemorrhage	3
Haematemesis	77	Uterine Haemorrhage	2
Haemoptysis	77	Acute Haemorrhagic Ulcerative Colitis	1
Subarachnoid Haemorrhage	38	Gastric Polyps	1
Haemarthrosis	32	Gastrointestinal Vascular Malformation Haemorrhagic	1
Lower Gastrointestinal Haemorrhage	28	Oesophageal Ulcer Haemorrhage	1
Haemorrhage Intracranial	27	Peptic Ulcer Haemorrhage	1
Duodenal Ulcer Haemorrhage	21	Vitreous Haemorrhage	1
Vaginal Haemorrhage	18		
Diverticulum Intestinal Haemorrhagic	15		

Limitations of FAERs Data

- **The information retrieved from the FAERS database should not be used to draw any conclusions** regarding the safety of the medicinal products as individual reports do not imply causality of the product The output is not considered "CDS" and are not intended to be designed, implemented, provided and/or used to influence clinical decisions or as clinical decision support (CDS).

- **FAERs is significantly limited by underreporting:** Despite the significant increases in AE reporting, limitations in the use of FAERS data for post-market surveillance remain. One of the biggest limitations is that not all adverse events are reported. As a spontaneous (i.e., voluntary) reporting system, it's simply not possible for every adverse event to be recorded. A systematic review of underreporting estimates that is 94%[4] . Therefore, the number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of the adverse event in association with the drug.

- **Rates of occurrence cannot be established with reports:** FAERs data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between drug products and are significantly impacted by the Weber effect which is often summarised by stating that AE reporting peaks at the end of the second year after.

- **FAERs data do not represent all known safety information** for a reported drug product and should be interpreted in the context of other available information when making drug-related or treatment decisions.

- **Information in reports has not been verified:** Safety reports submitted to FDA does not mean that the information included in it has been medically confirmed and does not reflect a conclusion by FDA or the marketing authorisation holder that the information in the report constitutes an admission that the drug caused or contributed to an adverse event.