1ISG-004 **ABSTRACT WITHDRAWN**

1ISG-005 **ASSESSMENT OF A MANAGEMENT TOOL REGARDING MEDICAL DEVICE VIGILANCE**

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Background and Importance Legislation regarding medical device vigilance requires the reporting of any incident involving medical devices. Within our hospital, the adverse event's declaration (AED) process has been entirely computerised since July 2019. Each adverse event (AE) reported is addressed to the dedicated vigilance officers.
Aim and Objectives The objective of this work is to carry out an assessment of the AED activity before and after the software rollout.
Material and Methods The reporting of AEs was initially processed through paper format in 2019 and after with the AE reporting software from January 2020 to December 2022. Each declaration of AE was analysed by a pharmacist and categorised based on its severity and preventability.
Results Over 212 AEDs were reported: 32 in 2019, 31 in 2020, 60 in 2021 and 89 in 2022. The main reporting departments are the: intensive care cardiac unit, surgery unit and haemodialysis unit with respectively 51%, 13% and 9% of the AED. Damage or visual defect of the medical device represents about 40% of the AED while product failure during use represents 45% of the reports. Following analysis, 16% of the AED have been classified as 'almost accident', 81% as 'undesirable events', 2% as 'serious adverse event with low impact' and 1% as 'serious adverse event'. All AEDs were declared to the French Agency for Medicines and Health Products Safety. Regarding their avoidability, the AEDs were classified as 'preventable', 'likely preventable', 'unavoidable' and 'likely unavoidable' with respectively 79%, 13%, 5% and 3% of the AEDs. The AEDs made in 2019, 2020 and 2021 are all treated and closed, for 38 AEDs we are still awaiting a response from the manufacturers.
Conclusion and Relevance In 4 years, the number of AEDs has nearly quadrupled. This increase is likely the result of accessibility and user friendliness of the software, as well as the implementation of local awareness campaigns regarding AEDs. A new overview of the AED should be scheduled.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

1ISG-006 **ECONOMIC SAVING OF THE PREPARATION OF SUBCUTANEOUS FORMULATIONS COMPARED TO INTRAVENOUS: FOCUS ON DARATUMUMAB IN THREE HEALTHCARE COMPANIES**

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Background and Importance The new onco-haematological formulations are moving more towards subcutaneous administration which represents a technological innovation compared to