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Correction

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Correction to: XANTUS: a real-world, prospective, observational study of patients treated with rivaroxaban for stroke prevention in atrial fibrillation

This is a correction to: A. John Camm, Pierre Amarenco, Sylvia Haas, Susanne Hess, Paulus Kirchhof, Silvia Kuhls, Martin van Eickels, Alexander G.G. Turpie, the XANTUS Investigators, XANTUS: a real-world, prospective, observational study of patients treated with rivaroxaban for stroke prevention in atrial fibrillation, *European Heart Journal*, Volume 37, Issue 14, 7 April 2016, Pages 1145–1153, https://doi.org/10.1093/eurheartj/ehv466.

In April 2022, the study sponsor, Bayer AG, received confirmation of a Good Clinical Practice (GCP) violation by one study site including 81 patients (\sim 1% of the study population). As a precaution, a sensitivity analysis was performed excluding patients from this site. The exclusion of this study site had almost no impact on the results. For example:

- The overall number of patients in the study changed from 6784 to 6703, thereby changing the denominator slightly in any proportional calculations
- · This resulted in very minor changes in baseline characteristics, limited to the tenths decimal place in most cases
- o The mean $CHADS_2$ score was 2.0 originally and 1.9 in the sensitivity analysis
- o The mean HAS-BLED score remained unchanged
- o The proportion of female patients was 40.8% originally and 40.7% in the sensitivity analysis
- o The proportion of patients receiving prior antithrombotic therapy was 73.1% originally and 73.4% in the sensitivity analysis
- Treatment duration was 329 days originally and 328 days in the sensitivity analysis
- Persistence with rivaroxaban was 79.9% originally and 79.6% in the sensitivity analysis
- The incidence proportion of treatment-emergent adverse events was 39.9% originally and 40.4% in the sensitivity analysis, whereas the incidence proportions of treatment-emergent serious adverse events were 17.7% originally and 17.9% in the sensitivity analysis
- The rates of the main study outcomes including major bleeding, fatal bleeding, intracranial bleeding and stroke or non-central nervous system systemic embolism did not change
 - o The rate of all cause death was 1.9 per 100 patient-years originally and 2.0 per 100 patient-years in the sensitivity analysis

The authors and editors reviewed the new results and concluded that the GCP violation did not impact the overall findings of the study.

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