

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**215859Orig1s000**

**STATISTICAL REVIEW(S)**



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Translational Sciences  
Office of Biostatistics

## STATISTICAL REVIEW AND EVALUATION

### Clinical Studies

**NDA #:** 215859  
**Supplement #:** 0001  
**Drug Name:** Xarelto (Rivaroxaban)  
**Indication(s):** 1) Venous thromboembolism (VTE) treatment and reduction of risk of VTE recurrence in pediatric patients (<18y)  
2) Thromboprophylaxis in pediatric patients (2y to 8y) with congenital heart disease after the Fontan procedure  
**Applicant:** Janssen Pharmaceuticals Inc.  
**Receipt Date:** Jun 22, 2021  
**PDUFA Date:** Dec 22, 2021  
**Review Priority:** Priority  
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**EDR Location:** \\CDSESUB1\evsprod\NDA215859\0001

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