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APPLICATION NUMBER:

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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 #: 203085

Drug Name: Stivarga® (Regorafenib)

Indication(s): Metastatic colorectal cancer

Applicant: Bayer HealthCare Pharmaceuticals

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Keywords: stratified log-rank test, interim analysis, K-M curve, Cox regression

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