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 - MEMO

NDA/BLA #:	NDA021986/S21
Drug Name:	Sprycel (Dasatinib)
Indication(s):	For the treatment of pediatric patients with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL) in combination with chemotherapy
Applicant:	Bristol-Myers Squibb Company
Date(s):	Submitted: 6/29/2018
	Review Completion: 12/12/2018
	PDUFA goal: 12/29/2018
Review Priority:	Priority
Biometrics Division:	Division of Biometrics V
Statistical Reviewer:	Jiaxi Zhou, M.S.
Concurring Reviewers:	Yuan-Li Shen, DrPH, Statistical Team Leader
	Thomas E. Gwise, Ph.D., Deputy Division Director
Medical Division:	Office of Hematology and Oncology Products (OHOP)/Division of Hematology Products
Clinical Team:	Aviva Krauss, MD, Clinical Reviewer
	Ann Farrell, M.D., Division Director
Project Manager:	Mara Bauman Miller, PharmD
Keywords:	Single arm trial, external control, EFS

The statistical review is complete and has been added to the Clinical and Statistical Review and Evaluation, which will be uploaded to DARRTS when it is finalized. Refer to the Clinical and Statistical Review and Evaluation for additional details. From a statistical standpoint, the NDA is acceptable to support approval.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JIAXI ZHOU
12/12/2018

YUAN L SHEN
12/12/2018

THOMAS E GWISE
12/14/2018