# Bortezomib, Lenalidomide and Dexamethasone vs. Lenalidomide and Dexamethasone in Patients (Pts) with Previously Untreated Multiple Myeloma Without an Intent for Immediate Autologous Stem Cell Transplant (ASCT): Results of the Randomized Phase III Trial SWOG S0777

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ASH, December 2015









# SWOG S0777 Study Design

**Eight 21-day Cycles of VRd** 

Randomization N = 525

**Stratification:** 

- ISS (I, II, III)
- Intent to transplant @ progression (yes/no)

Bortezomib 1.3/mg<sup>2</sup> IV
Days 1, 4, 8, and 11
Lenalidomide 25 mg/day PO
Days 1-14
Dexamethasone 20 mg/day PO
Days 1, 2, 4, 5, 8, 9, 11, 12

Six 28-day Cycles of Rd

Lenalidomide 25 mg/day PO Days 1-21 Dexamethasone 40 mg/day PO Days 1, 8, 15, 22

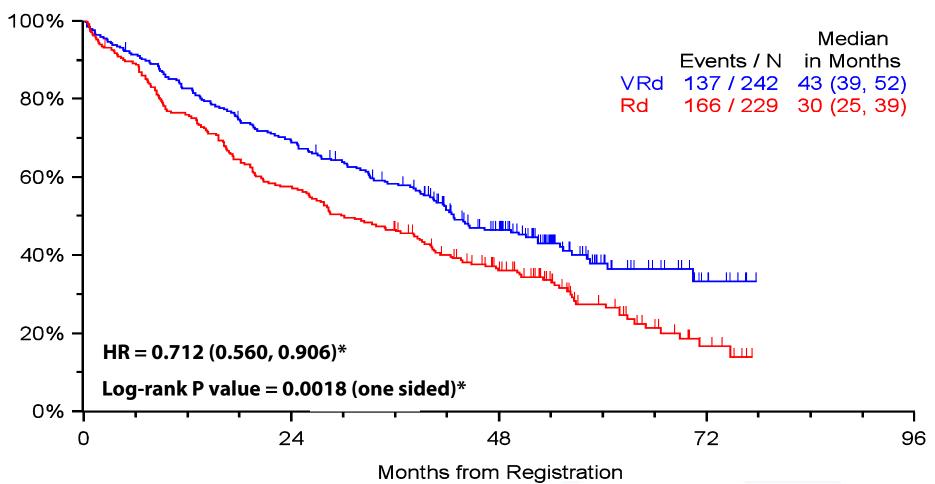








## **Progression-Free Survival By Assigned Treatment Arm**



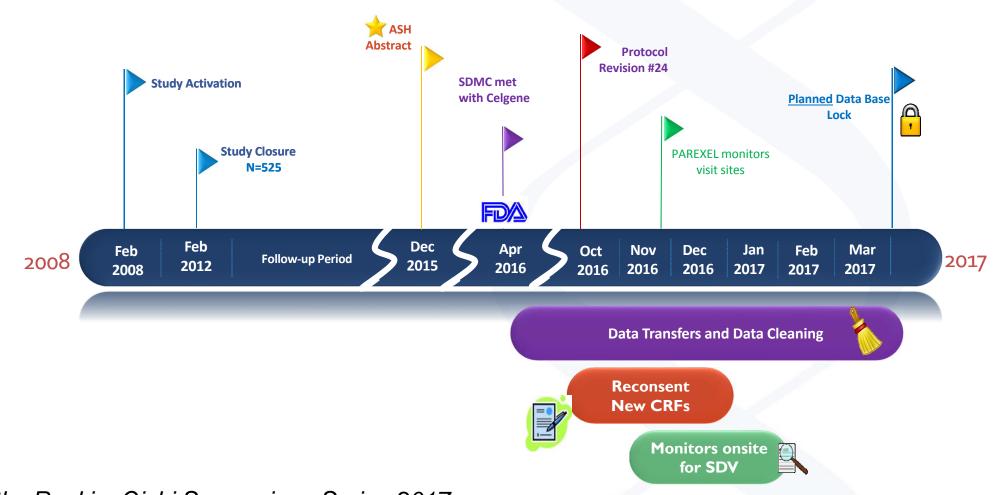






\*Stratified

## **S0777 Timeline**









## **SWOG SDMC Personnel**

## Original Study Team

- Statisticians
  - Rachael Sexton
  - Antje Hoering
- DCs
  - Jeri Jardine

#### Additional Staff for Celgene Collaboration – Core Team

- PM
  - Sarah Basse
- Statistician:
  - Cathy Rankin
- DM senior professional
  - Evonne Lackey
- DCs
  - Jeri Jardine
  - Laura Kingsbury
- Project Assistant
  - Sam Dzingle







## What happened since then?

#### - In Numbers

### Since April 2017

- Queries posted 2660
- Number of patients re-consented: 220
- Number of monitoring visits: 81
- Number of monitoring days: 238

## Since April 2016

- New CRFs submitted: 3056
- Queries posted 9364
- Number of monitoring visits: 242
- Number of monitoring days: 1032







## And now?

- We (YOU!) did it!
- Final data set and casebooks submitted to Celgene:
   September 2017
- FDA submission planned: January 2018
- Myeloma patients world-wide will hopefully have access to additional treatment choices.

## **THANK YOU!**





