# The Benefit of Daratumumab Plus Bortezomib, Lenalidomide, and Dexamethasone on Depth and Durability of Response in the Phase 3 CEPHEUS Trial: Updated Minimal Residual Disease Analysis

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# Disclosures

**COI statement of the presenting author:**

- **Research funding:** Johnson & Johnson, Takeda
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# CEPHEUS MRD: Introduction

- MRD is a strong prognostic indicator in MM and an accepted clinical trial endpoint

  MRD is a primary endpoint in the phase 3 CEPHEUS trial designed for TIE or transplant-deferred NDMM

- CEPHEUS previously demonstrated that DVRd improved depth of response and PFS versus VRd[1]

  After a median follow-up of over 6 years, the final analysis of the CEPHEUS trial demonstrated that DVRd continues to show superior efficacy over VRd across key endpoints in TIE patients[2]

  – Risk of disease progression or death was 45% lower for DVRd vs VRd; HR, 0.55

  – OS favored DVRd, especially when censoring for death due to COVID-19 (HR, 0.74)

- This final analysis - with >6 years of follow up - evaluates whether the MRD benefit with DVRd is deep, sustained, and clinically meaningful, linking MRD dynamics to durable disease control.

  Including 60-month sustained MRD-negativity ≥CR rates



DVRd, daratumumab plus bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; PFS, progression-free survival; TIE, transplant ineligible.

1. Usmani SZ, et al. *Nat Med* 2025;31:1195-202. 2. Usmani SZ, et al. Presented at ASCO 2026; Chicago, USA



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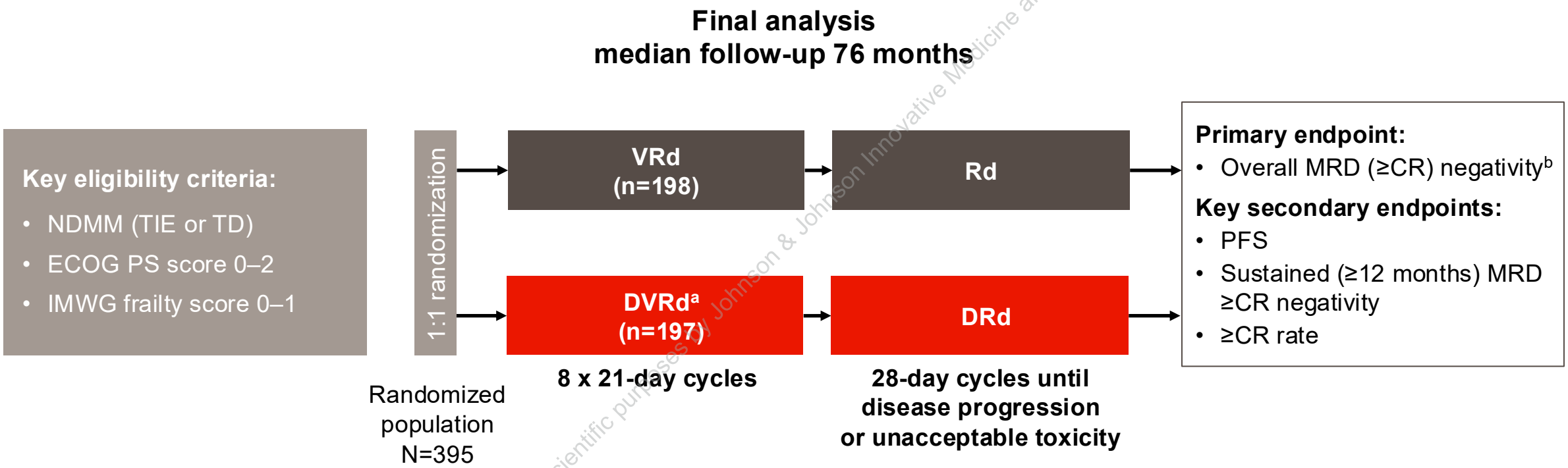
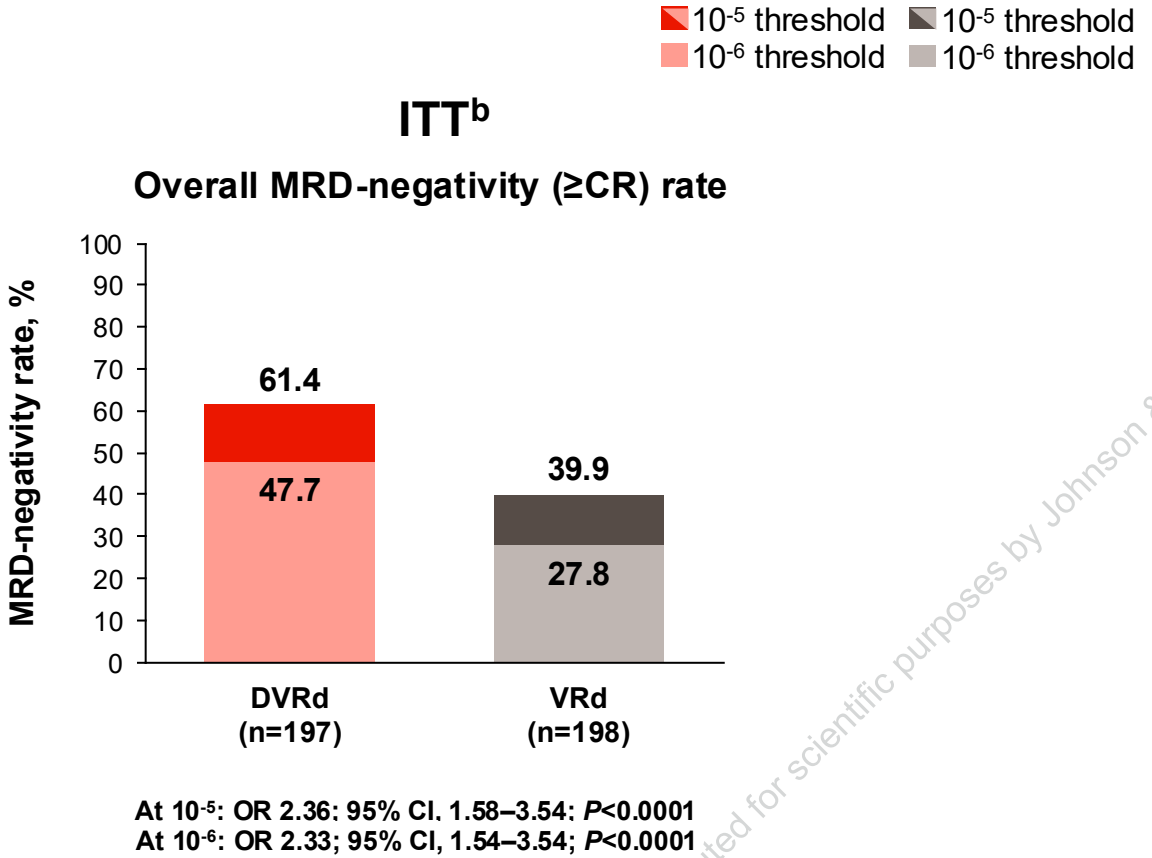
# CEPHEUS: Study Design






[a]Daratumumab 1,800 mg co-formulated with rHuPH20 (2,000 U/mL; ENHANZE® drug delivery technology, Halozyme, Inc., San Diego, CA, USA). [b]MRD was assessed via next-generation sequencing (clonoSEQ®; Adaptive Biotechnologies) using bone marrow aspirate samples obtained at baseline, at the time of suspected CR, and at 12, 18, 24, 30, and 36 months after the first dose and annually thereafter in patients with CR.
≥CR, complete response or better; DRd, daratumumab, lenalidomide, and dexamethasone; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; ITT, intent to treat; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; OS, overall survival; PFS, progression-free survival; Rd, lenalidomide and dexamethasone; TD, transplant deferred; TIE, transplant eligible; VRd, bortezomib, lenalidomide, and dexamethasone.
ClinicalTrials.gov Identifier: NCT03652064. Accessed August 11, 2026. Usmani, SZ, et al. *Nat Med* 2025;31:1195-202.

# CEPHEUS MRD: Overall MRD-Negativity ≥CR Rates[a]




**At $10^{-5}$: OR 2.36; 95% CI, 1.58–3.54; *P*<0.0001**
**At $10^{-6}$: OR 2.33; 95% CI, 1.54–3.54; *P*<0.0001**

**DVRd demonstrated superior overall MRD-negativity rates at $10^{-5}$ and $10^{-6}$ vs VRd**

[a]The proportion of patients who achieved both MRD-negativity (at or below a $10^{-5}$ threshold) and ≥CR at any point during the study. [b]For the TIE population, MRD-negativity rates were higher with DVRd vs VRd at $10^{-5}$ (61.1% vs 40.0%; OR 2.35; 95% CI, 1.47–3.77; *P*=0.0004) and at $10^{-6}$ (46.5% vs 27.6%; OR 2.27; 95% CI, 1.39–3.71; *P*=0.0010). ≥CR, complete or better response; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; ITT, intent to treat; MRD, minimal residual disease; OR, odds ratio; TIE, transplant ineligible; VRd, bortezomib, lenalidomide, and dexamethasone.





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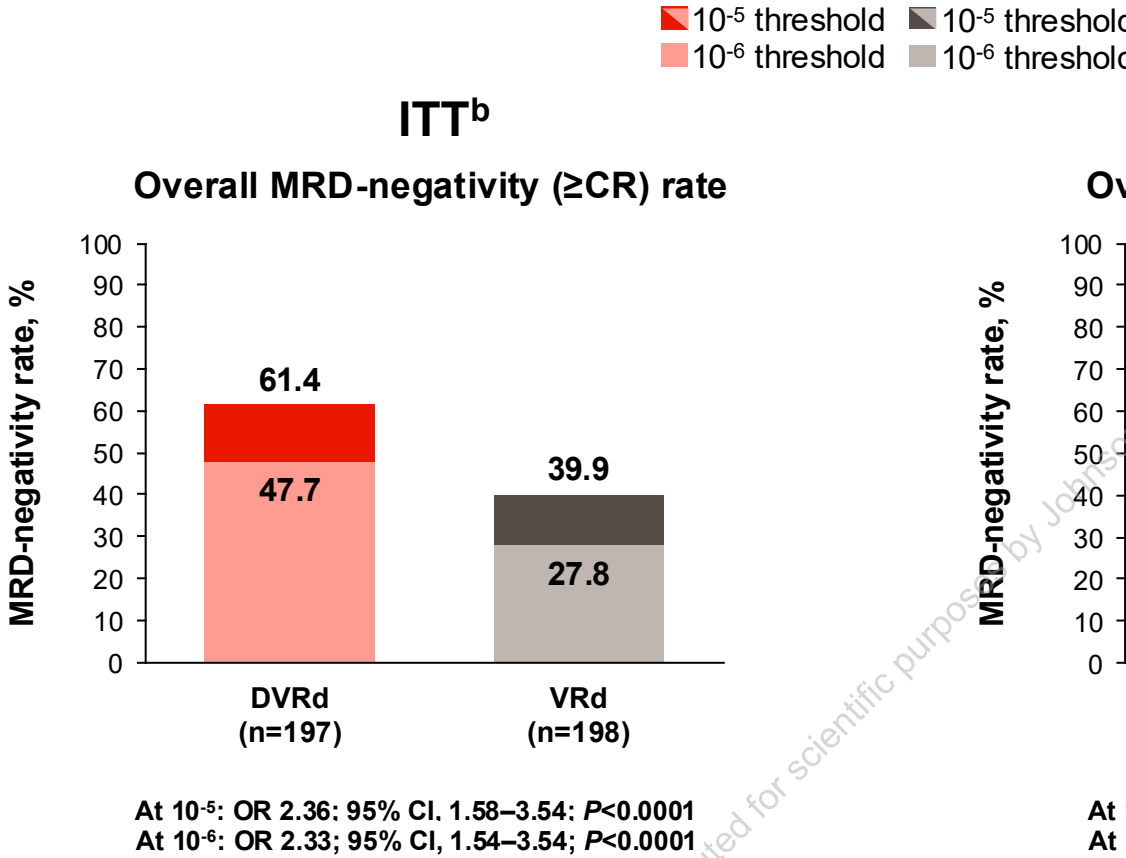
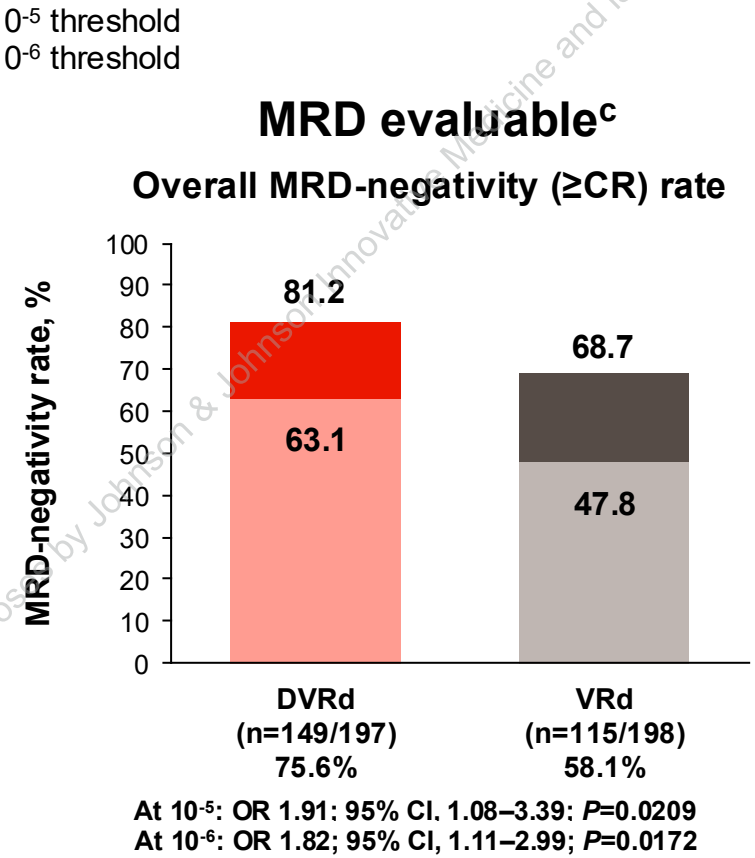
# CEPHEUS MRD: Overall MRD-Negativity ≥CR Rates[a]




**At $10^{-5}$: OR 2.36; 95% CI, 1.58–3.54; *P*<0.0001**
**At $10^{-6}$: OR 2.33; 95% CI, 1.54–3.54; *P*<0.0001**




**At $10^{-5}$: OR 1.91; 95% CI, 1.08–3.39; *P*=0.0209**
**At $10^{-6}$: OR 1.82; 95% CI, 1.11–2.99; *P*=0.0172**

### Loss of MRD negativity ($10^{-5}$)

| Subjects with ≥1 negative MRD test | DVRd (n=123) | VRd (n=82) |
|---|---|---|
| Subjects with loss of MRD negativity, n (%) | 19 (15.4) | 29 (35.4) |

Subjects with 1 negative sample followed by a positive result on any subsequent testing.

**DVRd demonstrated superior overall MRD-negativity rates at $10^{-5}$ and $10^{-6}$ vs VRd**

[a]The proportion of patients who achieved both MRD-negativity (at or below a $10^{-5}$ threshold) and ≥CR at any point during the study. [b]For the TIE population, MRD-negativity rates were higher with DVRd vs VRd at $10^{-5}$ (61.1% vs 40.0%; OR 2.35; 95% CI, 1.47–3.77; *P*=0.0004) and at $10^{-6}$ (46.5% vs 27.6%; OR 2.27; 95% CI, 1.39–3.71; *P*=0.0010). [c]The MRD-evaluable population was defined as patients with ≥CR, successful baseline calibration, MRD samples at each specified time point, and with ≥1 post-baseline MRD sample. ≥CR, complete or better response; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; ITT, intent to treat; MRD, minimal residual disease; OR, odds ratio; TIE, transplant ineligible; VRd, bortezomib, lenalidomide, and dexamethasone.





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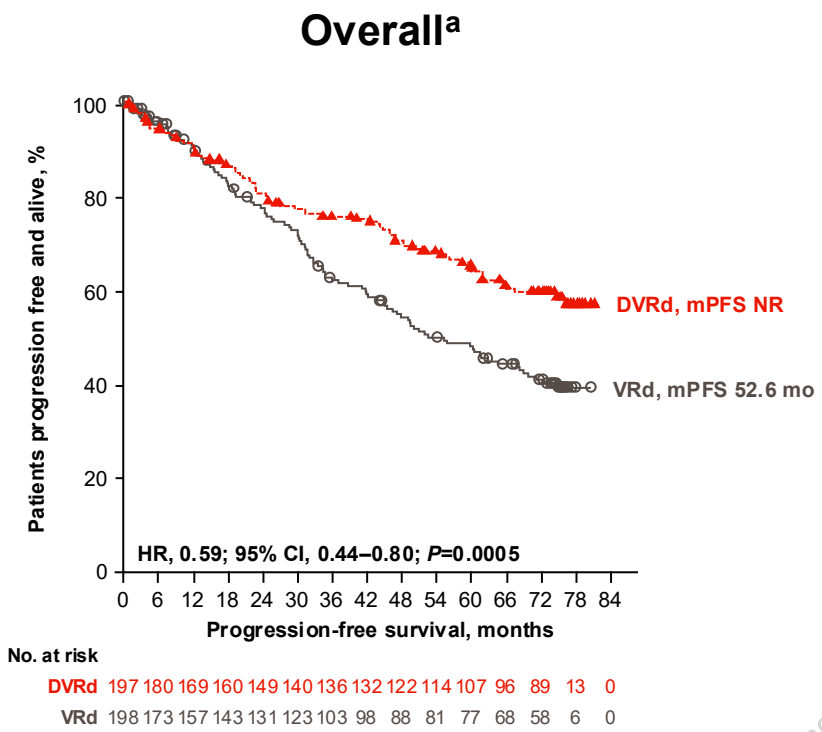
# ITT: Progression-Free Survival by MRD Status




**PFS improved with DVRd vs VRd in MRD-negative and MRD-positive patients**

[a]For the TIE population, DVRd improved PFS with 45% reduction in risk of disease progression or death vs VRd (HR, 0.55; 95% CI, 0.39–0.78; *P*=0.0007). DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; HR, hazard ratio; ITT, intent to treat; MRD, minimal residual disease; OR, odds ratio; PFS, progression-free survival per investigator assessment; VRd, bortezomib, lenalidomide, and dexamethasone; TIE, transplant ineligible.





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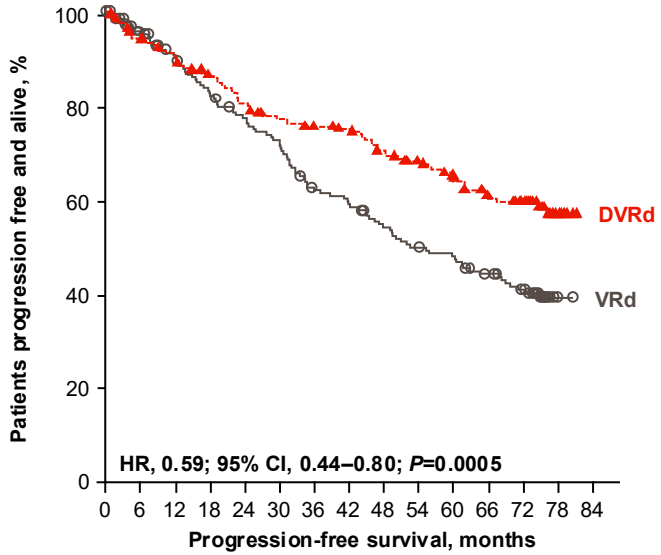
# ITT: Progression-Free Survival by MRD Status

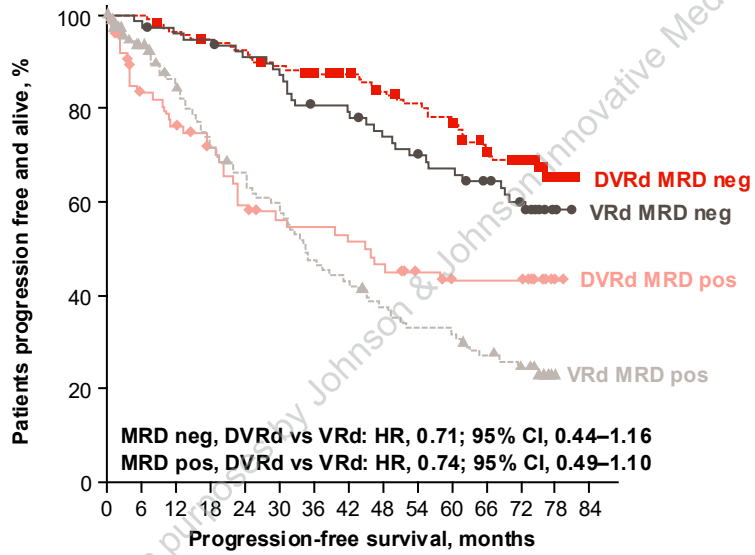
## Overall[a]




No. at risk

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DVRd | 197 | 180 | 169 | 160 | 149 | 140 | 136 | 132 | 122 | 114 | 107 | 96 | 89 | 13 | 0 |
| VRd | 198 | 173 | 157 | 143 | 131 | 123 | 103 | 98 | 88 | 81 | 77 | 68 | 58 | 6 | 0 |

## By MRD status ($10^{-5}$)[b]




No. at risk

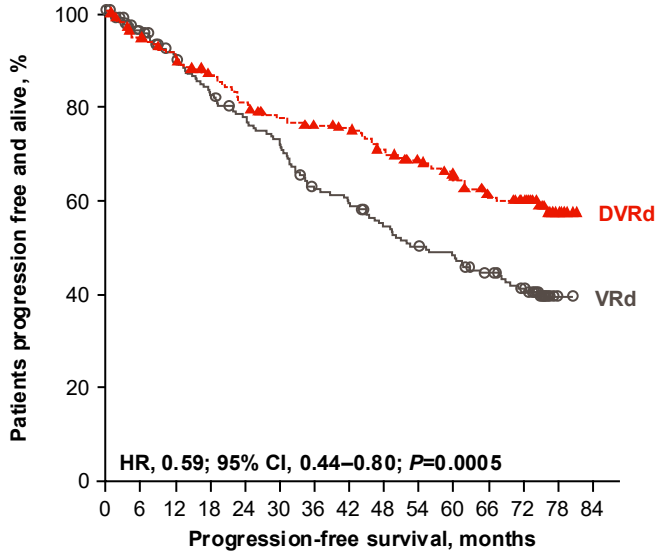
| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DVRd MRD neg | 121 | 121 | 116 | 113 | 110 | 105 | 102 | 99 | 93 | 89 | 84 | 74 | 67 | 12 | 0 |
| VRd MRD neg | 79 | 78 | 75 | 74 | 70 | 68 | 61 | 60 | 55 | 52 | 49 | 45 | 38 | 6 | 0 |
| DVRd MRD pos | 76 | 59 | 53 | 47 | 39 | 35 | 34 | 33 | 29 | 25 | 23 | 22 | 22 | 1 | 0 |
| VRd MRD pos | 119 | 95 | 82 | 69 | 61 | 55 | 42 | 38 | 33 | 29 | 28 | 23 | 20 | 0 | 0 |

**PFS improved with DVRd vs VRd in MRD-negative and MRD-positive patients**

[a]For the TIE population, DVRd improved PFS with 45% reduction in risk of disease progression or death vs VRd (HR, 0.55; 95% CI, 0.39–0.78; *P*=0.0007). [b]For the TIE population, median PFS improved in patients with DVRd vs VRd in patients achieving MRD-negativity at $10^{-5}$ (HR, 0.81; 95% CI, 0.46–1.44; *P*=0.4776) and in MRD-positive patients (HR, 0.56; 95% CI, 0.34–0.91; *P*=0.0170). DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; HR, hazard ratio; ITT, intent to treat; MRD, minimal residual disease; neg, negative; OR, odds ratio; PFS, progression-free survival per investigator assessment; pos, positive; TIE, transplant ineligible; VRd, bortezomib, lenalidomide, and dexamethasone.

# ITT: Progression-Free Survival by MRD Status

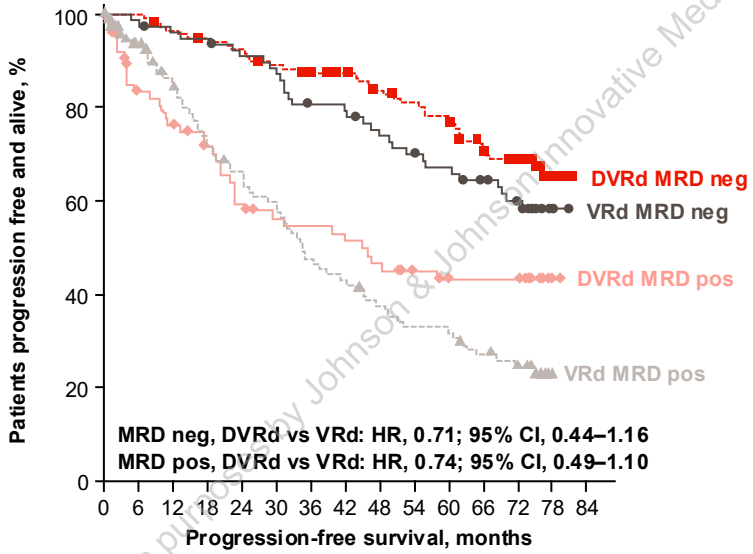
## Overall[a]




No. at risk

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DVRd | 197 | 180 | 169 | 160 | 149 | 140 | 136 | 132 | 122 | 114 | 107 | 96 | 89 | 13 | 0 |
| VRd | 198 | 173 | 157 | 143 | 131 | 123 | 103 | 98 | 88 | 81 | 77 | 68 | 58 | 6 | 0 |

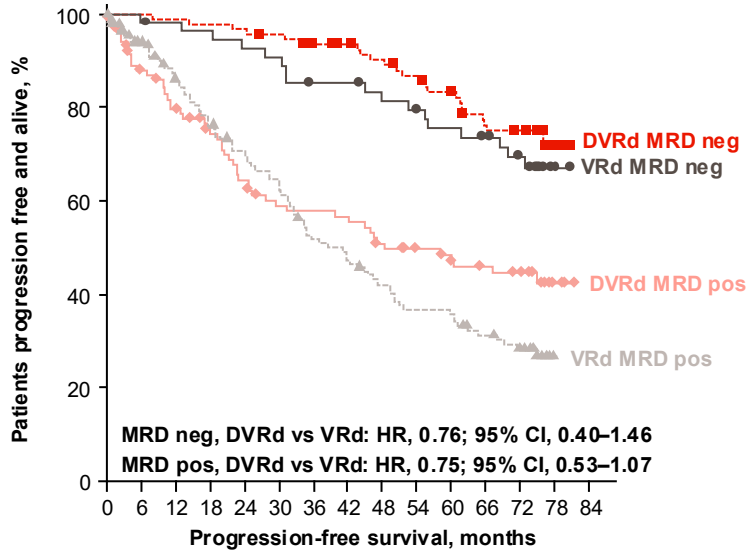
## By MRD status ($10^{-5}$)[b]




No. at risk

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DVRd MRD neg | 121 | 121 | 116 | 113 | 110 | 105 | 102 | 99 | 93 | 89 | 84 | 74 | 67 | 12 | 0 |
| VRd MRD neg | 79 | 78 | 75 | 74 | 70 | 68 | 61 | 60 | 55 | 52 | 49 | 45 | 38 | 6 | 0 |
| DVRd MRD pos | 76 | 59 | 53 | 47 | 39 | 35 | 34 | 33 | 29 | 25 | 23 | 22 | 22 | 1 | 0 |
| VRd MRD pos | 119 | 95 | 82 | 69 | 61 | 55 | 42 | 38 | 33 | 29 | 28 | 23 | 20 | 0 | 0 |

## By MRD status ($10^{-6}$)[c]




No. at risk

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DVRd MRD neg | 94 | 94 | 93 | 92 | 91 | 89 | 86 | 83 | 79 | 75 | 71 | 63 | 58 | 10 | 0 |
| VRd MRD neg | 55 | 55 | 53 | 52 | 50 | 49 | 45 | 45 | 42 | 41 | 38 | 36 | 30 | 5 | 0 |
| DVRd MRD pos | 103 | 86 | 76 | 68 | 58 | 51 | 50 | 49 | 43 | 39 | 36 | 33 | 31 | 3 | 0 |
| VRd MRD pos | 143 | 118 | 104 | 91 | 81 | 74 | 58 | 53 | 46 | 40 | 39 | 32 | 28 | 1 | 0 |

**PFS improved with DVRd vs VRd in MRD-negative and MRD-positive patients**

[a]For the TIE population, DVRd improved PFS with 45% reduction in risk of disease progression or death vs VRd (HR, 0.55; 95% CI, 0.39–0.78; *P*=0.0007). [b]For the TIE population, median PFS improved in patients with DVRd vs VRd in patients achieving MRD-negativity at $10^{-5}$ (HR, 0.81; 95% CI, 0.46–1.44; *P*=0.4776) and in MRD-positive patients (HR, 0.56; 95% CI, 0.34–0.91; *P*=0.0170). [c]For the TIE population, median PFS improved in patients with DVRd vs VRd in patients achieving MRD-negativity at $10^{-6}$ (HR, 1.18; 95% CI, 0.54–2.57; *P*=0.6735) and in MRD-positive patients (HR, 0.57; 95% CI, 0.37–0.87; *P*=0.0078). DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; HR, hazard ratio; ITT, intent to treat; MRD, minimal residual disease; neg, negative; OR, odds ratio; PFS, progression-free survival per investigator assessment; pos, positive; TIE, transplant ineligible; VRd, bortezomib, lenalidomide, and dexamethasone.





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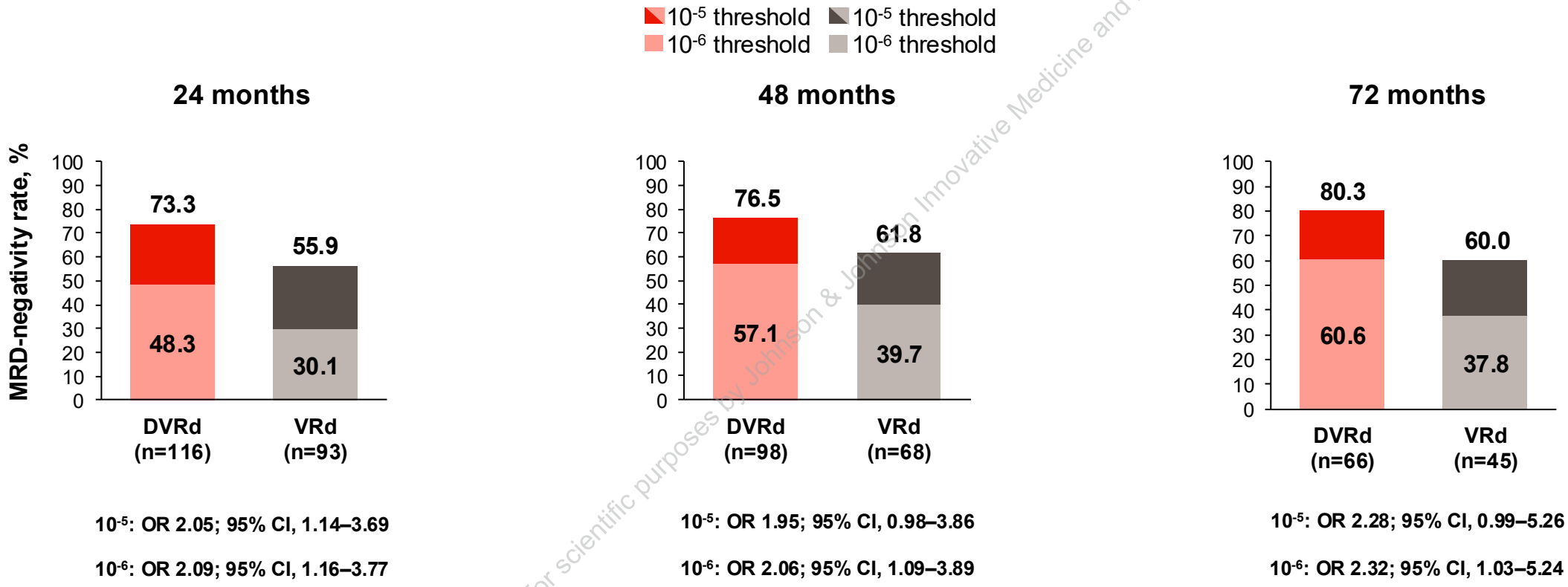
# MRD-Evaluable: MRD-Negativity ≥CR Rates[a] at Prespecified Landmark Time Points




**$10^{-5}$: OR 2.05; 95% CI, 1.14–3.69**

**$10^{-6}$: OR 2.09; 95% CI, 1.16–3.77**

**$10^{-5}$: OR 1.95; 95% CI, 0.98–3.86**

**$10^{-6}$: OR 2.06; 95% CI, 1.09–3.89**

**$10^{-5}$: OR 2.28; 95% CI, 0.99–5.26**

**$10^{-6}$: OR 2.32; 95% CI, 1.03–5.24**

**MRD-negativity rates were improved at all prespecified assessment time points up to 72 months with DVRd vs VRd in the MRD-evaluable population**

[a]The proportion of patients who achieved both MRD-negativity (at or below a $10^{-5}$ or $10^{-6}$ threshold) and ≥CR; calculated with the number of subjects with ≥CR and with MRD sample in each window as denominators. The number of patients per arm is the same for the $10^{-5}$ and $10^{-6}$ threshold. ≥CR, complete response or better; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; OR, odds ratio; VRd, bortezomib, lenalidomide, and dexamethasone.





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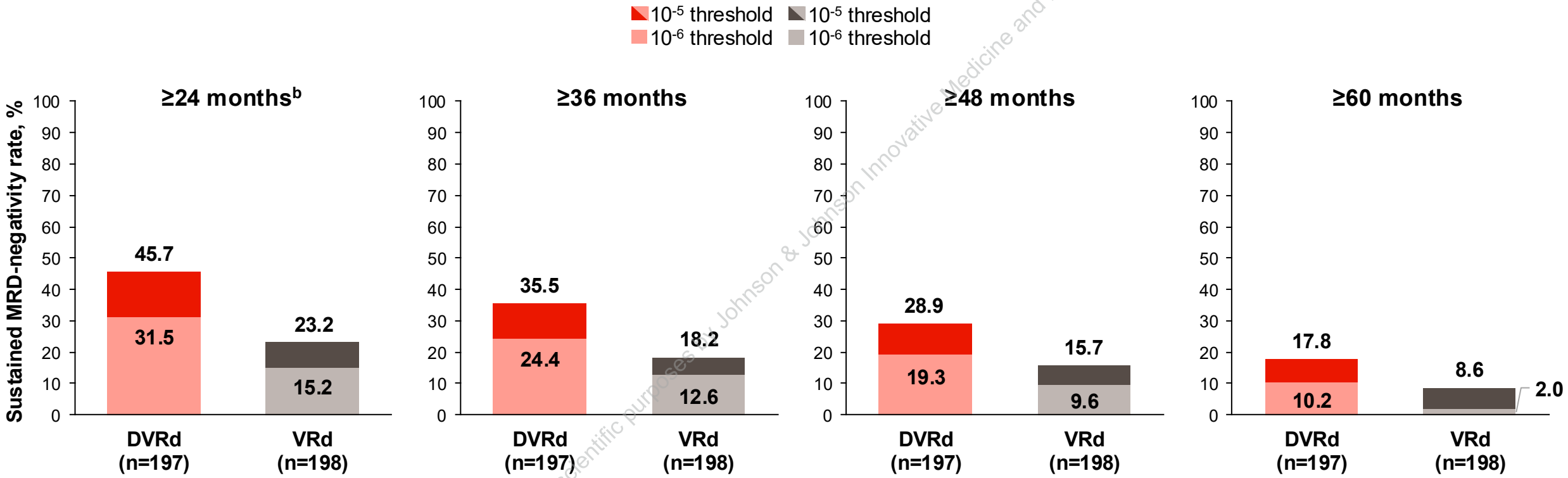
# ITT: Sustained MRD-Negativity ≥CR Rates[a]




**DVRd demonstrated superior sustained MRD-negativity rates over time vs VRd**

[a]Sustained MRD negativity was defined as 2 consecutive MRD negative reads ≥24, 36, 48, or 60 (±3) months apart with no MRD-positive result in between. [b]For the TIE population, 24-month sustained MRD-negativity rates were higher with DVRd vs VRd at $10^{-5}$ (44.4% vs 23.4%; OR 2.62; 95% CI, 1.58–4.36; *P*=0.0002) and at $10^{-6}$ (30.6% vs 15.2%; OR 2.45; 95% CI, 1.38–4.37; *P*=0.0020).

≥CR, complete response or better; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; ITT, intent to treat; MRD, minimal residual disease; OR, odds ratio; TIE, transplant ineligible; VRd, bortezomib, lenalidomide, and dexamethasone.





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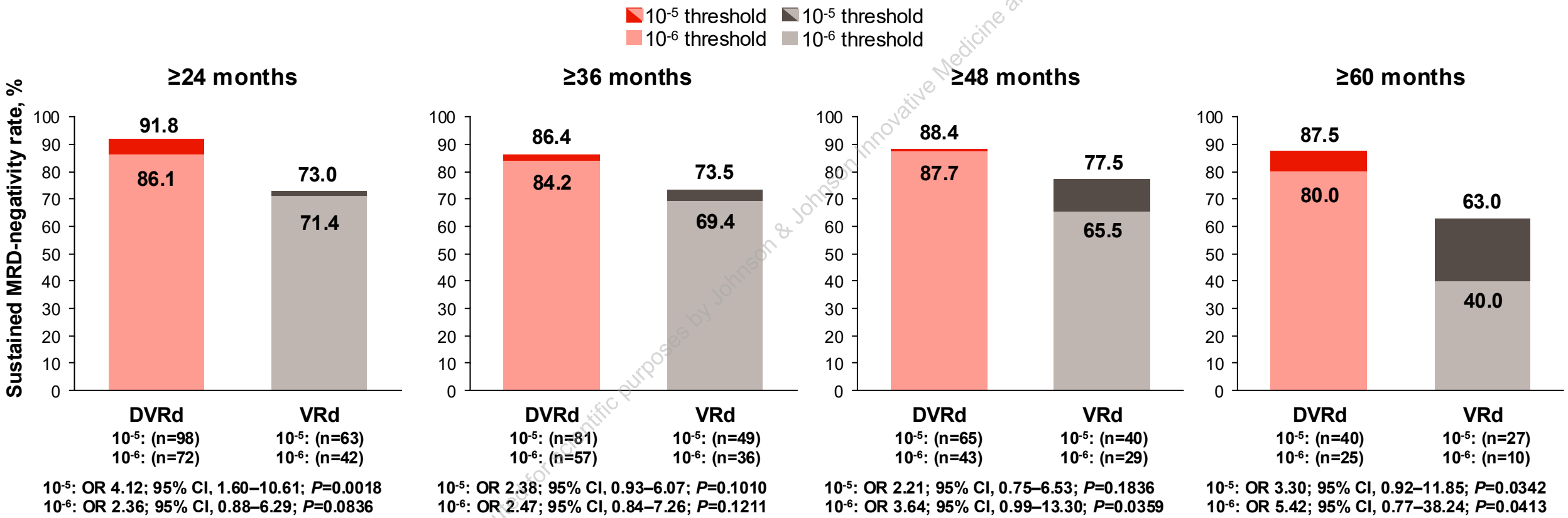
# MRD-Evaluable: Sustained MRD-Negativity ≥CR Rates[a]

**Patients achieved ≥CR and had an MRD-negative sample, followed by another MRD sample ≥24, 36, 48, or 60 months later**




**DVRd demonstrated superior sustained MRD-negativity rates at $10^{-5}$ and $10^{-6}$ vs VRd**

[a]Patients achieved ≥CR and had an MRD-negative sample, followed by another MRD sample ≥24, 36, 48, or 60 (±3) months later. Sustained MRD negativity was defined as 2 consecutive MRD negative reads ≥24, 36, 48, or 60 (±3) months apart with no MRD-positive result in between. MRD-evaluable population defined as patients with ≥CR, successful baseline calibration, and with an MRD-negative sample followed by another MRD sample 24, 36, 48, or 60 months later, respectively. ≥CR, complete response or better; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; OR, odds ratio; VRd, bortezomib, lenalidomide, and dexamethasone.





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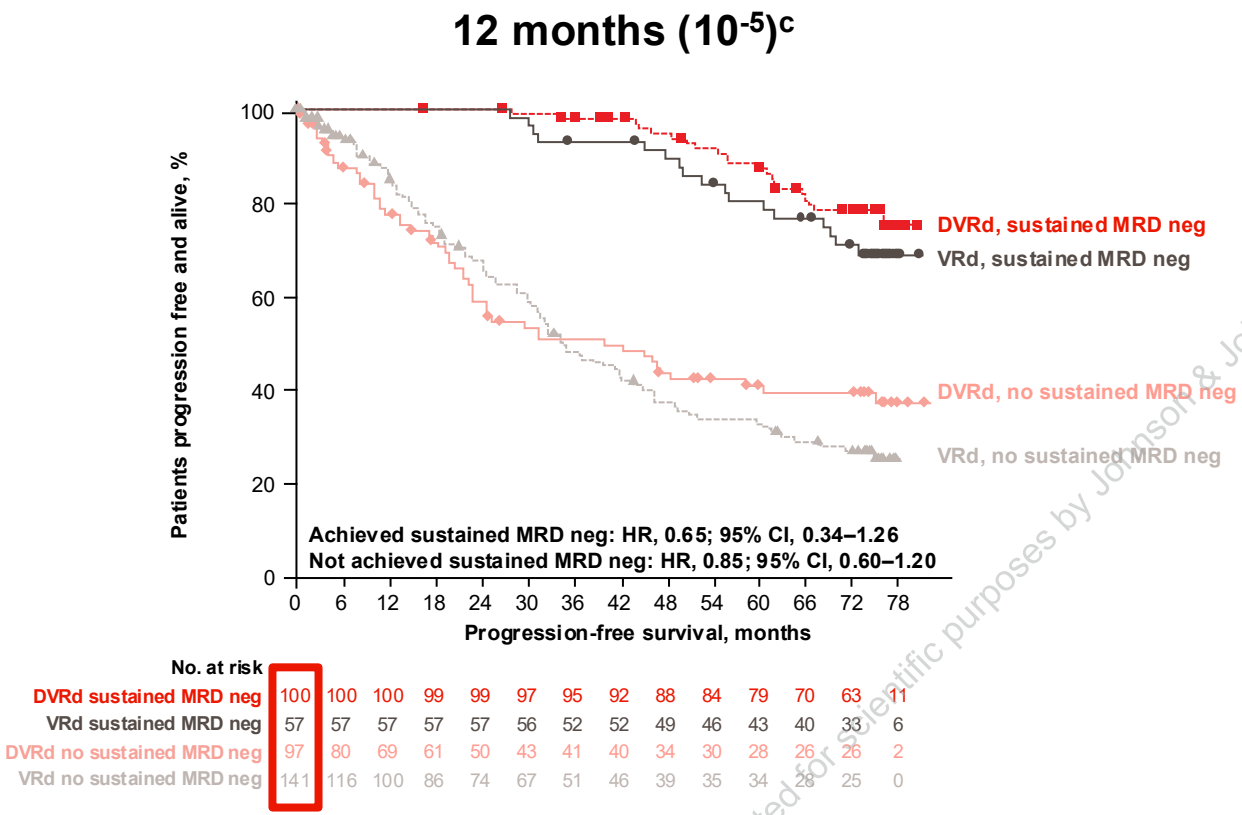
# ITT: Progression-Free Survival[a] by Sustained MRD-Negativity Status[b]




**PFS improved with DVRd vs VRd in patients with sustained MRD negativity**

[a]PFS per investigator assessment; [b]Sustained MRD negativity was defined as 2 consecutive MRD negative reads ≥12 (±1) or 24 months (±3) apart with no MRD-positive result in between. [c]For the TIE population, median PFS improved in patients with DVRd vs VRd in patients with 12-month sustained MRD-negativity (HR, 0.75; 95% CI, 0.35–1.60) and without 12-month sustained MRD-negativity (HR, 0.68; 95% CI, 0.45–1.03).
DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; HR, hazard ratio; ITT, intent to treat; MRD, minimal residual disease; neg, negative; OR, odds ratio; TIE, transplant ineligible; VRd, bortezomib, lenalidomide, and dexamethasone.





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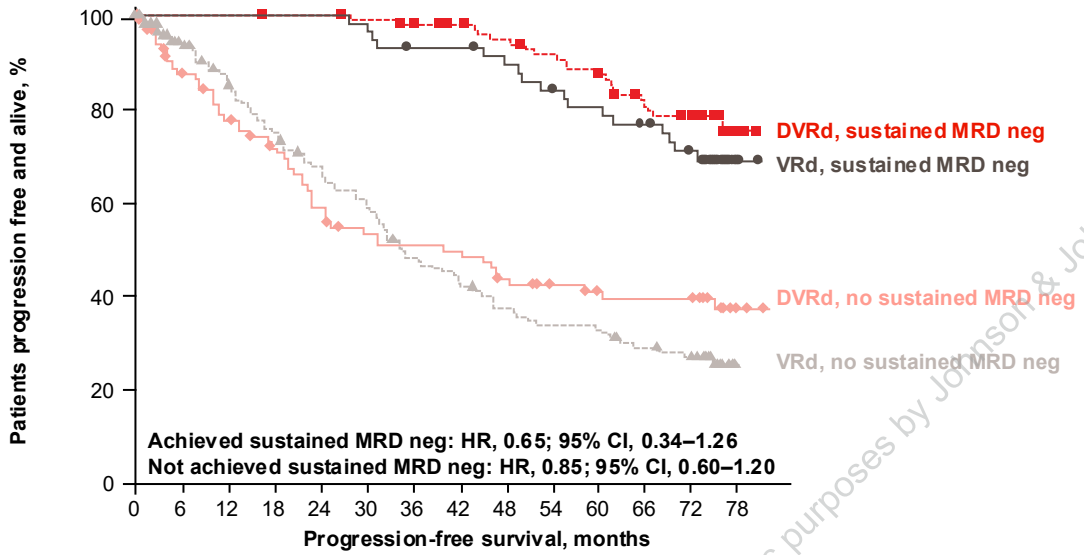
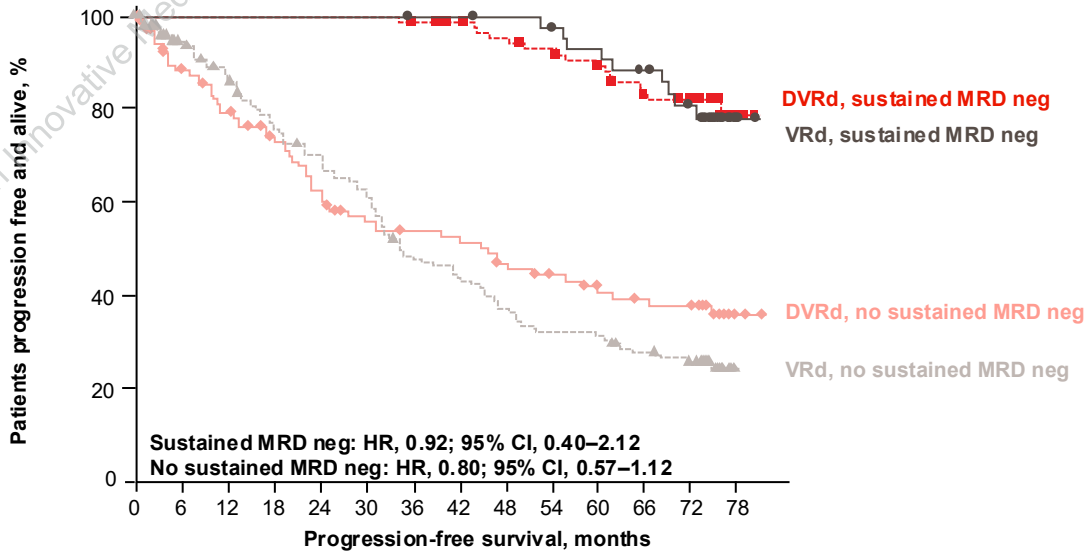
# ITT: Progression-Free Survival[a] by Sustained MRD-Negativity Status[b]

## 12 months ($10^{-5}$)[c]




| No. at risk | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DVRd sustained MRD neg | 100 | 100 | 100 | 99 | 99 | 97 | 95 | 92 | 88 | 84 | 79 | 70 | 63 | 11 |
| VRd sustained MRD neg | 57 | 57 | 57 | 57 | 57 | 56 | 52 | 52 | 49 | 46 | 43 | 40 | 33 | 6 |
| DVRd no sustained MRD neg | 97 | 80 | 69 | 61 | 50 | 43 | 41 | 40 | 34 | 30 | 28 | 26 | 26 | 2 |
| VRd no sustained MRD neg | 141 | 116 | 100 | 86 | 74 | 67 | 51 | 46 | 39 | 35 | 34 | 28 | 25 | 0 |

## 24 months ($10^{-5}$)




| No. at risk | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DVRd sustained MRD neg | 90 | 90 | 90 | 90 | 90 | 90 | 89 | 86 | 82 | 79 | 75 | 68 | 62 | 11 |
| VRd sustained MRD neg | 46 | 46 | 46 | 46 | 46 | 46 | 45 | 45 | 44 | 43 | 40 | 37 | 30 | 6 |
| DVRd no sustained MRD neg | 107 | 90 | 79 | 70 | 59 | 50 | 47 | 46 | 40 | 35 | 32 | 28 | 27 | 2 |
| VRd no sustained MRD neg | 152 | 127 | 111 | 97 | 85 | 77 | 58 | 53 | 44 | 38 | 37 | 31 | 28 | 0 |

**PFS improved with DVRd vs VRd in patients with sustained MRD negativity**

[a]PFS per investigator assessment. [b]Sustained MRD negativity was defined as 2 consecutive MRD negative reads ≥12 (±1) or 24 months (±3) apart with no MRD-positive result in between. [c]For the TIE population, median PFS improved in patients with DVRd vs VRd in patients with 12-month sustained MRD-negativity (HR, 0.75; 95% CI, 0.35–1.60) and without 12-month sustained MRD-negativity (HR, 0.68; 95% CI, 0.45–1.03).
DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; HR, hazard ratio; ITT, intent to treat; MRD, minimal residual disease; neg, negative; OR, odds ratio; TIE, transplant ineligible; VRd, bortezomib, lenalidomide, and dexamethasone.





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# CEPHEUS MRD: Conclusions

- **DVRd produced deeper responses than VRd, with higher MRD-negativity ≥CR rates at both $10^{-5}$ and $10^{-6}$ in the ITT and MRD-evaluable populations**
  - ITT: 61.4% vs 39.9% at $10^{-5}$; 47.7% vs 27.8% at $10^{-6}$
- **DVRd showed superior sustained MRD-negativity ≥CR rates, including the first report of improved 60-month sustained MRD-negativity ≥CR rates versus VRd in TIE/TD NDMM**
  - 24 months, ITT: 45.7% vs 23.2% at $10^{-5}$; 31.5% vs 15.2% at $10^{-6}$
  - 48 months, ITT: 28.9% vs 15.7% at $10^{-5}$; 19.3% vs 9.6% at $10^{-6}$
- **MRD negativity, particularly sustained MRD negativity, was associated with improved PFS, supporting sustained, deep response as a marker of durable disease control**
  - PFS for achieving overall MRD negativity: HR, 0.71 at $10^{-5}$; 12-month sustained: HR, 0.65 at $10^{-5}$

**With >6 years of follow-up, daratumumab + VRd continues to deepen responses and sustains MRD negativity with improved PFS, which supports durable disease control**



DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; HR, hazard ratio; ITT, intent to treat; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; PFS, progression-free survival; TD, transplant deferred; TIE, transplant ineligible; VRd, bortezomib, lenalidomide, and dexamethasone.



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# CEPHEUS MRD: Acknowledgments


- We thank the patients who participated in this study and their families/caregivers, staff members at the study sites, and the data and safety monitoring committee
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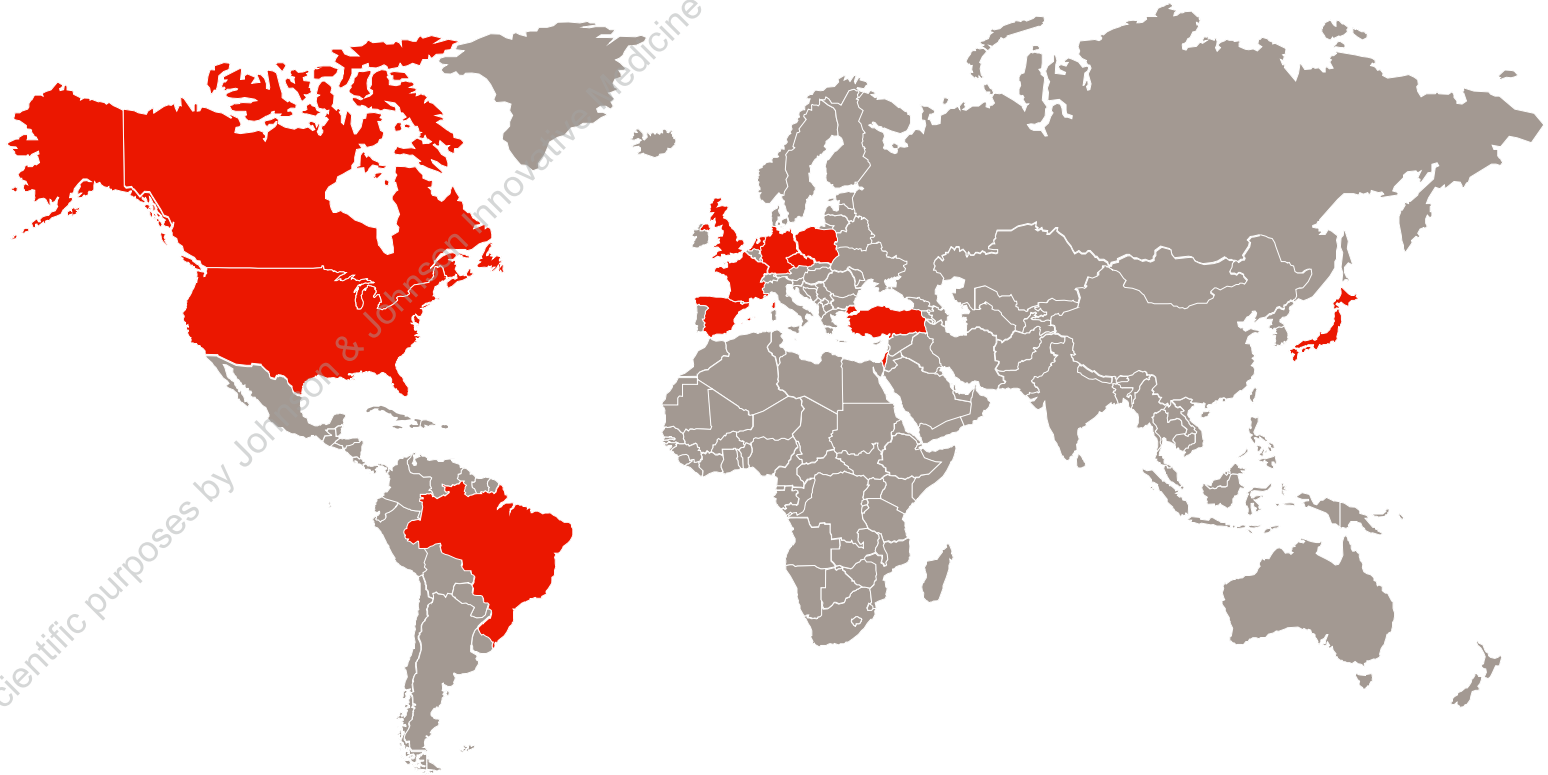



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