5-Year Sustained Minimal Residual Disease Negativity and Survival With Daratumumab Maintenance in Transplant-Eligible NDMM: CASSIOPEIA Registry

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Disclosures

COI statement of the presenting author:

- **Research funding:** BMS, Sanofi
- **Consultancy, honoraria, and travel fees:** Adaptive, BMS, Johnson & Johnson, Pfizer, Sanofi

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CASSIOPEIA: Introduction

- **CASSIOPEIA Part 1 established that DVTd improved efficacy outcomes vs VTd in TE NDMM**
- **CASSIOPEIA Part 2 showed D-maint significantly prolonged PFS from 2nd randomization vs OBS**
  - Sustained MRD negativity ≥12 months (10^{-5}) in 56% (DVTd+D-maint) vs 46% (DVTd+OBS) of patients
- **This interim analysis of the CASSIOPEIA registry describes long-term follow-up efficacy outcomes in patients with TE NDMM previously treated with daratumumab-based induction/consolidation and maintenance in CASSIOPEIA:**
  - High retention of eligible patients (96%) transitioning into registry
  - Balanced duration of follow-up across treatment arms

Supports the reliability of long-term follow-up after completion of 2 years maintenance treatment, exceeding 8.5 years overall (the longest reported follow-up for a quadruplet regimen)

DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; D-maint, daratumumab maintenance; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; OBS, observation; PFS, progression free survival; TE, transplant eligible; VTd, bortezomib, thalidomide, and dexamethasone.

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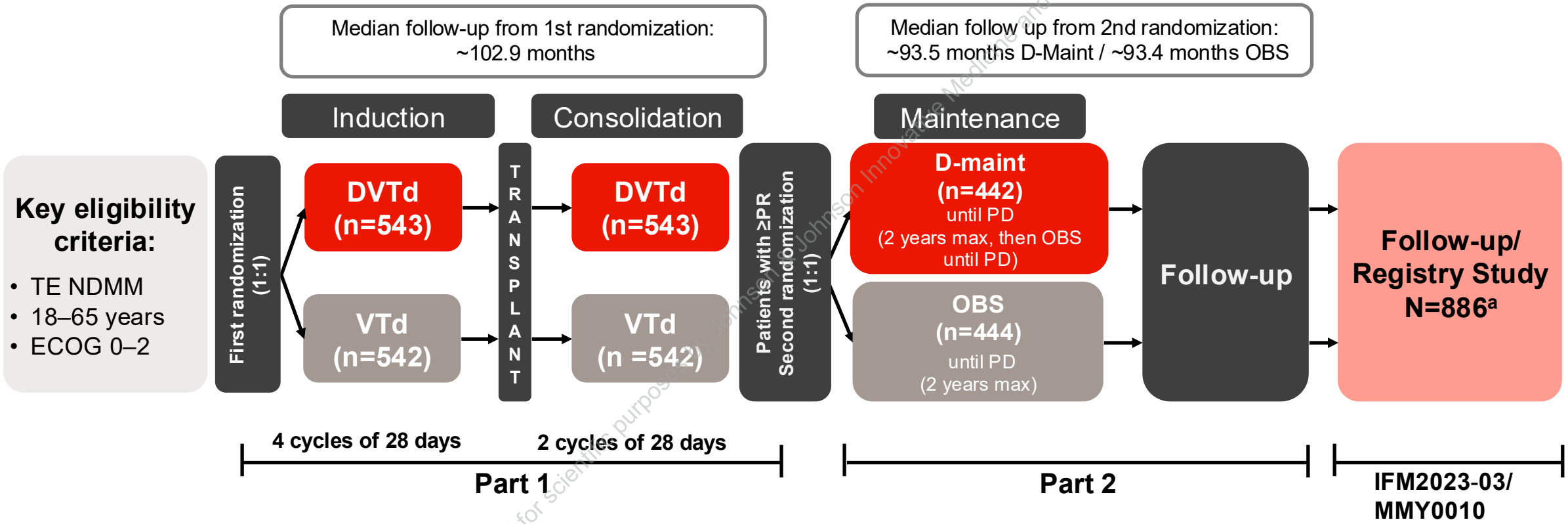
CASSIOPEIA: Study Design



Stratification factors:
- Site affiliation (IFM or HOVON)
- ISS disease stage (I, II, or III)
- Cytogenetic risk status (high or standard)

Stratification factors:
- Induction treatment (DVTd or VTd)
- Depth of response

[a]This is a maintenance-specific ITT population; 802 (96%) patients entered the Registry.
DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; D-maint, daratumumab maintenance; ECOG, Eastern Cooperative Oncology Group; HOVON, the Dutch-Belgian Cooperative Trial Group for Hematology-Oncology; IFM, Intergroupe Francophone du Myélome; ISS, International Staging System; NDMM, newly diagnosed multiple myeloma; OBS, observation; PD, progressive disease; PR, partial response; TE, transplant eligible; VTd, bortezomib, thalidomide, and dexamethasone.

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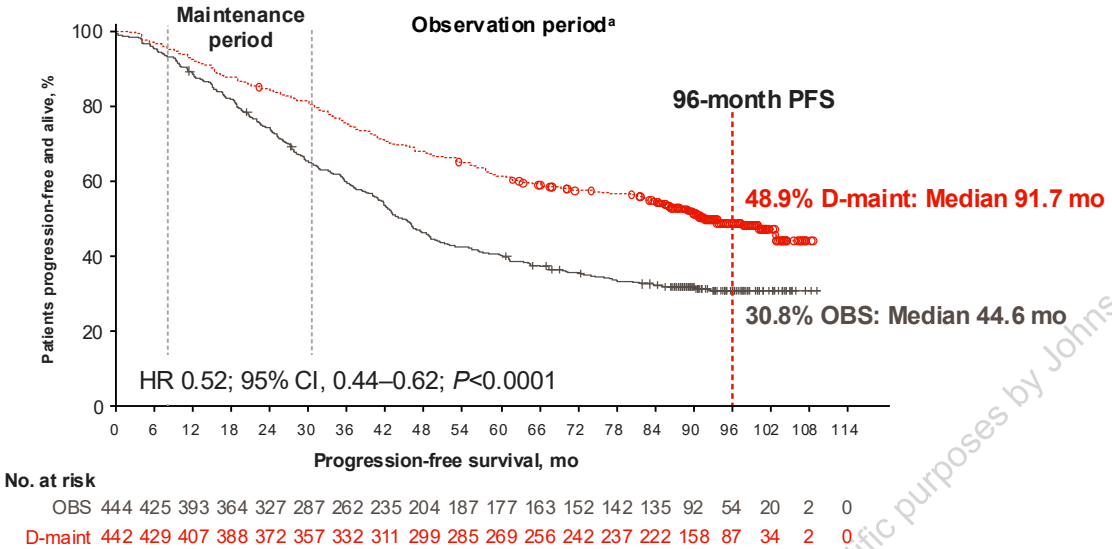
CASSIOPEIA Registry: PFS From 2nd Randomization

PFS from 2nd Randomization (maintenance-specific ITT)

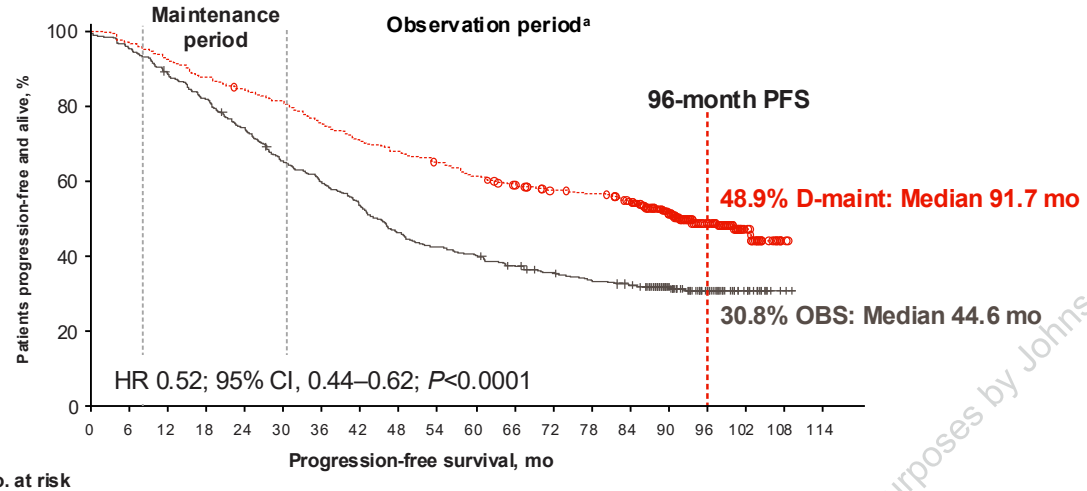


D-maint reduced the risk of progression or death by 48% vs OBS, more than doubling median PFS (91.7 vs 44.6 months)

[a] Observation period for all patients in all treatment arms.
D-maint, daratumumab maintenance; HR, hazard ratio; ITT, intent to treat; OBS, observation; PFS, progression-free survival.

CASSIOPEIA Registry: PFS From 2nd Randomization

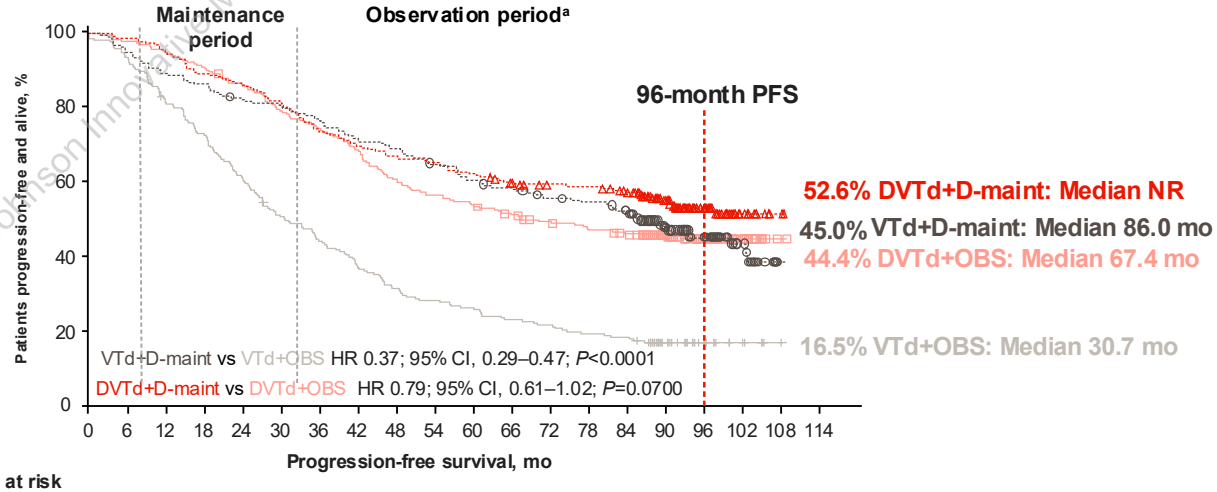
PFS from 2nd Randomization (maintenance-specific ITT)



No. at risk

OBS	444	425	393	364	327	287	262	235	204	187	177	163	152	142	135	92	54	20	2	0
D-maint	442	429	407	388	372	357	332	311	299	285	269	256	242	237	222	158	87	34	2	0

PFS from 2nd Randomization by Induction/Maintenance Treatment (ITT)



No. at risk

VTd+OBS	215	201	176	156	131	107	93	79	66	59	55	48	45	40	38	21	10	4	1	0
VTd+D-maint	213	203	190	184	174	171	163	152	146	136	127	122	114	111	103	70	44	20	0	0
DVTd+OBS	229	224	217	208	196	180	169	156	138	128	122	115	107	102	97	71	44	16	1	0
DVTd+D-maint	229	226	217	204	198	186	169	159	153	149	142	134	128	126	119	88	43	14	2	0

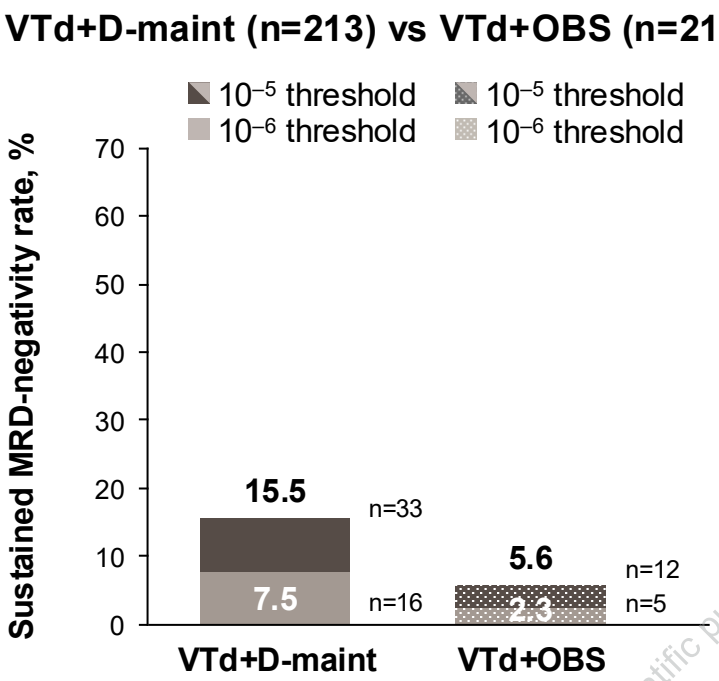
D-maint reduced the risk of progression or death by 48% vs OBS, more than doubling median PFS (91.7 vs 44.6 months)

Nearly 53% of patients treated with DVTd+D-maint were relapse free at 96 months

[a] Observation period for all patients in all treatment arms

DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; D-maint, daratumumab maintenance; HR, hazard ratio; ITT, intention to treat; NDMM, newly diagnosed multiple myeloma; OBS, observation; TE, transplant eligible; VTd, bortezomib, thalidomide, and dexamethasone; NR, not reached.

CASSIOPEIA Registry: 5-Year Sustained MRD Negativity (≥CR) From Post-Induction to End of Follow-Up (Maintenance-Specific ITT)[a]



10^{-5}: VTd + D-maint vs VTd+OBS: OR 3.23; 95% CI, 1.60–6.53; *P*=0.0007

10^{-6}: VTd + D-maint vs VTd+OBS: OR 3.44; 95% CI, 1.23–9.63; *P*=0.0132

[a]MRD analysis by NGS. Percentages are calculated with the number of subjects in each group as denominator. The analysis period of MRD results is considered from post-induction up to end of follow-up, no imputation for missing value. Subjects with ≥60 months of consistent MRD negativity (MRD negative at both the starting and ending point and no positive MRD between them) during the analysis period (and prior to subsequent antimyeloma therapy or disease progression if applicable) are considered as 5-year sustained MRD negativity. Subjects are considered as sustained MRD negativity and CR or better while both sustained MRD negativity and CR or better have been achieved during the MRD negativity period. ≥CR, complete response or better; D-maint, daratumumab maintenance; ITT, intent to treat; MRD, minimal residual disease; NGS, next-generation sequencing; OBS, observation; OR, odds ratio; VTd, bortezomib, thalidomide, and dexamethasone.

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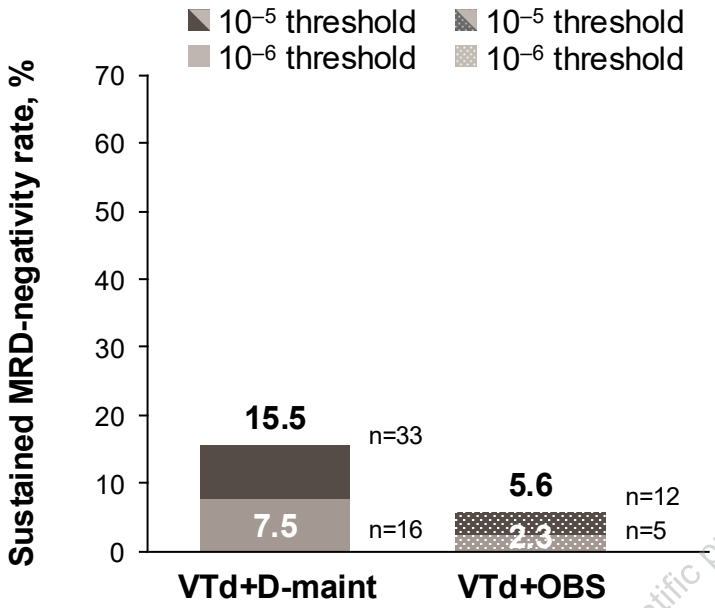
CASSIOPEIA Registry: 5-Year Sustained MRD Negativity (≥CR) From Post-Induction to End of Follow-Up (Maintenance-Specific ITT)[a]

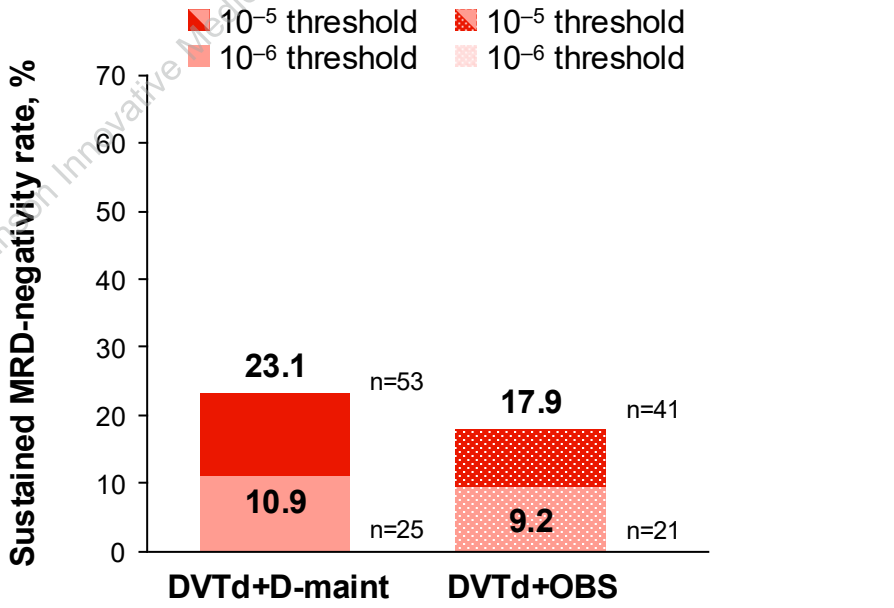
VTd+D-maint (n=213) vs VTd+OBS (n=215)



10⁻⁵: VTd + D-maint vs VTd+OBS: OR 3.23; 95% CI, 1.60–6.53; *P*=0.0007

10⁻⁶: VTd + D-maint vs VTd+OBS: OR 3.44; 95% CI, 1.23–9.63; *P*=0.0132

DVTd+D-maint (n=229) vs DVTd+OBS (n=229)



10⁻⁵: DVTd + D-maint vs DVTd-OBS: OR 1.40; 95% CI, 0.88–2.22; *P*=0.1589

10⁻⁶: DVTd + D-maint vs DVTd-OBS: OR 1.22; 95% CI, 0.66–2.25; *P*=0.5333

At the 10⁻⁵ threshold, ~1 in 4 patients treated with DVTd+D-maint achieved ≥5 years of sustained MRD negativity (23.1%)

[a]MRD analysis by NGS. Percentages are calculated with the number of subjects in each group as denominator. The analysis period of MRD results is considered from post-induction up to end of follow-up, no imputation for missing value. Subjects with ≥60 months of consistent MRD negativity (MRD negative at both the starting and ending point and no positive MRD between them) during the analysis period (and prior to subsequent antimyeloma therapy or disease progression if applicable) are considered as 5-year sustained MRD negativity. Subjects are considered as sustained MRD negativity and CR or better while both sustained MRD negativity and CR or better have been achieved during the MRD negativity period. ≥CR, complete response or better; DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; D-maint, daratumumab maintenance; ITT, intent to treat; MRD, minimal residual disease; NGS, next-generation sequencing; OBS, observation; OR, odds ratio; VTd, bortezomib, thalidomide, and dexamethasone.

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CASSIOPEIA Landmark Analyses: Characteristics and Demographics of Patients With ≥5 Years of Sustained MRD Negativity (10^{-5}, ≥CR)

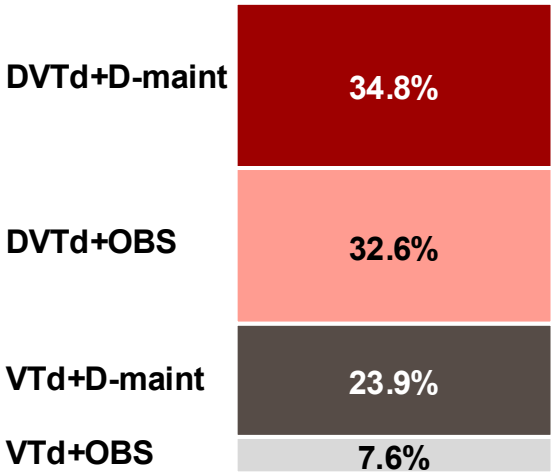
Patient characteristic and MRD-negativity duration	n (%)
Patients with sustained MRD negativity in ≥5 years[a]	**92 (8.5%)[b]**
Age, years, median (range) [IQR]	58 (40–65) [52-62]
Sex (%)	
Female (%)	45.7
Male (%)	54.3
Cytogenetic risk (%)	
Standard	90.2
High	9.8
Baseline ISS stage	
I	43 (46.7)
II	38 (41.3)
III	11 (12)
CRAB	82 (89.1)

Patient characteristics and MRD-negativity duration	n (%)
MRD-negativity duration, years, median (range) [IQR]	5.4 (5.0–6.8) [5.1–5.7]
First visit with MRD-negative result	
Postinduction (C4D28)	48 (52.2)
D100 post-ASCT	42 (45.7)
Week 25	2 (2.2)

[a]MRD-negative assessment per CMF or NGS, no positive result between first and last MRD assessment in ≥5 years. [b]of n=1085 randomized patients.
ASCT, autologous stem cell transplant; C, cycle; CMS, complete molecular and flow cytometry; CR, complete response; CRAB, myeloma-defining end-organ damage (hypercalcemia, renal insufficiency, anemia, and bone lesions); D100, day 100; D-maint, daratumumab maintenance; IQR, interquartile range; ISS, International Staging System; MRD, minimal residual disease; NGS, next-generation sequencing.

CASSIOPEIA Landmark Analyses: PFS by Sustained MRD Negativity

Patients with ≥5 Years of Sustained MRD Negativity (10^{-5}, ≥CR)



≥CR, complete response or better; D-maint, daratumumab maintenance; DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; MRD, minimal residual disease; OBS, observation; PFS, progression-free survival; VTd, bortezomib, thalidomide, and dexamethasone.

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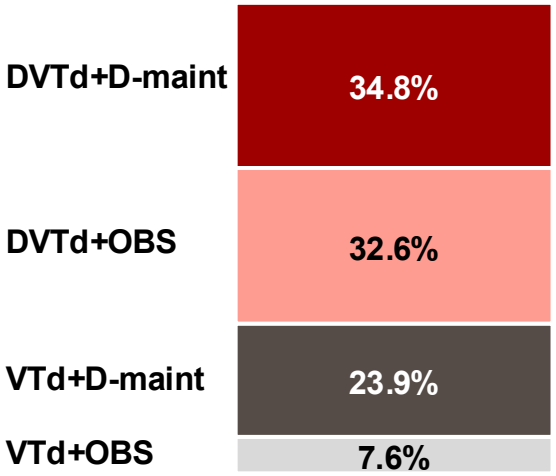
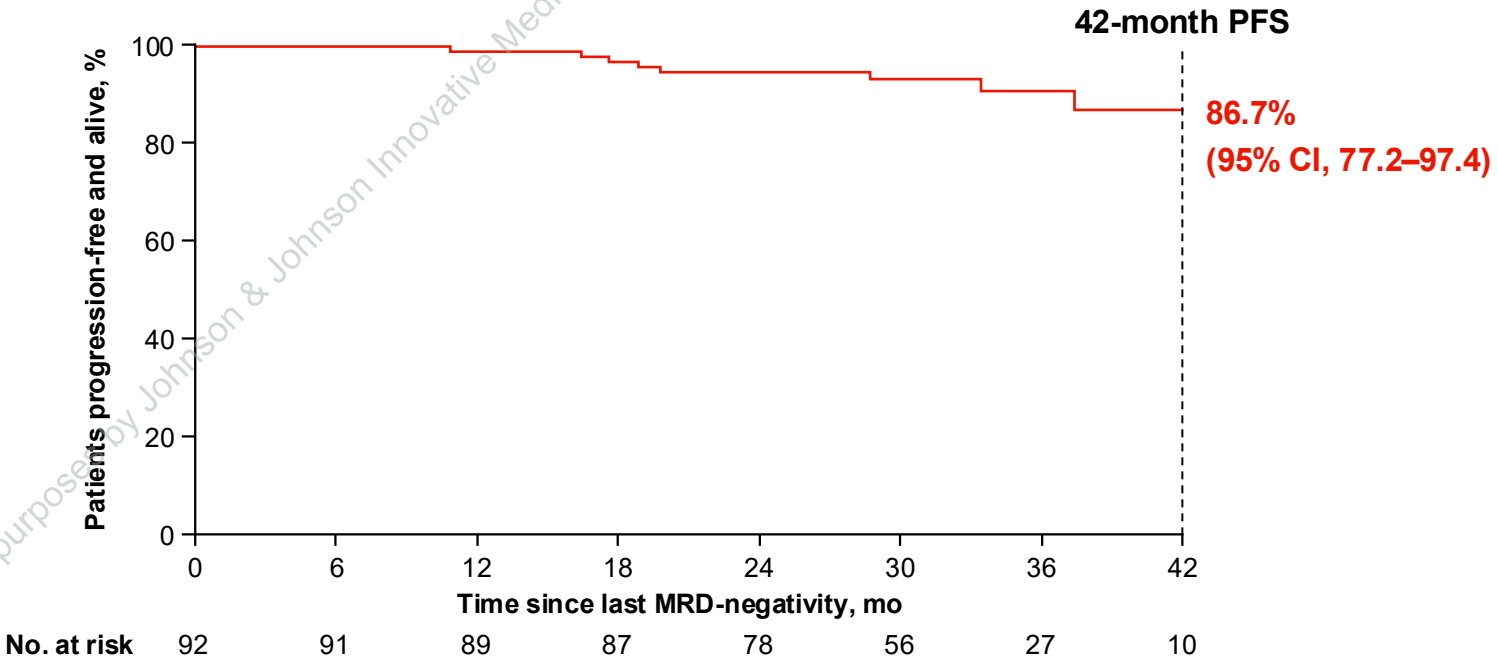
CASSIOPEIA Landmark Analyses: PFS by Sustained MRD Negativity

Patients with ≥5 Years of Sustained MRD Negativity (10^{-5}, ≥CR)





Deep and durable MRD responses were associated with excellent long-term outcomes, with 86.7% of patients remaining progression free 42 months after achieving ≥5 years of sustained MRD negativity

≥CR, complete response or better; D-maint, daratumumab maintenance; DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; MRD, minimal residual disease; OBS, observation; PFS, progression-free survival; VTd, bortezomib, thalidomide, and dexamethasone.

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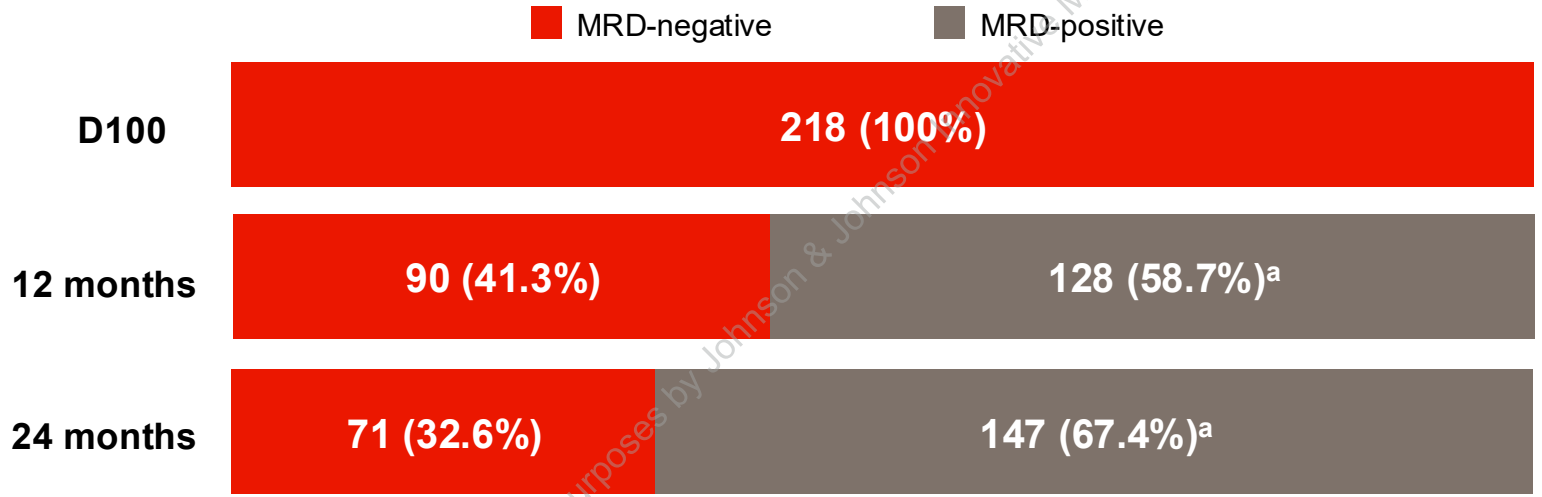
CASSIOPEIA Landmark Analyses: Evolution of MRD Status From Post-Consolidation (NGS 10^{-6})

702 evaluable patients at D100: 218 (31.1%) were MRD-negative



Approximately one-third of initially MRD-negative patients maintained MRD negativity through 24 months post-consolidation

[a]Patients with MRD positivity, progression/death before the landmark, or no qualifying NGS measurement within 60 days before the landmark, according to the primary worst-case analysis
D100, day 100; MRD, minimal residual disease; NGS, next-generation sequencing.

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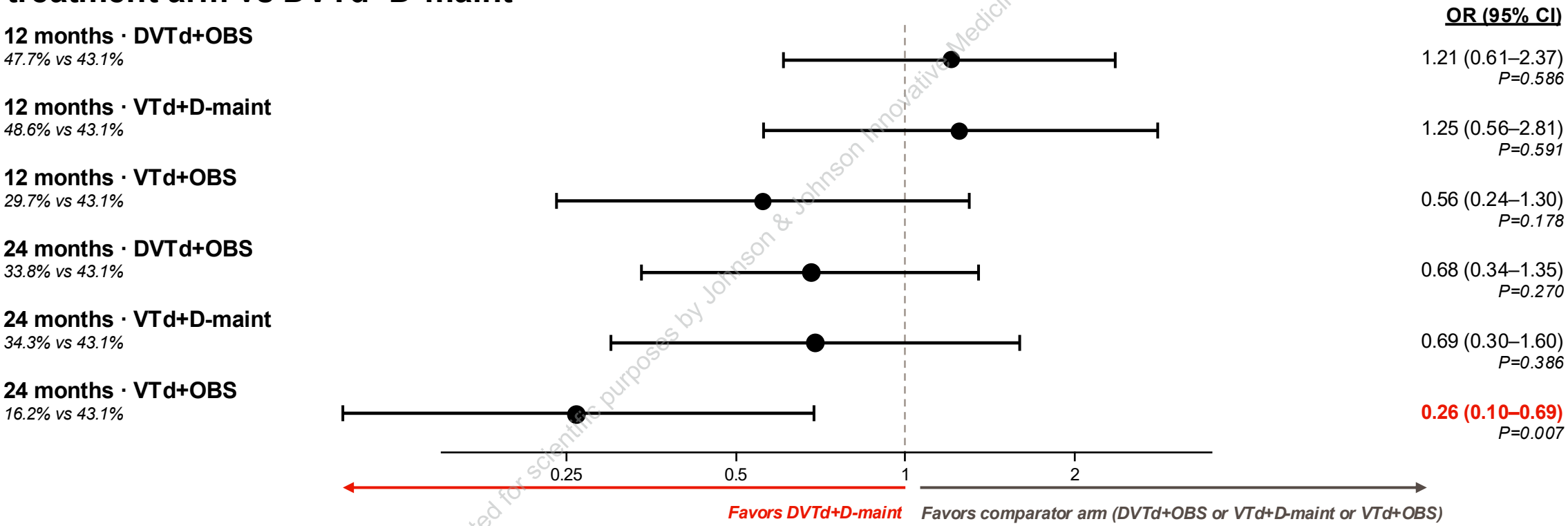
CASSIOPEIA Landmark Analyses: Sustained MRD-Negativity Status Over Time

MRD-negative patients at D100: OR of sustained MRD negativity (NGS 10^{-6}) at 12 and 24 months, by treatment arm vs DVTd+D-maint[a]



With longer follow-up, sustained MRD-negativity rates favored DVTd + D-maint

[a]Patients MRD-negative at D100 (N=218) - odds ratio of sustained MRD negativity at **12 months** and **24 months** post consolidation - all arms vs DVTd+D-maint (ref).
D100, day 100; DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; D-maint, daratumumab maintenance; MRD, minimal residual disease; NGS, next-generation sequencing; OBS, observation; OR, odds ratio; VTd, bortezomib, thalidomide, and dexamethasone.

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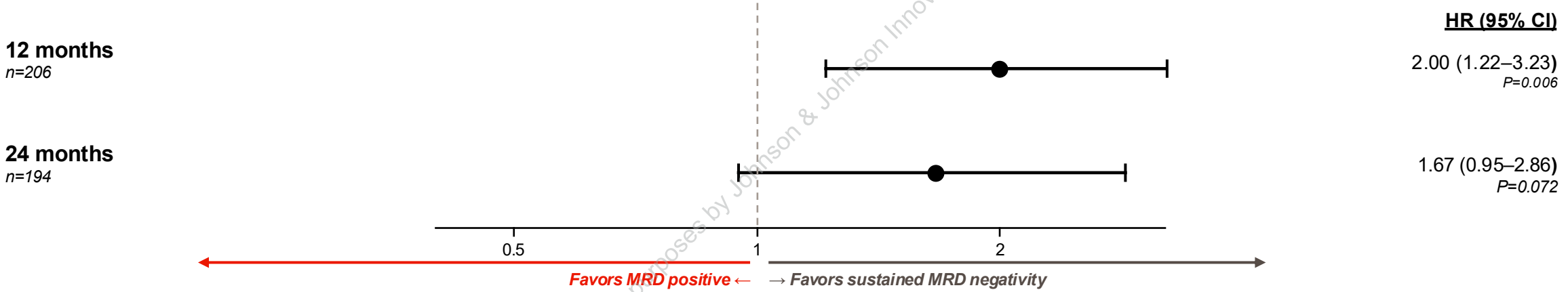
CASSIOPEIA Landmark Analyses: PFS by MRD Status

MRD-negative patients at D100: HR of progression or death by MRD status at 12 and 24 months[a]



Among patients MRD-negative at D100 post-ASCT, loss of sustained MRD negativity was associated with poorer long-term outcomes, with an approximately two-fold higher risk of progression or death at the 12-month landmark

[a]All arms pooled - landmark at **12 months** and **24 months** post consolidation - Cox HR, MRD-positive vs MRD-sustained at 12 months and 24 months (NGS 10^{-6}).
ASCT, autologous stem cell transplant; D100, day 100; DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; HR, hazard ratio; MRD, minimal residual disease; NGS, next-generation sequencing; PFS, progression-free survival; VTd, bortezomib, thalidomide, and dexamethasone.

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CASSIOPEIA: Subsequent Therapy Patterns and PFS2 (2nd Randomization)

Subsequent 1L therapy

Arm	Patients receiving subsequent tx, %[a]	Anti-CD38 as 1st subsequent tx, %[b]	Main triplet at relapse
DVTd + D-maint	**42.4%**	**44.3%**	KRd (35.1%)
VTd + D-maint	**46.0%**	**51.0%**	KRd (25.5%)
DVTd + OBS	**51.1%**	**65.8%**	DRd (50.4%)
VTd + OBS	**78.1%**	**69.9%**	DRd (57.7%)

Fewer patients needing next therapy (better)

- Most OBS patients received a daratumumab-based regimen at 1st relapse (~66–70% anti-CD38), likely diluting the between-arm PFS2 difference

Daratumumab maintenance reduced the need for subsequent therapy and significantly prolonged PFS2, supporting continued benefit beyond first progression

[a]Denominator is maintenance specific ITT population. [b]Denominator is patients who received a first-line subsequent therapy.
1L, first line; DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; D-maint, daratumumab maintenance; DRd, daratumumab, lenalidomide, and dexamethasone; KRd, carfilzomib, lenalidomide, and dexamethasone; OBS, observation; PFS2, progression-free survival on next line of therapy; tx, therapy; VTd, bortezomib, thalidomide, and dexamethasone

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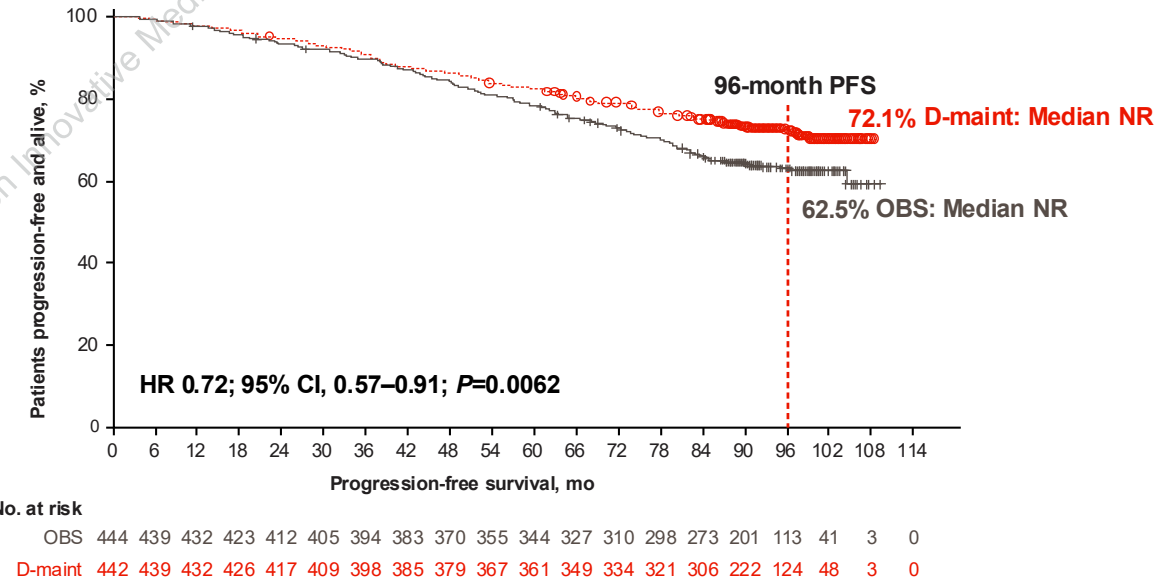
PFS2: time to progression on the next line of therapy



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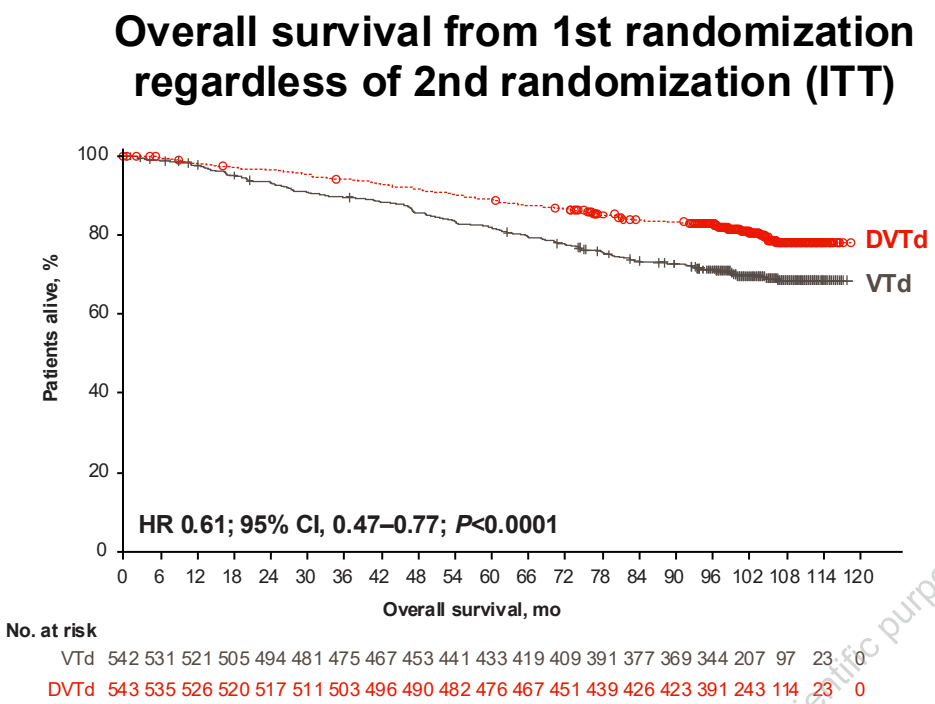
CASSIOPEIA: Overall Survival



OS rates significantly improved with DVTd, reducing risk of death by 39% vs VTd

DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; HR, hazard ratio; ITT, intent to treat; OS, overall survival; VTd, bortezomib, thalidomide, and dexamethasone.

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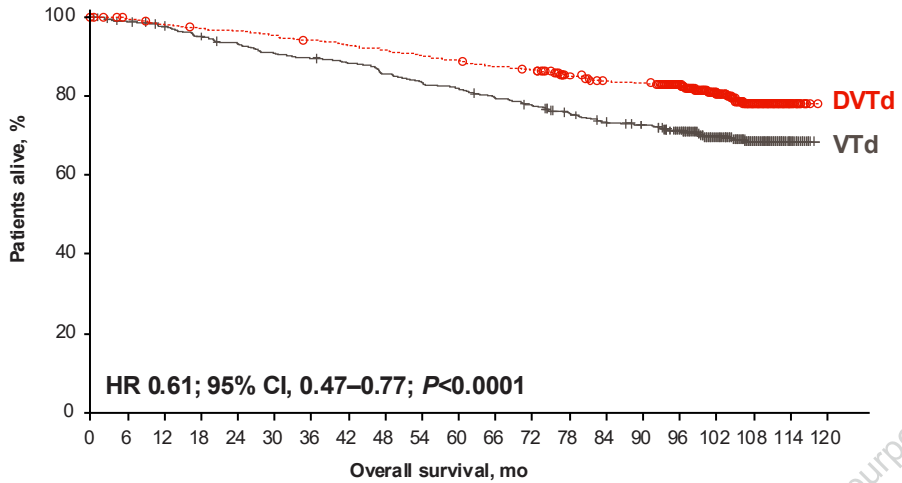
CASSIOPEIA: Overall Survival

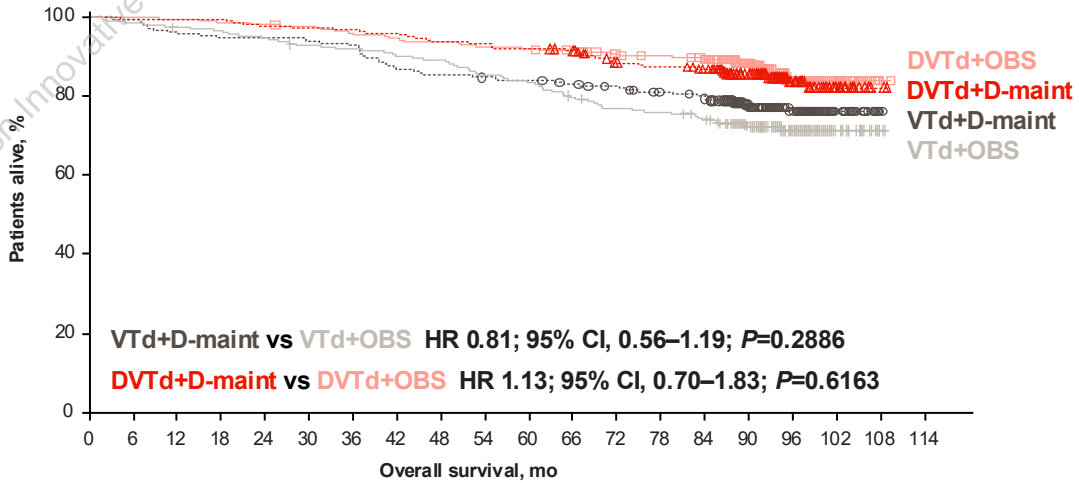
Overall survival from 1st randomization regardless of 2nd randomization (ITT)



No. at risk

VTd	542	531	521	505	494	481	475	467	453	441	433	419	409	391	377	369	344	207	97	23	0
DVTd	543	535	526	520	517	511	503	496	490	482	476	467	451	439	426	423	391	243	114	23	0

Overall survival by treatment arms from 2nd randomization (ITT)



No. at risk

VTd+OBS	215	212	209	207	203	198	196	192	190	182	178	169	162	160	154	112	61	22	2	0	
VTd+D-maint	213	212	204	202	202	201	198	185	182	180	178	174	170	163	157	109	69	27	0	0	
DVTd+OBS	229	229	228	226	225	223	218	216	214	211	210	206	199	196	190	144	74	28	2	0	
DVTd+D-maint	229	228	228	228	224	223	222	220	215	214	211	207	193	191	185	141	71	26	3	0	

OS rates significantly improved with DVTd, reducing risk of death by 39% vs VTd

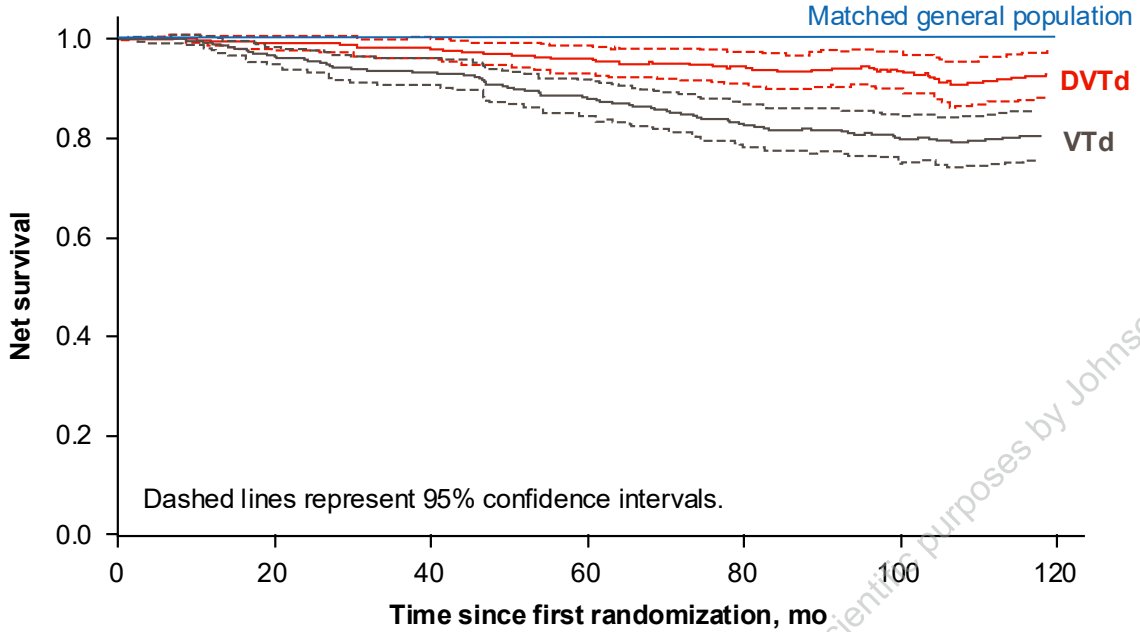
The overall survival benefit of DVTd appears to be maintained irrespective of second randomization assignment

DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; D-maint, daratumumab maintenance; HR, hazard ratio; ITT, intent to treat; OBS, observation; OS, overall survival; VTd, bortezomib, thalidomide, and dexamethasone.

Presented by J Corre at the 23rd International Myeloma Society (IMS) Annual Meeting; September 23–26, 2026; Glasgow, UK

CASSIOPEIA: Net Survival vs General Population

Pohar-Perme net survival relative to the matched general population[a] by treatment arm post-first randomization



Net survival at 96 months (~8 years) post-first randomization vs matched general population:

- DVTd only ~6% excess mortality beyond that expected in the general population
- DVTd: 94.3% (90.7–98.0) net survival
- VTd: 80.7% (76.4–85.2) net survival
- Excess hazard ratio in VTd vs DVTd: 2.40; 95% CI, 1.47–3.91; *P*<0.001

With DVTd induction/consolidation, patients approach general population mortality at 8 years – a hallmark of long-term disease control

[a]Life tables used to compute net survival were downloaded from the Human Mortality Database (www.mortality.org) for the French general population.
DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; VTd, bortezomib, thalidomide, and dexamethasone.

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CASSIOPEIA: Conclusions

After >8.5 years (81.3 months) median follow-up with 96% registry retention, CASSIOPEIA confirms deep and durable benefit of daratumumab-based treatment across induction/consolidation and maintenance settings

- DVTd improved long-term PFS versus VTd and daratumumab maintenance prolonged PFS and PFS2 versus observation
- Sustained MRD negativity was strongly associated with favorable long-term outcomes; loss of MRD negativity approximately doubled the risk of progression or death
- Patients maintaining MRD negativity for ≥5 years demonstrated exceptional durability, with **86.7%** remaining progression free 42 months after their last MRD-negative assessment
- Patients receiving DVTd achieved net survival approaching that of the matched general population

With >8.5 years of follow-up, CASSIOPEIA Registry represents the most mature and robust datasets in TE NDMM, demonstrating durable long-term benefits of daratumumab-based therapy

DVTd, daratumumab, bortezomib, thalidomide, and dexamethasone; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; PFS, progression-free survival; PFS2, progression-free survival on next line of therapy; TE, transplant eligible; VTd, bortezomib, thalidomide, and dexamethasone.

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https://www.congresshub.com/Oncology/IMS2026/Daratumumab/Corre

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