

# Highlights from IMS 20th meeting 2023

Giuseppe Mele

STATO DI FRAGILITA'  
E VULNERABILITA'

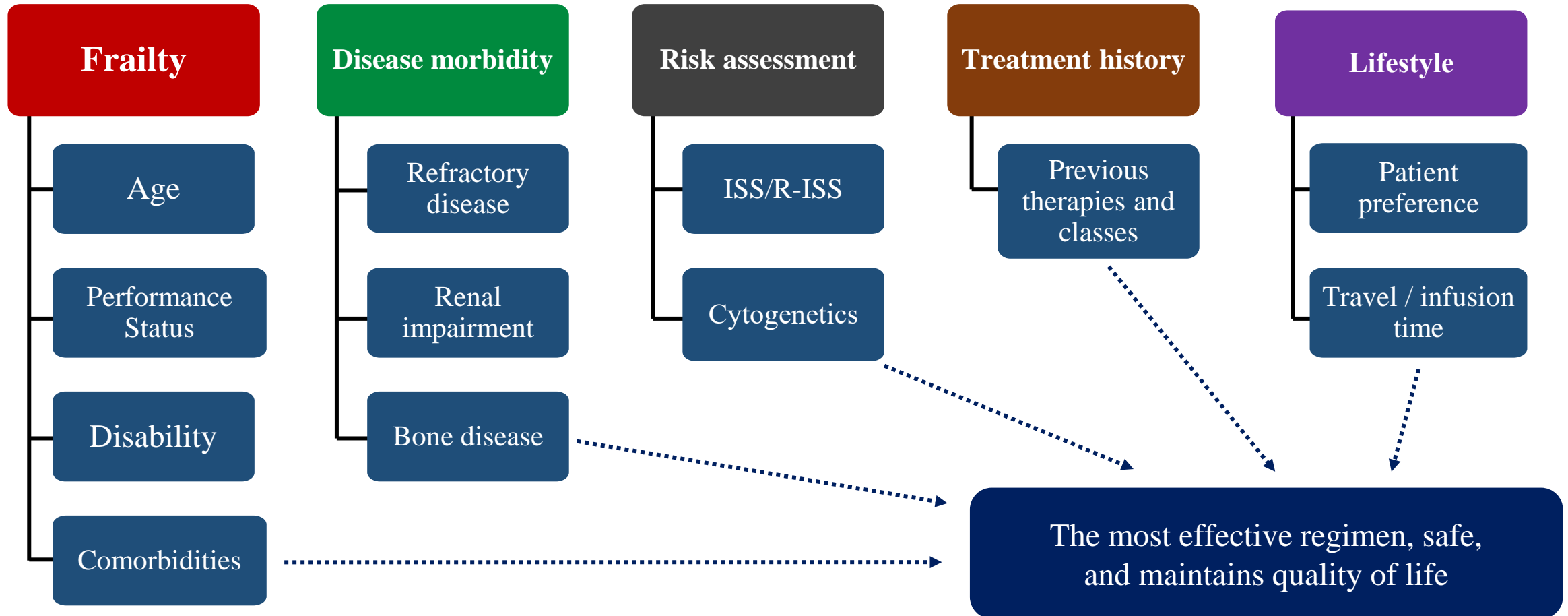
30-31 gennaio 2024

BOLOGNA, Royal Hotel Carlton

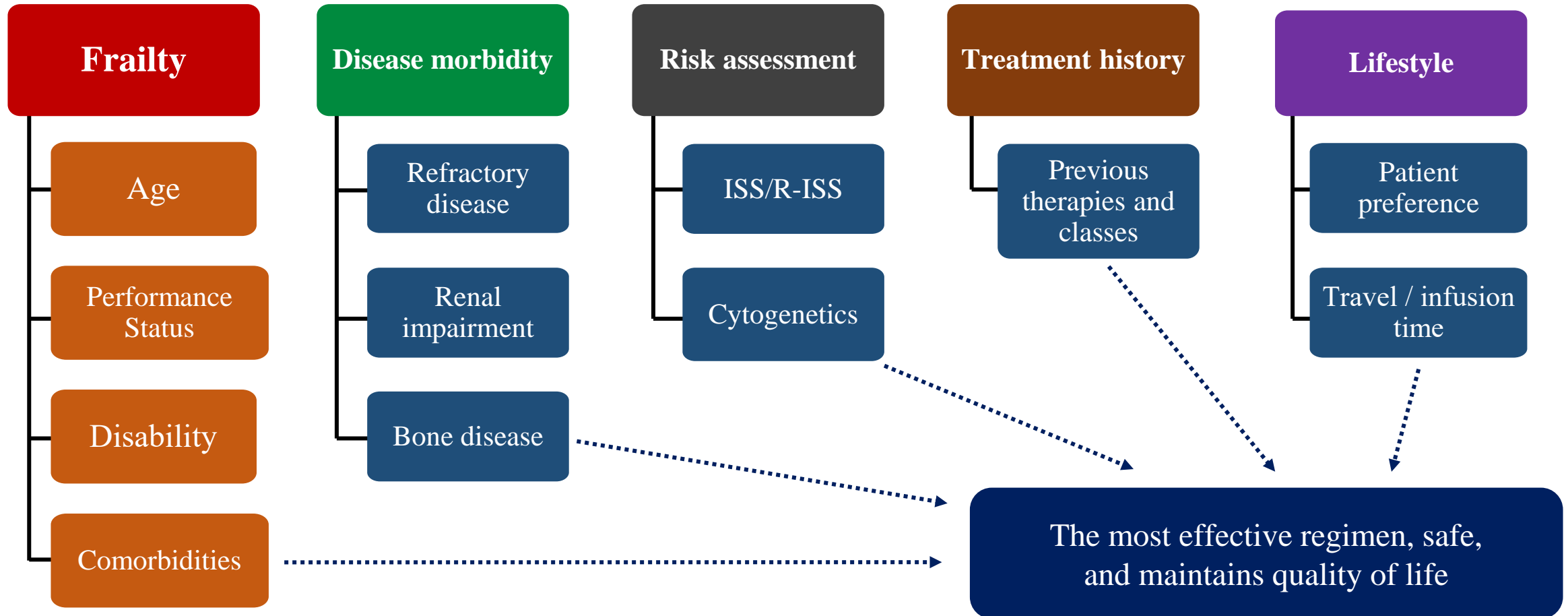
## DISCLOSURES

NO RELEVANT DISCLOSURES.

## Several factors influence treatment choices in multiple myeloma

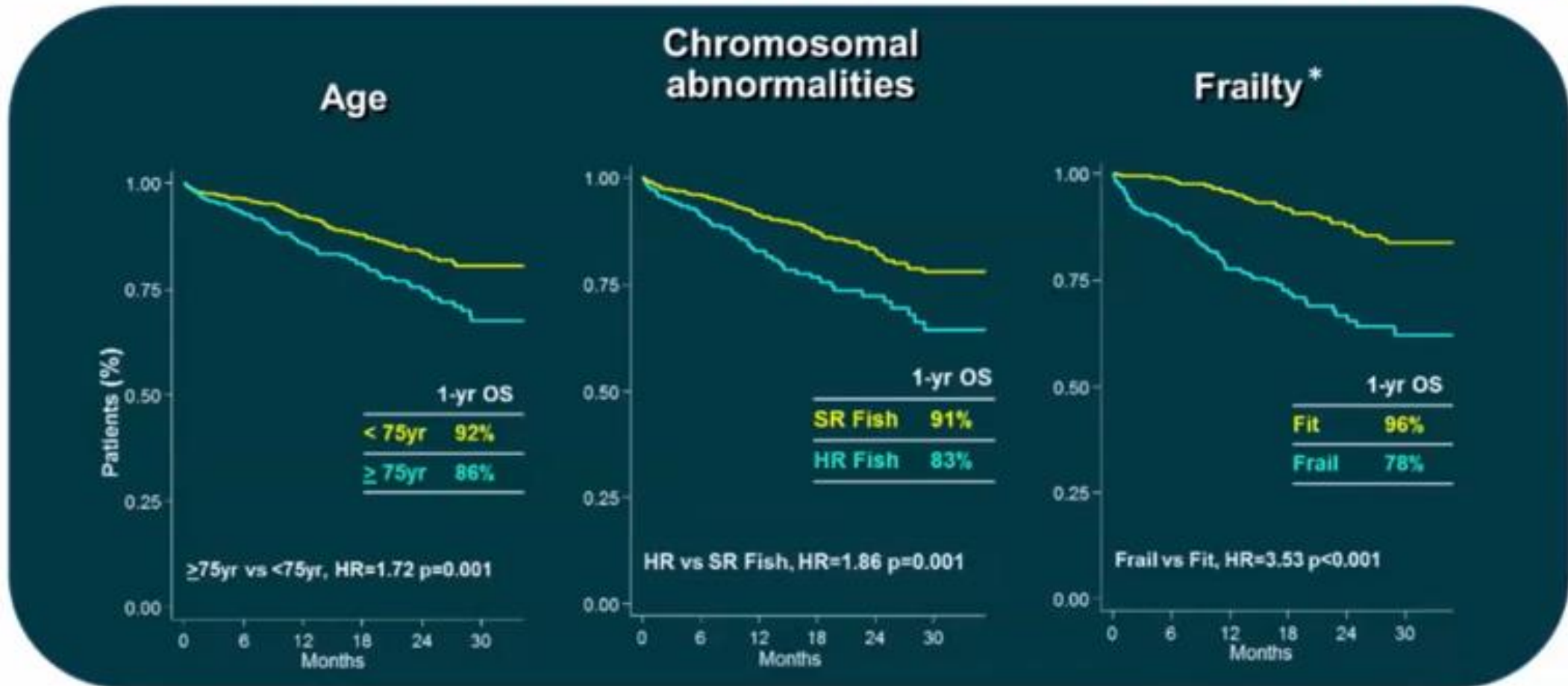


## Several factors influence treatment choices in multiple myeloma



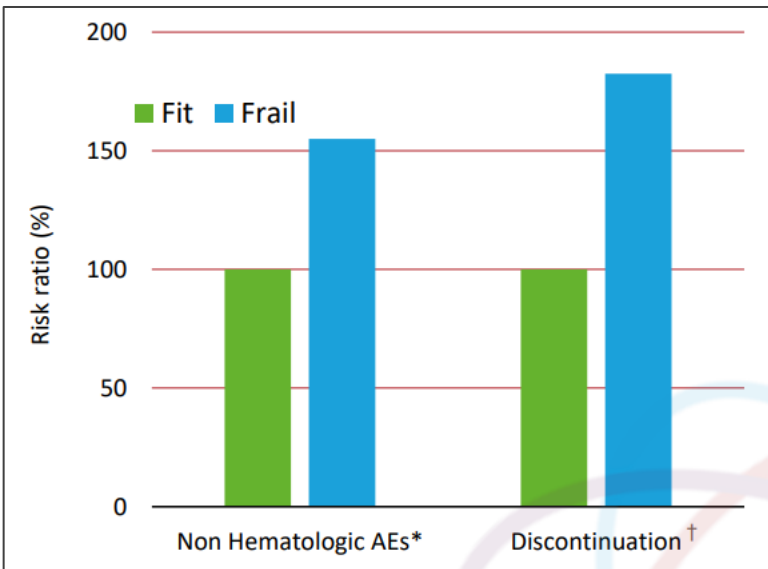
# FRAILITY IS THE MOST POWERFUL PREDICTOR OF OS

DATA FROM 869 PATIENTS FROM 3 EMN TRIALS TREATED WITH NOVEL AGENTS

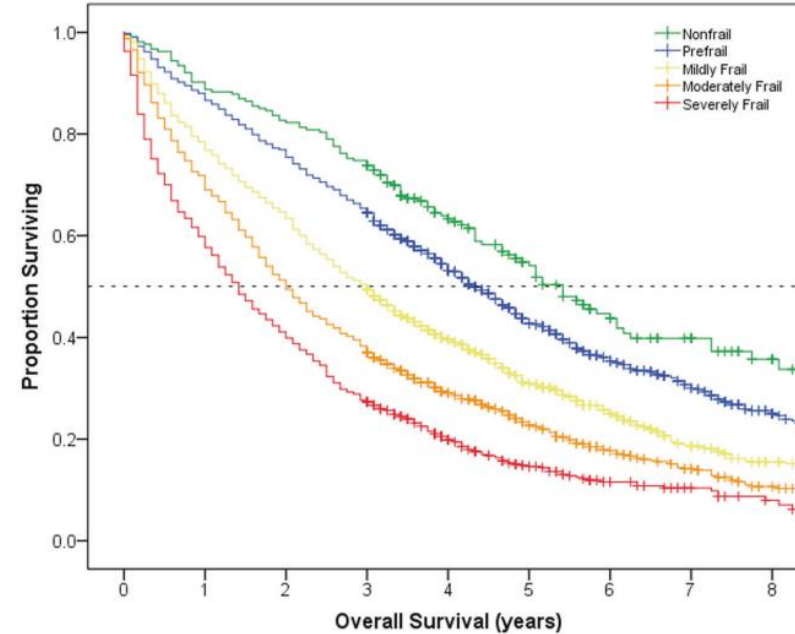


\* Frailty as defined by IMWG frailty index

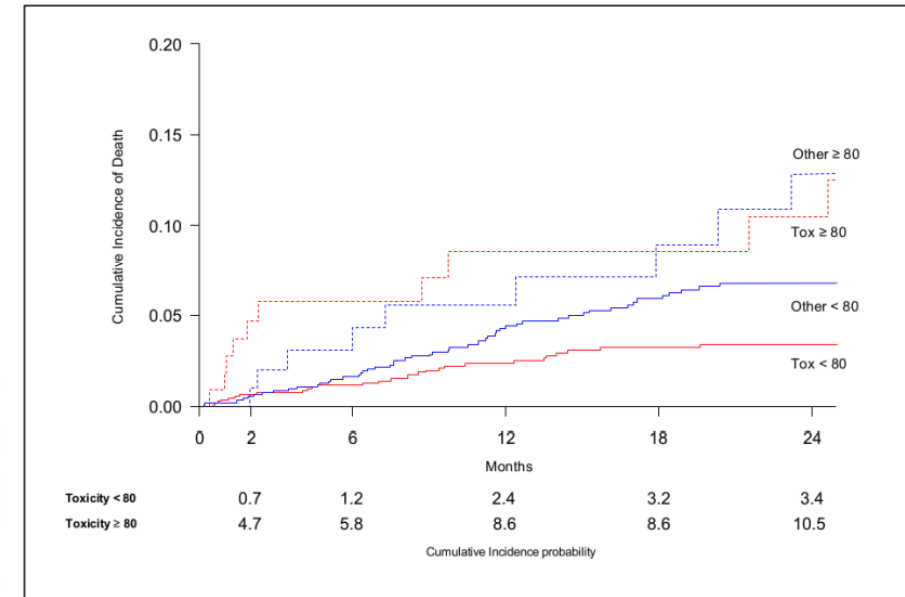
### Grade 3–5 AEs and discontinuation<sup>1</sup>



### Overall Survival<sup>2</sup>



### Toxic Deaths<sup>3</sup>



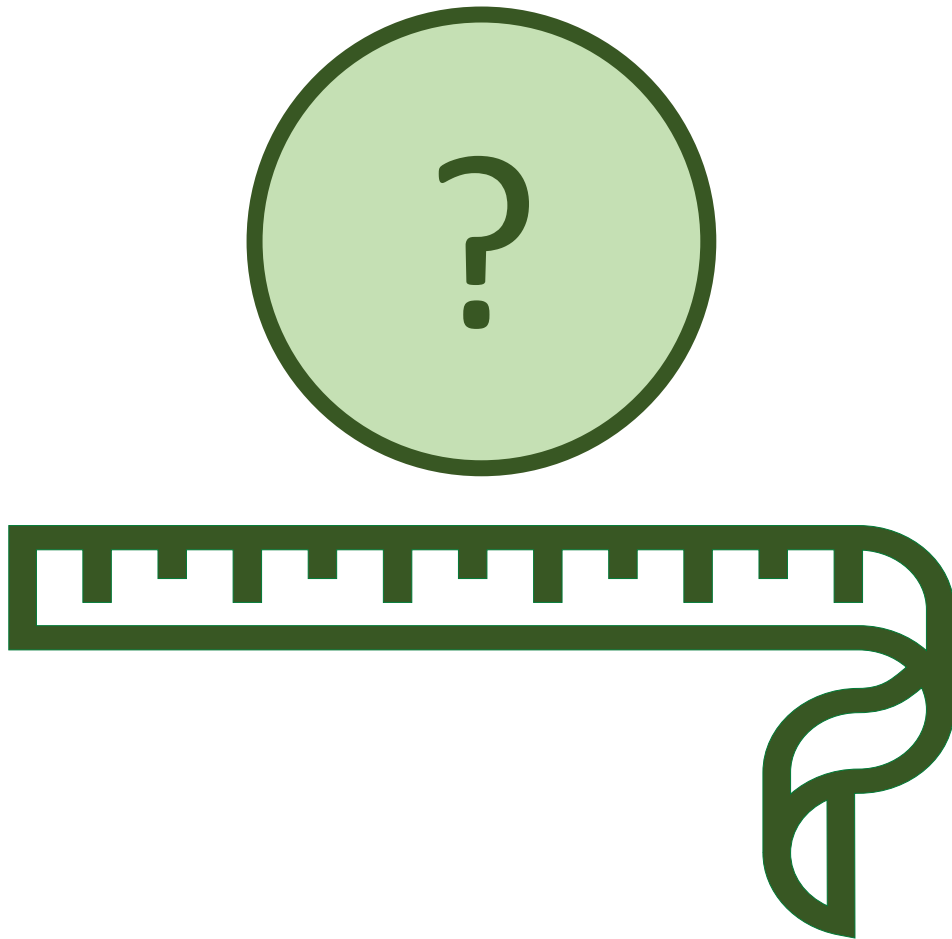
- Gli AEs di grado 3-5 prevalgono nei pazienti fragili<sup>1</sup>
- La fragilità impatta negativamente sulla sopravvivenza<sup>2</sup>
- La mortalità per tossicità e la mortalità per altre cause è rispettivamente 4 volte e 2 volte superiore nei pazienti  $\geq 80$  aa rispetto ai pazienti di età  $< 80$  aa<sup>3</sup>

1) Larocca A. et al; ASH 2013, Oral Presentation

2) Mian H. et al.; Blood Cancer Journal 2023

3) Bringham S. et al.; Crit Rev Oncol Hematol. 2018

When individualizing treatment, a number of questions should be considered



Qual è la migliore strategia di trattamento per il mio paziente in base alle condizioni cliniche?

E' possibile modificare il trattamento per garantire una durata ottimale?

In che modo posso tener conto del **FRAILTY SCORE** del mio paziente

In che modo il precedente trattamento, la risposta e le tossicità influiscono sulle decisioni terapeutiche in caso di recidiva?

Arnaldo Benini  
Patrizia Caraveo  
Gilberto Corbellini  
Paolo Legrenzi  
Vittorio Lingiardi  
Sebastiano Maffettone  
Giorgio Vallortigara

# Quello che ora sappiamo

Tutte le volte che la scienza  
ha cambiato idea

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# Dose/schedule-adjusted Rd-R vs continuous Rd for elderly, intermediate-fit patients with newly diagnosed multiple myeloma

Alessandra Larocca,<sup>1</sup> Francesca Bonello,<sup>1</sup> Gianluca Gaidano,<sup>2</sup> Mattia D'Agostino,<sup>1</sup> Massimo Offidani,<sup>3</sup> Nicola Cascavilla,<sup>4</sup> Andrea Capra,<sup>1</sup> Giulia Benevolo,<sup>5</sup> Patrizia Tosi,<sup>6</sup> Monica Galli,<sup>7</sup> Roberto Marasca,<sup>8</sup> Nicola Giuliani,<sup>9</sup> Annalisa Bernardini,<sup>1</sup> Elisabetta Antonioli,<sup>10</sup> Delia Rota-Scalabrini,<sup>11</sup> Claudia Cellini,<sup>12</sup> Alessandra Pompa,<sup>13</sup> Federico Monaco,<sup>14</sup> Francesca Patriarca,<sup>15</sup> Tommaso Caravita di Toritto,<sup>16</sup> Paolo Corradini,<sup>17</sup> Paola Tacchetti,<sup>18</sup> Mario Boccadoro,<sup>1</sup> and Sara Brinchen<sup>1</sup>

## KEY POINTS

- Dose/schedule-adjusted Rd-R prolonged EFS in elderly intermediate-fit patients with MM.
- Rd-R induced progression-free and overall survival similar to standard continuous Rd.

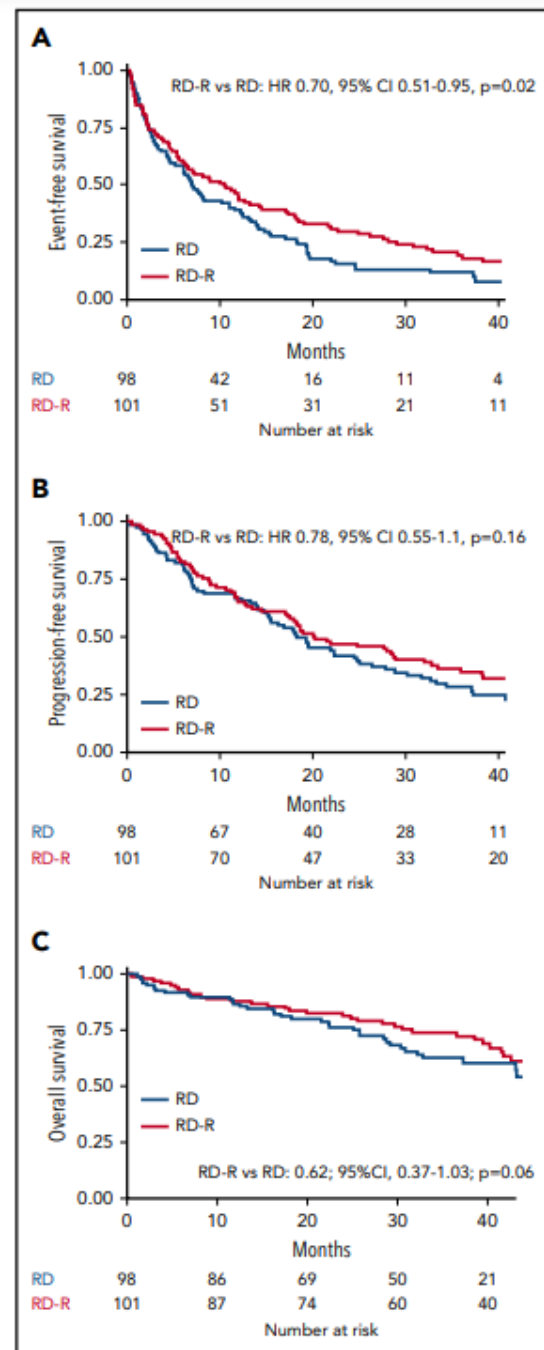
Lena  
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(21% vs 18%), infections (10% vs 12%), and peripheral nervous system AEs mainly related to dexamethasone AEs in 24% vs 30% and reduced incidence of switching to reduced-dose lenalidomide. *J Clin Oncol* 2021;39:137(22):3027-3036

## Discussion

This is the first randomized phase 3 trial comparing an adapted Rd-R treatment schedule sparing steroids and reducing lenalidomide dose at maintenance, with standard continuous Rd, in elderly intermediate-fit patients with NDMM ineligible for ASCT. After a median follow-up of 37 months, no difference in PFS or OS was observed between Rd-R and continuous Rd groups, whereas EFS (accounting for a combination of toxicity and efficacy) was significantly prolonged in the Rd-R arm. Furthermore, Rd-R resulted in better tolerability compared with Rd, particularly in terms of nonhematologic toxicity (grade  $\geq 3$ , 33% vs 43%) and lenalidomide dose reduction (45% vs 62%).

In multiple elderly patients with intermediate-fit, the use of dose/schedule-adjusted Rd-R was noninferior to standard continuous Rd. The use of dose/schedule-adjusted Rd-R was associated with a significantly lower rate of grade 3 to 4 nonhematologic toxicity (33% vs 43%) and a significantly higher rate of lenalidomide dose reduction (45% vs 62%).





Le nuove acquisizioni dal

# 20th IMS Annual Meeting 2023

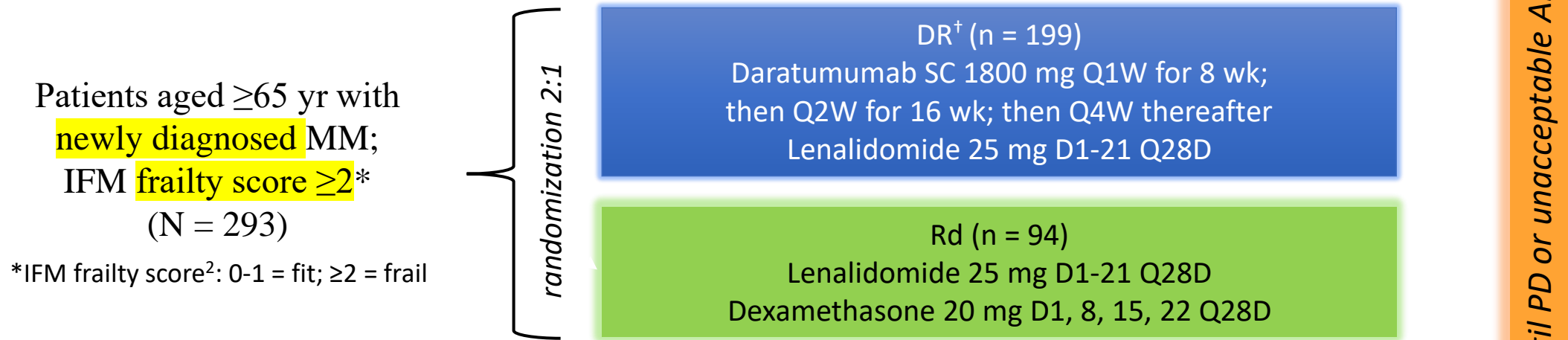
# IFM 2017-03: Phase III Trial of Daratumumab + Lenalidomide vs Lenalidomide + Dexamethasone in Frail Patients With Newly Diagnosed Multiple Myeloma

# Dexamethasone sparing regimen IFM 2017-03 trial (NCT03993912)

- Frailty is associated with increased risk of death, disease progression, higher rates of nonhematologic AEs, and treatment discontinuation in patients with MM
- DRd is a standard regimen for newly diagnosed transplant-ineligible patients with MM, but rates of pneumonia are higher with DRd vs Rd, particularly in frail patients<sup>3,4</sup>
- IFM 2017-03 is a phase III trial evaluating whether a Dexamethasone-sparing regimen of Dara+Lena would be effective and limit toxicity in frail patients compared with Lena+Dexamethasone
- Current interim analysis at 12 mo of therapy reported on response and safety<sup>5</sup>

# Dexamethasone sparing regimen IFM 2017-03 trial (NCT03993912)

- Randomized, open-label, multicenter phase III trial<sup>1</sup>  
*Stratification by ISS (I vs II vs III) and age (<80 vs ≥80 yr)*



- **Primary endpoint:** PFS
- **Interim analysis at 12 mo of therapy:** ORR, ≥ VGPR, MRD rate, grade ≥3 AEs

<sup>†</sup>DR included low-dose dexamethasone 20 mg/wk during cycles 1,2, along with SC daratumumab dosing

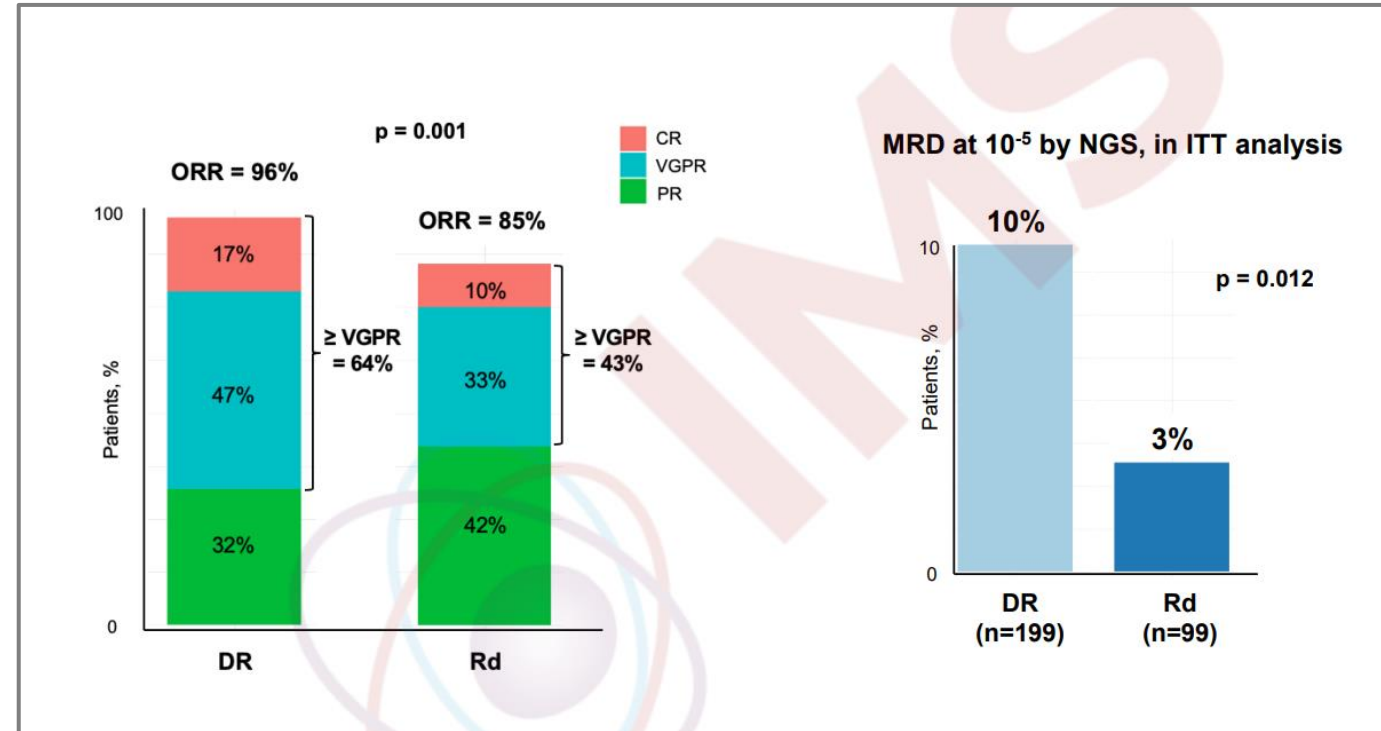
# Dexamethasone sparing regimen IFM 2017-03 trial (NCT03993912)

Characteristic	DR (n = 199)	Rd (n = 94)
Median age, yr (range)	81 (68-92)	81 (68-90)
Age category, n (%)		
▪ 65 to <70 yr	2 (1)	2 (2)
▪ 70 to <75 yr	30 (15)	13 (14)
▪ 75 to <80 yr	49 (25)	19 (20)
▪ ≥80 yr	118 (59)	61 (65)
Female, n (%)	101 (51)	48 (51)
ECOG PS 0/1/2, %	10/46/44	10/50/40
Charlson ≤1, n (%)	113 (58)	57 (61)
IFM frailty score, n (%)		
▪ ≤1	0	0
▪ 2	57 (29)	35 (37)
▪ 3	81 (41)	26 (28)
▪ 4	44 (22)	24 (26)
▪ 5	17 (9)	9 (10)

Characteristic	DR (n = 199)	Rd (n = 94)
ISS disease stage I/II/III, %	17/51/32	19/53/28
Measurable disease type, n (%)		
▪ IgG	113 (57)	49 (52)
▪ IgA	38 (19)	20 (21)
▪ PBJ only	21 (11)	10 (11)
▪ SFLC only	27 (14)	15 (16)
Cytogenetics profile,* n (%)		
▪ Standard risk	148 (83)	60 (78)
▪ High risk	31 (17)	17 (22)
▪ del17p	16 (9)	11 (14)
▪ t(4;14)	9 (5)	5 (6)
▪ t(14;16)	6 (3)	3 (3)
Creatinine clearance, n (%)		
▪ <30 mL/min	1 (1)	3 (3)
▪ 30 to <60 mL/min	119 (60)	50 (53)
▪ ≥60 mL/min	79 (40)	41 (44)

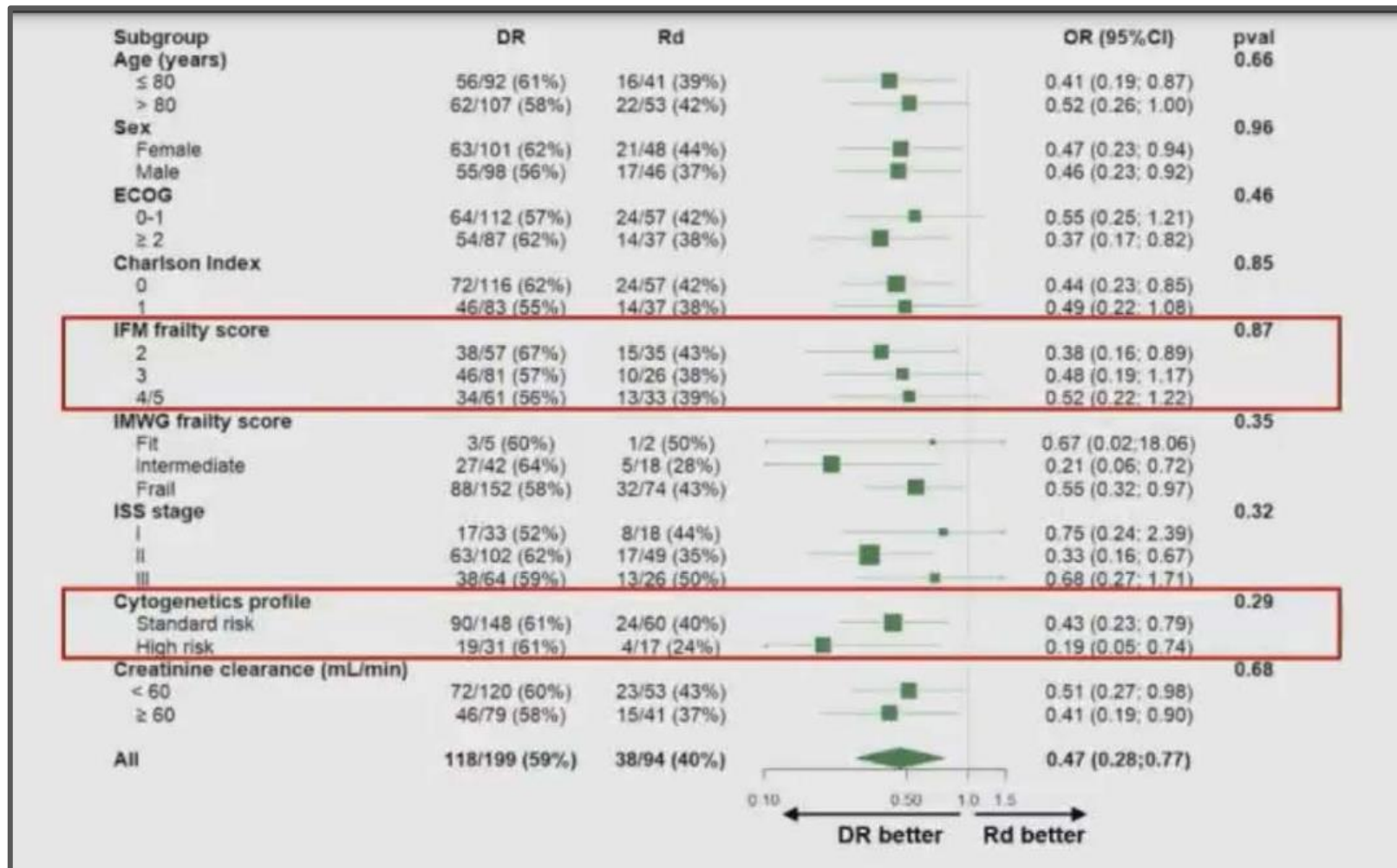
# Dexamethasone sparing regimen IFM 2017-03 trial = best response rate at 1 yr

Response	DR (n = 199)	Rd (n = 94)	P Value
<b>ORR, %</b>	<b>96</b>	85	.001
<ul style="list-style-type: none"> <li>■ CR</li> <li>■ VGPR</li> <li>■ PR</li> </ul>	17 47 32	10 33 42	
<b>≥ VGPR</b>	<b>64</b>	43	
<b>MRD</b> at 10 <sup>-5</sup> by NGS,* %	<b>10</b>	3	.012



Best overall response rate was significantly higher with DR

# Dexamethasone sparing regimen IFM 2017-03 trial = subgroup analysis of $\geq$ VGPR



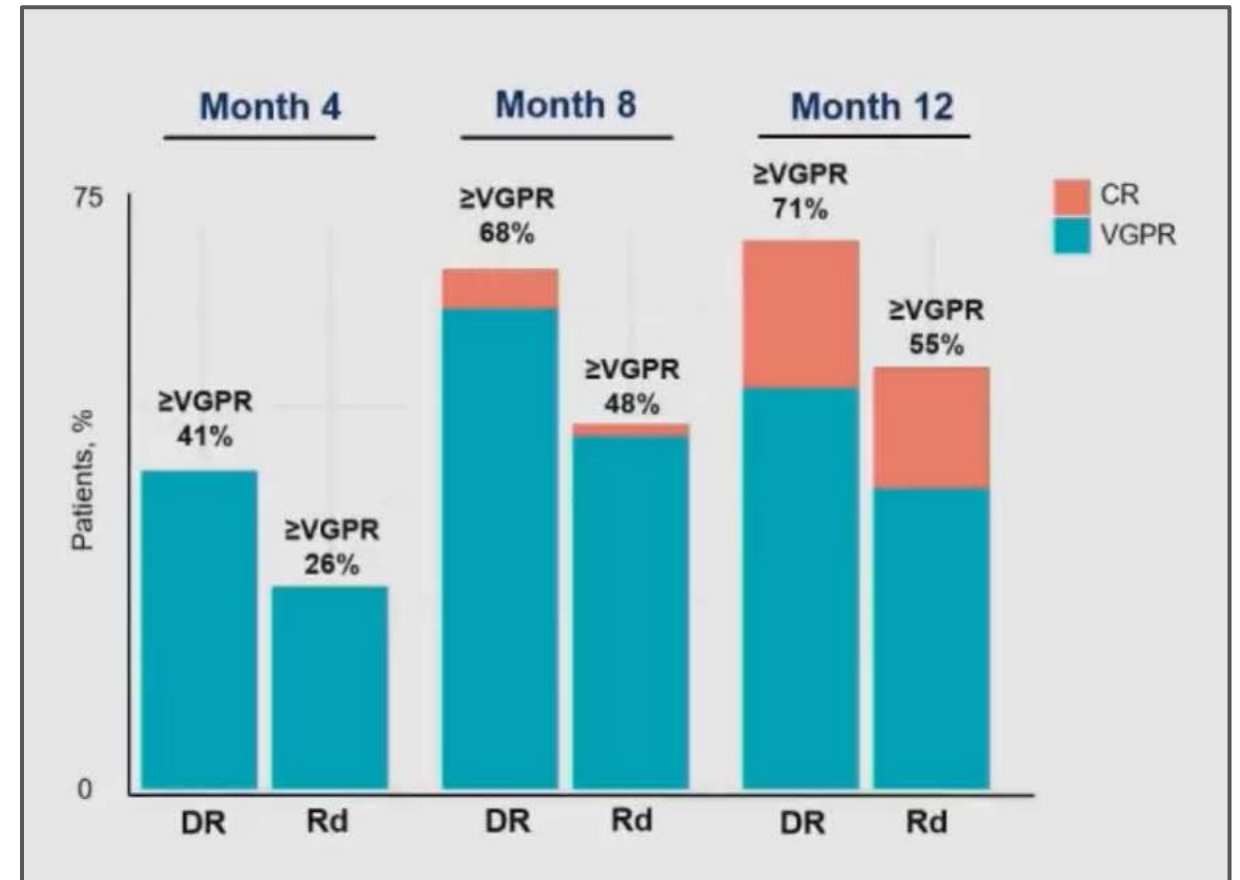
improvement in rate of  $\geq$  VGPR with DR  
 across all subgroups analyzed,  
 including IFM frailty score ( $P=.87$ )  
 and cytogenetic risk ( $p.29$ )



# Dexamethasone sparing regimen IFM 2017-03 trial = rate of $\geq$ VGPR over time

Rate of Response Over Time	% of patients with $\geq$ VGPR, %	
	DR (n = 199)	Rd (n = 94)
Mo 4	41	26
Mo 8	68	48
Mo 12	71	55

Deeper responses were obtained with DR at all time points, including at early time points



## Dexamethasone sparing regimen IFM 2017-03 trial = most common grade $\geq 3$ AEs

Most Common Grade $\geq 3$ AEs	DR (n = 199)	Rd (n = 94)	P Value
Any grade $\geq 3$ AE, n (%)	164 (82)	64 (68)	0.010
SAE, n (%)	109 (55)	59 (63)	0.21
Grade $\geq 3$ hematologic AEs, n (%)	109 (55)	24 (26)	<0.0001
▪ Anemia	21 (11)	2 (2)	0.010
▪ Neutropenia	91 (46)	17 (18)	<b>&lt;0.0001</b>
▪ Thrombocytopenia	18 (9)	3 (3)	0.089
Grade $\geq 3$ infection, n (%)	26 (13)	17 (18)	0.29
▪ Non-COVID-19 infections	17 (9)	13 (14)	0.21
▪ Pneumonia	5 (3)	7 (7)	0.060
▪ COVID-19	9 (5)	4 (4)	1
Treatment discontinuation for AE, n (%)	27 (14)	15 (16)	0.65

### DR vs Rd

- profilo di tossicità favorevole
- non si associa ad incremento del rischio di infezioni o polmoniti
- “treatment discontinuation rates” simile fra i gruppi

# Dexamethasone sparing regimen IFM 2017-03 trial = Infections

Most Common Grade $\geq 3$ AEs	IFM Frailty Score 2 + 3 (n = 199)			IFM Frailty Score 4 + 5 (n = 94)		
	DR (n = 138)	Rd (n = 61)	P Value	DR (n = 61)	Rd (n = 33)	P Value
SAE, n (%)	74 (54)	35 (57)	0.65	35 (57)	24 (73)	0.18
Infection, n (%)	13 (9)	8 (13)	0.46	13 (21)	9 (27)	0.61
▪ Non-COVID-19 infections	10 (7)	6 (10)	0.58	7 (11)	7 (21)	0.23
▪ Pneumonia	2 (1)	3 (5)	0.17	3 (5)	4 (12)	0.24
▪ COVID-19	3 (2)	2 (3)	0.64	6 (10)	2 (6)	0.71

## Sottogruppi di Fragilità

- DR vs Rd non si associa ad incremento del rischio di infezioni o polmoniti

## In phase III IFM 2017-03 trial assessing frail patients with NDMM

- DR was associated with higher response rates vs Rd
  - ORR: 96% with DR vs 85% with Rd
  - Higher MRD negativity rates (10% vs 3%, respectively) and rapid responses
- DR associated with favorable safety profile and
  - no increased risk of infection or pneumonia vs Rd
  - Treatment discontinuation rates were similar between arms
- Investigators concluded that results of this trial are encouraging regarding potential for dexamethasone-sparing strategy in frail patients, but longer follow-up is needed, and PFS analysis is ongoing

Arnaldo Benini  
Patrizia Caraveo  
Gilberto Corbellini  
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# Quello che ora sappiamo

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ha cambiato idea

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REVIEW ARTICLE

Multiple myeloma gammopathies



## Patient-centered practice in elderly myeloma patients: an overview and consensus from the European Myeloma Network (EMN)

Alessandra Larocca<sup>1</sup> · Sandra Maria Dold<sup>2</sup> · Sonja Zweegman<sup>3</sup> · Evangelos Terpos<sup>4</sup> · Ralph Wäsch<sup>1b,2</sup> · Mattia D'Agostino<sup>1</sup> · Sophia Scheubeck<sup>2</sup> · Hartmut Goldschmidt<sup>5</sup> · Francesca Gay<sup>1</sup> · Michele Cavo<sup>6</sup> · Heinz Ludwig<sup>7</sup> · Christian Straka<sup>8</sup> · Sara Bringhen<sup>1</sup> · Holger W. Auner<sup>1b,9</sup> · Jo Caers<sup>10</sup> · Martin Gramatzki<sup>11</sup> · Massimo Offidani<sup>12</sup> · Meletios A. Dimopoulos<sup>4</sup> · Hermann Einsele<sup>13</sup> · Mario Boccadoro<sup>1</sup> · Pieter Sonneveld<sup>14</sup> · Monika Engelhardt<sup>2</sup>

### GOAL OF TREATMENT

#### FIT

Efficacy: deep response

#### INTERMEDIATE

Balance efficacy and toxicity

#### FRAIL

Conservative approach, low toxicity

### TREATMENT

#### Full-dose therapy

ASCT  
TRIPLET REGIMENS  
VMP  
VRD  
DOUBLET REGIMENS  
Rd

#### Full- or reduced-dose therapy

DOUBLET REGIMENS  
Rd  
Vd  
Reduced-dose triplet

#### Reduced dose therapy

REDUCED-DOSE  
DOUBLET REGIMENS  
rd  
Vd  
Palliative + supportive care

	<b>FIT</b>	<b>INTERMEDIATE</b>	<b>FRAIL</b>
<b>IMWG-FRAILITY INDEX<sup>a</sup></b>	<b>0</b>	<b>1</b>	<b>≥ 2</b>
<b>R-MCI<sup>b</sup></b>	<b>1-3</b>	<b>4-6</b>	<b>7-9</b>
<b>DOSE LEVEL</b>	<b>0</b>	<b>-1</b>	<b>-2</b>
<b>Treatment doses</b>	<b>LEVEL 0</b>	<b>LEVEL -1</b>	<b>LEVEL -2</b>
<b>Prednisone</b>	2 mg/kg days 1-4 of a 4-6 week cycle 60 mg/m <sup>2</sup> days 1-4 of a 6 week cycle	1 mg/kg days 1-4 of a 4-6 week cycle 30 mg/m <sup>2</sup> days 1-4 of a 6 week cycle	0.5 mg/kg days 1-4 of a 4-6 week cycle 15 mg/m <sup>2</sup> days 1-4 of a 6 week cycle
<b>Dexamethasone</b>	40 mg day 1, 8, 15, 22 of a 28-day cycle	20 mg day 1, 8, 15, 22 of a 28-day cycle	10 mg day 1, 8, 15, 22 of a 28-day cycle
<b>Melphalan</b>	0.25 mg/kg days 1-4 of a 4-6 week cycle	0.18 mg/kg days 1-4 of a 4-6 week cycle	0.13 mg/kg days 1-4 of a 4-6 week cycle
<b>Thalidomide</b>	100 (- 200) mg/day	50 (- 100) mg/day	50 mg qod (- 50 mg/day)
<b>Lenalidomide</b>	25 mg days 1-21 of a 28-day cycle	15 mg days 1-21 of a 28-day cycle	10 mg days 1-21 of a 28-day cycle
<b>Pomalidomide*</b>	4 mg days 1-21 of a 28-day cycle	3 mg days 1-21 of a 28-day cycle	2 mg days 1-21 of a 28-day cycle
<b>Bortezomib</b>	1.3 mg/m <sup>2</sup> twice weekly Day 1,4,8,11 every 3 weeks	1.3 mg/m <sup>2</sup> once weekly Day 1, 8, 15, 22 every 5 weeks	1.0 mg/m <sup>2</sup> once weekly Day 1, 8, 15, 22 every 5 weeks
<b>Carfilzomib<sup>o*</sup></b>	20 mg/m <sup>2</sup> d 1, 2, 8, 9, 15, 16 cycle 1, 27 mg/m <sup>2</sup> cycle 2 every 4 weeks	20 mg/m <sup>2</sup> cycle1 -> 27 mg/m <sup>2</sup> cy2, d 1, 8, 15, once weekly every 4 weeks	20 mg/m <sup>2</sup> d 1, 8, 15, once weekly every 4 (5) weeks
<b>Ixazomib*</b>	4 mg d 1,8,15, every 4 weeks	3 mg d 1,8,15, every 4 weeks	2.3 mg d1,8,15, every 4 weeks
<b>Daratumumab*</b>	16 mg/kg bw cy 1-8: weekly; cy9-24: d1 + 15; week 25 onwards: every 4 weeks	16 mg/kg bw cy 1-8:weekly; cy9-24: d1 + 15, week 25 onwards: every 4 weeks Consider splitting the dose on 2 consecutive days in the first cycle.	16 mg/kg bw cy 1-8:weekly; cy9-24: d1 + 15, week 25 onwards: every 4 weeks Consider splitting the dose on 2 consecutive days in the first cycle.
<b>Elotuzumab*</b>	10 mg/kg bw d 1,8,15,22, cy 1 + 2, cy 3: d 1 + 15	10 mg/kg bw d 1,8,15,22, cy 1 + 2, cy3: d 1 + 15	10 mg/kg bw d1,8,15,22 cy 1 + 2, cy 3: d1 + 15
<b>Panobinostat*</b>	20 mg d1,3,5,8,10,12 every 4 weeks	15 mg d1,3,5,8,10,12 every 4 weeks	10 mg d1,3,5,8,10,12 every 5 weeks



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# Frailty and initial treatment intensity in patients newly diagnosed with multiple myeloma (MM)

Clark DuMontier, Jennifer La, John Bihn, June Corrigan, Cenk Yildirim, Mayuri Dharne, Hamza Hassan, Sarvari Yellapragada, Gregory A. Abel, J Michael Gaziano, Nhan V. Do, Mary Brophy, Dae H. Kim Sc.D, Nikhil C. Munshi, Nathanael R Fillmore, Jane A. Driver

\***Dana-Farber** Cancer Institute

# VRd vs Rd = Background and Objective

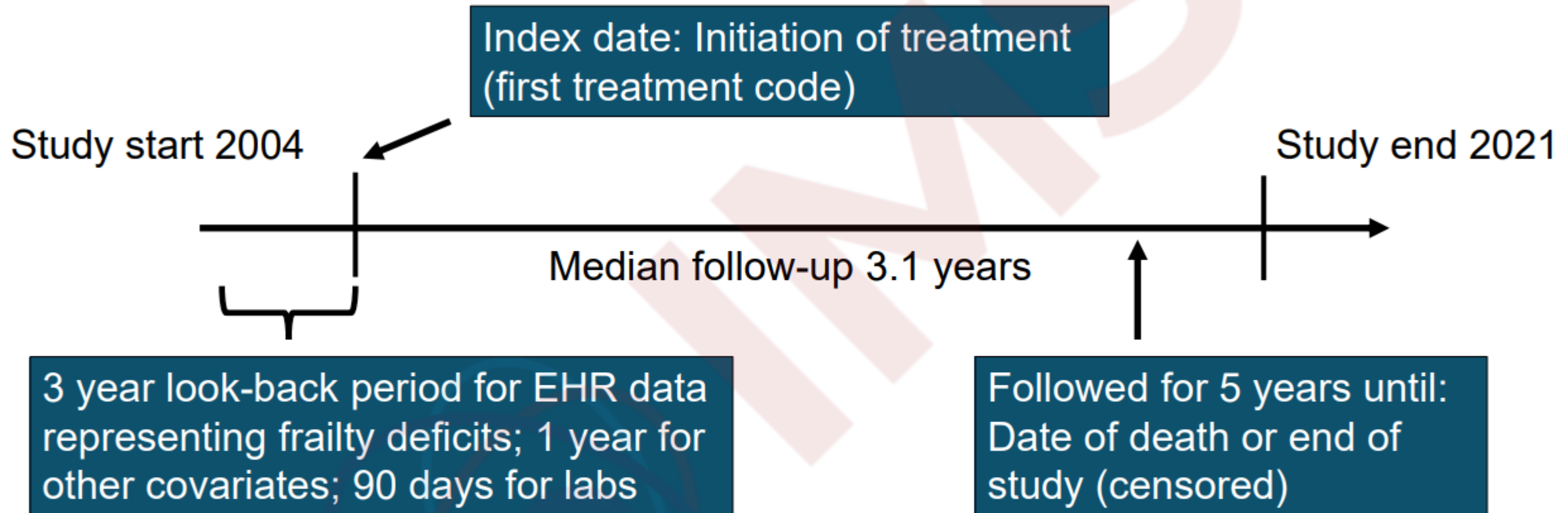
## Background

- Randomized trials suggest that initiation of the more intensive triplet VRd vs the less intensive doublet Rd in patients NDMM confers superior survival, but it is uncertain whether this survival benefit generalizes to frail patients
- Frailty = higher risk of adverse outcome on standard treatment
- SWOG S077 showed VRd vs Rd = mortality benefit
  - Only 14% of patients had ECOG >1
- 2-drugs vs 3-drugs regimens in frail patients with NDMM
  - Effective control vs treatment tolerability

## Objective =

- mortality benefit in U.S. Veterans with NDMM
- whether benefit diminished in those with high levels of frailty

# Methods: Study Schematic



1. Matched patients on MM stage and propensity score (1:1) within frailty cat.
2. Association of VRd vs. Rd with mortality, overall and by frailty

# RESULTS = balance in key covariates (n=2573)

	Rd after matching n = 788	VRd after matching n = 788	SMD after match
Age, median	68.3	69.7	0.04
Race/Ethnicity, n(%)			0.03
Nonhispanic	469 (59.5)	467 (59.3)	
Black	215 (27.3)	223 (28.3)	
Hispanic	42 (5.3)	42 (5.3)	
Other	62 (7.9)	56 (7.1)	
Frailty, n (%)			<0.01
Nonfrail (VA-FI >0.3)	389 (49.4)	389 (49.4)	
Mild frailty (VA-FI >0.3)	226 (28.7)	226 (28.7)	
Moderate-severe frailty (VA-FI >0.3)	173 (22.0)	173 (22.0)	

	Rd after matching n = 788	VRd after matching n = 788	SMD after match
Myeloma stage, n(%)			<0.01
Stage 1	76 (9.6)	76 (9.6)	
Stage 2	200 (25.4)	200 (25.4)	
Stage 3	318 (40.4)	318 (40.4)	
Missing	194 (24.6)	194 (24.6)	
Pretreatment Labs, median			
Creatinine (mg/dL)	1.2	1.2	0.03
Calcium (mg/dL)	9.2	9.2	0.02
Hgb (gr/dL)	11.0	11.0	0.01
Platelets (n per mL)	203.0	203.0	0.03

SMD (standardized mean difference) < 0.1 suggests adequate balance

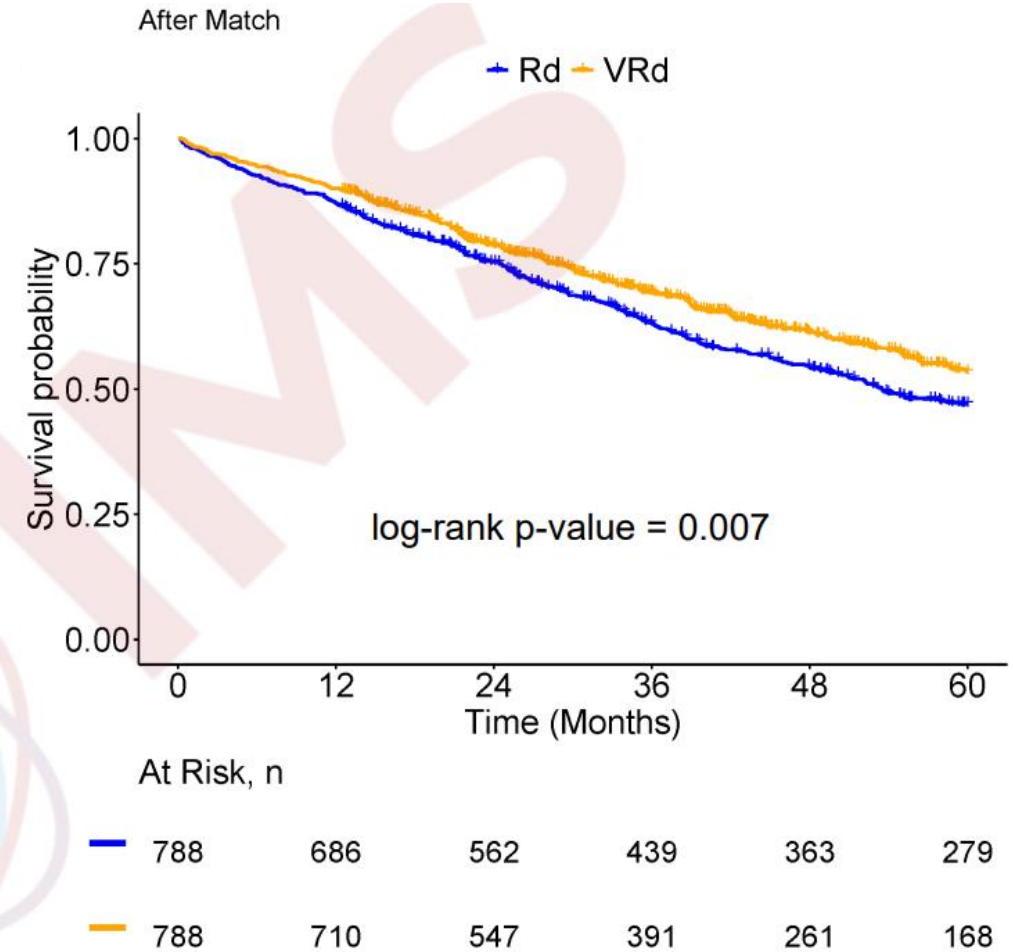
# RESULTS = mortality for combined overall population

nella popolazione globale

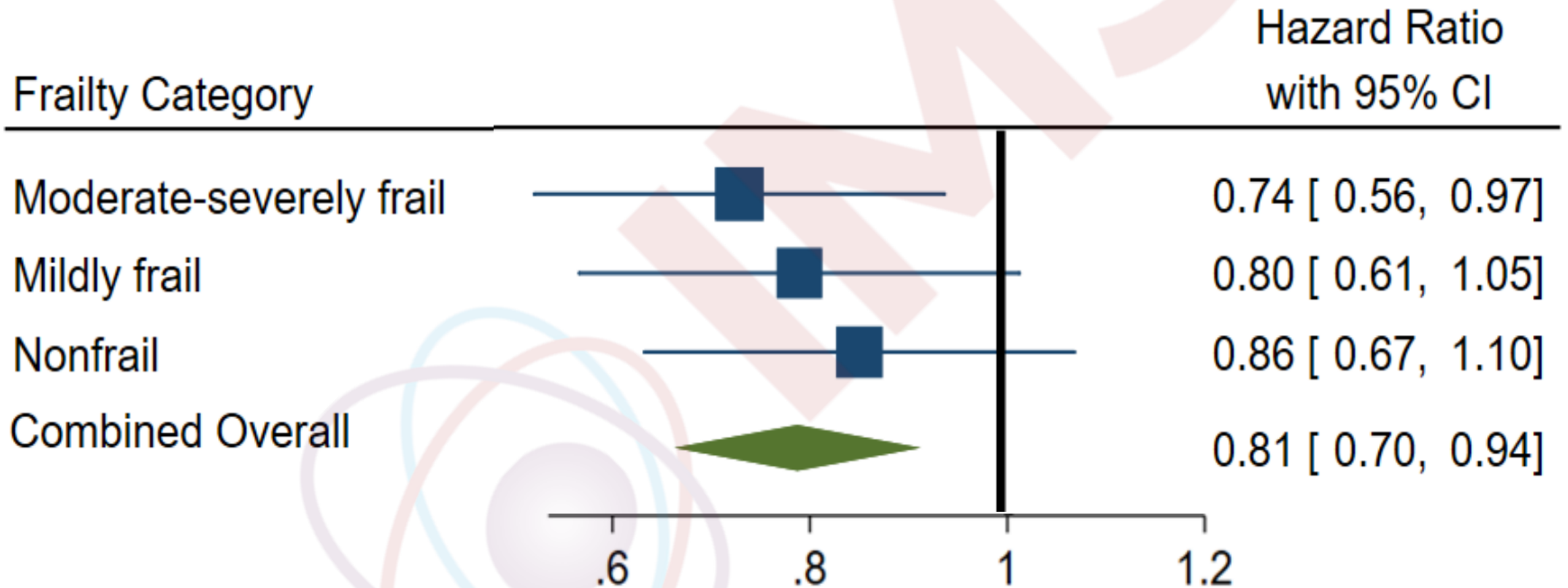
VRd vs Rd

è associato a una mortalità inferiore

**VRd vs. Rd HR = 0.81  
(95% CI = 0.70 - 0.94)**



# Results: VRd vs. Rd and mortality by frailty



# RESULTS = as frailty increased, prevalence of MM-related frailty deficits increased

Stage and MM-related frailty deficits n.(%)	Non Frail (VA-FI <0.2) n = 788	Moderate-severe frailty (VA-FI ≥0.3) n = 346
• Stage 3 MM	152 (19.5)	114 (32.9)
• Anemia	367 (47.2)	294 (85.0)
• Kidney failure	87 (11.2)	162 (46.8)
• Bone disease or pathological fracture	36 (4.6)	64 (18.5)

Conclusions = Our findings not only confirm the mortality benefit of VRd over Rd in U.S. veterans newly diagnosed with MM, but also suggest that this benefit is strongest in patients with the highest levels of frailty, countering historical recommendations to consider doublets in this population. These findings argue that a frail patient's cancer should be considered as a treatable cause of their frailty wherein more intensive treatment may be more effective.

# Isatuximab Plus Pomalidomide and Dexamethasone in Patients With Relapsed and/or Refractory Multiple Myeloma in Real-Life Context in France: IMAGE Subgroup Analysis Based on Subgroups of Interest

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# Introduction (1/8)

- Prior to Isa regulatory approval, Isa was available in France under 2 early access programs (EAPs) – compassionate early access and early-access authorization
  - In compassionate early access, Isa in combination with pomalidomide and dexamethasone (Isa-Pd) was given to participants with relapsed/refractory multiple myeloma (RRMM) after  $\geq 2$  prior lines of treatment (LOT)
  - In early-access authorization, Isa-Pd was given to participants with RRMM after  $\geq 2$  prior therapies
- IMAGE was a non-interventional, retrospective cohort study of participants with RRMM enrolled in EAPs for Isa-Pd in France
  - The median progression-free survival (PFS) in the overall effectiveness population has been previously reported at 12.4 months after a median follow-up of 14.2 months
- There are several high-risk characteristics that are associated with poor treatment outcome and shorter survival in multiple myeloma (MM) participants, such as advanced age, renal impairment, and high-risk cytogenetics
- Here, we report the results from the subgroup analyses of IMAGE based on subgroups of interest – **elderly (aged  $\geq 75$  years)**, **severe renal impairment ( $< 30$  mL/min/1.73 m<sup>2</sup>)** and high-risk cytogenetics (presence of del[17p], t[4;14], and t[14;16])

# Introduction (2/8)

- The total effectiveness population consisted of 294 participants, and the safety population of 299 participants
- 83 (28.2%) participants were aged  $\geq 75$  years, 25 (8.5%) participants had severe renal impairment ( $< 30$  mL/min/1.73 m<sup>2</sup>), and 40 (13.6%) participants had high-risk cytogenetics. Of note, 120 (40.8%) participants had unknown cytogenetic risk
- Roughly one third of participants across all subgroups had International Staging System Stage III disease – 30.1%, 44.0%, and 37.5% in elderly participants, severe renal impairment, and high-risk cytogenetics, respectively
- All subgroups had a median of 2 prior LOT, apart from participants with severe renal impairment, who had a median of 3 prior lines of therapy
- Similar to the overall effectiveness population, around 70% of participants in all subgroups were refractory to lenalidomide and to their last line of therapy
- A higher percentage of daratumumab-refractory participants was observed in participants with severe renal impairment (36.0%) and high-risk cytogenetics (32.5%) compared with the overall effectiveness population (19.1%) and the elderly subgroup (13.2%)

# Baseline Characteristics (3/8)

**Table 1.** Participant baseline characteristics in the overall effectiveness population and elderly, severe renal impairment, and high-risk cytogenetics subgroups (1/2)

	Effectiveness population (N=294)	Elderly (aged ≥75 years; n=83)	Severe Renal Impairment (eGFR <30 mL/min/1.73 m <sup>2</sup> ; n=25)	High-risk cytogenetics (n=40)
Median age, years (min–max)	70.2 (39.9–89.8)	79.1 (75.1–89.8)	69.9 (39.9–85.5)	67.8 (49.2–84.9)
ISS Stage, n (%)				
Stage I	46 (15.6)	7 (8.4)	3 (12.0)	6 (15.0)
Stage II	41 (13.9)	11 (13.3)	2 (8.0)	4 (10.0)
Stage III	107 (36.4)	25 (30.1)	11 (44.0)	15 (37.5)
Unknown/missing	100 (34.0)	40 (48.2)	9 (36.0)	15 (37.5)
ECOG PS, n (%)				
0	45 (15.3)	13 (15.7)	4 (16.0)	10 (25.0)
1	51 (17.3)	18 (21.7)	5 (20.0)	5 (12.5)
2	28 (9.5)	9 (10.8)	0	4 (10.0)
≥3	16 (5.4)	5 (6.0)	1 (4.0)	1 (2.5)
Missing	154 (52.4)	38 (45.8)	15 (60.0)	20 (50.0)

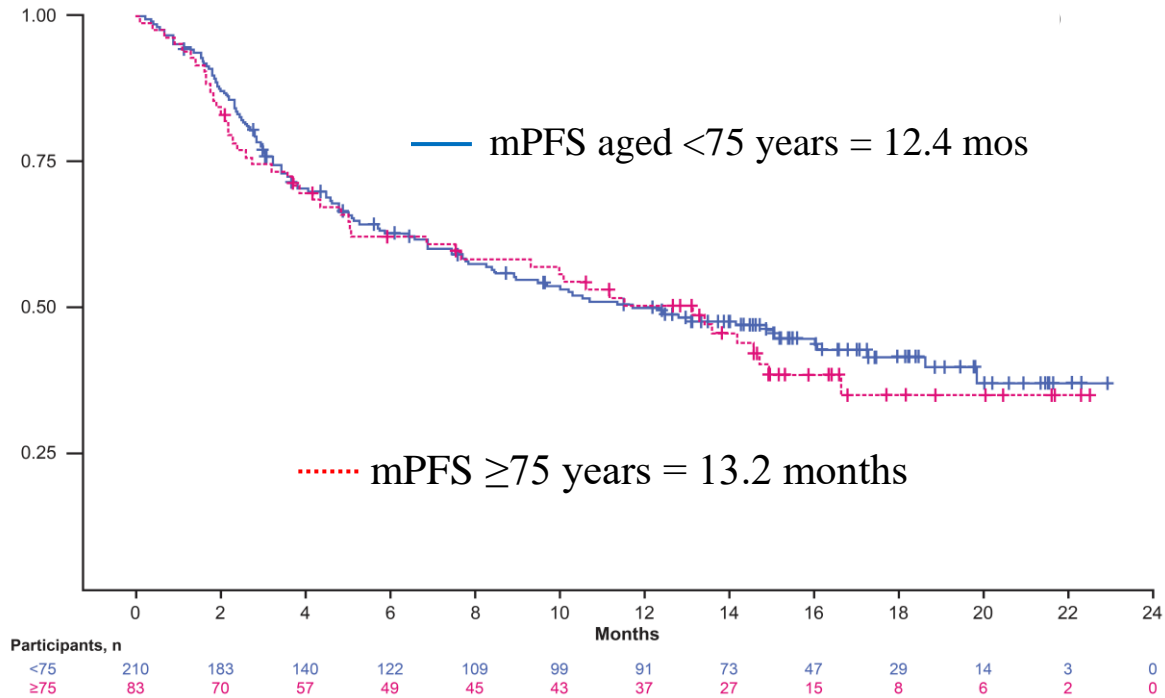
# Baseline Characteristics (4/8)

**Table 1.** Participant baseline characteristics in the overall effectiveness population and elderly, severe renal impairment, and high-risk cytogenetics subgroups (2/2)

	Effectiveness population (N=294)	Elderly (aged ≥75 years; n=83)	Severe renal impairment (eGFR <30 mL/min/1.73 m <sup>2</sup> ; n=25)	High-risk cytogenetics (n=40)
Prior lines of therapy, n (%)				
Median (min-max)	2.00 (1–9)	2.00 (1–9)	3.00 (1–7)	2.00 (1–8)
1	30 (10.2)	6 (7.2)	1 (4.0)	3 (7.5)
2	144 (49.0)	44 (53.0)	11 (44.0)	21 (52.5)
≥3	120 (40.8)	33 (39.8)	13 (52.0)	16 (40.0)
Refractory status, n (%)				
Lenalidomide	215 (73.1)	64 (77.1)	18 (72.0)	32 (80.0)
Daratumumab	56 (19.1)	11 (13.3)	9 (36.0)	13 (32.5)
Last line of therapy	207 (70.4)	59 (71.1)	17 (68.0)	29 (72.5)

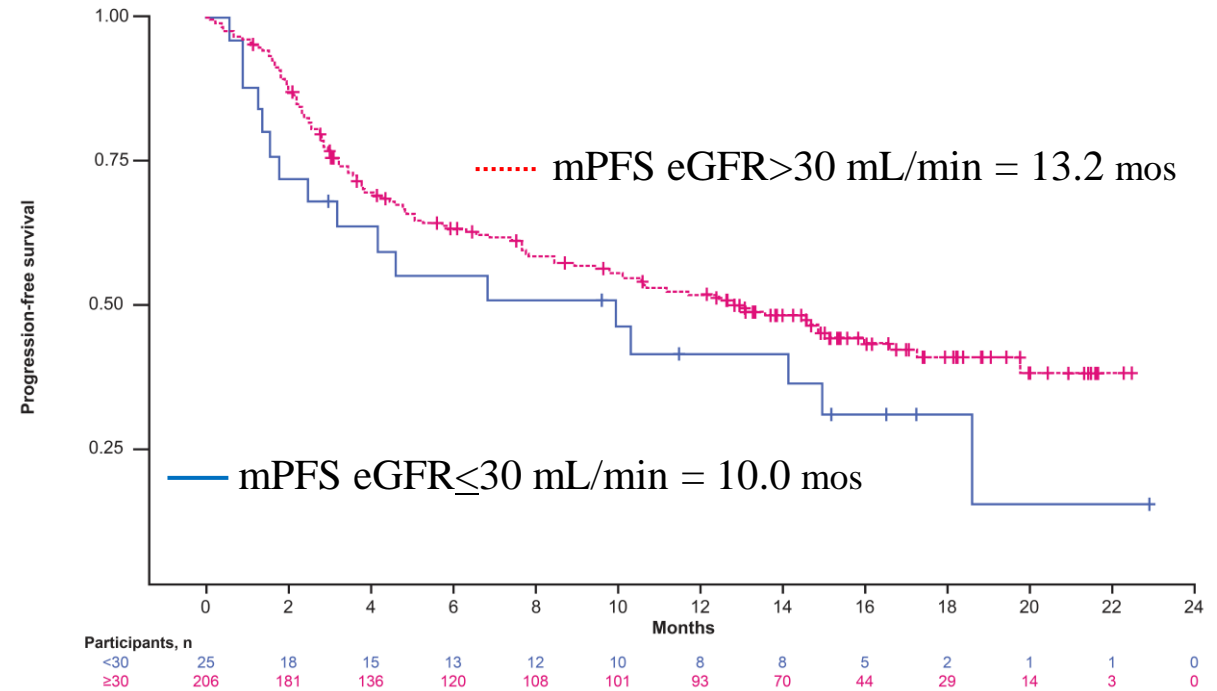
# Results (5/8)

Kaplan-Meier curve of median PFS stratified by age



Median PFS in the elderly subgroup (aged  $\geq 75$  years) was 13.2 months, similar to that observed in participants aged  $< 75$  years at 12.4 months

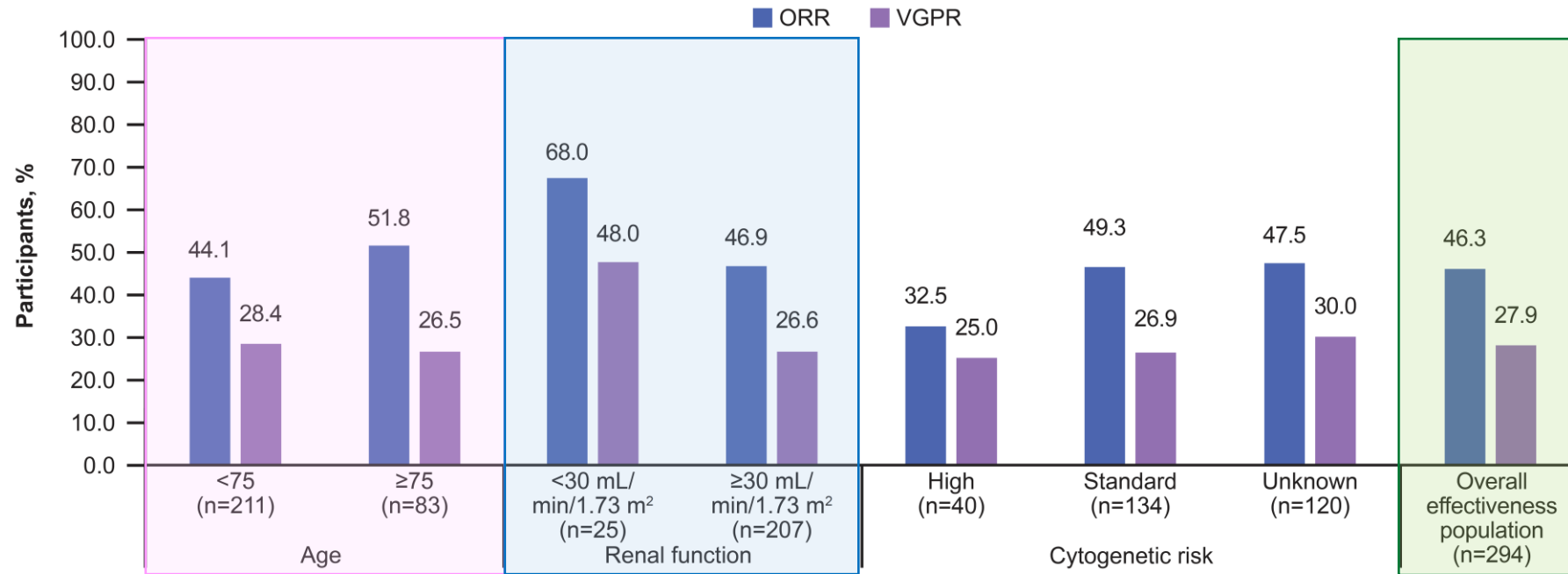
Kaplan-Meier curve of median PFS stratified by RI



Participants with severe RI (eGFR  $< 30$  mL/min/ $1.73$  m<sup>2</sup>) had a slightly shorter median PFS of 10.0 mos compared with 13.2 mos observed in those with renal function  $\geq 30$  mL/min/ $1.73$  m<sup>2</sup>

# Results (6/8)

ORR and VGPR rate by subgroup of interest



- Elderly participants had a similar ORR and VGPR rate (51.8% and 26.5%, respectively) to that of the overall effectiveness population (46.3% and 27.9%)
  - In severe Renal Impairment is ORR and VGPR 68.0% and 48.0%, although with a small population size

# Results (7/8)

Primary system organ class preferred term, n (%)	Safety population (N=299)	Elderly (aged ≥75 years; n=83)	Severe renal impairment (eGFR <30 mL/min/1.73 m <sup>2</sup> ; n=26)	High-risk cytogenetics (n=40)
Blood and lymphatic system disorders	54 (18.1)	16 (19.3)	4 (15.4)	6 (15.0)
Neutropenia	28 (9.4)	10 (12.0)	0	3 (7.5)
Thrombocytopenia	15 (5.0)	4 (4.8)	1 (3.8)	2 (5.0)
Cytopenia	8 (2.7)	3 (3.6)	2 (7.7)	1 (2.5)
General disorders and administration site conditions	10 (3.3)	6 (7.2)	2 (7.7)	2 (5.0)
Asthenia	4 (1.3)	4 (4.8)	0	1 (2.5)

n (%)	Safety population (N=299)	Elderly (aged ≥75 years; n=83)	Severe renal impairment (eGFR <30 mL/min/1.73 m <sup>2</sup> ; n=26)	High-risk cytogenetics (n=40)
<b>Infections</b> occurred in 3 participants in the overall population, 2 were in the elderly subgroup and 1 were in the elderly subgroup and 1 were in the elderly subgroup.				
At least one event	79 (26.4)	24 (28.9)	8 (30.8)	10 (25.0)
Leading to Isar temporary discontinuation	24 (8.0)	8 (9.6)	1 (3.8)	4 (10.0)
Leading to Isar permanent discontinuation	4 (1.3)	3 (3.6)	0	1 (2.5)
Leading to pomalidomide dose reduction	17 (5.7)	4 (4.8)	1 (3.8)	3 (7.5)
Leading to pomalidomide temporary discontinuation	32 (10.7)	14 (16.9)	3 (11.5)	2 (5.0)
Leading to Isar-Pd permanent discontinuation	9 (3.0)	1 (1.2)	1 (3.8)	0

# Conclusions (8/8)

- The effectiveness and safety profiles across elderly and severe renal impairment subgroups were similar to those observed in the overall effectiveness and safety population, despite a higher percentage of daratumumab-refractory participants in the severe renal impairment subgroup
- Of note, participants with severe renal impairment had greater response rates than the effectiveness population, although with a small sample size
- A real-world study of Isa-Pd use in the UK has reported a median PFS of 10.9 months after a median follow-up of 12.1 months, which is generally similar to that observed in IMAGE. In this dataset, 30.8% of participants were aged  $\geq 75$  years, 43% had eGFR  $< 60$  mL/min, and 14% had high cytogenetic risk<sup>11</sup>
- The results of these subgroup analyses continue to support Isa-Pd for the treatment of RRMM across subgroups



# The role of “lenalidomide-dexamethasone therapy” in elderly patients with multiple myeloma in clinical practice: comparison with “bortezomib-based therapy”

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# lenalidomide-dexamethasone therapy vs bortezomib-based therapy in elderly patients

## RESULTS = n.78

- 50% of 74.2% (n=39) received bortezomib-based (p=0.007), 41% (n=32) received Rd therapy as the first treatment
- Time to Best Response significantly longer in group V than in group R (5.28 vs 3.2 mos, p=0.003)
- mPFS was significantly different between groups (p=0.042) the distribution of risk groups according to the R-ISS
- Treatment Discontinuation due to treatment-related complications 55.6% (15 pts) in group R, 38.5% (15 pts) in group V (treatment terminated according to the plan)
- 64.1% (n=25) pts in group V received second-line lena-based therapy, whereas only 21.9% (n=6) patients in group R received secondary treatment
- The period from the completion of the 1<sup>st</sup> treatment to the start of the 2<sup>nt</sup> treatment was 1.0 mos in group R and 3.7 mos in group V (p=0.042)
- mPFS2 significantly longer in group V (22.6 mos) than in group R (5.4 mos) (p=0.001)
- The mOS was 26.6 months in group R vs 48.7 months in group V (p=0.010)

## CONCLUSIONS = The type of primary treatment did not affect OS

# “Isatuximab monotherapy” or “combination therapy with dexamethasone” in older adult patients with relapsed/refractory multiple myeloma: a single institution experience

Masaki Iino<sup>1</sup>, Takahiro Mikawa<sup>1</sup>, Shinji Kido<sup>1</sup>, Ken Fujimori<sup>1</sup>  
Yamanashi Prefectural Central Hospital

# Isatuximab monotherapy” or “combination therapy with dexamethasone” in older adult patients

**RESULTS** = n.15 with RRMM

- Disease control rate (i.e., t[4;14], t[14;16], del 17p, or 1q21 gain or better) was 80%
- **After a median of 8.3 months (range, 0–92)** months, the median TTNT was 7.5 months
- TSS stage 1/2/3 was 3.5/7 reached
- At the time of analysis, 8 pts had discontinued treatment (the main reason for treatment discontinuation was PD)
- **Regarding adverse events, no unexpected AEs were identified in this study**
- 8 pts had high-risk cytogenetic abnormalities (at least one of t[4;14], t[14;16], del 17p, or 1q21 gain/amplification)
- 11 pts had previously received daratumumab

**CONCLUSIONS** = Isa20 and Isa20+D remain useful and feasible treatment options in a real-world setting, even in frail older adult patients with RRMM

Arnaldo Benini  
Patrizia Caraveo  
Gilberto Corbellini  
Paolo Legrenzi  
Vittorio Lingiardi  
Sebastiano Maffettone  
Giorgio Vallortigara

# Quello che ora sappiamo

Tutte le volte che la scienza  
ha cambiato idea

24 ORE | Domenica






## Various Frailty Assessment Tools

	IMWG frailty score	UK-MRA MRP	Mayo risk score	IFM simplified frailty score
Biologica-Clinical components	Age CCI	Age R-ISS CRP	Age NT pro-BNP	Age CCI
Funcionalidad tests	ADL IADL	PS (WHO)	PS (WHO)	ECOG
Population	Clinical Trials	Clinical Trials Real-world	Real-world	Clinical Trials

### FRAIL PATIENTS HAVE

- shorter OS and PFS times
- higher incidence of non-haematological Adverse Events and treatment discontinuation

**FRAILTY ASSESSMENT**  
IMWG Frailty Score

<p><b>FIT PATIENTS</b> <b>(score 0)</b></p>  <p>age <math>\leq 75</math> + ADL <math>&gt; 4</math> + IADL <math>&gt; 5</math> + CCI <math>\leq 1</math></p> <p><i>Goal: efficacy</i></p>	<p><b>INTERMEDIATE-FIT PATIENTS</b> <b>(score 1)</b></p>  <p>age 76-80 or ADL <math>\leq 4</math> or IADL <math>\leq 5</math> + CCI <math>&gt; 1</math></p> <p><i>Goal: efficacy/safety</i></p>	<p><b>FRAIL PATIENTS</b> <b>(score <math>\geq 2</math>)</b></p>  <p>age <math>&gt; 80</math>; age 76-80 + ADL <math>\leq 4</math> or IADL <math>\leq 5</math> or CCI <math>&gt; 1</math>; age <math>\leq 75</math> + at least 2 ADL <math>\leq 4</math> or IADL <math>\leq 5</math> or CCI <math>&gt; 1</math></p> <p><i>Goal: safety</i></p>
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**APPROVED REGIMENS**

<p>Daratumumab-VMP Daratumumab-Rd VRd ASCT in pts <math>\leq 70</math> years old</p>	<p>(Daratumumab)-VMP, consider weekly V (Daratumumab)-Rd Vd VRd-lite</p>	<p>Dose-adjusted Rd <math>\pm</math> daratumumab Dose-adjusted Vd Palliative care</p>
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**EXPERIMENTAL REGIMENS with monoclonal antibodies**

<p>Daratumumab-VRd (NCT03652064) Isatuximab-VRd (NCT03319667) Isatuximab-VCd (NCT02513186) Belamaf-VRd (NCT04091126)</p>	<p>Daratumumab-Ixa-dex (NTR6297) Daratumumab-VRd lite (NCT04052880)</p>	<p>Daratumumab-Ixa-dex (NTR6297) Daratumumab-R (NCT03993912)</p>
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Le nuove acquisizioni dal

20th IMS Annual Meeting 2023



# The FiTNEss trial (Myeloma XIV, NCT03720041)



Induction (12 cycles)

**"REACTIVE"**  
(Standard dosing)

	All patients	Days
Ixazomib	4mg	1,8,15
Lenalidomide	25mg	1-21
Dexamethasone	40mg (<=75y) 20mg (>75y)	1,8,15,22

R1

**"ADAPTIVE"**  
(IMWG frailty score adjusted dosing)

	FIT	UNFIT	FRAIL	Days
Ixazomib	4mg	4mg	4mg	1,8,15
Lenalidomide	25mg	15mg	10mg	1-21
Dexamethasone	40mg	20mg	10mg	1,8,15,22

R2

Maintenance (to PD or intolerance)

Lenalidomide + placebo

Lenalidomide + ixazomib

The UKMRA Myeloma XIV FiTNEss trial is a phase III, multicentre, randomised controlled trial for NDMM patients ineligible for ASCT. Analysis of FS dynamism in IRd arm (n=319) calculating the FS at 2, 4, 6, 12 months =

1) FIT = 20.9% deterioration in FS score at any timepoint

2) UNFIT = 26.7% deterioration at any timepoint

3) to compare «early treatment cessation» (within 60 days of randomisation) between two groups

4) to compare «PFS» for maintenance in R vs R+Ixa. 16.2% PFS for maintenance at any timepoint

5) to compare «PFS» for maintenance in R vs R+Ixa. 16.2% PFS for maintenance at any timepoint

Population = 638 pts, median age 76 ys (62-93) (22.3% >80)

Punti di forza =

1) IMWG Frailty Score adjusted dosing

2) Analysis of Frailty Score Dinamism

# The FiTNEss trial (Myeloma XIV, NCT03720041)

Figure 1B: Baseline Characteristics

	Total (n=180)
<b>Age at Randomisation 1 (Years)</b>	
Mean (s.d.)	77.5 (5.20)
Median (range)	77.0 (64.0, 93.0)
IQR	74.0, 81.0
<b>Age Category at Randomisation 1 (Years)</b>	
Less than or equal to 75 years old	68 (37.8%)
76 - 80 years old	65 (36.1%)
More than 80 years old	47 (26.1%)
<b>Sex</b>	
Male	104 (57.8%)
Female	76 (42.2%)
<b>ECOG Status</b>	
0	35 (19.4%)
1	97 (53.9%)
2	31 (17.2%)
3	17 (9.4%)
<b>ISS Stage</b>	
Stage I	26 (14.4%)
Stage II	83 (46.1%)
Stage III	57 (31.7%)
Not yet available	14 (7.8%)
<b>IMWG Frailty Score at Baseline</b>	
Fit	43 (23.9%)
Unfit	53 (29.4%)
Frail	84 (46.7%)
<b>MRP Group at Baseline</b>	
Low-risk	45 (25.0%)
Medium-risk	46 (25.6%)
High-risk	75 (41.7%)
Not yet available	14 (7.8%)

L'analisi della fragilità è stata ripetuta eliminando il contributo dell'età.

Pazienti di età >80 anni (n = 47, 100% FRAIL)

- 42.6% pz (n=20) riclassificati come FIT
- 38.3% pz (n=18) riclassificati come UNFIT
- 19.2% pz (n=9) mantengono la categoria FRAIL

Pazienti di età  $\geq 76 < 80$  anni (n = 65, 53.8% UNFIT, 46.2% FRAIL)

- 53.8% pz UNFIT (n=35) riclassificati come FIT
- 29.2% pz FRAIL (n=19) riclassificati come UNFIT
- 16.9% pz FRAIL (n=11) mantengono la categoria FRAIL

La concordanza IMWG e MyelomaRiskProfile 48,9% dei pazienti (88/180)

- 37.2% pz FIT classificati come basso-rischio MRP
- 32.1% pz UNFIT classificati come rischio-intermedio MRP
- 65.5% pz FRAIL mantengono la categoria ad alto-rischio MRP

# The simplified frailty index (S-FI) identifies a less vulnerable population of frail patients than patients who are defined frail using the International Myeloma working Group Frailty index (IMWG-FI)

Kaz Groen, Febe Smits, Kazem Nasserinejad, Mark-David Levin, Josien Regelink, Gert-Jan Timmers, Esther de Waal, Matthijs Westerman, Gerjo Velders, Koen de Heer, Rineke Leys, Roel van Kampen, Claudia Stege, Maarten Seefat, Inger Nijhof, Ellen van der Spek, Saskia Klein, Niels van de Donk, Paula Ypma, Sonja Zweegman

# Simplified Frailty Index (S-FI) vs IMWG-Frailty Index = HOVON 123 and HOVON 143

HOVON 123 + HOVON 143

n=368 pts

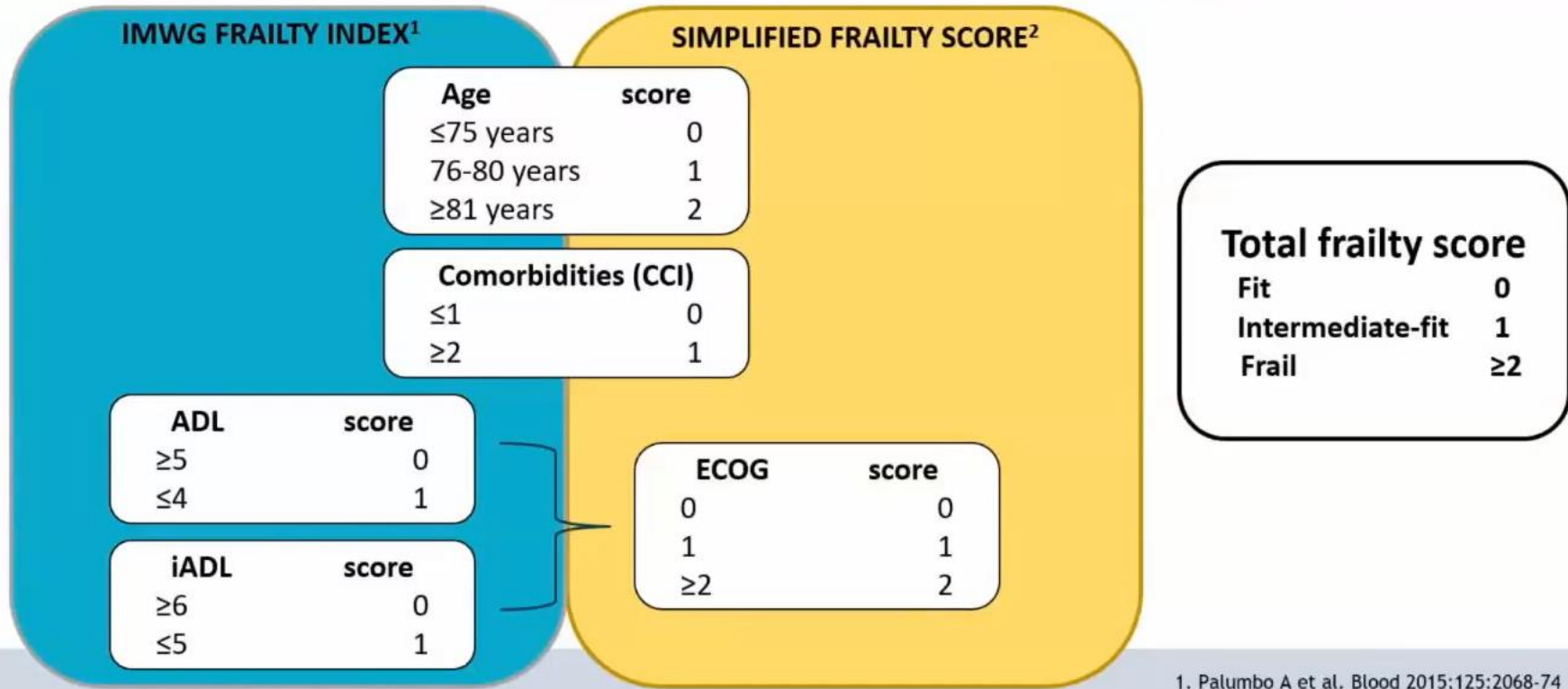
pts valutabili



n=341 pts

La fragilità è stato ricalcolata ricorrendo a IMWG\_FI

## THE GOLD STANDARD FOR FRAILTY = IMWG FRAILITY INDEX BUT IN MANY TRIALS ADL/IADL ARE MISSING: ECOG PERFORMANCE AS PROXY



ADL: activities of daily living; CCI: Charlson Comorbidity Index; iADL: Instrumental ADL  
 1. Palumbo A et al. Blood 2015;125:2068-74  
 2. Facon T et al. Leukemia 2020;34:224-233

# Simplified Frailty Index (S-FI) vs IMWG-Frailty Index = HOVON 123 and HOVON 143

HOVON 123 + HOVON 143

n=368 pts

pts valutabili



n=341 pts

La fragilità è stato ricalcolata ricorrendo a **IMWG\_FI**

67 pazienti **INTERMEDIATE-FIT sec. S-FI**

- **91%** pazienti (n=61) rimangono **INTERMEDIATE-FIT sec. IMWG-FI**

- **9%** pazienti (n=6) vengono riclassificati come **FRAIL sec. IMWG-FI**

272 pazienti **FRAIL sec. S-FI**

- **74%** pazienti (n=202) rimangono **FRAIL sec. IMWG-FI**

- **26%** pazienti (n=70\*) vengono riclassificati come **INTERMEDIATE-FIT sec. IMWG-FI**

- pazienti di età <80 aa = 0%,
- ADL indipendenti 69%,
- IADL indipendenti 93%,
- CCI  $\leq 1$  = 80%

**MESSAGGIO = I differenti SCORE DI FRAGILITA' possono identificare POPOLAZIONI DIFFERENTI**

# Development and validation of a prognostic survival model with Patient Reported Outcomes (PROs) for older adults with multiple myeloma

Hira Mian<sup>1</sup>, Rinku Sutradhar<sup>2</sup>, Matthew Cheung<sup>3</sup>, Anastasia Gayowsky<sup>4</sup>, Jason Tay<sup>5</sup>, Amaris Balitsky<sup>1</sup>, Tanya Wildes<sup>6</sup>, Arleigh McCurdy<sup>7</sup>, Alissa Visram<sup>8</sup>, Irwindeep Sandhu<sup>9</sup>, Hsien Seow<sup>1</sup>

<sup>1</sup>McMaster University, Hamilton, Ontario, Canada; <sup>2</sup>University of Toronto; <sup>3</sup>Sunnybrook Health Sciences Centre; <sup>4</sup>ICES McMaster; <sup>5</sup>University of Calgary; <sup>6</sup>University of Nebraska Medical Centre; <sup>7</sup>University of Ottawa; <sup>8</sup>The Ottawa Hospital; <sup>9</sup>University of Alberta, Edmonton, AB, Canada

# A prognostic survival model incorporating PROs for elderly patients with MM

Gli autori concorrono allo sviluppo e alla validazione di un modello di sopravvivenza che incorpora gli outcomes riportati dai pazienti.

In questo studio, il crescente numero di sintomi gravi riportati dai pazienti nell'anno precedente era associato ad una ridotta sopravvivenza.

Ciò ha consentito ai pazienti di far parte del processo decisionale.

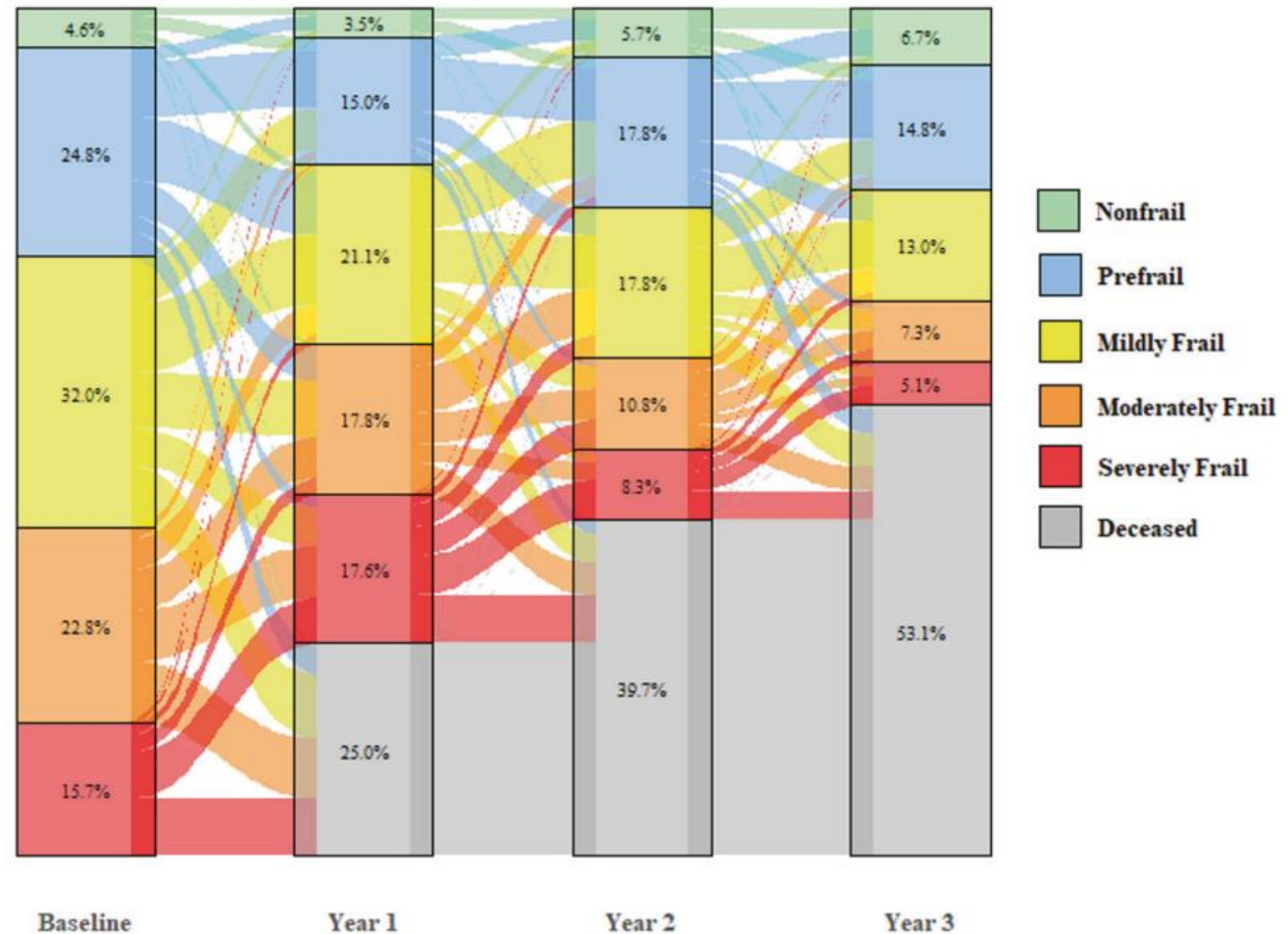
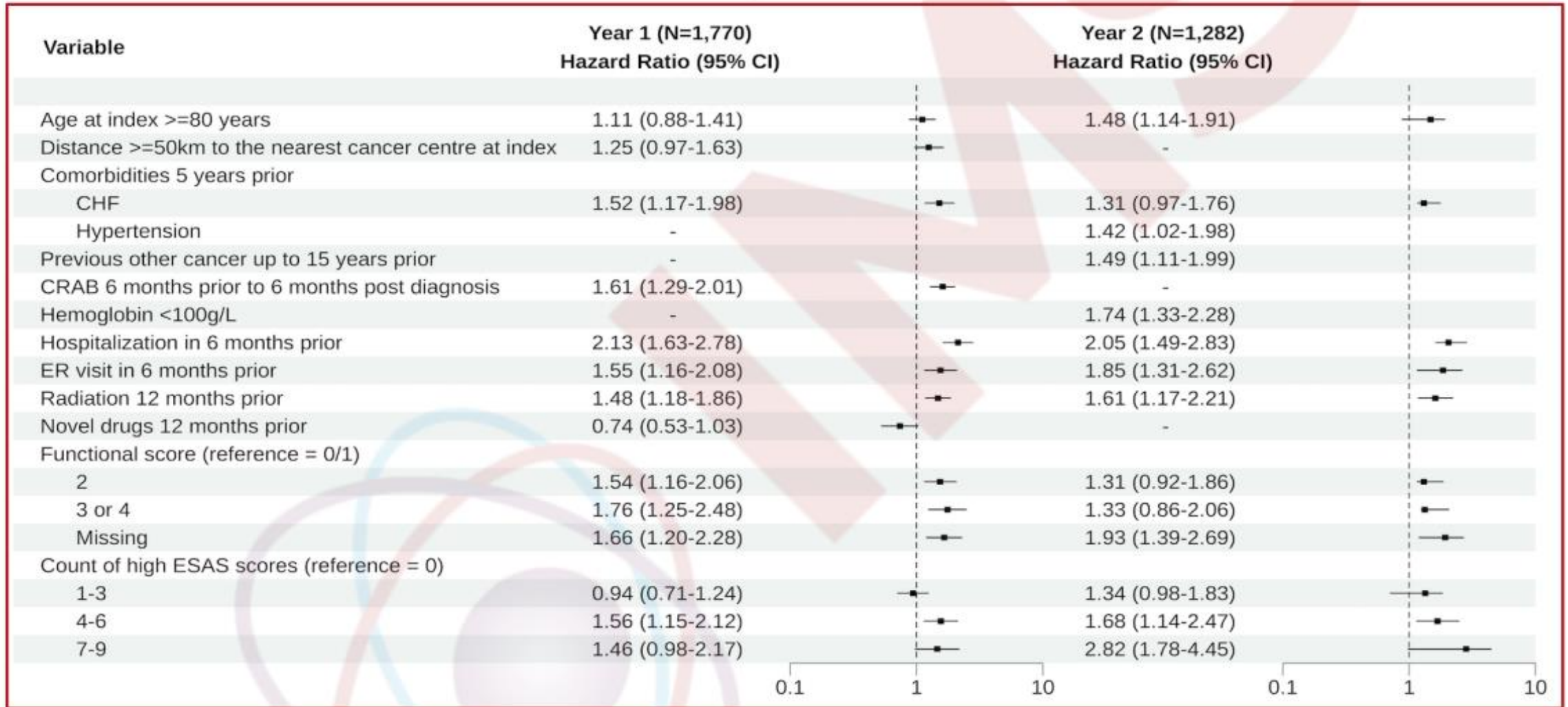


Fig. 2 Trajectories of frailty in the first 3 year following diagnosis among older adults with MM.

# A prognostic survival model incorporating PROs for elderly patients with MM

## Median Age 75 years





# A prognostic score based on age, eGFR (CKD-EPI), performance status and ultra-high-risk disease outperforms R2-ISS for elderly myeloma patients: an analysis of the Greek myeloma study group registry

Eirini Katodritou, Efstathios Kastritis, Dimitra Dalampira, Aggeliki Sevastoudi, Foteini Theodorakakou, Sosana Delimpasi, Emmanouil Spanoudakis, Ioannis Ntanasis-Stathopoulos, Theodora Triantafyllou, Aikaterini Daiou, Anastasia Pouli, Maria Gavriatopoulou, Evgenia Verrou, Meletios Dimopoulos, Evangelos Terpos

# Age, PS, eGFR and ultra-high-risk disease outperform R2-ISS in elderly pts

Variabili = età  $\geq 75$  ys, eGFR  $< 40$  ml/min/1.73 m<sup>2</sup>, ECOG  $\geq 2$ , ultra-high-risk MM, R-ISS, R2-ISS, ECOG  $\geq 2$ , anemia, lena-based-therapy, daratumumab-based-therapy

In uni e multivariata conservano valore prognostico negativo =

- Età  $\geq 75$  ys
- eGFR  $< 40$  ml/min/1.73 m<sup>2</sup>
- ECOG  $\geq 2$
- Ultra-high-risk MM

4 gruppi di rischio prognostico =

- Low = 0 punti
- Low-intermediate = 1 punto
- Intermediate-high = 2 punti
- High = 3 punti

OS per gruppo di rischio =

- Low = 79 mesi (65-92)
- Low-intermediate = 60 mesi (52-68)
- Intermediate-high = 42 mesi (36-48)
- High = 15 mesi (9-20)

# Determining the “impact of multimorbidity” in older patients initiating treatment for newly-diagnosed multiple myeloma using artificial intelligence/ machine learning methods

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## **CONCLUSIONS**

Our findings in a real-world population of older adults with MM initiating treatment highlight that including information on multimorbidity alongside MM-specific information yields far superior prediction of mortality compared to a focus only on MM-specific information. Further investigation into the disease-disease, disease-drug, and drug-drug interactions that mediate this risk will yield important clinical insights into the mechanisms of mortality in patients treated outside of clinical trials.

# Survey of multiple myeloma (MM) patients and healthcare professionals (HCPs) on the relevance of existing health quality-of-life (QoL) questionnaires (QoLQ) to real-world QoL issues of MM patients

Sotirios Bristogiannis, Catherine SY. Lecat, Dipal Mehta, Jahanzaib Khwaja, Yadanar Lwin, Emma Dowling, Nuno Correia, Kate Xu, Annabel McMillan, Neil Rabin, Jonathan Sive, Rakesh Popat, Xenofon Papanikolaou, Lydia Lee, Kwee Yong, Sosana Delimpasi, Charalampia Kyriakou

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# Highlights from IMS 20th meeting 2023

Giuseppe Mele

**GRAZIE**

30-31 gennaio 2024  
BOLOGNA, Royal Hotel Carlton