


The Myelodysplastic Syndromes

Aaron T. Gerds, MD, MS

Associate Professor of Medicine
Medical Director, Case Comprehensive
Cancer Center
 @AaronGerds



Disclosures



“It troubles me that we’re being led into battle by a person wearing a bow tie.”

-New Yorker | September 10, 2018

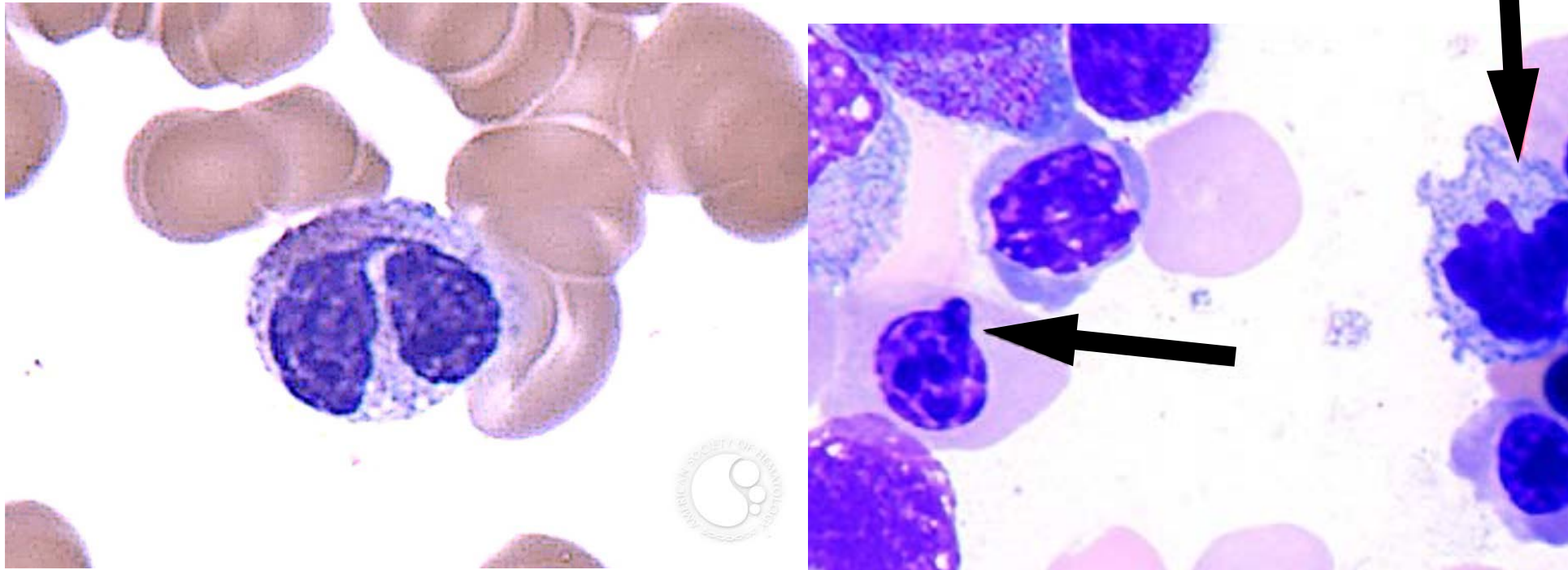
Overview – Myelodysplastic Syndromes

1. Organization, in general
2. Diagnosis and Classification
3. Epidemiology
4. Pathogenesis
 - a. Clonal Process
 - b. Secondary MDS
5. Risk stratification
 - a. IPSS-R
6. Treatment of Lower-risk MDS
 1. ESAs
 2. IMiDs
 3. Immunosuppressive therapy
7. Treatment of Higher-risk MDS
 1. Hypomehtylating agents
8. Transplantation for MDS
9. Discussion

What is MDS?

The Myelodysplastic Syndromes

- Gr. *myelos* – “marrow”
- Gr. *dys* + *plassein* – “abnormally form”



Maslak P, Pelger Huet Cell - 1. ASH Image Bank. 2011; 2011-2117.

Maslak P, Dysplastic Red Cell Changes (Bone Marrow Aspirate) I - 2. ASH Image Bank. 2011; 2011-3269.

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 **Cleveland Clinic**

MDS is a cancer?

Oxford dictionary: The disease caused by an uncontrolled division of abnormal cells in a part of the body (from Latin *cancer* meaning crab)



Mural Study for Cancer, 1948; Clarence Van Duzer (1920-2009)

Diagnosis and Classification of MDS

WHO Diagnostic Criteria

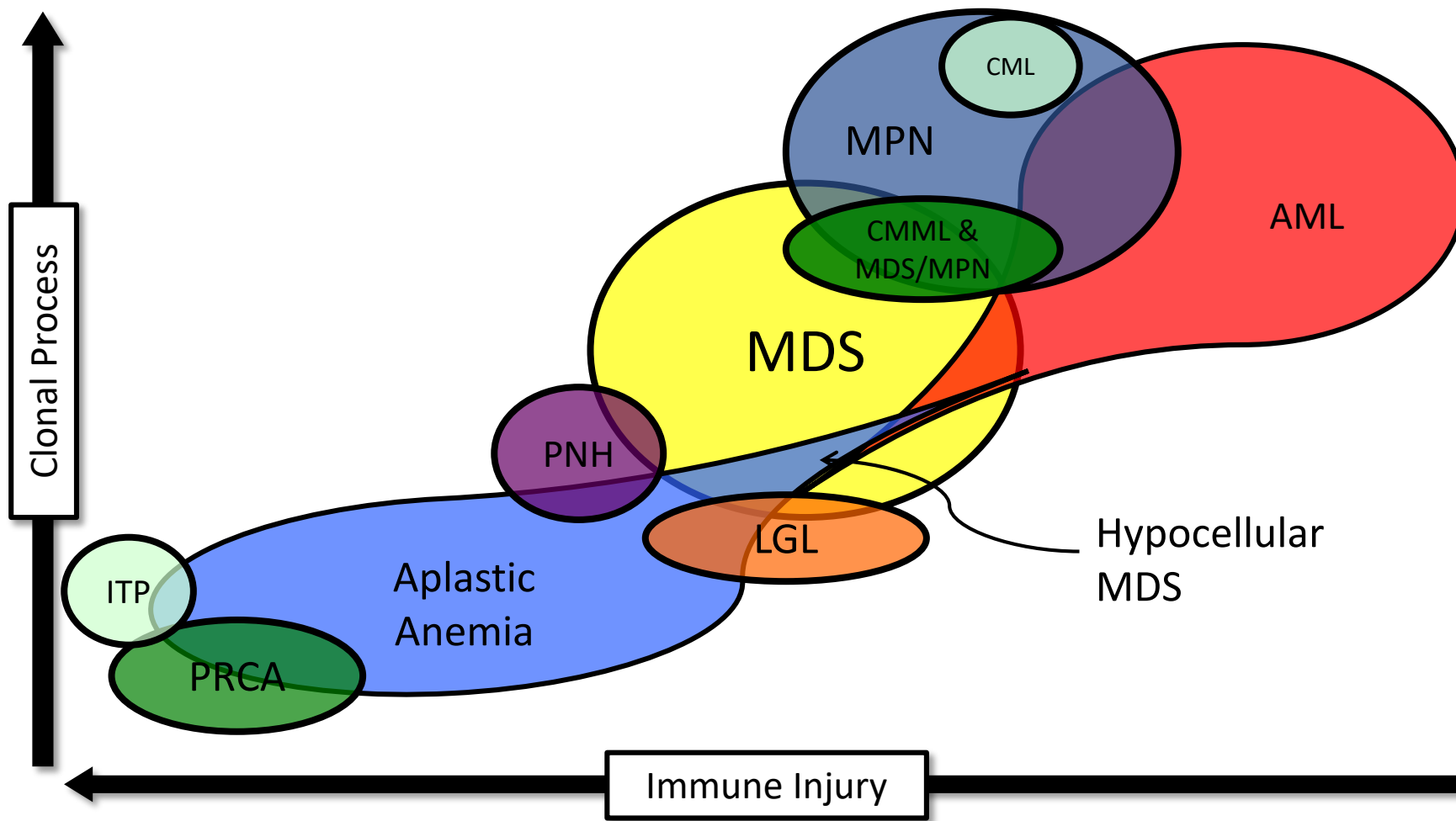
Minimal Morphologic Criteria

- $\geq 10\%$ of the cells ≥ 1 lineage must show dysplasia
- Dysplasia not required if:
 - Defining cytogenetics
 - BM blasts $\geq 5\%$, PB blasts $\geq 2\%$, or Auer rods
- At least one cytopenia present
- Causes of secondary dysplasia must be excluded

Defining Cytogenetics

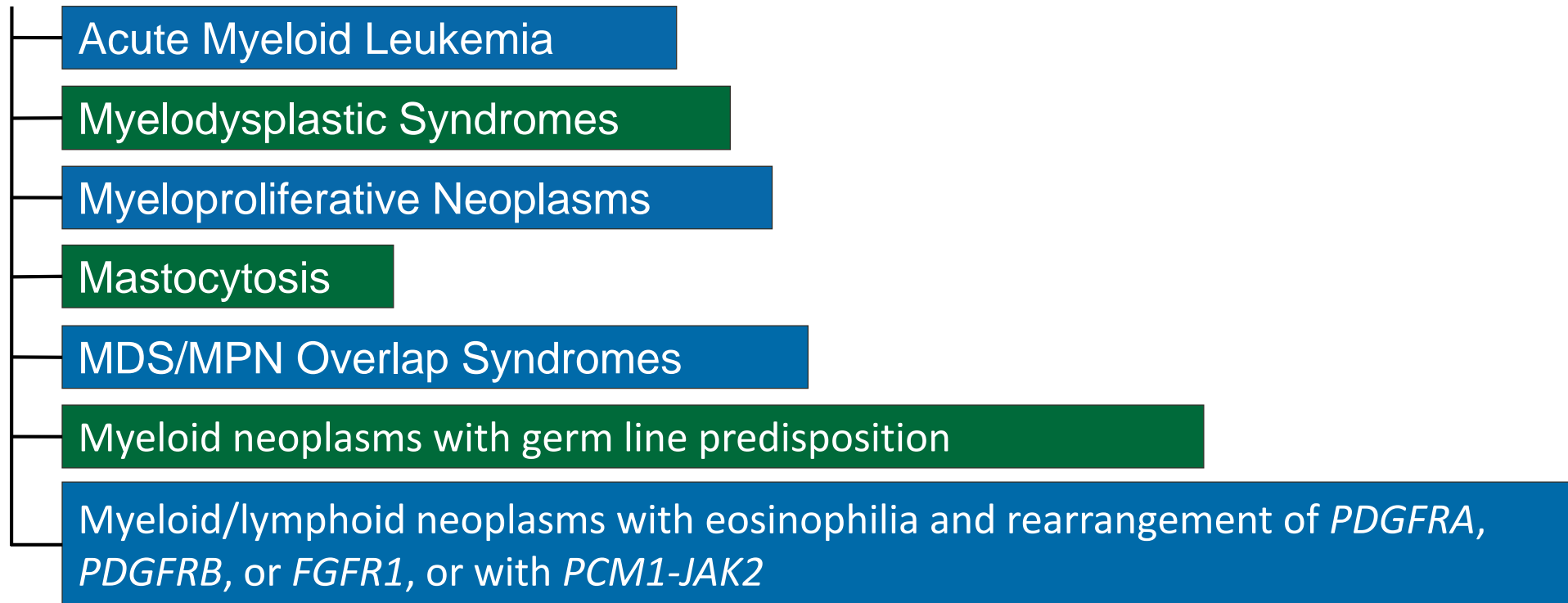
- -7 or $\text{del}(7q)$
- -5 or $\text{del}(5q)$
- $\text{del}(13q)$
- $\text{del}(11q)$
- $\text{del}(12p)$ or $\text{t}(12p)$
- $\text{del}(9q)$
- $\text{idic}(X)(q13)$
- $\text{t}(17p)$ or $\text{i}(17q)$
- $\text{t}(11;16)$
- $\text{t}(3;21)$
- $\text{t}(1;3)$
- $\text{t}(2;11)$
- $\text{inv}(3)$
- $\text{t}(6;9)$
- Complex

Spectrum of Marrow Failure



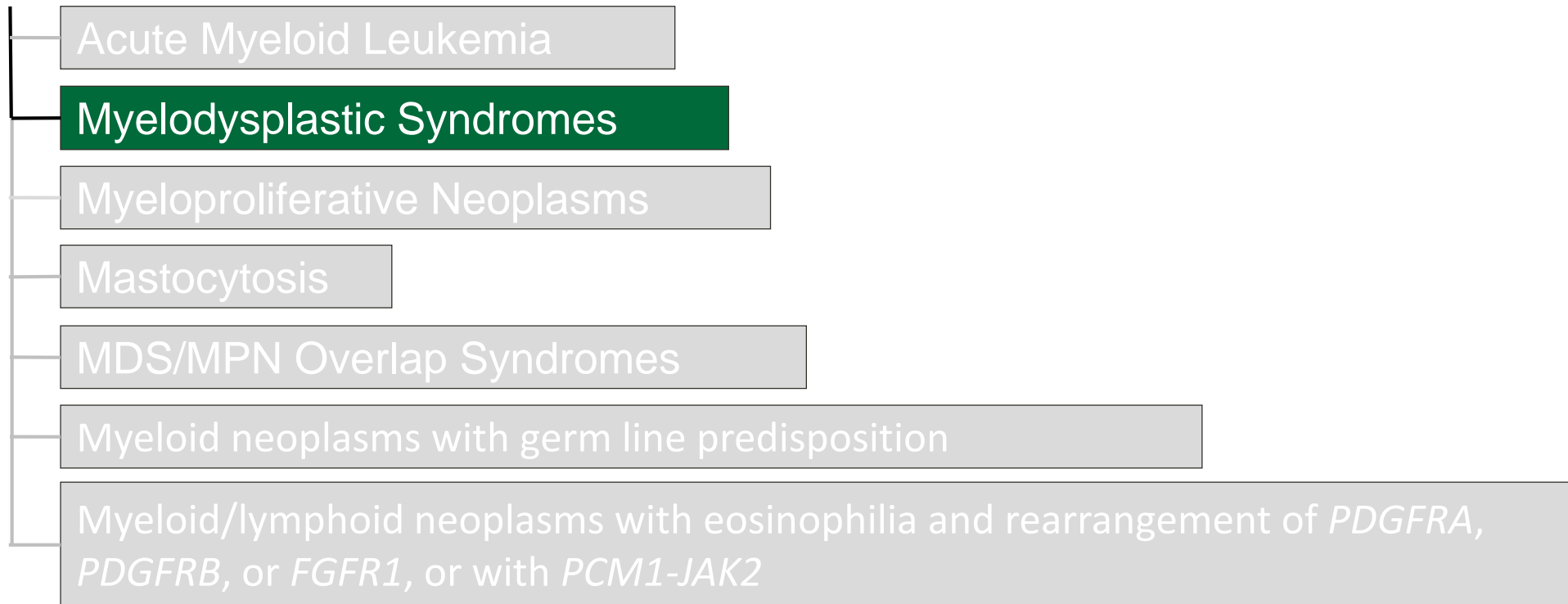
WHO Classification

Myeloid Neoplasms



WHO Classification

Myeloid Neoplasms



Name	Dysplastic lineages	Cytopenias*	Ringed sideroblasts as % of marrow erythroid elements	Bone marrow (BM) and peripheral blood (PB) blasts	Cytogenetics by conventional karyotype analysis
MDS with single lineage dysplasia (MDS-SLD)	1	1 or 2	<15%/<5%†	BM <5%, PB <1%, no Auer rods	Any, unless fulfills all criteria for MDS with isolated del(5q)
MDS with multilineage dysplasia (MDS-MLD)	2 or 3	1-3	<15%/<5%†	BM <5%, PB <1%, no Auer rods	Any, unless fulfills all criteria for MDS with isolated del(5q)
MDS with ring sideroblasts (MDS-RS)					
MDS-RS with single lineage dysplasia (MDS-RS-SLD)	1	1 or 2	≥15%/≥5%†	BM <5%, PB <1%, no Auer rods	Any, unless fulfills all criteria for MDS with isolated del(5q)
MDS-RS with multilineage dysplasia (MDS-RS-MLD)	2 or 3	1-3	≥15%/≥5%†	BM <5%, PB <1%, no Auer rods	Any, unless fulfills all criteria for MDS with isolated del(5q)
MDS with isolated del(5q)	1-3	1-2	None or any	BM <5%, PB <1%, no Auer rods	del(5q) ± 1 additional abnormality except -7 or del(7q)
MDS with excess blasts (MDS-EB)					
MDS-EB-1	0-3	1-3	None or any	BM 5%-9% or PB 2%-4%, no Auer rods	Any
MDS-EB-2	0-3	1-3	None or any	BM 10%-19% or PB 5%-19% or Auer rods	Any
MDS, unclassifiable (MDS-U)					
With 1% blood blasts	1-3	1-3	None or any	BM <5%, PB = 1%,‡ no Auer rods	Any
with single lineage dysplasia and pancytopenia	1	3	None or any	BM <5%, PB <1%, no Auer rods	Any
based on defining cytogenetic abnormality	0	1-3	<15%§	BM <5%, PB <1%, no Auer rods	MDS-defining abnormality
Refractory cytopenia of childhood	1-3	1-3	None	BM <5%, PB <2%	Any

MDS with $< 5\%$ blasts

MDS with excess ($\geq 5\%$) blasts

MDS, unclassifiable

Epidemiology of MDS

MDS Epidemiology

Age-Adjusted Incidence Rates^a for the 18 SEER Geographic Areas by Age and Race, 2009-2013

Site	Both Sexes		Males		Females	
	Rate	Count	Rate	Count	Rate	Count
Myelodysplastic Syndromes (MDS)						
By age						
Ages <40	0.1	335	0.1	164	0.1	171
Ages 40-49	0.7	459	0.8	233	0.7	226
Ages 50-59	2.4	1,406				
Ages 60-69	9.3	3,653				
Ages 70-79	30.2	6,539				
Ages 80+	59.8	8,946				
By race						
All Races	4.9	21,338				
White	5.1	17,978				
Black	4.1	1,617				
Asian/Pacific Islander	3.7	1,420				
American Indian/Alaska Native ^b	3.4	76	3.6	38	3.2	38
Hispanic ^c	3.5	1,644	4.4	866	2.9	778

Incidence Rate =
4.9/100,000 per
year

MDS Epidemiology

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Ages 40–49	0.7	459	0.8	233	0.7	226
Ages 50–59	2.4	1,406	2.7	781	2.0	625
Ages 60–69	9.3	3,653	11.5	2,131	7.4	1,522
Ages 70–79	30.2	6,539	40.3	3,861	22.2	2,678
Ages 80+	59.8	8,946	90.0	4,928	42.3	4,018
By race						
All Races	6.7	12,098	6.7	12,098	3.7	9,240
White	7.0	7,978	7.0	10,351	3.8	7,627
Black	4.1	1,617	5.3	806	3.4	811
Asian/Pacific Islander	3.7	1,420	4.8	777	2.8	643
American Indian/Alaska Native ^b	3.4	76	3.6	38	3.2	38
Hispanic ^c	3.5	1,644	4.4	866	2.9	778

Men > Women

MDS Epidemiology

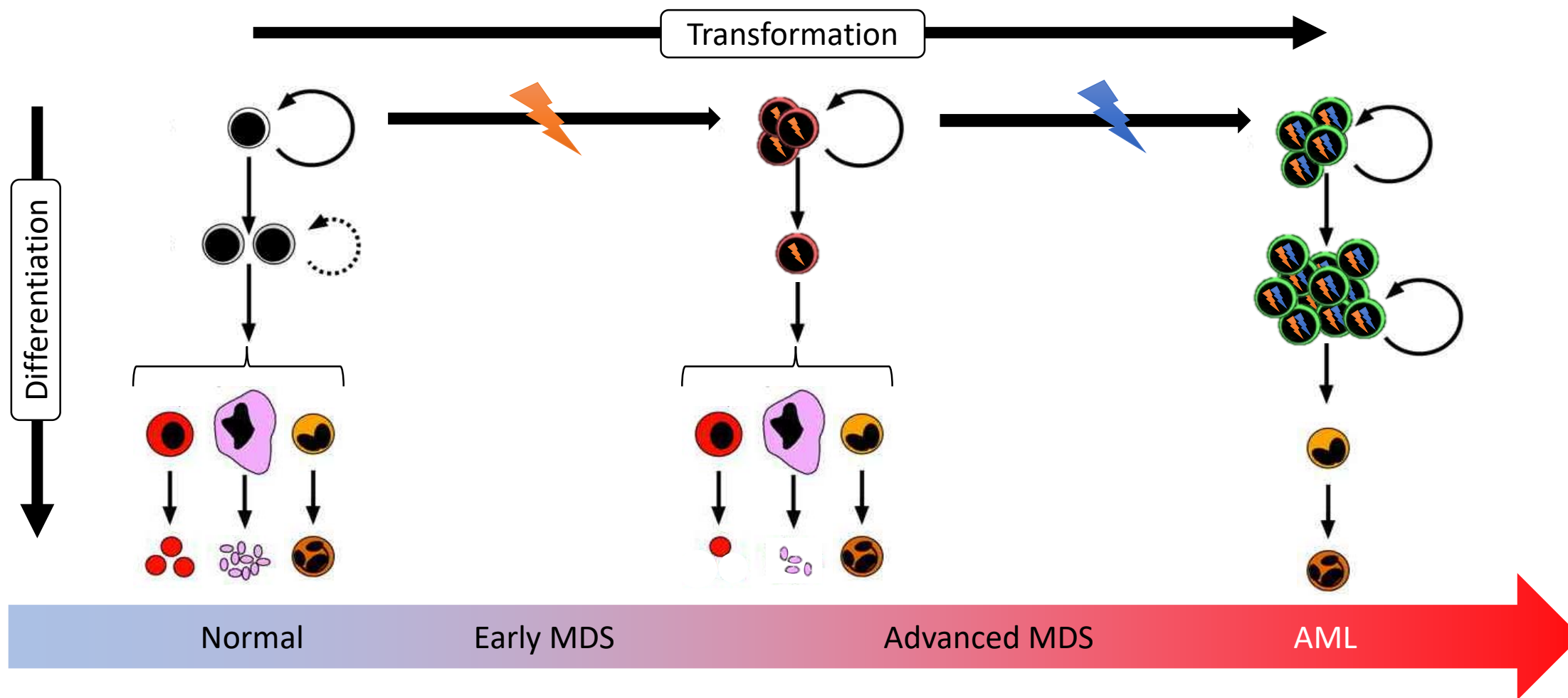
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White > African-American

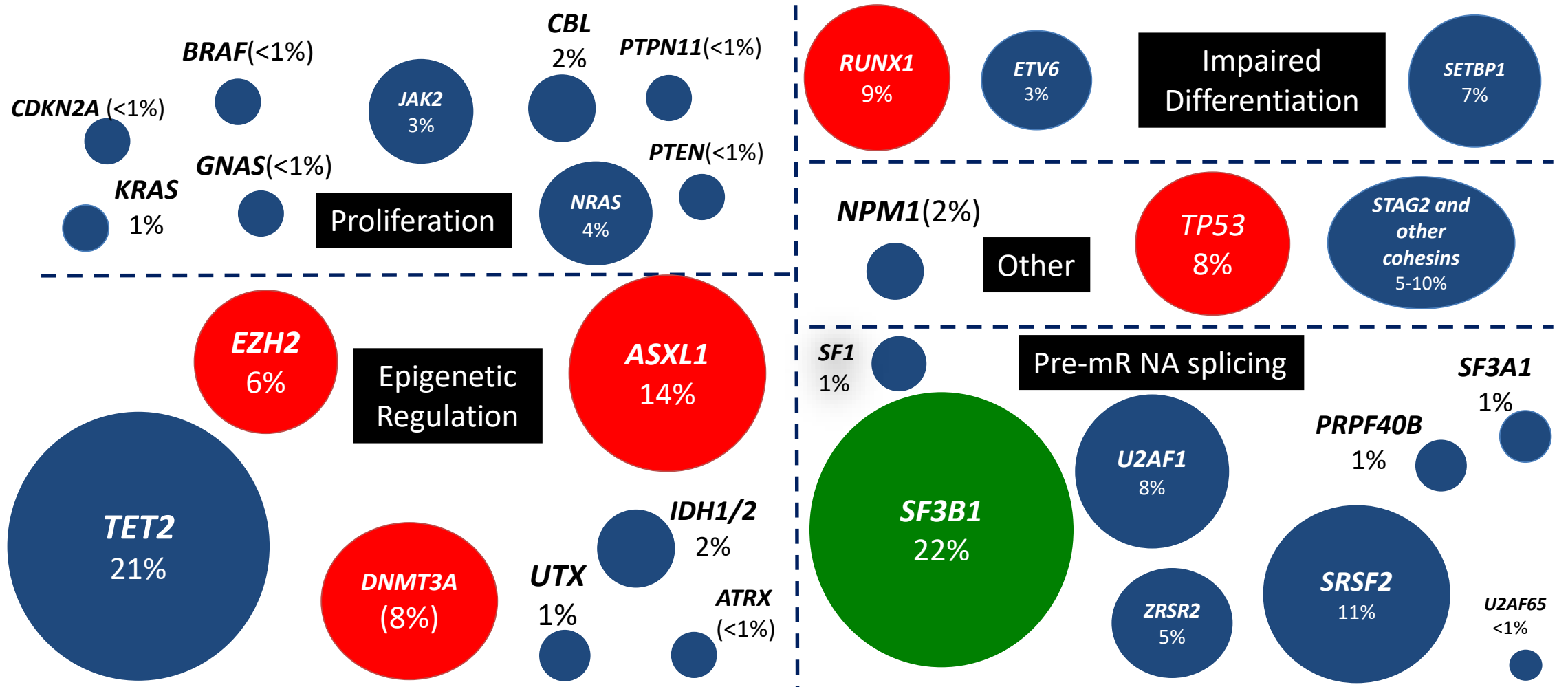
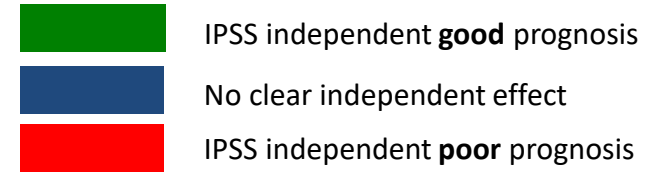
Pathogenesis of MDS

Pathogenesis of MDS



Adapted from: Passegué E, et al., Proc Natl Acad Sci. 2003 Sep 30;100 Suppl 1:11842-9.

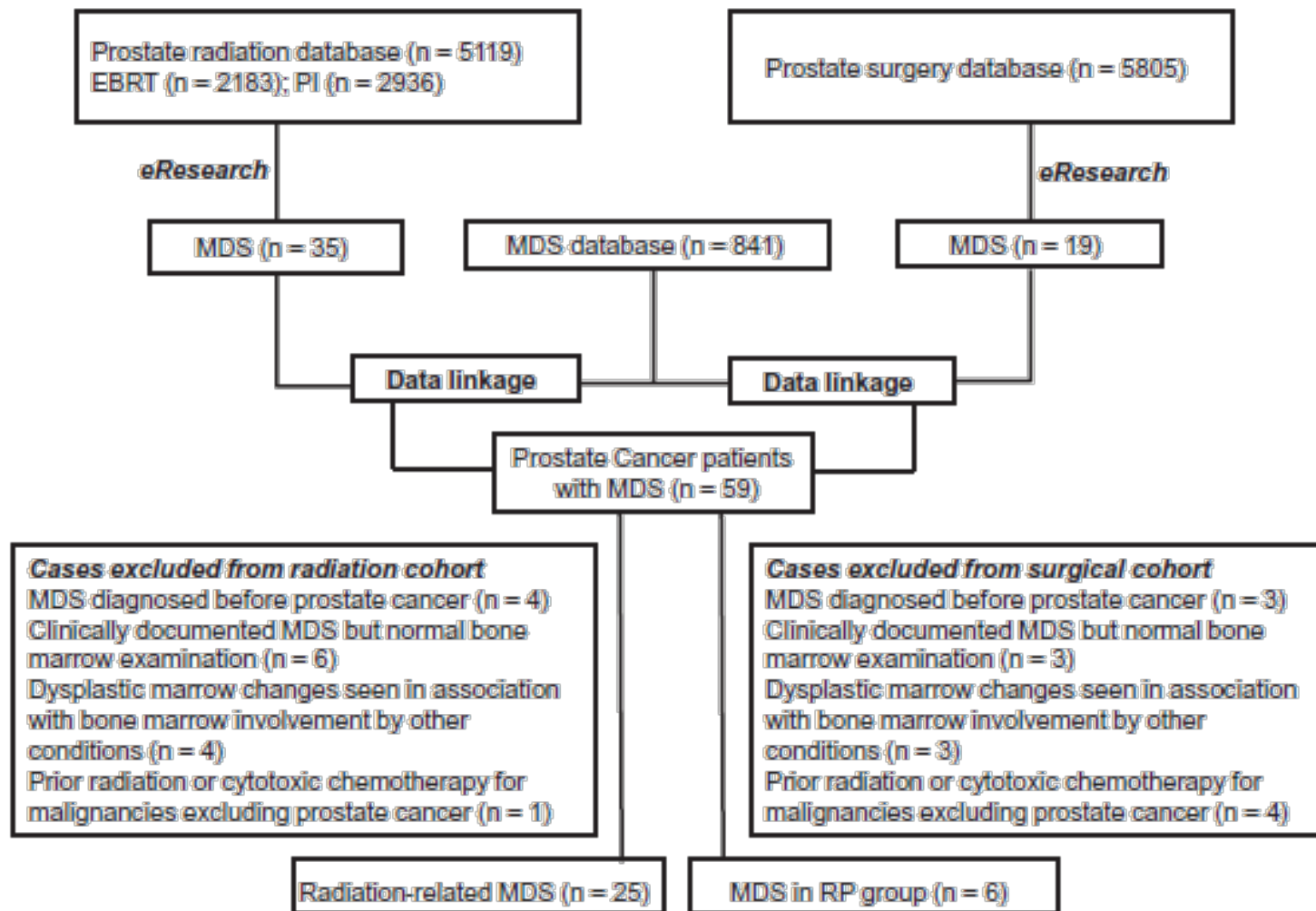
MDS Mutation Landscape



Cross-sectional analysis of 4,514 MDS patients in the U.S. in 2005-2007

Age (Median)	Newly diagnosed	71 years
	Established	72-75 years
Sex (Mean)	Male (Newly diagnosed)	55%
	(Established)	51-57%
Duration of MDS (Median)		13-16 months
MDS Status	Primary	88 – 93%
	Secondary	7 – 12%
Secondary	Chemotherapy	55 – 80%
Cause	Radiation	6 – 21%
	Chemical exposure	2 – 9%

MDS and Prostate Cancer Radiotherapy



MDS and Prostate Cancer Radiotherapy

	Risk regression model 2§		Risk regression model 4	
Age	1.13 (1.06 to 1.19)	<.001	1.20 (1.12 to 1.29)	<.001
BMI			1.12 (1.03 to 1.23)	.01
Radiation vs RP	1.63 (0.59 to 4.53)	.35	1.40 (0.26 to 7.67)	.70

MDS Risk Stratification

IPSS-R Cytogenetic Classification

Risk Group	Included karyotypes (19 categories)	Patients in group	Median survival (months)
Very good	del(11q), -Y	2.9%	60.8
Good	Normal, del(20q), del(5q) alone or with 1 other anomaly, del(12p)	65.7%	48.6
Intermediate	+8, del(7q), i17(q), +19, +21, any single or double anomaly not listed, two or more independent clones	19.2%	26.1
Poor	der(3q), -7, double with del(7q), complex (3 abnormalities)	5.4%	15.8
Very poor	Complex with ≥ 4 abnormalities	6.8%	5.9

Schanz J, et al., J Clin Oncol. 2012 Mar 10;30(8):820-9.; Greenberg PL, et al. Blood. 2012 Sep 20;120(12):2454-65.

 @AaronGerds



Scoring the IPSS-R

Parameter	Categories and associated score				
Cytogenetic risk group	Very Good	Good	Int	Poor	Very Poor
	0	1	2	3	4
Marrow blasts	≤ 2%	> 2% - < 5%	5% - 10%	>10%	
	0	1	2	3	
Hemoglobin	≥ 10 g/dL	8 - < 10 g/dL	< 8 g/dL		
	0	1	2		
Platelet count	≥ 100	50 - < 100	< 50		
	0	0.5	1		
ANC	≥ 0.8	< 0.8			
	0	0.5			

Scoring the IPSS-R

Prognostic variable	0	0.5	1	1.5	2	3	4
Cytogenetics	Very Good		Good		Int	Poor	Very Poor
BM Blast %	≤ 2		$>2 - <5\%$		5-10%	$>10\%$	
Hemoglobin	≥ 10		8- <10	<8			
Platelets	≥ 100	50- <100	<50				
ANC	≥ 0.8	<0.8					

IPSS-R Risk Groups

Risk group	Points	Patients	Median Survival (years)	Time until 25% develop AML (yr)
Very low	0 - 1.5	19%	8.8	NR
Low	> 1.5 - 3	38%	5.3	10.8
Intermediate	> 3 - 4.5	20%	3.0	3.2
High	>4.5 - 6	13%	1.6	1.4
Very High	> 6	10%	0.8	0.73

<http://www.ipss-r.com>

MDS Prognosis Made Easy!

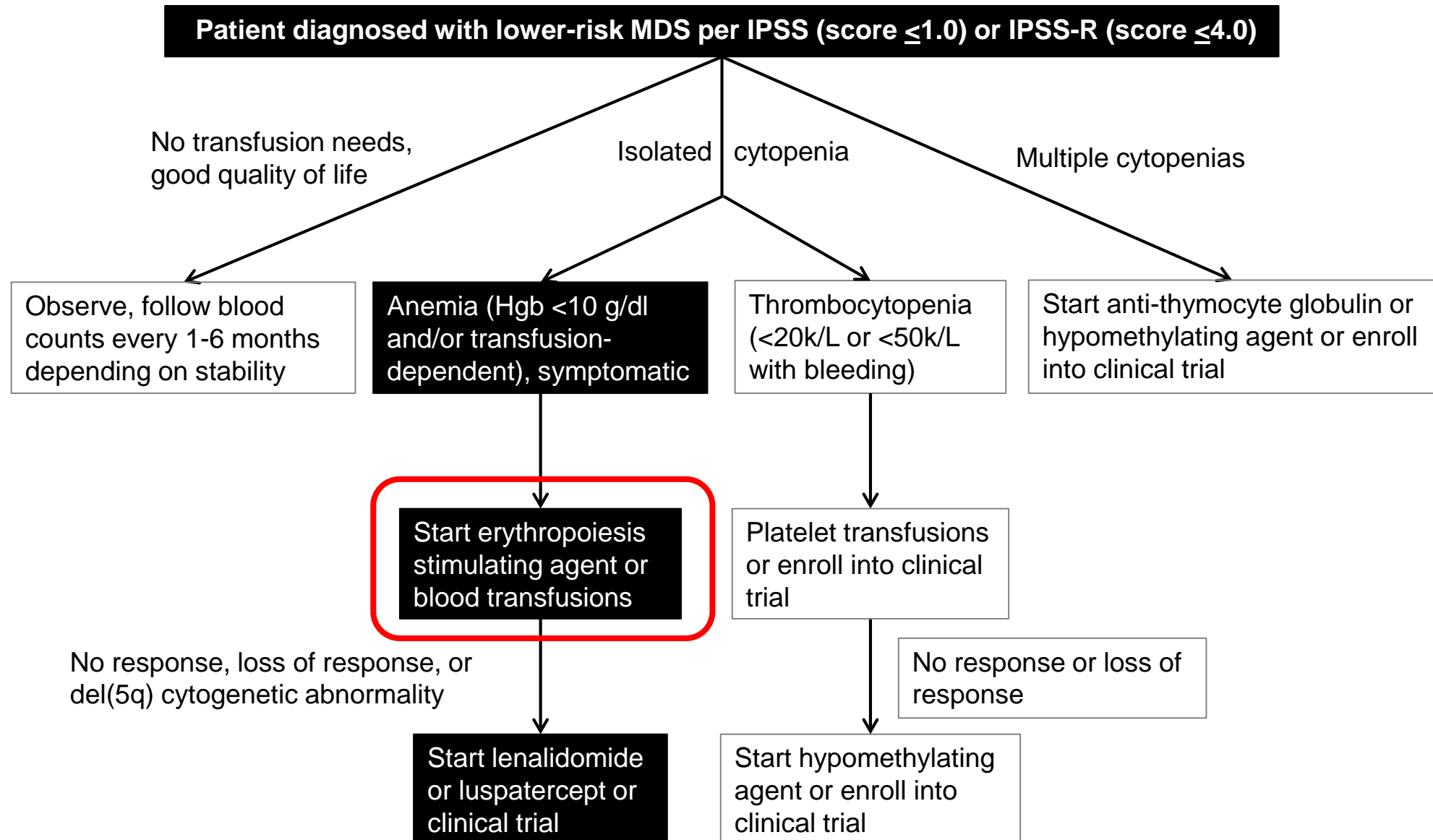
- **Lower Risk**

- MDS-SLD/MLD (*RA, RCMD, RCUD*)
- MDS-RS (*RARS*)
- MDS del (5q)
- MDS-U
- IPSS Low/Intermediate-1 (0-1.0)
- IPSS-R Very Low/Low/Intermediate (<3.5)

- **Higher Risk**

- MDS-EB-1, MDS-EB-2 (*RAEB-1, RAEB-2*)
- IPSS Int-2/High (>1.5)
- IPSS-R Intermediate/High/Very High (>3.5)

Treatment of Lower-risk MDS



Erythropoiesis Stimulating Agents

- Number of published regimens:
 - Erythropoietin 150 to 300 U/kg daily
 - Erythropoietin ≥ 150 U/kg three times weekly
 - Erythropoietin 40,000 U once per week
 - Darbepoetin alpha 75-400 mcg once/week
 - Darbepoetin alpha 500 mcg every 2-3 weeks
- Higher doses may be more effective than lower doses
- Responses may take up to 12-26 weeks

ORR for ESAs in MDS

	Patients (%)	Response rate	IWG response			Duration of response (median months, range)
			CR/PR	HI-E	HI-N/P	
Growth factors	100	39.5	9.1	66.8	24.1	18 (1–116)
EPO	57.3	39.4	6.1	93.9	–	17 (1–93)
EPO + GCSF	23.4	47.8	23.2	60.6	7.1	19 (2–62)
GMCSF	6.2	37.8	–	–	100	6 (1–18)
EPO + GMCSF	5.8	33.7	–	81.3	18.7	24 (1–116)
GCSF	3.0	47.9	–	4.5	95.5	3 (1–6)
IL3	3.0	17.0	–	–	100	3 (1–12)
IL6	1.3	38.1	–	–	100	5 (2–14)

Overall Response Rate ~40%

Predictive Model for ESA + GCSF

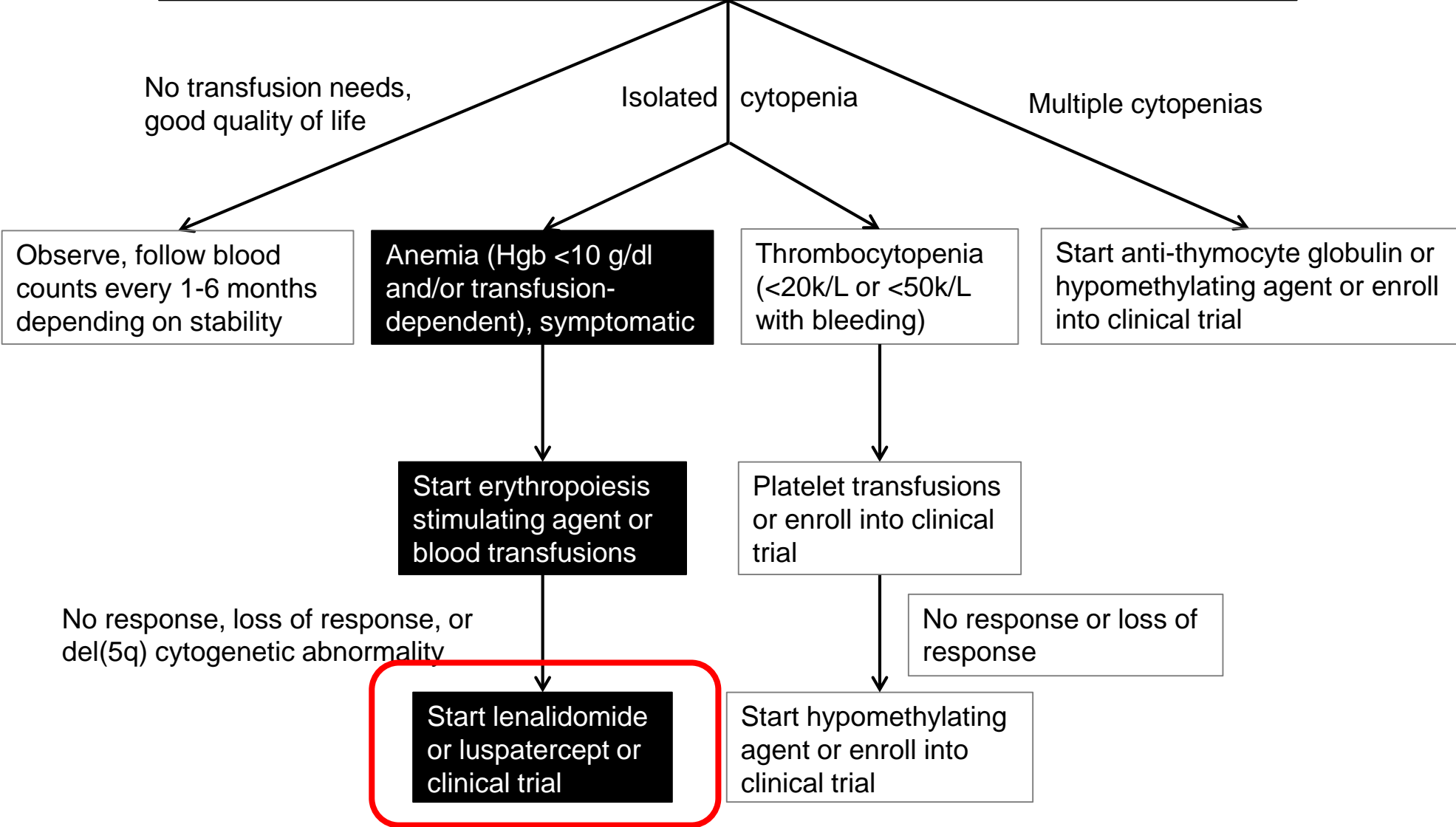
- Nordic MDS Group [N = 98]

Parameter	Points			
	+2	+1	-2	-3
Serum Epo (mU/mL)	< 100	100 - 500		> 500
RBC Transfusions	< 2 units/mo		≥ 2 units/mo	

Points	Patients	% Response
≥ 2	29	74%
-1 to 1	31	23%
< -1	34	7%

Hellstrom-Lindberg et al, Br J Haematol 1997; 99: 344.

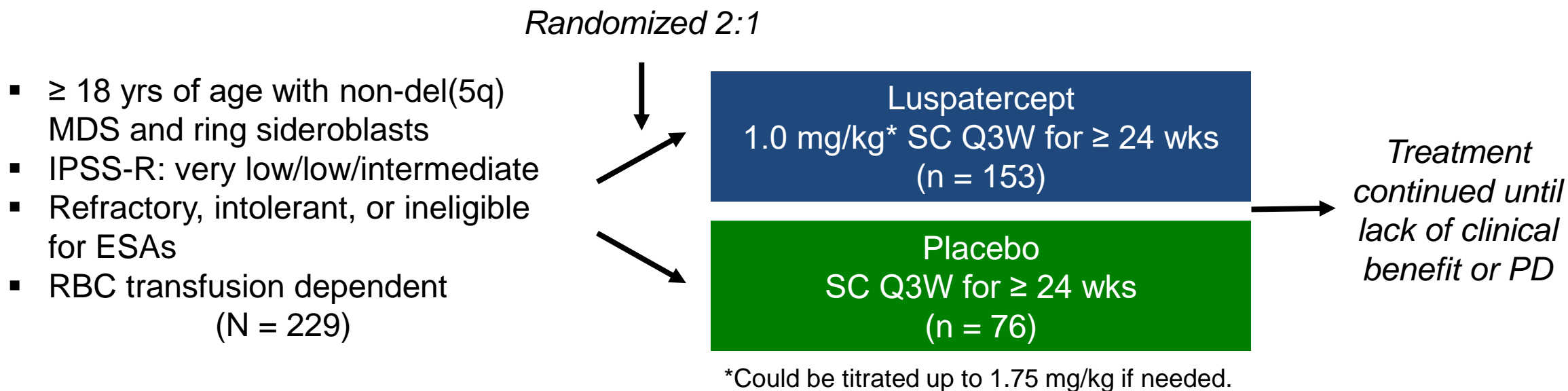
Patient diagnosed with lower-risk MDS per IPSS (score ≤ 1.0) or IPSS-R (score ≤ 4.0)



Luspatercept (Approved 4/3/2020)

- For the treatment of anemia
 - After ESA *AND*
 - Requiring ≥ 2 RBC units over 8 weeks *IN*
 - Very low- to intermediate-risk MDS-RS *OR* MDS/MPN-RS-T

MEDALIST: Study Design



Primary endpoint: RBC TI for ≥ 8 wks between Wk 1 and Wk 24

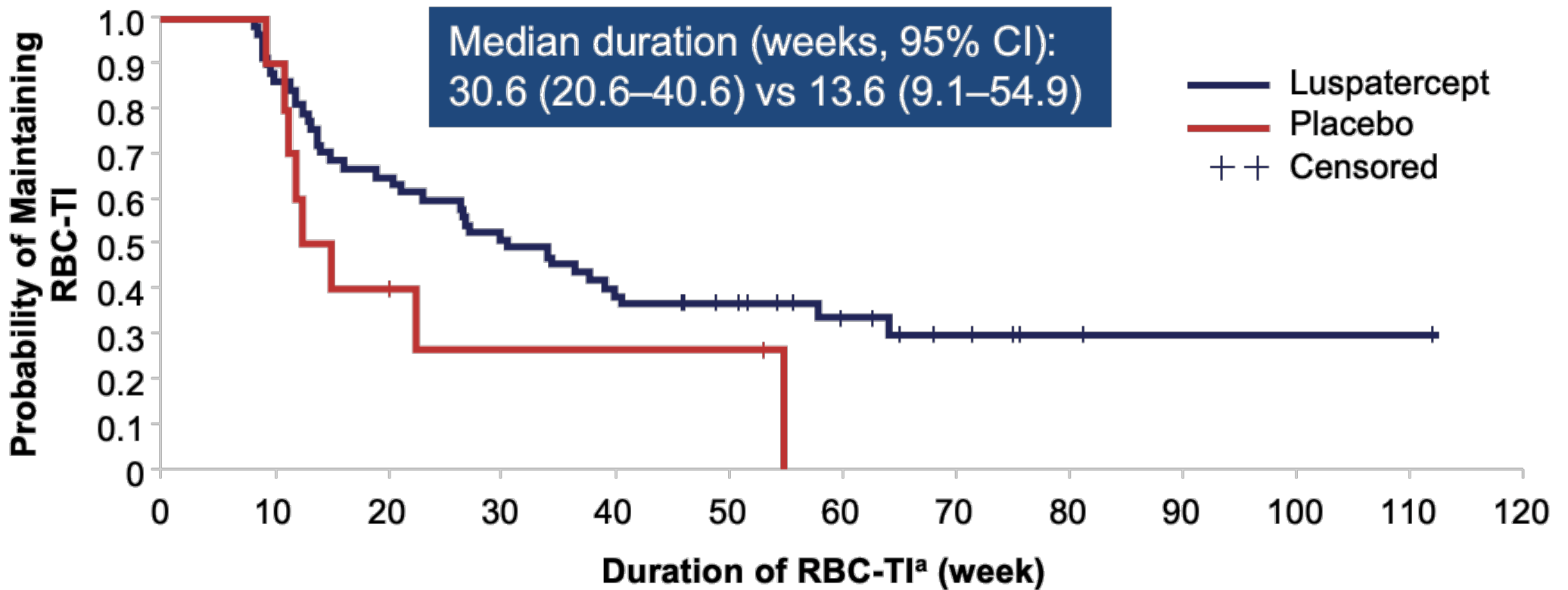
MEDALIST Trial: Primary Endpoint: RBC Transfusion Independence \geq 8 Weeks

RBC-TI \geq 8 weeks	Luspatercept (n = 153)	Placebo (n = 76)
Weeks 1–24, n (%)	58 (37.9)	10 (13.2)
95% CI	30.2–46.1	6.5–22.9
<i>P</i> -value ^a	< 0.0001	

^a Cochran–Mantel–Haenszel test stratified for average baseline RBC transfusion requirement (\geq 6 units vs $<$ 6 units of RBCs/8 weeks) and baseline IPSS-R score (Very Low or Low vs Intermediate).

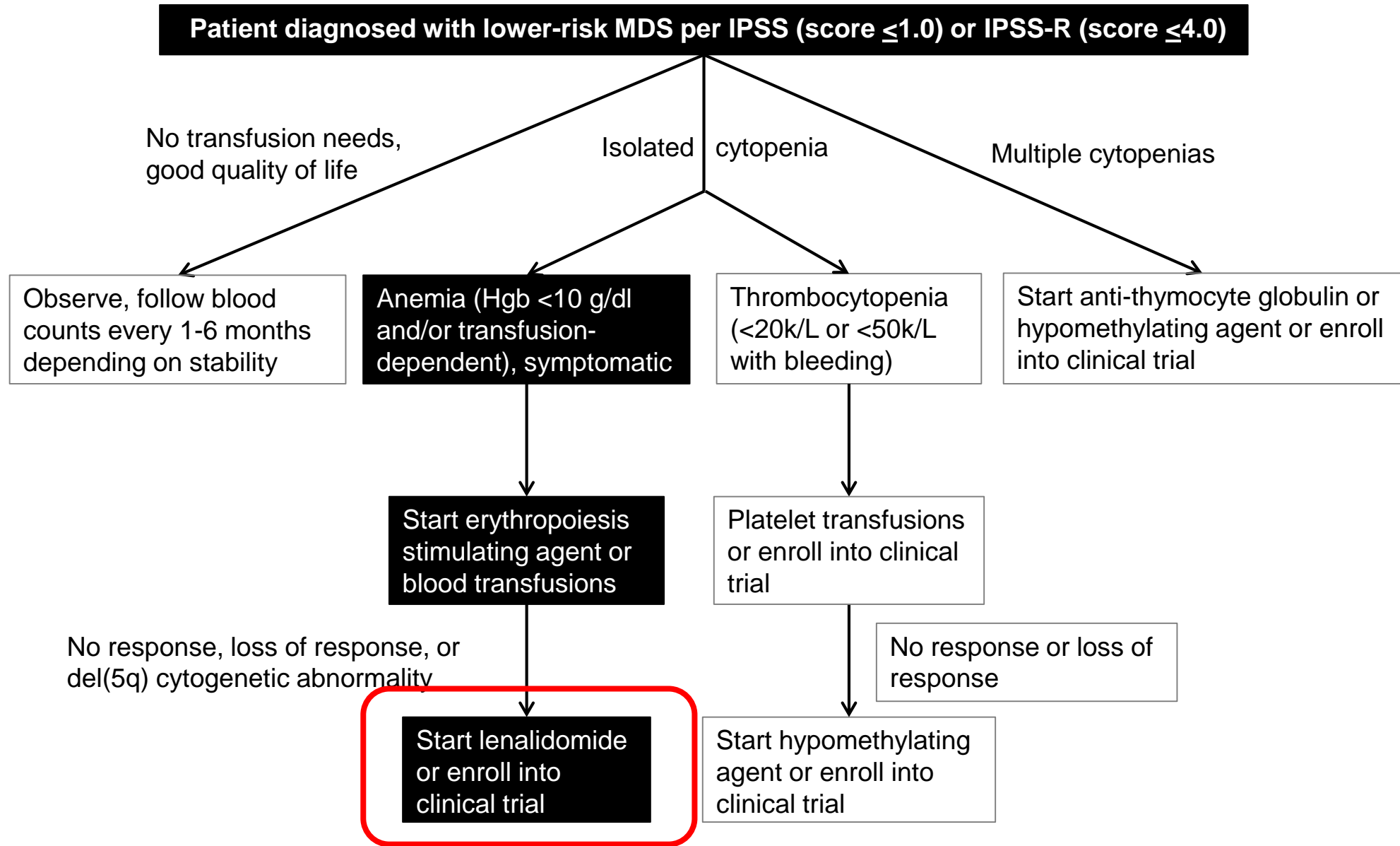
CI, confidence interval.

MEDALIST Trial: Duration of RBC-TI Response in Primary Endpoint Responders

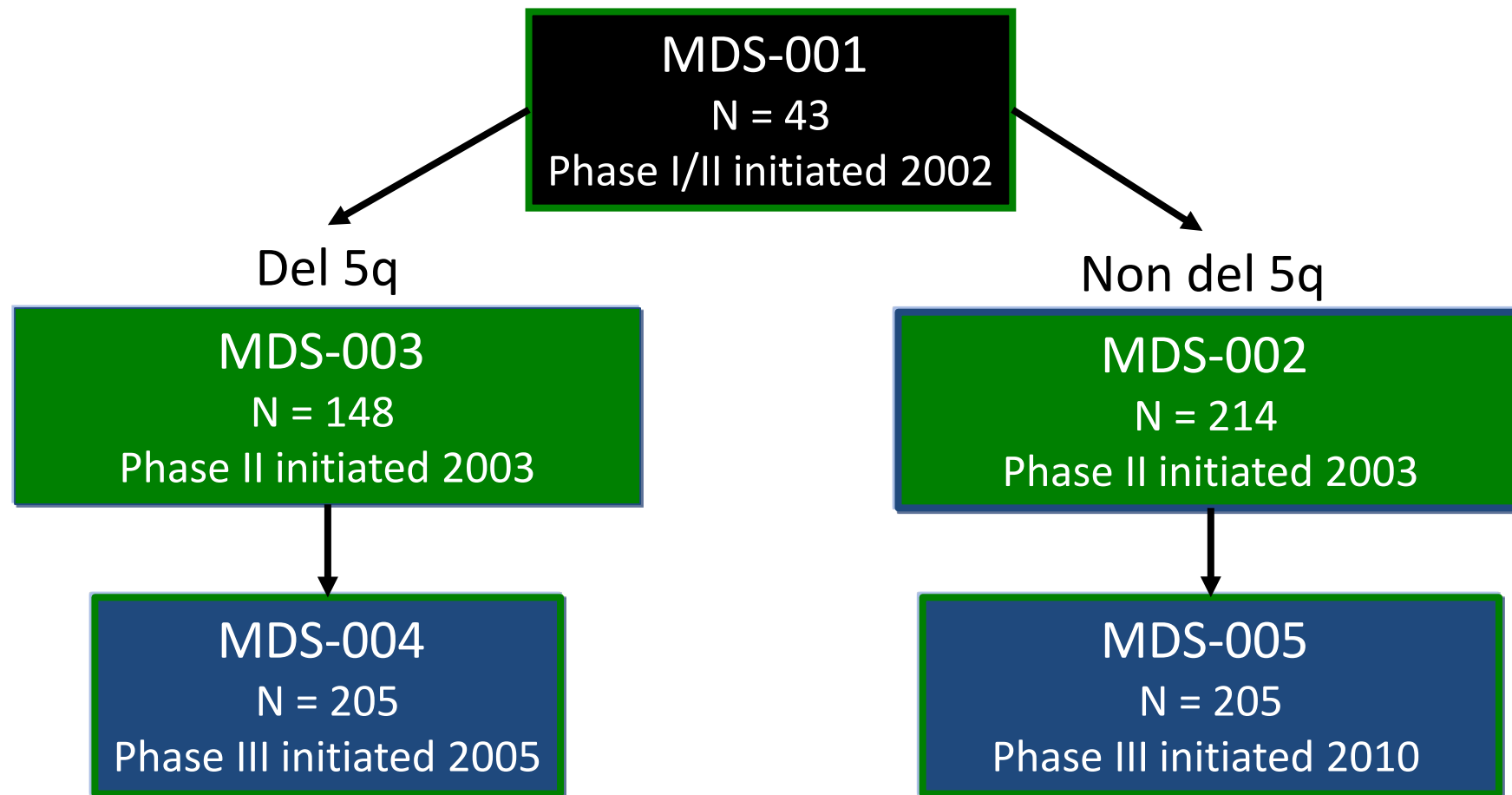


Number of patients

Luspatercept	58	49	37	29	22	18	10	6	3	2	1	1	0
Placebo	10	9	3	2	2	2	0						

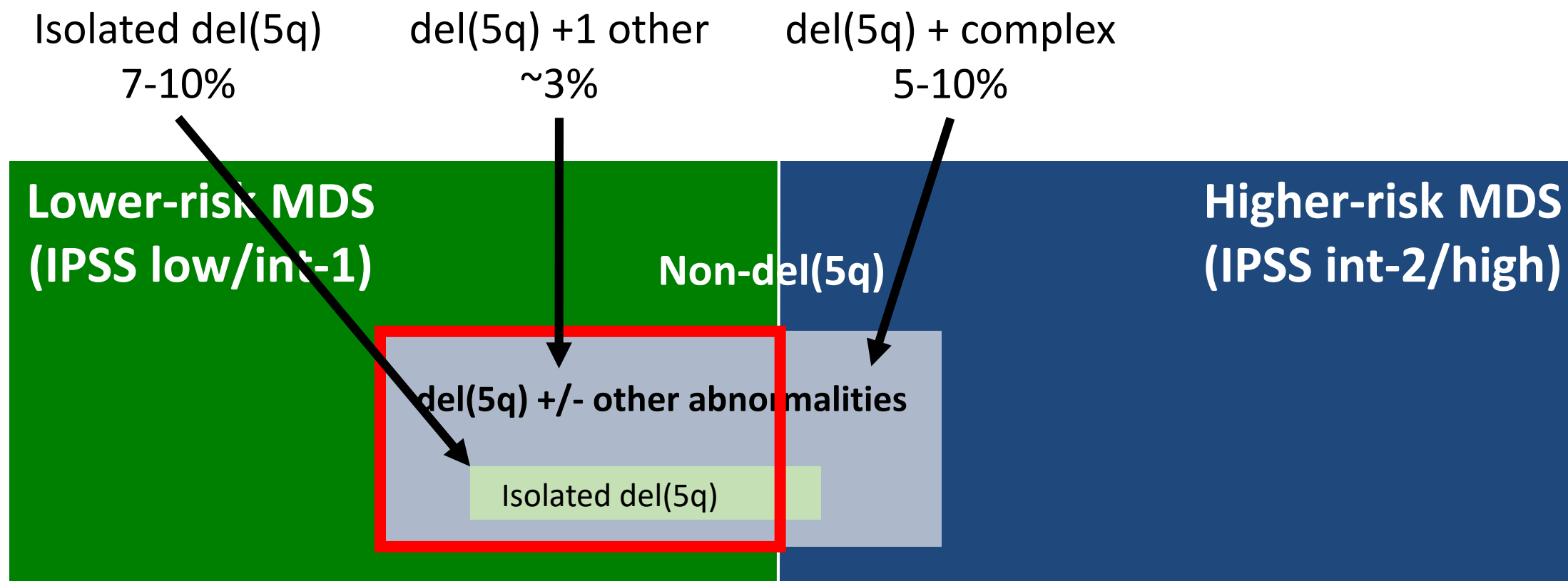


Development of IMiDs for MDS

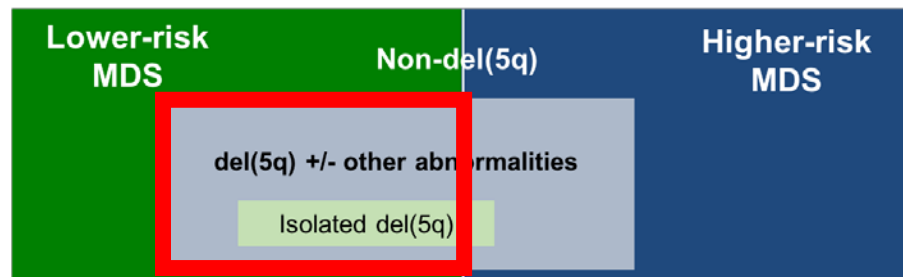


US FDA Indication for Lenalidomide

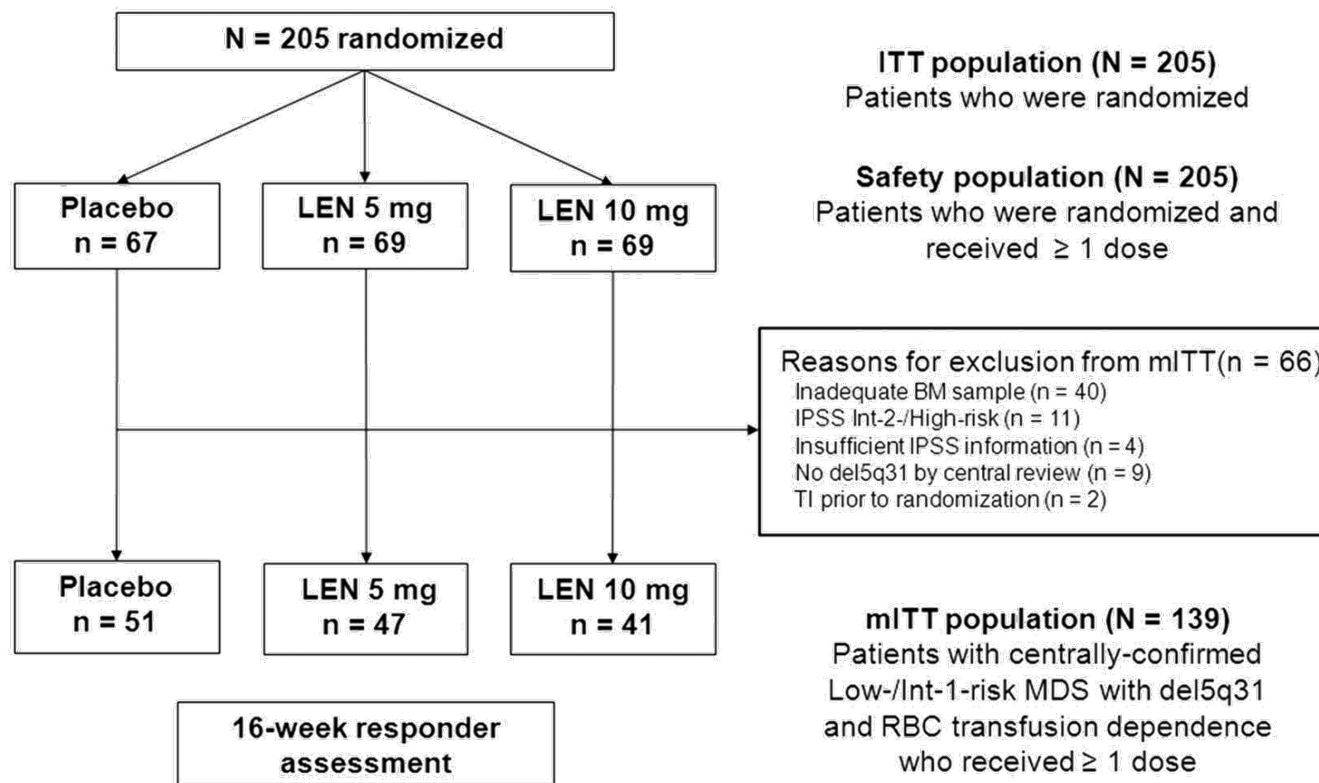
Warning: This figure is not to scale!



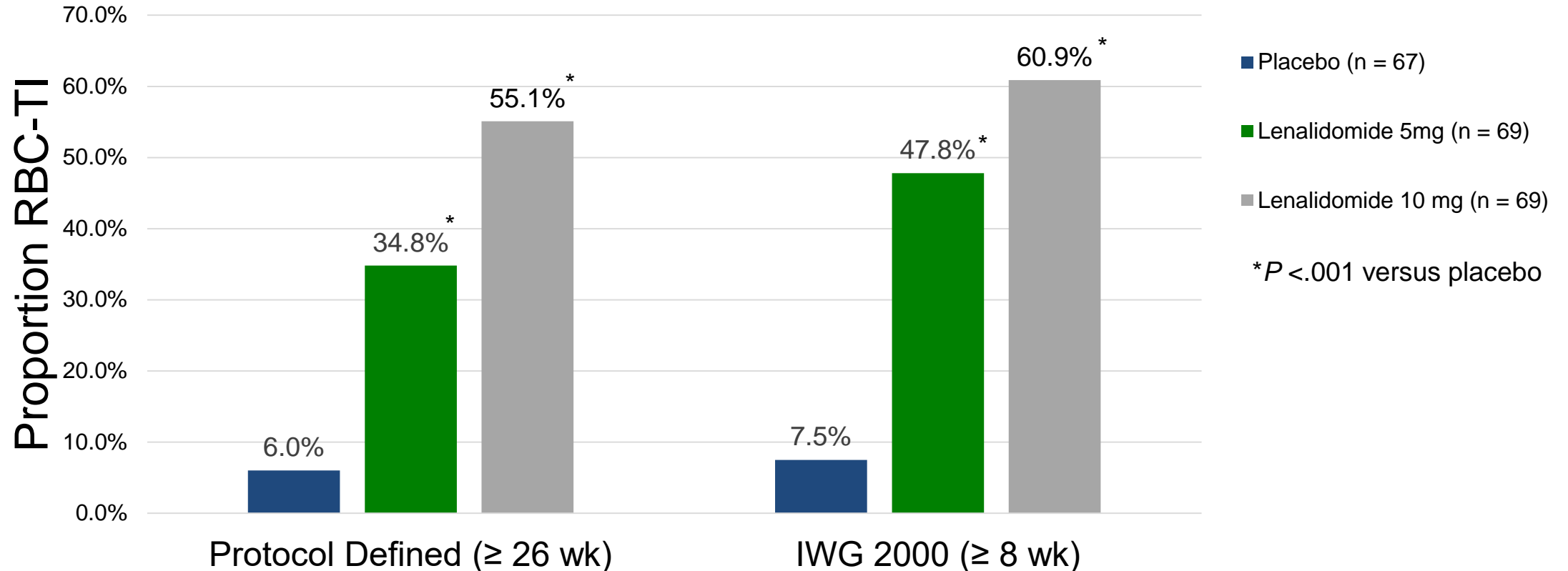
MDS-004 Study



- RBC-Transfusion dependent anemia
- Lenalidomide
 - 10 mg/day days 1 - 21
 - 5 mg/day days 1 - 28
 - Placebo



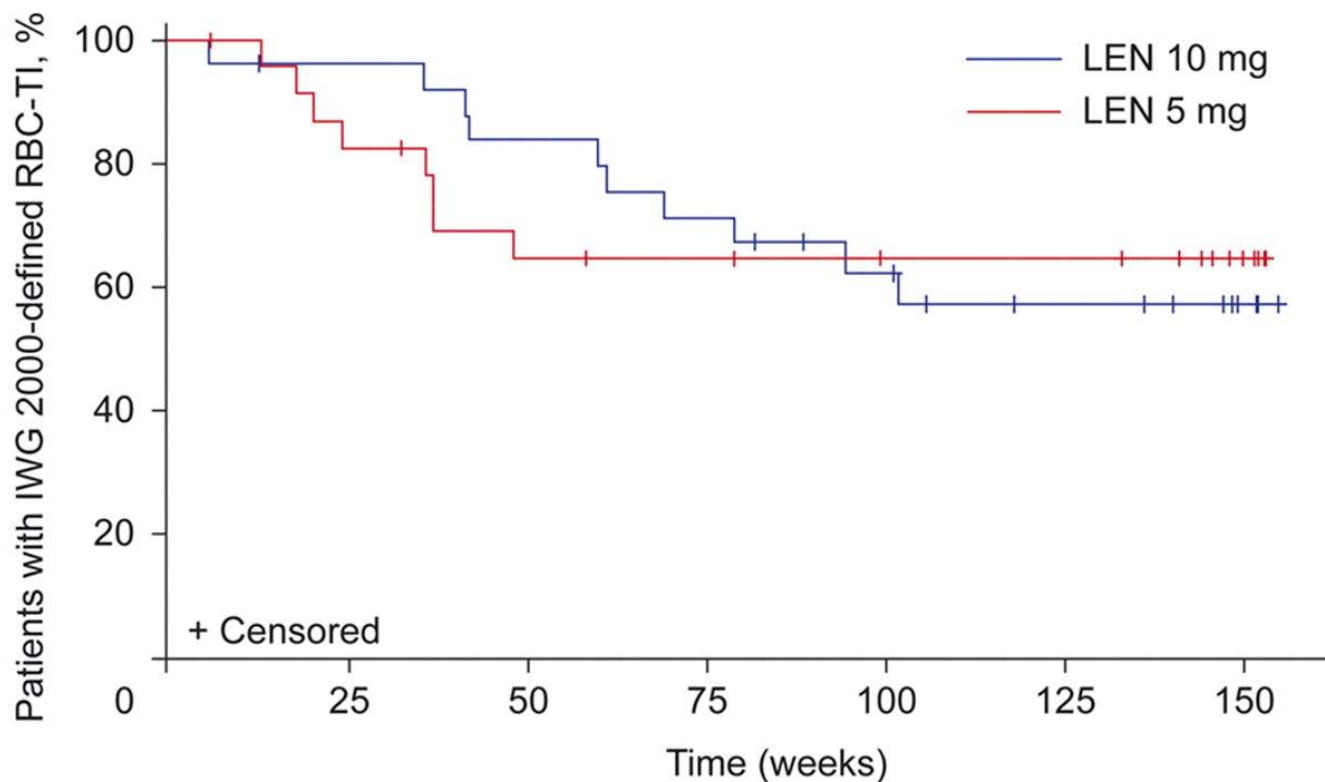
MDS-004 Study: Erythroid Response by RBC-TI



52% pre-treated with ESA, median time from diagnosis to enrolment 2.7 years (0.2-17.2)

MDS-004 Study: Response Duration

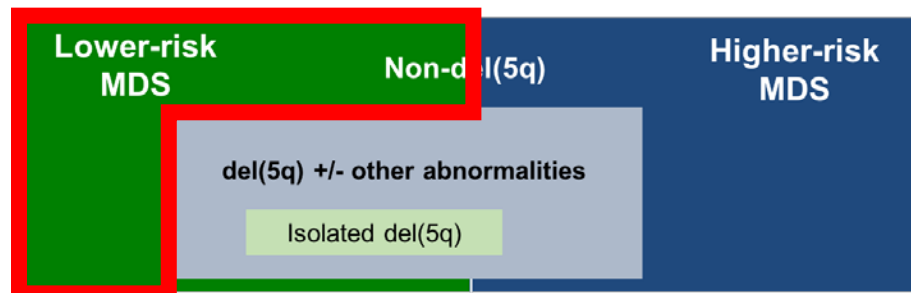
- Median (95% CI) duration of RBC-TI:
 - LEN 5mg: NR weeks (41.3-NR)
 - LEN 10mg: NR weeks (82.9-NR)
- 30% patients on LEN 10mg had a major cytogenetic response (20% minor)



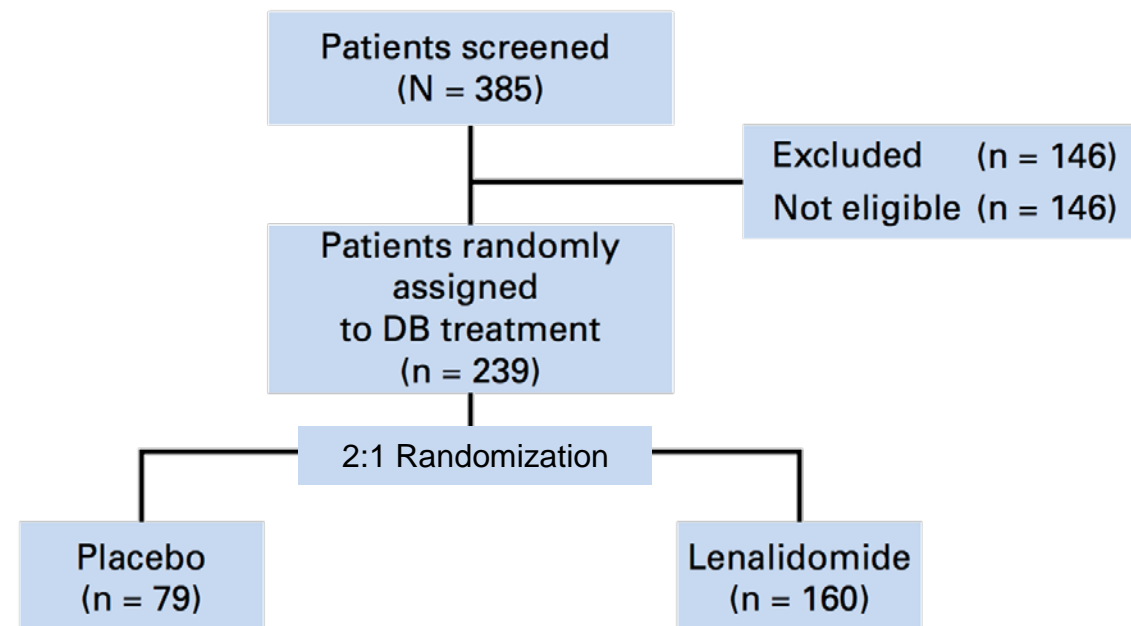
Patients at risk, n

LEN 10 mg	25	23	20	17	13	9	7
LEN 5 mg	24	20	15	13	12	11	7

MDS-005 Study

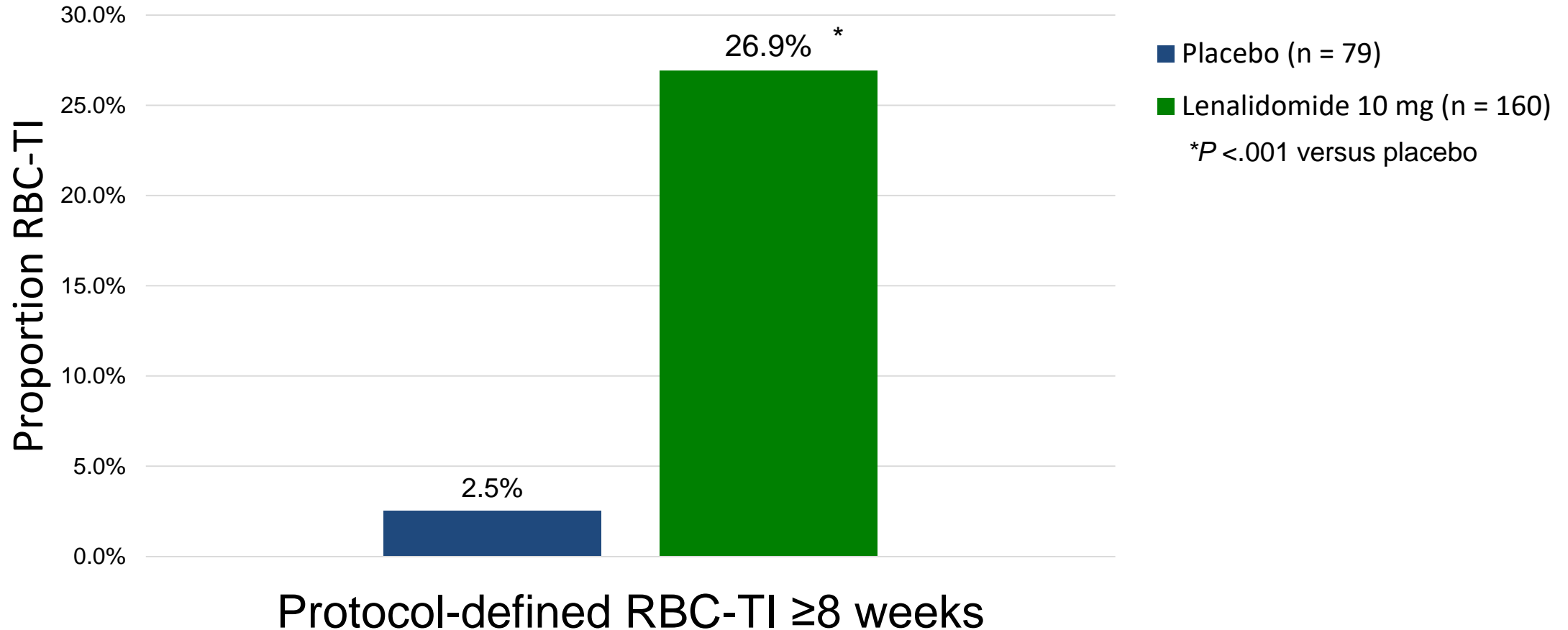


- RBC-Transfusion dependent anemia
- R/R or unlikely to respond to ESA
- Lenalidomide
 - 10 mg/day days 1 - 28
 - Placebo

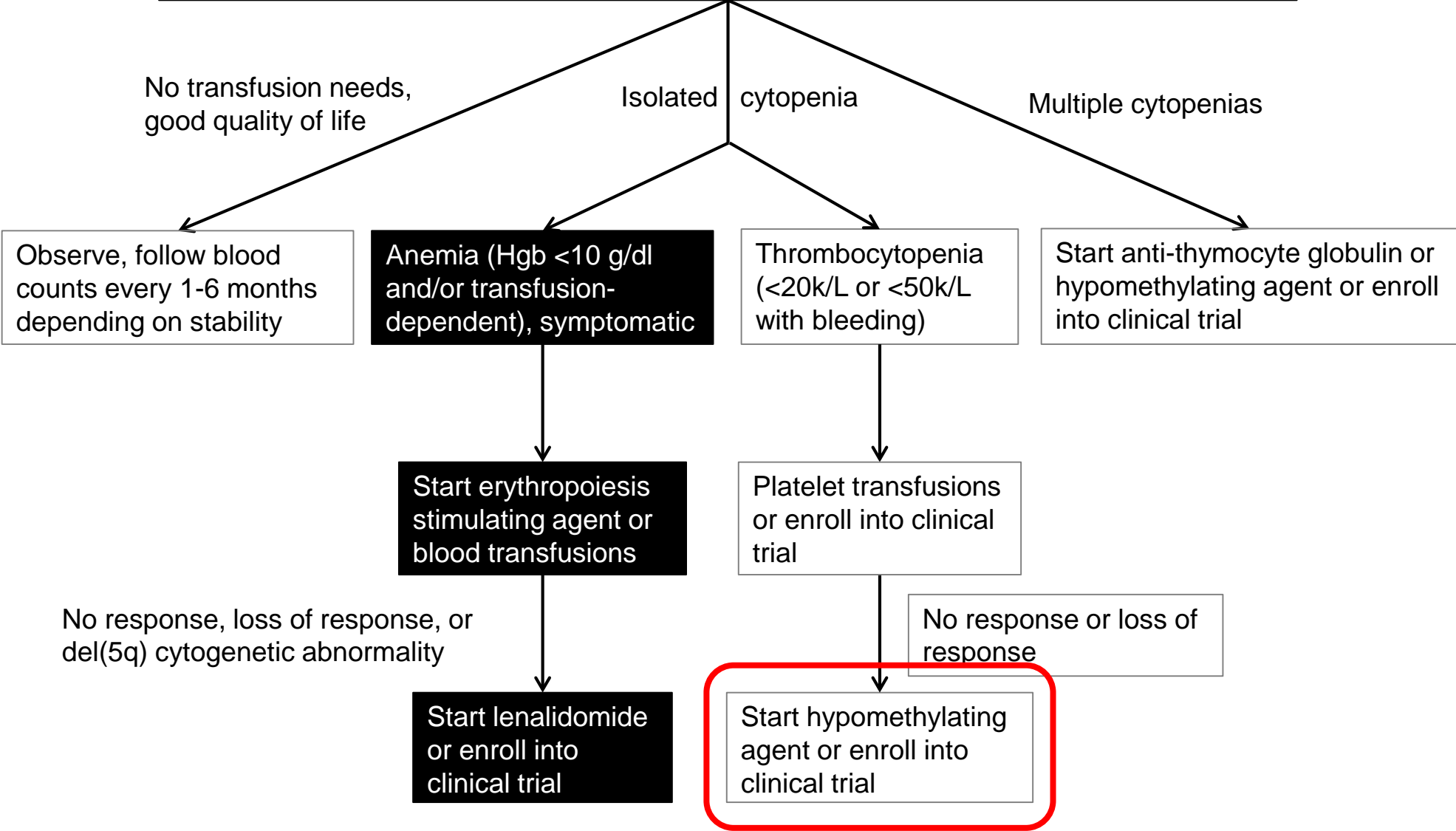


Somatic mutations (n = 198)	
SF3B1	58.6%
TET2	33.3%
ASXL1	23.2%
DNMT3A	13.6%

MDS-005 Study: Erythroid Response by RBC-TI



Patient diagnosed with lower-risk MDS per IPSS (score ≤ 1.0) or IPSS-R (score ≤ 4.0)



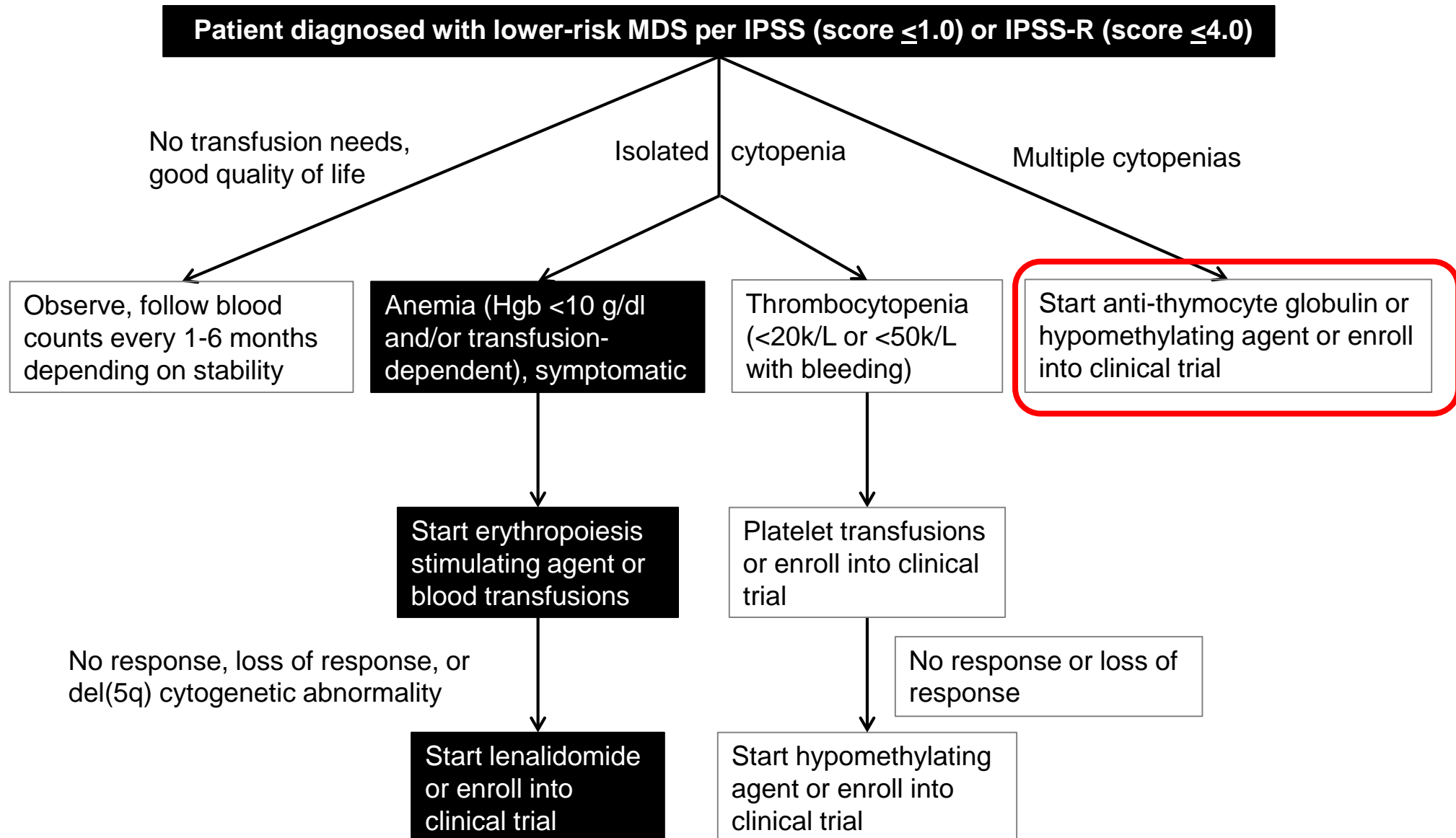
Low-Dose HMA for LR-MDS

- Regimens:
 - DAC 20 mg/m² IV D1-3 every 4 weeks
 - AZA 75 mg/m² IV/SC D1-3 every 4 weeks
- Response assessment by modified IWG 2006
- Between 11/2012 and 10/2015, 91 pts with LR-MDS treated and evaluable for response
- Median duration of follow-up = 14 months (range: 2-30 months)

Low-Dose HMA for LR-MDS

Response	N (%)
CR	33 (36)
mCR	8 (9)
HI	13 (14)
ORR	54 (59)
SD	31 (34)
PD	6 (7)

- Median time to best response: 2 months (range: 1-20)
- Median number of cycles received: 9 (range: 2-32)



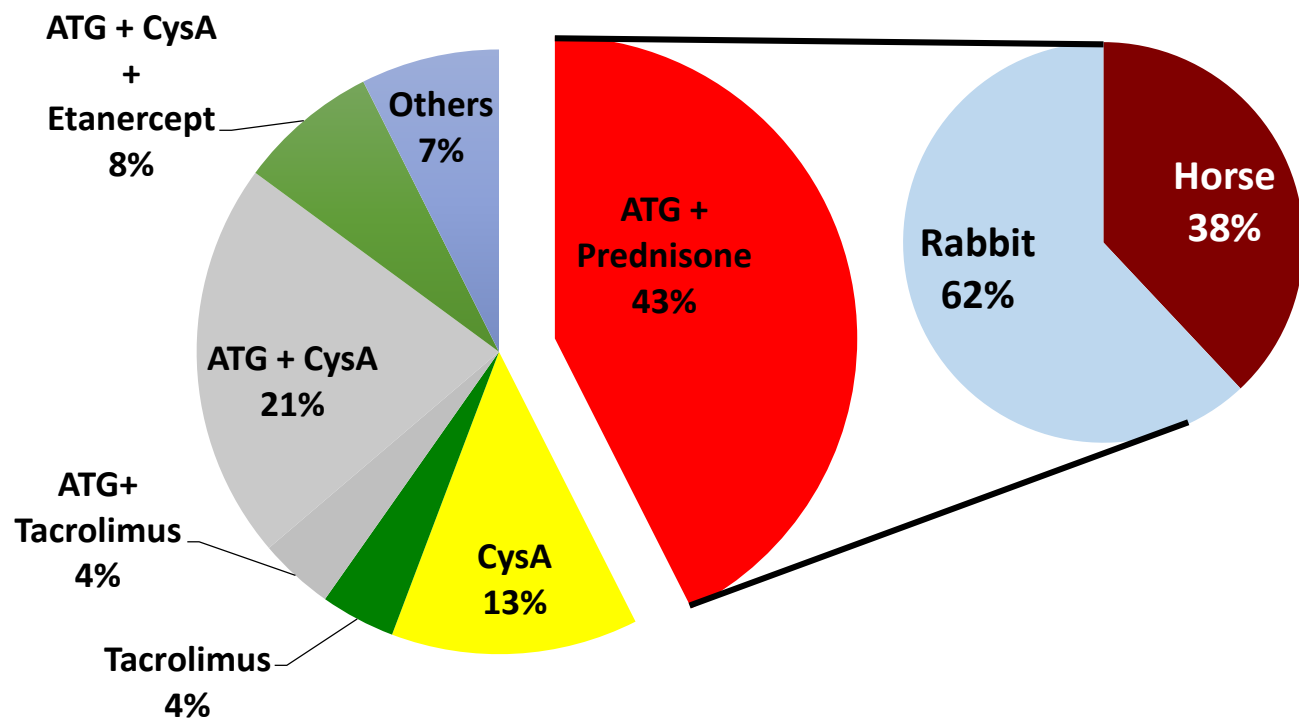
Anti-thymocyte Globulin for MDS

A retrospective cohort, International, multi-center, study
13 Centers: 8 USA and 5 Europe



Anti-thymocyte Globulin for MDS

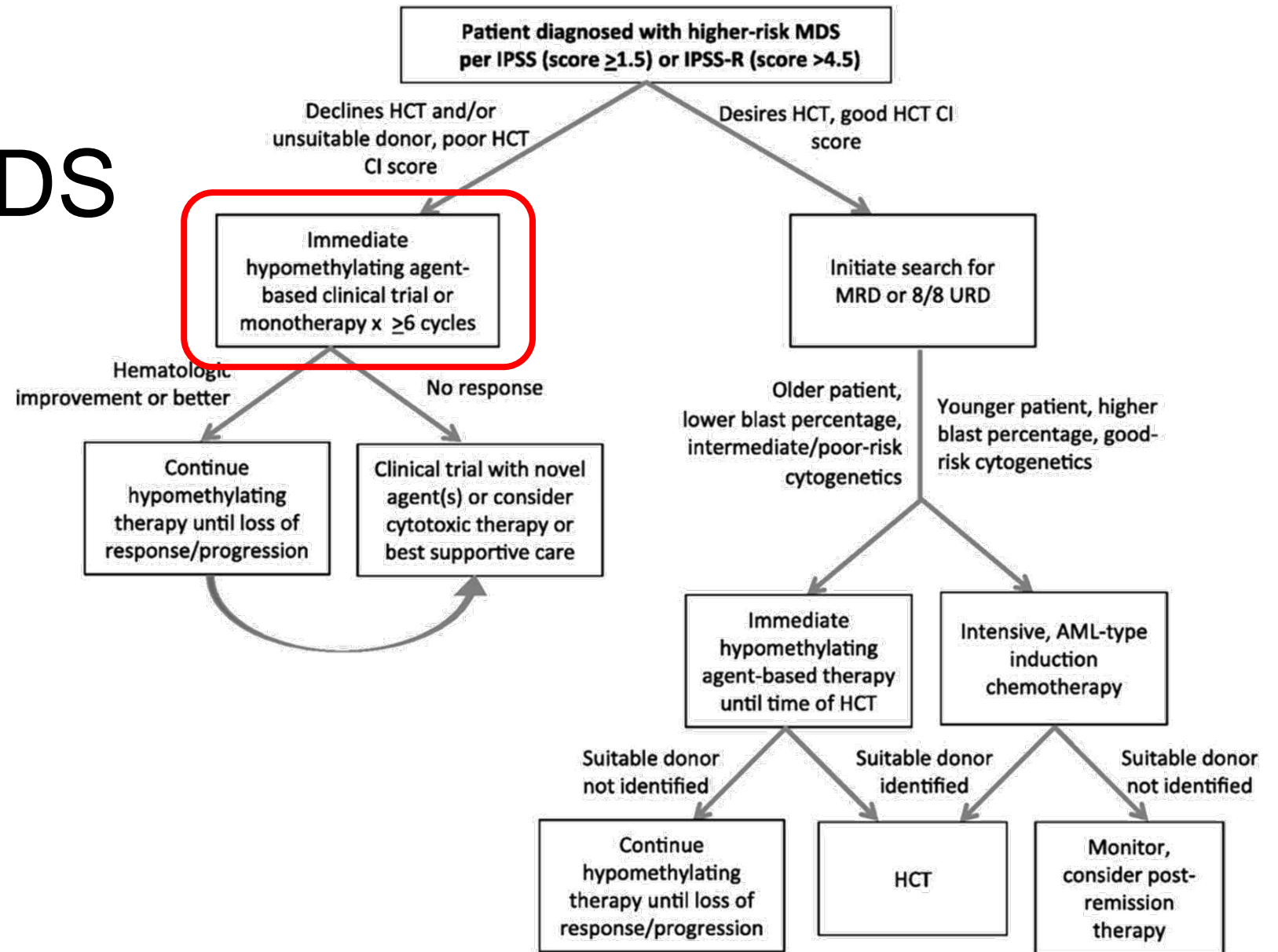
166 patients treated with ATG



Response	%	95%CI
CR	11.2	6.5-18.4
PR	5.6	2.5-11.6
HI	32.0	24.1-41.0
SD	39.2	30.7-48.4
PD	12.0	7.1-19.3
ORR	48.8	39.8-57.9

Treatment of Higher-risk MDS

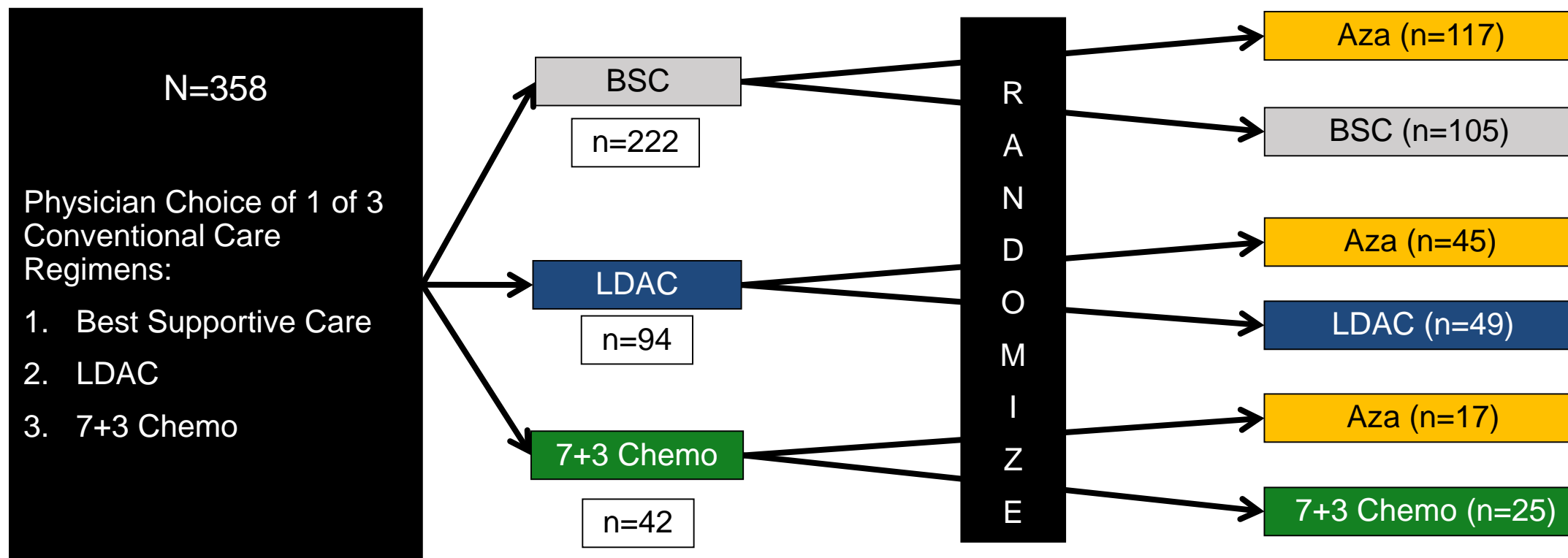
Treatment of Higher-risk MDS



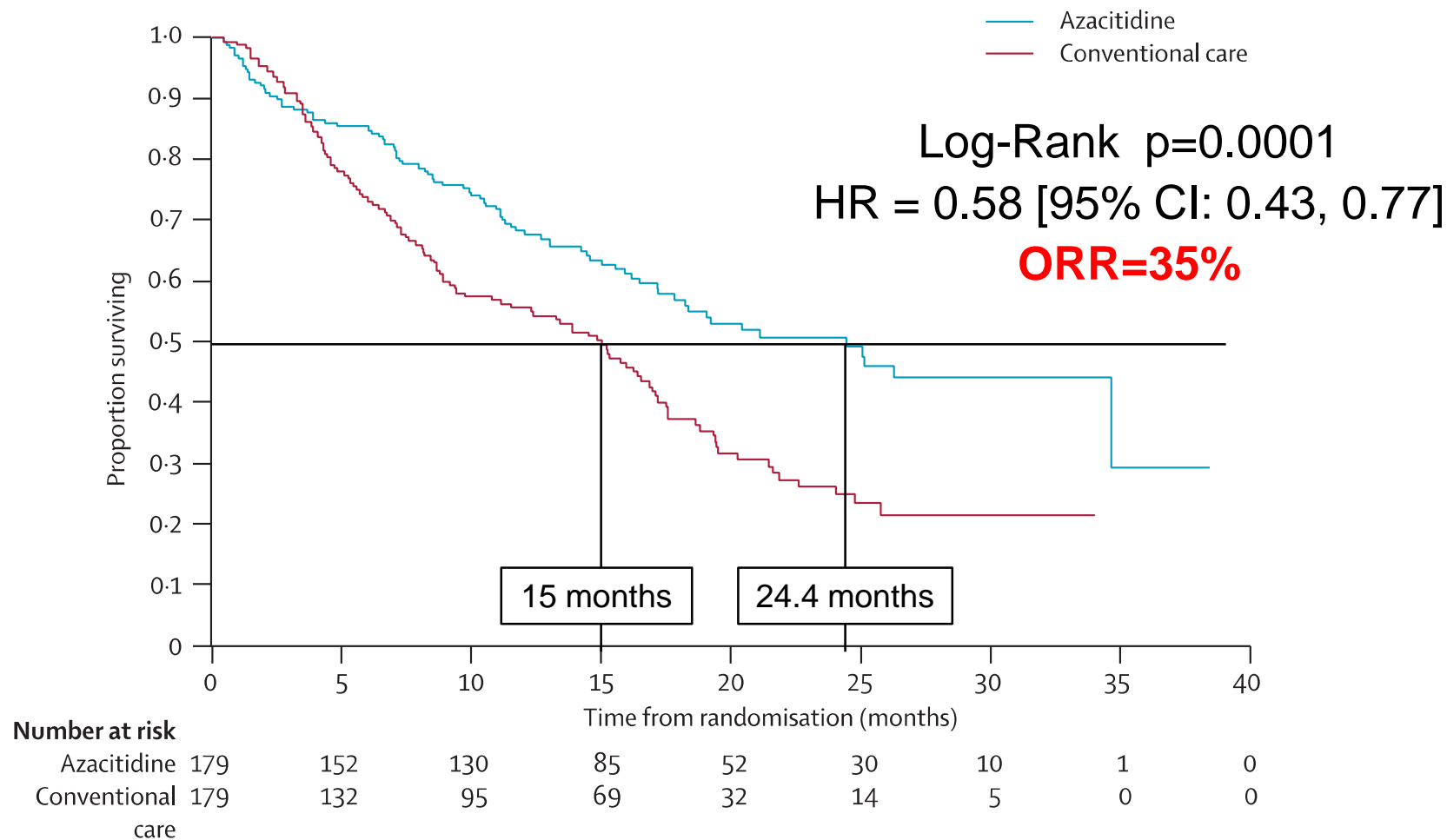
Hypomethylating Agents

- Azacitidine and decitabine
 - Favorable toxicity profile
 - Outpatient administration
 - Delay progression of MDS to AML
 - Shown survival advantage over conventional care (azacitidine)

AZA-001 Randomization Schema

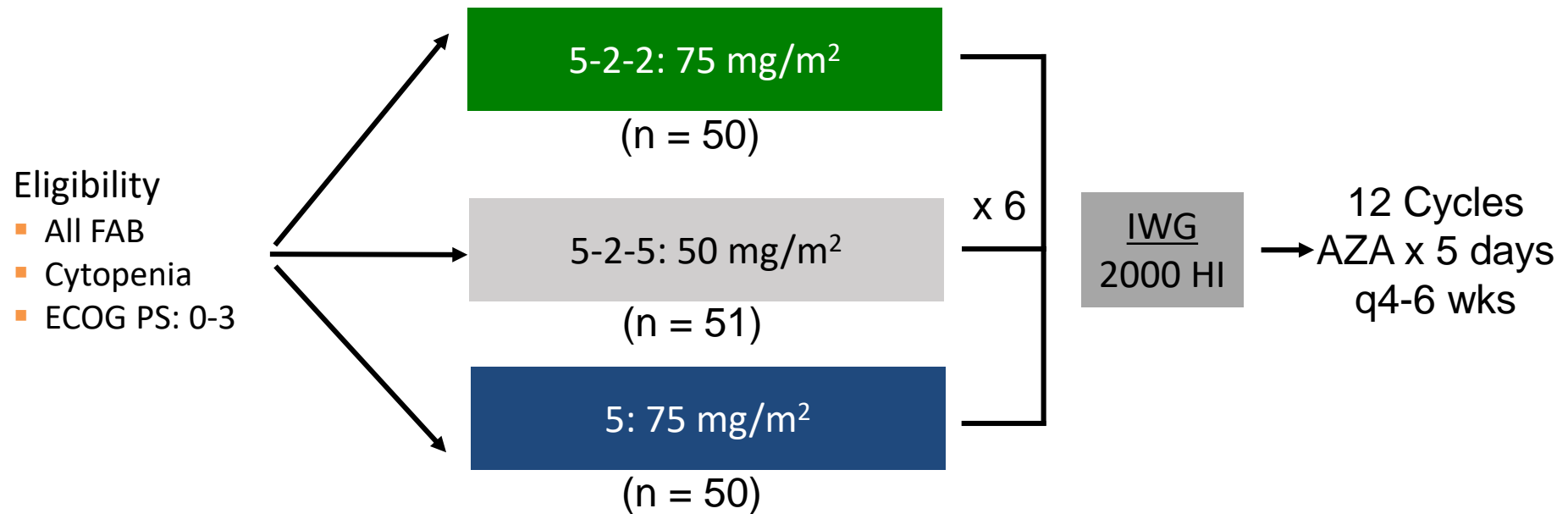


AZA-001 Overall Survival

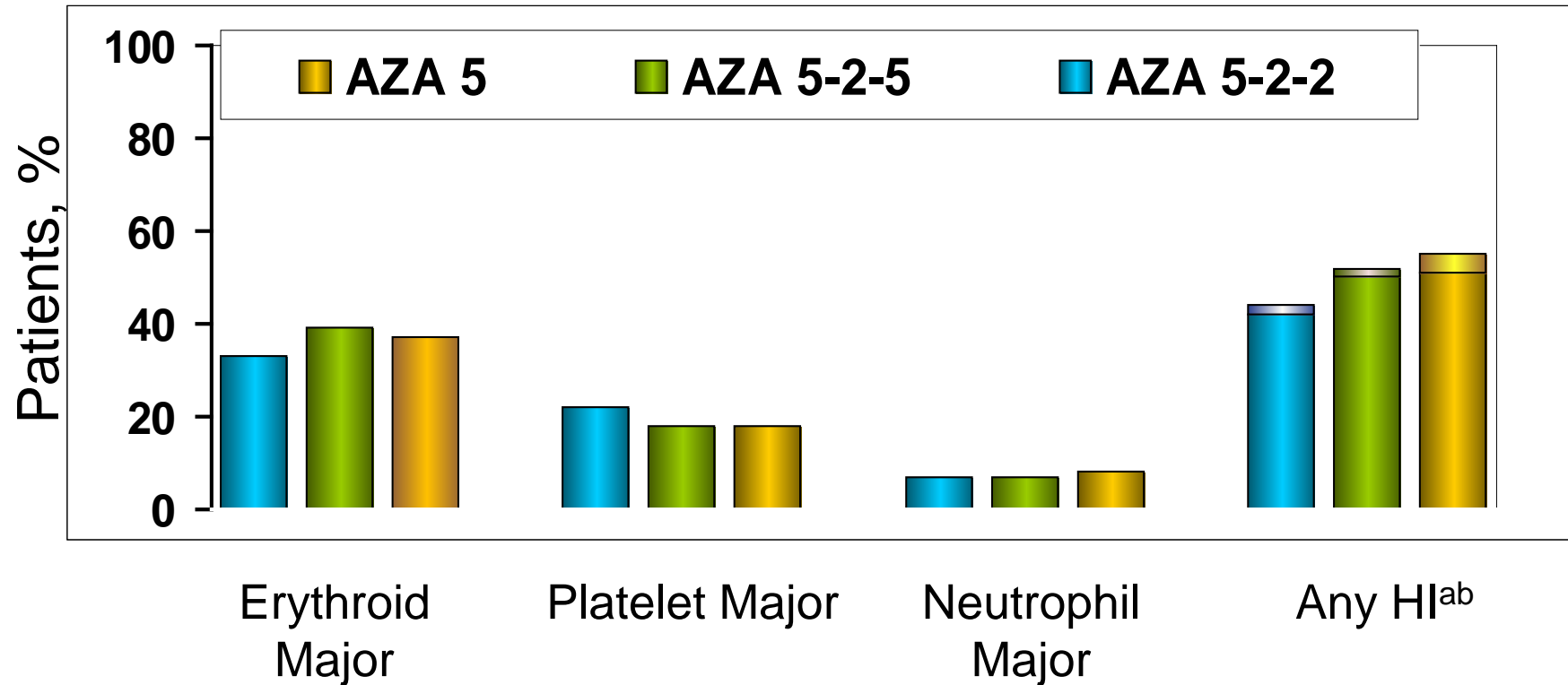


Randomized Phase II Study of Alternative AZA-002 Dose Schedules

Study Design (N = 151)



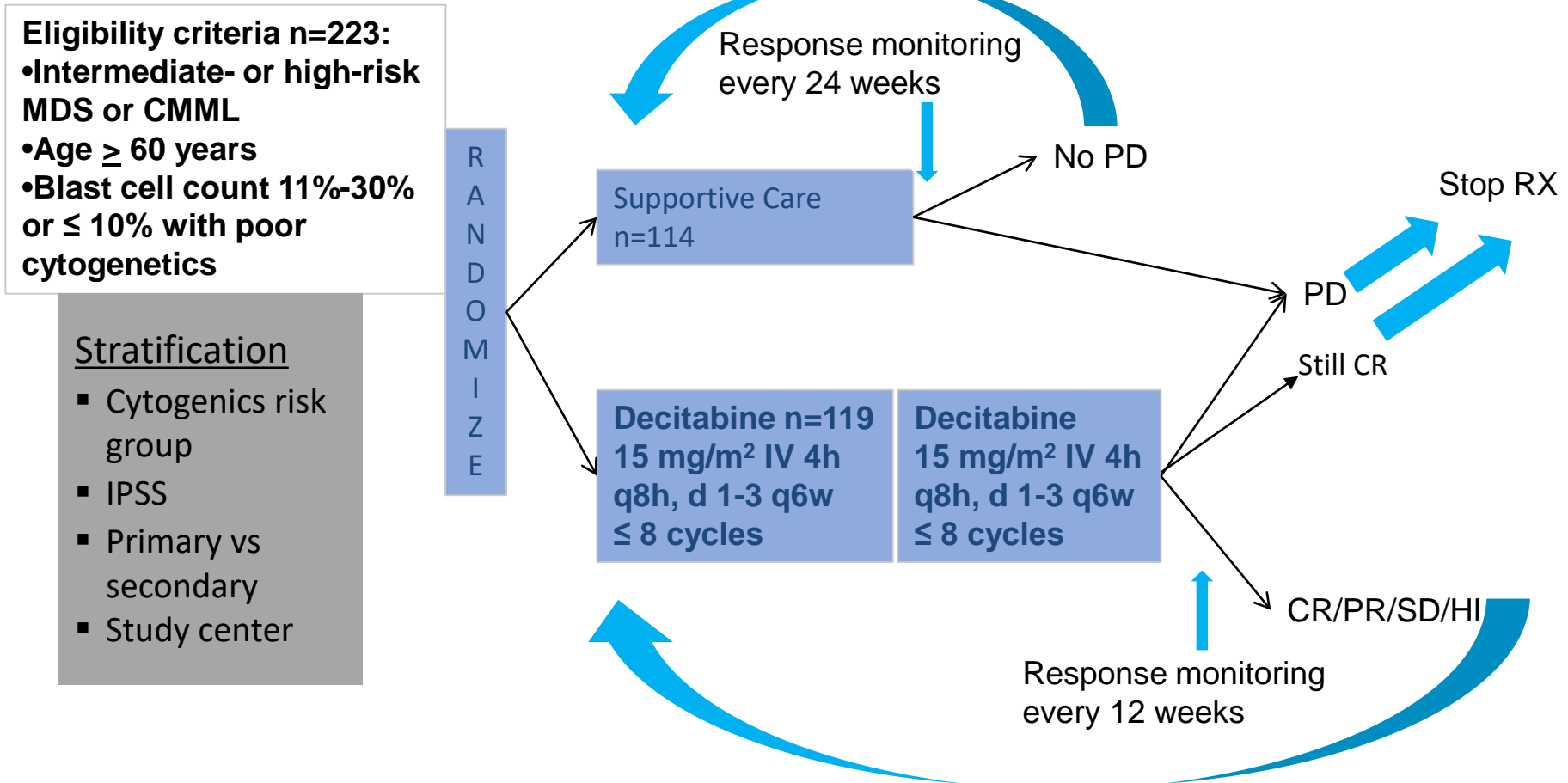
AZA-002: Hematologic Improvement



^a Patients counted only once for best response in an improvement category.

^b Minor improvement at top of HI columns.

Randomized Phase III Study of Low-Dose Decitabine for Patients With Higher-Risk MDS EORTC-06011

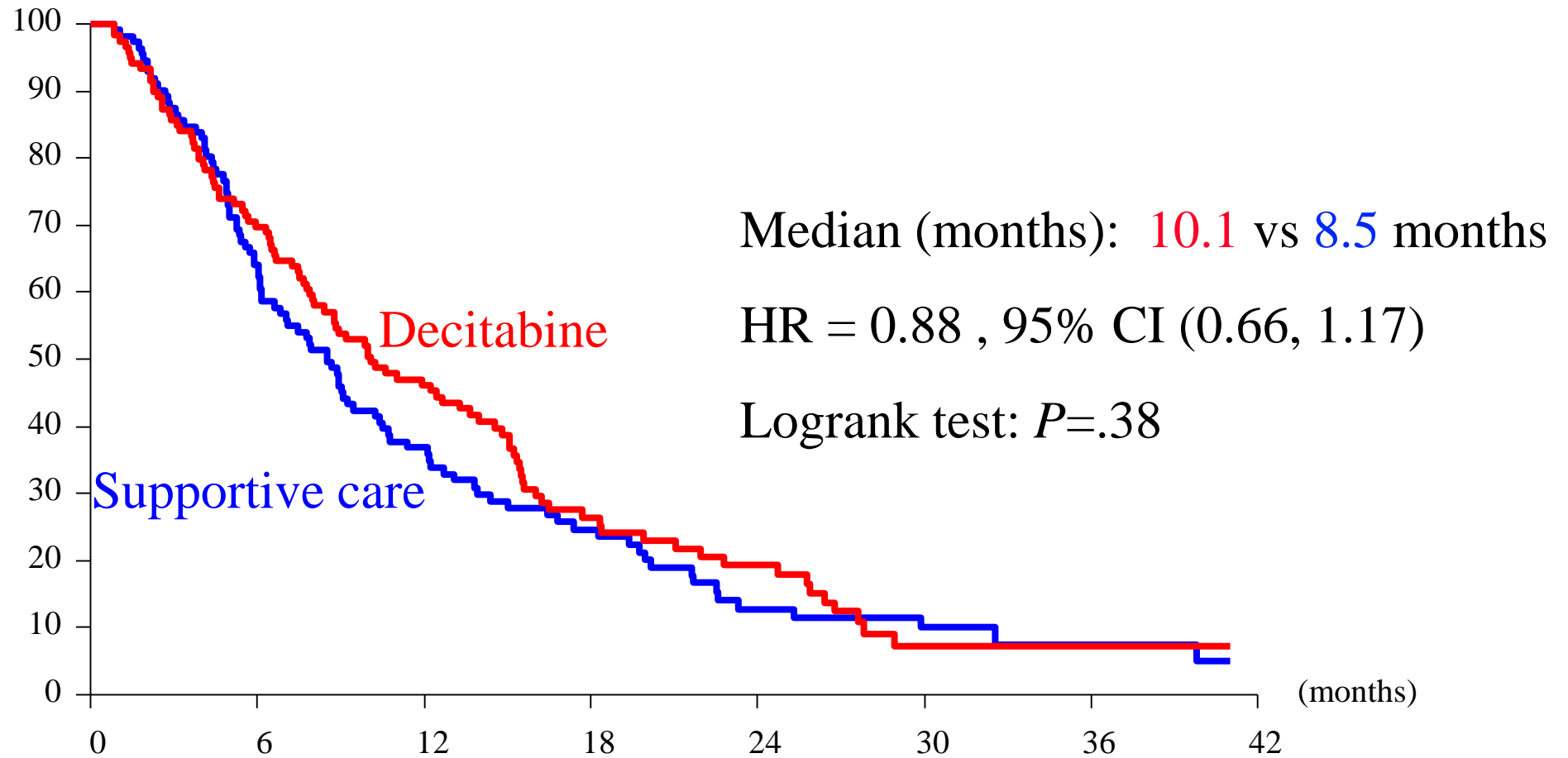


EORTC-06011 Reason for going off-protocol

	Supportive care N=114 (100%)	Decitabine N=119 (100%)
Normal completion	19 (16.7%)	31 (26.1%)
Progression of disease	55 (48.2%)	40 (33.6%)
Toxicity	NA	19 (16.0%)
Prolonged cytopenia	NA	5 (4.2%)
Death	17 (14.9%)	11 (9.2%)
Refusal	14 (12.3%)	6 (5.0%)
Protocol violations	5 (4.4%)	3 (2.5%)
Ineligible	1 (0.9%)	1 (0.8%)
Other	3 (2.6%)	3 (2.5%)

Median time to off-study: 112 days vs 180 days

EORTC-06011 Overall Survival



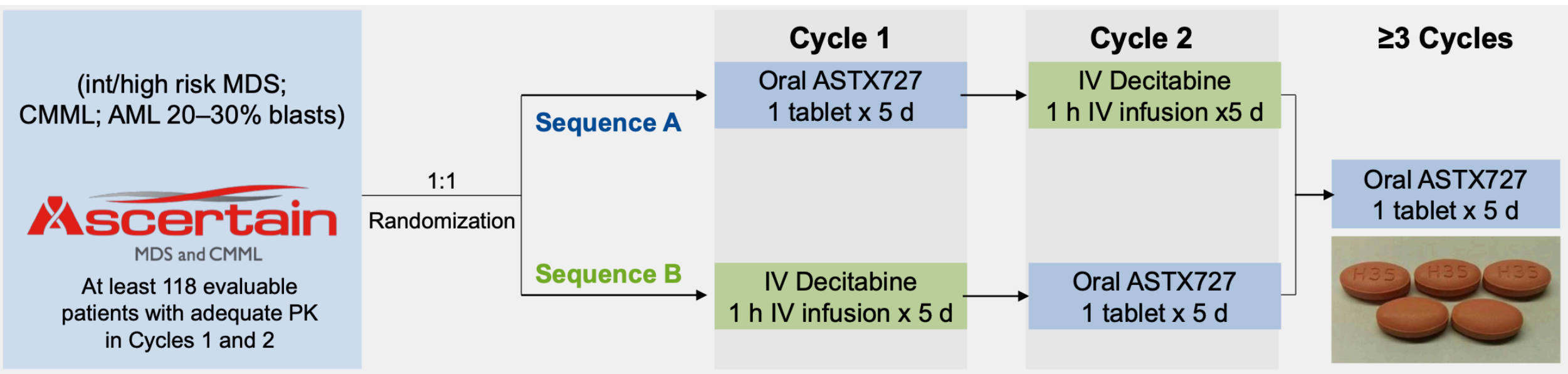
O	N	Number of patients at risk :							
96	114	71	38	22	10	6	3	— Supportive care	
99	119	83	53	24	15	4	4	— Decitabine	

No survival advantage for DAC?

- Number of treatments courses given
- Different populations and comparator groups
 - MDS duration
 - Cytogenetic risk groups
 - Performance status
- How the drug was given
- There is a true difference between aza and dac

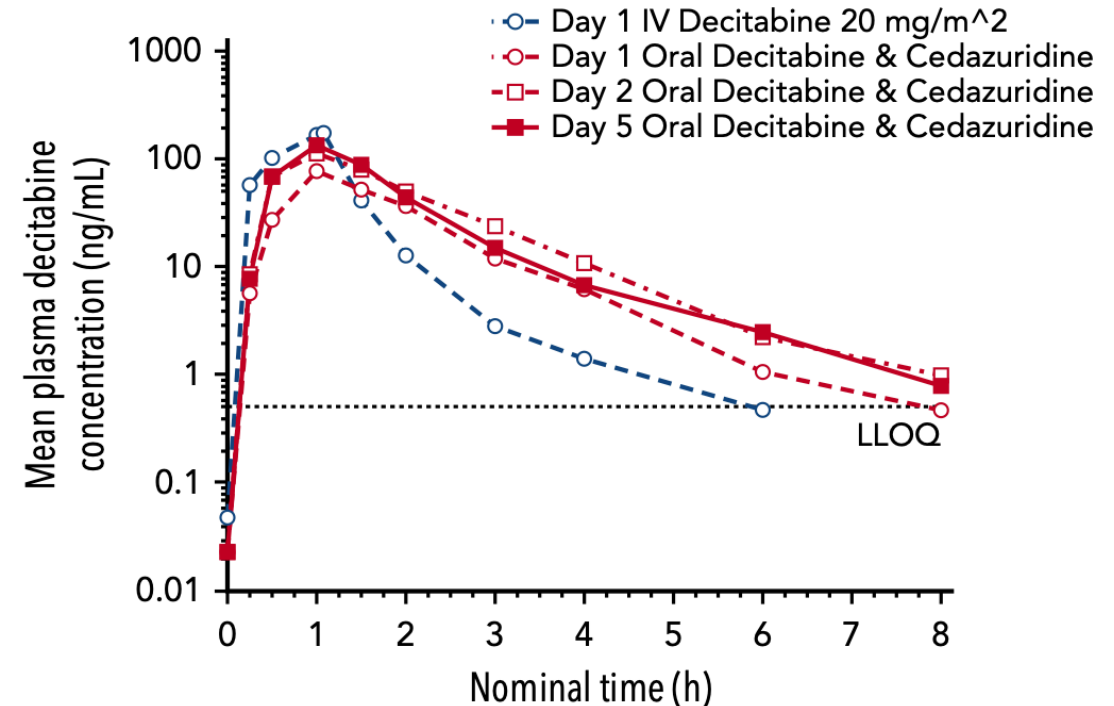
Oral Decitabine (Approval 7/7/2020)

- 35mg decitabine/100mg cedazuridine vs decitabine (20 mg/m²)
 - ASTX727-01-B (N=80) – Phase 1/2
 - ASTX727-02 (N=133) – Phase 3



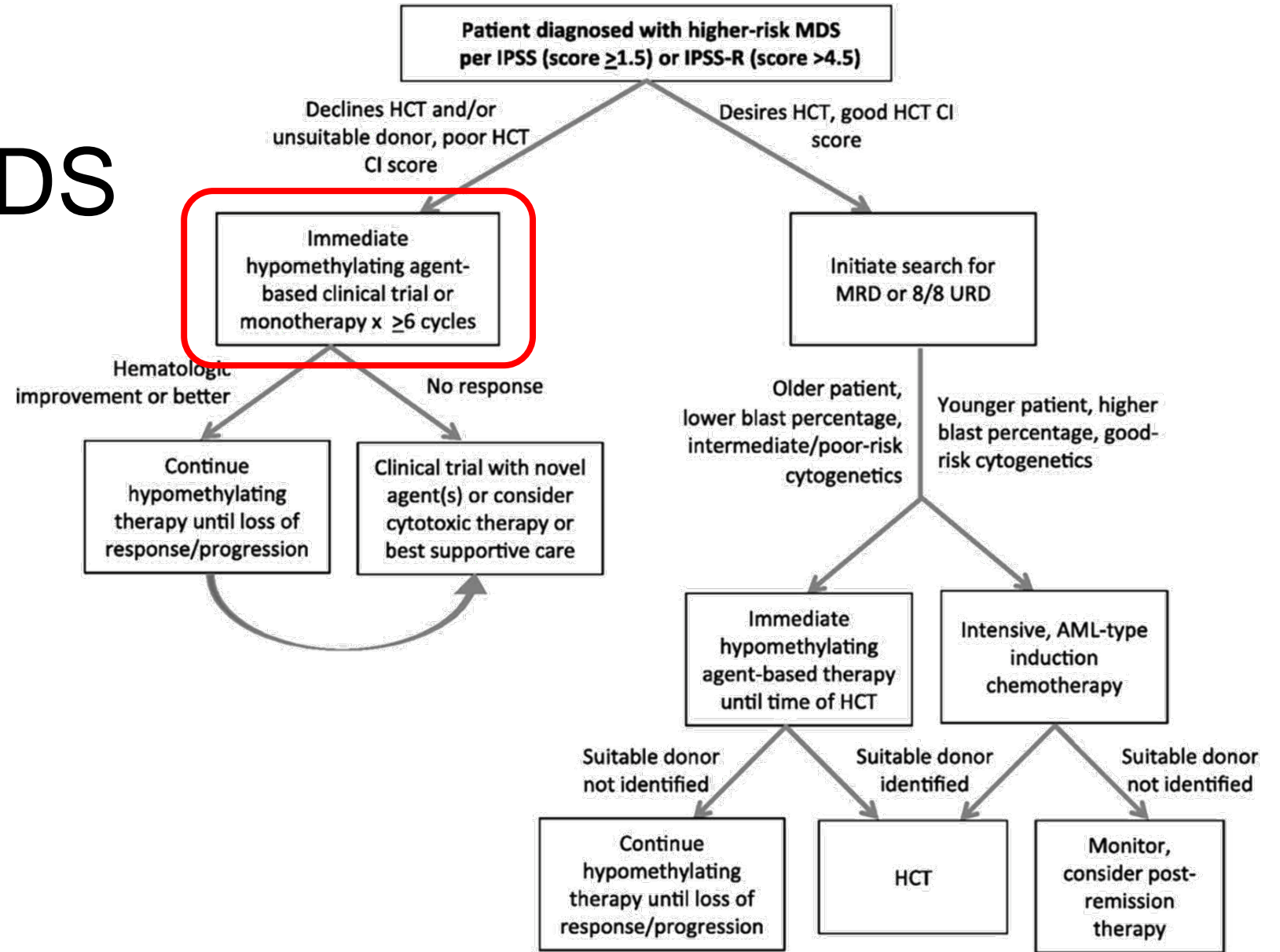
Oral Decitabine

- ASTX727-01-B
 - CR rate of 18% (95% CI, 10%-28%)
 - Median duration of CR 8.7 (range, 1.1-18.2) months
- ASTX727-02 (Ascertain)
 - CR rate of 21% (95% CI, 15%-29%)
 - Median duration of CR 7.5 (range, 1.6-17.5) months
- Both studies showed similar:
 - Side effect profiles/toxicity
 - PK data between oral and IV formulation
- Comparison of disease response between oral and IV was not possible because all patients received decitabine-cedazuridine starting in cycle 3

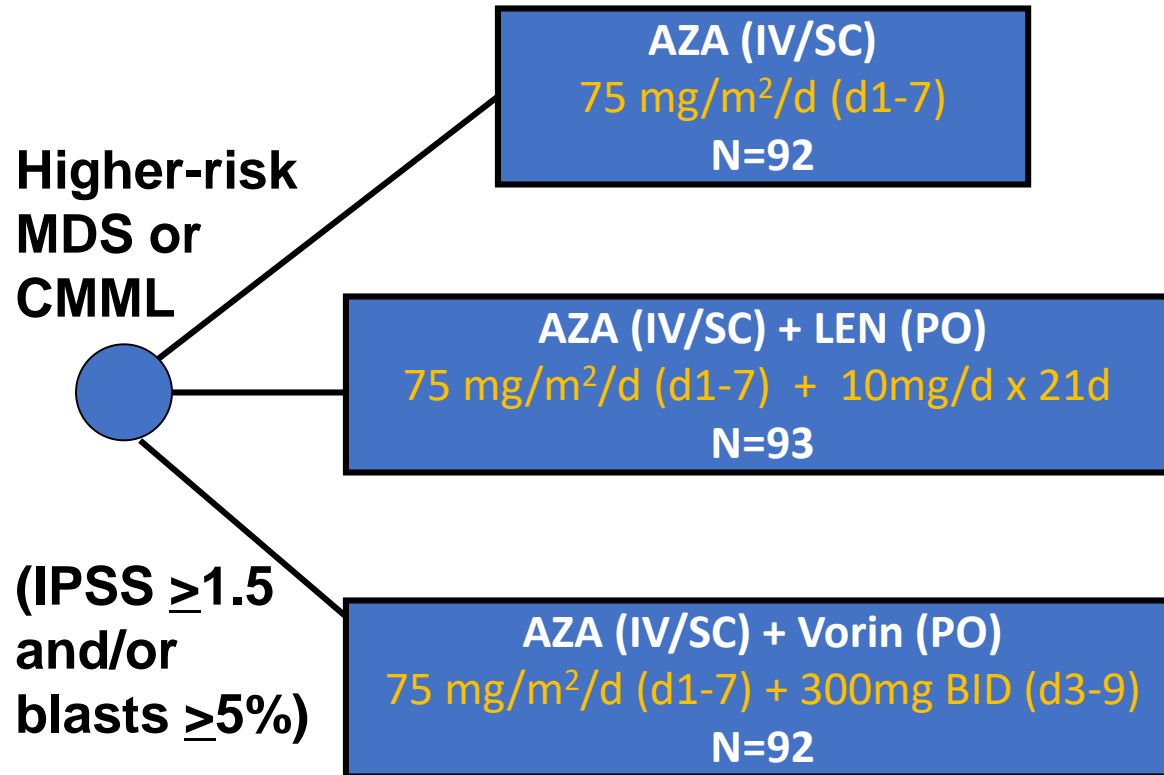


Treatment of Higher-risk MDS

Oral C-DEC?



North American Intergroup Randomized Phase 2 MDS Study S1117: Study Design



Groups: SWOG, ECOG,
Alliance, NCIC

Total Sample Size: 282/277

Primary Objective: 20% improvement of ORR
(CR/PR/Hi) based on 2006 IWG Criteria

Secondary Objectives: OS,
RFS, LFS

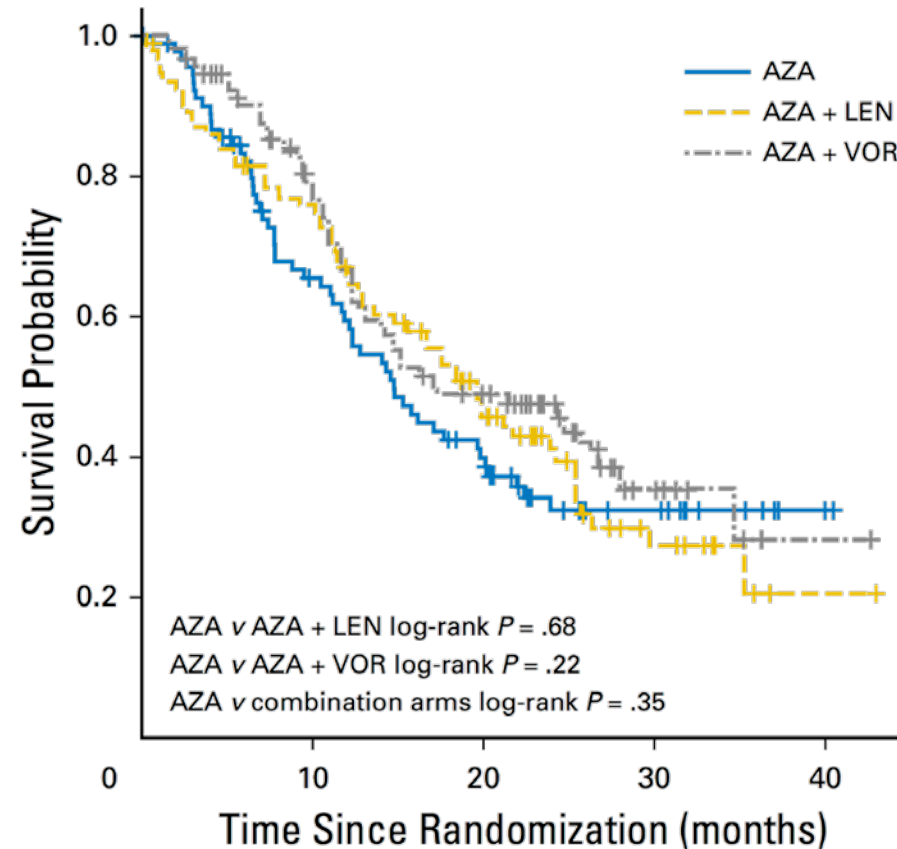
Power 81%, alpha 0.05 for
each combo arm vs. AZA

06/2012 – 06/2014

North American Intergroup Randomized Phase 2 MDS Study S1117: Response

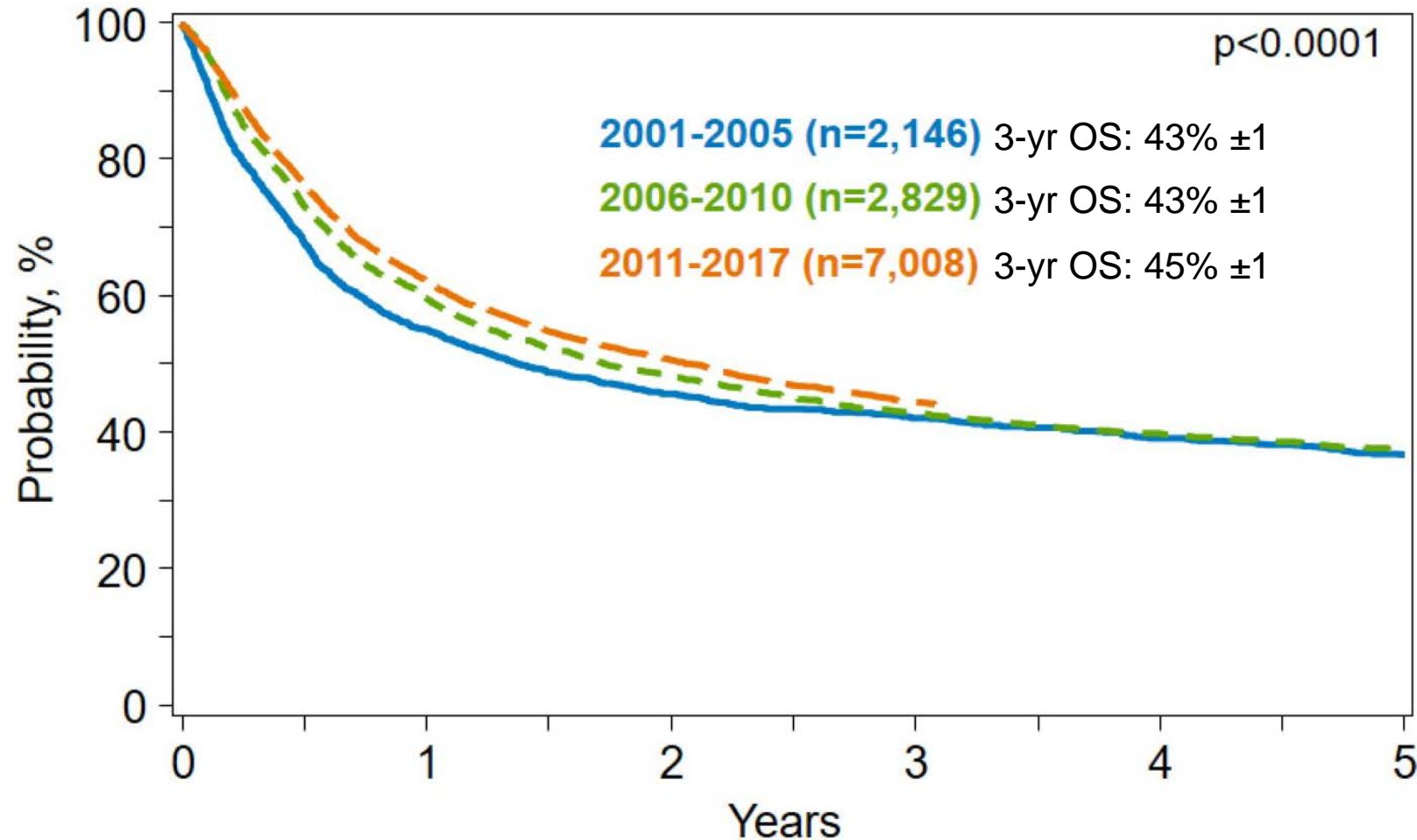
Response Variable	AZA	AZA+LEN (P-value vs. AZA)	AZA+VOR (P-value vs. AZA)	Total n=277
Median Tx Duration (Wks)	25	24	20	22
Overall Response Rate (%)	38	49 (.16)	27 (.16)	38%
CR/PR/Hi (%)	24/0/14	24/1/25	17/1/9	22/1/16%
CMML ORR (%)	5 (28)	13 (68) (.02)	2 (12) (.41)	37%
ORR Duration (median)	10 months	14 months (.41)	15 months (.31)	14 months

North American Intergroup Randomized Phase 2 MDS Study S1117: OS All Patients

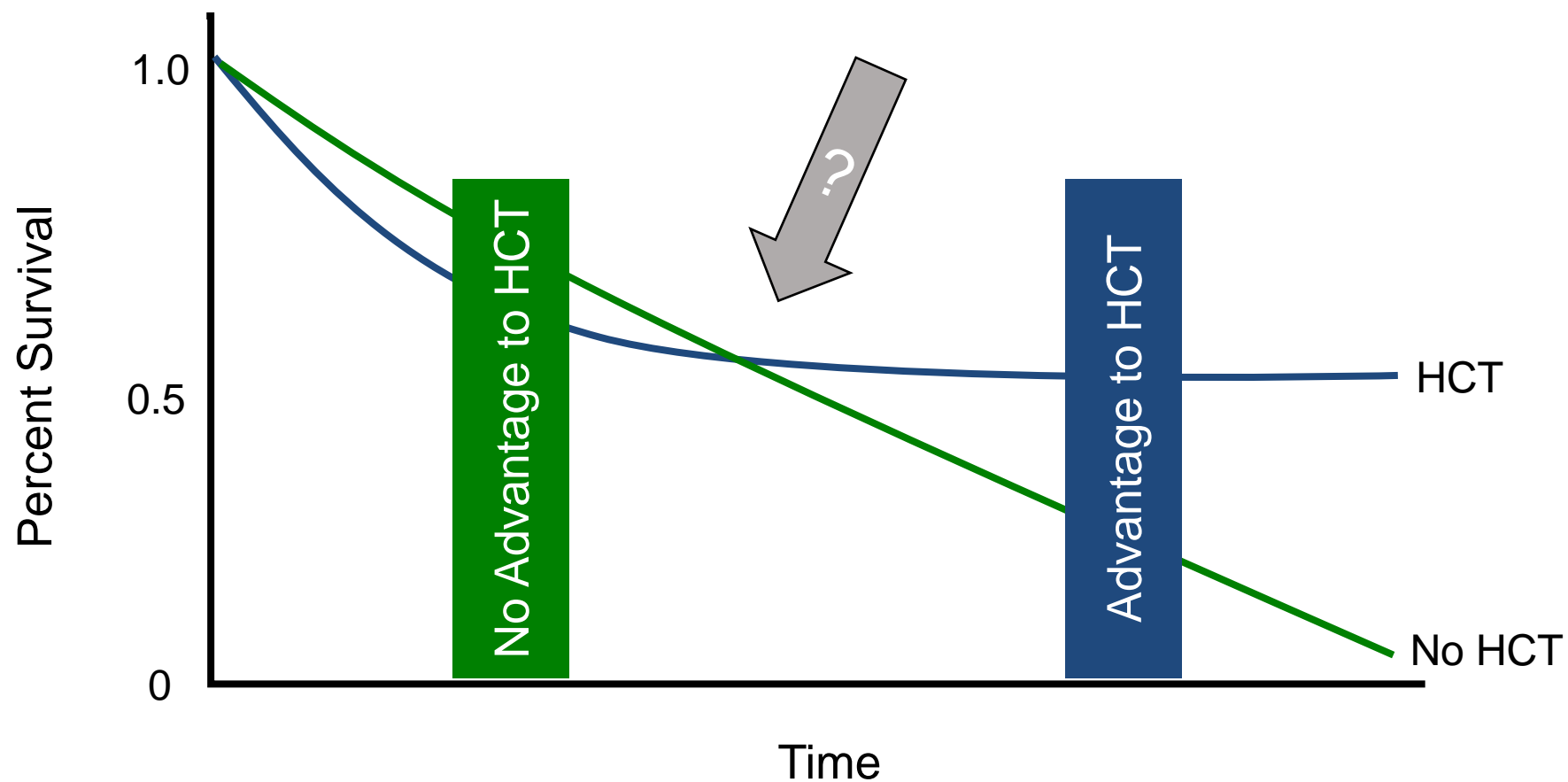


Blood and Marrow Transplantation for MDS

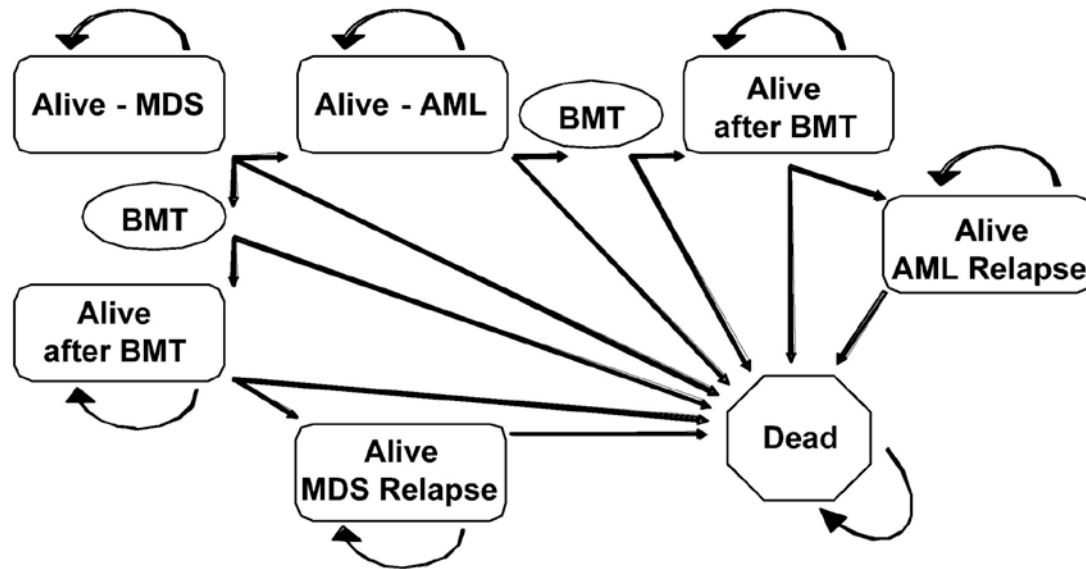
OS after HCT for MDS, 2001-2017



Allogeneic HCT for MDS



Markov Modeling in HCT



- Retrospective comparison
 - All Primary MDS
 - Marrow Grafts
 - HLA-identical donors
 - Myeloablative
- 184 Delayed transplant MDS
- 260 Transplant MDS at time of diagnosis
- 230 Transplant at progression to tAML

Decision Analysis

Estimated Life expectancy (years) after HCT for MDS (age < 60)

	Immediate HCT	HCT in 2 years	HCT at progression
IPSS RISK	Low	6.51	7.21
	Int-1	4.61	5.16
	Int-2	4.93	2.84
	High	3.20	2.75

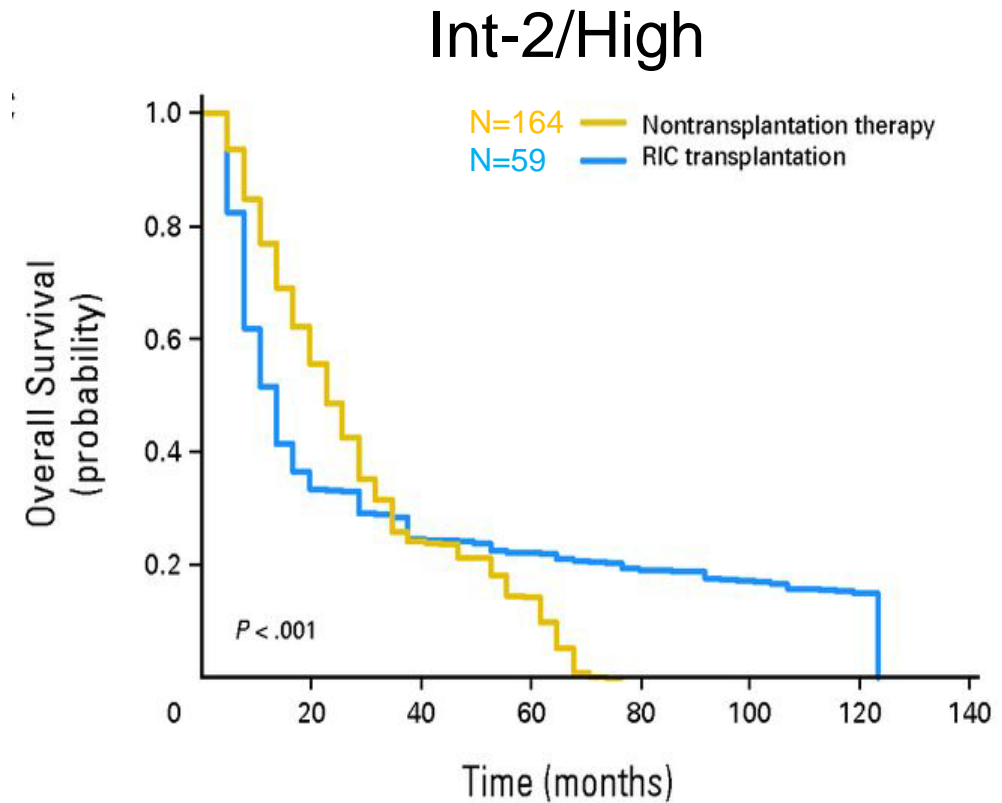
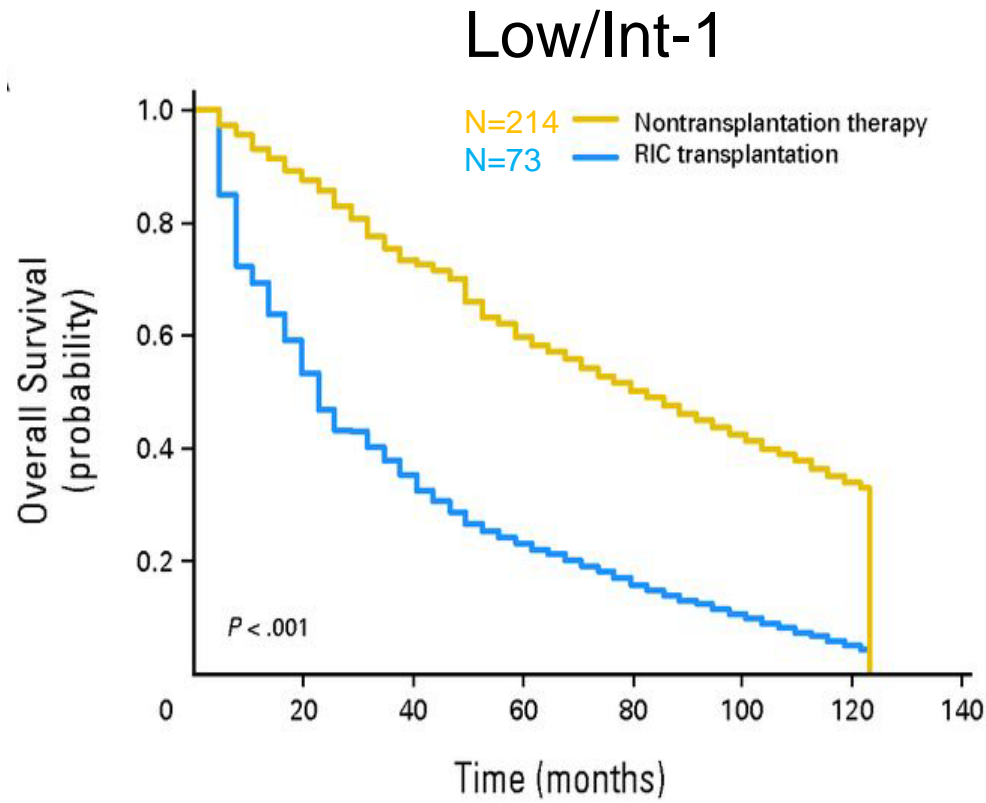
Decision Analysis

Estimated Life expectancy (years) after RIC-HCT for MDS (age \geq 60)

		Non-HCT	Early HCT	
IPSS RISK	Overall LE	6.42	3.17	
	Low/Int-1	QALE: TI	5.42	2.92
		QALE: TD	3.83	2.92
	Int-2/High	Overall LE	0.24	3.00
		QALE: HR-MDS	1.25	2.75
		QALE: GvHD	1.25	1.83

Timing of HCT by IPSS Using RIC

- *de novo* MDS 60-70 years of age
- Survival measured from start of therapy
- HLA Matched Donors
- Bu x 2 days or 2-4 Gy TBI (no T-cell depletion)



Summary – Myelodysplastic Syndromes

1. Organization, in general
2. Diagnosis and Classification
3. Epidemiology
4. Pathogenesis
 - a. Clonal Process
 - b. Secondary MDS
5. Risk stratification
 - a. IPSS-R
6. Treatment of Lower-risk MDS
 1. ESAs
 2. IMiDs
 3. Immunosuppressive therapy
7. Treatment of Higher-risk MDS
 1. Hypomehtylating agents
8. Transplantation for MDS
9. Discussion

Discussion

Thanks!

Mikkael Sekeres, MD, MS
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Matt Kalaycio, MD
Ronald Sobecks, MD
Betty Hamilton, MD
Aziz Nazha, MD
Bhumika Patel, MD
Yogen Sauntharajah, MD
Babal Jha, PhD



L&MD

Leukemia & Myeloid Disorders
Program

Tracy Cinalli, RN
Chondra Robinson, RN
Christine Cooper, RN
Andrea Smith, RN
Eric Parsons, RN
Samjhana Bogati, RN
Yolanda Curry, RN
Megan Nelson, RN
Rachel Bordwell, RN, NP
Raychel Berardinelli, RN, NP
Kaylee Root, BA
Jodi Campo, RN, NP
Barb Tripp, RN, NP
Alicia Bitterice, RN, NP
Meghan Scully, RN, NP
Ben Pannell, BA
Eric Wiedenfeld, BA
Matthew Polefko, BA
Allison Unger, BA
George Lucas, BA
Abigail Snow, BA
Enhxi Myrtaj, BA

Diane Banks, BA
Katarina Paulic, BA
John DeSamito, MD
Renee Gagnon, BA
Olivia Kodramaz
Caitlin Swann, PharmD
Madeline Waldron, PharmD
Kelly Gaffney, PharmD
Jenna Thomas, PharmD



And Our Patients!!!