Current and Emerging Therapies for Myelodysplastic Syndromes (MDS)

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Welcome & Introductions

Dr. Sekeres's slides are available for download at www.LLS.org/programs

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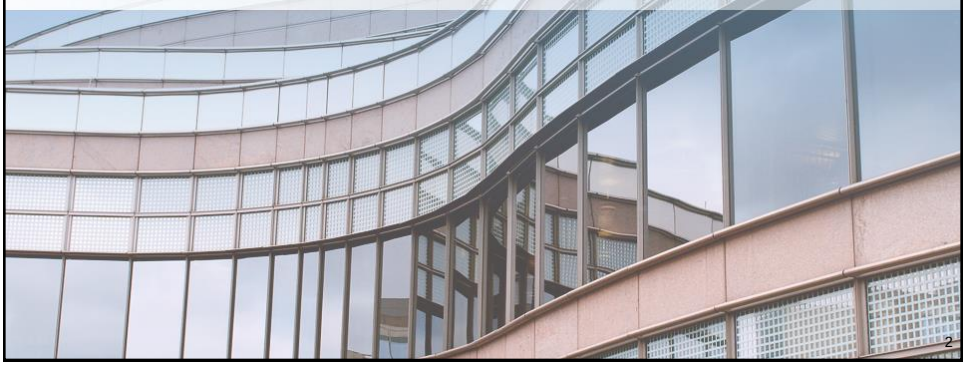
Current and Emerging Therapies for Myelodysplastic Syndromes

Mikkael A. Sekeres, MD, MS
Professor of Medicine
Director, Leukemia Program



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Disclosures

Mikkael A. Sekeres, MD, MS, has affiliations with Celgene (*Consultant*).

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MDS : Outline

- MDS Overview
- Treatment of Lower-risk Disease
- Treatment of Higher-risk Disease

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MDS Basics: Definition

- A heterogeneous clonal hematopoietic disorder derived from an abnormal multipotent progenitor cell

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MDS Basics: Definition

- A heterogeneous clonal hematopoietic disorder derived from an abnormal multipotent progenitor cell
  - **Heterogeneous** = many different forms!
  - **Clonal** = genetic basis (genetics that you inherit)
  - **Hematopoietic** = starts in the bone marrow, affects blood cells
  - **Multipotent progenitor** = changes occur in one bone marrow cell and are passed along

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MDS Basics: Definition

- Characterized by a hyperproliferative bone marrow, dysplasia of the cellular elements, and ineffective hematopoiesis

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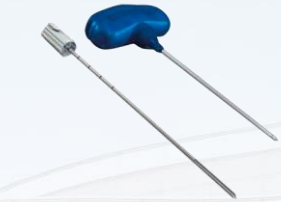
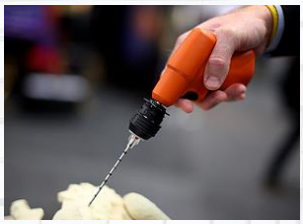
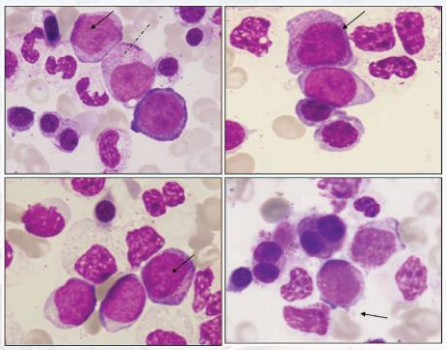
MDS Basics: How is it diagnosed?







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MDS Basics: Definition

- Characterized by a hyperproliferative bone marrow, dysplasia of the cellular elements, and ineffective hematopoiesis
  - **Hyperproliferative** = too many cells (for your age)
  - **Dysplasia** = bad growing cells
  - **Ineffective hematopoiesis** = can't make normal red blood cells, platelets, and/or white blood cells

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MDS: Epidemiology

Site	Both Sexes Rate	Both Sexes Count	Males Rate	Males Count	Females Rate	Females 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	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	4.9	21,338	6.7	12,098	3.7	9,240
White	5.1	17,978	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

Incidence Rate = 4.9/100,000 per year

Howlader et al. SEER Cancer Statistics Review, 2009-2013, http://seer.cancer.gov/csr/1975_2013/.

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Men > Women

Howlader et al. SEER Cancer Statistics Review, 2009-2013, http://seer.cancer.gov/csr/1975_2013/.

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Whites > African-Americans

Howlader et al. SEER Cancer Statistics Review, 2009-2013, http://seer.cancer.gov/csr/1975_2013/.

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MDS: Epidemiology

Cross-sectional analysis of 4514 MDS patients in the U.S. in 2005-7

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%**

Sekeres et al. J National Cancer Inst 2008;100:1542

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MDS Basics: WHO Classification

2008 Name	Abbrev.	2016 Name	Abbrev.
Refractory cytopenia with unilineage dysplasia	RCUD (includes RA, RN and RT)	**MDS with single lineage dysplasia**	MDS-SLD
Refractory anemia with ring sideroblasts	RARS	**MDS with ring sideroblasts**	MDS-RS
MDS w/ isolated del(5q)	Del(5q)	*unchanged*	*unchanged*
Refractory cytopenia with multilineage dysplasia	RCMD	**MDS with multilineage dysplasia**	MDS-MLD
		(with ring sideroblasts)	MDS-RS-MLD
Refractory anemia with excess blasts, type 1	RAEB-1	**MDS with excess blasts, type 1**	MDS-EB-1
Refractory anemia with excess blasts, type 2	RAEB-2	**MDS with excess blasts, type 2**	MDS-EB-2
MDS, Unclassifiable	MDS-U	*unchanged*	*unchanged*
Refractory cytopenia(s) of childhood	RCC	*unchanged*	*unchanged*

Higher Risk

Adapted from Arber et al. Blood 2016

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MDS Basics: IPSS

Calculation of prognostic score

Score	0	0.5	1.0	1.5	2.0
BM Blast %	< 5	5-10		11-20	21-29
Cytogenetics	Good	Intermediate	Poor		
Cytopenias	0/1	2/3			

Estimation of prognosis

Higher Risk

Overall Score	IPSS Subgroup	Median Survival (Years)
0	Low	5.7
0.5-1.0	Intermediate-1	3.5
1.5-2.0	Intermediate-2	1.2
≥2.5	High	0.4

Cytopenias: ANC < 1.5, HGB < 10.0, PLT < 100,000
Good Risk: [-Y,del(5q), del(20q),Nl]; Intermediate Risk: [8+,other]; Poor Risk: [Chr. 7 abn, ≥3 abn]

Greenberg P, et. al. *Blood* 1997:89:2079-88.

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MDS Staging: IPSS-R Prognostic Score Variables

VARIABLE	0	0.5	1	1.5	2	3	4
Cytogenetics	V. Good		Good		Intermediate	Poor	V. 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 Prognostic Risk Categories/Scores

RISK GROUP	Risk Score	Median Survival (Yrs)
Very Low	≤1.5	8.8
Low	>1.5-3	5.3
Intermediate	>3-4.5	3.0
High	>4.5-6	1.6
Very High	>6	0.8

Greenberg et al. Blood 2012;120:2454-65.

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MDS: Prognosis

MDS Prognosis Made Easy!!!

- **Lower Risk**
  - RA, RARS
  - RCMD, RCUD
  - MDS-U, MDS del (5q)
  - IPSS Low, Int-1 (0-1.0); **IPSS-R V. Low, Low, Int (≤3.5)**
- **Higher Risk**
  - RAEB (-1, -2)
  - IPSS Int-2, High (≥ 1.5); **IPSS-R Int (>3.5), High, V. High**

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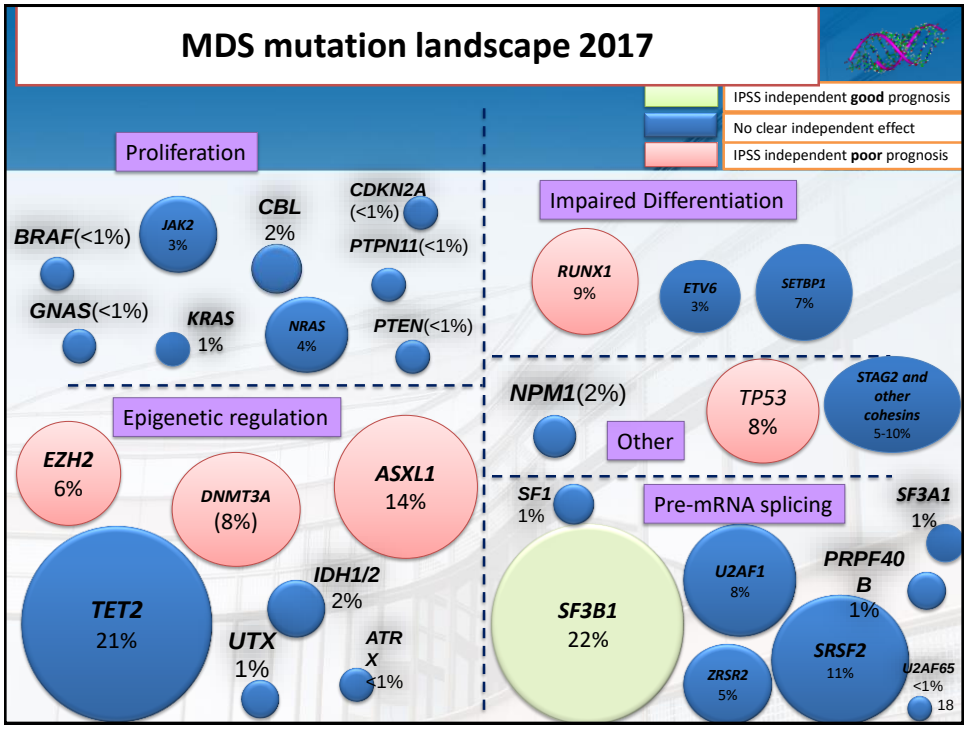
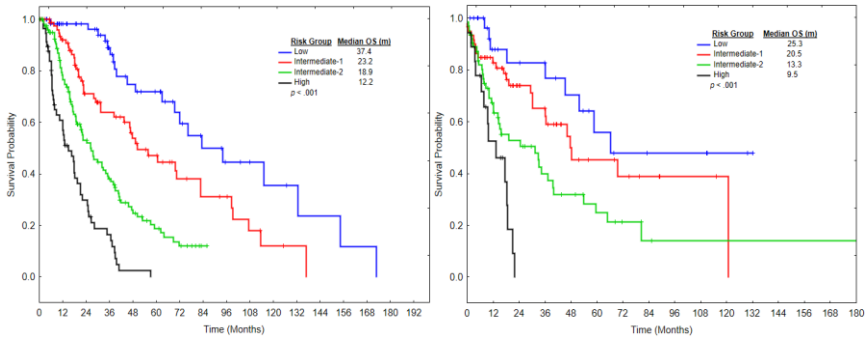


IPSS-R "molecular" (IPSS-Rm)



Training Cohort
C-Index = .74

Validation Cohort
C-Index = .65

Nazha et al. Leukemia 2016

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MDS : Outline

- MDS Overview
- **Treatment of Lower-risk Disease**
- Treatment of Higher-risk Disease

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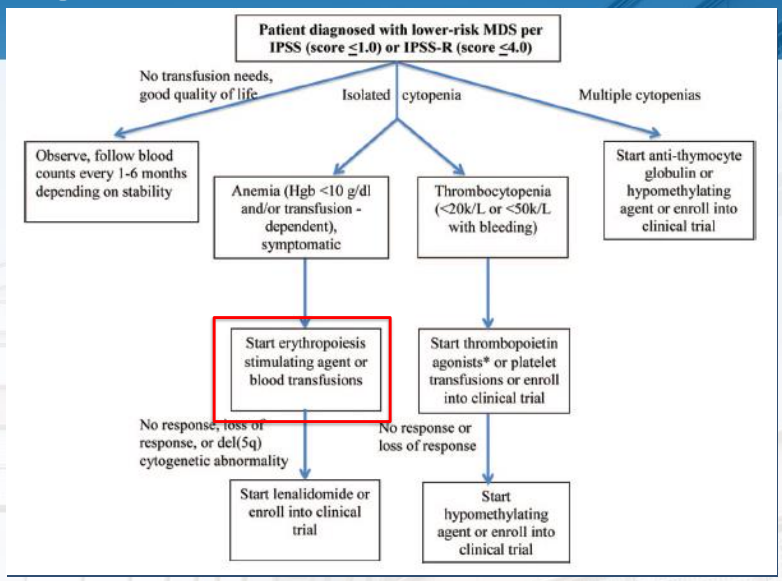
MDS: Lower-risk, Treatment Algorithm



Sekeres and Gerds Hematology (ASH Educ Program) 2014.

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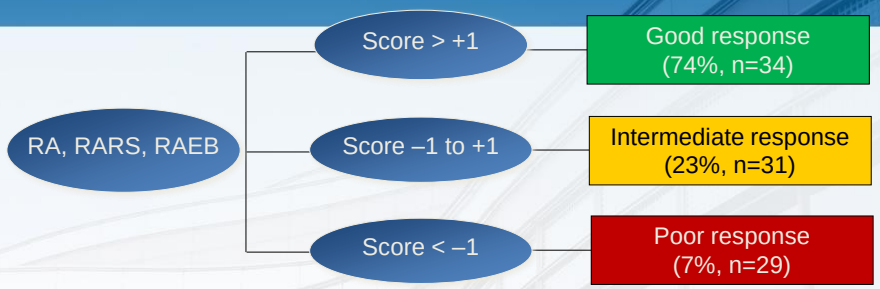
MDS: Patient Selection for ESAs



Treatment response score

s-epo	<100	+2
U/L	100–500	+1
	>500	–3
Transf	<2 units/m	+2
U RBC/m	= or >2 units/m	–2

Hellström-Lindberg E et al. *Br J Haematol*. 2003;120:1037

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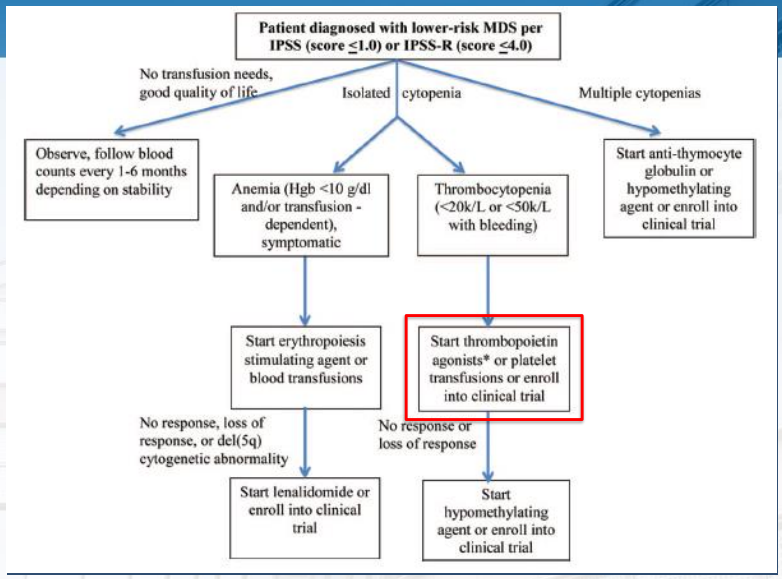
MDS: Lower-risk, Treatment Algorithm



Sekeres and Gerds Hematology (ASH Educ Program) 2014.

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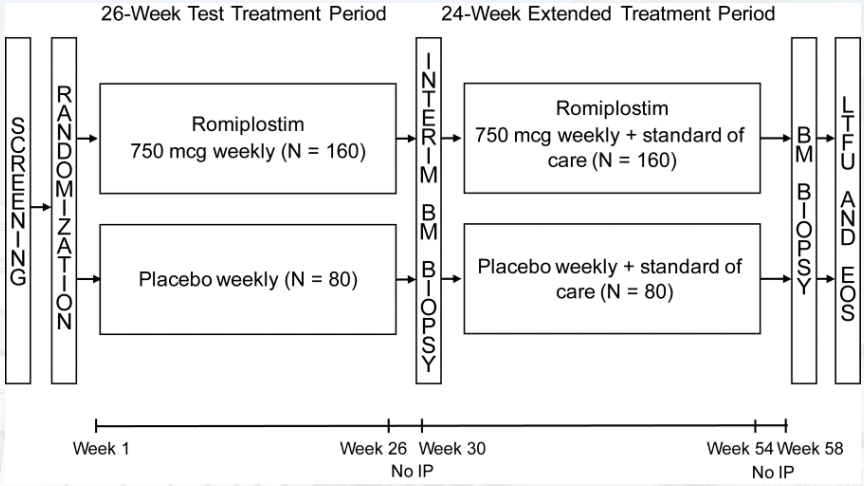
MDS: TPO Agonists



Giagounides et al. Cancer 2014;120:1838.

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MDS: TPO Agonists

	Baseline platelets < 20x10^9/L		Baseline platelets ≥ 20x10^9/L	
	Placebo (N = 43)	Romiplostim (N = 87)	Placebo (N = 40)	Romiplostim (N = 80)
CSBE (rate/100 pt-yr)	501.2	514.9	**226.4**	**79.5**
	RR = 1.03, p = 0.827		**RR = 0.35, p<0.0001**	
PTE (rate/100 pt-yr)	**1778.6**	**1250.5**	179.8	251.8
	RR = 0.71, p<0.0001		RR = 1.38, p = 0.1479	

Giagounides et al. Cancer 2014;120:1838.

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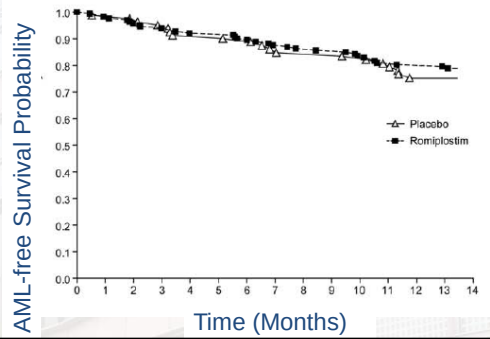
Lower-risk MDS: TPO Agonists

58 weeks of follow-up

	Romiplostim	Placebo	HR	95% CI
Deaths	**17.9% (30)**	**20.7% (17)**	**0.86**	**0.47, 1.56**
AML	**6.0% (10)**	**4.9% (4)**	**1.20**	**0.38, 3.84**
AML-free survival	**19.6% (33)**	**23.2% (19)**	**0.85**	**0.48, 1.50**



Giagounides et al.
Cancer 2014;120:1838.

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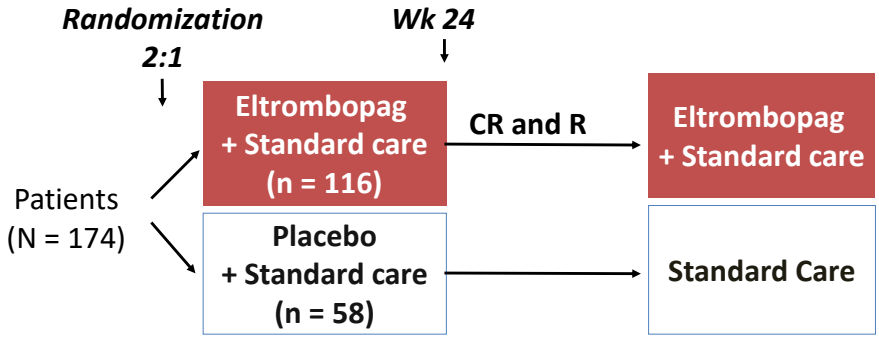
EQoL MDS

Study design



Dose start: 50 mg with increases every 2 weeks up to 300 mg daily.

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EQoL MDS

Platelet responses

Response	8 weeks Elt 41:placebo 17 Elt:Plac	24 weeks Elt 24:Placebo11 Elt:Plac
R, n	12 : 0	5 : 3
CR, n	9 : 0	8 : 0
NR	20 : 17	11 : 8
Total responses, n	21 : 0	13 : 3
WHO bleeding grade ≥ 2, events	1 : 2	3 : 1

Time to Response (TTR) :
Eltrombopag : median 14 (IQR 8-39) days
Placebo: median 85 (IQR 41-193) days (p =0.023) *

Median daily eltrombopag dose at response: 50 (IQR 50-150) mg.

Oliva Lancet Haematology 2017

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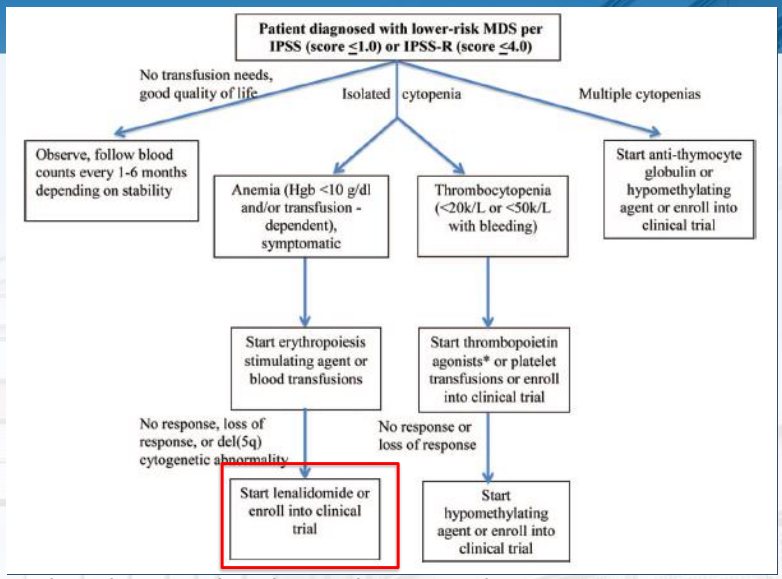
MDS: Lower-risk, Treatment Algorithm



Sekeres and Gerds Hematology (ASH Educ Program) 2014.

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Lower-risk MDS: Lenalidomide

MDS-001
N = 43
Phase I/II initiated 2002

Del 5q

MDS-003
N = 148
Phase II initiated 2003

MDS-004
N = 205
Phase III initiated 2005

Non del 5q

MDS-002
N = 214
Phase II initiated 2003

MDS-005
N = 205
Phase III initiated 2010

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MDS: Phase 3 Lenalidomide in del(5q) Lower-risk

	RBC-TI, n (%) [95% CI]		
	Placebo	Lenalidomide 5 mg	Lenalidomide 10 mg
mITT population	**n = 51**	**n = 47**	**n = 41**
Protocol defined (≥ 26 weeks)	3 (5.9) [1.2-16.2]	20 (42.6) [28.3-57.8]*	23 (56.1) [39.7-71.5]*
IWG 2000[13] (≥ 8 weeks)	4 (7.8) [2.2-18.9]	24 (51.1) [36.1-65.9]*	25 (61.0) [44.5-75.8]*
IWG 2006[14] (≥ 8 weeks)	3 (5.9) [1.2-16.2]	24 (51.1) [36.1-65.9]*	25 (61.0) [44.5-75.8]*

Fenaux et al. Blood 2011;118:3765-76.

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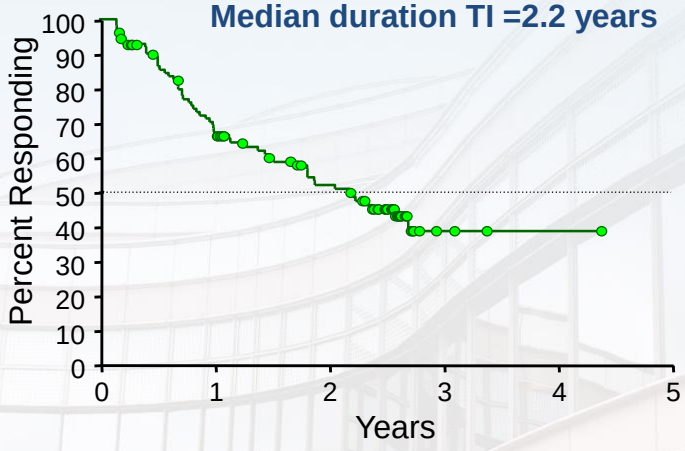
Lower-risk MDS: Lenalidomide in del(5q)



List et al. Leukemia 2014;28:1033.

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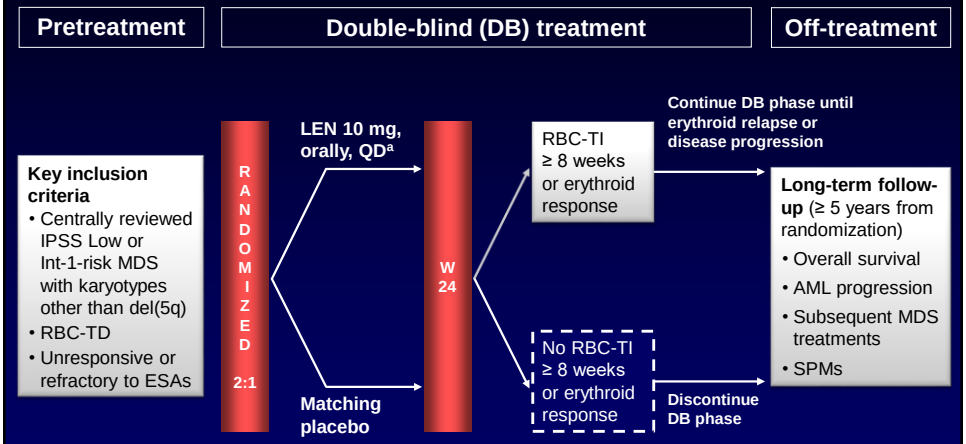
MDS-005: Study Design



Santini et al. JCO 2016;34:2988.

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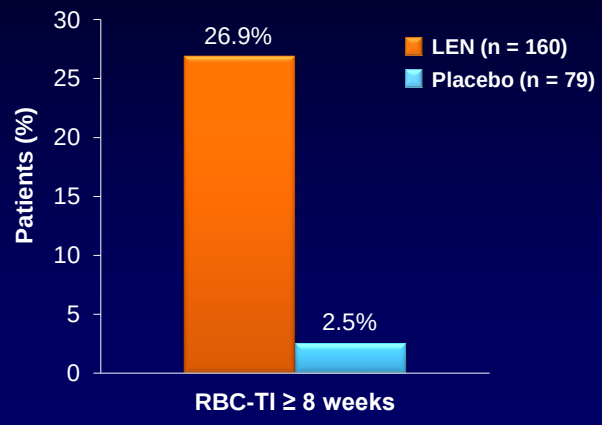
MDS-005: RBC-TI ≥ 8 Weeks

Significantly more LEN patients achieved RBC-TI ≥ 8 weeks versus placebo (*P* < 0.001)



Santini et al. JCO 2016;34:2988

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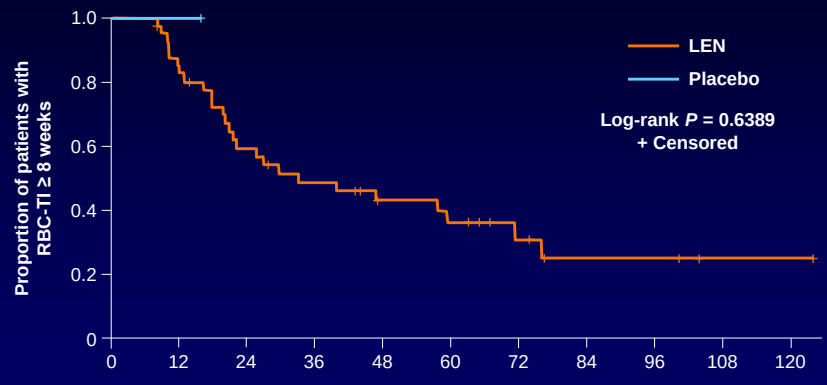
MDS-005: Duration of RBC-TI ≥ 8 Weeks

The median duration of response was 32.9 weeks (95% CI 20.7–71.1) among RBC-TI ≥ 8 weeks responders with LEN



No. of RBC-TI patients

LEN	41	34	23	18	13	11	6	3	3	1	1
Placebo	1	1	0								

Santini et al. JCO 2016;34:2988.

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Abstract # 92 Luspatercept Treatment Leads to Long Term Increases in Hemoglobin and Reductions in Transfusion Burden in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS): Preliminary Results from the Phase 2 PACE-MDS Extension Study

Aristoteles Giagounidis, MD, PhD[1], Uwe Platzbecker, MD[2], Ulrich Germing, MD[3], Katharina Götze, MD[4], Philipp Kiewe, MD[5], Karin Mayer, MD[6], Oliver Ottmann, MD[7], Markus Radsak, MD[8], Thomas Wolff, MD[9], Detlef Haase, MD[10], Monty Hankin[11], Dawn Wilson[11], Xiaosha Zhang[11], Adberrahmane Laadem, MD[12], Matthew L. Sherman, MD[11] and Kenneth M. Attie, MD[11]

[1]Marien Hospital Düsseldorf, [2]Universitätsklinikum Carl Gustav Carus, Dresden, [3]Universitätsklinikum Düsseldorf, [4]Technical University of Munich, [5]Onkologischer Schwerpunkt am Oskar-Helene-Heim, Berlin, [6]University Hospital Bonn, [7]Universitätsklinikum Frankfurt, Goethe Universitaet, Frankfurt/Main, [8]Johannes Gutenberg-Universität, Mainz, [9]OncoResearch Lerchenfeld UG, Hamburg, [10]Universitätsmedizin Göttingen, Germany; [11]Acceleron Pharma, Cambridge, MA, [12]Celgene Corporation, Summit, NJ, USA

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Response Rates by Baseline Characteristics

- Majority of patients in extension study were RS+; ≥ 50% patients responded to luspatercept who had EPO up to 500 I/U or prior ESA treatment

n (%)	IWG HI-E N=32	RBC-TI* N=22
All Patients	22/32 (69%)	11/22 (50%)
RS positive	21/29 (72%)	10/19 (53%)
Baseline EPO		
< 200 U/L	16/20 (80%)	7/13 (54%)
200-500 U/L	5/7 (71%)	2/4 (50%)
> 500 U/L	1/5 (20%)	2/5 (40%)
Prior ESA Treatment		
Yes	12/19 (63%)	7/14 (50%)
No	10/13 (77%)	4/8 (50%)

* **RBC-TI:** RBC transfusion independent ≥ 8 weeks; includes 19 HTB patients and 3 LTB patients evaluable for transfusion independence (at least 2 Units over 8 weeks pre-treatment)

Data as of 31 Aug 2015

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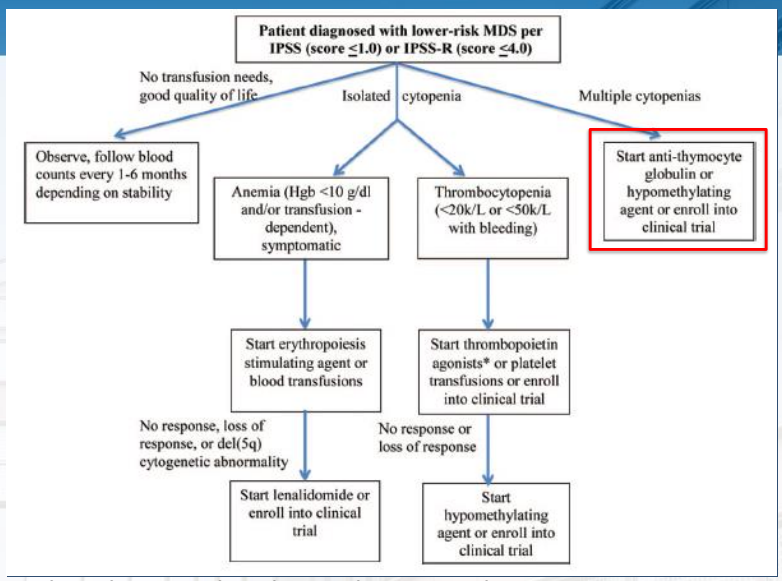
MDS: Lower-risk, Treatment Algorithm



Sekeres and Gerds Hematology (ASH Educ Program) 2014.

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Low-dose HMAs in LR-MDS: Treatment

- **Regimens:**
  - **DAC 20 mg/m^2 IV D1-3 every 4 weeks**
  - **AZA 75 mg/m^2 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)**

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Low-dose HMAs in LR-MDS: Response

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)

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MDS : Outline

- MDS Overview
- Treatment of Lower-risk Disease
- **Treatment of Higher-risk Disease**

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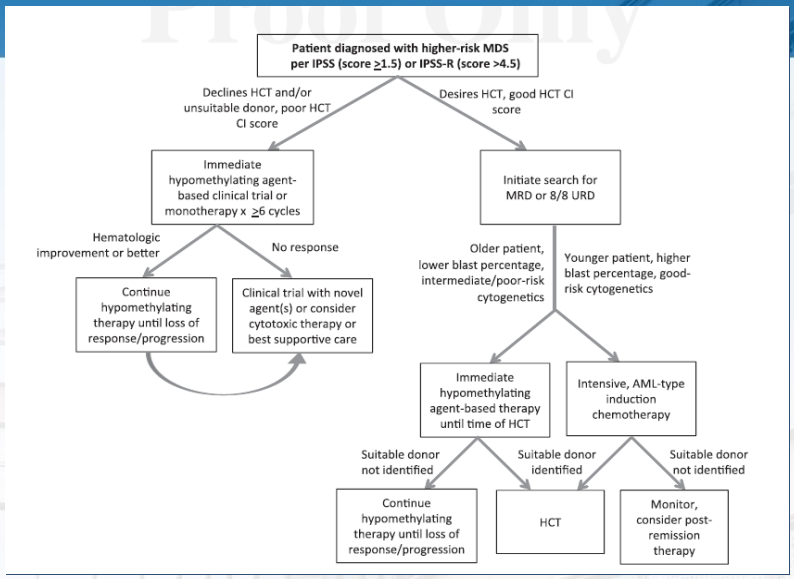
MDS: Higher-risk, Treatment Algorithm



Sekeres and Cutler Blood 2014;123:829.

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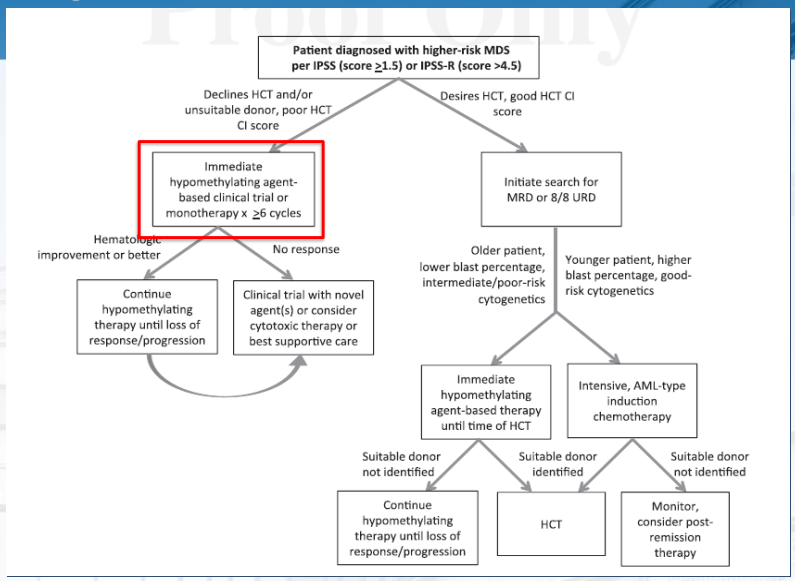
MDS: Higher-risk, Treatment Algorithm



Sekeres and Cutler Blood 2014;123:829.

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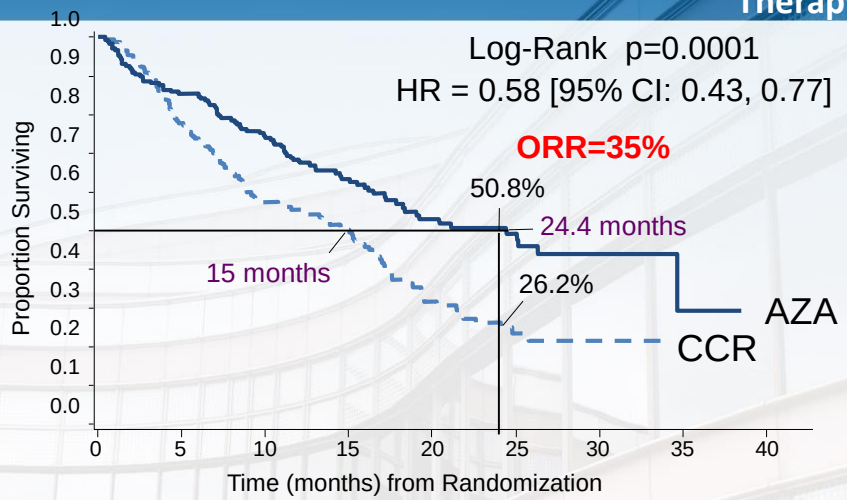
MDS: Higher-risk, Hypomethylating Therapy



Fenaux P, et al. Lancet Oncology 2009;10:223-232.

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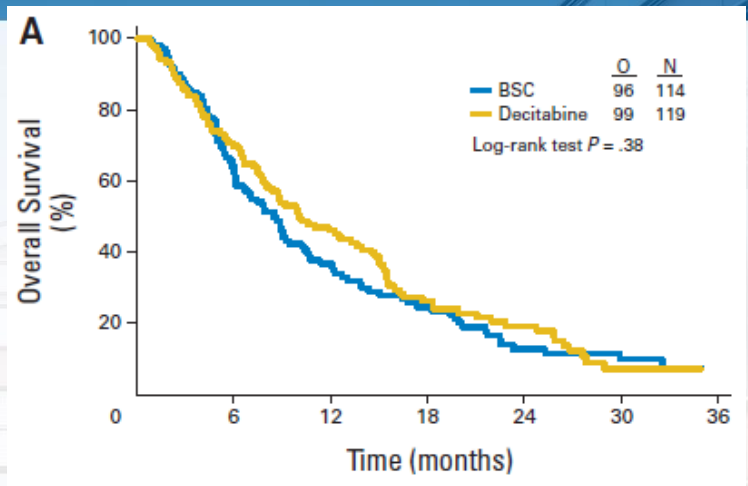
MDS: Higher-risk, Hypomethylating Therapy



Median OS 10.1 vs. 8.5 months

Lubbert et al. JCO 2011;29:1987.

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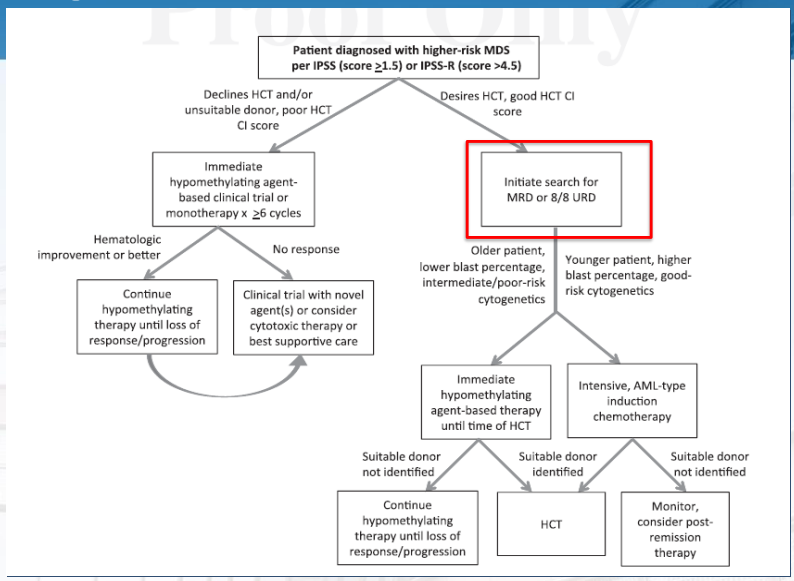
MDS: Higher-risk, Treatment Algorithm



Sekeres and Cutler Blood 2014;123:829.

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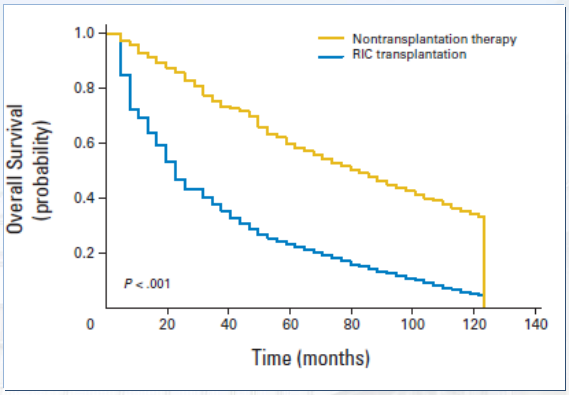
MDS: Higher-risk Therapy - HSCT



Test of Equality over Strata	
Test	**p**
Log-Rank	**<.0001**
Wilcoxon	**<.0001**
-2Log(LR)	**<.0001**

Low/Int-1 MDS

Koreth et al. JCO 2013;31:2662

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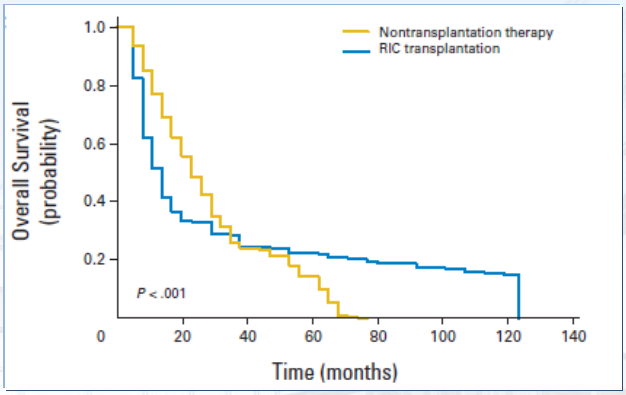
MDS: Higher-risk Therapy - HSCT



Test of Equality over Strata	
Test	**p**
Log-Rank	**<.0001**
Wilcoxon	**<.0001**
-2Log(LR)	**<.0001**

Int-2/High MDS

Koreth et al. JCO 2013;31:2662

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Higher-risk MDS

What happens when we add drugs together?

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

Higher-risk MDS or CMML

(IPSS ≥1.5 and/or blasts ≥5%)

- **AZA (IV/SC)** 75 mg/m²/d (d1-7) N=92
- **AZA (IV/SC) + LEN (PO)** 75 mg/m²/d (d1-7) + 10mg/d x 21d N=93
- **AZA (IV/SC) + Vorin (PO)** 75 mg/m²/d (d1-7) + 300mg BID (d3-9) N=92

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

Sekeres et al. JCO 2017

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North American Intergroup Randomized Phase 2 MDS Study S1117: Grade ≥3 Toxicities

Toxicity Variable	AZA	AZA+LEN (P-value vs. AZA)	AZA+VOR (P-value vs. AZA)	Total n=271
Febrile neutropenia (n)	10	13 (.66)	12 (.51)	36
GI (n)	4	12 (.10)	**14 (.02)**	28
Rash (n)	3	**14 (<.01)**	1 (1)	17
Off Tx due to Toxicity/Side Effect/Complication	8%	**20% (.05)**	**21% (.03)**	18%
Non-protocol defined dose modifications	24%	**43% (.002)**	**42% (.01)**	33%

Sekeres et al. JCO 2017

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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
CMML ORR Duration (median)	15 months	14 months (.87)	24 months (.69)	15 months

Sekeres et al. JCO 2017

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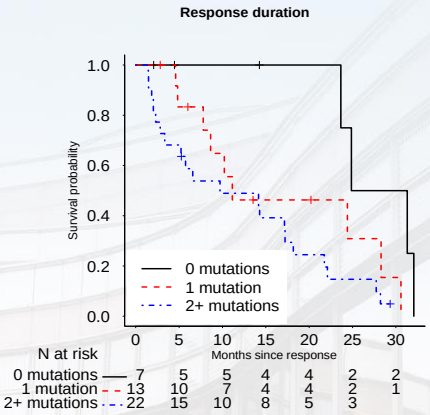
North American Intergroup Randomized Phase 2 MDS Study S1117: Response Duration By Number of Mutations



ORR was higher for **DNMT3A** (67% vs. 34%, p=.03), lower for **SRSF2** (17% vs. 41%, p=.04) and **ASXL1** (23% vs. 43%, P=.04).
Response Duration was worse for ***TET2*** (p=.046) and ***TP53*** (p=.003).

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MDS Summary

- In lower risk MDS promising results with
  - Lower dose HMA.
  - Eltrombopag for thrombocytopenia.
  - Luspatercept.
- Improving outcome in higher risk MDS remains an unmet need.

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Thanks to You and LLS!

Cleveland Clinic Leukemia/MDS Program

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And Our Patients!!!

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Current and Emerging Therapies for Myelodysplastic Syndromes (MDS)

LEUKEMIA & LYMPHOMA SOCIETY® fighting blood cancers
someday is today®

Q&A Session

Ask a question by phone:
- Press star (*) then the number 1 on your keypad

Ask a question by web:
- Click "Ask a question"
- Type your question
- Click "Submit"

Due to time constraints, we can only take one question per person. Once you've asked your question, the operator will transfer you back into the audience line.

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Aplastic Anemia and MDS International Foundation

The world's leading nonprofit health organization dedicated to patients and families living with aplastic anemia, MDS, PNH and related bone marrow failure diseases.

- **Free Educational Materials** in multiple languages: www.aamds.org/materials
- **Online Academy** with over 100 classes and expert interviews: www.aamds.org/learn
- **Free Patient and Family Conferences**: www.aamds.org/conferences
- **Personalized Support** through our Information Specialists: help@aamds.org or (800) 747-2820
- **Peer Support Network** with trained patient and caregiver volunteers: www.aamds.org/psn
- **Community Connections** support groups led by local volunteers around the United States: www.aamds.org/support/support-networks

Learning is hope.

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Current and Emerging Therapies for Myelodysplastic Syndromes (MDS)

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SUPPORT RESOURCES

- **Clinical Trials:** LLS provides personalized clinical trial navigation: **www.LLS.org/clinicaltrials**
- **What to ask:** Questions to ask your treatment team: **www.LLS.org/whattoask**
- **Free education materials: www.LLS.org/booklets**
- **Additional information on MDS : www.LLS.org/mds**
- **Join LLS Community:** Connect with others who share your diagnosis: **www.LLS.org/community**
- **Information Resource Center:** Speak one-on-one with an Information Specialist who can assist you through cancer treatment, financial, and social challenges.
  - **EMAIL: infocenter@LLS.org**
  - **TOLL-FREE PHONE: (800) 955-4572**

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