

# MDS/MPN Response Criteria

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[MDS Response Criteria](#)

[MPN Response Criteria](#)

## MDS Response Criteria

### Complete Remission (CR)

*Requires all of the following maintained for a minimum of four weeks:*

#### Bone marrow evaluation:

- < 5% myeloblasts with normal maturation of all cell lines

#### Peripheral blood evaluation:

- Hemoglobin  $\geq$  11 g/dL untransfused without erythropoietic support
- ANC  $\geq$  1000/mm<sup>3</sup> without myeloid growth factor support
- Platelets  $\geq$  100,000/mm<sup>3</sup> without thrombopoietic support
- 0% blasts in blood

Alternative CR criteria are accepted in the setting of **pediatric** MDS and are as follows:

- Complete donor chimerism ( $\geq$  95% donor chimerism without recipient cells detected)
- Hemoglobin  $\geq$  11 g/dL untransfused without erythropoietic support
- ANC  $\geq$  1000/mm<sup>3</sup> without myeloid growth factor support
- Platelets  $\geq$  100,000/mm<sup>3</sup> without thrombopoietic support

In some cases, there may not be a four-week interval between completion of therapy and the pre-transplant disease assessment. In this case, CR should still be reported as the status at transplant since it represents the “best assessment” prior to HCT. This is an exception to the criteria that CR be durable beyond four weeks; the pre-transplant disease status should not be changed based on early relapse or disease assessment post-transplant.

## Hematologic Improvement (HI)

*Requires one measurement of the following maintained for at least eight weeks without ongoing cytotoxic therapy:*

- ✿ Hypomethylating agents (e.g. Vidaza) should not be considered cytotoxic therapy; therefore, Hematologic Improvement may still be reported if the recipient meets the criteria below while continuing to receive hypomethylating agents.

### Hematologic improvement – erythropoietic (HI-E):

- Hemoglobin increase of  $\geq 1.5$  g/dL untransfused  
or
- For RBC transfusions performed for hemoglobin  $\leq 9.0$ : reduction in RBC units transfused in 8 weeks by  $\geq 4$  units compared to the number of units transfused in the 8 weeks prior to treatment

### Hematologic improvement – platelets (HI-P):

- For pre-treatment platelet count of  $\geq 20 \times 10^9$ , platelet absolute increase of  $\geq 30 \times 10^9$
- For pre-treatment platelet count of  $< 20 \times 10^9$ , platelet absolute increase of  $\geq 20 \times 10^9$  and  $\geq 100\%$  increase from pre-treatment level

### Hematologic improvement – neutrophils (HI-N):

- Neutrophil count increase of  $\geq 100\%$  from pre-treatment level and an absolute increase of  $\geq 500/\text{mm}^3$

## No Response (NR)/Stable Disease (SD)

Does not meet the criteria for at least HI, but no evidence of disease progression to AML

## Progression from Hematologic Improvement (Prog from HI)

*Requires at least one of the following in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.):*

- $\geq 50\%$  reduction from maximum response levels in granulocytes or platelets
- Reduction in hemoglobin by  $\geq 1.5$  g/dL

- Transfusion dependence

*Note: declining donor chimerism does not meet the criteria for progression. If the above criteria for progression have been met, but a hematologic improvement was not previously achieved, report “No Response (NR) / Stable Disease (SD)”.*

### Relapse from Complete Remission (Rel from CR)

*Requires at least one of the following:*

- Return to pre-treatment bone marrow blast percentage
- Decrease of  $\geq 50\%$  from maximum response levels in granulocytes or platelets
- Transfusion dependence or hemoglobin level  $\geq 1.5$  g/dL lower than prior to therapy

*Note: declining donor chimerism does not meet the criteria for relapse.*

### Progression to AML

$\geq 20\%$  blasts in the blood or bone marrow

### MPN Response Criteria<sup>1</sup>

#### CR (requires each of the following)

- Bone marrow with  $\leq 5\%$  myeloblasts (including monocytic blast equivalents in CMML) with normal maturation of all cell lines and return to normal cellularity
- Myelofibrosis absent or  $\leq$  grade 1 fibrosis (mild reticulin fibrosis)
- Peripheral blood counts showing:
  - WBC  $\leq 10 \times 10^9/L$
  - Hgb  $\geq 11$  g/dL
  - PLT  $\geq 100 \times 10^9/L$ ;  $\leq 450 \times 10^9/L$
  - Blasts 0%
  - Neutrophilic precursors reduced to  $\leq 2\%$
  - Monocytes  $\leq 1 \times 10^9/L$
- Resolution of any extramedullary disease present prior to therapy; this includes cutaneous disease, disease-related serous effusions, and palpable hepatosplenomegaly

#### Myelofibrosis CR<sup>2</sup>

- Bone marrow with  $\leq 5\%$  myeloblasts with normal maturation of all cell lines
- Myelofibrosis absent or  $\leq$  grade 1 fibrosis (mild reticulin fibrosis)
- Peripheral blood counts showing:
  - ANC  $\geq 1.0 \times 10^9/L$  and  $<$  upper limit of normal
  - Hgb  $\geq 11$  g/dL and  $<$  upper limit of normal
  - PLT  $\geq 100 \times 10^9/L$  and  $<$  upper limit of normal
  - Neutrophilic precursors reduced to  $\leq 2\%$
- Resolution of disease symptoms and no palpable hepatosplenomegaly; no evidence of extramedullary hematopoiesis

### Hematologic Improvement

*Requires one measurement of the following maintained for at least eight weeks without ongoing cytotoxic therapy:*

- Response of erythroid line requires:
  - Hgb increase  $\geq 2.0$  g/dL from baseline
  - Transfusion independence for patients requiring at least 4 packed RBC transfusions in the previous 8 weeks
- Response of platelets requires:
  - For pre-treatment platelet count of  $> 20 \times 10^9/L$ , platelet absolute increase of  $\geq 30 \times 10^9/L$
  - For pre-treatment platelet count of  $\leq 20 \times 10^9/L$ , platelet absolute increase of  $\geq 20 \times 10^9/L$  and  $\geq 100\%$  increase from pre-treatment level
- Response of neutrophils requires:
  - For pre-treatment ANC  $> 0.5 \times 10^9/L$  and  $\leq 1.0 \times 10^9/L$ , neutrophils with  $\geq 50\%$  increase and an absolute increase of  $\geq 0.5 \times 10^9/L$
  - For pre-treatment ANC  $\leq 0.5 \times 10^9/L$ , neutrophils with  $\geq 100\%$  and an absolute increase of  $\geq 0.5 \times 10^9/L$

### No response/stable disease

- Does not meet the criteria for at least HI but no evidence of disease progression to AML

### Progression from Hematologic Improvement

- Transfusion dependence defined by history of at least 2 units of red blood cell transfusions in the past month for a hemoglobin level  $< 8.5$  g/dL without other explanation
- Reduction in hemoglobin by  $\geq 1.5$  g/dL
- $\geq 50\%$  reduction from maximum response levels in granulocytes or platelets

*Note: if the above criteria for progression have been met, but a hematologic improvement was not previously achieved, report “No Response (NR) / Stable Disease (SD)”.*

### Relapse from CR

- Reappearance of bone marrow disease, including blasts, monocytic blast equivalents, or fibrosis
- New extramedullary disease, including new or reappearance of splenomegaly, hepatomegaly, skin lesions, etc.

<sup>1</sup> Savona, M. R., Malcovati, L., Komrokji, R., Tiu, R. V., Mughal, T. I., Orazi, A., ... & List, A. F. (2015). An international consortium proposal of uniform response criteria for myelodysplastic/myeloproliferative neoplasms (MDS/MPN) in adults. *Blood*, 125(12), 1857-1865.

<sup>2</sup> Tefferi, A., Cervantes, F., Mesa, R., Passamonti, F., Verstovsek, S., Vannucchi, A. M., ... & Barosi, G. (2013). Revised response criteria for myelofibrosis: international Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) and European LeukemiaNet (ELN) consensus report. *Blood*, 122(8), 1395-1398.

### Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please [click here](#) or reference the retired manual section on the [Retired Forms Manuals](#) webpage.

Date	Manual Section	Add/Remove/Modify	Description
6/7/17	MDS/MPN Response Criteria	Add	Added following bullet to CR criteria for Myelofibrosis: <ul style="list-style-type: none"> <li>• Myelofibrosis absent or <math>\leq</math> grade 1 fibrosis (mild reticulin fibrosis)</li> </ul>
9/27/15	MDS/MPN Response Criteria	Modify	Added language to NR/SD criteria: Does not meet the criteria for at least HI, but no evidence of disease progression <b>to AML.</b>
9/27/15	MDS/MPN Response Criteria	Add	Added <a href="#">MPN</a> criteria
6/26/15	MDS/MPN Response Criteria	Modify	Edited <a href="#">Progression to AML</a> text to read: $\geq$ 20% blasts in the <b>blood or</b> bone marrow
6/5/15	MDS/MPN Response	Modify	Changed the following text in <a href="#">HI-P</a> :

	Criteria		<ul style="list-style-type: none"> <li>• For pre- <del>transplant</del> <b>treatment</b> platelet count of <math>&gt; 20 \times 10^9</math>, platelet absolute increase of <math>\geq 30 \times 10^9</math></li> <li>• For pre- <del>transplant</del> <b>treatment</b> platelet count of <math>&lt; 20 \times 10^9</math>, platelet absolute increase of <math>\geq 20 \times 10^9</math> and <math>\geq 100\%</math> increase from pre-treatment level</li> </ul>
5/ 22/ 15	MDS/MPN Response Criteria	Add	<p>Added the following text to <a href="#">CR</a>:</p> <p>In some cases, there may not be a four-week interval between completion of therapy and the pre-transplant disease assessment. In this case, CR should still be reported as the status at transplant since it represents the “best assessment” prior to HCT. This is an exception to the criteria that CR be durable beyond four weeks; the pre-transplant disease status should not be changed based on early relapse or disease assessment post-transplant.</p>
6/ 24/ 16	MDS/MPN Response Criteria	Add	<p>Added information box to MDS Disease Status Criteria, <a href="#">Hematologic Improvement</a> Section:</p> <p>Hypomethylating agents (e.g. Vidaza) should not be considered cytotoxic therapy; therefore, Hematologic Improvement may still be reported if the recipient meets the criteria below while continuing to receive hypomethylating agents.</p>
6/ 24/ 16	MDS/MPN Response Criteria	Modify	<p>Added language to note beneath <a href="#">Progression from Hematologic Improvement</a> for MDS and MPN Response Criteria:</p> <p>If the above criteria for progression have been met, but a hematologic improvement was not previously achieved, report “No Response (NR) / Stable Disease (SD)”.</p>
6/ 24/ 16	MDS/MPN Response Criteria	Add	<p>Added language to MPN Disease Status Criteria, <a href="#">Hematologic Improvement</a>:</p> <p>Requires one measurement of the following maintained for at least eight weeks without ongoing cytotoxic therapy:</p>

*Last modified: 2018/10/18*