Clinical trial results:
A Randomized Multicenter, Open-label, Phase 2 Study Evaluating the Efficacy and Safety of Azacitidine Subcutaneous in Combination With Durvalumab (MEDI4736) in Previously Untreated Subjects with Higher-Risk Myelodysplastic Syndromes (MDS) or in Elderly (65 years) Acute Myeloid Leukemia (AML) Subjects Not Eligible for Hematopoietic Stem Cell Transplantation (HSCT).

Summary

EudraCT number	2015-003596-30
Trial protocol	GB NL PT ES AT DE BE PL IT
Global end of trial date	27 December 2021

Results information

Result version number	v1 (current)
This version publication date	08 January 2023
First version publication date	08 January 2023

Trial information

Trial identification

Sponsor protocol code	MEDI4736-MDS-001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02775903
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Street Address: Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 February 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluate the efficacy of subcutaneous (sc) azacitidine in combination with durvalumab as compared with subcutaneous azacitidine alone in the defined study population.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 June 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 11
Country: Number of subjects enrolled	Belgium: 8
Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Germany: 21
Country: Number of subjects enrolled	Italy: 25
Country: Number of subjects enrolled	Poland: 18
Country: Number of subjects enrolled	Portugal: 3
Country: Number of subjects enrolled	Spain: 39
Country: Number of subjects enrolled	United Kingdom: 21
Country: Number of subjects enrolled	United States: 44
Worldwide total number of subjects	213
EEA total number of subjects	138

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	12
From 65 to 84 years	173
85 years and over	28

Subject disposition

Recruitment

Recruitment details:

This study consisted of 2 cohorts: • Adults with previously untreated intermediate, high or very high risk myelodysplastic syndromes (MDS) not eligible for hematopoietic stem cell transplantation (HSCT). • Adults with previously untreated acute myeloid leukemia (AML) ≥ 65 years and not eligible for HSCT with intermediate or poor cytogenetic risk.

Pre-assignment

Screening details:

Within each cohort participants were randomized in a 1:1 ratio to receive either azacitidine plus durvalumab or azacitidine alone. Randomization was stratified according to cytogenetic risk: • Very good, good and intermediate versus poor and very poor for MDS • Intermediate versus poor for AML .

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	MDS: Azacitidine + Durvalumab

Arm description:

Participants with MDS received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks (Q4W) in combination with 1500 mg intravenous durvalumab on Day 1 of every 4 week cycle for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1500 mg on Day 1 Q4W

Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

75 mg/m2 for 7 days every 4 weeks [Q4W])

Arm title	MDS: Azacitidine Alone

Arm description:

Participants with MDS received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Arm type	Experimental

Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

75 mg/m2 for 7 days every 4 weeks [Q4W])

Arm title	AML: Azacitidine + Durvalumab

Arm description:

Participants with AML received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks (Q4W) in combination with 1500 mg intravenous durvalumab on Day 1 of every 4 week cycle for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1500 mg on Day 1 Q4W

Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

75 mg/m2 for 7 days every 4 weeks [Q4W])

Arm title	AML: Azacitidine Alone

Arm description:

Participants with AML received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Arm type	Experimental
Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

75 mg/m2 for 7 days every 4 weeks [Q4W])

Number of subjects in period 1	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab
Started	42	42	64
Completed	4	1	1
Not completed	38	41	63
Adverse event, serious fatal	7	11	12
Consent withdrawn by subject	7	5	5

Adverse event, non-fatal	-	1	12
Other reasons	7	8	2
Progressive disease	15	14	30
Lack of efficacy	2	2	2

Number of subjects in period 1	AML: Azacitidine Alone
Started	65
Completed	5
Not completed	60
Adverse event, serious fatal	11
Consent withdrawn by subject	8
Adverse event, non-fatal	3
Other reasons	12
Progressive disease	20
Lack of efficacy	6

Baseline characteristics

Reporting groups	
Reporting group title	MDS: Azacitidine + Durvalumab
Reporting group description:	
Participants with MDS received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks (Q4W) in combination with 1500 mg intravenous durvalumab on Day 1 of every 4 week cycle for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.	
Reporting group title	MDS: Azacitidine Alone
Reporting group description:	
Participants with MDS received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.	
Reporting group title	AML: Azacitidine + Durvalumab
Reporting group description:	
Participants with AML received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks (Q4W) in combination with 1500 mg intravenous durvalumab on Day 1 of every 4 week cycle for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.	
Reporting group title	AML: Azacitidine Alone
Reporting group description:	
Participants with AML received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.	

Reporting group values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab
Number of subjects	42	42	64
Age Categorical Units: participants			
< 65 years	2	10	0
≥ 65 to < 75 years	21	11	24
≥ 75 years	19	21	40
Age Continuous Units: years			
arithmetic mean	72.5	73.2	76.2
standard deviation	± 6.53	± 8.83	± 5.97
Sex: Female, Male Units: participants			
Female	14	12	24
Male	28	30	40
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	2	6
Not Hispanic or Latino	30	33	39
Unknown or Not Reported	7	7	19
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	1	0
Black or African American	1	0	0

Native Hawaiian or Other Pacific Islander	0	0	0
White	30	33	45
Not Collected or Reported	7	5	18
Other	2	3	1
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient’s level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: - 0 = Fully active, no restrictions; - 1 = Restricted activity but ambulatory, able to carry out work of a light nature; - 2 = Ambulatory and capable of all self-care but unable to carry out work activities; - 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; - 4 = Completely disabled, no selfcare, confined to bed or chair; - 5 = Dead			
Units: Subjects			
0 - Fully active	17	18	19
1 - Restricted but ambulatory	20	20	40
2 - Ambulatory but unable to work	3	4	5
3 - Limited self-care	0	0	0
4 - Completely Disabled	0	0	0
Missing	2	0	0

Reporting group values	AML: Azacitidine Alone	Total	
Number of subjects	65	213	
Age Categorical Units: participants			
< 65 years	0	12	
≥ 65 to < 75 years	28	84	
≥ 75 years	37	117	
Age Continuous Units: years			
arithmetic mean	75.3		
standard deviation	± 5.36	-	
Sex: Female, Male Units: participants			
Female	34	84	
Male	31	129	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	16	
Not Hispanic or Latino	41	143	
Unknown or Not Reported	21	54	
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	3	
Black or African American	1	2	
Native Hawaiian or Other Pacific Islander	0	0	
White	42	150	
Not Collected or Reported	21	51	
Other	1	7	
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status is used to describe a patient’s level of functioning in terms of their ability to			

care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: - 0 = Fully active, no restrictions; - 1 = Restricted activity but ambulatory, able to carry out work of a light nature; - 2 = Ambulatory and capable of all self-care but unable to carry out work activities; - 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; - 4 = Completely disabled, no selfcare, confined to bed or chair; - 5 = Dead			
Units: Subjects			
0 - Fully active	26	80	
1 - Restricted but ambulatory	32	112	
2 - Ambulatory but unable to work	7	19	
3 - Limited self-care	0	0	
4 - Completely Disabled	0	0	
Missing	0	2	

End points

End points reporting groups

Reporting group title	MDS: Azacitidine + Durvalumab

Reporting group description:

Participants with MDS received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks (Q4W) in combination with 1500 mg intravenous durvalumab on Day 1 of every 4 week cycle for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Reporting group title	MDS: Azacitidine Alone

Reporting group description:

Participants with MDS received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Reporting group title	AML: Azacitidine + Durvalumab

Reporting group description:

Participants with AML received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks (Q4W) in combination with 1500 mg intravenous durvalumab on Day 1 of every 4 week cycle for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Reporting group title	AML: Azacitidine Alone

Reporting group description:

Participants with AML received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Primary: MDS Cohort: Overall Response Rate

End point title	MDS Cohort: Overall Response Rate[1]

End point description:

Overall response rate (ORR) is defined as the percentage of participants achieving a complete remission (CR), partial remission (PR), marrow complete remission (mCR), and/or hematological improvement (HI) based on International Working Group (IWG) 2006 response criteria for MDS and central review. CR: ≤ 5% myeloblasts in bone marrow (BM), and peripheral blood: hemoglobin ≥ 11 g/dL; platelets ≥ 100 × 10/L; neutrophils ≥ 1.0 × 10/L; blasts 0% PR: BM blasts decreased by ≥ 50% but still > 5%; peripheral blood as for CR mCR: BM ≤ 5% myeloblasts and decrease by ≥ 50% HI: Any of the following: •Hemoglobin increase by ≥ 1.5 g/dL or reduction of units of red blood cell (RBC) transfusions of at least 4 RBC transfusions/8 weeks compared with pretreatment •Absolute increase in platelets of ≥ 30 × 10/L if pretreatment value > 20 × 10/L or increase from < 20 × 10/L to > 20 × 10/L and by at least 100% •At least 100% increase in neutrophils and an absolute increase of > 0.5 × 10/L

End point type	Primary

End point timeframe:

Response was assessed following every 3 treatment cycles until treatment discontinuation; median duration of treatment was 239 days (AZA) and 215 days (DUR) in the AZA + DUR group and 210 days in the AZA alone group.

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	42		
Units: percentage of participants				
number (confidence interval 95%)	61.9 (47.22 to 76.59)	47.6 (32.51 to 62.72)		

Statistical analyses

Statistical analysis title	Summary of Response
Comparison groups	MDS: Azacitidine Alone v MDS: Azacitidine + Durvalumab
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1838
Method	Wald asymptotic two-sided test

Primary: AML Cohort: Overall Response Rate

End point title	AML Cohort: Overall Response Rate[2]

End point description:

Overall response rate for AML is defined as the percentage of participants achieving an overall response of morphologic complete remission (CR) or morphologic complete remission with incomplete blood count recovery (CRi) based on modified IWG 2003 response criteria for AML and central review. CR: The following conditions must be met: •Absolute neutrophil count (ANC) ≥ 1.0 x10/L •Platelet count ≥ 100 x10/L •The bone marrow should contain less than 5% blast cells; •Auer rods should not be detectable; •No platelet, or whole blood transfusions for 7days prior to the date of the hematology assessment. CRi: Defined as a morphologic complete remission but the ANC count may be < 1.0 x10/L and/or the platelet count may be < 100 x10/L.

End point type	Primary

End point timeframe:

Response was assessed following every 3 treatment cycles until treatment discontinuation; median duration of treatment was 198 days (AZA) and 171 days (DUR) in the AZA + DUR group and 203 days in the AZA alone group.

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	65		
Units: percentage of participants				
number (confidence interval 95%)	31.3 (19.89 to 42.61)	35.4 (23.76 to 47.01)		

Statistical analyses

Statistical analysis title	Summary of Response
Comparison groups	AML: Azacitidine + Durvalumab v AML: Azacitidine Alone
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.618
Method	Wald asymptotic two-sided test

Secondary: MDS Cohort: Kaplan Meier Estimate of Time to First Response

End point title	MDS Cohort: Kaplan Meier Estimate of Time to First Response[3]

End point description:

Time to first response is defined as the time from randomization to the earliest date any response (complete remission (CR), partial remission (PR), marrow complete remission (mCR), and/or hematological improvement (HI)) based on International Working Group (IWG) 2006 response criteria for MDS and central review. Participants who did not achieve any defined response were censored at the date of last adequate response assessment, disease progression, or death, whichever occurred first. Response was assessed following every 3 treatment cycles until treatment discontinuation.

End point type	Secondary

End point timeframe:

From randomization to the earliest date any response (up to approximately 34 months)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	42		
Units: Weeks				
median (confidence interval 95%)	14.3 (11.3 to 20.9)	18.4 (8.1 to 26.1)		

Statistical analyses

Statistical analysis title	Summary of Time to First Response
Comparison groups	MDS: Azacitidine + Durvalumab v MDS: Azacitidine Alone
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7016
Method	Logrank

Secondary: MDS Cohort: Kaplan Meier Estimate of Relapse-free Survival

End point title	MDS Cohort: Kaplan Meier Estimate of Relapse-free Survival[4]

End point description:

The time from the date of first documented response (complete remission (CR), partial remission (PR)) to the date of disease relapse or death from any cause, whichever occurred first according to the International Working Group (IWG) 2006 response criteria for MDS and central review. Participants who were still alive and progression-free were censored at the date of their last response assessment. Participants who received a subsequent therapy before the date of disease relapse or death were censored at the time of subsequent therapy. Relapse after CR or PR is defined as at least one of the following: •Return to pretreatment bone marrow blast % •Decrement of ≥ 50% from maximum remission/response levels in granulocytes or platelets •Reduction in hemoglobin concentration by ≥ 1.5 g/dL or transfusion dependence. Response was assessed following every 3 treatment cycles until treatment discontinuation. NOTE: 99999 = NA; insufficient number of participants with events

End point type	Secondary

End point timeframe:

From randomization to to the date of disease relapse or death from any cause, whichever occurred first (up to approximately 34 months)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	4		
Units: Months				
median (confidence interval 95%)	3.7 (3.0 to 99999)	99999 (0.0 to 99999)		

Statistical analyses

Statistical analysis title	Summary of Relapse-free Survival
Comparison groups	MDS: Azacitidine + Durvalumab v MDS: Azacitidine Alone
Number of subjects included in analysis	7
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6076
Method	Logrank

Secondary: MDS Cohort: Percentage of Participants who Achieved a Cytogenetic Response

End point title	MDS Cohort: Percentage of Participants who Achieved a Cytogenetic Response[5]

End point description:

Cytogenetic response is defined as the percentage of participants who achieved a complete cytogenetic response or partial cytogenetic response according to the International Working Group (IWG) 2006 response criteria and central review. Complete cytogenetic response: Disappearance of the baseline chromosomal abnormality without appearance of new abnormalities. Partial cytogenetic response: At least 50% reduction of the chromosomal abnormality. Response was assessed following every 3 treatment cycles until treatment discontinuation.

End point type	Secondary

End point timeframe:

From randomization up to approximately 34 months

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	23		
Units: percentage of participants				
number (confidence interval 95%)	47.6 (26.26 to 68.98)	34.8 (15.32 to 54.25)		

Statistical analyses

Statistical analysis title	Summary of Cytogenetic Response
Comparison groups	MDS: Azacitidine + Durvalumab v MDS: Azacitidine Alone
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.384
Method	Wald asymptotic two-sided test

Secondary: MDS Cohort: Kaplan-Meier Estimate of Progression-free Survival (PFS)

End point title	MDS Cohort: Kaplan-Meier Estimate of Progression-free Survival (PFS)[6]

End point description:

Progression-free survival is defined as the time from randomization to the first documented progressive disease (PD), relapse, or death due to any cause during or after the treatment period, whichever occurred first, according to the International Working Group (IWG) 2006 response criteria for MDS and central review. Participants who were still alive and progression-free were censored at the date of their last response assessment. Progressive disease is defined as follows: - an increase in BM blasts relative to nadir: •If nadir less than 5% blasts: ≥ 50% increase in blasts to > 5% blasts •If nadir 5% - 10% blasts: ≥ 50% increase in blasts to > 10% blasts •If nadir 10% - 20% blasts: ≥ 50% increase in blasts to > 20% blasts •If nadir 20% - 30% blasts: ≥ 50% increase in blasts to > 30% blasts And any of the following: •At least 50% decrement from maximum remission/response levels in granulocytes or platelets •Reduction in Hgb concentration by ≥ 2 g/dL •Transfusion dependence

End point type	Secondary

End point timeframe:

From randomization to the first documented progressive disease (PD), relapse, or death due to any cause (up to approximately 34 months)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	42		
Units: Months				
median (confidence interval 95%)	8.7 (5.6 to 10.2)	8.6 (3.4 to 11.2)		

Statistical analyses

Statistical analysis title	Summary of Progression-free Survival
Comparison groups	MDS: Azacitidine + Durvalumab v MDS: Azacitidine Alone
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8961
Method	Logrank

Secondary: MDS Cohort: Kaplan-Meier Estimate of Duration of Response

End point title	MDS Cohort: Kaplan-Meier Estimate of Duration of Response[7]

End point description:

Duration of response is defined as the time from when the first overall response (complete remission (CR), partial remission (PR), marrow complete remission (mCR), and/or hematological improvement (HI)) was observed until relapse, progressive disease (PD), or death, as defined by the International Working Group (IWG) 2006 response criteria and central review. If no relapse, PD, or death was observed, the duration of response was censored at the last response assessment date that the participant was known to be progression-free. Response was assessed following every 3 treatment cycles until treatment discontinuation.

End point type	Secondary

End point timeframe:

From randomization to the first overall response, or death (up to approximately 34 months)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	20		
Units: Weeks				
median (confidence interval 95%)	33.9 (22.1 to 47.4)	39.7 (26.3 to 73.1)		

Statistical analyses

Statistical analysis title	Summary of Duration of Response
Comparison groups	MDS: Azacitidine + Durvalumab v MDS: Azacitidine Alone
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3591
Method	Logrank

Secondary: MDS Cohort: Kaplan-Meier Estimate of Time to AML Transformation

End point title	MDS Cohort: Kaplan-Meier Estimate of Time to AML Transformation[8]

End point description:

Participants were monitored for transformation to acute myeloid leukemia (AML) until death, lost to follow-up, withdrawal of consent for further data collection, or the end of the trial. Time to transformation to AML is defined as the time from the date of randomization until the date the participant had documented transformation to AML (defined as at least 30% of myeloblasts in the bone marrow). Participants with no transformation to AML were censored at the date of their last disease assessment. NOTE: 99999 = NA; insufficient number of participants with events

End point type	Secondary

End point timeframe:

From randomization to the date the participant had documented transformation to AML (up to approximately 34 months)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	42		
Units: Months				
median (confidence interval 95%)	20.8 (15.0 to 99999)	27.7 (11.3 to 99999)		

Statistical analyses

Statistical analysis title	Summary of AML Transformation
Comparison groups	MDS: Azacitidine + Durvalumab v MDS: Azacitidine Alone
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9031
Method	Logrank

Secondary: MDS Cohort: Percentage of Participants with Disease Transformation to

AML

End point title	MDS Cohort: Percentage of Participants with Disease Transformation to AML[9]

End point description:

Disease transformation to acute myeloid leukemia (AML) is defined as at least 30% myeloblasts in the bone marrow. Participants were monitored for transformation to AML until death, lost to follow-up, withdrawal of consent for further data collection, or the end of the trial. Participants with no transformation to AML were censored at the date of their last disease assessment.

End point type	Secondary

End point timeframe:

From randomization until death, lost to follow-up, withdrawal of consent for further data collection, or the end of the trial (up to approximately 34 months)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	42		
Units: Percentage of participants				
number (not applicable)	23.8	19.0		

Statistical analyses

No statistical analyses for this end point

Secondary: AML Cohort: Kaplan Meier Estimate of Time to First Response

End point title	AML Cohort: Kaplan Meier Estimate of Time to First

End point description:

Time to first response is defined as the time between the date of randomization and the earliest date any response (CR or CRi) was observed based on the modified International Working Group (IWG) 2003 response criteria for AML and central review. Participants who did not achieve any defined response were censored at the date of last adequate response assessment, disease progression, or death, whichever occurred first. Response was assessed following every 3 treatment cycles until treatment discontinuation. NOTE: 99999 = NA; insufficient number of participants with events.

End point type	Secondary

End point timeframe:

From randomization and the earliest date any response (up to approximately 34 months)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	65		
Units: Weeks				
median (confidence interval 95%)	99999 (14.3 to 99999)	25.3 (13.9 to 43.0)		

Statistical analyses

Statistical analysis title	Summary of Time to Response
Comparison groups	AML: Azacitidine + Durvalumab v AML: Azacitidine Alone
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2409
Method	Logrank

Secondary: AML Cohort: Percentage of Participants who Achieved a Complete Cytogenetic Response

End point title	AML Cohort: Percentage of Participants who Achieved a Complete Cytogenetic Response[11]

End point description:

Complete cytogenetic response (CyCR) based on the modified International Working Group (IWG) 2003 response criteria is defined as morphologic complete remission with a reversion to a normal karyotype. The following conditions must be met: • Absolute neutrophil count (ANC) ≥ 1.0 x10/L • Platelet count ≥ 100 x10/L • The bone marrow should contain less than 5% blast cells; • Auer rods should not be detectable; • No platelet, or whole blood transfusions for 7days prior to the date of the hematology assessment. AND • Reversion to normal karyotype at time of CR (based on ≥ 10 metaphases). Response was assessed following every 3 treatment cycles until treatment discontinuation.

End point type	Secondary

End point timeframe:

From randomization up to approximately 34 months)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	50		
Units: Percentage of participants				
number (confidence interval 95%)	11.3 (2.79 to 19.85)	16.0 (5.84 to 26.16)		

Statistical analyses

Statistical analysis title	Summary of Complete Cytogenetic Response
Comparison groups	AML: Azacitidine + Durvalumab v AML: Azacitidine Alone
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4894
Method	Wald asymptotic two-sided test

Secondary: AML Cohort: Kaplan Meier Estimate of Relapse-free Survival

End point title	AML Cohort: Kaplan Meier Estimate of Relapse-free Survival[12]

End point description:

Relapse-free survival is defined as time from the date of first documented response (morphologic complete remission (CR) or morphologic complete remission with incomplete blood count recovery (CRi)) to the date of disease relapse or death from any cause, whichever occurred first based on the modified International Working Group (IWG) 2003 response criteria for AML and central review. Participants who were still alive and progression-free were censored at the date of their last response assessment. Participants who received a subsequent therapy before the date of disease relapse or death were censored at the time of subsequent therapy.

End point type	Secondary

End point timeframe:

From randomization to the date of disease relapse or death from any cause, whichever occurred first (up to approximately 34 months)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	23		
Units: Months				
median (confidence interval 95%)	9.5 (5.0 to 15.0)	12.2 (3.5 to 19.3)		

Statistical analyses

Statistical analysis title	Summary of Relapse-Free Survival
Comparison groups	AML: Azacitidine + Durvalumab v AML: Azacitidine Alone
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0688
Method	Logrank

Secondary: AML Cohort: Percentage of Participants with Hematologic Improvement

End point title	AML Cohort: Percentage of Participants with Hematologic Improvement[13]

End point description:

Hematological improvement was defined as participants with a erythroid response (HI-E), platelet response (HI-P) or neutrophil response (HI-NE) for at least 8 weeks, according to the IWG 2006 response criteria: Hi-E (in participants with pretreatment hemoglobin < 11 g/dL or red blood cell (RBC)-transfusion dependent): Hemoglobin increase of ≥ 1.5 g/dL, or reduction in units of RBC transfusions of at least 4 RBC transfusions/8 weeks compared with the 8 weeks prior to pretreatment. HI-P (in participants with pretreatment platelet count < 100 × 10/L): Absolute increase in platelets of ≥ 30 × 10/L if pretreatment value > 20 × 10/L or increase from < 20 × 10/L to > 20 × 10/L and by at least 100%. HI-N (in participants with pretreatment neutrophils < 1.0 × 10/L): At least 100% increase in neutrophils and an absolute increase of > 0.5 × 10/L. Response was assessed following every 3 treatment cycles until treatment discontinuation.

End point type	Secondary

End point timeframe:

From randomization up to approximately 34 months

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	65		
Units: Percentage of participants				
number (confidence interval 95%)	42.2 (30.09 to 54.29)	38.5 (26.63 to 50.29)		

Statistical analyses

No statistical analyses for this end point

Secondary: AML Cohort: Kaplan-Meier Estimate of Duration of Response

End point title	AML Cohort: Kaplan-Meier Estimate of Duration of Response[14]

End point description:

Duration of response is defined as the time from the first response morphologic complete remission (CR) or morphologic complete remission with incomplete blood count recovery (CRi)) was observed until relapse, PD, or death based on the IWG 2003 response criteria and central review. If no relapse, PD, or death was observed, the duration of response was censored at the last response assessment date that the participant was known to be progression-free. Response was assessed following every 3 treatment cycles until treatment discontinuation.

End point type	Secondary

End point timeframe:

From randomization until relapse, PD, or death (up to approximately 34 months)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Endpoints are pre-specified for specific study arms

End point values	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	23		
Units: Weeks				
median (confidence interval 95%)	24.6 (16.4 to 48.0)	52.0 (15.1 to 84.0)		

Statistical analyses

Statistical analysis title	Summary of Duration of Response
Comparison groups	AML: Azacitidine + Durvalumab v AML: Azacitidine Alone
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0381
Method	Logrank

Secondary: Number of Participants with Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Participants with Treatment-emergent Adverse Events (TEAEs)

End point description:

TEAEs occurred or worsened on or after the first dose of study drug and within 90 days after last dose of durvalumab or 28 days after last dose of azacitidine. The intensity of AEs was graded according to the Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03: Grade 1 (Mild): asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. Grade 2 (Moderate): minimal, local or noninvasive intervention indicated; limiting age-appropriate activities of daily living. Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care. Grade 4: Life-threatening consequences; urgent intervention indicated. Grade 5: Death due to AE. NOTE: 99999 = NA; Participants did not receive study drug associated with the category of TEAE.

End point type	Secondary

End point timeframe:

From first dose to 90 days after last dose of durvalumab or 28 days after last dose of azacitidine proir to the extension study (up to approximately 34 months)

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	41	64	62
Units: Participants				
Any treatment-emergent adverse event (TEAE)	38	41	64	62
TEAE related to DUR	27	99999	50	99999
TEAE related to AZA	31	33	56	50
TEAE related to DUR or AZA	35	33	58	50
Grade 3 TEAE	36	30	60	50
Grade 3 TEAE related to DUR	18	99999	29	99999
Grade 3 TEAE related to AZA	18	16	32	27
Grade 3 TEAE related to DUR or AZA	22	16	38	27
Grade 4 TEAE	33	27	43	34
Grade 4 TEAE related to DUR	16	99999	18	99999
Grade 4 TEAE related to AZA	19	15	27	17
Grade 4 TEAE related to DUR or AZA	22	15	28	17
Grade 5 TEAE	10	9	26	11
Grade 5 TEAE related to DUR	2	99999	1	99999
Grade 5 TEAE related to AZA	1	1	1	1
Grade 5 TEAE related to DUR or AZA	2	1	1	1
Serious TEAE	34	29	56	45
Serious TEAE related to DUR	11	99999	33	99999
Serious TEAE related to AZA	9	10	25	16
Serious TEAE related to DUR or AZA	14	10	34	16
TEAE leading to discontinuation of DUR	5	99999	21	99999
TEAE leading to discontinuation of AZA	0	1	13	3
TEAE leading to discontinuation of DUR or AZA	5	1	22	3
TEAE leading to dose reduction of AZA	3	6	10	2
TEAE leading to dose interruption of DUR	24	99999	34	99999
TEAE leading to dose interruption of AZA	27	19	39	32
TEAE leading to dose interruption of DUR or AZA	28	19	41	32
TEAE leading to ongoing DUR infusion interruption	2	99999	2	99999

Statistical analyses

No statistical analyses for this end point

Secondary: Kaplan-Meier Estimate of Overall Survival

End point title	Kaplan-Meier Estimate of Overall Survival

End point description:

Overall survival is defined as the time between randomization and death/censored date. Participants who were alive at the time of the clinical data cut-off were censored at the last known alive date. NOTE: 99999 = NA; insufficient number of participants with events.

End point type	Secondary

End point timeframe:

From randomization to date of death or last known alive date (up to approximately 34 months)

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	64	65
Units: Months				
median (confidence interval 95%)	11.6 (9.5 to 99999)	16.3 (9.8 to 22.6)	13.0 (10.3 to 17.3)	14.4 (10.0 to 16.6)

Statistical analyses

Statistical analysis title	Summary of Overall Survival (AML)
Comparison groups	AML: Azacitidine + Durvalumab v AML: Azacitidine Alone
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0691
Method	Logrank

Statistical analysis title	Summary of Overall Survival (MDS)
Comparison groups	MDS: Azacitidine + Durvalumab v MDS: Azacitidine Alone
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8973
Method	Logrank

Secondary: One-year Survival

End point title	One-year Survival

End point description:

One-year survival is defined as the probability of survival at 1 year from randomization and is represented by the Kaplan-Meier estimate of the percentage of participants alive after 1 year.

End point type	Secondary

End point timeframe:

At 12 months after randomization

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	64	65
Units: Percentage of participants	49	58	52	55

Statistical analyses

No statistical analyses for this end point

Secondary: Durvalumab Serum Concentration

End point title	Durvalumab Serum Concentration[15]

End point description:

NOTE: The number of participants analyzed for each timepoint may vary depending on the number of participants with available serum concentration measurements.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 end of infusion (EOI), Cycle 2 Day 1 pre-infusion, Cycle 4 Day 1 pre-infusion and EOI, and Cycle 6 Day 1 pre-infusion

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are pre-specified for specific study arms

End point values	MDS: Azacitidine + Durvalumab	AML: Azacitidine + Durvalumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	62		
Units: ng/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 end of infusion	375548.511 (± 140777.0558)	378598.369 (± 201902.4363)		
Cycle 2 Day 1 pre-infusion	84380.032 (± 92174.3455)	54216.956 (± 28336.3692)		
Cycle 4 Day 1 pre-infusion	132266.794 (± 126971.6223)	78622.429 (± 41708.9956)		
Cycle 4 Day 1 end of infusion	433942.600 (± 233241.0329)	391523.395 (± 147928.1261)		
Cycle 6 Day 1 pre-infusion	114448.977 (± 64608.9007)	142517.871 (± 248212.8037)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Hematology Parameters I

End point title	Change from Baseline in Selected Hematology Parameters I

End point description:

Baseline values are defined as the last assessment of a particular parameter prior to administration of the participants first dose. NOTE: The number of participants analyzed for each laboratory parameter may vary depending on the number of participants with available laboratory test measurements.

End point type	Secondary

End point timeframe:

Cycle 2 - Days 1, 8, 15 and 22

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	33	56	57
Units: 10^9/L				
arithmetic mean (standard deviation)				
Hemoglobin (g/L)	2.1 (± 15.66)	5.7 (± 18.94)	2.2 (± 13.67)	-3.0 (± 13.91)
Leukocytes (10^9/L)	-1.330 (± 2.8158)	-0.497 (± 1.1452)	-2.050 (± 9.0236)	-0.941 (± 2.7708)
Lymphocytes (10^9/L)	-0.242 (± 0.5314)	-0.085 (± 0.3904)	-0.394 (± 1.6995)	-0.262 (± 0.9024)
Neutrophils, Segmented (10^9/L)	-0.665 (± 1.6364)	-0.266 (± 0.7576)	0.646 (± 0.7870)	-0.102 (± 0.7346)
Platelets (10^9/L)	26.7 (± 112.92)	-2.6 (± 82.05)	25.9 (± 92.86)	-0.9 (± 167.88)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Hematology Parameters II

End point title	Change from Baseline in Selected Hematology Parameters II

End point description:

Baseline values are defined as the last assessment of a particular parameter prior to administration of the participants first dose.

End point type	Secondary

End point timeframe:

Cycle 2 - Days 1, 8, 15 and 22

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	33	56	57
Units: g/L				
arithmetic mean (standard deviation)	2.1 (± 15.66)	5.7 (± 18.94)	2.2 (± 13.67)	-3.0 (± 13.91)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Chemistry Parameters I

End point title	Change from Baseline in Selected Chemistry Parameters I

End point description:

Baseline values are defined as the last assessment of a particular parameter prior to administration of the participants first dose.

End point type	Secondary

End point timeframe:

Cycle 2 - Days 1, 8, 15 and 22

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	33	56	57
Units: g/L				
arithmetic mean (standard deviation)	-1.8 (± 4.01)	-1.1 (± 2.93)	-1.8 (± 5.00)	-3.8 (± 4.78)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Chemistry Parameters II

End point title	Change from Baseline in Selected Chemistry Parameters II

End point description:

Baseline values are defined as the last assessment of a particular parameter prior to administration of the participants first dose. NOTE: The number of participants analyzed for each laboratory parameter may vary depending on the number of participants with available laboratory test measurements.

End point type	Secondary

End point timeframe:

Cycle 2 - Days 1, 8, 15 and 22

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	33	56	57
Units: U/L				
arithmetic mean (standard deviation)				
Alkaline Phosphatase (U/L)	8.7 (± 15.71)	4.5 (± 13.90)	12.3 (± 55.70)	15.5 (± 68.53)
Alanine Aminotransferase (U/L)	3.6 (± 16.96)	0.4 (± 9.40)	0.3 (± 21.05)	4.0 (± 19.41)
Aspartate Aminotransferase (U/L)	0.9 (± 10.52)	-0.8 (± 5.73)	-0.9 (± 16.83)	0.5 (± 14.22)
Lipase (U/L)	-5.4 (± 18.23)	-10.2 (± 25.80)	-2.0 (± 10.28)	3.1 (± 42.85)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Chemistry Parameters III

End point title	Change from Baseline in Selected Chemistry Parameters III

End point description:

Baseline values are defined as the last assessment of a particular parameter prior to administration of the participants first dose. NOTE: The number of participants analyzed for each laboratory parameter may vary depending on the number of participants with available laboratory test measurements.

End point type	Secondary

End point timeframe:

Cycle 2 - Days 1, 8, 15 and 22

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	33	56	57
Units: mmol/L				
arithmetic mean (standard deviation)				
Calcium (mmol/L)	0.004 (± 0.1013)	0.016 (± 0.1008)	-0.003 (± 0.1523)	-0.039 (± 0.1189)
Glucose (mmol/L)	-0.40 (± 2.210)	-0.19 (± 1.265)	-0.38 (± 2.513)	-0.02 (± 2.365)
Potassium (mmol/L)	0.15 (± 0.416)	-0.01 (± 0.451)	0.02 (± 0.411)	0.04 (± 0.622)
Sodium (mmol/L)	-0.2 (± 2.93)	0.3 (± 3.26)	-0.6 (± 4.49)	-1.6 (± 3.73)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Selected Chemistry Parameters IV

End point title	Change from Baseline in Selected Chemistry Parameters IV

End point description:

Baseline values are defined as the last assessment of a particular parameter prior to administration of the participants first dose. NOTE: The number of participants analyzed for each laboratory parameter may vary depending on the number of participants with available laboratory test measurements.

End point type	Secondary

End point timeframe:

Cycle 2 - Days 1, 8, 15 and 22

End point values	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab	AML: Azacitidine Alone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	33	56	57
Units: umol/L				
arithmetic mean (standard deviation)				
Bilirubin (umol/L)	2.2 (± 5.13)	1.2 (± 4.21)	2.4 (± 6.23)	-0.0 (± 5.31)
Creatinine (umol/L)	-4.0 (± 14.77)	-2.9 (± 10.19)	2.3 (± 16.39)	-0.6 (± 15.93)
Urate (umol/L)	6.8 (± 65.85)	-3.2 (± 67.06)	-15.1 (± 75.69)	-29.1 (± 80.85)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality was assessed from first dose to study completion. SAEs and NSAEs were assessed from first dose to 90 days after last dose of durvalumab or 28 days after last dose of azacitidine (up to approximately 66 months)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	MDS: Azacitidine + Durvalumab

Reporting group description:

Participants with MDS received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks (Q4W) in combination with 1500 mg intravenous durvalumab on Day 1 of every 4 week cycle for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Reporting group title	MDS: Azacitidine Alone

Reporting group description:

Participants with MDS received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Reporting group title	AML: Azacitidine + Durvalumab

Reporting group description:

Participants with AML received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks (Q4W) in combination with 1500 mg intravenous durvalumab on Day 1 of every 4 week cycle for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Reporting group title	AML: Azacitidine Alone

Reporting group description:

Participants with AML received 75 mg/m² subcutaneous azacitidine for 7 days every 4 weeks for at least 6 cycles. Participants who benefited from treatment may have continued treatment until loss of that benefit, disease progression or other treatment discontinuation criterion were met.

Serious adverse events	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab
Total subjects affected by serious adverse events			
subjects affected / exposed	34 / 38 (89.47%)	29 / 41 (70.73%)	56 / 64 (87.50%)
number of deaths (all causes)	22	27	48
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatocellular carcinoma			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transformation to acute myeloid leukaemia			
subjects affected / exposed	3 / 38 (7.89%)	4 / 41 (9.76%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	4 / 64 (6.25%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Raynaud's phenomenon			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Cellulitis	Additional description: Cellulitis of the right axillary region and respiratory distress		
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	9 / 64 (14.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 9
Generalised oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site haemorrhage			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site vesicles			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	5 / 38 (13.16%)	3 / 41 (7.32%)	8 / 64 (12.50%)
occurrences causally related to treatment / all	1 / 5	1 / 3	3 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Reproductive system and breast disorders			
Female genital tract fistula			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Epistaxis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	5 / 64 (7.81%)
occurrences causally related to treatment / all	1 / 1	0 / 0	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subdural haematoma			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Synovial rupture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure chronic			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic encephalopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intraventricular haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Loss of consciousness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 38 (7.89%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytopenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	14 / 38 (36.84%)	9 / 41 (21.95%)	23 / 64 (35.94%)
occurrences causally related to treatment / all	5 / 21	4 / 18	12 / 41
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	1 / 5	2 / 2	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	0 / 1	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	3 / 38 (7.89%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	2 / 3	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			

subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panniculitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pemphigoid			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic skin eruption			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	2 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

Autoimmune thyroiditis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspergillus infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			

subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingivitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	0 / 0	0 / 2	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site infection			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection fungal			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micrococcus infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oesophageal infection			

subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Perineal cellulitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	6 / 38 (15.79%)	3 / 41 (7.32%)	16 / 64 (25.00%)
occurrences causally related to treatment / all	2 / 9	0 / 3	11 / 25
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 3
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Progressive multifocal leukoencephalopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Sepsis			
subjects affected / exposed	1 / 38 (2.63%)	3 / 41 (7.32%)	4 / 64 (6.25%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 2
Septic shock			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	1 / 2	0 / 0	1 / 1
Serratia sepsis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	0 / 38 (0.00%)	2 / 41 (4.88%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection bacterial			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	3 / 38 (7.89%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			

subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Fluid retention			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Serious adverse events	AML: Azacitidine Alone		
Total subjects affected by serious adverse events			
subjects affected / exposed	45 / 62 (72.58%)		
number of deaths (all causes)	42		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatocellular carcinoma				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transformation to acute myeloid leukaemia				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour associated fever				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Haematoma				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypovolaemic shock				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral artery thrombosis				

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Raynaud's phenomenon				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Cellulitis	Additional description: Cellulitis of the right axillary region and respiratory distress			
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Asthenia				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	4 / 62 (6.45%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 3			
Generalised oedema				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Granuloma				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injection site haemorrhage				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Injection site reaction				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Injection site vesicles				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Mucosal inflammation				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	5 / 62 (8.06%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Sudden death				

subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Female genital tract fistula			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostatitis			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cough			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Epistaxis			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hypoxia			

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Interstitial lung disease				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infiltration				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Productive cough				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				

subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Patella fracture				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Synovial rupture				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transfusion reaction				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic fracture				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Traumatic intracranial haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute myocardial infarction				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure chronic				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiogenic shock				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Myocarditis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebral haemorrhage				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Cerebral infarction				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cerebrovascular accident				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depressed level of consciousness				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic encephalopathy				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intraventricular haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lumbar radiculopathy				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral sensory neuropathy				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cytopenia				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				

subjects affected / exposed	14 / 62 (22.58%)			
occurrences causally related to treatment / all	5 / 17			
deaths causally related to treatment / all	0 / 0			
Leukocytosis				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Diplopia				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Acute abdomen				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal fistula				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune colitis				

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Faecaloma				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer haemorrhage				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematochezia				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mouth haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic cirrhosis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertransaminasaemia				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Acute febrile neutrophilic dermatosis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Panniculitis				

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pemphigoid				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin lesion				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin ulcer				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxic skin eruption				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 1			
Calculus bladder				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Autoimmune thyroiditis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthritis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle haemorrhage				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Anal abscess				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			

Appendicitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis bacterial				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspergillus infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atypical pneumonia				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacterial infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast abscess				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchopulmonary aspergillosis				

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Corona virus infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocarditis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal bacteraemia				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterococcal infection				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Febrile infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal infection				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gingivitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				

subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injection site infection			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection fungal			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung infection			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus infection			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Micrococcus infection			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenic infection			

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences causally related to treatment / all	2 / 6			
deaths causally related to treatment / all	0 / 0			
Oesophageal infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perineal cellulitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	8 / 62 (12.90%)			
occurrences causally related to treatment / all	1 / 9			
deaths causally related to treatment / all	0 / 1			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia influenzal				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Progressive multifocal leukoencephalopathy				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal abscess				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	4 / 62 (6.45%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Septic shock				

subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Serratia sepsis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Staphylococcal abscess				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal sepsis				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Superinfection bacterial				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				

subjects affected / exposed	2 / 62 (3.23%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Urinary tract infection bacterial				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Vascular device infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract infection				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Fluid retention				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gout				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypophagia				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lactic acidosis				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	MDS: Azacitidine + Durvalumab	MDS: Azacitidine Alone	AML: Azacitidine + Durvalumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 38 (100.00%)	40 / 41 (97.56%)	63 / 64 (98.44%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	4 / 64 (6.25%)
occurrences (all)	5	2	8
Hypotension			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	7 / 64 (10.94%)
occurrences (all)	4	2	7
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	9 / 38 (23.68%)	14 / 41 (34.15%)	19 / 64 (29.69%)
occurrences (all)	12	32	30
General physical health deterioration			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	1 / 64 (1.56%)
occurrences (all)	0	3	1
Fatigue			
subjects affected / exposed	9 / 38 (23.68%)	6 / 41 (14.63%)	17 / 64 (26.56%)
occurrences (all)	12	6	19
Influenza like illness			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Injection site bruising			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences (all)	2	0	1
Injection site erythema			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	6 / 64 (9.38%)
occurrences (all)	2	2	8
Injection site pain			
subjects affected / exposed	3 / 38 (7.89%)	4 / 41 (9.76%)	4 / 64 (6.25%)
occurrences (all)	3	4	4
Injection site rash			

subjects affected / exposed	3 / 38 (7.89%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences (all)	3	0	1
Injection site reaction			
subjects affected / exposed	3 / 38 (7.89%)	4 / 41 (9.76%)	10 / 64 (15.63%)
occurrences (all)	4	5	13
Mucosal inflammation			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	4 / 64 (6.25%)
occurrences (all)	0	3	5
Oedema			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	7 / 64 (10.94%)
occurrences (all)	3	1	10
Oedema peripheral			
subjects affected / exposed	14 / 38 (36.84%)	7 / 41 (17.07%)	18 / 64 (28.13%)
occurrences (all)	16	9	29
Pain			
subjects affected / exposed	3 / 38 (7.89%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences (all)	3	1	1
Pyrexia			
subjects affected / exposed	12 / 38 (31.58%)	13 / 41 (31.71%)	23 / 64 (35.94%)
occurrences (all)	18	16	43
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	13 / 38 (34.21%)	11 / 41 (26.83%)	18 / 64 (28.13%)
occurrences (all)	15	12	20
Dyspnoea			
subjects affected / exposed	9 / 38 (23.68%)	4 / 41 (9.76%)	15 / 64 (23.44%)
occurrences (all)	10	4	20
Dyspnoea exertional			
subjects affected / exposed	3 / 38 (7.89%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences (all)	3	0	3
Epistaxis			
subjects affected / exposed	6 / 38 (15.79%)	4 / 41 (9.76%)	13 / 64 (20.31%)
occurrences (all)	7	5	16
Oropharyngeal pain			

subjects affected / exposed	2 / 38 (5.26%)	4 / 41 (9.76%)	4 / 64 (6.25%)
occurrences (all)	5	4	5
Productive cough			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	1 / 64 (1.56%)
occurrences (all)	2	0	2
Rhinorrhoea			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	1 / 64 (1.56%)
occurrences (all)	0	3	2
Pharyngeal erythema			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Upper-airway cough syndrome			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	1 / 64 (1.56%)
occurrences (all)	5	2	1
Confusional state			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences (all)	1	0	2
Insomnia			
subjects affected / exposed	9 / 38 (23.68%)	4 / 41 (9.76%)	11 / 64 (17.19%)
occurrences (all)	11	7	11
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Alanine aminotransferase increased			
subjects affected / exposed	8 / 38 (21.05%)	2 / 41 (4.88%)	2 / 64 (3.13%)
occurrences (all)	8	3	4
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 38 (10.53%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences (all)	5	0	3
Blood creatinine increased			

subjects affected / exposed	6 / 38 (15.79%)	2 / 41 (4.88%)	6 / 64 (9.38%)
occurrences (all)	8	2	8
Blood bilirubin increased			
subjects affected / exposed	4 / 38 (10.53%)	1 / 41 (2.44%)	4 / 64 (6.25%)
occurrences (all)	8	1	4
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences (all)	2	3	4
Weight decreased			
subjects affected / exposed	2 / 38 (5.26%)	5 / 41 (12.20%)	9 / 64 (14.06%)
occurrences (all)	2	5	10
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 38 (5.26%)	4 / 41 (9.76%)	1 / 64 (1.56%)
occurrences (all)	2	4	1
Fall			
subjects affected / exposed	4 / 38 (10.53%)	4 / 41 (9.76%)	6 / 64 (9.38%)
occurrences (all)	6	5	12
Skin laceration			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Infusion related reaction			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences (all)	2	3	0
Transfusion reaction			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences (all)	3	0	2
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences (all)	2	0	3
Tachycardia			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	4 / 64 (6.25%)
occurrences (all)	4	2	4
Atrial fibrillation			

subjects affected / exposed	4 / 38 (10.53%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences (all)	6	0	3
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 38 (21.05%)	3 / 41 (7.32%)	6 / 64 (9.38%)
occurrences (all)	10	3	8
Dizziness			
subjects affected / exposed	6 / 38 (15.79%)	8 / 41 (19.51%)	6 / 64 (9.38%)
occurrences (all)	8	9	7
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 38 (0.00%)	1 / 41 (2.44%)	4 / 64 (6.25%)
occurrences (all)	0	1	5
Syncope			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	2 / 64 (3.13%)
occurrences (all)	4	2	2
Sciatica			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	0 / 64 (0.00%)
occurrences (all)	0	4	0
Anaemia			
subjects affected / exposed	14 / 38 (36.84%)	15 / 41 (36.59%)	19 / 64 (29.69%)
occurrences (all)	27	23	52
Febrile neutropenia			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	5 / 64 (7.81%)
occurrences (all)	4	2	9
Leukopenia			
subjects affected / exposed	8 / 38 (21.05%)	3 / 41 (7.32%)	6 / 64 (9.38%)
occurrences (all)	18	3	19
Neutropenia			
subjects affected / exposed	23 / 38 (60.53%)	21 / 41 (51.22%)	20 / 64 (31.25%)
occurrences (all)	68	42	63
Thrombocytopenia			

subjects affected / exposed	19 / 38 (50.00%)	18 / 41 (43.90%)	24 / 64 (37.50%)
occurrences (all)	39	37	43
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 38 (0.00%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	3 / 38 (7.89%)	1 / 41 (2.44%)	7 / 64 (10.94%)
occurrences (all)	4	1	8
Constipation			
subjects affected / exposed	22 / 38 (57.89%)	20 / 41 (48.78%)	36 / 64 (56.25%)
occurrences (all)	31	30	54
Diarrhoea			
subjects affected / exposed	16 / 38 (42.11%)	14 / 41 (34.15%)	27 / 64 (42.19%)
occurrences (all)	20	21	47
Dry mouth			
subjects affected / exposed	4 / 38 (10.53%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences (all)	4	1	3
Dyspepsia			
subjects affected / exposed	4 / 38 (10.53%)	2 / 41 (4.88%)	3 / 64 (4.69%)
occurrences (all)	4	3	4
Gingival bleeding			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	6 / 64 (9.38%)
occurrences (all)	2	0	14
Haemorrhoids			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	5 / 64 (7.81%)
occurrences (all)	2	2	5
Mouth haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences (all)	1	0	2
Odynophagia			

subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	16 / 38 (42.11%)	11 / 41 (26.83%)	26 / 64 (40.63%)
occurrences (all)	25	17	50
Stomatitis			
subjects affected / exposed	2 / 38 (5.26%)	3 / 41 (7.32%)	6 / 64 (9.38%)
occurrences (all)	3	3	8
Rectal haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	2 / 41 (4.88%)	4 / 64 (6.25%)
occurrences (all)	1	2	4
Vomiting			
subjects affected / exposed	10 / 38 (26.32%)	10 / 41 (24.39%)	20 / 64 (31.25%)
occurrences (all)	15	15	25
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences (all)	3	1	3
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	5 / 38 (13.16%)	2 / 41 (4.88%)	2 / 64 (3.13%)
occurrences (all)	5	2	2
Ecchymosis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences (all)	1	1	1
Erythema			
subjects affected / exposed	2 / 38 (5.26%)	3 / 41 (7.32%)	5 / 64 (7.81%)
occurrences (all)	2	4	5
Night sweats			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Petechiae			
subjects affected / exposed	3 / 38 (7.89%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences (all)	3	0	4
Pruritus			

subjects affected / exposed	5 / 38 (13.16%)	5 / 41 (12.20%)	8 / 64 (12.50%)
occurrences (all)	8	7	11
Rash			
subjects affected / exposed	7 / 38 (18.42%)	3 / 41 (7.32%)	10 / 64 (15.63%)
occurrences (all)	8	3	11
Rash erythematous			
subjects affected / exposed	3 / 38 (7.89%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences (all)	3	0	2
Rash maculo-papular			
subjects affected / exposed	3 / 38 (7.89%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences (all)	5	0	2
Skin lesion			
subjects affected / exposed	3 / 38 (7.89%)	2 / 41 (4.88%)	3 / 64 (4.69%)
occurrences (all)	4	2	4
Urticaria			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	1 / 64 (1.56%)
occurrences (all)	2	2	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 38 (10.53%)	0 / 41 (0.00%)	5 / 64 (7.81%)
occurrences (all)	4	0	6
Dysuria			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Urinary incontinence			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences (all)	2	1	1
Urinary retention			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences (all)	2	0	5
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 38 (13.16%)	3 / 41 (7.32%)	11 / 64 (17.19%)
occurrences (all)	5	3	12
Arthritis			

subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	2 / 64 (3.13%)
occurrences (all)	2	1	3
Back pain			
subjects affected / exposed	4 / 38 (10.53%)	6 / 41 (14.63%)	15 / 64 (23.44%)
occurrences (all)	4	6	17
Muscle tightness			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	3	0	0
Muscular weakness			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences (all)	2	0	3
Musculoskeletal pain			
subjects affected / exposed	4 / 38 (10.53%)	1 / 41 (2.44%)	8 / 64 (12.50%)
occurrences (all)	4	1	10
Neck pain			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences (all)	2	1	1
Myalgia			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences (all)	2	1	1
Pain in extremity			
subjects affected / exposed	1 / 38 (2.63%)	2 / 41 (4.88%)	12 / 64 (18.75%)
occurrences (all)	1	2	14
Infections and infestations			
Cellulitis			
subjects affected / exposed	3 / 38 (7.89%)	5 / 41 (12.20%)	7 / 64 (10.94%)
occurrences (all)	3	5	10
Fungal infection			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Gingivitis			
subjects affected / exposed	0 / 38 (0.00%)	3 / 41 (7.32%)	1 / 64 (1.56%)
occurrences (all)	0	3	1
Influenza			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	3 / 64 (4.69%)
occurrences (all)	2	1	3

Laryngitis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	4 / 38 (10.53%)	5 / 41 (12.20%)	3 / 64 (4.69%)
occurrences (all)	4	5	4
Oral candidiasis			
subjects affected / exposed	6 / 38 (15.79%)	0 / 41 (0.00%)	2 / 64 (3.13%)
occurrences (all)	7	0	2
Oral herpes			
subjects affected / exposed	2 / 38 (5.26%)	2 / 41 (4.88%)	4 / 64 (6.25%)
occurrences (all)	2	2	4
Pharyngitis			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Paronychia			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Pneumonia			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	4 / 64 (6.25%)
occurrences (all)	2	1	4
Tooth infection			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	2 / 64 (3.13%)
occurrences (all)	2	1	2
Upper respiratory tract infection			
subjects affected / exposed	2 / 38 (5.26%)	4 / 41 (9.76%)	3 / 64 (4.69%)
occurrences (all)	2	6	3
Urinary tract infection			
subjects affected / exposed	6 / 38 (15.79%)	1 / 41 (2.44%)	8 / 64 (12.50%)
occurrences (all)	6	1	11
Vascular device infection			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	3	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	8 / 38 (21.05%)	7 / 41 (17.07%)	18 / 64 (28.13%)
occurrences (all)	12	13	24
Gout			
subjects affected / exposed	2 / 38 (5.26%)	1 / 41 (2.44%)	1 / 64 (1.56%)
occurrences (all)	2	1	1
Hyperglycaemia			
subjects affected / exposed	5 / 38 (13.16%)	3 / 41 (7.32%)	2 / 64 (3.13%)
occurrences (all)	5	3	2
Hypoalbuminaemia			
subjects affected / exposed	3 / 38 (7.89%)	3 / 41 (7.32%)	2 / 64 (3.13%)
occurrences (all)	4	4	2
Hypocalcaemia			
subjects affected / exposed	7 / 38 (18.42%)	0 / 41 (0.00%)	3 / 64 (4.69%)
occurrences (all)	7	0	4
Hypokalaemia			
subjects affected / exposed	5 / 38 (13.16%)	2 / 41 (4.88%)	13 / 64 (20.31%)
occurrences (all)	7	3	16
Hypomagnesaemia			
subjects affected / exposed	4 / 38 (10.53%)	4 / 41 (9.76%)	5 / 64 (7.81%)
occurrences (all)	5	7	6
Hypophosphataemia			
subjects affected / exposed	4 / 38 (10.53%)	1 / 41 (2.44%)	5 / 64 (7.81%)
occurrences (all)	4	1	7
Hyponatraemia			
subjects affected / exposed	7 / 38 (18.42%)	3 / 41 (7.32%)	2 / 64 (3.13%)
occurrences (all)	9	3	2
Hypoproteinaemia			
subjects affected / exposed	2 / 38 (5.26%)	0 / 41 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	AML: Azacitidine Alone		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	60 / 62 (96.77%)		
Vascular disorders			
Hypertension			

subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	9		
Hypotension			
subjects affected / exposed	8 / 62 (12.90%)		
occurrences (all)	8		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	12 / 62 (19.35%)		
occurrences (all)	21		
General physical health deterioration			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	11 / 62 (17.74%)		
occurrences (all)	12		
Influenza like illness			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Injection site bruising			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Injection site erythema			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	6		
Injection site pain			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Injection site rash			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Injection site reaction			
subjects affected / exposed	7 / 62 (11.29%)		
occurrences (all)	8		
Mucosal inflammation			

subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Oedema			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Oedema peripheral			
subjects affected / exposed	9 / 62 (14.52%)		
occurrences (all)	13		
Pain			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Pyrexia			
subjects affected / exposed	21 / 62 (33.87%)		
occurrences (all)	38		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	15 / 62 (24.19%)		
occurrences (all)	20		
Dyspnoea			
subjects affected / exposed	12 / 62 (19.35%)		
occurrences (all)	14		
Dyspnoea exertional			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	7		
Oropharyngeal pain			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Productive cough			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			

subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	3		
Pharyngeal erythema			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Confusional state			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	4		
Insomnia			
subjects affected / exposed	8 / 62 (12.90%)		
occurrences (all)	9		
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	4		
Alanine aminotransferase increased			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	6		
Blood creatinine increased			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Blood bilirubin increased			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	7		
Fall			
subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	6		
Skin laceration			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Transfusion reaction			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	4		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Tachycardia			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Atrial fibrillation			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 62 (11.29%)		
occurrences (all)	7		
Dizziness			

subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	6		
Peripheral sensory neuropathy			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Syncope			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	19 / 62 (30.65%)		
occurrences (all)	42		
Febrile neutropenia			
subjects affected / exposed	9 / 62 (14.52%)		
occurrences (all)	10		
Leukopenia			
subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	9		
Neutropenia			
subjects affected / exposed	21 / 62 (33.87%)		
occurrences (all)	72		
Thrombocytopenia			
subjects affected / exposed	27 / 62 (43.55%)		
occurrences (all)	66		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			

Abdominal discomfort				
subjects affected / exposed	4 / 62 (6.45%)			
occurrences (all)	4			
Abdominal pain				
subjects affected / exposed	6 / 62 (9.68%)			
occurrences (all)	6			
Constipation				
subjects affected / exposed	33 / 62 (53.23%)			
occurrences (all)	56			
Diarrhoea				
subjects affected / exposed	16 / 62 (25.81%)			
occurrences (all)	22			
Dry mouth				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences (all)	2			
Gingival bleeding				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences (all)	5			
Haemorrhoids				
subjects affected / exposed	5 / 62 (8.06%)			
occurrences (all)	5			
Mouth haemorrhage				
subjects affected / exposed	4 / 62 (6.45%)			
occurrences (all)	4			
Odynophagia				
subjects affected / exposed	2 / 62 (3.23%)			
occurrences (all)	2			
Nausea				
subjects affected / exposed	22 / 62 (35.48%)			
occurrences (all)	37			
Stomatitis				
subjects affected / exposed	4 / 62 (6.45%)			
occurrences (all)	5			

Rectal haemorrhage			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	15 / 62 (24.19%)		
occurrences (all)	23		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	7		
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	3		
Ecchymosis			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	4		
Erythema			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
Night sweats			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Pruritus			
subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	8		
Rash			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	4		
Rash erythematous			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			

subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Skin lesion			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Urticaria			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Dysuria			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Urinary incontinence			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	2		
Urinary retention			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 62 (11.29%)		
occurrences (all)	7		
Arthritis			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	6		
Muscle tightness			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Muscular weakness			

subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Musculoskeletal pain			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Neck pain			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Infections and infestations			
Cellulitis			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
Fungal infection			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Gingivitis			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
Influenza			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Laryngitis			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	7 / 62 (11.29%)		
occurrences (all)	8		
Oral candidiasis			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		

Oral herpes subjects affected / exposed occurrences (all)	2 / 62 (3.23%) 3		
Pharyngitis subjects affected / exposed occurrences (all)	0 / 62 (0.00%) 0		
Paronychia subjects affected / exposed occurrences (all)	0 / 62 (0.00%) 0		
Pneumonia subjects affected / exposed occurrences (all)	7 / 62 (11.29%) 7		
Tooth infection subjects affected / exposed occurrences (all)	2 / 62 (3.23%) 2		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	4 / 62 (6.45%) 4		
Urinary tract infection subjects affected / exposed occurrences (all)	5 / 62 (8.06%) 5		
Vascular device infection subjects affected / exposed occurrences (all)	0 / 62 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	10 / 62 (16.13%) 10		
Gout subjects affected / exposed occurrences (all)	1 / 62 (1.61%) 1		
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 62 (1.61%) 3		
Hypoalbuminaemia			

subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	5		
Hypocalcaemia			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	7		
Hypokalaemia			
subjects affected / exposed	12 / 62 (19.35%)		
occurrences (all)	21		
Hypomagnesaemia			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	5		
Hypophosphataemia			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	7		
Hyponatraemia			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	6		
Hypoproteinaemia			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 March 2017	Addition of an extra exclusion criteria, based on Investigator feedback. Table of events has been updated.
05 March 2019	Addition of Appendix O that provides an extension to the study to allow patients who were benefiting from treatment to continue treatment with either azacitidine alone or azacitidine and durvalumab

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Participants started the extension phase at the time of their next regularly scheduled dosing cycle for study drug azacitidine or azacitidine and durvalumab after Protocol Amendment 03.

Notes: