Baseline Characteristics: Common Quality-Control Review Issues

Results Database Train-the-Trainer Workshop

August 2021

Example 1

Find the Error

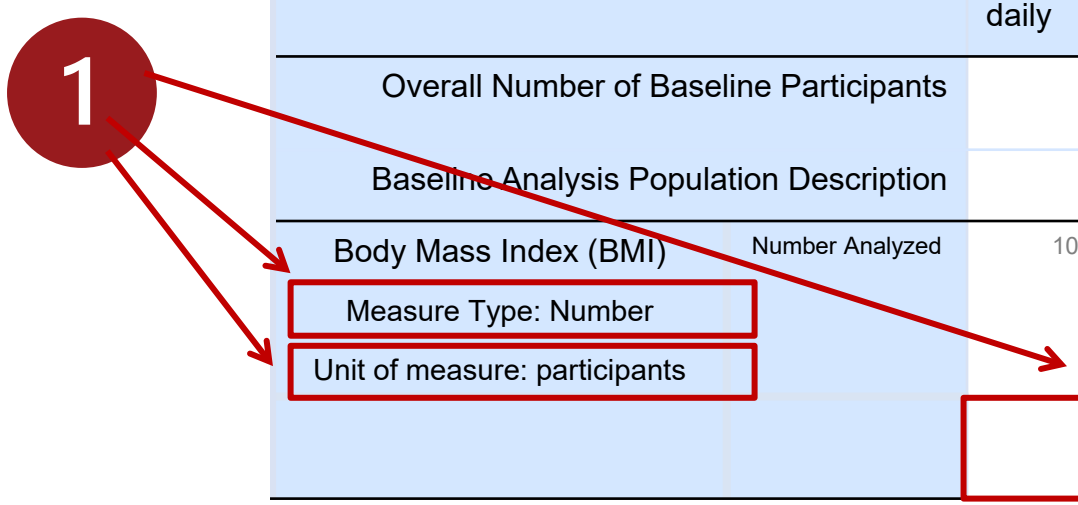
Results Baseline Characteristics

Arm/Group Title		Ender-G, Low Dose	Ender-G, High Dose	Total
Arm/Group Description		5 mg tablet, twice daily	10 mg tablet, twice daily	Total of all reporting groups
Overall Number of Baseline Participants		103	99	202
Baseline Analysis Population Description				
Body Mass Index (BMI) Measure Type: Number Unit of measure: participants	Number Analyzed	103 participants	99 participants	202 participants
		22.5	23.1	22.8

Error

Results Baseline Characteristics

Arm/Group Title	Ender-G, Low Dose	Ender-G, High Dose	Total
Arm/Group Description	5 mg tablet, twice daily	10 mg tablet, twice daily	Total of all reporting groups
Overall Number of Baseline Participants	103	99	202
Baseline Analysis Population Description			
Body Mass Index (BMI) — Number Analyzed	103 participants	99 participants	202 participants
Measure Type: Number			
Unit of measure: participants			
	22.5	23.1	22.8



Major Issues

Results Baseline Characteristics

	Arm/Group Title	Ender-G, Low Dose	Ender-G, High Dose	Total
Body Mass Index (BMI) Measure Type: Number Unit of measure: participants	Number Analyzed	103 participants	99 participants	202 participants
		22.5	23.1	22.8

Comments [1]

Major Issues:

1) Information within the measure appears inconsistent.

Corrected

Results Baseline Characteristics

Arm/Group Title		Ender-G, Low Dose	Ender-G, High Dose	Total
Arm/Group Description		5 mg tablet, twice daily	10 mg tablet, twice daily	Total of all reporting groups
Overall Number of Baseline Participants		103	99	202
Baseline Analysis Population Description				
Body Mass Index (BMI) Mean (Full Range) Unit of measure: kg/m^2	Number Analyzed	103 participants	99 participants	202 participants
		22.5 (19 to 31)	23.0 (18 to 33)	22.8 (18 to 33)

Example 2

Find the Error

Results Baseline Characteristics

	Arm/Group Title	Remuverol
ECOG Performance Status Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	79 participants
0		48
1		27
2		4

Error

Results Baseline Characteristics

	Arm/Group Title	Remuverol
ECOG Performance Status Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	79 participants
0		48
1		27
2		4

Error

Results Baseline Characteristics

		Arm/Group Title	Remuverol
ECOG Performance Status Measure Type: Count of Participants Unit of measure: participants		Number Analyzed	79 participants
	0		48
	1		27
	2		4

2

Major Issues

Results Baseline Characteristics

	Arm/Group Title	Remuverol
ECOG Performance Status Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	79 participants
0		48
1		27
2		4

Comments [1]

Major Issues:

1) The description of the scale or categories does not include sufficient information to understand the results reported.

Corrected

Results Baseline Characteristics

	Arm/Group Title	Remuverol
Eastern Cooperative Oncology Group (ECOG) Performance Status [1] Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	79 participants
0 – Fully Active		48
1 – Ambulatory, Restricted Strenuous Activity		27
2 – Ambulatory, No Work Activities		4
		[1] Measure Description: Eastern Cooperative Oncology Group (ECOG) Performance Status is a scale that measures how cancer affects a participant's daily living abilities. The scale ranges from 0 (fully active) to 5 (dead). 0 = Fully active without restriction; 1 = Restricted in physically strenuous activity; 2 = Ambulatory, capable of all selfcare; 3 = Capable of limited selfcare; 4 = Completely disabled; 5 = Dead.

Example 3

Find the Error

Results Participant Flow

Arm/Group Title	Cinacalcet	Placebo
Arm/Group Description	Participants received 80 mg/ml of Cinacalcet intravenously twice a day, for 12 weeks.	Participants received 80 mg/ml of Placebo intravenously twice a day, for 12 weeks.
Period Title: **Overall Study**		
Started	368	184
Completed	7	8
Not Completed	361	179

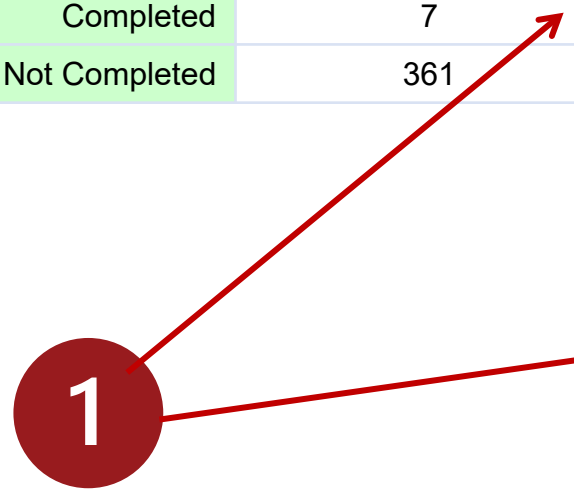
Results Baseline Characteristics

Arm/Group Title		Cinacalcet	Placebo	Total
Overall Number of Baseline Participants		280	150	430
Age, Continuous [1] Mean (Standard Deviation) Unit of measure: Years	Number Analyzed	280	150	430
		58.5 ± 999	58.3 ± 999	58.4 ± 999
		[1] Measure Description: 999 inserted because standard deviation was not calculated.		

Error

Results Participant Flow

Arm/Group Title	Cinacalcet	Placebo
Arm/Group Description	Participants received 80 mg/ml of Cinacalcet intravenously twice a day, for 12 weeks.	Participants received 80 mg/ml of Placebo intravenously twice a day, for 12 weeks.
Period Title: **Overall Study**		
Started	368	184
Completed	7	8
Not Completed	361	179



Results Baseline Characteristics

Arm/Group Title		Cinacalcet	Placebo	Total
Overall Number of Baseline Participants		280	150	430
Age, Continuous [1] Mean (Standard Deviation) Unit of measure: Years	Number Analyzed	280	150	430
		58.5 ± 999	58.3 ± 999	58.4 ± 999
		[1] Measure Description: 999 inserted because standard deviation was not calculated.		

Error

Results Participant Flow

Arm/Group Title	Cinacalcet	Placebo
Arm/Group Description	Participants received 80 mg/ml of Cinacalcet intravenously twice a day, for 12 weeks.	Participants received 80 mg/ml of Placebo intravenously twice a day, for 12 weeks.
Period Title: **Overall Study**		
Started	368	184
Completed	7	8
Not Completed	361	179

Results Baseline Characteristics

Arm/Group Title		Cinacalcet	Placebo	Total
Overall Number of Baseline Participants		280	150	430
Age, Continuous [1] Mean (Standard Deviation) Unit of measure: Years	Number Analyzed	280	150	430
		58.5 ± 999	58.3 ± 999	58.4 ± 999
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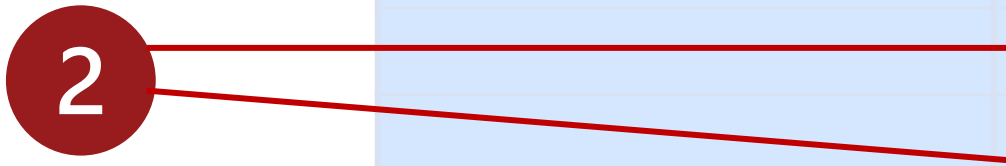

Major Issues

Results Baseline Characteristics

Arm/Group Title		Cinacalcet	Placebo	Total
Overall Number of Baseline Participants		280	150	430
Age, Continuous [1] Mean (Standard Deviation) Unit of measure: Years	Number Analyzed	280	150	430
		58.5 ± 999	58.3 ± 999	58.4 ± 999
		[1] Measure Description: 999 inserted because standard deviation was not calculated.		

Comments [1]

Major Issues:

1) One or more numbers in the table appear to be nonmeaningful placeholders that do not reflect data collected during the study.

Corrected

Results Participant Flow

Arm/Group Title	Cinacalcet	Placebo
Arm/Group Description	Participants received 80 mg/ml of Cinacalcet intravenously twice a day, for 12 weeks.	Participants received 80 mg/ml of Placebo intravenously twice a day, for 12 weeks.
Period Title: **Overall Study**		
Started	368	184
Modified Intention to Treat	280	150
Completed	7	8
Not Completed	361	179

Results Baseline Characteristics

Arm/Group Title		Cinacalcet	Placebo	Total
Overall Number of Baseline Participants		280	150	430
Age, Continuous Mean (Standard Deviation) Unit of measure: Years	Number Analyzed	280	150	430
		58.5 ± 15.5	58.3 ± 14.5	58.4 ± 14.8

Example 4

Find the Error

Results Participant Flow

Arm/Group Title	Sorafenib (Nexavar, BAY43-9006)
Arm/Group Description	Inpatient dose escalation of sorafenib from 400 mg orally twice daily (bid) for the first cycle, 600 mg bid for the second cycle, and 800 mg bid until disease progression, unacceptable toxicity, or withdrawal of consent. Each cycle is 28 days. Dose reductions due to toxicities were allowed.
Period Title: **Cycle 1 (28 Days)**	
Started	83
Completed	52
Not Completed	31
Period Title: **Cycle 2 (28 Days)**	
Started	52
Completed	44
Not Completed	8
Period Title: **Cycle 3 (28 Days)**	
Started	44
Completed	33
Not Completed	11

Results Baseline Characteristics

Arm/Group Title	Cycle 1, 400 mg	Cycle 2, 600 mg	≥Cycle 3, 800 mg	Total
Arm/Group Description	All participants who received the dose escalation of sorafenib 400 mg bid for the first cycle	All participants who received the dose escalation of sorafenib 600 mg bid for the second cycle	All participants who received the dose escalation of sorafenib 800 mg bid for the third and greater cycles	Total of all reporting groups
Overall Number of Baseline Participants	83	52	44	179
Age, Continuous Median (Full Range) Unit of measure: Years	61 (33 to 80)	63 (33 to 72)	55 (33 to 72)	61 (33 to 80)

ClinicalTrials.gov

Error

Results Participant Flow

Arm/Group Title	Sorafenib (Nexavar, BAY43-9006)
Arm/Group Description	Inpatient dose escalation of sorafenib from 400 mg orally twice daily (bid) for the first cycle, 600 mg bid for the second cycle, and 800 mg bid until disease progression, unacceptable toxicity, or withdrawal of consent. Each cycle is 28 days. Dose reductions due to toxicities were allowed.
Period Title: **Cycle 1 (28 Days)**	
Started	83
Completed	52
Not Completed	31
Period Title: **Cycle 2 (28 Days)**	
Started	52
Completed	44
Not Completed	8
Period Title: **Cycle 3 (28 Days)**	
Started	44
Completed	33
Not Completed	11

1

Results Baseline Characteristics

Arm/Group Title	Cycle 1, 400 mg	Cycle 2, 600 mg	≥Cycle 3, 800 mg	Total
Arm/Group Description	All participants who received sorafenib 400 mg bid for the first cycle	All participants who received the dose escalation of sorafenib 600 mg bid for the second cycle	All participants who received the dose escalation of sorafenib 800 mg bid for the third and greater cycles	Total of all reporting groups
Overall Number of Baseline Participants	83	52	44	179
Age, Continuous Median (Full Range) Unit of measure: Years	61 (33 to 80)	63 (33 to 72)	55 (33 to 72)	61 (33 to 80)

ClinicalTrials.gov

Major Issues

Results Baseline Characteristics

Arm/Group Title		Cycle 1, 400 mg	Cycle 2, 600 mg	≥Cycle 3, 800 mg	Total
Arm/Group Description		All participants who received the dose escalation of sorafenib 400 mg bid for the first cycle	All participants who received the dose escalation of sorafenib 600 mg bid for the second cycle	All participants who received the dose escalation of sorafenib 800 mg bid for the third and greater cycles	Total of all reporting groups
Overall Number of Baseline Participants		83	52	44	179
Baseline Analysis Population Description					
Age, Continuous Median (Full Range) Unit of measure: Years	Number Analyzed	83	52	44	179
		61 (33 to 80)	63 (33 to 72)	55 (33 to 72)	61 (33 to 80)

Comments [1]

Major Issues:

1) Participants appear to be counted more than once within a row.

Corrected

Results Participant Flow

Arm/Group Title	Sorafenib (Nexavar, BAY43-9006)
Arm/Group Description	Inpatient dose escalation of sorafenib from 400 mg orally twice daily (bid) for the first cycle, 600 mg bid for the second cycle, and 800 mg bid until disease progression, unacceptable toxicity, or withdrawal of consent. Each cycle is 28 days. Dose reductions due to toxicities were allowed.
Period Title: **Cycle 1 (28 Days)**	
Started	83
Completed	52
Not Completed	31
Period Title: **Cycle 2 (28 Days)**	
Started	52
Completed	44
Not Completed	8
Period Title: **Cycle 3 (28 Days)**	
Started	44
Completed	33
Not Completed	11

Results Baseline Characteristics

Arm/Group Title		Sorafenib (Nexavar, BAY43-9006)
Arm/Group Description		Inpatient dose escalation of sorafenib from 400 mg orally . . .
Overall Number of Participants		83
Age, Continuous [1] Median (Full Range) Unit of measure: Years		
Cycle 1	Number Analyzed	83 participants
		61 (33 to 80)
Cycle 2	Number Analyzed	52 participants
		63 (33 to 72)
Cycle 3	Number Analyzed	44 participants
		55 (33 to 72)
		[1] Measure Analysis Population Description: Not all participants continued to cycles 2 and 3.

Example 5

Find the Error

Results Baseline Characteristics

	Arm/Group Title	Mycophenolate Mofetil + Sirolimus	Mycophenolate Mofetil + Cyclosporine or Tacrolimus	Total
	Arm/Group Description	Mycophenolate mofetil orally twice daily at a . . .	Mycophenolate mofetil orally twice . . .	Total of all reporting groups
Overall Number of Baseline Participants		151	154	305
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	151	154	305
	<=18 years	0	0	0
	Between 18 and 65 years	102	106	208
	>=65 years	49	48	97
Age, Customized Mean (Standard Deviation) Unit of measure: years	Number Analyzed	151	154	305
		48.7 (12.9)	48.9 (12.7)	NA (NA) [1]
		[1] Age was not calculated for the total population.		

Error

Results Baseline Characteristics

	Arm/Group Title	Mycophenolate Mofetil + Sirolimus	Mycophenolate Mofetil + Cyclosporine or Tacrolimus	Total
	Arm/Group Description	Mycophenolate mofetil orally twice daily at a . . .	Mycophenolate mofetil orally twice . . .	Total of all reporting groups
Overall Number of Baseline Participants		151	154	305
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	151	154	305
	<=18 years	0	0	0
	Between 18 and 65 years	102	106	208
	>=65 years	49	48	97
Age, Customized Mean (Standard Deviation) Unit of measure: years	Number Analyzed	151	154	305
		48.7 (12.9)	48.9 (12.7)	NA (NA) [1]
		[1] Age was not calculated for the total population.		

1

Error

Results Baseline Characteristics

	Arm/Group Title	Mycophenolate Mofetil + Sirolimus	Mycophenolate Mofetil + Cyclosporine or Tacrolimus	Total
	Arm/Group Description	Mycophenolate mofetil orally twice daily at a . . .	Mycophenolate mofetil orally twice . . .	Total of all reporting groups
Overall Number of Baseline Participants		151	154	305
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	151	154	305
	<=18 years	0	0	0
	Between 18 and 65 years	102	106	208
	>=65 years	49	48	97
Age, Customized Mean (Standard Deviation) Unit of measure: years	Number Analyzed	151	154	305
		48.7 (12.9)	48.9 (12.7)	NA (NA) [1]
		[1] Age was not calculated for the total population.		

2

Major Issues

Results Baseline Characteristics

	Arm/Group Title	Mycophenolate Mofetil + Sirolimus	Mycophenolate Mofetil + Cyclosporine or Tacrolimus	Total
	Arm/Group Description	Mycophenolate mofetil orally twice daily at a . . .	Mycophenolate mofetil orally twice . . .	
Overall Number of Baseline Participants		151	154	305
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	151	154	305
	<=18 years	0	0	0
	Between 18 and 65 years	102	106	208
	>=65 years	49	48	97
Age, Customized Mean (Standard Deviation) Unit of measure: years	Number Analyzed	151	154	305
		48.7 (12.9)	48.9 (12.7)	NA (NA) [1]
		[1] Age was not calculated for the total population.		

Comments [1]

Major Issues:

1) The explanation provided is not sufficient to understand why one or more values are not available.

Corrected

Results Baseline Characteristics

	Arm/Group Title	Mycophenolate Mofetil + Sirolimus	Mycophenolate Mofetil + Cyclosporine or Tacrolimus	Total
	Arm/Group Description	Mycophenolate mofetil orally twice daily at a . . .	Mycophenolate mofetil orally twice . . .	Total of all reporting groups
Overall Number of Baseline Participants		151	154	305
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	151	154	305
	<=18 years	0	0	0
	Between 18 and 65 years	102	106	208
	>=65 years	49	48	97
Age, Continuous Mean (Full Range) Unit of measure: years	Number Analyzed	151	154	305
		48.7 (31 to 69)	48.9 (33 to 71)	48.8 (31 to 71)