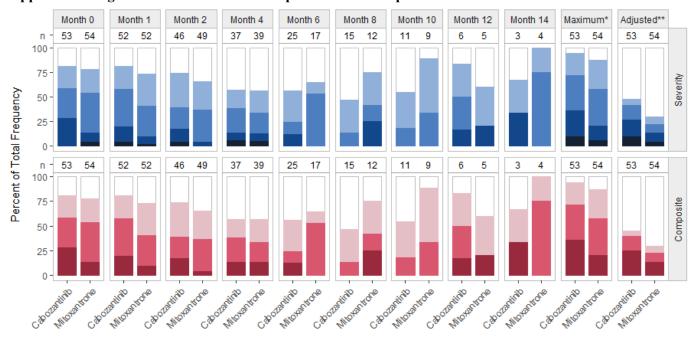
Supplemental Material for:

Evaluation of treatment tolerability utilizing a toxicity summary measure with Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) data

Blake T. Langlais, et al.

Supplemental Figures 1.	PRO-CTCAE Constipation Item Group and Density Histograms, by Arm
Supplemental Figures 2.	PRO-CTCAE Decreased Appetite Item Group and Density Histograms, by Arm
Supplemental Figures 3.	PRO-CTCAE Diarrhea Item Group and Density Histograms, by Arm
Supplemental Figures 4.	PRO-CTCAE Fatigue Item Group and Density Histograms, by Arm
Supplemental Figures 5.	PRO-CTCAE Insomnia Item Group and Density Histograms, by Arm
Supplemental Figures 6.	PRO-CTCAE Nausea Item Group and Density Histograms, by Arm
Supplemental Figures 7.	PRO-CTCAE Numbness/Tingling in Hands/Feet Item Group and Density Histograms, by Arm
Supplemental Figures 8.	PRO-CTCAE Pain Item Group and Density Histograms, by Arm
Supplemental Figures 9.	PRO-CTCAE Shortness of Breath Item Group and Density Histograms, by Arm
Supplemental Figures 10.	PRO-CTCAE Vomiting Item Group and Density Histograms, by Arm
Supplemental Figures 11.	Density Histograms for all PROCTCAE Items and Composites, by Arm

Supplemental Figure 1. PRO-CTCAE Constipation Item Group



Randomized Treatment Assignment

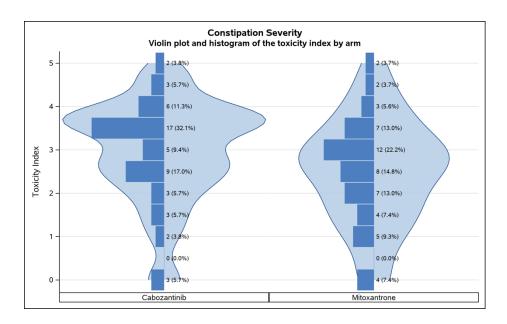
Severity: ☐ None / ■ Mild / ■ Moderate / ■ Severe / ■ Very severe

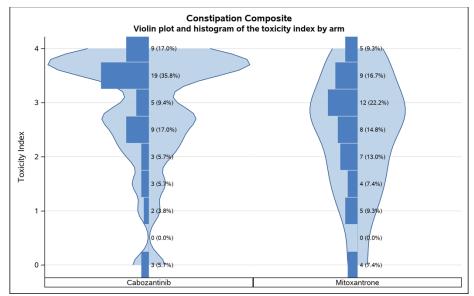
Composite Grade: ☐ 0 / ■1 / ■2 / ■3

Column labels (n) show the number of subjects with an observed symptom score or grade.

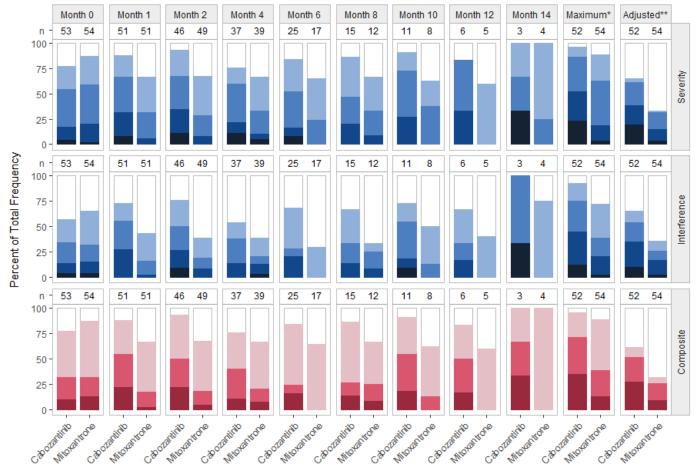
*Maximum score or grade reported post-baseline per patient.

**Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.





Supplemental Figure 2. PRO-CTCAE Decreased Appetite Item Group



Randomized Treatment Assignment

Severity: ☐ None / ■ Mild / ■ Moderate / ■ Severe / ■ Very severe

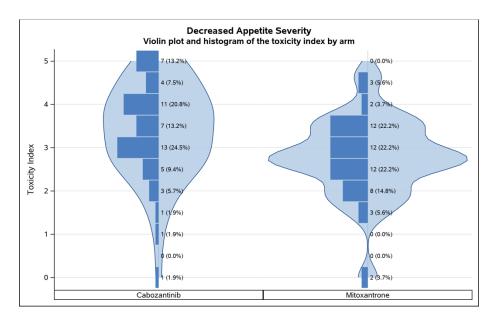
Interference: ☐ Not at all / ■ A little bit / ■ Somewhat / ■ Quite a bit / ■ Very much

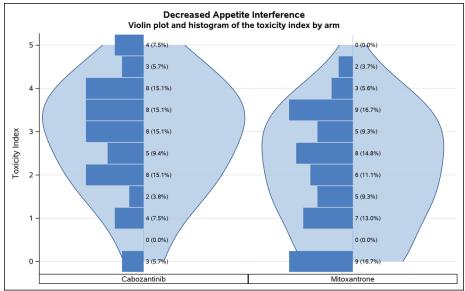
Composite Grade: ☐ 0 / ■ 1 / ■ 2 / ■ 3

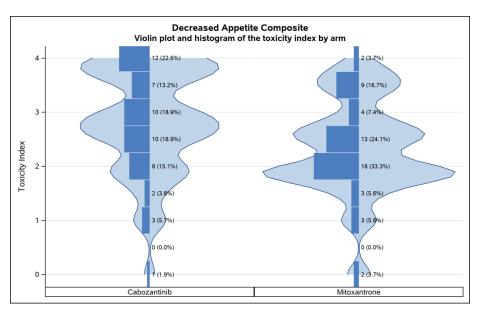
Column labels (n) show the number of subjects with an observed symptom score or grade.

*Maximum score or grade reported post-baseline per patient.

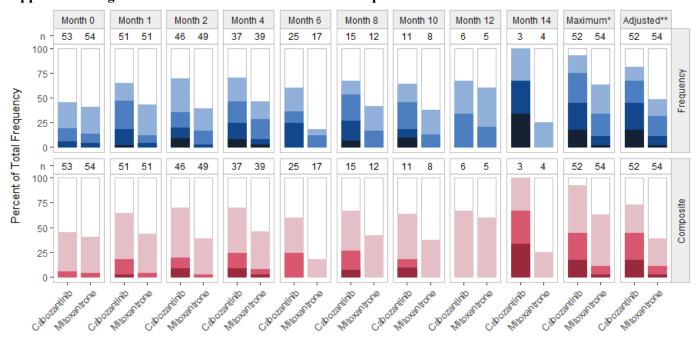
**Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.







Supplemental Figure 3. PRO-CTCAE Diarrhea Item Group

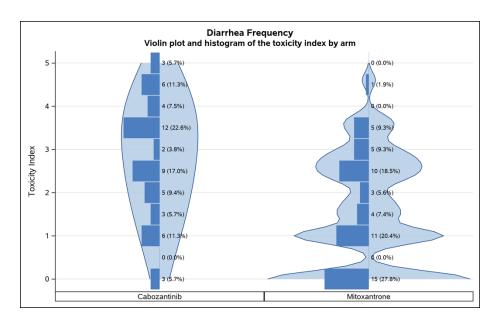


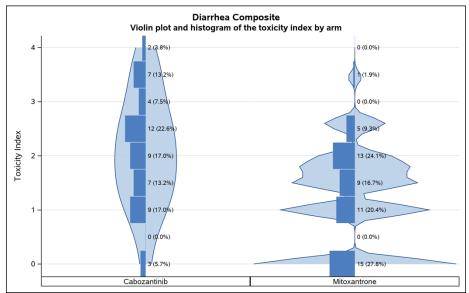
Randomized Treatment Assignment

Frequency: ☐ Never / ■ Rarely / ■ Occasionally / ■ Frequently / ■ Almost constantly

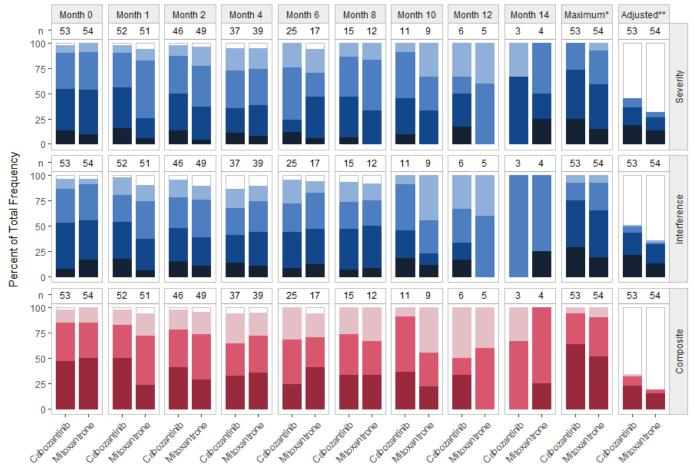
Composite Grade: ☐ 0 / ■ 1 / ■ 2 / ■ 3

Column labels (n) show the number of subjects with an observed symptom score or grade.
*Maximum score or grade reported post-baseline per patient.
**Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.





Supplemental Figure 4. PRO-CTCAE Fatigue Item Group



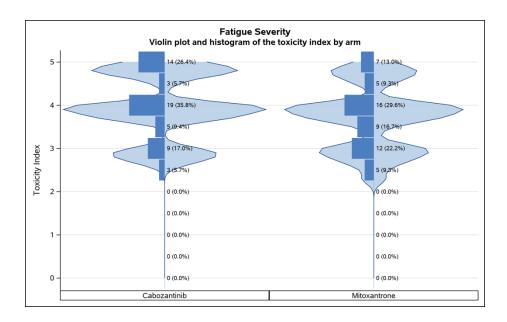
Randomized Treatment Assignment

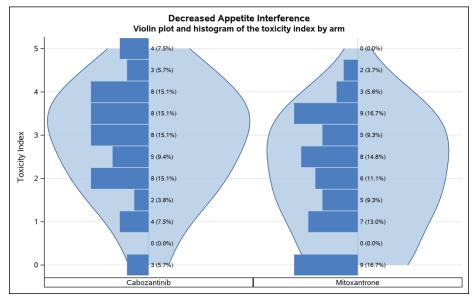
Severity: ☐ None / ■ Mild / ■ Moderate / ■ Severe / ■ Very severe

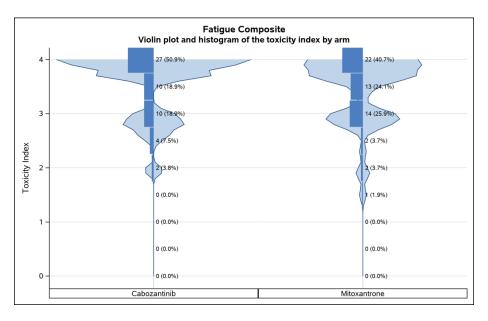
Interference: ☐ Not at all / ■ A little bit / ■ Somewhat / ■ Quite a bit / ■ Very much

Composite Grade: □ 0/■1/■2/■3

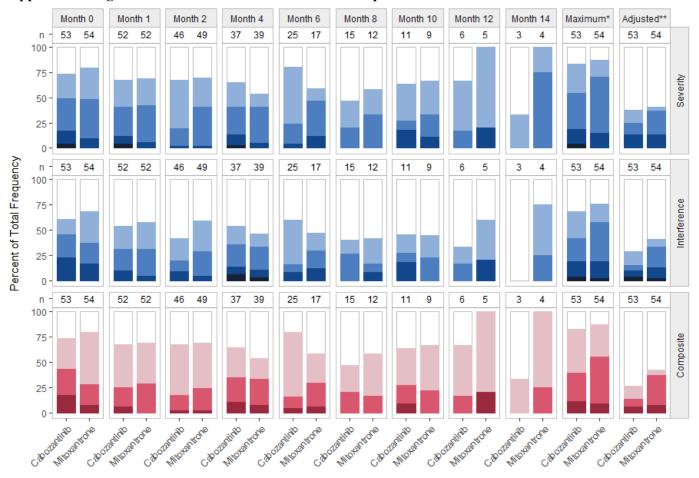
^{**}Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.







Supplemental Figure 5. PRO-CTCAE Insomnia Item Group



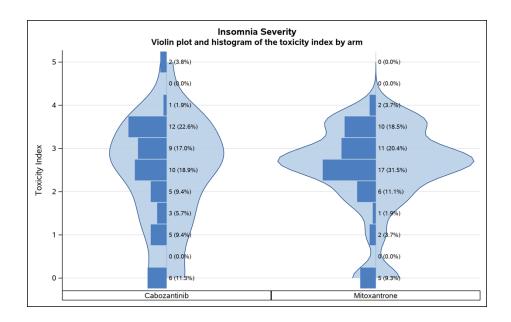
Randomized Treatment Assignment

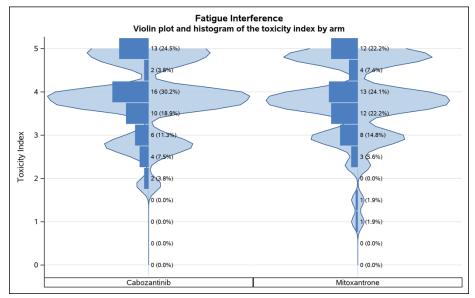
Severity: ☐ None / ■ Mild / ■ Moderate / ■ Severe / ■ Very severe

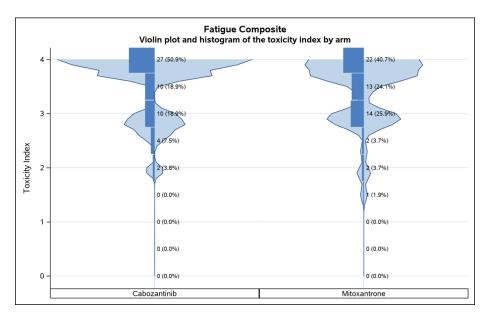
Interference: ☐ Not at all / ■ A little bit / ■ Somewhat / ■ Quite a bit / ■ Very much

Composite Grade: □ 0/■1/■2/■3

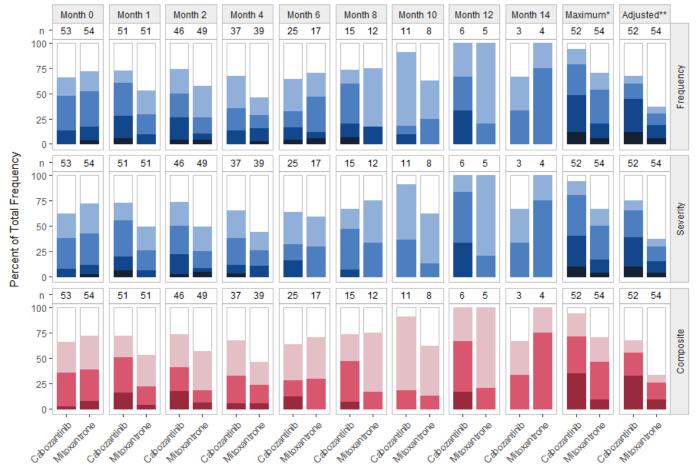
^{**}Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.







Supplemental Figure 6. PRO-CTCAE Nausea Item Group



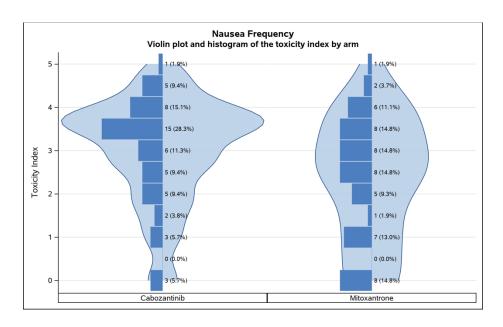
Randomized Treatment Assignment

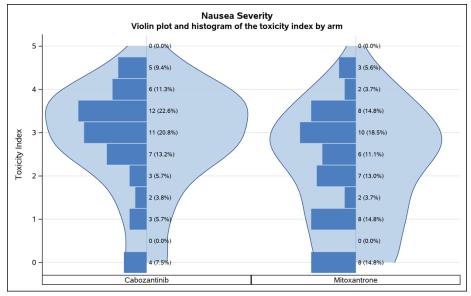
Frequency: ☐ Never / ■ Rarely / ■ Occasionally / ■ Frequently / ■ Almost constantly

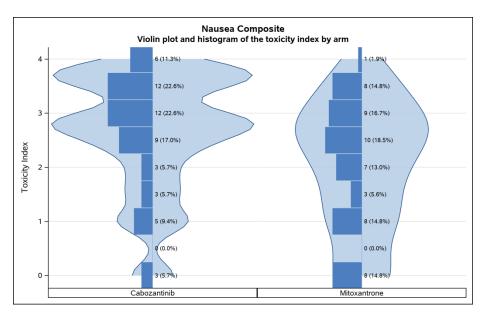
Severity: ☐ None / ■ Mild / ■ Moderate / ■ Severe / ■ Very severe

Composite Grade: ☐ 0 / ■ 1 / ■ 2 / ■ 3

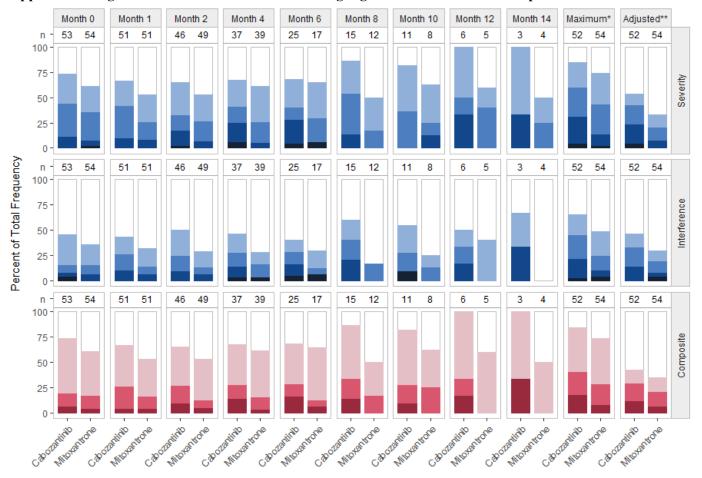
^{**}Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.







Supplemental Figure 7. PRO-CTCAE Numbness/Tingling in Hands/Feet Item Group



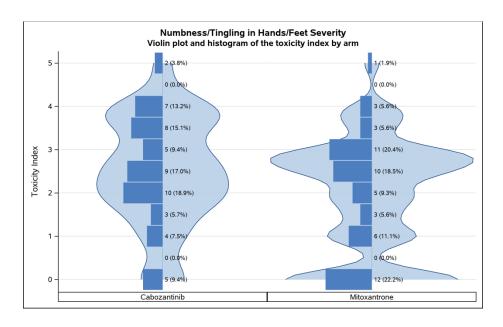
Randomized Treatment Assignment

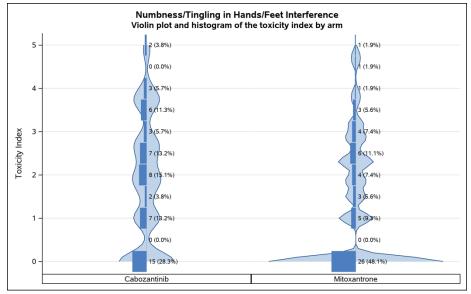
Severity: ☐ None / ■ Mild / ■ Moderate / ■ Severe / ■ Very severe

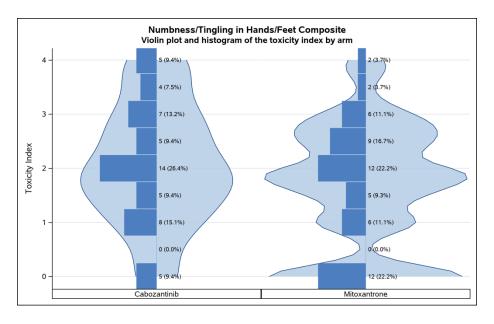
Interference: ☐ Not at all / ■ A little bit / ■ Somewhat / ■ Quite a bit / ■ Very much

Composite Grade: □ 0/■1/■2/■3

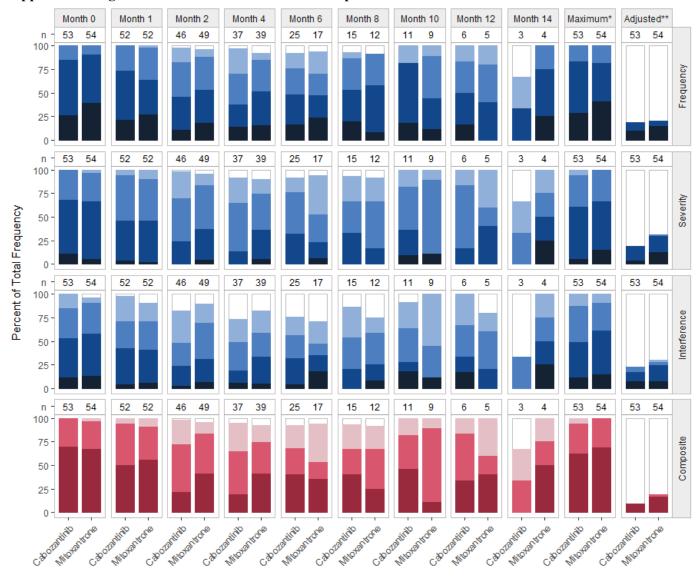
^{**}Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.







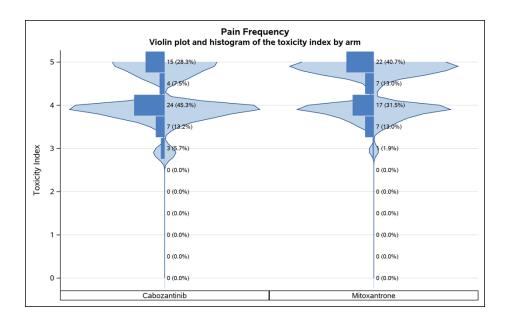
Supplemental Figure 8. PRO-CTCAE Pain Item Group

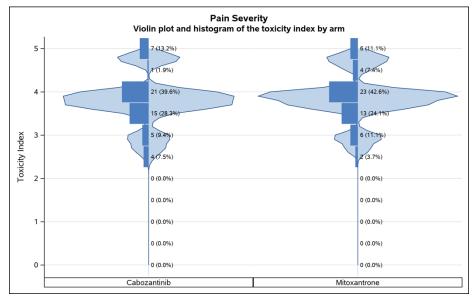


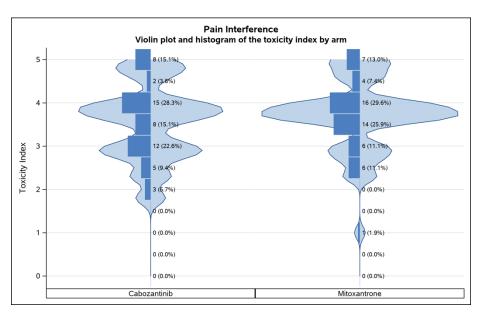
Randomized Treatment Assignment

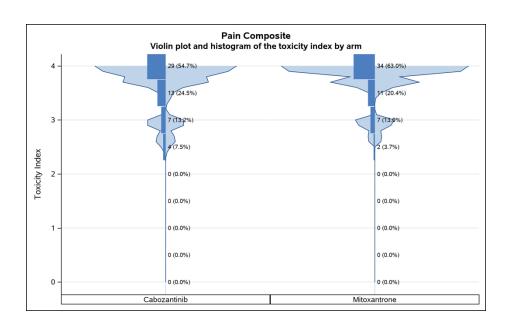


Column labels (n) show the number of subjects with an observed symptom score or grade.
*Maximum score or grade reported post-baseline per patient.
**Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.

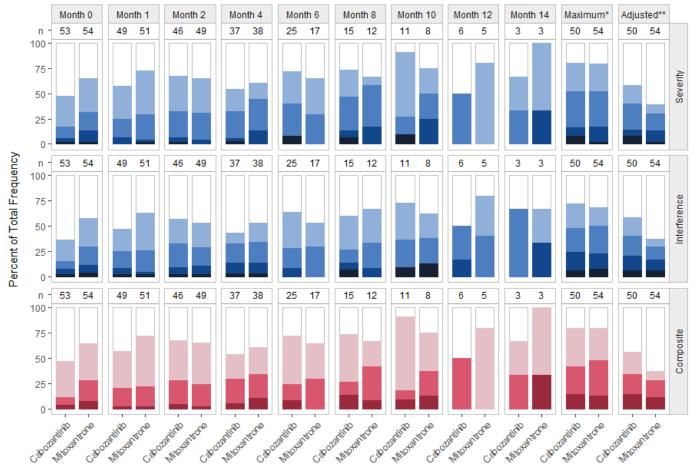








Supplemental Figure 9. PRO-CTCAE Shortness of Breath Item Group



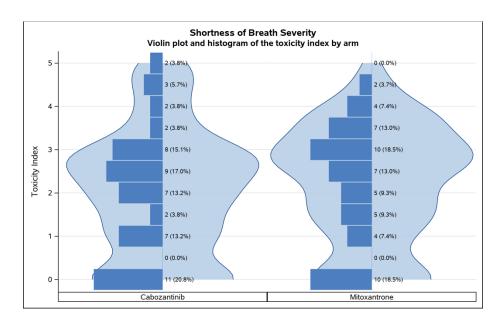
Randomized Treatment Assignment

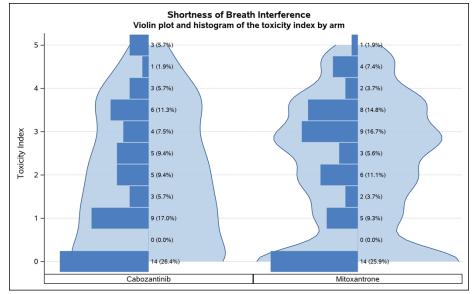
Severity: ☐ None / ■ Mild / ■ Moderate / ■ Severe / ■ Very severe

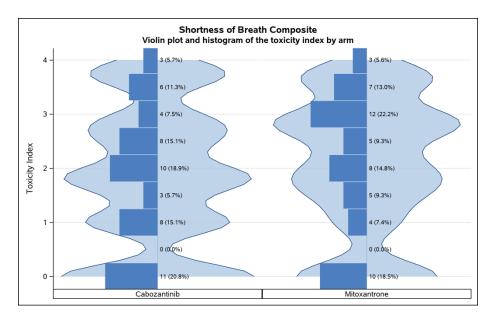
Interference: ☐ Not at all / ■ A little bit / ■ Somewhat / ■ Quite a bit / ■ Very much

Composite Grade: □ 0/■1/■2/■3

^{**}Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.







Supplemental Figure 10. PRO-CTCAE Vomiting Item Group



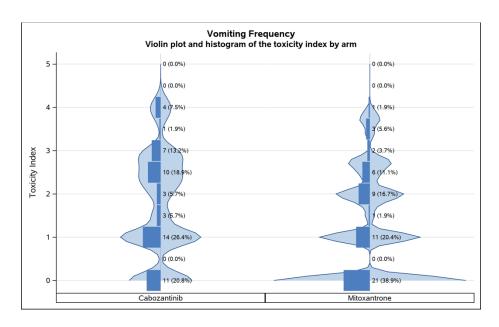
Randomized Treatment Assignment

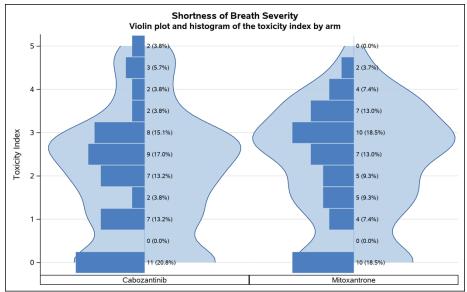
Frequency: ☐ Never / ■ Rarely / ■ Occasionally / ■ Frequently / ■ Almost constantly

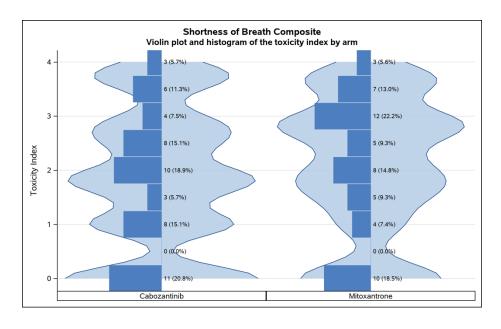
Severity: ☐ None / ■ Mild / ■ Moderate / ■ Severe / ■ Very severe

Composite Grade: ☐ 0 / ■ 1 / ■ 2 / ■ 3

^{**}Maximum score or grade reported post-baseline per patient when including only scores that were worse than the patient's baseline score.







Supplemental Figure 11. Density Histograms for all PROCTCAE Items and Composites, by Arm

