Errata to the FDA Briefing Document
February 26, 2019 ODAC Meeting

Page	Original	Replace
Page 23, Table 10	"Fatigue[a], 6 (7.6), 20 (16.3), 26 (12.9)"; "Fracture[d], 1 (1.3), 5 (4.1), 6 (3)"	"Fatigue[a], 6 (7.6), **19 (15.4)**, **25 (12.4)**"; "Fracture[d], 1 (1.3), **4 (3.3)**, **5 (2.5)**"
Page 24, Table 11	"Fatigue[†], 4 (5.1), 10 (8.1), 14 (6.9)"	"Fatigue[†], 4 (5.1), **9 (7.3)**, **13 (6.4)**"
Page 25, Table 12	"Mental status changes[c], 4 (5.1), 2 (1.6), 6 (3)"	"Mental status changes[c], **3 (3.8)**, 2 (1.6), **5 (2.5)**"
Page 28, Table 15	"Fracture[f], 4 (5.1), 5 (4.1), 9 (4.5)"; "Mental status changes[g], 6 (5.1), 8 (6.5), 14 (6.9)"	"Fracture[f], 4 (5.1), **4 (3.3)**, **8 (4.0)**"; "Mental status changes[g], **5 (6.3)**, 8 (6.5), **13 (6.4)**"
Page 29	"The most common TEAEs …fatigue (79.7%), … and dyspnea (22%)."	"The most common TEAEs … fatigue (**72.4%**), … and dyspnea (**21.1%**)."
Pages 29-31, Table 16	"Abdominal pain[b], 8 (10.1), 11 (8.9), 19 (9.4)"; "Fatigue[c], 62 (78.4), 98 (79.7), 160 (79.2)"; "Sepsis[f], 2 (2.5), 11 (8.9), 13 (6.4)"; "Fracture[h], 5 (6.3), 11 (8.9), 16 (7.9)"; "Hypercreatinemia[i], 16 (20.3), 13 (10.6), 29 (11.4)"; "Mental status changes[l], 14 (17.7), 21 (17.1), 35 (17.3)"; "Renal impairment[m], 4 (5.1), 7 (5.7), 11 (5.4)"; "Cough[n], 14 (17.7), 20 (16.3), 34 (16.8)"; "Dyspnea[o], 23 (29.1), 27 (22), 50 (24.8)"	"Abdominal pain[b], **7 (8.9)**, 11 (8.9), **18 (8.9)**"; "Fatigue[c], **58 (73.4)**, **89 (72.4)**, **147 (72.8)**"; "Sepsis[f], **1 (1.3)**, **12 (9.8)**, 13 (6.4)"; "Fracture[h], 5 (6.3), **9 (7.3)**, **14 (6.9)**"; "Hypercreatinemia[i], **15 (19.0)**, 13 (10.6), **28 (13.9)**"; "Mental status changes[l], **12 (15.2)**, 21 (17.1), **33 (16.3)**"; "Renal impairment[m], 4 (5.1), **6 (4.9)**, **10 (5.0)**"; "Cough[n], **13 (16.5)**, 20 (16.3), **33 (16.3)**"; "Dyspnea[o], **22 (27.8)**, **26 (21.1)**, **48 (23.8)**"
Page 32	"The most common Grade 3 or 4 TEAEs …fatigue (25.2%), and hyponatremia (20.3%)."	"The most common Grade 3 or 4 TEAEs … fatigue (**23.6%**), and hyponatremia (20.3%)."
Pages 32-33, Table 17	"Fatigue[a], 15 (19), 31 (25.2), 46 (22.8)"; "Sepsis[d], 1 (1.3), 7 (5.7), 8 (4)"; "Fracture[e], 3 (3.8), 6 (4.9), 9 (4.5)"; "Mental status changes[f], 8 (10.1), 7 (5.7), 15 (7.4)"	"Fatigue[a], 15 (19), **29 (23.6)**, **44 (21.8)**"; "Sepsis[d], 1 (1.3), **8 (6.5)**, **9 (4.5)**"; "Fracture[e], 3 (3.8), **5 (4.1)**, **8 (4.0)**"; "Mental status changes[f], **7 (8.9)**, 7 (5.7), **14 (6.9)**"
Page 33, Footnote	"[d] Includes terms sepsis and septic shock"	"[d] Includes terms sepsis and **staphylococcal sepsis**"
Page 35, Table 18	"Parameter, Q1 (N = 156), Q2 (N = 156), Q3 (N = 156), Q4 (N = 156)"; "Thrombocytopenia, 20 (12.8), 32 (20.5), 48 (31), 53 (34)";	"Parameter, Q1 (N = 156), Q2 (N = **155**), Q3 (N = **155**), Q4 (N = **155**)"; "Thrombocytopenia, **37 (23.7)**, **41 (26.5)**, **52 (33.5)**, **62 (40)**";

	"Neutropenia, 4 (2.6), 18 (11.5), 17 (11), 27 (17.3)"; "Hyponatremia, 3 (1.9), 8 (5.1), 16 (10.3), 33 (21.2)"; "Fatigue, 3 (1.9), 7 (4.5), 14 (9), 13 (8.4)"; "GI Disorders, 4 (2.6), 4 (2.6), 9 (5.8), 13 (8.4)"; "Decreased Appetite, 3 (1.9), 3 (1.9), 5 (3.2), 8 (5.2)";	"Neutropenia, **15** (**9.6**), **22** (**14.2**), **28** (**18.1**), **33** (**21.3**)"; "Hyponatremia, **8** (**5.1**), **11** (**7.1**), **19** (**12.3**), **35** (**22.6**)"; "Fatigue, **4** (**2.6**), **10** (**6.5**), **18** (**11.6**), **10** (**6.5**)"; "GI Disorders, **8** (**5.1**), **7** (**4.5**), **10** (**6.5**), **11** (**7.1**)"; "Decreased Appetite, **4** (**2.6**), 3 (1.9), **6** (**3.9**), **7** (**4.5**)";
Page 61	"In the 1/4/2019 IR, FDA stated that, to avoid confounding, patients in the STORM dataset who received treatments after selinexor should be excluded from a comparison of survival times."	"In the 1/4/2019 IR, …after **meeting the penta-exposed and triple class refractory criteria, but before** selinexor should be excluded from a comparison of survival times."
Page 71	"This analysis was performed for both the PK-safety set (N = 623 with PK from studies…).	"This analysis was performed for both the PK-safety set (N = **617** with PK from studies…).

Page 72 – Page 76: The original Figure 13 - Figure 22 should be replaced with the following figures.

Figure 13: Exposure-Response Relationship for Neutropenia and Decreased Neutrophil Count

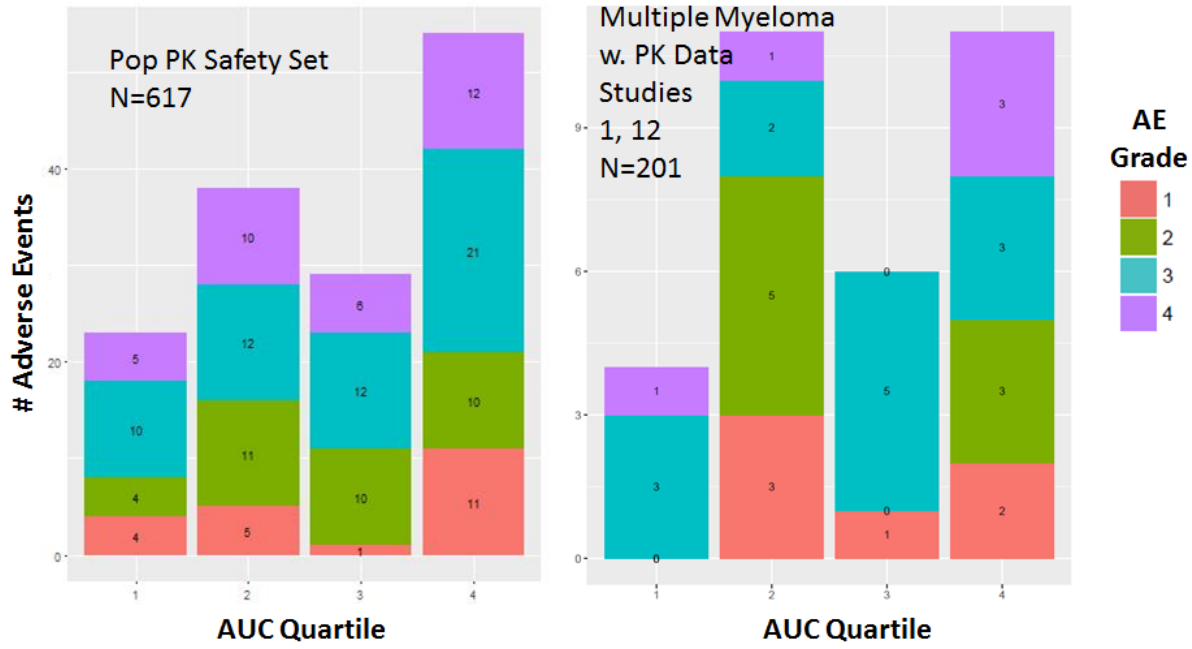

Figure 14: Exposure-Response Relationship for Thrombocytopenia

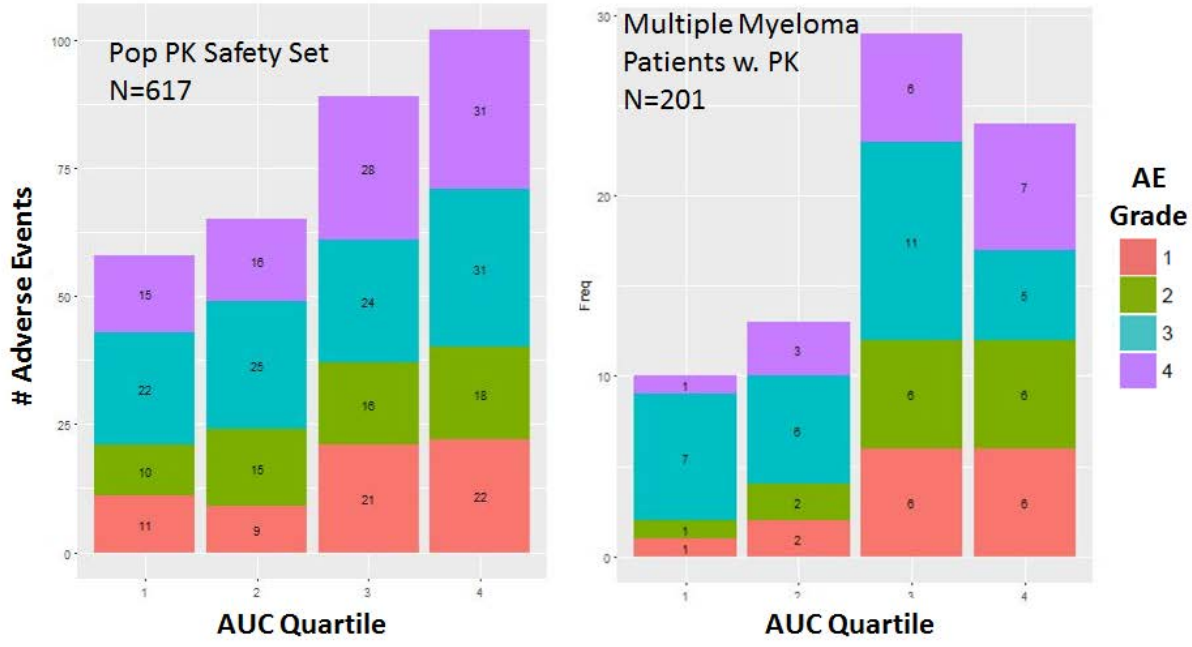

Figure 15: Exposure-Response Relationship for Gastrointestinal Disorders

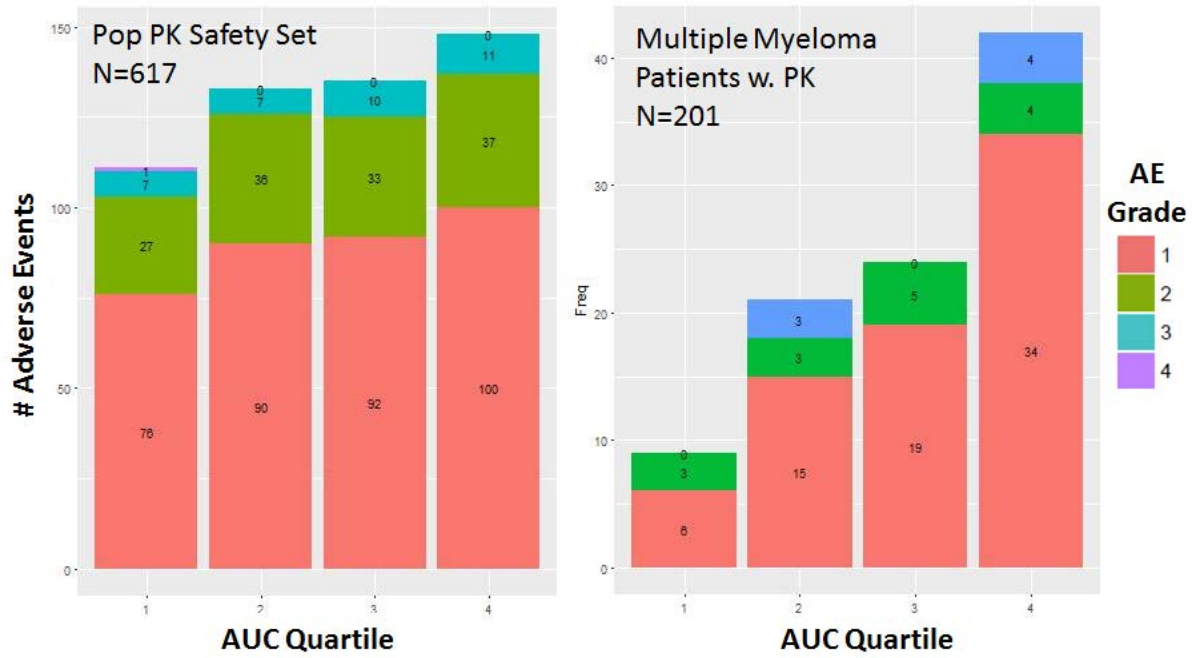

Figure 16: Exposure-Response Relationship for Diarrhea

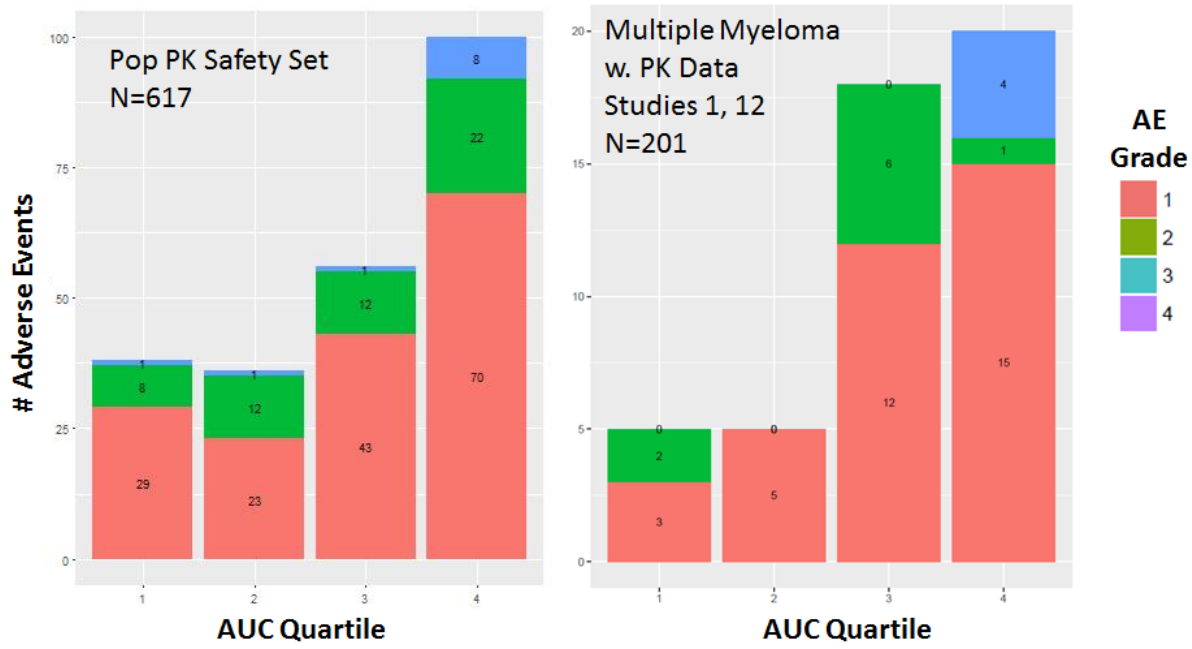

Figure 17: Exposure-Response Relationship for Vomiting

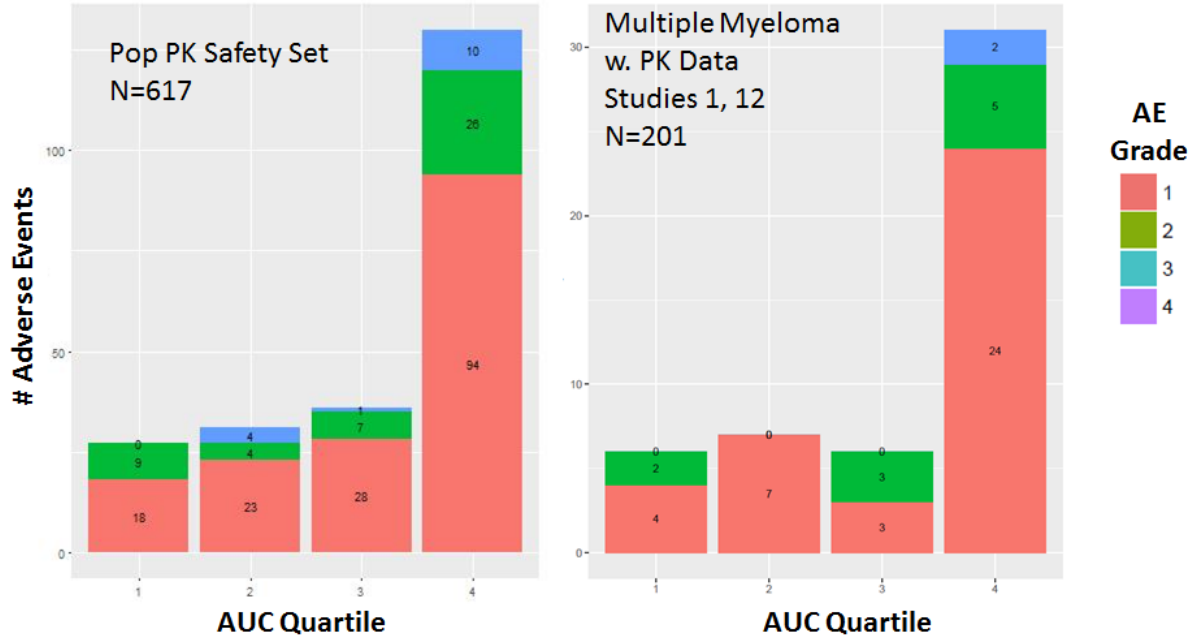

Figure 18: Exposure-Response Relationship for Decreased Appetite

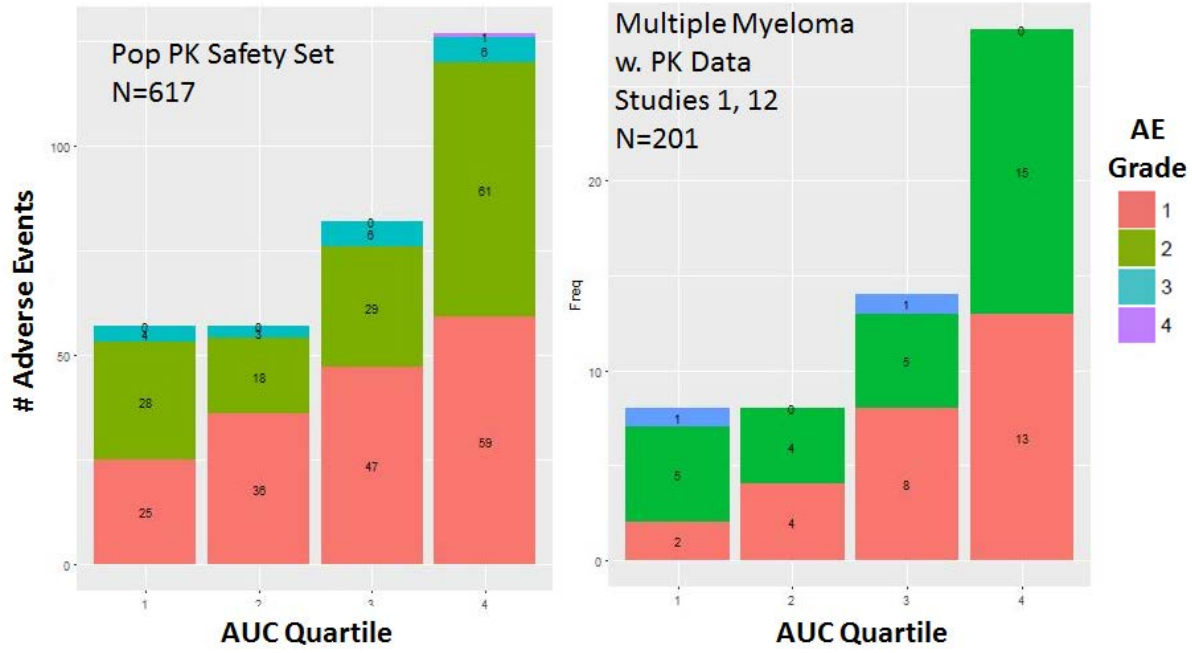

Figure 19: Exposure-Response Relationship for Decreased Weight

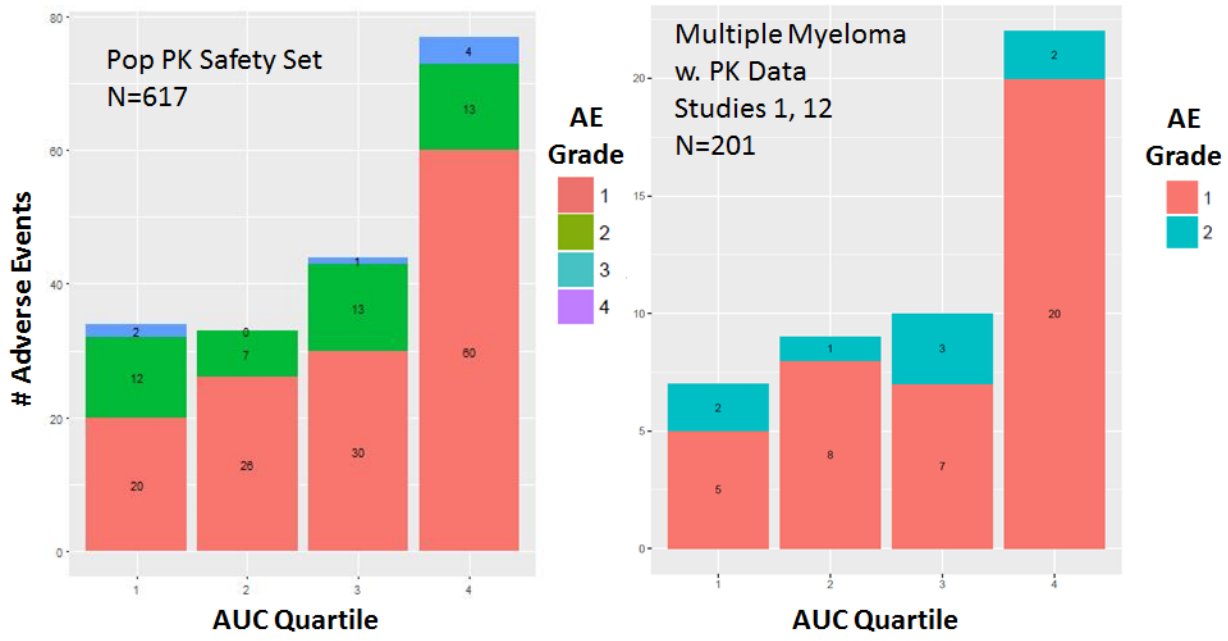

Figure 20: Exposure-Response Relationship for Fatigue

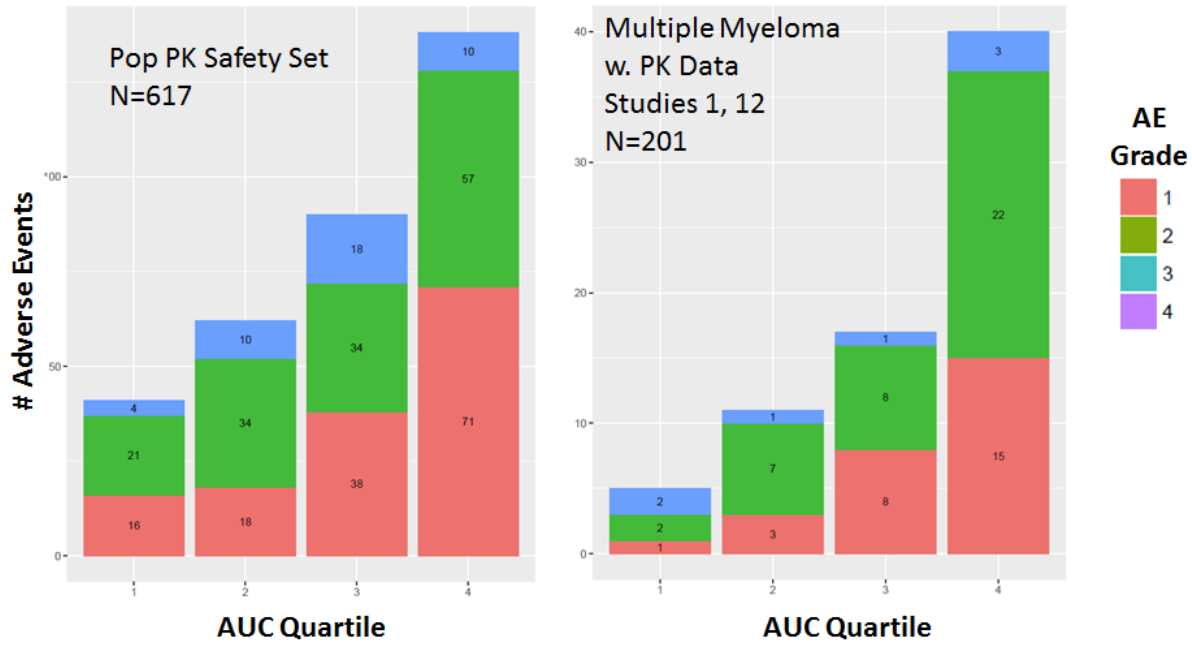

Figure 21: Exposure-Response Relationship for Hyponatremia

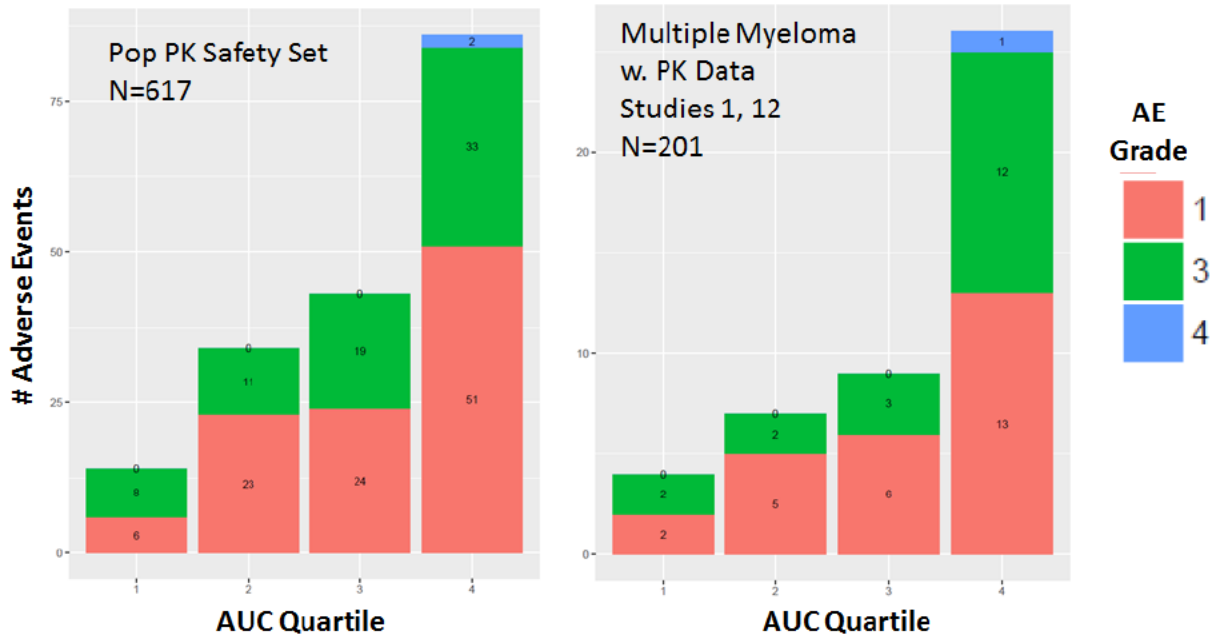

Figure 22: Exposure-Response Relationship for Ocular Safety Events