Supplementary Online Content

Basch E, Dueck AC, Rogak LJ, et al. Feasibility assessment of patient reporting of symptomatic adverse events in multicenter cancer clinical trials. *JAMA Oncol*. Published online February 16, 2017. doi:10.1001/jamaoncol.2016.6749

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. CALGB Linked Treatment Trials

Cancer Type	ClinicalTrials.gov	Treatment Trial Title
Breast	NCT00785291	Paclitaxel, Nab-paclitaxel, or Ixabepilone With or Without Bevacizumab in Treating Patients With Stage IIIC or Stage IV Breast Cancer (CALGB 40502)
Breast	NCT00601900	Tamoxifen Citrate or Letrozole With or Without Bevacizumab in Treating Women With Stage III or Stage IV Breast Cancer (CALGB 40503)
Breast	NCT00770809	Paclitaxel and Trastuzumab With or Without Lapatinib in Treating Patients With Stage II or Stage III Breast Cancer That Can Be Removed by Surgery (CALGB 40601)
Breast	NCT00861705	Paclitaxel With or Without Carboplatin and/or Bevacizumab Followed by Doxorubicin and Cyclophosphamide in Treating Patients With Breast Cancer That Can Be Removed by Surgery (CALGB 40603)
Colorectal	NCT00265850	Cetuximab and/or Bevacizumab Combined With Combination Chemotherapy in Treating Patients With Metastatic Colorectal Cancer (CALGB 80405)
Lung	NCT00693992	Sunitinib Malate as Maintenance Therapy in Treating Patients With Stage III or Stage IV Non-Small Cell Lung Cancer Previously Treated With Combination Chemotherapy CALGB)
Lung	NCT00698815	Pemetrexed and/or Sunitinib as Second-Line Therapy in Treating Patients With Stage IIIB or Stage IV Non-small Cell Lung Cancer (CALGB 30610)
Prostate	NCT00110214	Docetaxel and Prednisone With or Without Bevacizumab in Treating Patients With Prostate Cancer That Did Not Respond to Hormone Therapy (CALGB 90401)
Supportive Care	NCT00869206	Zoledronic Acid in Treating Patients With Metastatic Breast Cancer, Metastatic Prostate Cancer, or Multiple Myeloma With Bone Involvement (CALGB 70604)

eTable 2. Patient Adaptations of Adverse Event Items From the Common Terminology Criteria for Adverse Events (CTCAE). Patients were asked to: "Please answer the following questions to tell us the worst your symptoms have been since your last chemotherapy treatment. If you have not received chemotherapy, or your treatment has been held, please tell us the worst your symptoms have been since your last chemotherapy visit."

CTCAE Term	Patient Response Options
Pain	**None**: I have not had pain.
	Grade 1 (Mild): I have had mild pain, but it does not interfere with my normal functioning.
	Grade 2 (Moderate): I have had moderate pain, and my pain or my use of pain medications interferes with my normal functioning. But I am still able to carry out my normal daily activities.
	Grade 3 (Severe): I have had severe pain, and my pain or my use of pain medications severely interferes with my normal daily activities.
	Grade 4 (Disabling): My pain has been disabling.
Fatigue	**None:** I have not had fatigue compared to my usual baseline.
	Grade 1 (Mild): I have had mild fatigue compared to my usual baseline.
	Grade 2 (Moderate): I have had moderate fatigue compared to my usual baseline, or fatigue causing moderate difficulty performing my normal daily activities.
	Grade 3 (Severe): I have had severe fatigue that interferes with my normal daily activities.
	Grade 4 (Disabling): My fatigue had been disabling.
Nausea	**None:** I have not had nausea.
	Grade 1 (Mild): I have lost my appetite due to nausea, but I am able to eat.
	Grade 2 (Moderate): The amount I eat or drink is decreased due to nausea, but I have not lost weight or become dehydrated or malnourished. I have not needed IV fluids for greater than 24 hours.
	Grade 3 (Severe): I have not been eating or drinking adequately and have required IV fluids, tube feedings, or intravenous nutrition (TPN) for more than 24 hours.
Vomiting	**None:** I have not been vomiting.
	Grade 1 (Mild): I have had vomiting, but I have not vomited more than once in a 24-hour period.
	Grade 2 (Moderate): I have had vomiting between 2-5 times in a 24-hour period, or I have needed IV fluids for less than 24 hours.
	Grade 3 (Severe): I have had vomiting more than 6 times over a 24-hour period, or I have needed IV fluids/nutrition for more than 24 hours or longer due to vomiting.
	Grade 4 (Disabling): My vomiting has been disabling.
Diarrhea	**None:** I have not had more bowel movements than usual each day.
	Grade 1 (Mild): I have had 1-3 bowel movements more than usual each day.
	Grade 2 (Moderate): I have had 4-6 bowel movements more than usual each day, but I have not needed IV fluids for greater than 24 hours, and diarrhea is not interfering with my normal daily activities.
	Grade 3 (Severe): I have had greater than 6 bowel movements more than usual each day, or I have needed IV fluids for greater than 24 hours and diarrhea is interfering with my normal daily activities.

Constipation	**None:** I have not had constipation.
	Grade 1 (Mild): I have had occasional or intermittent constipation, or I am occasionally using stool softeners, laxatives, enemas, or dietary changes to help move my bowels.
	Grade 2 (Moderate): I have had persistent (ongoing) constipation, and cannot have bowel movements without the regular use of laxatives or enemas.
	Grade 3 (Severe): Constipation has interfered with my normal daily activities, or I have required disimpaction.
Anorexia	**None:** I have had no problems with my appetite or eating.
	Grade 1 (Mild): I have lost my appetite but have not changed my eating habits.
	Grade 2 (Moderate): I have been eating less but have not lost a lot of weight or become malnourished.
	Grade 3 (Severe): I am losing a lot of weight or I am malnourished, and I am taking in very little food or fluids (or I have needed to get IV fluids, tube feedings, or IV nutrition).
Mucositis	**None:** I have not had mouth sores.
	Grade 1 (Mild): I have had mild mouth sores without significant discomfort, and I am able to eat a normal diet.
	Grade 2 (Moderate): I have had uncomfortable mouth sores, but I am able to eat and swallow specially prepared foods.
	Grade 3 (Severe): I have had uncomfortable mouth sores which are preventing me from eating or drinking.
Watery Eyes	**None:** I have had no increase in watery eyes/tearing.
	Grade 1 (Mild): I have had increased watery eyes/tearing, but have not required any treatment for this.
	Grade 2 (Moderate): I have had increased watery eyes/tearing which is interfering with my functioning, but has not interfered with my ability to conduct my daily activities.
	Grade 3 (Severe): I have had increased watery eyes/tearing which has interfered with my ability to conduct my daily activities.
Peripheral Sensory Neuropathy	**None:** I have not had numbness or tingling in my hands or feet.
	Grade 1: I have had mild numbness or tingling in my hands or feet, but this has not affected my everyday activities, such as buttoning buttons, feeling small objects with my hands, or walking.
	Grade 2: I have had moderate numbness or tingling in my hands or feet, OR the numbness or tingling in my hands or fee makes it harder to do my everyday activities, such as buttoning buttons, feeling small objects with my hands, or walking.
	Grade 3: I have had severe numbness or tingling in my hands or feet, OR because of numbness or tingling in my hands or feet, I am not able to do my everyday activities such as buttoning buttons, feeling small objects with my hands, or walking.
	Grade 4: Because of numbness or tingling in my hands or feet, I rarely am able to get out of bed.

Cough	**None:** I have not had any coughing.
	Grade 1: I have had mild coughing, OR when I need to control my cough, I take over-the-counter medicine, herbal remedies, or supplements.
	Grade 2: I have had a fair amount of coughing, OR when I need to control my cough, I take medicine prescribed by my doctor.
	Grade 3: I have been coughing all the time, OR my cough is so bad that I have a lot of trouble doing my normal activities, such as eating, bathing, walking, and sleeping.
Dyspnea	**None:** I have not had any shortness of breath.
	Grade 1: I have had mild shortness of breath when I try to do something physical, such as exercise. But I can still walk up a flight of stairs or walk around the block without stopping.
	Grade 2: I have had moderate shortness of breath, OR I cannot walk up a flight of stairs or around the block without stopping to catch my breath.
	Grade 3: I have had severe shortness of breath, OR because of my trouble breathing, it's a lot harder for me to do my normal activities, such as eating, bathing, walking, and going to the bathroom.
Hand/Foot Syndrome	**None:** I have not had skin redness, peeling, or blisters on the palms of my hands or soles of my feet.
	Grade 1: I have had skin redness on the palms of my hands or soles of my feet, but this has not affected my being able to do my everyday activities, normal work, or walking.
	Grade 2: I have had peeling, blisters, bleeding, or swelling on the palms of my hands or soles of my feet, AND/OR this has made it a little bit harder for me to do my everyday activities, normal work, or walking.
	Grade 3: I have had skin changes or pain on the palms of my hands or soles of my feet, OR this has made it a lot harder for me to do my everyday activities, normal work, or walking.

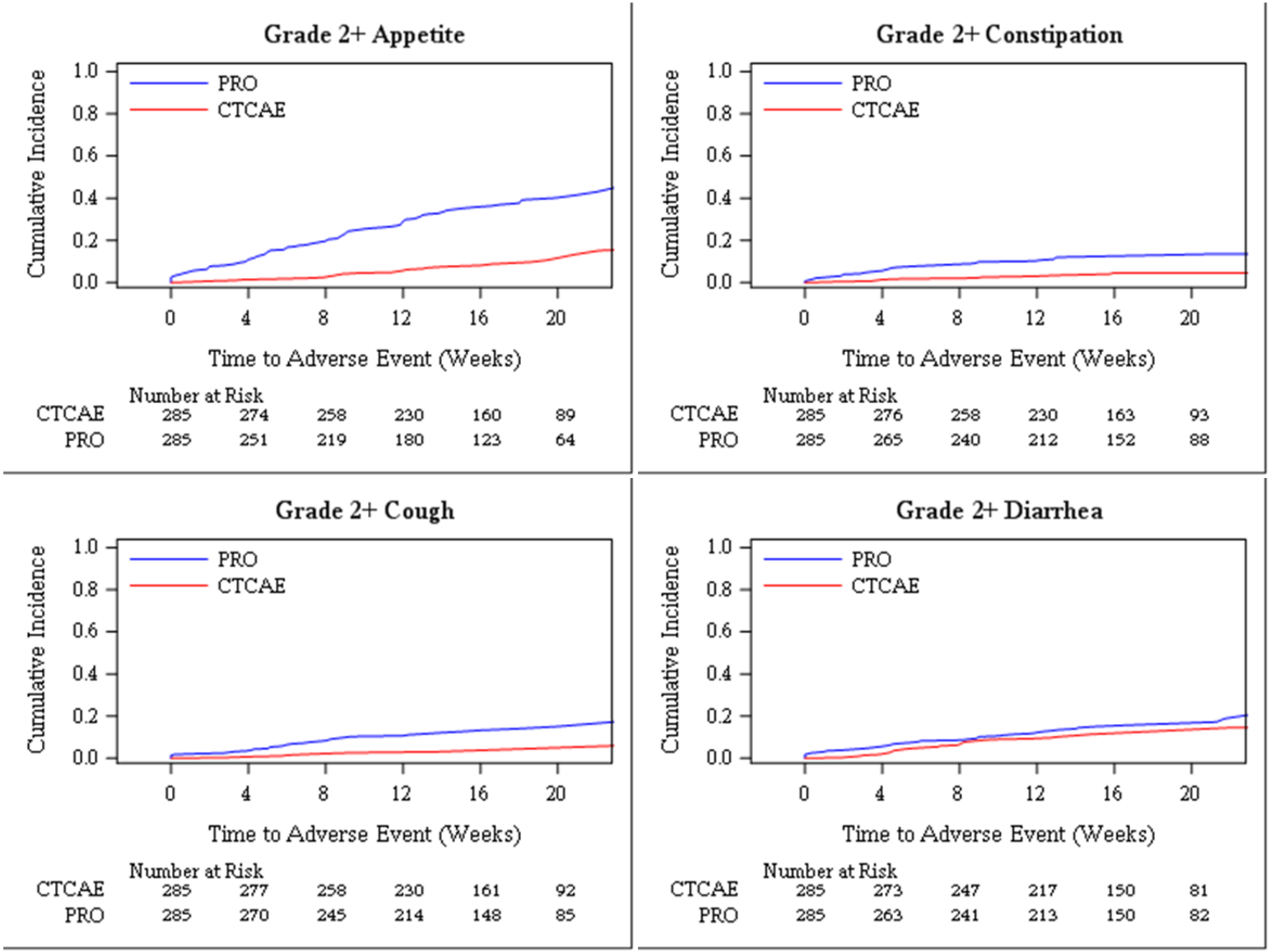
eTable 3. Example of Adverse Event Items by CTCAE and Patient Adaptation

Symptom	CTCAE version 3	Patient Adaptation
Fatigue	**Grade 0:** None	**None:** I have not had fatigue compared to my usual baseline.
	Grade 1: Mild fatigue over baseline	**Grade 1 (Mild)**: I have had mild fatigue compared to my usual baseline.
	Grade 2: Moderate or causing difficulty performing some Activities of Daily Living	**Grade 2 (Moderate)**: I have had moderate fatigue compared to my usual baseline, or fatigue causing moderate difficulty performing my normal daily activities.
	Grade 3: Severe fatigue interfering with Activities of Daily Living	**Grade 3 (Severe)**: I have had severe fatigue that interferes with my normal daily activities.
	Grade 4: Disabling	**Grade 4 (Disabling)**: My fatigue had been disabling.

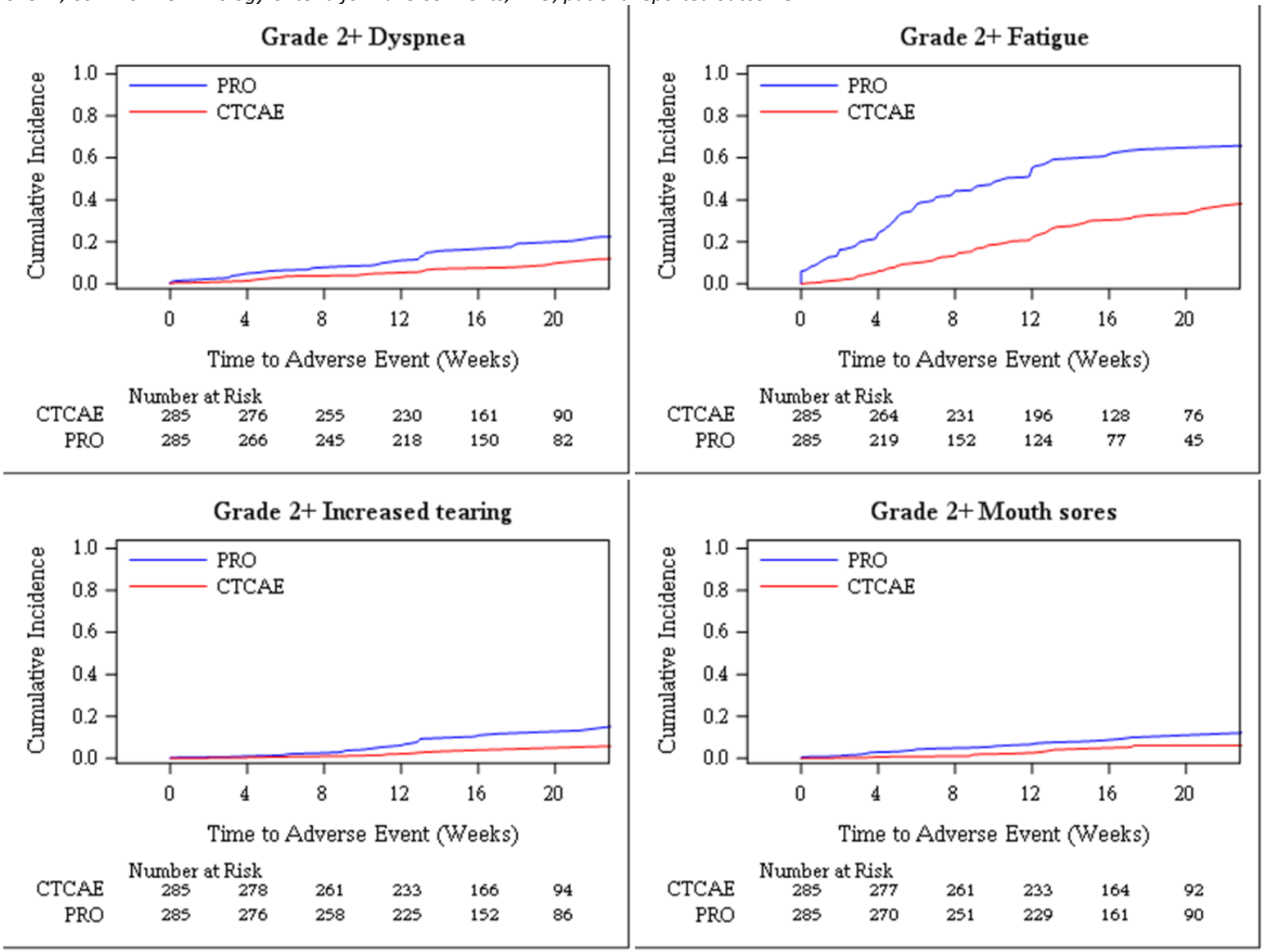
eAppendix. Institutional Review Boards

The following institutional review boards provided approval for the studies at each site:
Contra Costa Regional Medical Center
Hematology and Oncology Associates-Oakland
Christiana Healthcare Services - Christiana Hospital
Cooper Hospital/University Medical Center
Dana Farber Cancer Institute
Eastern Maine Medical Center
Dartmouth College, NCCC, Dartmouth Medical School
Greenville Health System Cancer Institute/Greenville CCOP
Missouri Baptist Medical Center
Oncology Associates of Central New York
Saint Luke's Hospital of Kansas City
Massachusetts General Hospital
Memorial Sloan-Kettering Cancer Center
Nevada Cancer Research Foundation-CCOP
University Medical Center-CCOP
LRGHealthcare-Lakes Region General Hospital
New Hampshire Oncology-Hematology P.A.
New Hampshire Oncology-Hematology P.A.- Hooksett
North Shore University Hospital
Memorial Hospital of South Bend-CCOP
Northern Indiana Cancer Research Consortium-CCOP
St. Joseph's Medical Center-CCOP
Rhode Island Hospital
FirstHealth of the Carolinas Moore Regional Hospital
Mission Hospitals, Inc
Wayne Memorial Hospital
Syracuse VA Medical Center
University Of California At San Diego
Louis A. Weiss Memorial Hospital
Department of Veterans Affairs Iowa City Health Care System
University of Iowa Hospitals and Clinic
University of North Carolina at Chapel Hill
University of Vermont
Wake Forest University School of Medicine
Yale University
CTSU/Westat – Rockville Maryland

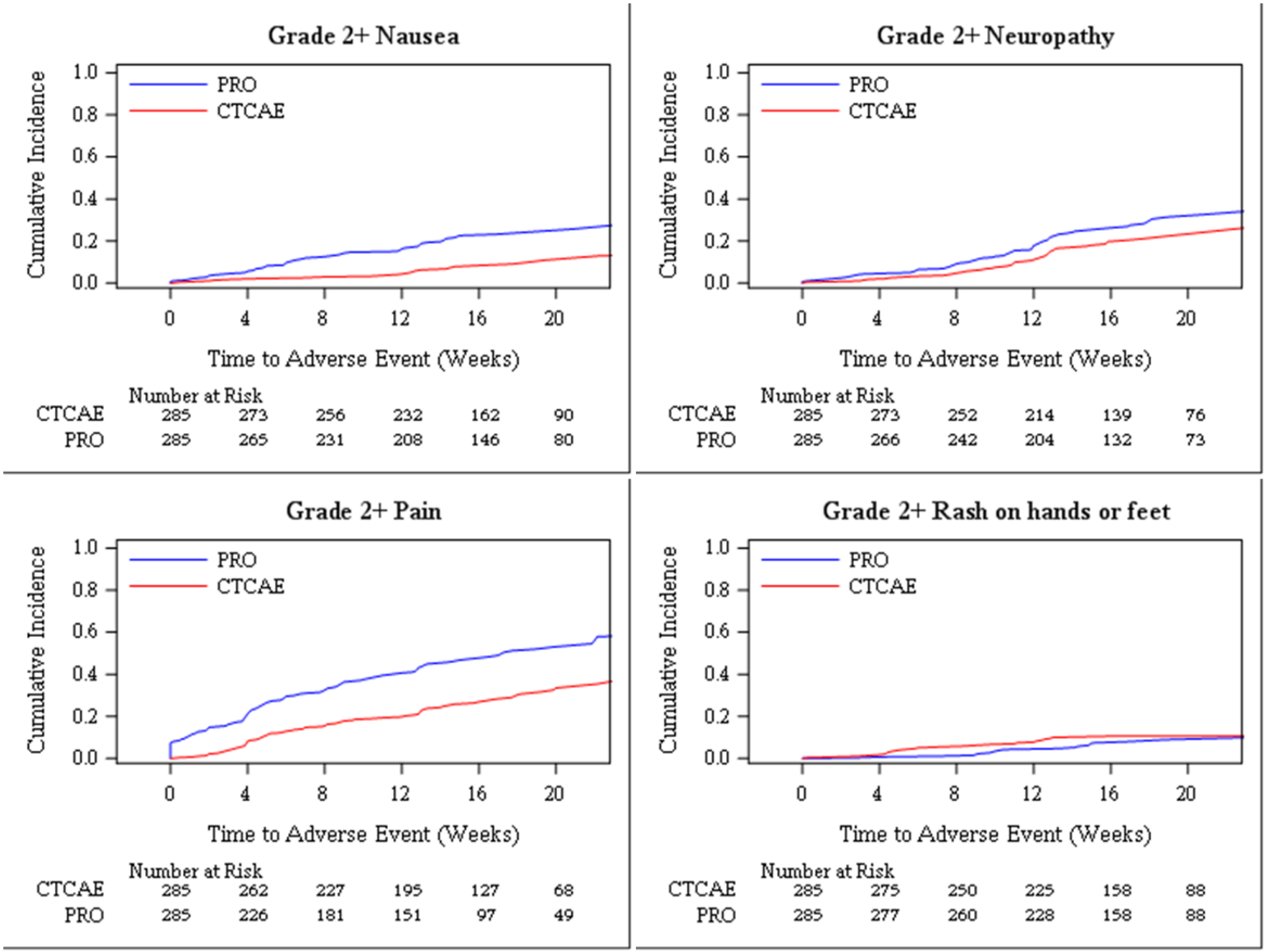
eFigure. Cumulative Incidence of CTCAE Grade 2 or Higher Patient-Reported and Clinician-Reported Adverse Events, Aggregated From Nine US Multicenter Clinical Trials for All 13 Adverse Events



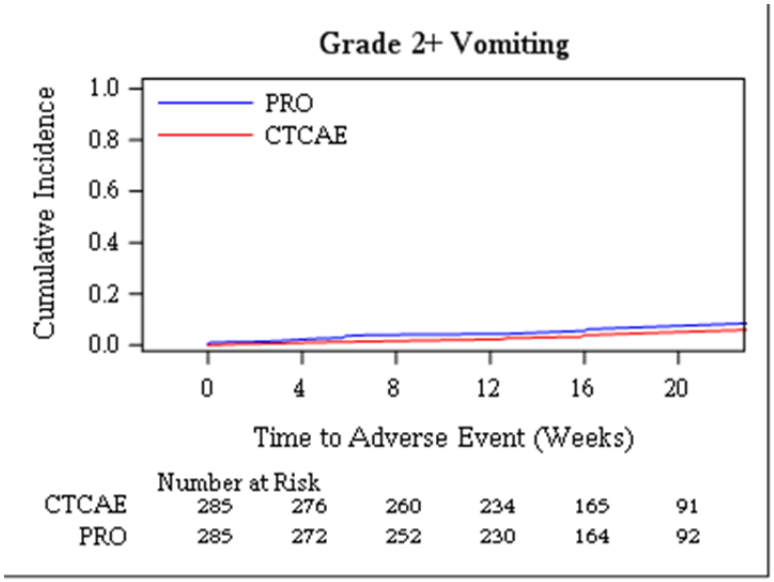
CTCAE, Common Terminology Criteria for Adverse Events; PRO, patient-reported outcome



CTCAE, Common Terminology Criteria for Adverse Events; PRO, patient-reported outcome



CTCAE, Common Terminology Criteria for Adverse Events; PRO, patient-reported outcome



CTCAE, Common Terminology Criteria for Adverse Events; PRO, patient-reported outcome

