The data in NCT00003809-D1 are the analysis data for E5397 results published in PMID 30926065.

Eze N, Lee JW, Yang DH, Zhu F, Neumeister V, Sandoval-Schaefer T, Mehra R, Ridge JA, Forastiere A, Chung CH, Burtness B: PTEN loss is associated with resistance to cetuximab in patients with head and neck squamous cell carcinoma. Oral Oncology 2019; 91: 69-78.

Dataset NCT00003809-D1 Description
General note: Blank field (for character variables) and field with "." (for numeric variables) indicate missing values.
• The coding "PTEN-neg/PIK3CA-mut" for PTEN/PIK3CA status is expressed as "PTEN null/PIK3CA mut" in Table 3.

Field	Name	Description	Coding/Notes
1	study	Study name	E5397
2	maskid	ECOG-ACRIN masked case ID	Numeric code, up to 7 digits
3	trt_num	Assigned treatment	"C225" = Cetuximab "Placebo"
4	age	Age at study entry	Numeric (years)
5	sex	Sex	"Female" "Male"
6	race_rcd	Race	"White" "Black" "Other"
7	ps	ECOG performance status (at baseline)	0 = fully active 1 = ambulatory, capable of light work
8	wtloss	Weight loss in previous 6 months (at baseline)	0 = <5% 1 = 5-<10% 2 = 10-<20% 3 = >/=20% (of body weight)
9	celldiff	Cell differentiability (at baseline)	1 = well differentiated 2 = moderately well differentiated 3 = poorly differentiated
10	os	Overall survival (time from study entry date to date of death or date of last known alive)	Numeric (months)
11	os_status	Survival status	0 = alive 1 = dead
12	pfs	Progression-free survival (time from study entry date to date of progression, death from any cause, or date of last known alive)	Numeric (months)
13	pfs_status	Progression-free survival status	0 = censor 1 = event
14	PTEN	PTEN score	Numeric
15	PTEN_epi_group	PTEN status	"Negative" = PTEN score </=570 "Positive" = PTEN score >570
16	PIK3CA	PIK3CA mutation status	"mutant" "wildtype" "NA" = unknown
17	PTEN_PIK3CA	PTEN/PIK3CA combined status	"PTEN-neg/PIK3CA-mut" = (PTEN_epi_group as negative or PIK3CA as mutant) "PTEN-pos/PIK3CA-wt" = (PTEN_epi_group as positive or PIK3CA as wildtype) Missing otherwise

| 18 | inanal | Inclusion in analysis | 1 = yes |