

Data dictionary for NCT02048813-D1

This data set corresponds to data presented in the following article:

Shanafelt TD, Wang XV, Kay NE, Hanson CA, O'Brien S, Barrientos J, Jelinek DF, Braggio E, Leis JF, Zhang CC, Coutre SE. et al  
Ibrutinib–rituximab or chemoimmunotherapy for chronic lymphocytic leukemia. New England Journal of Medicine.  
2019 Aug 1;381(5):432-43.

This file contains patient-level clinical data for all randomized patients. Patients with startyn='Yes' are included in the toxicity analysis. Blanks indicate missing value. Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Notes:

1. Table S9 footnote 5 should say that MRD results available for 95 of 175 patients.

1. Table S9 should say 48% of E1912 FCR patients had B2M > 3.5.

Variable	Description	Values
caseid	Unique blinded ID for each patient	Integer up to 7 digits
arm	Assigned treatment arm	A=IR, B=FCR
startyn	Started assigned protocol treatment or not	Yes, No
eligyn	Eligible or not	Yes, No
race	Race	White, Black or African American, Asian, American Indian or Alaska Native, Unknown, White/American Indian or Alaska Native
ethnicity	Ethnicity	Hispanic or Latino, Not Hispanic or Latino, Unknown
age	Age at randomization in years	Integer
gender	Gender	Female, Male
rai	Rai stage	0, I, II, III, IV
ps	ECOG performance status	0, 1, 2
hemoglobin	Hemoglobin, g/dL	Decimal
platelets	Platelets, 10 <sup>3</sup> /uL	Decimal
wbc	White blood cell, 10 <sup>3</sup> /uL	Decimal
b2m	Beta-2 microglobulin, mg/L	Decimal
b2mcat	Beta-2 microglobulin, categorical	Normal (<= 3.5 mg/L), Elevated (> 3.5 mg/L)
creat	Serum creatinine, mg/dL	Decimal
creatclearckd	Creatinine clearance, ml/min, based on the CKD-EPI formula	Decimal
coombs	Coombs test	Negative, Positive, Unknown
splenom	Splenomegaly	Yes, No
lymphadn	Lymphadenopathy	Yes, No
del11q22	Del(11q22.3)	Normal, Abnormal, Not Evaluated
dohner	Dohner classification	del(11q22) , del(13q), del(17p), normal, other, trisomy 12
ighv	IGHV mutation status	M=mutated, UM=unmutated
survtime	Days from randomization to death or last contact	Integer
survcensor	Vital status	0=censor, 1=death
pfs	Days from randomization to earlier of progression or death, or to last disease evaluation if no PFS event	Integer
pfscensor	Progression free survival status	0=censor, 1=event
strat1	Stratification variable 1 (age)	1 (< 60 years), 2 (>= 60 years)
strat2	Stratification variable 2 (ps)	1 (0 or 1), 2 (2)
strat3	Stratification variable 3 (Rai stage)	1 (0, I or II), 2 (III or IV)

strat4	Stratification variable 4 (Del(11q22.3))	1 (abnormal), 2 (normal)
cr12yn	Complete response or not at 12 months	Yes, No
respyn	Overall response or not	Yes, No
mrdcat	Minimal residual disease status, categorical	Low (<0.01%), Intermediate (0.01% to less than 1%), High (1% or more) Data for patients with an MRD status of "not interpretable" and those with missing data are blank for this variable.
contyn	Continuing treatment or not	Yes, No
fuyn	In follow-up or not	Yes, No
ncyc	Number of cycles	Integer
offreas	Reason off treatment	AE, Completion, Complication, Death, Insurance, Missed appointments, NPT (non-protocol therapy), Progression, Second primary, Withdrawal, Wound healing
secprim1	Second primary cancer occurrence 1	Character string
secprim2	Second primary cancer occurrence 2	Character string
basispd	Basis of progression	Absolute Lymphocyte Count and Physical Exam, Absolute Lymphocyte Count Only, Biopsy of conglomerate mass in right upper lobe lung, Death without progression, Physical Exam Only
vhfamily	VH family	VH 3-21, Other
sll	SLL or not	Yes, No
dosereduc	Dose reduction or not	Yes, No