

Progression-free Survival (PFS) Censoring Rules for Efficacy Analyses

Censoring of PFS will be performed as detailed in the tables below. Two approaches of censoring will be implemented: one based on the last adequate disease status assessment, and one based on the last clinical visit.

PFS Censoring based on Last Adequate Disease Status Assessment Situation		
Situation	Date of Event or Censoring	Outcome
A) No adequate baseline disease status assessment[1]	Date of first dose	Censored
B) No adequate post-baseline disease status assessment unless death occurs prior to first post-baseline assessment	Date of first dose + 1	Censored
C) Documented progression	Date of the earliest assessment that results in a finding of progression	Event
D) Death before progression documented and before last dose + 30 days	Date of death	Event
E) Death before progression being documented and after last dose + 30 days	Date of last adequate disease status assessment	Censored
F) No documented progression or death before data cutoff	Date of last adequate disease status assessment	Censored
G) New anticancer treatment or procedure started before documented progression	Date of last adequate disease status assessment prior to the new anticancer treatment or procedure.	Censored

[1] Patients who did not have a CT scan at baseline, but who were being followed and evaluated for disease progression will not be censored at baseline.

Note: An adequate post-baseline disease status assessment is any disease status assessment for which the investigator recorded disease status (eg, CR, PR, SD, and PD) per protocol-defined criteria.

PFS Censoring based on Last Clinical Visit

Situation	Date of Event or Censoring	Outcome
A) No adequate baseline disease status assessment [1]	Date of first dose	Censored
B) No adequate post-baseline disease status assessment unless death occurs prior to first post-baseline assessment	Last visit date (any visit [2] through the end of treatment visit) before data cutoff. If the last visit date is C1D1 then date of first dose + 1.	Censored
C) Documented progression	Date of the earliest assessment that results in a finding of progression	Event
D) Death before progression being documented and before last dose + 30 days	Date of death	Event
E) Death before progression being documented and after last dose + 30 days	Last visit date (any visit [2] through the end of treatment visit) before date of last dose + 30 days	Censored
F) No documented progression or death before data cutoff	Last visit date before data cutoff.	Censored
G) New anticancer treatment or procedure started before documented progression	Last visit date before new anticancer treatment or procedure date	Censored

[1] Patients who did not have a CT scan at baseline, but who were being followed and evaluated for disease progression will not be censored at baseline.

[2] Visits will include visits at which labs or vital signs are collected.

Note: An adequate post-baseline disease status assessment is any disease status assessment for which the investigator records disease status (eg, CR, PR, SD, and PD) per protocol-defined criteria.