

Statistical analysis plan for I216

June 28, 2017

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The analysis will be descriptive with continuous variable measured by mean and SD or median and range and categorical variable measured by percentage.

Table 1 to table 12 are the same as the meeting book table and no additional program is needed.

Table 13: Duration of response. Median (Min, Max) of the duration of the response will be reported for patients with CR/CRu and PR.

Response duration will be measured from the time measurement criteria for CR/PR (whichever is first recorded) are first met until the first date that recurrent or progressive disease is objectively documented, taking as reference the smallest measurements recorded on study (including baseline).

Figure 1. Waterfall plot for tumour shrinkage

Figure 2. KM plot for PFS