|  |  |
| --- | --- |
|  | **SAF (N=338)** |
| Total number of adverse events |  1681 |
| Patients with at least 1 adverse event [n (%)]a | 310 (91.7) |
| Patients with adverse events by intensity [n (%)]a,b |  |
|  CTC grade 1 | 213 (63.0) |
|  CTC grade 2 | 208 (61.5) |
|  CTC grade 3 | 130 (38.5) |
|  CTC grade 4 |  5 ( 1.5) |
|  CTC grade 5 |  68 (20.1) |
|  Missing data | 109 (32.2) |
| Patients with adverse events related to gemcitabine [% (n)]a | 156 (46.2) |
| Patients with adverse events related to erlotinib [n (%)]a | 222 (65.7) |
| Patients with adverse events by outcome [n (%)]a,b |  |
|  Recovered | 253 (74.9) |
|  Remaining harm |  4 ( 1.2) |
|  Not yet recovered | 132 (39.1) |
|  Exitusc |  68 (20.1) |
|  Unknown / Missing data | 147 (43.5) |
| Patients with at least 1 serious adverse event [n (%)]a | 171 (50.6) |
| Patients with adverse event ‘rash’ [% (n)]a | 174 (51.5) |
| Patients with adverse events requiring therapy [n (%)]a,b | 245 (72.5) |

a Percentages are based on the total number of patients in the SAF

b Multiple mentions per patient possible

c Overall, 133 patients died in the present study. However, as death due to a progression of the underlying tumor disease was defined as an effectiveness endpoint in this study setting, no additional documentation as an adverse event was required.