表 2.7.4.2.1-2　有害事象のまとめ（02CLLⅢFU）

Category	Number (%) of patients		
	BEN (N = 161)	CLB (N = 151)	Total (N = 312)
Any adverse event	143 (88.8%)	122 (80.8%)	265 (84.9%)
Number of adverse events	660	385	1045
Severe adverse events (grade 3 or grade 4 / Cheson or CTC)	85 (52.8%)	47 (31.1%)	132 (42.3%)
Number of severe adverse events	175	72	247
Severe hematologic adverse events with (grade 3 or grade 4)	54 (33.5%)	28 (18.5%)	82 (26.3%)
Number of severe hematologic adverse events	62	31	93
Severe nonhematologic adverse events (grade 3 or grade 4)	66 (41.0%)	26 (17.2%)	92 (29.5%)
Number of severe nonhematologic adverse events	113	41	154
Treatment-related adverse events[1]	132 (82.0%)	97 (64.2%)	229 (73.4%)
Number of treatment-related adverse events[1]	471	225	696
Serious adverse event	31 (19.3%)	19 (12.6%)	50 (16.0%)
Number of serious adverse event	38	22	60
Infections	66 (41.0%)	45 (29.8%)	111 (35.6%)
Number of infections	112	67	179
Withdrawals due to unacceptable toxicity / risk benefit assessment no longer acceptable	18 (11.2%)	5 (3.3%)	23 (7.4%)
Patients who died	31 (19.3%)	41 (27.2%)	72 (23.1%)

引用：CSR Table 53

また、治験中に発現した有害事象を表 2.7.4.2.1-3 に示す。

血液毒性の有害事象が両群を通じて認められ（47.7%、142/298 例）、本剤群で 58.4%（90/154 例）、クロラムブシル群で 36.1%（52/144 例）であった。