ARISTOTLE

Trial Number: A R I — ☐☐☐ **Patient Initials:** ☐☐☐

ADDITIONAL HAEMATOLOGY AND BIOCHEMISTRY FORM

Treatment week: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

***NB** All dates should be in DD-MM-YYYY format*

Page ____ / ____

1. HAEMATOLOGY & BIOCHEMISTRY

- *Use this form to report clinically significant haematology and biochemistry blood test results in cases where extra blood tests were done (e.g. in case of neutropenia)*
- ***Please ensure you fill in the page numbers above***

Name of Laboratory*: _____

Date of Blood Sample dd—mm—yyyy (e.g. 30 – 01 – 2011)	Test/Investigation	Test Result		Severity Grade[1] Grades 0-5	Causally related to protocol treatment[2]	Seriousness Criteria[3]	SAE Report Submitted[4] *Y /N*
		Value	units				

If this is a new laboratory, please submit a Laboratory Normal Ranges form

1) Enter grade corresponding to the test result. Use CTCAE v4.02 unless stated otherwise
2) Enter code: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely
3) Enter code: 0 = not serious; 1 = resulted in death; 2 = life threatening; 3 = required hospitalisation; 4 = resulted in disability/ incapacity; 5 = congenital anomaly or birth defect; 6 = other medically significant
4) If seriousness code is ≥ 1, ensure an SAE Report has been submitted to the UCL CTC, unless stated in protocol as exempt .

Completed by (print name): _____ **Signature:** _____ **Date Completed:** ☐☐ ☐☐ ☐☐☐☐

Site: _____

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____