

APPENDIX 1 BACSARM trial assessment schedule

	V1 (d0) Inclusion	V2 (d3)	V3* (W1, d7)	V4 (W2) EOT	V5 (W3,4,5)	V6 (W4 or W6) EOT	V7 (6 weeks after end of therapy) TOC
Inclusion/exclusion criteria	X						
Patient information sheet and consent	X						
Randomisation	X						
Comorbidities (Charlson Index)	X						
Pitt score, on day of positive blood culture	X						
Concomitant medication	X	X	X	X	X	X	X
Temperature and blood pressure	X	X	X	X	X	X	X
Physical exam	X	X	X	x	X	X	X
Haemoglobin-WBCs	X	X ^a	(X) ^c	X ^a	X ^a	X ^a	X ^a
Liver function (ALT, AST)	X	X ^a	(X) ^c	X ^a	X ^a	X ^a	X ^a
CPK	X	X ^a	(X) ^c	X ^a	X ^a	X ^a	X ^a
Renal (creatinine)	X	X ^a	(x) ^c	X ^a	X ^a	X ^a	X ^a
Pregnancy test (urine)	X						
Adverse event assessment ^b		X ^b	X ^b	X ^b	X ^b	X ^b	X ^b
Clinical response assessment				X		X	X
Blood cultures		X [#]	X [#]	X [#]		X [#]	X [#]

*This visit is required only if blood culture results are positive at 72h. W= week. V4: End of therapy (EOT) for uncomplicated bacteraemia. V6: EOT for complicated bacteraemia (all cases with prolonged therapy of up to 6 weeks require one clinical assessment per week until EOT). ^a A blood sample, which may be drawn up to 3 days before or after the visit, is required for haematology and chemistry tests, except for the V2 blood draw (at 72h). The V2 visit requires a different blood sample from the one taken at inclusion. ^b For an assessment of adverse events, the patient should be specifically asked about symptoms/signs of weakness/myalgia or diarrhoea and the skin should be explored to detect allergic reactions. For patients with diarrhoea, a *Cl difficile* test should be carried out, and if there is weakness/myalgia, CPK should be measured urgently. Adverse events of any grade leading to dose modifications/interruption/early discontinuation, grade IV or serious adverse events should be recorded on the clinical chart and e-CRF. ^c This is not mandatory. [#] *S. aureus* isolated prior to screening and in blood cultures taken at V2, V3, V4, V6 and V7 (TOC) must be stored locally and frozen at -70°C before being sent to the central laboratory (in the Hospital de Bellvitge). Blood cultures are mandatory at V2, V4, V6 and V7 (TOC)