Supplementary Table 1: Items from the World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT03147807
Date of registration in primary registry	10 May, 2017
Secondary identifying numbers	EudraCT 2016-A00941-50, IDRCB 2016-A00941-50
Source(s) of monetary or material support	French Health Ministry Program « Programme Hospitalier de Recherche Clinique 2015 » Biorad® Laboratories
Primary sponsor	Assistance Publique-Hôpitaux de Paris
Secondary sponsor(s)	-
Contact for public queries	*Marc Garnier*, MD, PhD APHP, Tenon University Hospital, Anaesthesiology and Critical Care Medicine Department +33(0)156016384, marcgarnier@gmail.com
Contact for scientific queries	*Marc Garnier*, MD, PhD APHP, Tenon University Hospital, Anaesthesiology and Critical Care Medicine Department +33(0)156016384, marcgarnier@gmail.com
Public title	βLACTA™ test for Early De-escalation of Empirical Carbapenems in Pulmonary, Urinary and Bloodstream Infections in Intensive Care Unit (BLUE CArbA)
Scientific title	Multicentre randomised controlled trial to investigate the usefulness of the rapid diagnostic βLACTA™ test performed directly on bacterial cell pellets from respiratory, urinary or blood samples for the early de-escalation of carbapenems in septic intensive care unit patients: the BLUE-CarbA protocol
Countries of recruitment	France
Health condition(s) or problem(s) studied	ICU pulmonary, urinary and bloodstream infections empirically treated with carbapenems
Intervention(s)	*Interventional group:* Early carbapenem adaptation before the second dose delivery based on the result of the betaLACTA® test directly performed on a bronchial aspirate sample and/or a urinary sample and/or a blood culture positive for Gram Negative Bacilli on direct examination. *Conventional group:* Carbapenem adaptation based on the results of the antibiotic susceptibility tests obtained after 48-72h of microbiological culturing.
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: both *Inclusion criteria:* ICU adult patient (≥ 18 years); suffering from a suspected pneumonia,

	and/or urinary tract infection, and/or primary blood-stream infection; leading to an empirical carbapenem prescription for <6 hours; with the presence of ≥2GNB/field on direct examination of a tracheo-bronchial aspirate sample, urinary sample or blood culture; written informed consent signed by the patient, the trustworthy person, the next-of-kin or close relative; or inclusion in case of emergency (followed by written informed consent signature by the patient as soon as possible); participating in a social security scheme or benefiting from such a scheme by means of a third party. *Exclusion criteria:* Pregnancy; allergy to beta-lactam antibiotics; ongoing treatment with carbapenems for another infection; aplasia; participation to another interventional study pertaining to an anti-infective treatment, whose primary aim is mortality and/or recurrence of the infection; patients in whom a procedure of withdrawing life-sustaining treatment was decided before inclusion; patient likely to die in the 48 hours following inclusion; patients benefiting from reinforced protection or persons deprived of freedom subsequent to a legal or administrative decision, majors under legal protection.
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: open-label study (no blindness for subject and investigators), with masking to the group assignment for the experts of the endpoint adjudication committee and the statisticians Primary purpose: curative anti-infectious treatment Phase III
Date of first enrolment	November 2017
Target sample size	646
Recruitment status	Recruiting
Primary outcome(s)	Composite endpoint combining 90-day mortality and proportion of infection recurrence (same GNB on the same site of infection) during the ICU stay (within the limit of 90 days).
Key secondary outcomes	1. Number of days with carbapenem treatment after inclusion during ICU stay (within the limit of 28 days); number of carbapenems Defined Daily Doses after inclusion during ICU stay (within the limit of 28 days); number of carbapenem-free and antibiotic-free days at day 28 after inclusion. 2. Proportion of new infections (same site of infection with another bacteria or other site of infection) during ICU stay (within the limit of 90 days). 3. New colonization of patients' digestive tractus with ESBL-producing and carbapenemase-producing Gram Negative Bacilli at day 3 and at the end of the antibiotic treatment of the current infection. 4. ICU and hospital lengths of stay following randomization; total cost and incremental cost-effectiveness ratio (cost per additional death/ infection averted).