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The PROWESS SHOCK trial: reply to Paramesh et al.

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Dear editor,
Drs. Paramesh and Zwaal suggest that any trial of activated protein C should be conducted independently of the drug manufacturer or anyone with financial links to the manufacturer, and without the involvement of anyone previously involved in trials of activated protein C [1]. This suggestion has great merit and we encourage Drs. Paramesh and Zwaal to conduct that trial. In the meantime, the academic members of the steering committee have joined with Lilly to conduct the PROWESS SHOCK trial and to build into that trial as many safeguards as possible; these include

giving the academics control over the interpretation and publication of the data and providing the academics with an absolute right to communicate publicly about the conduct of the trial. Additionally, we are pleased to announce that Robert M. Califf M.D., Kerry Lee Ph.D. and colleagues at the Duke Clinical Research Center will serve as the Academic Statistical Center for the trial.

Until trials such as PROWESS SHOCK can be funded and conducted by independent organisations we believe it is in the best interest of the medical community and our patients to work with industry to conduct the most methodologically rigorous and transparent trials possible, to conduct independent analysis and interpretation of the data and have the study publications written by academics rather than by industry. These processes are in place for the PROWESS SHOCK trial.

Reference

1. Paramesh KS, Zwaal J (2009) Prolonging resuscitation & postponing the death of activated protein C or is it? *Intensive Care Med.* doi:[10.1007/s00134-008-1389-9](https://doi.org/10.1007/s00134-008-1389-9)

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