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LETTERS

PHASE I STUDIES

Phase I studies: the role of publicly funded academic-healthcare partnerships

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Emanuel and colleagues' meta-analysis found that phase I studies are very safe.¹ However, the accompanying editorial mentioned that phase I studies are a "secret realm" and that "most studies are conducted outside academic medical centres at private facilities run by pharmaceutical companies or contract research organisations."²

After a major safety problem at a commercial phase I facility in 2006,³ the UK Medicines and Healthcare products Regulatory Agency (MHRA) introduced an accreditation scheme to enhance phase I safety standards in the UK. There are now four publicly funded phase I accredited clinical research facilities in the UK that have been open to non-commercial facilities since 2013. These include one university-hospital partnership (the Southampton National Institute for Health Research (NIHR) Wellcome Trust Clinical Research Facility) funded by the National Institute for Health Research. This provides an environment for early phase studies within the heart of an acute NHS hospital along with academic input from local university investigators. Phase I studies in patient populations and healthy

volunteers are a crucial part of drug development. The UK Department of Health NIHR experimental medicine infrastructure has created a setting that delivers industry and publicly funded phase I trials while allowing recruitment from the entire UK population.

Competing interests: NJB, HdG, and DFG are clinical research fellows and CJE and SNF the directors of the Southampton NIHR Wellcome Trust Clinical Research Facility.

- 1 Emanuel EJ, Bedarida G, Macci K, et al. Quantifying the risks of non-oncology phase I research in healthy volunteers: meta-analysis of phase I studies. *BMJ* 2015;350:h3271. (26 June.)
- 2 Kimmelman J. The secret realm of phase I trials in healthy volunteers. *BMJ* 2015;350:h3444. (26 June.)
- 3 Suntharalingam G, Perry MR, Ward S, et al. Cytokine storm in a phase 1 trial of the anti-CD28 monoclonal antibody TGN1412. *N Engl J Med* 2006;355:1018-28.

Cite this as: *BMJ* 2015;351:h3889

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