Leading societies support 'ethically correct' publication of negative findings

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Two leading pharmacology societies, the British Pharmacological Society (BPS) and the American Society for Pharmacology and Experimental Therapeutics (ASPET), have announced their support for the publication of negative findings from early clinical trials. Their jointly published journal, *Pharmacology Research & Perspectives*, is at the same time launching an efficient and timely means for researchers to publish negative findings in two important areas: preclinical papers that show a hypothesis to be incorrect, and papers on drugs that have failed in early clinical development that can inform whether further drug development in warranted.

Professor Phil Routledge, BPS President, comments: "It is ethically correct for pharmacologists working in academia, industry and the health services to publish negative findings. Openness not only ensures that the research community is collectively making the best possible use of resources, but also that clinical trial volunteers are not unnecessarily exposed to likely ineffective or potentially unsafe treatments when evidence may already suggest that the drug target in question is flawed."

Both BPS and ASPET are committed to the view that new opportunities for publishing negative findings are needed, in order to avoid unnecessary duplication of research and waste of resources[1]. It has been well-documented that it is difficult for authors to find journals prepared to publish negative findings[2]. In addition, once a trial shows negative results, resources within an organization may be reallocated so there may not be the opportunity to produce and submit a scientific

paper subsequently.

Dr Mike Curtis, BPS Fellow and Editor-in-Chief of Pharmacology Research & Perspectives, adds: "Historically, negative findings have tended to remain unpublished. As an author I found that journal referees often rejected papers on the grounds that the findings were negative. Now, as an Editor-in-Chief, I'm conscious that those who ignore history are condemned to repeat the mistakes of the past. When there is no record of history then it is inevitable that others will waste time and resources in unwitting replication of failed programmes."

Dr James Barrett, Chair of ASPET's Board of Publications Trustees, also comments: "The failure to publish preclinical and clinical findings that do not support a hypothesis or the therapeutic value of a drug because they are 'negative' and should remain generally unavailable may not be beneficial to progress. If such studies are based on appropriate methodology and conducted well, they can add valuable information that can provide a positive direction and momentum to both basic and clinical research. Adopting this policy places Pharmacology Research & Perspectives in a unique position to advance both preclinical and clinical research.

BPS Honorary Fellow, Professor Sir Michael Rawlins observes: "I have previously stated that I believe that all negative and positive trials should be in the public domain, so I welcome this move to ensure that negative findings related to early clinical trials can be submitted for publication."

"The announcement from BPS and ASPET is very welcome international leadership from societies who want to ensure clinical trial information is published. The results of around half of all trials are not published - this information is kept from doctors, researchers and regulators; resources are wasted repeating research that has been done and participants in further clinical trials are misled. I hope more

organisations will follow BPS and ASPET's lead and set out what they can do to ensure more clinical trials report their results," added Síle Lane, Sense About Science, one of the founding organisations of the AllTrials campaign.

More information: Hayes A, Hunter J. Why is publication of negative clinical trial data important? *Brit J Pharmacol*, 2010; 167: 1395–7. onlinelibrary.wiley.com/doi/10 … 381.2012.02215.x/pdf.

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