IRBs could use pre-clinical data better

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In this week's *PLoS Medicine*, Jonathan Kimmelman from McGill University in Montreal, Canada and Alex London from Carnegie Mellon University in Pittsburgh, USA argue that ethical reviewers and decision-makers pay insufficient attention to threats to validity in pre-clinical studies and consult too narrow a set of evidence.

They propose a better way for ethical and scientific decision makers to assess early phase studies: first, to attend to reporting and methodological quality in preclinical experiments that support claims of internal, construct, and external validity; and second, to consider evidence on risks and benefits of agents targeting related biological pathways.

In a Perspective article, James Lavery of the University of Toronto (uninvolved in the proposal) provides feedback on this proposal from the point of view of Institutional Review Boards (IRBs) and how they might better consider pre-clinical data in their deliberations.

He says that the Kimmelman and London proposal is valuable "because it encourages IRB members, and other reviewers, to engage with less familiar challenges and guard against complacency in reviewing risk and benefit data from pre-clinical studies. But its true potential value likely lies in the extent to which it can forge agreement throughout the research enterprise on the need for more creative approaches to presenting and contextualizing pre-clinical evidence, and on broadening the base of responsibility for these difficult judgements."

More information: Kimmelman J, London AJ (2011) Predicting Harms and Benefits in Translational Trials: Ethics, Evidence, and Uncertainty. PLoS Med 8(3): e1001010.doi:10.1371/journal.pmed.1001010