

Scientific Reproducibility Series

By Leverhulme-Bridges and Behavioural Science GRP



The Leverhulme Trust



Deborah Ashby OBE, FMedSci

School of Public Health, Imperial College London

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“Scientific reproducibility in the regulation of medicines”

For a medicine to gain a license it requires evidence of its efficacy and safety. Designs for studying the efficacy of new drugs are well established. For generic drugs (‘me-too’s), licensing is based on criteria of bio-equivalence, again with well-established study designs. Reproducibility plays an important role in each of these scenarios. Until recently, assessment of the benefit risk balance for a medicine especially in relation to alternatives has been entirely informal. There is now growing interest among drug regulators and pharmaceutical companies in the possibilities of more formal approaches to benefit-risk decision-making. One such initiative formed part of the Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) project, funded under the Innovative Medicines Initiative as a collaboration between academic, pharmaceutical, regulatory and patient organisations. Based on work from this project we will review current methodological approaches, and illustrate them with case-studies on medicines where benefit-risk is finely balanced. These approaches raise interesting new issues of reproducibility for regulators to grapple with.