Regulatory Policy Committee	***Opinion***	
Impact Assessment (IA)	Experimental Use and Bolar Exception	
Lead Department/Agency	Department for Business, Innovation and Skills	
Stage	Final	
IA number	BIS0402	
Origin	Domestic	
Expected date of implementation (and SNR number)	April 2014 (SNR7)	
Date submitted to RPC	13/06/2013	
RPC Opinion date and reference	19/07/2013	RPC12-BIS-1506(2)
Overall Assessment	**GREEN**	

RPC comments

The IA is fit for purpose. The One-in, Two-out (OITO) assessment appears to be robust. Although the potential impacts of the proposals have not been monetised, the assessment appears to be reasonable and proportionate.

Background (extracts from IA)

What is the problem under consideration? Why is government intervention necessary?

UK law puts the pharmaceutical industry at greater risk of patent infringement when running clinical trials and health technology assessment than most EU countries as the provisions in UK law are more narrowly drafted than in most other Member States. This is a problem because a) there is a cost to industry of assessing this risk; b) it makes the UK a less attractive location in which to do this work which has economic implications. Government intervention is required to address this issue as the industry considered the non-statutory options of industry agreements of non-infringement and guidance would not provide legal certainty and hence the risk of infringement would remain. Legislative change would provide certainty.

What are the policy objectives and the intended effects?

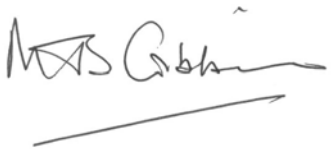
UK law should be changed to exempt from infringement activities involved in clinical trials, field trials and health technology assessment (HTA) for innovative drugs/therapies or drug/therapy combinations.

Changing the law will reduce the cost to industry as it will no longer be necessary to assess the infringement position prior to carrying out trials. Additionally, this will make the UK a more attractive location for clinical/field trials which may bring economic benefits to the UK.

Comments on the robustness of the OITO assessment

The IA states that the proposal is a deregulatory measure that has a direct net benefit to business (an 'OUT'). However, the IA explains why it has not been possible to monetise costs and benefits and states that the Department therefore considers this to be a Zero Net Cost measure. This assessment appears to be a

reasonable and in accordance with the Better Regulation Framework Manual (paragraph 1.9.12).
Comments on the robustness of the Small & Micro Business Assessment (SMBA) The proposals appear to be out of scope of the requirements for an SMBA in line with paragraph 1.6.4 of the Better Regulation Framework Manual. The SMBA is not required as the proposal does not increase the burden of regulation on business.
Quality of the analysis and evidence presented in the IA The IA has addressed the comment made in our Consultation Stage opinion (28/08/12). The IA reports additional evidence from the consultation on the costs and benefits of the proposal but explains why it has not been possible to present monetised estimates. This approach appears to be reasonable and proportionate.

Signed		***Michael Gibbons,*** *Chairman*