



## **ASSOCIATION OF BRITISH INSURERS RESPONSE TO THE EUROPEAN COMMISSION'S CONSULTATION ON THE CLINICAL TRIALS DIRECTIVE**

### **About the ABI**

The ABI is the voice of the UK's insurance, investment and long-term savings industry. It has over 300 members, which together account for around 90% of premiums in the UK domestic market.

The UK insurance industry is the third largest in the world and the largest in Europe, helping individuals and businesses protect themselves against the everyday risks they face. It pays out over £230 million per day in pension and life insurance benefits and over £50 million per day in general insurance claims. The industry is an important contributor to the UK's economy: it manages investments of £1.5 trillion, over 20% of the UK's total net worth; employs more than 300,000 people in the UK alone; is the fourth highest contributor of corporation tax; and is a major exporter, with one-fifth of its net premium income coming from overseas business.

### **Clinical Trials in the UK**

The United Kingdom is a thriving environment for clinical trials, with many pharmaceutical companies, and a large medical research sector. Much of this is based around leading universities. However, the presence of these trials in the UK is under threat, with many trials already moving to take place outside the European Union. We share the concerns that this poses significant risks. Ongoing cost-cutting could endanger subjects and could trigger a gradual loss of expertise; this could lead to the potential loss of these industries. It is crucial that we do what we can to protect this research sector, and the trials that represent an intrinsic part of it.

In the UK, there is a market for insurance for clinical trials and we are keen to maintain the strength and adaptability of this market. We believe that the market is currently functioning well, providing accessible insurance for trials of all types.

### **Response**

We welcome the EU's consultation paper and its attempts to differentiate between trials at different levels of risk. Particular consideration must be given to the type of risk, which refers not only to the drug being tested, but also to the competency of those conducting the trial and to the processes on which the trial is based.

We are limiting our comments to consultation item 14 on section 2.4 – 'Insurance/Indemnisation'.

We believe that participants in trials should always be fully informed about the risks they face, the cover they receive for these risks and if there are any gaps in cover. This would enable each participant to make an informed decision about whether they wish to participate in the trial and whether they need to take additional steps to cover any gaps in cover.

The ABI recognises that clinical trials do have differing risk profiles, as stated in the consultation document. We therefore strongly agree that flexibility needs to be built into the insurance and indemnity arrangements for these trials.



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We believe that the only way to achieve this flexibility is for member states to have the ability to vary the system of indemnity that they require for lower risk trials. This would have the benefit of allowing each member state to make a judgment based on the size and strength of the clinical trials sector in their country, the strength of the insurance market, and be adaptable to the different national liability regimes that exist.

**Association of British Insurers  
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