

# Data Sharing Review

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**Pfizer response to:**

## **Consultation paper on the use and sharing of personal information in the public and private sector**

### **List of questions for response**

We would welcome responses to the following questions set out in this consultation paper. Please follow the question order as set out in the consultation paper, leaving a blank response box for any questions not answered.

Please email your completed form to [contact@datasharingreview.gsi.gov.uk](mailto:contact@datasharingreview.gsi.gov.uk)

Alternatively you can send a hard copy response to:

**Data Sharing Review Secretariat  
5.26 Steel House  
11 Tothill Street  
London  
SW1H 9LJ**

Thank you.

### **Section 1: Background**

Question 1.

- As a Pharmaceutical company we collect a wide range of patient level information on participants in clinical trials in the process of drug development. The data collected range from demographics to test results to clinical outcomes and adverse events. All data are anonymised.
- The data are collected and held on our own databases but are anonymised and therefore not non-patient identifiable. This information may be shared globally but individual patients cannot be identified and therefore data sharing poses no risk to patient confidentiality.
- Our purpose in collecting and sharing such data is to support the clinical trials process into the safety, efficacy and benefit of the trial medicine in a specific patient population.

### **Section 2: Scope of personal information sharing, including benefits, barriers and risks of data sharing and data protection**

Question 2.

- The sharing of clinical trial data is crucial to drug development, however, this data is anonymised so that individual patients are not identifiable therefore it has no impact on patient confidentiality. The benefits of sharing such data is enormous both to individual patients and to society as a whole; in order to recruit the volume of patients required (particularly for rare diseases) for safety/efficacy studies (Phase III) a global approach is required which involves sharing data from multiple countries.
- The absence of the ability freely to share (anonymised) data between countries and within the UK would severely impact the ability to develop and register new medicines.
- Any regulatory change that inhibits the global sharing of data would inevitably lead to delays in innovative drug development and hence poorer outcomes for patients.

Question 3.

- Clinical trial data is anonymised and therefore poses no risk to individuals or society.

Question 4.

- The Pharmaceutical Industry has led the way in setting best practice standards for the collection, storage and sharing of confidential information. The Industry operates under well established, highly regulated and repeatable processes that ensure patient anonymity and data security.

Question 5.

Comments:

Question 6.

- Data for clinical trials is anonymous and does not contain identifiable personal information. The doctor treating the patient is the only person able to match collected data to the patient and this is subject to the usual patient/doctor confidentiality rules.

Question 7.

- The sharing of data between institutions e.g. Hospital Trust and University is necessary for the pooling of knowledge / giving power to statistical calculations and in the identification of specific types of patient groups for treatment purposes.
- Collaborative sharing of data anonymised by large Pharmaceutical companies and Clinical Research Organisations is necessary for drug development.

Question 8.

Comments:

### **Section 3: The legal framework**

Question 9.

Comments:

Question 10.

Comments:

Question 11.

Comments:

Question 12.

Comments:

Question 13.

Comments:

Question 14.

- No - Data is anonymous therefore secure. The only person able to match data to patient is the treating Physician who is bound in law to maintain patient confidentiality

Question 15.

Comments:

#### **Section 4: Consent and transparency**

Question 16.

- The process for consenting patients for participation in clinical trials is clear, defined in detail and highly regulated through legislation. There is no requirement for any change here.

Question 17.

- Not applicable – the consent process already a requirement and in place

Question 18.

- Level of regulation currently in place for dealing with patient data for clinical trial purposes is sufficient and there is no requirement for further tightening. The Industry produces patient information sheets that describe in detail to patients how their data will be used.
- The requirement for Pharmaceutical Companies to publish results from clinical trials is already in place (results are produced from anonymised data).

Question 19.

- We believe that the current legislation is fully transparent and subject to scrutiny with clear lines of accountability delivered through regulation. We believe this is an example of best practice and do not think that this policy review needs to make further recommendations on data sharing in the Pharmaceutical industry.

#### **Section 5: Technology**

Question 20.

Comments:

Question 21.

Comments:

Question 22.

- Sufficient techniques for anonymising data are already in place and the Pharma Industry has enforced this process for many years.

## **Section 6: International comparisons**

Question 23.

- Sharing of UK anonymised data with other Countries is well established in the field of clinical research but the fact that individuals cannot be identified mitigates against any threat to patient confidentiality..

Question 24.

Comments:

Question 25.

Comments:

Question 26.

Comments:

## **Section 7: Additional questions**

Question 27.

Comments:

Question 28.

- The processes in place for the conduct of clinical trials attempts to provide a gold standard with regard to the sharing of data information.