



## **Protocol for Data Transfer and Use within VPH-Share**

### **Background**

During the development of VPH-Share, Consortium Members may require the use of patient-derived data ('Applicable Data'), and this may be held by their own or another Consortium Member's institution, or may be external to the project. This paper describes the mandatory Protocol to be used in introducing such data into local project use by a single Consortium Member, and in transferring data for use by additional Consortium Members. The Protocol may be updated from time to time as the VPH-Share project develops.

### **Proposed VPH-Share Data-Transfer Protocol**

#### **Scope**

Applicable Data used in the VPH-Share project will be introduced, sought or shared only by adherence to this Protocol in its entirety.

#### **Definitions**

<i>Consortium Member</i>	<i>An Institution documented as having acceded to EC FP7 Project 269978, 'VPH-Share'</i>
<i>Applicable Data</i>	<i>Patient-derived data - regulated by a Data Controller</i>
<i>External Applicable Data</i>	<i>Patient-derived data regulated by a Data Controller which is not a Consortium Member</i>
<i>Data Controller</i>	<i>A 'person' (in law) who determines the purposes and manner of any processing of personal data</i>
<i>Providing Institution</i>	<i>The Consortium Member holding Applicable Data</i>
<i>Receiving Institution</i>	<i>The Consortium Member receiving Applicable Data</i>
<i>PMO Representative</i>	<i>Any authorised VPH-Share signatory from the Coordinating Institution (University of Sheffield)</i>

#### **Provisions**

##### **A. Use of Existing Applicable Data**

A1. Applicable Data held by a Consortium Member can only be used in the VPH-Share project by that Consortium Member if it is included in the Data Schedule of a 'VPH-Share Data Transfer/Use' agreement.

##### **B. Introduction and Use of External Applicable Data**

B1. The acquisition of external Applicable Data should take place under each Consortium Member's own institutional protocol. Thereafter introduction to VPH-Share should follow the provisions of Section A above.

##### **C. Sharing of Existing Applicable Data between Consortium Members for use in VPH-Share**

C1. The Providing and Receiving Institutions shall detail (in the 'Data Schedule' of a 'VPH-Share Data Transfer/Use' agreement):

- A schedule of the Applicable Data to be shared, and the purpose for which it is required.
- A schedule of the methods by which the data will be accessed, and by whom.
- A schedule of the security systems that will ensure auditable access only by authorised personnel.
- The duration of the requirement, and the method of subsequent data destruction.
- The approvals and/or restrictions applicable to the requested data, such that both the legality of, and procedure for, transfer may be determined. This information should include details of the necessary authorisation procedures within the Providing Institution required to enable the Institution's Data Controller to authorise data transfer, and the identities of relevant officers in each Institution.
- The mechanism proposed for the transfer, which must be endorsed by the VPH-Share WP3 Leader.

C2. An agreement (using template 'VPH-Share Data Transfer/Use') shall be concluded between the Providing and Receiving Institutions. This agreement requires the countersignatures of the PMO (to acknowledge Coordinator awareness of data utilisation) and the WP3 Leader (to confirm the acceptability of the transfer mechanism). Associated documents identifying ethical sanction may be required.

C3. Data may be shared only on completion of the agreement in C2. Formal records of any resulting data transfer must be maintained by both parties to the transfer for a period of five years beyond the end of the project.

C4. The Receiving Institution undertakes to destroy all copies of data immediately, at the request of the PMO, and to provide written confirmation of such destruction.

C5. Onward sharing of data by the Receiving institution, to recipients who may or may not be Consortium Members, may optionally be permitted or denied by appropriate completion of the Onward Sharing clause in the VPH-Share Data Transfer/Use Agreement. Any such further sharing within VPH-Share requires the completion of an additional VPH-Share Data Transfer/Use Agreement, as detailed in C2 above.

#### **Enforcement**

Adherence to this protocol has been declared mandatory for all Consortium Members by the Project Board.