

## INTRODUCTION TO THE GENERAL DATA PROCESSING REGULATION

### 1 OBJECTIVE

This document aims to introduce the European Union's ("EU") General Data Processing Regulation ("GDPR") as well as clarifying the roles of the parties associated with the MSBase Neuro-Immunology Registry.

### 2 BACKGROUND

The GDPR is a binding EU regulation, which is directly applicable in all EU Member States since 25 May 2018. It replaced the previous EU and Member State legislation on data protection to a large extent.

The GDPR has two main purposes. One is to strengthen the right of individuals to protection of their personal data. The other is to remove obstacles to the flow of data between EU Member States.

### 3 SCOPE AND APPLICATION

The GDPR applies in principle to all automated personal data processing and in some cases also manual processing of personal data (e.g. in filing systems of various kinds). Personal data is any information that refers to an identified or identifiable natural person.

The GDPR applies to personal data processing linked to the EU, either when the entity processing the personal data is established within the EU, such as a number of the Centers associated with the MSBase Registry, or when an entity outside the EU offers goods and services to people within the Union or monitors their behaviour here.

The GDPR applies in principle to every kind of operation and activity and regardless of who carries out the processing of the personal data. Thus, it applies to companies, associations, organisations, authorities and private individuals.

As non-compliance to the GDPR may result in severe fines, it is imperative that any processing of personal data linked to the EU (an EU individual or legal entity) is GDPR-compliant.

### 4 ROLES OF AN ENTITY PROCESSING PERSONAL DATA

#### 4.1 Background

The functional concepts of controller, joint controller and processor determine and allocate who shall be responsible for compliance with different data protection rules, and how data subjects can exercise their rights in practice.

Anyone who processes personal data is either a data controller or a data processor. A data controller is any person or entity that determines the purposes and means of the processing. A data processor is any person or entity that processes personal data on behalf of a data controller.

The GDPR defines obligations for those who process personal data. Many of the obligations that previously only applied to the data controller now also apply to the data processor.

Anyone who processes personal data must ensure that the processing is carried out in accordance with the provisions of the GDPR.

#### **4.2 Controller versus Joint Controllership**

A *controller*, typically an organisation (as opposed to an individual or body within an organisation), decides both the purposes and means of the processing, i.e. the why (an anticipated outcome or result that is motivating the actions) and how (how this outcome shall be reached and achieved). Non-essential practical aspects can be determined by the processor. Note that it is not possible for either to become a controller or to escape controller obligations simply by shaping the contract in a certain way where the factual circumstances say something else.

A *joint controllership* is indicated by joint participation of two or more entities in the determination of the purposes and means of a processing operation. Joint controllers shall determine and agree on their respective responsibilities for compliance with the obligations under the GDPR, with particular regard to, inter alia, the exercise of data subjects' rights and the duties to provide information. The essence of such arrangement shall be made available to the data subject.

#### **4.3 The role of MSBase**

As regards the processing activities performed by the MSBase organisation within the MSBase Neuro-Immunology Registry, we have made a thorough assessment and conclude that MSBase is a *processor* for the following processing activities:

- MSBase registry, the hosting of data;
- MSBase registry, the provision of services in relation to the data stored in the registry;
- Sub-studies (note that sponsored sub-studies are difficult to assess and it much depends on the circumstances in the actual case and the involvement of the sponsor); and

Consequently, we conclude that MSBase is a joint controller for the following processing activities:

- Commercial analysis/studies; and
- Special sub-studies (as regards the processing activities, including the transfer of personal data, which are determined together with a third party or parties).