



1 5 May 2014  
2 EMA/207866/2014

### 3 Terms of Use

#### 4 Draft

5 These Terms of Use ("Terms") govern the access and use of clinical study reports ("CSR"), clinical  
6 overviews and related clinical trial data that are made available to Users via the Proactive Publication  
7 of Clinical Trials Policy of the European Medicines Agency, Policy 0070. ("Policy"). By accepting these  
8 Terms and upon being granted access to the Information, you agree to be bound by these Terms.  
9 Please read them carefully.

#### 10 1. Definitions

11 In these Terms the terms below have the following meaning:

12 "EMA" means the European Medicines Agency.

13 "Information" means the Clinical Study Reports (Module 5, "CSR"), clinical overviews (Module 2.5)  
14 and clinical summaries (Module 2.7), together with Appendixes to the CSRs no. 16.1.1, 16.1.2 and  
15 16.1.9 which are accessible via the EMA web-portal as a result of the implementation of the Policy.

16 "Information Owner" means the natural or legal person(s) or organisation(s) that submitted the  
17 Information to the EMA in the context of applications in support of centralized marketing authorisations  
18 under Regulation (EC) No 726/2004, as well as any person(s) or organisation(s) who owns copyright or  
19 other intellectual property or proprietary rights in the Information.

20 "User" means the natural or legal person or organization who, having registered with the EMA's web-  
21 portal in connection with the implementation of the Policy, receives access to the Information.

#### 22 2. Access to the information under the policy

23 The User acknowledges that the Information is protected by copyright and proprietary rights of the  
24 Information Owner and can be considered commercially valuable when used for commercial and  
25 regulatory purposes.

26 The User acknowledges that the Information will be made available to the User in a "view-on-screen-  
27 only" mode, after completing the registration process. The User agrees that the User is not permitted  
28 to download, save, edit, photograph print, distribute or transfer the Information. The User agrees not  
29 to access the Information using a method other than the interface provided by the EMA, or remove,



30 bypass, circumvent, neutralise or modify any technological protection measures which apply to the  
31 Information.

### 32 3. Use of the information

33 The User agrees to use the Information according to these Terms and, in particular, that:

- 34 a) The User may use the Information solely for information, research and other non-commercial  
35 purposes, subject to these Terms.
- 36 b) The User is not granted any intellectual property or other commercial rights in relation to the  
37 Information other than as expressly set out in these Terms.

38 When using the Information, the User shall:

- 39 a) acknowledge its source and include any attribution statement specified by the Information Owner;
- 40 b) not use it in a way that suggests that the Information Owner endorses the User or the User's use  
41 of the Information for any other purpose than information, research and other non-commercial  
42 purposes;
- 43 c) ensure that the use of the Information complies at all times with applicable law;
- 44 d) not misrepresent the source of the Information;
- 45 e) not seek to re-identify the trial subjects or other individuals from the Information in breach of  
46 applicable privacy laws.

47 The User may not:

- 48 • use the Information to support an application to obtain any kind of regulatory and subsequent  
49 approval for a product anywhere in the world;
- 50 • share the User's username, password or other account details with a third party or otherwise  
51 provide a third party with access to the User's account;
- 52 • make any unfair commercial use of the Information.

53 If the User fails to accurately complete the registration process, comply with these conditions, or uses  
54 the Information in breach of these Terms of Use, the rights to access and use the Information will be  
55 revoked.

### 56 4. Warranties and liability

57 Without prejudice to any obligation of the marketing authorization holders/applicants in accordance  
58 with the Union legislation:

- 59 • The EMA and the Information Owner exclude all representations, warranties, obligations and  
60 liabilities in relation to the Information as accessible via the EMA web-portal to the maximum  
61 extent permitted by law;
- 62 • Neither the EMA nor the Information Owner are liable for any errors or omissions in the  
63 Information as provided via the EMA web-portal and shall not be liable for any loss, injury or  
64 damage of any kind caused by its use.

65 5. Third party rights

66 The restrictions and conditions and the warranty and liability provisions of these Terms are also made  
67 for the benefit of any and all Information Owners and, accordingly, each such Information Owner may  
68 in its own right enforce these Terms in accordance with the provisions of the Contracts (Rights of Third  
69 Parties) Act 1999.

70 6. Governing law

71 These Terms and any dispute or claim arising out of or in connection with them or their subject matter  
72 or formation (including non-contractual disputes or claims) shall be governed by and construed in  
73 accordance with the law of England and Wales.

74 7. Jurisdiction

75 The courts of England and Wales shall have non-exclusive jurisdiction to settle any dispute or claim  
76 arising out of or in connection with these Terms or their subject matter or formation (including non-  
77 contractual disputes or claims).

Draft for discussion, not for circulation