Navigating the EMA clinical data website

Raquel Billiones[1] and **Achim Schneider**[2]

1   Medical & Regulatory Writing Group,
    Clinipace Worldwide, Zurich, Switzerland
2   Independent Computer Scientist,
    Brüttisellen, Switzerland

Correspondence to:

Raquel Billiones
Clinipace AG
Chriesbaumstrasse 2
CH-8604 Volketswil, Zurich, Switzerland
rbilliones@clinipace.com

Abstract

This paper describes how to register, access, and navigate the EMA clinical data website. One of the authors (RB) is a medical writer and accessed the site from the perspective of a pharmaceutical industry professional. The other author (AS) is not affiliated with this industry and accessed the website from the perspective of a lay person. Both authors reside outside of the European Union and were impacted by the role of geography in access rights and terms of use.

The authors present a step-by-step account of their experience in accessing and navigating through the EMA clinical database from a location outside of the European Union (EU).

1. Create an EMA account and log in

If you do not have an EMA account, you first have to create one on the log in page of the website: https://clinicaldata.ema.europa.eu/ (Figure 1).

Creation of an account requires completion of a self-service registration form, providing personal information and answering several security questions (Figure 2).

Once the form is completed, you will receive

Figure 1. Log in page
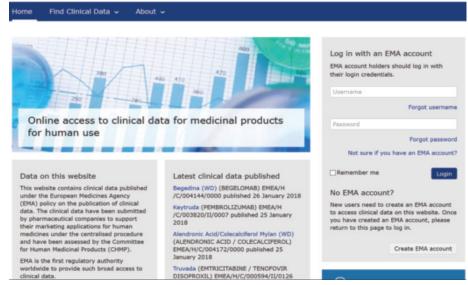
Figure 2. Self-registration form

Figure 3. Personal details needed for academic and other non-commercial research purposes

an email notification containing your registration information. With this information, you will be able to access the EMA clinical data website.

2. Access and terms of use

Choose the type of access you need. There are two categories of access to the data on this website, depending on the purpose. Each category has its corresponding terms of use. By accepting these terms, which you have to re-confirm each time you access the EMA site, you agree to be bound by these terms.

(a) Access for general information purposes

This access type is for users accessing the published clinical data for general information and other non-commercial purposes, including non-commercial research purposes. The user can only view the documents on screen. It does not allow the user to download, save, edit, photograph, print, distribute, or transfer any documents.

This type of access is available to everyone regardless of geographic location.

(b) Access for academic and other non-commercial research purposes

This is for users accessing the published documents for the purpose of non-commercial research and academic use. More access rights are allowed under these terms of use, including downloading, saving and printing clinical reports, to be used solely for academic and other non-commercial research purposes.

However, this access requires additional procedural steps and requirements. One of the requirements is to provide additional personal data, including date of birth, passport, or ID card number, and expiry date of the document. Another important requirement is provision of an address in the EU. The latter step cannot be circumvented because the pull down menu in the registration form only shows the 28 EU member states (Figure 3).

If you are residing outside of the EU, you can avail of the services of a third party resident of or domiciled in the EU. This third party shall be considered as the user for the purposes of these terms.

The authors are EU citizens but reside outside

Table 1a. Example of an export

Product Name	Active Substance	MAH	Product Status	Publication Date	Procedure Type	ATC Code
ILARIS	CANAKINUMAB	Novartis Europharm Ltd	Authorised	20/12/2017	Extension of indication	L04AC08
Zontivity	VORAPAXAR	Merck Sharp & Dohme Limited	Authorised	19/12/2017	Extension of indication	B01AC26
Trevicta	PALIPERIDONE	Janssen-Cilag International NV	Authorised	11/12/2017	Line Extension	N05AX13
Kyndrisa (WD)	DRISAPERSEN	BioMarin International Limited	Withdrawn	06/12/2017	Initial marketing authorisation	M09AX04

Table 1b. Further columns from export (product name column repeated for clarity)

Product Name	Generic	Bio-similar	Conditional Approval	Exceptional Circumstances	Orphan	Article 58 Procedure	Withdrawn Number	Procedure	No of Docs
ILARIS	No	No	No	No	No	No	No	EMEA/H/C/001109/II/0043	11
Zontivity	No	No	No	No	No	No	No	EMEA/H/C/002814/II/0005	18
Trevicta	No	No	No	No	No	No	No	EMEA/H/C/004066/X/0007/G	33
Kyndrisa (WD)	No	No	No	No	Yes	No	Yes	EMEA/H/C/003846/0000	105

Abbreviations: MAH, marketing authorisation holder

Figure 4. Browse search option

Figure 5. Advanced search option

Figure 6. Download page

of the EU and hence could only access the site through the first terms of use ("general information purposes"). However, one of the authors (RB) could upgrade her access rights to "academic and other non-commercial research purposes" after meeting the additional requirement of being able to provide a third party EU address. In this case, the third party was the affiliate of her company located in Germany.

3. Search options
Once granted access, you can search the site in two ways using the browse option or the advance option.

(a) Browse
You can browse by product name or by marketing authorisation holder name. Alternatively, you can browse by type of product or type of approval (Figure 4).

(b) Advanced search
The advanced search option entails entering search terms and applying additional filters such as date of publication and procedural type (Figure 5).

The search results can be downloaded as a table in *.csv format. Such a file can be opened in a spreadsheet software such as Excel. An example of the search results export is shown below in Table 1.

4. Downloading documents
In order to download, you have to access each procedure individually. The reports are grouped into four categories: clinical overview, clinical summary, clinical study reports, and anonymisation report. All documents within each procedure are searchable using text or keywords. The different documents under each category can be viewed by clicking on the "+" sign (Figure 6).

You can download the whole procedure or selected documents within a procedure. The documents are provided in *.pdf format and are not hyperlinked.

5. Other features
On the clinical data website home page, there are several important tabs (Figure 7). The first tab provides details on the terms of use. The "how to" tab is a very helpful user's tool and also provides additional information such as the most viewed clinical data to date.

The last two tabs are very important with respect to data protection. The "report patient re-identification" tab is part of the re-identification alert mechanism to ensure that the privacy of patients is protected.

Figure 7. Other tabs to help users

The "data protection" tab is about protecting the rights of the registered user. It details how EMA collects, processes, and stores the data you provided during registration.

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All screenshots are used with permission from the EMA.

Conflicts of interest
The authors declare no conflicts of interest.

Author information
Raquel Billiones, PhD (Head, Medical & Regulatory Writing at Clinipace Worldwide) has been a regulatory medical writer since 2006. Her core competencies include disclosure and data protection in clinical trial data reporting. See also article on p. 22.

Achim Schneider, PhD, is a computer scientist with many years of corporate experience across various industries; he has a keen interest in applications of information technology to foster human development.

The authors are married to each other.