

D4.10 Definition of user access requirements

116026 – HARMONY

Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in HematologY

WP4 – Data Platform

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Document History

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V1	15/11/2019	Final version

D4.10 DEFINITION OF USER ACCESS REQUIREMENTS

1. PUBLISHABLE SUMMARY

HARMONY is a European Network of Excellence that captures, integrates, analyzes and harmonizes data from high-quality multidisciplinary sources for the purpose of acquiring valuable knowledge across the spectrum of hematologic malignancies.

Although HARMONY's Big Data infrastructure is certificated by security standards and there is a strict control that guarantees a high level of security during the data intake process, it is also essential to define policies and procedures that ensure controlled access to data during the analysis of research questions.

This **Definition of user access requirements** describes the roles and responsibilities, procedures and steps for accessing the HARMONY Platform and datasets ensuring that the approved research questions can be answered while preserving the required levels of security for accessing those data.

2. TERMS AND CONDITIONS FOR RESEARCH USE OF DATA

As part of the Platform authorization procedure to access HARMONY data, the researchers must confirm that they accept the following terms and conditions to guarantee the objectives of the HARMONY project:

- Data access shall only be used for the approved research analysis.
- Detailed patient data (download, photograph, copy manually or extract by any other means) shall not be extracted.
- Attempts to identify individual participants from whom the data was obtained is forbidden.
- Research analysis results shall only be extracted from the platform to be published or shared with the HARMONY community (e.g. aggregate metrics of patients' cohorts, results of hypothesis testing, drawings, and other possible outcomes of analysis).
- Access shall not be shared with other people, and credentials shall be kept secure.
- The privacy of research subjects shall be protected by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the approved research.
- Any violation of these Terms and Conditions shall be reported as soon as it is discovered.
- Acknowledging in All oral or written presentations, disclosures, or publications shall acknowledge the HARMONY project and comply with article 29.4¹ of the Grant Agreement.

HARMONY expects that researchers and entities will follow these rules, taking **disciplinary and legal actions** against them **if they violate these terms and conditions** (according to Clause 4.5 of the Consortium Agreements and Section 6 of the Data Sharing Agreements).

We have used the most advanced technology to protect the platform from Internet risks and researchers cannot download or upload any data from the platform. However, we cannot stop an investigator from taking a picture of the screen or writing the content on a piece of paper. In these cases, we control and keep track of all user actions to detect suspicious access patterns and take possible legal actions.

¹ Unless the JU requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must: (a) display the JU logo, the logo of EFPIA; (b) display the EU emblem, and (c) include the following text: "This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 116026. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA". When displayed together with another logo, the logos and emblem must have appropriate prominence.

3. GUIDING PRINCIPLES

The guiding principles and procedures have been explicitly focused on the access related to subject level data unless otherwise specified. These subject level data is at the level of harmonised, de-facto anonymised data. Access to the raw data (at ingestion) or prior transformation is described in 'WP3-Data Access'.

- **Minimization principle:** Access to data is at all times limited to users who have a valid justification for a defined subset of data and is limited in time.
- **Segregation of concerns:**
 - a. Approvers and executors of access cannot have access to the data sets themselves.
 - b. Administrator privileges cannot be granted to users with access to the data.
 - c. The user account creation and access to the tools is initiated and approved by another person than the access to individual datasets.
- **Traceability:** granting, modifying, or deleting access for a particular user will be at all times traceable from request approval, through to completion of the research.

A graphical overview of the processes for user access is represented in Figure 1 below and explained in detail in the following paragraphs.

4. USER ACCESS TO HARMONY PLATFORM APPLICATIONS:

4.1. SCOPE

With access to the 'Harmony platform applications, the following is understood:

- Discovery application
- Taxonomy browser
- Zeppelin

The procedure below relates to user access to applications. More details about administrator roles and the respective access for those can be found in deliverable D3.09. This section specifically details the process for accessing the tools. The Deliverable can be found at <https://internal.harmony-alliance.eu/item/1057056>.

4.2. WHO IS ELIGIBLE FOR ACCESS

- Any person that is part of a HARMONY Beneficiary or is associated with such a Beneficiary:
 - a. HARMONY Third Parties under article 11 and 12 of the Grant Agreement
 - b. Linked Third Parties
 - c. Affiliates Entities
- Any person associated with an Associated Member organisation

The requests for access to the HARMONY Platform will be uploaded to Nuntiare ticketing tool for execution (<https://nuntiare.gmv.com/>). If the responsible of this request needs access to this tool, the access should be requested by email to harmony@gmv.com, who will manage the users' creation. Upon successful setup, the user will be notified with her/his user id and link for password setup.

4.3. PROCESS FOR OBTAINING ACCESS TO THE TOOLS

1. An assigned person per HARMONY Beneficiary or Associated Member organisation will be responsible for requesting access for individual users belonging to their respective organisations or affiliated organisations. That implies that organisations associated with a HARMONY Beneficiary can only request access through the respective HARMONY Beneficiary contact. The list of approved contacts will be maintained on the portal: <https://internal.harmony-alliance.eu/item/1340935>.
2. The request form is available on this link: <https://internal.harmony-alliance.eu/category/1405330> and covers the start of access, modification of access, as well as withdrawal of access to the individual tools.
3. The request will be uploaded to Nuntiare ticketing tool for execution.
4. Upon successful setup of the user with the selected profile, the user will have access to the available tools for that profile but still with no access to data.
5. The user will be requested to accept the Terms and conditions before getting their credentials.

6. The user accepts the Terms and Conditions.
7. The user will be notified with her/his user id and link for password setup.
8. The administrator will store all access requests, and these will be made available for audit.
9. It is the responsibility of the assigned persons that access is promptly withdrawn when an employee (or that of an Affiliated Entities, Sub-Contractors, Linked Third Parties), and agent leaves the respective organisation.
10. Every 6 months, the administrator will issue an overview of approved and active users of the tooling to every responsible from each organization. The assigned persons will review this list and ask to revoke any unneeded access through the same process.

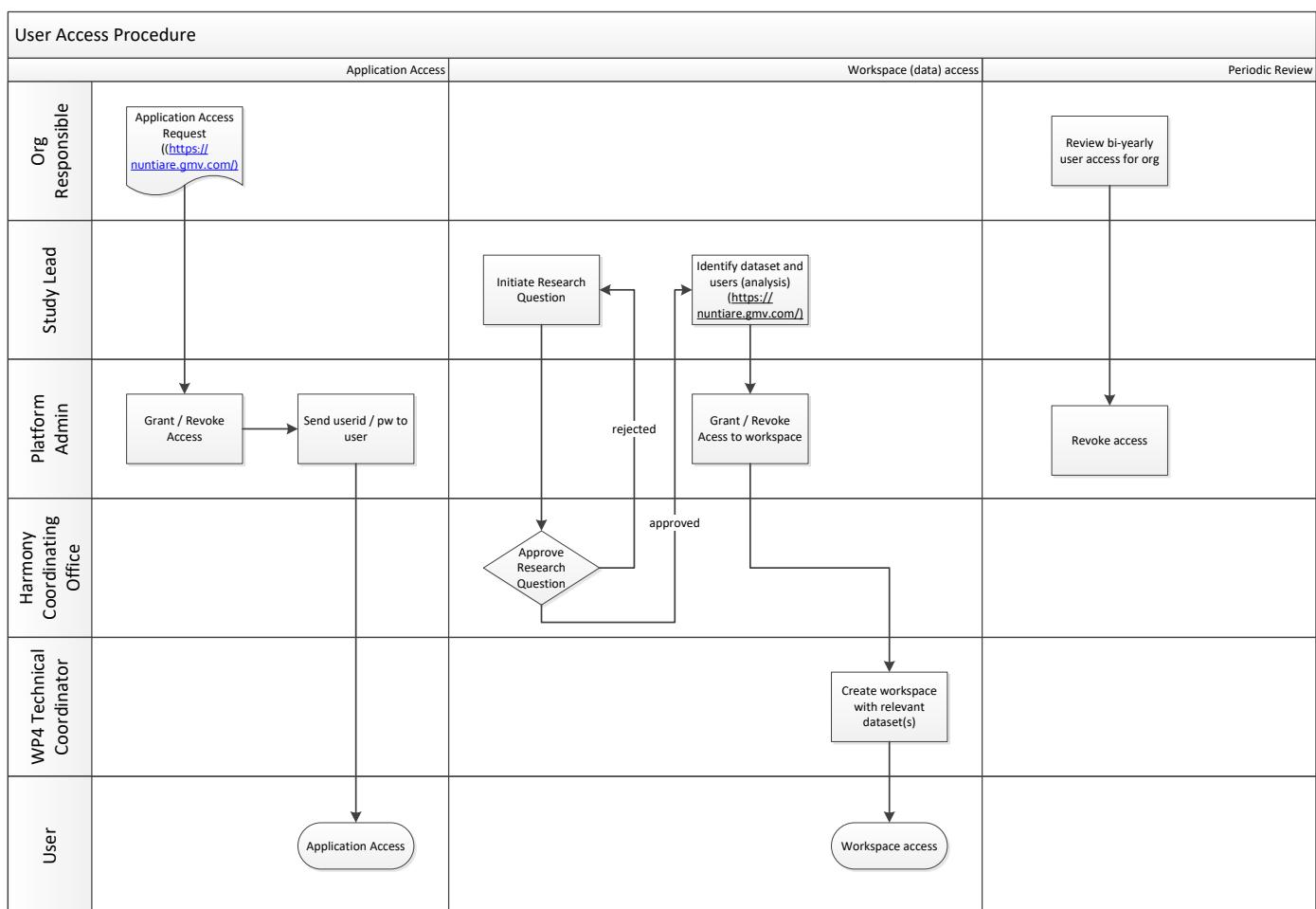


Figure 1 - User Access Procedure

4.4. ROLES & RESPONSIBILITIES OVERVIEW

Note that the roles defined below are independent from any data access which is described in section 5 of this document.

Role	Responsibility
Assigned person (per organisation)	Requesting and approving access and withdrawal of access for valid users from within the own organisation.
Harmony Platform Administrator	Execution of access granting, update and withdrawal of access to the tools for approved requests. Archiving of all requests.
User	Requesting access to the respective assigned person (internal process in the individual organisation). Note: this is the creation of the 'account'. The User can indeed have all required tools but at this stage, there is no data associated yet with the individual account.

5. USER ACCESS TO HARMONY DATASETS

5.1. SCOPE

This access procedure described in this paragraph relates to the access to harmonized, de-facto **anonymized subject level data sets or subsets** thereof.

Access to the raw data and/or data prior to harmonisation is not possible for users involved in the analysis or interpretation of analysis results and is therefore not considered in this procedure. Access to the **results of the analysis**, the so-called result data sets and/or **aggregated data sets** is also excluded.

5.2. WHO IS ELIGIBLE FOR ACCESS?

The following criteria have to be met:

- A person that is part of a HARMONY Beneficiary or is associated with such a Beneficiary that is participating in a research question²:
 - a. HARMONY Third Parties under article 11 and 12 of the Grant Agreement
 - b. Linked Third Parties
 - c. Affiliates Entities
- A person associated with an Associated Member organisation that is participating in a particular research question².
- Being a study contributor to the relevant research question for this data set³

The requests for access to different datasets will be uploaded to Nuntiare ticketing tool for execution (<https://nuntiare.gmv.com/>). If the responsible of this request needs access to this tool, the access should be requested by email to harmony@gmv.com, who will manage the users' creation. Upon successful setup, the user will be notified with her/his user id and link for password setup.

² 'participating in a research question' implies one of the following roles: either identification and/or definition of the research question, contributing to the research question by the provisioning of data or contributing in the analysis.

³ This requirement only relates to the access of subject level –de facto anonymized - datasets. It's not required for access to results of analysis or aggregated datasets where no subject level data is disclosed

5.3. PROCESS FOR ACCESS TO DATA SETS

1. The access procedure can only start with an approved research question.
2. Upon approval of a research question, the submitter of the research question or her/his designee (Technical manager) will determine in consultation with the leaders of WP4 and WP5 the following:
 - a. Finalized list of variables
 - b. Inclusion / exclusion criteria for subject selection
 - c. Organisations / entities and/or named individuals involved in the analysis
 - d. Required data analysis format
 - e. Expected timings for data analysis

The following restrictions must be met:

- It is not permitted to single out data sources unless there is a specific approval by the respective data source e.g. it's not allowed to ask for the data of just study X.
- It is not permitted to ask for 'all data'. According to the data minimisation principle, the relevant variables or categories of variables have to be specified.

3. Following this consultation, the submitter will request to the WP4 technical coordinator a data set (or multiple data sets) to be prepared including the request form fulfilled. The template is available on this link: <https://internal.harmony-alliance.eu/category/1405330> and covers the definition of the dataset (or any changes thereof), start of access, modification of access, as well as withdrawal of access. The study submitter or assigned designee is approving access to the respective study data set for one or more users for a defined period.
4. The WP4 technical coordinator will translate the requirements in a technical specification that will be executed by the WP4 technical team. The specification will be shared with the study lead or designee. The data extract will be provided and be further accessible as a study specific data set.
5. Upon successful setup of the workspace with the required dataset, if the user already had their credentials on previous workspaces, the user will automatically have access to the new workspace.
6. Individual users will have to acknowledge that access to the data sets is conditional on use and analysis is in line with the defined study question and no analysis (export) of the subject level data is allowed outside the HARMONY Platform.
7. Once the user has accepted the terms and conditions, the user will be notified with her/his user id and link for password setup. On the other hand, if the user already has credentials for another workspace, the access to the new one will be granted after accepting the Terms and Conditions.
8. Once a week, the users will receive a friendly reminder of the Terms and Conditions if they run queries in the HARMONY Platform.
9. Every 6 months, the administrator will issue an overview of approved and active datasets and their active users to every responsible from each organization. The assigned persons will review this list and ask to revoke any unneeded access through the same process.

5.4. ROLES & RESPONSIBILITIES

Role	Responsibility
Study Submitter	<p>Definition of the research question and specification of required data sets.</p> <p>Submission and approval for access requests to study data sets.</p> <p>Ensures that analysis methods and execution are in line with approved research question.</p>
Technical manager	When the study submitter designates an assignee to update the requests.
Harmony Coordinating Office	Coordination of review and final approval of research question.
WP4 Leader / Coordinator	Definition and provision of the analysis data set(s) for an approved research question.
WP5 Leader / Coordinator	Definition of analytical approach and input into the identification of resources for the analysis.
Harmony Platform Administrator	Granting, updating and withdrawal of access to individual users for approved requests.
User	<p>Analysis of data only in function and in line of the approved research question.</p> <p>No export of subject level data outside the Harmony platform.</p> <p>No attempts to try to link or join subject level data sets with external (i.e. not on the Harmony platform) data.</p>

6. ANNEX A: FORM FOR OBTAINING ACCESS TO THE TOOLS



REQUEST OF USER ACCOUNT FOR HARMONY PLATFORM

Date:

List of Analysts that should have access to it:

The following researchers and analysts

First name	Last name	Email address	Organisation	Participation Date *	Manage user
					New / Remove
					New / Remove

* Please complete this field if the Participation date for an analyst is different from the Expected end date for data analysis.

Request access to the Harmony platform applications located or distributed across INFN-CNAF ISMS ISO/IEC 27001 resources designed by CNAF-INFN (~~Viale Berti Pichat 6/2 Bologna~~).

CNAF contact person or Project Technical Manager: _____

TERMS AND CONDITIONS FOR RESEARCH USE OF DATA

As part of the Platform authorization procedure to access HARMONY data, the researchers must confirm that they accept INFN-CNAF Acceptable User Policy for the use of information technology resources (https://www.cnaf.infn.it/wp-content/uploads/2016/10/AUP_en.pdf) and the following terms and conditions to guarantee the objectives of the HARMONY project:

- Data access shall only be used for the approved research analysis.
- Detailed patient data (download, photograph, copy manually or extract by any other means) shall not be extracted.
- Attempts to identify individual participants from whom the data was obtained is forbidden.
- Research analysis results shall only be extracted from the platform to be published or shared with the HARMONY community (e.g. aggregate metrics of patients' cohorts, results of hypothesis testing, drawings, and other possible outcomes of analysis).
- Access shall not be shared with other people, and credentials shall be kept secure.
- The privacy of research subjects shall be protected by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the approved research.
- Any violation of these Terms and Conditions shall be reported as soon as it is discovered.
- Acknowledging in All oral or written presentations, disclosures, or publications shall acknowledge the HARMONY project and comply with article 29.4^a of the Grant Agreement.

^a Unless the JU requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must: (a) display the JU logo, the logo of EFPIA; (b) display the EU emblem, and (c) include the following text: "This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 116026. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA". When displayed together with another logo, the logos and emblem must have appropriate prominence.

Note: This is an example of the form. The most updated version of this form is available at:
<https://internal.harmony-alliance.eu/category/1405330>



HARMONY expects that researchers and entities will follow these rules, taking **disciplinary and legal actions against them if they violate these terms and conditions** (according to Clause 4.5 of the Consortium Agreements and Section 6 of the Data Sharing Agreements).

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7. ANNEX B: FORM FOR OBTAINING ACCESS TO THE DATASETS



Request of Analysis Workspace at HARMONY platform

Project name:

Research question:

Study submitter:

Disease:

<input type="checkbox"/> ALL	<input type="checkbox"/> CLL	<input type="checkbox"/> MM	<input type="checkbox"/> Pediatric HMs
<input type="checkbox"/> AML	<input type="checkbox"/> MDS	<input type="checkbox"/> NHL	

Inclusion / exclusion criteria (or selected DPs if known):

Selected variables to be included:

List of the analyses that the researcher wants to do (i.e. Overall survival, Kaplan Meyer of x, etc.):

Expected end date for data analysis:

List of Analysts that should have access:

First name	Last name	Email address	Organisation	Participation date (*)	Manage user
<input type="text"/>	<input checked="" type="checkbox"/> New <input type="checkbox"/> Remove				
<input type="text"/>	<input type="checkbox"/> New <input type="checkbox"/> Remove				
<input type="text"/>	<input type="checkbox"/> New <input type="checkbox"/> Remove				

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<input type="text"/>	<input type="checkbox"/> New <input type="checkbox"/> Remove				
<input type="text"/>	<input type="checkbox"/> New <input type="checkbox"/> Remove				

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TERMS AND CONDITIONS FOR RESEARCH USE OF DATA

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