



Guide to use the 'Holistic document with roles'

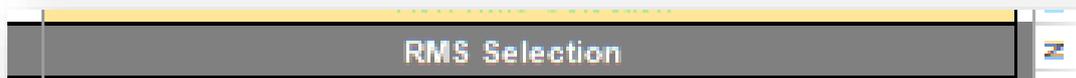
The 'Holistic document with roles' spreadsheet is a document prepared by IT4U and EMA, in partnership with Product Owners in the course of the Analysis and Design sessions supporting the development of CTIS. It shows what users can see or do in the system depending on their role(s) and linked permissions. This guide aims at helping users to interpret and understand how to use this document.

The document is structured in four sheets:

- **Key:** explains the meaning of the nomenclature used in the document.
- **Authority:** shows roles and permissions available in the authority workspace.
- **Sponsor & MAH:** shows roles and permissions available in the sponsor workspace, including those of sponsors and those of Marketing Authorisation Holders (MAH).
- **Notes:** Defines the default role available for all users self-registered in the system.

Each sheet is structured in two areas:

1. The columns refer to the actions that are performed in a given workspace.
2. The rows refer to the user group (only in the authority spreadsheet, e.g. EU Commission and Member State roles) and the roles available (e.g. EMA Admin, EC Admin, MS Admin, CT Coordinator, Sponsor Admin, CT Admin, etc).



Categories of actions performed during the life-cycle of a clinical trial are displayed in grey.

- *Each one can be expanded by clicking on the 'plus icon'  on top, and they will be shown on columns to the left.*

Once expanded, each category of CT-related actions contain one or several of the following:

Sub-category	Colour	Description
Tasks <i>(only available for Member States)</i> .	Light blue (bold font indicates a hard task , and normal font indicates a soft task) ¹	Activities performed in the system to complete each step of the evaluation of a CT.
Other actions	Yellow	Other actions that can be performed in the system associated with an activity or task related to a CT.
Notices and alerts	Green	Notices or alerts that a user with a given role will receive.

See an example below for the authority workspace, with 1 hard task, 2 notices and alerts, and 1 other actions *(the vertical columns from the spreadsheet are displayed horizontally for a better readability in this document)*:

Re-express willingness and agree RMS	R
<<Selected MSC>> has been selected as an Candidate RMS.	K
<selected RMS> has been selected as the RMS for the trial.	T
View RMS Selection	M
RMS Selection	N

For each role, the sub-categories of CT-related actions in which the role is involved are represented with a letter (A, C, R) that describes what the role can do specifically

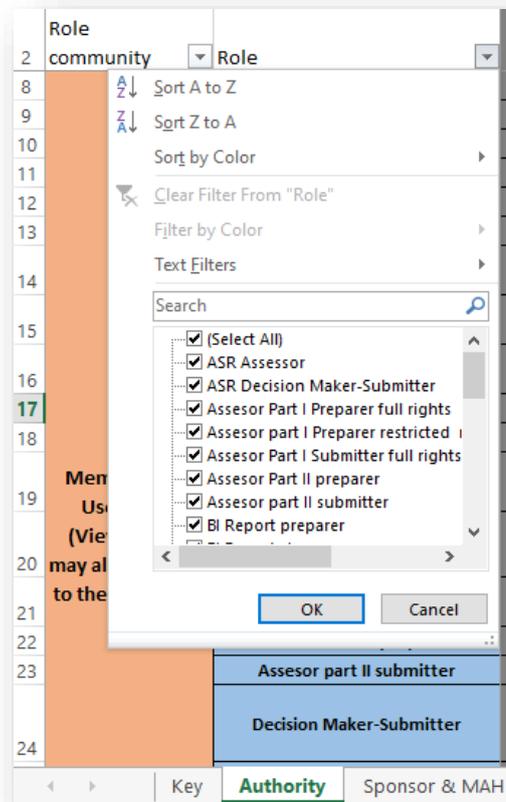
See an explanation below:

Letter	Action	Explanation
R	Receive	The user is able to receive a Task, Notice or Alert
A	Assign Task to others <i>(only available for the CT Coordinator role of the Member States)</i>	The user is able to assign tasks to other business users. Includes receive a Task.
C	Complete	The user is able to perform the action described in the row (e.g. view a document, complete a task, etc.). Includes Receive Task and Assign Task to yourself permissions.

¹ Hard tasks are mandatory actions expected to be performed by the user in the context of the evaluation and decision of a CTA, and ASRs. Soft tasks are non-mandatory actions which "guide" the user, but do not have direct effects on the assessment result itself. For more information, please refer to Module 4 (Support with workload management by workspace) materials.

In order to find the CT-related actions that a specific role is able to perform, **the user can use two types of filters**. In the Authority sheet, the user may filter by 'User group' or by 'Role'. In the sponsor sheet, the user may only filter by 'Role'.

See an example below:



In order to make efficient use of the document, it is suggested to consult also the following materials:

- eLearning.
- One-pager summary of roles per workspace.

Exercise cards

European Commission

Role: EC Admin

Actions to be completed:

Notices & Alerts to be received:

Role: Union Controller Viewer

Actions to be completed:

Notices & Alerts to be received:

Role: Union Controller Preparer

Actions to be completed:

Notices & Alerts to be received:

Role: Union Controller Submitter

Actions to be completed:

Notices & Alerts to be received:

Role: BI Report viewer

Actions to be completed:

Notices & Alerts to be received:

Role: BI Report preparer

Actions to be completed:

Notices & Alerts to be received:

Member States

Role: Viewer Part I Full rights

Actions to be completed:

Notices & Alerts to be received:

Role: Validator part II submitter

Actions to be completed:

Notices & Alerts to be received:

Role: Assessor Part I Submitter full rights

Actions to be completed:

Notices & Alerts to be received:

Role: Supervisor preparer

Actions to be completed:

Notices & Alerts to be received:

Role: Inspector preparer

Actions to be completed:

Notices & Alerts to be received:

Role: ASR Assessor

Actions to be completed:

Notices & Alerts to be received:

Role: BI Report preparer

Actions to be completed:

Notices & Alerts to be received:

Sponsors

Role: Application submitter

Actions to be completed:

Notices & Alerts to be received:

**Role: Part I Viewer (exc Q-
IMPD)**

Actions to be completed:

Notices & Alerts to be received:

Role: Part II Preparer

Actions to be completed:

Notices & Alerts to be received:

Role: Notifications submitter

Actions to be completed:

Notices & Alerts to be received:

Role: CT results Viewer

Actions to be completed:

Notices & Alerts to be received:

Role: ASR submitter

Actions to be completed:

Notices & Alerts to be received:

Role: MAH Admin

Actions to be completed:

Notices & Alerts to be received: