

## **Technical Guidelines for Editorial Groups (EG)**

This document provides instructions for reviewing, editing, and approving new records for addition to the Notify Library using a new tool on the new Notify website. This methodology replaces the work previously carried out on Google documents.

As new information emerges in the literature, this tool will permit the addition of a new record or the updating of an existing one, via a guided form directly on the Notify website, on a case by case basis, with review by the relevant editorial group prior to publication in the database.

To allow automated uploading to the new software, avoiding transcription errors, it is necessary to standardize the way in which the data is presented and to ensure that each entry in the database addresses just one type of adverse occurrence and one category of Medical Product of Human Origin (MPHO). Editorial Groups (EG) are asked to each review their topic-specific pending records for accuracy and to add missing information, where possible.

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## 1. Introduction

### a. What constitutes a database record?

Each record in the Notify Library describes a type of adverse occurrence for one type of Medical Product of Human Origin (MPHO) that has been documented in scientific or grey literature or in an official vigilance system. The record includes full references to the relevant publication(s) with links to the abstract or full paper if they are freely available online. Occurrences that are documented only in the popular media are not included. One record may reference one or many publications.

Experts compiling records for upload to the database should make two records for the same type of occurrence with the same MPHO if they consider that are substantially different from each other in terms of cause, method of confirmation of imputability or any other factor that is considered to have major didactic value. Where one record describes many cases and many publications, the experts should summarize the findings in the publications, using ranges, averages, etc.

### b. Review and approval of new records

All records are reviewed by an EG (there are currently 5: infectious transmissions, malignancy transmissions, living donor reactions, process, clinical complications including transfusion reactions not covered by the other groups). Following the approval of the EG, the NOTIFY team carries out a check of every record for consistency of terminology, spelling etc. before final approval for publication (see below). **Up to that point, all work on pending cases is invisible to the public.**

## 2. Registration and access to the “EG management record” panel

- Please go to the log in area at the top left of the Notify Library homepage in order to access the “EG management record” panel. Login to your member account using your username (usually surname name, i.e. surname space-bar first name) and password (you will use the same username and password that you had to access the forums on the old site). If you do not remember your password, click the “Request new password” tab. If you have never had a username and password for the site, select the “Create new account” tab and follow the instructions.
- Please check the CAPTCHA field to prevent automated spam submissions. This technology is used to demonstrate that you are a person and not a computer!
- Once you are logged in, you will see “**EG Management Record**” will appear on the top right of the screen. Click on this to see the EG with the pending records not yet public on the database. You can also filter records of interest by status (editing, ready to upload, rejected), using the relative drop down menu. You can make changes only on the records assigned to your EG but you can view the files of all EG.

### 3. How to edit pending records?

Please select the EG that you wish to work in if you have access to more than one and filter records by the “Editing” status. Now you can view or edit all records that are pending in the system.

**Once the editorial work is complete, please switch status from “Editing” to “Ready to upload” and save your changes.** The status change will automatically generate an email alert for the NOTIFY team who will carry out a check for consistency of terminology, keywords, spelling etc. before final approval for publication.

### 4. Proposing a NEW RECORD for submission in the NOTIFY library database

**Before proposing a new record, please search the library to see if it already exists.** You could do an **Adverse Occurrence Search** or a **Reference Search**. If you consider that the new case provides didactic value that is different to any existing database record, proceed to propose it. If you consider that you have a reference, or other information, that should be added to an existing record then choose, instead to update an existing record (see below).

To access the submission form for a new record, you can select “Add or update record” from the SEARCH LIBRARY drop down menu and then click on the “New record” button. Alternatively you can choose the “Add new Record” tab at the TOP right corner of the EG management record panel.

The form should be completed in the following fields (\*required fields for proposal submission; other fields can be left blank for other group members to add information or for later addition of information):

- a. **RECORD ID\* (FOR ADMINISTRATIVE USE ONLY)** – an automatically generated record ID number will appear. This number is unique and will refer to this record’s ID once uploaded in the Notify Library database. **This field is not editable.**
- b. **ADVERSE OCCURRENCE DESCRIPTION\*** - please enter here a title that describes the type of adverse occurrence you wish to enter, standardizing terminology as much as possible to what you consider most appropriate, using reference dictionaries, such as MESH, wherever possible.
- c. **ADVERSRE OCCURRENCE TYPE** - please refer to the **Adverse Occurrence taxonomy** and select the appropriate term for this type of occurrence. If you consider that new categories should be added to the taxonomy for more effective searching, **please propose the new category in the field NOTE at the end of the form.**
- d. **MPHO TYPE** - please refer to the **MPHO taxonomy** and select the appropriate term for this type of substance. If you consider that a new MPHO type is needed in the taxonomy **please propose the new category in the field NOTE at the end of the form.** Where there is a characteristic of the MPHO that is considered important in the occurrence but is not described in the taxonomy (e.g. method of preservation, microbial inactivation or sterilization, etc.) it is very important to include that information in the keywords (see below).

- e. **ESTIMATED FREQUENCY** - please add this information where quantitative data is available and relevant (for example, inserting a number of occurrences per number of interventions). If frequency data can be quoted from a vigilance database please mention the source in the field NOTE at the end of the form.  
Alternatively, since there is a large variation in epidemiology, in levels of system development and in information available across countries, descriptive information without quantitative data also have didactic value so please give some idea of frequency from your own experience and knowledge even if imprecise, or use a general term such as 'very rare', 'common', etc.
- f. **TIME TO DETECTION** – please enter the time, in minutes, days, months or years from the adverse occurrence to its detection. In case of more than one reference is described, please indicate the range reported in all references.
- g. **ALERTING SIGNALS, SYMPTOMS, EVIDENCE OF OCCURRENCE** – please enter the signs and symptoms that have been described in the references listed for that occurrence type and substance type or, if such information is not available, the normal alerting signals in the recipient or the donor based on your knowledge and experience. In the case of adverse occurrences that involve 'Risk of Harm' rather than actual harm, you should describe how the occurrence was detected. The text you enter will be searchable using keywords. Spell out any abbreviations, putting the abbreviation in brackets. Standardize terminology as much as possible to what you consider most appropriate, using reference dictionaries, such as MESH, wherever possible.
- h. **DEMONSTRATION OF IMPUTABILITY OR ROOT CAUSE** - please enter free text to describe the methods used to confirm imputability for this type of occurrence. It will be searchable using keywords. Spell out any abbreviations, putting the abbreviation in brackets. Standardize terminology as much as possible to what you consider most appropriate, using reference dictionaries, such as MESH, wherever possible. In the case of adverse occurrences that involve 'Risk of Harm' rather than actual harm, you should describe what is considered to be the root cause of the occurrence type.
- i. **IMPUTABILITY GRADE** – select a score for imputability from the dropdown menu. Please refer to the imputability scale provided. Please note that an imputability score is not applicable for occurrences involving Risk of Harm but no actual harm.
- j. **EXPERT COMMENTS FOR PUBLICATION** – all EG members are strongly encouraged to use this field for comments on a specific adverse occurrence or MPHO type in terms of latency, alerting signals, demonstration of imputability, etc, or for any other information that comes from their knowledge and experience. This field will be an additional value of the NOTIFYlibrary since it represents an invaluable didactic information source.
- k. **SUGGEST REFERENCES\***– add one or more references here that are good examples describing the occurrence type for that MPHO type. There is no limit to the number of references that can be entered per record. Please choose references that are didactic in terms of detection and confirmation of imputability or establishment of root cause. For accurate automated uploading, it is very important that you provide full references ideally copying them from a source such as PubMed. If the information comes from an official Health Authority or

Professional Society vigilance programme but the details are not published please give the name of the vigilance programme. The references will appear in the field “References” once imported and indexed (see below).

- I. REFERENCE ATTACHMENT** – you can attach one or more PDFs of relevant references for consultation by the other EG members (note that only EG members will have access to this content).
- m. REFERENCES (FOR ADMINISTRATIVE USE ONLY)** – to create the most accurate bibliography entry there are a number of fields that must be entered by the NOTIFY team to help locate or identify a reference (primary title, authors, periodical, volume, issue, publication year, DOI, etc). This field is not editable.
- n. KEYWORDS (FOR ADMINISTRATIVE USE ONLY)** – This field is not editable. This field will contain the keywords added by the EG members and linked to this specific adverse occurrence once the record is published by the NOTIFY team.
- o. SUGGEST NEW KEYWORDS** – please add here one or more keywords for this type of adverse occurrence associated with this type of substance. To add more keywords, please click the “Add another item” button. Include the substance type, the occurrence description, keywords from the ‘alerting signals’ or ‘demonstration of imputability’ fields and any other keyword that you think will be useful for free searching. Standardize terminology as much as possible to what you consider most appropriate, using reference dictionaries, such as MESH, wherever possible. Please note that the taxonomy does not describe MPHO in great detail; for example, it does not allow the description of how the MPHO is processed or stored, whether it is virally inactivated or if the record refers to autologous, allogeneic, allogeneic-related donation etc. circumstances. Where characteristics such as these are relevant to the occurrence, and you consider that users might search by these attributes, please ensure that they are entered as keywords.
- p. GROUPS AUDIENCE** – Please choose the EG that you consider should review this proposed record.
- q. NOTE** – you can use this field for internal communication only (text NOT for publication), as a message board for Editorial group members and/or interaction with the NOTIFY team.
- r. STATUS** – the EG can use this dropdown menu to classify the current status of the record: “Editing”, when the record is still under revision, “Ready to upload”, when the editorial work is finished, and “Rejected”.
- s. LAST UPDATE (FOR ADMINISTRATIVE USE ONLY)** – This field is updated automatically
- t. REVISION INFORMATION** – Click here to create a new revision by ticking the relevant box. You can use the revision log message to provide an explanation of the changes you are making. This will help other authors understand your reasons. Revisions allow you to track differences by comparing the different versions of your content.

In order to successfully submit your record proposal you must click the “SAVE” button.

## 5. Proposing an UPDATE to an existing NOTIFY RECORD

If you wish to add information or references to an existing record, you must note down the Record ID that you wish to edit. Then, to access the submission form, you can select “Add or update record” from the SEARCH LIBRARY drop down menu and then click on the “Update record” button. Alternatively you can choose the “Update record” tab at the TOP right corner of the **EG management record** panel.

**Please note that this selection will lead you to a blank submission form.** At this point we suggest that you open a second session with your browser (or open a different browser). This way you can search the record that you would like to change, copy and paste existing text and merge it with the new information while filling the submission form. The form should be completed in the following fields (\*required fields for proposal submission):

- **RECORD TO UPDATE\*** – Here you must enter the existing Record ID that you have noted down. To update more records, please click the “Add another item” button.
- Proceed by filling the fields you consider relevant following the guidelines above for new cases. The changes you make will not appear in the database until they have been reviewed and published by the EG and the NOTIFY team. The database will maintain the original information and allow comparison of the old information with the new, maintaining a log of changes made and by whom they were made (see Revision information above).
- You can use the field “**NOTE**” for internal communication for Editorial group members and/or interaction with the NOTIFY team.

**In order to successfully submit your update proposal you must click the “SAVE” button.**

Your proposal submission will automatically generate an email alert for the NOTIFY team who will carry out a check for consistency of terminology, keywords, spelling etc. before final approval for publication.

**Please record all your comments and suggestions for improvement to this new database tool!**