SYADEM
NUVA Terminology
Management policy

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Version	Date	Comment
0.0	2019-10-03	Initial version
0.1	2019-10-08	Precisions about Scientific and Ethical Committee Detail the impact of incidents Create the emergency update procedure
0.2	2022-03-30	Detail the editing rules
1.0	2023-10-13	Translate to English Remove restrictions for subscribing servers

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1 Purpose

This document describes the management policy applied by SYADEM to maintain the NUVA terminology.

2 Organization

The NUVA terminology is managed by SYADEM, editor for a network of specialized contributors, either as individuals, either as representants for their entities (associations, learned societies, manufacturers, etc.)

A Scientific and Ethical Committee outside of SYADEM validates the contributors, has a veto right on the publication of new versions and participates in the review of incidents. This role is currently held Groupe d'Etudes en Préventologie, the non-profit association that originally created SYADEM.

3 Roles and authorizations

Contributors update the terminology through a back-office server. They are all allowed to read all the resources constituting the terminology, but their write authorizations are customized according to the role, health jurisdictions and languages assigned to them according to their own competence.

The health jurisdiction impacts the brand name of vaccines, the languages the labels for generic vaccines, valences, and target diseases.

The editable resources are:

- The vaccines
- The valences
- The target diseases
- The alignment tables with external code systems

For each resource, two editing roles are defined:

- Authors can create, alter, or deprecate a concept or an alignment.
- Translators can only create, alter, or delete labels and alternative writings, restricted to the languages assigned to them.

Only authors are allowed to change the brand names for vaccines.

For each of these two roles, two levels of privilege are available:

- Submission
- Validation

Only the central administrators in SYADEM have the privilege to release a version from previously validated resources.

4 Administrative processes

4.1 Adding a contributor

The authorization form for a contributor thus comprises the following attributes:

Resource	Role	Privilege
Vaccines	None/Author/Translator	None/Submission/Validation
Valences	Idem	Idem
Target diseases	Idem	Idem
Code 1 alignment	Idem	Idem
…		
Code N alignment	Idem	Idem

It is complemented by the list of assigned jurisdictions and languages.

Contributors are always identified individuals, even when they represent an organization. The enrolment process for a contributor is as follows:

- Creation or completion by SYADEM of a request form, stating his identity, qualifications, potential conflicts of interest, proposed authorizations, jurisdictions, and languages.
- Validation of the request by the Scientific and Ethical Committee.
- Creation of account by SYADEM and delivery of credentials to the back-office.

Contributors accounts may be deactivated but are never removed.

The list of contributors is reviewed on a yearly basis by the Scientific and Ethical Committee. Idle accounts can be deactivated upon proposal by SYADEM.

5 Delivery process

5.1 Modifying the resources

The same process applies to the modification or creation of any resource:

- An author or translator with the Submission privilege on the given resource creates a request for change, consisting of the modified resource and a justification picked from a choice list, possibly complemented with a text written in English.
- An author or translator with the Validation privilege, distinct from the submitter, validates this proposal based only upon the communicated elements.
- A central administrator in SYADEM selects all or part of the validated changes and builds a preliminary release note transmitted to all contributors and to the Scientific and Ethical Committee. This release note includes a synthesis of the included changes, in French and English, and their detailed justification.
- The members of the Scientific and Ethical Committee have a one-week delay to express their opposition to publication. This opposition should be justified by a demonstration that all or part of the proposed publication contravenes to the economical and scientifical neutrality of the terminology. Any contributor may bring the case to the Committee during this delay.
- In case of such a veto, SYADEM may perform a partial publication by removing the litigious changes. Otherwise, the full publication will be available online one week after the release of the preliminary change note.
- SYADEM may, in case of emergency, perform an immediate release. The release note is then distributed to all contributors and to the Committee, together with an explanation for the emergency.

- The release note is published together with the release.
- Resources are versioned with the version number of the last release when they were altered.

5.2 Adding a language or a jurisdiction

Only the central administrators can add a new language or a new jurisdiction. This has the effect of creating the corresponding entries for all texts. These entries may be empty or produced by automated translation but are only available in submission state. The validated entries are with the English version until a contributor with the adequate validation privilege has validated a submission.

5.3 Adding an external code system

Only the central administrators can add the alignment table for an external code system. Authorizations for this code system will be then attributed explicitly to the competent contributors.

It belongs to SYADEM to check ahead the licensing conditions for the external code system, and if needed to fulfill the declaration or subscription conditions.

6 Incidents management

6.1 Detection

Incidents can be notified by any user having access to the back office: contributors, subscribing servers administrators or central administrators.

The notification is performed through an incident ticket, written in French or English, that will be used to track the incident along its processing.

6.2 Qualification

A SYADEM administrator will first qualify the event as a technical or semantic incidents. The processing of technical incidents is a general processus at SYADEM that is not described here. Tickets for events that are not considered as incidents can be closed at this stage.

A semantic incident can cause codification mistakes in vaccination histories, an incorrect vaccination status assessment for the regarded persons, over or under-vaccinations. Its level is assessed by evaluating:

- An impact, depending upon whether the error could create invalid records (e.g., crossing the labels between two vaccines) or not (an evidently correctable typographic mistake).
- A usage frequency of the faulty concept, that could be for a systematic vaccine or a very occasional one.

The table below gives then the incident level among: neglectable, minor, or major.

	Risk of induced mistake		
Usage frequency	Unlikely	Possible	Probable
>= 10% of population	Minor	Major	Major
>= 1% of population	Neglectable	Minor	Major
< 1% of population	Neglectable	Neglectable	Minor

The evaluations and their justifications are recorded in the ticket, as well as the exposure duration (the elapsed time since the faulty resource was published).

6.3 Treatment

The first treatment of the semantic incident consists in restoring the resources to a safe state.

For a neglectable incident, the normal modification process is used. For a minor or major incident, the proposition and validation are performed by central administrators within less than 2 working days, and the publication is done using the emergency process.

6.4 Communication

All tickets, current or past, are visible to all users having access to the back-office.

For semantic incidents at a minor or major level, a notification is sent by e-mail to all users when they are qualified, then for each of update of the ticket.

6.5 Documentation

The incident ticket constitutes its documentation. Before it is closed, a root cause analysis cause is attached, including recommendations for technical or organizational enhancements to avoid its reproduction.

6.6 Review

Once a year, all incident tickets are reviewed in a meeting between SYADEM and the Scientific and Ethical Committee. A report on the progress and efficiency of the enhancements is published to all users.

7 Editorial rules

These rules apply to all contributors. They are either recommendations (REC) or obligations (OBL). Whenever possible, they are checked automatically by the publication tools.

REC001 – Case for the vaccine labels

Except when the generally admitted use is different:

- The vaccine labels that are brand names are in uppercase.
- The labels for abstract vaccines have their first letter in uppercase, then lowercase.

OBL002 – Localization

Brand names are expressed without an associated language.

Labels for abstract vaccines, diseases, valences, descriptions, and notations are expressed in every available language. At least English and French labels are populated for each such resource.

OBL003 – Form of descriptions

The descriptions for vaccines are made of the list of their valences in a predefined order, with the characterization of each valence in parenthesis after the valence. After the list of valences come the needed precisions on the technology of the whole vaccine.

Example: "Diphtheria toxoid (low dose), tetanus toxoid, multicomponent acellular pertussis (5 components, low dose) and inactivated polio (trivalent) vaccine, adsorbed"@en

REC004 – Composite valences

The hierarchy of valences represents a notion of specialization, not of composition.

When using a composite valence addressing several serotypes of a same pathogen agent (such as PCV-13-valent), it is recommended to add a unitary valence for each of the serotypes. In this example, a pneumococcus vaccine with PCV-13 valence will be represented with the 13 unitary valences, plus the composite one.

REC005 – Intermediate valences

It may be useful for the readability of the hierarchy of valences to create intermediate valences, such as HPV-mono, even if they are not used in the description of any vaccine. Still any valence should either be used in a vaccine or the parent (generalization) of other valences.

OBL006-Unicity of abstract vaccines

For a given combination of valences, they can be only one single abstract vaccine.

OBL007-Unicity for an external code

For a given external code, there is one and only one associated vaccine code, corresponding to the exact precision level of the external code.

If several vaccines can be represented by a same external code (such as an ATC code), then it exists an abstract code that is exactly aligned with this external code. The valences for this abstract code are generalizations of the valences of all representable vaccines.

Yet, it is possible and usual to have several codes from a same external code system for a given vaccine. This is for example the case of presentation codes.