

IMI2 821520 - ConcePTION

ConcePTION

WP5 – Dissemination and education for HCPs and pregnant and breastfeeding women and the general public

D5.1 Report with description of the functionality of the knowledge database

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Document History

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Introduction

The aim of task 5.2 is to develop an EU centralised digital knowledge bank for up to date information on drug use before and during pregnancy and breastfeeding, and on the risks of untreated disease (in English), by combining information from different sources and providing common knowledge.

There are two main users of the knowledge bank. The first type of user is the Teratology Information Service (TIS) centres, and the second type of user are health care professionals and the general public who access the information through the website.

TIS centres will use the knowledge bank in two ways; populating the knowledge bank, and using the information in the knowledge bank when answering queries through their telephone service.

The knowledge bank developed within ConcePTION must be designed in such a way that it can be aligned with the information collection/dissemination processes within individual TIS centres and support their day to day work as well as making information about drug use during pregnancy and lactation available to health care professionals and the general public.

The public website will provide reliable, up to date information about drug use during pregnancy and lactation to support women and HCPs when taking decisions about drug use during these periods.

This document will describe the functional requirements of the knowledge bank.

Process

In order to define the functional requirements of the knowledge bank, telephone interviews were held with a number of TIS centres; both centres who have a public website already, and those who do not have any public information available, to learn more about their processes and needs.

User input from the two surveys conducted as part of Task 5.1 investigating Health Care Professional and pregnant and breastfeeding women's information need around medication use were also taken into account when designing the functionality of the knowledge bank.

Based on this information the functionality of the databank was discussed during a face to face meeting on 11-12 February in 's-Hertogenbosch, the Netherlands. WP5 knowledge bank team defined the functional requirements of the knowledge bank. Orcion, the partner that will build the knowledge bank will translate these functional requirements in a technical solution.

Functional requirements knowledge bank

The purpose of this chapter is to describe the functional requirements of the knowledge bank in such a detail that it is a good starting point for the technical development. It is not intended to be complete as in traditional "waterfall" development approaches, as we will use an agile development approach. Further details will be discussed during the actual development and in the corresponding sprint. This will keep this document readable, minimize abstract thinking and offer flexibility if new insights are obtained through stakeholder interactions.

After this document is approved, a prototype will be developed of the most important pages of the knowledge bank to get a realistic and visual view of the end result. Additional technical logic (like searching, saving etc.) will be added in upcoming sprints.

Some functionalities contain an issue number (i.e. #12344) which is a reference to an internal issue management system which will be used for sprint planning and development.

Non-functional requirements

1. The public website should be accessible using a desktop and a mobile device. The knowledge bank will be optimized for (recent versions of) Chrome, Firefox, Safari and Edge (Chromium version) covering a minimum of 90% of the browser market (statcounter, feb. 2020).
2. The knowledge bank will start with a minimum of 30 knowledge pages. The knowledge bank will support a minimum of 250 knowledge pages. According to Google research best practice is to keep loading time for end-users below 3 seconds. To achieve this performance while searching and showing knowledge pages additional indexing and/or caching technology will be implemented (#12558).
3. To ensure scalability of the infrastructure the knowledge bank will be hosted by a recognized cloud provider which is at a minimum ISO 27001 certified.
4. Using the Open Web Application Security Project (OWASP) potential high and medium security risks will be identified and be solved (#12557).
5. Existing solutions will be used where possible to prevent reinventing the wheel, with corresponding time and budget issues. To support the communication and collaboration processes during writing of knowledge pages a loose link will be created between the knowledge bank and Microsoft Teams, Microsoft Planner and Sharepoint. These platforms are being configured and customized at the moment.
6. The knowledge bank should be available 99% on average each year and will be monitored 24x7 using uptime monitoring.

Functional requirements

Public website

On the public website (#12555) the search will get a central place so that users can search without having to click and/or scroll. The search input will be matched with:

- The title of a knowledge page
- Keywords related to knowledge pages
- ATC code
- Generic drug name (in different languages if available in drug list)
- Brand name (in different languages if available in drug list)

No suggestions will be given while typing because of the different keywords, generic drug names and brand names in different languages.

The most recent updated knowledge pages will be shown on the homepage. Also, news items and/or indication-based information highlights can be added-for example, a drug which has received recent media coverage and is therefore expected to be of special interest to users.

Users are able to subscribe to a RSS feed containing updated knowledge pages / news items (#12556).

The website will be in English only and the search results will be displayed in English as well. The results consist of a clickable title, the first couple of sentences of the summary, and a tag. The tag is added so that users who search on a keyword, which is not shown in the search results (for example a brand name), recognize the search result as being relevant.

Paging will be added below the search results if there are more than 25 results found.

After clicking on the title of a knowledge page in the search result, the details will open. If there is information for a section (Pregnancy, Lactation) it will show, otherwise the heading will be hidden. If a section is translated a link will be shown so that the user can select the desired translation and based on the browser language a suggestion will be shown. If the detailed section is also translated this will change accordingly in the selected language.

The detailed information is only visible completely if a user clicks on the “Read more” link. The references will be shown if the user clicks on the corresponding link within the Detailed section.

On the right, additional knowledge pages are shown which might be interesting to the reader. If there is a drug specific update/news item released for this knowledge page, this item will be shown below the related knowledge pages.

A default English disclaimer will automatically be shown below each knowledge page.

Search Engine Optimization (SEO)

The keywords of knowledge pages will be included as metatags in the code and the title of the knowledge page will be shown using a H1 tag (#12534) on the website and will be part of the URL to increase the ranking on relevant keywords.

The summary will be (partially) used for the description metatag.

Also the requirements regarding speed and the custom sitemap (see below) will contribute to SEO.

Sitemap

For search engines like Google to be able to index the knowledge pages, a custom sitemap will be generated (#12535). This is needed because the knowledge pages are dynamically generated and are behind a custom search.

Admin knowledge bank database

The backend/admin part of the website is secured by a username (email) and password (#12499). The login credentials are created by an admin user (#12528) and the password can be reset by the user (#12500). Because of security reasons we do not actively show if the e-mail actually exists when using the password reset option but show a general confirmation that if the email exists the user will receive an e-mail to reset his/her password.

Knowledge pages overview

The backend will open with the knowledge pages overview (#12529) after a user successfully logs in. On this page users can search for knowledge pages similar to end users. Additionally, the following filters can be used:

- Status (Concept (*grey*), In review (*blue*), Published (*green*), Removed (*red*)). Multiple statuses can be selected to filter on.
- Translation. Multiple translations can be selected to filter on.
- Last changed from (date)
- Last changed to (date)

The result list will show the title, status (icon) + translation, date created and last updated date with the corresponding user. Because a knowledge page can have (multiple) translations, the English knowledge page can be extended (using an arrow icon) to show all translations in the overview. A knowledge page can simultaneously be published and be in concept/in review for an update, so it is possible that multiple statuses for a translation will be shown.

By clicking on the title, the knowledge page will open in detailed-view (non-edit mode). This is a similar view as end users have on the public website but with attachments and comments and with a button to edit the page. By clicking on the translation in the overview the corresponding translation/version will open in edit mode.

If there is no knowledge page available, the link “Create new page” can be used to create a new knowledge page.

New/Edit/Delete of knowledge page

This functionality (#12530) will open as a kind of pop-up (overlay) over the knowledge pages overview to have maximum space available to focus on the information relevant to a knowledge page.

Every knowledge page requires an English version before translations can be added. Using the dropdown behind the title of a knowledge page a different translation can be selected (if the user has sufficient rights). The sections can be translated and comments are translation specific. Also additional keywords can be added. The remaining information will be used from the English version.

The default status of a knowledge page is “Concept”. After that it can get the status “In review”. From the status “In review” it can get the status “Published” meaning the knowledge page (or translation) will be visible on the public website. Also a status “Removed” will be added. If changes are needed, the status can change from “Published” to “Concept”. To make sure the published version of the knowledge page remains accessible, a copy (new version) will be created as working version. Once this new version gets the status “Published” it will overwrite the existing version visible for patients and healthcare professionals. At any moment in time there can only be a maximum of two versions of a knowledge page (#12532).

If a new version of the English page gets published the existing translations can be outdated. A pop-up will be shown asking the user to change the status of translations to “Concept” automatically or in case there is already another version to “remove” (status Removed) the published version. Also there is an option to send an email to the email address connected to a translation to highlight the need for a new translation since the original text has been changed.

If the English knowledge page gets the status removed, all translations will get this status as well. An additional warning is shown to the user in this case (#12564).

Sections

A knowledge page consists of the following sections

- Pregnancy
 - o Details (show the first couple of sentences with read more..)
 - o References (expands on click)
- Lactation
 - o Details (show the first couple of sentences with read more..)
 - o References (expands on click)
- Internal comments
 - o Pregnancy
 - o Lactation

The sections can contain plain text, enumeration and bold/italic text.

The internal comments will never be visible on the public website and not be shared using the API. Only the admin, author and the user who added the comment can remove the comments.

References

References can be added (and removed) manually or by inserting a PubMed ID (#12549). Using the API of PubMed the citation information will be retrieved automatically and a link to the abstract will be shown (assuming the PubMed API supports this). References are separate for the pregnancy and lactation section and can be (re-)ordered.

Drugs, ATC and SNOMED

Optionally one or more drugs can be linked to a knowledge page. Based on the drug list (see corresponding chapter) language specific synonyms will be added automatically. These are read-only.

Drugs are identified by a generic name in combination with an ATC code. Optionally alternative ATC codes and/or SNOMED IDs can be linked to a knowledge page as well.

Keywords

Language specific keywords can be added so that users can search in different ways.

Link to other knowledge pages

By typing in the title of another knowledge page suggestions will be shown. After adding a knowledge page as a link it will be shown on the knowledge page as other relevant information. Linking is the same for all translations and read-only on translated pages.

Linking page A to page B does not automatically link B to A as well.

Collaboration

The process of writing knowledge pages as well as literature (re)search will be supported by Microsoft Teams, Microsoft Planner and Microsoft Sharepoint. Document libraries and lists will be

extended with custom columns and a first version is available at the moment of writing. Also Power Automate can be used to create custom flows for i.e. document approval. A basic demo workflow is built with a literature approval step.

Within the knowledge bank an external link can be added to Microsoft Teams and a (knowledge page specific) document library within Sharepoint.

Audit trail

Changes will be logged in an audit trail (#12536). The audit trail is version and translation dependent.

The following actions will be logged:

- Creating a knowledge page
- Deleting a knowledge page
- Changing a status of a knowledge page
- Changes in sections (pregnancy, lactation, details) without logging the actual change unless it is combined with a status change.
- Adding/removing/editing comments
- Adding/removing/editing references (and which)
- Adding/removing/editing a drug (and which)
- Adding/removing ATC codes (and which)
- Adding/removing SNOMED IDs (and which)
- Adding/removing keywords (and which)
- Adding/removing link to other knowledge pages (and which)

Also if the system performs an action, for example in case a new version is published and translations are unpublished, this will be logged.

With each action the following information is logged:

- User
- Timestamp
- Previous value (not with changes in sections unless the save action is combined with a change in status)
- New value (not with changes in sections unless the save action is combined with a change in status)

Attachments

Attachments can be uploaded for a knowledge page (#12537). Attachments are version and translation specific. For users searching using the admin (non-public) these are shown on the details page of a knowledge page, below relevant pages. English attachments are shown independent of the translation chosen; other attachments only if the user selects that translation. Attachments are not visible for patient / healthcare professionals on the public website.

Translations

Knowledge pages can be translated in different languages. English is the default “translation” and cannot be removed. Translations consists of the following properties:

- Name as being displayed in the translation dropdown for end-users
- Summary of Product Characteristics (SmPC) link(s) which is shown below the summary as an external link to the relevant medicine register(s). See <https://www.ema.europa.eu/en/medicines/national-registers-authorized-medicines> for the registers. The English “translation” will also have this link through which the SmPC can be consulted.
- Custom link(s) for example to a local knowledge management system
- An email address which is being used if translations are being unpublished in case an update of the English/main version of the knowledge is being published.

Drug list

At the time of writing, Drugbank.ca is evaluating if our business case meets the requirements for a non-commercial license of their drug data.

The drug list will determine how the user can search for information in the knowledge bank. Preferably users should be able to search on generic names and brand names in different languages as well as ATC codes (which can be relevant for the API).

The drug list will be imported and the import status is visible within the admin (#12552). Depending on the format, import functionality will be developed so that the drug list can be updated using the admin. After updating the drug list, a summary will be shown with knowledge pages which have a drug assigned which do not have a match within the new drug list, . These knowledge pages can be updated accordingly so they remain searchable based on the new drug list.

The imported drug list will be available in the database only (no front-end viewing/searching/editing).

Users

An admin user can invite new users and reset passwords. A temporary password will be emailed to the new user and on first log in the password must be changed before the user can access the admin part of the knowledge bank.

The following roles are relevant (increasing rights/possibilities):

- Viewer
 - o A viewer can search on knowledge pages and view them but is not able to make changes
- Editor (translation specific)
 - o An editor can create/edit/delete knowledge pages but is not able to change the status to “Published”.
- Publisher (translation specific)
 - o A user with the “Publisher role” is able to publish knowledge pages
- Admin (can also access Drug list, Translations, Api keys and users)

If a user is being deleted the name will remain visible in the audit trail.

Please note that Microsoft Teams, Microsoft Planner and Sharepoint users and roles are separate.

API

Using an API knowledge page information can be retrieved and integrated within other websites/apps (#12553). The following information can be retrieved.

Input:

- API key
- Keywords
- ATC + SNOMED codes
- Translations
 - o Default the information will be returned in English but additional translations can be requested in the API request.

Output

- Status
 - o 200 OK
 - o 400 Bad Request
 - o 401 Unauthorized

- 429 Too Many Requests (1.000 requests per 24 hours limit)
- 500 Internal Server Error
- Result
 - Pregnancy + details
 - Translation
 - Translation-content
 - Lactation + details
 - Translation
 - Translation-content
 - References
 - ATC codes
 - SNOMED IDs

The API calls together with the returned status, API key and timestamp will be logged in the database (no front-end) (#12559).

An API key is required to access the API and can be created/removed using the admin.

The website will get an /api page where information about the API can be found including examples for developers (#12554). Users can request an API key by sending a request to a predefined mail address.