Development of EUPATI Educational Library and Toolbox

Production process, quality assurance, editorial review, user testing, programme, author / expert reviewer guidelines

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Contents

1 Overall production process of material for the www.eupati.eu platform

The European Patients' Academy on Therapeutic Innovation (EUPATI) aims to build competencies and expert capacity among well informed patients and the public about the medicines research and development (R&D). It will ensure that patients can become more engaged and be more effective partners and advocates in medicines R&D. More specifically, the European Patients' Academy aims to:

- Develop and disseminate accessible, well-structured and user-friendly information and education resources on therapeutic.
- Build the ability and expert capacity among well-informed patients and the public at-large about pharmaceutical R&D.
- Create the leading public library on patient information in the seven most common languages in Europe.
- Establish a widely used, sustainable infrastructure for objective, credible, correct and up-to-date knowledge.
- Facilitate patient involvement in R&D to support industry, academia, authorities and ethics committees.

EUPATI was initiated and is being led by major patient umbrella organisations, and is run by a strong multi-stakeholder consortium of patient organisations, non-governmental organisations (NGOs), academia and industry. It will address training issues and significantly improve the availability of both patient-centric information for the public as well as educated patient experts that have the capacity and capability to contribute to medicines R&D.

Content for the Educational Library and Toolbox is intended to give educational tools for advocacy leaders from patient organisations, and the content is provided with the EUPATI 'Toolbox' including cutting edge educational material for patient advocates, including print material that can be easily shared, slide shows for face-to-face presentations and videos. 12,000 patient representatives are expected to use the Toolbox and 100'000 members of the health interested public are expected to make use of the library.

EUPATI is organized in seven Work Packages supporting each other in achieving the ambitious aims.

The Content Development Work Package is responsible for developing the methodology and content to provide the training, education and information material to the three audiences defined in EUPATI:

A. Patient Experts.

B. Educational Library and Toolbox for Advocacy Leaders within patient organisations.

C. Patients at large (the health interested public).

This development of content is supported by receiving in-depth input from qualitative and quantitative research conducted by the 'Need Assessment Gap Analysis' Work Package as well as expertise and insights from EUPATI Consortium members, network members and external advisors.

The content production for the toolbox is based on the syllabus and the six modules in the EUPATI Patient Expert training course. Content production teams were assigned areas of responsibility based on grouping of topics into subject areas.

The material from each of the six modules of the EUPATI Expert Training course covers the elements relevant to the development of medicines. The twelve topic areas covered on the EUPATI.eu platform are similar to the topic areas covered by the modules in the training course subdivided to increase usability of the website.

The thirteen categories found on EUPATI.eu are:

1. Basics of Medicine.
2. Pharmaceutical Development.
3. Regulatory Affairs.
4. Types of Medicine.
5. Clinical Development and Trials.
6. Health Technology Assessment.
7. Medicine Discovery.
8. Personalised Medicine.
9. Non-Clinical Studies.
10. Safety of Medicines.
11. Benefit and Risk Assessment.
12. Pharmacoepidemiology
13. Patient Involvement.

The material developed for the www.eupati.eu platform is built on the material developed for the Patient Expert training course, and adapted for a different audience following the Writing Guidelines **(Annex 1)**. Whereas participants in the training course went through a stringent application process than ensured a minimum level of existing knowledge of the medicines development field, experience of patient advocacy, and language skills in English, visitors to the public website will have a varying range of existing knowledge and language skills.

Though the content for the www.eupati.eu platform will be available in 7 languages (English, Germany, French, Italian, Polish, Russian, and Spanish) the content needs to be accessible by users who don't have one of the 7 EUPATI languages as a mother tongue and are located along the whole spectrum of knowledge about medicines development. Whereas content for the Patient Expert training course has been designed to be studied following a fixed order as laid out by the course curriculum and is delivered in a virtual learning environment, content on EUPATI.eu must be short and understandable in itself.

Further content is being developed for the Educational Library and Toolbox beyond the Patient Expert training course syllabus, mainly in the area of patient advocacy, an area that the training course participants already had pre-existing knowledge in.

Content for the patients (the health interested public) is designed for patients and lay public at large, and will be served by an online visual and multimedia library, explaining, e.g. specific aspects of the development process of medicines and related products (medical devices, combination products, etc.)

for patients and consumers with low (health) literacy. It is envisaged that this will reach 100,000 individuals.

2 Work structure

Work distribution of the Educational Library and Toolbox content creation

Adaptation of content for the Library and Toolbox began in December 2014.

The following roles have been defined and implemented in the Content Production process:

- **Work package coordinator** – overall coordination & interfaces to other Work Packages
- **Work coordinators** – Responsible to distribute material to authors and ensure quality of material produced.
- **Designated authors and adaptors** – Experts responsible for writing material and ensuring factual accuracy.
- **Expert reviewers** – Editorial review.
- **Translator** - Responsible for translating content ensuring consistency and flow of learning.
- **Translation reviewer** – Native language speakers validate translated material.
- **PLATA and SEO coordinator** – Responsible for having material available in PLATA templates for uploading in the website.

3 Production Plan for the Educational Library and Toolbox

3.1 Overall time plan

The Patient Expert Training Course was produced first before work was started on the Library and Toolbox. The Library and Toolbox content was produced in English before being translated in to French, German, Italian, Polish Russians, and Spanish.

3.2 Content production process

The planned time to produce final drafts of the prioritised topics for the Library and Toolbox ready for review by the advisory groups is four weeks. The process for producing articles is shown below:

EUPATI Production Process for Patient Expert Course and online Library and Toolbox

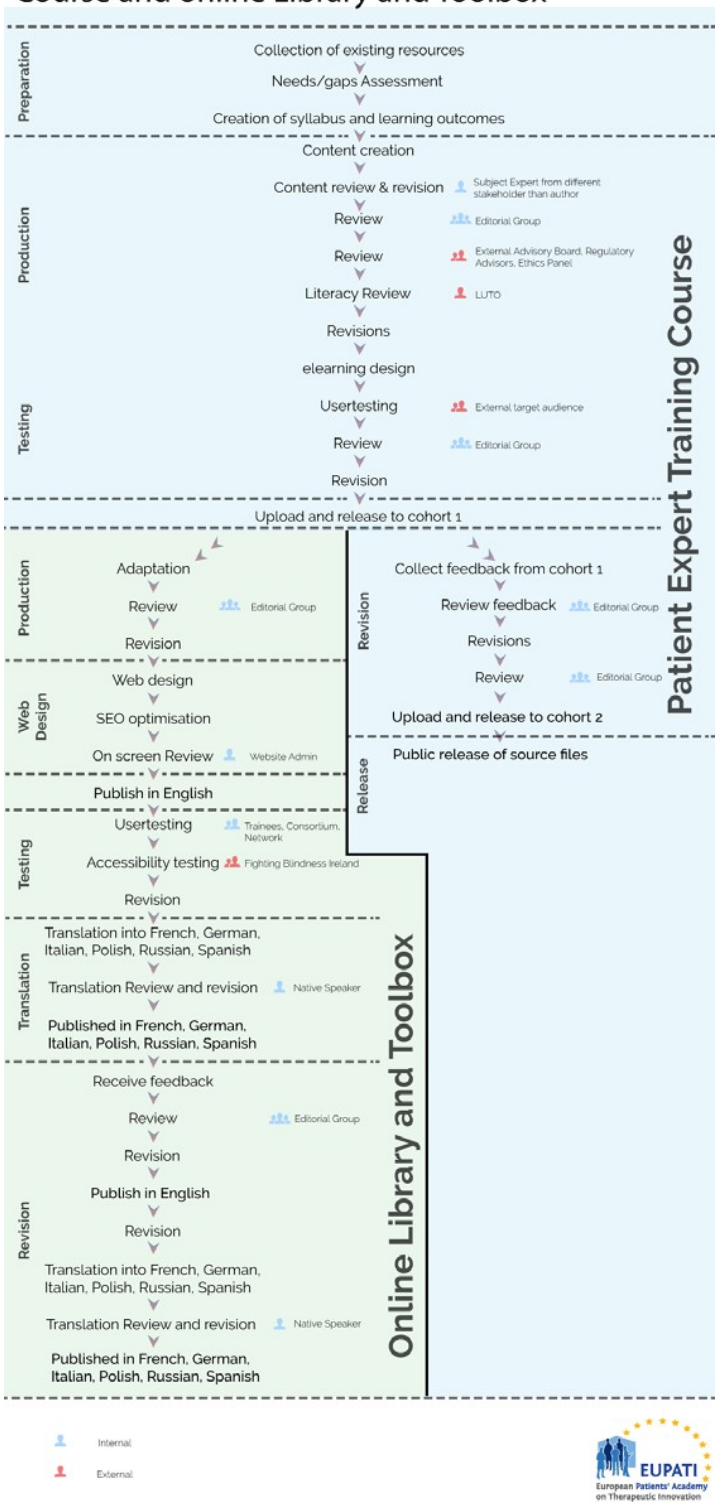

Figure 1 Content Production Workflow

4 Quality Assurance in the development of the EUPATI Educational Material for the Library and Toolbox, and General Public

The development of the EUPATI education material follows a workflow which ensures a high quality, factually accurate, transparent, and objective product. EUPATI builds on the strength of having a diverse group of stakeholders from different stages and perspectives of the medicines development process. In combining this collective knowledge, it is possible to produce a high quality product for the audience.

Educational materials will first be adapted and then reviewed in English. Once signed off, they are optimised for the internet and the information is translated into the six additional languages. Testing of the content and the website will be conducted in English. Translation is coordinated centrally. Translations will be reviewed by a dedicated group of native speakers of the EUPATI languages.

Work Package 4 has adapted the "*IMI Education and Training Shared Quality Standard for continuing professional development (CPD)"* laid out by the IMI EMTRAIN project to define standards for all content hosted on www.eupati.eu.

The EMTRAIN quality criteria are:

1. A system for approving, monitoring and reviewing the training offered
2. *Quality assurance of teaching staff*
3. *Regular review of the Quality Assurance/Quality Control process and demonstration that the training is further developed in light of this review*
4. *Defined and transparent admission criteria*
5. A predefined set of teaching objectives, leading to defined learning outcomes
6. *The facilities, infrastructure, leadership and competences available for the support of student learning*
7. *Assessment of the students' achievement in accordance with the agreed learning outcomes of the training offered*
8. *A system for collecting, assessing and addressing feedback from learners, teachers, technical / administrative staff and programme / course / module managers*
9. Availability of appropriate and regularly reviewed reference material (e.g. published articles, links, book chapters, scripts, etc)

Criteria 2, 3, 4, 6, 7 and 8 (in italic) are of course critical for the delivery of the training course but do not directly address the requirements and standards for producing educational material for Audience 2 and 3.

Ref 1: A system for approving, monitoring and reviewing the training offered
Although not a training course per-se, material for EUPATI.eu will be reviewed by content experts and representatives of the target audience before they are approved for release to participants.

Ref 5: A predefined set of teaching objectives, leading to defined learning outcomes

Learning objectives adapted from the Audience 1 training course syllabus were used to define the content of all content adapted and produced for Audiences 2 and 3.

Ref 9: Availability of appropriate and regularly reviewed reference material (e.g. published articles, links, book chapters, scripts, etc.)

It is important that material is suitable for the audience and factually accurate, to facilitate this, the following quality points are taken into account when developing EUPATI educational material, these are in line with the European Commission quality principles for patient information ("Core quality principles for patient information on diseases and treatment options"). All EUPATI material must be:

a. Objective
b. Evidence-based
c. Up-to-date
d. Reliable
e. Understandable
f. Transparent
g. Patient-oriented
h. Relevant
i. Consistent with Statutory Information

The authors and expert reviewers have to follow guidelines meeting the quality criteria mentioned above, and these guidelines are shown in the following section of this document.

The content developed by EUPATI authors combines the expert knowledge of the individual with existing material available on the subject, addressing the needs of the target audience.

Authors have been instructed that all reference material must be in the public forum so that participants may consult these resources for further information. Authors should also indicate further reading available where applicable for those wishing to learn more about the subject.

EUPATI Library and Toolbox Editorial Group

The EUPATI Library and Toolbox Editorial Group was convened based on a need to ensure that all material received was reviewed and signed off before translation could begin.

The Editorial Group comprises a representative of each stakeholder in the EUPATI Consortium:

- Industry – GlaxoSmithKline
- Industry/Academia – Bayer AG/Ruhr University Bochum
- NGO – DIA
- Patient Representative – European Aids Treatment Group
- Patient advocates involved as consultants

The purpose and the strength of this Editorial Group is that all perspectives (patient advocacy / audience perspective, industry R&D expertise, academic/teaching expertise) are well represented in the evaluation of each document received.

During the review process, the Editorial Group review the factual accuracy of all educational material, they additionally:

- Reviewed content for its accessibility by the target audience.
- Consolidated content (combined, adapted, eliminated) where necessary.
- Removed redundancies.
- Created harmonised diagrams.

5 Appendix 1 Writing Guidelines

5.1 Guidelines for authors

These guidelines are based on the editorial guidelines recommendations produced by members of WP4 and the guides referred to therein.

Language and writing style

The level of language used should be equivalent to 16 years of age, level of language is calculated by taking into account the length of the sentence and the number of syllables a word has. To ensure this please take note of the following advice:

- Complex words, medical jargon, abbreviations, and acronyms should be explained, it is important that we teach people the meaning of these terms. Acronyms should always be spelled out such as 'European Patients' Academy for Therapeutic Innovation (EUPATI)'. Teach the terms by explaining the concept first in plain language. Then give the new term. Also provide a simple pronunciation guide. For example, 'A normal heart beat starts in the upper right chamber of the heart, or atrium (ay-tree-yim)'.
- Keep most sentences 10-15 words long. Use varied sentence length to make them interesting, but keep sentences simple.
- Where appropriate, use bulleted lists instead of blocks of text to make information more readable.
- Use the active voice and vivid verbs. Here's an example:
  Active: Amanda used her inhaler today.
  Passive: The inhaler was used by Amanda today.
- Be consistent with terms. For example, don't use 'drugs' and 'medications' interchangeably in the same document. Terms should be checked with the EUPATI glossary and where missing should be marked for addition, if the existing definition needs updating please indicate how. The glossary will be updated after finalising the draft course material. When possible, say things positively, not negatively. For example, use 'Eat less red meat' instead of 'Don't eat lots of red meat.'
- For help in finding simple words to explain concepts please consult the University of Michigan Plain Language Dictionary http://www.lib.umich.edu/plain-language-dictionary
- Use illustrations and photos with concise captions. Keep captions close to photos and illustrations.
- Avoid graphs and charts unless they actually help understanding. If you do use them, make sure they are simple and clear.
- Balance the use of text, graphics, and clear or 'white space'. Try for 40 to 50% white space.
- Avoid using all capital letters. Upper and lower case are easier to read. To show emphasis, use bold, larger type size or different fonts.
- Avoid italics of more than a few words at a time.
- Use bolded headings and subheadings to separate and highlight document sections.
- When possible, use graphics or spell out fractions and percentages.

Existing material

Authors should conduct a thorough literary search on their responsible topics, this may include checking the articles submitted to EUPATI, checking the EMA and other national regulatory authorities' websites, or their own and colleague's material. Where ever possible it is recommended to

reuse existing material as long as copyright release has been granted (Creative Common license, or similar free usage clauses exist in the materials copyright). All material produced should thoroughly reference existing resources that are available openly to the public, alternatively usage rights should be requested using the EUPATI Creative Commons release form from the necessary authority.

5.2 Guidance for adaptation

The Library and Toolbox is designed for use by patient advocates to address their needs. It will be a broad collection of self-contained/self-explanatory (standalone) multilingual educational materials on the A to Z of medicines development process including patient involvement which can be:

- used directly without modification or
- further developed to form own material and
- to be applied within the patient advocacy community.

Each toolbox item must have as a minimum a text page (between 500-2000 words) which be delivered as the main search engine result plus additional resources.

The format of additional downloadable, reusable resources available from the toolbox could be slide shows, factsheets, and existing webinars (only if transcript provided for translation purposes). A glossary of terms will also be incorporated.

Content will be searchable to be viewed on EUPATI's new web-based platform (including via mobile devices) or for download as 'print ready' files enabling use offline.

The target number of users for the toolbox is 12,000. All the resources will be available in seven languages (English, French, German, Italian, Polish, Russian, and Spanish).

Content should be adapted from content that has been developed for the Patient Expert Training Course and approved through the rigorous production process. When adapting content the following should be considered:

1. Adapt with the target audience in mind. It cannot be assumed that users have existing knowledge on the topic or medicines development.
2. Retain the content list and glossary (simplify where required).
3. The document should be able to be used as a standalone summary brochure.
4. Summary in bullet point format on webpage; consider key points and present these first (this should not replace any introduction section).
5. Have associated glossary terms identified to ensure coordination with the Toolbox Glossary. Always spell out abbreviations; avoid jargon.
6. Elaborate engaging fact sheet for basics, Q&A for overview for documents longer than six to A4 pages.
7. Ensure diagrams can be easily understood. Use charts, infographics which contribute to the readers learning
8. Usually keep references and examples of further reading but reduce where possible. References should be explained in the text rather than displayed as hyperlinks to improve readability, though this approach should be decided on a case by case basis.
9. Some content is to be abstracted in fact sheets containing the main concepts.

10. Aim for approximately one page per factsheet.
11. Material to be self-contained/self-explanatory.
12. Address the needs of the patient advocate community!
13. PowerPoint presentations are an excellent way to present content, but not as a standalone method. If the content is available as a slide deck only from training course material, then a summary web page produced from the slides should be created.
14. Evaluate subjectivity of the language used in the topic. As a general rule employ neutral, diplomatic language and avoid giving opinions or drawing conclusions or presenting current situation as preferred status quo or practice in reality.
15. Different situations exist in different countries so consider guiding the reader by including 'in your country this might vary, read more here'.
16. Try to include case studies and best practice examples to bring topic to life and make content meaningful.
17. Consider public information leaflet style or interactive/audio-visual formats, to make content more appealing to soften the too academic/too scientific style of training course content.
18. Use of single quotation marks (‘), rather than double (”), throughout all documents for consistency.
19. Number style amended for consistency to 10,000 rather than 10 000, 10.000 or 10’000
20. When describing a range of numbers, i.e. 200 – 300, use ‘to’ rather than a dash for clarity.

Example of text structure:

- Introduction
- Content
- Patient involvement (this section should describe how the patient involvement takes place, with at least one example, or indicate where patient involvement is evolving / involvement could happen in the future)
- Further resources

9. Document revision history and copyright

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Revision History

Version and Date	Author	Changes
1.0-1.2 10/12/13	Matthew May Jytte Lyngvig	Initial versions
1.3	Jan Geißler	Review, comments, minor edits, added section on course admission criteria
1.4	Jan Geißler	Final check, Final draft for ExCo
1.5	Jan Geißler	Wording change
1.6 25/06/14	Jan Geißler, Jytte Lyngvig, Matthew May	Major review of the document, Revision of Timelines, QA, Syllabus, Added +Editing Team, +User Testing
1.9	Matthew May	Added regulatory review + LUTO
2.0	Matthew May Cecilia Carino	Updated Audience 1, added audience 2&3
3.0	Cecilia Carino	Adapted

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