Development of EUPATI Educational Material for the EUPATI Patient Expert training course

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

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1 Overall production process of material EUPATI Patient Expert Training Course

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 will:

- 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 research and development.

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

1. Project Coordination team.
2. Network Implementation team.
3. Need Assessment Gap Analysis team, responsible to giving in-depth input from qualitative and quantitative research conducted by the group, as well as expertise and insights from EUPATI Consortium members, Network members and external advisors.
4. A Content Development team, 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).
5. IT Infrastructure team.
6. Deployment and Quality Assurance team.
7. Future Topics and Sustainability team.

As an outcome of engagement within EUPATI, it is anticipated that patient experts will represent the patients' perspective in research groups, scientific committees, Health Technology Assessment (HTA) and health care bodies as well as towards industry, academia, regulatory authorities and ethics committees, to lead a train-the-trainer concept for patient organisations and to communicate the patient perspective on R&D-related topics in public media to patients.

The content development of the Patient Experts training course follows the normal path for course development: (1) agreement on the main areas for education, (2) development of a syllabus, (3) transformation into a curriculum in correspondence with learning outcomes, (4) division of the

curriculum into topics organised in modules on which the specific lesson and the educational material can be developed.

The EUPATI Patient Expert Training Course will be delivered in two rounds involving 50 participants each (the number of selected participants will actually be 55 as we expect up to 10% drop-out rate).

The syllabus of 103 topics for the Patient Experts' training course was created through a complex consensus process of 30 Consortium members including patient organisations, NGOs, academia and industry. It was reviewed by three advisory boards: Project Advisory Board (PAB), Regulatory Advisory Panel (RAP), and the Ethics Panel), and published on the EUPATI website in August 2013 to receive further public comments. The syllabus covers all elements and phases relevant to the development of medicines. **(See Syllabus in Annex 1**) It comprises six modules:

1. Discovery of Medicines and Planning of Medicine Development.
2. Non-Clinical Testing and Pharmaceutical Development.
3. Exploratory and Confirmatory Clinical Development.
4. Clinical Trials.
5. Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmaco-epidemiology.
6. Health Technology Assessment principles and practices.

The course material development built on the re-use of existing material, adapted for Patient Experts, or otherwise it was written from scratch. The Need Assessment Gap work package collected a large amount of pre-existing training, education and information material about medicines R&D. In addition, the authors also use their own knowledge of suitable material. There are six content production teams which all have specific topics assigned.
Re-use of material requires permission of the copyright holder. All materials to be developed and delivered within the EUPATI project should be compliant with defined and agreed quality criteria.

Relevant project management tracking tools are being utilised, and a flow chart reflecting the cycles, timelines and responsibilities in all production phases have been defined in order to effectively oversee the production process.

2 Work structure and Governance of the Content Development team

The following roles have been defined and implemented in the Content Production process for the Patient Expert training course:

- **Leadership / Management team** – overall coordination and interfaces to other teams.
- **Task force Leaderships** – Responsible to find authors and ensure quality of material produced.
- **Designated drivers, authors and expert reviewers** – Experts responsible for writing material and ensuring factual accuracy.
- **Content Coordinator** - Responsible for ensuring consistency and flow of learning, and to prevent repetition that may occur in similar topics.
- **Production Planner** – Responsible for facilitating the production process.

- **Project Advisory Board (PAB), Regulatory Advisory Panel (RAP) and Ethics Panel** – providing advice and ensuring the course material is in alignment with the aim and objectives of the EUPATI project as well as common quality criteria.
- **Editorial group** – responsible for ensuring the content of the documents is according to the EUPATI guidelines, and controls the final quality of the document.
- **LUTO** – readability testing was conducted by LUTO, independent experts from the University of Leeds specialised in the communication of science to the lay public.

3 Production Plan for educational material

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

This production plan shows the robust content development process that all EUPATI content went through.

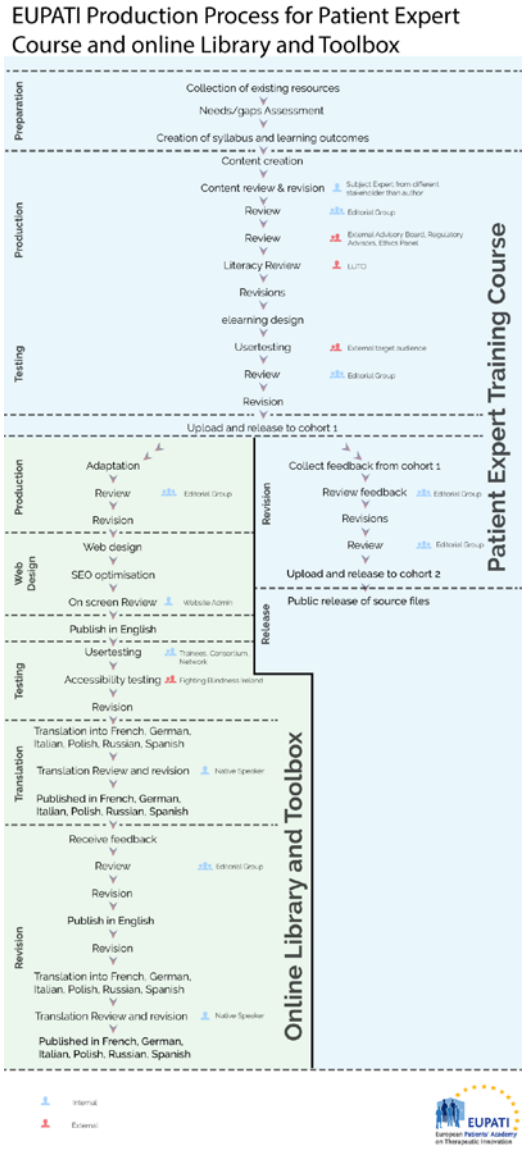

Figure 3-1: Workflow to produce content

Work distribution between the teams

The distribution of work among the six task forces of the content development Work Package was based on experience and competencies of the topics addressed. Table 3.1 accounts for the work distribution across different teams:

Medicines development process from research to	Personalized and predictive medicine task force	Drug safety and risk/benefit assessment of (novel	Pharmacoeconomics and health technology assessment task force	Design and objectives of clinical	Patients' roles and responsibilities in innovative medicines

approval task force		and existing) medicines task force		trials task force	development task force
Module 1 Module 2 Module 3 Module 4 Module 5	Module 1 Module 3 Module 5	Module 2 Module 5	Module 6	Module 1 Module 2 Module 3 Module 4 Module 5	Module 1 Module 2 Module 3 Module 4 Module 5 Module 6

Table 3.1 distribution across different teams and the links of topics and modules

Progress tracking
To manage the organisational complexity of topics, modules, taskforces and individual persons, a 'Team Progression Chart' is in use to track the progress of production of the different modules and module topics. It is continuously updated and provided by Editorial Group Management, coordinated by the Editorial Group Production Planner, to the six Teams on a weekly basis.

Guidance for authors of e-learning content
To facilitate the development of content, EUPATI has developed templates, guided by e-Learning experts, available to help authors to plan their online sessions.

The **module planning guide/form** provides a broad overview of the module as a whole, including the student engagement hours, the learning outcomes, the number of eLearning sessions, the number of face-to-face sessions, the topics covered in both e-learning and face-to-face, the topics to be adapted from existing material, the list of sources re-used and the list of topics to be newly created. It also helps to map the learning objectives for the sessions to outcomes.

The **session planning guide/form** has to be completed for each session an author is developing. It includes the module title, the syllabus topics covered, the learning outcome, the session length and the type/format of the session.

3.3 Editorial process

After the final drafts for all topics have been produced, they are reviewed by a subject matter expert from another stakeholder group before being reviewed the EUPATI Editorial Group and then by the advisory groups: The Project Advisory Board (PAB), the Regulatory Advisory Panel (RAP) and the Ethics Panel. **See Writing Editing Guidelines in Annex 2 Part 1: Writing guidelines**
The primary role of the PAB/RAP members is to provide high-level advice on the conduct, progress, program and methodologies of EUPATI overall, and to review overall modules. However, many advisors acted as expert reviewers in their field, and feedback was reviewed and integrated by the Editorial Group.
Where applicable, reviewed lessons are returned to authors with questions and/or comments for amendment, correction or adaptation.

3.3.1 Editorial Group:

The EUPATI Editorial Group was formed to ensure a horizontal view and harmonisation across all modules of lessons in the course whilst ensuring factual accuracy, and neutrality according to the EUPATI guidelines.

The Editorial Group comprises a representative of each stakeholder in the EUPATI Consortium: Industry, Industry/Academia, Non-governmental organisation and Patient Representatives. In addition, an external advisor retired from a National Regulatory Agency is involved as a member of the group. Each lesson is reviewed separately in sequence by every member of the EUPATI editorial group.
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 lesson received. **See Writing / editing guidelines in Annex 2 Part 2: Edition Guidelines**

The editorial group has, in addition to reviewing the syllabus topics:

- Reviewed the learning outcomes and their applicability.
- Consolidated content (combined, adapted, eliminated) where necessary.
- Removed redundancies.
- Created a harmonised diagram for medicines development.

3.3.2 Readability:

LUTO reviewed all content for harmonisation of language, style and comprehensibility/accessibility of the content. **See Writing / editing guidelines in Annex 2 Part 3: LUTO Guidelines**

The strength of the EUPATI training programme lies in its ability to select experts from a wide range of fields due to the diversity of the consortium partners. However, despite best efforts to ensure consistent delivery of material through the use of writing and style guides, it is inevitable that authors' voices speak through their writing, and writing for a different audience it is also a challenge for many. In order to combat these problems EUPATI works with LUTO, an organisation specialised in the communication of science in the medical field. LUTO reviews the EUPATI educational material to ensure the maximum understanding from an audience coming from different backgrounds and educational levels, including the differences in languages spoken. This ensures consistent delivery of material through the use of writing and style guides.

3.3.3 User testing:

The lessons were uploaded to the Moodle learning management system (LMS) and user testing conducted with volunteers from the target audience. User testing looked at both the usability of the LMS and the design and layout of the lessons.

3.3.4 Final revision:

The Editorial Group do a final revision incorporating all relevant feedback from readability and user testing, and control the final quality of the document before final upload to the Learning Management System and release to trainees.

3.3.5 Revision of Content

Feedback from the first cohort of trainees was collected and reviewed by the editorial group, and lessons and modules were updated, also to reflect latest developments in the medicines development and authorisation landscape.

3.3.6 Glossary terms

During every step of the editorial process, a large number of complex or technical terms have been identified for inclusion or harmonisation within the EUPATI glossary to support the training course. The glossary feature of the e-learning platform will automatically create links to explanations of terms

when they appear in a lesson's text. The editorial group also identified a number of key attributes to be applied horizontally to each topic and module during the review and copy editing process.

4 EUPATI Patient Expert training course assessment – basic outline

Assessing what students have gained in terms of knowledge, understanding and application is the final part of any learning process. If students are to receive a certificate from EUPATI which attests to their knowledge of the medicines development process, an assessment would be a prerequisite.

The purpose of the Patient Expert training programme is to educate as many patient experts as possible (100 in the remit of EUPATI) in the process of medicines development. It is in everyone's interest that as many participants as possible successfully complete the EUPATI training programme. To facilitate this, methods of assessment need to be carefully chosen to consolidate learning and to strengthen the knowledge and confidence of participants rather than acting as a barrier to completion of the course. To achieve this, assessment on the EUPATI training course should take 3 forms:

- unrecorded knowledge checks at the end of each lesson
- recorded multiple choice (MCQ) exams at the end of each module
- exercises during the Face to Face events

Knowledge checks
Knowledge checks will take the form of 1-2 multiple choice or free-form question at the end of each e-learning lesson. Students will be given feedback with an explanation of why an answer was correct/incorrect, or, in the case of a free form question, will be provided a model answer by the LMS. These assessments may be repeated an unlimited number of times and the result of the students attempt not recorded.

Multiple choice assessments
Multiple choice exams will be taken at the end of each course module throughout the EUPATI training programme. MCQ exams will consist of 20-40 questions depending on the module (Multiple true-false MCQs, Single best answer MCQs) drawn from a bank of questions for each module. Questions must test the learning outcomes of the module. This is fundamental and all learning outcomes should be tested in some way. The fixed pass mark will be 70%. Results will be recorded by the LMS (Learning Management System). Students will be required to have achieved a pass in each module before being awarded the EUPATI training programme certificate. All MCQ exams must be completed no more than 2 months after the date of the end of the 2nd Face to Face teaching event.

Face to Face exercises
During the Face to Face training events, participants will be seen by EUPATI staff and instructors. It is fundamental that participants take an active part in the little time given to Face to Face learning, and therefore staff and instructors will be asked to review participation and flag any concerns to the course organiser. Each participant will pass assuming they contribute in class and in exercises. Any concern over active participation should be addressed during the course of events.

Certification
Upon attaining a pass in each of the 6 modules, participants will be issued with an "EUPATI Certificate" confirming their successful completion of the EUPATI training programming. In order to make sure this has value WP4/WP7 and the Executive Committee will drive efforts to receive buy in from as many organisations/institutes/companies as possible ahead of the issue of the first certificates (starting with all consortium partners and members of advisory group). A page on the website shall be

maintained detailing an expanding list of these stakeholders, also explaining the competencies attained by participants.

5 Quality Assurance in the development of the EUPATI educational material for the Patient Expert training course

The development of the EUPATI education material follows a workflow which ensures a high quality, factually accurate, and transparent 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, we are able to produce a high quality product for our audience.

5.1 Quality criteria:

The Patient Expert training course aims to conform to the '*IMI Education and Training Shared Quality Standard for continuing professional development'* quality criteria laid out by the IMI EMTRAIN project. However, the Patient Expert training course is not a university course, hence not all criteria are applicable to this project.

EMTRAIN quality criteria:

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.).

5.1.1 Criteria 2, 4, 6 and 8

These are critical for the delivery of the training course but do not directly address the requirements and standards for producing educational material. These important criteria are being addressed by the Deployment and Quality Assurance team. They finalised criteria 4 (course admission), 2 (for face-to-face teachers), 6 (for tutors), and 8.

Criterion 4: Defined and transparent admission criteria.
Course participants need to apply for participation in the EUPATI course. Selection criteria, as agreed with the three EUPATI advisory boards, will include individual motivation, commitment to complete the full training course, commitment to use and apply learning, prior experience of being involved in medicines R&D, fluency in English, and regional spread of participants across Europe, and having participants from all major disease areas.

The selection of course participants for the first and second cohorts was done via a transparent process. All applications received by the published deadline were validated for their accuracy and completeness. Those applications that had passed initial screening were then evaluated for their content. Applications were assessed by an independent Selection Committee against weighted criteria according to a transparent scoring system. The independent Selection Committee consisted of five members: three representatives of the EUPATI Consortium (one patient organisation, one academic partner and one industry representative), one member of the EUPATI Ethics Panel, and one member of the EUPATI Project Advisory Board.
The detailed selection criteria can be found on the EUPATI website at
http://www.patientsacademy.eu/index.php/en/edu/guide#how-we-choose-participants

5.1.2 Criteria 1, 3, 5, 7 and 9

These criteria are central to the production process and are being addressed as follows for the Training Course.

Criteria 1 and 3: A system for approving, monitoring and reviewing the training offered, and regular review of the Quality Assurance/Quality Control process and demonstration that the training is further developed in light of this review.
All training course material for both face-to-face presentations and e-Learning materials will be reviewed by content experts and representatives of the target audience before they are approved for release to participants.
Student progress on the e-Learning system is monitored using the Learning Management System, and feedback will be collected during the face-to-face learning sessions.
The learnings will be incorporated before the launch of these lessons to the second course with 50 participants in 2015-2016.

Criterion 5: A predefined set of teaching objectives, leading to defined learning outcomes.
Following the development of the syllabus, specific learning outcomes were defined for topics, these have been consolidated to provide participants with comprehensive learning outcomes for each course module. The learning outcomes were reviewed and approved by the three advisory boards.
The learning outcomes can be accessed here:
http://www.patientsacademy.eu/index.php/en/edu/guide#about-the-training-topics-timing-cost

Criterion 7: Assessment of the students' achievement in accordance with the agreed learning outcomes of the training offered.
Course participants will undergo online assessments upon the completion of each module; they will also be required to participate in exercises during the face-to-face training.

Criterion 9: Availability of appropriate and regularly reviewed reference material (e.g. published articles, links, book chapters, scripts, etc.)
Authors have been instructed that all reference material must be in the public forum so that participants may consult these resources for further information. Where necessary, copyright release requests have been made so that materially not currently found within the public domain can be used for the course and distributed to participants. References may only be behind pay-walls as a last resort, and every effort should be taken to provide accessible references.

Additionally it is important that material is factually accurate and suitable for the audience. To facilitate this, quality points, in line with the European Commission quality principles for patient information ('Core quality principles for patient information on diseases and treatment options'), are taken into account when developing EUPATI educational material. 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

In order to meet these quality standards, the Content Development team identifies authors and expert reviewers with proven expertise in subjects chosen to be addressed by EUPATI. At least one author and one expert reviewer from each topic should be from different stakeholder groups (academia, industry, patients).
EUPATI will make public a list of all authors and expert reviewers who contributed to the creation of the EUPATI educational programmes on the EUPATI website. In addition Declarations of Interest are requested from all authors and expert reviewers, which are also made available on the EUPATI website.
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, whilst addressing the needs of the audience which is ensured through the collection of focus group and survey data from the target audience.

Review and validation of content items will be conducted:

- By expert reviewers.
- By the Editorial Group.
- By members of the Project Advisory Board, Regulatory Advisory Panel and Ethics Panel as ad-hoc experts in their area of expertise.

Major change requests coming from the reviewers is tracked and documented.

Annex 3 Face-to-face meeting programs. Event 1 and 2

5.2 Regulatory Review Group

The regulatory review group provide a further removed perspective when reviewing material, not only do they focus on ensuring the legal and factual accuracy of the content, but also provide insight to the interpretation of the writing style of possible stakeholders to ensure a neutral, accurate and transparent communication of information. Comments and issues raised by the regulatory review group will be dealt with by the Editorial Group.

Following the meeting with the EUPATI Project Advisory Board, Regulatory Advisory Panel and Ethics Panel, the Executive Director of EMA sent a request to the Heads of the National Competent Authorities requesting support for the EUPATI project to support with resources an additional regulatory review of the educational material for the Patient Expert training course.

This request resulted in five competent authorities volunteering to review the first and second module of the Patient Expert training course: The Italian National Institute of Health (ISS) and the regulatory authorities from Cyprus (Ministry of Health), Ireland (HPRA), Germany (BfArM) and Spain (AEMPS).

It was agreed that the review would take place to ensure: factual accuracy of the material and ensuring presentation of information from a neutral position (ensuring there was no promotion through the use of brand names, except were these were specifically required to illustrate an example). Where changes were necessary the reviewers would provide a corrected text or supplements.

5.3 User Testing

Technical functionality of the e-Learning system has been tested by Hibernia College. The testers were recruited from the user tester pool that volunteered to pilot the e-learning content set.
To validate whether the material in the online modules is understandable and readable by EUPATI's target audience of patient advocates, EUPATI is in the process of conducting a user test of 20% of the e-learning material. At the stage of the user testing, 19 topics were available for testing in the online system.

85 volunteer patient advocates were recruited with the criteria described in the EUPATI Patient Expert Training Course application. EUPATI did not require any previous knowledge on medicines R&D, as being a patient advocate was seen as sufficient. The required time commitment was three hours per volunteer for user testing and feedback. 43 user testers were required to work their way through the lesson(s) randomly assigned, guided by a short guidance document on how to do so. Each of the 19 sample topics was tested four times to account for variation in test results due to difference in level, language, country, expertise etc.

In total, approximately 20% of the total e-learning course was tested. Extensive comments were received. While technical issues and challenges to use the e-Learning system were immediately solved, content-related feedback was brought into the editorial process as soon as the user testing had been completed.

5.4 Evaluation and revision of training course material and programme after the first course cycle

Once the first cohort of 50 students were enrolled in the expert training programme, their use of the material and feedback were periodically monitored by speaking with individuals and through the use of evaluation forms.
To that end, the Deployment and quality Assurance team developed a set of Quality Assurance (QA) tools for the EUPATI Patient Expert Training Course.

The objectives of QA are as follows:

a) Ensuring that the training programme is delivered talking into account relevant recommendations developed by the Needs Assessment Gap Work Package.

b) Getting feedback from representative small cross-sectional sample of the first cohort of course participants on training programme delivery (as well as training material and online learning platform) and make recommendations for improving the second course.

c) Ensuring that the second course builds on outcomes of QA as well as evaluation (which will complement QA) conducted in respect of the first training course.

Quality Assurance will be complemented by comprehensive evaluation of the training programme against the various process, output, and outcome indicators set out in the EUPATI Evaluation Plan. While Quality Assurance is a process-oriented tool focusing on ensuring that standards of quality in delivering the EUPATI Patient Expert training course are being met, evaluation will primarily aim at

assessing the extent to which will the Programme contribute to meeting the outcome indicators identified in respect of the Patient Expert training course.

Outcomes of both QA and Evaluation have been used to modify the second programme in terms of both content, design, and delivery.

5.5 Updates to course content - cohort 2

Based on the feedback received for the first iteration of the Patient Expert training course, and changes within the landscape of medicines development, an update process was initiated revise the course content. Feedback was incorporated into lessons and teaching order and the editorial group convened and reviewed the proposed changes.

Changes considered are: feedback and questions from students, additional information needed, order of lessons, very long topics divided, and updates within the field and landscape of medicines development and approval.

Modules are released sequentially, as with version 1 of the course participants are to complete modules 1, 2, 3 and half of 4 and 5 before participants attend the first face-to-face event. Participants must complete further lessons from modules 4, 5, and 6 before attending the 2nd face-to-face event.

6 Public release of Expert Training course

The Patient Expert training course will be made available for public release under the terms of 'Creative Commons Public License, Version: Attribution-Non Commercial- ShareAlike 3.0 Unported'. More details in the license terms can be seen in the document included in **the Annex 4.**

The license is granted to the third party as a worldwide, royalty-free, non-exclusive license for the duration of the applicable copyright to use the information (the Work). The key elements and the restrictions of the license grant are detailed below:

License grants rights:

a) to reproduce the Work and to incorporate the Work into one or more Collections
b) to create and reproduce adaptations provided that any such adaptation, including any translation in any medium, takes reasonable steps to clearly label, demarcate or otherwise identify that changes were made to the original Work
c) to distribute and publicly perform the Work, collections including the Work and adaptations of the Work.

These rights may be exercised in all media and formats, and include the right to make modifications technically necessary for other media and formats.

License restrictions:

a) the license is granted directly to each interested party desiring to make use of the Work, thus, the Work may not be sublicensed.
d) a copy of the license or its Uniform Resource Identifier (URI) must be included with every copy of the Work distributed. All references to the license must always be kept intact in every copy of the Work distributed.
e) the rights granted may not be exercised in any manner that is primarily intended for commercial advantage or monetary compensation.

f) when distributing the Work or any adaptations, the user of the Work must keep intact all copyright notices for the Work and provide: (i) the name of the original author; (ii) the title of the Work; (iii) the URI, if any, that is associated with the Work and, (iv) in the case of an adaptation, a credit identifying the use of the Work in the adaptation.

7 Annexes

7.1 Annex 1: EUPATI Syllabus

Title of module	Syllabus number	Lesson Number (M = module, L = lesson)	Syllabus Topic	Learning Outcome
Learning outcomes module 1: 1A Explain the importance and describe the possible role of patients/patient organizations in medicines development 1B Describe the process of drug discovery and development and identify the critical factors and decision points, including patenting, and drug development in special populations 1C Describe the background to the development of regulation of medicines and the roles of the various stakeholders 1D Discuss the role of biomarkers in drug development 1E Discuss the potential application of the concept of personalized/stratified medicine in the medicine development process 1F Discuss the role of translational research in drug development 1G Outline the concepts of evidence based medicine and outcomes research 1H Describe predisposing factors and underlying mechanisms of disease and the different types of medicines and their mode of action				
Module One:	1	M1L2	Health and Disease	1H
Discovery of Medicines & Planning of Medicines Development	2	M1L5	Basic Principles of medicine discovery and development	1B, 3E
	3	M5L19	The concepts of incidence and prevalence	1B
	4	M1L7	Needs for development of new medicines for special populations	1A

Title of module	Syllabus number	Lesson Number (M = module, L = lesson)	Syllabus Topic	Learning Outcome
	5	M1L4	Types of medicines, their mode of action and use	1H, 1B
	6	M3L4	The concept of stratified (personalised) medicine	1E, 3C
	7	M1L8	The concept of efficacy and safety of medicines	1B
	8	M1L9	The concept of evidence-based medicine and outcomes research	1G
	9	M1L11 F2F1	Types of collaborations in medicines discovery and development	1A, 1C
	10	M1L12 M3L10 M6L3 F2F1	Roles and relationships of stakeholders in medicines development	1A, 1C
	11	M1L3	Underlying mechanism of disease	1H
	12	M1L10	Patenting of new chemical and biological compounds	1B
	13	M1L6	Principles of translational medicine. Relationship between animal and human pharmacology, molecular biology and physiology e.g. biomarkers, functional imaging, modelling and simulation	1F
	14	M1L12 F2F1	What is patient advocacy?	1A

Learning outcomes module 2: 2A Illustrate the choice and predictive value of the non-clinical testing programme as part of the overall medicine development plan (including scheduling of toxicology tests with respect to clinical trials).for chemical and biological compounds 2B Describe the non-clinical development steps of medicines, explain the milestones a compound needs to go through during non-clinical development in order to progress to the next phase	

2C illustrate non-clinical outcomes that can stop the development of a medicine 2D Discuss the need and requirements for pre-clinical studies prior to First-in-Human studies and the purpose of animal testing. (including toxicology, pharmacology, non-clinical safety studies) 2E Outline the steps in the medicinal development of a medicines substance and final medicines product (including chemical and biological compounds) 2F Based on the understanding of the blinding process, Identify ways in which you as patient advocate can contribute to the choice of blinding mechanisms 2G Outline differences in generic development vs. classical drug developments 2H Describe guidelines for the use of generics				
Title of module	**Syllabus number**	**Lesson Number (M = module, L = lesson)**	**Syllabus Topic**	**Learning Outcome**
Module Two Non-Clinical Testing and Pharma-ceutical Develop-ment	15	M2L1	Basic principles of non-clinical development	2A, 2B, 2C
	16	M2L2	The predictive value of non-clinical testing	2A, 2D
	17	M2L3	Basic concepts and requirements of development of galenic formulations	2E
	18	M5L9	Requirements for generics and biosimilars	2A, 2E, 2G, 2H 2I
	19	M3L8	The concept of bioavailability and bioequivalence	1B

Learning outcomes module 3: 3A Define intended therapeutic indication, its limitations and criteria for "go" "no-go" decisions and its final description 3B Describe the early clinical development plan and clinical study types (phases) and their objectives beginning with "first in human" and the different ways in which Patients/POs can contribute 3C Critically appraise the role of pharmacogenetics / pharmacogenomics in the development of medicines and discuss the ethical challenges 3D Outline the basic principles of pharmacokinetics and their application to dose-finding and in subsequent phases of drug development 3E Define Life Cycle Management of a medicine, its purposes and possible approaches via post marketing trials 3F Evaluate and compare the emerging techniques in specific product development or disease areas 3G Discuss the advantages and critical aspects of global coordination / harmonisation of clinical trial programmes before and after marketing authorisation				
Title of module	**Syllabus number**	**Lesson Number (M = module, L = lesson)**	**Syllabus Topic**	**Learning Outcome**
Module three	20	M3L1 F2F1	"Exploratory" and "confirmatory" clinical development versus "Phases I-IV of clinical development"	1B
Exploratory and Confirma-tory Clinical Develop-ment	21	M3L2	Definition of intended therapeutic indications, biomarkers, efficacy end-points and criteria for 'go', 'no-go' decisions	3A
	22	M3L6	Assessment of non-clinical data and risk as prerequisites before administration to man	2A
	23	M3L1 F2F1	The early clinical development plan: the objectives, designs including minimisation of bias, conduct and analysis of early exploratory development studies, incl. role of POs	3B

	24	M3L7	Principles of pharmacokinetics, ADME (absorption, distribution, metabolism and excretion) and pharmacodynamic models	1B
	25	M3L3	Pharmacogenetics/Pharmacogenomics	3C
	26	M3L6 M3L7	Applicability of pharmacokinetics to dosage regimen and study design	3D
	27	M3L6	First administration to patients: principles of proof-of-concept/proof of principle and dose-finding studies	3B
	28	M3L11	Overview of techniques involved (e.g. – omics)	3F
	29	M3L2 F2F1	The concept of biomarkers	1D

Learning outcomes module 4: 4A Outline the key strategic and operational issues in the clinical trial process, including legal, regulatory, & practical aspects and the possibilities of collaboration of different stakeholders 4B Appraise the principles and practical relevance of ethics in clinical research and the role patients can play e.g. in ethics committees 4C Explain and demonstrate the clinical trial approval process including the required documentation and the possible role of Patients/POs and provisions for special/vulnerable patient populations 4D Describe the main statistical methods used in clinical research 4 4F Describe the principles of data management and the associated study documentation and quality measures in clinical trials 4G Appraise the relevant aspects of patient compliance for study medication including its labelling, handling 4H Critically evaluate the content of clinical trial websites and their use in identification of trials in your disease area. (Including reporting of adverse events) 4I Differentiate types of clinical trials and their design, and Good Clinical Practice (GCP) 4J Discuss all aspects of the interpretation, publication and communication to patients of all clinical trial results				
Title of module	**Syllabus number**	**Lesson Number (M = module, L = lesson)**	**Syllabus Topic**	**Learning Outcome**
Module Four	30	M4L13	Investigator Brochure: content, review and maintenance	4C
Clinical Trials	31	F2F1	Stakeholder's role in organisation of a clinical trial	4A, 4I
	32	M4L2	Ethical issues in medicines development	4B, 4C
	33	M4L2	Ethics: history	4B, 4H
	34	F2F1	Where can patients find information on clinical trials – EUCTR – EU Clinical Trials Register and clinicaltrials.gov (FDA)	4B, 4C, 4H

	35	F2F1	Review of protocol content	4A, 4B, 4C, 4D, 4I
	36	M4L11	Principles of new trial designs e.g. adaptive design and their practical implications	4A, 4I, 4C, 4D
	37	F2F1	Non-interventional / observational study objectives and designs	4I
	38	F2F1	The role of patients in feasibility for investigator selection and recruitment planning The role of patients in investigator site feasibility, investigator selection and recruitment planning	4B, 4C
	39	M4L20	Basics of quality management in clinical trials	4A
	40	M4L19	Principles of clinical project management	4A
	41	F2F1	Collaboration models between academic groups and commercial sponsors, investigators and patient organisations in protocol preparation and review, informed consent process, patient recruitment and retention	4A, 4B, 4C, 4I
	42	M4L1	Approval process of clinical trials in different European countries by regulatory authorities	4B, 4C
	43	M4L3	Ethical review process by ethics committees and the potential role of patients	1A, 1C
	44	M4L14	Involvement of participants in clinical trials, incl. advertisement, recruitment, informed consent process, risk/benefit assessment, justification of burden, enrolment and protection of study subjects and the role of patient organisations	4A, 4B, 4C, 4E

	45	M4L12	Ethical and practical challenges in organising clinical trials in small populations (rare diseases, paediatric), personalised medicines	4B, 4C, 4D
	46	M4L3 M4L2 M4L12	Special information and enrolment conditions for vulnerable populations like children, mentally incapacitated adults, unconscious patients, patients in emergency situations and patients in emerging countries	4B, 4C
	47	F2F1	Relevant aspects of clinical trial organisation at the investigator site including management of patient visits and assessments	4B
	48	M4L16	Patient rights and obligations and the role that patient associations can play	4B, 4C
	49	M4L17	Subject damage compensation schemes	4E
	50	M4L17	Subject compensation and travel expense reimbursement	4B, 4C
	51	M4L18	Within-trial decisions,	4E
	52	F2F1	Relevant aspects of study medication handling and subject compliance assessment	4G

	53	F2F1	Relevance of patient safety reporting, concept of safety assessment and safety classification of events	4E
	54	M4L22	Concept of study documentation	4F
	55	M4L21	Options for data management and collection and patient-reported outcomes	4F
	56	M4L4	The purpose and fundamentals of statistics, incl. basics of hypothesis testing: the null hypothesis, Type I and Type II error, significance, power, confidence intervals	4D
	57	M4L5	Principles of sample size calculation	4C, 4D
	58	M4L10	Relevance of the Statistical Analysis Plan: statistical analysis of efficacy end-points and of safety data; interim analysis	4D
	59	M4L8	Interpretation of analyses; assessment of violations, withdrawals, errors, bias, risks of data manipulation, transformation and merging	4J
	60	M4L9	Clinical interpretation of trial results (Clinical significance vs. statistical significance)	4E, 4J
	61	M4L7	Critical review of clinical study report, publications and communication of study results to patients	4E, 4J
	62	M4L15	Fraud and misconduct in clinical research and development	4J
	63	M4L6	The concept of blinding in clinical trials	2F

1.1.1.1 Module 5 – Regulatory Affairs, Medicinal product Safety, Pharmacovigilance and Pharmacoepidemiology

Learning outcomes module 5: 5A Critically review the current EU regulatory requirements (pre and post-authorisation) for a medicinal product 5B Critically evaluate the pharmacovigilance of a medicinal product and the role of the various stakeholders 5C Discuss the various aspects of shortages of medicines and the role the different stakeholders 5D Discuss the role and importance of Regulatory Agencies and other stakeholders in particular patients/patient organizations throughout the lifecycle of a medicinal product 5E Describe the provisions of (1) off label use (2) compassionate use and (3) controlled medicinal products at a national and EU level 5F Outline the legislative background and review processes product information 5G Explain the role of different organizations in the development and implementation of regulatory legislation in Europe 5H Critically discuss treatment compliance and comprehension 5I Locate and navigate regulatory agencies' websites and sources of information on medicinal product interactions				
Title of module	**Syllabus number**	**Lesson Number (M = module, L = lesson)**	**Syllabus Topic**	**Learning Outcome**
Module 5 Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmaco-epidemio-logy	64	M5L1	Background to and general principles of medicines regulation,	4C, 4E, 5A
	65	M5L2	Principles of regulatory oversight and contribution of international bodies and competent authorities	4C, 5A

	66	M5L3	Principles of the development of regulatory legislation	4C
	67	M5L7	Principles of "GXP"	4C
	68	M5L1 M5L2 M5L3 M5L4 M5L5 M4L1	Regulatory affairs as integral part of medicines development	5A
	69	M5L8	Principles of the approval, appeals and referrals processes and maintenance of Marketing Authorisations for medicines in Europe	5A, 5E
	70	M5L4	Regulatory concepts and applicable legislation for approval of orphan medicinal products, paediatrics, advanced therapies, generics, biosimilars and medical devices and role of patient organisations	5A
	71	M5L5	Principles of preparation and submission of marketing applications	5A
	72	M5L6	Product Information to the public and involvement of patients organisations	5D, 5F
	73	M5L14	Concept of prescription-only and over-the-counter medicines; switches	4C
	74	M5L15	Provisions for and use of unlicensed medicines, incl. Off-label use, compassionate use, and misuse	5E
	75	M5L15	Controlled medicinal products, medicinal product abuse and dependence	5E
	76	M5L16	Implications of product shortages	5B, 5C

	77	M5L17	Concept of pharmacopoeias	5B
	78	M5L11	Principles of risk management.	5B
	79	M5L12	Handling of safety signal detection, interpretation and management	5B
	80	M5L12	The role and regulatory responsibilities of sponsors, investigators and patients in medicinal product safety and pharmacovigilance pre- and post- marketing, incl. spontaneous reporting: development safety update reports (DSURs), and Periodic Safety Update Report (PSURs) European Database on suspected adverse medicinal product reactions	5B
	81	M5L13	European Database (Eudravigilance)on suspected adverse medicinal product reactions	5I
	82	M5L18	Medicinal product adherence, compliance, and comprehension	5B, 5H, 5I
	83	M5L20	Principles of Pharmacoepidemiology	5B
	84		Navigating EMA and national competent authority websites	5B, 5I
	85	M5L21	Basic principles of risk communication	5B
	86	M5L22	Safety communication	5B
	87		Communicating to the public from competent authorities	5B
	88	M5L23	Advertising and information to the public and to health professionals: regulation, promotional material, incl. claims, ethics, control and approval, sponsored meetings (pre- vs. Post-marketing)	5F
	89	M5L24	Information to the public and to health professionals in industry and Patient organisations	5F
	90	M5L25	Direct healthcare professional communication	5F

	91	M1L7	Prescribing for special populations e.g. children, elderly, pregnant and breast-feeding women, patients with renal or hepatic impairment	1C
	92	M5L26	Codes of Conduct for the interaction between Patient Organisations and Pharmaceutical Industry	5B
	93	F2F1	Role, opportunities and risks of print media, social media and websites in communicating with patients and between patients	
	94	M5L10	The Paediatric Investigation Plan including paediatric formulation development: regulatory concept, content development, practical implications for the overall medicines development	1C

Learning outcomes module 6: 6A Describe what 'health technology', 'Health Technology Assessment', 'economic evaluation' are. 6B Understand Why HTA and Health Economic is important for health policy 6C Outline the fundamentals of what a 'good' HTA process looks like 6D Identify principles applicable to structuring and governing HTA organizations 6E Understand how patients can get involved in the HTA process and formulary decision) 6F Have a general understanding of what 'good' clinical benefit assessment, economics evaluation, and ELSI analysis looks like 6G Understand what type of information contributes to a better understanding of clinical benefit (e.g., randomised trials) 6H Understand differences in clinical information requirements for patients, payers, and regulators 6I Identify the main HTA agencies in Europe and their different approaches to evaluating medicine and health technologies 6J Understand the role of evidence-based medicine and how this relates to HTA in European agencies 6K Describe specific opportunities for patients in key agencies across Europe 6L Understand the concepts of quality of life, health-related quality of life, and patient-relevant outcomes and how these concepts are measured 6M Understand where patients can apply these to the HTA process and formulary decision in their country 6N Outline the difference between quantitative and qualitative research 6O Understand the principles, practical application and importance of patient reported outcomes in developing the evidence				
Title of module	**Syllabus number**	**Lesson Number (M = module, L = lesson)**	**Syllabus Topic**	**Learning Outcome**
Module Six: HTA principles and practices	95	M6L1	Introduction to Health Technology Assessment	6A,6B
	96	M6L4	Framework and key principles of Health Technology Assessment (HTA)	6C,6D,6E

	97	M6L5	Overview of HTA including clinical benefit assessment, economic evaluation, as well as Ethic, Legal and Social Implications (ELSI)	6F
	98	M6L6	Advanced clinical benefit assessment	6G,6H
	99	L6M2	Overview of main HTA systems in Europe	6I,6J, 6K
	100	M6L9	Concept of outcomes research and health-related quality of life (HrQoL). Overview of approaches to measure these	6O,6M
	101	M6L8	Patient Reported Outcomes (PRO) assessment and its role in supporting product development	6L
	102	M6L10	Quantitative and Qualitative research	6N
	103	M6L3 M6L7	Beyond HrQoL and PROs: Other sources of patient evidence	6O

7.2 Annex 2 EUPATI Writing / Editorial Guidelines

Guidelines for authors

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

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.

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.
- 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 40-50% 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.

B. Editorial Guidelines

Expert Reviewer Guidelines

EUPATI expert reviewers are responsible ensuring that EUPATI can deliver the highest quality product to the audiences we serve. Reviewers should ensure that EUPATI educational material is factually accurate, presents information without bias, and covers all important points required to effectively educate on a topic.

Please refer back to the learning outcomes for the module and the key topics identified and ensure they are covered, where they are not, this should be provided as feedback to the author for correction. If you have further resources or references that can be used to support and expand the education material please make note of these via comments in the document. Please use track changes in the documents provided to you.

Checklist of items to be addressed
All EUPATI educational material should be:

Objective
Information is objective when it is based on facts and not influenced by prejudices or personal/organisational perceptions. Educational material should be unbiased; it is unbiased when it is impartial, non-directive and balanced. Please note if external material referenced or referred to also meets this standard, if it does not, is it being used appropriately and transparently?

Evidence-based
The evidence base for any information resource needs to be clearly stated, including making clear the level of evidence. Information should be verifiable, based on comparisons and backed up by scientific peer review where possible. Educational material should be comprehensively referenced.

Up-to-date
Information should reflect the current practiced in medicines development and those that will come into effect in the near future, it should be clear to the reader what practices are current.

Reliable
Information needs to be factually correct and not misleading. Information should be scientifically valid and reflect latest knowledge.

Understandable
Information provided should be comprehensible for someone without a scientific background, EUPATI material aims to be understandable for someone with a reading age of 16 years old.

Transparent
This includes transparency of what is known as well as what is not known. Funding, sources of information, evidence for that source and transparency when there is known controversy about a particular subject, for example, all need to be made clear.

Patient-oriented
EUPATI educational material is aimed for use by patients and patient advocates. Information provided should be patient focused by clearly demonstrating where patient involvement takes place in the medicines development process.

Relevant

Information should include issues of relevance and importance to patients' decision-making and input into medicines development.

Consistent with Statutory Information
Information not regulated by statute should, nevertheless, be consistent with the legal requirements of European law (e.g. must not be designed to promote a medicine, reflecting the prohibition of direct to consumer advertising of prescription only medicines, must not be misleading etc.) and should refer, where appropriate, to statutory information approved through the process of regulation. Named medicines may only be used as part of case studies.

C. Luto editorial guidelines

General observations

Glossary terms / Technical language

Throughout the training topics, there is a requirement to include some level of technical language so that the trainees can learn about industry relevant terms. There were various comments from EUPATI reviewers that reference the EUPATI glossary and in some topics, hyperlinks were included to the glossary.

Luto suggestions:

- Where possible, it is of preference to include the explanation of the term in the topic, to ensure that the reader understands what it means in context. In most cases, this is possible and can be evidenced through Luto's suggestions. However, it does mean that the explanations are sometimes repeated across different topics. This probably isn't an issue as it acts as a reminder and consolidates learning.
- If referencing out to the EUPATI glossary is something you would like to do, it would be best if all relevant terms are represented.
- Use of 'call-out' boxes might be a useful alternative (this depends on functionality of the electronic training system) – i.e. where the trainee could hover over or click on certain key terms to show more information (or the definition) on the screen.

Structure of training topics

- Some topics contained learning objectives and quizzes. Learning objectives would be something that would be useful for the reader – consider including brief learning objectives consistently across the topics.

References

- Most documents included some references, either topics or articles in footnotes, or had a link to the reference page. This probably depends on the authors individual preferences.

Diagrams

- Ensure these are clear when presented in e-learning format. Where possible, it is good to align these, however may not be possible where diagrams are sourced externally.
- Source attribution of images – for copyright purposes, any copies from other sources should be referenced.

Stylistic changes

Structure of information

- Contents list added at start of document – this was already present on some documents and is considered a useful tool to aid the reader in understanding what each section of the training will cover.
- Section numbers added where not already present to highlight structure of each section of the training.
- Additional section headings added where considered necessary.

- Some paragraphs of text broken down into bullet points so that it is easier for the reader to digest the information. Round bullets used where possible as these are more visually apparent than other styles, such as dashes. Where multi-level bulleted list are used, consider use of bullets that are distinct, but still obvious to the reader.

Content

- Sentences shortened, where possible. Words replaced with words that are easier for a 'lay' reader to understand but ensured that technical terms are not removed completely, rather explained within the document.
- Explanation of key terms included in document rather than relying on the reader's use of a glossary.
- Use of single quotation marks, rather than double, throughout all documents for consistency.
- Quotation marks used to highlight first mention of a new or more complicated term within each document. No quotation marks on subsequent mentions of the same word.
- Acronyms spelt out in full for first mention in each module section. Not written in full again within same document.
- Phase I, II, III rather than Phase 1, 2, 3 (roman rather than Arabic numerals)
- Number style amended for consistency to 10.000 rather than 10 000 or 10'000 – EU format.
- When describing a range of numbers, i.e. 200 – 300, use 'to' rather than a dash for clarity.
- Tables, figures etc. labelled consistently, i.e. 'Figure X: description'.
- American spellings removed as intended for EU audience, i.e. randomi**z**ed changed to randomi**s**ed.
- Bold highlighting for emphasis – used sparingly so as not to lose its effect. Some suggestions to remove or add bold for particular words.
- Sentence case used over title case for headings, in general.

Words or phrases that are 'preferred' or should be used for consistency:

- 'Medicine' not 'drug' or 'medicinal product', except in the case of ADR and similar, or in the specific case of "candidate drug")
- 'health event', not 'health status'
- 'healthcare' as one word
- 'clinical trial' rather than 'study'
- 'non-clinical' in preference to 'pre-clinical', as this development can be carried out during the life cycle of a medicine. The term non-clinical is more inclusive.
- When talking about treatment 'patient' otherwise 'person living with'
- ICH are 'guidelines' not 'regulations'
- use 'participants' in a clinical trial rather than subjects.
- use 'doctor' not 'GP' or 'physician'
-

Words or phrases that are used interchangeably but where this is considered to be acceptable:

- Disease vs. condition vs. problem

Words or phrases that are presented in title case / capitalised across all documents:

- **S**tudy **P**rotocol
- **P**hase X
- **R**egulatory **A**uthorities

Style guidelines:

- UK English spelling
- Harmonisation of diagrams
- Language style to be harmonised
- Common facts and figures (e.g. Time and cost of medicines development)
- Monetary terms (should be in Euro and Pounds)
- Neutrality is important and to be maintained throughout – with respect to language used/content/ etc.
- Technical terms consistent throughout and lay terms then technical terms
- Learning outcomes – at the beginning of presentation
- Add links to references (e.g. directives and guidelines)
- Direct to explanatory notes
- Consistency check and flow between topics
- Check that the author stays on point
- Where ever possible give external references
- International conference ON harmonisation (ICH)
- Use 'adaptive pathway' instead of 'adaptive licensing' (EMA change, Dec 2014)
- Any FDA and other regions reading material should be listed in further reading
- 'member states' should be lowercase
- Use capital letters for protein and gene names. Do not use italics for enzymes
- 'EUPATI' should be capitalised (not Eupati)

7.3 Annex 3: Face-to-Face training course #1 – premarketing authorisation

Programme Face-to-Face Training Event 1
March 29 – April 2, 2015. Front-Marítim Hotel, Passeig García Faria 69-71 Barcelona, 08019 Spain

Sunday March 29, 2015
EUPATI and you

Time	*Session & Meeting room*	*Topic*
15:00 15:15	Welcome Grand Forum B	Introduction to EUPATI
15:15 15:45	Plenary Session Grand Forum B	Summary of outcomes from the online forum discussions
15:45 17:00	Round Table Grand Forum B	Participants to introduce themselves
Session 1: Introduction to Evidence Based Medicine		
17:00 18:00	Small group session	Evidence Based Medicine
19:00	Welcome Dinner	Barceloneta Restaurant *We will all meet in hotel lobby to take the bus to the restaurant. The bus will depart at 19:00. The Bus will return to the hotel at 21:30*

Monday March 30, 2015
Evidence based medicine, clinical trial methodology and statistics in clinical trials

Time	*Session & Meeting Room*	*Topic*
08:30 08:45	Introduction Grand Forum B	Presentation of the programme
Session 1: Introduction to Evidence Based Medicine (continued)		
08:45 10:15	Interactive lecture Grand Forum B	Introductory overview of medicines development process
Coffee Break 10:15-10:30		
Session 2: Clinical Trial Methodology		

10:30-12:00	Interactive Lecture Grand Forum B	Introduction to Clinical Trial Methodology
LUNCH 12:00-13:00		
13:00 14:15	Small group sessions	Clinical trial methodology
Session 3: Statistics in clinical trials		
14:15 15:30	Interactive Lecture Grand Forum B	Understanding the use of statistics in clinical trials
Coffee break 15:30 -15:45		
15:45 16:30	Small group sessions	Statistics in Clinical Trials
16:30 17:00	Wrap up Session Grand Forum B	Summary of Q and A

Tuesday March 31, 2015
Ethics, Regulatory Frameworks and Marketing Authorisation

Time	***Session And Meeting Room***	***Topic***
Session 4: Ethical principles		
08:40 08:45	Opening Grand Forum B	Daily Overview
08:45 09:45	Interactive Lecture Grand Forum B	Ethics in clinical trials
09:45 10:55	Small Group Session	Ethical Principles Introduction to Ethics Session Mock ethics committees (2 in parallel)
Coffee Break 10:55 to 11:10		
11:10 12:00	Small Group Session	Ethical Principles Introduction to Ethics Session Review of protocol

Session 5: Regulatory Framework		
12:00 13:00	Interactive Lecture Grand Forum B	Current regulatory framework – new legislations and relevance to stakeholders in medicines development.
LUNCH 13:00 -14:30		
Session 6: Marketing Authorisation		
14:30 15:30	Interactive Lecture Grand Forum B	Description and importance of different marketing authorisations available
15:30 16:30	Small Group Session	Marketing Authorisation
16:30 17:00	Wrap up Session Grand Forum B	Summary of Q and A

Wednesday April 1, 2015
The role of patients within European Regulatory Authorities

Time	***Session & Meeting Room***	***Topic***
Session 7: European Regulatory Authorities		
08:55 09:00	Opening Grand Forum B	Daily Overview
09:00 09:30	Interactive Lecture Grand Forum B	Introduction to the EMA and its Committees
09:30 10:00	Interactive Lecture Grand Forum B	Patients and the European Medicines Agency. Patients and Consumers' Working Party (PCWP)
10:00 10:45	Interactive Lecture Grand Forum B	The EMA Committee for Orphan Medicinal Products (COMP)
Coffee Break 10:45 – 11:00		
11:00 11:30	Interactive Lecture Grand Forum B	The EMA Committee for Advanced Therapies (CAT) Personalised/stratified medicine
11:30 12:00	Interactive Lecture Grand Forum B	The EMA Paediatric Committee (PDCO)

12:00 12:15	Short video screening Grand Forum B	The EMA Scientific Advice Working Party (SAWP)
12:15 12:45	Interactive Lecture Grand Forum B	The EMA Committee for Medicinal Products for Human Use (CHMP)
LUNCH 12:45-13:45		
Session 8: Product information, medical marketing & market access		
13:45 15:15	Interactive Lecture Grand Forum B	Training on review of product information
15.15 16.15	Interactive Lecture Grand Forum B	Critical review of medical marketing and market access approaches
16:15 16:30	Wrap up Session	Summary of Q and A
16:30 18:30	PRESS Conference led by Rob Camp in Forum A (Participation is optional)	

Thursday April 2, 2015
Hands on skills and tools for patient advocates

Time	***Session & Meeting Room***	***Topic***
Session 9: National Implementation		
08:55 09:00	Opening Grand Forum B	Daily Overview
09.00 10.00	Interactive Lecture Grand Forum B	National Competent Authorities: HMA
10:00 11.30	Group session Grand Forum B	Driving patient involvement nationally/internationally
Coffee break included in the room during the session from 10:00 to 11:30		
Session 10: Communication		
11:30 12:30	Interactive Lecture Grand Forum B	Communication to patients and between patients
LUNCH 12:30-13:30		

13:30 15:00	Round Table Grand Forum B	Follow up on outcomes from the event.
14:30 15:00	Closing Remarks Grand Forum B	

Face-to-Face training course #2 - Post-marketing authorisation

Programme Face to Face Training Event 2

Barcelona 14-18 September 2015

Monday 14 September
REGISTRATION AND WELCOME

Time	Activity	Topic
16:00 - 17:30	Registration	Trainees collect training material and badges
17:30 - 18:45	Welcome Note	Update on key EUPATI developments Dissemination and role of the trainees in supporting our outreach effort
18:45-19:00	Programme explanation	Overview of the programme of Face to Face Event 2
19:00 - 22:00	**WELCOME DINNER**	

Day 1 Tuesday 15 September
Benefit Risk Evaluation

Time	Activity	Topic
08:45 - 08:50	Plenary Session	Overview of the day by the daily moderator
08:50 - 09:30	Plenary Session	Latest development in Benefit-risk evaluation
09:30 - 11:00	Break-out session	AHP technique on psoriasis
09:30 - 11:00	Break-out session	Macbeth technique on Multiple Sclerosis

09:30 - 11:00	Break-out session	Discrete Choice Experiment technique on Myeloma
COFFEE BREAK 11:00 - 11:30		
11:30	Report Back Breakout	11.30-11.40 LIONS 11.40-11.50
12:00	**Sessions**	
12:00 - 12:45	Plenary Session	A real case in which industry makes a request for SA
LUNCH 12:45 – 14:00		
14:00 - 15:30	Training	Introduction on how patients can get involved in EMA Training Workshop How to equip yourself as a patient for working in Scientific Advice
15:30-16:00 COFFEE BREAK		
16:00 - 16:15	Plenary Session	Pilot study on patient involvement at EMA Committee for Human Medicinal Products (CHMP)
16:15 - 16-50	Workshop	Case study CHMP Round 1
16:50 - 17.25	Breakout	Case Study CHMP Round 2
16:50 - 17.25	Breakout	Case Study CHMP Round 2
17.25- - 17:45	Report Back	Case study CHMP

DAY 2 Wednesday 16 September
PHARMACOVIGILANCE

Time	Activity	Topic
09:00 - 09:05	Plenary session	Overview of the day by the daily moderator

09:05 – 10.05	Plenary Session	Introduction to Pharmacovigilance
10.05 - 10:30	Plenary Session	Case study Signal detection and management
10:30 - 11:15	Interactive Panel discussion	Role and regulatory responsibilities of sponsors, investigators and patients in medicinal product safety and pharmacovigilance pre & post-marketing
11.15-11.45 COFFEE BREAK		
11:45 12:05	Plenary Session	Risk Communication
12:05 - 12.30	Plenary session	Case study(s) Risk Communication
12:30 - 13:15	Plenary Session	SCOPE project and Patient Expert Consultation
13:15 - 14:45 LUNCH		
14:45- 15:30	Plenary Session	Future developments in Pharmacovigilance
15:30- 16:15	Interactive Panel discussion Q&A session	Future developments in Pharmacovigilance
16.15-16.45 COFFEE BREAK		
16:45- 18:15	Tutoring session	Optional Questions Clarifications on Module 5 topics

Day 3: Thursday 17 September
Health Technology Assessment

Time	Activity	Topic
08:45 - 08:50	Plenary Session	Overview of the day by daily moderator

08:50 - 10:45	Plenary Interactive Session	Introduction to patient advocacy
COFFEE BREAK 10:45 - 11:10		
11:10 - 11:20	Plenary Session	Introduction to the Health Technology Assessment
11:20 - 12:00	Interactive Plenary Session	Application of nine domains of the Core HTA model
12:00 - 13:15	Break-out session on HTA reports	HTA report review
12:00 - 13:15	Break-out session on HTA reports	HTA report review
12:00 - 13:15	Break-out session on HTA reports	HTA report review
12:00 - 13:15	Break-out session on HTA reports	HTA report review
LUNCH 13:15 - 14:45		
14:45 - 15:15	Plenary session	Feedback from the break-out session
15:15 - 16:00	Plenary session	Determining the value of a new therapy
COFFEE BREAK 16:00 -16:30		
16:30 - 17:30	Plenary Panel discussion	Health Technology Assessment: Early Dialogues

Day 4: FRIDAY September 18
HTA and Patient Involvement in R&D

Time	Activity	Topic
09:00 - 09:05	Plenary Session	Overview of the day by the daily moderator
09:05 - 09:45	Interactive Plenary Session	Patient involvement in HTA

09:45 - 10:45	Group exercise in Break-out sessions	HTA Patient Evidence
09:45 - 10:45	Group exercise in Break-out sessions	HTA Patient Evidence
09:45 - 10:45	Group exercise in Break-out sessions	HTA Patient Evidence
09:45 - 10:45	Group exercise in Break-out sessions	HTA Patient Evidence
COFFEE BREAK 10:45 – 11:15		
11:15 - 11:30	Plenary Session	Increasing patient involvement in HTA, Ethics and industry R&D
11:30 - 11:40	Interactive Plenary Session	How patients can get involved in the R&D process
11:40 - 12:50	Workshop	Key areas where patients want to be involved in R and D
11:40 - 12:50	Workshop	Key areas where patients want to be involved in R and D
11:40 - 12:50	Workshop	Key areas where patients want to be involved in R and D
11:40 - 12:50	Workshop	Key areas where patients want to be involved in R and D
12:50 - 13.15	Workshop report back	Key themes found in workshop and Q&A
13:15 - 13:30	Plenary	Wrap-up

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8 Document revision history and copyright

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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	Updated Audience 1, added audience 2&3
2.1 03/12/15	Cecilia Carino	Updated Audience 1, cohort 2
3.0	Matthew May	Updated for submission as deliverable
4.0	Cecilia Carino	Adapted

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