



Business Model C-COMEND

Based on Canvas

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Executive Summary

Translational research and medicines development is the continuum of translating basic scientific discoveries to clinical applications as innovative therapeutic, diagnostic or preventive products. The ultimate goal of translational biomedical research is to improve human health—an outcome that benefits the entire society. The interaction of several disciplines is required to translate knowledge. In order to be successful in this continuum, future professionals need to be aware of all development stages and research disciplines at stake in translational medicine and also understand the various roles played by academia, industry and regulatory authorities. The design of an effective curriculum in translational research is a challenge. The program must offer each of its trainees the opportunity to master a combination of scientific and transversal skills that are not taught together in traditional training programs, yet.

The business idea is therefore to support young scientists to develop the skills and competencies crucially needed in order to contribute towards the creation of new medicines. We provide hands-on, ready-to-use learning which complements the academic/scientific background our target population has. During the two year project, curricula for an intensive face-to-face course and a preparatory e-learning module which at the same time is suitable as a stand-alone course have been developed. The learning objectives address the general competencies such as basic knowledge, skills and behaviour considered essential for biomedical PhDs and postdocs involved in translational research, plus the explicit competencies required to perform state-of-the-art translational research.

The following training modules are offered by our business:

1. A joint curriculum for an e-learning course. The e-learning course is offered as an open-access non-moderated e-learning made available to a broad community with an interest in medicines development in general and clinical research in particular.
2. A joint curriculum for an interactive face-to-face workshop for biomedical PhDs and postdocs aiming at a role in translational research and medicines development including both scientific and transversal skills.

1. Product idea

1.1. C-COMEND project objective

C-COMEND was a two-year European training project supported by the Erasmus plus programme, which started on November 1st 2015, with the overall objective of bringing together stakeholders from different sectors and disciplines in order to develop a course aimed at PhD students and early postdocs, teaching the skills and competencies required to successfully contribute to translational research and medicines development. C-COMEND was led by the [European Infrastructure for Translational Medicine \(EATRIS\)](#), the Netherlands and consisted of 4 additional European partners: [Helmholtz Centre for Infection Research \(HZI\)](#), Germany, [Medical University of Vienna \(MUW\)](#), Austria, [Karolinska Institutet, Sweden \(KI\)](#) and [Elevate Health, The Netherlands](#).

Translational research and medicines development refers to the translation of basic scientific discoveries into clinical applications such as new therapeutic, diagnostic or preventive products. Translational research and medicines development thus lays at the foundation of any improvement of human health and quality of life, and is a motor for growth and innovation. In order to be successful in this field, professionals need to be aware of all stages and research disciplines and also understand the various roles played by academia, industry and regulatory authorities. The multidisciplinary, multi-sectorial and transnational nature of translational medicines underlines the need for a defined set of skills and qualifications which learners and professionals can rely on to move freely between different labour markets and countries.

The objective of C-COMEND was therefore to bring together players from different sectors and disciplines in order to develop curricula and provide a course aimed at PhD students and early postdocs, teaching the skills and competencies required to successfully contribute to translational research and medicines development. To ensure that the course indeed teaches the right skills and is relevant for the labour market, be it in academia, industry or the regulatory field, the course curriculum is based on a competency profile which has been developed during the project. The course was delivered as a blended course, where the face-to-face course is preceded by e-learning to bring learners to the same level of understanding, thus allowing more in-depth discussion during the face-to-face course.

The methodology to develop the courses and that will be used to maintain the high quality in the years after the C-COMEND project was the ADDIE principle. ADDIE stands for the steps needed to prepare an effective learning session and was implemented in this project accordingly:

1) During the analysis phase, the project has developed a competency profile for students and professionals in translational research and medicines development. Competency provides a shared “currency” applicable to learning of all types and at all career stages. The profile includes not only the scientific competencies but also competencies in transversal skills and entrepreneurship. The profile is complemented by a competency portfolio where participants can document the new competencies plus the competencies they already acquired during previous formal, informal and non-formal learning, to support the recognition of their competencies.

2) During the design phase, the consortium designed and documented curricula for courses based on the competency profile. The curriculum applies to multi-competency training including student presentations of their projects, which will teach the latest scientific developments but also improve their presentation skills.

3) During the development phase, the course content was designed including learning methods which promote the transfer of course content into observable competencies and cater for different learning styles.

4) The implantation phase consisted of the implementation of the e-learning module and the face-to-face course.

5) The feedback of the evaluation phase was used to optimise the 2nd delivery of the e-learning and face-to-face course.

1.2. Value proposition

Within the two-year project C-COMEND, curricula for an e-learning program and face-to-face workshops have been developed. The value that will be delivered is custom- built blended training, involving a preparatory e-learning module and a face-to-face course. The aim is to empower biomedical professionals to make a difference in translational medicine by understanding the complexity and multidisciplinary ecosystem of medicines development. Training of high quality content and didactic points of view will be provided to solve long-term issues in academia and industry. All courses are provided to maximise the potential audience.

The e-learning course has a student investment time of 10-12 hours. Selected participants for the face-to-face workshop will have to complete the e-learning module before the face-to-face workshops starts. The e-learning course will bring the participants of the face-to-face course to the same level and stimulate the interaction between participants thus allowing more active and in-depth discussion during the face-to-face course. The e-learning content is also freely accessible to

biomedical professionals across Europe and worldwide who are not participating in the face-to-face workshop.

The face-to-face course, takes 5 days and includes an overview about key aspects and decision making processes during translational research and medicines development. The course takes place at research & development sites of pharmaceutical industry and includes lecturers from pharmaceutical industry. This set-up maximises the exposure to the industry research & development process and corporate culture(s).

To ensure that the training meets its objective to be well aligned to the needs and opportunities of the labour market, the course curricula are based on a defined competency profile co-developed with pharmaceutical industry partners.

The hands-on, ready-to-use real-world training has a high practical impact on translational research for biomedical scientists. PhDs and postdocs will develop the skills and competencies crucially needed to contribute towards the creation of new medicines regardless of the discipline and whether they see their future career in academia, industry, or in the regulatory sector. The provided training will support young scientist in their career development as they will strongly profit from labour market relevant competencies and strongly profit from building a network with peers and teachers from academia, research and innovation. Young scientists are still open to new concepts and ideas and more likely to be mobile across sectors and disciplines.

This area of skills and qualifications where learners and professionals can move freely for job purposes or further learning is a strong need due to the multidisciplinary, multi-sectorial and transnational nature of translational research and medicines development.

2. Marketing

2.1 Customer Segments

The target group for the provided training are PhD students and early postdocs in translational research. The training will reach approximately 200 participants per cycle. The face-to-face workshop is designed for 30 participants. These persons will be involved as participants in the face-to-face and e-learning courses. While the e-learning course is open to anybody, the participants for the face-to-face course will be selected by the consortium.

2.2 Competition

Compared to traditional training programmes the development of hands-on, ready-to-use learning including a competency profile for translational medicine, the e-learning course and the face-to-face workshop is a unique approach.

Another workshop tackling translational medicine is the summer school of EUREKA in Utrecht, the Netherlands and their yearly Certificate Course held in Sicily. The target group for these workshops are early stage researchers related to translational medicine. Both the summer school and the certificate course cover the intrinsic difficulties of effective translational medicine in rare and orphan diseases and will give young scientists an insight in real-life science work. Course participants will be informed about the latest developments in translational medicine, inspired by rare diseases, and will develop professional skills that are essential to becoming a translational researcher. (Source: <https://www.utrechtsummerschool.nl/courses/life-sciences/why-translational-medicine-fails--and-what-to-do-about-it>) The summer school nor the certificate course, however, do not take place at a pharmaceutical industry which is one of the main elements of the C-COMEND workshops.

At the Institute for Interdisciplinary Innovation in Healthcare in Belgium, an interdisciplinary programme was developed for early and late stage researchers to provide healthcare stakeholder of the future with a basic knowledge and a holistic vision of the complex processes that translate scientific advances into novel standards of care. This course comprises a series of 5 seminars of 1.5 days each and welcomes master and PhD students as well as Post-doctoral fellows and professionals. Although the course is multidisciplinary and welcomes participants from many different faculties and backgrounds, this course is also not hosted by pharmaceutical industry and do not involve the training of transversal skills.

There are some E-learner providers that offer biomedical training, but none of them have an introductory course in translation medicine, but only very specialised topics on offer (e.g. https://zenosis.com/brands/zenosis/library/zenosis_module_catalogue.pdf)

This demonstrates that rarely any course addresses the whole pipeline, and mostly and mainly adhoc (e.g. courses listed under pharmatrain.eu, on-course.eu etc.)

2.3 Marketing Strategy

During the two year project a solid marketing strategy has been defined and can be further developed to advertise the e-learning course and the face-to-face workshop. The training has been advertised within certain channels, such as social media, websites and email communication and will be further explained in the section “2.4. Channels”.

2.3.1 Marketing Strategy e-learning course

To advertise the e-learning training course a flyer (Illustration 1) has been developed including quotes from participants who attended the first workshop. The flyer was mainly used for email distribution to relevant contacts of the consortium. The large education and training network of the consortium favours to advertise the course quickly to the relevant target groups across Europe and worldwide. The e-learning module was advertised on various online channels, such as LinkedIn, Facebook, Twitter and websites. The flyer was also distributed on relevant conferences. Within the two year project the aim was to reach 200 students completing the e-learning training. In June 2017, 168 participants had been reached. The course has been offered free of charge.

elevate your health knowledge



The Landscape of Translational Medicine

Translational medicine is a discipline in biomedical research that aims to turn observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public. This training course introduces you to key aspects of translational research and medicines development including:

- ✓ A general introduction to translational medicine.
- ✓ Different research and development phases of a new medicine, including the challenges, risks and costs
- ✓ Target validation
- ✓ Predictive models
- ✓ Biomarkers and personalised medicine
- ✓ European regulations in this field

Learning objectives:

By the end of this course, you will be able to:

- ✓ Identify the different steps that are necessary to take a new discovery from the lab to the patient's bedside and back again
- ✓ Describe the characteristics of good and bad preclinical models
- ✓ Give a definition of personalized medicine and biomarkers
- ✓ Sum up the aspects of the process to get a new medicine on the market

What our students say:

Rita Silva:

"The course has been great: the learning units are well designed, the activities are pedagogical, the online platform works perfectly."

Albert Gris Oliver:

"I think it is a great opportunity to have a general view of the drug development procedure. It is very interactive. But the best part is that it is supported by different international organisations: universities, Erasmus+ programme, EATRIS and Elevate Health."

[Visit our course page](#) to find out more about this course.

elevate

Online academy that educates international health professionals, elevating professional knowledge and improving health worldwide.

For whom?

- ✓ PhD students
- ✓ PostDocs

Facts

- ✓ Continuous
- ✓ 2 Weeks
- ✓ 8 hrs/week workload
- ✓ 0 ECTS
- ✓ Online learning
- ✓ English
- ✓ Web lectures, e-modules, mindmap assignments, quizzes
- ✓ Tablet enabled
- ✓ Free course

Course is offered with support of



More info at:

www.elevatehealth.eu

Illustration 1 - Information flyer e-learning created by Elevate health

Moreover, an animation and an interactive roadmap as an advertisement tool have been developed for the e-learning course (<https://www.youtube.com/watch?v=QIOcRYIcels>)

2.3.2 Marketing Strategy face-to-face workshop

The face-to-face workshop has been advertised on various media channels. The main source to advertise the course was the contact list of the consortium by sending regular emails to potential participants and relevant stakeholders. ORPHEUS (represented by Robert Harris, KI) was an important contributor in ensuring that the stakeholder involvement and the recruitment of course participants had a broad outreach to the Central/Eastern European PhD providers. Within the network of Orpheus, a broad network has been reached across Europe (<http://www.orpheus-med.org/index.php/about-us/members-of-orpheus2>).

The following marketing materials have been developed to promote the face-to-face course:


- A YouTube video has been created and reached 340 clicks (July 2017). The video can be found here: <https://www.youtube.com/watch?v=XfXFZVwlqco>. Against a small fee the video can reach an even broader outreach
- An animation video has been developed and an interactive roadmap as an advertisement tool: <https://www.youtube.com/watch?v=QlOcRYlcels>
- A poster has been created for the EMBL Conference on Lifelong Learning in Heidelberg, July 2016 and has been presented during the 3 day workshop (Illustration 2)
- Another poster has been created for the EATRIS Conference, September 2017 in Prague (Illustration 3)
- A flyer has been developed to advertise the face-to-face course on relevant conference and for online advertisement on social media (Illustration 4)
- Newsletters have been sent out to the consortium's education and training community on a regular basis
- Social Media channels, such as LinkedIn, Twitter and Facebook have been used to advertise the course (Illustration 5)
- Relevant information regarding the face-to-face workshop has been shared on various websites, such as EATRIS.eu, lifetrain.eu, and on-course.eu
- Emails to previous attendees of the face-to-face workshop have been sent asking to forward the information to interested colleagues
- A "learners journey" timeline has been sent to selected participants for the face-to-face workshop (Illustration 6)



 **Erasmus+** C-COMEND is funded by the Erasmus+ programme and includes the following partners and supporters:




Illustration 2 - Poster EMBL Conference in Heidelberg, July 2016



C-COMEND: an ERASMUS+ funded project to train the next generation of translational scientists


WWW.EATRIS.EU



C-COMEND is a two-year European training project supported by the Erasmus plus programme, which started on November 1st 2015. The overall objective is bringing together stakeholders from different sectors and disciplines in order to develop a course aimed at PhD students and early Post-Docs, teaching the skills and competencies required to successfully contribute to translational research and medicines development.

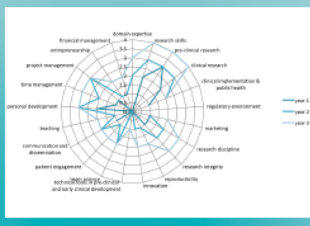
The project has generated 4 different outputs: a competency profile, online and face-to-face courses and a business plan to ensure sustainability of the project.

<https://eatris.eu/c-comend.html>



COMPETENCY PROFILE

A competency profile has been developed to describe the interdisciplinary skills and knowledge that are required in translational research and medicines development. The C-COMEND profile describes the skills and personal qualities in the following categories: Research, Interdisciplinary knowledge, scientific rigor & reproducibility, Innovation & tools, communication and complementary skills. It thus complements competency profiles for specific professions contributing to the medicines development process such as regulatory affairs or industrial pharmacy. The profile was developed with input from a wide range of stakeholders and is now open to stakeholder consultation. The C-COMEND competency profile has also been used to develop the curriculum for a short course Translational Research and Medicine Development targeted at PhD students and early Postdocs.



THE C-COMEND COURSE


The C-COMEND Course consists of an introductory e-learning module followed by a 5-day face-to-face workshop and is intended for late PhDs and early postdocs who are involved in translational research.

FACE-TO-FACE COURSE

The 5-day face-to-face workshop hosted by industry provides participants with the knowledge, philosophy and tools needed in translational research and medicines development, empowering them to make a difference. A drug development board game, elevator pitches, patient stories and interaction from experts in field are some of the learning activities featured in this course.

FREE ONLINE COURSE

The free online course entitled *The Landscape of Translational Medicine* has been developed with experts in the field from Radboud UMC (NL), NIHR/NCATS (US), University of Birmingham (UK), I'MHedix (BE), ECRIN (FR) and industry.



The course is open to anyone interested in exploring themes within the translational medicine field (e.g. biomarker development, target validation, predictive models, regulatory environment). It requires approximately 8 hours of investment time and comprises of a wide variety of learning activities such as lectures, mindmaps, videos, E-modules and quizzes.

WHAT OUR STUDENTS SAY

"All lectures and activities were a real insight into the pharma-industry and what are the actual activities happening and qualities needed if one wants to work in the industry!"


"The speakers were very approachable"


"The e-learning has been great: the learning units are well designed, the activities are pedagogical, the online platform works perfectly"


"I would heartily recommend this course to other PhD students!"


BUSINESS PLAN


To ensure sustainability a business plan was developed, describing how the face-to-face and online courses can be maintained to enable broad participation and reduce costs for participants. As a result of these efforts we can proudly announce a new round of courses in April 2018 in Berlin, Germany. Registration will open soon (<https://eatris.eu/c-comend.html>)














Illustration 3 - Poster for the EATRIS Conference in Prague, September 2017



Call for application: Course on Translational Research and Medicine Development

Empowering scientists to make a difference in translational medicine

The C-COMEND Course is a course consisting of an introductory e-learning (~20 hours student investment time) followed by a 5-day face-to-face workshop. The course is intended for PhD students in the second half of their PhD and early postdocs who are involved in translational research. The course will empower participants to make a difference in translational medicine through inspiration and awareness.

Dates

E-learning course First 3 weeks of November 2016
Face-to-face course 28th November – 2nd December 2016

Location

The course will be hosted by AstraZeneca in Alderley Park near Manchester, UK

Registration (now open)

Apply today to participate (deadline July 31st, 2016)

→ [click here](#) to register

Participants will be selected in August and all applicants informed of the outcome no later than September 1st, 2016

Upon successful completion of the course participants will...

- ✓ have gained a holistic understanding of the medicines development process
- ✓ have met and discussed with experts from academia and pharma at eye level
- ✓ have learned about new approaches in the medicines development sciences
- ✓ have networked with peers from different research areas and countries

Find out more

→ [course video](#)

→ e-learning [video](#) and [demo](#):

→ [C-COMEND web site](#):

→ In case of questions please send an email to ccomend@eatris.eu

About: C-COMEND is funded by the Erasmus+ programme and includes the following partners:



Illustration 4 - Flyer face-to-face workshop

Rebecca Ludwig @RebeccaLudwig2 · May 10
Free #workshop in #transnationalresearch for #PhDStudents #postdocs #Berlin
Apply by 1.June bit.ly/1V8VNHw For speakerlist see pic



Call for application
Free Course on Translational Research and Medicine Development

Dates face to face Course:
9th - 13th October 2017

Location:
Berlin

Speakers include:
Bob Harris,
Professor Immunotherapy, Karolinska
Matthias Gottwald,
Head of R&D Policy & Networking, BAYER

What our 2016 students say
"All lectures & activities were a real insight into the pharma-industry"
"The speakers were very approachable"
"I would heartily recommend this course!"

About: C-COMEND is funded by the Erasmus programme and includes the following partners:



Twitter advertisement

Medizinische Universität Wien hat Helmholtz-Zentrum für Infektionsforschung Beitrag geteilt.
11. Mai · 🌐

Das Helmholtz-Zentrum für Infektionsforschung bietet gemeinsam mit Kollegen des Karolinska Institutet, EATRIS, Elevate Health und der Medizinische Universität Wien einen interaktiven Trainingskurs zu translationaler Forschung und Medikamentenentwicklung für Doktoranden und Postdocs. Der Kurs findet vom 9. bis 13. Oktober 2017 in Berlin statt. Die Teilnahme ist dank Förderung durch Erasmus+ kostenlos. Bewerbt Euch jetzt! 📌



Helmholtz-Zentrum für Infektionsforschung
11. Mai · 🌐

Das HZI bietet gemeinsam mit Kollegen des Karolinska Institutet, EATRIS, Elevate Health und Medizinische Universität Wien einen interaktiven Trainingskurs zu tr...

[Mehr anzeigen](#)



C- COMEND Course: Translational Research and Medicine Development
Empower scientists to make a difference in translational medicine. 9th October – 13th October 2017, Berlin
HELMHOLTZ-HZI.DE

Facebook advertisement

Nancy Rogler posted this



COMEND

Call for application: Course on Translational Research and Medicine Development
Nancy Rogler on LinkedIn
April 12, 2017

[Edit](#) [Delete](#) [68 clicks of your article](#)

LinkedIn advertisement

Illustration 5 - Social Media advertisement

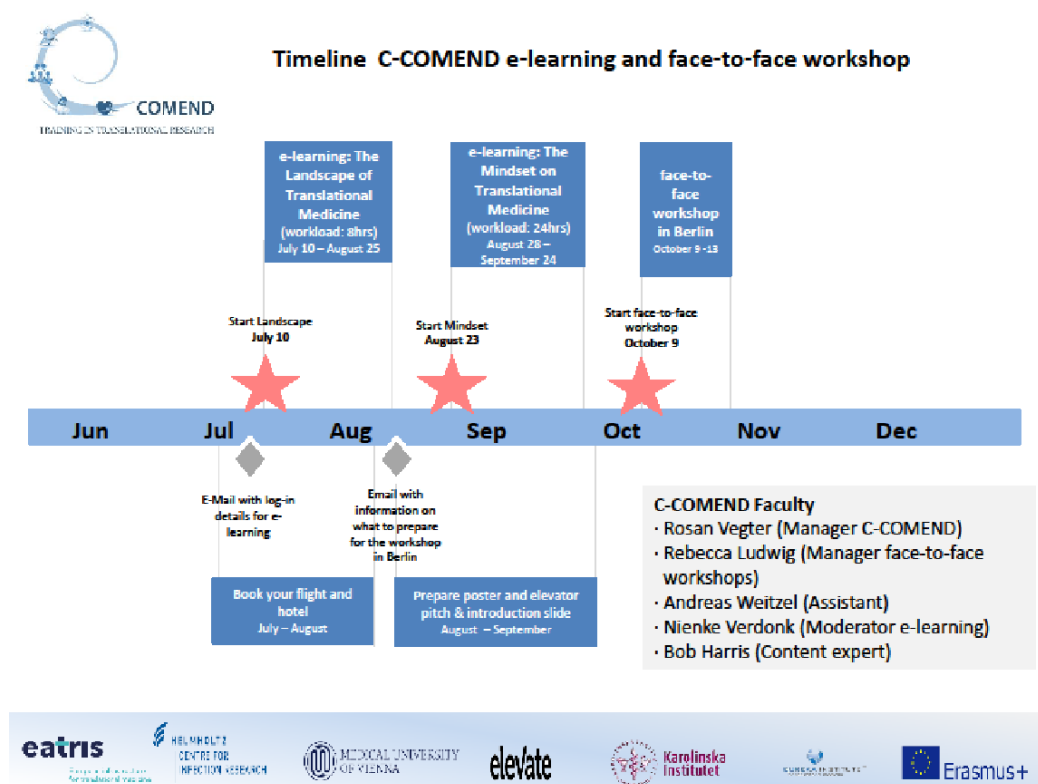


Illustration 6 - Learners journey

2.3.3 Marketing Strategy for prospective e-learning courses and face-to-face workshops

After the official project end of C-COMEND the consortium as such and the relevant contact lists of the education and training community will remain available. However, participants for following face-to-face workshops will have to pay a small fee whereas the face-to-face workshops within the project have been offered for free. Therefore the marketing strategy will be continuously adapted with the support of a social media expert and a communication officer. For the social media campaign, existing marketing material can be used including participant feedback from previous workshops.

An example of such a campaign is the “learner’s journey” (similar to Illustration 6). The learner’s journey is a timeline visualising the tasks, the different workloads and the expectations on participants for the e-learning course and the face-to-face workshop. Interested students will get an idea of what to expect from the training, when the different tasks should be fulfilled and how much work/effort will be required.

2.4 Channels

Information regarding the e-learning course and the face-to-face workshop and the invitation to apply will be sent by email to potential participants and interested stakeholder using the contact lists of the consortium and if available of the host of the face-to-face workshop. Personalised emails to relevant supervisors of PhD students, education and training project leaders and the education and training community asking to forward the information to interested students has proven a successful tool that will be maintained and supported by the advertising material (video, map) . The emails will be sent out 9 months before the course starts with reminders at appropriate intervals prior to the closure of the application, using the partners contact list (estimated 5.000).

Social media (LinkedIn, Facebook, Twitter and YouTube) is another channel that will be used to promote our offered training. Regular news messages via Twitter, LinkedIn and Facebook have been sent out to reach a broad target group. A video informing about our training has been produced and uploaded on YouTube (<https://www.youtube.com/watch?v=XfXFZVwlqco>). More recently, we have developed a whiteboard animation as an advertising tool (<https://www.youtube.com/watch?v=QIOcRYlcels>). The social media advertisement has been used for free; however, there is a possibility to promote the offered training on these channels for a small amount to reach an even broader target group.

Another channel that was used to promote the e-learning module and the face-to-face workshops was via regular new flashes on consortiums websites. During relevant conferences produced poster and flyers have been promoted (see illustrations 1-3).

2.5 Customer Relationships

Our short-term customer relationships will be based on two pillars:

- a. On a virtual basis for the e-learning course
- b. On a physical basis for the face-to-face workshop

For the e-learning course a large group of participants (expected 100 per year) will be connected on a virtual basis. The participants and the consortium will only meet virtually, not face-to-face. However, participants can ask questions and exchange information with other students via the online forum or email communication. The relationship with our customers will be for the time being of the e-learning course (one month). However, students can always contact the consortium via email in case of further questions or assistant.

For the face-to-face workshop a small group (maximum of 30 participants) will be connected on a physical basis for the time being of the workshop (5 days). The students can ask questions directly to the consortium members and to the lecturers. Participants of the workshop can stay in touch with the consortium for content related questions as well as with other student's after the workshop. A LinkedIn group will be established after the face-to-face workshop for the participants to stay in contact and to exchange relevant information.

Students that have successfully completed the e-learning course and the face-to-face workshop will most probably not attend the training for a second round as the content as such will not change. Our customers are therefore one-time customers.

3. Business Organisation

3.1 Team

During the C-COMEND project, a consortium consisting of Rebecca Ludwig (Project Manager at HZI and contact person for any content related questions), Rosan Vegter (Training Manager at EATRIS) and Bob Harris (Professor at Karolinska Institutet) has been built to keep the established training alive and to create a new business after the official end of the funded project C-COMEND.

Rebecca Ludwig was the Education & Training manager for the EMTRAIN project (www.emtrain.eu) which established the Education & Training platform for the Innovative Medicines Initiative, a Public Private Partnership of FP7 and EFPIA; the European Federation of Pharmaceutical companies. Rebecca Ludwig holds a PhD in Microbiology and complements her experience by studying Human Resources Development at the Technical University of Braunschweig. In EMTRAIN Rebecca Ludwig was co-leading the development of a web-based toolkit for trainers on goal-oriented and innovative teaching methods. Rebecca Ludwig is also involved in the LifeTrain initiative (www.lifetrain.eu) for Continuing Professional Development in the biomedical sciences which promotes the use of competency as a shared 'currency' applicable to learning of all types and at all career stages. She was also involved in the organisation of a course on medicines development target at public private partnership PhD students. In addition, she works as a consultant supporting consortia in proposal preparation, reporting or project management.

Rosan Vegter is Training Manager at EATRIS, in charge of coordinating EATRIS training activities, and particularly the training opportunities in translational research, offered by the C-COMEND project.

Robert Harris is not only a Professor within the Centre for Molecular Medicine, a designated translational medicine centre at Karolinska, but also a Central Director of Doctoral Education at

Karolinska Institutet. In this latter role, he works specifically with developing quality control of doctoral education through a variety of teaching and organisational activities, which he also teaches widely at international institutions. In 2014, he was one of two recipients of the KI pedagogy prize, the first to receive it for his contributions to doctoral education. Robert Harris is also President of ORPHEUS, The Organisation for PhD Education in Biomedicine and Health Sciences in the European System which aims to stimulating quality assurance of PhD research and education and strengthening career opportunities for PhD graduates.

3.2 Legal framework

The ownership of the face-to-face workshop and the content of the e-learning course stay within the consortium. Once a potential host is identified a light contract between the consortium and the host will be drafted.

The ownership for the MOOC stays with EATRIS. Elevate health will assure to cover the upcoming year 2018. After this EATRIS is the owner for the MOOC and owns all legal rights that come along with it.

3.3 Key partnerships

For the realisation of our business the following key partnerships have been identified:

1. Key partners for the business realisation are between a host and sponsor for the face-to-face workshops. One key partner already identified is Elevate health for 2018. Elevate health will host and maintain the already established e-learning module. After 2018 EATRIS will own the e-learning course and shall exercise its best efforts to make the Course available to the public, free of charge. The course as such needs no further input as the content has been created during the project C-COMEND. The unmoderated e-learning course will be provided free of charge.

Universities in the field of medicine and the pharma industry, both across Europe, are other key partners for our business realisation. For the face-to-face workshops a host is needed to sponsor the course, in detail the catering, workshop rooms, equipment, administrative support and travel support for the participants. Moreover, lectures are needed for the face-to-face workshops and can be provided by a pharma industry or Universities. Participants will have to pay a fee to attend the workshop which will cover the costs for the workshop partly. However, a sponsor will thus be needed to perform the face-to-face workshops. A potential host can sponsor the workshop once or for a certain timeframe. The details will be clarified in a light contract between the sponsor and the consortium.

2. Key supplier for the business realisation for the e-learning module is Elevate health for 2018 and EATRIS in the following years. EATRIS will own the MOOC and will make the course available to the public, free of charge. The content as such has already been established within the two years' project. Elevate health and EATRIS will maintain the platform and provide the necessary support.

For the face-to-face workshop lectures presenting a selected topic in the field of translational medicine are required. Lectures can either come from Universities, pharma industry or external. The presenter can give a maximum of 180 minutes' talk and will be selected by the consortium. There is no honorarium foreseen for the presenter; travel costs, however, will be covered.

The pharma industry as potential host and sponsor for the face-to-face workshop is another key supplier for our business. The sponsor will provide the necessary equipment for the course and give the participants of the workshop an insight into their working environment.

4. Realisation schedule

4.1 Time plan

A detailed time plan can be found in Annex 2. Briefly, selection of a potential host needs to start 18 month prior to the start of the face-to-face workshop. The date of the workshop should be preferably planned end of fall- beginning of winter. Timely implementation of a website, a registration procedure and promotional materials are needed as well as identifying faculty speakers and the first outline of the programme.

Agenda Overview C-COMEND course “Translational Research & Medicine Development” AZ, Manchester (November 2016)

Monday Helicopter view	Tuesday Target validation	Wednesday Patient focus, Ethics & IP	Thursday Reach the clinic	Friday Helicopter view
	The Extroductor - an innovative medical device <i>Bob Harris</i>	Student Elevator Pitches (2/2) <i>Nancy Rogler</i>	Safety related drug attrition: challenges and opportunities <i>Ruth Roberts</i>	Workshop: Project Management in Pharmaceutical Development Projects <i>Christa Janko & Mike Hardman</i>
	Break	Break	Break	
	Student Elevator Pitches (1/2) <i>Nancy Rogler</i>	What it's like to live with a rare disease? A parent's perspective <i>Chloe Joyner</i>	Developing medicines for children <i>Roslan Vegter</i>	
	Tour to High Throughput Screening Facility	Immunology & Cancer <i>Viia Valge-Archer</i>	Entrepreneurship & Meet & Greet Startup representative	Closing: Personal Learning, next steps <i>Sietske Zegers</i>
Arrival & light lunch	Lunch	Lunch	Lunch	Lunch & Farewell
Welcome AZ & C-COMEND	Validation and use of imaging biomarkers <i>John Waterton</i>	Ethics <i>Sarah Morgan</i>	Competency Group work 1: “Effortless successes” <i>Rebecca Ludwig</i>	
Board Game: From test tubes to tablets <i>Keith Williams</i>	Target validation exercise	Break	Break	
Break	Break	Poster session 2/2 15 posters	Case study: Eteplirsin FDA hearing <i>Tim Moser</i>	
Target Product Profile /TPC & Reverse Planning <i>Mike Hardman</i>	Poster Session 1/2 15 posters	IP <i>Hilde Stevens</i>	Competency Group work 2: “Portfolio”	
Wrap up	Opportunities and challenges in industry/ academic collaboration <i>Jeff Kipling</i>	The Extroductor - an innovative medical device <i>Bob Harris</i>		

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Illustration 7 – face-to-face workshop agenda 2016

4.2 Key resources

The proposed business is a scope driven business. The aim is to provide our value proposition, training, to our targeted customer segment, PhDs and early postdocs in the field of translational medicine. The following section defines the kind of material needed, the kind of equipment required and the types of human resources necessary to establish our business and bringing our value proposition to life.

Our business has only a limited number of seats available for the face-to-face workshop. We can therefore state a clear request for key resources as the demand as such will not increase. Our key resources are directly relevant to the number and type of key activities we engage in. For the e-learning training as well as for the face-to-face workshop the below listed resources are required:

Physical resources:

For the e-learning course a functional platform provider, is needed to keep the already established e-learning platform alive. EATRIS will own the MOOC and make it available to the public free of charge. For the face-to-face workshop, detailed requirements are listed in Annex 1 (SOP). Most

importantly, the workshop room needs to accommodate for at least 25 participants and a maximum of 30 participants, 3 consortium members and the lecturer. Moreover, a speaker as well as microphones, a beamer and a blackboard are required. The room as such needs to include chairs and tables which are not fixed and can be moved freely. Furthermore, additional space is needed for the poster session during the course, accommodating up to 15 posters at a time and enough space for 30 participants to freely move around during the poster sessions. Before and during the workshop certain inventory is required such as paper, a printer, pins for the posters and a laptop for the workshop presentations. For further details please see Annex 1 “SOP”.

For interested students and potential participants taking notice about the face-to-face workshop and the preparatory e-learning module, a large distribution network across Europe is required. The consortium team as well as the sponsor will use their contacts to advertise the offered training. For the face-to-face workshop a minimum of 25 participants and a maximum of 30 is our aim. For the e-learning at least 200 interested people can participate.

Intellectual resources

These are the non-physical, intangible resources such as our partnerships and our customer knowledge. Being able to provide any kind of training, e-learning or face-to-face, certain partnerships need to be established. For the face-to-face workshop a yearly or permanent partnership with a potential sponsor will be generated. Moreover, certain short term partnerships with the lectures for the face-to-face workshop will be established for the duration of the workshop. During and after each course the face-to-face workshop participants are asked to fill out a feedback form related to the course content, the individual lecturers, general workshop related questions as well as meeting venue and catering, to enable improvement of the course (curriculum). The detailed survey and the results from previous CCOMEND courses can be seen from Annex 3. (“Communication”).

Human resources

The consortium as such is established and suffices to meet the set business requirements. For the e-learning course the responsible IT specialist has been identified, too. For the face-to-face workshop an administrative support will be recruited to help during the organisation of the workshop. For the face-to-face workshop program lectures are needed to give a presentation about a relevant topic. For the 5 day workshop up to 8 lecturers will be asked to give a talk.

Financial resources

Our business is a non-profit organisation. To being able to provide the training, a sponsor is needed for the e-learning and the face-to-face workshop.

4.3 Distribution of tasks

The business team consists of Rebecca Ludwig, Rosan Vegter and Robert Harris. The lead of the business engagements and contact person for all general questions is Rebecca Ludwig. Decisions regarding the content for the e-learning platform and the face-to-face workshop will be made on an equal shared basis. During the face-to-face workshop, all business partner will be present. The distribution of tasks below assumes that the work contracts allow for these commitments. If this is no longer the case the partners will identify alternative solutions.

For all relevant questions regarding the e-learning course Rosan Vegter will be the contact person. Rosan will organise regular TC's between the business partners and write corresponding minutes. As already established during the C-COMEND project the business team will use an online sharing tool for uploading all relevant documents. The consortium will meet face-to-face on a needs basis, to be organised by Rosan. The location can vary amongst preferred locations, flight connections etc. Regular email communication and TC's, however, will be the basic communication tool amongst the business partner. The working experience between the business partners in the past has shown that each partner was able to provide their input on the given deadlines although the communication mainly took place virtually.

Robert Harris will be responsible for the general communication for the business content and contact person for all marketing/ communication related questions.

Rebecca Ludwig will be the contact person for all questions regarding the face-to-face workshop. Rebecca together with an administrative support will organise the workshop, including identifying a potential sponsor for the face-to-face workshop. Rebecca will be the first contact person for the host in all relevant questions. Rebecca will draft the workshop agenda and identify potential lecturers for the face-to-face workshop. Together with the other two businesses members Rebecca will draft the evaluation sheet for the face-to-face workshop participants and prepare the online survey. Rebecca will be responsible for the financial controlling of the business.

All business members will be involved in the contingency planning and financial resource planning. Moreover, it is the consortium to select the participants for the face-to-face workshop. The selection criteria will include a sound and relevant scientific documented in the Europass CV format, a motivation letter explaining the rationale for joining the course and how it links to current and future work, ensuring a fair geographic distribution of participation and dissemination by the participants to

their local networks. The selection will be based on a first-comes- first-serves basis if applicants meet the minimum requirements (point-award system).

Any output (interim or final) will undergo a quality assurance (QA) procedure. This consists of internal and external QA. Internally, the expertise of the partners and feedback of all partners on the output shall ensure a high quality of the outputs. Output drafts will be circulated, improved and approved by the consortium internally. On top of the internal QA, the consortium will call for the support of external experts such as the Life Train group which will provide input on certain outputs. Input and feedback given will be evaluated and respectively included. For the courses the project will define which of the of nine quality standards, developed jointly by the IMI Education and Training projects and supported by LifeTrain's signatories will apply. Course participant feedback forms will be prepared. Since 2011 the project EMTRAIN is an affiliate of ENQA, the European Association for Quality Assurance in Higher Education. ENQA disseminates information, experiences and good practices in the field of quality assurance (QA) in higher education to European QA agencies, public authorities and higher education institutions, demonstrating the importance of quality to this consortium

4.4 Key activities

For the e-learning course the content as such is established. To keep the platform alive maintenance via the e-learning provider is required including hosting of the online tutorial and administrative work. Key activities for the e-learning platform include licensing, hosting, technical maintenance, administration and helpdesk. Content will be evaluated and updated accordingly. Additionally, promotion of the course within the consortium network will be needed several times a year.

For the face-to-face workshop the following key activities are required:

- The consortium needs to define and establish the face-to-face workshop content; find a potential host/ sponsor located in an adequate meeting venue and define a marketing strategy. It is further the consortium to select the participants for the workshop and to evaluate the feedback forms after the face-to-face workshop. Input and feedback given will be evaluated and respectively included for the next workshop.
- Administrative work to support the consortium during the face-to-face workshop organisation.
- Marketing for the face-to-face workshop within the consortium networks and on social media (LinkedIn, Twitter, Facebook) across Europe to reach a broad target group in the field

of translational medicine for PhDs and early postdocs. The sponsor of the workshop will advertise the course in their platforms, too.

- Lectures for the course program of the face-to-face workshop in the field of translational medicine to talk about one specific topic.
- Sponsorship of a pharma industry willing to provide adequate workshops rooms, catering for the whole duration of the workshop (5 days) administrative support and the possibility of a lab tour within the facilities of the company for the participants of the workshop.

A potential host for the workshop needs to (partly) sponsor for the course. Details of host and course requirements are provided in the SOP (Annex 1)

5. Risks, Impacts and Opportunities

5.1 Consortium risk management

The consortium is largely sharing the same goals, values and enthusiasm. They can call upon their own experiences in working in cross-national collaborations and they know and trust each other largely from previous projects with each other. The defined and agreed on working culture builds on openness, mutual trust, responsibility, effectiveness, professionalism and solidarity.

The risks are mainly related to:

- Finances/costs
- Time
- Personnel
- Conflict between consortium members and sponsors

The risk management consist of:

- Identification of risks at the planning phase and the planning of ways to avoid, mitigate or react to it
- Controlling of identified risks during the implementation
- Early identification of new/missed risks by the consortium, the communication of those risks and the joint planning of counter measures

Open communication throughout the business realisation will contribute to avoiding or mitigating the risk of conflict between the consortium. In case conflicts nevertheless occur, a neutral third party

will be identified and involved as a mediator. The risk of staff dropping out for illnesses or career changes is managed by the fact that all consortium members can contribute to each task.

In case a consortium member is not able to work any longer for the business, e.g. due to maternity leave, change of working position or retirement the leaving consortium member will assure to replace the position within time and corresponding qualification of the new team member. In the unlikely case the position cannot be staffed within time, the other two consortium members can take over the role of the third person for a certain period. The consortium members can, however, count on support from their own company, as well. A potential sponsor for the face-to-face workshop can provide personnel for the organisation of the face-to-face workshop, too.

5.2. Product risk management

The consortium has defined certain go and no go criteria for the product risk management. If the consortium cannot recruit sufficient participants for the face-to-face workshop a go or no go decision for the workshop will be made, depending on the actual numbers of interested participants.

The face-to-face workshop is aligned for 30 participants. The break even for the workshop costs is reached when at least 25 participants are registered. In case of less than 25 participants showing interest for the course the consortium together with the potential host will make a go/ no go decision. This scenario will be defined in a light contract between the potential host and the consortium team. A possible solution could be that the sponsor agrees upfront to compensate for the missing income. The condition will be based on at least 20 participants registering for the face-to-face workshop. In the unlikely case that less than 20 participants can be recruited for the training the workshop will be cancelled and an alternative date will be provided. However, the consortium and the sponsor will ensure that there are no conflicts with other major internal activities or events (e.g. conferences) in the city at the same time and examine whether there are concurrent 'competing' PhD conferences around the world.

As the consortium members are aware that recruiting sufficient participants for the courses is critical to success, all members are strongly committed to advertise the courses in their organisation and associated networks. Previous workshops were, however, free of charge and participants only had to compensate their travel costs. Future face-to-face workshops will show if participants are still interested to attend if the participation of the offered training includes a small fee.

Another potential risk is the host cancelling the face-to-face workshop on short notice. The consortium members and the host will agree on a light contract to avoid such a conflict. In case the host has to cancel for any reason it is their responsibility to provide an adequate alternative within the same city on the already agreed conditions. In the unlikely case that the host cannot provide an alternative for the face-to-face workshop, the host will have to compensate for the costs occurred thus far, for the consortium members as well as for the participants (e.g. already booked flights, organisational costs etc.). Moreover, it is the host to provide an alternative date within a 6-month time frame after the actual agreed date for the face-to-face workshop.

5.3. Impacts and Opportunities

The envisaged impact on the course participants is to improve career opportunities and/ or higher employability via the delivery of skills, knowledge and competencies required by the labour market (including transversal skills, entrepreneurship) in academia, industry or the regulatory field. Also important is building a cross-disciplinary, cross-sector and transnational network with other professionals, as well as the ability to use the competency portfolio to document their competencies and to plan further professional development activities. Lastly, support of mobility (between countries and between the public & private sector).

The envisaged impact on the participant organisations is to give organisations the opportunity to train their PhD students and early postdocs with the skills and competencies required by the labour market in translational research and medicines development in academia, industry or the regulatory field. The building a network of organisations in translational research and medicines development that are keen to move education, research and innovation closer together is a second goal, ensuring interaction with pharmaceutical industry representatives.

The envisaged impact on other stakeholders, depends on their background. For pharmaceutical industry, Biotech SMEs, academia and regulatory agencies it will ensure more staff with the competencies required. For Universities across Europe, A competency profile co-developed with Industry will increase labour market relevance of their learning provision. For Universities and research institutes across Europe, it will give their PhDs and postdocs the opportunity to enrol to the e-learning course free of charge. For Europe's Innovation Union, it will increase interaction between research, education and innovation and consequently enable the knowledge triangle to work by

jointly developing a competency profile and curriculum. Creating an international cohort of course participants with different scientific and sectorial backgrounds that share a common understanding and vision of translational research and medicine will enable exchange of expertise and support to each other.

Longer term benefits are 1) the Delivery of skills and competencies (incl. entrepreneurship) ensuring the European competitiveness of Medicines Development 2) Improvements in human health thanks to better trained professionals 3) Reduced costs for companies due to more efficient assessment of potential employees skills and thus a more efficient recruitment process 4) Contribution to strategic planning of professional development of biomedical PhD and postdoc candidates via a publically available competency profile 5) More scientific ideas turned into innovative products bringing growth and jobs to the European economy

The envisaged impact for the Biomedical community in Europe and beyond:

- Increased interaction of the knowledge triangle, between stakeholders active in the fields of research, education and innovation by jointly developing a competency profile and curriculum
- Pooling of an international cohort of course participants with different scientific and sectorial backgrounds, sharing a common understanding and vision of translational research and medicine, who will exchange expertise and support each other
- Support of geographical and public/ private sector mobility
- Delivery of skills and competencies (including entrepreneurship) ensuring the European competitiveness of Medicines Development
- Improvements in human health thanks to better trained professionals
- More scientific ideas turned into innovative products bringing growth and jobs to the European economy

Impact at local and regional level:

- The course participants are selected on their ideas how to integrate their experiences from the course into their local and regional communities, the offered training also aims at leveraging the impact on local level. The impact factors are the same as the ones for the course participants
- The curricula and the competency profile are available for any University, research or other organisation, enabling them to provide labour-market relevant courses locally and regionally

6. Cost structure

6.1. Cost structure e-learning course

The costs for maintaining the e-learning course on a professional platform are mainly for the maintenance and hosting of the platform as illustrated in the table below:

Category	How often?	Participants	Costs per participant or hour	Budget
Licence & hosting	1 / yearly	Fixed price	NA	1.500 €
Maintenance/ technical support	1 / course	Fixed price	NA	520 €
Administration & helpdesk	per participant / year	25	10 - 50 € *	250 - 1250 €
Evaluation & Updating content	1 / yearly	NA	95 €/hr	760 €
Upgrade (new) content	TBD	NA	95 €/hr	TBD
Moderation (reminders every 2 months)	50	16	80 €/p	1.280 €
Marketing	TBD	NA	80 €	640 €

The yearly costs for the e-learning training as listed in table above are amounting to **5.460€** ex. VAT. The price includes the administration of 25 participants. Not included in the price are upgrades of the platform, moderation and adding new content. The administration fee, however, varies depending on the actual numbers of participants:

- 15 - 50 participants = € 50,- per participant / year
- 51 - 100 participants = € 25,- per participant / year
- > 100 = € 10,- per participant / year

For our business product, it is currently not foreseen to provide the e-learning course against a fee. For this reason, the consortium is investigating the building of an open source E-learning platform, to be able to provide the course free of charge after 2018. Being in the position of adding new content or even offer the course in a moderated version, an external sponsor could provide the necessary financial support. Experience with previous e-learning trainings have shown that a moderator is very helpful for the participants to work themselves through the different units and is also a kind of

motivator for the students. However, in case of any questions participants of the e-learning module can always contact the consortium members.

6.2. Cost structure face-to-face workshop

The costs for the face-to-face workshop will have to be partly covered externally as otherwise the participation fees would increase considerably (i.e. venue, catering, printing of materials). Other cost categories (e.g. sponsored dinner, city tour, travel support) should be negotiated to be sponsored by a potential host to lower the total costs for the students participating in the face-to-face workshop. Funding for these costs, however, is not coercively needed for the workshop to run. The cost overview is based on experience:

- For the cost overview, it is assumed that in total 34 participants are present for the duration of the 5-day workshop, including 3 faculty members and an external lecturer per day. In total 5-6 external lectures will be invited for the workshop.
- The prices are without / excl. VAT.
- It is not foreseen to pay an honorarium for the lectures. To cover the travel costs, including flight and hotel costs, a maximum travel support of 600€ per lecturer will be granted.
- For the workshop a board game is foreseen. Experiences in the past have shown that this is an ideal “ice-breaker” and a good start for the face-to-face workshop.
- The external sponsor is encouraged to provide travel support for the students participating in the workshop as we experienced with the past two face-to-face workshops, that students had a hard time to get a travel grant for the course.
- If the venue is not easily accessible by public transportation, the sponsor will also be asked to cover for coach transport from and to the venue.

Total Costs Workshop:

Category	Costs per Category	How often	Participants	Total Costs
Room rental	350€ per day	5 days	34	1.750,00 €
Technique/ Meeting equipment	80€ per day	5 days	34	400,00 €
Marketing workshop	300 €	once	-	300 €
Registration site	1.000,00 €	once	-	1.000,00 €
Lecturer (travel support)	600 €	per lecturer	6	3.600,00 €
Board Game	1.000 €	once	34	1.000,00 €
Staff cost preparation	250€ per day	52 days one person	-	13.000,00 €
Catering during workshop	25€ per participant/ day	5 days	34	4.250,00 €
A sponsored Dinner	22,00 €/ per participant	once	34	748,00 €
				26.048,00 €

To cover some of the fixed costs for the face-to-face workshop participants will have to pay a fee. As students also need to cover for their own travel costs, including flight and hotel, the costs for the workshop must be put in relation to the overall costs that occur for the participants.

One possible solution for the face-to-face workshop fee is to offer an early bird pricing, e.g. 300€ and a normal fee of 500€. As investigated in an earlier survey amongst C-COMEND FTF participants, two third of the participants mentioned to be willing to spend between 300€ and 600€ additional money for the course. The actual amount of the workshop fee will depend on the potential sponsor and will be discussed and bounded once the host is identified.

6.2. Revenue Streams

The type of revenue stream for our business is **transaction revenue**, as our revenues will be earned from the customers making a one-time payment for the offered product, training. Students attending the face-to-face workshop will pay a fee for the workshop, once. Participants successfully completed the workshop will most probably not attend the training for a second time.

The pricing strategy for the offered product will be **dynamic pricing**. The fee for the workshop changes according to the variables that are necessary to create the workshop as well as the conditions prevalent in the market. Moreover, the final fee for each workshop is dependent on the customers and their perception of the worth of the value the product holds. The fee for the workshop will therefore be defined for each workshop.

In general, our customers are willing to pay a fee for the training and the expertise they will gain, as investigated recently in a survey amongst CCOMEND alumni (summary of the feedback collected can be found in annex 3). As the first cycle of the e-learning module and face-to-face workshop has shown, the training is supporting the personal career development of the course participants. However, previous workshops have been for free. The e-learning course as such will remain for free. The face-to-face workshop will be promoted against a small fee to cover some of the costs for the course. It is to find out if the minimum of 25 participants can still be recruited including the attendance of the workshop against a small fee.

The fee for the workshop has been defined with 300€ per participant (early bird) or 500€ for the normal rate, if at least 25 participants can be recruited for the workshop. In case less than 25 students show interest for the course a go/ no go decision will be made by the consortium together with the potential host. The payment system still needs to be determined:

- Permanent account to transfer the money before the workshop via credit card or online transfer
- Invoice for each participant to be sent via email
- Including an early bird price offer

6.4. Cash flow, income

As we are a non-for-profit business there will not be any profit or cash flow. Any potential profit will be reinvested in the course e.g. to host the e-learning.

6.5 Controlling

The part of the internal controlling, best practice, will be performed by Rebecca Ludwig. The following elements of managerial controlling will be included:

- **Characteristics of elements to be controlled:** for our business product, controlling will be based on the output training and the numbers of course participants; a minimum of 25 participants are favoured to be recruited for the face-to-face course. It is the manager's task

to analyse the recruitment procedure after the first cycle and discuss necessary steps to follow-up together with the consortium.

- **Sensory system:** the measurement toll(tool?) by which the actual results and the benchmark result will be measured in will be based on the sales level, i.e. the number of participants attending the offered training course.
- **Comparator:** The comparison takes place after each cycle of e-learning and face-to-face learning.
- **Activator:** In case the set benchmark is not reached, the manager together with the consortium will act to correct the workflow and bring the business to a new process that will help us to achieve the benchmark. Possible solutions would be to update the e-learning training with new content that will attract more participants; to lower the fee for the face-to-face workshop and to start a paid advertisement campaign for the training.

6.5.1 Measurement of success

The defined activities to assess the business success are described in the quality assurance procedures. The objects of consideration (in quantitative and qualitative terms) are that the output is within the set parameters with respect to quality and timely delivery.

In addition, for the specific output the following activities and indicators of achievement will be used:

- Define clear targets for number of participants for the training activities and ensure that those targets are met (a maximum of 25 and a total of 30 participants per face-to-face course)
- To ensure the quality of the course the IMI Education & Training quality indicators and student evaluation forms will be used.
- Using the ADDIE process for the planning of the course.