



**Faculdade de Ciências da Saúde da  
Universidade Fernando Pessoa**

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## **RELATÓRIO DO CICLO DE ESTUDOS**

### **THERAGNOSTICS, INTELLECTUAL PROPERTY & ETHICS**

RELATÓRIO DO CICLO DE ESTUDOS APRESENTADO A PROVAS PÚBLICAS DO TÍTULO ACADÉMICO DE AGREGADO,  
A QUE SE REPORTA A ALÍNEA B) DO ARTIGO 5º DO DECRETO-LEI N.º 239/2007  
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**Universidade Fernando Pessoa**  
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## 1. INTRODUCTION

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The Doctoral Course entitled “**Theragnostics, Intellectual Property and Ethics**” proposed in this Accreditation Report, is the interplay between the development of nanoparticulate carriers specifically tailored with targeting moieties for Cancer Therapy and Diagnosis, and the Intellectual Property and Ethical Issues behind the fundamental and applied research.

Cancer is a complex pathology, characterized by abnormal transformation of healthy cells into cancerous cells involving cell proliferation, invasion into surrounding tissues and sometimes metastization [1]. It is defined by an uncontrolled growth that continues along the cell cycle, producing new abnormal cells that can reach systemic blood circulation. Metastasis leads to formation of newer colonies in vital organs not affected by the primary cancer, giving rise to secondary tumours [2]. Despite great achievements on understanding its aetiology, in parallel with the biotechnological development of new anticancer drugs, cancer remains one of the leading causes of death worldwide. Preclinical and clinical studies demonstrated successful gene transfer and suppression of tumour growth when functional wild-type tumour suppressor gene contained in a viral vector were administered intra-tumourally [3]. However, this approach holds the risk of immunogenicity by producing antiviral antibodies, thereby limiting repeated treatments. Current anticancer therapies require systemic gene delivery approach, nevertheless viral vectors have low therapeutic efficacy when administered intravenously. Non-viral vectors are being exploited as potential alternatives. When comparing conventional anticancer treatments with novel approaches based on nanoparticulates, it has long been reported that targeted and *in situ* drug delivery provide a selective killing process of cancer cells, minimizing the toxicity on healthy organs and tissues and consequent adverse side effects. However, even if located in the tumour region, the efficacy of anticancer drugs can be affected by the development of multidrug resistance [4, 5]. This phenomenon is characterized by a broad-spectrum resistance to chemotherapy in human cancer, being one of the most important problems in chemotherapy. Multidrug resistance occurs when exposure of tumour cells to a single cytotoxic agent accounts for cross-resistance to other structurally unrelated classes of cytotoxic agents [6]. It mainly results in unreasonable tumour size reduction or recrudescence after initial therapeutic effect. Nevertheless, even some nanoparticulates were able to overcome the problem of multidrug resistance to some extent [7]. This type of less aggressive approach is critically more cost effective and shows greater patients' compliance. Examples of nanoparticulates include superparamagnetic iron oxide cores, gold nanoparticles, hyperbranched polymers, polysaccharide-based nanoparticulates, dendrimers, liposomes, core-multishell nanoparticles, and other lipid nanoparticulates [8-11].

Targeted nanoparticulates for cancer therapy and diagnosis are a novel approach, so-called **Theragnostics**, comprising a very important scientific domain of study, witnessing rapid growth and wide scope of applications [12, 13]. Among these examples, lipid nanoparticulates are being pointed out as great promise for cancer diagnosis and therapy, since they have the advantage of multifunctionalization for simultaneous imaging analysis and delivery of anticancer drugs, genes and vaccines [14]. These nanoparticulates may be passively or actively targeted to solid tumours, where the drug is slowly released inside the tumour. Furthermore, lipid nanoparticulates can act as sustained-release delivery system, and control of properties, such as diameter, surface charge, pharmacokinetic and bioavailability profiles and dosing schedule, can significantly improve the therapeutic outcome of anticancer drugs. These nanoparticulates are composed of well-tolerated and physiological lipids, thus non-immunogenicity and biodegradability are other advantages, along with facilities to be produced in large scale, and possibility to deliver therapeutic genes to treat localized tumours.

The proposed Doctoral Course deals with the current state of the art and challenges in the field of nanoparticulates, for delivery and target of anticancer drugs for chemotherapy, on how the changes of some of the nanoparticulate properties can impact the therapeutic efficacy and adverse side effects, and discusses the potential use of these multifunctional nanoparticulates for image-guided drug delivery (*i.e.* diagnosis and therapy). The first module of the course deals with the fundamentals behind the rationale of developing nanoparticulates for

cancer diagnosis, prevention and therapy. The second course module is focused on Intellectual Property issues behind the development of a novel potential approach, dealing with the projected market for nanotechnology and training the students in patents analysis, data protection and litigation. Finally, the third course module covers the Ethical issues providing the students with useful information concerning the development of ethical conduct with respect to scientific research in the field of Theragnostic approaches and possible clinical outcomes.

The challenge presented to the students relies on the combination of Cancer Nanotechnology and Intellectual Property and Ethics, with a worldwide dimension. To reach such attempt, the enrolment of several European High Education Institutions (HEIs)<sup>3</sup> is proposed, which should excel their scientific activity and proficiency in similar and related fields. A European Doctoral Programme is described following the guidelines released by the Education, Audiovisual and Culture Executive Agency (EACEA)<sup>4</sup> under the scope of the Erasmus Mundus framework to deliver a joint PhD Degree.

When looking at protecting **Nanotechnology Rights**, the researcher faces new and unique challenges, especially when it comes to the licensing and transferring of such rights. In the field of Theragnostics, **Ethics** plays an important role, in particular the risk of dual-use. This issue raises important questions about the responsibilities of scientists, research institutions, the scientific community, publishers, and policymakers. This Doctoral Course will cover potential pitfalls and suggest strategies for both licensors and licensees when negotiating licence agreements, to avoid liability and to have maximum protection against future events in this exciting and unique field.

## 2. SCOPE OF THE DOCTORAL COURSE

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The society is aware about the unpredictable future of nanotechnology. Nevertheless, the prolific research in this field testifies great promising in different areas such as medicine (so-called Nanomedicine), environment, sanitation, electronics, energy production, information technology, lithography, data storage, optics, aerospace, and molecular robotic manufacturing processes. In the field of medicine, many other potential uses for nanotechnology include production of materials and devices capable of e.g. gene delivery, site-specific targeting, chemotherapy, imaging diagnosis, and controlled release.

According to the European Science Foundation (ESF)<sup>5</sup>, **Nanomedicine** is the use of nanotechnology to improve healthcare, and is currently defined as “the science and technology of diagnosing, treating and preventing disease and traumatic injury, of relieving pain and of preserving and improving human health”. In a broader sense, it is focused on the development of drug delivery systems. The pharmaceutical industry always faced the challenge of designing formulations to deliver the right doses of a drug to a specific target. However, this has been unachievable in most cases, and drugs must be administered in very high doses, thereby increasing side and toxic effects [15]. Targeted nanoparticulates are a promising pathway to overcome traditional therapeutic limitations, since they are engineered and developed to depict high affinity to a specific target [16, 17]. With these formulations, the controlled release of the drug is expected for a certain period of time, but also the specificity for a organ-site or disease, provision of new routes for drug administration, decreasing thereafter the toxic side effects, with increased patient’s compliance [15]. In addition to therapy, if combining diagnostic tools in the same nanoparticulate carrier, a novel strategy can be drawn. The concept relies on the ability to develop a device that should simultaneously identify the diseased tissue or organ, targeting and delivering the drug for therapy [18, 19]. Apart from the current economic and technological framework behind this scientific field, the value of research in Nanomedicine is measured by the number of patents being granted worldwide. There are three ways to identify the scope of the subject matter of Intellectual Property [20-22], namely: (i) the exclusive rights on commercial or industrial intangible assets, which can be considered as analogous to property rights on any new immaterial

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<sup>3</sup> [http://eacea.ec.europa.eu/erasmus\\_mundus/tools/documents/action2\\_faq\\_hei\\_jan2011.pdf](http://eacea.ec.europa.eu/erasmus_mundus/tools/documents/action2_faq_hei_jan2011.pdf)

<sup>4</sup> [http://eacea.ec.europa.eu/index\\_en.php](http://eacea.ec.europa.eu/index_en.php)

<sup>5</sup> <http://www.esf.org/>

creation, whether defined or not by the law; (ii) all the rights on intangible assets defined by the law (e.g. industrial property, creations protected by copyright, and unfair competition); or in a stricter sense (iii) the Intellectual Property defined in contrast with Industrial Property. This last definition finds an important reference in the system of the two archetypical treaties of the Berne Convention, of September 9, 1886, and the Paris Convention, of March 20, 1883.

The importance of covering these issues in a Doctoral Course relies on the fact that “new goods” whether intellectual creations or not, are necessarily objects of rights and, for this reason, they must be protected as such using legal tools. The concept of “property”, though intellectual and immaterial, remains the essential focus. The best way to obtain an answer to the new legal issues arising with Nanomedicine seems to be a discussion about property, both intellectual and private – through an interpretation oriented towards human rights, which can track down meanings which fit the knowledge economy. The contrast between an over-regulatory approach, as is seemingly taking root in the European Union<sup>6</sup> (EU), and a free-riding approach, cannot discourage the search for a balance among the different issues raised by developments in the field of nanotechnology. The issue of regulating, on the one hand, suppliers’ rights of access to the networks and to control the use and distribution, and, on the other hand, the patients’ right of access to these “new goods”, represents the essential challenge that policymakers and the competent authorities must undertake.

The use of technological protection measures, in particular, ensures a protected environment for the production, management, and distribution. Nevertheless, at the same time, it may jeopardize a series of rights traditionally recognized by the consumer. Technological protection measures are nevertheless recognised independently on the patients’ expectations.

Research projects are nowadays even more expensive, promise more and consequently carry more risks of all types than before. Projects are open to many external factors including legislation and cultural differences between countries. In view of this, a good code of ethics is very important for any research project. Ethics should not be seen as a bother but something that should get a high priority. When the project uses the web for any activity, the user must bear in mind the Ethical obligations to the public. In particular, if the project gathers any Personal Data, all aspects of data protection, actions must be adhered to with respect to the gathering, use and storage of such information. Privacy usually refers to people, while confidentiality usually refers to information. One conflict that must be balanced is the need to improve care while maintaining protection of patients’ data. The data must be accessible only to those that are involved in the research. Following these guidelines, the proposed Doctoral Course programme will have in place a security policy with respect to data protection and must communicate to all involved and monitored by the Ethical Board. Other areas where ethical issues could arise could be in decision making.

Two areas of research on Nanomedicine that have been increasing recently, both addressing Ethical concerns, are **Cancer Therapy** and **Diagnosis**. While the former is applied to control delivery of drugs, diagnostic tools will identify the spot and state of disease. In the case of *in situ* diagnosis, they are still in the early stages of development and all the risks have not yet been quantified.

The PhD students working in this and related fields should be fully trained in all aspects of Ethical behaviour and be familiar with the different legislation released in this field. The curriculum of the proposed **Doctoral Course** has been thought to cover a 3-year programme running over two periods, namely the first year, where the teaching modules will be carried out in the Home Institution, University Fernando Pessoa<sup>7</sup> (UFP), followed by two years, devoted to a specific PhD research project. During the 2-year research period, collaboration with other HEIs in Europe, holding the Erasmus University Charter<sup>8</sup> (EUC) is envisaged, and also encouraged the approach of other stakeholders from a non-academic environment. Pharmaceutical companies, legal practitioners, patent officers, should be considered as potential stakeholders and incorporate them in the programme for knowledge transfer towards licensing strategies with respect to Nanotechnology/Nanomedicine-related agreements.

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<sup>6</sup> [http://europa.eu/index\\_en.htm](http://europa.eu/index_en.htm)

<sup>7</sup> <http://www.ufp.pt/>

<sup>8</sup> [http://ec.europa.eu/education/erasmus/doc890\\_en.htm](http://ec.europa.eu/education/erasmus/doc890_en.htm)

### 3. PROGRAMME OF THE DOCTORAL COURSE

The programme of the proposed Doctoral Course comprises **3 Core Modules** (Theranostics, Intellectual Property and Ethics), each of them containing specific **Teaching Units**, to be lectured during the academic period. The second and third years will be focused on the research project specifically tailored for each PhD student enrolled in the programme. The PhD student will have to be approved for **180 ECTS**, *i.e.* European Credit Transfer and Accumulation System (ECTS)<sup>9</sup>. Table 1 summarizes the structure and ECTS given to each of the teaching units.

**Table 1:** Structure of the 3-Years Doctoral Course.

Course Year	Core Modules	Teaching Units	ECTS
YEAR 1 Academic Period	MODULE 1 Theranostics (36 ECTS)	1. Chemotherapy	6
		2. Targeting Strategies	6
		3. Diagnostic Approaches	6
		4. Nanoparticulate Carriers	6
		5. Hybrid Structures	6
		6. Gene Based Structures	6
	MODULE 2 Intellectual Property (16 ECTS)	1. Intellectual Property Background	4
		2. Technical Protection and Patients' Rights	4
		3. Patentability Criteria and Patent Claims	4
		4. Licencing Agreements	4
	MODULE 3 Ethics (8 ECTS)	1. Bioethics and Ethics Disclosure	4
		2. Current and Emerging Nanoethics	4
YEAR 2 Research Period	THESIS	Research Project	60
YEAR 3 Research Period	THESIS	Research Project	60

<sup>9</sup> [http://ec.europa.eu/education/lifelong-learning-policy/doc48\\_en.htm](http://ec.europa.eu/education/lifelong-learning-policy/doc48_en.htm)





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## **SUMÁRIO DA LIÇÃO**

### **TARGETED LIPID NANOCARRIERS FOR THERAGNOSTICS**

SUMÁRIO PORMENORIZADO DA LIÇÃO APRESENTADA A PROVAS PÚBLICAS DO TÍTULO ACADÉMICO DE  
AGREGADO, A QUE SE REPORTA A ALÍNEA C) DO ARTIGO 5º DO DECRETO-LEI N.º 239/2007  
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### 3.1. MODULE 1

#### 3.1.1. Theragnostics

The treatment of cancer with conventional chemotherapy is generally followed by deleterious side effects since these anticancers are toxic to both cancerous and non-cancerous cells [23]. The use of nanoparticulates can improve the pharmacological response to traditional anticancers by changing the drug pharmacokinetics and its biodistribution [24]. Nanoparticulates can be directly conjugated to the cytotoxic agent to yield various nanosized assemblies and other protein-drug conjugates, or alternatively be non-covalently associated with the anticancer drug.

**Theragnostics** is a novel treatment strategy that combines therapy with diagnosis [13]. In the treatment of cancer, it associates both a diagnostic tool that identifies the damaged tissue, most likely to be helped or harmed by the chemotherapeutic, and targeted drug therapy based on the test results. Examples of diagnostic tools are the paramagnetic residues loaded in nanoparticles [25-27], or even fluorescent dyes for imaging analysis [28-30]. Bioinformatics, genomics, proteomics, and functional genomics are molecular biology tools essential for the progress of molecular Theragnostics [31]. Theragnostics includes a wide range of disciplines (such as personalized medicine, pharmacogenomics, and molecular imaging) which are of particular relevance to develop efficient new targeted therapies with adequate benefit/risk to patients and better understand how to optimize drug therapy [32]. This strategy aims at monitoring the response to the treatment, increase drug efficacy and safety [33]. In the future, it is expected that Theragnostics may eliminate the unnecessary treatment of patients for whom therapy is not appropriate, resulting in significant drug cost savings for the healthcare system. However, the introduction of Theragnostic tests into routine healthcare requires both a demonstration of cost-effectiveness and the availability of appropriate accessible testing systems. Intellectual Property is an additional issue since **Theragnostics** may change the usual business model of pharmaceutical companies from the classic strategies toward targeted therapies. The use of particles as drug carriers to enhance bioavailability, and reduce random distribution of anticancers, has been reported as an alternative approach to target the drug to a particular site, and to exploit controlled release and drug targeting. Smaller sized nanoparticulates have shown to enhance leakage rates when compared to their larger counterparts. Therefore, the use of certain type of nanoparticulates may have an associated increased risk of premature release of the drug prior to reaching the intended target. Ethics addresses the most urgent issues arising from research on these types of Nanomedicines today and in the near future. From the human condition to risk and regulation, research on Theragnostics requires a holistic approach.

In modern medicine, chemotherapy is most widely accepted for treating multiple types of cancers. The accumulated dose of many anticancers, and therefore their therapeutic effect, is limited by irreversible non-target tissue toxicity. Recent advances in nanotechnology using biodegradable materials as drug carriers have gained increased importance and have led to the discovery of new therapeutic agents and novel materials for the treatment of cancers. A wide range of nanoparticulates (e.g. polymeric, lipid, polysaccharide or protein-based nanoparticulates, liposomes, dendrimers, core-multishell nanoparticles) have emerged as potential candidates and the system is chosen on the basis of its biodegradability and biocompatibility. These nanoparticulates successfully increase the dosage and residence time in the body, while reducing side effects by offering a sustained release profile. Nanoparticulates chemistry has numerous research possibilities among which the field of multi-functional nanoparticles has taken precedence in recent times. Multifunctional nanoparticles bring the advantages of combining co-delivery, drug targeting and imaging of tumours in a single delivery system, in the fighting against cancer.

### 3.1.2. Recommended Literature for Module 1

In this section, a list of recommended literature is proposed to cover the scientific topics addressed in Module 1:

23. E. B. Souto (Editor), Lipid Nanocarriers in Cancer Diagnosis and Therapy, by *i* Smithers - *Creative Publishing Solutions* ([www.iSmithers.net](http://www.iSmithers.net)), ISBN: 78-1-84735-4-778 (Hardback); ISBN: 978-1-84735-4-785 (Softback) (2011).
24. E. B. Souto (Guest Editor), A Special Issue on Lipid-based Delivery Systems: Liposomes, Lipid Nanoparticles, Lipid Matrices and Medicines, Journal of Biomedical Nanotechnology, Volume 5, Number 4, August (2009) 315-444. ([http://www.aspbs.com/JBN/editorial\\_ibn.htm](http://www.aspbs.com/JBN/editorial_ibn.htm)).
25. E. B. Souto (Guest Editor), An Overview on the Design, Development, Characterization and Applications of Novel Nanomedicines for Brain Targeting, Current Nanosciences, Bentham Publications (<http://www.bentham.org/cnano>), Volume 7 (2011).
26. F. Bhaijee, D.J. Pepper, K.T. Pitman, and D. Bell, Cancer stem cells in head and neck squamous cell carcinoma: A review of current knowledge and future applications. Head Neck (2011).
27. Y. Ling, K. Wei, Y. Luo, X. Gao, and S. Zhong, Dual docetaxel/superparamagnetic iron oxide loaded nanoparticles for both targeting magnetic resonance imaging and cancer therapy. Biomaterials 32 (2011) 7139-50.
28. D. Kryza, J. Taleb, M. Janier, L. Marmuse, I. Miladi, P. Bonazza, C. Louis, P. Perriat, S. Roux, O. Tillement, and C. Billotey, Biodistribution study of nanometric hybrid gadolinium oxide particles as a multimodal SPECT/MR/optical imaging and Theragnostic agent. Bioconjug Chem 22 (2011) 1145-52.
29. H. Fattahi, S. Laurent, F. Liu, N. Arsalani, L. Vander Elst, and R.N. Muller, Magnetoliposomes as multimodal contrast agents for molecular imaging and cancer nanoTheragnostics. Nanomedicine (Lond) 6 (2011) 529-44.
30. W.Y. Huang, and J.J. Davis, Multimodality and nanoparticles in medical imaging. Dalton Trans 40 (2011) 6087-103.
31. J.L. Arias, L.H. Reddy, M. Othman, B. Gillet, D. Desmaele, F. Zouhiri, F. Dosio, R. Gref, and P. Couvreur, Squalene based nanocomposites: a new platform for the design of multifunctional pharmaceutical Theragnostics. ACS Nano 5 (2011) 1513-21.
32. M.A. Zarbin, C. Montemagno, J.F. Leary, and R. Ritch, Nanotechnology in ophthalmology. Can J Ophthalmol 45 (2010) 457-76.
33. C. Fang, and M. Zhang, Nanoparticle-based Theragnostics: Integrating diagnostic and therapeutic potentials in nanomedicine. J Control Release 146 (2010) 2-5.
34. G.M. Lanza, P.M. Winter, S.D. Caruthers, M.S. Hughes, G. Hu, A.H. Schmieder, and S.A. Wickline, Theragnostics for tumour and plaque angiogenesis with perfluorocarbon nanoemulsions. Angiogenesis 13 (2010) 189-202.
35. D. Majumdar, X.H. Peng, and D.M. Shin, The medicinal chemistry of Theragnostics, multimodality imaging and applications of nanotechnology in cancer. Curr Top Med Chem 10 (2010) 1211-26.
36. P.C. Hermann, S. Bhaskar, M. Cioffi, and C. Heeschen, Cancer stem cells in solid tumours. Semin Cancer Biol 20 (2010) 77-84.
37. F. Pene, E. Courtine, A. Cariou, and J.P. Mira, Toward Theragnostics. Crit Care Med 37 (2009) S50-8.
38. G. Lippi, Wisdom of Theragnostics, other changes. MLO Med Lab Obs 40 (2008) 6.

The first reference of this list is the recently released book, edited by the Course Coordinator. This book gathers a group of international researchers (from Brazil, Canada, China, France, India, Japan, Portugal, Spain, Taiwan, and USA), who have contributed with their most valuable expertise bringing a first-hand continuing professional experience, in lipid-based nanoparticulates used in cancer diagnosis and therapy.

The second reference, considered an additional fundamental tool within the scope of this Doctoral Course, is the special issue published in the Journal of Biomedical Nanotechnology in 2009, also edited by the Course

Coordinator. This special issue addresses the application of liposomes, lipid nanoparticles and other lipid matrices in Medicines and in Pharmaceuticals, in a comprehensive approach, starting from fundamentals to special topics. It addresses questions about how lipid nanoparticulates can be used for drug therapy, diagnostics and imaging, including some other examples on their applications in biomedical, and pharmaceuticals. It discusses the topics of anticancer therapy and the molecular basis of complement activation, the multifunctional siRNA tumour targeting, brain targeting, as well as their use for skin and mucosal injuries. In the development of these multifunctional carriers, their physicochemical properties settle their stability and *in vivo* performance. Original research papers deal with topics, such as the size determination of commercially available fat emulsions, the important role of microemulsions as templates in the production of lipid nanoparticles, paying also particular attention to the stability of biomolecules (e.g. proteins) when loaded in lipid-based delivery systems, to the effect of formulation parameters of liposomes on their haemolytic activity. Recent literature published in 2011 is also listed to allow students the early contact and awareness for the need of searching new information in this emerging field of research.

## 3.2. MODULE 2

### 3.2.1. Intellectual Property

Over the recent years, researchers have been witnessing the rising interest and development of Nanotechnology and Nanomedicine. Nowadays, the commercial products containing nanoparticulates are widely increasing due to the benefits one can draw by applying nanotechnology to formulations. The medical field is very appealing and attracts continuous investment and financial support [34]. Therefore, researchers and stakeholders looking to protect nanotechnology rights face new and unique challenges when licensing and transferring Intellectual Property rights. This module aims at providing the essential tools to identify potential shortcomings and presents strategies for both licensors and licensees when negotiating licensing agreements in Nanomedicine-based research.

Teaching units of this module include the analysis of the role of consumer law in that realm, as a recognized branch of civil law. Their contribution discusses the concepts of “consumer versus patient” and “consumption versus disease” in the framework of Intellectual Property. Particular issues tackled include the position of contracts involving Industrial Property rights within the Portuguese legal framework, but also within the Community Law. Starting from the historical evolution of the concept of Intellectual and Industrial Property, the students will be trained in topics of civil and antitrust law provisions relevant to the licensing of Intellectual Property rights, to the practice of franchising, trademark merchandising and technology transfer agreements. Recent initiatives aimed at combating organized Intellectual Property crime will also be addressed. European Commission’s proposal for a directive on the harmonization of criminal measures is analysed in the light of existing international and regional rules, from the Agreement on Trade-Related Aspects of Intellectual Property Rights<sup>10</sup> (TRIPs) to the Intellectual Property Rights Enforcement Directive<sup>11</sup> (IPRED). The aim is to achieve a practical interpretation of substantial criminal law notions as regards their compatibility with Intellectual Property law. The evaluation and study of predictable legal difficulties encountered in the Draft Criminal Enforcement Directive<sup>12</sup> should also be envisaged. These are built on a transnational discussion within EU case law regarding refusals to license by dominant companies from industry and on a diligent analysis of the objectives of both Intellectual Property and competition law. Criteria involved in unlawful refusals to license Intellectual Property

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<sup>10</sup> [http://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm)

<sup>11</sup> [http://ec.europa.eu/internal\\_market/iprenforcement/directives\\_en.htm](http://ec.europa.eu/internal_market/iprenforcement/directives_en.htm)

<sup>12</sup> <http://www.fipr.org/copyright/draft-ipr-enforce.html>

rights by resorting to both Article 102<sup>13</sup> of the Treaty on the Functioning of the EU (relating to the abuse of dominant position) and to EU case law are also addressed.

### 3.2.2. Recommended Literature for Module 2

In this section, a list of recommended literature is proposed to cover the scientific topics addressed in Module 2:

1. E.B. Souto (General Editor), *Patenting Nanomedicines*, by Springer ([www.springer.com](http://www.springer.com)), under preparation, estimated press-released in February 2012.
2. J. Zhang, S. Li, X. Li, Polymeric nano-assemblies as emerging delivery carriers for therapeutic applications: a review of recent patents, *Recent Pat Nanotechnol* 3 (2009) 225-231.
3. L.C. du Toit, V. Pillay, Y.E. Choonara, Nano-microbicides: challenges in drug delivery, patient ethics and intellectual property in the war against HIV/AIDS, *Adv Drug Deliv Rev* 62 (2010) 532-546.
4. B. Mishra, B.B. Patel, S. Tiwari, Colloidal nanocarriers: a review on formulation technology, types and applications toward targeted drug delivery, *Nanomedicine* 6 (2010) 9-24.
5. K.Y. Kim, Implications of recent US Supreme Court IP ruling for nanomedicine patents, *Nanomedicine (Lond)* 3 (2008) 141-143.
6. K.J. Morrow, Jr., R. Bawa, C. Wei, Recent advances in basic and clinical nanomedicine, *Med Clin North Am* 91 (2007) 805-843.
7. R. Bawa, Patents and nanomedicine, *Nanomedicine (Lond)* 2 (2007) 351-374.
8. R. Bawa, Will the nanomedicine "patent land grab" thwart commercialization?, *Nanomedicine* 1 (2005) 346-350.
9. R. Bawa, S.R. Bawa, S.B. Maebius, T. Flynn, C. Wei, Protecting new ideas and inventions in nanomedicine with patents, *Nanomedicine* 1 (2005) 150-158.
10. S. Prakash, A.G. Kulamarva, Recent advances in drug delivery: potential and limitations of carbon nanotubes, *Recent Pat Drug Deliv Formul* 1 (2007) 214-221.
11. L.C. du Toit, V. Pillay, Y.E. Choonara, S. Pillay, S.L. Harilall, Patenting of nanopharmaceuticals in drug delivery: no small issue, *Recent Pat Drug Deliv Formul* 1 (2007) 131-142.

The first reference of the list refers to a book that is being edited by the Course Coordinator. It is expected to be released by February 2012, and is devoted to the relevant and complex issues of patenting Nanomedicines. The book describes the scenario of drug delivery and targeting in nanomedicine covering different types of nanoparticulates with a thrust to the various patents granted worldwide. Patents available on these systems are comprehensively summarized in each chapter, presenting the current challenges and future prospects. Research and review papers crossing these areas are now in the pipelines given the novel international journals of open access that have been recently launched, such as the *Recent Patents on Nanomedicine*<sup>14</sup>, the *Recent Patents on Nanotechnology*<sup>15</sup>, and the *Expert Opinion on Therapeutic Patents*<sup>16</sup>.

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<sup>13</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E102:EN:NOT>

<sup>14</sup> <http://www.benthamscience.com/nanom/>

<sup>15</sup> <http://www.benthamscience.com/nanotec/index.htm>

<sup>16</sup> <http://informahealthcare.com/loi/etp>

### 3.3. MODULE 3

#### 3.3.1. Ethics

This module is aimed at providing useful information concerning the ethical conduct with respect to scientific development of novel Theragnostic strategies and clinical practice. Discussion towards very different points of view is of outmost relevance, since the very same facts may result in very different ethical arguments and conclusions for different people.

A view about ethical issues related to nanoparticulates is closer to the claim that none of these applications raises any substantially new concerns [35]. If only privacy issues and toxicity of raw materials used for the production of these nanoparticulates are the major issues to be taken into account, the risk assessment could easily be measured. However, risk has changed when nanoparticulates are involved not only because of particle size but also because of the very different behaviors that nanoparticles exhibit. A report of the US FDA<sup>17</sup>, released in 2007 entitled "Nanotechnology," notes that "Nanoscale materials often have chemical, physical, or biological properties that are different from those of their larger counterparts. Such differences may include special magnetic features, different electrical or optical activity, increased structural integrity or modified chemical or biological activity. Nano-scaled materials may pose different safety issues than their larger or smaller (molecular) counterparts." Nanotechnologists, nanoethicists, physicians and the general public are already aware that nanoparticles do not behave as the other particles [36]. Therefore, risk assessment needs to be taken into account because of the unpredictability of nanoparticle behaviour, as well as their size. The US FDA<sup>18</sup> further notes that "Studies have also shown that modifying the surface of nano-scaled materials with surfactants or biocompatible polymers reduced the toxicity *in vitro* and altered the half-life and tissue deposition *in vivo*. Such findings are relevant to drug delivery for example, for understanding the potential distribution of nanoscale materials in the body, and for evaluating toxicity and biocompatibility". The presence of nanoparticulates in products and the information about *in vivo* in tissue deposition is relevant to medical applications. There are new concerns related to nanoparticles which need to be tackled. Tools to analyse ethical issues in this field will be offered by this joint Doctoral Course.

#### 3.3.4. Recommended Literature for Module 3

In this section, a list of recommended literature is proposed to cover the scientific topics addressed in Module 3:

1. K. N. Nielsen, B. N. Fredriksen and A. I. Myhr, "Mapping Uncertainties in the Upstream: The Case of PLGA Nanoparticles in Salmon Vaccines" (2011) 5 Nanoethics 57-71.
2. K. N. Nielsen, T. G. Am and R. Nydal, "Centre and Periphery of Nano-A Norwegian Context" (2011) 5 Nanoethics 87-98.
3. B. K. Myskja, "Trustworthy Nanotechnology: Risk, Engagement and Responsibility" (2011) 5 Nanoethics 49-56.
4. A. I. Myhr and B. K. Myskja, "Precaution or Integrated Responsibility Approach to Nanovaccines in Fish Farming? A Critical Appraisal of the UNESCO Precautionary Principle" (2011) 5 Nanoethics 73-86.
5. K. L. Kjolberg and R. Strand, "Conversations About Responsible Nanoresearch" (2011) 5 Nanoethics 99-113.
6. T. G. Am, "Trust in Nanotechnology? On Trust as Analytical Tool in Social Research on Emerging Technologies" (2011) 5 Nanoethics 15-28.
7. H. Am, "Trust as Glue in Nanotechnology Governance Networks" (2011) 5 Nanoethics 115-128.

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<sup>17</sup> <http://www.fda.gov/downloads/scienceresearch/specialtopics/nanotechnology/ucm110856.pdf>

<sup>18</sup> <http://www.fda.gov/downloads/scienceresearch/specialtopics/nanotechnology/ucm110856.pdf>

8. C. Shelley-Egan, "The Ambivalence of Promising Technology" (2010) 4 Nanoethics 183-189.
9. R. Macklin, "The death of bioethics (as we once knew it)" (2010) 24 Bioethics 211-7.
10. J. F. Jacobs, I. van de Poel and P. Osseweijer, "Sunscreens with Titanium Dioxide (TiO<sub>2</sub>) Nano-Particles: A Societal Experiment" (2010) 4 Nanoethics 103-113.
11. C. Cormick, "The Challenges of Community Engagement" (2010) 4 Nanoethics 229-231.
12. G. B. White, "Missing the boat on nanoethics" (2009) 9 Am J Bioeth 18-9.
13. P. P. Verbeek, "Ambient Intelligence and Persuasive Technology: The Blurring Boundaries Between Human and Technology" (2009) 3 Nanoethics 231-242.
14. H. van den Belt, "Playing God in Frankenstein's Footsteps: Synthetic Biology and the Meaning of Life" (2009) 3 Nanoethics 257-268.
15. T. Toth-Fejel and C. Dodsworth, "A sibling rivalry on personhood, procreation, and evil" (2009) 9 Am J Bioeth 43-5.
16. T. Swierstra, R. van Est and M. Boenink, "Taking Care of the Symbolic Order. How Converging Technologies Challenge our Concepts" (2009) 3 Nanoethics 269-280.
17. T. Swierstra, M. Boenink, B. Walhout and R. Van Est, "Converging Technologies, Shifting Boundaries" (2009) 3 Nanoethics 213-216.
18. D. Schuurbiers, S. Sleenhoff, J. F. Jacobs and P. Osseweijer, "Multidisciplinary Engagement with Nanoethics Through Education-The Nanobio-RAISE Advanced Courses as a Case Study and Model" (2009) 3 Nanoethics 197-211.
19. M. Schermer, "The Mind and the Machine. On the Conceptual and Moral Implications of Brain-Machine Interaction" (2009) 3 Nanoethics 217-230.
20. D. Koepsell, "Let's Get Small: An Introduction to Transitional Issues in Nanotech and Intellectual Property" (2009) 3 Nanoethics 157-166.
21. M. C. Kelty, "Beyond Implications and Applications: the Story of 'Safety by Design'" (2009) 3 Nanoethics 79-96.
22. C. Kagawa, "[Neuroethics and bioethics--implications of Balkanization controversy]" (2009) 61 Brain Nerve 11-7.
23. S. Johnson, "The era of nanomedicine and nanoethics: has it come, is it still coming, or will it pass us by?" (2009) 9 Am J Bioeth 1-2.
24. C. Cormick, "Why Do We Need to Know What the Public Thinks about Nanotechnology?" (2009) 3 Nanoethics 167-173.
25. M. Boenink, "Tensions and Opportunities in Convergence: Shifting Concepts of Disease in Emerging Molecular Medicine" (2009) 3 Nanoethics 243-255.
26. M. Godman, "But is it unique to nanotechnology?: reframing nanoethics" (2008) 14 Sci Eng Ethics 391-403.
27. M. Ebbesen and B. D. Pedersen, "The principle of respect for autonomy--concordant with the experience of oncology physicians and molecular biologists in their daily work?" (2008) 9 BMC Med Ethics 5.
28. M. Ebbesen, T. G. Jensen, S. Andersen and F. S. Pedersen, "Ethical perspectives on RNA interference therapeutics" (2008) 5 Int J Med Sci 159-68.
29. P. Litton, "'Nanoethics'? What's new?" (2007) 37 Hastings Cent Rep 22-5.

### 4.1. Organization of the Doctoral Course

#### 4.1.1. Structure of the Doctoral Course

The proposed Doctoral Course is a 3-year programme running over two distinct periods, *i.e.* the first academic year and the 2 following research years. Students will have to complete 180 ECTS<sup>19</sup> to be awarded with the Ph.D. by the Home University (University Fernando Pessoa<sup>20</sup>) and at least 60 of those ECTS must be taken in a second EU Institution (HEIs). These HEIs should hold the EUC<sup>21</sup>.

The universities to be enrolled should issue a Cooperation Agreement specifying the recognition policy of the components of the research activities and the recognition of the full Doctoral Course programme. The curriculum of the teaching programme to be lectured in the Home Institution should include collaboration expertise by the HEIs partner, and also by potential stakeholders from non-academic backgrounds (*e.g.* INPI<sup>22</sup>, UNESCO<sup>23</sup>, WHO<sup>24</sup>, WIPO<sup>25</sup>, EPO<sup>26</sup>, USPTO<sup>27</sup>, JPO<sup>28</sup>, ARIPO<sup>29</sup>, CGPDTM<sup>30</sup>). The course reflects its organization in a structured and integrated way by complementing and offering joint initiatives to the students from the beginning till the end of the programme. A solid network between the HEIs enrolled in the programme is envisaged built on the basis of a qualified Doctoral Course programme following the EACEA<sup>31</sup> framework. The research lines will be offered by the Home Institution of the network, in cooperation with the HEIs partners. Nevertheless, most of the research lines will be under the responsibility of researchers from different HEIs that will provide a component of methodological diversity required at this level of academic training followed by the students. Each HEIs partner of the network should ensure a wide spectrum of competence and integrated expertise.

The expertise of each partner (HEIs, potential stakeholders) figuring in the network should be able to enhance excellence and international collaboration, proven by the number and quality of funded projects and scientific papers published in international peer reviewed journals in the field of the different modules.

The Doctoral Course is organised in a structured and integrated way. After an initial period of studying basic subjects, introductory to research activities (*e.g.* data collection and elaboration, uses of data banks, writing of papers, planning of experiments) and topics on the main research lines on Theragnostics, each student will choose a scientific pathway of interest. More specifically, after the first year period carried out in the Home Institution (Awarding Institution) each student will choose a research line to be followed. The third year will be finished in the Home Institution although the research activities are advised to be finished in the selected foreign HEIs. This scientific internship can be between the second and third year and the student needs to complete 60 ECTS. A report of the local coordinator will certify that student has successfully accomplished the expected aims and reached positive outcomes. The complementarities among research lines will be defined by the Doctoral Board. The participation of HEIs in the course gives a unique possibility for testing a consensual convergence

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<sup>19</sup> [http://ec.europa.eu/education/lifelong-learning-policy/doc48\\_en.htm](http://ec.europa.eu/education/lifelong-learning-policy/doc48_en.htm)

<sup>20</sup> <http://www.ufp.pt/>

<sup>21</sup> [http://ec.europa.eu/education/erasmus/doc890\\_en.htm](http://ec.europa.eu/education/erasmus/doc890_en.htm)

<sup>22</sup> <http://www.marcaspatentes.pt/index.php?section=1>

<sup>23</sup> <http://www.unesco.org/new/en/unesco/>

<sup>24</sup> <http://www.who.int/en/>

<sup>25</sup> <http://www.wipo.int/portal/index.html.en>

<sup>26</sup> <http://www.epo.org/>

<sup>27</sup> <http://www.uspto.gov/>

<sup>28</sup> <http://www.jpo.go.jp/>

<sup>29</sup> <http://www.aripo.org/>

<sup>30</sup> <http://www.ipindia.nic.in/>

<sup>31</sup> [http://eacea.ec.europa.eu/index\\_en.php](http://eacea.ec.europa.eu/index_en.php)



between EU countries in terms of PhD degree awarding procedure. It is expected that the implementation of the project will create a valuable assistance to a desired convergence of high level education in the EU countries. In that sense ECTS should become a known and understood in the entire network. To ensure the international recognition, all HEIs should agree to support the ECTS scheme by signing the Cooperation Agreement. All enrolled HEIs should integrate the Bologna Process. They are expected to use the ECTS in their practices. Recognition of the degree through the European Network of National Information Centres (ENIC)<sup>32</sup> on academic recognition and mobility and the National Academic Recognition Information Centres (NARIC)<sup>33</sup>, the Universities will inform the competent national authorities of the existence of the European Joint Ph.D. programme in “Theragnostics, Intellectual Property and Ethics” degree based on a fully integrated programme and with no substantial differences.

The international recognition of the Ph.D. programme is fundamental. Recognition implies a formal acknowledgement by a Competent Authority of the value to give access to further educational and/or employment activities at EU and worldwide levels. For international recognition of the awarding qualification, ENIC and NARIC networks<sup>34</sup> should be notified to provide full information on the given degree. For this purpose, the Cooperation Agreement between Home Institution and the HEIs should follow the recommendations of ENIC and NARIC Networks and the Lisbon Recognition Convention<sup>35</sup>. Within Europe, actions taken at the national level in accordance with the Berlin Communiqué<sup>36</sup>, should further assist recognition. In this Communiqué, the Ministers agreed to engage at the national level, to remove legal obstacles to the establishment and recognition of such degrees, and to actively support the development and adequate quality assurance of integrated curricula, leading to Joint Degrees. The Ministerial meeting at Bergen in May 2005<sup>37</sup> confirmed the commitment to establishing the European Higher Education Area (EHEA)<sup>38</sup> by 2010 and welcomed 5 new countries into the Bologna Process. The Portuguese Ministry of Higher Education and Science has published the legislation relevant to the Bologna Process. A Decree Law (*Decreto Lei I Série 67/2005*<sup>39</sup>) was passed specifically for the recognition of Joint Degrees. Decree Law 42/2005<sup>40</sup> deals with ECTS, the Diploma Supplement, and mobility and learning agreements. For Home Institution to be entitled to create a course in the framework of Erasmus Mundus, the programmes need to be approved by the Portuguese Ministry of Higher Education and Science<sup>41</sup> and formal approval published in *Diário da República*<sup>42</sup>.

The fully integrated programme and the mobility of teaching staff should provide and reflect a good practice. The modules structure is assembled for a fully integrated and dedicated Doctoral Course towards achieving the learning outcomes set for the course as a whole. The network should work towards implementation of a transnational quality assurance scheme via this Ph.D. programme, as mentioned in the Bergen Communiqué and by following ENQA<sup>43</sup> developments. The network should make full use of ENIC and NARIC networks to assess the foreign qualifications of candidates. The strong link between EHEA and the European Research Area (ERA)<sup>44</sup> is also very important and will be reinforced by this Doctoral Course.

For each specific Module listed in Tables 2, 3 and 4, the learning outcomes will be based on the ability of the student excelling on the following tools:

- Science communication in the specific scientific research;
- Communication including scientific writing and presentations;

<sup>32</sup> [http://www.coe.int/t/dg4/highereducation/recognition/enic\\_EN.asp](http://www.coe.int/t/dg4/highereducation/recognition/enic_EN.asp)

<sup>33</sup> <http://www.enic-naric.net/index.aspx?c=Portugal>

<sup>34</sup> <http://www.enic-naric.net/index.aspx?c=Portugal>

<sup>35</sup> [http://www.coe.int/t/dg4/highereducation/recognition/lrc\\_EN.asp](http://www.coe.int/t/dg4/highereducation/recognition/lrc_EN.asp)

<sup>36</sup> [http://www.bologna-bergen2005.no/Docs/00-Main\\_doc/030919Berlin\\_Communique.PDF](http://www.bologna-bergen2005.no/Docs/00-Main_doc/030919Berlin_Communique.PDF)

<sup>37</sup> [http://www.aic.lv/bologna/acebook/Bologna\\_reports.pdf](http://www.aic.lv/bologna/acebook/Bologna_reports.pdf)

<sup>38</sup> <http://www.ehea.info/>

<sup>39</sup> <http://dre.pt/pdf1sdip/2005/03/052A00/22652266.pdf>

<sup>40</sup> <http://dre.pt/pdf1sdip/2005/02/037A00/14941499.pdf>

<sup>41</sup> <http://www.mctes.pt/?idl=2>

<sup>42</sup> <http://www.dre.pt/>

<sup>43</sup> <http://www.enqa.eu/>

<sup>44</sup> [http://ec.europa.eu/research/era/index\\_en.htm](http://ec.europa.eu/research/era/index_en.htm)

- Formulation of research questions;
- Testing hypothesis based on applying scientific methods;
- Literature review of scientific research;
- Drafting scientific dissemination instruments (research papers, patents, conference, books, proceedings, ethical reports, and other relevant scientific documents);
- Sampling design laboratory, field and global surveys in scientific research;
- Group working;
- Language module English writing.

**Table 2:** An outline of the seminar series, given ECTS, and scientific content of Module 1 “Theragnostics”.

<b>Theragnostics 36 ECTS</b>	<b>Selected Seminar Series (Training Skills)</b>	<b>Scientific Content (Specific topics)</b>
Chemotherapy 6 ECTS	Classical and Novel Chemotherapeutic Drugs 3 ECTS	Drug Classification and Mechanism of Action Signal Transduction Inhibitors, Anti-Angiogenesis Monoclonal Antibodies
	Therapeutic Regimens and Adverse Side Effects 3 ECTS	Current Regimens Modified Release Regimens Toxicity and Nanotoxicity
Targeting Strategies 6 ECTS	Passive and Active Targeting Approaches 3 ECTS	Role of Physicochemical Properties of Nanoparticulates Cancer Targets Aptamers and other Targeting Moieties
	Cell-Based Therapies 3 ECTS	Selected Cell Lines and Cell Cultures Training Biomarkers
Diagnostic Approaches 6 ECTS	Imaging analysis 3 ECTS	Classical and Novel Imaging techniques Biophysical Methods, STEM methods
	Superparamagnetic nanoparticles 3 ECTS	Iron Oxide Cores Gold Nanoparticles Quantum Dots
Nanoparticulate Carriers 6 ECTS	Types of Nanoparticulates 3 ECTS	Polymeric, Polysaccharide, Lipid Nanoparticles, Liposomes Hyperbranched Polymeric Assemblies Core-Multishell Nanoparticles
	Multifunctionalization of Nanoparticulates 3 ECTS	Functional and Applied Molecular Genetics Synthesis and Production Methods Applications
Hybrid Structures 6 ECTS	Dendrimers 3 ECTS	Structures, Functionalities and Conjugation Production, Toxicity and Applications
	Lipid-Drug Conjugates 3 ECTS	Structures, Functionalities and Conjugation Production, Toxicity and Applications
Gene Based Structures 6 ECTS	Supramolecular Structures 3 ECTS	Monoclonal Antibodies Targeting-based Approaches
	Intracellular Gene Silencing 3 ECTS	Mechanism of Action Applications

Research management, education and media, will also be part of the entire academic period through the more applied teaching units, and also during the research period. The students will learn how to use their knowledge to integrate different disciplines to develop a holistic understanding of Theragnostic tools based on nanoparticulate carriers. Attendance of selected seminars will be mandatory and students will be asked to identify and propose how the improvements in the research skills through a Ph.D. programme will benefit these case studies.

**Table 3:** An outline of the seminar series, given ECTS, and scientific content of Module 2 “Intellectual Property”.

<b>Intellectual Property 16 ECTS</b>	<b>Selected Seminar Series (Training Skills)</b>	<b>Scientific Content (Specific topics)</b>
Intellectual Property and Patent Background 4 ECTS	Introduction to Intellectual Property Issues 2 ECTS	European Intellectual Property Architecture Intellectual Property Downturn, Global Expansion and Effective Management
	Current Challenges in Patent Information 2 ECTS	Introduction to Patent Searching Introduction to Contemporary Search Technology Patent Costs, Registered Rights and Trade Secrets
Technical Protection and Patients' Rights 4 ECTS	Ownership of the Rights 2 ECTS	Freedom to Operate and Collaborative ventures Intellectual Property Management in R&D* Collaborations Competitive Landscape
	New Frontiers in Intellectual Property 2 ECTS	Intellectual Property Codes and Conflict of Interests New Therapeutic Uses and Experimental Use Exemption The Global Perspective of New Therapeutics
Patentability Criteria and Patent Claims 4 ECTS	Technology Commercialization 2 ECTS	Brand Rights and Trade Mark Challenges Patents for Credit and Venture Capital
	Intellectual Property Security 2 ECTS	New Sources and New Techniques Valuation of Patents
Licensing Agreements for Nanomedicines 4 ECTS	Knowledge Business 2 ECTS	Organization of Intellectual Asset Management Intellectual Property into Strategy
	Case Law 2 ECTS	Litigation, Counterfeiting and Piracy Intellectual Property Risk Transfer

\* R&D, Research and Development

**Table 4:** An outline of the seminar series, given ECTS, and scientific content of Module 3 “Ethics”.

<b>Ethics 8 ECTS</b>	<b>Seminar Series (General topics)</b>	<b>Scientific Content (Specific topics)</b>
Bioethics and Ethics Disclosure 4 ECTS	Foundational Issues and Human Condition 1 ECTS	Definition of Ethics and Ethical Ground Worldwide Equity Opportunities and Risks for Developing Countries
	Bioethics and Nanotechnology 1 ECTS	Nanotechnology, Society and Ethics Ethical Aspects of Nanomedicine: EGE Opinion 21 <sup>45</sup> Definition of Nanoethics
	Ethical Awareness and Disclosure 1 ECTS	Responsible Approaches to Dealing with Risk Assessment Environment, Health and Safety Human Protection, Confidentiality and Privacy
	Regulations and Policy 1 ECTS	Research Funding Legal and Regulatory Frameworks Transnational Policies (EC <sup>46</sup> , FDA <sup>47</sup> )
Current and Emerging Nanoethics 4 ECTS	Public Perception of Nanoethics 1 ECTS	Autonomy and Justification of Nanoethics Societal and Ethical Implications of Nanoparticulates Equity and Access Considerations
	Emerging Issues on Nanoethics 1 ECTS	Clinical Translation Concerns Precautionary Principle Potential Dual Use
	Hot and Forbidden Topics 1 ECTS	Research on Children Research on Human Embryos and/or Foetuses Animal Experiments
	Global Discussions on Nanoethics 1 ECTS	Controversy and Accountability Role of Ethicists Cultural Diversity

<sup>45</sup> [http://ec.europa.eu/bepa/european-group-ethics/index\\_en.htm](http://ec.europa.eu/bepa/european-group-ethics/index_en.htm)

<sup>46</sup> [http://ec.europa.eu/index\\_en.htm](http://ec.europa.eu/index_en.htm)

<sup>47</sup> <http://www.fda.gov/>

Teaching of research skills and methods are essential tools of any Ph.D. programme as they are keys to preparing the candidates for their career. A week of field activities will be included in which students will meet practitioners currently working in various fields. Key taught skills and methods will include:

- Communication, both in written and verbal formats. Students will be asked to carry out a number of exercises, making presentations to the class, writing scientific reports including data which they have collected and analyzed. In the end of the 1 year academic period, a 3-day workshop will be organized by the PhD students, open to internal and external researchers and scholars.
- Data management and interpretation, for the development of the students' interpretation skills and improve their use of language to build arguments and develop scientific discussions.
- Field and laboratory techniques data collection, to develop practical scientific skills such as field data collection, analysis in the laboratory, interpretation, and presentation.
- Data and mathematical modelling, including statistical analysis.
- Research proposal design and writing, problem identification, and management of funded projects.

Professors from Home Institution will be entitled for each Seminar Series, but is nevertheless recommended to enrol academics and scholars from the cooperating HEIs and stakeholders from non-academic environment to give lectures in a specific topic. In this way, testimonies of professional experience on real situations will be transferred to students, discussing case studies on a daily-basis.

While it is an admission requirement that the students hold a scientific degree, the candidates will come from a wide variety of backgrounds. Some may have graduated or Master very recently while others may have been in the workplace for a decade. A wide variety of disciplines may be represented in the cohort of students. Therefore, experienced board of professors and lecturers should be strongly recommended. Some students may come from a very different educational background where the nature of the learning environment is different. The aim of these core modules is to develop the knowledge and skills of all students to the high level required for the offered modules and especially for the research period the students will carry out to fulfil the Ph.D. requirements. A series of other seminars and open lectures may be offered in international HEIs and in other local universities, to aware the students about key current issues in “Theragnostics, Intellectual Property and Ethics”, and open career opportunities. In the second period, the students will be required to select the research lines (RL) from the list proposed at Home Institution, in agreement with the cooperating HEIs. An updated list of research topics will be released each year following the current trends and state-of-art. These specialized research topics have been chosen as they represent key areas required to address the core issues of this Doctoral Course. A list of the research topics is given in Table 5.

Research Lines 1 (RL1) report on technology-based training lines, whereas Research Lines 2 (RL2) are ground on molecular/cellular based research. Both are complementary since the outcomes obtained from one cohort will be used in the other.

By requiring the students to complete 60 ECTS of the entire programme in a foreign HEI, they will develop an interdisciplinary understanding of the Intellectual Property and Ethical issues, but focused on the core research topic selected. Such an interdisciplinary knowledge has been identified as being essential to successfully accomplish the expected aims. Between 25-30 hours study is required for 1 ECTS. They will be provided by experts in their chosen field selected from the network of which includes those involved with the EU framework research programmes, but also other potential stakeholders, from INPI<sup>48</sup>, UNESCO<sup>49</sup>, OECD<sup>50</sup>, WHO<sup>51</sup>, WIPO<sup>52</sup>, EPO<sup>53</sup>, USPTO<sup>54</sup>, JPO<sup>55</sup>, ARIPO<sup>56</sup>, CGPDTM<sup>57</sup>. Representatives from EU pharmaceutical companies will also be

<sup>48</sup> <http://www.marcaspatentes.pt/index.php?section=1>

<sup>49</sup> <http://www.unesco.org/new/en/unesco/>

<sup>50</sup> [http://www.oecd.org/home/0,2987,en\\_2649\\_201185\\_1\\_1\\_1\\_1\\_00.html](http://www.oecd.org/home/0,2987,en_2649_201185_1_1_1_1_00.html)

<sup>51</sup> <http://www.who.int/en/>

<sup>52</sup> <http://www.wipo.int/portal/index.html.en>

<sup>53</sup> <http://www.epo.org/>

<sup>54</sup> <http://www.uspto.gov/>

included. All the professors will be part of the network institutions, from the stakeholders or specialists invited to participate in the programme based on their excellence and quality for high education in Ph.D. programmes. The research project is worth to 120 ECTS and will be carried out after the first year in the coordination institution in Portugal. Students will be encouraged to work on their dissertation in advance, preparing their proposal in agreement with a supervisor pointed out for each candidate and undertaking background research. A very wide range of topic areas will be available for study reflecting the range of expertise existing in the HEIs network. Table 5 shows the wide range of possibilities in the different institutions involved for each research line. The candidate can select one research line (RL1.1; RL1.2; RL1.3; RL2.1; RL2.2; RL2.3) recommended in cooperation with a specific HEI of the network, but the 60 ECTS secondment will also have to include a short internship in a second and third HEI for Intellectual Property and Ethical issues training. The selection and mobility will be approved and tacked by the Doctoral Board. A proposed scheme for the timeline and mobility of students is shown in Table 6.

**Table 5:** Research lines proposed for the second and third year and suggested cooperation EU HEIs for students' secondments.

Research Lines	Research Topics		Proposed Cooperating EU Institutions	
RL1 (Technology-based training lines)	RL1.1	Lipid Nanoparticulates (e.g. Liposomes, Micro/nanoemulsions, Solid Lipid Nanoparticles)	Institute of Pharmacy, Department of Pharmaceutics, Biopharmaceutics & NutriCosmetics, Freie Universität Berlin, Berlin, Germany	University of Siena, Faculty of Law, Via Mattioli, Siena, Italy
	RL1.2	Polymeric Nanoparticulates (e.g. silica, PACA, PLGA, perfluorocarbons)	Institute of Nanoscience and Nanotechnology, University of Barcelona, Av. Joan XXIII Barcelona, Spain	
	RL1.3	Paramagnetic and Fluorescent Nanoparticulates	Department of Pharmacy, University of Tromsø, Tromsø, Norway	
RL2 (Molecular/Cellular-based training lines)	RL2.1	Cancer stem cells	Department of Radiation Oncology, Universite Catholique de Louvain, St-Luc University Hospital, Brussels, Belgium	Medical Ethics and Philosophy of Medicine, ErasmusMC, Room AE 340, PO Box 2040, 3000 Rotterdam, The Netherlands
	RL2.2	Genomics and Proteomics	University of Copenhagen Analytical Chemistry Biomacromolecular Drug Delivery, Copenhagen, Denmark	
	RL2.3	Cancer Targets and Modern Cell Lines (e.g. MCF-7, MDA-MB231, PC3, C4-2, A549, ATCC A2058, BT325, U251, HeLa, HOS)	Unite mixte INSERM 594/Universite Joseph Fourier, Laboratoire de Recherche Conventione du CEA No. 30V, Hopital Albert Michallon, and European Synchrotron Radiation Facility, Grenoble, France	

<sup>55</sup> <http://www.jpo.go.jp/>

<sup>56</sup> <http://www.aripo.org/>

<sup>57</sup> <http://www.ipindia.nic.in/>

**Table 6:** Timeline and Mobility Scheme for the Doctoral Course Programme.

Course Year	Month	Core Research Lines/Institution					
		RL1.1	RL1.2	RL1.3	RL2.1	RL2.2	RL2.3
ACADEMIC PERIOD	September	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)
	October						
	November						
	December						
	January						
	February						
	March						
	April						
	May						
	June						
	July						
	August						
RESEARCH PERIOD	September	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)
	October						
	November						
	December						
	January						
	February						
	March	HEI-1 (Germany)	HEI-1 (Spain)	HEI-1 (Norway)	HEI-1 (Belgium)	HEI-1 (Denmark)	HEI-1 (France)
	April						
	May						
	June						
	July						
	August						
RESEARCH PERIOD	September	HEI-2 (Italy)	HEI-2 (Italy)	HEI-2 (Italy)	HEI-2 (Netherlands)	HEI-2 (Netherlands)	HEI-2 (Netherlands)
	October						
	November						
	December	HEI-3 (Netherlands)	HEI-3 (Netherlands)	HEI-3 (Netherlands)	HEI-3 (Italy)	HEI-3 (Italy)	HEI-3 (Italy)
	January						
	February						
	March	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)	Home Institution (UFP)
	April						
	May						
	June						
	July						
	August						

UFP, University Fernando Pessoa; HEI-1, foreign High Education Institution for the 1<sup>st</sup> Secondment; HEI-2, foreign High Education Institution for the 2<sup>nd</sup> Secondment; HEI-3, foreign High Education Institution for the 3<sup>rd</sup> Secondment.

For each candidate, a supervisor (and co-supervisor, if applicable) will be pointed out by the Doctoral Board at Home Institution. A Local Coordinator will be nominated at each of the visiting HEIs (HEI-1, HEI-2 and HEI-3). The supervisor (and co-supervisor, if applicable) will establish in cooperation with the Course Coordinator and the 3 Local Coordinators the student PhD project plan to be registered at Home Institution.

#### 4.1.2. Students Admission Criteria

The application, selection and admission procedures have been designed following fairness and transparency and include the principles and processes adopted in the evaluation of European Commission (EC)<sup>58</sup> programmes described in the Code of Conduct for the Recruitment of Researchers<sup>59</sup>. There will be a single application to the course with common standards for recruitment and admission. The application form will be downloaded from the website of the Home Institution and returned to the coordinator. The application form is designed to allow the Doctoral Board to identify and select the most highly qualified and motivated students. The application should include a detailed CV form containing the Academic Qualifications and Language competencies, Personal Statement, Motivation, Financial Forms, and Referee/Recommendation Letters.

##### 4.1.2.1. Eligibility Criteria

Eligibility criteria will be assessed prior to the evaluation of the candidate's curriculum. For European students national and residential eligibility issues are examined first. Qualifications will then be checked according to the Lisbon Recognition Convention<sup>60</sup>. Second cycle degrees (Master) should give access, to third cycle programmes (Doctorate), thus these candidates can be eligible for the Doctoral Course. Applicants must therefore hold a higher education qualification which is considered as any degree, diploma or other certificate issued by a competent Higher Education authority attesting the successful accomplishment of a higher education programme of at least 300 ECTS. Candidate may also be admitted and selected conditionally on the basis that their admission only becomes effective when they fulfil the eligibility criteria. An example of this would be a student who expects to graduate in mid-June but has to apply by May.

Eligibility criteria are governed by the EC rules on Nationality, Residence, and Geographical Balance. The Course Coordinator and Doctoral Board will also monitor gender balance. Eligible candidates include graduates from all countries. After the eligibility checks, the students are ranked. Selection procedure of students from third country candidates will follow the same rules.

##### 4.1.2.2. Selection Process

The selection process will be carried out by the Doctoral Board composed of the Course Coordinator and the 3 Local Coordinators from each of the HEIs enrolled in the different research lines, and the list of selected candidates approved by the Rector at Home Institution (Awarding Institution), following the aims to accomplish the Bologna Process<sup>61</sup>. Invited representatives from potential stakeholders chosen to balance the different disciplines will also be considered. The Doctoral Board should organise a confidential, fair and equitable evaluation of each candidate application according to the evaluation criteria, in full respect of the relevant procedures, local and EU rules and regulations. In such way, it is ensured that the process runs smoothly and fairly, that access to the information pertaining to candidate's CV is strictly confidential, and that the most efficient selection process is carried out.

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<sup>58</sup> [http://ec.europa.eu/index\\_en.htm](http://ec.europa.eu/index_en.htm)

<sup>59</sup> <http://ec.europa.eu/euraxess/index.cfm/rights/codeOfConduct>

<sup>60</sup> [http://www.coe.int/t/dg4/highereducation/recognition/lrc\\_EN.asp](http://www.coe.int/t/dg4/highereducation/recognition/lrc_EN.asp)

<sup>61</sup> [http://www.ufp.pt/index.php?option=com\\_content&view=article&id=772&Itemid=515](http://www.ufp.pt/index.php?option=com_content&view=article&id=772&Itemid=515)



#### 4.1.2.3. Evaluation Criteria

The evaluation process is based on Eligibility Check, Individual Evaluation Monitoring Statistics, Consensus and Ranking. The procedure is designed to allow the Doctoral Board to identify and select highly qualified and motivated students. Evaluation criteria will include the quality of previous qualifications, language proficiency, students' motivation and potential, candidates' suitability for the course and letters of recommendations from referees.

- Quality of Previous Qualifications: Appropriate background in Biomedical, Medical, Pharmaceutical, Chemical, Biological Sciences, or related Master degrees. Candidates are required to submit transcripts of supporting documents (e.g. Bachelors' degree and Master degree). Qualifications should follow the ENIC and NARIC network. Documentation should also include study records, and publications if applicable.
- Proficiency in Languages: Candidates are required to demonstrate their proficiency in English. Possible examples include GCSE<sup>62</sup>, AS Level, A Level, IB, TOEFL<sup>63</sup> scores paper 575 / computer 232, Cambridge Proficiency Certificate level 4-5, Oxford Higher Certificate, International Certificate Conference (ICC Stage 3 Technical), IELTS<sup>64</sup> scores 6.5. The proficiency in other languages will be an added value in the selection procedure, and it will be assessed during the evaluation and selection process.
- Motivation and Potential: This criterion will evaluate the benefit of the Doctoral Course to the candidate. Potential for the development of the candidate is based on the motivation letter and the expectations of the candidate to pursue a career of research or management in the field, at the end of the Ph.D. programme.
- Suitability: Match between the candidate's profile and the Doctoral Course is based on the suitability of students' skills and the letter of motivation according to the CV. Appropriate professional experience of candidates with non-standard academic backgrounds is evaluated.
- Recommendations: These are based on the evaluation forms returned by the referees appointed by the candidates to the Doctoral Course.

It is expected to be a competitive process, based on the documented academic performance and credentials of the applicants. The Doctoral Board should only select high quality students, (threshold for each criterion is 4). For each criterion, scores between 0-5 will be attributed for ranking, where "0" stands for "fail to address the criteria or information is missing"; "1" is given if the criterion is poorly addressed, the information is confusing or the information is of poor content; "2" is given if notable weaknesses are pointed out during the assessment of that criterion; "3" is given when the criterion is fairly addressed where some good points and some weaknesses can still be pointed out; "4" is given when the criterion shows some very good points but certain improvements are still possible; "5" is given when the criterion cannot be improved and has high degree of agreement among the Doctoral Board.

#### 4.1.2.4. Examination Criteria

The Cooperating Agreement between the HEIs covers assessment regulations (pass or fail). Most student evaluations are based on student output rather than examinations or tests. The criteria will be fully described in each Module and grading is based on ECTS. Evaluations taken at Home University will be fully and automatically recognized by the other HEIs of the network. A range of different assessment methods are used such as laboratory reports, literature review, seminar presentations, poster, press releases, public information leaflets.

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<sup>62</sup> <http://www.gcseguide.co.uk/englishgcseguide.htm>

<sup>63</sup> <http://www.ets.org/toefl>

<sup>64</sup> <http://www.ielts.org/>



The ECTS grades will be the recommendable scale for the assessment, although national grades will be accepted and converted to ECTS if required.

#### 4.1.2.5. Dissertation Thesis

Doctoral students should defend their original research work according to the Portuguese legislation since awarding University is UFP<sup>65</sup>. The defence will be public and implies that the candidate will present a written document including the hypothesis, objectives, material and methods of the work, the results, discussion and final conclusions, which should have character of positive outcomes. The public presentation will be in form of a summarizing oral presentation covering all the above-mentioned items followed by a discussion with members of a Jury during a period of time no longer than one hour. The total duration of the defence should be up to a maximum of three hours including the questions of the Jury. The Jury will be composed by experts in research area of the dissertation and includes the Course Coordinator, the 3 Local Coordinators and the scientific supervisor (and co-supervisor, if applicable). To obtain the European Doctoral Degree, the candidate should include in the thesis an extended abstract in a second European language, and the Jury should include at least two members from different EU Member States or Associate Countries. The Jury will be headed by the Rector of the Home Institution, the entitled official Responsible for the Degree.

#### 4.1.2.6. Admissions Conditions

Students must have fulfilled all the application criteria, and registration criteria including the payment of first fee instalment to be admitted in the programme. Students must respect the calendar set annually for registration.

#### 4.1.2.7. Tuition Fees

Tuition Fees are governed by the Home Institution in Porto, *i.e.* the Awarding Institution. Nevertheless, students are asked to present a budget for their study period and travel, based on regular tuition fees' system, in particular if the candidate comes from a Third Country. Tuition fees include the registration under the national rules, the issue of diploma or other related costs, *e.g.* exam fees, bench fees.

#### 4.1.2.9. Life Long Learning Requirements

The Doctoral Course has been designed following the Life Long learning specific objectives, to promote high performance and innovation, and offer European dimension in the field of practice. With the proposed Doctoral Course, it is expected to accomplish social cohesion, intercultural dialogue, gender equality, competitiveness, employability, language learning, knowledge transfer, respect for other people and cultures. Cooperation in quality assurance of scientific research in Europe will be pursued encouraging the best use of results, developing innovative approaches and processes, exchange good practice and improve the quality of education and training.

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<sup>65</sup> <http://www.ufp.pt/>

## 4.2. Pedagogic Assessment of the PhD Programme

### 4.2.1. Evaluation Scheme of Students Performance

#### 4.2.1.1. Supervision at Home Institution

The entitled professors for each of the teaching units composing the three different Modules (Table 1) will deliver the assessment of the students' grades after the validation, and under the supervision of the Course Coordinator at the Home Institution. All the grades must be provided according to ECTS scale. Students will be asked to organize a scientific interactive 3-day workshop in the end of the academic year. The workshop will give the participants a comprehensive overview of the different modules, through a combination of didactic lectures and interactive discussion sessions. Students and attendees will learn about the key principles and concepts emphasized in "Theragnostics, Intellectual Property and Ethics". Specific case-studies will be presented and discussed throughout the workshop. Students and attendees will have the opportunity to practice answering question types during the scientific event. The quality principles applied in the organization of the event are expected to release high quality indicators to attract valuable stakeholders.

#### 4.2.1.2. Dissertation Thesis

The Doctoral Board, in cooperation with the supervisor, co-supervisor (if applicable), local coordinators, will examine the PhD students. Experts from external HEIs, private sectors, non-profit organizations, may be invited to join the panel. Annually, two dates for the Defence of the thesis will be decided in advance, and students will be adequately informed. Thesis will be delivered in advance to the Jury enabling the reading before the defence. Each thesis will have to be submitted with the report of the supervisor and co-supervisor (if applicable), and reviews by two international referees.

Publication of results in the scientific journals (JCR/SCI<sup>66</sup> quoted) before the Thesis defence will be strongly suggested, and will be taken into consideration during the final evaluation. In the absence of previously published, peer reviewed papers, the candidate will have to clearly organize the final document to demonstrate the originality, innovation and potential for publication of data/findings.

Before approving the thesis, the supervisor, co-supervisor (if applicable), local coordinators, and the Doctoral Board will check, among other criteria, whether the work provides new insights into the current knowledge in the field, as represented by published and generally available results of research, paying particular attention to the following:

- Scope and relevance of the research proposal
- Clarity of the research question
- Originality of the produced data and documents
- Academic level of the organization
- Analysis and handling of the material
- Inference of new insights and new ideas from the analysis of the outcomes
- Purity of the method employed in the analysis
- Merit of the doctoral candidate's conclusions in the light of the current state-of-art knowledge

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<sup>66</sup> [http://thomsonreuters.com/products\\_services/science/science\\_products/a-z/journal\\_citation\\_reports/](http://thomsonreuters.com/products_services/science/science_products/a-z/journal_citation_reports/)

- Creative approach to the field under discussion
- Balanced structure
- Clarity of style

The supervisor and co-supervisor (if applicable) will inform the doctoral candidate in writing whether the thesis has been approved within two months of the submission of the manuscript. The doctorate procedure for conferring the title of “PhD degree in Theragnostics, Intellectual Property and Ethics” will require a written dissertation in one or more fields covered by the Doctoral Course, and a defence of the dissertation against an evaluation committee specifically assigned, *i.e.* the Jury. The dissertation has to reflect an independent scientific achievement that advances the state of research in a particular field beyond the current knowledge.

For the admission to the final thesis examination, the doctoral candidate should produce at least two papers (at least one as a first author) to be published in a journal on the topic of the doctoral thesis. These papers should be published or accepted for publication.

The Doctoral Board will be entitled to appoint members to the Jury after approval and discussion with the Official Representative of Home Institution, to assess the dissertation. At least one referee should be external (an international scholar expert in the field). The dissertation will also be available for inspection at the faculty offices at all HEIs involved in the programme, using the facilities offered by their websites. The Doctoral Board members may issue opinions. If the dissertation is approved, the candidate has to defend it orally against the Jury. The defence will be open to public and will be held at Home Institution. If the defence has failed, it may be repeated once. All documents concerning reports and evaluation will be collected in the website platform.

#### 4.2.1.3. Criteria for Final Evaluation

Criteria for the final evaluation will focus on the originality and innovation of the work, candidate autonomy and involvement in the work, interdisciplinarity, ability of consistent and pertinent written and oral discussions, clarity, publications in scientific journals, potential contribution to innovation, and knowledge improvement. An extended summary of each defended thesis may be published on the website of the enrolled HEIs and stakeholders.

#### 4.2.1.4. Final Joint Degree

The final degree delivered should be a Joint Degree, a single Diploma issued by the universities (*i.e.* HEIs) where the student has pursued the integrated studies. The Agreement of Cooperation should follow the Draft Recommendations on the Recognition of Joint Degrees<sup>67</sup> DGIV/EDU/HE (2003) 4; Draft Explanatory Memorandum to the Draft Recommendations on the Recognition of Joint Degrees DGIV/EDU/HE (2003) 3 rev.2; Joint Council of Europe/UNESCO 1997 Convention on the Recognition of Qualifications concerning Higher Education in the European Region - Lisbon Recognition Convention), according to the European University Association<sup>68</sup> (EUA). A template of the Joint Degree Diploma is described in Table 7.

Students will additionally obtain a Diploma Supplement using ECTS, issued by the Home Institution. The Diploma Supplement should clearly indicate the study programme elements and the institutions at which the different parts of the degree have been earned (HEI-1, HEI-2 and HEI-3). This Diploma Supplement is detailed in Table 8. The purpose of the supplement is to provide sufficient independent data to improve the international transparency and fair academic and professional recognition of qualifications (diplomas, degrees, certificates). It is designed to provide a description of the nature, level, context, content, quality assurance and status of the studies pursued

<sup>67</sup> [http://www.eua.be/eua/jsp/en/upload/FAQ\\_Recommendation%20on%20Joint%20Degrees.1070637590566.pdf](http://www.eua.be/eua/jsp/en/upload/FAQ_Recommendation%20on%20Joint%20Degrees.1070637590566.pdf)

<sup>68</sup> [http://www.ond.vlaanderen.be/hogeronderwijs/bologna/actionlines/joint\\_degrees.htm](http://www.ond.vlaanderen.be/hogeronderwijs/bologna/actionlines/joint_degrees.htm)

and successfully accomplished by the student, named on the original qualification to which this supplement is attached. It should be free from any value judgement, equivalence statements or suggestions about recognition.

**Table 7:** Description of the characteristics of the Joint Ph.D. Degree Diploma.

Item	Description
<i>Descriptor</i>	University Fernando Pessoa
<i>Logos</i>	Flag of the European Union and Logo of the Joint Ph.D.
<i>Title</i>	Joint Diploma European Ph.D. Degree
<i>Subject</i>	Theragnostics, Intellectual Property and Ethics
<i>Name of Student</i>	Conferred by the Full Name of the Student
<i>Original names of the Universities</i>	Conferred by the Names of the Universities
<i>ERASMUS codes</i>	ERASMUS Codes of the Entitled Universities
<i>Academic years</i>	For Attending and successfully Completing the Course Academic Year
<i>Duration</i>	Over 36 months
<i>ECTS</i>	180 ECTS
<i>Home University UFP</i>	University Logo Home University UFP signed by the Rector
<i>University HEI-1</i>	University Logo HEI-1 signed by the Official Representative of HEI
<i>University HEI-2</i>	University Logo HEI-2 signed by the Official Representative of HEI
<i>University HEI-3</i>	University Logo HEI-1 signed by the Official Representative of HEI

#### 4.2.2. Quality of Supervision and Monitoring

Attendance of courses and dedicated activities is mandatory. Any absence needs to be duly justified and approved by the supervisor. Shared personal calendars on the website will allow supervisors and the Doctoral Board to monitor the activity of each doctoral candidate at any moment.

For each candidate, a supervisor will be appointed, who should have previous experience in supervising PhD students. A co-supervisor may also be appointed and can belong to the pool of potential stakeholders (private or public sectors, non-profit organizations). Supervisors will be in charge of advising on all aspects of the candidate's education and will report to the Doctoral Board every six months. The supervisor shall supervise the doctoral candidate via regular meetings every three weeks and by internet technologies. Meetings will be scheduled via the shared personal calendars to assist the monitoring process. When hosted in a different institution to that of the supervisor, candidates should send a quarterly report.

Within two months after starting the Doctoral Course, the PhD candidate, in agreement with the assigned supervisor and the Course Coordinator will draft the PhD project plan following the proposed research lines (RL1 and RL2) listed in Table 5, providing a preliminary title of the thesis. The PhD project plan will be re-described in detail at the end of the first year and adapted if required. The PhD project plan also serves as a criterion for assessing the doctoral candidate at the end of the second year (*i.e.* first year of the research period) and forms the basis of annual performance reviews to be held with the PhD supervisor. The Committee Board will meet in the end of every term for officially monitoring the quality of the research work carried out by each student and for assessing the certification required for admission to the following course term or to the final thesis examination.

Admission to the second and third year of the programme is decided by the Doctoral Board on the basis of the supervisor's interim reports, the quality of the work submitted every year, and the results of examinations for taught courses. In cases where the Doctoral Board dissents the thesis, or where the doctoral candidate needs more time for finalizing the thesis, the doctoral candidate may seek an extension for one year. The request shall be submitted in writing at least three months before the third year ends.

**Table 8:** Description of the characteristics of the Diploma Supplement.

Section	Description						
1	<b>INFORMATION IDENTIFYING THE HOLDER OF THE QUALIFICATION</b>						
	<ul style="list-style-type: none"><li>– Surname(s)</li><li>– First name(s)</li><li>– Date of birth (day/month/year)</li><li>– Identification number: personal identification number (identity card or - if foreign student- passport)</li></ul>						
2	<b>INFORMATION IDENTIFYING THE QUALIFICATION</b>						
	<ul style="list-style-type: none"><li>– Date of issue</li><li>– Name of qualification and (if applicable) title conferred (in original language)</li><li>– Name of qualification and (if applicable) title conferred in official translation into English</li><li>– Name(s) of the Quality Assurance Agency responsible for the programme assessment/accreditation</li><li>– The validity period of the programme assessment/accreditation</li><li>– Information on quality labels awarded to the programme (if applicable) and validity period</li><li>– Main field(s) of study for the qualification</li><li>– Name (in original language) and status of awarding institution</li><li>– Name (in original language) where the degree holder has followed studies</li><li>– Language(s) of instruction</li></ul>						
3	<b>INFORMATION ON THE LEVEL OF THE QUALIFICATION</b>						
	<ul style="list-style-type: none"><li>– Level of qualification: PhD</li><li>– Official length of programme: (ECTS credits)</li><li>– Access requirement(s)</li><li>– Adequacy of the qualification to the corresponding level (doctorate)</li></ul>						
4	<b>INFORMATION ON THE CONTENT AND AWARDING RESULTS</b>						
	<ul style="list-style-type: none"><li>– Mode of study: Full-time/part timer/mixed.</li><li>– Degree requirements: Theory (no. credits) Practice (no. credits) project (no. of credits)</li><li>– Programme details (e.g. modules/ units/subjects studied), and the individual grades/marks/credits obtained. Example:<table><tr><td>Module Code</td><td>Level*</td><td>ECTS credits</td><td>Module Title**</td><td>Marks</td><td>ECTS Grades</td><td>No. attempts at module/subject</td></tr></table><p>*The level should indicate equivalence to Bologna cycles ** Where a module/subject is studied in another institution(s), this information should also be provided.</p></li><li>– Grading scheme and grade distribution guidance.</li></ul>	Module Code	Level*	ECTS credits	Module Title**	Marks	ECTS Grades
Module Code	Level*	ECTS credits	Module Title**	Marks	ECTS Grades	No. attempts at module/subject	
5	<b>INFORMATION ON THE FUNCTION OF THE QUALIFICATION</b>						
	<ul style="list-style-type: none"><li>– Access to further study: (This qualification gives access to....)</li><li>– Qualification objectives (including competences, whenever possible): (synthesis of objectives and general competences included in the programme of studies)</li><li>– Professional status (if applicable)</li></ul>						
6	<b>ADDITIONAL INFORMATION</b>						
	<ul style="list-style-type: none"><li>– Additional information: (include, at least, web page(s) address(es) of awarding institution(s) (If applicable)</li><li>– Description of the Joint Degree programme with reference to the programme/agreement in which the qualification is framed, participating institutions and other relevant data</li><li>– Other information of interest</li></ul>						
7	<b>CERTIFICATION OF THE SUPPLEMENT</b>						
	<ul style="list-style-type: none"><li>– Date</li><li>– Signature and official stamp or seal (if used)</li><li>– Capacity: Official Responsible for Degrees</li></ul>						
8	<b>INFORMATION ON THE NATIONAL HIGHER EDUCATION SYSTEM OR THE EUROPEAN HIGHER EDUCATION SYSTEM</b>						
	<ul style="list-style-type: none"><li>– In the case of the National Higher Education System it is related to the national system as described, updated and approved by the University Council</li><li>– In the case of the European Higher Education System it is related to the European system, a description of the European Qualification Framework –EQF- should be provided)</li><li>– In both cases the objective is to identify which level from the ones described corresponds to the degree.</li></ul>						

The supervisors and co-supervisors will jointly ensure that the doctoral research is conducted in accordance with the Code of Conduct. The research project will be screened by an Ethical Review Panel according to the EC rules<sup>69</sup>. The Ethical Table will be filled and each item conveniently addressed and explained if required (Table 9). A positive opinion from a Regulatory Committee composed by Member States and/or Associate Countries' representatives is required. Participants in research projects must seek the approval of the relevant national or local ethics committees prior to the start of the research activities. Topics of major relevance include the risk dual use, research with children, research with animals and research involving human embryos and/or fetuses.

#### **4.2.2.1. Dual Use**

Dual use is a term often used in politics and diplomacy to refer to technology which can be used for both peaceful and military aims, usually in regard to the proliferation of nuclear weapons. Ethical issues of dual use might arise in cases where classified information, materials or techniques, dangerous or restricted materials are used in research, and if the specific results of the research could present a danger to participants, or to society as a whole, if they were improperly disseminated.

Following the EC recommendations regarding implications for the use of and misuse of the research and products, the following measures and strategies should be applied:

- The researchers and PhD students should be aware of potential risks to participants in the project and society as a whole from inappropriate dissemination of the results;
- Appropriate measures to deal with dangerous or restricted materials should be detailed (if applicable);
- An appropriate strategy to deal with issues of informed consent and risk management for participants and for society where classified information, materials or techniques are concerned should be demonstrated;
- The Advisory Board should identify risks to participants from particular research activities and devise a strategy for minimizing and dealing with these risks;
- The dissemination and communication strategy of the project outcomes to a wider audience should be controlled by the Advisory Board, which should report to the Coordinator on a regular basis.

#### **4.2.2.2. Research with Children**

To demonstrate understanding and implementation of ethics when involving children in the research project, the EC provides an overview of the information to be given to authorities and the issues that need to be addressed for ethical review. While an ethics review committee is looking to ensure that the necessary boxes have been ticked (Table 9), in that informed consent procedures are clear, and required protections and insurances are in place. It should also be guaranteed that researchers have a clear understanding of the ethical issues that exist in relation to children. There should be a clear explanation of the informed consent/assent procedure, an indication of any child-relevant, data to be provided, and/or to be made for recruiting the required cohort of children.

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<sup>69</sup> [http://ec.europa.eu/commission\\_2010-2014/sefcovic/administration/ethics/index\\_en.htm](http://ec.europa.eu/commission_2010-2014/sefcovic/administration/ethics/index_en.htm)

**Table 9:** Identification of Ethical Issues<sup>70</sup>.

	<b>Research on Human Embryo/ Foetus</b>	<b>YES</b>	<b>NO</b>
*	Does the proposed research involve human Embryos?		
*	Does the proposed research involve human Foetal Tissues/ Cells?		
*	Does the proposed research involve human Embryonic Stem Cells (hESCs)?		
*	Does the proposed research on human Embryonic Stem Cells involve cells in culture?		
*	Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?		
	<b>Research on Humans</b>	<b>YES</b>	<b>NO</b>
*	Does the proposed research involve children?		
*	Does the proposed research involve patients?		
*	Does the proposed research involve persons not able to give consent?		
*	Does the proposed research involve adult healthy volunteers?		
	Does the proposed research involve Human genetic analysis?		
	Does the proposed research involve Human biological samples?		
	Does the proposed research involve Human data collection?		
	<b>Privacy</b>	<b>YES</b>	<b>NO</b>
	Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?		
	Does the proposed research involve tracking the location or observation of people?		
	<b>Research on Animals</b>	<b>YES</b>	<b>NO</b>
	Does the proposed research involve research on animals?		
	Are those animals transgenic small laboratory animals?		
	Are those animals transgenic farm animals?		
*	Are those animals non-human primates?		
	Are those animals cloned farm animals?		
	<b>Research Involving Developing Countries</b>	<b>YES</b>	<b>NO</b>
*	Does the proposed research involve the use of local resources (genetic, animal, plant, etc)?		
	Is the proposed research of benefit to local communities (e.g. capacity building, access to healthcare, education, etc)?		
	<b>Dual Use</b>	<b>YES</b>	<b>NO</b>
*	Research having direct military use		
*	Research having the potential for terrorist abuse		
	<b>Other Ethical Issues</b>	<b>YES</b>	<b>NO</b>
Are there <b>OTHER</b> activities that may raise <b>Ethical Issues</b> ?			
If <b>YES</b> please specify:			

\* Research involving activities in the left column in the table below will be referred automatically to Ethical Review.

<sup>70</sup> [http://cordis.europa.eu/fp7/ethics\\_en.html#ethics\\_cl](http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl)

Supervisors and candidates must also be able to justify the use of children, their age range and the particular procedures selected, including providing evidence or quoting other research as part of the justification. They should also be able to convince the ethical review panel that the selected protocol or procedure provides a lower risk or burden than other equivalent procedures. If there are special ethical difficulties with a particular procedure, these should be highlighted rather than ignored and justification or solutions proposed. The project should be able to identify what the specific ethical issues are in line with the research in question, and provide a realistic assessment of the potential risk and burden to participants. A clear justification should include the need of the research, the appropriateness of the children's participation and the potential benefits to the participating child. If direct benefit to participating children cannot be demonstrated, then the ethical issues increase complexity. Justifications should focus on the lack of alternatives, the benefit to science as a whole, and also the benefit to others with the same disorder. The levels of risk and burden should be clearly defined and addressed. However, there can be no justification for increasing the level of risk beyond minimal, even if this would potentially yield greater benefits.

The project should give sufficient details of the research protocol for the ethics review panel to judge whether all the pointed out queries are covered in the participant information sheet and consent form, a similar form as given in Table 9. If possible, copies of consent forms and information sheets should be included with research proposals, as well as age-relevant information. Failing this, the researchers should at least indicate the key points that these consent forms will contain, no financial inducement, levels of risk and burden, ability to opt-out at any time without disadvantage, data and privacy protection, compensation arrangements, plus any specific provisions to take account of the vulnerability of the child. The supervisor, co-supervisor (if applicable), the local coordinators, the candidate, signed by the Course Coordinator, should be able to convince the ethics review panel that they have taken all the necessary steps to safeguard the health of the child and to minimize any possible risk and burden.

#### **4.2.2.3. Research with Animals**

To improve the process of ethical review of research involving animals, the following aims should be ensured:

- Animals are of high quality and scientifically mandatory;
- Wherever possible, the use of animals is replaced, refined or reduced (policy of 3Rs);
- Research should improve public confidence in the review process;
- Research should enable those responsible for ensuring the acceptability of work in their institutions to carry out their duties, as effectively and efficiently as possible.

For integrating ethics into EU Animal Research<sup>71</sup>, a statement should be made that no replacements are available that would achieve the scientific objectives of the proposed work, and reasons should be given to explain to lay persons what relevant measures can be made on living animals that a replacement method cannot reproduce. The role of any *in vitro* or *in silico* work should be explained in the context of the overall research programme. The resources used to search for alternatives should be listed. If possible, the research plan should develop a Replacement or a Refinement method that may require extra animals and funds in the short term. If the work involves the production of monoclonal antibodies, the used sources to search for their purchase should be listed. If monoclonal antibodies are to be produced *in vitro* using the ascitic mouse method, this has to be justified as a replacement method is easily available. It is strongly recommended that professional statistical advice is sought before advancing with the number of animals to be used in the research project, and that a detailed statistical section is given to show that due consideration has been given to reduction. The issues to be considered include the statistical methods for data analysis, the needing power of the experiments, the confidence limit sought, the

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<sup>71</sup> [http://ec.europa.eu/environment/chemicals/lab\\_animals/home\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm)



probable variance based on previous work, all of which will influence the choice of group size. The number of groups will be influenced by the experimental design, as well as the order in which they are investigated.

It may be possible to carry out key experiments first that may preclude or include particular lines of enquiry e.g. if a drug is ineffective at a high dose there would be no need to try lower doses. When including controls, it should be carefully considered what is being controlled (sham, vehicle, untreated) and why, and if historical data can be used. Re-use has also to be carefully considered as to whether earlier work may have a carryover effect and so affect data collected. A careful literature search of what has been done should be documented.

Staging of experiments could incorporate non-animal methods and their use should be explained as often they provide useful information and complement the *in vivo* work. Some key experiments may help determining what paths of investigations are best followed.

To avoid duplication of experiments, current best practice should be followed, as well as working with other research groups to reach a maximum harmonization, which is more likely to lead to a mutual acceptance of data. Appendix A from the Council of Europe Convention on Research Animals should be adopted when Directive 86/609/EEC<sup>72</sup> is revised. By following these guidelines, the scientific outcomes are less likely to be affected by the husbandry and care, and should produce reliable science. If animals comply with an approved health status for the animals (e.g. compliance with FELASA<sup>73</sup> guidelines) then the data is less likely to be skewed by disease. Justification should be given for any deviation from these guidelines.

Recognition of animal suffering is a critical first step in refinement and an attempt should be made to assess the degree of suffering in terms of intensity, duration, and incidence *i.e.* the numbers of affected animals. Particular attention should be paid to genetically modified organisms. Steps that have been taken to avoid any suffering in the first place (e.g. pilot studies, thorough literature review, and any alleviation or justification if no alleviation), should be given. Furthermore, the different research projects (within each Research Line) should detail the adopted steps to be taken to avoid unnecessary animals suffering, such as using humane endpoints. These endpoints should be enacted as soon as the scientific objective has been achieved, or when the animal is physiologically or psychologically disturbed that the scientific integrity is compromised. The steps that have been taken to ensure that all those involved in the research are trained, competent and are aware of good and poor practices, should also be listed. Assurance of benchmarks for success rate of the technical aspects and the possibility of using of less invasive and non-invasive methods should also be stated. The research project should include justification for the species of animal chosen in relation to the scientific objective and that it is of the lowest neurophysiological development. Justification is also mandatory for e.g. primates, veterinary research, that the model being used is one that has been validated in some way (e.g. it is a useful and reliable test for therapeutic activity and that it causes the least suffering of those available), or if it is a genetically modified organism. The overall numbers of animals to be used should be duly justified. There may be a possibility to reduce the number of animals to be used or to gain more data from the proposed use through collaborative working (e.g. further tests on samples to be taken, sharing and exchanging data, and sharing of tissues). The fate of the animal at the end of the experiment should be given, e.g. method of euthanasia, release into the wild (is it fit to survive), or adoption as a pet.

#### **4.2.2.4. Research with human embryos and/or fetuses**

Research on human embryos, human embryonic stem cells (hESC) and/or fetuses is a sensitive area requiring major ethical justification by the researchers, in particular:

- Justifying the use of hESC;
- Providing full details regarding the source of hESC and/or the source of human foetal tissue;
- Describing the procedure of how you obtain informed consent.

<sup>72</sup> [http://www.ecbr.eu/directive-86609\\_2.htm](http://www.ecbr.eu/directive-86609_2.htm)

<sup>73</sup> <http://www.felasa.eu/>

When involving the use of hESC in the research projects, supervisors and candidates should take into account and specify:

- That the project does not include research activities which destroys embryos including for the procurement of stem cells;
- Whether the researchers have taken into account the legislation, regulations, ethical rules and/or codes of conduct in place in the country(ies) where the research using hESC is to take place, including the procedures for obtaining informed consent;
- The source of the hESC;
- The measures taken to protect personal data, including genetic data, and privacy;
- The nature of financial inducements (if applied).

Each project involving the use of hESC should be assessed by at least two independent ethical reviewers, namely, one in the country itself where the research will be carried out, and one at the EU level. If the research raising ethical issues is to be carried out in more than one country (*i.e.*  $n$  countries), it implies that more than two ethical reviews will be performed (*i.e.*  $n+1$  ethical reviews).

#### **4.2.2.5. Studies involving humans**

With respect to studies involving humans while it is not essential to submit the informed consent documents, the proper understanding of the issues in the ethics section needs to be demonstrated. The key issues specifically required to be address are the following:

- If there is a clinical trial, the researchers should explain in clear language the trials to be followed, including all invasive procedures.
- Foreseeable risks or inconveniences to the subject should be listed, including the reasonably expected benefits and when there is no intended clinical benefit to the person involved. Compensation and/or treatment available to the subject in the event of trial-related injury should also be stated, as well as if there are anticipated expenses to the subject for participating in the trial.
- Clearly state that the subject's participation in the trial is voluntary, and they can refuse to participate or withdraw from the trial at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- State that records which are identifying patients are confidential and to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. The number of patients involved in the study or trial should be given.
- Detail data protection practice should follow EU rules. If biological samples are collected, processed and reported as necessary for the purposes of the study, the name and location of the organization that will retain the samples, how long they will be retained, who will have access to the samples and results, the procedure for handling any retained identifiable samples, and the plans to be anonymous or destroy samples after analysis.

When consent is with children, great care to explain all procedures (section 4.2.2.2.) should be taken into account with parents/guardians, and followed the national and EU regulations. If the study is being undertaken in a developing country, where written consent is not common practice, detail what practices to apply to obtain informed consent.

### 5.1. Doctoral Course Management

#### 5.1.1. Information and Promotion Strategy

This Doctoral Course is expected to adopt several dissemination activities to reach EU candidates and also potential candidates from Third Countries. The websites of HEIs involved in the network will advertise the course to reach high quality PhD candidates. The websites should provide information for the application. The students will also find information regarding the Doctoral Course programme in each member network's website. A simple folder and a more extensive brochure will be prepared for downloading. The complete information package will be fed into a handbook in CD-PDF format. The promotional dissemination of the Doctoral Course will be carried worldwide in during Seminars and Workshops, Presentations and in Conferences and Meetings, as well as visits, presentations, and short courses in academic institutions worldwide. Other national and international networks and associations (e.g. INPI<sup>74</sup>, UNESCO<sup>75</sup>, WHO<sup>76</sup>, WIPO<sup>77</sup>, EPO<sup>78</sup>, USPTO<sup>79</sup>, JPO<sup>80</sup>, ARIPO<sup>81</sup>, CGPDTM<sup>82</sup>) should also be contacted for promoting the course, and will be approached to disseminate and to attract the interest of the best potential candidates. The Doctoral Course should have a multipurpose webpage hosted at the Home Institution' server with a hierarchical access granted to all enrolled HEIs. It will be linked to their websites by means of a "national" subpage for the purpose of better visibility and information provided in the language of the HEIs. A rapid identification of the course will be achieved by means of a Logo which will be used by all participating HEIs. A newsletter will be periodically delivered to the HEIs and other potentially interested research centres, public and private industries, non-profit organizations, policy makers and stakeholders. A direct contact between Home Institution and scientific societies of Third Countries will assure a capillary dissemination of the information. A help desk will be available during the whole project activities.

#### 5.1.2. Complementarity and Networking Capacity

This proposal is expected to involve several HEIs located in different countries, either in Europe or outside Europe, as full members or as stakeholders. A summarized list of selected institutions is provided in Table 5, reflecting the inter-sectoral and inter-organizational aspects of the network.

A wide spectrum of connected, joint and inter-related research modules and research lines is proposed (Table 5) to cover the potential interests of students enrolled in the Doctoral Course. Also, potential stakeholders to be approached should offer the possibility to increase the excellence and quality of the education and management including inter-sectoral and inter-organizational collaboration and mobility.

The enrolled HEIs will produce a complementary excellence and quality in the programme, especially in the modules and research areas in which they are involved in the programme. Research institutions, associations, and private research companies, will put in the programme a different point of view in the research performed and

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<sup>74</sup> <http://www.marcaspatentes.pt/index.php?section=1>

<sup>75</sup> <http://www.unesco.org/new/en/unesco/>

<sup>76</sup> <http://www.who.int/en/>

<sup>77</sup> <http://www.wipo.int/portal/index.html.en>

<sup>78</sup> <http://www.epo.org/>

<sup>79</sup> <http://www.uspto.gov/>

<sup>80</sup> <http://www.jpo.go.jp/>

<sup>81</sup> <http://www.aripo.org/>

<sup>82</sup> <http://www.ipindia.nic.in/>

oriented more towards the aspects that increase the future graduate's employability success. The participation of national and international bodies that deal with the management of Intellectual Property areas, such as the INPI<sup>83</sup>, UNESCO<sup>84</sup>, WHO<sup>85</sup>, WIPO<sup>86</sup>, EPO<sup>87</sup>, USPTO<sup>88</sup>, JPO<sup>89</sup>, ARIPO<sup>90</sup>, CGPDTM<sup>91</sup>, will provide a global point of view to the study applied to the management of the areas and research topic proposed in the programme. The participation of stakeholders will ensure the validity of the research conducted in the programme to the employment of the students, and transference to the private and public socio-economic sectors in Europe and outside Europe. During the academic period at Home Institution, in the first year the students will select the research lines. After this selection, the 2<sup>nd</sup> and 3<sup>rd</sup> year will visit at least 3 different HEIs (Table 6) to accomplish the 60 ECTS and be entitled to receive the European PhD degree award. In addition, part of this secondment may also be spent in National Agencies, private companies, private and public research institutions, private consultants. Within this scheme, the programme will ensure an inter-sectoral and inter-organisational dimension. All the research lines are conducted in collaboration with foreign HEIs, a practice that will favour the mobility between the different institutions. Each student will be able to choose among several scientific pathways, with the possibility to stay in 3 or more locations after the initial 1-year period. This opportunity is important for the understanding of different environmental and socio-economic conditions and for realizing social and cultural background of different countries. The proposed Doctoral Course programme aims at developing a set of skills that can be quickly transferred to the appropriate organizations or governmental bodies, aiming at improving the quality of management and governance. Some research lines are linked to activities of interest to the industry/private sector. This ensures that the industry/private sector participate in the development of knowledge and in acquisition of new competences. Besides, the participation in the network of several members from outside the academic sector will boost the orientation towards the societal and economical needs. The institutions views during the design and development of the programme will improve the success in the graduates' employability.

The complementarity is inherent to the modules (Table 1) and research lines proposed in the programme (Table 5). Each proposed HEI has expertise in different fields and a diverse curriculum that could not be offered by a single University. During the academic period (12 months), the teaching and research staff from all HEIs, including stakeholders will work together as a team, to provide an integrated curriculum to the students at the Home Institution.

The network is well balanced, and provides a complete coverage of all the topics included in this wide Doctoral Course programme. Simultaneously, complementary will be exploited avoiding overlapping topics. First year fundamental courses are provided at Home Institution and suitable advanced topics are added at later stages during the research training period, depending on the selected research line. The differentiation of the offer ensures that the students are well supported to pursue advanced topics within their respective topic of research. With respect to Intellectual Property training, this will be offered by Law Schools, differing in legal traditions depending on the country. This diversity is essential to understand the wide context of European/Community Law which is composed of very different legal systems. Analogously, the size and age of the enrolled HEIs is different. This variety allows students to experience different kinds of relationships with teachers and researchers. The partners are complementary on the respective scientific sectors. Some should be most active in nanotechnology, physics, chemistry, medicine, biotechnology, others are excelling their scientific activity in bioethics, philosophy of law, information and communication technology law, privacy and sociology, European comparative law, computer law, legal ontology and comparative law, in logical formalization of normative reasoning and legal argumentation.

<sup>83</sup> <http://www.marcaspatentes.pt/index.php?section=1>

<sup>84</sup> <http://www.unesco.org/new/en/unesco/>

<sup>85</sup> <http://www.who.int/en/>

<sup>86</sup> <http://www.wipo.int/portal/index.html.en>

<sup>87</sup> <http://www.epo.org/>

<sup>88</sup> <http://www.uspto.gov/>

<sup>89</sup> <http://www.jpo.go.jp/>

<sup>90</sup> <http://www.aripo.org/>

<sup>91</sup> <http://www.ipindia.nic.in/>

The Doctoral Course is expected to approach the Nanotechnology European Platform<sup>92</sup> so it can also cover these topics. It is also expected to approach the European Network of Mobility Centres EURAXESS<sup>93</sup> and EraCareer<sup>94</sup>, to provide proximity assistance services to the academic mobility.

#### **5.1.2.1. Role of University**

The Doctoral Course entitled “Theragnostics, Intellectual Property and Ethics” is a wide field, and the proposed programme covers only some of the possible topics. This course is expected to approach HEIs which are prospective new partners in the long term, which plays a role also in the teaching activities of the proposal, to further receive financial support. Universities play a relevant role in international consortia when applying for grants. All partners will be offering internships, seminars and co-supervision, to support sustainability and create a wider network, subject to acceptance as stakeholders by the funding institution.

#### **5.1.2.2. Role of Stakeholders**

Research centres and other non-profit organization (public or private non-profit centres) are expected to be part of the network to improve the quality of the students' research path. Further support from international associates aiming at promoting knowledge transfer by building new networks is envisaged. The Legal Framework for the Information Society (LEFIS)<sup>95</sup> will be approached to provide support from the research perspective. The European Association for Cancer Research<sup>96</sup> (EACR) will be approached to promoting innovative events, courses, conferences with the aim to join humanist and scientific disciplines around cancer-based initiatives. Promotional and networking activities will be supported by European platforms of reference, interacting with the EC regulators, local and national governments, as well as with business and institutions, involved in projects and networks such as the European Thematic Network on Legal Aspects of Public Sector Information (LAPSI)<sup>97</sup>, Legal Framework and Regional Policies (EVPSI)<sup>98</sup>, and the EU thematic network on the digital public domain. Industrial partners, e.g. pharmaceutical companies, will promote the programme and host internships and secondments. Their main role will be to host candidates for short internships (i.e., voluntarily 1-2 weeks) during the research period, and to provide input on what topics are of interest for the industry. They should express interest in employing candidates. Further links with the industrial sector will be provided by Research and Technological Centres, whose mission is to foster interaction and collaboration with industrial, international, and governmental partners. Representatives of these stakeholders should figure in the Advisory Board, established to assist in the promotion, implementation, evaluation and sustainable development of the Doctoral Course. To this end, the Advisory Board provides guidance and feedback in the selection of the topics of the thesis, choice of topics to be discussed in seminars and suggest names of people operating in the professional sectors that can contribute to the curriculum. Stakeholders play a role in the knowledge transfer by offering seminars on occasional basis and offering short-term research visits or internships within their institutions. Stakeholders are also invited to attend seminars and lectures organized during the course of the programme. Individuals of the

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<sup>92</sup> <http://cordis.europa.eu/nanotechnology/nanomedicine.htm>

<sup>93</sup> <http://ec.europa.eu/euraxess/index.cfm/services/networks>

<sup>94</sup> <http://www.eracareers.pt/>

<sup>95</sup> [http://www.lefis.org/index.php?option=com\\_content&task=view&id=44&Itemid=449](http://www.lefis.org/index.php?option=com_content&task=view&id=44&Itemid=449)

<sup>96</sup> <http://www.eacr.org/>

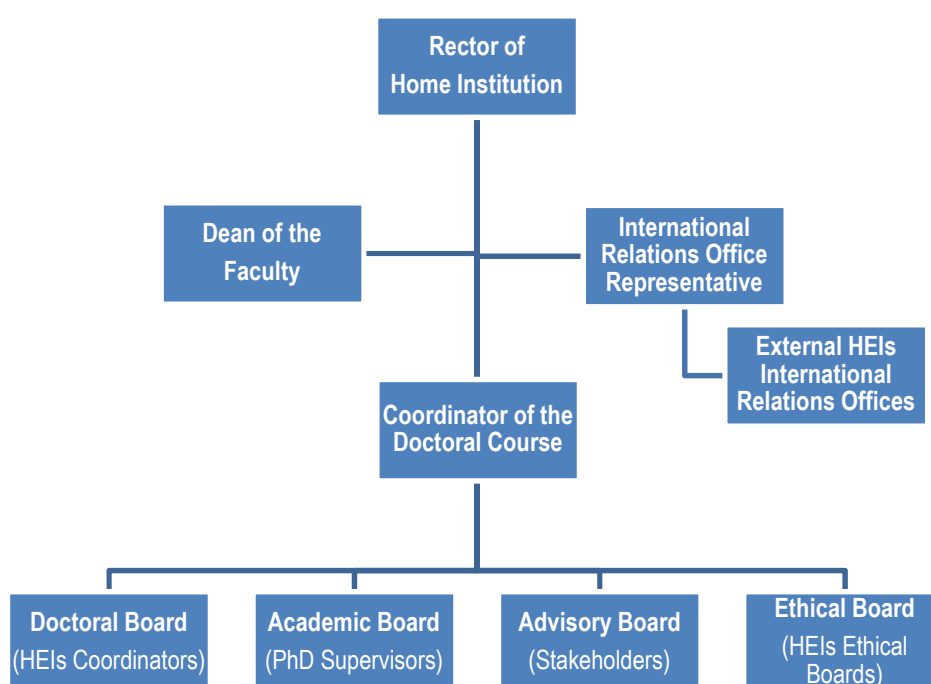
<sup>97</sup> <http://www.lapsi-project.eu/>

<sup>98</sup> [http://epsiplatform.eu/news/news/evpsi\\_public\\_launch](http://epsiplatform.eu/news/news/evpsi_public_launch)

cooperating institutions can also join some research projects e.g. by co-authoring papers or by being involved as additional advisors.

### 5.1.3. Organizational and Cooperation Mechanisms

The Doctoral Course will be a unified programme regulated by a Cooperation Agreement signed by all HEIs with the Home Institution. The governance bodies include four main organisms for coordinating the Doctoral Course: the Doctoral Board, the Academic Board, the Advisory Board and the Ethical Board, hierarchically responding to the Dean of the Faculty and to the Rector of the University. International Office Representative is a key element of the Advisory Board. The proposed organizational and cooperation mechanisms between boards is schematically described in Figure 1.



**Figure 1:** Organizational and Cooperation Mechanisms.

The Doctoral Board is composed of 2 representatives from Home Institution and no more than 1 coordinator from each of the HEIs enrolled in the programme. The Board will be in charge of the Doctorate Programme management and quality control. The Board has full control of all the activities of the Doctoral Course, defines the specific commitment of each Partner University to the implementation of the joint doctoral programme and has an active role on sustainability, admission application criteria, and on the Defence modality. It will be entitled to meet at least twice per year, *i.e.* in January and in September, while it is constantly in charge of monitoring the development of the programme. Each HEI can count on dedicated administrative staff, on top of the staff of the respective international offices. The Academic Board is composed by all the supervisors or co-supervisors of Doctoral candidates. The Academic Board is composed of the supervisor for each student and monitors the working progress, following a quality assurance model. All the scientific issues regarding the research work of students, the events, the conferences and the definition and organization of teaching initiatives, specifically dedicated to the Doctoral Course, will be discussed by the Academic Board and approval by the Coordinator.

The Advisory Board, composed by members of stakeholders and by the International Office Representative, provides helpful recommendations on curriculum development, research activity and internship opportunities and the members could become co-supervisors.

The Ethical Board will be composed by the Course Coordinator and by the elements of the Ethical Committees from Home Institution and from HEIs. The Ethical Board will provide a wider discussion on consultation about Ethical issues at institutional level, aiming at encompassing discussion on rules of decision-making, and fostering an atmosphere of public trust and confidence.

The cooperation and social networking between the different boards will make use of a dedicated website, which will also be used to support the students, to build their webpages, to share documents and comment on them, and organize virtual meetings. Professional collaboration instruments will allow the scholars of the board and committee to cooperate in a remote manner, increasing the opportunities of communication, and decreasing the need of travelling for meeting at the minimum.

#### **5.1.4. Services Provided to Host Doctoral Candidates**

The Home University is fully adapted to host European and International students. The enrolled HEIs should also offer excellent facilities to candidates. This is a condition *sine qua non* for successfully accomplishing the work programme.

The provisions will include special services for e.g. tutoring, 2 induction weeks, international services. The International Offices should be fully prepared to advise and aid incoming foreign students. Full information will be available on the website, including information on how to reach the University Headquarters, the cost of living, tourist information. The University has an Accommodation Office which helps ensure that students find suitable housing for their stay. A wide range of cultural activities are offered, with monthly leaflets and informative bulletins. European and International students will have full access to the following facilities:

a) International Office: The International Office receives several international exchange students every year. Most major European languages are spoken (English, Spanish, German, Italian, French, and Portuguese), and staff is fully prepared to advise and aid incoming foreign students. Full information is available on the Institution website<sup>99</sup>. The Home University is member of the official Erasmus Student Network, initially established to support Socrates Erasmus students and also offers its services (mainly cultural activities) to international students. The Course Coordinator will prepare a handbook which is mailed to all international students accepted in the Doctoral Course.

b) Student Tutors for Third Country Participants: The University offers guidance and counselling services to all students, in particular for those coming from Third Countries, with a strong student support system. They will be provided with regular information regarding cultural activities, and be able to make full use of the excellent sports facilities available in the Campus. There are extensive library services<sup>100</sup> on Campus, as well as access to computers and internet<sup>101</sup>.

c) Housing Facilities: The University has a Hall of Residence able to accommodate students. Application forms can be found in the Accommodation Office website<sup>102</sup>. Costs are also explained. A wide range of private accommodation is also available. Directions, maps and procedure on arrival will be communicated to all

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<sup>99</sup> <http://english.ufp.edu.pt/>

<sup>100</sup> [http://www.ufp.pt/index.php?option=com\\_content&view=article&id=1418%3Alibrary&catid=25%3Abibliotecas&Itemid=600](http://www.ufp.pt/index.php?option=com_content&view=article&id=1418%3Alibrary&catid=25%3Abibliotecas&Itemid=600)

<sup>101</sup> <http://ci.ufp.pt/>

<sup>102</sup> [http://www.ufp.pt/index.php?option=com\\_content&view=article&id=523&Itemid=404](http://www.ufp.pt/index.php?option=com_content&view=article&id=523&Itemid=404)



successful applicants. An allocation of rooms on student residences are reserved and negotiated for international students.

d) Provisions for Students with Specific Needs: The University has established a service for attention to special needs. This service is available to any student who requires support in areas such as finding adapted housing for the disabled, and also offers psychological and pedagogical support to those who require it. University nursery facilities also exist, with child care facilities<sup>103</sup> available on Campus.

e) Cultural Activities: The Home University offers a huge range of activities every month. Activities included are related to Seasonal courses, Gender studies, Club Cinema, forums, Literature courses, Exhibitions, among others. The city also offers a wide range of activities easily found on Campus.

f) Sports Facilities: The University has a gym<sup>104</sup> which includes a wide offer of different sport activities, and also it offers other activities in agreement with many other facilities in the city.

g) Other Supporting Measures: Other facilities at the University include ID student card, free access to loan books, journals, electronic journals and databases at the Library, wifi internet, banking services, cafes and restaurants, copy shop, and information about transport.

#### **5.1.5. Language Policy**

Language diversity in Europe is seen as an added-value of studies in Europe. Students are provided with the possibility of using at least two European languages and as many as possible depending on the selection of the research lines and the visiting HEIs to accomplish 60 ECTS. Students may be given the opportunity to learn two or more foreign languages: the language of the host country, the language of academic communication (principally English) and the language of other visiting countries.

##### **5.1.5.1. Language of Instruction**

The language for academic communication (mainly teaching and examinations) will be English. However, some modules may be offered in another language although only Language units (extra attended) and other specifically related to a given research are expected to be in a different language than English.

##### **5.1.5.2. Language of Examinations**

Few of the teaching modules in the course are examined, assessment generally depends on the student's output and tasks. Most of these tasks will be carried out in English. However, many of the lecturers are bilingual and will accept assignment in English. The professor responsible for each teaching unit will indicate English as the working language in the programme of that subject and which other languages may be acceptable. The language for the Ph.D. dissertation is also the English and the format of pre-submitted scientific papers will be recommended.

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<sup>103</sup> [http://www.ufp.pt/index.php?option=com\\_content&view=article&id=525&Itemid=407](http://www.ufp.pt/index.php?option=com_content&view=article&id=525&Itemid=407)

<sup>104</sup> [http://www.ufp.pt/index.php?option=com\\_content&view=article&id=1114&Itemid=579](http://www.ufp.pt/index.php?option=com_content&view=article&id=1114&Itemid=579)



### **5.1.5.3. Offered Language Learning Support System**

Language support is recognized as very important, and will be provided by each of the host Universities. It is recommended to offer a summer language school prior to enrolment. While preparing the students for mobility, a second language training may be required. Home University may offer language classes throughout the year in a number of European languages, and all the other HEIs should also be prepared to offer similar courses. HEIs should be identified with a special Language training centre for foreign students. The special methods of intensive language study should be used to help students during adaptation period.

### **5.1.5.4. Language of Thesis Dissertation**

To obtain the European Doctoral Degree the Ph.D. Thesis dissertation should be written in English, but the oral presentation can be in at least in two different languages.

## **5.2. Doctoral Course Quality Assurance**

### **5.2.1. Course Integration within the EU Context**

To accomplish the EU strategic agenda and the Lisbon treaty, the PhD graduate School proposed to offer this Doctoral Course should reflect a holistic approach in terms of scientific quality Assurance, Research Vision and Strategy, Training and Education. The course integration strategy is schematically represented in Figure 2.

This Doctoral Course creates a pool of challenging opportunities, which is based on highly integrated research and technologies. Several research groups will be involved in this course significantly to the state of the Theragnostics, Intellectual Property and Ethics, highlighting the international importance of the European research. Furthermore, the high historical and natural value of ERA<sup>105</sup> justifies the efforts of the scientific community towards the implementation of updated strategies in this field of research. The scientific quality of the education, training and research programme is described through the structure of the programme.

The Doctoral Course is a fully integrated doctoral programme. In order to develop a real interdisciplinary dialogue and exchange, candidates will constitute a single group for the first 12 months (Table 6). They will start the programme together in Porto. The students can participate in other initiatives during the entire programme such as attending additional lectures offered by host institutions. The Course Coordinator, in agreement with the HEIs will decide the destination of the candidates in the beginning of the programme, to balance the efforts of the different partners, allocating grants in equal measures to the three different tracks. In structuring the proposal the Course Coordinator the Tuning approach to doctorates (Applying the Tuning Approach to the Third Cycle<sup>106</sup>) has been adopted, using ECTS as a measure of student workload expressed in time (through ECTS credits) for both course work and research. ECTS credits are used as a measure of time to ensure that the demands made on candidates are reasonable. As such, the amount of research and analysis that students are asked to do is consistent with the length of studies, and help organizing the internships, while carrying out the PhD project. Sharing concerns on the actual recognition of credits for research by different Doctoral Offices of the network, only the ECTS will be used reference measure when describing the PhD project. The courses follow the Tuning approach in distinguishing between the generic competences, or the so-called “transferable skills”, and the

<sup>105</sup> [http://ec.europa.eu/research/era/index\\_en.htm](http://ec.europa.eu/research/era/index_en.htm)

<sup>106</sup> <http://www.unideusto.org/tuningeu/tuning-3rd-cycle/introduction.html>

subject specific competences. Doctoral candidates take courses aimed at developing analytical skills and providing methodological insights.



**Figure 2:** Scheme of Course Integration within EU context.

The credits for the first year for the mandatory course work and lectures (and not including language courses) count for 60 credits. There will be 60 credits for the second year, while the third year, which will include work on the thesis at Home Institution (6 months), will also count for 60 credits. The list of courses attended and grades obtained will be recorded in the candidate's career file. In the end of the programme, on top of the doctoral degree, the candidate will obtain a certificate which specifies individual courses passed with grades, the title of their thesis, the name of their supervisor and eventual co-supervisor and administrative information. The integration of scholars and doctoral candidates within the programme will be enhanced by an advanced website offering a dedicated social network among other things. Candidates will have the opportunity to build their own webpages, to share and comment on the documents they publish, to keep in touch with their supervisors and local coordinators when they are not in the same university, to have a public repository of publications and theses, to share the schedule of courses, the calendars with events and deadlines. An e-learning website based on the open source will be used to coordinate the courses, enabling students to register for courses, to receive news, to download teaching material, to upload reports for examination, and to assign readings to students. Other instruments such as Adobe connect, will allow candidates to have virtual meetings with their supervisors and with each other. At the same time, this website will allow the Doctoral Board to monitor students' course attendance when they are in different partner universities.

#### 5.2.1.1. Added value for Students and Lecturers

Studying in accordance to a programme set on the best expertise of the international HEIs provides an obvious added value to students. Learning in another institution and country will open up new ways of thinking, as well as a wealth of new cultural opportunities, including the possibility to develop and extend language-learning skills. There is no doubt that such learning experiences change lives, broaden intellectual horizons and offer new professional perspectives. Benefits to students arise from the experience of studying and working together in multi-cultural environments, opportunities that arise to experience and absorb European culture and influence,

development of pan-European social or technological knowledge and the formation of permanent network links across Europe that may directly assist future employment prospects. The experience has been found to give considerable added value to graduates' curricula, when employers are seeking people who are flexible and adaptable to different environments. For academics, the programme also provides professional development opportunities outside a national context, and allows research contacts and projects in Europe. It is expected that students and scholars will gain from different academic environments/traditions. From the different social environments (language learning, culture), students will develop international research/work experience.

### 5.2.1.2. Innovative Aspects

The innovative aspects are inherent to the core programme and the complementary research lines offered in collaboration between HEIs in the network and stakeholders that embrace international and national research institutions, government agencies, private consultancy, policy makers, and the international participation of e.g. INPI<sup>107</sup>, UNESCO<sup>108</sup>, WHO<sup>109</sup>, WIPO<sup>110</sup>, EPO<sup>111</sup>, USPTO<sup>112</sup>, JPO<sup>113</sup>, ARIPO<sup>114</sup>, CGPDTM<sup>115</sup>. It will also imply mobility to meet research objectives among all the institutions. The students will start the programme in the Home Institution where a core programme of 60 ECTS will be offered. There will be no options in this academic period and it will prepare the students for all the subsequent optional modules and for the research and dissertation periods. After this compulsory academic period, the research period will start in accordance with the research lines proposed. The teaching units will be provided by experts from inside and outside the network (including stakeholders) and will be organised into specific clusters to ensure the modules offered each year address an appropriate range of topics. For a second period the students will move to a second and a third HEI (Table 6), where a range of research lines will be available to enable the students to specialize in their primary area of interest (Table 5). Upon completing the taught modules the students will progress to their dissertation, registered at Home University. While students may also work in collaboration with many other stakeholders (private, public, non-profit organizations), within existing research projects, they will always have a network supervisor responsible for providing support, guidance and final assessment. Industries and private sectors usually show great interest in Intellectual Property and Patent issues. It is therefore expected to receive some type of sponsorship and/or investment, according to the legislation, or develop advanced research. Therefore, collaborations with these sectors should be envisaged, towards applicative research activities and future job opportunities.

### 5.2.2. Development and Sustainability

Because of the continuous and unpredictable technological and scientific advances the Doctoral Course proposal will require a systematic updating and, in the near future, broadening network to other partners. From the beginning the Doctoral Board, together with stakeholders, will identify new needs and possible new full partners to develop the doctorate to the level of a wider network at European and worldwide level. Furthermore, assuring sustainability is a first concern of the partners, and they commit in the agreement to seek additional sources for

<sup>107</sup> <http://www.marcasepatentes.pt/index.php?section=1>

<sup>108</sup> <http://www.unesco.org/new/en/unesco/>

<sup>109</sup> <http://www.who.int/en/>

<sup>110</sup> <http://www.wipo.int/portal/index.html.en>

<sup>111</sup> <http://www.epo.org/>

<sup>112</sup> <http://www.uspto.gov/>

<sup>113</sup> <http://www.ipo.go.jp/>

<sup>114</sup> <http://www.aripo.org/>

<sup>115</sup> <http://www.ipindia.nic.in/>

funding fellowships. The starting point will be the national funding agencies usually financing specific doctoral projects, such as FCT<sup>116</sup>, DAAD<sup>117</sup>, FNRS<sup>118</sup>, Gobierno de España<sup>119</sup>. The Doctoral Board will promote the integration of the Doctoral Course in the local HEIs which offer grants to their doctoral programmes, assuring that the recruitment procedure will satisfy the regulations of the course. Another possibility would be promoting a programme of life-long education involving HEIs and stakeholders to enable them and other industries and institutions to allow their staff to follow the doctorate.

### 5.2.3. Students Career Prospects

The Doctoral Course aims at building an important challenge for the academic and teaching practices and processes of the Europe contributing not only to the interdisciplinary of the academic modules, but also to the multi-nationality and interactivity of different nations not only in Europe but worldwide. The Doctoral Course will also focus on each candidate's individual potential, research activities and interests concerning how to face new challenges that the scientific and technological developments pose to the contemporary society and, in particular, legal systems, trying to support any of the academic and professional initiatives. This goal will be achieved by offering to the candidates' internships and training opportunities in different organizations, institutions and centres. Perspective employers, represented by the different types of associate partners, range, from public and private research centres to law firms working on Intellectual Property, privacy, patenting, from high tech enterprises developing systems for compliance, access control, e-commerce, social networks, multimedia distribution, to large enterprises, from regulatory bodies who have to deal with law concerning new technologies to ethical committee in biobanks and pharmaceutical industries.

The staff of all partner HEIs will do their best to keep the candidates always updated on job openings, post doctoral and faculty positions in similar and related fields. A career development plan should be discussed and prepared for each PhD student by the end of the academic period (*i.e.* before starting the research period, split between Home Institution and the visiting HEIs. After the PhD graduation, the students will be contacted on a regular basis to monitor and assist their career development, and further information may be collected and tackled via web-based professional networks, such as LinkedIn. Former candidates may log in to the doctorate website, to update their professional profiles and to share information and experiences, leading the way to the creation of an alumni association.

The former candidates will be also asked to provide feedback on their own experience and suggestions on ways to improve the programme, so as to facilitate their entry in the employment world or academic career, and also to guarantee the future candidates with the better programme.

All candidates will sign a Doctoral Candidate Agreement. The agreement will include information about: the programme, language policy, timetables, the course load (hours and ECTS), deadlines, thesis's requirements and procedure, logistics (*e.g.* venues, contacts, facilities). The agreement will also include information related to the payment of the scholarships and will describe in detail all the further candidates' rights and obligations.

The Doctoral Candidate Agreement will include a clause regarding dispute resolution. The Doctoral Course programme will be drafted to make this programme visible and interesting to the society, enhancing the profession of and trust in academic researcher, favouring scientific debates and bringing nearer such debate and the common citizens.

The accomplishment of these objectives will be made in each and every part of this programme starting with the recruitment procedure which will be open and transparent and finishing with the monitoring of the candidates after they conclude the programme in order to assist their future careers.

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<sup>116</sup> <http://www.fct.pt/index.phtml.en>

<sup>117</sup> <http://www.daad.de/en/index.html>

<sup>118</sup> <http://www2.frs-fnrs.be/>

<sup>119</sup> <http://www.educacion.gob.es/portada.html>

The programme will also insist on inviting the candidates to focus their research interests to expand the frontiers of scientific knowledge and innovate the ways of looking at, having always in mind ethical standards and good practices in research. The candidates will also be provided with the opportunity to be placed with their supervisors who will take care of the candidates' research directions, interests and further issues. Candidates will also be invited to contact any of the HEIs staff members whenever the candidates will need an academic advice or ask for general coaching which may include, but it is not limited to, advice on how to develop a career, guidance for the personal or professional motivation.

In line with the "General Principles and Requirements" of the "Code of Conduct of Recruitment of Researchers"<sup>120</sup>, candidates are expected to focus their research for expanding the frontiers of scientific knowledge, taking into consideration the ethical standards, the good practice in research, and closely working with their supervisors in accordance with agreed schedules.

The working conditions of all candidates are appropriate and essential for a successful performance on their research (also for disabled candidates, or candidates who travel and join the course with their families).

The successful doctoral candidate should acquire throughout the duration of training and research a set of technical skills in terms of data acquisition, management and interpretation, which are highly valuable and directly applicable to the labour market. These skills are designed to prepare the successful candidates for careers in management or research relevant to the implementation of important EU legislation. Close contact is kept with the network, to ensure that the training is up to date and relevant. The Course Coordinator should pursue the PhD students with the challenges facing applied science beyond the academic environment. Therefore, a special attention will be given to the contacts with the local/regional stakeholders from the very beginning of academic programme. The PhD students' profiles may be uploaded on the Doctoral Course website, with information about scientific education, social capabilities and other skills. Every organization linked to the Doctoral Course programme (European and Third Country institutions, centres of research and other potentially interested players) will be able to withdraw information about students during the PhD course, as well as after its end. The stakeholders will also have the opportunity to open on line a job position. The students can also profit from the different Universities using the Job and Career Office in each institution. Private and public bodies, industries, have access to insert job offers and get information about graduated students. Centres of employment targets professional orientation of the students and postgraduates, establish links and partnerships with private or public bodies and industries, monitor labour market from point of view related to specialties and educational orientation. The centres carry out their activities by upgrading and improvement of candidates' curricula for students and scientific research lines for postgraduates, taking into account needs of labour market, and by forming of interface between interested employers and graduates. The Doctoral Board will also provide possibility for monitoring of career prospects and analysis of employment of graduates.

#### **5.2.4. External and Internal Evaluation of the Doctoral Course**

Quality assurance in higher education generally takes the form of a set of principles and procedures that ensure the standard of awards and enhance the quality of the academic provision. Quality Assurance is important to guarantee the quality of the award for graduates and prospective students, to ensure responsiveness to the labour market, to assure that the university is performing at the correct level, and to give accountability that funds are being correctly used.

Quality assurance is also very important for the international recognition of the degree. In the case of national degrees, the responsibility is clear, being in line with the national body. In the case of Joint Degrees, there is no single system.

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<sup>120</sup> [http://ec.europa.eu/eracareers/pdf/am509774CEE\\_EN\\_E4.pdf](http://ec.europa.eu/eracareers/pdf/am509774CEE_EN_E4.pdf)

The European Association for Quality Assurance in Higher Education (ENQA)<sup>121</sup> is the entity entitled for the European Quality Assurance (EUA)<sup>122</sup>, but so far there is no single accepted mechanism. For this Doctoral Course the integrated curriculum and project should follow the Quality Assurance mechanisms. Dialogue should be maintained with EUA and ENQA to adopt European Quality Assurance mechanisms. In Portugal, the Ministry of Higher Education and Science<sup>123</sup> monitors the Quality of Higher Education courses using an independent commission of experts in the field.

The EUA<sup>124</sup> is responsible for the external evaluation of the quality of any operations at all HEIs and public and private research bodies which receive State funding, on the basis of an annual plan. The agency is also evaluating the coordination and supervision of the internal evaluation processes carried out by individual evaluation units within HEIs and research bodies, and in the assessment of the efficiency and efficacy of State plans aimed at funding and stimulating research and innovation.

Licensing and accreditation procedures include integrated audit of HEIs activity, and are based on academic tasks, quality assurance, accordance of content academic programs to state educational standards, as well as university science, management, audits, laboratories, finances. Accreditation procedure defines the status of HEIs. The main activities concerning this system include, professional orientation work with scholars, determination of requirements of labour market, intermediate control of the students' academic results and knowledge, analysis of placing in a job, analysis of university management, and analysis of student participation process.

The Internal Quality Assurance system should be in line with the "Standards and Guidelines for Quality Assurance" in the EHEA<sup>125</sup>, namely on the approval, monitoring and reviewing the degree courses and awards and on the policy, procedures, and initiatives. According to the national legislation, HEIs have to comply with a formal procedure for the approval of their degree courses and qualifications. The institutions have also to monitor the courses to grant the periodical review of the regulations of individual degree programmes.

Students should also participate in the Doctoral Course evaluation by means of questionnaires in the evaluation of teaching activities. Criteria for students' assessment will be included in the teaching regulations of which should be available online.

During the internal evaluation, HEIs and stakeholders can participate. Personnel from these organizations can address and conduct the internal evaluations by adopting the following integrated self-evaluation tools on which partners agree and cooperate:

- Online feed-back forms for the teaching activities, to be filled in anonymously by the candidates, to evaluate the quality of courses and seminars, as well as the infrastructures and organization. These course evaluation forms are taken into careful consideration by the Doctoral Board, which engages every year in curriculum improvement (September meeting).
- Starting from the second year, the results of the research carried out by the doctoral candidates are presented during the 3-day workshop which counts with the participation of external players and speakers. These participants provide feedback on the quality of the research and, indirectly, of the supervision.
- The members of the Doctoral Board meet at least twice a year (in September and January of each year). In both occasions, two representatives of each cohort of doctoral candidates are invited to participate and to advance suggestions, complaints, and proposals. The Doctoral Board solicits suggestions and proposals also from the Advisory Board.

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<sup>121</sup> <http://www.engq.eu/>

<sup>122</sup> <http://www.egausa.com/>

<sup>123</sup> <http://www.mctes.pt/?idl=2>

<sup>124</sup> <http://www.egausa.com/>

<sup>125</sup> [http://www.engq.eu/files/ESG\\_3edition%20%282%29.pdf](http://www.engq.eu/files/ESG_3edition%20%282%29.pdf)

- The Advisory Board provides feedback on the quality of the research carried out in the programme. Furthermore, whenever an internship takes place, the stakeholder will fill in a feed-back form on the quality of the candidates. A similar formulary is also filled in by the student who has carried out the internship.
- The evaluation of the candidates' final thesis by a joint defence Jury as described in section 4.2.1.2.

It is advised that documents resulting from the evaluation will be maintained on the website and will be accessible to the different Boards, evaluators and the funding institutions. In particular, the evaluation results will be used to:

- Change offered teaching units, improve the programme, brief or even change professors;
- Revise the advertisement procedure;
- Improve management and coordination and monitoring of students during their mobility;
- Seek new stakeholders to better fit candidates' needs to make experience in the professional world;
- Update the research programme to adapt to the evolution of technologies and major changes in the legal queries and scientific press-releases and patents on Theragnostics;
- Revise the role of the current partnership.

## 6. CONCLUSIONS

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The aim of this Doctoral Course in "Theragnostics, Intellectual Property and Ethics" is to create an interdisciplinary integrated programme to face the new challenges that society and the newly emerging technologies will increasingly pose in the future in the legal domain and the socio-ethical field. Research on Theragnostics has gained great attention in last few decades resulting in a large number of patents. The solutions to these challenges have direct impact not only on innovation capacity, competitiveness and living standards in Europe, but also on its cultural and religious identity.

The emerging technological, economic and social framework (the so-called Information Society, or Knowledge Society) offers new opportunities for individual and social development, as well as serious risks. To produce innovative solutions that enrich quality of life, it is essential that opportunities are fostered and risks are minimized and that different competences are combined in a holistic way. This is only possible if technologies are viewed through the lens of law, ethics, human rights, economics, and in turn, that social humanist disciplines acquire genuine understanding of the technological principles, languages and methodologies. Otherwise the risk is advancement in the state of the art in technology, which is not matched by social innovation.

This Doctoral Course programme seeks to shorten the gap between disciplines and to create innovative researchers and professional experts. This requirement is urgent and mandatory when facing the third industrial revolution. Potential outcomes in form of market launches in different forms and developed by research groups have been able to meet some of the critical needs of certain diseases. As such, the significance of Intellectual Property in this field has led to many start-up companies to patent their technology. Licensing agreements have been one of the important options for many entrepreneurs with suitable benefit to both parties. Due to initiatives taken by government, the industry-academia collaborative research activities have significantly increased. This has led to commercialization of more and more Nanomedicines for the benefit of consumers.

The Doctoral Course is expected to attract students with different backgrounds from all over the world, training them in three different curricula and research fields. To achieve this objective the network to be built should be composed of European High Education Institutions (HEIs) from different backgrounds, and well known for innovation and excellence in Cancer, Nanotechnology, Legal Studies, Ethics and Bioethics, as well as interdisciplinary centres, institutions and companies.



In the current level of scientific knowledge and academic offer in EU Universities, and others worldwide, this Doctoral Course brings new instruments in sectors of the life sciences that are rapidly evolving and require ethical instruments for avoiding malpractices and for ensuring a good governance of innovative solutions. Topics of discussion will include the application of Ethical concepts in Theragnostics, the nature of informed consent concerning testing and research, confidentiality and the duty to warn, individual and group privacy interests concerning identifiable health data and biobanks, ethical analysis of public health initiatives (genetic screening, national repositories), insurance and employment discrimination based on genetic predispositions, Intellectual Property issues relating to development of Theragnostic tools, and a survey of cutting-edge research. The application of nanotechnology in diagnosis and therapy raises high expectations for efficient and affordable healthcare, and has the potential to deliver promising solutions to cancer. Also, in this sector, legal and ethical issues play a fundamental role in shaping policy and strategy in conducting, disseminating and delivering the results of scientific research to industry. Interdisciplinary approaches and competencies are mandatory in the graduate market to widen vision and strategy.

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