Health2Innovation

WP 2: State-of-the-art analysis and Health2Innovation Training Course Structure

D2.2: Qualification Scheme

UNICERT

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1. About the project

The challenge

The European Union aspires to reinforce EU's competitiveness in digital technologies and to ensure that every business in Europe in whichever sector and location can fully benefit from digital innovation. To achieve this, the EU launched the Digitising European Industry Strategy in 2016 followed by the strategy "A Europe fit for the digital age" in 2020 to enable the integration of digital innovation in all sectors, including Health, while becoming a climate-neutral continent by 2050. Digital technologies and solutions are key in improving our health and care, but to really unlock their innovation potential, the reinforcement of digital skills and competences in addition to complementary skills, such as entrepreneurial and leadership skills is priority.

There is a growing demand of (1) digital skills for the development and use of cutting-edge technologies to accelerate the digital transformation of healthcare in Europe, (2) green skills to cope with the transition to a climate-neutral continent and the need for new professions, and (3) entrepreneurial skills and viable business models to create new, sustainable and profitable companies in Europe providing innovative solutions that will redefine healthcare delivery, which will in turn strengthen innovation, sustainable development and competitiveness.

In line with the above priorities of the European Commission, the mission of Health2Innovation is to inspire, mentor, train and empower students and graduates through the enhancement of skills needed by a digitally transformed health sector, in order to boost innovation and competitiveness of the European health market, address current societal and health challenges and facilitate the digital health transformation and the green transition of the sector.

Health2Innovation brings together Higher Education Institutions (HEI), research centres, incubators, Vocational Education Training (VET) providers, SMEs and tech experts from Sweden, Germany, Portugal, Spain, France, Ireland, Greece, Cyprus, Lithuania, Poland, Romania and Luxembourg to exchange knowledge and best practices, co-design and deliver a training course targeting students and/or graduates in Life Sciences, Medicine, Business, Engineering or ICT-related studies. The Health2Innovation training course aims to reinforce learners' digital, green, entrepreneurial and transversal skills, as well as their understanding in key areas related to digital health, such as eHealth and mHealth, data literacy, artificial intelligence, cybersecurity and sustainability. The Health2Innovation partnership will also develop a digital learning hub and a mobile app and it will also bring to life a Health Innovation Bootcamp and an Apprenticeship programme in innovative health clusters, namely the

Medicon Valley in Denmark and Sweden and the Lille Northern France Health Cluster in France.

Project's Objectives

The specific objectives (O) of Health2Innovation are:

O1: Enhance the cooperation between education and training, research, business and public sector to support the adoption of the European competence frameworks EntreComp, DigComp and GreenComp and EU instruments that recognise and validate qualifications, including microcredentials. Health2Innovation aims to create a modular training course fostering the skills needed to accelerate the digital transformation, green transition and resilience of the healthcare sector. To do so, the project brings together academics, training providers, businesses and life science business clusters/associations from around Europe with an expertise in complementary areas, such as digital skills development, entrepreneurship training, transversal skills development, digital health, circular economy, computer engineering. External experts in digital health and other related areas, including SMEs and public representatives, will be invited to the online webinars (T9.7) and the Health Innovation Bootcamp (WP5), enhancing the exchange of knowledge and practices among consortium member and external stakeholders. The consortium will incorporate EntreCom, DigComp and GreenComp at the preparatory stage of the training course structure to ensure that the learning outcomes address the enhancement of these competences. Furthermore, the proposed qualification scheme will utilise the EU instruments EQF, ESCO and microcredentials for validating and certifying the learning outcomes.

O2: Empower university students and graduates in Life Sciences, Medicine, Business, Engineering or ICT-related studies to pursue opportunities in the digital health market and become more employable, entrepreneurial and innovative. The project aims to empower and inspire undergraduate or postgraduate students and graduates in the disciplines mentioned above to contribute to the development of innovative solutions and services for health and care, through the implementation of training workshops, webinars, Bootcamp and apprentices in health-related companies. The skills needed by the health market to become more digital, resilient and innovative will be mapped in WP2 to ensure that the market's actual needs in terms of knowledge, competences and skills will be met by the training activities and modules developed by the consortium.

O3: Promote new career paths for students and graduates with an interest in healthcare via the development of an innovative digital learning hub and mobile app offering training, guidance, mentoring and networking activities. Students and graduates will be inspired by consortium members and external stakeholders with an expertise in health-related areas to choose forward-looking professions. The digital transformation and green transition that the

healthcare section is undergoing, has revealed the need for new professions and new skills that the Health2Innovation project aims to promote. The proposed digital learning hub and mobile app will facilitate matchmaking between the target audience and relevant stakeholders, such as trainers, consultants, investors and career counsellors that can help students/graduates make the right career choices that match with their skillset and interests.

O4: Inspire students/graduates by immersing them in the diverse innovation ecosystem of healthcare via mobility activities including a Health Innovation Bootcamp and an Apprenticeship programme. A two-day face-to-face Health Innovation Bootcamp will take place in Sweden hosted by the SmiLe incubator, during which participants will learn about the global trends, challenges and opportunities associated with digital health and connect with a network of fellow entrepreneurs and innovators from across Europe. Workshops will be delivered by both consortium members and external guest speakers. In addition, the target audience has the opportunity to join an industry-based apprenticeship programme in the innovative health ecosystems Medicon Valley and Lille Northern France Health Cluster that collectively represent more than 100 health-related companies.

O5: Promote the digital transformation and green transition of the healthcare sector and contribute to the adoption of innovative solutions and services in healthcare. The Health2Innovation training course, Bootcamp and apprenticeship programme aim to foster the knowledge, skills and attitudes the health sector needs to harmonise not only with the digital age but also a more sustainable future. The ultimate goal of the project's activities is to boost the talent pool and improve university students and graduates' skillset in order to foster an ecosystem that helps drive digitalisation, sustainability and innovation in the health and care sector.

Consortium Partnership

The Health2Innovation consortium brings together 14 partners from 12 countries (Portugal, Romania, Lithuania, Spain, Cyprus, Germany, Sweden, France, Greece, Poland, Ireland and Luxembourg) with multidisciplinary expertise in Digital Technologies, Life Sciences, Digital Health, Entrepreneurship and Incubator programmes. There is a high level of complementarity among partners that comprise HEIs, research centres, VET providers, NGOs, SMEs, Incubators and a multi-stakeholder international organization.

UNIVERSIDADE BEIRA INTERIOR	**P1 – Universidade da Beira Interior - UBI**
ktu kauno technologijos universitetas 1922	**P2 – Kaunas Univesity of Technology - KTU**
UNIVERSITY OF PATRAS ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΑΤΡΩΝ	**P3 – University of Patras - UPAT**
VNIVERSITAT DE VALÈNCIA	**P4 – University of Valencia**
UNICERT Universal Certification Solutions	**P5 – Universal Certification Solutions S.A - UNICERT**

Universitatea Ştefan cel Mare Suceava USV	**P6 – Stefan cel Mare University of Suceava - USV**
GrantXpert	**P7 - GRANTXPERT**

	**P8 - Institute of Entrepreneurship Development - IED**
	**P9 - CWEP**
	**P10 - ISOB**
	**P11 - EURASANTE**
	**P12 - Smile Incubator**
	**P13 - European Connected Health Alliance Group - ECHA**
	**P14 - Vass EU**

Target groups

The primary target group of Health2Innovation consists of:

- Undergraduate or postgraduate students in the disciplines of Life Sciences, Medicine, Engineering or ICT-related studies.
- Graduates in Life Sciences, Medicine, Engineering or ICT-related studies.

Health2Innovation will also reach the following secondary target groups that will benefit as follows:

- HEIs at a national and European level reached through dissemination activities. HEIs can promote the Health2Innovation resources and results to students, graduates and alumni members, who are seeking for extra-curricular training opportunities and/or access to career counsellors, incubators, entrepreneurs, mentors or investors.
- Training providers, including VET organisations, consultants, mentors and incubators, who can utilise the project's learning resources in their own training courses.
- Start-ups and SMEs interested in expanding their activities to the digital health sector can utilise the Health2Innovation learning resources to deepen their understanding in key areas and technologies. Additionally, they can gain access to recent graduates with the right skills and key stakeholders via the Health Innovation Community.
- Representatives of local authorities, such as Ministries of Innovation, Digital Transformation, Education, Commerce and Industry, as well as national and EU policymakers reached through dissemination activities and stakeholder roundtables, will utilise results to support the integration of digital and green skills development in existing curricula and digital transformation of health.
- EU networks or initiatives, such as EIT Health, Digital Health Network, MedTech Europe and Digital Innovation Hubs (EDIH), and their members can benefit from the Health2Innovation training course and learning materials and the development of new talent and skills that will steer the development of the digital health market and improve Europe's readiness for the digital age.

2. Introduction

This deliverable describes the methodology for the qualification scheme and the certification of the competences of the Health2Innovation curriculum. In this document will be detailed described the methodology and the steps which need to be follow for the completion of the certification procedure.

2.1. Structure of the deliverable

The deliverable is divided into 4 main sections.

- **Section1:** introduces the deliverable. More specifically, Section 2.1 describes the structure of the deliverable and Section 2.2 outlines the dependencies with other WPs and deliverables and finally.
- **Section 2:** describes the certification framework.
- **Section 3:** describes the methodology for the development of the certification scheme.
- **Section 4**: describes how micro-credentials will be integrated into the Health2Innovation .

2.2. Dependencies with other WPs and deliverables

The deliverable 'D2.2: Qualification scheme' has direct connections with the following WPs and deliverables:

- **Work Package 2:** State-of-the-art analysis and Health2Innovation Training Course Structure and deliverable **D2.3 Health2Innovation training course structure**
- **Work Package 3:** Development of the Health2Innovation Learning Resources and deliverable **D3.1 Health2Innovation learning resources**
- **Work Package 4:** Health2Innovation Digital Learning Hub and Mobile App and deliverable **D4.2 Health2Innovation Digital Learning Hub**

3. The European Qualifications Framework (EQF)

The **European Qualifications Framework (EQF)** is a common European reference framework whose purpose is to make qualifications more readable and understandable across different countries and systems. Covering qualifications at all levels and in all sub-systems of education and training, the EQF provides a comprehensive overview over qualifications in the 38 European countries currently involved in its implementation.

The **EQF is an 8-level**, learning outcome-based framework for all types of qualifications that serves as a translation tool between different national qualifications frameworks. This framework helps to improve transparency, comparability and portability of people's qualifications and makes it possible to compare qualifications from different countries and institutions.

The European Qualifications Framework (EQF) recommendation and its main reference level descriptors were taken into consideration for the development of this deliverable:

- **Knowledge** is the outcome of the assimilation of information through learning. Knowledge is composed of the body of facts and figures, principles, theories, and practices which are already established and support the understanding of a certain area or subject.
- **Skills** are defined as the ability and capacity to carry out processes and use the existing knowledge to achieve results (the ability to apply knowledge and use know-how to complete tasks and solve problems),
- **Competences**: The European Qualifications Framework (EQF) defines competence as the ability to use knowledge, skills and personal, social and/or methodological abilities, in work or study situations and in professional and personal development. In the context of the EQF competence is described in terms of responsibility and autonomy. Fostering competences is the object of all educational programmes. Competences are developed in all course units and assessed at different stages of a programme. Some competences are subject-area related (specific to a field of study), others are generic (common to any degree course). It is normally the case that competence development proceeds in an integrated and cyclical manner throughout a programme.

The Health2Innovation Curriculum composes of modules of various EQF level. The vast majority of which represent level 5-7. The table below, lists in detail the EQF levels:

Table 2. EQF level

EQF Level	Knowledge	Skills	Competence
Level 1	Basic general knowledge	Basic skills required to carry out simple tasks	Work or study under direct supervision in a structured context
Level 2	Basic factual knowledge of a field of work or study	Basic cognitive and practical skills required to use relevant information to carry out tasks and to solve routine problems using simple rules and tools	Work or study under supervision with some autonomy
Level 3	Knowledge of facts, principles, processes, and general concepts, in a field of work or study	A range of cognitive and practical skills required to accomplish tasks and solve problems by selecting and applying basic methods, tools, materials, and information	Take responsibility for completion of tasks in work or study; adapt own behaviour to circumstances in solving problems
Level 4	Factual and theoretical knowledge in broad contexts within a field of work or study	A range of cognitive and practical skills required to generate solutions to specific problems in a field of work or study	Exercise self- management within the guidelines of work or study contexts that are usually predictable, but are subject to change; supervise the routine work of others, taking some responsibility for the evaluation and improvement of work or study activities
Level 5	Comprehensive, specialized, factual and theoretical knowledge within a field of work or study and an awareness of the boundaries of that knowledge	A comprehensive range of cognitive and practical skills required to develop creative solutions to abstract problems	Exercise management and supervision in contexts of work or study activities where there is unpredictable change; review and develop performance of self and others

Level 6	Advanced knowledge of a field of work or study, involving a critical understanding of theories and principles	Advanced skills, demonstrating mastery and innovation, required to solve complex and unpredictable problems in a specialized field of work or study	Manage complex technical or professional activities or projects, taking responsibility for decision-making in unpredictable work or study contexts; take responsibility for managing professional development of individuals and groups
Level 7	Highly specialized knowledge, some of which is at the forefront of knowledge in a field of work or study, as the basis for original thinking and/or research. Critical awareness of knowledge issues in a field and at the interface between different fields	Specialized problem-solving skills required in research and/or innovation in order to develop new knowledge and procedures and to integrate knowledge from different fields	Manage and transform work or study contexts that are complex, unpredictable and require new strategic approaches; take responsibility for contributing to professional knowledge and practice and/or for reviewing the strategic performance of teams
Level 8	Knowledge at the most advanced frontier of a field of work or study and at the interface between fields	The most advanced and specialized skills and techniques, including synthesis and evaluation, required to solve critical problems in research and/or innovation and to extend and redefine existing knowledge or professional practice	Demonstrate substantial authority, innovation, autonomy, scholarly and professional integrity and sustained commitment to the development of new ideas or processes at the forefront of work or study contexts including research

Source: European Qualifications Framework for Lifelong Learning, 2008

4. European Credit Transfer and Accumulation System (ECTS)

The **European Credit Transfer and Accumulation System (ECTS)** is a tool of the European Higher Education Area (EHEA) for making studies and courses more transparent and thus helping to enhance the quality of higher education.

The terminology is explained bellow:

1. **ECTS** is a learner-centred system for credit accumulation and transfer, based on the principle of transparency of the learning, teaching and assessment processes. Its objective is to facilitate the planning, delivery and evaluation of study programmes and student mobility by recognising learning achievements and qualifications and periods of learning.
2. **ECTS credits** express the volume of learning based on the defined learning outcomes and their associated workload. 60 ECTS credits are allocated to the learning outcomes and associated workload of a full-time academic year or its equivalent, which normally comprises a number of educational components to which credits (on the basis of the learning outcomes and workload) are allocated. ECTS credits are generally expressed in whole numbers.
3. **Learning outcomes** are statements of what the individual knows, understands and is able to do on completion of a learning process. The achievement of learning outcomes has to be assessed through procedures based on clear and transparent criteria. Learning outcomes are attributed to individual educational components and to programmes at a whole. They are also used in European and national qualifications frameworks to describe the level of the individual qualification.
4. **Workload** is an estimation of the time the individual typically needs to complete all learning activities such as lectures, seminars, projects, practical work, work placements and individual study required to achieve the defined learning outcomes in formal learning environments. The correspondence of the **full-time** workload of an **academic year** to **60 credits** is often formalised by national legal provisions. In most cases, workload ranges from **1,500 to 1,800 hours for an academic year**, which means that **one credit (1 ECTS credit)** corresponds to **25 to 30 hours** of work. It should be recognised that this represents the typical workload and that for individual students the actual time to achieve the learning outcomes will vary.
5. **Assessment methods** are the whole range of written, oral and practical tests/examinations, projects, performances, presentations and portfolios that are used to evaluate the learner's progress and ascertain the achievement of the learning outcomes of an educational component (unit/module).

5. Template for EQF & ECTS Classification of Modules

During the Health2Innovation project will be created a training module that aligns with the European Qualifications Framework (EQF) and requires a structured approach to ensure that the content and learning outcomes meet the standard criteria associated with the designated EQF level. Below is a template that you can use as a guideline to structure your training module, ensuring that it's relevant and compliant with EQF standards.

Table 3 Template for EQF modules

Name of Modules	
Description	
EQF Level	
Learning Outcomes	
Knowledge	
Skills	
Competences	
Assessment methods	
Total Training Hours (Workload)	
ECTS Credits	

This table will be filled-in for each training module upon the completion of module development. An initial form of this table is also demonstrated in D2.3. This table represents an initial descriptive stage and portraits a general idea of the details related to the modules. This table is an initial estimation and description of the modules, and it will be improved during the development of the materials.

6. Certification Framework

Health2Innovation course aims to provide participants with 2 different types of certifications.

(A) Attendance certificate

(B) The official accredited certificate of Health2Innovation Course: **Health2Innovation Certification of Knowledge**

The consortium will provide automatically *via* the platform an attendance certificate to the participants who will successfully complete a module. This certification will not be accredited and therefore is not related with this deliverable.

For (B) UNICERT S.A. will develop the certification framework for the project participants' gained knowledge, competencies, and skills, as well as the certification process.

The certification will be accepted on the market because it will be made using a final method of accreditation that is recognized by the EU and is in line with the rules and procedures of the national accreditation bodies of E.A. countries and states (European Cooperation for Accreditation).

Within the certification framework we offer the information required for the validation and certification of knowledge for the people who attend the online courses, throughout the consortium's member countries.

In the framework of Health2Innovation project we will develop one accredited (1) Certification:

Health2Innovation Certification of Knowledge

The compulsory steps for the certification will be:

Attend and complete at least 50% of the Health2Innovation Course

7. Methodology: Development of Certification Scheme

7.1. Application for new schemes (UNICERT S.A. and Partners)

Developing and implementing new certification schemes often involves a structured process that includes the submission of an application.

Definition of a Scheme:

The development of a new scheme requires the completion of the "Application Development Form", in order to communicate the purpose of the new scheme to all interested parties. Schemes can be introduced by governmental bodies, non-profit organizations, businesses, or other entities to address various needs within a community, sector, or industry.

Reasons for Introducing New Schemes:

1. Addressing Unmet Needs. New schemes are often developed to address gaps or unmet needs within a community or sector. This could include social, economic, or environmental challenges that require targeted interventions.
2. Policy Objectives. Governments may introduce new schemes as part of their broader policy objectives. These schemes are designed to implement and support policy goals, such as improving public health, enhancing education, or stimulating economic growth.
3. Innovation and Adaptation. Schemes can be created to encourage innovation, adapt to changing circumstances, or leverage emerging technologies. This allows organizations to stay relevant and effective in a dynamic environment.

Application Development Form:

The "Application Development Form" is a key component of the process for introducing a new scheme. This form serves several purposes:

1. Communication of Purpose. The form is a tool for clearly articulating the purpose and objectives of the proposed scheme. It should provide a detailed explanation of why the scheme is necessary, what issues it aims to address, and how it aligns with broader organizational or societal goals.
2. Stakeholder Engagement. By requiring completion of the form, the organization ensures that all relevant stakeholders are aware of and can provide input into the

development of the scheme. This fosters transparency and inclusivity in the decision-making process

3. Evaluation Criteria. The form may include criteria for evaluating the feasibility, impact, and sustainability of the proposed scheme. This helps decision-makers assess whether the scheme aligns with organizational priorities and can achieve its intended outcomes.

Application Process Steps:

1. Initiation. The process typically begins with the identification of a need or opportunity that warrants the development of a new scheme.
2. Formulation of Proposal. Stakeholders involved in scheme development work together to formulate a detailed proposal. This proposal includes the objectives, target beneficiaries, budgetary considerations, and anticipated outcomes.
3. Application Submission. The completed Application Development Form, along with the proposal, is submitted to the relevant authority or committee responsible for reviewing and approving new schemes.
4. Review and Evaluation. The submitted application undergoes a comprehensive review. This may include assessments of the scheme's feasibility, impact, budget, and alignment with organizational or policy goals.
5. Decision and Approval. Based on the evaluation, a decision is made regarding the approval, modification, or rejection of the proposed scheme. Approved schemes move forward to the implementation phase.
6. Implementation and Monitoring. Once approved, the scheme is implemented according to the outlined plan. Monitoring and evaluation mechanisms are put in place to assess progress and make adjustments as necessary.

The application for new schemes is a structured process designed to ensure that proposed initiatives are well-defined, purposeful, and aligned with broader organizational or societal objectives. The Application Development Form is a critical tool in this process, serving as a means of communication, stakeholder engagement, and evaluation. Through this process, organizations can introduce innovative and impactful schemes that contribute to positive social, economic, or environmental outcomes.

7.2. Application review (UNICERT S.A.)

The application review process is a crucial component of many decision-making contexts. The primary objectives of application review encompass a thorough assessment of the proposed scheme's feasibility, impact, and alignment with organizational priorities. Reviewers aim to identify the strengths and weaknesses of each application, considering factors such as innovation, sustainability, and the ability to address identified needs or challenges. The overarching goal is to select schemes that demonstrate the greatest potential for success and positive impact.

Responsible for reviewing the application is the Quality Management Department of UNICERT S.A. The department examines whether the Certification Body has the capacity to respond to the submitted application.

Reviewers employ predefined criteria to assess the quality of each application. These criteria may include clarity of objectives, feasibility of implementation, anticipated outcomes, budgetary considerations, and alignment with organizational strategies or policy objectives. The establishment of clear and measurable criteria ensures a standardized evaluation process, promoting fairness and transparency in decision-making.

In some cases, the review process involves input from various stakeholders, including experts in the relevant field, or other individuals affected by the proposed scheme. Engaging stakeholders ensures diverse perspectives are considered, contributing to a more comprehensive evaluation and fostering a sense of inclusivity in the decision-making process.

Based on the findings of the review, a decision is made regarding the approval, modification, or rejection of each application. The decision-making process may involve a committee or panel responsible for evaluating applications, and their decisions are often guided by the predefined evaluation criteria. Approved schemes move forward to the implementation phase, while rejected proposals may receive feedback to encourage improvement for future submissions.

The application review process is not only a mechanism for selecting schemes but also an opportunity for continuous improvement. Feedback provided to applicants, whether their proposals are accepted or declined, serves as a valuable tool for enhancing the quality of future submissions. This iterative feedback loop contributes to a culture of learning and refinement in the development and review of schemes.

In conclusion, the application review phase is a pivotal component of the scheme development process, ensuring that selected initiatives align with organizational goals and have the potential for meaningful impact. By employing systematic evaluation criteria, engaging stakeholders, and fostering a commitment to continuous improvement, organizations can enhance the effectiveness of their application review processes and ultimately contribute to the success of the implemented schemes.

7.3. Development of certification scheme regulations (UNICERT S.A. & Partners)

The development of a certification scheme regulation, often accompanied by a syllabus, is a meticulous and strategic process aimed at establishing a framework for assessing and validating individuals' knowledge and skills in a particular domain. Certification schemes play a vital role in various industries, ensuring that professionals meet predefined standards and competencies. The creation of a regulation and syllabus is essential for maintaining consistency, transparency, and credibility in the certification process.

The primary purpose of developing a certification scheme regulation is to provide a clear and comprehensive set of guidelines governing the certification process. This includes defining the scope and objectives of the certification, eligibility criteria for candidates, examination procedures, and the criteria for successful certification. Regulations help maintain the integrity of the certification scheme, instilling confidence in stakeholders and ensuring that certified individuals possess the necessary qualifications.

A well-crafted certification scheme regulation typically includes several key components. These may encompass a detailed description of the certification program, the qualifications and experience required for candidates, the structure of the examination, the grading system, and any ethical or professional standards that candidates must adhere to. The regulation serves as a reference document for both certification bodies and candidates, providing clarity on the expectations and requirements.

In conjunction with the regulation, the syllabus outlines the specific topics, skills, and knowledge areas that candidates are expected to master to achieve certification. The syllabus is a roadmap that guides the content of the examination and ensures that it is aligned with the industry or field's current standards and best practices. The development of the syllabus involves input from subject matter experts, industry stakeholders, and educators to ensure its relevance and comprehensiveness.

Certification scheme regulations and syllabi are typically designed to align with prevailing industry standards and practices. This alignment ensures that certified individuals possess the latest knowledge and skills required for success in their respective fields. Regular updates to the regulation and syllabus may be necessary to reflect advancements in the industry and maintain the certification's relevance.

The development of certification scheme regulations incorporates quality assurance measures to uphold the credibility of the certification process. This may include mechanisms for validating examination content, ensuring fair and unbiased evaluation, and implementing secure and standardized testing procedures. Standardization is crucial for fostering

consistency in the certification process across different cohorts of candidates and examination sessions.

Successful development of certification schemes involves collaboration with various stakeholders, including industry experts, practitioners, educational institutions, and regulatory bodies. Engaging these stakeholders ensures that the certification scheme's content and requirements are well-informed and reflective of the industry's needs. Transparent communication with stakeholders is essential to garner support and trust in the certification process.

The certification scheme regulation and syllabus are dynamic documents that should undergo periodic reviews and updates. Continuous improvement processes, informed by feedback from certified professionals, changes in industry trends, and advancements in knowledge, contribute to the ongoing relevance and effectiveness of the certification scheme.

The development of a certification scheme regulation and syllabus is a multifaceted process that requires careful consideration of industry standards, stakeholder input, and quality assurance measures. A well-defined and transparent certification framework ensures that certified individuals possess the necessary competencies, contributing to the overall professionalism and credibility of the industry or field in which the certification operates.

7.4. Syllabus

Module Number	Module Name	ECTS Credits
1	Digital Literacy for Healthcare	1
2	Digital Communication and Outreach	1
3	Project Management in Healthcare	1
4	Leadership	1
5	Healthcare Entrepreneurship	1
6	Marketing in Healthcare	1
7	Sustainability in Healthcare	1
8	Advanced Healthcare Technologies	2
9	Immersive Technologies in Healthcare	1
10	Healthcare Information Security	1
11	Funding Opportunities	1
12	Regulatory Compliance in Healthcare	n/a

7.5. General Certification Specifications

To create the regulation concerning the sector, it needs to be given:

I. the name of the subject of the certification of a professional, its scope and, where appropriate, its possible graduations or certification levels,

II. the detailed description of the tasks and work duties of the individuals / professionals targeted by the subject,

III. the subject of competence of the certified person and the corresponding knowledge framework,

IV. the physical characteristics of the candidate such as vision, hearing, physical abilities, etc., when required,

V. the prerequisites of the path to certification (e.g. education, work experience, physical characteristics, etc.), when required,

VI. the code of conduct, where appropriate;

VII. the requirements for getting a certificate in the first place, keeping it, getting it renewed, and suspending or taking it away,

VIII. the methods of evaluation of the candidate for initial certification, for maintaining the certification, for recertification and

IX. the criteria for possibly changing the field/level of the certified person.

Table 1. General Certification Specifications

Name of the Course	
Description	
Objective /knowledge	
Physical characteristics of the candidate	
Prerequisites (if required)	
Code of conduct (if required)	
Requirements	
Methods of evaluation	
Changing level of candidate	

This table will be filled-in upon the completion of course development.

Participation in the certification process of subject is possible for persons who compulsorily meet the age requirement to be over the age of 18. Additional requirements concerning educational background and professional experience may as well apply but this is a decision that will be made at a later stage.

7.6. Prerequisites for participation in the training programme and the certification

Health2Innovation course aims to provide participants with 2 different types of certifications.

(A) Attendance certificate
(B) The official accredited certificate of Health2Innovation Course

For (A) no requirements are mandatory. The consortium will provide automatically *via* the platform an attendance certificate to the participants who will successfully complete a module. The final evaluation of the modules will be performed via a short self- assessment test that will be designed and developed along with WP3 and WP4 and is not associated with this deliverable.

For (B) the official accreditation certificate will be provided to participants who will complete the following:

The potential prerequisites of the level of knowledge are evidenced by diplomas, while those of the work experience are supported by tax or insurance data accompanied by an appropriate employer's declaration or an employer's recommendation letter mentioning the participant's relevant job description and the period of the assignment. These documents will be requested during the applicants' expression of interest in participating in the certification and will be defined in detail at a later stage of the project.

7.7. Physical Characteristics of the Candidate – Prerequisites for Participation in the Examinations for the Official, Accredited, H2I Certificate

The supporting documents for participation in the certification exams are submitted to UNICERT S.A. electronically and are the following:

- Signed application for certification of the candidate.
- A valid photocopy of the identity form of himself or his legal representative (with a corresponding valid authorization form).

Valid identity forms must include:

- Identity card or relevant temporary certificate from the competent authority; passport; driver's license; individual insurance booklet for Greek citizens.
- Identity card and passport for citizens of a European Union member state.
- For citizens of countries other than the European Union: entry permit, residence permit, and work permit. A valid photocopy of a compulsory education qualification

In addition, people with disabilities can participate in the certification process as long as their difficulty does not affect the proper performance of the work duties of the subject under certification. In these cases, an opinion from an official and legal body is required.

7.8. Syllabus control (UNICERT S.A.)

The primary purpose of syllabus control is to maintain the currency, relevance, and effectiveness of educational programs. It ensures that course content reflects the latest developments in the field, incorporates feedback from learners and educators, and aligns with broader educational goals. Syllabus control is integral to fostering a dynamic and responsive learning environment that equips students with the knowledge and skills needed for success in their chosen disciplines.

One of the key aspects of syllabus control is ensuring alignment with predefined learning objectives. Syllabi should articulate clear and measurable learning outcomes that guide instructional design and assessment strategies. Regular reviews help educators assess whether the content and activities outlined in the syllabus contribute to the achievement of these objectives, allowing for adjustments as needed.

Syllabus control involves a feedback loop that includes input from both educators and learners. Educators provide insights into the effectiveness of the syllabus in facilitating learning, while learners offer perspectives on the clarity of instructions, relevance of content, and overall educational experience. Integrating this feedback into syllabus revisions promotes a student-cantered approach to curriculum design and enhances the overall quality of the educational program.

In dynamic fields, such as technology, science, or business, syllabus control becomes particularly crucial. Regular updates ensure that course content remains in line with industry best practices, emerging trends, and the latest research findings. This adaptability is essential for preparing students to navigate evolving professional landscapes and remain competitive in their chosen fields.

Syllabus control contributes to quality assurance by establishing standards for curriculum development and delivery. It ensures consistency in course content, assessment methods, and learning outcomes. Standardization through syllabus control supports equitable educational experiences for all students and facilitates comparisons across different courses or institutions.

In educational settings, syllabus control also plays a role in ensuring compliance with regulatory standards and accreditation requirements. By regularly reviewing and updating syllabi, educational institutions can demonstrate their commitment to meeting established benchmarks for curriculum quality and academic rigor.

Syllabus control has evolved in response to technological advancements. Educational institutions increasingly use digital platforms to manage and distribute syllabi, enabling real-time updates and seamless communication between educators and students. This integration of technology enhances the efficiency of syllabus control processes.

7.9. Developing Questions for the accredited certificate

The process of developing questions requires careful consideration of educational goals, cognitive levels, and the diverse needs of learners. The first step in developing questions is to align them closely with the learning objectives of the lesson or course. Questions should be explicitly tied to what learners are expected to know or be able to do. This alignment ensures that assessments are meaningful and directly contribute to the overall educational goals, providing a clear roadmap for both educators and learners.

Effective question development involves employing a variety of question types to engage learners and assess different skills. The choice of question type should align with the learning outcomes, the nature of the content, and the desired depth of understanding.

Clear and precise language is crucial in question development. Ambiguity or vagueness can lead to misinterpretation and inaccurate assessment of students' knowledge. Well-constructed questions are specific, avoiding double negatives or complex sentence structures that may confuse learners. Additionally, questions should be free from bias to ensure fair assessment.

Questions should be relevant to the content being assessed and presented in a context that resonates with students. Real-world scenarios or examples that connect the material to practical applications can enhance the authenticity of assessments. This relevance fosters a deeper understanding of the subject matter and demonstrates the practical value of the knowledge being acquired.

Inclusive question development involves considering the diverse needs and backgrounds of learners. Questions should be accessible to learners with different learning styles, linguistic abilities, and cultural perspectives. Providing options for demonstrating understanding, such as through written or verbal responses, can accommodate diverse learner needs.

The development of questions is an iterative process that benefits from feedback and continuous improvement. Educators can assess the effectiveness of questions through student performance and adjust future assessments accordingly. Analysing the results of assessments helps educators identify areas where students may be struggling and refine questions to better meet the learning objectives.

Ethical considerations are paramount in question development. Questions should avoid unintentional bias, respect cultural sensitivities, and uphold the principles of fairness.

Educators should be mindful of the potential impact of questions on different groups of students and strive to create a supportive and inclusive assessment environment.

7.10. Criteria and methods of accredited certification

The assessment of the examinee includes only theoretical certification exams.

The "Health2Innovation Certification Exam" procedure will last **100 minutes** and is composed of **72 questions** (closed-ended questions), which are distinguished based on their degree of difficulty into introductory, core, advanced and are separated by **40%, 25% and 35%**, respectively.

- *Selecting the correct answer from a list of options (problems with selecting the correct answer from a list of options)*
- *Choose at least two correct answers from the given options (there are many correct options from many).*

Successful participation in the exam means giving the correct answer to at least **70% of the examination subjects, in which case the corresponding certificate is issued.**

If the examinations fail, the candidate has the option of retaking them up to two times within the same year. If he/she fails the third time he/she is examined after the end of a calendar year since the last exam.

7.11. Selection of exam questions for the accredited certificate

The examination topics are drafted in the English language and are adapted to modern requirements, depending on the nature of the certification.

For example, if special computer software is required, on a specific platform and software version, the examination system is adapted to them.

The examination system of the Institution is configured in such a way that it selects for each test at least one question of low, one of medium and one of high difficulty from each section to be examined. For each examinee, a different set of examination subjects is selected, and each test is unique.

The examinations are designed to assess a person's ability in accordance with the scheme's requirements and may include both a theoretical and a practical component.

The evaluation is carried out through questions that belong to the following categories:

- **Low-difficulty questions (Introductory) -** 40% of all questions in each exam
- **Moderate difficulty (Core) -** 25% of all questions in each exam
- **High degree of difficulty (Advanced) -** 35% of all questions in each exam

The software of the examination system automatically selects questions from all the cognitive units of the syllabus, respecting the above proportions of introductory, core, advanced questions. The percentage of each cognitive unit is produced in a random way. This ensures that there will be no cognitive sections in the exam that do not correspond to questions.

Each question's level of difficulty:

- Introductory
- Core
- Advanced

As a result (see table 4), **each course contains:**

- 29 Introductory,
- 18 Core, and
- 25 Advanced questions.

Table 4. Sample of Question pool

Course		
Degree of difficulty	**Introductory**	29
	Core	18
	Advanced	25
Total		**72**

Next table is a template for the provided questions for the certification scheme.

Table 5. Template for gathering questions for each training module.

QUESTION No	COURSE	QUESTION	CHOICE 1	CHOICE 2	CHOICE 3	CHOICE 4	CORRECT	DIFFICULTY
1								
2								
4								
5								

The total number of questions which must be created is **multiplied 4 times.**

For example, assuming that the exam of a course will contain 72 questions, a set of 288 questions must be created in total for this specific course.

7.12. Scoring

The certification examination platform will automatically award one (1) point for each correct answer and zero (0) point for each incorrect answer. There is no negative score.

7.13. Duration of accreditation

The validity period of the Health2Innovation certification is five (5) years from the date of certification indicated on the Certificate of Competency.

The five-year period was chosen as a parameter of the scheme based on the fact that within 5 years it can be considered that the Special Regulation for the Certification of Subject Matter Health2Innovation that does not rapidly change the sector, the technology and equipment used, the methodologies and techniques and the certified competence is finally kept relevant, while the possibility of someone certified losing his ability due to a decrease in his contact with the work object is considered moderate.

In the event that there is a change in the legislation or technology and method concerning the Health2Innovation sector in the new digital environment, then the certification ceases to be valid as it is. UNICERT S.A informs all certified persons of the termination of the certification, as well as the conditions and the way in which they can obtain the certification under the new regulation.

7.14. Recertification

Before the expiry of the validity period of the certificate, the holder may be renewed for a new period by UNICERT S.A. Recertification includes participation only in exams corresponding to the original. In the event that the subject matter has changed, he is obliged to follow the new procedure from the beginning.

People with disabilities can participate in the certification process as long as their difficulty does not affect the proper performance of the work duties of the subject under certification. In these cases, an opinion from an official and legal body is required.

7.15. Review and Check Questions (UNICERT S.A.)

Reviewing and checking questions is an essential step in the assessment. This systematic review process is crucial for identifying potential issues, refining questions, and improving the overall effectiveness of assessments. It involves scrutiny of question clarity, alignment with learning objectives, appropriateness of language, and consideration of diverse learner needs.

The first aspect of reviewing questions involves assessing their alignment with the learning objectives. Each question should directly contribute to the measurement of specific knowledge, skills and competencies outlined in the educational goals. This alignment ensures that assessments are focused, meaningful, and contribute to the overall learning outcomes of the instructional program.

Reviewing questions for clarity and precision is fundamental to avoiding ambiguity and misinterpretation. Ambiguous or confusing language can lead to inaccurate assessments of learners' understanding. Reviewing questions involves an examination of their fairness and inclusivity. Questions should be free from cultural bias and avoid language or references that may disadvantage specific groups of learners. The review process ensures that questions are accessible to students with diverse backgrounds, linguistic abilities, and learning styles, promoting a fair and equitable assessment environment. Questions must be contextually relevant to the material being assessed.

Validity and reliability are critical considerations in question review. Validity ensures that questions measure what they are intended to measure, while reliability ensures consistency in assessment outcomes. The review process involves examining whether questions effectively gauge the targeted constructs and whether they yield consistent results across different administrations.

The step-by-step process:

- For the review and approval of the questions of each subject, a meeting with the partners who developed the questions with the members of the Technical Committee is held.
- The Technical Committee is set up to discuss the examination topics of the new schemes and the methodology for selecting the examination topics.
- Specifically, the observance of the methodology of the examination subjects, the number of examination subjects, the correct performance of the subjects and the difficulty of their understanding by the certified candidates are checked.
- In addition, syntactic and grammatical errors are checked.

7.16. Pilot exams (UNICERT S.A.)

Pilot exams, also known as trial or experimental exams, are a crucial component of the assessment development process. These exams serve as a preliminary testing phase before the official administration of assessments, providing educators and assessment designers with valuable insights into the effectiveness, fairness, and validity of the test items. Conducting pilot exams is a systematic and strategic approach to refining assessment instruments, ensuring that they accurately measure the intended learning outcomes.

The primary purpose of pilot exams is to identify and address potential issues with test items, instructions, and overall assessment design. By administering a smaller-scale version of the exam to a representative sample of the target population, educators can gather data on the clarity of questions, the appropriateness of difficulty levels, and any unforeseen challenges that may arise during the actual administration. This process contributes to the enhancement of the assessment's overall quality.

Pilot exams allow for in-depth item analysis and psychometric evaluation. Analysing the performance of each test item provides valuable information about its discriminatory power, difficulty level, and effectiveness in distinguishing between high and low performers.

Pilot exams simulate actual testing conditions to a certain extent, providing an opportunity to identify and address logistical challenges. This includes considerations such as timing constraints, technological issues (if applicable), and any unforeseen difficulties that may arise during the administration. Identifying and resolving these issues during the pilot phase contributes to a smoother and more reliable administration during the official exam.

When conducting pilot exams, it is essential to select a representative sample of the target population. This ensures that the feedback obtained is reflective of the diverse characteristics and abilities of the intended test-takers. A well-chosen sample helps identify potential biases

and ensures that the final assessment is fair and valid for all individuals within the target population. They provide a valuable testing ground for refining test items, simulating real testing conditions, addressing logistical challenges, and ensuring ethical practices.

7.17. Application to the national accreditation system - Accreditation of a new subject (UNICERT S.A.)

The application for the accreditation of a new subject within the National Accreditation System is a comprehensive process that involves the submission of detailed documentation to ensure that the proposed subject meets established standards and contributes to the overall quality of education. This theoretical overview outlines the key components and considerations involved in the application process for accrediting a new subject.

The first and foremost consideration in the accreditation process is ensuring that the new subject aligns with established accreditation standards set by the national education authority or accrediting body. These standards typically encompass aspects such as curriculum design, learning outcomes, assessment strategies, and the qualifications of instructors. The application must clearly demonstrate how the proposed subject meets or exceeds these standards.

The steps for this procedure are:

- After the completion of the validation process of the new subject by the Institution, an application is sent to the ESYD for its accreditation.
- ESYD appoints an evaluation team with experts specialized in the subject of accreditation.
- After the end of the evaluation and if the procedure is accepted, the ESYD approves the accreditation of the new subject, and the Certification Body can now conduct examinations.