COMPETENCY framework in Personalized Precision Medicine for *healthcare professionals*

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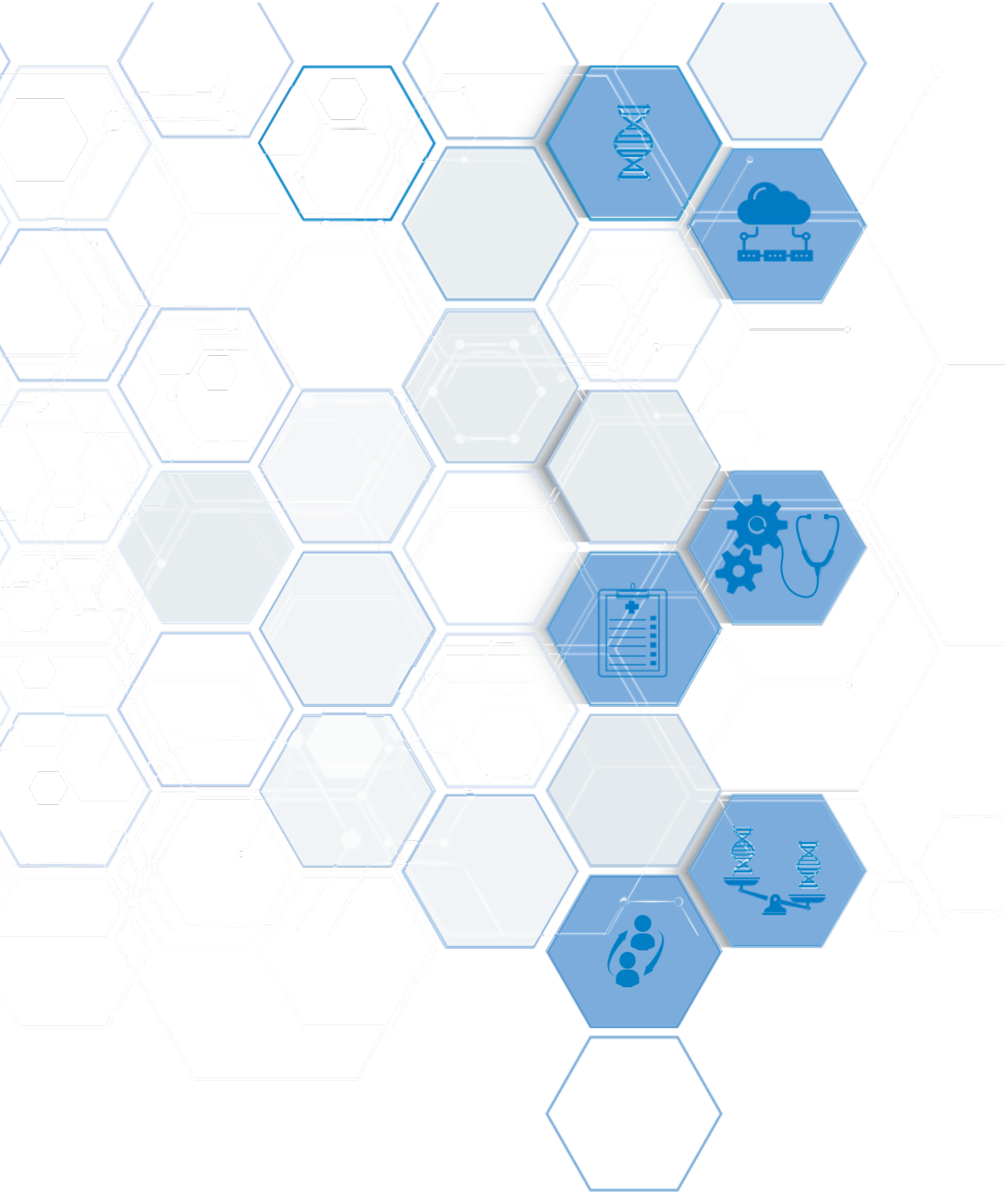

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Executive Summary

Personalized Precision Medicine represents a paradigm shift and a new reality for the healthcare system, with **training** being a fundamental tool to contribute to its full implementation and application in clinical practice. In this sense, healthcare professionals face **educational challenges** related to the acquisition of competencies aimed at performing their professional practice in an optimal, efficient and quality manner in this new environment.

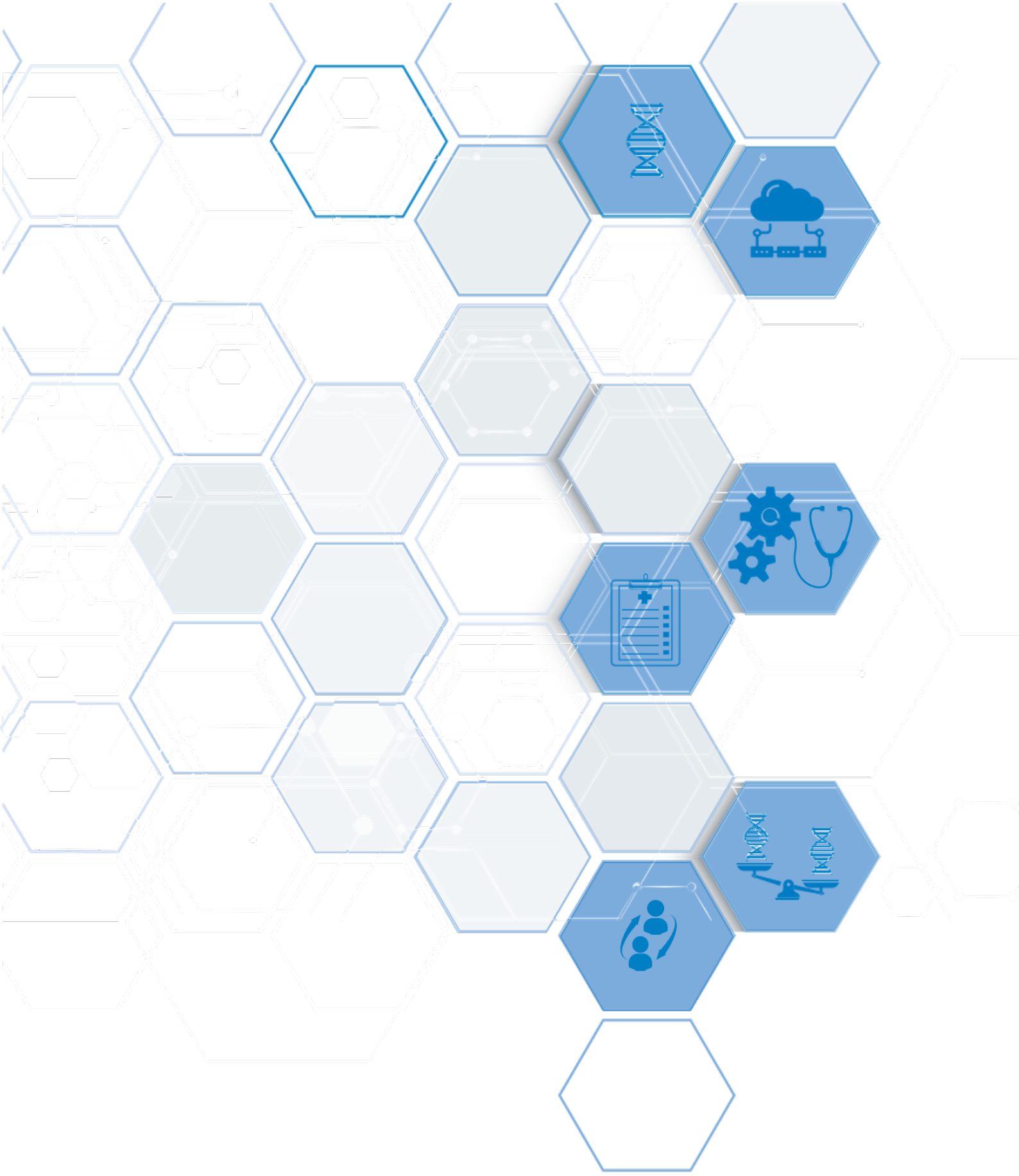
The **definition of competencies** for healthcare professionals provides a **clear guide** on the level of **knowledge, skills and attitudes** required to adequately carry-out their professional practice. In this context, the acquisition of competencies by healthcare professionals can be defined as a dynamic and longitudinal process over time, by which they use knowledge, skills, attitudes and good judgment associated with their profession in order to be able to develop it effectively in all situations corresponding to their field of practice.

In this line, the aim of this document is to define a **proposal of essential knowledge domains and common competencies for all healthcare professionals, necessary to optimally develop their professional practice in Personalized Precision Medicine as a fundamental part of the Medicine of the Future.**

Based on the analysis carried out and with the vision of a multidisciplinary group of experts, a new **competency framework** was defined that would guarantee the optimal performance of the healthcare occupations in Personalized Precision Medicine. As a basis for the development of this report, the most relevant national and international competency frameworks and training programs were analyzed to identify those aspects that are having an impact on the application of Personalized Precision Medicine and that will have to be considered when developing the competencies of the professionals of the future.

This report defines a framework made up of **58 competencies** structured into **five essential domains**: Health determinants, Biomedical informatics, Practical applications, Participatory health and Bioethics plus a **cross-cutting domain** that impacts the overall performance of the competencies linked to each of the above domains.

Likewise, **6 professional profiles** were identified and defined to which this proposal of competency framework is addressed according to the area where they carry out their professional activity: **Healthcare, Laboratory, Digital Health, Community Health, Research, Management and Planning**. In addition, a classification is proposed by progressive levels of training that would be advisable to acquire for each competency according to the professional profile.



Acknowledgements

To the working group of experts gathered for the development of the project and the preparation of this document. For sharing their perspectives on the key elements and training needs for the definition of competencies in the areas of interest of Personalized Precision Medicine as a fundamental pillar of the Medicine of the Future, starting from the current situation. Their knowledge, multidisciplinary vision and valuable contributions have made possible to elaborate a competency framework, so necessary in the current socio-health context.

To the experts in different fields of knowledge, whose valuable participation through individual interviews, has allowed us to incorporate their knowledge and vision on the subject to complete and enrich this document from the position and criteria of all areas of knowledge.

Thank you very much for your collaboration and commitment.

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1. Introduction

The growing and continuous incorporation of new knowledge and technologies poses major challenges to healthcare and health care professionals who must face the need of continuous update in their practice. Training is a fundamental pillar to the implementation of new competencies due to science advance and therefore to create a continuous learning environment, is essential. This has to be adapted to the current and future context, able to respond to the demands of the population and which places the patient at the center of the system.

In 2019, the NHS[1] published the Topol report "*Preparing the healthcare workforce to deliver the digital future*", which identifies key areas for addressing the healthcare challenges of the XXI century. This report concludes that *"Educating current and future healthcare professionals is key to enabling the implementation of the revolutionary changes in clinical practice and medical care that technological advancement will bring for the benefit of patients, caregivers and citizens*".[2]

Personalized Precision Medicine represents a paradigm shift in healthcare and a new reality for the healthcare system, favoring the use of more effective and safer preventive, diagnostic and therapeutic health interventions and contributing to the sustainability of the healthcare system. However, the full incorporation of Personalized Precision Medicine and its application to clinical practice, raises important training challenges for healthcare professionals who will need to acquire those competencies aimed at performing their professional practice in an optimal, efficient and quality manner in the healthcare system.

A competency is the ensemble of knowledge and skills (S) and the application of them to the expected performance in the workplace. In 16/2003 Spanish Law on Cohesion and Quality of the National Health System, in art. 42, a competency is defined as "*the aptitude of the healthcare professional to integrate and apply the knowledge, skills and attitudes associated with the good practices of his or her profession to resolve the situations that arise*".

In this context, the acquisition of competencies by healthcare professionals can be defined as a dynamic and longitudinal process over time, by which a person uses knowledge, skills, attitudes, and good judgment to perform effectively in all situations in their field of practice.

In summary, the definition of healthcare professionals' competencies in Personalized Precision Medicine allows us to establish a clear orientation on the level of knowledge, skills and attitudes necessary to carry out their professional practice in an adequate manner.

For years, the Roche Institute Foundation has been intensely involved in the generation of consensus and recommendations aimed at the rational and efficient incorporation of Personalized Precision Medicine into daily care practice. Therefore, aware of the existing training challenges, the ROCHE institute has promoted the elaboration of this document, with the purpose of defining, b a competency framework of for healthcare professionals who will carry out their professional work in the field of Personalized Precision Medicine. This has been done by consensus with a multidisciplinary group of experts.

The purpose of this competency framework is to serve as a support instrument for the implementation of programs and initiatives aimed at the training and certification of healthcare

[1] **NHS**: National Health Service
[2] Topol report: "**Preparing the healthcare workforce to deliver the digital future**" (2019)

professionals working in the field of Personalized Precision Medicine. In this sense, its possible applications are o serve as support in the development and accreditation of training contents and programs, in the development and implementation for the certification and recertification systems of healthcare professionals, among others.

Finally, in order to guarantee its usefulness over time, the competency framework is designed as a dynamic document that can be adapted to the changes that will happen with the advance of Personalized Precision Medicine as a fundamental area of the Medicine of the Future.

2. Objectives

The main objective of the project is to define a **proposal of common domains and competencies** for all healthcare professionals, necessary to optimally develop their professional practice in the field of Personalized Precision Medicine as a fundamental part of the Medicine of the Future.

In order to achieve this objective, the following actions were undertaken:

- An analysis of international **competency frameworks and relevant training programs** related to the fields of interest in Personalized Precision Medicine and, more specifically, the definition of competencies in these areas was carried out in order to identify and extract those elements that may be key.

  The **essential domains** in Personalized Precision Medicine, which have to be addressed within a training and performance plan for the professional practice of future healthcare professionals, were identified, with the ultimate objective of guaranteeing the optimal development of their activity in the field of Personalized Precision Medicine.

- With the ultimate objective of guaranteeing the optimal development of their activity in the field of Personalized Precision Medicine, the **competencies** that healthcare professionals should acquire, within each essential domain, were identified and defined, as well as the level of training according to the professional profile.

3. Work methodology

The methodology of this project took a **broadly participatory and multidisciplinary approach** in line with the very nature of Personalized Precision Medicine, in which different areas of knowledge and professionals take on a joint relevance for its development and complete implementation.

Two groups of experts were set up:

A **Working Group** of experts whose functions included the analysis of articles and reports of interest, and the identification of competency frameworks and training programs to express opinions and issue recommendations on different aspects, of the framework and to review and validate the documentation generated.

In addition, other **experts,** from different fields of knowledge were identified. These experts, through individual interviews, contributed to the identification of the areas of knowledge and competencies to be developed or acquired by health professionals working in the field of Personalized Precision Medicine.

Both the members of the Working Group and the other experts interviewed, participated individually in the project.

The development of the actions was structured in two work phases:

Phase 1: Identification of key elements and training needs of healthcare professionals in Personalized Precision Medicine

During this phase:

- An analysis of reference documents on competency frameworks and training programs aimed at healthcare professionals was carried out. This analysis served on one hand, to conceptualize the structure of the framework to be developed and, on the other, to identify the areas of knowledge that could be used as domains for the Personalized Precision Medicine competency framework.

- Also, the analysis of the key reports and articles identified by the Working Group was performed, with the purpose to identify those aspects that are having and will have an impact on the application of Personalized Precision Medicine and that will have to be taken into consideration when developing the competencies of the professionals of the future.

  Interviews were conducted with the experts of the Working Group to identify the training needs of healthcare professionals in the field of Personalized Precision Medicine, as well as to define the essential domains as the basic structure of the competency framework.
- **A FIRST WORKSHOP**: After the analysis of the documentation, a workshop was held with the Working Group with the objective of reaching a consensus on the structure of the competency framework through the different essential domains, and to carry out a preliminary identification of the main lines to be addressed within each domain in the form of competencies.

Phase 2: Definition of competencies y level of qualification

During this phase:

- Individual interviews were carried out with the experts panel with the aim of identifying competencies for each of the six already defined domains in the first phase as well as to relate those competencies with the professional profiles to easy their work in the field of Personalized Precision Medicine.

- Based on the information obtained in Phase 1 and the information and vision provided by the experts in the interviews, a proposal of competencies for healthcare professionals in Personalized Precision Medicine was drawn up.

- **In the SECOND WORKSHOP**: A consensus was reached on the competencies, the target professional profiles and the level of qualification to be achieved by each group of professionals for each competency.

4. Analysis of competency frameworks and training programs

The emergence of new areas of knowledge, such as Digital Health or Genomics, has sometimes been accompanied by the design and definition of competency frameworks developed by Scientific Societies and other organizations with the aim of ensuring similar training among professionals.

As a starting point, a series of competency frameworks were identified and grouped into four large blocks: those that define transversal competencies for healthcare professionals, outstanding frameworks in the areas of Digital Health and Genomics and, finally, national and international training programs in the field of Personalized Precision Medicine. The analysis of these frameworks allows us to lay the foundations in terms of structure and methodology for the definition of the competency framework for Personalized Precision Medicine.

The following is a list of the competency frameworks and training programs analyzed, as well as the main conclusions of the review.

Documents defining competency frameworks and training programs

Transversal	**CanMEDS Competency Framework** – Royal College of Physicians and Surgeons of Canada (1997) **Formación Especializada Basada en Competencias (FEBC)** – Hospital Universitario de Cruces (2008) **Learning Health System Competency Framework** – Agency for Healthcare Research and Quality (AHRQ) (2017) **Promoting Excellence: Standards for Medical Education and Training** – General Medical Council U.K. (2018)
Digital Health	**Recommendations for Biomedical and Health Informatics Education** – International Medical Informatics Association (IMIA) (2010) **Health Informatics Core Competencies** – Digital Health Canada (2012) **The Australian Health Informatics Competencies Framework and Its Role in the Certified Health Informatician Australasia (CHIA) Program** – Health Informatics Society of Australia (2013) **A Digitally Competent Health Workforce: Scoping Review of Educational Frameworks** – Nazeha, Nuraini et al. (2016) **Core competencies for applied health informatics education at the master's degree level** – American Medical Informatics Association (AMIA) (2017) **Digital Health Educational Framewroks** – J.A. Montero Delgado et al. (2018) **Technology Informatics Guiding Reform (T.I.G.E.R): An International Recommendation Framework of Core Competencies in Health Informatics for Nurses** – Hübner, U. et al. (2018)

	Digital Literacy Competency Framework – NHS England (2018) **Digital Competency Framework for Allied Health Professionals** – NHS England (2020)
Genetics and Genomics	**Essentials of Genetic and Genomic Nursing: competencies, curricula guidelines and outcome indicators** – American Nurses Association (2009) **Essential Genetic and Genomic Nursing Competencies for the Oncology Nurse** – American Nurses Association (ANA) (2011) **Framework for development of physicians' competencies in genomic medicine** – National Human Genome Research Institute (2014) **Facilitating genomic testing: a competency framework for consent** – Genomics Education Programme. NHS Health Education England (2014) **Core Competencies in Genetics form Healthcare Professionals: results from a Literature Review and a Delphi Method** – BMC Medical Education (2019)
Personalized Precision Medicine	**Bridge Translational Excellence Programme** – Copenhagen University. (2018) **Personalized Medicine Inquiry-Based Education (P.R.O.M.I.S.E.)** – Erasmus+ Mediterranean Institute for Life Sciences (2019) **Plus Summer School in Personalised Medicine** – European Infrastructure for Translational Medicine (EATRIS) (2021) **Precision Medicine Training Program** – Junta de Andalucía (2021)

In addition, this analysis was reinforced by conducting a literature review, including key reports and articles identified by the Working Group. This review allowed the identification of the areas of knowledge that should be integrated into the domains of the future competency framework in Personalized Precision Medicine (See **Annex**).

Conclusions of the documents analyzed

1 There are several examples of **general competency frameworks for healthcare professionals** that are intended to guide the design of training programs. In general, these frameworks include both **professional competencies** (e.g. knowledge of scientific and clinical fundamentals) and **cross-cutting competencies** (e.g. communication, leadership, management and collaboration skills) and **competencies focused on professional values and skills.**

2 In general, competency frameworks are **structured in competency domains**, and some also classify competencies according to their level or degree of specialization and the professional profile to whom they are addressed.

3 In the field of **Digital Health and Health Informatics** numerous examples of competency frameworks for healthcare professionals were identified. Generally, competency frameworks include **health and biomedical science competency domains** (e.g., health systems), **technological competencies** in the use of informatics tools**, competencies in the use and management of data** (including aspects related to data security and protection), and **cross-cutting competencies** (e.g., ethics, management, leadership, communication, collaboration).

4 In the field of **genomics**, competency frameworks aimed at **different profiles of health professionals** were identified. The competency frameworks analyzed go beyond **basic knowledge** in this area, with a focus on the **analysis and interpretation of results**, **aspects related to information management** and **communication to patients**, and other **ethical, legal and social aspects**.

5 Most of the identified competency frameworks, despite being focused on a specific field of knowledge (e.g. digital health or genomics), incorporate, in most cases, more **cross-cutting competencies** such as communication, strategy, research, bioethics, leadership, change management and governance.

6 At the European level, there are examples of **training programs in the field of Personalized Precision Medicine** (e.g. the EATRIS summer school in personalized medicine, the PROMISE project of the ERASMUS+ program and the BRIDGE program of translational excellence of the University of Copenhagen). These programs combine both **training elements in clinical and basic research**, as well as **cross-cutting knowledge and skills**, e.g., in communication and patient engagement, ethics, and in management and leadership in translational medicine.

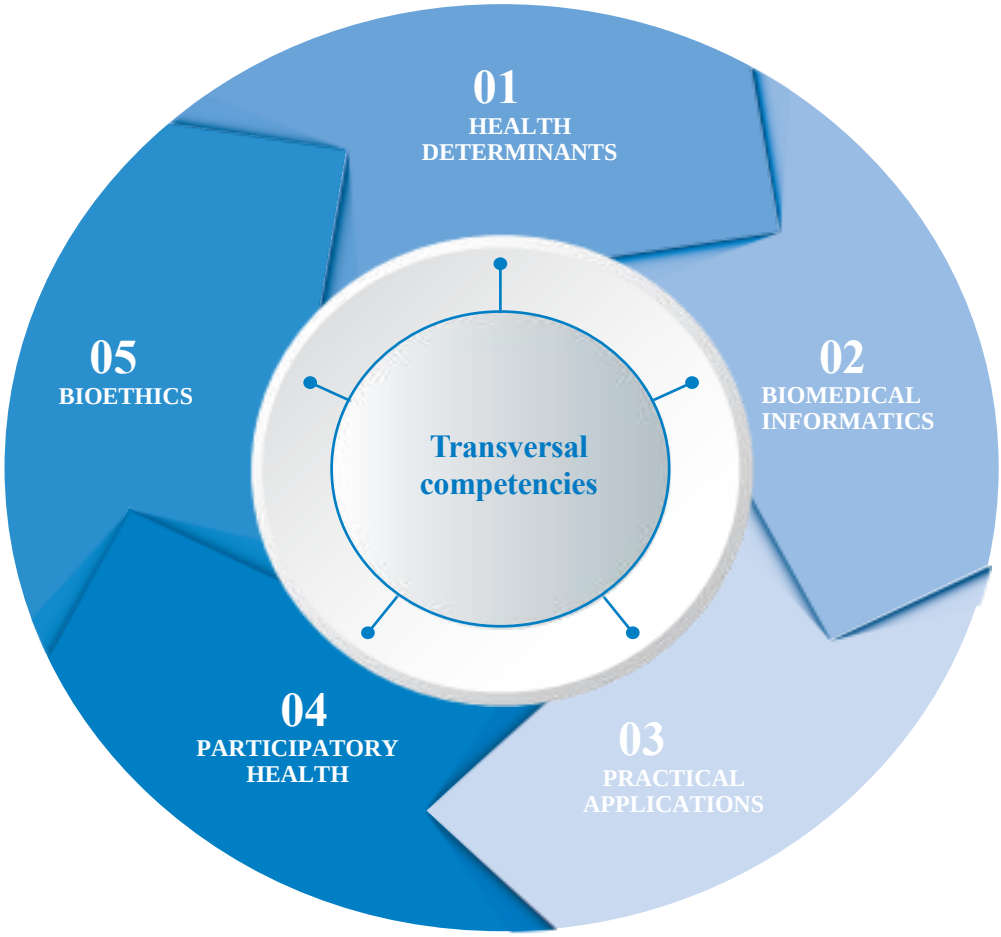
7 At the national level, the **Integrated Strategy for Personalized Medicine in Navarra** highlights the **need to have specific competencies in Personalized Precision Medicine for professionals in different fields** To achieve this objective, one of the axes of this strategy focuses on training in areas identified as relevant in the field of Personalized Precision Medicine: genomics and multiomics, ICTs and Digital Health, bioinformatics, data science, ethical-legal regulations and data protection, evaluation of scientific evidence, and research methodology.

8	**Personalized Precision Medicine** is a **key element of the Medicine of the Future** and, in combination with the development of digital tools and artificial intelligence techniques, it will make possible to combine clinical, genomic, and environmental information (social and environmental determinants of health) to improve the planning of therapeutic, preventive, and diagnostic strategies.
9	**Genomics, digital medicine, artificial intelligence,** and **robotics** are **key areas for addressing the healthcare challenges of the future**. Therefore, **educating current and future healthcare professionals** in these areas is **critical** to enable the implementation of the revolutionary changes in clinical practice and healthcare of the future.
10	Addressing the **future challenges of medicine** requires a **shift from the traditional disease-free approach** to a **health-oriented medicine** that holistically addresses all aspects of an individual's health.
11	Based on the current **definitions of health and Personalized Precision Medicine**, as well as the current situation in terms of their application and translation to clinical practice, **areas and knowledge that must be considered** to achieve an **optimal future medicine** that responds to the **individual needs of each individual** are identified.
12	After the analysis was carried out, the **importance** of considering **areas of knowledge** such as **genomics** and **other omic sciences**, **digital medicine**, **tools for management, interpretation and support for decision making based on data** (e.g., artificial intelligence) and **general aspects** such as **multidisciplinary work**, **leadership**, **ethical** and **safety conditions**, etc., became clear.

5. Structure of the competency framework and professional profiles

The analysis of the most relevant competency frameworks and training programs, the interviews with a multidisciplinary group of professionals and the workshops held with the Working Group have made possible to define the structure of a competency framework that would respond to the needs and challenges posed by the complete incorporation of Personalized Precision Medicine.

Figure 1. Structure of the competency framework for healthcare professionals in Personalized Precision Medicine.



The competency framework is structured in five essential domains: Health determinants, Biomedical informatics, Practical applications, Participatory health, and Bioethics plus a sixth cross-cutting domain that impacts the overall performance of the competencies linked to each of the previous domains

- **Domain 1. Health determinants:** includes those competencies that enable healthcare professionals to take a holistic approach that includes biological, environmental and other determinants of health within the framework of Personalized Precision Medicine.
- **Domain 2. Biomedical informatics:** includes those competencies that enable healthcare professionals to develop their activity incorporating technical and practical aspects linked to the digital transformation of the healthcare system,

digitization, and related tools, for the full incorporation of Personalized Precision Medicine.

- **Domain 3. Practical applications:** includes those competencies that enable health professionals to develop strategies based on Personalized Precision Medicine, both at individual and community levels, for the prevention, diagnosis, treatment, and follow-up on the disease.
- **Domain 4. Participatory health:** includes those competencies that enable healthcare professionals to promote patient participation by taking into account their needs and preferences and ensuring respectful, empathetic and individualized communication.
- **Domains 5. Bioethics:** includes those competencies that enable healthcare professionals to apply the principles of bioethics in the practice and development of Personalized and Precision Medicine.
- **Domain 6. Transversal competencies:** includes those competencies that have an impact on the general performance of the competencies linked to the other five domains, helping healthcare professionals to perform their professional work optimally in the field of Personalized Precision Medicine and the health system.

Within these domains it is essential to define the **professional profiles** to which this proposal of competencies is addressed. In this sense, for the application of the competency framework and taking into account the field in which the health professionals carry out their professional activity, six generic professional profiles are proposed. Although new profiles and professionals will emerge with scientific advances, six generic professional profiles were defined:

1. **Clinical:** healthcare professionals who carry out their work in the field of healthcare in contact with patients (hospital care, primary care, and secondary care.
2. **Laboratory:** healthcare professionals who work in the laboratory or other units of a healthcare center without direct contact with patients.
3. **Digital Health:** all the new professional profiles arising from the digital transformation of the healthcare system.
4. **Community health:** professionals working in the field of public health.
5. **Research:** professionals who work in research in the field of Personalized Precision Medicine.
6. **Management and planning:** professionals working in positions with responsibilities on healthcare management and planning.

6. Proposal of competencies in Personalized Precision Medicine for healthcare professionals

Each of the six defined domains includes a series of competencies that healthcare professionals should acquire to guarantee the optimal development of their practice in the field of Personalized Precision Medicine.

In total, the competency framework includes **58 competencies** structured in the six domains as follows:

- **Domain 1. Health determinants [10]**
- **Domain 2. Biomedical informatics [15]**
- **Domain 3. Practical applications [12]**
- **Domain 4. Participatory health [5]**
- **Domain 5. Bioethics [5]**
- **Domain 6. Transversal competencies [11]**

Domain 1. Proposal of Competencies on **HEALTH DETERMINANTS**

Biological determinants	
D1.1	**Principles of the molecular and pathophysiological basis of diseases** for their approach based on the omic sciences.
D1.2	**Principles of the different omics sciences,** their current **field of application** (clinical/research field) and their **advantages and limitations.**
D1.3	**Sources and types of data** that can be obtained with the different **omics technologies available** and what information can be provided by each one of them.
D1.4	Information derived from **the study of omics data** and its **clinical and/or epidemiological implications.**
Environmental determinants	
D1.5	Principles of **environmental toxicology** and **environmental risk factors with impact on health.**
D1.6	**Environmental behavior** of **chemical contaminants** and **environmental radiation.**
D1.7	Most common **routes and pathways of exposure** and the tools to apply this information to an individual (exposome).
D1.8	**Bioaccumulation and biomagnification** of pollutants along the trophic chain and their metabolism to understand how they reach individuals and how to interpret possible related findings.
D1.9	**Prediction and evaluation of risks** to environmental determinants in order to include them in decision-making.
Other health determinants	
D1.10	Use of the **psychosocial model** in the evaluation of the individual, including psychological, socioeconomic, and cultural factors, as well as habits and lifestyles and not only biological and environmental determinants.

Domain 2. Proposal of competencies on **BIOMEDICAL INFORMATICS**

Data collection	
D2.1	Differences between **data, information and knowledge**, and their relationship.
D2.2	Most relevant **sources and types of data** in the field of Personalized Precision Medicine, as well as the information that each of them can provide.
D2.3	**Primary and secondary use** of health data, main databases, and their applications in the specific areas of activity.
D2.4	Strategies to improve **data quality.**
D2.5	**Data life cycle** and the importance of complying with **FAIR principles** to enable its use.
D2.6	**Sharing of data, information and knowledge** generated within the framework of Personalized Precision Medicine, as well as the main national and international initiatives in health data management.
Data management	
D2.7	**Mechanisms to guarantee confidentiality, protection, and security and/or maintain anonymity** in the storage of health data and/or information, ensuring the right to privacy and making appropriate use of the information.
D2.8	Most common data **storage resources** (centralized/federated databases) and the possibilities offered by each one of them.
D2.9	**Main ontologies and normalization standards** in the field of health which would facilitate interoperability and data exchange.
D2.10	Incorporation of **information in the Electronic Health Record** in an appropriate manner, ensuring its quality to guarantee it subsequently used.
D2.11	**Legislative framework on the use and management of sensitive data and digital rights**: European regulation GDPR (General Data Protection Regulation) and national regulation LOPDGDD (Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights).[3]
Data analysis and interpretation of information	
D2.12	**Methodologies available to perform data analysis**: how the analysis is performed, the difficulties and limitations it presents, the level of quality of the data, etc.
D2.13	**Software** available for use in current clinical practice.
D2.14	**Programming languages** in health data analysis.
D2.15	**Main technological trends** that would be more important in the immediate future (e.g., artificial intelligence, Big Data, Internet of Things, etc.).

[3] Sources:

- https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en
- https://www.boe.es/buscar/doc.php?id=BOE-A-2018-16673

Domain 3. Proposal of competencies on **PRACTICAL APPLICATIONS**

Individual interventions	
D3.1	**Updating of knowledge and advances generated** in the field of Personalized Precision Medicine especially those specific to its field of work.
D3.2	**Available technologies** linked to the **collection of omic data** to **select the most appropriate** one, depending on the information that need be obtained, the pathology and the phase of the care process in which the patient is.
D3.3	**Databases** for the correct **clinical interpretation** of the results derived from the omic tests performed.
D3.4	**Process to reach a conclusion** or **recommendation** from the **interpretation of health data analysis** as a support tool for clinical decision making.
D3.5	**Diagnostic, prognostic and treatment biomarkers** that allow stratification of patients, especially those biomarkers specific to f its fields of work.
D3.6	**Predictive biomarkers** for the design of the **individualized therapeutic plan** taking into account the therapies associated with the expression of each of the biomarkers and the clinical situation of the patient.
D3.7	Determinants of the **pharmacogenetic phenotype**, pharmacological interactions and determinants of drug response to optimize the design of the individualized therapeutic plan.
D3.8	**Clinical decision support systems based on artificial intelligence** and designed from the evidence generated from the analysis of large amounts of data.
D3.9	**Personalized habit and lifestyle measures** and **recommendations** based on the individual's environmental exposures and risk assessment.
D3.10	Existing **tools** to apply a **family approach** in those clinical situations or patients who require it.
D3.11	**Genetic counselling** based on the results of genetic analysis and the individual's situation, recognizing the implications derived from these analyses in terms of **limitations, family repercussions, unexpected findings and possible interventions in prevention** taking in consideration the ethical and legal derivations of this practice.
Precision community interventions	
D3.12	**Precision health** based on the design of actions to promote and maintain health, based on data, information and analysis derived from omics sciences and data science, among others.

Domain 4. Proposal of competencies on **PARTICIPATORY HEALTH**

Participatory health	
D4.1	Information necessary to promote the informed participation of patients in **shared clinical decision-making** (autonomy over their health decisions), taking into account the complexity of the information associated with Personalized Precision Medicine.
D4.2	Contemplate **patients' preferences** taking into consideration the degree of depth with which they want to know the results derived from their health data, the diagnostic tests and treatments.
D4.3	**Appropriate communication skills** to ensure individualized and quality face-to-face and/or telematic care. to secure patient **understanding of information** and considering their needs and circumstances (e.g., language, culture, socioeconomic status) and expectations.
D4.4	Necessary skills for **self-awareness** (limits, biases and external influences) and **emotional self-regulation** of the professional as a key aspect for a humanized care.
D4.5	Needs and demands of **Patients Associations** to foster their participation as key agents in decisions at the institutional level.

Domain 5. Proposal of competencies on **BIOETHICS**

Bioethics	
D5.1	**Principles of bioethics** in Personalized Precision Medicine.
D5.2	Incorporation of **ethical aspects in the design of the new healthcare processes** derived from the incorporation of Personalized Precision Medicine into clinical practice.
D5.3	Functioning and role of the **Ethics Committees** and the criteria they use when reaching consensus for the application of Personalized Precision Medicine.
D5.4	Ethical issues regarding the **management and protection of health data**, especially in the new scenarios that have arisen in the context of Personalized Precision Medicine.
D5.5	**Patient's power over their health data**, providing the necessary information in a way that, in an informed manner, they can authorize or not its use for biomedical research, contributing to the advancement of Personalized Precision Medicine.

Domain 6. Proposal of **TRANSVERSAL** competencies

Management	
D6.1	**Planning tools, policies and health regulations** linked to the development and implementation of Personalized Precision Medicine in the health system.
D6.2	**Health strategy and management tools** that would contribute to the implementation of Personalized Precision Medicine at health care level.
D6.3	**Health economics** tools to ensure compliance with the principle of equity and promote sustainability in the health system.
D6.4	**New developments in the field of Personalized Precision Medicine that imply changes in the organization and/or provision of healthcare** to adapt or develop new healthcare processes.
Personal development	
D6.5	**Cross-disciplinary thinking and innovative attitude** based on continuous learning to identify improvements and new solutions that contribute to the development of Personalized Precision Medicine.
D6.6	**Collaboration and coordination with other professionals** as part of a **multidisciplinary team** recognizing the knowledge and skills of each professional and promoting shared decision making.
D6.7	**Training skills** to transfer the knowledge of Personalized Precision Medicine to other health professionals.
D6.8	**Critical analysis of information and interpretation of results**, understanding the differences between levels of evidence and degrees of recommendation.
D6.9	**Health research methods** to advance and **translate** Personalized Precision Medicine to clinical practice, incorporating research as another aspect of their professional work.
D6.10	**Communication skills** to **disseminate scientific advances to citizens** and promote their participation in the development of Personalized Precision Medicine.
D6.11	**Up-to-date performance** of all competencies in the field of Personalized Precision Medicine and the **identification of opportunities for improvement** in the professional practice.

7. Proposal of training level for each competency and professional profile.

The defined knowledge is applicable to any healthcare professional who develops or will develop his or her professional activity in the field of Personalized Precision Medicine. However, the level of training required for each area of knowledge will depend on the profile of the specific professional.

As developed in detail above, six professional profiles were identified and defined. For each professional profile, a difference level of training for each of the defined competencies would be advisable. To this end, a classification of progressive levels of development according to the degree of depth that a professional should acquire for each competency is established. Three levels of training: basic, intermediate, and advanced were identified

- **Basic level**: Healthcare professionals are able to **understand** and i**dentify** the subject matter knowledge, and **explain** the meaning of related information.

- **Intermediate level:** Healthcare professionals are able to **apply** the knowledge in their daily practice, demonstrating also the ability to **interpret** the information and/or results and **transfer** its application to different contexts.

- **Advanced level:** Healthcare professionals are able to **integrate** knowledge in a complete, consistent and up-to-date manner, demonstrating the ability to **critically analyze** and **evaluate** the results. They are also able to **innovate** on the knowledge acquired to contribute to the development of Personalized Precision Medicine as part of the Medicine of the Future.

The following are the matrices of the level of competency training by professional profile for each domain.

Domain 1. Health determinants (D1)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
Biological determinants						
D1.1. Principles of the molecular and pathophysiological basis of diseases for their approach based on the omic sciences.	A	A	I	I	A	B
D1.2. Principles of the different omics sciences, their current **field of application** (clinical/research field) and their **advantages and limitations.**	A	A	I	I	A	I
D1.3. Sources and types of data that can be obtained with the different **omics technologies available** and what information can be provided by each of them.	I	A	A	I	A	I
D1.4. Information derived from **the study of omics data** and its **clinical and/or epidemiological implications**.	A	A	A	A	A	I
Environmental determinants						
D1.5. Principles of **environmental toxicology** and **environmental risk factors** with impact on health.	I	B	B	A	A	B
D1.6. Environmental behavior of **chemical contaminants** and **environmental radiation**.	I	B	B	A	I	B
D1.7. Most common **routes and pathways of exposure** and the tools to apply this information to an individual (exposome).	I	B	B	A	I	B
D1.8. Bioaccumulation and biomagnification of pollutants along the trophic chain and their metabolism to understand how they reach individuals and to know how to interpret possible related findings.	B	B	B	I	A	B
D1.9. Prediction and evaluation of risks to environmental determinants in order to include them in decision-making.	I	B	B	A	I	B

Domain 1. Health determinants (D1)						
COMPETENCIES	PROFESSIONAL PROFILES					
	Assistive	*Laboratory*	*Digital Health*	*Community health*	*Research*	*Management and planning*
Domain 1. Health determinants (D1)						
COMPETENCIES	PROFESSIONAL PROFILES					
	Assistive	*Laboratory*	*Digital Health*	*Community health*	*Research*	*Management and planning*
Other determinants						
D1.10. Use of the **psychosocial model** in the evaluation of the individual, including not only biological and environmental determinants, but also psychological, socioeconomic and cultural factors, as well as habits and lifestyles.	**A**	**I**	**B**	**A**	**B**	**B**

Domain 2. Biomedical informatics (D2)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
Data collection						
D2.1. Differences between **data, information and knowledge** and their relationship.	A	I	A	A	A	I
D2.2. Most relevant **sources and types of data** in the field of Personalized Precision Medicine, as well as the information that each of them can provide.	A	I	A	I	A	I
D2.3. Primary and secondary use of health data, main databases and their applications in your area of activity.	I	I	A	I	A	I
D2.4. Strategies to improve **data quality.**	I	I	A	I	A	B
D2.5. Data life cycle and the importance of complying with **FAIR principles** to enable its use.	I	B	A	I	I	B
D2.6. Sharing of data, information and knowledge generated within the framework of Personalized Precision Medicine, as well as the main national and international initiatives in health data management.	I	I	A	I	A	I
Data management						
D2.7. Mechanisms to guarantee confidentiality, protection and security and/or maintain anonymity in the storage of health data and/or information, ensuring the right to privacy and privacy and making appropriate use of the information.	I	I	A	A	A	A
D2.8. Most common data **storage resources** (centralized/federated databases) and the	I	I	A	I	A	I

Domain 2. Biomedical informatics (D2)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
possibilities offered by each of them.						
D2.9. Main ontologies and normalization standards in the field of health that facilitate interoperability and data exchange.	I	I	A	I	A	I
D2.10. Incorporation of the **information in the Electronic Health Record** in an appropriate manner, ensuring its quality so that it can be subsequently used.	A	I	A	I	I	I
D2.11. Legislative framework on the use and management of sensitive data and digital rights: European regulation GDPR (General Data Protection Regulation) and national regulation LOPDGDD (Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights).	I	I	A	I	A	A
Data analysis and interpretation of information						
D2.12. Methodologies available to perform data analysis: how the analysis is performed, the difficulties and limitations it presents, the level of quality of the data, etc.	B	I	A	I	A	I
D2.13. Software available for use in current clinical practice.	I	I	A	I	I	I
D2.14. Programming languages in health data analysis.	B	B	A	B	I	B
D2.15. Main technological trends that are going to be more important in the immediate future (e.g. artificial intelligence, Big Data, Internet of Things, ...).	I	I	A	I	A	I

B BASIC I INTERMIDIATE A ADVANCED

Domain 3. Practical applications (D3)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
Individual interventions						
D3.1. Updating of knowledge and advances generated in the field of Personalized Precision Medicine and especially those specific to their field of work.	**A**	**A**	**I**	**A**	**A**	**I**
D3.2. Available technologies linked to the **collection of omic data** in order to **select the most appropriate** one depending on the information to be obtained, the pathology and the phase of the care process in which the patient is.	**A**	**A**	**I**	**I**	**A**	**I**
D3.3. Databases for the correct **clinical interpretation** of the results derived from the omic tests performed.	**A**	**A**	**A**	**B**	**B**	**B**
D3.4. Process to reach a conclusion or **recommendation** from the **interpretation of health data analysis** as a support tool for clinical decision making.	**A**	**I**	**A**	**I**	**I**	**B**
D3.5. Diagnostic, prognostic and treatment biomarkers that allow stratification of patients, especially those biomarkers specific to their field of work.	**A**	**A**	**I**	**I**	**A**	**B**
D3.6. Predictive biomarkers for the design of the **individualized therapeutic plan** taking into account the therapies associated with the expression of each of the biomarkers and the clinical situation of the patient.	**A**	**I**	**I**	**B**	**A**	**B**

Domain 3. Practical applications (D3)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
D3.7. Determinants of the **pharmacogenetic phenotype**, pharmacological interactions and determinants of drug response to optimize the design of the individualized therapeutic plan.	A	A	B	B	A	B
D3.8. Clinical decision support systems based on artificial intelligence and designed from the evidence generated from the analysis of large amounts of data.	A	I	A	B	A	I
D3.9. Personalized habit and lifestyle measures and **recommendations** based on the individual's environmental exposures and risk assessment.	A	I	I	I	A	B
D3.10. Existing **tools** to apply a **family approach** in those clinical situations or patients who require it.	A	I	B	I	I	B
D3.11. Genetic counselling based on the results of genetic analysis and the individual's situation, recognizing the implications derived from these analyses in terms of **limitations, family repercussions, unexpected findings and possible interventions in prevention** and considering the ethical and legal derivations of this practice.	A	I	B	I	I	B
Precision community interventions						
D3.12. Precision health based on the design of actions to promote and maintain health based on data and information derived from omics sciences, among others, and their analysis based on data science.	I	I	A	A	A	I

B BASIC I INTERMIDIATE A ADVANCED

Domain 4. Participatory health (D4)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
D4.1. Information necessary to promote the informed participation of patients in **shared clinical decision-making** (autonomy over their health decisions), taking into account the complexity of the information associated with Personalized Precision Medicine.	A	I	I	I	I	I
D4.2. Consideration of **patient preferences** regarding the degree of depth with which they want to know the results derived from their health data, the performance of diagnostic tests and treatments.	A	B	I	I	I	I
D4.3. **Appropriate communication skills** to ensure individualized and quality face-to-face and/or telematic care, ensuring patient **understanding of information** and considering their needs, circumstances (e.g. language, culture, socioeconomic status) and expectations.	A	B	I	I	I	I
D4.4. Necessary skills for **self-awareness** (limits, biases and external influences) and **emotional self-regulation** of the professional as a key aspect for a humanized care.	A	I	I	I	I	I
D4.5. Needs and demands of **Patients Associations** to foster their participation as key agents in decisions at the institutional level.	A	B	I	I	I	I

B BASIC I INTERMIDIATE A ADVANCED

Domain 5. Bioethics (D5)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
D5.1. Principles of bioethics in Personalized Precision Medicine.	A	I	I	A	I	A
D5.2. Incorporation of **ethical aspects in the design of the new healthcare processes** derived from the incorporation of Personalized Precision Medicine into clinical practice.	A	I	A	I	I	A
D5.3. Functioning and role of the **Ethics Committees** and the criteria they use when reaching consensus for the application of Personalized Precision Medicine.	A	I	I	A	I	A
D5.4. Ethical issues regarding the **management and protection of health data**, especially in the new scenarios that have arisen in the context of Personalized Precision Medicine.	A	A	A	A	A	A
D5.5. Patient's power over their health data, providing the necessary information so that, in an informed manner, they can authorize or not its use for biomedical research, contributing to the advancement of Personalized Precision Medicine.	A	I	A	I	I	I

B BASIC I INTERMIDIATE A ADVANCED

Domain 6. Transversal competencies (D6)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
Management						
D6.1. Planning tools, policies and health regulations linked to the development and implementation of Personalized Precision Medicine in the health system.	I	I	I	I	I	A
D6.2. Health strategy and management tools that contribute to the implementation of Personalized Precision Medicine at the health care level.	I	I	I	I	I	A
D6.3. Health economics tools to ensure compliance with the principle of equity and promote the sustainability of the health system.	I	B	I	I	B	I
D6.4. New developments in the field of Personalized Precision Medicine that imply changes in the organization and/or healthcare to adapt or develop new healthcare processes.	A	I	A	I	I	A
Personal development						
D6.5. Cross-disciplinary thinking and innovative attitude based on continued learning to identify improvements and new solutions that contribute to the development of Personalized Precision Medicine.	A	A	A	A	A	A

Domain 6. Transversal competencies (D6)						
COMPETENCIES	**PROFESSIONAL PROFILES**					
	Assistive	***Laboratory***	***Digital Health***	***Community health***	***Research***	***Management and planning***
D6.6. Collaboration and coordination with other professionals as part of a **multidisciplinary team** recognizing the knowledge and skills of each professional and promoting shared decision making.	A	A	A	A	A	A
D6.7. Training skills to transfer the knowledge of Precision Personalized Medicine to other health professionals.	A	I	A	A	I	A
D6.8. Critical analysis of information and interpretation of results, understanding the differences between levels of evidence and degrees of recommendation.	A	I	A	A	A	I
D6.9. Health research methods to advance **translate** Personalized Precision Medicine to clinical practice, incorporating research as another aspect of their professional work.	I	A	I	I	A	B
D6.10. Communication skills to **disseminate scientific advances to citizens** and promote their participation in the development of Personalized Precision Medicine.	A	I	I	I	A	B
D6.11. Up-to-date performance of all competencies in the field of Precision Personalized Medicine and the **identification of opportunities for improvement** in the professional practice.	A	A	A	A	A	A

B BASIC I INTERMIDIATE A ADVANCED

Glossary of terms:

Omic sciences: knowledge derived from the application of a set of technologies that enable the study at the molecular level of the different elements that make up biological systems (cells, tissues, individuals) in all their complexity, including the result of the interactions and relationships that occur between the internal components of the individual and the external elements with which it interacts. The main omics sciences refer to genomics, epigenomics, metagenomics, transcriptomics, proteomics and metabolomics.[4]

Competencies: dynamic and longitudinal process in time, by which a person uses knowledge, skills, attitudes and good judgment, associated with his or her profession, in order to be able to practice it effectively in all situations that correspond to the field.[5]

Primary use data: data that are used for the purpose for which it was collected (e.g., a patient's clinical data to provide healthcare).

Secondary use data: data that are used for a purpose other than that for which it was collected (e.g., when the same clinical data are used in aggregated form in a research study).

Exposome: those environmental factors (understood in this context as non-genetic factors) to which an individual is exposed from the prenatal period and which may condition the state of health or disease when they have an impact on the organism.[6,7]

Artificial intelligence: science that seeks to develop systems that exhibit intelligent behavior, which basically consists in trying to understand their environment and emulate the capacity for information management, reasoning, perception, learning and creation that we humans have. In the field of health, artificial intelligence consists in the application of algorithms and techniques that try to imitate these faculties of human intelligence in such a way that it is possible to create tools capable of learning from the analysis of large amounts of accumulated data, from which they draw conclusions autonomously, contributing to the resolution of complex health problems.[8]

Personalized Precision Medicine: the identification and application of the most effective preventive, diagnostic and therapeutic approach for each patient, through the integration of genomic and other omics data with the clinical data set of the patient and his/her environment..[9]

FAIR Principles: guidelines or characteristics that provide a set of precise and measurable qualities that a data publication should follow to make data Findable, Accessible, Interoperable and Reusable. [10]

Precision Health: scientific discipline, which encompasses Personalized Precision Medicine, and aims to proactively develop personalized solutions to improve diagnosis and treatment, and to

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[4] **Anticipating Reports: Omic Sciences. Observatory of Trends in Personalized Precision Medicine. Roche Institute Foundation** (2020).

[5] **Fernández Araque AM. Competencies of the health professions. Nursing** (Lond). 2008;26(7):56-64. https://www.elsevier.es/es-revista-nursing-20-articulo-competencias-profesiones-sanitarias-13125849

[6] **Anticipating Reports: Exposome. Observatory of Trends in Personalized Precision Medicine. Roche Institute Foundation** (2020).

[7] **Wild CP. Complementing the genome with an "exposome**": The outstanding challenge of environmental exposure measurement in molecular epidemiology. Cancer Epidemiol Biomarkers Prev. 2005;14(8):1847-1850. doi:10.1158/1055-9965. EPI-05-0456

[8] **Anticipating Report: Artificial Intelligence in Health. Ethical and Legal Challenges. Observatory of Trends in Personalized Precision Medicine. Roche Institute Foundation** (2020).

[9] **Digital Transformation of the Healthcare System for the Incorporation of Personalized Precision Medicine. Proposal of Recommendations. Roche Institute Foundation** (2021).

[10] Wilkinson, M., Dumontier, M., Aalbersberg, I. *et al.* **The FAIR Guiding Principles for scientific data management and stewardship.** *Sci Data* **3,** 160018 (2016). https://doi.org/10.1038/sdata.2016.18

focus on disease prediction and prevention, integrating interindividual genetic variability, lifestyle and environmental factors, including those interventions related to public health (sometimes referred to as "precision public health"). Precision health also includes actions that citizens can take to protect their health.

Digital Health: field of knowledge and practice related to the development and use of digital technologies to improve health.[11]

Environmental toxicology: scientific discipline based on the study of the damage caused to living organisms by different chemical substances or agents, called toxicants or environmental pollutants. Environmental toxicology also deals with the risk assessment of environmental toxicants.[12]

Digital Transformation: a comprehensive and integrated process of information, management and research based on technological tools and data, which seeks to achieve a model based on the generation of knowledge and the measurement of results to obtain value. The Digital Transformation of the National Health System implies a cultural and organizational change compared to traditional medicine. In addition, it will make it possible to achieve care based on prevention and personalization of healthcare, always centered on the patient in order to achieve the complete incorporation of Personalized Precision Medicine.[9]

[11] **Draft global strategy on digital health 2020-2025, World Health Organization, available at**: https://www.who.int/docs/default-source/documents/200067-lb-full-draft-digital-health-strategy-with-annex-cf-6jan20-cf-rev-10-1-clean-sp.pdf?sfvrsn=4b848c08_2

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