

Component	Subcomponent	Description
D5.C1. Strategy	C1.1 Digital strategy	<p>The government, whether of the institution or the country, has in place a digital strategy which defines a plan to extend ICT as a fundamental part of economic and social development. This envisages pluriannual plans for its execution, and the communications and infrastructure to enable the interoperability of the EHR.</p> <p>It also caters for the training and empowerment of IT and communications engineering professionals. It is necessary for the digital agenda to be allocated an execution budget, which should be pluriannual. By doing this, the government supports the EHR expressly and explicitly.</p>
	C1.2 Health strategy	<p>The health strategy establishes the objectives, actions and criteria for success of the health system which, in turn, define the objectives of the EHR. The government employs a health strategy as an instrument for improving the general health of the population.</p> <p>This includes actions for enhancing the efficacy, efficiency, effectiveness and quality of the health system. To this end, it is essential that measures be taken for information processing and knowledge management, inter alia. In fact, the public health information generated in clinical activity flows from the operational systems.</p>
	C1.3 EMR and EHR strategy	<p>As part of the health strategy, we find the MR strategy, which is the plan to extend this instrument at both the levels of primary care and hospitals. This strategy has been allocated a pluriannual budget which guarantees sufficient funds for its fulfillment, in addition to having a plan for the deployment and implementation of the EHR with a perspective of, at least, seven years.</p>

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	C1.4 Strategic alignment	<p>The government ensures that the digital agenda and the health and EHR strategies are mutually coherent, so as to guarantee synergies and fulfillment of the general objectives.</p> <p>On the one hand, the digital strategy guarantees the availability of the infrastructures which render possible meeting the targets set by the EHR strategy and professionals for implementation of the EHR. Furthermore, there is coordination with the health authorities for planning the training of professionals. On the other hand, the EHR strategy coordinates its general and specific objectives with those of the health strategy. The budget allocated to the digital agenda and the EHR allows the actions necessary to reach the objectives of the health strategy to be taken. Moreover, the EHR strategy envisages adding value to the digital agenda thanks to its investments, the participation of empowered professionals who collaborate on the training of their new colleagues, the experience acquired by companies in the ICT sector, and the participation of patients in using the functionality of the EHR.</p>
D5.C2. Institutional support	C2.1 Organization for MR improvement	<p>In the areas of decision at the national level, a working group or stable commission is set up with the responsibility of guaranteeing a harmonious development of the contents of the MRs (in whatever format they are) at the national level.</p> <p>Among the responsibilities of this organization is not only the definition of the content of the MRs but also the evaluation of the quality of these contents and the inclusion of proposals to improve these files, always with the perspective of positively influencing the care results.</p>
	C2.2 Institutional support	<p>The implementation of the HIS at national level, and in particular the information related to healthcare processes, requires express commitment from the government of the institution (or the country), setting out clearly the relevance conferred by information as a vehicle for improving the quality and efficiency of healthcare services.</p>

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D5.C3. Leadership	C3.1 Institutional leadership	In these situations, the health authorities designate a person responsible for the EHR, who should direct a team of persons from different disciplines (doctors, nurses, engineers and economists, among others).
	C3.2 Leadership	<p>The managers of hospitals form part of the working groups responsible for taking the major decisions. For their part, the clinical and ICT professionals form part of formally established working groups.</p> <p>These working groups have different functions: Firstly, they discuss and participate in the decisions on the model of medical record, its functionality and usability, among other points. They also participate in determining the objectives and validating the value these add and encourage the election of leaders who will collaborate on designing and implementing the EHR. Finally, they assess the results against each target and put forward improvements.</p>
D5.C4. Data protection	C4.1 Data protection	<p>The data protection law (or regulations) provides guarantees on access, confidentiality, availability and the custody of personal data. Specifically, the norms governing access and data protection for medical records establish the ownership of the rights of access, rectification, erasure and objection with respect to medical information, and allow for the peculiar features of this information and distinguish it specifically for this reason, demanding the highest level of protection.</p> <p>The legislation requires guaranteeing the access of clinical professionals to the medical information of the patient when they attend the same, irrespective of where that information was generated. To ensure compliance with these norms, there should be a data protection supervisory authority with the power to impose penalties, with access to the health centers and services, and to whom citizens can have recourse to exercise their rights. It follows that there exist standardized procedures guaranteeing access by patients to their own medical information and access by clinical professionals to that of their patients.</p>

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D5.C5. Validity and uses of the MR and interoperability	C5.1 Validity and uses of the MR and interoperability	<p>The legislation confirms the validity of the medical information without the need to employ paper or handwritten signatures. It imposes mandatory requirements on the compilation and custody of the EHR, its security and its accessibility by the persons authorized in each case. It also provides that the EHR has the following uses: healthcare, quality evaluation, health inspection, public health, generator of knowledge and as a document of legal force; and it establishes the data protection conditions necessary for each of these uses.</p> <p>In addition to all this, the legislation specifies the indispensable elements which the EHR should possess and how the clinical reports issued in each case should be structured: discharge report, out-patient consultancy, laboratory, imaging, emergency, primary care, inter alia.</p> <p>In summary, the legislation sets out the EHR model and the standards which should be employed to guarantee its interoperability, referring both to the different EHR solutions and to the specific ones for its different components.</p> <p>With respect to the national government, this has a unique identification system for persons accessible to the health system to identify patients. This identifier is what is employed in the medical record and is indispensable for interoperability. Furthermore, there should be established a catalog of medicaments which identifies the active principle, the excipient, the form, the mode of employment and the dose, among other fields, which is employed by all the health professionals, centers and services.</p> <p>The country holds a register of the healthcare professionals authorized to practice, which classifies their specializations and professional competences, and which register is employed to identify each professional who records and accesses medical information, while there is also a register cataloging all the healthcare centers and services, which is employed to identify the place where the medical information was recorded.</p>

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D5.C6. Empowerment and training	C6.1 Empowerment and training	<p>The EHR needs professionals from the ICT field who have been trained in health issues and professionals from the clinical and health sectors who have been trained in ICT. To guarantee this training, the country has qualifications at different academic levels in relation to ICT, such as technicians and engineers, and specific undergraduate or graduate degrees in ICT for the health sector, or health informatics.</p> <p>Thus, there are care and clinical personnel with specific training in health information technologies and systems, and specific training plans and programs for users of the EHR.</p> <p>With respect to the users of the EHR, the specific training for them continues after the initial implementation with the assistance necessary, as well as for the new versions and new utilities added. Thus, the EHR has professionals assigned from the ICT and health disciplines, who have received specific training in both fields.</p>
D5.C7. Planning	C7.1 Planning	<p>The cycle of an EHR is the viability study, analysis, development, preproduction, production, evaluation, maintenance and evolution.</p> <p>It is necessary for the planning of this cycle so define specific final objectives, the short-term objectives, the criteria for success, the detection of possible improvements, maintenance, evolution and continuous improvement.</p> <p>There exists a plan prepared by the EHR managing entity which includes the approval of the EHR model, its components, and the standards and structure for the information. The plan has a budget which is pluriannual and modifiable, to enable the incorporation of modifications and improvements, which includes the costs of the preliminary studies, analysis, development, preproduction, production, evaluation, maintenance, evolution, training and support for users. Furthermore, the plan provides for the evaluation of the objectives and targets of the EHR and details the tests, improvements, implementation and evaluation of the same.</p>

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D5.C8 Change management	C8.1 Change management	<p>Implementing an EHR successfully is mirrored in better quality of care, user orientation and timely access to full information. Despite its potential benefits, its implementation is a difficult and complex task whose success depends on many factors. One of these, without any doubt, is paying the attention necessary to managing the change, which the professionals and users of the new system are unavoidably going to pass through, and if this is not properly handled, it will become a decisive factor in the failure of the adoption of the EHR.</p> <p>The aim of change management is to facilitate and achieve the successful implementation of new processes, which implies working with and for persons on their acceptance and assimilation of the change and on reducing resistance, facilitating this change brought about by the new mode of operation.</p> <p>For this reason, it becomes indispensable to put into practice a Change Management methodology, with a series of stages from the Definition of the Vision of Change up to its development and tracking, to accompany the process of implementing the EHR within an organization.</p>