2. Interoperability and standards requirements

Standards		
Requirements	**Associated questions**	**Equivalence with HL7**

The system has the ability to operate seamlessly with systems that adhere to recognized standards of **semantic exchange**. These systems include other EHRs, subcomponents of an EHR system, or other (authoritative, non-EHR) systems.
 	
All of these refer to terminology standards and catalogues such as SNOMED CT, LOINC, ICD-10, etc.
	• Does the system have the capacity to receive information using semantic information exchange standards, which are specific to the system and not recognized by official international entities?
	• Does the system have the ability to receive information using semantic information exchange standards recognized by official international standards (SNOMED CT, LOINC, ICD-10, for example)?
	  ○ ICD-9
	  ○ ICD-10
	  ○ SNOMED CT
	  ○ LOINC
	  ○ DICOM
	  ○ CDA
	• Does the system have the capacity to transmit information using semantic information exchange standards, which are specific to the system and not recognized by official international entities?
	• Does the system have the capacity to receive information using internationally recognized terminology and classification standards
		TI.4.1
		
		TI.5.1

Standards		
Requirements	**Associated questions**	**Equivalence with HL7**
	(SNOMEC CT, LOINC, ICD-10, for example)? Check which of the following are being used: ○ ICD-9 ○ ICD-10 ○ SNOMED CT ○ LOINC ○ DICOM ○ CDA	
The system has the ability to operate seamlessly with systems that adhere to recognized inter-application interchange standards. These systems include other EHR systems, subcomponents of an EHR system, or other (authorized, non-EHR) systems. Reference is made here to information transfer standards such as HL7, FHIR, DICOM, CDA, etc.	• Does the system have the capability to receive information using messaging exchange standards, which are proprietary to the system and not recognized by official international entities? • Does the system have the capability to receive information using messaging exchange standards recognized by official international entities (e.g., HL7, FHIR)? • Does the system have the capability to transmit information using messaging exchange standards, which are proprietary to the system and not recognized by official international entities?	TI.5.1

Standards		
Requirements	**Associated questions**	**Equivalence with HL7**
	• Does the system have the capability to transmit information using messaging exchange standards recognized by official international entities (HL7, FHIR, for example)?	
The system has the ability to operate with structured documents. A structured document contains tab pages that identify text fields and document attributes. For example, HL7's Clinical Document Architecture (CDA) is an XML-based standard for document markup that specifies the structure and semantics of clinical documents for the purpose of facilitating their exchange in an interoperable environment.	• Does the system have the ability to operate with structured documents? • Does the system follow an internationally recognized standard for operating with structured documents, e.g., CDA?	TI.5.1.2
The system has the ability to operate with images.	• Does the system have the ability to operate with images? • Does the system follow an internationally recognized standard for operating with images, DICOM for example?	

Standards		
Requirements	**Associated questions**	**Equivalence with HL7**
	• Does the system follow a local or proprietary standard for operating with images? • Does the system have the ability to handle images in any type of PNG, JPG, etc. format? • Does the system have the ability to access diagnostic images stored in a PACS? • Does the system follow an internationally recognized standard for storing images, DICOM for example? • Does the system follow a local or proprietary standard for storing images? • Does the system have the ability to implement or configure policies for storing images according to time periods?	
The system has the ability to operate with structured messages.	• Does the system have the ability to operate with structured messages? • Does the system follow an internationally recognized standard for operating with structured messages, HL7 for example?	TI.5.1.3

Standards		
Requirements	**Associated questions**	**Equivalence with HL7**
	• Does the system follow a local or proprietary standard for operating with messages? • Does the system have a validation procedure for the structure/format of a message? (For example, XML validation v1.0/1.1)	
The system has the ability to integrate and transport data between different applications or EHR systems that adhere to recognized information exchange standards. These systems include other EHR systems, subcomponents of an EHR system, or other (authorized, non-EHR) systems. We refer here to messaging and communication standards, such as JSON, XML, Web services, etc.	• Does the system have the capacity to receive information using exchange standards, which are specific to the system and not recognized by official international entities? • Does the system have the capacity to receive information using exchange standards recognized by official international entities? • Does the system have the capability to transmit information using exchange standards that are specific to the system and not recognized by official international entities? • Does the system have the capability to transmit information using exchange standards recognized by official international entities?	TI.5.1

Standards		
Requirements	**Associated questions**	**Equivalence with HL7**
Interoperability standards may change throughout their lifecycle; these changes are often labeled with "version" numbers. EHR systems need to control the different versions of the interchange standards used within an EHR implementation and adapt to changes that arise with each version.	• Does the system have the ability to use different versions of the standards at the same time? • Does the system have the ability to integrate with other systems using previously supported versions of an interoperability standard? • Does the manufacturer have an established policy of revising and incorporating new versions of standards in an agile and reliable manner?	TI.5.2
Semantic interoperability: Version control allows multiple sets or versions of the same terminology to exist and be clearly recognizable over time.	• Does the system offer the capability to manage data using different versions of terminologies (either local or standard)? • Does the system offer the capability to maintain terminologies (whether local or standard)? • Does the system maintain relationships between versions of a terminology to enable the preservation of interpretation over time? • Does the system provide the capability to receive and harmonize data and transmit data to other systems that use different known versions of a terminology standard while preserving the meaning of that data?	TI.4.2

Standards		
Requirements	**Associated questions**	**Equivalence with HL7**
	• Does the system offer the capability to deprecate terminologies that become obsolete? • Does the system offer the capability to update individual codes within a terminology to an obsolete state? • Does the system provide the capability to update terms with their equivalent when terminology changes, when coded terminology content is embedded in clinical models (e.g., templates and custom forms)? • Does the system offer the capability to update standard terminologies used to enter clinical content (through templates, custom forms, etc.)? • Does the system provide the capability to maintain an audit trail or history of system changes at the individual code level, for versions used, dates implemented and updated to allow correct interpretation of historical data over time?	
Exchange agreements must be in place to specify the rules, responsibilities, expectations, and methods by	• Does the system have described agreements and specifications for the exchange of information with third parties?	TI.5.4

Standards		
Requirements	**Associated questions**	**Equivalence with HL7**
which the system interacts with other systems or applications to exchange information.	• Does the system follow the standards set (if any) in the exchange agreement with a third party?	
The system must be capable of mapping or translating from one terminology to another as one terminology to another as required by local, regional, national or international interoperability requirements.	• Does the system have the capability to manage data using terminology maps that can be provided by terminology mapping services (internal or external)? • Does the system have the capability to update terminology maps using standard terminology services (internal or external)? • Does the system have the capability to generate technical quality and data quality reports for a user to determine the validity of terminology mappings using approved mapping techniques? • Does the system have the capability for a user to maintain custom terminology maps using approved mapping techniques where formal standard terminology maps are not available? • Does the system have the capability for a user to maintain custom terminology maps in formal standard terminology maps to support the use of historical data?	TI.4.3

Operation and monitoring		
Requirements	**Associated questions**	**Equivalence with HL7**
If your system transforms data using a coding system or catalog, you must maintain the original version and all previously changed versions of the Record Entry, keeping each version instance unaltered.	• When transformations are applied to source data, does the system retain the original, unedited version of the record? • Does the system maintain an identifiable and searchable record for each version/modification made to the data?	RI1.1.3.
The system must have event planning mechanisms for message reprocessing and deferred message operations, i.e., simply because of business requirements or to relieve the volume of incoming and outgoing messaging on the platform, the system must be able to manage the messages that could not be processed at the time. For example, reprocessing patient records, synchronization of catalogs.	• Does the system have a deferred message handling mechanism, a queuing system? • Does the system have an event planner for messaging queues? • Does the system have a volume control or message batches?	
Messaging flow management capabilities must be available, including management and configuration of queues and system interfaces.	• **NOTE:** If you do not answer yes to the above, these questions do not apply. • Does the system have a mechanism to manage and configure the rules for handling the flow of information?	TI.7

Operation and monitoring		
Requirements	**Associated questions**	**Equivalence with HL7**
Implementation functions that use business rules related to the flow of information are also necessary, for example, discarding unprocessed messages after a certain time, retrying or not the sending of a message, etc. CLARIFICATION: It refers to the prioritization of the sending/reception of messages of a certain type or subject matter, of a certain hospital, etc.	• Does the system have an alert and notification mechanism for events related to these rules and regulations? • Does the system have the ability to determine and update resource allocation and/or prioritize the information flow queue according to established rules and ad hoc needs that may arise?	
The system must be able to trace and monitor any information exchange events with third parties, both sending and receiving.	• Does the system have the ability to determine whether information transmitted to another system has been successfully received by that other system? • Does the system have the capacity to inform a third party when it has been unable to adequately process the information received from the third party? • Does the system have a record of each data exchange (transaction) stored when transmitting information with external systems? • Does the system have the ability to **send** information records to third parties keeping the original record unaltered, with its signatures, metadata, origin, etc.?	TI.5.1 RI.1.1.8 RI.1.1.9.1

Operation and monitoring		
Requirements	**Associated questions**	**Equivalence with HL7**
	• Does the system record the date, time, originating entity, message type, etc. of messaging transactions in the logs? • Does the system have an enabled mechanism for consulting and monitoring these logs? • Does the system have an alert mechanism in place to monitor the exchange of information with third parties? • Does the system have the possibility to configure the persistence time of these logs? • Is the log persistence time defined in the system longer than one month? • Does the system have an automatic periodic log cleaning mechanism enabled? • Does the system have the ability to exchange information with medical devices (APPs, measuring devices, etc.,)? • If so, does the system store a unique and unique identifier of the device it is communicating with?	RI.1.1.1.1.1, item 7
Any interoperability system should have an end-to-end monitoring process, not only of the status of the service, but also of the correct functioning of the	• Does the system have a built-in transversal monitoring tool for the application's "services", that is, for the different functional use cases of the application?	

Operation and monitoring		
Requirements	**Associated questions**	**Equivalence with HL7**
internal messaging. This monitoring will indicate the functional health of our solution.		
The system must have mechanisms for message queuing and reprocessing in case of system failure.	• Does the system have a messaging repository where information is stored until communication between the systems is re-established? • If you have a queuing system, do the stored messages have an expiration date? • Is there a retry or reinstatement queuing system in place? • Does the system have a repository of undelivered messaging? • If the message was not delivered, does the solution include message reprocessing?	
Interoperability activities should be regularly monitored and reviewed. Indicator monitoring reports should be generated and distributed to evaluate the quality of the indicators should be generated and distributed to assess the quality of the implemented interoperability.	• Does the system have mechanisms in place to report on indicators to monitor the effectiveness and quality of information exchange with third parties? • Are these reports available by default in the system?	

Operation and monitoring		
Requirements	**Associated questions**	**Equivalence with HL7**
The efficiency of interoperability mechanisms should be evaluated; in particular, mechanisms and metrics should be in place to assess the quality of information exchanged with third parties.	• Does the system have mechanisms in place to assess the quality of data exchanged through interoperability mechanisms? • Does the system have metrics in this regard?	