1 10 October 2014
2 EMA/42176/2014 Corr.*[1]

3 Draft Functional specifications for the EU portal and EU 4 database to be audited

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Sign off by Executive Director	Planned for December 2014

6

Comments should be provided using this template. The completed comments form should be sent to GCP@ema.europa.eu

7

[1] A correction has been made to ensure the box entitled 'Interface with MSs CT systems' in figure 1 is properly aligned.

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Contents

1. Introduction

The new Clinical Trial Regulation (EU) No 536/2014 (hereinafter “the Regulation) establishes a harmonised approach to submission, assessment and reporting of clinical trials (CTs) with the implementation of consistent rules throughout the member States (MSs). These processes are to be supported by a EU portal and EU database which will ensure a centralised workflow with monitoring by the relevant parties. This Regulation repeals the Directive on clinical trials 2001/20/EC implemented in 2004 and which was the initial European legislation that aimed to simplify and harmonise the administrative requirements for clinical trials across the EU, whilst ensuring the safety of clinical trial participants, the ethical soundness of trials and the reliability and robustness of data generated. While achieving some of its aims, the Directive has also increased the administrative burden, costs and approval process of conducting clinical trials in the EU.

The application of the new Regulation is conditional on the conduct of an audit of the EU portal and the EU database showing that the system has achieved full functionality. The aim of this document is to draw up the functional specifications to be audited as specified in article 82 of the Regulation.

2. Legal Basis

In accordance with Regulation (EU) No 536/2014 of the European Parliament and of the Council of clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, the European Medicines Agency has the following obligations:

- In accordance with Article 80, the Agency shall, in collaboration with the Member States and the Commission, set up and maintain a portal at Union level as a single entry point for the submission of data and information relating to clinical trials in accordance with this Regulation. The portal shall be technically advanced and user-friendly so as to avoid unnecessary work. Data and information submitted through the EU portal shall be stored in the EU database referred to in Article 81.
- In accordance with Article 81, the Agency shall, in collaboration with the Member States and the Commission, set up and maintain a database at Union level. The Agency shall be considered to be the controller of the EU database and shall be responsible for avoiding unnecessary duplication between the EU database and the EudraCT and EudraVigilance databases. The EU database shall contain the data and information submitted in accordance with this Regulation.
- In accordance with Article 82, the Agency shall, in collaboration with the Member States and the Commission draw up the functional specifications for the EU portal and the EU database, together with the timeframe for their implementation.

The Management Board of the Agency shall, on the basis of an independent audit, inform the Commission when the EU portal and the EU database have achieved full functionality and meet the functional specifications drawn up pursuant to the third paragraph.

The Commission shall, when it is satisfied that the Union portal and the EU database have achieved full functionality, publish a notice to that effect in the Official Journal of the European Union. Six months after the publication of this notice, the Regulation shall apply.

3. Scope

The Regulation clearly states that all information that is submitted through the EU portal is stored in the EU database (Article 80). Whenever the articles of the Regulation explicitly require that information goes via the portal, then it is stored in the EU database (see table 1). .

According to Article 81(4), the EU database shall be made publicly available unless, for all or part of the data and information contained therein, confidentiality is justified on the grounds outlined in that Article.

The functional specifications required by Article 82(1) of the Regulation describe the requirements for the EU portal and the EU database. In order for the EU portal and the EU database to function correctly certain other technical features are essential and these are provided by the workspace. The workspace is required in order to support activities such as the preparation and compilation of the clinical trial application by the sponsor, the drafting of the assessment reports (ARs) by the Member States (Articles 6(5), 16(6) and 18(4)) prior to submission via the EU portal, as well as other features essential to track and control of these activities. Whilst the workspace is essential to the functioning of the EU portal and EU database, and is therefore included in the scope of the audit, its content is outside of the EU portal and the EU database as defined by the Regulation.

Schematic representation of the clinical trial systems is provided in Figure 1:

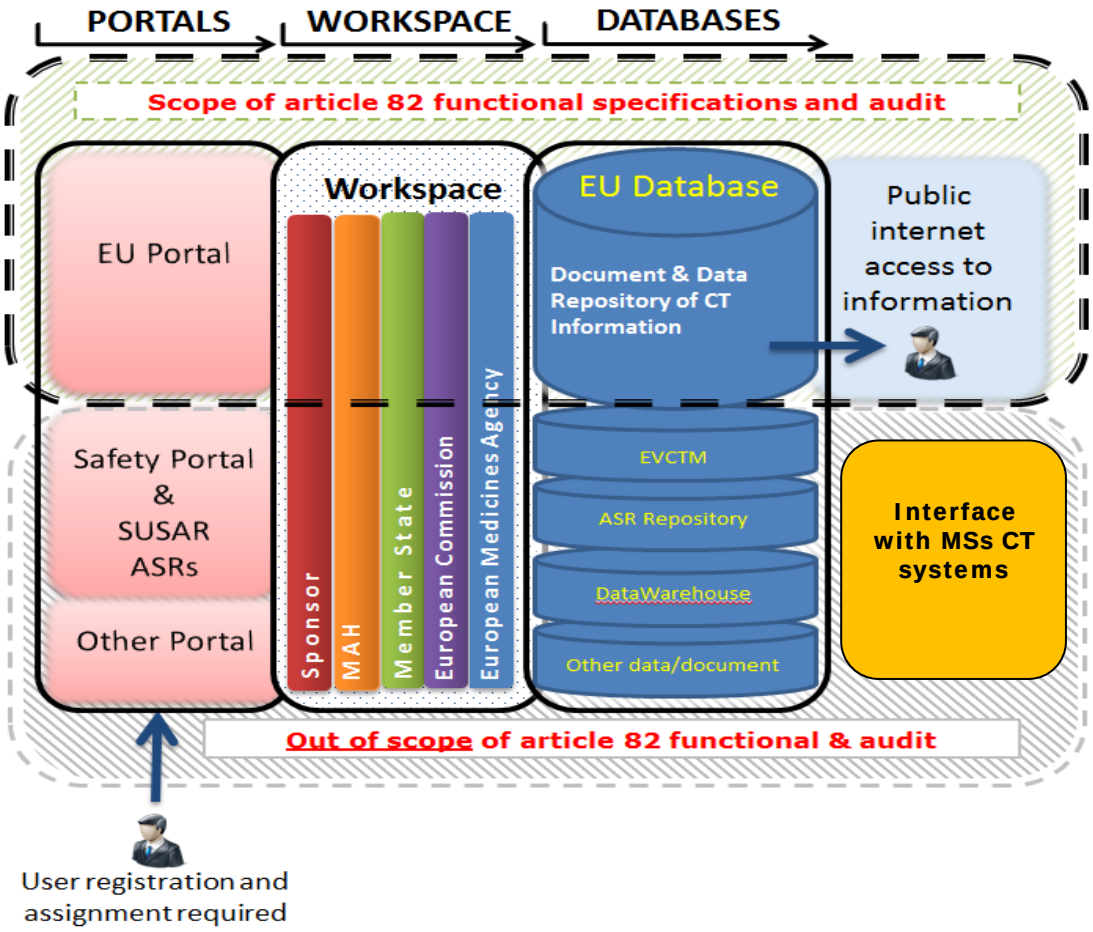

Figure 1: High level overview of the clinical trial systems

The legal requirements that set out the data and information to be submitted through the EU portal to the EU database are presented in section 4. The functional specifications identified in line with those legal requirements are presented in section 5.

4. Overview of the activities required in the Clinical Trial Regulation

4.1. Legal requirements of the EU portal and EU database

The EU portal and EU database and associated workspace are to provide sponsors, applicants to a marketing authorisation, MS, the Commission and the Agency an effective network tool to streamline and facilitate the flow of information for the authorisation and supervision of clinical trials in the EU and to support publication of information on clinical trials. An overview of the legal requirements for the submission of data and information through the EU portal to the EU database and the key actors is provided in table 1.

Table 1: EU clinical trial portal and EU database activities and requirements

EU clinical trials portal and EU database activities and requirements				
Stakeholder	Role (high level)	Requirement	Requirement ID No.	Legal Basis (Art)
Sponsor	Submit an initial CT application, substantial modification or an additional MS in a CT/Conduct of the trial, supervision by the sponsor	Request of a unique EU trial number to identify each CT	Req. 1	Art. 81(1)
		Record and submission of medicinal products and substances to the Medicinal Product Dictionary, including the request of the EU Medicinal Product number and EU active substance code	Req. 2	Art. 81(3)
		Submission of application related to CT (initial, additional MS and substantial modifications)	Req. 3	Art. 5(1), 14(1), 16
		Submission of the requested additional information by the Reference Member State (RMS) or Member State Concern (MSC), as applicable	Req. 4	Initial application: Art. 5(5) for validation, Art. 6(8) for Part I and Art. 7(3) for Part II. Additional MS: Art. 14(6) Part I and Art. 14(8) Part II. Substantial modification: Art. 17(4) for validation, Art. 18(6) for Part I, Art. 20(6) for Part II, Art. 22(3) for Part II.

EU clinical trials portal and EU database activities and requirements				
Stakeholder	Role (high level)	Requirement	Requirement ID No.	Legal Basis (Art)
		Submission of Inspection reports of third country authorities concerning a clinical trial conducted by that sponsor	Req. 5	Art. 53(2)
		Notifications	Req. 6	Reasons for withdrawal- Art. 12. Start of the clinical trial- Art. 36(1). First visit of the first subject- Art. 36(2). End of the recruitment- Art. 36(3). Re-start of recruitment- Art. 36(3). End of Trial- Art. 37(1) (in relation to each Ms concerned), Art. 37(2) (within the EU), Art. 37(3) (global end). Temporary Halt- Art 37(5) (for reasons not affecting benefit-risk balance) and Art. 38 (for reasons affecting benefit-risk balance). Restart of the trial after temporarily halt- Art. 37(6). Early termination- Art. 37(7) (for reasons not affecting benefit-risk balance) and Art. 38 (for reasons affecting benefit-risk balance). Serious Breaches- Art. 52(1). Unexpected events which affect the benefit-

EU clinical trials portal and EU database activities and requirements				
Stakeholder	Role (high level)	Requirement	Requirement ID No.	Legal Basis (Art)
				risk balance- Art. 53(1). Urgent safety measures – Art. 54.
		Submission CT results intermediary data analysis (when applicable)	Req. 7	Art. 37(4), 37(8)
	Update of information	Update any changes to the clinical trials which are not substantial modification but are relevant for the supervision of the CTs by the MSs	Req. 8	Art. 81(9) Art. 55, Investigator's brochure.
Applicants (marketing authorisation)		Submission Clinical Study Report	Req. 9	Art 37(4)

EU clinical trials portal and EU database activities and requirements				
Stakeholder	Role (high level)	Requirement	Requirement ID No.	Legal Basis (Art)
MSC	Authorisation and supervision of clinical trials	Determination and notification of RMS	Req. 10	Art. 5(1)
		Submission of considerations relevant to the application by the additional MSC	Req. 11	Art. 14(5)
		Request for additional information* *Validation not identified in the Regulation for Articles 11 and 14 and therefore should be addressed by the MS through request for additional information	Req. 12	Initial application- Art. 5(5) for validation, Art. 6(8). for Part I and Art. 7(3) for Part II. Additional MS- Art. 14(6) for Part I and Art. 14(8) for Part II. Substantial modification- Art. 17(4) for Part I validation, Art. 18(6) for Part I, Art. 20(6) for Part II, Art. 22(2) for Part II. Request for translation of the third country inspection report (Article 53(2))
		Submission of final ARs (Part I and Part II) and its conclusions	Req. 13	Initial application- Art 6(4) for Part I, Art 7(2)for Part II Substantial modification- Art 18(3) for Part I, Art 20(5) for Part II, Art 20(6), Art 22.1 for Part II
		Notifications (Validation outcome, decision, disagreement on Part I, revoke , suspend a CT, surveillance)	Req. 14	Validation- Art. 5(3), 17(2), 17(4), 20(1), 20(3). Decision- Art. 8.1, 14(3), 19(1), 20(5), 23(1).

EU clinical trials portal and EU database activities and requirements				
Stakeholder	Role (high level)	Requirement	Requirement ID No.	Legal Basis (Art)
				Disagreement on Part I- Art. 8(2), 14(4), 19(2), 23(2). Corrective measures (revoke/suspend/request for modification)- Art. 77(2) and 77(3).
		Supervise compliance with the Regulation: Inspection planned/outcome inspections conducted	Req. 15	Art. 78(3)
		Submission Inspection Reports	Req. 16	Art. 78(6)
Commission	Supervision of regulatory systems in EU and outside EU	Submission Union Control Reports	Req. 17	Art. 79(2)
Public	View the clinical trial related information	The EU database shall be publicly accessible unless, for all or parts of the data and information contained therein, confidentiality is justified on any of the following grounds: – protecting personal data in accordance with Regulation (EC) No 45/2001; – protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product unless there is an overriding public interest in disclosure; – protecting confidential communication between Member States in relation to the preparation of the	Req.18	Art. 81(4)

EU clinical trials portal and EU database activities and requirements				
Stakeholder	Role (high level)	Requirement	Requirement ID No.	Legal Basis (Art)
		assessment report; – ensuring effective supervision of the conduct of a clinical trial by Member States.		
The Agency	Database controller	Administrative and maintenance of the database Integration of data and documents held in the EU database and other databases managed by the Agency	Req. 19	Art. 81(1)

4.2. Systems Overview

The functional specifications have to address the following systems requirements:

- Secure electronic submission system for the stakeholders listed in Table 1;
- User access management system to enable MS and sponsors to create and log on with their credentials (username and password), administer their own user group, assign roles, enable electronic signatures etc.;
- A secure document management system of clinical trial information to facilitate the capture, titling, retrieval, maintenance and disposal of records of clinical trial information (data and documents);
- A management platform/dashboard for the users, to be accessed and/or configured by authorised users only and with a workflow control tool to track activities (submissions, notifications, validations/assessment activities etc.) and the timelines required in the legislation including the possibility to shorten the timelines but also whenever required as per the assessment procedure extend the timelines within the limits set by the Regulation;
- A publication module/system to make publicly available clinical trial information allowing search and download functionalities.

In accordance with the legal requirements as set out in Article 81 of the Clinical Trials Regulation, the current functionalities need to be maintained, adapted or further developed where necessary to adequately support the EU clinical trial activities and processes of the Agency and the EU Regulatory Network.

5. Functional specifications

The functional specifications of the EU portal and the EU database and associated workspace are outlined below and are considered necessary to enable the EU portal and the EU database to be fully functional.

In accordance with the Regulation, the EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the grounds outlined in Article 81(4). Therefore the functional specifications and underlying principles to support the transparency requirements of the CT Regulation will be included as an addition to this document entitled “Functional Specification of the EU Portal and EU database to be audited”. This addition will be made by adding one or more paragraphs to this section 5 of the text and by adding the necessary functional specifications to section 4.3 of Table 2, which addresses the publication of clinical trial information from the EU database. This additional text and additions to Table 2 will become integral parts of the Functional Specifications and will not change the existing text in this document. This additional text and table section will be agreed via the same bodies as the current Functional Specification document, that is to say review and agreement within the clinical trials information system expert group in collaboration with the Member States and the European Commission, a short public consultation, then consultation of the European Commission and the Member States on the final document and endorsement of the EMA Management Board followed by sign-off by the EMA Executive Director and publication. This process will need to be completed at the latest by March 2015.

In addition to the functionalities outlined in this document, system performance, scalability and security are to be audited taking into account the need to support multiple users and an increase in volume of data over time.

Additional requirements to be made available in the workspace but outside of the scope of the functional specifications and audit as described in Article 82 are provided in Annex 1 for information.

133 Table 2- Functional Specifications

134

1- General Functional Specifications					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
1.1	User registration and authentication	Y	Y	Allows users to register and to log on to access to the EU portal and EU database. The system will limit access and rights to authorised users only. Allow authorised users to log on with their credentials to access the systems according to their user's role(s) (user rights and access). The users of the EU portal will have access to workspace functionalities according to their user's role(s), so the system will display the appropriate data, as well as, to make available the appropriate activities to be executed according to their user's role(s) in the system. Enable the identification of a super user for each trial at the sponsor level and for each MS. Enable the sponsor super user for a given clinical trial to be linked to the sponsor details (name and address) provided at the time of trial submission and to any subsequent update of the sponsor information. Enable the trial number to be linked to the sponsor details (name and address) provided at the time of trial submission and to any subsequent update of the sponsor information.	Req. 1 to 17 and 19

1- General Functional Specifications					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
				Allow single logging for MS users (according to their roles) through the EU portal for accessing the clinical trial workspace, the EudraVigilance database, the medicinal product dictionary and the data ware house of the EU portal and EU database.	
1.2	Security control and levels	Y	Y	EMA to assign and administer super users for the regulatory network, according to the member state requirements, and the Commission. Enable the automated assignment of the sponsor super user when creating the trial in their dashboard. Enable all super users to administer and manage their group of users and assign roles/work packages to users either per trial or per group of trials including all trials they administer if necessary. The assignment may be done by assigning several roles/work packages to a user. Enable the sponsor super user to update the sponsor information during the life cycle of the trial (e.g. address, contact details) and ensure traceability at all time.	Req. 1 to 17 and 19
1.3	Audit record	Y	Y	The requirement to create Clinical Trial audit records is to record the activities that were performed during the lifecycle of a CT from application to end of reporting. The system use	Req.1 to 17 and 19

1- General Functional Specifications					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
				cases should indicate the point at which the audit records are created.	
1.4	System performance and scalability	Y	Y	Performance and scalability to be defined during the preparation of the detailed requirements.	Req. 1 to 19

135

2- EU PORTAL					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
2.1	Support the recording and submission to the Medicinal Product Dictionary, contained in the Eudravigilance database, of all the data on medicinal products without a marketing authorisation in the Union and substances not authorised as part of a medicinal product in the Union, that are necessary for the maintenance of that dictionary	Y	N	Sponsor to be able to submit information related to a new IMP and a new substance through the EU Portal and obtain a provisional EU MP number and a provisional substance code until the final EU MP number or substance code can be granted. The request for an EU MP number should be linked to a specific EU CT number and to the submission of the IMPD Quality part. For an IMP with a marketing authorisation, for the preparation of the clinical trial dossier, the sponsor should refer to the product and active substance numbers recorded in the medicinal product dictionary. The EU MP number for product in development and the product number for marketed product to be used to link clinical trials and medicinal products.	Req. 2
2.2	Submission of documents/data	Y	Y	Allow submission by sponsors (e.g. CT Dossier, notifications) or by MSC (e.g. decision on which MSC is RMS, final assessment report Part I and/or Part II, validation outcome etc.) of validated packages/documents/data, as applicable, that comply with the validation rules. An overview of all the information submitted through the portal is provided in annex 2.	Req. 1 to 17

2- EU PORTAL					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
				Acknowledge receipt of submitted packages/documents/data as applicable.	
2.3	Communication between sponsor and Member States	Y	Y	MSC to put request for information to the sponsors and for the sponsor to communicate back to the MSC in relation to these requests. Allow MS to notify to sponsor the outcome of decision. Allow MSC to request correction to an application dossier and for the sponsor to communicate back to the MSC in relation to these requests. Allow MS super user to request the deletion/withdrawal of an application/notification & provide a reason (e.g. duplicate). Allow such request to put the assessment on hold if applicable.	Req. 4 and 12;
2.4	Withdrawal of an application	Y	N	Allow the sponsor to withdraw an application at any time until the reporting time and to submit reason for withdrawal.	Req. 3 to 4
2.5	Planning and reporting on MS inspection	N	Y	Allow MS to notify inspection dates (planned and conducted) to the EU database through the EU portal in relation to one or several clinical trials performed in its territory or in a third country.	Req. 15

2- EU PORTAL					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
				Allow MS to report on inspection findings to the EU database through the EU portal. Allow for validation of the structured data field before submission to the EU database. Allow for the submission of inspection report to the EU database.	
2.6	Portal interface	Y	Y	The portal interface should have the capacity to incorporate multiple languages whereas the strict user interface of the EU database should be in all the official languages.	Req. 18
2.7	Dependencies on other systems	Y	Y	To avoid duplication of entry, the portal will allow for data stored in other systems to be readily available for selection in the portal. This feature applies to user access management tools and master data (e.g. substances, products, organizations, referential, other master data` source) to be made available in the portal. Enable the transition from using current Master data system (e.g. EUTCT) to future master data management (e.g. Substance and Product management systems, organisation management system and referential management system). Enable the request and entry of new Master data terms.	Req. 1 to 19

2- EU PORTAL					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
				To be able to use Master data in such a way that it can be linked to future versions of those terms.	

137

3- Workspace					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
3.1	Dashboard	Y	Y	Have a dashboard to allow a friendly presentation and enable the tracking of the flows in relation to the processes that the users monitor. Have the features to enable the functional specifications presented in this table (e.g. preparation of application and notification, e.g. submission) and according to the user's roles enable read, write and edit.	Req. 1 to 17
3.2	Preparation of documents/ data	Y	Y	Initial clinical trial application to be uniquely identified by a unique EU CT number. Each application to be assigned a sequence number in numeric order to maintain a chronological order of submission within the life cycle of a clinical trial. The EU CT number format should be: yyy-xxxxxx-zz. For those years where EudraCT and Portal are both operational the best	Req. 1 to 17

3- Workspace					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
				options proposed are as follow: Portal: yyyy-5xxxxx-zz EudraCT: yyyy-0xxxxx-zz Allow sponsors to prepare CT application form, dossier, notifications and update information as foreseen by the Regulation. Allow sponsors to prepare application dossier using a dossier builder including the upload feature for documents formats including PDF and commonly available document formats and documents consisting of structured data (e.g. XML for the EU CT form). The application dossier should be customised to the nature of the application (initial application, substantial submission, part 1 submission only) performed by the user. Allow MS to prepare their validation, assessment (e.g. assessment report) and decision tasks. This functionality is covered under the functionality described below “collaboration between Member States in the context of assessment and supervision of clinical trials”.	
3.3	Collaboration between Member States in the context of assessment and supervision of clinical trials	N	Y	The workflow is to be supported with communication features (structured and un-structured) essential for the operation of the EU portal and the EU database.	Req. 10 to 16

3- Workspace					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
				These features are to address the MSC collaboration in the event that more than one MS is concerned by the application and the features are to enable: (a) reporting Member State to manage the initial assessment phase (b) a coordinated review phase involving all Member States concerned (c) reporting Member State to manage the consolidation phase These features revolve around the assessment and would lead to: • determination of the RMS • generation and review of requests of additional information • preparation, review and consolidation of the assessment report including communicate disagreement with conclusion of part 1 • preparation, review and consolidation of assessment of clinical trial related information during the life cycle of a trial including sponsor responses • preparation of MSC decision The gathering of the detailed requirements will enable to identify the structure and unstructured data to be collected in the systems to enable the assessment and supervision of trials by member states.	
3.4	Communication between	Y	Y	Allow MSC to request additional information in relation to the	Req. 6 and 12

3- Workspace					
No	**Functional specification**	**Sponsor/ Applicant**	**MS/EC**	**Details**	**Link to the legal requirements presented in Table 1**
	sponsor and Member States			notifications made by the sponsors (articles 36, 37, 38, 42, 43, 44, 53, 54, 55, 77) or to address informal requests in those cases where the Regulation does not define a validation phase like in the case of articles 11 and 14.	
3.5	Assessment Report (AR) templates	N	Y	Make available AR template for the MS to prepare the assessment report for part I and part II	Req.12
3.6	Upload/Download	Y	Y	Allow users to upload or download different document format (e.g. pdf,). Allow users to upload or download data as an XML (or similar technology).	Req.2 to 17
3.7	Technical Validation of application before submission of documents/data	Y	Y	The system must perform certain validation checks, in order to ensure compliance with the system specifications. Validation checks to validate the correctness of specific fields or documents, number of documents attached to ensure completeness (e.g. of the application dossier) or prior to confirm the submission to the EU database. Users to be able to validate their application package at any time during the course of the dossier preparation and receive feedback on the validation errors.	Req.1 to 17
3.8	Workflow Control	Y	Y	Automated tracking and alerting functionalities for the user to	Req.1 to 16

3- Workspace					
No	**Functional specification**	**Sponsor/ Applicant**	**MS/EC**	**Details**	**Link to the legal requirements presented in Table 1**
				assist the assessment procedure: -The system should be able to predict the timelines based on the MSC calendar solution adopted for the application which will include an informally agreed clock stop[2] between 23rd December to 7th January (for multinational CT only) and the reference time zone adopted for the system (the CET). The calendar solution will consider the requirements of Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971. - The system should be able to track the timelines based on the MSC calendar solution adopted. - The system should be able to track activities (submissions, notifications, validations/assessment activities etc.) and inform users that a new pending task has arrived or a deadline is coming. -Alerts with direct link to the task (e.g. additional request for information). -User should also be able to reassign/redirect tasks if they cannot handle them (people on leave for instance).	

[2] The clock stop, even if does not have a legal basis in the Regulation and therefore cannot be legally enforced, is based on the informal agreement between the users of the Portal comparable to the solutions adopted now in the VHP.

3- Workspace					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
				- Allow for user to enter information structured and unstructured data in the UI through the workflow and in relation to the pending task - MS user (super user) to be able to extend or shorten the deadlines within limits set by the Regulation. - MS user (super user) to have the administrative right to delete or update MS information submitted and to enter a reason. - Allow MS user (super user) to revert a decision & to provide reason (e.g. appeal).	
3.9	Reporting features	Y	Y	Possibility to create reports for the users to monitor the processes governed by the workflow.	Req.1 to 17
3.10	Search functionalities	Y	Y	The system should allow the users to search and filter specific topics based on basic search criteria (e.g. CT EU number, product number, product name, MSC…). Authorised users should be able to query the system from their workspace by use of metadata based on fields present in the information stored in the EU database and be able to retrieve the information requested.	Req.1 to 17

3- Workspace					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
3.11	Training and help for users	Y	Y	Allow for online help and tooltips to be made available to the users to assist in the use of the system features, understand the navigation and explain the user interface.	Req.1 to 17
3.12	Dependencies on other systems	Y	Y	Link to the master data as defined in the EU Portal functional specification 2.7 to be made available in the workspace.	Req. 1 to 17
3.13	Workspace database	Y	Y	The workspace database should enable the storage and retrieval of documents and data as being saved in the workspace. The document and data store should allow: • Metadata elements associated with all documents and data to be captured. • Support multiple aggregations without duplication. • Every record and associated aggregation must have a unique identifier persistently linked to it. This allows to the user to locate records and helps them to distinguish between versions. • Establish a classification scheme that can facilitate the capture, titling, retrieval, maintenance and disposal of records by defining the way in which individual electronic records are grouped together (aggregated). • Records may be altered or deleted by system administrators.	Req. 1 to 17

4- EU DATABASE			
No	**Functional specification**	**Details**	**Link to the legal requirements presented in Table 1**
4.1	Document store and database	The EU database should enable the storage and retrieval of documents and data specified by the legislation as being saved in the EU database. The document and data store should allow: • Metadata elements associated with all documents and data to be captured. • Support multiple aggregations without duplication. • Every record and associated aggregation must have a unique identifier persistently linked to it. This allows to the user to locate records and helps them to distinguish between versions. • Establish a classification scheme that can facilitate the capture, titling, retrieval, maintenance and disposal of records by defining the way in which individual electronic records are grouped together (aggregated). • Records may be altered or deleted by system administrators.	Req. 1 to 17
4.2	Document and data retention	Retention period to be unlimited.	Req. 1-17
4.3	Publication of CT data and information	The clinical trial data and information is to be made publicly available through a publication module according to detailed rules to be defined. The rules are to be automated and implemented through the publication module taking into consideration the workflow of the trial.	Req. 18
4.4	Search functionality	The public user interface to allow querying the clinical trial information by use of metadata based on fields present in the application dossier, MSC notification and decision and to have download functionalities.	Req. 18

3- Workspace					
No	**Functional specification**	**Sponsor / Applicant**	**MS / EC**	**Details**	**Link to the legal requirements presented in Table 1**
4.5	Presentation of the information	Allow related information to be grouped together by way of the EU trial number with links or display of data and document of relevance.			Req. 18
4.6	Download option	The public user interface to enable the download of document and data as XML and other document format (e.g. pdf, word, excel etc).			Req. 18
4.7	Public interface	The public interface to support all Union official languages.			Req.18
4.8	Help and training features	Allow for online help and tooltips to be made available to the public to assist in the understanding of the information published.			Req.18
4.9	Dependencies with other systems	The data terms in the EU database to use the master data list. Enable the transitions from using current Master data system (e.g. EUTCT) to future Master data management (e.g. Substance and Product management systems, organisation management system and referential management system). To be able to use master data in such a way that it can be linked to future versions of those terms.			Req. 1 to 17

138

Annex 1: Additional requirements to be made available in the workspace (not to be audited)

The following additional requirements are identified which are not part of the functional specifications to be audited as set out in the Article 82. Taking into account the provisions set out in Article 82 of Regulation (EU) No 536/2014, the functionalities to be audited are those outlined in section 5.

The following additional key functionalities were requested to be included in the EU clinical trial systems. The detailed requirements will be collected for these features:

1. Allowing communication features to be made available to MS for general discussion related to clinical trials and not related to a unique trial.
2. Automated two-way exchange of documents and related data held in the EU portal/EU database between National Competent Authorities (NCAs) systems and the EU portal/EU database to reduce administrative burden for NCAs.
3. Additional reporting capabilities linking the clinical trial systems allowing a full range of statistics reports (per year, per month, per user, per MS, etc.).
4. Without prejudice to the legal role and responsibilities of the RMS, an execution of that role may be delegated to another MSC.
5. Option to initiate ad hoc-workflow/case management for the assessment of clinical trial related notifications, safety information or other issues.

These additional functionalities, beyond those to be audited, are to be provided in future post-audit releases of the EU portal for which further business requirements will be developed with Member States in consultation with the Commission.

Based on the initial implementation experience, an iterative approach will be followed allowing for improvement of functionalities if necessary.

Annex 2: Submission through the EU portal to the EU database