ICTRP Registry Profile

EU Clinical Trials Register (EU-CTR)

Basic Information

I. Name of person completing this form	**Francesca Scotti**
II. Role of the person completing this form (that is, the role of this person in the registry making this application)	**EMA Business representative of EudraCT database**
III. Date this form was completed	___27___ / ___01___ / _____2023___ *dd* *mm* *yyyy*
IV. Signature of person completing this form	
V. Official Name of Registry *(list abbreviation used, if relevant)* Eg Australian and New Zealand Clinical Trials Registry (ANZCTR)	**EU Clinical Trials Register (EU-CTR)**
VI. Registry postal address	**European Medicines Agency** **Domenico Scarlattilaan 6** **1083 HS Amsterdam** **The Netherlands**
VII. Registry street address (if different to postal address)	
VIII. Registry URL *(Registry's web site address)*	**https://www.clinicaltrialsregister.eu/**
IX. Registration URL *(Web site where users go to register a trial)*	**https://eudract.ema.europa.eu/** **This is where Clinical Trial Application (CTA) form is completed prior to submission to National Competent Authorities (NCAs) who load the data from the CTA form XML into EudraCT and from where it is automatically loaded to EU-CTR**
X. Application type	Application for Primary Registry status ☒ Application for Partner Registry status ☐ The original application was submitted in 2011, we are currently updating the information submitted
XI. What is the name of the agency (or agencies) that funds the registry?	**European Medicines Agency**
XII. What is the name of the agency that manages the registry?	**European Medicines Agency**

XIII.	

XIV.	Does the registry have an Advisory Board? *	Yes ☒ No ☐
XV.	If the registry has an Advisory Board, please describe its terms of reference, which organizations are represented on the Board, and how often it meets. If necessary, please attach this information to the application as a separate document.	***EMA – information provided by Fergus Sweeney in 2011 when applying for a primary registry status:*** The EU-CTR is overseen by the EudraCT TIG (Telematics Implementation Group) which reports to the EMA Management Board Telematics Steering Committee. The EudraCT TIG is composed of representatives from each EU Member State NCA (references to EU in this document include EEA member states also). The TIG in addition has a Joint Operational Group (JOG) made of the TIG membership plus representative of Health Care Professional, Patients Representatives and Stakeholders from the Industry. The TIG is chaired by EMA (Fergus Sweeney). There is also a Project Board composed of EMA business and IT representatives and a representative of the NCAs. **EudraCT TIG Mandate is attached.** Please note: the above information is not up-to-date, however I understand that it was requested solely at the time of application and it will not be published.
XVI.	Is registration of a clinical trial a legal requirement in the country (or countries) covered by the registry? * **If yes**, please provide the title of the relevant law and information on how a copy of the law can be obtained (including the relevant web address)	Yes ☒ No ☐ ***EMA:*** EU-CTR displays to the general public information on clinical trials as they are contained in the EudraCT database created in accordance with Art 11 of Directive 2001/20/EC. Member States in the EU load in EudraCT database clinical trial applications for clinical trials to be started in their territories, and add data on their authorisation, conduct and completion. Art 57 (2) of Regulation No (EC) 726/2004 and Art 41 of Regulation No (EC) 1901/2006 require that data on clinical trials contained in EudraCT should be made available to the general public, in accordance with guidelines published by the European Commission.
XVII.	Is registration of a clinical trial a requirement to obtain ethics approval in the country (or countries) covered by the registry? * **If yes**, please provide the title of the relevant document	Yes ☐ No ☒ ***EMA:*** Not per se' but Ethics Committee approval is required by the same legislation which requires registration of clinical trials in EudraCT. Trials can only appear in EU-CTR once they have been reviewed by an Ethics Committee. As defined by Art 9 of Directive 2001/20/EC a

	describing this requirement and information on how this document can be obtained (including the relevant web address)	clinical trial cannot be started in any Member State in the EU until the Ethics Committee has issued a favourable opinion and the National Competent Authority of the Member State concerned has not informed the sponsor of any grounds for non-acceptance. Clinical Trial Applications are submitted by the sponsors to both bodies and the NCAs are responsible for loading the submitted CTA in EudraCT database and entering the Ethics Committee opinion and their own NCA decision. The information will then appear in EU-CTR.
XVIII.	Is the registry currently accepting clinical trials for registration?	Yes ☒ No ☐

XIX. How many trials are on your database?

On __27___/_01____/_2023____ there were ____over 68000 trials recorded, of which 43206_____are publicly available on the registry database.

Note: The ICTRP cannot consider a registry for Primary Registry status until it contains at least 10 trials submitted directly by Responsible Registrants. It is not acceptable for a registry to only include trial information that has been downloaded and imported from another registry.

XX.	Does the registry agree in principle to comply with the International Standards for Clinical Trial Registries?	Yes ☒ No ☐

1. Content

1.1. The Registry will accept prospective registration of interventional clinical trials submitted by Responsible Registrants

1.1.1. Does the Registry register trials before the first participant has been recruited?	Yes ☒ No ☐
a) Does the Registry query submissions where registration is being sought after the first participant has been recruited? ***EMA:*** All trials have to be submitted to the National Competent Authority and loaded into EudraCT before they are authorised, so this query is not applicable. EMA queries late entries by NCAs.	Yes ☒ No ☐
b) Does the Registry make it clear to Responsible Registrants that prospective registration means that a trial must complete the registration process, **and** have a trial registration number issued, **before** the recruitment of the first participant.	Yes ☒ No ☐
1.1.2. Does the Registry register trials that have already recruited the first participant? (Also referred to as retrospective registration). ***EMA:*** This occurred in the early days of EudraCT as Member States were implementing legislation.	Yes ☒ No ☐
1.1.3. Does the Registry register other types of studies, including observational studies	Yes ☐ No ☒
1.1.4. Does the Registry register all trials submitted by Responsible Registrants. ***EMA:*** The Clinical Trials appearing in the EU-CTR are those that meet the publication criteria as required by the EC Regulations.	Yes ☒ No ☐
a) Does the Registry accept trials submitted by Responsible Registrants? ***EMA:*** See above.	Yes ☒ No ☐
b) Does the Registry ask the person submitting a trial for registration to verify that they meet the terms and conditions for being a Responsible Registrant before being able to proceed to trial registration.	Yes ☒ No ☐
c) Does the Registry use the contact details provided by the Responsible Registrant to verify that those details are correct?	Yes ☒ No ☐
d) As a minimum, Registries must send an email to the address given and receive a reply from that same address. When possible, the telephone number and/or surface mail address will also be verified in a similar fashion. ***EMA:*** This is checked by NCAs who are in contact with the sponsor when authorizing the trial.	Yes ☒ No ☐
e) Does the Registry ensure that all Responsible Registrants are associated with an institution or organization? ***EMA:*** This happens via NCAs who authorize the trials.	Yes ☒ No ☐

f) Does the Registry obtain institutional contact details for the Responsible Registrant, including name and telephone number of the institution?	Yes ☒ No ☐
1.1.5. Does the Registry accept studies for registration when the data is submitted as an electronic data file (eg as an xml file) Note: This is not a requirement and is being asked for information only.	Yes ☒ No ☐

1.2. The registry will be open to all prospective registrants (either internationally or within one or more specific countries) *(ICMJE requirement)*

a) Which type of study does the Registry accept for registration? ☒ Interventional studies ☐ Observational studies
b) If registration is restricted in some way (eg only accepts trials from a particular sponsor, or in a particular health care condition (eg cancer) or intervention) please specify how it is restricted: ***EMA***: Registration is not limited to any particular kind of trial but it only applies to interventional trials on investigational medicinal products.
c) From which countries does the Registry accept trials for registration: ***EMA:*** All interventional clinical studies conducted with at least 1 centre in the EU/EEA or conducted completely outside of the EU/EEA if they form part of an agreed Paediatric Investigation Plan, or they are under Article 45 and 46 of Regulation (EC) No 1901/2006 (starting from 10th March 2011) are registered in EU-CTR.

1.3. The Registry will be able to collect and publicly display the WHO Trial Registration Data Set (TRDS) *(ICMJE requirement)*.

a) Does the Registry collect and display, on a publicly accessible web site, all of the items in the WHO Trial Registration Data Set	Yes ☒ No ☐
b) Does the Registry have quality control procedures in place to ensure all items in the TRDS contain meaningful data?	Yes ☒ No ☐
c) Does the Registry collect the optional TRDS data items? If yes, please specify: ***EMA*** : Approval	Yes ☒ No ☐

1.4. The Registry will make an effort to keep registered information up-to-date.

a) Does the Registry permit Responsible Registrants to update information about their trial?	Yes ☒ No ☐
b) Does the Registry have a reminder system to facilitate the submission of updated information by the Responsible Registrants. If yes, please state how often the Registry reminds Responsible Registrants to update their data (eg once ever 6 months; once every year): ***EMA:*** Applicants are required by law to submit substantial amendments and end of trial notices. NCAs are reminded by EMA to complete information – we run data quality checks and these are being increased now that we have data warehouse. Note: This is not a requirement and is being asked for information only.	Yes ☒ No ☐
c) Does the Registry display the date the trial record was last updated? ***EMA:*** Not at the moment but it will be implemented. We are going to add this data as part of a release in the next future.	Yes ☐ No ☒

Note: This is not a requirement and is being asked for information only.	
d) Does the Registry request updates from Responsible Registrants at least annually until the Registrant has recorded meaningful information about the publication of the trial results (e.g. has listed a citation in a "Publications" field). ***EMA:*** Applicants are required by law to submit substantial amendments and end of trial notices. NCAs are reminded by EMA to complete information – we run data quality checks also through the use of an internal data warehouse. They will be reminded about results once we have enabled these to appear in the Register. Note: This is not a requirement and is being asked for information only.	Yes ☐ No ☒

1.5. The Registry will never remove a trial once it has been registered.

a) Does the Registry ever delete a trial record from their database once a registration number has been issued? If yes, please explain the circumstances under which a record would be deleted: ***EMA:*** There is the technical possibility to remove records from the EU-CTR but it applies only under exceptional circumstances due to excessively misleading or fraudulent information, and even in those cases the information may remain public but with warnings attached. The only other case would be in the rare event that a duplicate record entered the system (highly unlikely).	Yes ☐ No ☒
b) Does the Registry inform Responsible Registrants at the time of registration that a trial cannot be deleted once it has been registered? ***EMA:*** We will put a notice on the website about this.	Yes ☒ No ☐
c) Does the Registry have clear and transparent processes for dealing with requests to remove a trial record from public view, and have these processes been documented in the SOPs? ***EMA:*** We do not remove records – but there is in the new results guidance some information on this. We have a clear process and will document this.	Yes ☒ No ☐

2. Quality and Validity

2.1. The Registry will have processes in place to make sure that registered data is complete and accurate.

a) Does Registry staff routinely check all data submitted about a trial for completeness and meaningfulness to ensure that all TRDS fields are populated and comply with the minimum standards? ***EMA:*** This process takes place especially at National level when the NCAs perform the review of the CTA application.	Yes ☒ No ☐
b) If one or more items in the TRDS submitted for registration are incomplete or not meaningful, does Registry staff contact the	Yes No

Responsible Registrant and attempt to obtain complete and meaningful data. ***EMA:*** Same as above	☒ ☐
c) Does the Registry's database system apply automated checking procedures (e.g. range checks, logic rules) to data items to facilitate validity checking. ***EMA:*** Business rules apply when fulfilling the CTA and when loading to EudraCT, plus applicants have to submit validation report to NCAs and justify any deviations.	Yes ☒ No ☐
a) Does the Registry have processes in place for deciding whether to register trials where the Responsible Registrant remains non-compliant with requests to provide complete and meaningful data? ***EMA:*** Sponsors have to submit a valid application to NCAs in order to get a trial authorized.	Yes ☒ No ☐
b) Does the Registry undertake regular internal quality control audits to assess the level of completeness and accuracy of the data collected?	Yes ☒ No ☐

2.2. The Registry will have documented Standard Operating Procedures (SOPs). These SOPs will be aligned with the International Standards for Clinical Trial Registries.

a) Registries must have written standards for all procedures and processes employed by the registry. These are known as Standard Operating Procedures (SOPs).	Yes ☒ No ☐
b) Does the Registry use these SOPs to train all staff processing trial registrations to ensure that common standards for ensuring data completeness and meaningfulness are adhered to.	Yes ☒ No ☐
c) Are the internal registry-specific SOPs aligned with the WHO International Clinical Trial Registry Platform International Standards for Clinical Trial Registration? ***EMA:*** These take the form of commission guidance, on line help and use cases.	Yes ☒ No ☐

2.3. The Registry will have processes in place to make sure that people and trials exist

2.3.1. Does the Registry make sure that the person registering the trial exists and that they are the appropriate Responsible Registrant? ***EMA:*** This is a legal process via the clinical trial application to the NCAs.	Yes ☒ No ☐
2.3.2. Does the Registry make sure that the trial exists? If yes, please briefly describe what the registry does to make sure that the trial exists. This is a legal process as it is controlled by the Clinical Trial Application and authorisation legislation. ***EMA:*** The EU-CTR displays information based on official applications provided by the sponsors to the relevant NCAs and IECs when requesting authorization on starting a clinical trial in their territory. Status of the trial is updated by the sponsor and information provided the NCAs that update the EudraCT database.	Yes ☒ No ☐
a) Does the Registry obtain written third-party confirmation that a trial exists? If yes, please specify the method of confirmation: See answer above, the "third party" is the National Competent Authority	Yes ☒ No ☐
b) Does the Registry display in the trial record: a. if the registry has obtained written third party confirmation of the trial's existence, and b. the name of the third party from whom confirmation was received (eg the name of the ethics committee) It is stated which authority has authorized the trial.	Yes ☒ No ☐

2.4. The Registry will have a publicly accessible audit trail so that changes made to the WHO TRDS for an individual trial can be tracked.

a) Does the Registry allow Responsible Registrants to update their registered trial records? ***EMA:*** Via legally required substantial amendment and end of trial notification to the NCAs.	Yes ☒ No ☐
b) Does the Registry make available a publicly accessible audit trail of any changes to any TRDS items?	Yes ☒ No ☐
c) Does the have quality control procedures in place to ensure any updated information continues to fulfil the standards for each TRDS item.	Yes ☒ No ☐
d) Does the Registry use the most up-to-date information as the default display?	Yes ☒ No ☐
e) Can the TRDS, as originally registered, be accessed at all times? ***EMA:*** All versions are recorded in EudraCT and visible to NCAs	Yes ☒ No ☐

2.5. The Registry agrees to comply with the International Standards for Clinical Trial Registries (ISCTR).

a) Does the Registry Administrator have a thorough working knowledge of the operational aspects of their registry.	Yes No

	☒ ☐
b) Is the Registry Administrator committed to ensuring that all Registry staff are familiar with the standards described in the ISCTR?	Yes ☒ No ☐
c) Are all Registry staff familiar with the contents of the ISCTR?	Yes ☒ No ☐

3. Accessibility

3.1. The Registry will make the WHO TRDS for all registered trials accessible to the public at no charge *(ICMJE requirement)*.

a) Does the Registry make the WHO TRDS items for all studies in their register (i.e. the registry database) accessible online at no charge to the end user?	Yes ☒ No ☐

3.2. The Registry will make it possible for the WHO TRDS for all registered trials to be searched electronically *(ICMJE requirement)*.

a) Is it possible to search the Registry online using electronic searches of text words and phrases via a simple, single search box?	Yes ☒ No ☐
b) Does the online search allow users to search in at least the condition field and the intervention field?	Yes ☒ No ☐
c) When the results of a trial identified by a search are displayed, are all items in the WHO TRDS visible?	Yes ☒ No ☐
d) Does the online search have an advanced search option? Note: This is not a requirement and is being asked for information only.	Yes ☒ No ☐

3.3. The Registry will allow Responsible Registrants to submit a trial for registration at any time of day on any day of the week (24 hours a day, seven days a week).

a) Is it possible to submit a trial to the registry 24 hours a day, seven (7) days a week? ***EMA:*** EudraCT is available 24/7 for completion of CTA information by sponsors and for its upload by NCAs. EU CTR checks EudraCT at least every 30 minutes for updates. Data are first submitted by the sponsors to the NCAs and then by the NCAs loaded in EudraCT during the normal working days, but the system per se is constantly available.	Yes ☒ No ☐
b) If the Registry is planning downtime, does it publish advance notice of downtime at least one (1) week beforehand?	Yes ☒ No ☐

3.4. The Registry will allow their register database to be searched at any time of day on any day of the week (24 hours a day, seven days a week).

a) Is it possible to search the register online 24 hours a day, 7 days a week?	Yes ☒ No ☐

3.5. It is desirable that Registries in the WHO Registry Network also make the WHO TRDS available in the language(s) of the country or countries served by the registry.

a) Does the Registry accept and/or display trial information in languages others than English? If yes, please specify the languages used: ***EMA:*** Information is displayed in the EU-CTR in the language in which the data are loaded in EudraCT database. EU sponsors and citizens have the right to use an EU Official language. It means that for single country clinical trials the information can appear on the official language of that country where the application is submitted and the trial conducted and it might not always have been in English. As of 10th March 2011 and launch of EudraCT v8.0 all free text fields can be entered first in English and then in any additional languages and each language entry is in a separate added field, labelled with the name of the language, but part of the same registration file for each country.	Yes ☒ No ☐
Only answer the remaining questions in this section if the answer to the above question is *yes*.	
b) Does the Registry have quality control procedures in place to ensure that all translations are accurate? ***EMA:*** This is controlled by NCAs at CTA review stage.	Yes ☐ No ☒
c) Are all TRDS items for all records also available in English? ***EMA:*** In general yes and for future see 3.5 above.	Yes ☒ No ☐
d) Are all trial records translated into English by the Responsible Registrant checked by registry staff against the non-English submission before being accepted for registration? ***EMA:*** By NCAs when applicable.	Yes ☒ No ☐
e) Are all trial records translated by Registry staff checked by at least one other staff member? Not applicable	Yes ☐ No ☒
f) If there is a discrepancy in a translation, is the translation checked by a third person? Not applicable it would be queried by NCA with sponsor.	Yes ☐ No ☒
g) Does the Registry make users of the Registry aware of who performed the translation (the Responsible Registrant or Registry staff) of a registered record. Not applicable	Yes ☐ No ☒
h) If a trial is registered in more than one language then will the Registry submit the "Scientific Title", and a language identifier, to the ICTRP Search Portal for each language used?	Yes ☒ No ☐

4. Unambiguous Identification

4.1. The Registry will have in place processes to prevent the registration of a single trial more than once on their database.

a) Does the Registry make sure that a trial that has been submitted for registration is not already been included in their register by first searching and checking their own database? Not applicable, as a trial is only registered once per Member State due to clinical trial authorization process.	Yes ☐ No ☒
b) Does the Registry have policies and procedures in place to deal with inadvertent duplicate registration of the same trial within their own register? It would not happen see a above.	Yes ☒ No ☐

4.2 The Registry will facilitate the retrospective linking (or bridging) on the WHO Search Portal of a single trial registered with more than one registry by entering secondary identifiers. This includes the UTN, and the unique identifiers allocated by other registries in the WHO Registry Network.

a) Does the Registry require responsible Registrants to make an entry in the *Secondary Identifiers* field? ***EMA:*** Sponsors are reminded to do so but it is not possible to check at present. We will in future seek to index against other public information. In particular, we will add a default entry of information not available.	Yes ☒ No ☐
b) If there are no known secondary identifiers, does the Registry require Responsible Registrants to enter 'Nil known' in the *Secondary Identifiers* field? ***EMA:*** We can if this is required, not at present.	Yes ☐ No ☒
c) Does the Registry require Responsible Registrants to enter a UTN? Note: This is not a requirement and is being asked for information only.	Yes ☐ No ☒

4.3. It is desirable that Primary Registries will search the ICTRP Search Portal and attempt to determine if the trial has already been registered by another Primary Registry in the WHO Registry Network or an ICMJE approved registry.

a) Does the Registry attempt to determine whether a submitted trial has been registered in another Primary Registry or an ICMJE approved registry before registration? Note: This is not a requirement and is being asked for information only.	Yes ☐ No ☒

5. Technical Capacity

5.1. The Registry will submit the WHO TRDS for all records on their register, in English, to the WHO ICTRP Central Repository.

a) Will the Registry submit the WHO TRDS items for **all records** on their register, in English, to the WHO ICTRP Central Repository? ○ **Note**: If a registry accepts study types other than interventional trials (i.e. observational studies) these must be provided as well. ***EMA:*** All public items in EU CTR go to WHO ICTRP.	Yes ☒ No ☐
b) Will the Registry submit records in the format requested by the WHO ICTRP (e.g. xml file) at least once per month?	Yes ☒ No ☐
c) Will the Registry, after the initial data transfer of all records, only submit new or updated records each time (rather than the entire data set every time). ***EMA:*** Copy of the data takes place as required by the WHO ICTRP.	Yes ☒ No ☐

5.2. The Registry will have access to a database that is used to store and manage the submitted data.

a) Does the Registry use database software and hardware that guarantees reliable access to registered data and data safety at all times?	Yes ☒ No ☐

5.3. The Registry will have access to adequate information technology support.

a) Does the Registry have access to reliable information technology support?	Yes ☒ No ☐
b) Does the Registry have access to all of the following? a. reliable application, database, backup and mail servers b. good internet connectivity speed c. sound operating systems d. appropriate software for servers, desktops and laptops e. database and web development and maintenance personnel f. other skilled information technology personnel to support these systems, as required	Yes ☒ No ☐

c) Please briefly describe the Registry's information technology infrastructure. (A separate document may be submitted separately if necessary)

EMA: The EudraCT database and the EU-CTR are hosted and managed by the European Medicines Agency, a decentralised Agency of the European Union, located in Amsterdam. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. Role of the Agency has been first described in the Regulation (EEC) No 2309/93 replaced by Regulation (EC) 726/2004. The EMA has an advanced and powerful infrastructure and a large / strong ICT department committed in long term to deliver and maintain large amounts of ICT projects. Its technologies are based on the latest industry standards (multi-tier web applications backed by robust databases and running on robust middleware servers) and its ICT processes are strictly controlled and properly managed. Back up procedures on-side and off-side and tools are in place for the full data set managed at the Agency. Finally, since both the Agency itself and the EU-CTR are established by European Union legislation their long term availability is guaranteed.

5.4. The Registry will have adequate security and other provisions against data corruption and loss.

a) Does the Registry have documented procedures for ensuring adequate data security and other provisions to prevent data corruption and loss.	Yes ☒ No ☐
b) Does the Registry issue alerts in advance of website downtime? If yes, please briefly describe how these alerts are circulated and who is responsible for circulating them.	Yes ☒ No ☐

6. Administration and Governance

6.1. The Registry will have at least a national remit, and the support of government within the country (or region) to act as the Primary Registry for that country or region (defined as a group of countries and not a group of states within a country).

a) Does the Registry have at least a national remit? ***EMA:*** It is based on Art 11 Directive 2001/20/EC, Art 57(2) of Regulation (EC) No. 726/2004 and Art 41 of Regulation (EC) No.1901/2006.	Yes ☒ No ☐
b) Does the Registry have a letter of support, or other appropriate documentation, from the Ministry of Health or other relevant national or regional agencies? Note: The letters of support must be submitted to the ICTRP Secretariat as part of the application	Yes ☒ No ☐
c) From which country (or countries) does the Registry have the remit to act as the national (or regional) clinical trial registry? ***EMA:*** As described by law from all the EU Member States – so all EU Member States.	
d) Please specify the name of the national agencies that have given their support to the Registry: ***EMA:*** All the 27 EU Member States and 3 additional EEA Member States.	

6.2. The Registry will publicly disclose ownership, governance structure and not-for-profit status.

a) Is the Registry managed by a not-for-profit agency? It is managed by law by EMA which is a public EU body.	Yes ☒ No ☐
b) Does the Registry publicly disclose its ownership, governance structures and not-for-profit status in a prominent place on the registry's website? EMA is a public body	Yes ☒ No ☐
c) What is the web address for the page where the ownership, governance and not-for-profit information is displayed? www.ema.europa.eu	
d) Will the Registry inform the ICTRP immediately if their ownership, governance structures or not-for-profit status change in any way. It is not possible for this to change as it is set out in law.	Yes ☒ No ☐

6.3. The Registry agrees that, should it cease to function, at least the WHO TRDS (original and updated) for all trial records will be transferred to a Primary Registry in the WHO Registry Network.

a) Will the Registry transfer at least the WHO TRDS (original and updated) for all trial records to another Primary Registry in the WHO Registry Network if it ceases to function? It is not possible for this to happen as it is set out in law.	Yes ☒ No ☐

6.4. The Registry will have a strategy in place ensure the medium to long term sustainability of the registry

a) Does the Registry have a documented business plan?	Yes ☒ No ☐
b) Does the Registry's business plan include strategies to ensure its medium to long term sustainability?	Yes ☒ No ☐

7. The Trial Registration Data Set (TRDS)

7.1. The Registry will collect and publicly display all items in the WHO Trial Registration Data Set (TRDS)

	Item/Label	Does the registry collect this data item?	Does the registry publicly display this data item?
1	Primary Registry and Trial Identifying Number	Yes ☒ No ☐	Yes ☒ No ☐
2	Date of Registration in Primary Registry	Yes ☒ No ☐	Yes ☒ No ☐
3	Secondary Identifying Numbers	Yes ☒ No ☐	Yes ☒ No ☐
4	Source(s) of Monetary or Material Support	Yes ☒ No ☐	Yes ☒ No ☐
5	Primary Sponsor	Yes ☒ No ☐	Yes ☒ No ☐
6	Secondary Sponsor(s)	Yes ☒ No ☐	Yes ☒ No ☐
7	Contact for public queries	Yes ☒ No ☐	Yes ☒ No ☐
8	Contact for scientific queries ***EMA note***: Same contact is used in accordance with legal guidance of EU.	Yes ☒ No ☐	Yes ☒ No ☐
9	Public title	Yes ☒ No ☐	Yes ☒ No ☐
10	Scientific title	Yes ☒ No ☐	Yes ☒ No ☐
11	Countries of Recruitment	Yes ☒ No ☐	Yes ☒ No ☐
12	Health condition(s) or problem(s) studied	Yes ☒ No ☐	Yes ☒ No ☐
13	Interventions	Yes ☒ No ☐	Yes ☒ No ☐
14	Key Inclusion and Exclusion Criteria	Yes ☒ No ☐	Yes ☒ No ☐
15	Study type	Yes ☒ No ☐	Yes ☒ No ☐
16	Date of first enrolment ***EMA note***: Currently date of authorisation, i.e. from which point enrolment is permitted, enrolment per se will be added in v8.2	Yes ☐ No ☒	Yes ☐ No ☒
17	Sample size	Yes ☒ No ☐	Yes ☒ No ☐
18	Recruitment status ***EMA Note:*** Information on trial status (ongoing, completed, prematurely ended, transitioned) is available at the moment. Trials are “ongoing” from the date of	Yes ☐ No ☒	Yes ☐ No ☒

	Item/Label	Does the registry collect this data item?	Does the registry publicly display this data item?
	authorisation until the end of the trial (i.e. last patient last visit).		
19	Primary Outcome(s)	Yes ☒ No ☐	Yes ☒ No ☐
20	Key Secondary Outcome(s)	Yes ☒ No ☐	Yes ☒ No ☐
21	Ethics Review	Yes ☒ No ☐	Yes ☒ No ☐
22	Completion date	Yes ☒ No ☐	Yes ☒ No ☐
23	Summary Results	Yes ☒ No ☐	Yes ☒ No ☐
24	IPD sharing statement	Yes ☐ No ☒	Yes ☐ No ☒

7.2. The Registry may choose to collect and publicly display other data items. It is recommended that registries consider the following optional, additional data items:

	Item/Label	Does the registry collect this data item?	Does the registry publicly display this data item?
	Lay Summary / Synopsis ***EMA note***: Title for lay people is available at the moment, summary is not required, scientific information is favoured.	Yes ☐ No ☒	Yes ☐ No ☒
	Approvals	Yes ☒ No ☐	Yes ☒ No ☐
	Results links	Yes ☒ No ☐	Yes ☒ No ☐

	URL	Yes ☒ No ☐	Yes ☒ No ☐

8. Partner Registries

8.1. Primary Registries in the WHO Registry Network will have the capacity to partner with other Registries.

a) Is the Registry willing and able to form partnerships with other Registries that do not themselves fulfil the criteria for a Primary Registry in the WHO Registry Network? ***EMA***: It is not very clear what this really implies. As EudraCT has a legal framework and mandate it cannot simply start to accept data from other sources.	Yes ☐ No ☒
b) Does the Registry currently have any Partner Registries? If yes, please provide the name(s) of these partners: Not applicable, there are not partnerships in place at the moment.	Yes ☐ No ☐
c) If the registry has partners, are they listed on the proposed Primary Registry's web site? Not applicable If yes, please provide the address of this web page: Note: A completed Registry Profile form is required for all Partner Registries. This profile will be published on the ICTRP's web site.	Yes ☐ No ☐

8.2. Primary Registries in the WHO Registry Network will ensure that potential Partner Registries meet WHO minimum standards requirements.

a) Does the proposed Primary Registry agree that, before agreeing to accept a Partner Registry and their trial registration records, they will make sure that the Partner Registry meets all the WHO minimum standards listed in the International Standards for Clinical Trial Registries.	Yes ☒ No ☐
b) Has a Registry Profile form been completed and submitted for all of the Registry's Partner Registries? Not applicable	Yes ☐ No ☐

8.3. Primary Registries will have procedures in place to enable exchange of data with Partner Registries. Not applicable see above.

a) Is the Registry able to accept data (that is, as electronic data files) from Partner Registries or other appropriate data providers?	Yes ☐ No ☐
b) Does the Registry agree to establish a Memorandum Of Understanding (MOU) or other such agreement with each Partner Registry or other data providers, as per the requirement described in the International Standards for Clinical Trial Registries?	Yes ☐ No ☐
c) Does the Primary Registry agree the area of coverage/responsibility of their Partner Registries or other data providers (such as geographical location, health condition, intervention type, etc) and incorporate this into their SOPs and instructions to Registrants to avoid any confusion or unintentional duplicate registration?	Yes ☐ No ☐
d) Does the Primary Registry record the identification number and date of registration in the Partner Registry within the trial record on the Primary Registry?	Yes ☐ No ☐

e)	Does the Primary Registry identify records that have been sourced from Partner Registries or other data providers so users are aware of the data source?	Yes ☐ No ☐
f)	Before announcing Partner Registries, Primary Registries must have successfully imported data into the Primary Registry?	Yes ☐ No ☐

Contact Information

Administrator
The Administrator is the person employed to manage the Registry and will be the primary point of contact between the Registry and the ICTRP Secretariat.

Title *(Dr/Prof/Mr/Mrs/Ms/Miss)*	
Given Name	Francesca
Family Name	Scotti
Telephone number	+31 (0)88 781 6000
Fax	N/A
Email	Francesca.scotti@ema.europa.eu

Secondary Contact
The Secondary Contact must not be the same as the Administrator. Secondary contact details are requested for circumstances when the Administrator is unavailable.

Title *(Dr/Prof/Mr/Mrs/Ms/Miss)*	Dr
Given Name	Pieter
Family Name	Vankeerberghen
Telephone number	+31 (0)88 781 6000
Fax	N/A
Email	pieter.vankeerberghen@ema.europa.eu

Information Technology Officer
The Information Technology Officer should be the person who will be responsible for submitting the data for inclusion on the ICTRP Central Repository. They should have a good understanding of all of the IT issues relevant to the registry.

Title *(Dr/Prof/Mr/Mrs/Ms/Miss)*	
Given Name	
Family Name	EMA IM Division's representatives
Telephone number	+31 (0)88 781 6000
Fax	N/A
Email	https://support.ema.europa.eu/esc