ICTRP Registry Profile

Clinical Trials Information System (CTIS)

Basic Information

I.	Name of person completing this form	**Oskia Bueno Zaragüeta /** **Ana Rodriguez Sanchez Beato**
II.	Role of the person completing this form (that is, the role of this person in the registry making this application)	**EMA CTIS Subject Matter Expert/** **EMA CTIS Product Owner**
III.	Date this form was completed	_ 19 / _ 09_ / ___2024____ *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)	**Clinical Trials Information System (CTIS)**
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://euclinicaltrials.eu/**
IX.	Registration URL *(Web site where users go to register a trial)*	**Sponsors Workspace:** **https://euclinicaltrials.eu/ct-sponsor-services/login**
X.	Application type	Application for Primary Registry status ☒ Application for Partner Registry status ☐
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.	Does the registry have an Advisory Board? *	Yes ☒ No ☐
XIV.	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.	CTIS is overseen by the CTIS Governance and follows Agile methodology. The different groups involved are as follows: - The Agile CTIS Product Owners and Subject Matter Experts, which is represented by EMA and clinical trials experts from Member States and sponsors. - CTIS Forum, which is represented by the whole stakeholder's community (EMA, EU Commission, Member States and sponsors). - ACT EU Steering Group, which involved delegated representatives from Member State, EU Commission and EMA.
XV.	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 ☐ Legal requirement set by the Clinical Trial Regulation EU No 536/2014 (Art 5): https://eur-lex.europa.eu/eli/reg/2014/536/2022-12-05, "In order to obtain an authorisation, the sponsor shall submit an application dossier to the intended Member States concerned through the portal referred to in Article 80 (the 'EU portal')."
XVI.	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 describing this requirement and information on how this document can be obtained (including the relevant web address)	Yes ☒ No ☐ Legal requirement set by the Clinical Trial Regulation EU No 536/2014: https://eur-lex.europa.eu/eli/reg/2014/536/2022-12-05 As defined in Art 4 of the CTR, "a clinical trial shall be subject to scientific and ethical review and shall be authorised in accordance with this Regulation. The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The review by the ethics committee may encompass aspects addressed in Part I of the assessment report for the authorisation of a clinical trial as referred to in Article 6 and in Part II of that assessment report as referred to in Article 7 as appropriate for each Member State concerned."
XVII.	Is the registry currently accepting clinical trials for registration?	Yes ☒ No ☐
XVIII.	How many trials are on your database?	

On 19 /09/2024, there were 5981 trials publicly available on the registry database.

dd *mm* *yyyy*

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.

XIX.	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 through CTIS before they are authorised, and therefore, before the first participant is recruited, so this query is not applicable.	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)	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	Yes ☒ No ☐
a) Does the Registry accept trials submitted by Responsible Registrants?	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? ***EMA***: CTIS retrieves data from the Organisation Management System (OMS) of EMA, where organization data is validated.	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***: Same as above. In addition, Member States that assess the clinical trial are in contact with the sponsor and submit requests for information via CTIS, when applicable.	Yes ☒ No ☐
e) Does the Registry ensure that all Responsible Registrants are associated with an institution or organization?	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 types of study does the Registry accept for registration? (*tick all that apply*) **X** 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***: Interventional clinical studies conducted with at least 1 site in the EU/EEA are registered in CTIS.

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: Synopsis of the protocol Approvals Results links (including Layperson Summary of results)	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 Registrant. If yes, please state how often the Registry reminds Responsible Registrants to update their data (eg once every 6 months; once every year): ***EMA*:** All records in CTIS contained updated information, as the submission and assessment of the EU/EEA CTs take place through CTIS. Applicants are required by law to submit i.e.: substantial modifications, start of recruitment notification, end of trial notification, trial results etc. 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? Note: This is not a requirement and is being asked for information only.	Yes ☒ No ☐
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	Yes ☒ No ☐

citation in a “Publications” field) ***EMA*:** Same as above. Regarding the submission of trial results, CTIS sends reminders to sponsors in the system. Note: This is not a requirement and is being asked for information only.	

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, or remove it from public view, 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 CTIS public view, but it applies only under justified grounds. There is a process implemented to manage requests to amend publication under required conditions, users can request to have data and/or documents removed from the CTIS public website, including request of data subjects’ to address their rights to have their personal data removed in line with the provisions of the Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 (EUDPR) and of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (GDPR).	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*:** Before the submission of the CTA, CTIS displays a screen with related information to application withdrawal and publication rules.	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?	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) Do 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***: CT applications are validated and assessed by the Member States (National Competent Authorities and Ethics Committees) that will submit Requests for Information (RFI) to sponsors in case information is incomplete.	Yes ☒ No ☐
b) If one or more items in the TRDS submitted for registration are incomplete or not meaningful, do Registry staff contact the Responsible Registrant and attempt to obtain complete and meaningful data? ***EMA***: Same as above.	Yes ☒ No ☐
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*:** CTIS applies automated checking procedures (technical validation) for mandatory data items and documents to ensure that information is accurate and complete. In addition, there is a human validation process when the Member States perform the review of the CT application(s).	Yes ☒ No ☐

d) 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?	Yes ☒ No ☐
e) Does the Registry undertake regular internal quality control audits to assess the level of completeness and accuracy of the data collected? ***EMA***: Quality control process is performed for each application as there is an automated checking procedure (technical validation) for mandatory data items and documents.	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) Does the Registry have written standards for all procedures and processes employed by the registry? ○ *These written standards 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? ***EMA*:** There is an online modular training programme and supporting material to help clinical trial sponsors, national competent authorities, ethics committees, European Commission and EMA staff prepare for using the Clinical Trials Information System (CTIS). On top there are Information and training events. https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support	Yes ☒ No ☐
c) Are the internal registry-specific SOPs aligned with the WHO International Clinical Trial Registry Platform International Standards for Clinical Trial Registration?	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?	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. ***EMA***: CTIS requires that the sponsor organisation is registered in OMS, ensuring that all organisation data has been validated. CT applications are assessed by Member States (National Competent Authorities and Ethics Committees). Moreover, there are routine/triggered inspections of clinical trials in the EU/EEA.	Yes ☒ No ☐
a) Does the Registry obtain written third-party confirmation that a trial exists? If yes, please specify the method of confirmation: ***EMA***: Same as above	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 the name of the third party from whom confirmation was received (eg the name of the ethics committee) ***EMA***: The Member States that assess the trial are displayed in the CTIS public portal.	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?	Yes ☒ No ☐
b) Does the Registry make available a publicly accessible audit trail of any changes to any TRDS items? ***EMA***: For each trial, there is an audit trail to identify all the applications submitted (i.e.: substantial modification applications) with information on the Member States that assessed them and their decision.	Yes ☒ No ☐
c) Does the Registry 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***: CTIS displays the most updated information by default in the public portal and for each trial, it is possible to identify all the subsequent applications (i.e: substantial modifications) submitted since the authorisation. For the Sponsor and the Authorities, TRDS as originally registered are accessible at all times.	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 (ie 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? ***EMA***: The advanced search of the public portal allows to search trials by indicating different terms.	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?	Yes ☒ No ☐
b) If the Registry is planning downtime, does it publish advance notice of downtime at least one (1) week beforehand? ***EMA***: Planned system interruptions are published in the section "Website outages and system releases" of the CTIS public portal.	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*:** The public interface is available in all official European Union (EU) languages, as well as in Icelandic and Norwegian. The information on specific clinical trials, including documents, is available in the languages in which they are submitted to the Clinical Trials Information System (CTIS). This depends on the language requirements of the countries where the clinical trial takes place: in some countries the data need to be in the national language or languages; in others, they need to be in a language that is commonly understood within the medical field. However, in CTIS, on top of the original entries, the sponsor users can add further EU/EEA translations.	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 National Competent Authorities during the CTA review stage.	Yes ☐ No ☒
c) Are all TRDS items for all records also available in English?	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*:** Translations are reviewed by National Competent Authorities during the CTA assessment stage.	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? ***EMA*:** CTIS in line with the requirements of the Regulation, sponsor can submit one single application involving one or more EU/EEA Member States and linked with a unique EU number identifier. In addition, once an initial application is submitted, the Member States involved will validate the application and during this process can identify if the same application (but with different EU number) might be submitted and in that case will ask the sponsor to withdraw one of the application.	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? ***EMA*:** Same as 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?	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?	Yes ☐ No ☒
c) Does the Registry require Responsible Registrants to enter a UTN? *a. The UTN may be entered into either the Secondary Identifiers field or a field designated specifically for collection of the 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 (or does) 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.	Yes ☒ No ☐
b)	Will (or does) 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 (or does) 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)?	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 have access to a database that is used to store and manage the submitted data?	Yes ☒ No ☐
b)	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: CTIS serves to implement the Clinical Trials Regulation (Regulation (EU) No 536/2014). The European Medicines Agency (EMA) maintains CTIS and the public website, together with the EU Member States, EEA countries and European Commission. EMA is 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. CTIS has segregated domains for the Member States, Sponsors and Public users. The domains are supported by enterprise grade high-capacity IT infrastructure. Individual domains are hosted by dedicated set of servers and IT infrastructure to ensure data integrity. Ensuring user experience as per the defined SLAs, in line with the industry standards, is prime focus. Adequate network and computational resources are provisioned for the application components to meet the system performance.

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. ***EMA***: Planned system interruptions are published in the section "Website outages and system releases" of the CTIS public portal: https://euclinicaltrials.eu/website-outages-and-system-releases/?lang=en	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?	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? ***EMA:*** It is a legal requirement of the Clinical Trials Regulation (EU) No 536/2014. 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:*** All the 27 EU Member States and 3 additional EEA 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? ***EMA:*** EMA is a public 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?	Yes ☒ No ☐
c) What is the web address for the page where the ownership, governance and not-for-profit information is displayed? ***EMA:*** It is maintained by law by EMA, in collaboration with the Member States and the European Commission. This information is displayed in the following web address: https://euclinicaltrials.eu/contact/?lang=en	
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 change 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	Yes No

medium to long term sustainability?	☒ ☐

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	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	Yes ☒ No ☐	Yes ☒ No ☐
17	Sample size	Yes ☒ No ☐	Yes ☒ No ☐
18	Recruitment status	Yes ☒ No ☐	Yes ☒ No ☐
19	Primary Outcome(s)	Yes ☒ No ☐	Yes ☒ No ☐

	Item/Label	Does the registry collect this data item?	Does the registry publicly display this data item?
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	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***: CTIS has a legal framework and mandate and cannot simply start to accept data from other sources.	Yes ☐ No ☒
b) Does the Registry currently have any Partner Registries? Not applicable. If yes, please provide the name(s) of these partners:	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 ☐
d) 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)*	Dr
Given Name	Oskia
Family Name	Bueno Zaragüeta
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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
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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