



ICTRP Registry Profile

When complete, this form should be returned to the ICTRP Secretariat by emailing to ictrpinfo@who.int.

Instructions

This form is to be completed by all registries applying for the status of Primary Registry in the WHO Registry Network. Please refer to the ICTRP web site for detailed guidance on how to submit an application (<http://www.who.int/ictrp/en/>).

Before completing this form it is strongly recommended that the Registry Administrator obtain a copy of the International Standards for Clinical Trial Registries. These Standards can be obtained by asking the ICTRP Secretariat for access to the Registry Network Sharepoint. The Sharepoint contains a number of useful documents including the Standards, which provide detailed information on the expectations of Primary Registries. The numbering of each item in the Standards is directly compatible with the numbering of each item on this profile form.

ALL questions on this form must be answered before the form is submitted. Incomplete applications will result in a delay in the consideration of your application.

The answer to all questions on this form (except those marked with an asterisk *) must be "yes" if a registry is to be considered potentially eligible for Primary Registry status.

Questions marked with an asterisk (*) provide valuable background information and must be completed.

If a registry achieves Primary Registry status then the profile will be published on the ICTRP web site.

Updating


All Primary Registries are required to keep their profile up-to-date. Once each year, each Primary Registry will be required to resubmit an updated profile. This annual profile will be used to monitor registries and ensure continued compliance with ICTRP requirements. All profiles will be published on the ICTRP web site.

Approval Process for new applications

The completed Registry Profile should be submitted to the ICTRP Secretariat, along with the letter/s of support from the relevant ministry and/or other relevant national or regional agency/ies demonstrating that the registry has at least a national remit. The application will be reviewed by the ICTRP Primary Registry Panel and the registry will receive formal notification of the result of their application within 12 weeks of the application deadline. Submission deadlines and more details on the approval process are available on the ICTRP web site: <http://www.who.int/ictrp>.



Basic Information

I. Name of person completing this form	Yasuo Iimura
II. Role of the person completing this form (that is, the role of this person in the registry making this application)	Director of Office of Promotion of Clinical Trials, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare
III. Date this form was completed	<u>11</u> / <u>10</u> / <u>2023</u> <i>dd mm yyyy</i>
IV. Signature of person completing this form	Yasuo Iimura 
V. Official Name of Registry (list abbreviation used, if relevant) Eg Australian and New Zealand Clinical Trials Registry (ANZCTR)	Japan Registry of Clinical Trials (JRCT)
VI. Registry postal address	100-8916
VII. Registry street address (if different to postal address)	Kasumigaseki 1-2-2, Chiyoda, Tokyo, Japan
VIII. Registry URL (Registry's web site address)	https://jrct.niph.go.jp/
IX. Registration URL (Web site where users go to register a trial)	https://jrct.niph.go.jp/
X. Application type	Application for Primary Registry status <input checked="" type="checkbox"/> Application for Partner Registry status <input type="checkbox"/>
XI. What is the name of the agency (or agencies) that funds the registry?	Ministry of Health, Labour and Welfare
XII. What is the name of the agency that manages the registry?	Ministry of Health, Labour and Welfare National Institute of Public Health



<p>XIII. Does the registry have an Advisory Board? *</p>	<p>Yes No</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/></p>
<p>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.</p>	
<p>XV. Is registration of a clinical trial a legal requirement in the country (or countries) covered by the registry? *</p> <p>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)</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p> <p>Clinical Trials Act http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000163413.pdf (Only Japanese)</p> <p>Act on the Safety of Regenerative Medicine https://www.mhlw.go.jp/content/10800000/000428265.pdf (Only Japanese)</p> <p>PFSB/ELD Notification No. 0831-9 of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated August 31, 2020. https://www.mhlw.go.jp/content/11120000/000665717.pdf (Only Japanese)</p>
<p>XVI. Is registration of a clinical trial a requirement to obtain ethics approval in the country (or countries) covered by the registry? *</p> <p>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)</p>	<p>Yes No</p> <p><input type="checkbox"/> <input checked="" type="checkbox"/></p>
<p>XVII. Is the registry currently accepting clinical trials for registration?</p>	<p>Yes No</p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>



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XVIII. How many trials are on your database?

On 01 / 06 / 2023 there were 11516 trials 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
<input checked="" type="checkbox"/>	<input type="checkbox"/>



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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
a) Does the Registry query submissions where registration is being sought after the first participant has been recruited?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
1.1.2. Does the Registry register trials that have already recruited the first participant? (Also referred to as retrospective registration)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
1.1.3. Does the Registry register other types of studies, including observational studies	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
1.1.4. Does the Registry register all trials submitted by Responsible Registrants	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
a) Does the Registry accept trials submitted by Responsible Registrants?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the Registry use the contact details provided by the Responsible Registrant to verify that those details are correct?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
e) Does the Registry ensure that all Responsible Registrants are associated with an institution or organization?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
f) Does the Registry obtain institutional contact details for the Responsible Registrant, including name and telephone number of the institution?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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)	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

Note: This is not a requirement and is being asked for information only.



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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)
<input checked="" type="checkbox"/> Interventional studies
<input checked="" type="checkbox"/> 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:
No restriction.
c) From which countries does the Registry accept trials for registration:
Studies conducted in Japan only are registered.

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
	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b) Does the Registry have quality control procedures in place to ensure all items in the TRDS contain meaningful data?	Yes	No
	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c) Does the Registry collect the optional TRDS data items? If yes, please specify:	Yes	No
	<input checked="" type="checkbox"/>	<input type="checkbox"/>
jRCT: Information of medicine, medical devices or Regenerative medical products used in clinical trials and their suppliers. Name of auditors, data managers, monitors, biostatisticians, a project manager.		

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
	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b) Does the Registry have a reminder system to facilitate the submission of updated information by the Responsible Registrant.	Yes	No
	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, please state how often the Registry reminds Responsible Registrants to update their data (eg once every 6 months; once every year):		
<u>Note: This is not a requirement and is being asked for information only.</u>		
c) Does the Registry display the date the trial record was last updated?	Yes	No
	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>Note: This is not a requirement and is being asked for information only.</u>		
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)	Yes	No
	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>Note: This is not a requirement and is being asked for information only.</u>		



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

<p>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?</p> <p>If yes, please explain the circumstances under which a record would be deleted:</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> </table>	Yes	No	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Yes	No				
<input type="checkbox"/>	<input checked="" type="checkbox"/>				
<p>b) Does the Registry inform Responsible Registrants at the time of registration that a trial cannot be deleted once it has been registered?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				
<p>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?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				

2. Quality and Validity

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

<p>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?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				
<p>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?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				
<p>c) Does the Registry's database system apply automated checking procedures (e.g. range checks, logic rules) to data items to facilitate validity checking?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				
<p>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?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				
<p>e) Does the Registry undertake regular internal quality control audits to assess the level of completeness and accuracy of the data collected?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				

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

<p>a) Does the Registry have written standards for all procedures and processes employed by the registry?</p> <p>o <i>These written standards are known as Standard Operating Procedures (SOPs)</i></p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				
<p>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?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				
<p>c) Are the internal registry-specific SOPs aligned with the WHO International Clinical Trial Registry Platform International Standards for Clinical Trial Registration?</p>	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				



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 <u>Responsible Registrant</u> ?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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. It is undertaken through the fulfilment including the approval of ethical review committee.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
a) Does the Registry obtain written third-party confirmation that a trial exists? If yes, please specify the method of confirmation: The approval sheet of ethical review would be submitted to jRCT by the registrant.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry make available a publicly accessible audit trail of any changes to any TRDS items?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
d) Does the Registry use the most up-to-date information as the default display?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
e) Can the TRDS, as originally registered, be accessed at all times?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Is the Registry Administrator committed to ensuring that all Registry staff are familiar with the standards described in the ISCTR?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Are all Registry staff familiar with the contents of the ISCTR?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the online search allow users to search in at least the condition field and the intervention field?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) When the results of a trial identified by a search are displayed, are all items in the WHO TRDS visible?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
d) Does the online search have an advanced search option?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<i>Note:</i> This is not a requirement and is being asked for information only.		

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) If the Registry is planning downtime, does it publish advance notice of downtime at least one (1) week beforehand?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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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: In Japanese	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Are all TRDS items for all records also available in English?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
e) Are all trial records translated by Registry staff checked by at least one other staff member?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
f) If there is a discrepancy in a translation, is the translation checked by a third person?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>



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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry have policies and procedures in place to deal with inadvertent duplicate registration of the same trial within their own register?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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 <i>Secondary Identifiers</i> field?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) If there are no known secondary identifiers, does the Registry require Responsible Registrants to enter 'Nil known' in the <i>Secondary Identifiers</i> field?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Does the Registry require Responsible Registrants to enter a UTN? a. <i>The UTN may be entered into either the Secondary Identifiers field or a field designated specifically for collection of the UTN</i>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Note: This is not a requirement and is being asked for information only.		

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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Note: This is not a requirement and is being asked for information only.		



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? <ul style="list-style-type: none"> Note: If a registry accepts study types other than interventional trials (i.e. observational studies) these must be provided as well. 	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry use database software and hardware that guarantees reliable access to registered data and data safety at all times?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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

a) Does the Registry have access to reliable information technology support?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry have access to all of the following? <ul style="list-style-type: none"> 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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) Please briefly describe the Registry's information technology infrastructure. (A separate document may be submitted separately if necessary) <p>The system of jRCT is a web application developed in PHP language with MySQL(RDS). jRCT runs under Amazon Linux AMI with Apache server. Registrants for jRCT will be controlled to login by ID and PW.</p> <p>Data servers is Amazon RDS. Web servers is Amazon EC2. For Amazon web services (AWS), the strengthened security by introducing WAF. For backup of RDS and EC2 (AMI), 14 generations of daily snapshot are stored. Each storage place is at the RDS service or AWS S3.</p>		

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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International Clinical Trials Registry Platform

<p>b) Does the Registry issue alerts in advance of website downtime?</p> <p>If yes, please briefly describe how these alerts are circulated and who is responsible for circulating them.</p> <p>On jRCT website.</p>	<table><tr><td>Yes</td><td>No</td></tr><tr><td><input checked="" type="checkbox"/></td><td><input type="checkbox"/></td></tr></table>	Yes	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input checked="" type="checkbox"/>	<input type="checkbox"/>				



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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Note: The letters of support must be submitted to the ICTRP Secretariat as part of the application		
c) From which country (or countries) does the Registry have the remit to act as the national (or regional) clinical trial registry?	Japan	
d) Please specify the name of the national agencies that have given their support to the Registry:	Ministry of Health, Labour and Wealth	

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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) What is the web address for the page where the ownership, governance and not-for-profit information is displayed?	http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000163417.html https://jrct.niph.go.jp/	
d) Will the Registry inform the ICTRP immediately if their ownership, governance structures or not-for-profit status change in any way?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry's business plan include strategies to ensure its medium to long term sustainability?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
2	Date of Registration in Primary Registry	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
3	Secondary Identifying Numbers	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
4	Source(s) of Monetary or Material Support	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
5	Primary Sponsor	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
6	Secondary Sponsor(s)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
7	Contact for public queries	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
8	Contact for scientific queries	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
9	Public title	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
10	Scientific title	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
11	Countries of Recruitment	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
12	Health condition(s) or problem(s) studied	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
13	Interventions	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
14	Key Inclusion and Exclusion Criteria	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
15	Study type	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
16	Date of first enrolment	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
17	Sample size	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
18	Recruitment status	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
19	Primary Outcome(s)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
20	Key Secondary Outcome(s)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
21	Ethics Review	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



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	Item/Label	Does the registry collect this data item?		Does the registry publicly display this data item?	
22	Completion date	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
23	Summary Results	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
24	IPD sharing statement	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	Approvals	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	Results links	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

	URL	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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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?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Does the Registry currently have any Partner Registries? If yes, please provide the name(s) of these partners: University Hospital Medical Information Network Clinical Trials Registry (UMIN CTR)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
c) If the registry has partners, are they listed on the proposed Primary Registry's web site? If yes, please provide the address of this web page: UMIN CTR : https://www.umin.ac.jp/ctr/index-j.htm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<small>Note: A completed Registry Profile form is required for all Partner Registries. This profile will be published on the ICTRP's web site.</small>		

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
b) Has a Registry Profile form been completed and submitted for all of the Registry's Partner Registries?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

8.3. Primary Registries will have procedures in place to enable exchange of data with Partner Registries.

a) Is the Registry able to accept data (that is, as electronic data files) from Partner Registries or other appropriate data providers?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>
f) Before announcing Partner Registries, Primary Registries must have successfully imported data into the Primary Registry?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



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	Ritei
Family Name	Uehara
Telephone number	+81-48-458-6220/6204
Fax	+81-48-469-3875
Email	uehara.r.aa@niph.go.jp

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	Keiko
Family Name	Yukawa
Telephone number	+81-48-458-6311
Fax	+81-48-469-3875
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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)	Dr.
Given Name	Mariko
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