WEBINAR 26 June 2019
Introduction to the ICTRP

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ICTRP Webinar list

Webinar – Introduction to the ICTRP: 26th of June 2019
Webinar - ICTRP Standards
Webinar – ICTRP Search Portal and Web services
Webinar – ICTRP Primary Registries
Webinar – ICTRP filters – Rare disease

Guest speakers will be invited in next Webinars
Dates of the next Webinars will be announced

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Webinar Outline
Introduction to the ICTRP

I. What is ICTRP?
What does it do?
What are its values?

II. ICTRP Network
- Primary registries
- Data providers
- 24 items TRDS

III. ICTRP Search Portal
- Search pages
- UMLS
- Bridging
- UTN
- web service
- xml download
What is ICTRP?

- The International Clinical Trials Registry Platform (ICTRP) is a global initiative that aims to make information about all clinical trials involving human beings publicly available.

- It was established in 2006 in response to demand from countries through the World Health Assembly Resolution WHA58.22

- It is the position of the ICTRP that the registration of all interventional trials is a scientific and ethical responsibility.

"a voluntary platform to link clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials with a view to enhancing access to information by patients, families, patient groups and others"
Clinical Trials Transparency Flow

- 2006: WHO calls for the registration of all interventional trial and defines the 20 elements data set (TRDS)
- 2015: WHO calls for the reporting of the results of past and new trials
- 2017: The TRDS is expanded to 24 elements
Correlation between ICTRP values and Clinical Research

1. Identify Gaps in Research
2. Improve trial design, conduct and reporting
3. Meet ethical obligations
4. Ensure Greater Accountability
5. Prevent unnecessary duplication and encourage necessary replication
6. Improve Public Trust
7. Facilitate the building of research infrastructure and capacity
8. Improve Transparency
9. Prevent Publication Bias and Selective Reporting

Step 1: Discovery and Development, Scientific Research
Step 2: Preclinical Research: Protocol Design
Step 3: Ethics Review
Step 4: Authorization
Step 5: Registration
Step 6: Clinical Research: Patient recruitment
Step 7: Clinical Research Investigation
Step 8: Results disclosure
Step 9: Publication

Improve health
I. What is ICTRP? What does it do? What are the values?

**What does it do?**

**International Clinical Trials Registry Platform**

- **Publishes the ICTRP Search Portal**
  - Search for free, data provided by clinical trial registries

- **Supports the WHO Registry Network**
  - a forum for Registries

- **Supports countries and regions**
  - wanting to establish clinical trial registries or policies on trial registration
WHO ICTRP Registry Network

- **17 Primary Registries & Data Providers:**
  Australia (ANZCTR), Brazil, China, Republic of Korea, India, Cuba, EU, Germany, Iran, ISRCTN (UK), Japan, Netherlands, South Africa, Sri Lanka, Thailand, USA, Peru

- **2 Partner Registries (China)**
What is a Primary Registry?

Meet criteria for:

1. Content (prospective, TRDS 24 items)
2. Quality and Validity (SOP, public audit trail)
3. Accessibility (24/7 registration and search, local language)
4. Unambiguous Identification (use sec ids for bridging)
5. Technical Capacity (xml transfer, IT)
6. Administration & Governance (national remit, Not-for profit)
## 24 Items dataset

<table>
<thead>
<tr>
<th>1. Primary registry / Trial ID</th>
<th>13. Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Date of registration</td>
<td>14. Inclusion/Exclusion criteria</td>
</tr>
<tr>
<td>3. Secondary ID</td>
<td>15. Study type</td>
</tr>
<tr>
<td>4. Source of support</td>
<td>16. Date of first enrolment</td>
</tr>
<tr>
<td>5. Primary sponsor</td>
<td>17. Target &amp; final* sample size</td>
</tr>
<tr>
<td>7. Contact (public)</td>
<td>19. Primary outcomes</td>
</tr>
<tr>
<td>8. Contact (scientific)</td>
<td>20. Secondary outcomes</td>
</tr>
<tr>
<td>9. Public Title</td>
<td><strong>21. Ethics approval</strong>*</td>
</tr>
<tr>
<td>10. Scientific Title</td>
<td><strong>22. Date of study completion</strong>*</td>
</tr>
<tr>
<td>11. Countries of recruitment</td>
<td><strong>23. Summary results</strong>*</td>
</tr>
<tr>
<td>12. Health Conditions</td>
<td><strong>24. IPD sharing</strong>*</td>
</tr>
</tbody>
</table>

* New data elements added
II. ICTRP Network

ICTRP Registry Network and Data by WHO regions (January 2019)
III. ICTRP Search Portal

ICTRP Search Portal

http://www.who.int/trialsearch

International Clinical Trials Registry Platform (ICTRP)

ICTRP Search Portal Search Tips

General Instructions

1. The Clinical Trials Search Portal provides access to a central database containing the trial registration data sets provided by the registries listed on the right. It also provides links to the full original records.
2. To facilitate the unique identification of trials, the Search Portal bridges (groups together) multiple records about the same trial. More information
3. It is possible to export the results of the search into XLS. More information
4. Crawling the ICTRP database requires a username/password. To request access to the crawling pages please send an email to ictrpinfo@who.int
5. A new field called 'Prospective registration' has been added to the ICTRP database. More details about this new field can be found here
6. To search for studies with results, click on the filter "with results only". After entering your search term, activate the filter, in order to quickly identify trials with results. This function can be used as well in the standard as in the advanced search.

Flags

- **Prospective Registration**: When a trial is registered in a primary registry before the recruitment of the first patient. The ICTRP database flags prospective records by comparing the 2 fields 'date of registration' of the trial and 'date of first enrolment' of patients. Prospective is when (by ICTRP standards) the 'date of registration' field is prior to the 'date of first enrolment' field.
- **Results available**: The 'Results available' field will appear as 'Yes' whenever at least one of the following fields 'Results date posted', 'Results URL', 'Results summary' or the 'Results outcomes' holds the according information.
III. ICTRP Search Portal

ICTRP website

- [http://www.who.int/ictrp](http://www.who.int/ictrp)

- The ICTRP website is in all 6 official WHO languages: English, French, Spanish, Arabic, Chinese, Russian
Thank you

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