Welcome to the WHO ICTRP
Bienvenue à l’ICTRP de l’OMS
Bienvenido a la ICTRP de la OMS
欢迎访问世卫组织 国际临床试验注册平台
مرحبًا بكم في منبر منظمة الصحة العالمية للسجلات الدولية للتجارب السريرية
Добро пожаловать на МПРКИ ВОЗ

Ghassan Karam
ICTRP Project Manager
WHO, Geneva

World Health Organization
I. What is ICTRP?
- Definition
- Governance
- Transparency flow
- Values
- Functions

II. Registry Network
- Primary registries
- Data providers
- 24 items TRDS
- Website
- Stats
- Data model

III. Search Portal
- Search pages / UMLS
- Bridging
- UTN
- web service / xml download
- REGTRAC
- Webinars

IV. Kofam (Switzerland)
- Swiss stats
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"
Governance

- The ICTRP Secretariat:
  - Ghassan Karam

- The ICTRP advisory panel
  - Established in August 2013, meets 2 to 4 times yearly
  - Gives advice to the Secretariat and the ADG on policy issues related to Clinical trials and on new and existing primary registries
  - 8 members (5 external and 3 from primary registries)
  - Alltrials.net
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

<table>
<thead>
<tr>
<th>ICTRP Values</th>
<th>Clinical Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Identify gaps in research</td>
<td>• Step 1: Discovery and development, scientific research</td>
</tr>
<tr>
<td>• Improve trial design, conduct and reporting</td>
<td>• Step 2: Preclinical research: Protocol design</td>
</tr>
<tr>
<td>• Meet ethical obligations</td>
<td>• Step 3: Ethics review</td>
</tr>
<tr>
<td>• Ensure greater accountability</td>
<td>• Step 4: Authorization</td>
</tr>
<tr>
<td>• Prevent unnecessary duplication and encourage necessary replication</td>
<td>• Step 5: Registration</td>
</tr>
<tr>
<td>• Improve public trust</td>
<td>• Step 6: Clinical research patient recruitment</td>
</tr>
<tr>
<td>• Building of research infrastructure and capacity</td>
<td>• Step 7: Clinical research investigation</td>
</tr>
<tr>
<td>• Improve transparency</td>
<td>• Step 8: Results disclosure</td>
</tr>
<tr>
<td>• Prevent publication bias and selective reporting</td>
<td>• Step 9: Publication</td>
</tr>
</tbody>
</table>

**Improve health**
What does it do?

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

• **18 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, Lebanon

• **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

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

* New data elements added
**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
ICTRP Stats

- Database receives 2000 daily users and 15000 daily hits

Note: These numbers may slightly change every year because of retrospective registrations.
ICTRP Data Model

WHO Registry Platform
The Registry Network
(Data by WHO region from January 2019)

- **USA**
- **UK**
- **EU**
- **Netherlands**
- **Germany**
- **Iran**
- **India**
- **Sri Lanka**
- **China**
- **Republic of Korea**
- **Japan**
- **South Africa**
- **Australia & NZ**
- **Brazil**
- **Cuba**
- **Peru**

The map shows the distribution of registry networks globally, with data by WHO region from January 2019. The regions are color-coded as follows:

- **African Region**: 8945
- **Region of the Americas**: 158638
- **South-East Asia Region**: 31386
- **European Region**: 155441
- **Eastern Mediterranean Region**: 30209
- **Western Pacific Region**: 127010

The map highlights the number of registries in each region, with a legend indicating the color-coding for each region.
Bridging – How it was done?

- Matching main and secondary identifiers found in trial records wherever they existed

- With 550,000+ records in our database, bridging has linked 86,000 records (identifying 22,000 parent trials)
Universal Trial Number - UTN

- Launched in June 2009
- Facilitate the unambiguous identification of trials

- Permanently attached to the trial
- Used a secondary id
- Part of the trial’s identity
- Documented in the trial protocol
- Submitted every time the trial is registered

NOT a registration number
Web/Crawling services

- XML free download function / some prefer using a webservice
- A way to allow another website to search our database without using our search portal
- Nutrition e-lena, Switzerland, Univadis, Orphanet, Cochrane, ClinicalTrials.gov, AllTrials
- Crawling service with more than 150 users
- Listserv with 900 subscribers
The WHO Database of Regulatory Information Tracking of Clinical Trials Registration & Ethics Committees (REGTRAC)

<table>
<thead>
<tr>
<th>Country</th>
<th>Region</th>
<th>Yes/No</th>
<th>Regulation URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ukraine</td>
<td>EU</td>
<td>Yes</td>
<td><a href="https://www.admin.ch/opc/en/classified-correlation/20121177/index.html">URL</a></td>
</tr>
</tbody>
</table>

Clinical Trials

- **Regulation Yes/No**: Yes
- **Regulation detail**: First link: Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301.
  Second link: Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, Clio), RS 810.305.
  Third link: Ordinance of 20 September 2013 on Organizational Aspects of the Human Research Act (HRA Organisational Ordinance, OrgHRA), RS 810.308.
- **Legislation Yes/No**: Yes
- **Legislation detail**: First link: Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Chapter 8, 9
  Second link: Federal Act of 19 June 1992 on Data Protection (FADP), RS 235.1
- **Date of Last Update**: 5/28/2019

**Country**: Switzerland
ICTRP Webinars

http://www.who.int/ictrp/about/learning

The ICTRP Learning material

Webinar - Introduction to ICTRP - 26 June 2019

The first ICTRP webinar was on 26 June 2019 (Introduction to ICTRP). The content was mainly about What is ICTRP? and a brief description of the Registry Network and the Search Portal.

ICTRP webinar - Introduction to ICTRP
pdf, 2.38Mb

Playback Recording link

Webinar Q&A
pdf, 570kb

Future webinars

1. ICTRP Standards
   Detailed ICTRP standards such as criteria for being a primary registry in the ICTRP Network, and topics on governance and ethics.

2. ICTRP Search Portal and Web Service
   An overview of how to search the ICTRP database using different options of the search portal.

3. ICTRP Primary Registries
   Information on existing registries and data providers explaining the relationship between the registries and ICTRP. Guest speakers will be invited in the Webinar to talk about their registry.

4. ICTRP filters – Collaboration with Orphanet on Rare diseases filter
   Rare disease filter in the ICTRP database and the collaboration project between ICTRP and the Orphanet which is an organization specialised in Rare diseases.

More information on how to subscribe in the ICTRP mailing list
The portal for human research in Switzerland

kofam.ch is the Federal Office of Public Health’s (FOPH) portal for human research in Switzerland. On this website you’ll find extensive basic information on the regulation of human research in Switzerland as well as various tools for researchers.

Human research
Key points in a nutshell

A brief summary of the key points on human research in Switzerland

Applications & procedure
Requirement to obtain authorisation, categorisation and submission of applications

All information on the requirement to obtain authorisation, categorisation and submission of applications is available here:
## ICTRP & Kofam

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Recruitment Status</th>
<th>Description</th>
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<tbody>
<tr>
<td>DRKS00013209</td>
<td>Closed</td>
<td>Zweiteiliges Keramikimplantat</td>
</tr>
<tr>
<td>DRKS00013250</td>
<td>Closed</td>
<td>Household transmission of ESBL-producing Enterobacteriaceae after hospital discharge of an ESBL-positive patient</td>
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<tr>
<td>DRKS00013220</td>
<td>Open</td>
<td>Bedeutung der Darmsonographie zur Überwachung des Krankheitsverlaufs von Patienten mit Morbus Crohn und Colitis Ulcerosa unter einer Behandlung mit Vedolizumab</td>
</tr>
<tr>
<td>DRKS00014580</td>
<td>Open</td>
<td>BEAT: Binge-Eating Adolescent Treatment - ein Behandlungsprogramm für Jugendliche mit Essstörungen</td>
</tr>
</tbody>
</table>

Site of trial:
- Basel, Zürich
- Zürich
- Bern, Freiburg
- Source of data: BASEC

Display trial:
- Display trial
### Swiss Stats on ICTRP

<table>
<thead>
<tr>
<th>Total</th>
<th>8829</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novartis</td>
<td>532</td>
<td>6.03</td>
</tr>
<tr>
<td>Bayer</td>
<td>151</td>
<td>1.71</td>
</tr>
<tr>
<td>Uni</td>
<td>2929</td>
<td>33.17</td>
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<tr>
<td>Prospective</td>
<td>6552</td>
<td>74.21</td>
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<tr>
<td>clinicaltrials.gov</td>
<td>6352</td>
<td>71.94</td>
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<tr>
<td>EUCTR</td>
<td>1195</td>
<td>13.53</td>
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<tr>
<td>Recruiting</td>
<td>1929</td>
<td>21.85</td>
</tr>
<tr>
<td>Interventional</td>
<td>6975</td>
<td>79.00</td>
</tr>
<tr>
<td>Phase 1/2</td>
<td>1786</td>
<td>20.23</td>
</tr>
<tr>
<td>Phase 3/4</td>
<td>2332</td>
<td>26.41</td>
</tr>
<tr>
<td>Phase NA</td>
<td>3202</td>
<td>36.27</td>
</tr>
<tr>
<td>Only CH</td>
<td>3262</td>
<td>36.95</td>
</tr>
<tr>
<td>Cancer</td>
<td>1034</td>
<td>11.71</td>
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<tr>
<td>Diabetes</td>
<td>216</td>
<td>2.45</td>
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<tr>
<td>Hypertension</td>
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<td>2.45</td>
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<tr>
<td>Arthritis</td>
<td>189</td>
<td>2.14</td>
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<tr>
<td>HIV</td>
<td>134</td>
<td>1.52</td>
</tr>
<tr>
<td>Nutrition</td>
<td>105</td>
<td>1.19</td>
</tr>
</tbody>
</table>
## Swiss Stats on ICTRP

### Trials registered by year

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>487</td>
</tr>
<tr>
<td>2011</td>
<td>493</td>
</tr>
<tr>
<td>2012</td>
<td>643</td>
</tr>
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<td>2013</td>
<td>595</td>
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<td>2014</td>
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<td>2016</td>
<td>711</td>
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<tr>
<td>2017</td>
<td>740</td>
</tr>
<tr>
<td>2018</td>
<td>807</td>
</tr>
<tr>
<td>2019</td>
<td>329</td>
</tr>
</tbody>
</table>
Health Condition cloud
Thank you

Email: ictrpinfo@who.int

Website: http://www.who.int/ictrp

Search Portal: http://www.who.int/trialsearch