ICTRP Webinar Introduction to the ICTRP Q&A
26 June 2019 at 10AM

Q 1. What is the status of those clinical trials not registered?

Approximately, it is estimated that 30-50% of all clinical trials are not registered, depending on the region. There are diverse reasons associated with the rate of non-registration. The trials can remain not registered until there is a reason for registration. For example, some trials are registered when they are to be published because trials registration is required for peer-reviewed journals. Then, the trials can be registered retrospectively. The outcome of the clinical trials either positive or negative can also affect registration. As to enforcing registration, WHO works with different governments and some governments have policies on registration.

Q 2. Is there data duplication between German and Netherlands registries? And what is in EU data?

Yes, there is data duplication not only between German and Netherlands registries but also across many registries, mostly because of multi-country studies. Whereas a single-country study will be registered with a single registry, multi-country study can result in duplication as it can be registered in multiple registries. However, WHO manages this problem by linking studies which registered in more than one registry.

The EudraCT registry contains all trials approved by European National Competent Authorities. There is no registration in the EU CTR, the registration is done in EudraCT and it is linked to the approval of the trial by the NCAs. Once the NCAs will input the approval in EudraCT, the system will trigger the publication of the trial in the EU Register (based on specific business rules).

Q 3. How is it possible to join as a partner registry or a primary registry?

By sending us an email we can provide you a set of criterions. If you are personnel of an institution or a government and wish to create partner or primary registry, we can send you official documents.

For primary registry, once we receive your application with detailed information about your registry, we will review and assess eligibility to proceed further. If you are registering as a partner registry, WHO will link your registry with a primary registry of your country because there is a lot of collaboration that needs to happen between the partner and the primary registry of a country. We also have a number of countries which are working to become primary registries.

Q 4. Are there differences between the biomedical/health and social sciences registration?

This is related to the types of studies registered on the ICTRP. ICTRP is designed to accept interventional studies, but we now have approximately 20% of non-interventional studies such as observational studies. This also depends on the decision made by the registry administrator in the country whether to accept non-interventional studies.

Q 5. Would it be possible to link trial registration to ethics approval at an academic level?

Linking ethics to trial registration is also depending on the country. Some countries have their policy to make a linkage between ethics and trial registration whereas some don't. Currently, some registries do not accept clinical trials for registration unless there is an ethics approval and some registries tentatively accept by applying publication restriction until meeting the ethics approval. Others publish the registration, but they link ethics approval to the recruitment status which means that clinical trials do not allow patients recruitment until obtaining ethical approval. Therefore, mostly ethics approval is required at certain stage across the course of the registration. More information can be found here https://www.who.int/ictrp/network/factsheet/en/

Q 6. Does ICTRP only consider clinical trials registered prospectively?

ICTRP advocate prospective registration of clinical trials, however ICTRP also allows retrospective registration. It is better for trials to be registered retrospectively than not at all.

Q 7. Are trials registered in a country also registered in the ICTRP with a secondary ID?

No, ICTRP does not accept registration because ICTRP is not a registry. ICTRP is a platform which collects data from registries. You can only register with the countries and not with ICTRP. ICTRP only collect and display data and make them available to the public.

Q 8. Do you require summary results to be added?

We require some of the results when they are available once the trial is completed. For example, there is a timeline to respect by registering their study within 1 year after the completion of the study, all explained in the WHO official position here https://www.who.int/ictrp/results/reporting/en/

Q 9. Do you chase where registrations are out of date and not updated?

ICTRP issues standards that registries should comply with and practice. All the necessary actions associated with the management of the registry are carried out at the registry level. Outdated registration is also managed at the registry level. As part of the registry function and the Standard Operating Procedure (SOP), registry have a role to follow up and send automatic reminders to the registrant to inform them that they should update their study information.

Q 10. Are there any plans to make the results of searches downloadable in RIS file format for use in reference management software such as Refman or Endnote? Will there be other export formats, beside xml, such as RIS?

The only publicly available export format is xml because it allows to export from xml to other formats. There are plans to make the results accessible in a different format but not at some early date. If we create a new search portal for ICTRP in the future, there will be other export format. Unfortunately, we have other important technical priorities. Nevertheless, we will keep considering further improvement based on suggestions.

Q 11. Can you give information about the use of wildcards?

We will run several webinar sessions on different topics and one session will be devoted to Search Portal. Please see the upcoming webinar events or refer the search tips page addressing wildcards on the WHO ICTRP website. https://www.who.int/ictrp/search/searchtips/en/

Q 12. It looks like that ICTRP now (compared to the past) supports brackets in search terms. Can you confirm?

Currently, ICTRP does not support brackets. Please find more information in a future webinar on the topic of Search Portal and read the search tips to know what are the best ways to search ICTRP https://www.who.int/ictrp/search/searchtips/en/

Q 13. Do you follow up on trials that are incomplete?

The first follow up is done at the registry level and then ICTRP makes sure the registries are following up. Also, we have a system for random data quality check on the registered trials which we use to report on data quality issues and follow up on them with the registries.

Q 14. Can you give more information about how you can crawl the studies? Do you need an account for this?

Usually, crawling is interested by IT experts. If you are interested in data crawling, please send us an email to receive more detailed information about the process. More information about crawling can be found here https://www.who.int/ictrp/search/crawling_service/en/

Q 15. What is the difference between ClinicalTrials.gov and the primary registries?

Whether to be considered as a primary registry or as a data provider is a choice made by each registry and there can be many reasons for these decisions. The ClinicalTrials.gov as a data provider meets the primary registry criteria and is a part of the network group. Therefore, ICTRP collaborates with them as we do with the primary registries. The difference is that they are not obliged to follow ICTRP standards in the same way as other primary registries do.

Q 16. If there are no results available, could they still be published somewhere?

Yes. As shown in the Clinical Trials Workflow presented in the Webinar, we are now in the result disclosure step in the process. Currently, some of the primary registries have not even finished yet adding all the result information and it will require some more time.

Q 17. Can I find intervention studies that are not clinical in ICTRP, health systems intervention studies for example?

Yes, you can.

Q 18. Is there any authority (administrative, scientific, etc.) supervising the methodology, content of the registered trials or is only a matter of transparency?

Yes, there is in most cases and it also depends on the management by registries if there is are experienced people such as scientists or methodologists. In most cases, registration is based on the protocol which is written according to international scientific standards and approved by experts such as ethics committees or regulators.

Q 19. Can someone from outside intervene on a registered trial?

No, the public cannot directly intervene in the registration process. However, it could happen only to make a correction on missing information or mistakes in trials. Once ICTRP received emails from the public users that need to be reflected on the trial records, we then inform the registry to make necessary amendments.

Q 20. Is there a collaboration between ICTRP, ClinicalTrials.gov, Cochrane Controlled Register of trials (CENTRAL) and other registers, or does one have to search in all registers?

Yes, there is very strong collaboration between ICTRP and Cochrane, and ClinicalTrials.gov is also part of ICTRP Network. Cochrane Central takes data from ICTRP and indexes it. Even though the data is the same everywhere, search methods are not the same, so the advice is to understand how each search is designed and then decide which one to use.

Q 21. The EU CT Regulation is bringing in a mandate for lay summaries for registered trials. In terms of global efforts to move towards transparency, is WHO and the ICTRP doing anything to improve transparency of trials in your registry network?

EU is a regulator whereas WHO is not. ICTRP WHO advocates and offers guidance to countries and regulators nevertheless, it is up to the regulators to enforce transparency. WHO can improve but cannot enforce transparency. Thus, we work with countries to create mandatory regulation for improving transparency.

Q 22. Have you been in touch with the AllTrials people?

Yes, we have. This is similar to the collaboration between ICTRP and Cochrane. The ICTRP governance is an example, an 8-members advisory panel composed with one of the members from AllTrials. https://www.who.int/ictrp/about/details/en/

Q 23. I have a search string used in your 2017 with ICTRP resulting in about 10.000 results. Today the same strings results in only about 2.000 results. Can you explain?

One potential reason is a problem with the search string which might have occurred during that time. Otherwise, it could be because of database update at a particular time. For more support regarding search string, please email to ICTRP directly or join the future webinar on the topic of Search Portal. *This matter was investigated after the webinar and we couldn't replicate the problem, the user search was giving 12000 results and not 2000 and they claimed.*

Q 24. Where can I find the published trial results? Are they available on WHO?

Currently, we only display if the trial results exist and two other relevant information in the trial records. The full results can only be found in the primary registry websites. Hopefully, we will start displaying additional results information available on the ICTRP website next year.

Q 25. Are all studies from clinicaltrials.gov included in ICTRP? A test search on "bullying" results in 90 hits in clinicaltrials.gov, but only 61 in ICTRP. Can you explain what causes the difference?

Yes. This is normal, because ICTRP and ClinicalTrials.gov don't use the same search logic and you will always find more results in Clinicaltrials.gov for the same search. However, all studies from clinicaltrials.gov are included in ICTRP.