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**International Clinical Trials
Registry Platform**

WHO ICTRP Registry Network meeting

Geneva 9-10/11/2015, Room M605

Summary report

Meeting objectives

1. Provide an update and share experiences from each of the registries: including scope and coverage, key achievements or results to date and plans for the future;
2. Share some of the recent analyses using data from ICTRP and the registries to discuss and explore how to maximize the use and utility of ICTRP and the registries;
3. Discuss ways in which ICTRP, the registry Network and trial registration in general can be improved, e.g., how to increase compliance with trial registration, data quality issues and including results of clinical trials.

Meeting summary

This two-day meeting was well appreciated and welcomed by everyone as registry members always asked for the opportunity to meet face to face to discuss common issues of concern. All the participants were committed and engaged and the discussions were very enriching with many new ideas coming up. A lot of follow-up work is expected in 2016 and beyond.

On day one, each registry gave an update including their scope and coverage, key achievements or results to date and plans for the future. They also shared some of the recent analyses using data from ICTRP and their registries to discuss and explore how to maximize the use and utility of ICTRP and the registries. These updates are available as power point slides. This was followed by a discussion on how the ICTRP, the registry Network and trial registration in general can be improved, e.g., how to increase compliance with trial registration, data quality issues and including results of clinical trials.

On Day two, two key points were discussed in more detail. These included how to improve data quality and possibilities for establishing a results database. The discussion led to the decision to create two working groups to further explore these two areas:

1. Working group on next steps for results disclosure and threaded documents, implementing additional data element(s): [Interested members: ISRCTN, ClinicalTrials.gov, ReBec, EUCTR, NTR]. The aim is to formulate suggestions on issues around making protocols, results, participant-level data and other documents related to the trial publicly accessible and for linking these documents to bring it back to the larger network.



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2. Working group on clinical trial data quality control: [Interested members: ISRCTN, PACTR, SLCTR, ReBec]. The aim is to review international standards for trial registration & develop separate guidance for observational trials.

Absent registry members have the possibility to join either of these groups. ICTRP Secretariat can facilitate the convening of these two groups with Chairs selected among the WG members to lead the group work and draft the specific terms of reference for the group.

Summary of main discussion points

The main discussion points related to the each of the two working groups are highlighted below.

Data and results sharing/transparency

- The group held discussions about the broader movements towards greater data sharing, and acknowledged that registries have an important part to play beyond registration itself. In parallel it was agreed that compliance with registration is still severely lacking in many parts of the world and that a major focus must continue to encourage and enforce universal trial registration.
- Participant-level data sharing or Individual Patient Data (IPD) and aggregate results sharing have different considerations. The legitimate privacy concerns with IPD do not apply to results sharing.
- WHO's adoption of a position on results sharing in 2015 was discussed and WHO shared its concern about the high percentage of trials that have delayed reporting or non-reporting. The many compelling reasons for prompt public disclosure of results were discussed. -It was clarified that journals have no objection to sharing information through posting of results summaries in a standardized format prior to publication.
- In the short term, a new field with "yes/no" options for whether results are available was agreed to be a "low hanging fruit" that could be implemented. Where the answer is yes, a link can be provided to the publication or the website where the results are available.
- A separate discussion was held about IPD. If the results disclosure field is added, a second field could also be added along similar lines ie "yes/no" with link to location of IPD availability.
- Finally it was agreed that the registries should encourage or consider making mandatory the uploading of clinical trial protocols, although further discussion will be needed as to how best to implement this. It may be most appropriate to begin by allowing this as an optional element. It was acknowledged that access to clinical trial protocols could be very helpful in assessing the concerns with selective reporting of clinical trials. If the results disclosure field is added, a third field could also be added along similar lines ie "yes/no" for the presence of a clinical trial protocol, with link to location of the protocol.
- With respects to developing a "results" database, the general thinking was that it would be ideal to have a centralised results database but this will be very challenging. Clinicaltrials.gov and EMA offered their expertise, since they have a results database. It was not possible to reach agreement during this meeting on the best way forward with some participants preferring to independently set up their own clinical trial results databases, and others who see multiplication of non-compatible and non-standardised efforts as counterproductive. WHO reiterated that aggregation and standardisation of results databases is very important, to allow for aggregated summaries and analysis between different databases to inform policy and decision-making. It is worth mentioning that Clinicaltrials.gov and EMA have different experiences in terms of the cost for running such a results database, which is something to take into consideration for the future.



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- Given the complexities and the many issues that need to be discussed and resolved, it was agreed that a working group need to be convened to move forward with results disclosure and other threaded documents relating to trials, as described above.

Data quality control/assurance:

- One of the points raised was what to do with small errors in data entry, who corrects them, the registries or registrants? After some discussion this was perceived as an issue that has to be resolved by each of the registries themselves.
- There were still issues with data entry format standards that ICTRP is still struggling with and registries were encouraged to comply with the standards of ICTRP to enhance the possibility to use and analyse the data.
- Existing software for automated protocol data entry (SEPTRE) was described by Prof An-Wen Chan and registries were encouraged to test it.
- There was a long discussion on Deduplication and how useful is the UTN number? Can the current bridging system be improved to link different registry entries and develop unambiguous lists of unique clinical trials? Mandatory use of the UTN may be useful for multi-country studies. Who will do the quality check? There was a general consensus not to change the UTN for now and keep it as a secondary trial number. It was noted that the UTN may fulfil a broader function than for registration alone: it may allow for trial lists to request a UTN not at the stage of registration, but at the stage of protocol development, by giving the protocol a Unique Trial Number. This would expand the potential use and relevance of the UTN and allow for it to be a unique identifier across all 'threaded documents' that follow after the protocol.
- There was a request to improve the download function of ICTRP and Create an XML bulk download. The ICTRP Secretariat will follow up on this and improvements will be implemented in 2016.
- Concerns were raised about the raw data download function of the ICTRP. It was noted that it is important that the data on the ICTRP are available for download, but some noted this currently does not function well. Not all registries allow downloading data in raw format at the moment; all agreed that raw data downloads should be available free of charge to the public, as this is public information. Some registries encouraged to also make analyses of these data available on the websites (e.g. numbers of trials in certain health areas annually). How to deal with retrospective registration? Some registries flag retrospective registrants in an effort to shame them and discourage them from this malpractice. Registries welcome and encourage prospective registration.

Other issues discussed

Concerns were raised about implementing expansions to the capabilities of registries without specific and sustainable funding. Many registries suggested issuing a statement on the importance of funding at the national level. ICTRP will keep trying to identify partners in order to support registries both in the technical and scientific areas.



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Conclusions/ next steps

After long and fruitful discussions, two main topics were generating a lot of interest on the second day of the meeting and the group felt the discussions should be continued after the meeting. Two working groups were created for that purpose and the interest in being member of the groups were expressed, which is also open for members of absent registry members. ICTRP will moderate the discussions for these two groups by organising phone calls and each group will formulate the TORs and objectives of the group in their first meetings.

1. Working group on next steps for results disclosure and threaded documents, implementing additional data element(s): [Interested members: ISRCTN, ClinicalTrials.gov, ReBec, EUCTR, NTR]. The aim is to formulate suggestions on issues around making protocols, results, participant-level data and other documents related to the trial publicly accessible and for linking these documents to bring it back to the larger network.
2. Working group on clinical trial data quality control: [Interested members: ISRCTN, PACTR, SLCTR, ReBec]. The aim is to review international standards for trial registration & develop separate guidance for observational trials.

The group agreed that it would be useful to meet again on annual basis, pending funding availability, and it was suggested to aim for the same time in November 2016 for the next meeting, the exact date and place to be confirmed. Following the meeting, a social forum for the registries was created under the Yammer platform and registries are encouraged to use it. It is moderated by the ICTRP Secretariat.



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Meeting participants

Name/Contact info (Registries)	Coming from	
Dr Lisa Askie Australian New Zealand Clinical Trials Registry (ANZCTR)	Australia	WebEx / AM
Ms Luiza Rosangela da Silva & Mr Marcelo Alves Brazilian Clinical Trials Registry (ReBec)	Brasilia, Brazil	Yes
Prof Taixiang Wu Chinese Clinical Trial Registry (ChiCTR)	Beijing, China	Yes
Ms Noemie Manent EU Clinical Trials Register (EU-CTR)	EU-UK	Yes
Dr Susanne Jena German Clinical Trials Register (DRKS)	Germany	Yes
Dr Masoud Solaymani-Dodaran Iranian Registry of Clinical Trials (IRCT)	Tehran, Iran	Yes
Ms Helene Faure ISRCTN.org	UK	Yes (day 2 only)
Dr Lotty Hooft The Netherlands National Trial Register (NTR)	The Netherlands	Yes
Ms Elizabeth Pienaar Pan African Clinical Trial Registry (PACTR)	Cape Town, South Africa	Yes
Dr Ashwini de Abrew	Colombo, Sri Lanka	Yes



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Sri Lanka Clinical Trials Registry (SLCTR)		
Dr Kittisak Kulvichit Thai Clinical Trials Register (NCTR)	Bangkok, Thailand	Yes
Dr Deborah Zarin Clinicaltrials.gov	USA	WebEx / PM
Dr Hans Vásquez Peruvian National Institute of Health	Peru	Yes
Prof Arvind Pandey Clinical Trials Registry - India (CTRI)	India	WebEx

Name/Contact info (Advisory group)	Coming from	Confirmed
Prof An-Wen Chan Associate Professor, Dept of Medicine, University of Toronto	Canada	Yes
Dr Ségolène Aymé Emeritus director of research, INSERM	France	Yes

WHO staff	
Dr Ties Boerma IER (Director)	
Mr Ghassan Karam REK/IER	ICTRP
Ms Olga Gkotsopoulou REK/IER (Intern)	ICTRP
Dr Taghreed Adam REK/IER	Research team
Dr Rik Viergever REK/IER	Global Observatory on Research & Development



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Mrs Maria Magdalena Guraiib REK/IER	Global Health Ethics
Mr Philippe Boucher CTS/IER	Global Health Observatory
Mr Rob Terry RCS/TDR	Tropical Diseases Research
Dr Vasee Moorthy IVR/IVB	Vaccines/Emergency R&D
Dr Marie-Charlotte Bouesseau SDS	Service Delivery and Safety
Dr Susan Norris	Guidelines Review Committee

Apologies

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Dr Ida Sim Professor of Medicine, University of California, San Francisco (UFSC)
Prof Arvind Pandey Clinical Trials Registry - India (CTRI)
Dr Prathap Tharyan Director, South Asian Cochrane Centre, Moses Centre for Research & Training in Evidence-Informed Healthcare and Health Policy