Chinese Clinical Trial Registry

A statement of promoting sharing the clinical trial data

The World Health Organization Clinical Trial Registration Platform (WHO ICTRP) published a statement about engaged with multiple initiatives related to data sharing, and supports sharing of health research datasets in August 2015, and the International Committee of Medical Journal Editors (ICMJE) published a proposal about sharing clinical trial data on 20 January 2016. The Chinese Clinical Trial Registry totally agree with them for that these points entirely keeping with our concept of clinical trial transparency we are disseminating and promoting to medical research practice. These points reflecting a highly respect of whole society to those participants of clinical trials who have made and are making their great contribution by bearing risk of themselves, and presenting the medical researchers' strongly social responsibility.

For following the WHO ICTRP and ICMJE's initiative, Chinese Clinical Trial Registry decides to make some requirements in the trial registration from 14 March, 2016, in which, following items are mandatory required:

1. Clinical trial data plan sharing, this includes individual participants data (metadata) and study protocol. If public database platform will not be used, a way will be used for public access should be described.
2. The repository and management of the data. Specify how to deposit the metadata, what database will be used, whether a public management platform will be used or not.
3. How and when will allow public access the individual participant data should be added in the informed consent (refer to an updated model of informed consent on the homepage of ChiCTR).

We propose all medical research ethics committees puts the sharing clinical trial data, clinical trial registration and no biased reporting results together in the fundamental requirement of medical research ethics.

Special statement about IPD sharing:

1. **Sharing IPD should ask for agreement of researcher**

(1) IPD should be able to public sharing, but the date of launching the sharing should be decided by the researcher, which was required no later than 6 months after the study results been published;

(2) ResMan could be a public platform for IPD sharing, please note which is just used to access only but does not provide download of IPD; download IPD should contact the researcher;

(3) IPD sharing has to be approved by ethics committee, and the sharing does not includes any private information of the study participants.

2. About compensated use IPD

Because of coasts are needed for conducting the clinical study and collecting the IPD, if the researcher and/or stockholder of the funding agency require for compensated use IPD, if such requirement is not for purpose of gain benefit and is properly, we consider it's understandable and acceptable. Open IPD for public sharing is the ethics responsibility and obligation of the researchers and organizers of clinical study, we appreciate their contributions for human society, and do not think the properly requirement of compensated use IPD will reduce the value of their contribution.

3. Use of ResMan for sharing IPD is free

We recommend to use ResMan (www.medresman.org) to be the platform of sharing IPD which is a web based electronic data capture, and could be a sharing platform of IPD. Use of ResMan is no charge, please read the notification for detail information: (http://www.chictr.org.cn/uploads/documents/201712/c9e00ca56df94f19aae642770545d501.pdf)