REPORT

The upgraded Clinical Trials Registry India: a summary of changes

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The Clinical Trials Registry-India (CTRI) was launched on July 20, 2007 and since then has grown to become a significant contributor to the global pool of accessible clinical trial data (1). Trial registration in the CTRI is now mandatory. Currently more than 1,800 trials are registered in the CTRI.

An upgraded version of the CTRI software application was launched on March 15, 2011 in order to simplify the trial registration process as well as improve the search facility. In the revised version, the dataset points remain much the same as before; a few sub-points have been added to ease data collection, analysis and retrieval. The major revisions are highlighted below.

Revised CTRI dataset points

The CTRI dataset form is divided into eight parts. Part 1 must be filled first; the remaining may be filled at the convenience of the registrant.

Study type: To enable better categorisation of trials, the dataset point 'study type" captures information regarding whether a trial is observational, interventional or post-marketing surveillance or a BA/BE study. Interventional trials are further expected to be categorised as per a defined list. Trials conducted as part of a postgraduate thesis submission are also recorded.

Site/s of study details: The earlier version of the CTRI did not have an "edit" facility in this section, making site detail modifications an onerous task, particularly for multi-centre trials. An edit facility has been included in the new version.

Name of ethics committee(s) and approval status: Two major revisions have been incorporated in this section. Ethics approval (and Drugs Controller General of India approval) documents are to be uploaded from the dataset form. The uploaded documents will, however, not be available in the public domain. This dataset point also collects information on the type of ethics committee, independent or institutional.

Multi-country global trials: In the earlier version of the CTRI, for multi-country trials, information regarding the Indian target sample size, date of first enrollment and status of recruitment was recorded in the Brief Summary. In the revised version of the CTRI, this information is captured in the main dataset form alongside the global information, in separate dedicated text boxes.

A separate field has been added for recording publication details that arise directly out of the trial.

Trial submission

In the earlier version of the CTRI, a trial could be submitted to the CTRI for review upon filling certain mandatory fields. However, in the revised version, a trial is not submitted unless all dataset points have been filled. This feature has been introduced to ensure that complete trial information is recorded.

Review process

Unlike the earlier version, in which an entire trial was reverted to the Edit Mode, in the revised version, only the dataset points which need clarifications or modifications are modifiable, while the others are locked for editing to avoid the need for re-scrutiny of all dataset points.

Flagging of trials

In the revised version of the CTRI, upon registration, trials are immediately flagged according to the date of trial registration i.e. "retrospective" or "prospective" registration. "Prospective registration" indicates that the trial is registered before the enrollment of the first patient in India. "Retrospective registration" indicates that the trial is registered after the enrollment of the first patient in India.

Audit trail

On registration, a trial is expected to be regularly updated. In the revised version, these updates have been brought into the public domain and are now viewable under "modifications." This feature is expected to further enhance transparency and accountability of clinical trials.

Trial transfer

The need was felt for the option to transfer trials between registrants. In the revised version, it is now possible to transfer a trial from one registrant to another, within a company or between companies, upon submission of the appropriate authorisation documents.

Conclusion

The registration of trials in CTRI is online and free. Key information of registered clinical trials is freely searchable from the CTRI site. The revised and upgraded version of the CTRI software is designed to simplify the trial registration process as well as improve data retrieval. It is hoped that the information available in the CTRI / database will be used by patients, social activists, parliamentarians, healthcare professionals, the pharmaceutical industry, and healthcare policy makers.

Reference

1. Pandey A, Aggarwal AR, Seth SD, Maulik, M, Juneja A. Strengthening ethics in clinical research. *Indian J Med Res*. 2011 Mar; 133(3):339-40.