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The ClinicalTrials.gov Results Database

TO THE EDITOR: Zarin et al. (March 3 issue)¹ provide an update on ClinicalTrials.gov, currently the only publicly available database reporting trial results; it should be used in systematic reviews and meta-analyses. Of the researchers who wrote more than 12,000 such reviews and meta-analyses published and indexed in PubMed between 2009 and 2010, less than 2% reported using ClinicalTrials.gov to search for unpublished data.² The scarce utilization suggests the scientific community is not sufficiently aware of ClinicalTrials.gov or else struggles with implementation of this key resource for synthesis of research.

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No potential conflict of interest relevant to this letter was reported.

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TO THE EDITOR: We report an experience with ClinicalTrials.gov and our international randomized, controlled trial CHIPS (Control of Hypertension In Pregnancy Study). CHIPS is funded by the Canadian Institutes of Health Research, which mandates registration and assignment of an International Standard Randomised Controlled Trial Number (ISRCTN) (no. 71416914). However, one of our active international sites discovered that CHIPS had been registered on ClinicalTrials.gov by another interested (but not active) site. The

ClinicalTrials.gov entry contained many factual errors. Although we have now overridden this submission, is there a mechanism to prevent duplicate and inaccurate registration?

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TO THE EDITOR: There are considerable disincentives to the reporting requirement in ClinicalTrials.gov. Three examples include the fact that all data entry has to be performed manually rather than being uploaded with the use of commonly used software programs and formats such as Microsoft Word, Adobe Portable Document Format (PDF), Microsoft Excel, or SAS statistical software. Another problem is that the different measures of “dispersion” (e.g., standard error, standard deviation, 95% confidence interval, and interquartile range) within studies add complexity to data entry in various tables. Finally, the space allotted to specific sections (e.g., statistical analysis) is insufficient.

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TO THE EDITOR: ClinicalTrials.gov has important quality-control measures to prevent information in registered records from being omitted, incomplete, incorrect, or uninformative. Unfortunately,

the quality of registered trial data across registries remains a problem. Using one of the criteria proposed by Zarin et al., we identified “internal inconsistency” as a problem in about 9% of records in the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) search portal.¹ In the records for these trials, multiple descriptors that are not compatible — such as “single-group” and “controlled or randomized”; “open-label” and “blinded”; and “double-blinded without subject or investigator blinding” — were used.

The ICTRP has now established International Standards for Clinical Trial Registries, which set a minimum requirement for quality-control processes performed and data recording practices used by individual registries. The intention is to implement these minimum standards and monitor compliance by registries in the WHO Registry Network to ultimately achieve the recording of more complete and meaningful clinical-trial information.

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Dr. Gherzi reports being the team leader of the International Clinical Trials Registry Platform of the World Health Organization. No other potential conflict of interest relevant to this letter was reported.

1. Viergever RF, Gherzi D. The quality of registration of clinical trials. *PLoS ONE* 2011;6(2):e14701.

THE AUTHORS REPLY: We agree with Wyler von Ballmoos and Oliveira that ClinicalTrials.gov is an important resource for systematic reviewers as well as for anybody else (e.g., members of institutional review boards) who seeks the complete evidence base on a given topic. Since the results of many clinical trials remain unpublished,¹ even years after completion, it is clear that a literature search alone will not result in a complete picture of the evidence.

Magee and Menzies raise the issue of duplicate and inaccurate registrations. We previously addressed the importance of preventing duplicate registrations and ensuring the accuracy of reg-

istrations.² To prevent unintended duplicate registrations, the sponsor, study sites, and all relevant parties must identify the one person who will be responsible for trial-registration and related reporting activities; that person would be designated as the responsible party in ClinicalTrials.gov. Individual study-site investigators should not register their study unless they serve as the responsible party for the overall trial. If a study must be submitted to multiple registries (e.g., to comply with regional policies), we ask that the NCT number and other registry identifiers be listed in all registrations to allow for the identification of (intentional) duplicate records. Regarding inaccuracies, although our staff manually reviews each record, certain factual errors cannot be detected without access to the study data. It is essential that the responsible party has the necessary expertise to submit accurate and informative data.

Camilleri notes that ClinicalTrials.gov does not allow for the uploading of data in formats used by popular software platforms. However, ClinicalTrials.gov does support the uploading of data in the Extensible Markup Language (XML) format, a standard method of encoding information in an unambiguous machine-readable structure — unlike the data-file formats mentioned by Camilleri. Without the structured numeric entries afforded by the XML format, it would not be possible for the ClinicalTrials.gov system to perform automated validation of entries or to provide consistent displays of data.

We agree with Viergever and Gherzi that registries must implement quality-control measures. However, the quality of entries will always be dependent on the diligence and integrity of the person entering the data.

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Since publication of their article, the authors report no further potential conflict of interest.

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