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Shortage of quality assurance data fields for investigational medicinal products in major clinical trial registries

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Background:
Medicines marketed in developing countries are worryingly of poor quality as suggested by 64% rate of substandard quality antimalarials in Africa. As potential source for investigational medicinal products (IMPs), marketed medicines of poor quality are probably used in clinical trials. Nevertheless, IMPs seem to have been exempted from quality compliance issues until publications of two product quality defects in clinical trials.
By regulation, study sponsors must assure the quality of IMPs and describe quality measures taken in a clinical trial protocol. We reviewed study protocols of major Clinical Trial Registries (CTR) to assess quality assurance data availability for IMPs.

Methods:
Two independent reviewers screened English versions of CTRs of ICH and WHO platforms by using a checklist. Data was collected on "brand name", "manufacturer", "regulatory" "approval", "approving authority", "Good Manufacture Practices", and "quality testing". In case of discrepancy in assessment of the two reviewers, consensus was sought. The collected data was analysed in a spreadsheet.

Results:
Nineteen CTRs were screened, accordingly. Nine and 5 of these CTRs belonged to WHO and ICH, respectively, while the remaining 5 were part of both platforms. All CTRs had an "intervention" field. But the Canadian CTR used "drug name" rather than "intervention". Three CTRs, namely that of EU, Peru, and UK BioMed Central, had fields for "brand name". Only the EU-CTR had fields for "manufacturer name", "product approval", and "approving authority". Of all CTRs, data fields were available neither on "good manufacturing practices" nor on "quality testing".

Conclusions:
This study demonstrates a shortage of quality assurance fields at CTRs and contrasts the product quality requirements of WHO and ICH clinical trial guidelines. The results show that the clinical trial regulations regarding IMP quality are not implemented. Considering the implications for clinical trial data validity and the safety of study participants, the gap of IMP quality assurance should be bridged by including fields on "brand name", "manufacturer", "GMP", "product approval", "approving authority", and "quality testing" at CTRs. To that end, WHO and International Committee of Medical Journals Editors guidelines on clinical trial registration should be adjusted. Until this is done, EU-CTR should be favoured.