OC - (8469) - REVIEWING INVESTIGATIONAL PRODUCT’S QUALITY ASSURANCE DOCUMENTATION IN MAJOR CLINICAL TRIAL REGISTRIES FOR POST-MARKETING CLINICAL TRIAL STUDIES

Doua, Joachim (Belgium)\textsuperscript{1,2}; Dominicus, Hanneke (Netherlands)\textsuperscript{1,3}

1 - Consortium for African Regulatory Expertise Development (CARED), Voorburg, The Netherlands; 2 - Benelux Pharmacovigilance Office, Global Medical Organization, Johnson&Johnson; 3 - Dominicus Medicus Consultancy, Voorburg, The Netherlands

BACKGROUND
The proven worrisome quality of medicines marketed in developing countries also affects clinical trials (CTs) as they may be used as Investigational Medicinal Products (IMPs). By regulation, CT sponsors should assure IMP’s quality and describe their quality measures in CT protocols that should be registered in a CT Registry (CTR). To check compliance with this regulation, we reviewed major CTRs to assess the availabilities of data fields on IMP quality for post-marketing CTs.

METHODS
Two reviewers independently assessed English versions of CTRs of International Committee of Medical Journal Editors (ICJME) and WHO platforms in July 2017. Each CTR was checked on availability of data fields on: brand name; manufacturer’s name; regulatory approval status; approving regulator; manufacturer’s compliance with Good Manufacturing Practices (cGMP); and quality testing (IMP appearance, impurities, microbial contamination, dosing). In case of discrepancy, consensus was sought.

RESULTS
Of 19 CTRs identified, 8 and 6 belonged to WHO and ICMJE, respectively, and 5 were equally part of both platforms. All CTRs had an “intervention” data field to capture data on IMPs and IMP comparators. Unlike all others, the Canadian CTR used “drug name” rather than “intervention”. Only the EU CTR had data fields for “manufacturer’s name”, “product approval status”, and “approving authority”. None of the CTRs had data fields on “cGMP” or “quality testing”.

CONCLUSION
None of the CTRs of ICMJE and ICTRP has adequate data fields to establish that the source of post-marketing IMPs is of assured quality. This is astonishing given the extensive requirements in WHO and ICMJE guidelines. The gap of quality assurance fields should be bridged by adding them to CTRs. Specifically, IMP quality testing should be conducted before, during, and after clinical trial completion. Until adoption of these measures, EU-CTR should be favored for registration of CTs conducted in developing countries.