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| Title (in title case) | Planning Phase 3 Clinical Trials More Efficiently Using An Evidence-Mapping Approach |
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| Abstract (do not indent; must include OBJECTIVES, METHODS, RESULTS, CONCLUSION unless a Conceptual Papers submission) Abstract has a 300 maximum word count | OBJECTIVES: For a new technology to be accurately compared directly and indirectly to standard care, it needs to have compatible comparators and outcomes to enable a network meta-analysis (NMA) to be conducted. We propose an efficient and accurate method of determining an existing network using data from abstracts only, to assist in planning a phase 3 clinical trial. METHODS: A recent systematic literature review (SLR) with NMA comparing efficacy and safety of two antiretroviral therapies for HIV was used as the gold standard. Using an Evidence Mapper tool (www.evidencemapper.co.uk), abstracts from the 206 studies included in the SLR were indexed by fields including each comparison, trial name and reported outcomes. A network-feasibility tool assessed the possibility of creating a connected network for a hypothetical new drug that would include efavirenz as a key comparator. RESULTS: The Mapper allowed an easy determination of the most commonly assessed interventions and outcomes per trial. Viral suppression at 48 and 96 weeks, CD4 cell count at 48 and 96 weeks, discontinuations and treatment-related adverse event rates were the most commonly reported outcomes. The Mapper sensitivity for predicting the network for these outcomes was 73% to 100% and specificity was 50% to 100%. For a new technology to be compared indirectly to efavirenz for the six most common outcomes, its trial comparator could be atazanavir/ritonavir, doravirine, darunavir/ritonavir, dolutegravir, lopinavir/ritonavir, nevirapine, raltegravir or rilpivirine. However, the strongest network for these outcomes would exist where raltegravir, rilpivirine or dolutegravir were the direct comparators for the new drug. CONCLUSIONS: A network of high accuracy was created for common outcomes using data indexed only from abstracts of relevant publications. This method can be used to efficiently plan a phase 3 clinical trial to best support direct and indirect comparisons with the most important existing technologies. |