The number of Indian trials registered with the European Union Clinical Trial Register: Identifying discrepancies in the results by different search methodologies

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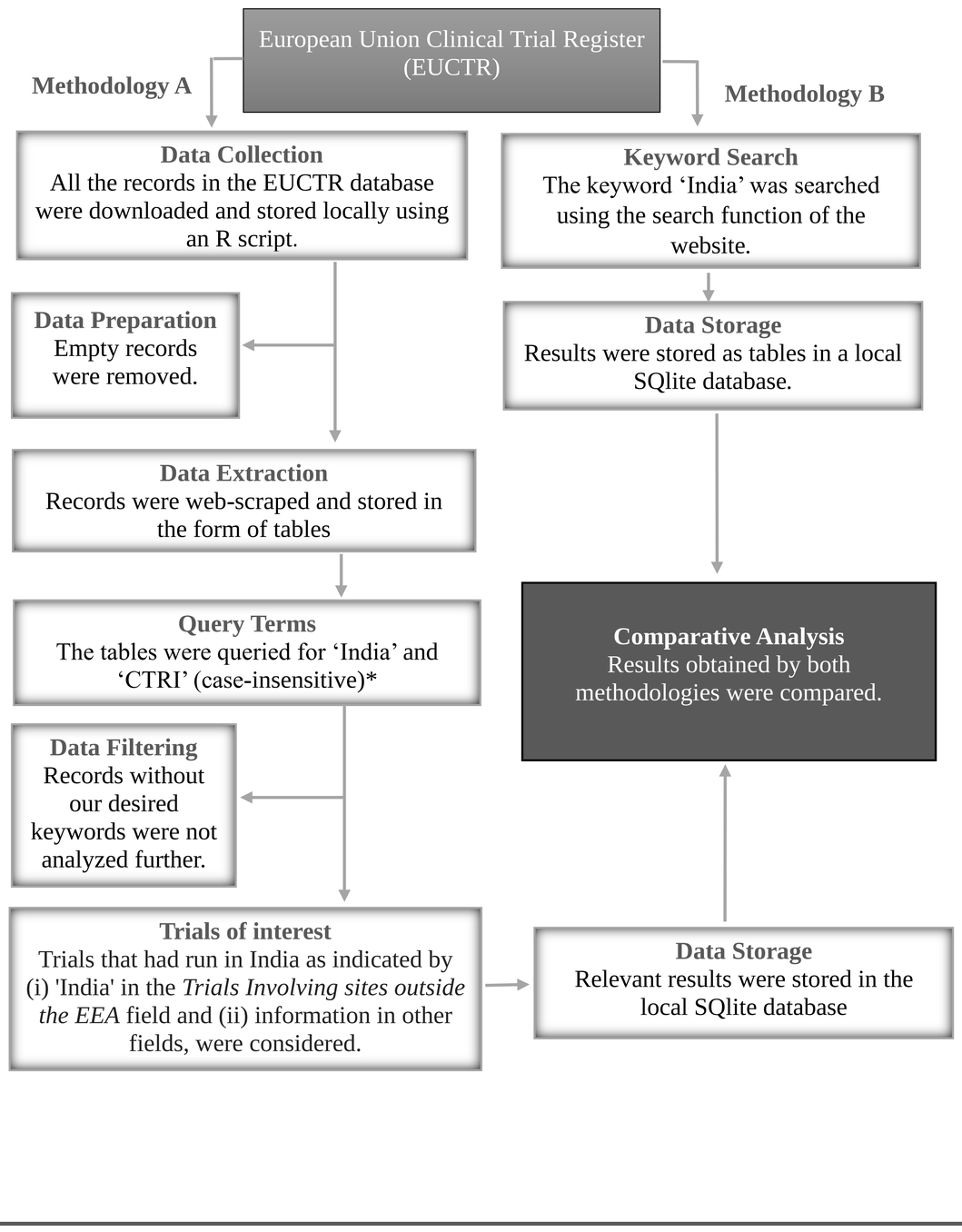
ABSTRACT

For a government to keep track of certain biomedical innovations, it must be able to identify the clinical trials that have run in the country. Clinical trial registries are databases that play an important role in keeping track of trials. The data in these registries serve many purposes such as empowering patients and public with information about ongoing trials, and helping to identify gaps in the research enterprise. There are various reasons why clinical trials must be monitored, such as (i) trials whose results are not made public could lead to research waste [1], and (ii) trials that are published only if the results are positive leads to a bias in the evidence base [2]. Therefore, these registries must be designed in a user-friendly manner, must yield correct search results and must provide up-to-date, accurate and comprehensive data [3]. We are based in India and are interested in the trials run locally. In order to determine what steps need to be taken in order to identify every trial run in India, in other work (next poster) we identified the trials that were registered in other non-Indian registries. However, the European Union Clinical Trials Register (EUCTR) is complex, as a given trial might have run in different countries of the EU and therefore a given trial ID might have multiple records. In this work we have determined the steps that it takes to identify all the trials run in India that are registered with EUCTR.

OBJECTIVE

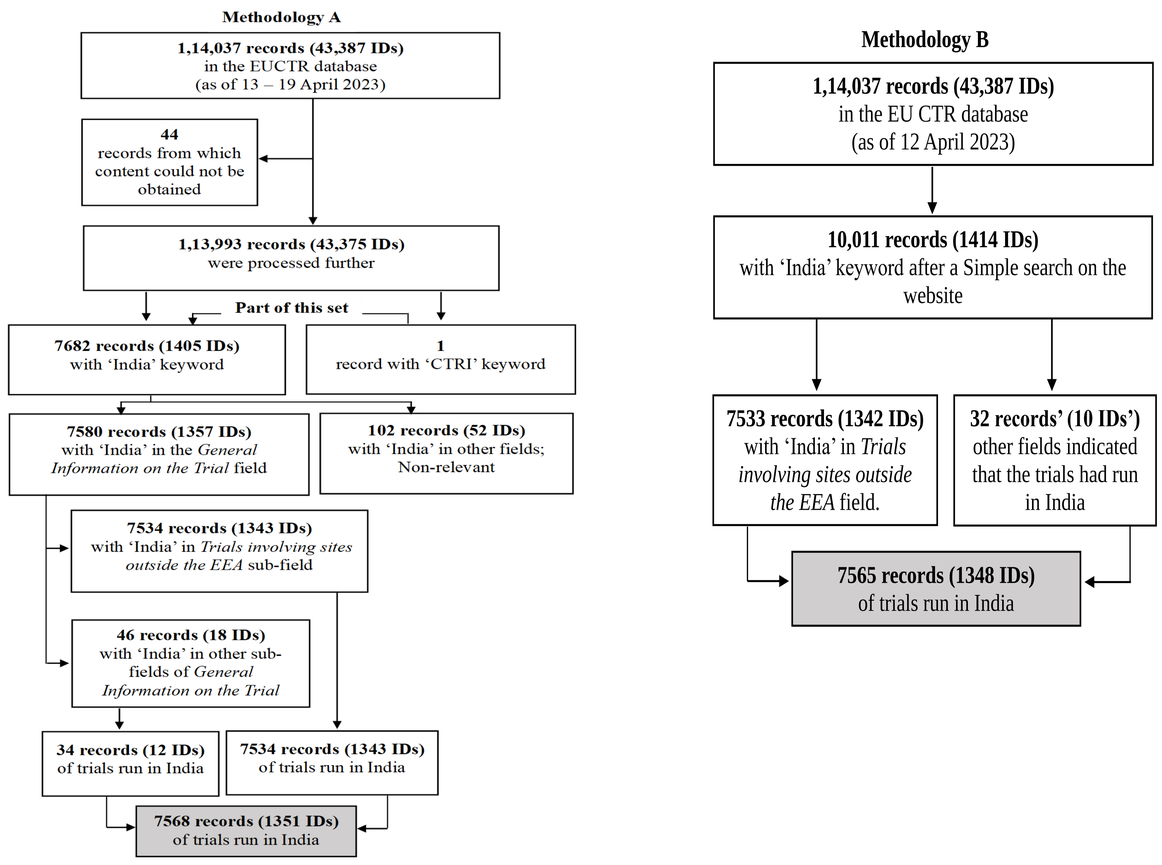
To determine the number of trials conducted in India, and registered with EU-CTR.

METHODOLOGY

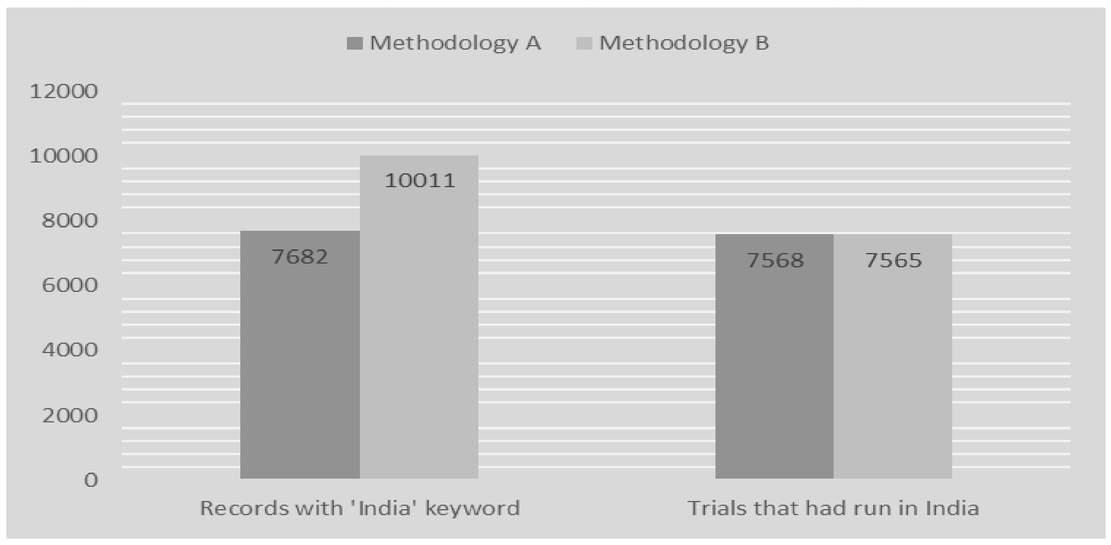


RESULTS

The flowcharts below present a concise summary of the results obtained from both methodologies.



Discrepancies in the results obtained by both the methodologies are shown in the bar graph below.



DISCUSSION

The aim of our study was to identify possible discrepancies between the number of records retrieved through two search methods, indicating potential limitations in the search function of the EU Clinical Trial Register (EUCTR) website. The absence of an 'advanced search' option prevents researchers from conducting precise searches, potentially resulting in the omission of relevant records. We have two major findings: (i) the number of trials identified as having being conducted in India were largely similar across both search methods (7534 and 7533 by Methodologies A and B respectively). (ii) However, we found that in some cases (34 and 32 cases respectively), India was not listed in the countries of recruitment although information in fields such as *Principal Inclusion Criteria, Principal Exclusion Criteria, and Primary end point(s)* indicated that the trials had run in India. Whereas the first result indicates that a 'simple search' of EUCTR is likely to provide an accurate representation of the trials conducted in India, the second result contradicts this. The second result in particular, highlights the importance of maintaining accurate and up-to-date records throughout the lifecycle of the clinical trial. It also serves as a reminder of the need for continuous monitoring and updating of trial records. This study highlights the need for further improvement in the search capabilities of the new EU website, to enhance the accuracy and comprehensiveness of the data available to researchers. Our findings contribute to the ongoing discussions surrounding clinical trial transparency and data accessibility, geared towards fostering a more robust research environment for evidence-based healthcare decision making [3].

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*CTRI: Trials registered with numbers indicating registration in Clinical Trials Registry-India

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