Are data reviews or exempt research excluded from registration and results reporting?

Because data reviews are retrospective and largely observational in nature and, in general, exempt research studies are not controlled clinical trials, nor involving an FDA-regulated intervention, they would not need to be registered or reported on ClinicalTrials.gov.

However, the ICJME may have a different opinion if exempt research involves any of the following:

- Drugs;
- surgical procedures;
- devices;
- behavioral treatments;
- dietary interventions;
- process-of-care change.
- biomedical or health-related measures including pharmacokinetic measures and adverse events.

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Source URL:https://www.researchgo.ucla.edu/are-data-reviews-or-exempt-research-excluded-registration-and-results-reporting

Drupal.jQueryUiFilter.globalOptions('accordion');