Adapted Targeted Literature Review (ATLR) for Landscaping Trends in Pregnancy Post Authorization Safety Studies (PASS)

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Background

- Pregnant women are often excluded from clinical trials, thus limited to no data on drug safety is available for this population.
- Post approval safety studies (PASS) try to bridge this gap by offering valuable insights for clinical practice and contribute to informative product labeling.
- In 2019, the FDA and EMA produced specific guidelines for pregnancy PASS requiring robust data collection and analysis methods utilizing a wider range of data sources.
- Over the last decade, there has been an increasing number of PASS in secondary databases to evaluate real-world safety in pregnant women.

Objectives

This ATLR aimed to identify the number of published pregnancy PASS over the past 10 years that specifically leverage secondary data study designs and methods, describe the utilized data sources and their time of publication.

Methods

ATLR search algorithm:

In June 2024 the following databases were searched with a combination of indexing terms and free-text keywords specific to pregnancy PASS using secondary data sources between January 2014 and June 2024:

MEDLINE, CINAHL (via Ebscohost)	HMA-EMA, clinicaltrials.gov (CTG)
Published reports of completed studies	Published protocols

Results were ordered by recency and duplicates were removed.

ATLR screening and extraction:

Titles and abstracts from the search output were screened manually to include those answering to the following criteria:

- Population: pregnant or lactating women, AND
- Interventions: any, AND
- Study context: post-authorization safety study OR post approval safety study, AND
- Study design: observational studies where there is a retrospective analysis of data.

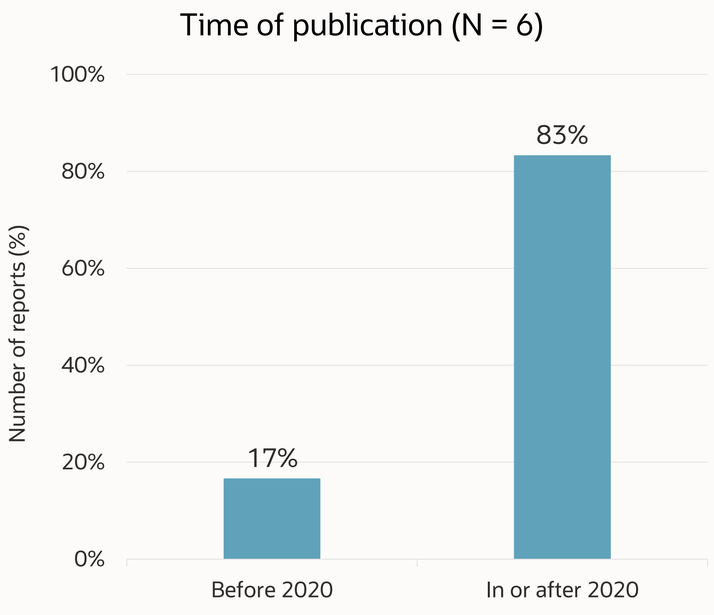
Data were extracted regarding publication date and data source(s) utilized.

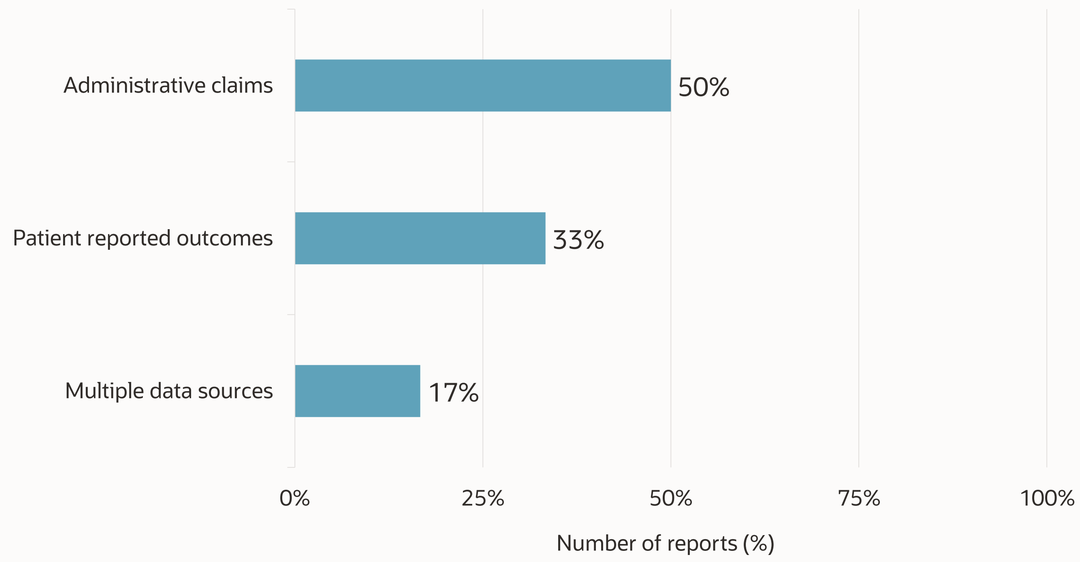
Results

Published reports

Search output: 18 reports

Included reports: 33% (N = 6)



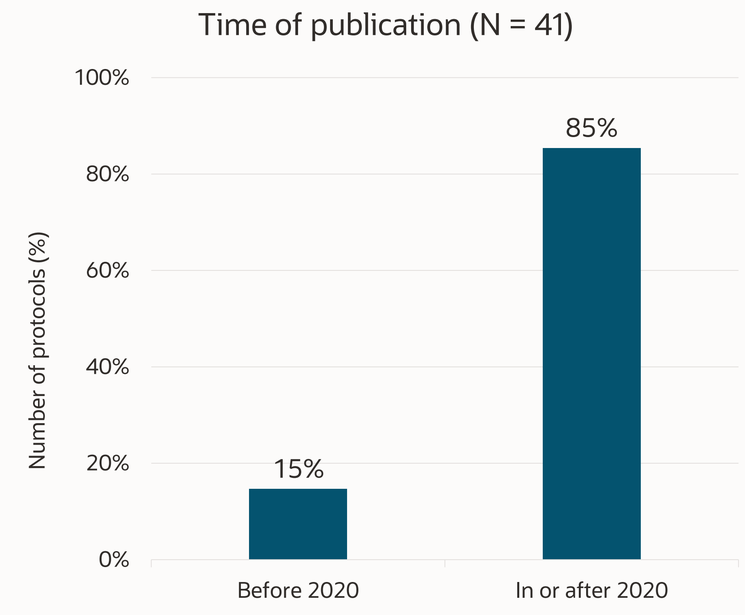


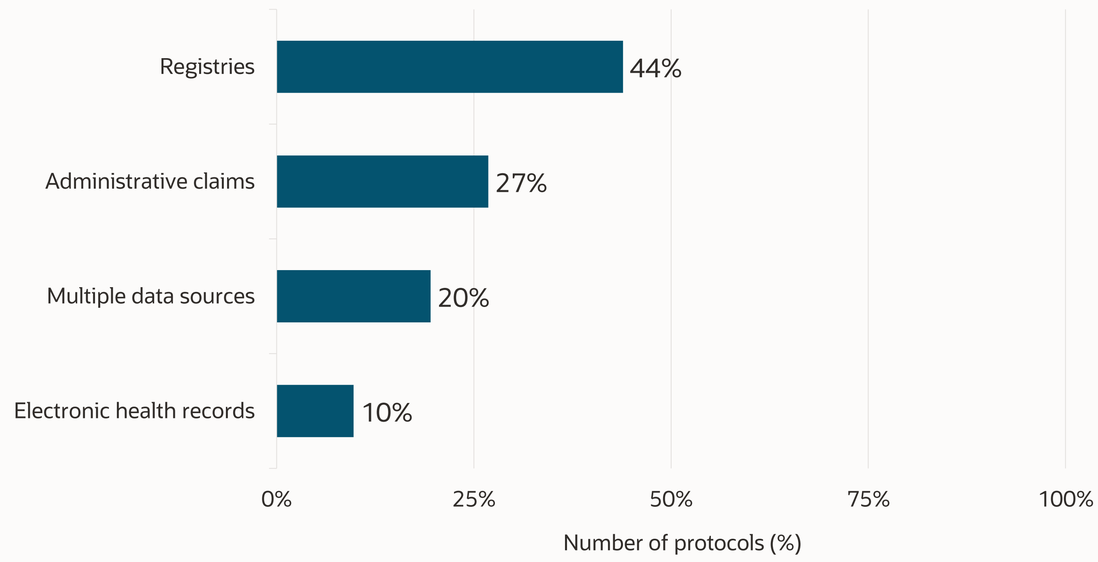
Published protocols

Search output: 1645 protocols

CTG: 45% (N = 746) from HMA-EMA: 55% (N = 899)

Included protocols: 2% (N = 41)





Conclusion

We identified few published completed reports of pregnancy PASS based in secondary data.

Both the number of published reports and protocols based in secondary data (particularly administrative claims and registries) increased after 2020.

There is increasing recognition of the role that real-world secondary data can play in evaluating drug safety during pregnancy.

Reference

Lopez-Leon et al., Drug Utilization Studies in Pregnant Women for Newly Licensed Medicinal Products: A Contribution from IMI ConcePTION, Journal of Pregnancy, 2024, 8862801, 13 pages, 2024. https://doi.org/10.1155/2024/8862801

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