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Commentary

Improving data harmonization in pregnancy safety studies: Demonstrating the feasibility of standardized data analysis of pregnancy reports–A contribution from the conception project

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Abstract

Introduction: Aligned with the Innovative Medicines Initiative (IMI) ConcePTION project's goal of advancing drug safety research in pregnancy, we explored the feasibility of employing a standardized list of core data elements (CDEs) and statistical outputs to harmonize data collection and analysis across various study partners.

Methods: Study partners from public research institutions and pharmaceutical companies extracted pregnancy safety data on disease-modifying therapies for multiple sclerosis from their databases, mapped them to the CDE framework, and analysed datasets using a common statistical analysis plan (SAP). Questionnaires were used to gather contextual information on data collection practices, including data definitions and infant follow-up, and to evaluate the feasibility and practicality of the proposed methodology.

Results: The study demonstrated the feasibility of harmonizing pregnancy safety data using standardized CDEs and a common SAP. All six study partners successfully mapped their data into the CDE framework and produced standardized outputs. Challenges were identified in aligning with recommended definitions, such as classifying 'prospective cases' based on differing criteria—pregnancies reported while ongoing, before fetal malformation diagnosis, or before any prenatal screening—and categorizing congenital anomalies using the EUROCAT system. The feasibility questionnaires revealed strong support for the methodology, with all six study partners reporting access to the necessary expertise and all six finding the statistical guidance easy to follow.

Conclusions: This study demonstrates the feasibility of employing standardized CDEs and a common SAP to describe pregnancy exposure and outcome data across diverse data providers. The methodology shows promise for improving consistency in pregnancy safety research but requires addressing challenges such as resource constraints and variability in data collection for broader adoption.

Keywords: Feasibility, Pregnancy pharmacovigilance, Teratogen surveillance, Medicines, Pregnancy

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Introduction

Medication use during pregnancy often raises concerns for both women and their healthcare providers. Studies indicate that 50% to 81% of pregnant women report using at least one medication during pregnancy [1,2]. Pregnancy safety studies are essential for evaluating maternal and fetal risks; however, fragmented and independently operating primary data collection systems limit the ability to gather sufficient exposure data, slowing the process of conducting rapid and reliable analyses. Although sufficient safety data likely exist across these systems, differences in data granularity and the absence of standardized definitions create challenges for interoperability and meaningful comparisons.

The Innovative Medicines Initiative (IMI) ConcePTION project aims to address these barriers by improving methodologies for studying drug safety during pregnancy, with a key focus on standardizing data collection and analysis [3]. A central component of this project is the development of a reference framework of core data elements (CDEs) and a statistical analysis plan (SAP). These tools provide a structured approach to harmonize pregnancy safety data from diverse sources, enhancing the potential for meta-analyses and comparative evaluations [4]. The ConcePTION CDE framework for primary data collection is openly available through the European Network of Teratology Information Services (ENTIS) (http://www.entis-org.eu/cde) and the ConcePTION website (https://www.imi-conception.eu/results/core-data-elements/) [5].

This publication is part of a larger demonstration study conducted within the IMI ConcePTION project [5], which builds on previous work assessing the feasibility of mapping data variables from participating data access providers (DAPs) to the CDE framework [6]. Here, we evaluate the feasibility of implementing the CDE framework, analyzing data using the SAP, and assessing whether data collection centers have the resources to independently conduct similar studies on a routine basis.

Methods

Data source

Data for this study were provided by public institutions and pharmaceutical companies, which collected or captured pregnancy safety data on disease-modifying therapies for multiple sclerosis (MS). The focus on MS therapies was chosen because these drugs are covered by several disease-specific and product-specific pregnancy registries.

A description of these DAPs has been previously published and includes pregnancy exposure registries, enhanced pharmacovigilance programs, and Teratology Information Services (TIS) [6].

Participating DAPs were:

A. Pregnancy Registries: Gilenya pregnancy registry (fingolimod, Novartis; global), Teriflunomide pregnancy registry (Aubagio, Sanofi; Europe and Australia) EUPAS5602, Teriflunomide OTIS pregnancy registry (Aubagio, Sanofi via the Organization of Teratology Information Specialists [OTIS]; United States and Canada) NCT03198351; EUPAS17065.

B. Enhanced Pharmacovigilance Programs: Gilenya PRegnancy outcomes Intensive Monitoring (PRIM; Novartis; global), Worldwide Pregnancy Surveillance Program of oral Cladribine (MAPLE-MS; Merck Healthcare KGaA; global).

C. The ENTIS consortium provided data on the following medications for which a minimum of 10 cases with known pregnancy outcomes were available: dimethylfumarate, fingolimod, glatiramer acetate, interferon beta-1a, interferon beta-1b, and natalizumab. The Teratology Information Services (TIS) involved included the European Network of Teratology Information Services (ENTIS) consortium, comprising Jerusalem TIS (Israel), Swiss TIS (Switzerland), UK TIS (United Kingdom), Zerifin TIS (Israel).

Study design and data processing

This study focuses on DAPs that utilize primary data collection methodologies, where data are gathered directly from pregnant women or their healthcare providers using bespoke data collection tools. For this study, each DAP extracted pregnancy safety data from their respective databases and recoded study variables as necessary to align their data with the definitions provided in the CDE framework [6]. The mapped datasets were then analyzed locally using a common SAP, which provided detailed guidance on analysis conventions and presentation of results. The SAP required DAPs to produce summary tables covering essential information on pregnancies, maternal characteristics, and pregnancy outcomes for the medications being studied.

Patient-level data remained internal to each organization, with only aggregate data shared through a secure portal on the Data Research Environment (DRE) platform (Azure DRE; anDREa consortium (andrea-cloud.eu)). To support the DAPs, an organizational team with diverse expertise (GF, MSt and UW) facilitated regular discussions on data mapping, analysis strategies, and other methodological considerations. This team ensured open communication and was available to address queries or provide clarifications.

Assessment of data alignment and feasibility

In the earlier phase of the demonstration study, DAPs were evaluated on their ability to align collected data with CDE definitions, assessing 51 specific items from the CDE framework recommendations to determine whether each item could be directly matched, derived, divergent, or unavailable [6]. This background assessment provided context for understanding data compatibility with the CDE framework. Building on this, two questionnaires were administered in the later phase of the study to assess feasibility. The first collected detailed information on how each DAP applied the CDE framework. The first questionnaire included specific questions to explore two key CDE elements: the definition of prospective pregnancies and the classification of congenital malformations. During the development of the CDE framework, several definitions of a prospective pregnancy were identified. Briefly, these included a simple definition of a prospective pregnancy (pregnancies reported to the data collection system while the patient was still pregnant), the European Medicines Agency (EMA) definition (pregnancies reported to the data collection system before any diagnosis of a fetal malformation had been made via prenatal screening), and a true definition of a prospective pregnancy (pregnancies reported to the data collection system while the patient was still pregnant, but before any prenatal screening capable of identifying adverse fetal outcomes had been performed). Given that different data collection systems can use different definitions of prospective pregnancies to determine which cases meet their inclusion criteria, it was important to establish which definition of prospective pregnancy had been utilized by each DAP to assess the feasibility of combining the datasets using the distributed analysis approach. The first questionnaire therefore explored whether the CDE definitions had been used for classifying the prospective status of pregnancies. It also assessed whether EUROCAT guidelines were applied for categorizing congenital malformations and examined how infant follow-up practices were conducted.

After DAPs submitted their analyses, a follow-up questionnaire assessed the perceived practical feasibility and applicability of extending the methodology beyond the scope of IMI ConcePTION. Questions included Likert-scale items (1: strongly disagree to 4: strongly agree) on methodology acceptability, implementation, and resource requirements. Yes/no questions were also included, and participants were encouraged to provide comments to clarify or expand on their answers [7].

Results

All DAPs successfully applied the methodology, analyzed their data according to the SAP, and provided the required summary tables. **Table 1** provides an overview of the number of cases categorized by prospective and retrospective pregnancy statuses across these data sources. There were significant variations in case numbers among different data providers and prospective/retrospective categories, with Gilenya PRIM contributing the highest number of cases.

Variations in definitions and practices across DAPs

Most of the DAP data variables assessed in the earlier phase of the project aligned with the CDE items and definitions; 85% were directly taken from existing fields, and 12% were derived by combining different variables [6]. For very few of the DAP variables, alignment with the CDE items was not possible, either because the definitions were different from the CDE definition (1%) or because the variables were not collected by the DAPs (2%) [6]. Alignment was consistent across types of data collection methods, with 96% of variables aligned in pregnancy registries, 99% in enhanced pharmacovigilance programs, and 98% in ENTIS centers [6]. One DAP, the Dutch Pregnancy Drug Register, which contributed to the earlier phase, did not provide data for this part of the study due to insufficient data for this focus. The study's emphasis on disease-

Table 1. Number of maternal and fetus exposure reports according to prospective or retrospective status.

		GPR	TPR	TOPR	Gilenya PRIM	MAPLE-MS	ENTIS Consortium*
PROSPECTIVE	**Maternal reports – all**	200	45	18	1399	150	247
	Maternal reports - Pregnancy outcome known	184	40	13	705	49	156
	Fetal reports – all	202	48	18	1424	49	247
	Fetal reports - Fetal outcome known	187	41	12	722	49	156
RETROSPECTIVE	**Maternal reports – all**	94	0	2	594	30	0
	Maternal reports - Pregnancy outcome known	89	-	2	582	27	-
	Fetal reports – all	95	-	2	599	27	-
	Fetal reports - Fetal outcome known	89	-	2	575	27	-

GPR: Novartis Gilenya Pregnancy Registry; TPR: Teriflunomide Pregnancy Registry; TOPR: Teriflunomide OTIS Pregnancy Registry; Gilenya PRIM: Novartis Gilenya Pregnancy outcomes Intensive Monitoring; MAPLE-MS: Worldwide pregnancy surveillance program of oral cladribine; ENTIS consortium: European Network of Teratology Information Service consortium (Swiss TIS, UK TIS, Zerifin TIS, Jerusalem TIS); * the numbers presented for the ENTIS consortium include data for multiple medications (dimethylfumarate, fingolimod, glatiramer acetate, interferon beta-1a, interferon beta-1b, and natalizumab).

The categorization of cases as "prospective" or "retrospective" was based on the definitions used by each DAP.

Pregnancy outcomes considered: live birth, spontaneous abortion, stillbirth, elective termination, termination of pregnancy for fetal anomaly

modifying therapies for MS was based on the availability of disease-specific and product-specific pregnancy registries, particularly for drugs marketed by EFPIA partners. This focus was chosen to demonstrate the feasibility of aligning datasets for this project.

While the overall alignment with CDE recommendations was high, some variations were observed in the definitions and practices among DAPs. For instance, three DAPs adhered to the recommended 'simple prospective' definition, while three others applied the 'EMA prospective definition' (**Table 2**). The categorization of congenital malformation cases also showed divergence: the Gilenya Pregnancy Registry categorized cases into 'major', 'minor', 'not otherwise specified' or 'chromosomal/mendelian anomaly/genetic disorder', without applying the initial step outlined in the CDE guidance to classify cases into genetic and non-genetic categories. The Teriflunomide OTIS Pregnancy Registry used the Metropolitan Atlanta Congenital Defects Program (MACDP) coding system, which classifies malformations as 'major,' 'functional' (not included in the CDE), or 'not counted', and excluded 'minor malformations' from the dataset. All the DAPs conducted infant follow-ups until 9 to 12 months after birth (MAPLE-MS only when congenital anomaly was suspected/confirmed), with some extending the follow-up period to 2 years, involving a range of 1-4 follow-up assessments.

Feasibility assessment

All DAPs unanimously supported the acceptability, implementation, and practicality of the standardization steps proposed by ConcePTION to enhance comparability of study results (**Table 3**). They also acknowledged that, in the context of this demonstration study, resources on-site were available, with access to

Table 2. Comparative assessment of prospective status definition, malformation classification, and infant follow-up in different DAPs.

	GPR	TPR	TOPR	Gilenya PRIM	MAPLE-MS	ENTIS Consortium
Did the DAP use the CDE definition of "simple prospective" in classifying pregnancy cases? (yes/no)	Yes	No	No	No	Yes	Yes
If no, what other definition was used?	Main approach : true prospective	EMA prospective definition	EMA prospective definition	EMA prospective definition	-	-
Were congenital malformation cases categorized according to the guidance in the CDE document? (yes/no)	No	Yes	No	Yes	Yes	Yes
How long does the DAP generally follow up infants within the first year?	1 year	1 year	9 to 15 months	1 year	1 year only if suspected/ confirmed congenital anomaly	2 weeks to 2 years
How often does the DAP generally follow up infants within the first year?	2	4	2	1	2	1

GPR: Novartis Gilenya Pregnancy Registry; TPR: Teriflunomide Pregnancy Registry; TOPR: Teriflunomide OTIS Pregnancy Registry; Gilenya PRIM: Novartis Gilenya Pregnancy outcomes Intensive Monitoring; MAPLE-MS: Worldwide pregnancy surveillance program of oral cladribine; ENTIS consortium: European Network of Teratology Information Service consortium (Swiss TIS, UK TIS, Zerifin TIS, Jerusalem TIS)

Infant follow-up: The data on infant follow-up were compiled by DAPs from reports provided by healthcare providers or directly from parents during follow-up contacts.

Table 3. DAPs views on feasibility of standardizing data analysis and presentation.

	GPR	TPR	TOPR	Gilenya PRIM	MALPLE-MS	ENTIS	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	YES	NO
QUESTION 1 To what extent do you agree or disagree with the statement "In the future, it will be important to include data from other organizations alongside our own pregnancy pharmacovigilance data in an analysis that presents "side by side" results or meta-analysis approach?	STRONGLY AGREE	STRONGLY AGREE	AGREE	STRONGLY AGREE	STRONGLY AGREE	AGREE	4 (66.7%)	2 (33.3%)	0	0	-	-

QUESTION 2 To what extent do you agree or disagree with the statement "In the future, it will be important to compare our own pregnancy pharmacovigilance data with data from other organizations/similar products"?	AGREE	AGREE	STRONGLY AGREE	AGREE	STRONGLY AGREE	AGREE	2 (33.3%)	4 (66.7%)	0	0	-	-
QUESTION 3-a To what extent do you agree or disagree with the statement "This work fits well with our organizational structure"?	AGREE	STRONGLY AGREE	AGREE	AGREE	STRONGLY AGREE	AGREE	2 (33.3%)	4 (66.7%)	0	0	-	-
QUESTION 3.b Did you have access to all expertise skills needed?	Yes	Yes	Yes	Yes	Yes	Yes	-	-	-	-	6 (100%)	0
QUESTION 4.a To what extent do you agree with the following statement: "The instructions provided in the statistical guidance document were easy to follow."	AGREE	STRONGLY AGREE	AGREE	AGREE	AGREE	AGREE	1 (16,7%)	5 (83,3%)	0	0	-	-
QUESTION 4.b Did you need help during the work from someone outside your organization ?	Yes	Yes	No	Yes	Yes	No	-	-	-	-	4 (66,7%)	2 (33,3%)
QUESTION 5 To what extent do you agree with the following statement: "The resources needed to perform this task balance well with my perceived future needs for conducting meta-analysis and/or comparative evaluation.'	AGREE	DISAGREE	AGREE	AGREE	AGREE	AGREE	0	5 (83,3%)	1 (16,7%)	0	-	-

necessary expertise and skills. However, one DAP, the Teriflunomide Pregnancy Registry, reported that the resources required to implement the same approach outside the demonstration project would likely be insufficient to complete the process. Furthermore, all DAPs reported that the work integrated well within their respective organizational structures and that the instructions in the statistical guidance were easy to follow. All DAPs, except the Teriflunomide Pregnancy Registry, concurred that the required resources for this task aligned effectively with anticipated future needs for conducting meta-analysis and/or comparative evaluations. Comments from the DAP questionnaire highlighted the importance of carefully assessing diverse datasets, considering data collection methods, and addressing potential biases, such as differences in populations, reporters, drug-use regions, and data completeness regarding other potential risk factors. Neglecting these considerations could lead to significant variations and biases in results, making clinical interpretation difficult and limiting or preventing appropriate comparison or meta-analysis of study results. DAPs also emphasized the importance of a dedicated central co-ordination team throughout the process to assist with queries related to definitions, statistics, and structure, and to organize the distributed analysis approach.

Discussion

In this study, we demonstrated the feasibility of implementing our proposed standardization methods across various private and public DAPs, including pregnancy registries, enhanced pharmacovigilance programs, and TIS to report medication exposure in pregnancy and associated outcome data.

Our earlier publication showed a high degree of alignment in data collection variables and definitions across these DAPs [6]. Building on this foundation, the current evaluation focused on the practical aspects and implications of implementing these standardized methods, with a primary emphasis on assessing the feasibility of standardized data analysis. Implementation aligned well with the existing operational frameworks of these DAPs. Furthermore, the guidance provided was well-received. Our method was found to be versatile, demonstrating feasibility when applied to existing datasets while also holding potential value for guiding new data collections. The publicly available CDE and SAP [4] provide a standardized framework to harmonize definitions and streamline the presentation of results. These resources also serve as essential tools for the design and implementation of new pregnancy safety studies, fostering the adoption of standardized methodologies and enhancing consistency in future research efforts. Although our study focused specifically on MS drug exposures during pregnancy, we are confident that if new data collection systems adopt the CDE and SAP frameworks during their design, their data could be seamlessly combined with other datasets using the approach applied here. The principles underlying the standardization methods and the observed feasibility of implementation are broadly applicable and have the potential to extend to other therapeutic domains.

Harmonizing pregnancy exposure and outcome data through standardized definitions and statistical methodologies is influenced by factors such as the data collection setting, definitions of 'prospective cases', and the classification system used for birth defects. These differences can introduce bias, affect the comparability of results across datasets, and influence the robustness of conclusions about drug safety in pregnancy. Key elements of the data collection setting, such as inclusion and exclusion criteria, timing of initial contact, informed consent practices, and the demographic characteristics of the population, are inherent to the initial data collection process and cannot be modified retrospectively. Clear documentation of these characteristics is essential to evaluate sampling bias, dataset compatibility, and the generalizability of combined results. As part of our efforts to improve comparability, we recommend that DAPs classify cases using the CDE definition of 'prospective cases' and adopt the EUROCAT classification for congenital malformations. However, some DAPs experienced challenges in adhering to these recommendations. For example, classifying 'prospective cases' often relied on information recorded in case narratives rather than programmable database fields, complicating recoding efforts. This issue was particularly pronounced in industry-based enhanced pharmacovigilance systems, which are designed around regulatory-mandated fields and lack the flexibility to accommodate alternative data analysis approaches [8]. Additionally, one DAP (the Teriflunomide OTIS Pregnancy Registry) was required to use the MACDP code list instead of the EUROCAT classification. These challenges highlight how variations in definitions and classification systems can influence reported congenital anomaly rates when data are combined from datasets where such variations exist. Careful assessment as to the suitability of combining datasets, whilst considering the potential for the introduction of important methodological biases is recommended before combining data from multiple sources. Establishing a dedicated organizational team to oversee harmonization and ensure alignment in data collection variables and definitions is crucial. Regular engagement with stakeholders, combined with comprehensive support and training, facilitates a shared understanding and refinement of methodologies, thereby enhancing the likelihood of success.

While our study provides valuable insights into the practical application of standardized methods for analyzing pregnancy pharmacovigilance data, several limitations must be acknowledged. Further work is needed to systematically assess and reduce sources of variability across data providers, including improving harmonization of key definitions and classification systems, to strengthen the robustness and comparability of pregnancy safety studies. This study was conducted to investigate the feasibility of combining primary source datasets, and the results should not be assumed to be generalizable to other methods of pregnancy safety data collection (such as secondary-use administrative healthcare datasets, e.g. population-based linked prescription and healthcare records). The significant experience and expertise in pregnancy pharmacovigilance held by the participating DAPs may have positively influenced their ability to adopt the approach.

Conclusion

Despite methodological challenges arising from variations in data collection and storage across DAPs, our approach has shown that diverse datasets can be successfully mapped to a standardized framework of definitions and statistical outputs. By providing the CDE framework and guidance for statistical analysis, our goal is to promote widespread adoption and collaboration among diverse stakeholders engaged in primary-source pregnancy pharmacovigilance studies. These resources are designed to promote harmonization across several key steps involved in the performance of pregnancy pharmacovigilance studies, from the selection of data variables and their definitions to considerations for data storage, analysis, and presentation. The wide-scale adoption of these resources also helps to address the current limitations associated with collecting pregnancy drug safety study data, particularly if applied when new data collections are initiated.

Author Contributions

UW, GF, JLR, A Moore, YG, AO, SS, ODC, MB, A Mor, M Sabidó, EvP, LMY, and M Stellfeld contributed to study conception and design. UW, GF, JLR, A Moore, YG, AO, SS, ODC, MB, TDH, A Mor, M Sabidó, SdS, CC, EvP, LMY, and M Stellfeld contributed to acquisition of data. UW, GF, JLR, and M Stellfeld contributed to data analysis. UW, GF, JLR, A Moore, YG, VJ, AO, SS, ODC, MB, TDH, DB, AP, A Mor, M Sabidó, SdS, CC, EvP, LMY, FG, and M Stellfeld contributed to interpretation of data, and drafting and revising of the manuscript for intellectual content.

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Conflict of Interests

Conflict of interest UW, GF, JLR, AO, SS, ODC, MB, TDH, DB, AP, CC, EvP, and FG declare no conflicts of interest, no other

financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years, and no previous or ongoing relationships or activities that could appear to have influenced the submitted work. A Moore was a Novartis associate whilst working on this manuscript and other aspects of the ConcePTION project and holds shares in Novartis Pharma AG. YG, and VJ are employees of Novartis Pharma AG. M Stellfeld is an employee of Novo Nordisk A/S. M Sabidó and SdS are employees of Merck Healthcare KGaA. LMY received honoraria from Sanofi Genzyme South Africa on two occasions in 2021 for 1. an Advisory Board presentation on genetic testing in Gaucher's disease (April 2021), and 2. a conference lecture on Genetic testing in the cardiac clinic' (September 2021). A Mor is an employee of Sanofi and holds shares in Sanofi.

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