Supplementary Material

Exploratory Signal Detection of Maternal and Perinatal Adverse ART Drug Events in EudraVigilance: Insights from Network and Cluster Analyses

Bárbara Costa [1,2] and Nuno Vale [1,2,3,*]

[1] PerMed Research Group, RISE-Health, Faculty of Medicine, University of Porto, Alameda Professor Hernâni Monteiro, 4200-319 Porto, Portugal; bcosta@med.up.pt
[2] RISE-Health, Department of Community Medicine, Health Information and Decision (MEDCIDS), Faculty of Medicine, University of Porto, Rua Doutor Plácido da Costa, 4200-450 Porto, Portugal
[3] Laboratory of Personalized Medicine, Department of Community Medicine, Health Information and Decision (MEDCIDS), Faculty of Medicine, University of Porto, Rua Doutor Plácido da Costa, 4200-450 Porto, Portugal
* Correspondence: nunovale@med.up.pt; Tel.: +351-22-0426537

Table S1. Top 20 drug–reaction pairs identified in the Pregnancy subgroup. Data are from disproportionality analysis of EudraVigilance reports. Metrics include the observed counts (Observed count = drug–event reports, N_B = reports with the drug but not the event; N_C = reports with the event but not the drug), proportional reporting ratio (PRR with 95% CI), reporting odds ratio (ROR with 95% CI), information component (IC with 95% CI), and the signal flag. Only the top 20 most frequent drug–reaction pairs are shown. Puerperium (n = 11 reports) and Perinatal (n = 146 reports) subgroups had insufficient signals to generate a similar table.

Drug	Reaction	Observed count	N_B	N_C	PRR	ROR	IC
Efavirenz	Drug interaction (n/a - Unknown - Other Medically Important Condition)	23	76	35	14.77	20.82	2.53
Adalimumab	Foetal death (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	22	44	22	637.00	1273.00	3.89
Infliximab	Foetal death (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	22	43	22	652.50	1334.30	3.92
Rituximab	Foetal death (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	22	44	22	637.00	1273.00	3.89
Abatacept	Foetal death (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	21	43	22	207.83	405.47	3.86
Etanercept	Foetal death (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	20	43	22	118.90	221.75	3.79

Adalimumab	Fluid retention (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	20	44	20	580.38	1065.16	3.89
Adalimumab	Psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	20	44	20	580.38	1065.16	3.89
Infliximab	Fluid retention (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	20	43	20	594.50	1112.23	3.92
Infliximab	Psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	20	43	20	594.50	1112.23	3.92
Rituximab	Fluid retention (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	20	44	20	580.38	1065.16	3.89
Rituximab	Psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	20	44	20	580.38	1065.16	3.89
Abatacept	Fluid retention (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	19	43	20	188.50	337.73	3.85
Abatacept	Psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	19	43	20	188.50	337.73	3.85
Efavirenz	Pregnancy with implant contraceptive (n/a - Unknown - Other Medically Important Condition)	18	76	20	58.14	76.21	2.96
Etanercept	Fluid retention (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	18	43	20	107.30	184.42	3.77
Etanercept	Psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	18	43	20	107.30	184.42	3.77
Adalimumab	Drug intolerance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	16	44	16	467.13	737.00	3.88

Infliximab	Drug intolerance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	16	43	16	478.50	765.00	3.91
Rituximab	Drug intolerance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	16	44	16	467.13	737.00	3.88

Table S2. Summary of Subgroups.

Subgroup	Deduplicated reports	Drug–Reaction pairs	Signals detected
Pregnancy	680	7011	470
Puerperium	11	75	0
Perinatal	146	1224	0