APPENDIX

Effectiveness of COVID-19 mRNA primary and booster vaccination during pregnancy: a target trial emulation and meta-analysis of data from 4 European countries

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## **Appendix Table 1:** Baseline characteristics of the study population in the SCIFI-PEARL database, for the Complete Schema vs. Unvaccinated analysis.

| **Covariate** | **Covariate level** | **Estimate** | **Cohort** | |
| --- | --- | --- | --- | --- |
| **Unexposed** | **Exposed** |
| **Number records** | - | N | 36,398 | 36,398 |
| **Age (Years)** | - | Median (Q25 - Q75) | 31 (28 - 35) | 31 (28 - 35) |
| **Age Group** | 12 to 24 | N (%) | 2,353 (6.5%) | 2,328 (6.4%) |
| 25 to 39 | N (%) | 32,407 (89.0%) | 32,427 (89.1%) |
| 40 to 55 | N (%) | 1,638 (4.5%) | 1,643 (4.5%) |
| **Gestational Trimester** | T1 | N (%) | 9,441 (25.9%) | 9,441 (25.9%) |
| T2 | N (%) | 18,782 (51.6%) | 18,782 (51.6%) |
| T3 | N (%) | 8,175 (22.5%) | 8,175 (22.5%) |
| **Vaccine Product** | Moderna | N (%) | - | 7,348 (20.2%) |
| Pfizer | N (%) | - | 29,050 (79.8%) |
| **Previous Pregnancies** | - | Median (Q25 - Q75) | 1.00 (1.00 - 2.00) | 2.00 (2.00 - 2.00) |
| **Healthcare Visits (Past Year)** | - | Median (Q25 - Q75) | 4.00 (1.00 - 14.00) | 8.00 (2.00 - 22.00) |
| **Days of Prior Observation** | - | Median (Q25 - Q75) | 2,378 (2,338 - 2,413) | 2,379 (2,344 - 2,416) |
| **COVID-19 Infection (Any Time Prior)** | - | Median (Q25 - Q75) | 0.00 (0.00 - 0.00) | 0.00 (0.00 - 0.00) |
| **Comorbidities (Any Time Prior)** | Chronic hypertension | N (%) | 995 (2.7%) | 1,267 (3.5%) |
| Heart conditions | N (%) | 388 (1.1%) | 474 (1.3%) |
| Pneumonia | N (%) | 565 (1.6%) | 499 (1.4%) |
| Venous thromboembolism | N (%) | 188 (0.5%) | 193 (0.5%) |
| Anxiety disorder | N (%) | 4,483 (12.3%) | 4,908 (13.5%) |
| Stroke | N (%) | 25 (0.1%) | 27 (0.1%) |
| Anemia | N (%) | 3,535 (9.7%) | 2,978 (8.2%) |
| Diabetes (any type) | N (%) | 463 (1.3%) | 563 (1.5%) |
| Hypothyroidism | N (%) | 1,640 (4.5%) | 1,693 (4.7%) |
| Asthma | N (%) | 1,502 (4.1%) | 1,778 (4.9%) |
| PCOS | N (%) | 1,250 (3.4%) | 1,235 (3.4%) |
| Depressive disorder | N (%) | 3,265 (9.0%) | 3,521 (9.7%) |
| HIV | N (%) | 17 (0.0%) | 15 (0.0%) |
| Interstitial lung disease | N (%) | 35 (0.1%) | 36 (0.1%) |
| Renal impairment | N (%) | 57 (0.2%) | 77 (0.2%) |
| Pregnancy induced hypertension | N (%) | 730 (2.0%) | 921 (2.5%) |
| **Medications Prescribed (Last 180 Days)** | Antithrombotics | N (%) | 590 (1.6%) | 620 (1.7%) |
| Immunosupressants | N (%) | 167 (0.5%) | 234 (0.6%) |
| Progestogens | N (%) | 2,605 (7.2%) | 2,917 (8.0%) |
| Estrogens | N (%) | 1,461 (4.0%) | 1,711 (4.7%) |
| Antimycotics systemic | N (%) | 466 (1.3%) | 443 (1.2%) |
| Antidepressants | N (%) | 2,529 (6.9%) | 3,427 (9.4%) |
| Analgesics and antipyretics | N (%) | 5,043 (13.9%) | 5,450 (15.0%) |
| Corticosteroids | N (%) | 592 (1.6%) | 639 (1.8%) |
| Antihistamines systemic | N (%) | 7,469 (20.5%) | 7,985 (21.9%) |
| Antibacterials systemic | N (%) | 3,667 (10.1%) | 3,333 (9.2%) |
| Drugs ulcer and gords | N (%) | 1,964 (5.4%) | 1,846 (5.1%) |
| Antiepileptics | N (%) | 244 (0.7%) | 310 (0.9%) |
| Antiinflammatory antirehumatic | N (%) | 1,337 (3.7%) | 1,326 (3.6%) |

## **Appendix Table 2:** Baseline characteristics of the study population in the SCIFI-PEARL database, for the Booster vs. Complete Schema analysis.

| **Covariate** | **Covariate level** | **Estimate** | **Cohort** | |
| --- | --- | --- | --- | --- |
| **Unexposed** | **Exposed** |
| **Number records** | - | N | 26,195 | 26,195 |
| **Age (Years)** | - | Median (Q25 - Q75) | 31 (29 - 34) | 31 (29 - 34) |
| **Age Group** | 12 to 24 | N (%) | 1,121 (4.3%) | 1,085 (4.1%) |
| 25 to 39 | N (%) | 24,203 (92.4%) | 24,244 (92.6%) |
| 40 to 55 | N (%) | 871 (3.3%) | 866 (3.3%) |
| **Gestational Trimester** | T1 | N (%) | 5,558 (21.2%) | 5,558 (21.2%) |
| T2 | N (%) | 15,411 (58.8%) | 15,411 (58.8%) |
| T3 | N (%) | 5,226 (20.0%) | 5,226 (20.0%) |
| **Vaccine Product** | Moderna | N (%) | - | 5,008 (19.1%) |
| Pfizer | N (%) | - | 21,187 (80.9%) |
| **Previous Pregnancies** | - | Median (Q25 - Q75) | 2.00 (1.00 - 2.00) | 2.00 (2.00 - 2.00) |
| **Healthcare Visits (Past Year)** | - | Median (Q25 - Q75) | 4.00 (0.00 - 15.00) | 6.00 (0.00 - 20.00) |
| **Days of Prior Observation** | - | Median (Q25 - Q75) | 2,591 (2,572 - 2,659) | 2,592 (2,574 - 2,665) |
| **COVID-19 Infection (Any Time Prior)** | - | Median (Q25 - Q75) | 0.00 (0.00 - 0.00) | 0.00 (0.00 - 0.00) |
| **Comorbidities (Any Time Prior)** | Chronic hypertension | N (%) | 895 (3.4%) | 870 (3.3%) |
| Heart conditions | N (%) | 286 (1.1%) | 362 (1.4%) |
| Pneumonia | N (%) | 370 (1.4%) | 366 (1.4%) |
| Venous thromboembolism | N (%) | 123 (0.5%) | 131 (0.5%) |
| Anxiety disorder | N (%) | 3,427 (13.1%) | 3,598 (13.7%) |
| Stroke | N (%) | 18 (0.1%) | 19 (0.1%) |
| Anemia | N (%) | 2,156 (8.2%) | 1,922 (7.3%) |
| Diabetes (any type) | N (%) | 330 (1.3%) | 341 (1.3%) |
| Hypothyroidism | N (%) | 1,111 (4.2%) | 1,154 (4.4%) |
| Asthma | N (%) | 1,081 (4.1%) | 1,310 (5.0%) |
| PCOS | N (%) | 927 (3.5%) | 879 (3.4%) |
| Depressive disorder | N (%) | 2,415 (9.2%) | 2,488 (9.5%) |
| HIV | N (%) | 5 (0.0%) | 5 (0.0%) |
| Interstitial lung disease | N (%) | 31 (0.1%) | 40 (0.2%) |
| Renal impairment | N (%) | 47 (0.2%) | 51 (0.2%) |
| Pregnancy induced hypertension | N (%) | 658 (2.5%) | 613 (2.3%) |
| **Medications Prescribed (Last 180 Days)** | Antithrombotics | N (%) | 535 (2.0%) | 421 (1.6%) |
| Immunosupressants | N (%) | 173 (0.7%) | 177 (0.7%) |
| Progestogens | N (%) | 1,796 (6.9%) | 1,979 (7.6%) |
| Estrogens | N (%) | 1,077 (4.1%) | 1,211 (4.6%) |
| Antimycotics systemic | N (%) | 311 (1.2%) | 302 (1.2%) |
| Antidepressants | N (%) | 2,304 (8.8%) | 2,491 (9.5%) |
| Analgesics and antipyretics | N (%) | 3,675 (14.0%) | 3,767 (14.4%) |
| Corticosteroids | N (%) | 439 (1.7%) | 434 (1.7%) |
| Antihistamines systemic | N (%) | 5,799 (22.1%) | 6,038 (23.1%) |
| Antibacterials systemic | N (%) | 2,766 (10.6%) | 2,629 (10.0%) |
| Drugs ulcer and gords | N (%) | 1,249 (4.8%) | 1,099 (4.2%) |
| Antiepileptics | N (%) | 217 (0.8%) | 225 (0.9%) |
| Antiinflammatory antirehumatic | N (%) | 827 (3.2%) | 784 (3.0%) |

## **Appendix Table 3:** Baseline characteristics of the study population in the UiO database, for the Complete Schema vs. Unvaccinated analysis.

| **Covariate** | **Covariate level** | **Estimate** | **Cohort** | |
| --- | --- | --- | --- | --- |
| **Unexposed** | **Exposed** |
| **Number records** | - | N | 15,443 | 15,443 |
| **Age (Years)** | - | Median (Q25 - Q75) | 31.00 (28.00 - 34.00) | 31.00 (28.00 - 34.00) |
| **Age Group** | 12 to 24 | N (%) | 1,360 (8.8%) | 1,367 (8.9%) |
| 25 to 39 | N (%) | 13,512 (87.5%) | 13,507 (87.5%) |
| 40 to 55 | N (%) | 571 (3.7%) | 569 (3.7%) |
| **Gestational Trimester** | T1 | N (%) | 5,201 (33.7%) | 5,201 (33.7%) |
| T2 | N (%) | 6,421 (41.6%) | 6,421 (41.6%) |
| T3 | N (%) | 3,821 (24.7%) | 3,821 (24.7%) |
| **Vaccine Product** | Moderna | N (%) | - | 5,248 (34.0%) |
| Pfizer | N (%) | - | 10,195 (66.0%) |
| **Previous Pregnancies** | - | Median (Q25 - Q75) | 2.00 (1.00 - 2.00) | 2.00 (2.00 - 2.00) |
| **Healthcare Visits (Past Year)** | - | Median (Q25 - Q75) | 20.00 (11.00 - 34.00) | 30.00 (16.00 - 48.00) |
| **Days of Prior Observation** | - | Median (Q25 - Q75) | 4,964 (4,859 - 4,992) | 4,979 (4,923 - 4,993) |
| **COVID-19 Infection (Any Time Prior)** | - | Median (Q25 - Q75) | 0.00 (0.00 - 0.00) | 0.00 (0.00 - 0.00) |
| **Other Vaccinations (Any Time Prior)** | Influenza | N (%) | 3,154 (20.4%) | 4,307 (27.9%) |
| Tdap | N (%) | 97 (0.6%) | 90 (0.6%) |
| **Comorbidities (Any Time Prior)** | Diabetes (any type) | N (%) | 822 (5.3%) | 821 (5.3%) |
| Chronic hypertension | N (%) | 1,049 (6.8%) | 1,122 (7.3%) |
| Anemia | N (%) | 2,892 (18.7%) | 2,509 (16.2%) |
| Anxiety disorder | N (%) | 1,745 (11.3%) | 1,722 (11.2%) |
| Venous thromboembolism | N (%) | 243 (1.6%) | 250 (1.6%) |
| Stroke | N (%) | 38 (0.2%) | 37 (0.2%) |
| Renal impairment | N (%) | 80 (0.5%) | 63 (0.4%) |
| Heart conditions | N (%) | 796 (5.2%) | 839 (5.4%) |
| Asthma | N (%) | 2,004 (13.0%) | 2,207 (14.3%) |
| Hypothyroidism | N (%) | 890 (5.8%) | 865 (5.6%) |
| Pneumonia | N (%) | 1,203 (7.8%) | 1,213 (7.9%) |
| HIV | N (%) | 19 (0.1%) | 15 (0.1%) |
| Pregnancy induced hypertension | N (%) | 850 (5.5%) | 901 (5.8%) |
| PCOS | N (%) | 534 (3.5%) | 618 (4.0%) |
| Interstitial lung disease | N (%) | 4 (0.0%) | 6 (0.0%) |
| Depressive disorder | N (%) | 1,714 (11.1%) | 1,757 (11.4%) |
| **Medications Prescribed (Last 180 Days)** | Antihistamines systemic | N (%) | 2,768 (17.9%) | 3,239 (21.0%) |
| Antibacterials systemic | N (%) | 2,095 (13.6%) | 1,948 (12.6%) |
| Antithrombotics | N (%) | 718 (4.6%) | 774 (5.0%) |
| Antidepressants | N (%) | 622 (4.0%) | 718 (4.6%) |
| Antiinflammatory antirehumatic | N (%) | 1,150 (7.4%) | 1,203 (7.8%) |
| Estrogens | N (%) | 1,835 (11.9%) | 2,063 (13.4%) |
| Drugs ulcer and gords | N (%) | 693 (4.5%) | 676 (4.4%) |
| Antiepileptics | N (%) | 146 (0.9%) | 166 (1.1%) |
| Immunosupressants | N (%) | 74 (0.5%) | 114 (0.7%) |
| Antimycotics systemic | N (%) | 134 (0.9%) | 146 (0.9%) |
| Progestogens | N (%) | 1,512 (9.8%) | 1,536 (9.9%) |
| Corticosteroids | N (%) | 292 (1.9%) | 308 (2.0%) |
| Analgesics and antipyretics | N (%) | 1,173 (7.6%) | 1,243 (8.0%) |

## **Appendix Table 4:** Baseline characteristics of the study population in the UiO database, for the Booster vs. Complete Schema analysis.

| **Covariate** | **Covariate level** | **Estimate** | **Cohort** | |
| --- | --- | --- | --- | --- |
| **Unexposed** | **Exposed** |
| **Number records** | - | N | 10,791 | 10,791 |
| **Age (Years)** | - | Median (Q25 - Q75) | 31.00 (28.00 - 34.00) | 31.00 (28.00 - 34.00) |
| **Age Group** | 12 to 24 | N (%) | 727 (6.7%) | 709 (6.6%) |
| 25 to 39 | N (%) | 9,770 (90.5%) | 9,778 (90.6%) |
| 40 to 55 | N (%) | 294 (2.7%) | 304 (2.8%) |
| **Gestational Trimester** | T1 | N (%) | 3,372 (31.2%) | 3,372 (31.2%) |
| T2 | N (%) | 6,200 (57.5%) | 6,200 (57.5%) |
| T3 | N (%) | 1,219 (11.3%) | 1,219 (11.3%) |
| **Vaccine Product** | Moderna | N (%) | - | 2,020 (18.7%) |
| Pfizer | N (%) | - | 8,771 (81.3%) |
| **Previous Pregnancies** | - | Median (Q25 - Q75) | 2.00 (2.00 - 2.00) | 2.00 (2.00 - 2.00) |
| **Healthcare Visits (Past Year)** | - | Median (Q25 - Q75) | 24.00 (12.00 - 40.00) | 26.00 (16.00 - 44.00) |
| **Days of Prior Observation** | - | Median (Q25 - Q75) | 5,126 (5,092 - 5,144) | 5,127 (5,098 - 5,146) |
| **COVID-19 Infection (Any Time Prior)** | - | Median (Q25 - Q75) | 0.00 (0.00 - 0.00) | 0.00 (0.00 - 0.00) |
| **Other Vaccinations (Any Time Prior)** | Influenza | N (%) | 5,481 (50.8%) | 6,534 (60.6%) |
| Tdap | N (%) | 84 (0.8%) | 69 (0.6%) |
| **Comorbidities (Any Time Prior)** | Diabetes (any type) | N (%) | 534 (4.9%) | 518 (4.8%) |
| Chronic hypertension | N (%) | 806 (7.5%) | 816 (7.6%) |
| Anemia | N (%) | 1,782 (16.5%) | 1,690 (15.7%) |
| Anxiety disorder | N (%) | 1,083 (10.0%) | 1,085 (10.1%) |
| Venous thromboembolism | N (%) | 185 (1.7%) | 176 (1.6%) |
| Stroke | N (%) | 35 (0.3%) | 36 (0.3%) |
| Renal impairment | N (%) | 58 (0.5%) | 56 (0.5%) |
| Heart conditions | N (%) | 654 (6.1%) | 623 (5.8%) |
| Asthma | N (%) | 1,589 (14.7%) | 1,700 (15.8%) |
| Hypothyroidism | N (%) | 625 (5.8%) | 670 (6.2%) |
| Pneumonia | N (%) | 860 (8.0%) | 869 (8.1%) |
| HIV | N (%) | 3 (0.0%) | 5 (0.0%) |
| Pregnancy induced hypertension | N (%) | 642 (5.9%) | 647 (6.0%) |
| PCOS | N (%) | 426 (3.9%) | 448 (4.2%) |
| Interstitial lung disease | N (%) | 5 (0.0%) | 3 (0.0%) |
| Depressive disorder | N (%) | 1,138 (10.5%) | 1,186 (11.0%) |
| **Medications Prescribed (Last 180 Days)** | Antihistamines systemic | N (%) | 2,291 (21.2%) | 2,408 (22.3%) |
| Antibacterials systemic | N (%) | 1,652 (15.3%) | 1,614 (15.0%) |
| Antithrombotics | N (%) | 511 (4.7%) | 538 (5.0%) |
| Antidepressants | N (%) | 413 (3.8%) | 424 (3.9%) |
| Antiinflammatory antirehumatic | N (%) | 808 (7.5%) | 782 (7.2%) |
| Estrogens | N (%) | 1,443 (13.4%) | 1,623 (15.0%) |
| Drugs ulcer and gords | N (%) | 468 (4.3%) | 443 (4.1%) |
| Antiepileptics | N (%) | 111 (1.0%) | 116 (1.1%) |
| Immunosupressants | N (%) | 60 (0.6%) | 91 (0.8%) |
| Antimycotics systemic | N (%) | 102 (0.9%) | 99 (0.9%) |
| Progestogens | N (%) | 1,004 (9.3%) | 975 (9.0%) |
| Corticosteroids | N (%) | 199 (1.8%) | 210 (1.9%) |
| Analgesics and antipyretics | N (%) | 910 (8.4%) | 914 (8.5%) |

## **Appendix Table 5:** Baseline characteristics of the study population in the SIDIAP database, for the Complete Schema vs. Unvaccinated analysis.

| **Covariate** | **Covariate level** | **Estimate** | **Cohort** | |
| --- | --- | --- | --- | --- |
| **Unexposed** | **Exposed** |
| **Number records** | - | N | 7,479 | 7,479 |
| **Age (Years)** | - | Median (Q25 - Q75) | 32.00 (28.00 - 36.00) | 32.00 (28.00 - 36.00) |
| **Age Group** | 12 to 24 | N (%) | 760 (10.2%) | 757 (10.1%) |
| 25 to 39 | N (%) | 6,103 (81.6%) | 6,112 (81.7%) |
| 40 to 55 | N (%) | 616 (8.2%) | 610 (8.2%) |
| **Gestational Trimester** | T1 | N (%) | 2,183 (29.2%) | 2,183 (29.2%) |
| T2 | N (%) | 3,351 (44.8%) | 3,351 (44.8%) |
| T3 | N (%) | 1,945 (26.0%) | 1,945 (26.0%) |
| **Vaccine Product** | Moderna | N (%) | - | 1,496 (20.0%) |
| Pfizer | N (%) | - | 5,983 (80.0%) |
| **Previous Pregnancies** | - | Median (Q25 - Q75) | 2.00 (1.00 - 2.00) | 2.00 (2.00 - 2.00) |
| **Healthcare Visits (Past Year)** | - | Median (Q25 - Q75) | 20.00 (10.00 - 36.00) | 32.00 (16.00 - 52.00) |
| **Days of Prior Observation** | - | Median (Q25 - Q75) | 5,658 (2,816 - 5,700) | 5,664 (2,822 - 5,702) |
| **COVID-19 Infection (Any Time Prior)** | - | Median (Q25 - Q75) | 0.00 (0.00 - 0.00) | 0.00 (0.00 - 0.00) |
| **Other Vaccinations (Any Time Prior)** | Influenza | N (%) | 1,752 (23.4%) | 2,107 (28.2%) |
| Tdap | N (%) | 3,366 (45.0%) | 3,329 (44.5%) |
| **Comorbidities (Any Time Prior)** | Asthma | N (%) | 370 (4.9%) | 455 (6.1%) |
| Pneumonia | N (%) | 206 (2.8%) | 245 (3.3%) |
| Interstitial lung disease | N (%) | 2 (0.0%) | 5 (0.1%) |
| Stroke | N (%) | 6 (0.1%) | 8 (0.1%) |
| PCOS | N (%) | 251 (3.4%) | 305 (4.1%) |
| Chronic hypertension | N (%) | 155 (2.1%) | 178 (2.4%) |
| Pregnancy induced hypertension | N (%) | 78 (1.0%) | 80 (1.1%) |
| Anemia | N (%) | 1,876 (25.1%) | 1,647 (22.0%) |
| Hypothyroidism | N (%) | 596 (8.0%) | 659 (8.8%) |
| Depressive disorder | N (%) | 420 (5.6%) | 423 (5.7%) |
| Heart conditions | N (%) | 142 (1.9%) | 176 (2.4%) |
| Diabetes (any type) | N (%) | 402 (5.4%) | 442 (5.9%) |
| HIV | N (%) | 4 (0.1%) | 8 (0.1%) |
| Anxiety disorder | N (%) | 2,067 (27.6%) | 2,060 (27.5%) |
| Renal impairment | N (%) | 9 (0.1%) | 22 (0.3%) |
| Venous thromboembolism | N (%) | 49 (0.7%) | 48 (0.6%) |
| **Medications Prescribed (Last 180 Days)** | Estrogens | N (%) | 590 (7.9%) | 548 (7.3%) |
| Antiinflammatory antirehumatic | N (%) | 1,186 (15.9%) | 1,215 (16.2%) |
| Antithrombotics | N (%) | 347 (4.6%) | 283 (3.8%) |
| Drugs ulcer and gords | N (%) | 439 (5.9%) | 444 (5.9%) |
| Immunosupressants | N (%) | 9 (0.1%) | 13 (0.2%) |
| Antidepressants | N (%) | 330 (4.4%) | 416 (5.6%) |
| Progestogens | N (%) | 410 (5.5%) | 409 (5.5%) |
| Antiepileptics | N (%) | 106 (1.4%) | 132 (1.8%) |
| Analgesics and antipyretics | N (%) | 2,467 (33.0%) | 2,528 (33.8%) |
| Antihistamines systemic | N (%) | 1,068 (14.3%) | 1,186 (15.9%) |
| Antibacterials systemic | N (%) | 1,691 (22.6%) | 1,738 (23.2%) |
| Corticosteroids | N (%) | 184 (2.5%) | 181 (2.4%) |
| Antimycotics systemic | N (%) | 39 (0.5%) | 43 (0.6%) |

## **Appendix Table 6:** Baseline characteristics of the study population in the SIDIAP database, for the Booster vs. Complete Schema analysis.

| **Covariate** | **Covariate level** | **Estimate** | **Cohort** | |
| --- | --- | --- | --- | --- |
| **Unexposed** | **Exposed** |
| **Number records** | - | N | 2,218 | 2,218 |
| **Age (Years)** | - | Median (Q25 - Q75) | 34.00 (31.00 - 37.00) | 34.00 (31.00 - 37.00) |
| **Age Group** | 12 to 24 | N (%) | 56 (2.5%) | 64 (2.9%) |
| 25 to 39 | N (%) | 1,981 (89.3%) | 1,973 (89.0%) |
| 40 to 55 | N (%) | 181 (8.2%) | 181 (8.2%) |
| **Gestational Trimester** | T1 | N (%) | 719 (32.4%) | 719 (32.4%) |
| T2 | N (%) | 1,018 (45.9%) | 1,018 (45.9%) |
| T3 | N (%) | 481 (21.7%) | 481 (21.7%) |
| **Vaccine Product** | Moderna | N (%) | - | 1,545 (69.7%) |
| Pfizer | N (%) | - | 673 (30.3%) |
| **Previous Pregnancies** | - | Median (Q25 - Q75) | 2.00 (2.00 - 2.00) | 2.00 (2.00 - 2.00) |
| **Healthcare Visits (Past Year)** | - | Median (Q25 - Q75) | 26.00 (14.00 - 46.00) | 30.00 (16.00 - 52.00) |
| **Days of Prior Observation** | - | Median (Q25 - Q75) | 5,847 (4,332 - 5,876) | 5,842 (3,665 - 5,872) |
| **COVID-19 Infection (Any Time Prior)** | - | Median (Q25 - Q75) | 0.00 (0.00 - 0.00) | 0.00 (0.00 - 0.00) |
| **Other Vaccinations (Any Time Prior)** | Influenza | N (%) | 1,063 (47.9%) | 1,228 (55.4%) |
| Tdap | N (%) | 934 (42.1%) | 887 (40.0%) |
| **Comorbidities (Any Time Prior)** | Asthma | N (%) | 133 (6.0%) | 145 (6.5%) |
| Pneumonia | N (%) | 58 (2.6%) | 52 (2.3%) |
| Interstitial lung disease | N (%) | 2 (0.1%) | 1 (0.0%) |
| Stroke | N (%) | 1 (0.0%) | 0 (0.0%) |
| PCOS | N (%) | 97 (4.4%) | 86 (3.9%) |
| Chronic hypertension | N (%) | 35 (1.6%) | 53 (2.4%) |
| Pregnancy induced hypertension | N (%) | 14 (0.6%) | 22 (1.0%) |
| Anemia | N (%) | 443 (20.0%) | 413 (18.6%) |
| Hypothyroidism | N (%) | 200 (9.0%) | 218 (9.8%) |
| Depressive disorder | N (%) | 116 (5.2%) | 118 (5.3%) |
| Heart conditions | N (%) | 55 (2.5%) | 49 (2.2%) |
| Diabetes (any type) | N (%) | 89 (4.0%) | 111 (5.0%) |
| HIV | N (%) | 0 (0.0%) | 1 (0.0%) |
| Anxiety disorder | N (%) | 609 (27.5%) | 551 (24.8%) |
| Renal impairment | N (%) | 6 (0.3%) | 5 (0.2%) |
| Venous thromboembolism | N (%) | 10 (0.5%) | 16 (0.7%) |
| **Medications Prescribed (Last 180 Days)** | Estrogens | N (%) | 128 (5.8%) | 130 (5.9%) |
| Antiinflammatory antirehumatic | N (%) | 368 (16.6%) | 372 (16.8%) |
| Antithrombotics | N (%) | 164 (7.4%) | 122 (5.5%) |
| Drugs ulcer and gords | N (%) | 135 (6.1%) | 117 (5.3%) |
| Immunosupressants | N (%) | 1 (0.0%) | 1 (0.0%) |
| Antidepressants | N (%) | 112 (5.0%) | 106 (4.8%) |
| Progestogens | N (%) | 126 (5.7%) | 126 (5.7%) |
| Antiepileptics | N (%) | 28 (1.3%) | 35 (1.6%) |
| Analgesics and antipyretics | N (%) | 720 (32.5%) | 705 (31.8%) |
| Antihistamines systemic | N (%) | 316 (14.2%) | 366 (16.5%) |
| Antibacterials systemic | N (%) | 463 (20.9%) | 410 (18.5%) |
| Corticosteroids | N (%) | 61 (2.8%) | 68 (3.1%) |
| Antimycotics systemic | N (%) | 16 (0.7%) | 10 (0.5%) |

## **Appendix Table 7:** Baseline characteristics of the study population in the CPRD GOLD database, for the Complete Schema vs. Unvaccinated analysis.

| **Covariate** | **Covariate level** | **Estimate** | **Cohort** | |
| --- | --- | --- | --- | --- |
| **Unexposed** | **Exposed** |
| **Number records** | - | N | 2,741 | 2,741 |
| **Age (Years)** | - | Median (Q25 - Q75) | 32.00 (28.00 - 35.00) | 32.00 (28.00 - 35.00) |
| **Age Group** | 12 to 24 | N (%) | 272 (9.9%) | 265 (9.7%) |
| 25 to 39 | N (%) | 2,318 (84.6%) | 2,331 (85.0%) |
| 40 to 55 | N (%) | 151 (5.5%) | 145 (5.3%) |
| **Gestational Trimester** | T1 | N (%) | 1,107 (40.4%) | 1,107 (40.4%) |
| T2 | N (%) | 954 (34.8%) | 954 (34.8%) |
| T3 | N (%) | 680 (24.8%) | 680 (24.8%) |
| **Vaccine Product** | Moderna | N (%) | - | 280 (10.2%) |
| Pfizer | N (%) | - | 2,461 (89.8%) |
| **Previous Pregnancies** | - | Median (Q25 - Q75) | 2.00 (2.00 - 2.00) | 2.00 (2.00 - 2.00) |
| **Healthcare Visits (Past Year)** | - | Median (Q25 - Q75) | 20.00 (11.00 - 38.00) | 24.00 (14.00 - 42.00) |
| **Days of Prior Observation** | - | Median (Q25 - Q75) | 3,290 (1,394 - 6,545) | 3,020 (1,344 - 6,577) |
| **COVID-19 Infection (Any Time Prior)** | - | Median (Q25 - Q75) | 0.00 (0.00 - 0.00) | 0.00 (0.00 - 0.00) |
| **Other Vaccinations (Any Time Prior)** | Tdap | N (%) | 1,439 (52.5%) | 1,562 (57.0%) |
| Influenza | N (%) | 830 (30.3%) | 964 (35.2%) |
| **Comorbidities (Any Time Prior)** | PCOS | N (%) | 64 (2.3%) | 62 (2.3%) |
| Venous thromboembolism | N (%) | 11 (0.4%) | 7 (0.3%) |
| Anemia | N (%) | 114 (4.2%) | 120 (4.4%) |
| Pregnancy induced hypertension | N (%) | 12 (0.4%) | 20 (0.7%) |
| Renal impairment | N (%) | 2 (0.1%) | 2 (0.1%) |
| Stroke | N (%) | 2 (0.1%) | 0 (0.0%) |
| Chronic hypertension | N (%) | 28 (1.0%) | 30 (1.1%) |
| Heart conditions | N (%) | 12 (0.4%) | 23 (0.8%) |
| Hypothyroidism | N (%) | 64 (2.3%) | 73 (2.7%) |
| Anxiety disorder | N (%) | 229 (8.4%) | 185 (6.7%) |
| Depressive disorder | N (%) | 444 (16.2%) | 372 (13.6%) |
| Diabetes (any type) | N (%) | 94 (3.4%) | 110 (4.0%) |
| Interstitial lung disease | N (%) | 0 (0.0%) | 1 (0.0%) |
| Asthma | N (%) | 173 (6.3%) | 212 (7.7%) |
| Pneumonia | N (%) | 12 (0.4%) | 12 (0.4%) |
| HIV | N (%) | 0 (0.0%) | 0 (0.0%) |
| **Medications Prescribed (Last 180 Days)** | Estrogens | N (%) | 17 (0.6%) | 21 (0.8%) |
| Drugs ulcer and gords | N (%) | 244 (8.9%) | 257 (9.4%) |
| Antiinflammatory antirehumatic | N (%) | 151 (5.5%) | 136 (5.0%) |
| Corticosteroids | N (%) | 20 (0.7%) | 30 (1.1%) |
| Antithrombotics | N (%) | 33 (1.2%) | 33 (1.2%) |
| Antihistamines systemic | N (%) | 422 (15.4%) | 436 (15.9%) |
| Antidepressants | N (%) | 419 (15.3%) | 423 (15.4%) |
| Progestogens | N (%) | 84 (3.1%) | 86 (3.1%) |
| Antimycotics systemic | N (%) | 22 (0.8%) | 15 (0.5%) |
| Immunosupressants | N (%) | 2 (0.1%) | 3 (0.1%) |
| Antiepileptics | N (%) | 52 (1.9%) | 37 (1.3%) |
| Antibacterials systemic | N (%) | 567 (20.7%) | 512 (18.7%) |
| Analgesics and antipyretics | N (%) | 260 (9.5%) | 279 (10.2%) |

## **Appendix Table 8:** Baseline characteristics of the study population in the CPRD GOLD database, for the Booster vs. Complete Schema analysis.

| **Covariate** | **Covariate level** | **Estimate** | **Cohort** | |
| --- | --- | --- | --- | --- |
| **Unexposed** | **Exposed** |
| **Number records** | - | N | 1,892 | 1,892 |
| **Age (Years)** | - | Median (Q25 - Q75) | 32.00 (29.00 - 35.00) | 32.00 (29.00 - 35.00) |
| **Age Group** | 12 to 24 | N (%) | 109 (5.8%) | 104 (5.5%) |
| 25 to 39 | N (%) | 1,713 (90.5%) | 1,714 (90.6%) |
| 40 to 55 | N (%) | 70 (3.7%) | 74 (3.9%) |
| **Gestational Trimester** | T1 | N (%) | 894 (47.3%) | 894 (47.3%) |
| T2 | N (%) | 712 (37.6%) | 712 (37.6%) |
| T3 | N (%) | 286 (15.1%) | 286 (15.1%) |
| **Vaccine Product** | Moderna | N (%) | - | 668 (35.3%) |
| Pfizer | N (%) | - | 1,224 (64.7%) |
| **Previous Pregnancies** | - | Median (Q25 - Q75) | 2.00 (2.00 - 2.00) | 2.00 (2.00 - 2.00) |
| **Healthcare Visits (Past Year)** | - | Median (Q25 - Q75) | 28.00 (16.00 - 44.00) | 30.00 (18.00 - 46.00) |
| **Days of Prior Observation** | - | Median (Q25 - Q75) | 3,340 (1,441 - 6,708) | 2,768 (1,218 - 6,664) |
| **COVID-19 Infection (Any Time Prior)** | - | Median (Q25 - Q75) | 0.00 (0.00 - 0.00) | 0.00 (0.00 - 0.00) |
| **Other Vaccinations (Any Time Prior)** | Tdap | N (%) | 1,000 (52.9%) | 995 (52.6%) |
| Influenza | N (%) | 655 (34.6%) | 665 (35.1%) |
| **Comorbidities (Any Time Prior)** | PCOS | N (%) | 49 (2.6%) | 59 (3.1%) |
| Venous thromboembolism | N (%) | 11 (0.6%) | 8 (0.4%) |
| Anemia | N (%) | 89 (4.7%) | 71 (3.8%) |
| Pregnancy induced hypertension | N (%) | 12 (0.6%) | 12 (0.6%) |
| Renal impairment | N (%) | 4 (0.2%) | 7 (0.4%) |
| Stroke | N (%) | 1 (0.1%) | 2 (0.1%) |
| Chronic hypertension | N (%) | 30 (1.6%) | 25 (1.3%) |
| Heart conditions | N (%) | 19 (1.0%) | 10 (0.5%) |
| Hypothyroidism | N (%) | 46 (2.4%) | 51 (2.7%) |
| Anxiety disorder | N (%) | 124 (6.6%) | 110 (5.8%) |
| Depressive disorder | N (%) | 293 (15.5%) | 228 (12.1%) |
| Diabetes (any type) | N (%) | 61 (3.2%) | 70 (3.7%) |
| Interstitial lung disease | N (%) | 0 (0.0%) | 0 (0.0%) |
| Asthma | N (%) | 131 (6.9%) | 145 (7.7%) |
| Pneumonia | N (%) | 6 (0.3%) | 8 (0.4%) |
| HIV | N (%) | 0 (0.0%) | 0 (0.0%) |
| **Medications Prescribed (Last 180 Days)** | Estrogens | N (%) | 15 (0.8%) | 10 (0.5%) |
| Drugs ulcer and gords | N (%) | 194 (10.3%) | 164 (8.7%) |
| Antiinflammatory antirehumatic | N (%) | 109 (5.8%) | 78 (4.1%) |
| Corticosteroids | N (%) | 32 (1.7%) | 28 (1.5%) |
| Antithrombotics | N (%) | 21 (1.1%) | 27 (1.4%) |
| Antihistamines systemic | N (%) | 351 (18.6%) | 297 (15.7%) |
| Antidepressants | N (%) | 305 (16.1%) | 283 (15.0%) |
| Progestogens | N (%) | 52 (2.7%) | 60 (3.2%) |
| Antimycotics systemic | N (%) | 20 (1.1%) | 16 (0.8%) |
| Immunosupressants | N (%) | 7 (0.4%) | 4 (0.2%) |
| Antiepileptics | N (%) | 34 (1.8%) | 32 (1.7%) |
| Antibacterials systemic | N (%) | 427 (22.6%) | 392 (20.7%) |
| Analgesics and antipyretics | N (%) | 180 (9.5%) | 190 (10.0%) |

## **Appendix Table 9:** Additional information on follow-up and reasons for censoring. SCIFI-PEARL database, for the Complete Schema vs. Unvaccinated analysis.

| **Cohort** | **Reason** | **N** | **Median (Q25-Q75)** |
| --- | --- | --- | --- |
| **Exposed** | End of pregnancy | 11,568 | 123.00 (77.00 - 166.00) |
| Next COVID-19 vaccine dose | 755 | 161.00 (147.50 - 179.00) |
| Pair matched next COVID-19 vaccine dose | 10,084 | 21.00 (10.00 - 41.00) |
| No second dose | 1,270 | 42.00 (42.00 - 42.00) |
| Second dose before recommended time | 11 | 13.00 (9.00 - 17.50) |
| Second dose after recommended time | 12,655 | 42.00 (42.00 - 42.00) |
| Second dose after recommended time; unexposed 1st dose | 29 | 42.00 (42.00 - 42.00) |
| Unexposed 1st dose; no second dose | <5 | - |
| Unexposed 1st dose; second dose after recommended time | 23 | 42.00 (42.00 - 42.00) |
| **Unexposed** | End of pregnancy | 11,778 | 123.00 (77.00 - 166.00) |
| Next COVID-19 vaccine dose | 9,773 | 20.00 (10.00 - 39.00) |
| Pair matched next COVID-19 vaccine dose | 765 | 161.00 (148.00 - 180.00) |
| No second dose | 1,282 | 42.00 (42.00 - 42.00) |
| Second dose before recommended time | 11 | 13.00 (9.00 - 17.50) |
| Second dose after recommended time | 12,739 | 42.00 (42.00 - 42.00) |
| Second dose after recommended time; unexposed 1st dose | 27 | 42.00 (42.00 - 42.00) |
| Unexposed 1st dose; no second dose | <5 | - |
| Unexposed 1st dose; second dose after recommended time | 20 | 42.00 (42.00 - 42.00) |

## **Appendix Table 10:** Additional information on follow-up and reasons for censoring. SCIFI-PEARL database, for the Booster vs. Complete Schema analysis.

| **Cohort** | **Reason** | **N** | **Median (Q25-Q75)** |
| --- | --- | --- | --- |
| **Exposed** | End of pregnancy | 15,707 | 138.00 (98.00 - 174.00) |
| Next COVID-19 vaccine dose | 556 | 168.00 (138.00 - 218.00) |
| Pair matched next COVID-19 vaccine dose | 9,932 | 21.00 (10.00 - 48.00) |
| **Unexposed** | End of pregnancy | 15,764 | 138.00 (97.00 - 174.00) |
| Next COVID-19 vaccine dose | 9,901 | 21.00 (9.00 - 48.00) |
| Pair matched next COVID-19 vaccine dose | 530 | 169.00 (137.25 - 218.00) |

## **Appendix Table 11:** Additional information on follow-up and reasons for censoring. UiO database, for the Complete Schema vs. Unvaccinated analysis.

| **Cohort** | **Reason** | **N** | **Median (Q25-Q75)** |
| --- | --- | --- | --- |
| **Exposed** | End of pregnancy | 5,728 | 75.00 (42.00 - 125.00) |
| Next COVID-19 vaccine dose | 115 | 171.00 (167.00 - 178.50) |
| Pair matched next COVID-19 vaccine dose | 5,123 | 22.00 (9.00 - 60.00) |
| No second dose | 669 | 42.00 (42.00 - 42.00) |
| Second dose before recommended time | 15 | 20.00 (20.00 - 21.00) |
| Second dose after recommended time | 3,777 | 42.00 (42.00 - 42.00) |
| Second dose after recommended time; unexposed 1st dose | 16 | 42.00 (42.00 - 42.00) |
| **Unexposed** | End of pregnancy | 5,259 | 87.00 (55.50 - 136.00) |
| Next COVID-19 vaccine dose | 5,130 | 22.00 (9.00 - 62.00) |
| Pair matched next COVID-19 vaccine dose | 210 | 175.50 (168.00 - 188.00) |
| No second dose | 718 | 42.00 (42.00 - 42.00) |
| Second dose before recommended time | 15 | 20.00 (20.00 - 21.00) |
| Second dose after recommended time | 4,099 | 42.00 (42.00 - 42.00) |
| Second dose after recommended time; unexposed 1st dose | 11 | 42.00 (42.00 - 42.00) |
| Exposed 3rd dose; unexposed 1st dose | <5 | - |

## **Appendix Table 12:** Additional information on follow-up and reasons for censoring. UiO database, for the Booster vs. Complete Schema analysis.

| **Cohort** | **Reason** | **N** | **Median (Q25-Q75)** |
| --- | --- | --- | --- |
| **Exposed** | End of pregnancy | 6,956 | 149.00 (97.00 - 184.00) |
| Next COVID-19 vaccine dose | 22 | 168.00 (140.25 - 240.50) |
| Pair matched next COVID-19 vaccine dose | 3,813 | 14.00 (7.00 - 27.00) |
| **Unexposed** | End of pregnancy | 6,918 | 154.00 (109.00 - 190.00) |
| Next COVID-19 vaccine dose | 3,855 | 14.00 (7.00 - 27.00) |
| Pair matched next COVID-19 vaccine dose | 18 | 158.50 (124.00 - 178.50) |

## **Appendix Table 13:** Additional information on follow-up and reasons for censoring. SIDIAP database, for the Complete Schema vs. Unvaccinated analysis.

| **Cohort** | **Reason** | **N** | **Median (Q25-Q75)** |
| --- | --- | --- | --- |
| **Exposed** | End of pregnancy | 3,549 | 113.00 (70.00 - 162.00) |
| Next COVID-19 vaccine dose | 81 | 199.00 (175.00 - 209.00) |
| Pair matched next COVID-19 vaccine dose | 2,612 | 27.00 (12.00 - 55.00) |
| No second dose | 711 | 42.00 (42.00 - 49.00) |
| Second dose before recommended time | <5 | - |
| Second dose after recommended time | 520 | 42.00 (42.00 - 42.00) |
| Second dose after recommended time; unexposed 1st dose | <5 | - |
| Unexposed 1st dose; no second dose | <5 | - |
| **Unexposed** | End of pregnancy | 3,625 | 113.00 (70.00 - 162.00) |
| Next COVID-19 vaccine dose | 2,509 | 25.00 (12.00 - 51.00) |
| Pair matched next COVID-19 vaccine dose | 90 | 199.50 (175.25 - 209.75) |
| No second dose | 717 | 42.00 (42.00 - 49.00) |
| Second dose before recommended time | 5 | 15.00 (14.00 - 15.00) |
| Second dose after recommended time | 531 | 42.00 (42.00 - 42.00) |
| Second dose after recommended time; unexposed 1st dose | <5 | - |
| Unexposed 1st dose; no second dose | <5 | - |

## **Appendix Table 14:** Additional information on follow-up and reasons for censoring. SIDIAP database, for the Booster vs. Complete Schema analysis.

| **Cohort** | **Reason** | **N** | **Median (Q25-Q75)** |
| --- | --- | --- | --- |
| **Exposed** | End of pregnancy | 1,736 | 139.50 (90.00 - 192.00) |
| Next COVID-19 vaccine dose | 13 | 182.00 (154.00 - 195.00) |
| Pair matched next COVID-19 vaccine dose | 469 | 19.00 (8.00 - 42.00) |
| **Unexposed** | End of pregnancy | 1,753 | 139.00 (90.00 - 196.00) |
| Next COVID-19 vaccine dose | 453 | 18.00 (8.00 - 40.00) |
| Pair matched next COVID-19 vaccine dose | 12 | 171.50 (152.50 - 196.75) |

## **Appendix Table 15:** Additional information on follow-up and reasons for censoring. CPRD GOLD database, for the Complete Schema vs. Unvaccinated analysis.

| **Cohort** | **Reason** | **N** | **Median (Q25-Q75)** |
| --- | --- | --- | --- |
| **Exposed** | End of pregnancy | 229 | 42.00 (19.00 - 98.00) |
| Next COVID-19 vaccine dose | 8 | 146.50 (142.25 - 178.50) |
| Pair matched next COVID-19 vaccine dose | 357 | 20.00 (11.00 - 31.00) |
| No second dose | 226 | 42.00 (42.00 - 42.00) |
| Second dose before recommended time | <5 | - |
| Second dose after recommended time | 1,913 | 42.00 (42.00 - 42.00) |
| Second dose after recommended time; unexposed 1st dose | <5 | - |
| **Unexposed** | End of pregnancy | 213 | 43.00 (30.00 - 97.00) |
| Next COVID-19 vaccine dose | 344 | 19.00 (10.00 - 31.00) |
| Pair matched next COVID-19 vaccine dose | 12 | 164.50 (143.75 - 185.50) |
| No second dose | 227 | 42.00 (42.00 - 42.00) |
| Second dose before recommended time | <5 | - |
| Second dose after recommended time | 1,937 | 42.00 (42.00 - 42.00) |
| Second dose after recommended time; unexposed 1st dose | <5 | - |

## **Appendix Table 16:** Additional information on follow-up and reasons for censoring. CPRD GOLD database, for the Booster vs. Complete Schema analysis.

| **Cohort** | **Reason** | **N** | **Median (Q25-Q75)** |
| --- | --- | --- | --- |
| **Exposed** | End of pregnancy | 1,030 | 163.00 (103.00 - 221.00) |
| Next COVID-19 vaccine dose | 6 | 119.50 (44.75 - 135.75) |
| Pair matched next COVID-19 vaccine dose | 856 | 17.00 (8.00 - 37.00) |
| **Unexposed** | End of pregnancy | 1,039 | 162.00 (101.50 - 220.00) |
| Next COVID-19 vaccine dose | 847 | 17.00 (7.00 - 36.00) |
| Pair matched next COVID-19 vaccine dose | 6 | 119.50 (44.75 - 135.75) |

## **Appendix Figure 8:** Distribution of index dates (enrollment date) across all databases and analyses.

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## **Appendix Table 17:** Count and percentage of re-enrolled pregnant women across analyses and databases.

| **Analysis** | **CDM name** | **N (%)** |
| --- | --- | --- |
| **Booster vs. Complete Schema** | CPRD GOLD | 333 (9.65%) |
| SCIFI-PEARL | 7126 (15.74%) |
| SIDIAP | 316 (7.67%) |
| UiO | 2760 (14.66%) |
| **Complete Schema vs. Unvaccinated** | CPRD GOLD | 561 (11.4%) |
| SCIFI-PEARL | 10920 (17.65%) |
| SIDIAP | 2205 (17.29%) |
| UiO | 4907 (18.89%) |

## **Appendix Figure 9:** Hazard ratios for COVID-19 infection and COVID-19-related hospitalization, stratified by vaccine product, across databases, and analysis

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## **Appendix Figure 10:** Kaplan-Meier curves for COVID-19 infection, across databases, and analysis

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## **Appendix Figure 11:** Kaplan-Meier curves for COVID-19-related hospitalisation, across databases, and analysis

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## **Appendix Figure 12:** Log-Log plots for COVID-19 infection, across databases, and analysis

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## **Appendix Figure 13:** Log-Log plots for COVID-19-related hospitalisation, across databases, and analysis

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| --- |
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## **Appendix Figure 14:** Negative Control Outcomes results for SCIFI-PEARLdatabase.

## **Appendix Figure 15:** Negative Control Outcomes results for UiOdatabase.

## **Appendix Figure 16:** Negative Control Outcomes results for SIDIAPdatabase.

## **Appendix Figure 17:** Negative Control Outcomes results for CPRD GOLDdatabase.