

POST-AUTHORIZATION SAFETY STUDY (PASS)**PROGRESS REPORT 3**

Title	A Post-Authorisation Safety Study (PASS) of ABRYSVO (Respiratory Syncytial Virus Stabilised Prefusion F Subunit Vaccine) in Pregnant Women and their Offspring in a Real World Setting in Europe and UK
Protocol number	C3671026
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Main author	Vjola Hoxhaj, PharmD, Miriam Sturkenboom PhD, on behalf of the VAC4EU Network ABRYSVO Maternal Immunisation PASS Research team. Department of Data Science & Biostatistics, Julius Global Health, University Medical Center Utrecht (UMCU), Utrecht, the Netherlands.
EU Post Authorisation Study (PAS) register number	Cynthia de Luise, PhD, MPH Safety Surveillance Research Pfizer, Inc 66 Hudson Blvd E New York, NY, 10001 United States EUPAS1000000399
Medicinal product	ABRYSVO vaccine (RSV subgroup A stabilized prefusion F antigen 60 mg RSV subgroup B stabilized prefusion F antigen B 60 mg)
Marketing Authorization Holder(s)	Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium

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1. MILESTONES

Milestone	Applicable Regulatory Agency	Planned/Actual Date of Deliverable¹
Registration in the HMA-EMA Catalogue of RWD studies	N/A	13 January 2025
Start of data collection ^{2,3}	N/A	15 January 2025
Progress Report 1 ⁴	All	30 June 2025
Progress Report 2	All	31 December 2025
Progress Report 3	FDA only. For EMA and other regulatory agencies, the progress of the study will be described in the PSUR	30 June 2026
Progress Report 4	FDA only. For EMA and other regulatory agencies, the progress of the study will be described in the PSUR	30 June 2027
Progress Report 5	FDA only. For EMA and other regulatory agencies, the progress of the study will be described in the PSUR	30 June 2028
Interim report ⁵	All	31 December 2026
End of data collection ^{6,7}	N/A	30 March 2029
Final study report ⁷	All	28 September 2029

1. The schedule is dependent on the protocol endorsement date, uptake of ABRYSVO, approvals for data extraction and contracts with data expert and access providers (DEAPs). Some data extraction approvals may require a final or endorsed protocol.

2. The start of data collection is "the date from which information on the first study subject is first recorded in the study dataset or, in the case of secondary use of data, the date from which data extraction into the CDM starts." Simple counts are not part of this definition.

3. Protocol endorsement is anticipated in Quarter 3 of 2024. Deliverable dates will be updated once the protocol endorsement date is known.

4. The first Progress Report is anticipated 9 months after protocol endorsement.

5. The timing of the interim report is dependent on having achieved adequate sample size. The number of exposures triggering the first interim report analysis is 600 vaccinated women based on 80% power, a 2% prevalence rate and targeting a minimal detectable risk ratio of 2.5. If the combined number of vaccinated participants across all sites is below 600, the interim analysis will be deferred until this threshold is met. However, reaching this threshold earlier than expected will not accelerate the timing of the report; the analysis will proceed according to the predefined schedule.

6. End of data collection is "the date from which the analytical data set is completely available."

7. The study will continue until sufficient power to detect a RR of 2.0 for the specified pregnancy and neonatal outcomes have been achieved.

2. RATIONALE AND BACKGROUND

Respiratory syncytial virus (RSV) is a leading cause of bronchiolitis and viral pneumonia in infants and a major cause of lower respiratory tract illness (LRTI).^[1, 2] Severe disease occurs more often in infants with underlying cardiopulmonary conditions or limited access to healthcare. In 2019, RSV caused an estimated 33 million LRTIs in children under five years old, leading to 3.6 million hospitalisations and about 100,000 deaths worldwide, half of them in infants younger than six months.^[3] Historically, it was reported that virtually all infants were infected with RSV by the age of 2, however recent studies in Finland and USA reported that between 60% to 70% of infants were seropositive at age 2.^[4-6]

In Europe, RSV shows consistent seasonality, with peaks in winter, usually 6 to 8 weeks before influenza epidemics. Between 2010 and 2016, the median length of the RSV season was similar: 16 and 18 weeks, respectively for sentinel and non-sentinel surveillance, with peak detections around calendar week 4.^[7] During the COVID-19 pandemic, RSV circulation patterns dramatically changed with typical winter epidemics largely absent in 2020-2021 across many European countries. The onset, peak, and duration of RSV epidemics shifted and in some cases epidemics were delayed or occurred outside normal seasonality periods.^[8] After the end of the pandemic, RSV incidence increased again.^[9] On 23 August 2023, the European Commission authorised Pfizer's RSV vaccine, ABRYSVO, for maternal immunisation between 24 weeks and 36 weeks of gestation to provide passive protection against lower respiratory tract disease (LRTD) in infants up to 6 months of age. The approval covers 27 European Union (EU) member states, as well as Iceland, Liechtenstein, and Norway.^[10] On 21 August 2023, the U.S. Food and Drug Administration (FDA) approved ABRYSVO for administration at 32 0/7 to 36 6/7 weeks of gestation to reduce the risk of LRTD and severe LRTD in infants.^[11] In November 2023, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) authorised ABRYSVO for use between 28 and 36 weeks of gestation.^[12]

ABRYSVO is a bivalent RSV prefusion F vaccine (RSVpreF), containing stabilised antigens from RSV A and B. In the MATISSE trial (NCT04424316, C3671008), pregnant women vaccinated between 24 weeks and 36 weeks' gestation transferred protective antibodies to their infants, reducing RSV-associated LRTI.^[13] The trial excluded immunocompromised women and those with high-risk pregnancies, so safety in these subgroups remains unknown.^[14] However, a phase 3 randomised, double-blinded trial evaluating the safety and immunogenicity of RSVpreF in pregnant women living with human immunodeficiency virus (HIV) in South Africa and their infants reported a robust immune response to RSVpreF and efficient antibody transfer to infants, with no new safety signals detected and similar preterm birth frequencies in the RSVpreF and placebo groups (8.8% and 7.8%, respectively). Guillan-Barré syndrome (GBS) was reported in the clinical trial in older adults aged ≥60 years old (C3671013), and it has been added by the Marketing Authorisation Holder (MAH) as an important potential risk in the EU Risk Management Plan (RMP) for both older adults and pregnant women intended to be vaccinated with ABRYSVO, although it was not reported in the clinical trial in pregnant women. GBS was reclassified to an important identified risk in the EU RMP and in the US Pharmacovigilance Plan.

This study, which supports the safety evaluation of ABRYSVO in pregnant populations, is included as an additional pharmacovigilance activity (Category 3 study) in the EU RMP and

the GB/UK-specific Annex to the EU RMP and is also a post-marketing requirement to the FDA.

3. RESEARCH OBJECTIVES

The main research question is: What is the occurrence of safety events of interest, in particular, preterm birth, preterm delivery or any reduction in time between vaccination and live and non-live births, among all pregnant women who receive ABRYSVO (and their offspring) compared with a matched cohort of pregnant women who do not receive ABRYSVO during pregnancy (and their offspring)?

The primary study objective is to estimate the incidence, birth prevalence, prevalence ratios and risk ratios (depending on the specific outcome) and time between vaccination and birth (live or non-live) of the following adverse pregnancy, maternal and birth outcomes in women who receive ABRYSVO during pregnancy (and their offspring), compared with a matched group of pregnant women who do not receive ABRYSVO during pregnancy (and their offspring):

- Pregnancy outcomes
 - Preterm delivery or birth (less than 37 weeks) among livebirths:
 - Extremely preterm delivery or birth (less than 28 weeks)
 - Very preterm delivery or birth (28 to less than 32 weeks)
 - Moderate to late preterm delivery or birth (32 to less than 37 weeks)
 - Time between vaccination and birth among live and non-live births (vaccination date for unvaccinated pregnant woman is the vaccination date of their matched vaccinated pregnant woman)
 - Stillbirth among live and non-live births
- Maternal outcomes during pregnancy
 - Hypertensive disorders of pregnancy
 - Guillain-Barré Syndrome (GBS)
 - Placental abruption
- Birth outcomes (at birth)
 - Low birth weight among live births
 - Small for gestational age among live births

The secondary objectives are:

- To estimate the incidence, birth prevalence, prevalence ratios and risk ratios (depending on the specific outcome) of the abovementioned pregnancy, maternal and birth outcomes and time between vaccination and birth (live or non-live) in immunocompromised pregnant women or women with high-risk pregnancies who receive ABRYSVO during pregnancy (and their offspring), compared with a matched group of immunocompromised pregnant women or women with high-risk pregnancies who do not receive ABRYSVO during pregnancy (and their offspring).
- To estimate the prevalence ratio of preterm delivery or birth and time between vaccination and birth (live or non-live) between pregnant women who receive ABRYSVO (and their offspring) compared with a matched group of pregnant women who do not receive ABRYSVO during pregnancy (and their offspring), by week of gestation of vaccination.

This study uses electronic healthcare data sources from the participating European countries.

This document serves as the third 6-month progress report. Following this report, progress reports will be submitted annually through June 2028 (**Section 1**).

This progress report provides an update on:

- national immunisation technical advisory groups (NITAGs) and national guidelines on ABRYSVO use for the maternal indication in the countries selected in this study;
- an update on ethics approvals of the protocol received by the participating data expert and access partners (DEAPs);
- the total number of identifiable and eligible pregnant women (at least 24 weeks of gestation) from the participating data sources or publicly available data;
- vaccine uptake among pregnant women over calendar time from the data sources or publicly available data;
- the characteristics of vaccinated pregnant women and all pregnant women at 24 weeks of gestation, including immunocompromised status and high-risk pregnancy status, when available; and
- the cumulative incidence of vaccination by gestational week, starting from week 24 in the participating data sources, when available.

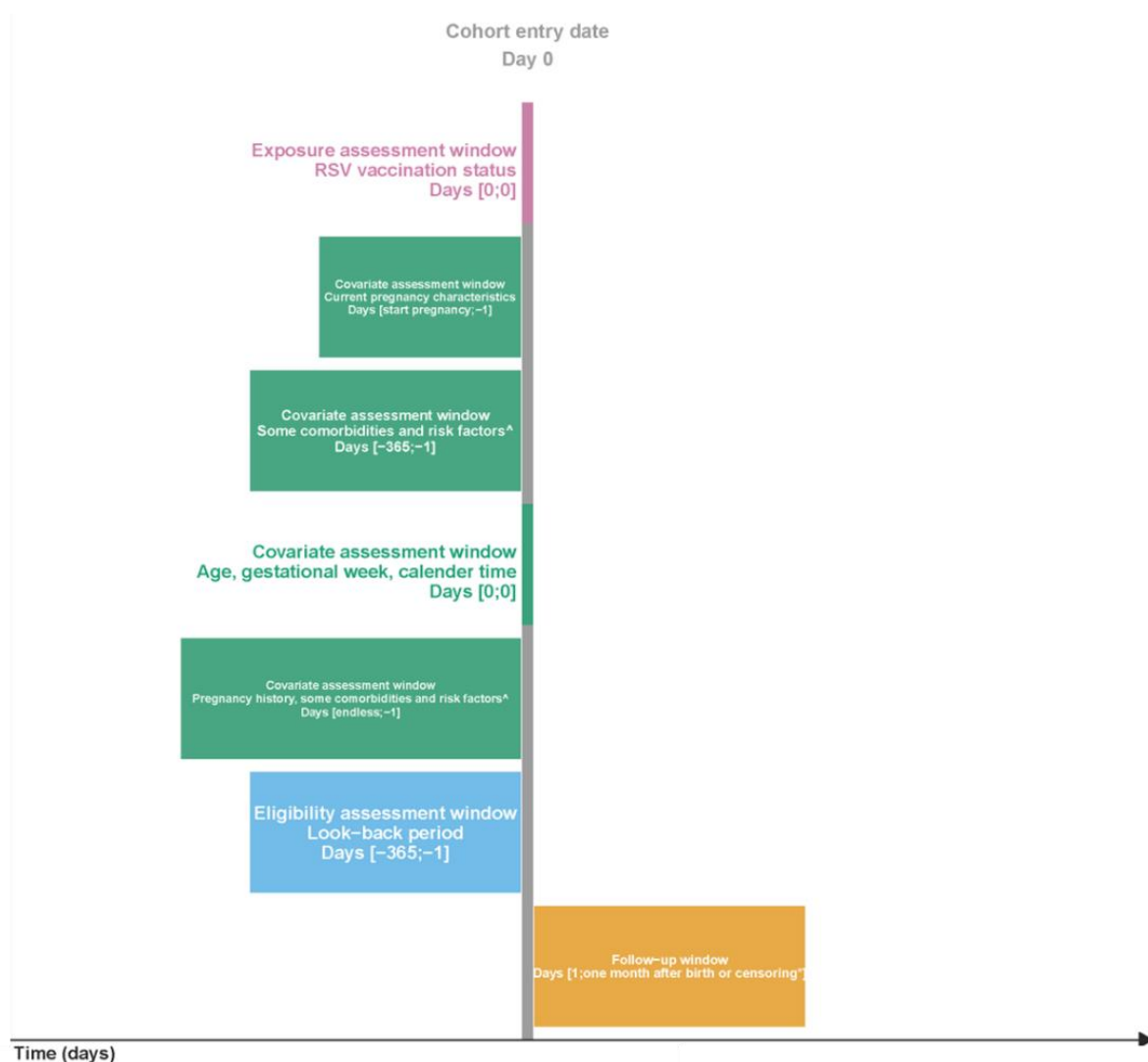
4. RESEARCH METHODS

This is a retrospective, matched cohort study using data from healthcare data sources in the United Kingdom (UK) France (FR), Denmark (DK), the Netherlands (NL), Norway (NO), and Spain (ES). The study design is shown in **Figure 1**. The target study population was all pregnant women who received a single dose of ABRYSVO during pregnancy from 24-36

weeks of gestation compared with a matched comparator cohort of pregnant women who did not receive ABRYSVO during pregnancy in the participating data sources.

For the progress report, the study population included all eligible pregnancies in women aged between 12 and 55 years at pregnancy start date that reached 24 0/7 weeks of gestation on or after 23 August 2023 and for which the 24-week gestational time point occurred within the study period and before the data cut-off date. The study period was between 23 August 2023 and the date of the last data available for each DEAP. To be eligible, the pregnant women were required to have at least 365 days of available follow-up before the pregnancy start date. Pregnant women exposed to another RSV vaccine during pregnancy were excluded. Time zero was defined as the date on which all eligibility criteria were met, and the women were vaccinated with ABRYSVO for vaccinated women. For all pregnancies, time zero was defined as the calendar date on which the women reached 24 0/7 weeks gestation. Covariates were assessed during the period from at least 365 days before time zero up to a maximum of 10 years before time zero.

The analyses of all ABRYSVO-exposed pregnancies included pregnancies irrespective of gestational age at vaccination. The analyses for all vaccinated pregnancies from 24 0/7 weeks gestation up to the end of pregnancy excluded pregnancies vaccinated before 24 weeks of gestation. The vaccinated cohort was restricted to pregnancies in which ABRYSO was administered between 24 and 36 weeks of gestation. More complete details are available in the Statistical Analysis Plan (SAP).

Figure 1. Schematic representation of study design

*Censoring included death, disenrollment or migration, end of data availability in the data source, treatment crossover (unexposed becoming exposed) or occurrence of a given outcome.

[^] Chronic comorbidities and risk factors were assessed from database entry up to T0, for a maximum of 10 years, while time-varying comorbidities and risk-factors were assessed for a minimum of 1 year (365 days) and a maximum of 10 years prior T0. The covariate assessment time window were covariate-specific to allow comprehensive covariate capture and to improve control of confounding by tailoring the observation period to the clinical relevance of the covariate.

Figure based on Schneeweiss et al.^[15]

4.1. Data Sources For This Study

Details about the DEAPs and data sources that are participating in the study can be found in [Appendix Table 1](#).

4.2. Data Collection For Third Progress Report

4.2.1. Update On The National Guidelines And Recommendations

DEAPs provided updates on NITAG and other country-specific recommendations for maternal immunisation with ABRYSVO for RSV prevention in infants as of 01 May 2026. This included the recommendation status, i.e., currently recommended or expected to be included or not included for women during pregnancy in their national vaccination schedules, and the status of reimbursement for this population in the participating countries.

4.2.2. Update On Ethics Approval Status

Information on the status of country-level ethics approvals of the PASS protocol was provided by each participating DEAP.

4.2.3. ABRYSVO Uptake

Information about ABRYSVO uptake was collected in one of three ways for this progress report depending on the DEAP:

- 1) As described in the protocol, using transformation to the ConcePTION common data model (CDM) and running common scripts;
- 2) Based on actual data, but analysed by the DEAP without transformation to the CDM;
- 3) Based on publicly available online resources.

5. STUDY PROGRESS

5.1. National Recommendations And Reimbursement For Maternal RSV Vaccination

ABRYSVO has been authorised for maternal use through a centralised procedure in the EU member states, Switzerland, and other non-EU countries in Europe as well as in the UK. The vaccine can be prescribed and dispensed based on specific authorisation conditions. In many European countries, independent national or regional bodies, NITAGs or regional immunisation technical advisory groups (RITAGs) provide evidence-based recommendations to national health authorities on immunisation policies. NITAGs and RITAGS play a central role in decisions concerning the inclusion of a vaccine in the national or regional immunisation programmes, which, in turn, influence decisions concerning access and public funding. These assessments are typically based on both benefit-risk evaluations and health economic analyses.

A summary of the status of NITAG recommendations, implementation and reimbursement status for ABRYSVO in each country participating in this study is provided below and in [Table 1](#).

Table 1. Summary of recommendations, implementation and reimbursement status for ABRYSVO vaccination in pregnant women in participating countries

Country	Start date of vaccination programme	Gestational week for vaccination	Vaccination period	Free or out-of-pocket
United Kingdom*	01 September 2024	28 to end	All year round	Free
France**	August 2024	32-36	Seasonal (September to January)	Free
Denmark**	01 October 2025	32 (24, if risk of premature birth)	Seasonal (May to January)	Free
Norway**	None; available in pharmacies from 01 December 2023	24-36	All year round	Out-of-pocket
Netherlands**	None; available from GP or privately	24-36	All year round	Out-of-pocket
Spain**	None	24-36 (preference 32-36)	All year round	Out-of-pocket

* ABRYSVO was authorised in the UK in November 2023 by the MHRA (Medicines and Healthcare Products Regulatory Agency);

** ABRYSVO was authorised in the European Union on 23 August 2023 by the European Commissions (EC)

5.1.1. United Kingdom – England (DSRU)

ABRYSVO is recommended by the Joint Committee on Vaccination and Immunisation (JCVI) and by the UK Health Security Agency (UKHSA) in the UK for routine RSV vaccination of all pregnant women from 28 weeks of gestation up to the end of pregnancy for infant protection.^[16-18] The vaccine has been available to pregnant women since 01 September 2024 in England all year round, at no cost to eligible individuals through the National Health Service (NHS) from maternity services, general practitioners (GPs) and some community pharmacies. After 01 September 2024, pregnant women who reach 28 weeks' gestation become eligible and remain eligible up to the end of pregnancy.

5.1.2. France (BPE)

The Haute Autorité de Sante (HAS, National Health Authority) recommended vaccination of pregnant women between 32 and 36 weeks of gestation with ABRYSVO from September to January.^[19] The programme is implemented through maternity hospitals and healthcare professionals, including pharmacists. The vaccination campaign is timed to coincide with the RSV epidemic season (September to January in Metropolitan France) to maximise protection. Since 28 August 2024, the vaccine is officially on the market and reimbursed by Maternity Insurance (Assurance Maternité) as part of the standard reimbursement for care provided to pregnant women, starting from the first day of the sixth month of pregnancy, provided they are vaccinated between 32 and 36 weeks of gestation, as per the official recommendations.^[20, 21]

5.1.3. Denmark (Aarhus University)

In Denmark, seasonal RSV vaccination with ABRYSVO is recommended and free of charge for pregnant women.^[22, 23] The general recommendation is that ABRYSVO is given at gestational week 32 from May to January during routine prenatal visits with the general practitioner. Women at risk of a preterm birth due to carrying two or more infants, or for any other reason, can be offered the vaccine earlier, from 24 0/7 weeks gestation. The vaccination programme started on 1 October 2025. Pregnant women in gestational weeks 33 to 36 were included in a catch-up programme at the start of the programme.

5.1.4. Norway (University of Oslo)

In Norway, maternal RSV vaccination with ABRYSVO has been available to pregnant women on request all year round since 01 December 2023, following the European Commission marketing authorisation issued on 23 August 2023 but it is not reimbursed by the public health system.^[24-26] Vaccination of pregnant women at their own expense is recorded in the vaccination database, SYSVAK, as part of the individual's vaccination history.

ABRYSVO vaccination has now been recommended for pregnant women by the Norwegian Institute of Public Health (NIPH) as part of national guidelines, although it is not yet part of the national immunisation programme.^[27] On 27 November 2025, NIPH submitted a formal recommendation to include maternal RSV vaccination or infant antibody prophylaxis in the national immunisation programme to the Norwegian Ministry of Health and Care Services, which is still under review.^[28] This recommendation and a completed health technology assessment by the Norwegian Medical Products Agency (Direktoratet for medisinske produkter: DMP) are currently being reviewed by the Ministry of Health and Care Services.

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Introduction is anticipated no earlier than the 2026–2027 RSV season, although timelines are not fixed and may vary depending on cost-effectiveness, budget impact, pricing negotiations, and policy prioritisation.^[29]

5.1.5. The Netherlands (PHARMO)

In the Netherlands, maternal RSV vaccination is not currently recommended as part of the national immunisation programme and is not reimbursed through the mandatory basic health insurance. Maternal RSV vaccination with ABRYSVO is licensed for pregnant women between 24 and 36 weeks of pregnancy, with advice that it is most effective when administered from 30 weeks onwards. ABRYSVO can be administered by general practitioners, at private vaccination centres or at travel vaccination clinic by the Municipal Public Health Services (GGDs), at their own expense, all year round, particularly for women expected to deliver between November and March.^[30] There is currently no immunisation register capturing voluntary vaccinations with ABRYSVO.

5.1.6. Spain (IACS, IDIAP JGoI, FISABIO)

In Spain, maternal RSV vaccination is not currently recommended as part of the national immunisation programme. The Interterritorial Council of the Ministry of Health and the Public Health Commission have prioritised the use of monoclonal antibody immunisation for all infants, which is provided free of charge. Maternal RSV vaccination with ABRYSVO is licensed for use between 24 and 36 weeks of gestation, with a preference for between 32 and 36 weeks of gestation. Regional health authorities in autonomous communities such as those participating in this study, i.e., Catalunya, Valencia, and Aragon, follow these national recommendations, but with local variations in implementation logistics and reimbursement. For the 2024-2025, and 2025-2026 seasons, ABRYSVO was available through community pharmacies all year round at women's own expense.^[31]

5.2. Ethics And Other Approvals

Table 2 provides an overview of the status of ethics approvals of the study protocol in the participating DEAPs. While the majority of ethics approvals have been obtained, approval is pending in PHARMO for the full study, with current approvals limited to the data required for progress reports, and a signed agreement is pending for BPE from the data provider, i.e., the French National Health Insurance Fund (Caisse Nationale d'Assurance Maladie: CNAM).

Table 2. Overview of ethics approvals of protocol in each participating DEAP

Country	DEAP	Ethics approvals
UK	DSRU	Approved by the CPRD RDG team on 23 December 2024.
France	BPE	Approved by the CESREES Committee on 13 February 2025. Approved by the CNIL on 10 July 2025. Agreement from the CNAM, i.e., the data provider, was received on 06 May 2026 and is currently pending signature by Pfizer and UMCU, as data controllers of the study results.
Denmark	AU	Ethics approval of registry-based studies is not required in Denmark, but the Danish Data Protection Agency has been notified of the study via registration with the Aarhus University's list of research projects.
Norway	UiO	Ethical approval was received on 18 December 2024. The DPIA was done on 05 May 2025.
Netherlands	PHARMO	Pending approval for the full study, with current approvals limited to the data required for progress reports by the STIZON compliance committee (PHARMO Data Network) and Perined.
Spain	IACS	Approved by IDIAP JGoI for all sites on 27 November 2024 (national coordinating centre).
Spain	IDIAP JGoI	
Spain	FISABIO	

AU: Aarhus University; BPE: Bordeaux PharmacoEpi; CESREES: Ethics and Scientific Committee for Research, Studies, and Evaluations in Health [Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé]; CNAM: National Health Insurance Fund [Caisse nationale d'Assurance Maladie]; CNIL: National Commission for Information Technology and Civil Liberties [Commission Nationale de l'Informatique et des Libertés]; CPRD: Clinical Practice Research Datalink; DPIA: Data protection impact assessment; DSRU: Drug Safety Research Unit; RDG team: FISABIO: Foundation for the Promotion of Health and Biomedical Research of the Valencian Community; IACS: Instituto Aragonés de Ciencias de la Salud; IDIAP JGoI: Institut Universitari d'Investigació en Atenció Primària Jordi Gol; Perined: Perinatal Registry; PHARMO: PHARMO Institute for Drug Outcomes Research; Research Data Governance team; UiO: University of Oslo; UMCU: University Medical Center Utrecht

5.3. Data Availability

The data available to each DEAP on pregnancies and ABRYSVO uptake for this progress report are summarised in **Table 3**.

Table 3. Data availability to DEAPs for the third progress report

Data source/DEAP /country	Data availability, last update and mode of analysis
CPRD Aurum/DSRU/UK	The DSRU converted the CPRD Aurum June 2025 data release that included data up to 31 March 2025 into the ConcePTION CDM. The Pregnancy Register and Mother-Baby Link algorithm derived datasets available for the same release were also used. As the Mother-Baby link for this release was complete up to 31 December 2024, pregnancies ongoing beyond this date were excluded only when linked baby records were required and were otherwise retained.

Table 3. Data availability to DEAPs for the third progress report

Data source/DEAP /country	Data availability, last update and mode of analysis
SNDS/BPE/FR	Data from SNDS were not available for this progress report as the agreement with the data provider is pending signature. Estimates of RSV vaccine uptake in pregnancy were obtained from public information up to 31 December 2024 from OpenMedic ^[32] and Medic'AM. ^[33] Open Medic and Medic'AM data are currently available up to 31 st December 2025.
DHR/AU/DK	Aarhus University converted the Danish Health Registries data, that was complete up to to 30 September 2025, into the ConcePTION CDM.
NHR/UiO/NO	For this progress report, no NHR data were available because data extraction from the registry is ongoing by the registry holder. Therefore, UiO estimated RSV vaccination uptake among women of reproductive age who paid out-of-pocket for vaccination using publicly available data up to 31 December 2024. The number of women dispensed an RSV vaccine, identified by ATC code J07BX05, was obtained from the Norwegian Institute of Public Health medicine statistics portal, FHI Legemiddelstatistikk.^[34] The study population denominator and number of live births were obtained from Statistics Norway (SSB).^[35] Annual and monthly birth counts were used to derive the total number of live births during the study period. The total number of pregnancies was then estimated by applying pregnancy outcome proportions from a published Norwegian pregnancy algorithm to the live birth count.^[36] As ABRYSVO is the only RSV vaccine approved and recommended for maternal use in Norway in this age group,^[37] and AREXVY (the RSV vaccine manufactured by GSK) is contraindicated during pregnancy, dispensing of ATC code J07BX05 among women aged 10 to 54 years* were assumed to represent ABRYSVO vaccinations. Nearly all ABRYSVO dispensed were assumed to have been administered to pregnant women.
PHARMO and Perined/PHARMO /NL	Maternal vaccination with ABRYSVO is not yet recommended or reimbursed in The Netherlands but it is available privately at women's own expense. PHARMO independently identified the population of women aged 12 to 55 years and pregnancies within this population to estimate the number of vaccinations obtained privately. Estimates were based on outpatient pharmacy (OAPO) data linked to the national Perinatal Registry, Perined. The observation period for this progress report covered Perined data from 24 August 2023, i.e., the date ABRYSVO became available in the Netherlands to 31 December 2024, i.e., the date of the most recently data available from PHARMO and Perined data for this third progress report. The cohort entry was defined as 24 0/7 gestational age, as specified in the protocol. Perined includes data for terminated pregnancies only, therefore, only data for pregnancies that terminated within the study period were included in this progress report.
EpiChron/IACS/ES	At present, the maternal RSV vaccine is not recommended in Spain. No data were accessible by IACs for this progress report.

Table 3. Data availability to DEAPs for the third progress report

Data source/DEAP /country	Data availability, last update and mode of analysis
SIDIAP/IDIAP JGoI/ES	At present, the maternal RSV vaccine is not recommended in Spain. No data were accessible by IDIAPJGoI for this progress report.
VID/FISABIO/ES	At present, the maternal RSV vaccine is not recommended in Spain. No data were accessible by VID for this progress report. A previous data instance with data from Q3 2020 to Q4 2021 was reused to estimate the size of the pregnant population per year. Pregnancies with imputed start and end dates were excluded from the pregnancy counts. In addition, information on ABRYSVO-vaccinated women was updated through a direct query to the regional vaccination registry database, managed by the Dirección General de Salud Pública as of 15 April 2026.

**The age range 10-54 reflects the publicly available Norwegian statistics that are reported in 5-year age bands (10-14 to 50-54). The next available age band is 55-59 years and was therefore not included. Non-maternal use of RSV dispensed vaccines, retrieved using the ATC code J07BX05, cannot be excluded since 2.8% (2024) and 0.9% (2025) were recorded in males of the same age range.*

AU: Aarhus University; BPE: Bordeaux PharmacoEpi; CPRD: Clinical Practice Research Datalink; DHR: Danish health registries; DPIA: Data protection impact assessment; DSRU: Drug Safety Research Unit; RDG team: FISABIO: Foundation for the Promotion of Health and Biomedical Research of the Valencian Community; IACS: Instituto Aragonés de Ciencias de la Salud; IDIAP JGoI: Institut Universitari d'Investigació en Atenció Primària Jordi Gol; Perined: Perinatal Registry; NHR: Norwegian health registries; PHARMO: PHARMO Institute for Drug Outcomes Research; Research Data Governance team; SNDS: French National Health Data System [Système National des Données de Santé]; UiO: University of Oslo; UMCU: University Medical Center Utrecht; VID: Valencia Health System Integrated Database

5.4. Study Population Size And Uptake Of ABRYSVO

The study population and uptake of ABRYSVO in pregnant women between ages 12 and 55 years, either actual (from participating data sources) or estimated from publicly available data, are described below and in [Table 4](#).

5.4.1. CPRD Aurum, Provided By DSRU (UK)

In CPRD Aurum only data for pregnant women were converted to the ConcepTION CDM for this progress report. DSRU used CPRD Aurum denominator data to estimate a total of 5,843,895 females between ages 12 to 55 years during the study period.

A total of 309,736 women were pregnant at least once at any gestational age during their pregnancy during the study period, corresponding to a total of 345,697 pregnancies. Among these pregnancies, 167,367 had a recorded pregnancy end date after last menstrual period (LMP)+24 weeks, and 28,584 (8.27%, of all pregnancies in the study period without restrictions) were exposed to ABRYSVO. Most ABRYSVO vaccinations were administered in Q3 and Q4 of 2024, consistent with the start of the vaccination campaign and data availability for this progress report, which covered the period up to 31 March 2025.^[38]

Most ABRYSVO-exposed pregnancies (N=28,584) had vaccination recorded between 24 to 36 weeks of gestation (N=24,591, 86.03%). In addition, vaccination was recorded before 24 weeks of gestation in 2.29% pregnancies, and after 36 weeks of gestation in 11.68%

pregnancies among the vaccinated pregnancies, which is outside the EMA licensed indication, but within the MHRA's approved indication. In the UK, the MHRA licensed gestational age for maternal vaccination is 28 to 36 weeks, however the UK Health Security Agency (UKHSA) recommends that RSV vaccination is given from 28 weeks onwards, up until the women goes into labour, if necessary.

5.4.2. SNDS, Provided By BPE (France)

Actual data from the SNDS data source are not yet available and therefore, SNDS estimated from public data (Open Medic and Medic'AM) that there were approximately 18.5 million females aged 12 to 55 years during the study period, and approximately 1 million women per year with at least one pregnancy in France.^[32, 33]

Public EPI-PHARE data from the first French maternal RSV vaccination campaign showed substantial uptake (27.23%) of ABRYSVO among eligible pregnant women.^[39] Between 15 September 2024 and 31 January 2025, 264,471 pregnant women reached the recommended gestational window for vaccination, defined as 32 to 36 weeks of gestation, and ABRYSVO vaccination was recorded in 72,026 pregnancies. Most pregnancies had a vaccination recorded between 32 and 36 weeks of gestation (80.6%). There were 9.8% pregnancies with a vaccination record before 32 weeks of gestation and 9.6% after 36 weeks of gestation, which is outside the EMA licensed indication.

5.4.3. Danish Health Registries (DHR), Provided By Aarhus University (Denmark)

In DHR, 1,975,675 females aged 12 to 55 years were identified during the study period. A total of 131,411 women were pregnant at least once during the study period, corresponding to a total of 144,667 pregnancies recorded from the start of the study period up to 30 September 2025. Of these, 133,482 had both a pregnancy start and end date recorded. A total of 102,375 pregnancies had a recorded pregnancy end date after LMP+24 weeks, and 4,349 (3.01%, among all pregnancies) were exposed to ABRYSVO. The majority of ABRYSVO vaccinations were recorded in Q3 2025, with 56.27% (N=2,447) of vaccinations and 12.58% (N=547) in Q2 2025 among exposed pregnancies.

Most pregnancies had an ABRYSVO vaccination record between 24 and 36 weeks of gestational age (N=[4,284-4,287], approximately 98.5% among ABRYSVO exposed pregnancies). Fewer than five (less than 0.1%) pregnancies had a vaccination record before 24 weeks of gestation, and 61 (1.4%) after 36 weeks of gestation among ABRYSVO exposed pregnancies.

5.4.4. Norwegian Health Registries (NHR), Provided By University Of Oslo (Norway)

Data from the NHR data source are not yet available, therefore, publicly available data were used. Based on Statistics Norway data, there were 1,561,264 females aged 12 to 54 years in Norway during the study period. Over the same period, 75,074 live births were recorded between August 2023 and December 2024.^[35, 40, 41] Applying pregnancy outcome proportions from the UiO pregnancy algorithm to the live birth count, the total number of pregnancies during the study period was estimated at approximately 100,000.^[36]

Public dispensing data from the Norwegian Institute of Public Health medicine statistics portal showed that 838 women aged 18 to 54 years were dispensed an RSV vaccine by the end of 2024.^[42] As ABRYSVO is the only RSV vaccine approved for adults aged 18 years and older and recommended for use during pregnancy in Norway,^[43] these dispensed vaccines were assumed to be ABRYSVO vaccinations. Most, if not all, are expected to have occurred among pregnant women, however non-maternal use, cannot be entirely excluded, as a small proportion of RSV vaccination (ATC = JO7BX05) units dispensed in the same age range occurred among males in 2024 (3.0%) and 2025 (0.9%).^[34] The estimated ABRYSVO uptake among pregnant women, who paid out-of-pocket costs in Norway, was approximately 1.6% in 2024, based on 838 units dispensed among women aged 10 to 54 and 54,013 live births in 2024.^[40]

Publicly available data for 2025 showed a marked increase in uptake. A total of 8,513 women aged 10 to 54 years were dispensed an RSV vaccine in 2025, corresponding to an estimated uptake of approximately 15%, based on 55,401 live births. This represents an approximately 10-fold increase compared with 2024 and coincides with the formal NIPH recommendation issued in November 2025. These data indicate rapidly increasing uptake of maternal RSV vaccination in Norway.^[34]

5.4.5. PHARMO Data Network, Provided By PHARMO Institute (The Netherlands)

NL has not yet recommended and reimbursed the maternal vaccine which is only available privately at the woman's own expense. Based on the PHARMO outpatient pharmacy data linked to Perined, 2,731,361 females aged 12 to 55 years were identified between August 2023 and 31 December 2024. During the study period, 60,784 females had at least one recorded pregnancy with a total of 62,304 pregnancies. Of these 43,919 (70.5%) pregnancies reached 24 0/7 weeks of gestation during the study period.

Overall, 71 pregnancies had an ABRYSVO dispensing recorded in the PHARMO pharmacy data, mostly between 24 to 36 weeks of gestational age (n=60, 84.51%, among ABRYSVO exposed pregnancies). Five pregnancies (7.04%) had a recorded ABRYSVO dispensing before 24 weeks of gestation, and six (8.45%) after 36 weeks of gestation among ABRYSVO exposed pregnancies, based on pharmacy dispensing dates. Fewer than five pregnancies had a vaccine record outside of the observable follow-up period and were therefore excluded from the overall counts.

5.4.6. VID, Provided By FISABIO, Valencia Region (Spain)

At present, the maternal RSV vaccination is not recommended in Spain.

Based on the regional vaccination registry, five women of childbearing age have been vaccinated with ABRYSVO at their own expense since its commercialisation in the Valencian Region. Fewer than five women were recorded as being pregnant at the time of vaccination.

Table 4. Total numbers of identifiable pregnancies in females aged 12–55 years reaching 24 0/7 weeks of gestation within the study period and ABRYSVO vaccination uptake using either data extracted from the data sources or publicly available data sources

	CPRD Aurum*	SNDS*	DHR*	NHR*	PHARMO*	VID*
Females aged 12-55 years**	5,843,895	~ 18.5 million ^{[44]a}	1,975,675	1,561,264 ^a	2,731,361	1,376,389
Females aged 12-55 years with ≥1 recorded pregnancy, n (%) ^b	309,736 (5.30)	~ 1 million (5.41) per year ^{[45]c}	131,411 (6.65)	~100,000 (5.05) per year ^d	60,784 (2.23)	55,101 (4.00)
Pregnancies recorded from start of study period to end of data availability and aged 12-55 years ^b (all pregnancies)	345,697	N/A	144,667	~ 100,000	62,304 ^h	57,459
with pregnancy start date but no pregnancy end date recorded within the study period, n (% among all pregnancies)	48 (0.01) ⁱ	N/A	11,185 (7.73)	N/A	0 (0)	7,405 (12.9)
with pregnancy start and end date recorded, n (% among all pregnancies)	345,649 (99.99)	N/A	133,482 (92.27)	~ 100,000	62,304 (100)	50,054 (87.1)
AND with end pregnancy date ≥24 weeks of gestational age, n (% among all pregnancies)	167,367 (48.42)	N/A	102,375 (70.77)	Estimated. 75,500	43,919 (70.5)	N/A
AND received ABRYSVO, n (% among all pregnancies)	28,584 (8.27) ^e	66,759 women aged 0-59 received Abrysvo in 2024 ^{i [32]}	4,349 (3.01)	838 ^f (upper bound) ^{[34]***}	71 (0.16) ^f	[1-4] (<0.01)**
Number exposed by calendar quarter, n (% based on ABRYSVO exposed)						
Q3 2023	0 (0)	0	0 (0)	N/A	N/A	N/A
Q4 2023	0 (0)	0	39 (0.90)	N/A	N/A	N/A
Q1 2024	0 (0)	0	[54-58] (1.24-1.33)**	N/A	N/A	N/A
Q2 2024	[1-4] [0.00-0.01]**	0	135 (3.10)	N/A	N/A	N/A

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Table 4. Total numbers of identifiable pregnancies in females aged 12–55 years reaching 24 0/7 weeks of gestation within the study period and ABRYSVO vaccination uptake using either data extracted from the data sources or publicly available data sources

	CPRD Aurum*	SNDS*	DHR*	NHR*	PHARMO*	VID*
Q3 2024	8,190 (28.65)	3,339 Abrysvo units reimbursed ^d [33]	[221-225] (5.08-5.17)**	N/A	N/A	N/A
Q4 2024	[16,962-16,965] (59.34-59.35)**	66,752 Abrysvo units reimbursed ^d [33]	[571-575] (13.13-13.22)**	N/A	N/A	N/A
Q1 2025	3,428 (11.99)	32,270 Abrysvo units reimbursed ^d (source: Medic'AM)	328 (7.54)	N/A	N/A	N/A
Q2 2025	0 (0)	1,877 Abrysvo units reimbursed ^d (source: Medic'AM)	547 (12.58)	N/A	N/A	N/A
Q3 2025	0 (0)	N/A	2,447 (56.27)			
High risk pregnancy (among ABRYSVO exposed)	5,761 (20.15)	N/A	695 (15.98)	N/A	N/A	N/A
Immunocompromised (among ABRYSVO exposed)	1,342 (4.69)	N/A	338 (7.77)	N/A	N/A	N/A
Gestational age at exposure (among ABRYSVO exposed)		N/A			N/A	N/A
<week 24	655 (2.29)	N/A	[1-4] (0.02-0.09)**	N/A	5 ^g	N/A
week 24	132 (0.46)	N/A	14 (0.32)	N/A	60 ^g	N/A
week 25	176 (0.62)	N/A	33 (0.76)	N/A		N/A
week 26	372 (1.30)	N/A	43 (0.99)	N/A		N/A
week 27	1,053 (3.68)	N/A	65 (1.49)	N/A		N/A

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Table 4. Total numbers of identifiable pregnancies in females aged 12–55 years reaching 24 0/7 weeks of gestation within the study period and ABRYSVO vaccination uptake using either data extracted from the data sources or publicly available data sources

	CPRD Aurum*	SNDS*	DHR*	NHR*	PHARMO*	VID*
week 28	2,602 (9.10)	N/A	94 (2.16)	N/A		N/A
week 29	2,737 (9.58)	N/A	142 (3.27)	N/A		N/A
week 30	2,706 (9.47)	N/A	210 (4.83)	N/A		N/A
week 31	2,860 (10.01)	N/A	401 (9.22)	N/A		N/A
week 32	2,906 (10.17)	N/A	695 (15.98)	N/A		N/A
week 33	2,452 (8.58)	N/A	681 (15.66)	N/A		N/A
week 34	2,300 (8.05)	N/A	[908-911] (20.88-20.95)**	N/A		N/A
week 35	2,281 (7.98)	N/A	743 (17.08)	N/A		N/A
week 36	2,014 (7.05)	N/A	255 (5.86)	N/A	6 ^g	N/A
>week 36	3,338 (11.68)	N/A	61 (1.40)	N/A		N/A

24 0/7 weeks: Exactly 24 weeks and 0 days. N/A: not available, due to absence of information in the data source used;

*CPRD Aurum and DHR data are based on running of study scripts. SNDS, NHR, PHARMO and VID calculated their own estimates or retrieved them from external sources;

**Number and percentages masked with ranges for secondary disclosure control;

***Age data for Norway was available by 5-year categories, so upper age limit was 54 years and lower limit was 10 years;

aOn 01 January 2024;

bPregnancies reaching 24 weeks after the last data availability are excluded from the total;

cEstimated from number of live births in 2024, 660,800. 96.2% of pregnancies have a live birth pregnancy outcome.^[45];

dEstimated using a pregnancy algorithm and 75,074 live births (Aug 2023 – Dec 2024) based on SSB data.^[36] retrieved from the vaccination registry;

eIdentified using medcodeids and prodcodeids and confirmed using the manufacturer information;

fIdentified using and ATC code (J07BX05);

gGestational age at vaccination was based on pregnancy dates as recorded in the Perined registry and pharmacy dispensing dates, which may not reflect the actual date of vaccine administration. For dispensing before 24 weeks of gestation administration may have occurred within the eligible window but could not be confirmed. For dispensing after 36 weeks, <5 occurred within a few days of the cut-off, and <5 were likely related to another pregnancy not included in the current Perined data extraction given the long interval between 36 weeks of gestation and the dispensing date;

hRetrieved from the Perined registry, which contains only completed pregnancies;

iFor ongoing pregnancies at the data cut time, the latest antenatal record in the pregnancy episode was provided as the pregnancy end date;

Table 4. Total numbers of identifiable pregnancies in females aged 12–55 years reaching 24 0/7 weeks of gestation within the study period and ABRYSVO vaccination uptake using either data extracted from the data sources or publicly available data sources

	CPRD Aurum*	SNDS*	DHR*	NHR*	PHARMO*	VID*
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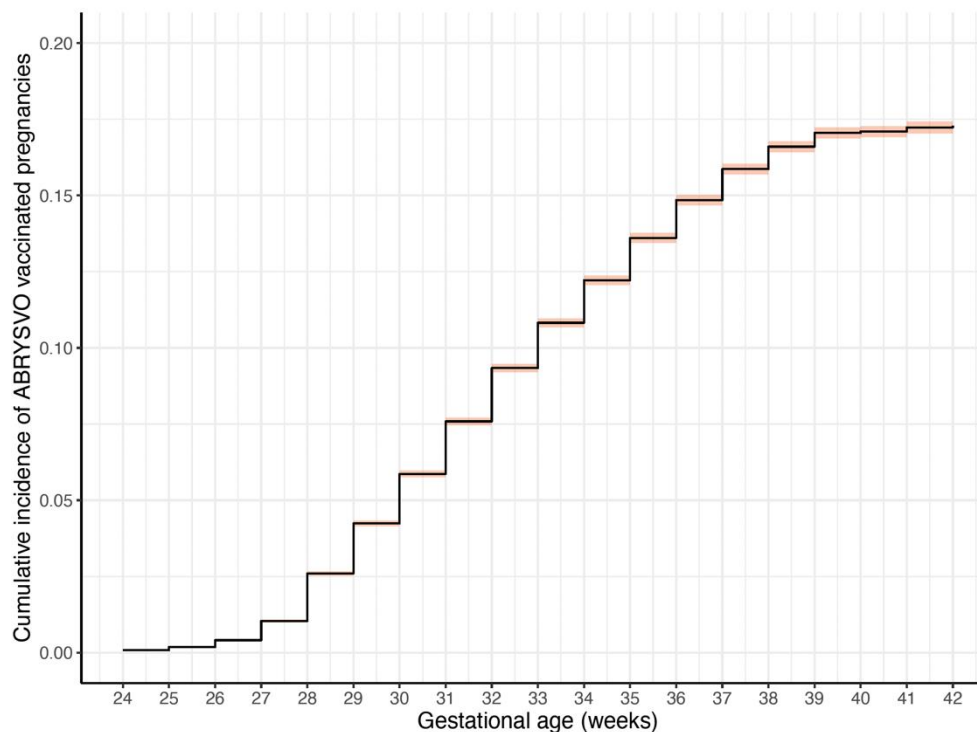
jMedic'AM reports number of reimbursed units, not vaccinated women, and was used because it allows stratification by calendar period. Counts may therefore differ from Open Medic which reports number of units by age and sex and may include rare coding errors.

5.5. Characteristics Of The Population Of ABRYSVO-Vaccinated Pregnancies And All Eligible Pregnancies

In CPRD Aurum, 167,367 of all the 345,697 pregnancies identified in the study period, reached 24 weeks of gestational age during the study period, and 28,584 (8.27%) of all pregnancies had an ABRYSVO vaccination recorded during pregnancy. In DHR, 102,375 of the 144,667 pregnancies were identified in the study period, reached 24 weeks of gestational age during the study period and 4,349 (3.01%) of all pregnancies had an ABRYSVO vaccination recorded during pregnancy ([Table 4](#)). Please note that [Table 4](#) includes data for all pregnancies that were vaccinated with ABRYSVO, including those that were vaccinated before week 24 of gestation and after week 36 of gestation.

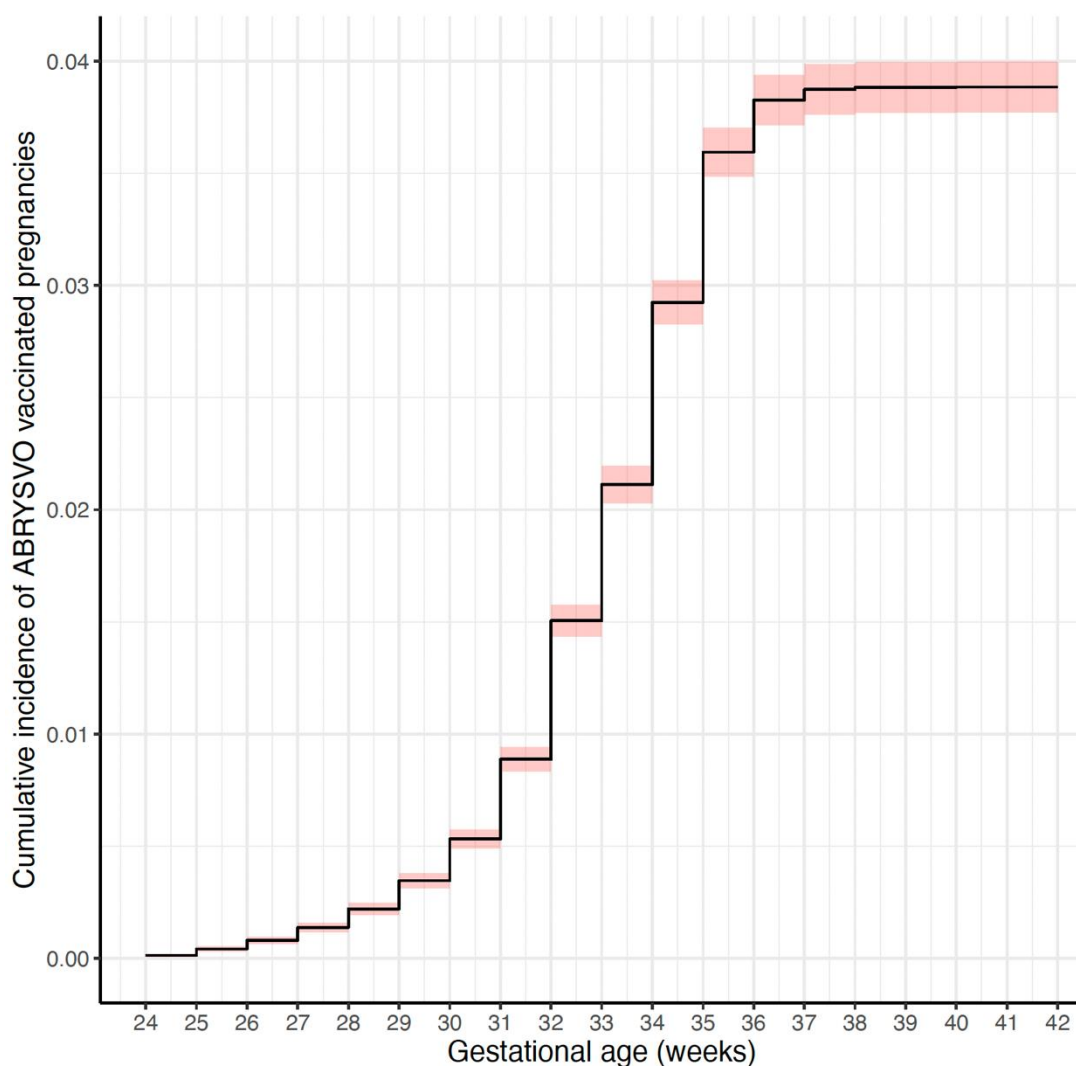
The cumulative incidences of ABRYSVO-vaccinated pregnancies by gestational age, from 24 weeks and without censoring at 36 weeks, in CPRD Aurum and DHR are shown in [Figure 2](#) and [Figure 3](#), respectively.

Figure 2. Cumulative incidence of ABRYSVO-vaccinated pregnancies from week 24 of gestation in CPRD Aurum



The cumulative incidence is the estimated proportion of vaccinated pregnancies by gestational week from week 24 onwards. Estimates were calculated as $1 - \text{Kaplan-Meier probability of remaining unvaccinated}$. Vaccination was treated as the event and pregnancy end before vaccination was treated as censoring. Pregnancies contributed person-time up to vaccination or censoring. Steeper increases indicate gestational windows where vaccinations were more frequent.

Figure 3. Cumulative incidence of ABRYSVO-vaccinated pregnancies from week 24 of gestation in DHR



The cumulative incidence is the estimated proportion of vaccinated pregnancies by gestational week from week 24 onwards. Estimates were calculated as $1 - \text{Kaplan-Meier probability of remaining unvaccinated}$. Vaccination was treated as the event and pregnancy end before vaccination was treated as censoring. Pregnancies contributed person-time up to vaccination or censoring. Steeper increases indicate gestational windows where vaccinations were more frequent.

Table 5 shows the absolute number of ABRYSVO vaccinations during pregnancy in CPRD Aurum and DHR, per gestational week, from 24 weeks of gestation till the end of pregnancy. In CPRD Aurum, the peak of ABRYSVO vaccination occurred between 28 and 35 weeks of gestation. In DHR, ABRYSVO vaccination peaked between 31 and 35 weeks of gestation. **Figure 4** and **Figure 5** are the graphical representation of **Table 5**, in CPRD Aurum and DHR, respectively. There were substantially more ABRYSVO vaccinations in CPRD Aurum

after gestational week 36, than in DHR, 11.96% (N=[3,338-3,341] out of 27,929) vs. 1.33-1.47% (N=[58-64] out of [4,345-4,348]), respectively.

Table 5. Number of ABRYSVO-vaccinated pregnancies by estimated gestational age in CPRD Aurum and DHR from 24 weeks of gestation to end of pregnancy

	CPRD Aurum	DHR
Total, N	27,929^a	4,345-4348^{a*}
Gestational age in weeks, N (%)		
24	132 (0.47)	14 (0.32)
25	176 (0.63)	33 (0.76)
26	372 (1.33)	43 (0.99)
27	1053 (3.77)	65 (1.49-1.50)*
28	2602 (9.32)	94 (2.16)
29	2737 (9.80)	142 (3.27)
30	2706 (9.69)	210 (4.83)
31	2860 (10.24)	401 (9.22-9.23)*
32	[2903-2906]* (10.39-10.40)	695 (15.98-16.00)*
33	2452 (8.78)	681 (15.66-15.67)*
34	2300 (8.24)	[908-911]* (20.88-20.97)*
35	2281 (8.17)	743 (17.09-17.10)*
36	2014 (7.21)	255 (5.86-5.87)*
37	1569 (5.62)	[48-51]* (1.10-1.17)*
38	1081 (3.87)	9 (0.21)
39	622 (2.23)	0 (0)
40	53 (0.19)	[1-4]* (0.02-0.09)
41	12 (0.04)	0 (0)
42	[1-4]* (<0.01-0.01)	0 (0)

^aVaccinated pregnancies between 24 and 42 6/7 weeks of gestation age, with 12-month lookback period prior T0, 24 0/7 weeks gestation age reached between the study start date and the data cut date, and age at start pregnancy between 12 and 55 years old; *Number masked with range for secondary disclosure control.

Figure 4. Number of ABRYSVO-vaccinated pregnancies by estimated gestational age (in weeks) at the time of ABRYSVO vaccination in CPRD Aurum

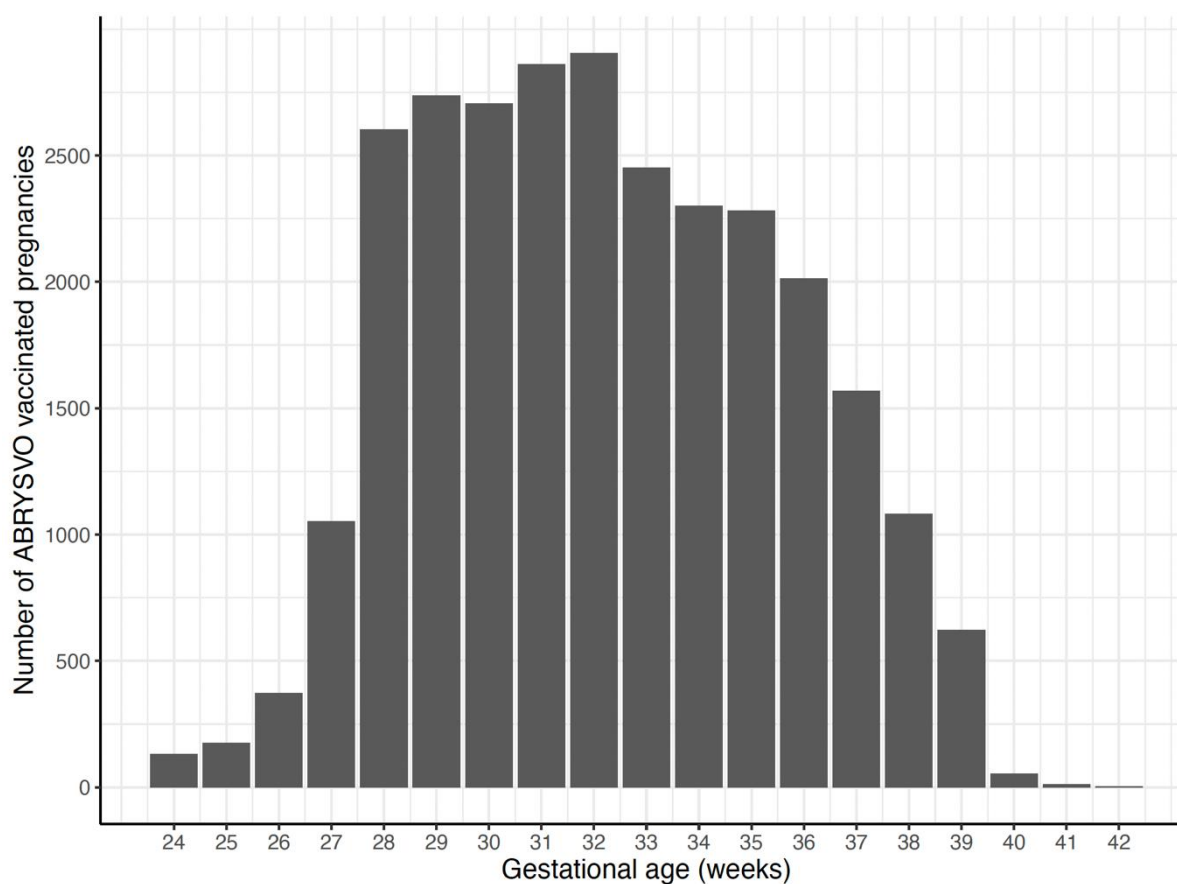
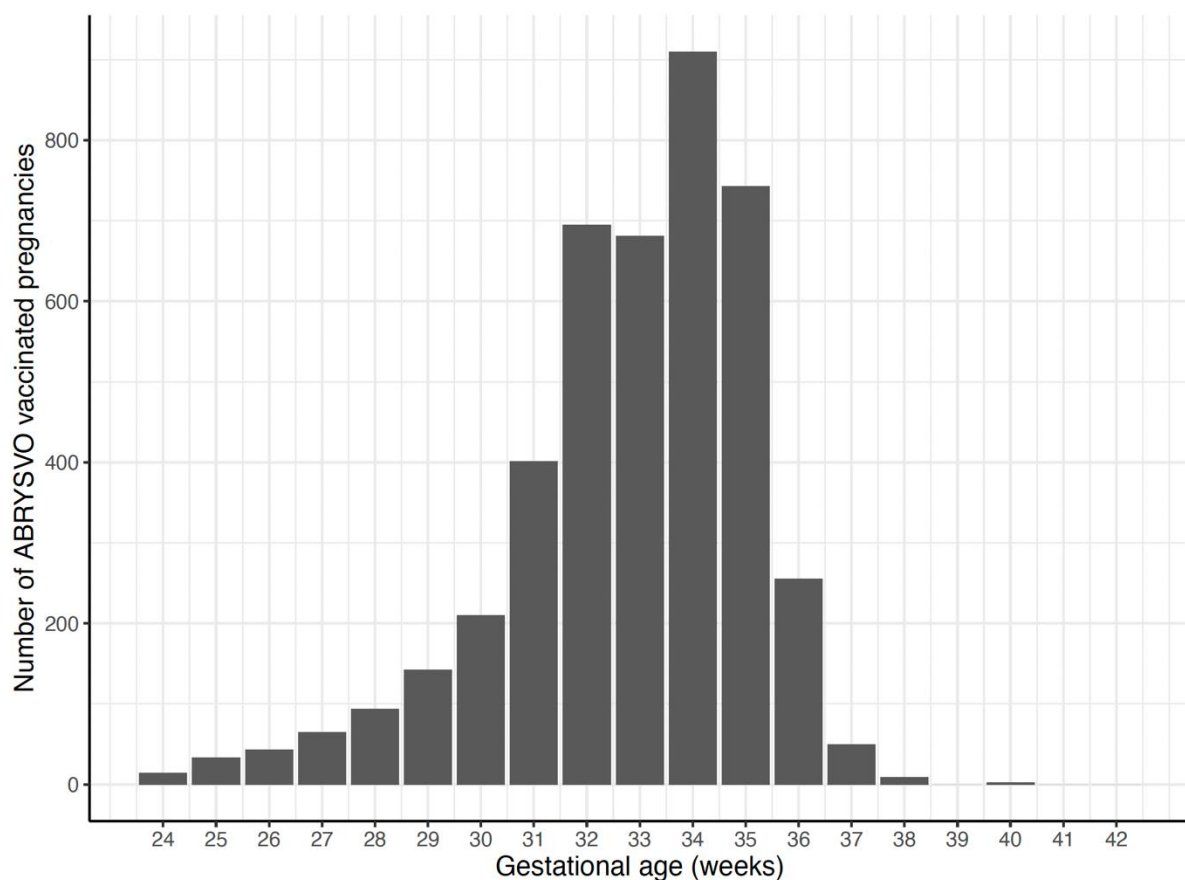


Figure 5. Number of ABRYSVO-vaccinated pregnancies by estimated gestational age (in weeks) at time of ABRYSVO vaccination in DHR



The characteristics of ABRYSVO-vaccinated pregnancies (at the time of vaccination) and all pregnancies at 24 weeks gestational age in CPRD Aurum and DHR with the adjusted standardised differences (ASDs) are summarized in [Table 6](#). The median age of the ABRYSVO -vaccinated cohort was slightly higher than that of the overall pregnancy cohort in both data sources. In CPRD Aurum, the median maternal age was 32 years in the vaccinated cohort compared with 31 years in all pregnancies (ASD 0.20). In DHR, the medians were the same as CPRD Aurum with an ASD of 0.24.

In CPRD Aurum, ABRYSVO vaccination started in Q3 2024 and Q4 2024 with about 61.9% occurring in Q4 2024 alone although the total number all pregnancies was similar in each quarter throughout the study period from Q3 2023 onwards. In DHR, ABRYSVO vaccination started in Q4 2023. The highest percentage of recorded ABRYSVO vaccinations was observed in Q3 2025 (56.14%).

The characteristics of the ABRYSVO-vaccinated pregnancies and all pregnancies were similar in both CPRD and DHR except for gestational diabetes ([Table 6](#)). At the time of

vaccination gestational diabetes was more prevalent in the ABRYSVO vaccinated cohorts than at 24 weeks of gestation, as assessed in all pregnancies in both data sources (7.17% vs. 1.90%, ASD: 0.26 in CPRD Aurum and 4.41% vs. 1.49%, ASD:0.17 in DHR, respectively). The prevalence of obesity was slightly lower in the ABRYSVO vaccinated cohort compared with all pregnancies in DHR (1.84% vs 2.09%, ASD:0.02), while in CPRD it was similar (9.53% vs 9.44%, ASD: 0.00). The prevalence of immunocompromised and high-risk pregnancy at time of vaccination was higher in the ABRYSVO vaccinated cohort compared with the prevalence at 24 weeks of gestation in all pregnancies in CPRD Aurum, 4.67% vs 3.95% (ASD: 0.04), and 19.86% vs 15.90% (ASD: 0.10), respectively. The same pattern was observed in DHR where the prevalences of immunocompromised and high-risk pregnancy were higher in the vaccinated cohort compared with all pregnancies, 7.70% vs 6.37% (ASD: 0.05), and 15.90% vs 14.45% (ASD: 0.04), respectively.

Table 6. Characteristics of ABRYSVO-vaccinated pregnancies between 24 and 36 weeks of gestational age, and all pregnancies at 24 weeks gestational age in CPRD Aurum and DHR, with absolute standardised differences

	CPRD			DHR		
	Vaccinated ^a	All ^b	ASD	Vaccinated ^a	All ^b	ASD
Total, N	24,591	167,415		4,284	113,560	
Demographics						
Maternal age (years)			0.20			0.24
Mean (SD)	31.76 (5.18)	30.65 (5.59)		32.07 (4.05)	31.03 (4.52)	
Median (Q1, Q3)	32.00 (29.00, 35.00)	31.00 (27.00-35.00)		32.00 (29.00, 35.00)	31.00 (28.00, 34.00)	
Calendar quarter for T0^f, n (%)			2.33			1.48
Q3 2023	0 (0)	13,826 (8.26)		0 (0)	5,278 (4.65)	
Q4 2023	0 (0)	33,698 (20.13)		39 (0.91)	13,875 (12.22)	
Q1 2024	0 (0)	33,701 (20.13)		53 (1.24)	14,113 (12.43)	
Q2 2024	[1-4] (0 - 0.02) ^e	33,710 (20.14)		135 (3.15)	14,139 (12.45)	
Q3 2024	6,475 (26.33)	32,730 (19.55)		220 (5.14)	13,502 (11.89)	
Q4 2024	[15,225-15,228] (61.91 - 61.93)	19,309 (11.53)		570 (13.31)	14,127 (12.44)	
Q1 2025	2,887 (11.74)	441 (0.26)		321 (7.49)	14,792 (13.03)	
Q2 2025	0	0		541 (12.63)	15,190 (13.38)	
Q3 2025	0	0		2,405 (56.14)	8,544 (7.52)	
Immunocompromised status (at least one below)	1,149 (4.67)	6,618 (3.95)	0.04	330 (7.70)	7,231 (6.37)	0.05
Medical condition						
Diagnosed with symptomatic HIV/AIDS	40 (0.16)	333 (0.20)	0.01	19 (0.44)	312 (0.27)	0.03
Diagnosed with haematologic malignancy ^c	28 (0.11)	155 (0.09)	0.01	5 (0.12)	100 (0.09)	0.01
Diagnosed with solid malignancy	168 (0.68)	973 (0.58)	0.01	29 (0.68)	680 (0.60)	0.01
Diagnosed with rheumatologic/inflammatory conditions	546 (2.22)	3,268 (1.95)	0.02	152 (3.55)	3,588 (3.16)	0.02
Immunosuppressive treatments						
Organ transplant recipients or islet transplant recipients taking immunosuppressive therapy	[1-4] (0.00-0.02) ^e	15 (0.01)	0.00	9 (0.21)	203 (0.18)	0.01
CAR-T-cell therapy or hematopoietic stem cell transplant recipients taking immunosuppressive therapy	0 (0)	[1-4] (0.00-0.00) ^e	0.00	[1-4] (0.02-0.09) ^e	16 (0.01)	0.02
Rheumatologic/inflammatory conditions treated with anti-suppressive therapy	144 (0.59)	898 (0.54)	0.01	60 (1.40)	1,387 (1.22)	0.02

Table 6. Characteristics of ABRYSVO-vaccinated pregnancies between 24 and 36 weeks of gestational age, and all pregnancies at 24 weeks gestational age in CPRD Aurum and DHR, with absolute standardised differences

	CPRD			DHR		
	Vaccinated ^a	All ^b	ASD	Vaccinated ^a	All ^b	ASD
Active treatment (at time of vaccination) with various immunomodulating agents	478 (1.94)	2,488 (1.49)	0.04	140 (3.27)	2,713 (2.39)	0.05
Specific medical procedures						
Organ transplant recipients or islet transplant recipients	8 (0.03)	63 (0.04)	0.00	42 (0.98)	945 (0.83)	0.02
CAR-T-cell therapy or hematopoietic stem cell transplant recipients	[1-4] (0.00-0.02) ^e	13 (0.01)	0.00	[1-4] (0.02-0.09) ^e	37 (0.03)	0.02
High-risk pregnancy (any of the following condition)	4,885 (19.86)	26,617 (15.90)	0.10	681 (15.90)	16,413 (14.45)	0.04
Condition in current pregnancy						
Obesity	2,344 (9.53)	15,798 (9.44)	0.00	79 (1.84)	2,370 (2.09)	0.02
Chronic hypertension	38 (0.15)	312 (0.19)	0.01	10 (0.23)	140 (0.12)	0.03
Pre-eclampsia/eclampsia	24 (0.10)	96 (0.06)	0.01	6 (0.14)	42 (0.04)	0.04
Multifetal pregnancy	259 (1.05)	1,620 (0.97)	0.01	77 (1.80)	1,754 (1.54)	0.02
Diabetes	295 (1.20)	1,824 (1.09)	0.01	18 (0.42)	777 (0.68)	0.04
Gestational diabetes	1,763 (7.17)	3,187 (1.90)	0.26	189 (4.41)	1,691 (1.49)	0.17
Condition in previous pregnancies (last 10 years)						
Gestational diabetes	747 (3.04)	5,497 (3.28)	0.01	106 (2.47)	3,443 (3.03)	0.03
Preeclampsia/eclampsia	104 (0.42)	671 (0.40)	0.00	104 (2.43)	2,884 (2.54)	0.01
Stillbirth	92 (0.37)	659 (0.39)	0.00	0 (0)	119 (0.10)	0.05
Late miscarriage	252 (1.02)	1,685 (1.01)	0.00	87 (2.03)	2,295 (2.02)	0.00
Small for gestational age or fetal growth restriction	17 (0.07) ^d	96 (0.06) ^d	0.00	73 (1.70)	2,598 (2.29)	0.04
Congenital anomaly	52 (0.21) ^d	332 (0.20) ^d	0.00	72 (1.68)	1,669 (1.47)	0.02

ASD – absolute standardised difference; *Number ranges masked, with secondary disclosure control;

a Vaccinated pregnancies between 24 0/7 and 36 6/7 weeks of gestation age, with 12 months of lookback period prior T0, 24 0/7 weeks gestation age reached within the study period and the data cut time, and age at start pregnancy between 12 and 55 years old;

b All pregnancies with 12 months of lookback period prior LMP date+24 0/7 weeks, 24 0/7 weeks gestation age reached within the study period and the data cut time, and age at start pregnancy between 12 and 55 years old;

c hematologic malignancy, e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, Hodgkin lymphoma, multiple myeloma, acute leukemia);

d Based only on pregnancies within the study period (August 2023 – March 2025), due to missing mother-baby linkage for pregnancies outside this period.

e Number masked with ranges for secondary disclosure control;

T0 defined as vaccination date for the vaccinated cohort, and as the date of reach 24 0/7 weeks of gestation for all pregnancies cohort.

5.6. Study Conduct

5.6.1. Data Quality

In this third progress report, the INSIGHT data quality assessment of the ConcePTION CDM was completed for CPRD Aurum and DHR only.^[46] INSIGHT is an open-source data quality assessment tool developed to evaluate completeness, consistency and fit-for-purpose of observational health data standardised to the ConcePTION CDM. Estimates were provided for the other data sources, based on publicly available data or previous data instances that could not be verified by the Lead Scientific Centre (UMCU).

In CPRD Aurum, not all RSV vaccines were labelled by brand. It was assumed for this report that RSV vaccines used during pregnancy in the UK were ABRYSVO, as it is the only vaccine licensed for maternal vaccination.

5.6.2. Other Deviations

Quality control (QC) was not completed for all steps included in the Transformation 3 step of the analytical pipeline, which creates the study variables. The QC process focused on a predefined set of study variables, including variables with more complex logic and that shared functionality with the other study variables. In addition, results were reviewed against expected patterns and benchmarked, where possible, against published literature or external reference sources. Although these checks support the overall reliability of findings, some uncertainty remains for the variables with more complex derivations or limited external comparators.

5.7. Actions Taken For Safety Reasons

Regulatory actions that have been taken for safety reasons since the initiation of the C3671026 study are summarised in [Table 7](#).

Table 7. Regulatory actions taken for safety reasons since study initiation

Issue	Country	Action taken	Date
Safety labelling change – Guillain-Barré syndrome	Australia	On 16 January 2025, the TGA issued a SSR submission to update the ABRYSVO Product Information and Consumer Medicines Information with a warning for GBS in sections 4.4 and 4.8, prompted by a post-marketing observational study conducted by the US FDA. The revised Product Information was approved on 20 March 2025.	16 January 2025
Changes to the informed consent document relating to safety concerns	Global change	The MAH updated the safety text for clinical study informed consent documents to align with the recent updates to the CDS (updates to GBS wording, addition of lymphadenopathy, rash, urticaria, anaphylaxis).	03 March 2025
New post-marketing safety study – Guillain-Barré syndrome in pregnant individuals (C3671081)	United States	In their letter dated 25 October 2024, FDA requested Pfizer to conduct a post marketing study to assess the risk of GBS following administration of ABRYSVO in pregnant individuals. Initially, Pfizer proposed to revise the existing PASS, <i>A rapid surveillance and cohort postmarketing safety study to evaluate the safety of ABRYSVO exposure during pregnancy in the United States</i> (C3671027), to include GBS as a primary study objective, as indicated in the FDA approval letter dated 06 January 2025. On 15 May 2025, FDA confirmed their agreement with Pfizer's revised proposal for Study C3671027 to remain unchanged, and for a new PASS, C3671081, to be initiated to assess the risk of GBS in pregnant individuals as the primary endpoint. This is reflected in the Release from postmarketing requirement/New postmarketing requirement letter issued on 15 May 2025. Final report for C3671081 is planned for March 2035.	15 May 2025

Table 7. Regulatory actions taken for safety reasons since study initiation

Issue	Country	Action taken	Date
Medicines safety update publication – Guillain-Barré syndrome	Australia	On 19 May 2025, the TGA published a Medicines Safety Update regarding the risk of GBS relating to use of ABRYSVO and Arexvy (GSK). Safety information for both vaccines has been updated to reflect the low risk of people contracting GBS following vaccination. Health professionals should be aware of the higher GBS risk in people following vaccination with ABRYSVO or Arexvy. Vaccinees should be warned of this possible but rare risk and encouraged to seek medical attention if they experience symptoms, as early medical care can reduce severity and improve outcomes. The benefit-risk profile remains strongly in favour of vaccination in the target groups.	19 May 2025
DSU – Guillain-Barré syndrome	United Kingdom	On 07 July 2025, MHRA published a Drug Safety Update (DSU) for ABRYSVO related to the risk of GBS. The DSU is based on preliminary unpublished post-marketing study data from the UK Health Security Agency and Public Health Scotland studies in adults aged 75-79 years. MHRA has not requested any additional changes to ABRYSVO UK SmPC, however they did request updates to the ABRYSVO UK Patient Information Leaflet (PIL), to further emphasise the importance of seeking immediate medical attention in case of any signs and symptoms of GBS.	07 July 2025
Update of PVP – Guillain-Barré syndrome	United States	On 01 August 2025, the FDA sent an Information Request asking to reclassify GBS as an Important Identified Risk instead of as an Important Potential Risk in the US PVP, given the available data supporting GBS as an identified risk. The ABRYSVO United States Prescribing Information (USPI) already includes a warning on GBS; the FDA has not	01 August 2025

Table 7. Regulatory actions taken for safety reasons since study initiation

Issue	Country	Action taken	Date
		requested any additional changes to the ABRYSVO USPI, or any additional pharmacovigilance/risk minimisation measures related to GBS.	
Partial clinical hold (children <12 years of age) Reported in PSUR #4 due to inadvertent omission in PSUR #3	United States	On 09 August 2024, the FDA placed ABRYSVO (PF-06928316) IND under partial clinical hold preventing the enrollment of children <2 years of age and requiring children who are 2 through <5 years of age to be screened to confirm RSV seropositivity. The hold was imposed "Due to concerns that the cases reported above [by a Sponsor developing an RSV vaccine in infants] represent a potential safety signal for VAERD." On 30 September 2024, FDA sent Written Responses regarding the design of Pfizer's planned Study C3671017 in children 5 through <18 years of age in which FDA informed Pfizer to "not initiate clinical testing in individuals younger than 12 years of age until FDA has reviewed the additional data from your nonclinical testing program and provided feedback to you". A meeting of the FDA's VRBPAC to discuss considerations for RSV vaccine safety in pediatric populations was held on 12 December 2024 and did not result in any specific regulatory guidance. The clinical hold in the US remains in effect to date. The MAH is not conducting any clinical studies in the pediatric population.	09 August 2024
Update of PASS protocols – placental abruption	United States	On 11 December 2025, the FDA requested Pfizer to include placental abruption as a prespecified outcome in the maternal exposure postmarketing requirement safety studies for ABRYSVO (studies C3671026, C3671027, C3671041, and C3671042). The FDA has not requested any additional changes to the ABRYSVO USPI, or any additional	11 December 2025

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Table 7. Regulatory actions taken for safety reasons since study initiation

Issue	Country	Action taken	Date
		pharmacovigilance/risk minimization measures related to placental abruption.	
Update of EU product information – medication errors involving neonates	European Union	In view of available data on medication errors from spontaneous reports involving neonates (described in PSUR #4, reporting interval 01 Dec 2024-30 May 2025), on 29 January 2026 the EMA's CHMP concluded that the ABRYSVO EU Product information should be updated in section 4.1 of the EU SmPC (to reword the indication for use in pregnant individuals) and in section 7 of the labelling (inclusion of a warning on the outer cartons to clarify that the product should be given to adults or pregnant individuals only).	29 January 2026

Abbreviations: CHMP: Committee for Human Medicinal Products (EMA); DSU: drug safety update; EMA: European Medicines Agency; FDA: Food and Drug Administration; GBS: Guillain-Barré syndrome; MAH: marketing authorisation holder; PASS: post-authorisation safety study; PSUR: periodic safety update report; PVP: pharmacovigilance plan; RSV: respiratory syncytial virus; SmPC: summary of product characteristics; SSR: safety related request; TGA: Therapeutic Goods Administration; USPI: United States Prescribing Information; VAERD: vaccine-associated enhanced respiratory disease; VRBPAC: Vaccines and Related Biological Products Advisory Committee

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5.8. Overall Conclusions

5.8.1. NITAG Recommendations

This third progress report highlights substantial variation in the implementation of maternal RSV vaccination programmes across the participating European countries. Uptake was higher in the UK, France and Denmark, where ABRYSVO has been incorporated into routine maternal immunisation programmes and provided free of charge. However, the data available for this progress report from DHR did not cover the period of the implementation of this programme or inclusion of ABRYSVO in the routine immunisation programme. In the Netherlands and Spain the vaccine is currently not recommended or reimbursed and is available only through private market access. Observed uptake in PHARMO in the Netherlands was limited and may not reflect actual uptake because information on vaccination administered in private or municipal vaccination centres is not captured in the data source. In Norway, maternal RSV vaccination is now recommended by the Norwegian Institute of Public Health as part of national guidelines, although implementation into the national immunisation programme is still under review.

These findings suggest that national recommendations and reimbursement policies are important determinants of maternal RSV vaccine uptake. The observed differences between participating countries also illustrate the importance of continued monitoring of changes in national immunisation policies, which may substantially influence future uptake and the feasibility of comparative safety analyses across countries. The national recommendations in participating countries in this study will continue to be monitored closely for any changes.

Inclusion of additional data sources from countries with established or expanding maternal RSV vaccination programmes may further strengthen the study and increase the number of exposed pregnancies available for future analyses. For example, Scotland's national immunisation programme offers RSV vaccination to pregnant women reaching 28 0/7 weeks gestation. The DEAP, University of Dundee, in Scotland has agreed to participate in this study and their data will be available for the final report.

5.8.2. ABRYSVO Uptake

In CPRD Aurum, 24,591 ABRYSVO-vaccinated pregnancies between 24 and 36 weeks of gestation were identified among 167,415 pregnancies reaching at least 24 weeks of gestation during the study period, corresponding to approximately 14.69% of eligible pregnancies ([Table 6](#)). In DHR, 4,284 ABRYSVO-vaccinated pregnancies between 24 and 36 weeks of gestation were identified among 113,560 eligible pregnancies, corresponding to 3.77% uptake ([Table 6](#)). Publicly available French data also demonstrated substantial uptake during the first maternal RSV vaccination campaign, with 72,026 ABRYSVO-vaccinated pregnancies identified among 264,471 pregnancies reaching the recommended gestational vaccination window, corresponding to 27.23% uptake ([Table 4](#)). In the Netherlands, 71 ABRYSVO-exposed pregnancies were identified among 43,919 pregnancies (0.16%) reaching 24 weeks of gestation, while in Norway, public dispensing data identified 838 women aged 10-54 years who had a recorded RSV vaccine (assumed to be ABRYSVO) in 2024, corresponding to an estimated uptake of approximately 1.6% ([Table 4](#)). Fewer than five ABRYSVO-vaccinated pregnancies were identified in the Valencia region in Spain.

Although most ABRYSVO vaccinations were administered within the recommended gestational age window, vaccinations outside the recommended gestational period were also observed ([Table 4](#)). In CPRD Aurum, 2.29% pregnancies were vaccinated before 24 weeks of gestation and 11.68% after 36 weeks among exposed pregnancies (N=28,584) ([Table 4](#)). In DHR, fewer than 0.1% vaccinations occurred before 24 weeks gestation and 1.4% after 36 weeks among ABRYSVO exposed pregnancies (N=4,349) ([Table 4](#)). Similar patterns were observed in France in the EPI-PHARE study, where approximately 9.8% of vaccinated women received vaccination before 32 weeks of gestation and 9.6% after 36 weeks ([Section 5.4.2](#)). These findings indicate that real-world vaccination practices do not fully align with regulatory recommendations or national guidance and may reflect differences in healthcare delivery, timing of antenatal care visits, or the use of dispensing dates rather than administration dates in some data sources.

The descriptive analyses also suggested some differences between vaccinated pregnancies and the overall eligible pregnancy population, which includes the vaccinated. Vaccinated pregnancies in both CPRD Aurum and DHR were associated with slightly older maternal age compared with all eligible pregnancies ([Table 6](#)). Gestational diabetes in the current pregnancy episode was more frequently recorded among vaccinated pregnancies in both data sources. This may reflect the covariate assessment windows that differ for the ABRYSVO vaccinated pregnancies and all pregnancies. Also, the time point at which prevalence was measured was at 24 weeks for all pregnancies and at the time of first ABRYSVO vaccination for vaccinated. Since this is later in pregnancy, prevalence of pregnancy-related conditions could be higher. Specifically gestational diabetes was assessed from 20 weeks of gestation to the vaccination date for vaccinated pregnancies, but only from 20 to 24 weeks for all pregnancies. As most vaccinations occurred after 24 weeks, and gestational diabetes is commonly diagnosed between 24 and 28 weeks,^[47] vaccinated pregnancies had a longer period in which gestational diabetes could be recorded. The prevalence of immunocompromised and high-risk pregnancy was higher in the vaccinated pregnancies compared with all pregnancies in both data sources. In both data sources, the differences in high-risk pregnancy prevalence could be attributed to the difference prevalence of gestational diabetes in the vaccinated pregnancies since all other components were similar in both groups. A similar explanation may apply to the higher prevalence of immunocompromised status among vaccinated pregnancies. The difference appeared to be mainly driven by active treatment with immunomodulating agents during the current pregnancy (1.94% vs 1.49%, ASD: 0.04 in CPRD Aurum and 3.27% vs 2.39, ASD: 0.05 in DHR). The assessment window extended from pregnancy start date till date of vaccination for the vaccinated pregnancies, but only to 24 weeks of gestation for all pregnancies, allowing for a longer opportunity for immunomodulating treatment to be recorded. These findings may reflect differences in healthcare utilisation, risk perception, or prioritisation of vaccination among women with increased pregnancy-related risk factors and underline the importance of appropriate confounding adjustment in future comparative safety analyses.

5.8.3. Limitations

Several limitations should be considered when reviewing the data in this progress report. Full data access was not available in all participating countries during this reporting period. SNDS data extraction is pending because the agreement with the data provider has not yet

been finalised, while extraction of Norwegian registry data is on-going. Quality control procedures for some covariates and prior pregnancy outcomes have not been completed. In addition, some participating data sources relied on public aggregate data or historical data instances, limiting the level of detail available for this report. In the Netherlands and Spain, vaccination through the private market may not be completely captured, potentially resulting in underestimation of exposure. Furthermore, incomplete mother-baby linkage in the CPRD Aurum June 2025 release restricted some analyses to pregnancies ending before 31 December 2024.

5.8.4. Next Steps And Considerations

The current findings from data available up to the date of this report support the feasibility of the planned interim analyses. The protocol-defined threshold of a minimum of 600 vaccinated pregnancies required for the interim report has already been substantially exceeded, based on currently available data. CPRD Aurum and DHR together contributed more than 34,000 pregnancies exposed to ABRYSVO during the current reporting period. It is expected that data from CPRD Aurum and DHR will be available for inclusion in the interim analyses planned for submission by 31 December 2026. The contribution of data from other individual countries (SNDS, NHR) will continue to depend on data access timelines, regulatory approvals, and completion of quality control procedures.

Future work will focus on completion of quality control procedures, inclusion of additional data sources where possible, and comparative analyses of pregnancy, maternal, and neonatal outcomes among vaccinated and unvaccinated pregnancies. Continued monitoring of changes in national recommendations and reimbursement policies will also remain important, as these factors are expected to substantially influence vaccine uptake and the number of exposed pregnancies available for future safety evaluations. There are currently no national recommendations for maternal RSV vaccination in the Netherlands and Spain, two of the six countries included in this study. Private use of ABRYSVO is not fully captured in the Dutch data source (PHARMO Data Network) and some of the Spanish data sources (SIDIAP, EpiChron). Therefore, Pfizer will continue to monitor these countries for any changes in national recommendations. In Norway maternal RSV vaccination is fully captured through SYSVAK registry, and the marked increase in uptake observed in 2025 public data will be assessed within the study period in subsequent reports

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Appendix Table 1. Data elements and algorithms used to identify pregnancies

Data Source/DEAP/country	ConcePTION or DEAP pregnancy algorithm			Streams of information used for ConcePTION algorithm	Delay for birth register linkage
	Algorithm for LMP identification	End of pregnancy identification algorithm	Inclusion of ongoing pregnancies algorithm		
CPRD Aurum /DSRU/UK	Based on the algorithm used by CPRD to generate the CPRD Aurum Pregnancy Register			NA	Approximately 2 months but this can vary (however in line with data in the relevant linked CPRD Aurum database release)
SNDS /BPE/FR	LMP available in each pregnancy inpatient stay (e.g., monitoring, delivery)	Own ^[48] and CONCEPTION	CONCEPTION	1. Hospital diagnoses and GHM (<i>Groupes homogenes de maladies</i> : Diagnosis Related Groups) data 2. In- and out-patients acts and procedures (CCAM – <i>Classification Commune des Actes Medicaux</i>) 3. In- and out-patient laboratory analyses (NABM – <i>Nomenclature des Actes de Biologie Medicale</i>)	NA (no linkage with birth registry), pregnancy data are available only in in-patient data (data for year N-1 available from Q3 year N)
DHR / Aarhus University/DK	ConcePTION	ConcePTION	ConcePTION	Medical Birth Registry Diagnoses and gestational age for abortive outcomes from hospital encounters	None
NHR /University of Oslo/NO	<u>ConcePTION</u>	<u>ConcePTION</u>	<u>ConcePTION</u>	Medical birth registry	Updated data for the prior year received in June annually
PHARMO Data Network and Perined /PHARMO Institute/NL	No algorithm. Actual LMP from Perined register	Own (because of linkage to Perined Perinatal Registry)	NA (because of linkage to Perinatal Registry, includes data on completed pregnancies only)	NA (because of linkage to Perinatal Registry)	1.5-year lag time (compared with 1 year lag time for in-house databases of the PHARMO data network)
EpiChron /IACS/ES	ConcePTION	ConcePTION	ConcePTION	Mother-child linkage	None

Appendix Table 1. Data elements and algorithms used to identify pregnancies

Data Source/DEAP/country	ConcePTION or DEAP pregnancy algorithm			Streams of information used for ConcePTION algorithm	Delay for birth register linkage
	Algorithm for LMP identification	End of pregnancy identification algorithm	Inclusion of ongoing pregnancies algorithm		
SIDIAP/IDIAP JGol/ES	ConcePTION	ConcePTION	ConcePTION	ASSIR variables, mother-child linkage (70%)	None
VID/FISABIO/ES	ConcePTION	ConcePTION	ConcePTION	Population database, hospital registry and metabolopathies database (mother-child linkage)	None

Abbreviations: ASSIR: *Atenció a la salut sexual i reproductiva (Sexual and reproductive healthcare)*; CPRD Aurum: *Clinical Practice Research Datalink Aurum*; DEAP: *Data Expert and Access Partner*, DHR: *Danish Health Registers*; EpiChron: *EpiChron Research Group*, IACS: *Instituto Aragonés de Ciencias de la Salud*; NHR: *Norwegian Health Registers*; PHARMO: *PHARMO Data Network*; VID: SIDIAP: *Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària (Information System for Research in Primary Care)*; SNDS: *Système National des Données de Santé (National Health Data System)*; Valencia Health system *Integrated Database*

7. LIST OF STANDALONE DOCUMENTS

Appendix 1. PROTOCOL

Appendix 2. STATISTICAL ANALYSIS PLAN

Appendix 3.CODE LISTS AND DRUG PROXIES

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