Supplementary Table: Post-authorisation studies required by Risk Management Plans and data availability

Information from Risk Management Plan[1,2]		Data available[a]
Study IDs (registration numbers)	Study focus	
Pfizer-BioNTech Covid-19 mRNA vaccine[b]		
C4591001 (EU: 2020-002641-42; US: NCT04368728)	Safety, tolerability, immunogenicity, and efficacy, including the occurrence of VAED. Duration: 2 years.	Regulatory data (EMA, CA) Full study protocol[3] Protocol information (EU-CTR, US)
C4591015 (US: NCT04754594)	Safety and immunogenicity in pregnant women.	Protocol information (US)
C4591010	Adverse events in real-world use.	*Protocol information not retrievable*
C4591011, C4591012, and ACCESS/VAC4EU (EU: EU-PAS40404)	Adverse events of interest, including severe or atypical Covid-19 in Department of Defence Healthcare System population (C4591011) and real-world use (C4591012, ACCESS/VAC4EU).	*Protocol information not retrievable* (C4591011, C4591012) Full study protocol (EU-PAS40404, EU-PAS)
C4591014, (US: NCT04848584) WI235284, and WI255886	Effectiveness against hospitalisation and emergency department admission.	Protocol information (C4591014, US) *Protocol information not retrievable* (WI235284, WI255886)
BNT162-01 Cohort 13 (EU: 2020-001038-36; US: NCT04380701)	Assess potentially protective immune responses in immunocompromised adults.	Protocol information (EU-CTR, US)
C4591018	Safety, immunogenicity over 12 months. Description of COVID-19 cases. RA activity by Clinical Disease Activity Index. N-antigen antibodies for detection of asymptomatic infection.	*Protocol information not retrievable*
Study ID not given	Safety, immunogenicity over 12 months in frail elderly, immunocompromised, autoimmune and other high-risk individuals. Description of COVID-19 cases. N-antigen antibodies for detection of asymptomatic infection.	*Protocol information not retrievable*
Study ID not given	Safety and immunogenicity of BNT162b2 and quadrivalent seasonal influenza vaccine when administered separately or concomitantly.	Not yet applicable (Protocol submission: 30-Sep-2021)

Moderna Covid-19 mRNA vaccine[c]		
20-0003 (US: NCT04283461)	Safety and reactogenicity at different dose levels, plus booster dose. Duration: 2 years.	Regulatory data (EMA, CA) Protocol information (US)
mRNA-1273-P201 (US: NCT04405076)	Safety, reactogenicity and immunogenicity of 2 dose levels.	Protocol information (US)
mRNA-1273-P301 (US: NCT04470427)	Long-term safety data and durability of vaccine effectiveness.	Full study protocol[4] Protocol information (US)
Study ID not given	Safety, reactogenicity and immunogenicity in immunocompromised adults.	*Protocol information not retrievable*
Study ID not given	Enhanced pharmacovigilance study to provide additional evaluation of adverse events of special interest and emerging validated safety signals.	*Protocol information not retrievable*
Study ID not given (EU: EU-PAS 40404)	Enhanced pharmacovigilance study to provide additional evaluation of adverse events of special interest and emerging validated safety signals in European populations. Use in pregnant women.	Full study protocol (EU-PAS)
Study ID not given (US: NCT04958304)	Outcomes of pregnancies.	Protocol information (US)
mRNA-1273- P901	Real-world and long-term effectiveness in preventing COVID-19 and severe COVID-19 disease: a) by age, sex, race/ ethnicity, comorbid conditions, b) in immunocompromised patients, c) in frail individuals and autoimmune/inflammatory disorders, d) co-administration of other vaccines, e) durability of one or two doses and severe COVID-19 disease.	*Protocol information not retrievable*

[a]Data available as observed by the authors searching the internet, websites of regulators, i.e. European Medicines Agency (EMA) and Health Canada (CA), and registration databases, i.e. EU electronic register of Post-Authorisation Studies (EU-PAS), EU Clinical Trials Register (EU-CTR) and ClinicalTrials.gov (US).
[b]Risk Management Plan, date of final sign off: 29 April 2021
[c]Risk Management Plan, date of final sign off: 6 January 2021
RA: rheumatoid arthritis; VAED: vaccine associated enhanced disease

References

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