Electronic Supplemental material 2 – Core data elements in the study
Description of frequencies of reported adverse events following immunization among four different COVID-19 vaccine brands
Drug Safety – Original Research
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CORE DATA ELEMENTS

Registration form (on the study website; compulsory)

- Participant is a proxy vs vaccine recipient (i.e. whose e-mail address is used for the study?)
- Informed consent (Example in Annex 2)
    - If 12-16 years, or adult unable to fill in the questionnaire: Both vaccine recipient and proxy need to provide informed consent
- Previously received a COVID-19 vaccine?
    - If this was ≤2 days ago: complete follow-up on ADRs can still be done for that dose.
- E-mail address & password (to be chosen by the participant)

Baseline questionnaire (compulsory)

- Gender
- Age (e.g. calculated based on date of birth)
- National identification number, if the data can be linked to a vaccination register
- Geographical area (closed question; e.g. NUTS2 or 3 area)
- Planned vaccination date
- Medical history (current conditions) and pregnancy (closed questions):
    - Impaired immune function (e.g. due to disease or due to treatment)
    - Lung disease (including chronic obstructive pulmonary disease and asthma)
    - Liver disease
    - Neurological disease or injury (including epilepsy)
    - Psychiatric condition (including depression)
    - Cardiovascular disease
    - Hypertension
    - Kidney disease
    - Diabetes
    - Malignancy / cancer
    - Allergy (y/n) with subquestion (checkbox): pollen (hay fever), dust mites, animal (e.g. cat), food (e.g. egg), insect bites and stings, medication, other (namely:…)
    - Other disease:…
    - Pregnancy (subquestion on gestational age)
    - None of the above

- Health care worker/ informal caregiver (y/n)? If yes sub question (radio button): medical doctor, pharmacist, nurse, other paramedical (e.g. midwife, physiotherapist), informal caregiver, other (namely:…)
- Previous infection with SARS-CoV2 / COVID-19 disease (yes, confirmed with a test; yes but no test; probably but no test; no)?
    - Date of symptom onset
    - Severity (asymptomatic, cold-like symptoms, considerable symptoms without hospitalisation, hospitalized due to symptoms)
- Height (in cm)
- Weight (in kg)
- Current medication (including over the counter medication; ATC-coded locally)
- Vaccinations (other than COVID-19 vaccine) in the past 2 years (namely: …)

Extra questions for identification of special groups

- Have you ever experienced an allergic reaction in the past after receiving a vaccine (of any kind)?
- Have you ever had any allergic reaction (e.g. anaphylactic shock) that has required emergency treatment or A&E admission?
- Did you take any medication (e.g., antihistamines or corticosteroids) before COVID-19 vaccination to prevent vaccine-related allergy?
    - Please specify:_____
- Are you immunocompromised due to any medical conditions (e.g., HIV/AIDS, transplants, autoimmune diseases, leukaemia/lymphoma)?
    - HIV/AIDS
    - Transplantation
    - Leukaemia/lymphoma
    - Autoimmune diseases
    - Other, please specify:_____
- Do you currently take any medications that affect your immune system (e.g., chemotherapy, glucocorticoids, anti-rheumatics)?
    - No
    - Yes, Please specify:_____
- Will or have you stopped your medication in the period immediately preceding or following the COVID-19 vaccination?
    - No
    - Yes, I have stopped/will stop my medication preceding my COVID-19 vaccination
    - Yes, I have stopped/will stop my medication following my COVID-19 vaccination
    - Yes, I have stopped/will stop my medication both in the period preceding and following my COVID-19 vaccination

Additional component to baseline questionnaire – if already vaccinated

- COVID-19 vaccination date
- Immunizer (e.g. GP, employer, municipal health authority, etc.)
- Vaccination site (arm which one…)
- Antipyretics intake (if applicable, as prophylaxis)
- Vaccine brand (GTIN code) and batch number: It should be ensured that the vaccine recipients receive this information themselves, e.g. through a vaccination certificate that is obtained at the point of vaccination, in a vaccination booklet that is updated at the point of vaccination, and/or - less preferable - that they can look it up in a digital account (e.g. linked with the vaccination register). The participant can then either report the name of vaccine brand or the GTIN, or upload a photo (e.g. of the barcode or GTIN) to the LIM web app.
    - In addition, this information should be derived from a vaccination register to improve data quality / completeness.

Verification of vaccination on planned vaccination date (dose 1)

- Have you received the vaccination?
    - If yes:
        - COVID-19 vaccination date
        - Immunizer (e.g. GP, employer, municipal health authority, etc.)
        - Antipyretics intake (if applicable, as prophylaxis)
        - Vaccine brand (GTIN code) and batch number: It should be ensured that the vaccine recipients receive this information themselves, e.g. through a vaccination certificate that is obtained at the point of vaccination, in a vaccination booklet that is updated at the point of vaccination, and/or - less preferable - that they can look it up in a digital account (e.g. linked with the vaccination register). The participant can then either report the name of vaccine brand or the GTIN, or upload a photo (e.g. of the barcode or GTIN) to the LIM web app.
            - In addition, this information should be derived from a vaccination register to improve data quality / completeness.
    - If no:
        - New planned date
            - This same questionnaire will be sent on the new planned date

Q1: 7 days after dose 1

- Have you experienced an adverse reaction vaccination (y/n)? If yes:
    - Injection site reaction on the right side (closed question)
        - Subquestion (closed) on symptoms (redness, warmth, pain, itch, haematoma, swelling, induration)
            - Closed subquestion to assess extensive limb swelling (if swelling and/or redness are ticked)
    - Injection site reaction on the left side (closed question)
        - Subquestion (closed) on symptoms (redness, warmth, pain, itch, haematoma, swelling, induration)

            - Closed subquestion to assess extensive limb swelling (if swelling and/or redness are ticked)
    - Fever (closed question) - sub question on highest temperature that was measured:
        - Category:
            - 37.5 – 37.9 degrees Celsius
            - 38.0 – 40.4 degrees Celsius
            - 40.5 – 42.0 degrees Celsius
            - Higher than 42 degrees Celsius
            - Not measured
        - Temperature as continuous variable (1 decimal)
    - Chills (closed question),
    - Headache (closed question),
    - Nausea (closed question),
    - Myalgia / muscle pain (closed question),
    - Arthralgia / joint pain (closed question),
    - Malaise (closed question),
    - Fatigue (closed question),
    - Other ADR (open question)
- Information collected for each reported ADR:
    - Latency (i.e. date of onset as well as in seconds, minutes, hours, days after vaccination)
    - Outcome (recovered, recovering, not recovered)
        - If recovered: duration of symptoms (date as well as in seconds, minutes, hours, days after onset)
    - Visited a medical doctor/GP because of the adverse reaction? (if there were tests done, the outcomes of these tests will be asked, e.g. blood test or ECG)
    - Was the adverse reaction treated? (including over the counter medication; ATC-coded locally)
    - Impact of the reaction (5-point scale from not severe to very severe)
    - Seriousness according to CIOMS (hospitalisation >24h; life-threatening situation; other medically important reaction). If ticked: open subquestions.
    - Possibility to upload a picture of the reaction and/or documents such as a hospital discharge letter (participant should not be identifiable).

Q2: 3 weeks after dose 1

<u>Old adverse reactions:</u>

- Outcome of each of the ADRs from which the participant had not (yet) recovered in the previous questionnaire (recovered, recovering, not recovered)
    - If recovered: duration of symptoms (date as well as in seconds, minutes, hours, days, weeks after onset)
- Visited a medical doctor/GP because of the adverse reaction? (if there were tests done, the outcomes of these tests will be asked, e.g. blood test or ECG)
- Was the adverse reaction treated? (including over the counter medication; ATC-coded locally)
- Impact of the adverse reaction (5-point scale from not severe to very severe)

- Seriousness according to CIOMS (hospitalisation >24h; life-threatening situation; other medically important adverse reaction). If ticked: open sub-questions.
- Possibility to upload a picture of the adverse reaction and/or documents such as a hospital discharge letter (participant should not be identifiable).

New adverse reactions: Identical to Q1

Q3 & Q4: 5 & 8 weeks after dose 1

Identical to Q2, and In addition, it includes the following questions:

- Have you received a second dose of the vaccination?
    - If yes:
        - COVID-19 vaccination date
        - Immunizer (e.g. GP, employer, municipal health authority, etc.)
        - Antipyretics intake (if applicable, as prophylaxis)
        - Vaccine brand (GTIN code) and batch number: It should be ensured that the vaccine recipients receive this information themselves, e.g. through a vaccination certificate that is obtained at the point of vaccination, in a vaccination booklet that is updated at the point of vaccination, and/or - less preferable - that they can look it up in a digital account (e.g. linked with the vaccination register). The participant can then either report the name of vaccine brand or the GTIN, or upload a photo (e.g. of the barcode or GTIN) to the LIM web app.
            - In addition, this information should be derived from a vaccination register to improve data quality / completeness.
    - If not: reason for not taking it or for delay? (practical reason, because of the experienced side effects of the first dose, other)

Q5: 3 months after dose 1

Identical to Q3 & Q4, and In addition, it includes the following questions:

- Infection with SARS-CoV2 / COVID-19 disease since vaccination? (yes, confirmed with a test; yes but no test; probably but no test; no)?
    - Date of symptom onset
    - Severity (asymptomatic, cold-like symptoms, considerable symptoms without hospitalisation, hospitalized due to symptoms)

Q6: 6 months after dose 1

Identical to Q5, except that 2 questions are adapted as follows:

- Infection with SARS-CoV2 / COVID-19 disease since the last questionnaire? (yes, confirmed with a test; yes but no test; probably but no test; no)?
    - Date of symptom onset
    - Severity (asymptomatic, cold-like symptoms, considerable symptoms without hospitalisation, hospitalized due to symptoms)
- Seriousness according to CIOMS (hospitalisation >24h; life-threatening situation; other medically important adverse reaction; disability). If ticked: open sub-questions.