**VAERS ADE & DRUG Annotation Guidelines — RPC 2.0**

**1. Definitions**

* **ADE (Adverse Drug Event)**  
  Any undesirable medical condition, symptom, diagnosis, or abnormal clinical finding **occurring after vaccination**, whether or not causality is proven.
* **DRUG**  
  The vaccine or drug product administered, annotated exactly as stated in the report.

**2. General Principles**

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| **Rule** | **Example ✅** | **Example ❌** |
| Include full medical term exactly as reported (no partial cuts). | "shortness of breath" | "breath" |
| Include severity modifiers if part of ADE description. | "severe headache" | "headache" (if severity given) |
| Exclude time duration from ADE span. | "fever" (from "fever for 2 days") | "fever for 2 days" |
| Annotate **each ADE/DRUG mention separately**, even if repeated. | "fever", "headache", "fever" | Merging both "fever"s |
| Use the longest medically accurate term when available. | "acute respiratory distress syndrome" | "respiratory distress" |
| Keep casing exactly as in text. | "shortness of breath" | "Shortness of Breath" (unnecessary capitalization) |

**3. ADE Annotation Rules**

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| **Case** | **Rule** | **Example** |
| Specific symptom or diagnosis | Mark full phrase describing the condition. | "extreme fatigue" → ADE "extreme fatigue" |
| Resolved/improved symptoms | Still annotate; status words ("subsided", "recovered") don’t exclude it. | "headache subsided" → ADE "headache" |
| Lab results with clinical meaning | Annotate if abnormal finding is stated. | "fever 101" → ADE "fever" |
| Vague/non-clinical terms | Skip overly general phrases. | "not feeling well" → Skip |
| Pre-existing conditions | Skip unless worsened post-vaccination. | "bone marrow disorder" (pre-existing) → Skip |
| Administrative issues | Skip unless followed by a symptom. | "product dose omission" → Skip |
| Breakthrough infection | ADE if after vaccination. | "COVID-19 infection after vaccination" |
| Multi-word ADEs | Keep whole phrase if medically one concept; exclude unrelated info. | ✅ "chronic obstructive pulmonary disease" / ❌ "chronic obstructive pulmonary disease causing cough" |
| Compound ADE phrases | If separate symptoms, split; if fixed expression, keep as one. | "fever and headache" → "fever", "headache" / "nausea and vomiting" → one span (normally appears together in clinical reporting) |

**4. DRUG Annotation Rules**

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| **Case** | **Rule** | **Example** |
| Exact name given | Annotate full product name. | "Moderna COVID-19 vaccine" |
| Code name given | Annotate as written. | "mRNA-1273" |
| Both brand & code mentioned | Annotate both separately. | "mRNA-1273", "Moderna COVID-19 vaccine" |
| Generic mention | Annotate exactly as in text. | "vaccine", "COVID-19 vaccinated" |
| Brand not given | Do not guess — keep as stated. | "received the vaccine" → DRUG "vaccine" |
| Vague mention with disease target | Include full phrase. | "COVID-19 vaccinated" |
| Booster/general terms | Annotate if clearly product given. | "booster shot" |
| Past or unrelated drug | Skip. | "chemotherapy" (past use) |
| Multiple occurrences | Label each separately. | "Pfizer vaccine ... Pfizer vaccine" |

**5. Skip Annotation When**

* Administrative only, no symptom (e.g., “product dose omission”).
* Vague, non-clinical, or purely numeric (e.g., “body temperature”, “BP: 180/110” or “not feeling well” without diagnosis).
* Clearly pre-existing, unrelated to vaccination.
* Past/discontinued drug use.
* Non-medical events (e.g., “fell asleep”, “argued with spouse”).

**6. Special Notes**

* **Repeat all ADE/DRUG mentions** — do not merge.
* **Exclude time references** from ADE spans.
* **Death** is not ADE unless cause is stated ("cardiac arrest" ✅, "died" ❌).
* "Patient died due to cardiac arrest" -> ADE: "cardiac arrest", **Not**: "died"
* "Patient died" → Skip ADE (no medical event named).
* "Death occurred two days after vaccination" → Skip ADE (outcome only).
* **Hospitalization** is not ADE, but the reason for it might be.
* Synonyms in same record (e.g., "myocardial infarction", "heart attack") are both annotated as ADE.
* **COVID-19 mentions**
  + "COVID-19 infection" / "COVID-19 pneumonia" → ADE
  + "tested positive for COVID-19" → ADE "COVID-19"
  + "COVID-19 vaccination" → DRUG

## ****When COVID-19 is NOT an ADE**** ❌

1. It’s only mentioned as part of **vaccine name**.
   * "Moderna COVID-19 vaccine" → DRUG only, no ADE.
   * "COVID-19 vaccination completed" → DRUG only.
2. It’s **past history** before vaccination.
   * "History of COVID-19 last year" → Skip.
3. It’s just a **risk factor or contact history**, not an actual infection.
   * "Exposed to COVID-19 positive person" → Skip.
4. It’s mentioned in a **negative test result**.
   * "Tested negative for COVID-19" → Skip.

**7. Quick ADE Span Checklist**

✅ Symptom/diagnosis present  
✅ Post-vaccination (not history only)  
✅ Specific & clinically meaningful (not vague)  
✅ Include **severity** if given (e.g., severe headache)  
✅ Include **location** if given (e.g., left arm swelling)  
✅ Duration/time excluded  
✅ Administrative terms excluded unless symptom follows  
✅ Multi-word kept the full medical concept  
✅ Each occurrence labelled separately