### Eastern Mediterranean Regional COVID-19 Vaccine Effectiveness Study – Status Update

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WHO EMRO COVID-19 Vaccine Effectiveness Study;
Status Update and Important Considerations
17 November 2022



#### Overview

The two main types of activities in the EM Regional COVID-19 VE Study include:

- 1 Enhancing processes and structures in the Region
- Building national technical capacity among EM Countries



## Enhancing processes and structures in the Region

- 1. Establishment of a multidisciplinary Regional COVID-19 VE technical team
- 2. Development of the COVID-19 VE **Dashboard** for the EM Region
- 3. Standardization of methods and data analysis
- 4. Issuance of the Regional Ethical Clearance
- 5. Development of the Regional **Data Entry Platform** (REDCap)



## Responsibilities of the EM Regional COVID-19 Vaccine Effectiveness Technical Team

- ✓ Review of **technical and financial proposals**: Proposals from each country underwent several rounds of revision before being selected as part of the the EM Regional COVID-19 VE Study
- ✓ Evaluation of **regulatory / technical documents** from each study: for e.g., for ethical clearance: PI checklist, study protocols, questionnaires, etc.
- ✓ Regular (monthly) consultation meetings with each country's research team
- ✓ Data management: collection, validation, aggregation, and statistical analysis of study results



## <u>COVID-19 Vaccine Effectiveness Dashboard</u>: 12 studies evaluated from Sep 2021 – Nov 2022 (Requesting EMRO's technical and financial support)

The Dashboard is updated weekly including the following information:

|                           |   | Ethical<br>clearanc | COVID-19 VE Proposal Shared             |  | desig                          | Study In line with design / VE Protocol or SARI) |   | •                                |  | d development /   |  |                    | Revision rounds & dates                        | •  |   |
|---------------------------|---|---------------------|---|--|--------------------------------|--|---|----------------------------------|--|---|--|--------------------|--|--|---|
| EM country                | Insti   | itution             | National ethical committee              | PI (direct contact point w/<br>country and email)    | COVID-19 VE<br>Proposal shared | Stu  | udy design  | In line with w/<br>WHO protocols | WHO/EMRO support requested / offered                 | COVID-19 VE proposa<br>study phase and decisi           |  | Last revision date | First F2F Consultation<br>w/ VE technical team | Second F2F<br>Consultation w/ VE<br>technical team | Third F2F<br>Consultation w/ VE<br>technical team |
| Egypt 2                   | Academic Med C<br>Al Azhar Universi                     |                     | Yes                                     | Dr. Zeinab NABIL SAID<br>zeinabnabil@azhar.edu.eg    | Yes                            | Cohort study a<br>(mix retrospec                 | among HCWs<br>tive + prospective)                             | Yes                              | Both technical & financial                           | Proposal revised and eligi<br>for regional CVE study    | ble Third-round of revisions by<br>VE technical team   | 15-Nov-21          | 4-Oct-21                                       | 9-Dec-21   | 17-Apr-23   |
| Iran<br>3                 | MoH & Shahrood University of<br>Medical Sciences (SUMS) |                     | NA                                      |  | Yes                            | Cohort (sero s                                   | urvey)  | No                               | Both technical & financial                           | Proposal revised and not<br>eligible for regional CVE s | First-round of revisions by<br>VE technical team       | 6-Sep-21           | NA   | NA   | NA  |
| Iran                      | Kerman Universit<br>Sciences (KMU)                      | y of Medical        | NA                                      | Dr. Ali MIRZAZADEH<br>ali.mirzazadeh@ucsf.edu        | Yes                            | Cohort or nest                                   | ed case-control study   | No                               | Both technical & financial                           | Proposal revised and not eligible for regional CVE s    | Second-round of revisions<br>tudy by VE technical team | 16-Nov-21          | NA   | NA   | NA  |
| Iran                      | Voc   |                     | Dr. Farid NAJAFI<br>farid_n32@yahoo.com | Yes  | Case-control (                 | ,  | Yes   | Both technical & financial       | Proposal revised and eligi<br>for regional CVE study | ble Third-round of revisions by<br>VE technical team    | 23-Apr-22  | 16-May-22          | NA   | TBD  |   |
| Iran<br>6                 | Pasteur Institute of Iran                               |                     | Yes                                     | Dr. Ehsan Mostafavi                                  | Yes                            | antibodies and                                   | logy of anti-spike<br>d retro evaluation of<br>n Iranian HCWs | Partial                          | Both technical & financial                           | Proposal revised and not<br>eligible for regional CVE s | Third round of revision by<br>tudy VE technical team   | 18-Aug-22          | 28-Jun-22                                      | NA   | NA  |
| Jordan<br>7               | МоН   |                     | Yes                                     | Dr. Fatima ZERRIOUH THNEIBAT<br>toom832016@gmail.com | Yes                            | Case-control (                                   |   | Yes                              | Both technical & financial                           | Proposal revised and eligi<br>for regional CVE study    | ble Second-round of revisions<br>by VE technical team  | 21-Nov-21          | 13-Oct-21                                      | 9-Dec-21   | 18-Apr-22   |
| Lebanon<br>8              | МоРН  |                     | Yes                                     | Dr. Moubadda ASSI<br>assimo@who.int                  | Yes                            | Cohort study a<br>(retrospective                 | _   | Partial                          | Technical support                                    | Proposal revised and not eligible for regional CVE s    | Fourth-round of revisions by VE technical team         | 2-Nov-21           | 30-Sep-21                                      | NA   | NA  |
| Morocco                   | МоН   |                     | NA                                      |  | No                             | NA   |   | NA                               | NA   | Initial interest  | NA   | NA                 | NA   | NA   | NA  |
| Oman<br>10                | МоН   |                     | NA                                      | Dr. Warda AL AMRI<br>alamri.warda@gmail.com          | No                             | NA   |   | NA                               | NA   | Initial interest  | NA   | NA                 | 6-Oct-21                                       | NA   | NA  |
| Pakistan<br>11            | Khyber Pakhtunk<br>University (KMU)                     |                     | Yes                                     | Dr. Sheraz FAZID (PI)<br>sherazvs@gmail.com          | Yes                            | Cohort study a<br>(prospective)                  | among HCWs  | Yes                              | Both technical & financial                           | Proposal revised and eligi<br>for regional CVE study    | ble Third-round of revisions by<br>VE technical team   | 14-Nov-21          | 21-Oct-21                                      | 9-Dec-21   | NA  |
| Palestine (oPt)           | MoH/PNIPH   |                     | NA                                      |  | Yes                            | Cross-section<br>serosurvey (b                   | household<br>efor / after study)                              | No                               | Both technical & financial                           | Proposal revised and not<br>eligible for regional CVE s | Other  | NA                 | NA   | NA   | NA  |
| Tunisia<br>13             | МоН   |                     | Yes                                     |  | No                             | Cross-section<br>serosurvey<br>(before/after     | household<br>vaccination) or Case-                            | NA                               | NA   | Initial interest  | NA   | NA                 | 11-Oct-21                                      | NA   | NA  |
| 14<br>15 Initial Interest | Proposal under revisi                                   | on                  | Eligible for Regional S                 | t Not in line with WHO VE Protocol                   | Unknown                        |  |   |                                  |  |   |  |                    |  |  |   |



## <u>COVID-19 Vaccine Effectiveness Dashboard</u>: 26 studies as of 10 November 2022 (all planned, ongoing or published studies from the EMR identified in <u>view-hub.org</u>)

The Dashboard which is updated weekly includes the following information:

| Country   | Author an<br>Title Publicatio  |                           | tart and<br>nd Dates  | Population                     | Outcomes V  | accine Products Varia   | -CoV-2<br>nts  |  | ılts published / link<br>ublication   |
|---|--|---------------------------|---|--------------------------------|---|---|--|--|---|
| Country   | Title  | Author & Publication Year | Start & End Dates   | Population                     | Outcomes  | Vaccine Products (Brands)   | SARS-CoV-2 Variant   | Results Published                      | Link To Results   |
| Egypt   | Effectiveness and safety of inactivated SARS-CoV2 vaccine (8818P-CorV) among<br>healthcare workers: A seven-month follow-up study at fifteen hospitals                                     | Ashmawy, 2022             | 1 May 2021 to 30 September 2021                                     | Healthcare workers             | Symptomatic disease, Any infection, Hospitalization   | Beijing CNBG (BBIBP-CorV)   | Delta (8.1.617.2)  | Under peer review<br>11 March 2022     | https://www.researchsquare.com/article/rs-1431715/v1                                |
| Egypt   | N/A (Planned or ongoing study)   | N/A                       | Expected start date: March 2021,<br>Results expected: November 2021 | Healthcare workers             | Any infection   | AstraZeneca (Vaxxevria), Janssen (Ad26.COV 2.5), Beijing CNBG (88IBP-<br>CorV), Gamalaya (Gam-Covid-Vac), Sinovac (CoronaVac)   | N/A  | N/A                                    | N/A   |
| 4 Iran  | N/A (Planned or ongoing study)   | N/A                       | Expected start date: TBD<br>Results expected: Unknown               | Adults                         | Hospitalization, Death  | AstraZeneca (Vaxzevria), Beijing CNBG (BBIBP-CorV), Gamalaya (Gam-<br>Covid-Vac), Bharat (Covavin)  | N/A  | N/A                                    | N/A   |
| Jordan  | N/A (Planned or ongoing study)   | N/A                       | Expected start date: September 2021<br>Results expected: 2022       | Adults                         | Severe disease, Hospitalization   | Pfizer BioNTech (Comimaty), AstraZeneca (Vaxzevria), Beijing CNBG (BBIBP-CorV), Gamalaya (Gam-Covid-Vac)  | N/A  | N/A                                    | N/A   |
| 6 Kuwait  | Effectiveness of BNT162b2 and ChAdOx1 Vaccines against Symptomatic COVID-<br>19 among Healthcare Workers in Kuwait: A Retrospective Cohort Study   | Alali, 2021               | 24 December 2020 to 15 June 2021                                    | Healthcare workers             | Symptomatic disease   | AstraZeneca (Vaxzevria), Pfizer BioNTech (Comimaty)   | Alpha (8.1.1.7)  | Published results<br>7 December 2021   | https://www.mdpi.com/2227-9032/9/12/1692/htm.                                       |
| 7 Kuwalt  | Effectiveness of BNT162b2 and ChAdOx1 vaccines against symptomatic COVID-<br>19 among Healthcare Workers in Kuwait: A retrospective cohort study   | Alali, 2021               | 24 December 2020 to 15 June 2021                                    | Healthcare workers             | Any infection   | AstraZeneca (Vaxzevria), Pfizer BioNTech (Comimaty)   | Alpha (8.1.1.7)  | Published results<br>29 July 2021      | https://www.medniv.org/content/10.1101/2021.07.25.212<br>61083v1.full.edf           |
| 8 Lebanon   | N/A (Planned or ongoing study)   | N/A                       | Expected start date:September 2021<br>Results expected:2022         | Healthcare workers             | Any infection   | Pfizer Bio/NTech (Comimaty), AstraZeneca (Vaxzevria), Beijing CNBG (BBIBP-CorV), Gamalaya (Gam-Covid-Vac)   | N/A  | N/A                                    | N/A   |
| 9 Morocco   | Long term effectiveness of inactivated vaccine 88/BP-CorV (Vero Cells) against COVID-19 associated severe and critical hospitalization in Morocco  | Belayachi, 2022           | 2 February 2021 to 1 October 2021                                   | Adults                         | Hospitalization   | Beijing CNBG (88I8P-CorV)   | Mixed VOC and Non-VOC  | Published results<br>27 Jan 2022       | https://www.medney.org/content/10.1101/2022.01.25.222<br>59822v1.full.pdf           |
| 10 Morocco  | Real-world study of the effectiveness of BBIBP-CorV (Sinopharm) COVID-19<br>vaccine in the Kingdom of Morocco  | Zhang, 2022               | 1 February 2021 to 30 June 2021                                     | Adults                         | Hospitalization   | Beijing CNBG (BBIBP-CorV)   | Alpha (8.1.1.7)  | Published results<br>5/27/2022         | https://www.medniv.org/content/10.1101/2022.04.23.222<br>74112v1.full.edf           |
| Pakistan<br>11                                    | N/A (Planned or ongoing study)   | N/A                       | Expected start date:TBD,<br>Results expected:Unknown                | Healthcare workers             | Any infection   | Pfizer BioNTech (Comimaty), Moderna (mRNA-1273), AstraZeneca<br>(Vaxzerria), Beijing CNBG (88189-CorV), Gamalaya (Gam-Covid-Vac),<br>CasSino (445-pCOV), Sinovac (Compat/ac). | -  | N/A                                    | N/A   |
| Qatar 12  | Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants  | Abu-Raddad, 2021          | 1 February 2021 to 31 March 2021                                    | Adults                         | Any infection, Severe   | Pfizer BioNTech (Comimaty)  | Alpha (8.1.1.7), Beta (8.1.351)                                | Published results<br>8 July 2021       | https://www.nejm.org/doi/10.1056/NEJMc2104974                                       |
| Qatar<br>13                                       | mRNA-1273 COVID-19 vaccine effectiveness against the 8.1.1.7 and 8.1.351 variants and severe COVID-19 disease in Qatar   | Chemaitelly, 2021         | 1 February 2021 to 10 May 2021                                      | Adults                         | Any infection, Severe, Symptomatic disease,<br>Asymptomatic infection                                 | Modema (mRNA-1273)  | Alpha (8.1.1.7), 8eta (8.1.351)                                | Published results<br>9 July 2021       | https://doi.org/10.1038/s41591-021-01446-v  |
| Qatar<br>14                                       | Associations of Vaccination and of Prior Infection With Positive PCR Test<br>Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar  | Bertollini, 2021          | 18 February 2021 to 26 April 2021                                   | Adults                         | Any infection   | Pfizer BioNTech (Comimaty) & Modema (mRNA-1273)   | Beta (8.1.351) & Alpha<br>(8.1.1.7) & non-VOC                  | Published results<br>9 June 2021       | https://iamanetwork.com/journals/jama/fullarticle/2781112                           |
| 15 Qatar  | SARS-CoV-2 vaccine effectiveness in preventing confirmed infection in pregnant women   | Butt, 2021                | 20 December 2020 to 30 May 2021                                     | Pregnant women                 | Any infection   | Pfizer BioNTech (Comimaty) & Modema (mRNA-1273)   | Alpha (8.1.1.7) & non-VOC                                      | Published results<br>22 June 2021      | https://www.researchsquare.com/article/rs-522782/v1                                 |
| Qatar Qatar                                       | SARS-CoV-2 vaccine effectiveness in immunosuppressed kidney transplant<br>recipients   | Chemaitelly, 2021         | 1 February 2021 to 21 July 2021                                     | Other                          | Any infection, Severe   | Pfizer BioNTech (Comimaty) & Modema (mRNA-1273)   | 1  | Published results<br>9 August 2021     | https://www.medniv.org/content/10.1101/2021.08.07.212<br>51578v1.full.pdf           |
| Qatar<br>17                                       | BNT162b2 and mRNA-1273 COVID-19 vaccine effectiveness against the Delta (B.1.617.2) variant in Qatar   | Tang, 2021                | 23 March 2021 to 21 July 2021                                       | 12+ years                      | Any infection, Severe, Symptomatic disease,<br>Asymptomatic infection                                 | Modema (mRNA-1273), Pfizer BioNTech (Comimaty)  | Delta (8.1.617.2)  | Published results<br>11 August 2021    | https://doi.org/10.1101/2021.08.11.21251885   |
| Qatar Qatar                                       | Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar  | Chemaitelly, 2021         | 1 January 2021 to 15 August 2021                                    | Adults, Older Adults           | Any infection, Symptomatic disease, Asymptomatic<br>infection, Severe                                 | Pfizer BioNTech (Comimaty)  | Alpha (8.1.1.7), Beta (8.1.951),<br>Delta (8.1.617.2)          | Published results<br>27 August 2021    | https://doi.org/10.1101/2021.08.25.21262584   |
| Qatar 19  | Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar  | Chemaitelly, 2021         | 1 January 2021 to 5 September 2021                                  | Older Adults, 12+ years        | Any infection, Symptomatic disease, Asymptomatic<br>infection, Severe                                 | Pfizer BioNTech (Comimaty)  | Alpha (8.1.1.7), Beta (8.1.351),<br>Delta (8.1.617.2)          | Published results<br>6 October 2020    | https://www.neim.org/doi/10.1056/NEIMoa2114114                                      |
| Qatar Qatar                                       | Waning of mRNA-1273 vaccine effectiveness against SARS-CoV-2 infection in<br>Qatar   | Abu-Raddad, 2021          | 1 January 2021 to 5 December 2021                                   | Adults                         | Any infection, Symptomatic disease, Asymptomatic<br>infection, Hospitalization                        | Moderna (Spikevax)  | Mixed VOC  | Published results<br>16 December 2021  | https://www.medntiv.org/content/10.1101/2021.12.16.212<br>57902v1.full.pdf          |
| Qatar<br>21                                       | Effectiveness of BNT162b2 and mRNA-1273 COVID-19 boosters against SARS-<br>CoV-2 Omicron (B.1.1.529) infection in Qatar  | Abu-Raddad, 2022          | 5 January 2021 to 9 January 2022                                    | Adults                         | Any infection, Symptomatic disease  | Pfizer BioNTech (Comimaty) - Booster dose, Moderna (Spikevax) -<br>Booster dose   | Omicron (8.1.1.519), Delta<br>(8.1.617.2)                      | Published results<br>14 January 2022   | https://www.medney.org/content/10.1101/2022.01.18.222<br>59452v2.full.pdf           |
| Qatar Qatar                                       | Duration of protection of BNT162b2 and mRNA-1273 COVID-19 vaccines<br>against symptomatic SARS-CoV-2 Omicron infection in Qatar  | Chemaitelly, 2022         | 23 December 2021 to 28 February 2022                                | Adults                         | Symptomatic disease, Severe disease   | Moderna (Spikevax), Pfizer BioNTech (Comimaty), Moderna (Spikevax)<br>Booster dose, Pfizer BioNTech (Comimaty) - Booster dose   | Omicron (8.1.1.519), other                                     | Published results<br>13 March 2022     | https://www.medniv.org/content/10.1101/2022.02.07.222<br>70568v1.full.pdf           |
| Qatar Qatar                                       | Effect of prior infection, vaccination, and hybrid immunity against symptomatic<br>8A.1 and 8A.2 Omicron infections and severe COVID-19 in Qatar   | Altarawneh, 2022          | 23 December 2021 to 21 February 2022                                | Adults                         | Any infection, Symptomatic disease, Other Outcome   | Moderna (Spikevax), Pfizer BioNTech (Comimaty), Moderna (Spikevax)<br>Booster dose, Pfizer BioNTech (Comimaty) - Booster dose   | Other, Omicron (8.1.1.519)                                     | Published results:<br>22 March 2022    | https://www.medniv.org/content/10.1101/2022.03.22.222<br>22745v1.full.pdf           |
| Qatar Qatar                                       | Effectiveness of the BNT162b2 vaccine against SARS-CoV-2 infection among<br>children and adolescents in Qatar  | Chemaitelly, 2022         | 1 February 2021 to 12 July 2022                                     | Children less than 18 y/o      | Any infection   | Pfizer BioNTech (Comimaty)  | Omicron (8.1.1.519), Mixed VO                                  | Published results:<br>26 July 2022     | https://www.medniv.org/content/10.1101/2022.07.26.222<br>78045v1                    |
| Qatar<br>25                                       | N/A (Planned or ongoing study)   | N/A                       | Expected start date: December 2020<br>Results expected: —           | Adults, Older Adults, Children | Any infection, Asymptomatic infection, Symptomatic disease,<br>Severe disease, Hospitalization, Death | Pfizer BioNTech (Comimaty) - Booster dose, Moderna (Spikevax) - Booster dose  | Alpha (8.1.1.7), Beta (8.1.351),<br>Delta (8.1.617.2), Omicron | N/A                                    | N/A   |
| Saudi Arabia                                      | The Impact of COVID-19 Vaccine on Rate of Hospitalization and Outcome of COVID-19 Infection in a Single Center in the Eastern Province of Saudi Arabia                                     | Alkhafaji, 2021           | 1 April 2021 to 31 July 2021  | Adult COVID-19 cases           | ICU admission, mechanical ventilation, death, length o<br>hospital stay                               | Pfizer BioNTech (Comimaty) & other brands   | _  | Published results<br>11 October 2021   | https://www.researchsquare.com/article/rs-903562/v2                                 |
| United Arab Emirates                              | An analysis of antibody responses and clinical sequalae of the Sinopharm H802 COVID19 vaccine in dialysis patients in the United Arab Emirates   | Holt, 2021                | 15 March 2020 to 20 June 2021                                       | Hemodialysis patients          | Antibody / humoral responses and clinical sequalae  | Sinopharm vaccine   | _  | Published results<br>27 September 2021 | https://onlinelibrary.wiley.com/doi/10.1111/nep.13980                               |
| United Arab Emirates                              | Sinopharm (88I8P-CorV) vaccine effectiveness on preventing hospital admission<br>and deaths: results from a retrospective study in the Emirate of Abu Dhabi,<br>United Arab Emirates (UAE) | Al Hosani, 2022           | 1 September 2020 to 1 May 2021                                      | Adults                         | Hospitalization, other, Death   | Sinopharm (Beijing): 88IBP-CorV (Vero Cells)<br>Vaccine Type: Inactivated<br>This vaccine may also be referred to as Covilo   | Mixed VOC<br>Beta (8.1.351) & Alpha<br>(8.1.1.7)               | Published results<br>27 October 2020   | https://www.sciencedirect.com/science/article/pii/S0264410<br>X220017487via%30thub= |
| United Arab Emirates                              | Effectiveness of BBIBP-CorV vaccine against severe outcomes of COVID-19 in<br>Abu Dhabi, United Arab Emirates (UAE)  | Al Kaabi, 2022            | 1 October 2020 to 31 July 2021                                      | Adults                         | Hospitalization, Critical care admission, Death   | Sinopharm (Beijing): B8IBP-CorV (Vero Cells)<br>Vaccine Type: Inactivated<br>This vaccine may also be referred to as Covilo   | Non-VOC  | Published results<br>9 June 2022       | https://www.nature.com/articles/s41457-022-30835-1#Sec9                             |
| 31 Planned or ongoing<br>32 Published / completed |  |                           |   |                                |   |   |  |  |   |



# Categories of countries based on COVID-19 vaccine effectiveness proposal or study status in the EMR (as of November 2022)

Countries interested in conducting COVID-19 VE study with support from WHO-EMRO

Countries with COVID-19 VE studies <u>independent</u> of WHO-EMRO's support

Expressed interest in or submitted proposal to WHO/EMRO:

<u>Lebanon</u>, <u>Morocco</u>, <u>Oman</u>,

Palestine, and Tunisia

Submitted proposals in line with WHO protocol and currently under reviews by WHO/EMRO's VE technical team:

NA

Proposal deemed eligible to participate in Regional COVID-19 VE study and in implementation phase:

<u>Iran</u>, <u>Jordan</u>, <u>Egypt</u> and <u>Pakistan</u>

Planned, ongoing, or completed COVID-19 VE studies in the EMR: Bahrain, Egypt, Iran, Jordan, Kuwait, Lebanon, Morocco, Qatar, Saudi Arabia and the UAE



### Standardization of methods and data analysis plans

- Technical proposals with study designs in line with the two main WHO protocols
  (TND in SARI and cohort study in HCWs) were selected; following which their
  methods and statistical analysis plans were standardized / harmonized to allow
  pooling data across countries and reporting Regional VE estimates
- The study details of the four countries which were selected to participate in the EM Regional COVID-19 VE Study are presented in the next slides



#### Jordan – Ministry of Health

**Study design:** Prospective TND in SARI

**Study sites:** 4 hospitals of King Abdullah, Prince Hamza, Zarka and Karak

**COVID-19 vaccines:** Pfizer, AstraZeneca, Sinopharm and Baharat

Sample size: 943 cases: 1,886 control (so far, 708 participants enrolled; 130 positive case; 549 negative; 31

pending)

Study dates:

data collection: 12 months of data from 4 June 2022 – 2023

data entry in REDCap started: 5 June 2022

**Current status:** On track / plan with study implementation; monthly data validation ongoing



## Iran — Ministry of Health & Shahroud University of Medical Sciences

**Study design:** Retrospective TND in SARI

**Study sites:** 7 provinces of Mashhad, Shahroud, Qom, Kerman, Tabriz, Kermanshah, Kurdistan, and Hamedan

**COVID-19 vaccines:** AstraZeneca, Sinopharm, Sputnik, Baharat and domestic brands (e.g., Barekat, PastoCovac, Fakhravac, and Spikogen)

**Sample size:** 12,688 cases : 12,688 controls (~25,000 total)

10 months of data from May 2021 – March 2022

**Study dates:** Start date: 20 May 2022

End date: 30 September 2022

Current status: Standardization and importation of datasets into RECap in progress; so far data from 4 provinces

received



### Pakistan – Khyber Medical University (KMU)

**Study design:** Mix retrospective-prospective cohort study in HCWs

**Study sites:** 3 hospitals of Saidu, Mardan and Kohat

**COVID-19 vaccines:** Pfizer, Moderna, AstraZeneca, and Sinopharm

**Sample size:** 1,627 planned (of which 1,414 have been enrolled; 90 additional participants to be recruited)

Study enrollment: December 2021 **Study dates:** 

Data entry into REDCap: 16 June 2022

Study end date: 31 January 2023

**Current status:** In process of completing data entry in REDCap, follow-up and data validation ongoing



### Egypt – Al-Azhar University

**Study design:** Prospective cohort study in HCWs

**Study sites:** 5 hospitals of Al-Zahraa, Al-Hussein, Bab Al-Sheria Damiatta and Assiut

COVID-19 vaccines: Sinopharm, Sinovac, AstraZeneca, Janssen, Baharat, Pfizer, Moderna

Sample size: 1,006 HCWs (enrollment complete)

12 months from mid-Aug 2022 – 2023 Participant enrollment started: 1 July 2022

Data entry in REDCap started: 31 July 2022

**Current status:** Participant follow-up in progress



**Study dates:** 

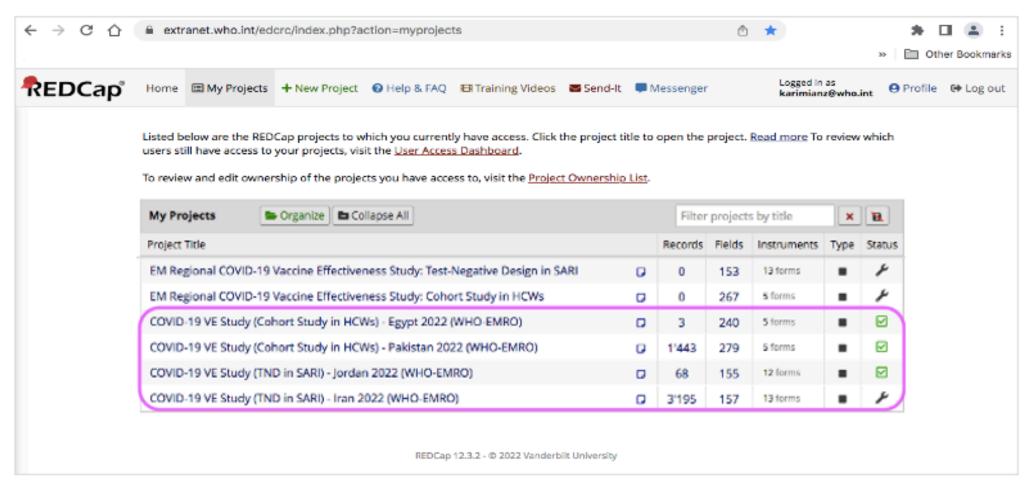
#### Selected countries to participate in EM Regional COVID-19 VE Study

| Natio                                 | nal COVID-19 VE Studies                                     | Study design and method   | Sample size and study sites   | Study duration                        |  |
|---------------------------------------|---|---|---|---------------------------------------|--|
| Countries and Investigative Institute | <b>Egypt</b><br>Al-Azhar University                         | Prospective Cohort Study in Health<br>Care Workers (HCWs)   | 1,006 participants<br>From 5 hospitals                              | From 08/2022 – 08/2023<br>(12 months) |  |
|                                       | <b>Iran</b><br>Kermanshah University of<br>Medical Sciences | Retrospective Test-Negative case-<br>control Design (TND) in Sever Acute<br>Respiratory Infections (SARI) | ~25,000 Participants<br>From 7 provinces                            | From 05/2021 – 03/2022<br>(10 months) |  |
|                                       | <b>Jordan</b><br>MOH  | Prospective Test-Negative case-control<br>Design (TND) in Sever Acute<br>Respiratory Infections (SARI)    | 1,000 cases:<br>2,000 controls<br>(3,000 total)<br>From 4 hospitals | From 06/2022 – 06/2023<br>(12 months) |  |
|                                       | <b>Pakistan</b><br>Khyber Medical University                | Mix Retrospective-Prospective Cohort<br>Study in Health Care Workers (HCWs)                               | ~1,500 participants<br>From 3 hospitals                             | From 11/2021 – 01/2023<br>(15 months) |  |





## REDCap The Regional Data Entry Platform



https://extranet.who.int/edcrc/



## Building national technical capacity among EM Countries

General training programs targeting all countries (e.g., generic WHO protocols, updated WHO guidance for conducting COVID-19 VE studies)

Specialized (customized) training programs developed based on the needs of investigators partaking in the EM Regional COVID-19 VE Study



#### Capacity-building for the EM Regional COVID-19 VE Study (2021-2022)

| Participants  | Capacity-building session  | Date         |
|---|--|--------------|
| For all EM Countries  | EM Regional COVID-19 VE Study using WHO protocol for Cohort study in HCWs  | 13 Dec 2021  |
| (general training program)                                      | EM Regional COVID-19 VE Study using WHO protocol for TND in SARI   | 15 Dec 2021  |
| For EM Countries partaking in the EM Regional COVID-19 VE Study | Interactive capacity-building trainings on the use of <a href="REDCap">REDCap</a> for study design and data management using WHO protocol for TND in SARI          | 7 March 2022 |
| (specialized training program)                                  | Interactive capacity-building trainings on the use of <a href="REDCap">REDCap</a> for study design and data management using WHO protocol for Cohort study in HCWs | 8 March 2022 |



#### Special thanks to the EMR COVID-19 VE Technical Team!

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