Article:
Andreoli, L., Lini, D., Schreiber, K. et al. (184 more authors) (2024) COVID-19 vaccine safety during pregnancy and breastfeeding in women with autoimmune diseases: results from the COVAD study. Rheumatology, 63 (5). pp. 1341-1351. ISSN 1462-0324

https://doi.org/10.1093/rheumatology/kead382

COVID-19 Vaccine Safety during Pregnancy and Breastfeeding in Women with Autoimmune Diseases: Results from the COVAD Study

Author list

Laura Andreoli * [1]

Daniele Lini [1]

Karen Schreiber [2,3,4]

Ioannis Parodis [5,6]

Parikshit Sen [7]

Naveen R [8]

Jessica Day [9,10,11]

Mrudula Joshi [12]

Kshitij Jagtap [13]

Arvind Nune [14]

Elena Nikiphorou [15,16]

Vishwesh Agarwal [17]

Sreoshy Saha [18]

Ai Lyn Tan [19,20]

Samuel Katsuyuki Shinjo [21]

Nelly Ziade [22,23]

Tsvetelina Velikova [24]

Marcin Milchert [25]

Abraham Edgar Gracia-Ramos [26]

Lorenzo Cavagna [27]

Masataka Kuwana [28]

Johannes Knitza [29]

Ashima Makol [30]

Aarat Patel [31]

John D Pauling [32,33]

Chris Wincup [34,35]

Bhupen Barman [36]

Erick Adrian Zamora Tehozol[37]

Jorge Rojas Serrano[38]

Ignacio García-De La Torre[39]

Iris J. Colunga-Pedraza[40]

Javier Merayo-Chalico[41]

Okwara Celestine Chibuzo [42]

Wanruchada Katchamart [43]

Phonpen Akawatcharangura Goo[44]

Russka Shumnalieva[45]

Yi-Ming Chen[46,47]

Leonardo Santos Hoff [48]

Lina El Kibbi[49]

Hussein Halabi[50]

Binit Vaidya[51]

Syahrul Sazliyana Shaharir [52]

A T M Tanveer Hasan [53]

Dzifa Dey[54]

Carlos Enrique Toro Gutiérrez[55]

Carlo Vinicio Caballero-Uribe[56]

James B. Lilleker[57,58]

Babur Salim[59]

Tamer Gheita[60]

Tulika Chatterjee[61]

Miguel A Saavedra[62]

Oliver Distler [63]

COVAD study group[64]

Hector Chinoy[65,66]

Vikas Agarwal[67]

Rohit Aggarwal [68]

Latika Gupta* [69,70,71,72]

*Laura Andreoli and Latika Gupta contributed equally

Affiliations

[1] Rheumatology and Clinical Immunology Unit, ASST Spedali Civili Brescia; Department of Clinical and Experimental Sciences, University of Brescia, 25123 Brescia, Italy

[2] Danish Hospital for Rheumatic Diseases, 6400 Sønderborg, Denmark.

[3] Department of Regional Health Research (IRS), University of Southern Denmark, 5230 Odense, Denmark.

[4] Thrombosis and Haemostasis, Guys and St Thomas' NHS Foundation Trust, London SE1 7EH, UK.

[5] Division of Rheumatology, Department of Medicine Solna, Karolinska Institutet and Karolinska University Hospital, Stockholm, Sweden ORCiD: 0000-0002-4875-5395.

[6] Department of Rheumatology, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. ORCiD: 0000-0002-4875-5395.

[7] Maulana Azad Medical College, 2-Bahadurshah Zafar Marg, New Delhi, Delhi-110002, India. ORCID ID: 0000-0002-1630-6026.

[8, 68, 69] Department of Clinical Immunology and Rheumatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India. ORCID ID: 0000-0003-2014-3925 (Naveen R), 0000-0002-4508-1233 (Vikas Aggarwal), 0000-0003-2753-2990 (Latika Gupta).

[9] Walter and Eliza Hall Institute of Medical Research, Parkville, VIC 3052 Australia. ORCiD: 0000-0001-8528-4361.

[10] Department of Medical Biology, University of Melbourne, Parkville, VIC 3052 Australia. ORCiD: 0000-0001-8528-4361.

[11] Department of Rheumatology, Royal Melbourne Hospital, Parkville, VIC 3050, Australia. ORCiD: 0000-0001-8528-4361.

[12] Byramjee Jeejeebhoy Government Medical College and Sassoon General Hospitals, Pune, India. Orcid ID: 0000-0001-7312-351X

[13] Seth Gordhandhas Sunderdas Medical College and King Edwards Memorial Hospital, Mumbai, Maharashtra, India. ORCiD: 0000-0003-2729-737X

[14] Southport and Ormskirk Hospital NHS Trust, Southport, PR8 6PN, UK. ORCiD: 0000-0002-3849-614X.

[15] Centre for Rheumatic Diseases, King's College London, London, UK. ORCiD: 0000-0001-6847-3726.

[16] Rheumatology Department, King's College Hospital, London, UK. ORCiD: 0000-0001-6847-3726.

[17] Mahatma Gandhi Mission Medical College, Navi Mumbai, Maharashtra, India. ORCiD: 0000-0002-0986-8354.

[18] Mymensingh Medical College, Mymensingh, Bangladesh. ORCiD: 0000-0001-6745-9770.

[19] NIHR Leeds Biomedical Research Centre, Leeds Teaching Hospitals Trust, Leeds, UK. ORCiD: 0000-0002-9158-7243.

[20] Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK. ORCiD: 0000-0002-9158-7243.

[21] Division of Rheumatology, Faculdade de Medicina FMUSP, Universidade de Sao Paulo, Sao Paulo, SP, Brazil. ORCiD: 0000-0002-3682-4517

[22] Rheumatology Department, Saint-Joseph University, Beirut, Lebanon. ORCiD: 0000-0002-4479-7678.

[23] Rheumatology Department, Hotel-Dieu de France Hospital, Beirut, Lebanon. ORCiD: 0000-0002-4479-7678.

[24] Medical Faculty, Sofia University St. Kliment Ohridski, 1 Kozyak Str., 1407, Sofia, Bulgaria. ORCiD: 0000-0002-0593-1272.

[25] Department of Internal Medicine, Rheumatology, Diabetology, Geriatrics and Clinical Immunology, Pomeranian Medical University in Szczecin, ul Unii Lubelskiej 1, 71-252, Szczecin, Poland. ORCID ID: 0000-0002-0943-8768.

[26] Department of Internal Medicine, General Hospital, National Medical Center "La Raza", Instituto Mexicano del Seguro Social, Av. Jacaranda S/N, Col. La Raza, Del. Azcapotzalco, C.P. 02990 Mexico City, Mexico. ORCiD: 0000-0003-1842-2554.

[27] Rheumatology Unit, Dipartimento di Medicine Interna e Terapia Medica, Università degli studi di Pavia, Pavia, Lombardy, Italy. ORCiD: 0000-0003-3292-1528.

[28] Department of Allergy and Rheumatology, Nippon Medical School Graduate School of Medicine, 1-1-5 Sendagi, Bunkyo-ku, Tokyo 113-8602, Japan. ORCiD: 0000-0001-8352-6136.

[29] Medizinische Klinik 3 – Rheumatologie und Immunologie, Universitätsklinikum Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg, Ulmenweg 18, 91054, Erlangen, Deutschland. ORCiD: 0000-0001-9695-0657.

[30] Division of Rheumatology, Mayo Clinic, Rochester, Minnesota, USA. ORCiD: 0000-0002-8748-898X.

[31] Bon Secours Rheumatology Center and Division of Pediatric Rheumatology, Department of Pediatrics, University of Virginia School of Medicine, Charlottesville, VA, USA.

[32] Bristol Medical School Translational Health Sciences, University of Bristol, UK. 0000-0002-2793-2364.

[33] Department of Rheumatology, North Bristol NHS Trust, Bristol, UK. 0000-0002-2793-2364.

[34] Department of Rheumatology, Division of Medicine, Rayne Institute, University College London, UK . ORCiD: 0000-0002-8742-8311.

[35] Centre for Adolescent Rheumatology Versus Arthritis at UCL, UCLH, GOSH, London, UK. ORCiD: 0000-0002-8742-8311.

[36] Department of General Medicine, All India Institute of Medical Sciences (AIIMS), Guwahati, India

[37] Rheumatology, Medical Care & Research, Centro Medico Pensiones Hospital, Instituto Mexicano del Seguro Social Delegación Yucatán, Yucatán, Mexcio. ORCiD: 0000-0002-7888-3961.

[38] Rheumatologist and Clinical Investigator, Interstitial Lung Disease and Rheumatology Unit, Instituto Nacional de Enfermedades Respiratorias, Mexico City, Mexico. ORCiD: 0000-0001-6980-7898.

[39] Departamento de Inmunología y Reumatología, Hospital General de Occidente and Universidad de Guadalajara, Guadalajara, Jalisco, Mexico. ORCiD: 0000-0002-9261-678X.

[40] Rheumatology, Hospital Universitario Dr Jose Eleuterio Gonzalez, Monterrey, Mexico. ORCiD: 0000-0002-2786-5843.

[41] Department of Immunology and Rheumatology, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City, Mexico. ORCiD: 0000-0002-5870-0523.

[42] Department of Medicine, University of Nigeria Teaching Hospital, Ituku-Ozalla/University of Nigeria, Enugu Campus, Enugu, Nigeria

[43] Division of Rheumatology, Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. ORCiD: 0000-0002-8952-5967.

[44] Department of Medicine, Queen Savang Vadhana Memorial Hospital, Chonburi, Thailand.

[45] Department of Rheumatology, Clinic of Rheumatology, University Hospital "St. Ivan Rilski", Medical University-Sofia, Bulgaria, ORCiD: 0000-0003-2321-6536

[46] Division of Allergy, Immunology and Rheumatology, Department of Internal Medicine, Taichung Veterans General Hospital, Taichung City, Taiwan. ORCiD: 0000-0001-7593-3065.

[47] Department of Medical Research, Taichung Veterans General Hospital, Taichung, Taiwan. ORCiD: 0000-0001-7593-3065.

[48] School of Medicine, Universidade Potiguar (UnP), Brazil. ORCiD: 0000-0002-2083-4796

[49] Rheumatology Unit, Internal Medicine Department, Specialized Medical Center, Riyadh, Saudi Arabia. ORCiD: 0000-0003-1710-9996.

[50] Department of Internal Medicine, Section of rheumatology, King Faisal Specialist Hospital and Research Center, Jeddah, Saudi Arabia. ORCiD: 0000-0002-5174-8292.

[51] National Center for Rheumatic Diseases (NCRD), Ratopul, Kathmandu, Nepal. ORCiD: 0000-0002-4840 8924.

[52] Faculty of Medicine, Universiti Kebangsaan Malaysia, 56000, Cheras, Kuala Lumpur. ORCiD: 0000-0002-9068-8114.

[53] Department of Rheumatology, Enam Medical College & Hospital, Dhaka, Bangladesh. ORCiD: 0000-0002-5332-3319.

[54] Rheumatology Unit, Department of Medicine and Therapeutics, University of Ghana Medical School, College of Health Sciences, Korle-Bu, Accra, Ghana.

[55] General Director, Reference Center for Osteoporosis, Rheumatology and Dermatology, Pontifica Universidad Javeriana Cali, Colombia. ORCiD: 0000-0002-6084-7049

[56] Department of Medicine, Hospital Universidad del Norte, Barranquilla, Atlantico, Colombia.

[57,65,70] Division of Musculoskeletal and Dermatological Sciences, Faculty of Biology, Medicine and Health, Manchester Academic Health Science Centre The University of Manchester, Manchester, UK. ORCiD: 0000-0002-9230-4137 (James Lilleker) ORCiD: 0000-0001-6492-1288 (Hector Chinoy) ORCiD: 0000-0003-2753-2990 (Latika Gupta)

[58] Manchester Centre for Clinical Neurosciences, Salford Royal NHS Foundation Trust, Salford, UK ORCiD: 0000-0002-9230-4137.

[59] Rheumatology Department, Fauji Foundation Hospital, Rawalpindi, Pakistan. ORCiD: 0000-0001-8430-9299.

[60] Rheumatology Department, Kasr Al Ainy School of Medicine, Cairo University, Cairo, Egypt. ORCiD: 0000-0002-1155-9729.

[61] Department of Internal Medicine, University of Illinois College of Medicine at Peoria, Illinois. ORCiD: 0000-0001-8844-851X.

[62] Departamento de Reumatología Hospital de Especialidades Dr. Antonio Fraga Mouret, Centro Médico Nacional La Raza, IMSS, Mexico City, Mexico. ORCiD: 0000-0003-0687-9944.

[63] Department of Rheumatology, University Hospital Zurich, University of Zurich, Zurich, Switzerland. ORCiD: 0000-0002-0546-8310.

[64] (The complete list of authors part of the COVAD Study Group as well as their affiliations are provided in the Supplement).

[66] Department of Rheumatology, Salford Royal Hospital, Northern Care Alliance NHS Foundation Trust, Salford, UK. ORCID ID: 0000-0001-6492-1288

[68] Division of Rheumatology and Clinical Immunology, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA. ORCiD: 0000-0001-7531-8038.

[71] Department of Rheumatology, Royal Wolverhampton Hospitals NHS Trust, Wolverhampton, UK. ORCiD: 0000-0003-2753-2990.

[72] City Hospital, Sandwell and West Birmingham Hospitals NHS Trust, Birmingham, United Kingdom. ORCiD: 0000-0003-2753-2990.

Correspondence to:
Dr. Latika Gupta
Dept of Rheumatology, Royal Wolverhampton Hospitals NHS Trust, Wolverhampton, WV10 0QP, United Kingdom. ORCID ID: 0000-0003-2753-2990
Email: drlatikagupta@gmail.com Phone: +44 01902 307999

Running Title: COVID-19 Vaccine Safety in Pregnant and Breastfeeding women with AID

Acknowledgments:
The authors are grateful to all respondents for completing the questionnaire. The authors also thank the Myositis Association, Myositis India, Myositis UK, Myositis Support and Understanding, the Myositis Global Network, Deutsche Gesellschaft für Muskelkranke e.V. (DGM), Dutch and Swedish Myositis patient support groups, Cure JM, Cure IBM, Sjögren's India Foundation, Patients Engage, Scleroderma India, Lupus UK, Lupus Sweden, Emirates Arthritis Foundation, EULAR PARE, ArLAR research group, AAAA patient group, Myositis Association of Australia, APLAR myositis special interest group, Thai Rheumatism association, PANLAR, AFLAR NRAS, Anti-Synthetase Syndrome support group, and various other patient support groups and organizations for their contribution to the dissemination of this survey. Finally, the authors wish to thank all members of the COVAD study group for their invaluable role in the data collection.

COVAD Study Group Authors: Zoltán Griger, Sinan Kardes, Melinda Nagy Vince, Yogesh Preet Singh, Rajiv Ranjan, Avinash Jain, Sapan C Pandya, Rakesh Kumar Pilania, Aman Sharma, Manesh Manoj M, Vikas Gupta, Chengappa G Kavadichanda, Pradeepta Sekhar Patro, Sajal Ajmani, Sanat Phatak, Rudra Prosad Goswami, Abhra Chandra Chowdhury, Ashish Jacob Mathew, Padnamabha Shenoy, Ajay Asranna, Keerthi Talari Bommakanti, Anuj Shukla, Arunkumar R Pande, Kunal Chandwar, Akanksha Ghodke, Hiya Boro, Zoha Zahid Fazal, Binit Vaidya, Döndü Üsküdar Cansu, Reşit Yıldırım, Armen Yuri Gasparyan, Nicoletta Del Papa, Gianluca Sambataro, Atzeni Fabiola, Marcello Govoni, Simone Parisi, Elena Bartoloni Bocci, Gian Domenico Sebastiani, Enrico Fusaro, Marco Sebastiani, Luca Quartuccio, Franco Franceschini, Pier Paolo Sainaghi, Giovanni Orsolini, Rossella De Angelis, Maria Giovanna Danieli, Vincenzo Venerito, Silvia Grignaschi, Alessandro Giollo, Alessia Alunno, Florenzo Iannone, Marco Fornaro, Lisa S Traboco, Suryo Anggoro Kusumo Wibowo, Jesús Loarce-Martos, Sergio Prieto-González, Raquel Aranega Gonzalez, Akira Yoshida, Ran Nakashima, Shinji Sato, Naoki Kimura, Yuko Kaneko, Takahisa Gono, Stylianos Tomaras, Fabian Nikolai Proft, Marie-Therese Holzer, Margarita Aleksandrovna Gromova, Or Aharonov, Zoltán Griger, Ihsane Hmamouchi, Imane El bouchti, Zineb Baba, Margherita Giannini, François Maurier, Julien Campagne, Alain Meyer, Daman Langguth, Vidya Limaye, Merrilee Needham, Nilesh Srivastav, Marie Hudson, Océane Landon-Cardinal, Wilmer Gerardo Rojas Zuleta, Álvaro Arbeláez, Javier Cajas**,** José António Pereira Silva, João Eurico Fonseca, Olena Zimba, Doskaliuk Bohdana, Uyi Ima-Edomwonyi, Ibukunoluwa Dedeke, Emorinken Airenakho, Nwankwo Henry Madu, Abubakar Yerima, Hakeem Olaosebikan, Becky A., Oruma Devi Koussougbo, Elisa Palalane, Ho So, Manuel Francisco Ugarte-Gil, Lyn Chinchay, José Proaño Bernaola, Victorio Pimentel, Hanan Mohammed Fathi, Reem Hamdy A Mohammed, Ghita Harifi, Yurilís Fuentes-Silva, Karoll Cabriza, Jonathan Losanto, Nelly Colaman, Antonio Cachafeiro-Vilar, Generoso Guerra Bautista, Enrique Julio Giraldo Ho, Raúl González, Lilith Stange Nunez, Cristian Vergara M, Jossiell Then Báez, Hugo Alonzo, Carlos Benito Santiago Pastelin, Rodrigo García Salinas, Alejandro Quiñónez Obiols, Nilmo Chávez, Andrea Bran Ordóñez, Sandra Argueta, Gil Alberto Reyes Llerena, Radames Sierra-Zorita, Dina Arrieta, Eduardo Romero Hidalgo, Ricardo Saenz, Idania Escalante M, Roberto Morales, Wendy Calapaqui, Ivonne Quezada, Gabriela Arredondo

Declarations: This research was supported by the NIHR Manchester Biomedical Research Centre (NIHR203308).

Conflicts of Interest/Competing interests:

ALT has received honoraria for advisory boards and speaking for Abbvie, Gilead, Janssen, Lilly, Novartis, Pfizer, and UCB.

EN has received speaker honoraria/participated in advisory boards for Celltrion, Pfizer, Sanofi, Gilead, Galapagos, AbbVie, and Lilly, and holds research grants from Pfizer and Lilly.

HC has received grant support from Eli Lilly and UCB, consulting fees from Novartis, Eli Lilly, Orphazyme, Astra Zeneca, speaker for UCB, and Biogen.

IP has received research funding and/or honoraria from Amgen, AstraZeneca, Aurinia Pharmaceuticals, Elli Lilly and Company, Gilead Sciences, GlaxoSmithKline, Janssen Pharmaceuticals, Novartis and F. Hoffmann-La Roche AG.

JBL has received speaker honoraria/participated in advisory boards for Sanofi Genzyme, Roche, and Biogen. None is related to this manuscript.

JD has received research funding from CSL Limited.

NZ has received speaker fees, advisory board fees, and research grants from Pfizer, Roche, Abbvie, Eli Lilly, NewBridge, Sanofi-Aventis, Boehringer Ingelheim, Janssen, and Pierre Fabre; none are related to this manuscript.
JDP has undertaken consultancy work and/or received speaker honoraria from Astra Zenaca, Boeringer Ingelgheim, Sojournix Pharma, Permeatus Inc, Janssen and IsoMab Pharmacueticals.
OD has/had consultancy relationship with and/or has received research funding from and/or has served as a speaker for the following companies in the area of potential treatments for systemic sclerosis and its complications in the last three calendar years: 4P-Pharma, Abbvie, Acceleron, Alcimed, Altavant, Amgen, AnaMar, Arxx, AstraZeneca, Baecon, Blade, Bayer, Boehringer Ingelheim, Corbus, CSL Behring, Galderma, Galapagos, Glenmark, Gossamer, iQvia, Horizon, Inventiva, Janssen, Kymera, Lupin, Medscape, Merck, Miltenyi Biotec, Mitsubishi Tanabe, Novartis, Prometheus, Redxpharma, Roivant, Sanofi and Topadur. Patent issued "mir-29 for the treatment of systemic sclerosis" (US8247389, EP2331143).
RA has a consultancy relationship with and/or has received research funding from the following companies: Bristol Myers-Squibb, Pfizer, Genentech, Octapharma, CSL Behring, Mallinckrodt, AstraZeneca, Corbus, Kezar, Abbvie, Janssen, Kyverna Alexion, Argenx, Q32, EMD-Serono, Boehringer Ingelheim, Roivant, Merck, Galapagos, Actigraph, Scipher, Horizon Therepeutics, Teva, Beigene, ANI Pharmaceuticals, Biogen, Nuvig, Capella Bioscience, and CabalettaBio.
TV has received speaker honoraria from Pfizer and AstraZeneca, non-related to the current manuscript.
Rest of the authors have no conflict of interest relevant to this manuscript.

Funding: No specific funding was obtained for this manuscript.

Ethical approval: Ethical approval was obtained from the Institutional Ethics Committee of the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, 226014

Contribution of authors:
Conceptualization: LG, LA, DL, and KS. Data curation: All authors. Formal analysis: DL; Funding acquisition: N/A. Investigation: LG, LA, DL, and PS. Methodology: LG, VA, LA, and DL; Software: LG. Validation: VA, RA, JBL, and HC. Visualization: RA, VA, and LG. Writing-original draft: LA, DL, KS, IP and LG. Writing-review and editing: all authors.

Disclaimer: No part of this manuscript has been copied or published elsewhere either in whole or in part.

Data Availability Statement: The datasets generated and/or analyzed during the current study are not publicly available but are available from the corresponding author upon reasonable request

Patient and Public Involvement Statement: It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

Word Count: 3,036

Keywords: pregnancy, breastfeeding, autoimmune diseases, COVID-19 vaccination, adverse events, disease flare, treatment

Key messages:

- Pregnant/breastfeeding patients with autoimmune diseases did not experience post-COVID-19 vaccination adverse events more frequently than healthy controls.
- Disease flares after vaccination were reported by one fifth of pregnant/breastfeeding patients.
- Reassuring safety observation will strengthen clinician-patient communication in the uptake of COVID-19 vaccination during gestational and post-partum periods.

ABSTRACT

Objectives: We investigated COVID-19 vaccine safety in pregnant and breastfeeding women with autoimmune diseases (AID) in the COVID-19 Vaccination in Autoimmune Diseases (COVAD) study.

Methods: Delayed-onset (>7 days) vaccine-related adverse events (AE), disease flares (DF), and AID-related treatment modifications were analyzed upon diagnosis of AID versus healthy controls (HC) and the pregnancy/breastfeeding status at the time of at least one dose of vaccine.

Results: Among the 9201 participants to the self-administered online survey, 6787 (73.8%) were women. Forty pregnant and 52 breastfeeding patients with AID were identified, of whom the majority had received at least one dose of COVID-19 vaccine (100% and 96.2%, respectively). AE were reported significantly more frequently in pregnant than in non-pregnant patients (overall AE 45% vs. 26%, p=0.01; minor AE 40% vs. 25.9%, p=0.03; major AE 17.5% vs. 4.6%, p<0.01), but no difference was found in comparison with pregnant HC. No difference was observed between breastfeeding patients and HC with respect to AE. Post-vaccination DF were reported by 17.5% of pregnant and 20% of breastfeeding patients, and by 18.3% of age- and disease-matched non-pregnant and non-breastfeeding patients (n=262). All pregnant/breastfeeding patients who experienced a DF were managed with glucocorticoids; 28.6% and 20% of them required initiation or change in immunosuppressants, respectively.

Conclusion: This study provides reassuring insights into the safety of COVID-19 vaccines administered to women with AID during the gestational and post-partum periods, helping overcome hesitant attitudes, as the benefits for the mother and the fetus by passive immunization appear to outweigh potential risks.

INTRODUCTION

Vulnerable individuals such as those living with autoimmune diseases (AID), both rheumatic (rAID) and non-rheumatic (nrAID), and women in the antenatal period are likely to be particularly concerned and hesitant towards vaccinations, yielding insufficient rates of vaccinated individuals (1, 2). In particular, concerns about the long-term safety of COVID-19 vaccines constitute a major impediment to global vaccination. The COVAD study was designed to collect self-reported data from patients with AID worldwide (3, 4).

The onset of AID frequently occurs in women of childbearing age; therefore, information about reproductive issues and pregnancy should be effectively communicated, including the implications of viral infections during pregnancy and the importance of vaccinations as a preventive measure (5). In fact, pregnant women are at a high risk of developing both maternal and fetal complications during viral infections (6), including COVID-19 which enhances the risk of maternal need for respiratory support, intensive care unit (ICU) admission, and preterm birth (7, 8).

Despite this evidence, being a pregnant woman can enhance COVID-19 vaccine hesitancy (9, 10). Such hesitancy constitutes an even more prominent concern in vulnerable groups such as patients with AID, for whom information about safety in situations such as the antenatal period is virtually non-existent (11). In addition to the concerns experienced by the general obstetric population, vaccine hesitancy in women with AID can be driven by the fear of adverse pregnancy outcomes (APO) and/or disease flares that might be difficult to manage during pregnancy or breastfeeding.

To aid physician-patient communication about the risk-benefit ratio of COVID-19 vaccination during pregnancy and breastfeeding in patients with AID, the COVAD study database was used to provide information regarding the safety of vaccination in terms of minor and major adverse events (AE) as well as disease worsening upon vaccination.

METHODS

Study design

The COVAD survey is an ongoing international, cross-sectional, multi-center, and patient-self-reported electronic survey. After vetting by international experts, pilot testing, revisions, validation and translation into 18 languages, the survey was hosted on an online platform (http://surveymonkey.com) and circulated by the international COVAD study group (106 physicians) across 94 countries, as well as through numerous social media platforms and online patient support groups. Convenience sampling was used and all participants aged over 18 years were included. Duplicate responses were removed manually. The methods have been detailed in the published COVAD study protocol (3).

Informed consent was obtained electronically through an initial question in the online survey, prior to the main study questionnaire. No incentives were offered for completing the survey. Central approval was obtained from the Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS) ethics committee according to local guidelines [Institutional Ethics Committee of Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, 226014 (IEC Code: 2021–143-IP-EXP-39)]. A report of study results adhered to the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (12).

Data collection

Upon completion of the COVAD 1 study, a validated follow-up COVAD 2 survey was hosted on the same online platform upon translation and pilot testing and circulated by the international COVAD Study Group in February 2022, with the primary aim to address questions regarding the long-term effects of COVID-19 vaccination. The questions retained the original question set of the baseline survey including demographics, details of autoimmune disease, previous COVID-19 infection history and course, and vaccination details including adverse events (short-term adverse events occurring <7 days from the vaccination, or long-term adverse events occurring >7 days from the vaccination). Comorbidities conferring a higher risk of severe COVID-19 were listed according to the Centers for Disease Control and Prevention (CDC) (13). Additional questions on patient-reported outcomes included physical function, pain, fatigue, and quality of life, as well as flares, booster vaccinations, and *de novo* emergence of autoimmune diseases. The survey questions and methods have been detailed in the COVAD 2 protocol previously published (4).

Data were retrieved on June 21st, 2022. Men and participants who had not fully completed the survey were excluded from the analysis (Figure 1).

Adverse events following vaccination

AE were categorized into injection site pain or reaction, minor AE, major AE, and hospitalizations, including ICU admission and oxygen supplementation (as per the CDC symptoms set) (14). Minor AEs included myalgia, body aches, fever, chills, nausea and vomiting, headache, rashes, fatigue, diarrhea, abdominal pain, high pulse rate or palpitations, rise in blood pressure, fainting, difficulty in breathing, dizziness, and chest pain. Major AE comprised serious reactions to vaccination, requirement of urgent medical attention but not hospital admission, including anaphylaxis, a marked difficulty in breathing, throat closure (choking), and severe rashes. Other AE that were not listed among close-ended responses were extracted from the open-ended clarification to "others".

Respondents were asked if they were pregnant or breastfeeding, and if so, when their expected or actual delivery date was.

Disease activity

Active and inactive disease state four weeks prior to vaccination was estimated through the patient's response to the question "What was the status of your autoimmune disease in the four weeks (prior to) before the 1st dose of COVID-19 vaccine?". Responses of active and worsening/static/improving disease were grouped together to designate "active disease". Patients who indicated "inactive" as a response formed the inactive disease group. Those who responded "I don't know" or "other" were assessed for activity on an individual basis based on answers to the following questions: (i) What were your symptoms four weeks prior to vaccination? (ii) If you have any swelling in your joints, how many joints are swollen? (iii) Did you require an increase in the dose of any of these [referring to previous answers] immunosuppressant medications, or did you start a new immunosuppressant medicine within the six months prior to the first COVID-19 vaccine?

Patient-self-reported disease activity prior to COVID-19 infection and vaccination were considered equivalent if the time between the two events was shorter than three months.

Statistical analysis

Data are presented as numbers and percentages for categorical variables and as the median values (interquartile range) for continuous variables.

Pregnant and breastfeeding women with AID were compared with pregnant and breastfeeding HC and with non-pregnant/non-breastfeeding women with AID. Chi-square (χ^2) and Mann-Whitney *U* tests were used for comparisons between groups for categorical and continuous variables, respectively.

A *p* value less than 0.05 was considered statistically significant.

RESULTS

Characteristics of study participants

Of the 9201 survey participants, 2414 (26.2%) were men and those with undisclosed sex (2331; 25.3%) were excluded. Incomplete responses (0.9%) were omitted (Figure 1). Among the study population (n=6787), 4954 patients with AID (73%) and 1833 HC (27%) were deemed eligible for analysis. The median age of the respondents was 47 (35-58) years, the most frequently reported ethnicity was Caucasian (47.5%), and at least one comorbidity was reported by 55.4% of the respondents. Anxiety, arterial hypertension, and depression were the most common comorbidities in our study population, with rates of 18.5%, 17.3%, and 15.6%, respectively. The three most represented countries were the United States of America (13%), the United Kingdom (12.5%), and Mexico (9.2%) (Supplementary Table S1).

Among the total study population, 6632 (97.7%) women received at least one dose of COVID-19 vaccination (4843 AIDs, 1789 HC), whereas 155 (2.3%) were unvaccinated (111 AIDs, 44 HC). Long-term safety concerns emerged as the most common reasons for not taking the vaccine, namely “long-term safety concern or fear” (33.5%) and “planning to wait for more time/data regarding safety before I have the vaccine” (29.7%) (Table 1). The highest rates of unvaccinated women were reported in low-income countries (Supplementary Table S1).

Among vaccinated women, 73.2% had taken at least three doses of the COVID-19 vaccine, and the most common vaccine received was Pfizer-BioNTech (BNT162b2) in 48.4%. The other characteristics of study participants are detailed in Tables 1 and 2.

Characteristics of pregnant and breastfeeding women

According to their pregnancy or breastfeeding status, women with AIDs and HC were subdivided into six groups, as shown in Tables 1 and 2, group A: non-pregnant or breastfeeding women with AIDs (n=4862); group B: pregnant women with AIDs (n=40); group C: breastfeeding women with AIDs (n=52); group D: non-pregnant or breastfeeding HC (n=1749); group E: pregnant HC (n=31); group F: breastfeeding HC (n=53).

Caucasian ethnicity was the most frequently reported in groups A, B, C, and D, while Hispanic ethnicity was the most common in groups E and F.

The reasons for not taking the vaccine were similarly distributed across the six groups. The vaccination frequencies (at least one dose received) were 97.8%, 100%, 96.2%, 97.8%, 96.8%, 92.5% in groups A to F, respectively. The most common vaccine received was Pfizer-BioNTech (BNT162b2) for all groups, and the majority of the individuals in each group received at least three doses of vaccine.

Adverse events after COVID-19 vaccination

Post-vaccination AE occurred in 1837 (25.4%) individuals (Table 2). Injection site pain and soreness were reported by 9.5%. Minor and major AE occurred in 24.3% and 4.3%, respectively. Hospitalization was required in 1.1%.

The frequency of AE was higher in group B than in the other groups (45% vs. 23.3-28%). Notably, the frequencies of overall AE, minor AE, and major AE were significantly higher as compared to group A (45% vs. 26%, p=0.01; 40% vs. 25.9%, p=0.03; 17.5% vs. 4.6%, p<0.01). Although AE and hospitalization were more frequent in group B, their frequencies were not significantly higher as compared to group E.

No thromboembolic events attributed to vaccination were reported in the study cohort.

Changes in disease activity after COVID-19 vaccination in pregnant and breastfeeding patients with AID and comparison with age- and disease-matched controls

Among the patients with AID, 40 women who received at least one dose of COVID-19 vaccine during pregnancy and 50 who received it during breastfeeding were compared with age- and disease-matched non-pregnant and non-breastfeeding women. A 1:3 matching was performed (with age allowed to be ± 2 years), yielding a control group composed of 262 women with AID (Table 3).

The three most represented diseases among pregnant and breastfeeding women with AID were systemic lupus erythematosus (SLE) (27.5%, 20%), rheumatoid arthritis (RA) (10%, 20%), and autoimmune thyroid disease (hypo- or hyperthyroid) (10%, 22%). Disease activity prior to vaccination was reported to be inactive by 37.5%, 48%, and 38.5% among pregnant, breastfeeding, and control women with AID, respectively, whereas active and worsening disease was experienced by 5%, 2%, and 6.1%, respectively (Table 4). Ongoing medications prior to vaccination are listed in Table 4; 50%, 42%, and 41.6% of pregnant, breastfeeding, and control women with AID were taking glucocorticoids, mostly at moderate or low dosages (<10 mg/day of prednisone equivalent), respectively.

Worsening AID status after vaccination was reported by 17.5%, 20%, and 18.3% of pregnant, breastfeeding, and control women with AID, respectively. Treatment modification was declared by all pregnant and breastfeeding women; glucocorticoids were either commenced or increased in all cases, while a new immunosuppressant was switched/added in nearly one fifth of the patients (Table 4).

DISCUSSION

As the COVID-19 pandemic is gradually dwindling to endemicity with adequate population-level vaccination, vaccine hesitancy among vulnerable groups remains a concern. It is currently recommended to offer COVID-19 vaccination to pregnant and breastfeeding women as data hitherto showed no association between vaccination and an increased APO rate (15, 16) or problems during the lactation period (17). Vaccine hesitancy can be alleviated by targeted information campaigns that effectively address the fears and concerns of women during their reproductive phase (18, 19). There are no dedicated studies or clinical trials on COVID-19 vaccination and its possible side-effects in pregnant or breastfeeding patients with rAID or nrAID. Therefore, we aimed at filling this knowledge gap by using data collected within the framework of the COVAD 2 study, a large international study based on a patient-reported survey of patients' experience with COVID-19 vaccination.

Among 6787 female respondents, we identified 40 pregnant patients with AID (group B) and 31 pregnant HC (group E), and 52 breastfeeding patients with AID (group C) and 53 breastfeeding HC (group F). The vaccination frequency (at least one dose received) was very high, ranging from 92.5% in group F to 100% in group B. This high level of adherence to COVID-19 vaccination may be explained by selection bias, as people who were vaccinated were more likely to undertake a survey whose primary aim was to investigate the safety of COVID-19 vaccination. Interestingly, reasons for not taking the vaccine were similar between patients and HC, and included concerns about the long-term effects of vaccines and the need for more safety data. Adherence to COVID-19 vaccination may also have been influenced by accessibility issues and the availability of vaccines. Supportive of this notion was that the highest frequencies of unvaccinated women were reported in low-income countries.

In terms of AE, pregnant patients with AID (group B) reported a significantly higher proportion of any AE, minor AE, and major AE as compared with non-pregnant/non-breastfeeding patients with AID (group A). This may be due to report bias assuming that patients carrying high-risk pregnancies are inclined to reporting any kind of symptoms (while non-pregnant patients may not have recollected some AE, especially minor ones), or it may reflect an enhanced vulnerability of pregnant patients with AID towards AE on the basis of the physiological changes induced by pregnancy. However, the latter hypothesis is weakened by the absence of a difference between group B and pregnant HC (group E), as well as by the available evidence that led to the approval of COVID-19 vaccines for use during pregnancy by regulatory agencies. The greater frequency of hospitalization in group B could be due to a cautious approach towards pregnant patients with AID rather than the severity of post-vaccination AEs. Importantly, no thrombotic events were reported in pregnant women. Thromboembolic complications constitute a matter of concern in patients with rAID, especially in those carrying antiphospholipid

antibodies or in an active phase of their disease, which are factors that can augment the gestational thrombophilic state. Since COVID-19 *per se* and/or the COVID-19 vaccination may increase the risk of thrombosis (20), it is of great importance to underscore the lack of thrombotic complications in this study cohort.

Another substantial fear of patients with AID is the experience of a disease flare after vaccination. The COVAD survey investigated changes in disease activity and the need for treatment modifications due to the worsening of disease symptoms. To investigate whether post-vaccination flares occurred more frequently in pregnant and breastfeeding patients with AID, we matched them by age and disease with patients in group A (Table 3). The majority of pregnant and breastfeeding patients with AID in the present study were affected by SLE, which is the prototypical AID emerging during fertile age; we have already described the lack of post-vaccination flares in these 11 pregnant women with SLE (21). A higher number of pregnant women than expected was observed for Idiopathic Inflammatory Myopathies (IIM), which are rare diseases that do not preferentially affect young women. However, this disproportionally large subgroup can be explained by the study design, as the COVAD survey was originally designed for patients with IIM and was therefore preferentially distributed to IIM patient groups. We previously reported the outcomes of COVID-19 vaccination in six pregnant patients with IIM from the COVAD study (22). Pregnant patients with IIM who were not in remission experienced a disease flare after vaccination; therefore, we concluded that a personalized evaluation of the risk-benefit ratio and timing of vaccination should be performed.

As a group, pregnant and breastfeeding patients with AID did not display disease worsening more frequently than control AID (Table 4). This was the case for both rAID and nrAID patients (data not shown). Disease flares in seven pregnant (17.5%) and 10 breastfeeding (20%) patients were managed with glucocorticoids in all cases, while only a few cases required commencement or modification of immunosuppressive drugs (Table 4). These findings support the general statement that pregnant and breastfeeding patients with AID can undergo COVID-19 vaccination according to recommendations for non-pregnant and non-breastfeeding patients (23, 24), provided that each case is assessed individually for risk factors that *per se* may constitute reasons for holding or postponing the vaccination.

This study has some limitations. First, the study was entirely based on self-reported patient data, with no possibility of verifying the validity of the responses through medical charts or healthcare professionals. Second, online surveys introduce inherent recall bias, as well as selection bias due to an expected higher participation willingness from patients who experienced AE, a potential lack of Internet access for individuals of lower socioeconomic status, and the likely lower representation of patients with severe disability. Third, the small number of pregnant and breastfeeding women should be acknowledged, as the survey itself was not designed and disseminated on the purpose to capture this specific population.

Heterogeneity in disease groups and treatments, and the lack of information about pregnancy outcomes should be also recognized as limitations of the study. Fourth, it was beyond the scope of this study to explore humoral responses to vaccines, which may also affect the development of AE. Fifth, in order to capture all the available information with regard to AE, patients in group A were not age-matched with those in groups B and C, resulting in a significantly older age (Table 1). Nevertheless, the large number of study participants, the high rate of complete survey responses, and wide geographical spread of survey respondents constituted major strengths of the study. The anonymized and self-reported nature of the questionnaire may also be considered a strength, since it is expected to facilitate direct and likely unbiased (without external influence) patient and HC representation.

Our data may help physicians navigate discussions regarding the risk-benefit ratio of COVID-19 vaccination in women who carry high-risk pregnancies due to underlying disease. The major benefits of vaccination not only for the mother but also for the fetus who will receive passive immunization should be emphasized, along with the message that vaccination protects against severe COVID-19 (25). Data on pregnant women entered into the COVID-19 Global Rheumatology Alliance as of February 2022 showed that unvaccinated pregnant women with rheumatic diseases and COVID-19 experienced a greater number of preterm births compared with fully vaccinated pregnant women against COVID-19; importantly, no safety issues or post-vaccination disease flares were raised in that descriptive study (26). The value of vaccination during breastfeeding should be also highlighted, as SARS-CoV-2-specific antibodies are secreted into breastmilk and are detected in infant stools following maternal vaccination (27).

In conclusion, the findings of the present study provide reassurance regarding the safety of COVID-19 vaccination in pregnant and breastfeeding women with AID. Our results will hopefully contribute in greater confidence and improved uptake of COVID-19 vaccines in this vulnerable group of patients.

REFERENCES

(1) Neusser S, Neumann A, Zur Nieden P, *et al*. Facilitators and barriers of vaccine uptake in patients with autoimune inflammatory rheumatic disease: a scoping review. *RMD Open* 2022; 8:e002562.

(2) Kilich E, Dada S, Francis MR, *et al*. Factors that influence vaccination decision-making among pregnant women: A systematic review and meta-analysis. *PLoS One* 2020;15:e0234827.

(3) Sen P, Gupta L, Lilleker JB, et al; COVAD Study Group. COVID-19 vaccination in autoimmune disease (COVAD) survey protocol. *Rheumatol Int* 2022; 42:23-29.

(4) Fazal ZZ, Sen P, Joshi M, *et al; COVAD Study Group*. COVAD survey 2 long-term outcomes: unmet need and protocol. *Rheumatol Int* 2022; 42:2151-2158.

(5) Qiu X, Bailey H, Thorne C. Barriers and Facilitators Associated With Vaccine Acceptance and Uptake Among Pregnant Women in High Income Countries: A Mini-Review. *Front Immunol* 2021; 12:626717.

(6) Yu W, Hu X, Cao B. Viral Infections During Pregnancy: The Big Challenge Threatening Maternal and Fetal Health. *Matern Fetal Med* 2021; 4:72-86.

(7) Deng J, Ma Y, Liu Q, Du M, Liu M, Liu J. Association of Infection with Different SARS-CoV-2 Variants during Pregnancy with Maternal and Perinatal Outcomes: A Systematic Review and Meta-Analysis. *Int J Environ Res Public Health* 2022; 19:15932.

(8) Villar J, Soto Conti CP, Gunier RB, *et al*; INTERCOVID-2022 International Consortium. Pregnancy outcomes and vaccine effectiveness during the period of omicron as the variant of concern, INTERCOVID-2022: a multinational, observational study. *Lancet* 2023; Epub ahead of print.

(9) Azami M, Nasirkandy MP, Esmaeili Gouvarchin Ghaleh H, Ranjbar R. COVID-19 vaccine acceptance among pregnant women worldwide: A systematic review and meta-analysis. *PLoS One* 2022;17:e0272273.

(10) Bhattacharya O, Siddiquea BN, Shetty A, Afroz A, Billah B. COVID-19 vaccine hesitancy among pregnant women: a systematic review and meta-analysis. *BMJ Open* 2022; 12:e061477.

(11) Tariq J, Gupta L. Safety and efficacy of COVID-19 vaccines in pregnant women with rheumatic diseases: an immunologic perspective. *Rheumatol Int* 2021; 41:1545-1547.

(12) Eysenbach G. Improving the Quality of Web Surveys: The Checklist for Reporting Results of Internet E-Surveys (CHERRIES). *Journal of Medical Internet Research* 2004; 6:e132. doi:10.2196/jmir.6.3.e34.

(13) People with certain medical conditions | Understanding your risk | CDC | https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

(14) Understanding Adverse Events and Side Effects | Vaccine Safety | CDC | https://www.cdc.gov/vaccinesafety/ensuringsafety/sideeffects/index.html.

(15) Magnus MC, Örtqvist AK, Dahlqwist E, *et al*. Association of SARS-CoV-2 Vaccination During Pregnancy With Pregnancy Outcomes. *JAMA* 2022; 327:1469-1477.

(16) Tormen M, Taliento C, Salvioli S, *et al*. Effectiveness and safety of COVID-19 vaccine in pregnant women: A systematic review with meta-analysis. *BJOG* 2022 Nov 28. doi: 10.1111/1471-0528.17354. Epub ahead of print.

(17) Muyldermans J, De Weerdt L, De Brabandere L, Maertens K, Tommelein E. The Effects of COVID-19 Vaccination on Lactating Women: A Systematic Review of the Literature. *Front Immunol* 2022; 13:852928.

(18) Galanis P, Vraka I, Siskou O, Konstantakopoulou O, Katsiroumpa A, Kaitelidou D. Uptake of COVID-19 Vaccines among Pregnant Women: A Systematic Review and Meta-Analysis. *Vaccines (Basel)* 2022; 10:766.

(19) Kharbanda EO, Vazquez-Benitez G. COVID-19 mRNA Vaccines During Pregnancy: New Evidence to Help Address Vaccine Hesitancy. *JAMA* 2022; 327:1451–1453.

(20) Burn E, Li X, Delmestri A, *et al*. Thrombosis and thrombocytopenia after vaccination against and infection with SARS-CoV-2 in the United Kingdom. *Nat Commun* 2022;13:7167.

(21) Giannopoulou N, Gupta L, Andreoli L, *et al*. COVID-19 vaccine safety during pregnancy and lactation in women with systemic lupus erythematosus. *Autoimmunity Rev* 2023; epub ahead of print.

(22) Andreoli L, Sen P, Lini D, *et al*. COVID-19 vaccine safety during the antenatal period in women with idiopathic inflammatory myopathies. *Rheumatology (Oxford)* 2022 Nov 12:keac644. doi: 10.1093/rheumatology/keac644. Epub ahead of print.

(23) Curtis JR, Johnson SR, Anthony DD, *et al*. American College of Rheumatology Guidance for COVID-19 Vaccination in Patients With Rheumatic and Musculoskeletal Diseases: Version 1. *Arthritis Rheumatol* 2021; 73:1093–107.

(24) Landewé RBM, Kroon FPB, Alunno A, *et al*. EULAR recommendations for the management and vaccination of people with rheumatic and musculoskeletal diseases in the context of SARS-CoV-2: the November 2021 update. *Ann Rheum Dis* 2022; 81:1628-1639.

(25) Engjom H, van den Akker T, Aabakke A, *et al*. Severe COVID-19 in pregnancy is almost exclusively limited to unvaccinated women - time for policies to change. *Lancet Reg Health Eur* 2022; 13:100313.

(26) Maguire S, Al-Emadi S, Alba P, *et al; COVID-19 Global Rheumatology Alliance*. Obstetric Outcomes in Women with Rheumatic Disease and COVID-19 in the Context of Vaccination Status. *Rheumatology (Oxford)* 2022:keac534. Epub ahead of print.

(27) Stafford LS, Valcarce V, Henry M, *et al*. Detection of SARS-CoV-2 IgA and IgG in human milk and breastfeeding infant stool 6 months after maternal COVID-19 vaccination. *J Perinatol* 2023; Epub ahead of print.

Figure 1: Flowchart of the study showcasing excluded respondents and distribution of vaccinated women according to being a patient with AID or a HC and to the status of being a pregnant or breastfeeding woman. Group A: non-pregnant or breastfeeding women with AID; group B: pregnant women with AID; group C: breastfeeding women with AID; group D: non-pregnant or breastfeeding HC; group E: pregnant HC; group F: breastfeeding HC. **Abbreviations:** AID: Autoimmune diseases; HC, healthy controls; nrAID: non-rheumatic autoimmune diseases; rAID: rheumatic autoimmune diseases.

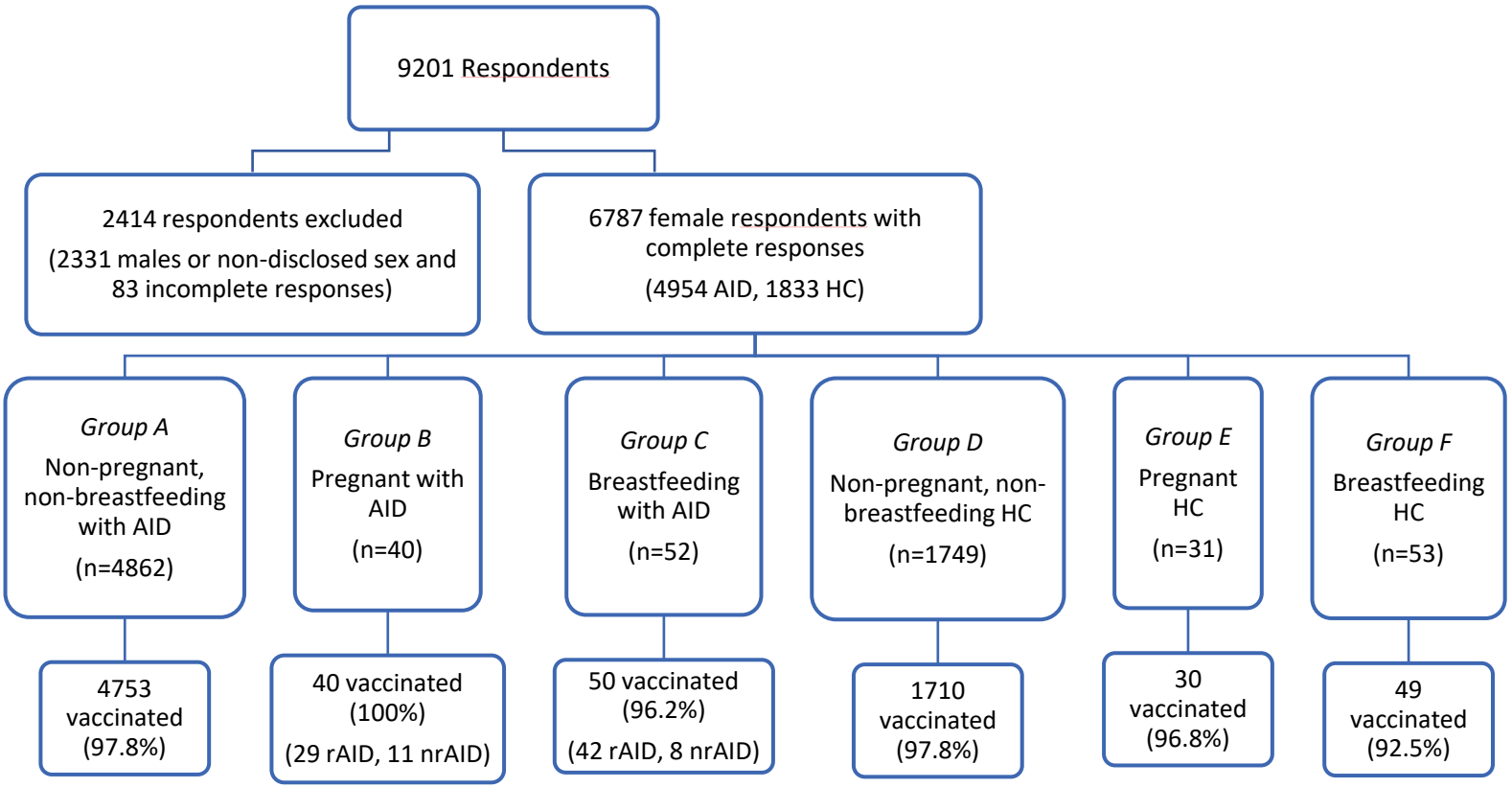

Table 1. Features about demography and comorbidities of the total cohort of female individuals who participated in the COVAD study. Percentages are reported in parenthesis. Subgroups were identified according to the diagnosis of AID versus HC and the pregnancy/breastfeeding status. Group A: non-pregnant or breastfeeding women with AID; group B: pregnant women with AID; group C: breastfeeding women with AID; group D: non-pregnant or breastfeeding HC; group E: pregnant HC; group F: breastfeeding HC. *Pregnancy/breastfeeding status at the time of the survey and/or at the time of at least one dose of COVID-19 vaccine.

Abbreviations: AID, Autoimmune diseases; COPD, Chronic obstructive pulmonary disease; HC, Healthy control; HIV-AIDS: Human immunodeficiency virus-acquired immunodeficiency syndrome; ILD, Interstitial lung disease; IQR, interquartile range.

	Women (total) (n=6787)	**Group A Non-pregnant, non-breastfeeding with AID (n=4862)**	**Group B Pregnant with AID* (n=40)**	**Group C Breastfeeding with AID* (n=52)**	**Group D Non-pregnant, non-breastfeeding HC (n=1749)**	**Group E Pregnant HC* (n=31)**	**Group F Breastfeeding HC* (n=53)**
Age (median, IQR)	47, 35-58	50, 38-61	34, 31-35.25	33, 30-35	39, 29-49	34, 30-36.5	33, 30-36
Ethnicity, n (%)							
Caucasian	3225 (47.5)	2634 (54.1)	12 (30)	22 (42.3)	538 (30.8)	7 (22.6)	12 (22.6)
African American or of African origin	338 (5)	277 (5.7)	6 (15)	3 (5.8)	50 (2.9)	1 (3.2)	1 (1.9)
Asian	1303 (19.2)	875 (18)	7 (17.5)	13 (25)	392 (22.4)	6 (19.4)	10 (18.9)
Hispanic	1071 (15.8)	519 (10.7)	6 (15)	5 (9.6)	508 (29)	12 (38.6)	21 (39.5)
Native American/ Indigenous/ Pacific Islander	50 (0.7)	32 (0.7)	0 (0)	1 (1.9)	13 (0.7)	2 (6.5)	2 (3.8)
Mixed	331 (4.9)	188 (3.9)	4 (10)	4 (7.7)	132 (7.5)	0 (0)	3 (5.7)
Other	256 (3.8)	195 (4)	5 (12.5)	3 (5.8)	51 (2.9)	1 (3.2)	1 (1.9)
Do not wish to disclose	213 (3.1)	142 (2.9)	0 (0)	1 (1.9)	65 (3.7)	2 (6.5)	3 (5.7)
Comorbidities, n (%)							
Asthma	747 (11)	609 (12.5)	4 (10)	4 (7.7)	119 (6.8)	6 (19.4)	5 (9.4)
Chronic Kidney Disease	224 (3.3)	209 (4.3)	1 (2.5)	3 (5.8)	10 (0.6)	0 (0)	1 (1.9)
Chronic Liver Disease	67 (1)	63 (1.3)	0 (0)	0 (0)	4 (0.2)	0 (0)	0 (0)
COPD	147 (2.2)	130 (2.7)	1 (2.5)	0 (0)	16 (0.9)	0 (0)	0 (0)
ILD	321 (4.7)	316 (6.5)	1 (2.5)	1 (1.9)	3 (0.2)	0 (0)	0 (0)
Coronary/Ischemic Heart Disease	127 (1.9)	118 (2.4)	1 (2.5)	1 (1.9)	7 (0.4)	0 (0)	0 (0)
Diabetes mellitus	379 (5.6)	315 (6.5)	0 (0)	2 (3.8)	62 (3.5)	0 (0)	0 (0)
Epilepsy	59 (0.9)	51 (1)	2 (5)	2 (3.8)	4 (0.2)	0 (0)	0 (0)
Hyperlipidemia	836 (12.3)	721 (14.8)	2 (5)	4 (7.7)	104 (5.9)	2 (6.5)	3 (5.7)
HIV-AIDS	6 (0.1)	4 (0.1)	1 (2.5)	0 (0)	1 (0.1)	0 (0)	0 (0)
Arterial hypertension	1177 (17.3)	1023 (21)	0 (0)	3 (5.8)	147 (8.4)	2 (6.5)	2 (3.8)
Stroke	53 (0.8)	49 (1)	1 (2.5)	0 (0)	3 (0.2)	0 (0)	0 (0)
Tuberculosis	47 (0.7)	38 (0.8)	1 (2.5)	0 (0)	8 (0.5)	0 (0)	0 (0)
Organ transplant	19 (0.3)	16 (0.3)	1 (2.5)	0 (0)	2 (0.1)	0 (0)	0 (0)
Anxiety	1257 (18.5)	993 (20.4)	6 (15)	12 (23.1)	234 (13.4)	5 (16.1)	7 (13.2)
Insomnia	489 (7.2)	424 (8.7)	2 (5)	4 (7.7)	59 (3.4)	0 (0)	0 (0)
Bipolar disorder	46 (0.7)	34 (0.7)	0 (0)	0 (0)	12 (0.7)	0 (0)	0 (0)
Depression	1062 (15.6)	865 (17.8)	7 (17.5)	8 (15.4)	173 (9.9)	4 (12.9)	5 (9.4)
Eating disorders	147 (2.2)	107 (2.2)	6 (15)	5 (9.6)	29 (1.7)	0 (0)	0 (0)
Schizophrenia	12 (0.2)	7 (0.1)	2 (5)	2 (3.8)	1 (0.1)	0 (0)	0 (0)
Substance abuse	15 (0.2)	14 (0.3)	0 (0)	0 (0)	1 (0.1)	0 (0)	0 (0)
Other	506 (7.5)	464 (9.5)	0 (0)	1 (1.9)	39 (2.2)	0 (0)	2 (3.8)
None	3027 (44.6)	1815 (37.3)	19 (47.5)	36 (69.2)	1102 (63)	17 (54.8)	38 (71.7)

Table 2. Features about COVID-19 vaccination and associated adverse events (AE) of the total cohort of female individuals who participated in the COVAD study. Percentages are reported in parenthesis. Subgroups were identified according to the diagnosis of AID versus HC and the pregnancy/breastfeeding status. Group A: non-pregnant or breastfeeding women with AIDs; group B: pregnant women with AIDs; group C: breastfeeding women with AIDs; group D: non-pregnant or breastfeeding HC; group E: pregnant HC; group F: breastfeeding HC. *Pregnancy/breastfeeding status at the time of the survey and/or at the time of at least one dose of COVID-19 vaccine. Chi squared test: ~ p=0.01; ° p=0.03; § p<0.01.
Abbreviations: AID, Autoimmune diseases; HC Healthy controls; IQR, interquartile range.

	Total Women (n=6787)	**Group A Non-pregnant, non-breastfeeding with AID (n=4862)**	**Group B Pregnant with AID* (n=40)**	**Group C Breastfeeding with AID* (n=52)**	**Group D Non-pregnant, non-breastfeeding HC (n=1749)**	**Group E Pregnant HC* (n=31)**	**Group F Breastfeeding HC* (n=53)**
Vaccine taken?							
No, n (%)	155 (2.3)	109 (2.2)	0 (0)	2 (3.8)	39 (2.2)	1 (3.2)	4 (7.5)
Reasons of the choice (multiple responses possible), n (%):							
Not available to me so far but I plan to have the vaccine as soon as possible	3 (1.9)	1 (0.9)	0 (0)	0 (0)	1 (2.6)	0 (0)	1 (25)
I don't believe in the science behind COVID vaccines	34 (21.9)	28 (25.7)	0 (0)	0 (0)	5 (12.8)	0 (0)	1 (25)
Will not have the vaccine due to long-term safety concern or fear	52 (33.5)	39 (35.8)	0 (0)	1 (50)	11 (28.2)	0 (0)	1 (25)
Planning to wait for more time/data regarding safety before I have the vaccine	46 (29.7)	31 (28.4)	0 (0)	1 (50)	14 (35.9)	0 (0)	0 (0)
I have scheduled my vaccine, but have not received yet	3 (1.9)	2 (1.8)	0 (0)	0 (0)	1 (2.6)	0 (0)	0 (0)
Not recommended as I had COVID-19 infection recently	12 (7.7)	7 (6.4)	0 (0)	0 (0)	4 (10.3)	0 (0)	0 (0)
Unsure	18 (11.6)	9 (8.3)	0 (0)	0 (0)	9 (23.1)	0 (0)	0 (0)
Other	37 (23.9)	32 (29.4)	0 (0)	0 (0)	2 (5.1)	1 (100)	2 (50)
Yes Number of vaccinated women, n (%)	6632 (97.7)	4753 (97.8)	40 (100)	50 (96.2)	1710 (97.8)	30 (96.8)	49 (92.5)
Number of doses received per each type of vaccine, n (%):							
Pfizer-BioNTech	8988 (48.4)	6978 (51.9)	50 (45.1)	77 (56.2)	1799 (38.7)	36 (42.4)	48 (37.5)
Oxford/Astra Zeneca	3437 (18.5)	2499 (18.5)	26 (23.4)	21 (15.3)	842 (18.1)	15 (17.6)	34 (26.6)
Johnson & Johnson (J&J)	184 (1)	131 (1)	2 (1.8)	3 (2.2)	44 (0.9)	0 (0)	4 (3.1)
Moderna	2542 (13.7)	2116 (15.7)	9 (8.1)	12 (8.8)	393 (8.5)	8 (9.4)	4 (3.1)
Novavax	12 (0.1)	8 (0.1)	0 (0)	0 (0)	4 (0.1)	0 (0)	0 (0)
Covishield (serum institute India)	520 (2.8)	314 (2.3)	4 (3.6)	4 (2.9)	195 (4.2)	1 (1.2)	2 (1.6)
Covaxin (Bharat Biotech)	76 (0.4)	50 (0.4)	0 (0)	3 (2.2)	23 (0.5)	0 (0)	0 (0)
Sputnik	445 (2.4)	158 (1.2)	2 (1.8)	0 (0)	281 (6)	2 (2.4)	2 (1.6)
Sinopharm	891 (4.8)	414 (3.1)	5 (4.5)	5 (3.6)	457 (9.8)	6 (7.1)	4 (3.1)
Sinovac-CoronaVac	1172 (6.3)	559 (4.1)	9 (8.1)	10 (7.3)	572 (12.3)	8 (9.4)	14 (10.9)
I am not sure	222 (1.2)	176 (1.3)	4 (3.6)	2 (1.5)	17 (0.4)	9 (10.6)	14 (10.9)
Others	76 (0.4)	51 (0.4)	0 (0)	0 (0)	23 (0.5)	0 (0)	2 (1.6)
Number of doses received, n (%)							
1 dose	215 (3.2)	161 (3.4)	2 (5)	3 (6)	46 (2.7)	1 (3.3)	2 (4.1)
2 doses	1567 (23.6)	1009 (21.3)	12 (30)	14 (28)	509 (29.8)	6 (20)	17 (34.7)
3 doses	3721 (56.1)	2620 (55.1)	19 (47.5)	26 (52)	1007 (58.9)	21 (70)	28 (57.1)
4 doses	1118 (16.9)	952 (20)	7 (17.5)	7 (14)	148 (8.6)	2 (6.7)	2 (4.1)
5 doses	11 (0.2)	11 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Vaccine AE, n							
None	4950 (74.6)	3517 (74)~	22 (55)~	36 (72)	1312 (76.7)	22 (73.3)	36 (73.5)
Injection site (arm) pain and soreness	630 (9.5)	471 (9.9)	7 (17.5)	7 (14)	138 (8.1)	2 (6.7)	5 (10.2)
Minor AE	1614 (24.3)	1232 (25.9)°	16 (40)°	12 (24)	338 (19.8)	7 (23.3)	10 (20.4)
Major AE	285 (4.3)	196 (4.6)§	7 (17.5)§	1 (2)	77 (4.5)	1 (3.3)	3 (6.1)
Hospitalization	74 (1.1)	51 (1.1)	2 (5)	0 (0)	20 (1.2)	0 (0)	1 (2)

Table 3. Demographic and clinical characteristics prior to vaccination of patients with AID who received at least one dose during pregnancy or breastfeeding and disease- and age-matched control patients. * same patient; ** only one patient suitable for matching; § same patient. Group A: non-pregnant or breastfeeding women with AID; group B: pregnant women with AID; group C: breastfeeding women with AID.
Abbreviations: AID, Autoimmune diseases; CTD, Connective tissue disorders; IQR, interquartile range; TNF: tumour necrosis factor; JAK: Janus kinase.

	Group B **Pregnant patients (n=40)**	**From Group C** **Breastfeeding patients (n=50)**	**From Group A** **Control group patients (n=262)**
Systemic lupus erythematosus	11 (27.5)	10 (20)	63 (24)
Antiphospholipid Syndrome	0 (0)	2 (4)	6 (2.3)
Undifferentiated connective tissue disease	3 (7.5)	3 (6)	18 (6.9)
Sjögren's syndrome	2 (5)	1 (2)	9 (3.4)
Systemic sclerosis	1 (2.5)*	1 (2)*	3 (1.1)
Mixed connective tissue disorder	0 (0)	2 (4)	6 (2.3)
Dermatomyositis	2 (5)	0 (0)	6 (2.3)
Juvenile dermatomyositis	1 (2.5)	0 (0)	1 (0.4)**
Polymyositis	1 (2.5)	1 (2)	6 (2.3)
Overlap myositis with other CTD	1 (2.5)	1 (2)	6 (2.3)
Systemic vasculitis	2 (5)	2 (4)	12 (4.6)
Rheumatoid arthritis	4 (10)	10 (20)	42 (16.1)
Ankylosing spondylitis or psoriatic arthritis	3 (7.5)	3 (6)	18 (6.9)
Hypothyroid or hyperthyroid	4 (10)	11 (22)	45 (17.2)
Hemolytic anemia	1 (2.5) §	1 (2) §	3 (1.1)
Multiple sclerosis	3 (7.5)	1 (2)	12 (4.6)
Myasthenia gravis	0 (0)	1 (2)	3 (1.1)
Morphea	1 (2.5)	0 (0)	3 (1.1)
Age, years (median, IQR)	33, 31-35	33, 30-35	29, 31-36
Disease duration, years (median, IQR)	5, 4-7	6, 4-10	6, 3-12
Ongoing medications prior to vaccination, n (%)			
No steroids	20 (50)	29 (58)	161 (61.5)
<10 mg/day of steroids	13 (32.5)	13 (26)	74 (28.2)
10-20 mg/of day steroids	5 (12.5)	6 (12)	17 (6.5)
>20 mg/day of steroids	2 (5)	2 (4)	10 (3.8)
Hydroxychloroquine	20 (50)	19 (38)	109 (41.6)
Methotrexate	0 (0)	0 (0)	58 (22)

Mycophenolate mofetil	0 (0)	0 (0)	24 (9.2)
Azathioprine	4 (10)	7 (14)	25 (9.5)
Sulfasalazine	3 (7.5)	4 (8)	9 (3.4)
Leflunomide	0 (0)	0 (0)	6 (2.3)
Calcineurin inhibitors	6 (15)	4 (8)	9 (3.4)
Cyclophosphamide	0 (0)	0 (0)	9 (3.4)
TNF inhibitors	3 (7.5)	3 (6)	13 (5)
Rituximab	0 (0)	1 (2)	10 (3.8)
Other biologic agents	0 (0)	0 (0)	13 (5)
JAK inhibitors	0 (0)	0 (0)	3 (1.1)
Intravenous immunoglobulins	0 (0)	0 (0)	6 (2.3)

Table 4. Disease activity and treatment changes after COVID-19 vaccination in patients with AID who received at least one dose during pregnancy or breastfeeding and disease- and age-matched control patients. Group A: non-pregnant or breastfeeding women with AID; group B: pregnant women with AID; group C: breastfeeding women with AID.
Abbreviations: AID, Autoimmune diseases; CRP, C-reactive protein; ESR, Erythrocyte sedimentation rate.

	Group B **Pregnant patients (n=40)**	**From Group C** **Breastfeeding patients (n=50)**	**From Group A** **Control group patients (n=262)**
Number of doses received, n (%)			
1 dose	2 (5)	3 (6)	12 (4.6)
2 doses	12 (30)	14 (28)	81 (30.9)
3 doses	19 (47.5)	26 (52)	134 (51.1)
4 doses	7 (17.5)	7 (14)	35 (13.4)
Disease activity prior to vaccination, n (%)			
Inactive/remission	15 (37.5)	24 (48)	101 (38.5)
Active but stable and manageable	13 (32.5)	17 (34)	85 (32.4)
Active but improving	3 (7.5)	2 (4)	21 (8.1)
Active and worsening	2 (5)	1 (2)	16 (6.1)
Not sure	7 (17.5)	6 (12)	39 (14.9)
Change in the status of AID after vaccination, n (%)			
Unchanged	29 (72.5)	39 (78)	208 (79.4)
Improved	4 (10)	1 (2)	8 (3.1)
Worsened	7 (17.5)	10 (20)	46 (17.6)
Number of patients with symptoms after COVID vaccination, n (%)			
Skin Rashes	4 (10)	1 (2)	75 (28.6)
Muscle weakness	0 (0)	3 (6)	21 (8)
Muscle pain	0 (0)	3 (6)	22 (8.4)
Joint pain/swelling in hands	5 (12.5)	5 (10)	19 (7.3)
Joint pain/swelling of other joints	6 (15)	0 (0)	22 (8.4)
Pain in shoulders and hips	0 (0)	2 (4)	15 (5.7)
Raynaud's phenomenon	0 (0)	0 (0)	53 (20.2)
Skin thickening of hands	1 (2.5)	0 (0)	0 (0)
Skin thickening in new areas of the body not previously affected	1 (2.5)	0 (0)	0 (0)

Fingertip ulcers or pits	2 (5)	1 (2)	1 (0.4)
Shortness of breath	1 (2.5)	0 (0)	9 (3.4)
Chest pain	1 (2.5)	0 (0)	9 (3.4)
Difficulty in swallowing	0 (0)	0 (0)	3 (1.1)
Fever	0 (0)	0 (0)	6 (2.3)
Fatigue	0 (0)	3 (6)	23 (8.8)
Dry eyes	1 (2.5)	1 (2)	13 (5)
Dry mouth	1 (2.5)	0 (0)	10 (3.8)
Oral or nasal ulcers	0 (0)	1 (2)	4 (1.5)
Severe loss of hair or bald spots	0 (0)	0 (0)	5 (1.9)
Headache due to disease	0 (0)	1 (2)	12 (4.6)
Active kidney disease from AID	0 (0)	1 (2)	5 (1.9)
Elevated muscle enzymes in blood	1 (2.5)	2 (4)	0 (0)
Elevated inflammatory markers in the blood (high ESR or CRP)	1 (2.5)	2 (4)	16 (6.1)
Treatment modifications due to AID worsening symptoms, n (%)	7 (17.5)	10 (20)	29 (11.1)
Started or increased steroids	7/7 (100)	10/10 (100)	25/29 (86.2)
Switched/added new immunosuppressive treatment besides steroids	2/7 (28.6)	2/10 (20)	16/29 (55.2)

Supplementary Material to the manuscript entitled:
"COVID-19 Vaccine Safety during Pregnancy and Breastfeeding in Women with Autoimmune Diseases: Results from the COVAD Study".

- **Supplementary Table S1**
- **COVID-19 Vaccination in Autoimmune Diseases (COVAD) Study Group**

Supplementary Table S1. Vaccination status per single country according to residency. Group A: non-pregnant or breastfeeding women with AID; group B: pregnant women with AID; group C: breastfeeding women with AID; group D: non-pregnant or breastfeeding HC; group E: pregnant HC; group F: breastfeeding HC. *Pregnancy/breastfeeding status at the time of the survey and/or at the time of at least one dose of COVID-19 vaccine.
Abbreviations: AID, Autoimmune diseases; HC Healthy controls; *Pregnancy/breastfeeding status at the time of the survey and/or at the time of at least one dose of COVID-19 vaccine.

Country of residence (number of individuals)	**Total Women Population**		**Group A Non-pregnant, non-breastfeeding with AID**		**Group B Pregnant with AID***		**Group C Breastfeeding with AID***		**Group D Non-pregnant, non-breastfeeding HC (%)**		**Group E Pregnant HC* (%)**		**Group F Breastfeeding HC***	
	Vaccinated n (%)	**Unvaccinated n (%)**	**Vaccinated n (%)**	**Unvaccinated n (%)**	**Vaccinated n (%)**	**Unvaccinated n (%)**	**Vaccinated n (%)**	**Unvaccinated n (%)**	**Vaccinated n (%)**	**Unvaccinated n (%)**	**Vaccinated n (%)**	**Unvaccinated n (%)**	**Vaccinated n (%)**	**Unvaccinated n (%)**
Afghanistan (2)	2 (100)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Albania (1)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Algeria (10)	3 (30)	7 (70)	1 (16.7)	5 (83.3)	0 (0)	0 (0)	0 (0)	0 (0)	2 (50)	2 (50)	0 (0)	0 (0)	0 (0)	0 (0)
Angola (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Anguilla (1)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Argentina (67)	66 (98.5)	1 (1.5)	56 (98.2)	1 (1.8)	0 (0)	0 (0)	0 (0)	0 (0)	9 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
Armenia (2)	1 (50)	1 (50)	1 (50)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Australia (77)	72 (93.5)	5 (6.5)	66 (93)	5 (7)	0 (0)	0 (0)	0 (0)	0 (0)	6 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Austria (6)	6 (100)	0 (0)	4 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bahrain (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bangladesh (71)	71 (100)	0 (0)	22 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	48 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
Belgium (3)	3 (100)	0 (0)	3 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bolivia (19)	19 (100)	0 (0)	7 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	11 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
Brazil (162)	160 (98.8)	2 (1.2)	107 (98.2)	2 (1.8)	0 (0)	0 (0)	0 (0)	0 (0)	50 (100)	0 (0)	0 (0)	0 (0)	3 (100)	0 (0)
British Virgin Island (1)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bulgaria (151)	118 (78.2)	33 (21.8)	73 (73.7)	26 (25.3)	0 (0)	0 (0)	5 (83.3)	1 (16.7)	37 (90.2)	4 (9.8)	0 (0)	0 (0)	3 (60)	2 (40)
Canada (92)	86 (93.5)	6 (6.5)	79 (92.9)	6 (7.1)	0 (0)	0 (0)	1 (100)	0 (0)	6 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Central African Republic (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Chile (85)	84 (98.8)	1 (1.2)	49 (98)	1 (2)	0 (0)	0 (0)	3 (100)	0 (0)	31 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)
China (6)	4 (67)	2 (33)	2 (50)	2 (50)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Colombia (158)	147 (93)	11 (7)	64 (90.1)	7 (9.9)	0 (0)	0 (0)	1 (100)	0 (0)	79 (95.2)	4 (4.8)	1 (100)	0 (0)	2 (100)	0 (0)
Costa Rica (73)	72 (98.6)	1 (1.4)	53 (98.1)	1 (1.9)	1 (100)	0 (0)	1 (100)	0 (0)	17 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Croatia (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Cyprus (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Czech Republic (2)	2 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
Dominican Republic (44)	39 (88.6)	5 (11.4)	29 (93.5)	2 (6.5)	1 (100)	0 (0)	0 (0)	1 (100)	9 (81.8)	2 (18.2)	0 (0)	0 (0)	0 (0)	0 (0)
Ecuador (96)	96 (100)	0 (0)	84 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)
Egypt (150)	135 (90)	15 (10)	111 (90.2)	12 (9.8)	0 (0)	0 (0)	0 (0)	0 (0)	23 (92)	2 (8)	0 (0)	1 (100)	1 (100)	0 (0)
El Salvador (3)	3 (100)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)
Ethiopia (4)	1 (25)	3 (75)	1 (25)	3 (75)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Finland (4)	4 (100)	0 (0)	4 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
France (52)	52 (100)	0 (0)	26 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	24 (100)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)

Germany (53)	51 (96.2)	2 (3.8)	45 (97.8)	1 (2.2)	0 (0)	0 (0)	1 (100)	0 (0)	5 (83.3)	1 (16.7)	0 (0)	0 (0)	0 (0)	0 (0)
Ghana (71)	66 (93)	5 (7)	60 (92.3)	5 (7.7)	0 (0)	0 (0)	3 (100)	0 (0)	3 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Guatemala (153)	147 (96.1)	6 (3.9)	27 (96.4)	1 (3.6)	0 (0)	0 (0)	0 (0)	0 (0)	115 (95.8)	5 (4.2)	3 (100)	0 (0)	2 (100)	0 (0)
Haiti (2)	2 (100)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Honduras (7)	6 (85.7)	1 (14.3)	3 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	1 (50)	1 (100)	0 (0)	1 (100)	0 (0)
Hungary (43)	38 (88.4)	5 (11.6)	32 (86.5)	5 (13.5)	0 (0)	0 (0)	0 (0)	0 (0)	6 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Iceland (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
India (245)	237 (96.7)	8 (3.3)	144 (95.4)	7 (4.6)	1 (100)	0 (0)	4 (100)	0 (0)	87 (98.9)	1 (1.1)	0 (0)	0 (0)	1 (100)	0 (0)
Indonesia (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Iraq (18)	17 (94.4)	1 (5.6)	1 (50)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	15 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)
Ireland (17)	16 (94.1)	1 (5.9)	15 (93.8)	1 (6.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Italy (281)	271 (96.4)	10 (3.6)	244 (96.4)	9 (3.6)	0 (0)	0 (0)	1 (50)	1 (50)	25 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)
Jamaica (1)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Japan (77)	73 (94.8)	4 (5.2)	59 (93.7)	4 (6.3)	0 (0)	0 (0)	0 (0)	0 (0)	14 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Jordan (16)	15 (94)	1 (6)	8 (88.9)	1 (11.1)	0 (0)	0 (0)	0 (0)	0 (0)	7 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Kuwait (26)	21 (80.8)	5 (19.2)	19 (79.2)	5 (20.8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Kyrgyzstan (1)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)
Lebanon (60)	54 (90)	6 (10)	15 (83.3)	3 (16.7)	0 (0)	0 (0)	1 (100)	0 (0)	36 (92.3)	3 (7.7)	1 (100)	0 (0)	1 (100)	0 (0)
Libya (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Luxembourg (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Malawi (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Malaysia (145)	144 (99.3)	1 (0.7)	123 (99.2)	1 (0.8)	0 (0)	0 (0)	3 (100)	0 (0)	15 (100)	0 (0)	1 (100)	0 (0)	2 (100)	0 (0)
Malta (2)	2 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mauritius (25)	23 (92)	2 (8)	12 (85.7)	2 (14.3)	0 (0)	0 (0)	0 (0)	0 (0)	11 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mexico (622)	609 (97.9)	13 (2.1)	242 (95.7)	11 (4.3)	0 (0)	0 (0)	3 (100)	0 (0)	342 (99.1)	2 (0.9)	8 (100)	0 (0)	14 (100)	0 (0)
Morocco (71)	68 (95.8)	3 (4.2)	14 (93.3)	1 (6.7)	0 (0)	0 (0)	0 (0)	0 (0)	54 (96.4)	2 (3.6)	0 (0)	0 (0)	0 (0)	0 (0)
Nepal (107)	101 (94.4)	6 (5.6)	67 (91.8)	6 (8.2)	0 (0)	0 (0)	0 (0)	0 (0)	30 (100)	0 (0)	2 (100)	0 (0)	2 (100)	0 (0)
Netherlands (7)	7 (100)	0 (0)	4 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
New Zeland (2)	2 (100)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nicaragua (3)	3 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nigeria (80)	55 (68.8)	25 (31.2)	39 (76.5)	12 (23.5)	1 (100)	0 (0)	0 (0)	0 (0)	15 (53.6)	13 (46.4)	0 (0)	0 (0)	0 (0)	0 (0)
Oman (9)	9 (100)	0 (0)	9 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pakistan (67)	66 (98.5)	1 (1.5)	22 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	42 (100)	0 (0)	0 (0)	0 (0)	2 (67)	1 (33)
Panama (102)	100 (98)	2 (2)	74 (97.4)	2 (2.6)	0 (0)	0 (0)	0 (0)	0 (0)	25 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
Paraguay (15)	15 (100)	0 (0)	7 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
Perù (131)	131 (100)	0 (0)	63 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	65 (100)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)
Philippines (70)	66 (94.3)	4 (5.7)	51 (92.7)	4 (7.3)	1 (100)	0 (0)	1 (100)	0 (0)	13 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Poland (144)	135 (94)	9 (6)	99 (92.5)	8 (7.5)	0 (0)	0 (0)	2 (100)	0 (0)	32 (97)	1 (3)	1 (100)	0 (0)	1 (100)	0 (0)

Portugal (28)	23 (82.1)	5 (7.9)	23 (82.1)	5 (7.9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Russian Federation (47)	43 (91.5)	4 (8.5)	4 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	39 (90.7)	4 (9.3)	0 (0)	0 (0)	0 (0)	0 (0)
Sao Tome and Principe (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Saudi Arabia (78)	75 (96.2)	3 (3.8)	63 (96.9)	2 (3.1)	0 (0)	0 (0)	0 (0)	1 (100)	12 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Serbia (2)	1 (50)	1 (50)	1 (50)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Singapore (1)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
South Africa (5)	3 (60)	2 (40)	3 (60)	2 (40)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Spain (120)	115 (95.8)	5 (4.2)	103 (95.4)	5 (4.6)	0 (0)	0 (0)	2 (100)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sudan (1)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sweden (66)	62 (93.9)	4 (6.1)	49 (92.5)	4 (7.5)	0 (0)	0 (0)	1 (100)	0 (0)	12 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Switzerland (14)	14 (100)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	12 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Syrian Arab Republic (2)	2 (100)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Taiwan (138)	131 (94.9)	7 (5.1)	105 (94)	7 (6)	1 (100)	0 (0)	0 (0)	0 (0)	25 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tajikistan (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thailand (316)	305 (96.5)	11 (3.5)	228 (95.4)	11 (4.6)	3 (100)	0 (0)	3 (100)	0 (0)	71 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tunisia (1)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Turkey (53)	53 (100)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	39 (100)	0 (0)	1 (100)	0 (0)	2 (100)	0 (0)
Tuvalu (1)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Ukraine (3)	3 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
United Arab Emirates (52)	52 (100)	0 (0)	27 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	24 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
United Kingdom of Great Britain and Northern Ireland (849)	832 (98)	17 (2)	785 (98)	16 (2)	1 (100)	0 (0)	6 (100)	0 (0)	39 (97.5)	1 (2.5)	0 (0)	0 (0)	1 (100)	0 (0)
United States of America (885)	812 (91.8)	73 (8.2)	772 (91.5)	72 (8.5)	0 (0)	0 (0)	2 (100)	0 (0)	36 (97.3)	1 (2.7)	2 (100)	0 (0)	0 (0)	0 (0)

COVID-19 Vaccination in Autoimmune Diseases (COVAD) Study Group

India

1. **Dr Yogesh Preet Singh**- Division of Rheumatology and Clinical Immunology, Department of General Medicine, Himalayan Institute of Medical sciences, Swami Rama University, Jolly Grant, Dehradun, Uttarakhand, India.
2. **Dr Rajiv Ranjan**- Clinical Immunology & Rheumatology at Columbia Asia, Palam Vihar, Gurgaon, Haryana, India.
3. **Dr Avinash Jain**- Department of Clinical Immunology and Rheumatology, SMS Medical College and Hospital, Jaipur, Rajasthan.
4. **Dr Sapan C Pandya**- Clinical Immunologist and Rheumatologist, Rheumatic Disease Clinic, Vedanta Institute of Medical Sciences, Navrangpura, Ahmedabad 380009, Gujarat.
5. **Dr Rakesh Kumar Pilania**- Pediatric Allergy Immunology Unit, Department of Pediatrics, Post Graduate Institute of Medical Education and Research, Chandigarh.
6. **Dr Aman Sharma**- Professor, Clinical Immunology and Rheumatology Services, Department of Internal Medicine, Post Graduate Institute of Medical Education and Research, Chandigarh, India
7. **Dr Manesh Manoj M**- Department of Clinical Immunology and Rheumatology, AKG Memorial Hospital and Dr Shenoy's CARE (Centre for Arthritis and Rheumatism Excellence), Kannur, Kerala
8. **Dr Vikas Gupta**- Dayanand Medical College and Hospital, Ludhiana, Punjab 141001, India.
9. **Dr Chengappa G Kavadichanda**- Department of Clinical Immunology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India.
10. **Dr Pradeepta Sekhar Patro**- Department of Clinical Immunology and Rheumatology, Sunshine Hospitals, Plot No 208, Cuttack Puri Road, Laxmisagar, Bhubaneshwar, Odisha.
11. **Dr Sajal Ajmani**- Arthritis and Rheumatology clinic, New Delhi, Delhi.
12. **Dr Sanat Phatak**- Rheumatology & Immunology, Department of Rheumatology and Immunology, KEM Hospital, Pune, Maharashtra.
13. **Dr Rudra Prosad Goswami**- Department of Rheumatology, All India Institute of Medical Sciences, New Delhi, Delhi.
14. **Dr Abhra Chandra Chowdhury**- AMRI Hospital, Dhakuria, Kolkata, West Bengal.
15. **Dr Ashish Jacob Mathew**- Dept Clinical Immunology & Rheumatology, Christian Medical College and Hospital, Vellore, Tamil Nadu 632004.
16. **Dr Padnamabha Shenoy**- Dr Shenoy's CARE (Centre for Arthritis and Rheumatism Excellence), Kannur, Kerala.
17. **Dr Ajay Asranna**- Department of Neurology, NIMHANS, Bengaluru, Karnataka.
18. **Dr Keerthi Talari Bommakanti**- Yashoda hospital, Behind Hari Hara Kala Bhavan, Secunderabad - 500003, T.S. Hyderabad, Telangana.
19. **Dr Anuj Shukla**- Niruj Rheumatology Clinic, 209 Rajvi Complex, Rambaug, Ahmedabad, 380008, Gujarat.

20. **Dr Arunkumar R Pande**- Sahara Hospital, Gomti Nagar, Lucknow, Uttar Pradesh.
21. **Akanksha Ghodke**- Mahatma Gandhi Mission Medical College, Navi Mumbai, Maharashtra, India.
22. **Dr Kunal Chandwar**- Department of Clinical Immunology and Rheumatology, King George's Medical University, Lucknow, Uttar Pradesh, India.
23. **Dr Hiya Boro**- MD, DM, Endocrinology, Department of Endocrinology and Metabolism, Aadhar Health Institute, Hisar, Haryana, India.

United Kingdom

1. **Dr Armen Yuri Gasparyan-** Departments of Rheumatology and Research and Development, Dudley Group NHS Foundation Trust, Russells Hall Hospital, North Block, Clinical Research Unit, Dudley, West Midlands, DY1 2HQ, United Kingdom

Turkey

1. **Dr Sinan Kardeş**- Department of Medical Ecology and Hydroclimatology, Istanbul Faculty of Medicine, Istanbul University, Capa-Fatih, 34093, Istanbul, Turkey.
2. **Dr Döndü Üsküdar Cansu**- Division of Rheumatology, Department of Internal Medicine, Eskişehir Osmangazi University, 26480, Eskişehir, Turkey.
3. **Dr Reşit Yıldırım**- Osmangazi University, Division of Rheumatology.

Italy

1. **Dr. Nicoletta Del Papa**, Unità operativa complessa (UOC) Day Hospital Reumatologia via Gaetano Pini 9, Centro Specialistico Ortopedico Traumatologico, Gaetano Pini-CTO, Milano, Italy.
2. **Dr. Gianluca Sambataro**, Medico Immunologia e reumatologia presso, Artoreuma S.R.L., Cors S. Vito 53, 95030 Mascalucia, CT, Italy.
3. **Dr. Atzeni Fabiola**, Rheumatology Unit, University of Messina, Messina, Italy.
4. **Dr. Marcello Govoni**, Professor, Department of Medical Sciences, Complex Operative Unit and Rheumatology Unit of S.Anna University Hospital, University of Ferrara, Via A. Moro 8, 44124- Cona (FE), Italy.
5. **Dr Simone Parisi**, Epidemiology Unit, Italian Society for Rheumatology, Milan, Italy; Rheumatology Unit, Azienda Ospedaliera Città della Salute e della Scienza di Torino, Torino, Italy.
6. **Dr Elena Bartoloni Bocci**, Associate Professor, Department of Medicine and Surgery, MED/16- Rheumatology, Università degli studi di Perugia, P.zza Università - 06123 – Perugia, Italy.
7. **Dr. Gian Domenico Sebastiani**, U.O.C. Reumatologia, Ospedale San Camillo-Forlanini, Roma, Italy.

8. **Dr Enrico Fusaro**, Rheumatology Unit, Azienda Ospedaliero-Universitaria Città della Salute e della Scienza di Torino, Torino, Italy.
9. **Dr Marco Sebastiani**, Rheumatology Unit, University of Modena and Reggio Emilia, Azienda Ospedaliero-Universitaria Policlinico di Modena, Via del Pozzo, 41125, Modena, Italy.
10. **Dr Luca Quartuccio**, Clinic of Rheumatology, Department of Medicine (DAME), ASUFC, University of Udine, Udine, Italy.
11. **Dr Franco Franceschini**, Rheumatology and Clinical Immunology Unit, Department of Clinical and Experimental Sciences, ASST Spedali Civili and University of Brescia, Italy.
12. **Dr Pier Paolo Sainaghi**, Department of Translational Medicine, Università del Piemonte Orientale UPO, Novara, Italy; Division of Internal Medicine, Immunorheumatology Unit, CAAD (Center for Translational Research on Autoimmune and Allergic Disease) Maggiore della Carità Hospital, Novara, Italy; IRCAD, Interdisciplinary Research Center of Autoimmune Diseases, Novara.
13. **Dr Giovanni Orsolini**, Department of Medicine, Rheumatology Unit, University of Verona, Verona, Italy.
14. **Dr Rossella De Angelis**, Rossella De Angelis, Rheumatology Unit, Department of Clinical and Molecular Sciences, Polytechnic University of Marche.
15. **Dr Maria Giovanna Danieli**- Clinica Medica, Dipartimento di Scienze Cliniche e Molecolari, Università Politecnica delle Marche e Azienda Ospedali Riuniti, Ancona, Italy.
16. **Dr Vincenzo Venerito**- Department of Emergency and Organ Transplantations-Rheumatology Unit, University of Bari "Aldo Moro", Bari, Italy.
17. **Dr Silvia Grignaschi**- Rheumatology Unit, Dipartimento di Medicine Interna e Terapia Medica, Università degli studi di Pavia, Pavia, Lombardy, Italy.
18. **Dr Alessandro Giollo**- 1. Rheumatology Section, Department of Medicine, University of Verona, 37129 Verona, Italy. 2. Rheumatology Section, Department of Medicine, University of Padova, 35128 Padova, Italy.
19. **Dr Alessia Alunno**- Internal Medicine and Nephrology Unit, MeSVA Department. University of L'Aquila, Italy.
20. **Dr Florenzo Iannone**- Rheumatology Unit, Department of Emergency and Organ Transplantation, University of Bari, Bari, Italy.
21. **Dr Marco Fornaro**- Rheumatology Unit, Department of Emergency and Transplantation, University of Bari, Bari, Italy.

France

1. **Dr. Margherita Giannini**, Explorations fonctionnelles musculaires, service de physiologie, Hôpitaux universitaires de Strasbourg; EA3072, fédération de médecine translationnelle.

2. **Dr François Maurier-** Service de Médecine Interne, Hôspital Robert Schuman, Rue de Champ Montoy, 57070 Vantoux, France.

3. **Dr Julien Campagne-** Service de Médecine Interne, Hôspital Robert Schuman, Rue de Champ Montoy, 57070 Vantoux, France.

4. **Dr Alain Meyer-** 1. Centre National de Référence des Maladies Systémiques et Auto-immunes Rares Grand-Est Sud-Ouest (RESO), Service de humatologie, Service de physiologie, Unité d'explorations fonctionnelles musculaires, Hôpitaux Universitaires de Strasbourg, Strasbourg, France; 2. EA3072, Fédération de Médecine Translationelle, Université de Strasbourg, Strasbourg, France.

Philippines

1. **Dr Lisa S Traboco**- Philippine Rheumatology Association, St Luke's Medical Center- Global City (Visiting), Philippines.

Indonesia

1. **Dr Suryo Anggoro Kusumo Wibowo**, Rheumatology Division, Department of Internal Medicine, Fakultas Kedokteran, Universitas Indonesia, Indonesia.

Spain

1. **Dr Jesús Loarce-Martos**, Rheumatology Department, Hospital Universitario Ramón y Cajal, Carretera de Colmenar Viejo, 9, 1 km, 28043, Madrid, Spain.

2. **Dr Sergio Prieto-González**, Department of Internal Medicine, Hospital Clinic of Barcelona, University of Barcelona, Barcelona, Spain.

3. **Dr Raquel Aranega,** Systemic Autoimmune Diseases Unit, Vall d'Hebron General Hospital, Medicine Dept, Universitat Autónoma de Barcelona, Barcelona, Spain.

Brazil

1. **Dr Jucier Gonçalves Junior-** Division of Rheumatology, Faculdade de Medicina FMUSP, Universidade de Sao Paulo, Sao Paulo, SP, Brazil.

Japan

1. **Dr Akira Yoshida**- Nippon Medical School Graduate School of Medicine, Tokyo, Japan.

2. **Dr Ran Nakashima**, Department of Rheumatology and Clinical Immunology, Graduate School of Medicine, Kyoto University, 54 Shogoin-Kawahara-cho, Sakyo-ku, Kyoto 606-8507, Japan.
3. **Dr Shinji Sato**, Division of Rheumatology, Department of Internal Medicine, Tokai University School of Medicine, 143 Shimokasuya, Isehara, 259-1193, Japan.
4. **Dr Naoki Kimura**, Department of Lifetime Clinical Immunology, Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University (TMDU), Tokyo, Japan.
5. **Dr Yuko Kaneko**, Division of Rheumatology, Department of Internal Medicine, Keio University School of Medicine, Tokyo, Japan.
6. **Dr Takahisa Gono**- Department of Allergy and Rheumatology, Nippon Medical School Graduate School of Medicine, Tokyo, Japan.

Germany

1. **Dr Stylianos Tomaras**- Department of Rheumatology, Helios Clinic Vogelsang-Gommern, 39245 Gommern, Germany.
2. **Dr Fabian Nikolai Proft**- Department of Gastroenterology, Infectiology and Rheumatology (including Nutrition Medicine), Charité - Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt- Universität zu Berlin, Berlin, Germany.
3. **Dr Marie-Therese Holzer-** 1. III. Department of Medicine, University Medical Center Hamburg-Eppendorf, Hamburg, Germany. 2. Department of Rheumatology and Immunology, Klinikum Bad Bramstedt, Bad Bramstedt, Germany.

Russian Federation

1. **Dr Margarita Aleksandrovna Gromova**, Pirogov Russian National Research Medical University (RNRMU), Moscow, Russian Federation.

Israel

1. **Mr Or Aharonov**, Department of Gerontology, Faculty of Social Welfare and Health Science, University of Haifa, Haifa, Israel.

Morocco

1. **Dr Ihsane Hmamouchi-** Professor (Associate), Laboratoire d'épidémiologie et de recherche clinique, La Faculté de Médecine et de Pharmacie de Rabat, Morocco.
2. **Dr Pr Imane El bouchti**, Head of the Rheumatology Department, Mohammed VI University Hospital, Marrakech, Morocco.
3. **Dr. Zineb Baba**: Department of Rheumatology, Mohammed VI University Hospital, Marrakech, Morocco.

Nigeria

1. **Dr Uyi Ima-Edomwonyi-** Consultant, Department of Internal Medicine, Lagos University Teaching Hospital, Lagos, Nigeria.

2. **Dr Ibukunoluwa Dedeke**- Department of Medicine, University College Hospital Ibadan, Ibadan, Nigeria.
3. **Dr Emorinken Airenakho**- Consultant Rheumatologist, Irrua Specialist Teaching Hospital, KM 87 Benin Auchi Rd, 310115, Irrua, Nigeria.
4. **Dr Nwankwo Henry Madu**- Lecturer 1, Department of Medicine, Nnamdi Azikiwe University, Awka.
5. **Dr Abubakar Yerima**- Department of Medicine, University of Maiduguri Teaching Hospital, Maiduguri, Borno State, Nigeria.
6. **Dr Hakeem Olaosebikan**- Consultant Rheumatologist, Lagos State University Teaching Hospital/ Lagos State University College of Medicine,Ikeja, Lagos, Nigeria.

Ethiopia

1. **Dr Becky A.** Rheumatology Unit, Internal Medicine Department, Addis Ababa University, Addis Ababa, Ethiopia.

Mauritius

1. **Dr Ouma Devi Koussougbo**. Rheumatology, Victoria hospital, Mauritius.

Australia

1. **Dr Daman Langguth**- Department of Immunology, Sullivan Nicolaides Pathology, Brisbane, Queensland, Australia.
2. **Dr Vidya Limaye**- Consultant Rheumatologist, Royal Adelaide Hospital, Associate Professor of Rheumatology, Discipline of Medicine, University of Adelaide, Australia.
3. **Dr Merrilee Needham**- 1. Neurology Department, Fiona Stanley Hospital, Murdoch, Australia; 2. Institute for Immunology and Infectious Diseases, Murdoch University, Murdoch, Australia; 3. Perron Institute for Neurological and Translational Science, Nedlands, Australia; 4. University of Notre Dame, Fremantle, Australia.
4. **Dr Nilesh Srivastav**- Alfred Health, The Alfred, Caulfield Hospital, Sandringham Hospital, Melbourne, Victoria, Australia.

Canada

1. **Dr Marie Hudson-** Department of Medicine, McGill University, Montreal, Quebec; Division of Rheumatology, Jewish General Hospital, Montreal, Quebec, and Lady Davis Institute, Jewish General Hospital, Montreal, Quebec, Canada.
2. **Dr Océane Landon-Cardinal-** Department of Medicine, University of Montreal, Montreal, Canada. Department of Medicine, CHUM Research Centre, Montreal, Canada.

Colombia

1. **Dr Wilmer Gerardo Rojas Zuleta**- Department of Rheumatology, Universidad de Antioquia, Cl. 67 #53 - 108, Medellín, Colombia. Wgroj
2. **Dr. Álvaro Arbeláez- Médico especialista en Reumatología y Medicina Interna. Universidad Libre. Clínica Imbanaco. Clínica de Artritis Temprana. Cali, Valle, Colombia.**
3. **Dr. Javier Cajas:** Institute of Rheumatology Ferdinand Chalem, Bogota, Colombia.
4. **Dr. Adriana Vanegas**- 1. Group of Rheumatology, Faculty of Medicine, University of Antioquia, Medellín, Colombia. 2. Rheumatology Service, Hospital Universitario San Vicente Foundation, Medellín, Colombia.

Portugal

1. **Dr José António Pereira Silva**- Rheumatology Department, Centro Hospitalar e Universitário de Coimbra EPE, and Coimbra Institute of Clinical and Biomedical Research (iCBR), Faculty of Medicine, University of Coimbra, Portugal.

2. **Dr João Eurico Fonseca**- Hospital de Santa Maria, Centro Hospitalar Lisboa Norte Centro Académico de Medicina de Lisboa, Lisboa, Portugal; Instituto de Medicina Molecular, Faculdade de Medicina, Universidade de Lisboa, Lisboa, Portugal.

Ukraine

1. **Dr Olena Zimba-** Department of Internal Medicine #2, Danylo Halytsky Lviv National Medical University, Lviv, Ukraine.
2. **Dr Doskaliuk Bohdana**- Department of Pathophysiology, Ivano-Frankivsk National Medical University, Ivano-Frankivsk, Ukraine.

Hong Kong

1. **Dr Ho So**- Assistant Professor, Department of Medicine & Therapeutics, Faculty of Medicine, The Chinese University of Hong Kong.

Peru

1. **Dr Manuel Francisco Ugarte-Gil**- Servicio de Reumatología, Hospital Nacional Guillermo Almenara Irigoyen, EsSalud, Lima, Peru. School of Medicine, Universidad Científica del Sur, Lima, Peru.
2. **Dr. Lyn Chinchay**: Seguro Social de Salud del Peru (ESSALUD), Lima, Peru.

3. **Dr. José Proaño Bernaola**: 1. Cayetano Heredia National Hospital, Lima, Peru. 2. Anglo-American Clinic. San Isidro, Lima, Peru. 3. Peruvian University Cayetano Heredia, Lima, Peru. 4. Rheumatologist, San Judas Tadeo Clinic - Research Center (ENDOMED), Lima. 5. Environmental and Food Health - DIRIS – Lima.
4. **Dr. Victorio Pimentel**: Rheumatology Department, Hospital Guillermo Almenara Irigoyen, EsSalud, Av. Grau 800, La Victoria, Lima 13, Lima, Peru.

Egypt

1. **Dr Hanan Mohamed Fathi**- Rheumatology and Autoimmune Diseases, Faculty of Medicine, Fayoum University, Faiyum, Egypt.

United Arab Emirates

1. **Dr Ghita Harifi**- Department of Rheumatology, Mediclinic Parkview Hospital, 3 Umm Suqeim St - Al Barsha Al Barsha South, Dubai, United Arab Emirates.

Pakistan

1. **Zoha Zahid Fazal**- Medical College, The Aga Khan University, Karachi, Pakistan.

Venezuela

1. **Dr. Yurilís Fuentes-Silva**: 1. Health Sciences School, University of Oriente– Bolivar Nucleus, Ciudad Bolivar, Venezuela. 2. Centro Clínico Universitario de Oriente, Ciudad Bolivar, Venezuela.

Paraguay

1. **Dr. Karoll Cabriza**:
2. **Dr. Jonathan Losanto**: Hospital de Clínicas, San Lorenzo, Paraguay.
3. **Dr. Nelly Colaman**: Hospital de Clínicas, San Lorenzo, Paraguay.

Panama

1. Dr. **Antonio Cachafeiro-Vilar**: Pacífica Salud-Hospital Punta Pacífica, Ciudad de Panamá, Panamá.
2. **Dr. Generoso Guerra Bautista**: Centro de Investigación Marbella, Paitilla Panamá, Panamá.
3. **Dr. Enrique Julio Giraldo Ho**: Rheumatologist, Universidad de Panamá, República de Panamá.
4. **Dr. Raúl González**

Chile

1. **Dr. Lilith Stange Nunez**: Rheumatologist, University of Valparaiso, Pontifical Catholic University of Chile.
2. **Dr. Cristian Vergara M**: Departamento de Medicina Interna, Escuela de Medicina Dirección de PostGrado y Post Título, Facultad de Medicina, Universidad de Valparaíso, Santiago, Chile.

Dominican Republic

1. **Dr. Jossiell Then Báez**: MD, Hospital Metropolitano de Santiago (HOMS), Santiago, Dominican Republic.

Honduras

1. **Dr. Hugo Alonzo**: Jefe del Departamento de Medicina Interna en Hospital de Especialidades del Seguro Social en Tegucigalpa, Honduras.
2. **Dr. Carlos Benito Santiago Pastelin**: Médico especialista, Instituto Hondureño del Seguro Social, Honduras.

Argentina

1. **Dr. Rodrigo García Salinas**: Rheumatology Unit, La Plata Italian Hospital, Buenos Aires, Argentina.

Guatemala

1. **Dr. Alejandro Quiñónez Obiols**: MD, PhD, Universidad Mariano Gálvez de Guatemala, Guatemala City, Guatemala.
2. **Dr. Nilmo Chávez**: MD, Instituto Guatemalteco de Seguridad Social - Universidad San Carlos de Guatemala, Ciudad de Guatemala, Guatemala.
3. **Dr. Andrea Bran Ordóñez**:
4. **Dr. Sandra Argueta**:
5. **Dr. Daniel Quijivix**:

Cuba

1. **Dr. Gil Alberto Reyes Llerena**: Surgical Medical Research Center (CIMEQ), Rheumatology Service, 216th Street and 11B, Siboney. Beach. Havana, Cuba. Phone: 209-1431.

Puerto Rico

1. **Dr. Radames Sierra-Zorita**: University of Puerto Rico, School of Medicine, San Juan, Puerto Rico.

Costa Rica

1. **Dr. Dina Arrieta**: Hospital México, Caja Costarricense del Seguro Social, San José de Costa Rica, Costa Rica.

2. **Dr. Eduardo Romero Hidalgo**: Jackson's Memorial Medical Center, San Ramon, Alajuela, Costa Rica.
3. **Dr. Ricardo Saenz**: Jefe Servicio Reumatología Hospital Dr. Calderón Guardia C.C.S.S..

Nicaragua

1. **Dr. Idania Escalante M**.: 1. Internal Medicine, Rheumatologist, Oscar Danilo Rosales School Hospital. Leon-Nicaragua. 2. Medicine professor of National Autonomous University of Nicaragua.
2. **Dr. Roberto Morales**

Ecuador

1. **Dr. Wendy Calapaqui**: Instituto Ecuatoriano de Seguridad Social. Centro de atención ambulatoria "El Batán", Quito, Ecuador.
2. **Dr. Ivonne Quezada**: Hospital de Especialidades Eugenio Espejo, Quito, Ecuador.

Bolivia

1. **Dr. Gabriela Arredondo**