
Supplementary Appendix to:

**Outpatient Treatment with the SARS-CoV-2–Neutralizing
Antibody Combination AZD7442 (Tixagevimab/Cilgavimab)
Prevented COVID-19 Hospitalizations Over 6 Months and
Reduced Symptom Progression in the
Phase 3 TACKLE Trial**

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Supplementary Appendix

Definition of Serious Adverse Events

A serious adverse event (SAE) is an AE occurring during any study phase (i.e., run-in, treatment, washout, follow-up) that fulfils one or more of the following criteria:

- results in death
- immediately life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability or incapacity
- a congenital abnormality or birth defect
- an important medical event that may jeopardize the participant or may require medical treatment to prevent one of the outcomes listed above

Adverse Event Severity Rating Scale

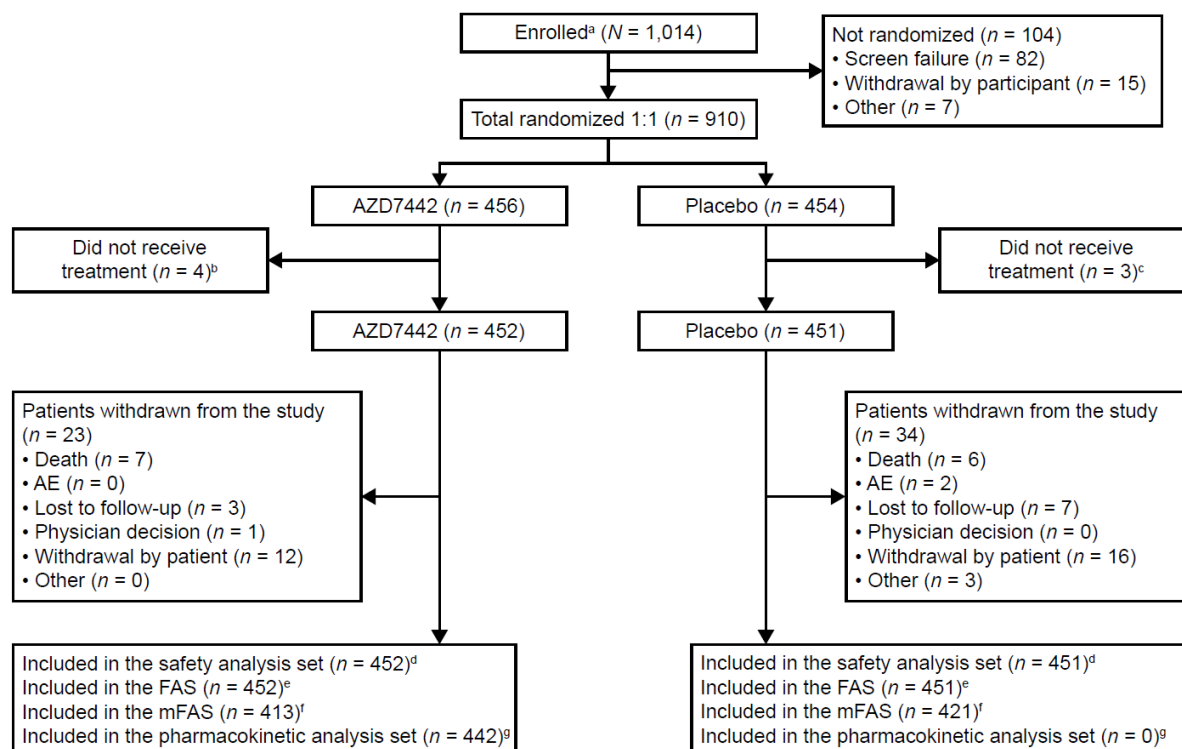
- Grade 1: An event of mild intensity that is usually transient and may require only minimal treatment or therapeutic intervention. The event does not generally interfere with usual activities of daily living.
- Grade 2: An event of moderate intensity that is usually alleviated with additional, specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort, but poses no significant or permanent risk of harm to the participant.
- Grade 3: A severe event that requires intensive therapeutic intervention. The

event interrupts usual activities of daily living or significantly affects the clinical status of the participant.

- Grade 4: An event, and/or its immediate sequelae, that is associated with an imminent risk of death.
- Grade 5: Death as result of an event.

It is important to distinguish between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined by the criteria mentioned in the section above. An AE of severe intensity need not necessarily be considered serious. For example, nausea that persists for several hours may be considered severe nausea, but is not an SAE unless it meets the criteria for an SAE. Conversely, a stroke that results in only a limited degree of disability may be considered a mild stroke but would be an SAE when it satisfies the SAE criteria.

Figure S1. Participant disposition (CONSORT flow diagram).



Data cut-off, January 14, 2022.

^aInformed consent received.

^bDue to physician decision ($n = 1$) or withdrawal by participant ($n = 3$).

^cDue to withdrawal by participant ($n = 1$) or other reason ($n = 2$).

^dComprised all participants who received study drug (erroneously treated participants were analyzed according to the treatment they actually received).

^eComprised all randomized participants who received study drug.

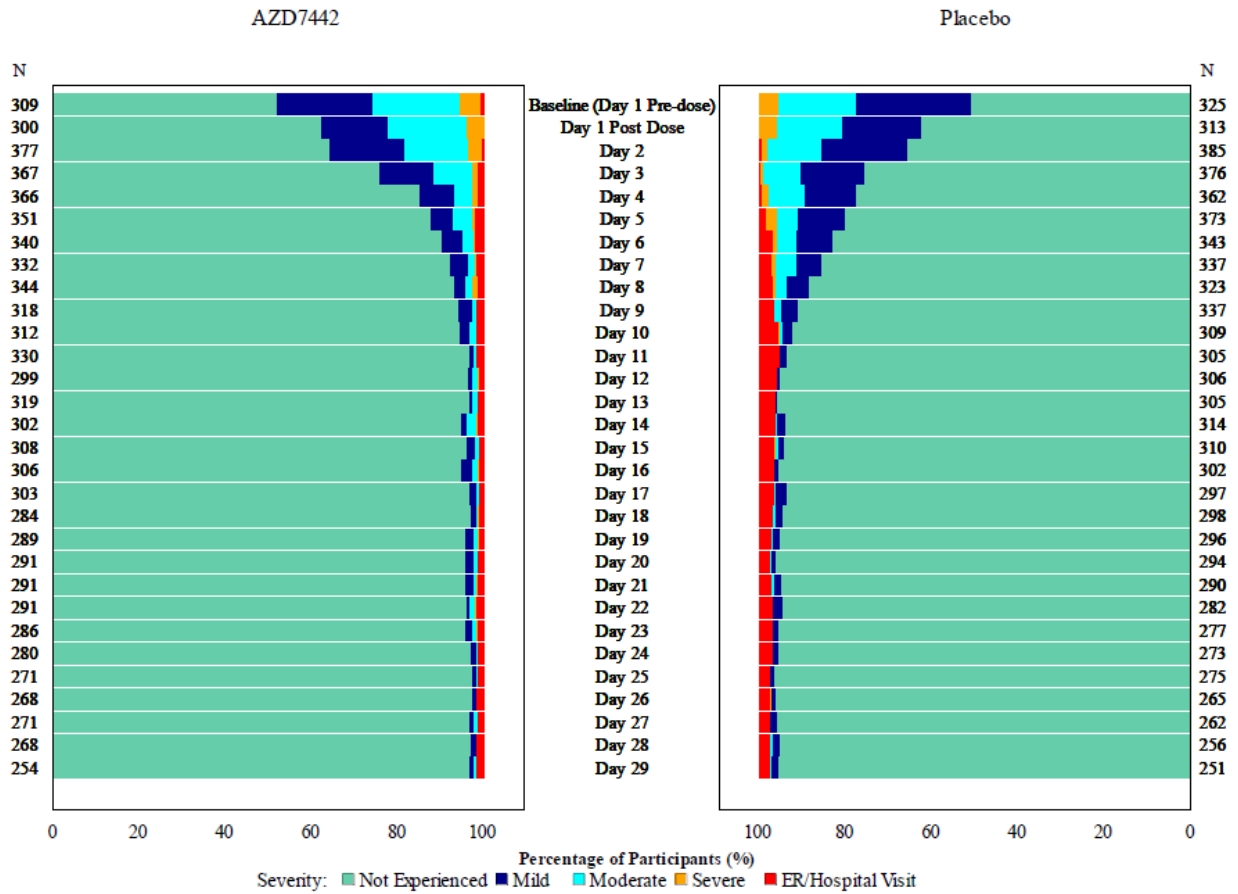
^fComprised all participants in the FAS who received study drug ≤ 7 days from symptom onset and were not hospitalized at baseline (\leq Day 1) for isolation purposes.

^gComprised all participants who received AZD7442 with ≥ 1 quantifiable serum pharmacokinetic observation post-dose.

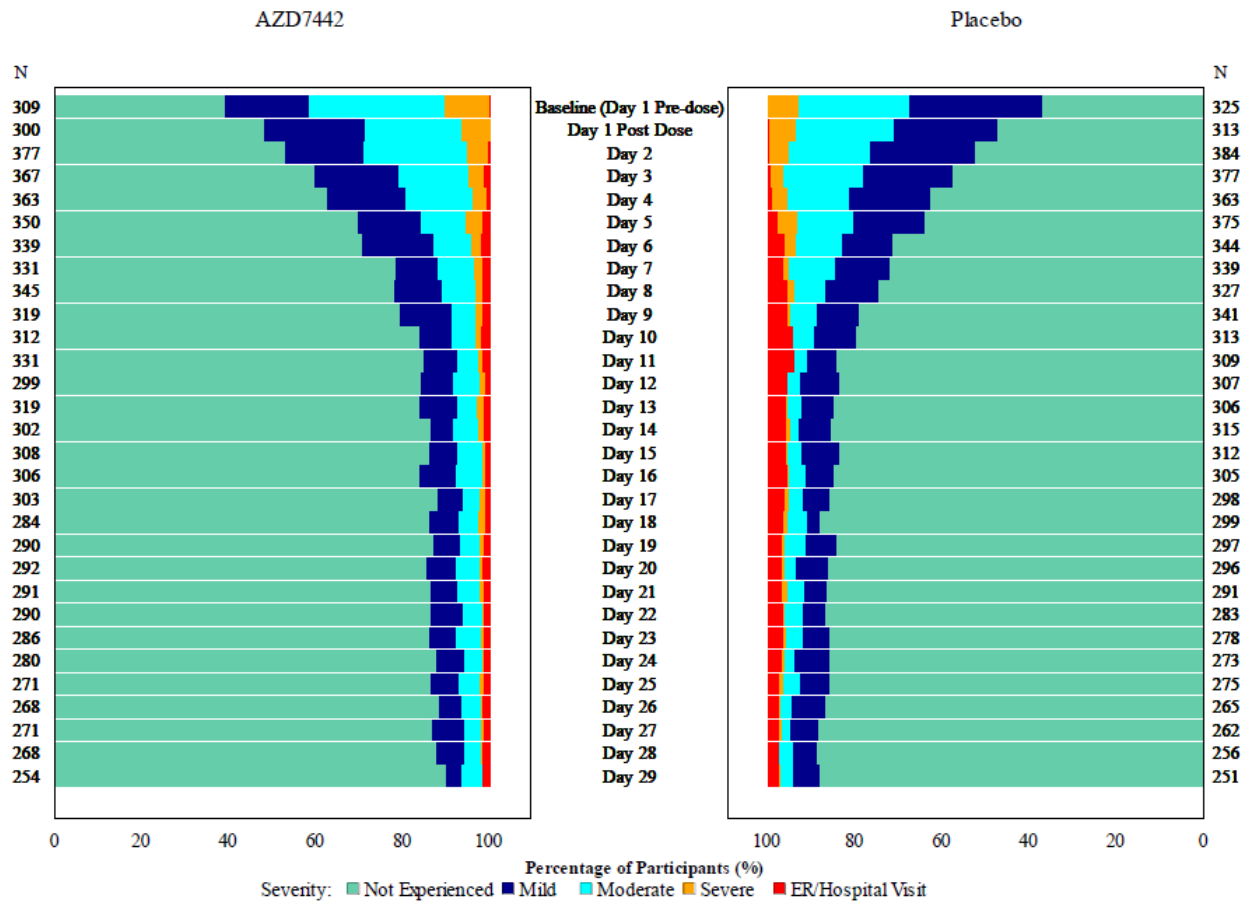
AE adverse event, FAS full analysis set, mFAS modified FAS.

Figure S2. Proportion of participants at each symptom severity level by study day for (a) chills, (b) body aches, (c) diarrhea, (d) fatigue, (e) headaches, (f) nausea, and (g) runny nose (mFAS).

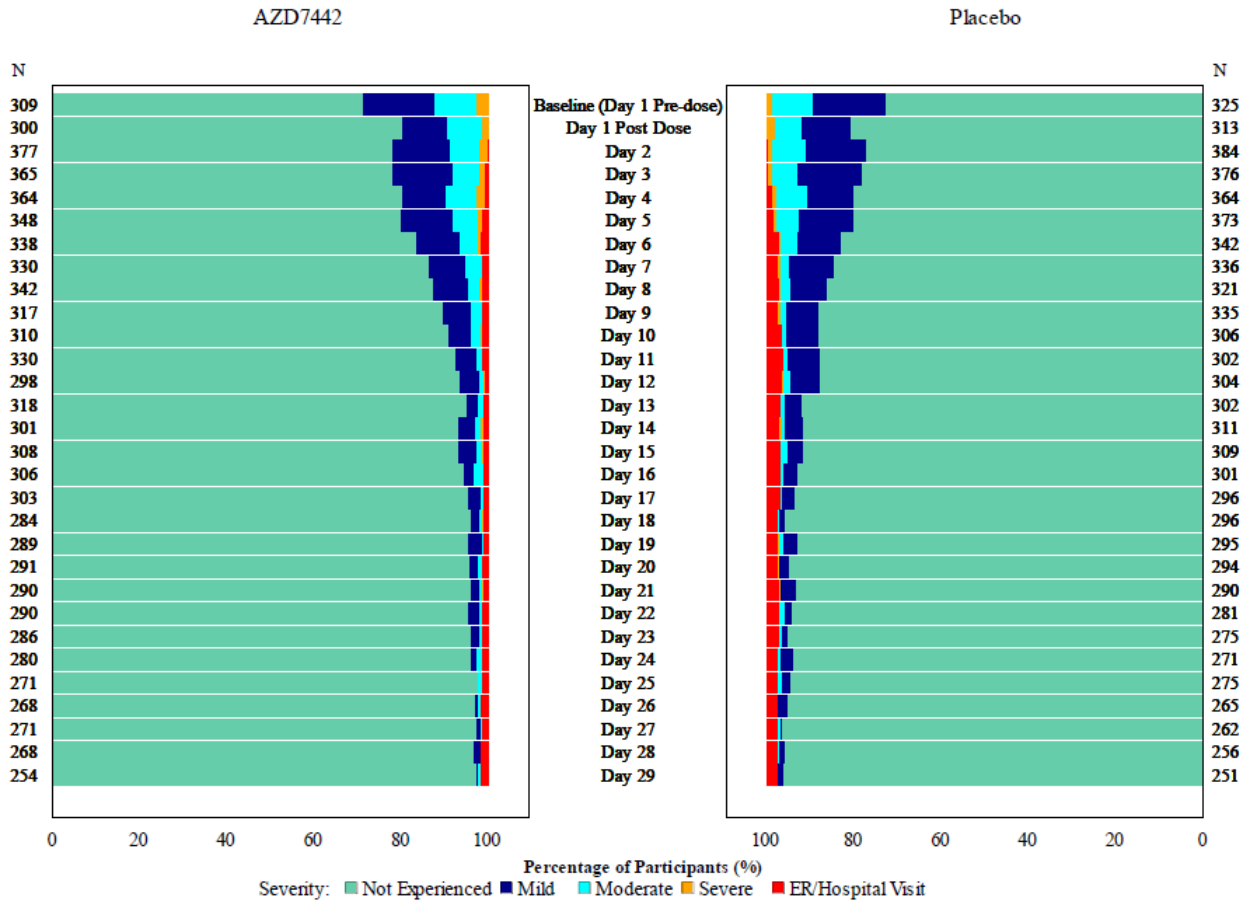
(a) Chills



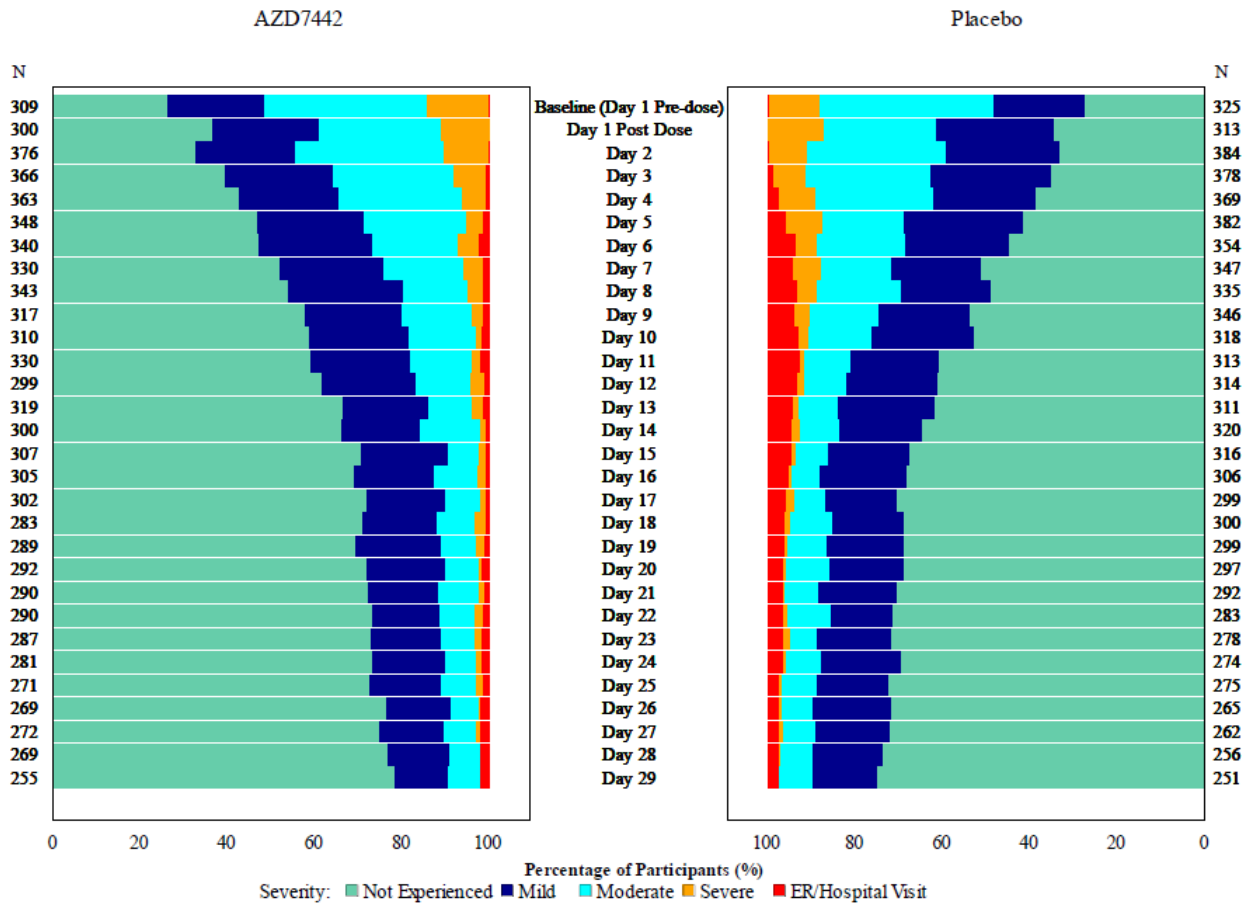
(b) Body aches



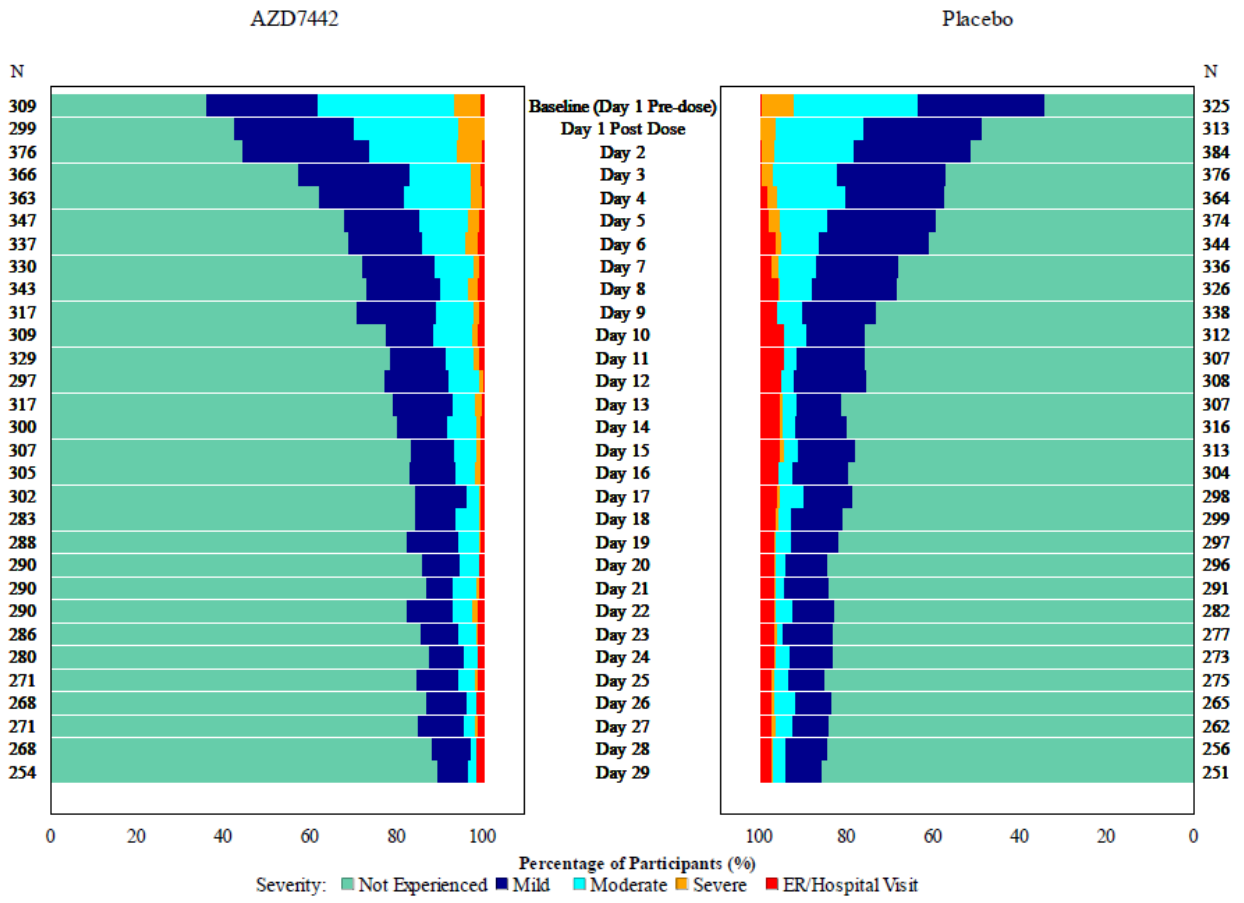
(c) Diarrhea



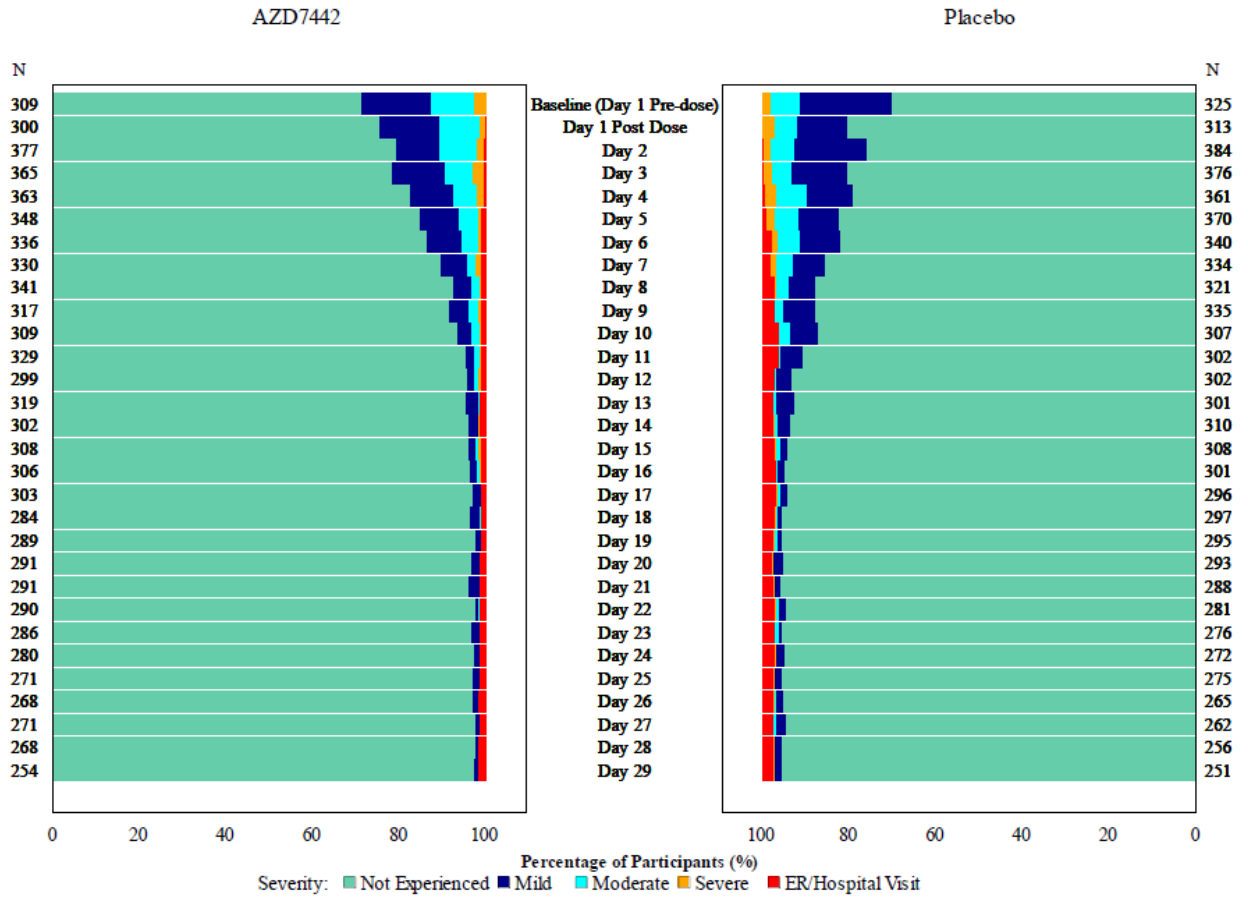
(d) Fatigue



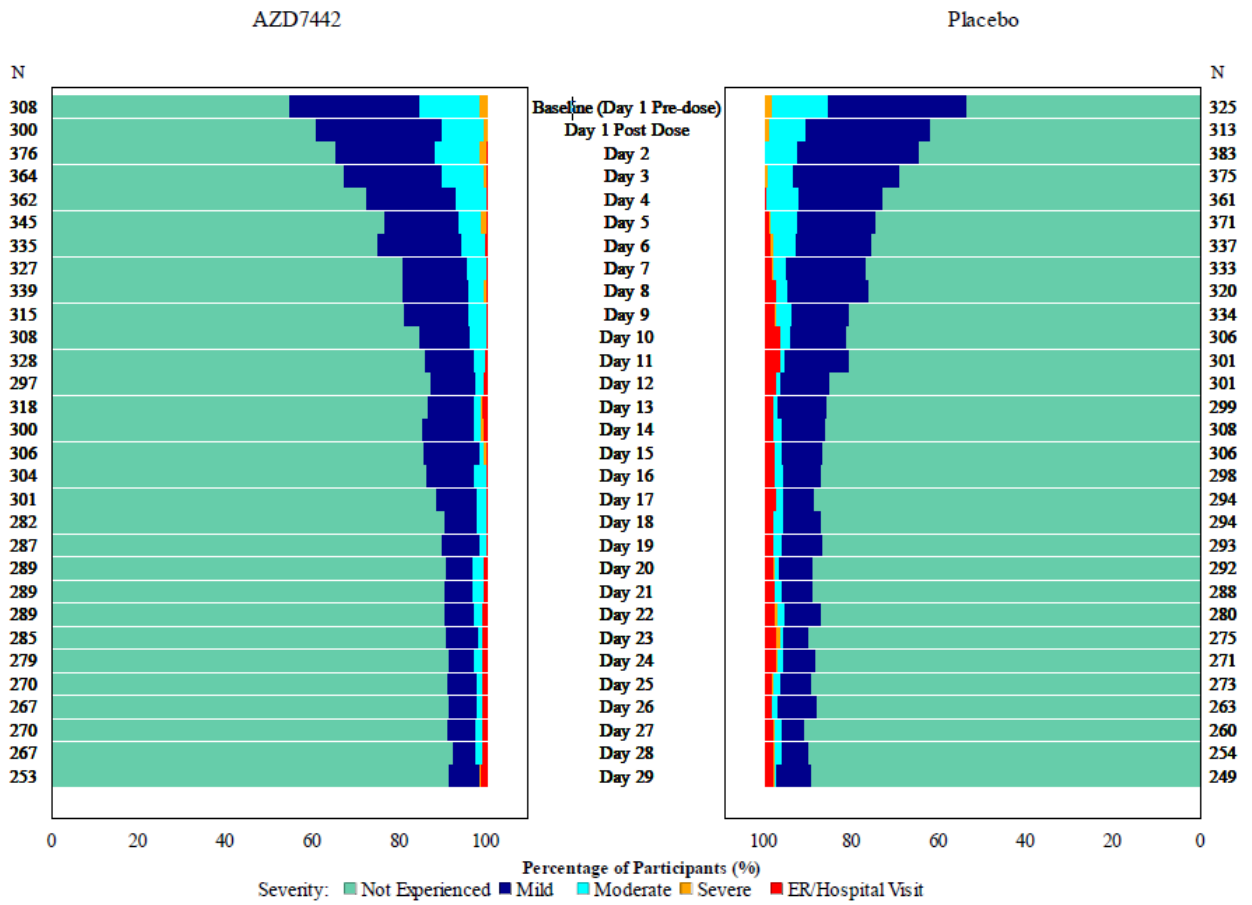
(e) Headache



(f) Nausea



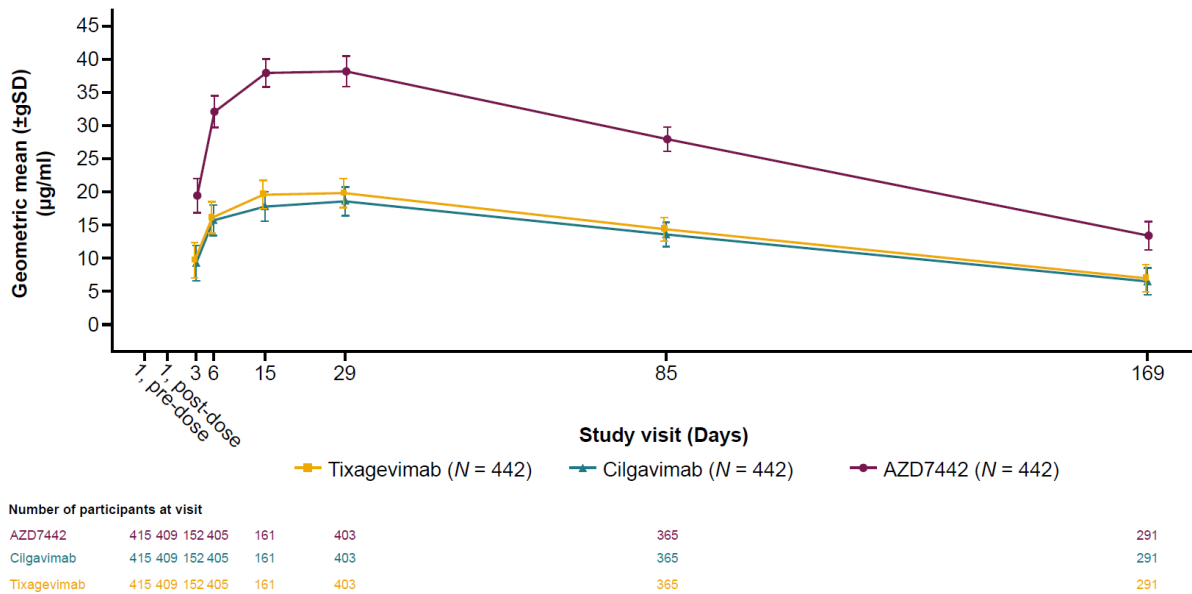
(g) Runny nose



The mFAS comprised all participants in the FAS who received study drug ≤ 7 days from symptom onset and were not hospitalized at baseline (Day 1) for isolation purposes. The FAS comprised all randomized participants who received study drug.

ER emergency room, FAS full analysis set, mFAS modified FAS.

Figure S3. Serum concentrations of AZD7442 over time (pharmacokinetic analysis set).



Includes participants from the pharmacokinetic analysis set, defined as all dosed participants for whom an adequate (measurable drug concentration) pharmacokinetic profile has been obtained.

Serum samples were analyzed for tixagevimab and cilgavimab concentrations by PPD[®] Laboratories (Richmond, VA, USA) using a validated ultra-high performance liquid chromatography method coupled with tandem mass spectrometry with positive electrospray. As previously described [1], 20-µl samples were diluted and extracted with streptavidin magnetic beads coated with biotinylated SARS-CoV-2 receptor binding domain. Isolated analytes were digested (denaturation, reduction, alkylation, and trypsin digestion) and the extract fortified with stable isotope-labeled peptide internal standard working solution. Unknown samples were quantified using a linear, 1/concentration² weighted, least-squares regression algorithm.

Pharmacokinetic analysis set comprised all participants who received AZD7442 with ≥ 1 quantifiable serum pharmacokinetic observation post-dose.

gSD geometric standard deviation, SARS-CoV-2 severe acute respiratory syndrome coronavirus 2.

Reference

1. Loo YM, McTamney PM, Arends RH, et al. The SARS-CoV-2 monoclonal antibody combination, AZD7442, is protective in nonhuman primates and has an extended half-life in humans. *Sci Transl Med.* 2022;14(635):eabl8124.

Table S1. List of study sites and IRB approvals

Country	Centre no.	Name and address of IEC/IRB	Chairman of IEC/IRB	Date of Approval	Approval ID
Argentina	202	CEI Centro de Investigaciones Médicas Mar del Plata Av. Colón 3083 5th Floor, Mar del Plata, Buenos Aires, 7600	Martin Donadio	25-Mar-21	VV-TMF-005864214
Argentina	203	Comité de Ética Independiente de la Clínica Privada Independencia, Luis María Drago 5681, Munro, Buenos Aires, 1605	Marcelo Baggio	05-Apr-21	VV-TMF-006058052
Argentina	205	Comité Independiente de Ética Prof. Dr. Luis J. E. Uriburu 774 1st floor, Buenos Aires, Caba, C1027AAP	Luis Zieher	10-Apr-21	VV-TMF-005938003
Argentina	206	Comité Independiente de Ética Prof. Dr. Luis	Luis Zieher	20-Apr-21	VV-TMF-005970977

		J. E. Uriburu 774 1st floor, Buenos Aires, Caba, C1027AAP			
Brazil	702	Comitê de Ética em Pesquisa do Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo Campus Universitário, SN, Prédio Central, Subsolo Ribeirão Preto/SP 14048-900	Dra. Mariana Guimarães Villanova	29-Apr-21	4.679.639
Brazil	704	Comitê de Ética em Pesquisa do Instituto de Saúde e Bem Estar da Mulher Manoel da Nóbrega Street, 784 São Paulo/SP 04001-002	Valdinéia Agnelo Pires da Silva	06-May-21	4.696.784

Brazil	706	<p>Comitê de Ética em Pesquisa INVESTIGA - Institutos de Pesquisa</p> <p>Dr. Romeu Tórtima Avenue, 739</p> <p>Campinas/SP</p> <p>13084-791</p>	Cristiana Madjarof	12-May-21	4.707.118
Brazil	707	<p>Comitê de Ética em Pesquisa em Seres Humanos CEPH da Fundação Universidade Regional de Blumenau</p> <p>Antonio da Veiga Street, 140 Bloco A 2nd Floor</p> <p>Blumenau/SC</p> <p>89030-903</p>	Professor Márcio Cristiano de Souza Rastelli	12-May-21	4.707.536
Brazil	709	<p>Comitê de Ética em Pesquisa do Hospital das Clínicas de Porto Alegre</p> <p>Ramiro Barcelos Street, 2350 Room 2229</p>	Têmis Maria Félix	05-May-21	4.692.755

		Porto Alegre/RS 90035-903			
Czech Republic	1901	Eticka komise Cesky Tessin Hrabinska 895/50, Cesky Tesin, 737 01	Mgr. Petr Papuga	29-Mar-21	1/2021
Czech Republic	Central: 1901	Eticka komise Fakultni nemocnice Ostrava 17. listopadu 1790/5, Ostrava – Poruba, 708 52	Doc. MUDr. Karol Zelenik, Ph.D., MBA	25-Mar-21	255/2021
Czech Republic	1902	Eticka komise Oblastni nemocnice Kolin, a.s. Zizkova 146, Kolin 280 02	Martin Novacek	26-Mar-21	KO-016/2021
Czech Republic	Central: 1902	Eticka komise Fakultni nemocnice Ostrava	Doc. MUDr. Karol Zelenik, Ph.D., MBA	25-Mar-21	255/2021

		17. listopadu 1790/5, Ostrava – Poruba, 708 52			
Czech Republic	1903	Eticka komise pro Pardubickou a Svitavskou nemocnici Kyjevská 44, Pardubice, 532 02	MUDr. David Stuchlik	09-Apr-21	638/9.4.2021
Czech Republic	Central: 1903	Eticka komise Fakultni nemocnice Ostrava 17. listopadu 1790/5, Ostrava – Poruba, 708 52	Doc. MUDr. Karol Zelenik, Ph.D., MBA	25-Mar-21	255/2021
Germany	2602	Ethikkommission (EC) der Landesärztekammer Hessen Hanauer Landstraße 152, Frankfurt,	Prof. Dr. med. Sebastian Harder	03-Feb-21	Nr. 9545_AMG_M_2021

		60314			
Germany	2603	<u>Ethikkommission der Landesärztekammer Rheinland-Pfalz,</u> Deutschhausplatz 3, Mainz, 55116	Univ.-Prof. Dr. med. Dipl. Ing. Stephan Letzel	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2604	<u>EC Landesamt für Gesundheit und Soziales (LAGeSo)</u> Geschäftsstelle der Ethik-Kommission des Landes Berlin, Turmstraße 21, Haus A Berlin, 10559	Prof. Dr. med. K. Thomas Moesta	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2605	<u>EC Landesamt für Gesundheit und Soziales (LAGeSo)</u> Geschäftsstelle der Ethik-Kommission des Landes Berlin, Turmstraße 21, Haus A	Prof. Dr. med. K. Thomas Moesta	01-Mar-21	Nr. 9545_AMG_M_2021

		Berlin, 10559			
Germany	2606	<u>Ethik-Kommission der Medizinischen Fakultät der LMU</u> Pettenkoferstr. 8a München, 80336	Prof. Dr. Wolfgang Eisenmenger	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2607	<u>Ethikkommission (EC) der Ärztekammer Nordrhein</u> Tersteegenstraße 9 Düsseldorf 40474	Prof. Dr. Kurt Racké	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2608	<u>EC Landesamt für Gesundheit und Soziales (LAGeSo)</u> Geschäftsstelle der Ethik-Kommission des Landes Berlin, Turmstraße 21, Haus A	Prof. Dr. med. K. Thomas Moesta	03-Feb-21	Nr. 9545_AMG_M_2021

		Berlin, 10559			
Germany	2609	EC Ethik-Kommission der Ärztekammer Hamburg, Weidestrasse 122b Hamburg, 22083	Prof. Dr. med. Rolf Stahl	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2610	EC Bayerische Landesaerztekammer Muehlbaurstraße 16 München 81677	Prof. Dr. med. Hasford	01-Mar-21	Nr. 9545_AMG_M_2021
Germany	2612	Landesärztekammer Rheinland-Pfalz EC Deutschhausplatz 3 Mainz 55116	Univ.-Prof. Dr. med. Dipl. Ing. Stephan Letzel	22-Apr-21	Nr. 9545_AMG_M_2021

Hungary	Central: 3302	Ethics Committee of Hungary – Central Egészségügyi Tudományos Tanács / Medical Research Council Klinikai Farmakológiai Etikai Bizottság/Ethics Committee for Clinical Pharmacology Alkotmány u. 25. Budapest 1054	Prof. Dr. Bitter István	01-Mar-21	OGYEI/5496-8/2021
Hungary	Central: 3305	Ethics Committee of Hungary - Central Egészségügyi Tudományos Tanács / Medical Research Council Klinikai Farmakológiai Etikai Bizottság/Ethics Committee for Clinical Pharmacology Budapest 1054	Prof. Dr. Bitter István	01-Mar-21	OGYEI/5496-8/2021
Italy	4101	INMI 'L.Spallanzani' - IRCCS Via Portuense 292	Cinzia Caporale	09-Feb-21	VV-TMF-005801409

		Roma, RM 149			
Italy	4102	Comitato Etico dell'Ospedale San Raffaele Via Olgettina 60 Milano 20132	Elisabetta Riva	25-Feb-21	VV-TMF-005845206
Italy	4104	Comitato Etico Dell'Area Vasta Emilia Nord – Sede di Reggio Emilia Viale Umberto I Reggio Emilia 43123	Roberto Giuseppe Grilli	02-Mar-21	NA (receipt of CEC approval)
Italy	4105	Comitato Etico Dell'Area Vasta Emilia Nord – Sede di Piacenza Via Giuseppe Taverna 49 Piacenza	Roberto Giuseppe Grilli	02-Mar-21	NA (receipt of CEC approval)

		29100			
Italy	4108	Azienda Ospedaliero – Universitaria Pisana via A. Cocchi, 7/9 Pisa 56121	Romano Danesi	25-Feb-21	NA (receipt of CEC approval)
Japan	4301	Institutional Review Board of Tohoku Medical and Pharmaceutical University Hospital 1- 12-1 Fukumuro, Miyagino-ku Sendai-shi Miyagi 983-8512	Kazuhiro Murakami	08-Mar-21	NA
Japan	4303	Maebashi Red Cross Hospital Institutional Review Board 389-1 Asakura-machi Maebashi-Shi	Yutaka Uehara	22-Feb-21	NA

		Gunma 371-0811			
Japan	4304	Saitama Medical University Hospital Institutional Review Board 38 Morohongo Moroyama-machi Iruma-Gun Saitama- Ken 350-0495	Keiji Yamamoto	02-Mar-21	NA
Japan	4305	Showa University Hospital Institutional Review Board 1-5-8, Hatanodai Shinagawa-ku Tokyo 142-8666	Takaaki Matsuyama	08-Mar-21	NA
Japan	4306	Tokyo Medical University Hachioji Medical Center Institutional Review Board	Hiroyuki Jimbo	25-Mar-21	NA

		1163, Tatemachi Hachioji-shi Tokyo 193-0998			
Japan	4307	Institutional Review Board of International University of Health and Welfare 1-24-1 Minami-Aoyama Amity Nogizaka Bldg. Minato-ku , Tokyo 107-0062	Tsutomu Yamazaki	25-Feb-21	NA
Japan	4308	Center Hospital of the National Center for Global Health and Medicine IRB 1-21-1 Toyama Shinjuku-ku Tokyo 162-8655	Takeshi Tamaki	03-Mar-21	NA
Japan	4309	Chiba Aoba Municipal Hospital Institutional Review Board	Tomoyuki Rokkaku	24-Feb-21	NA

		1273-2, Aobacho Chuo-ku Chiba-shi, Chiba 260-0852			
Japan	4310	Institutional Review Board of Tokyo Shinagawa Hospital 6-3 22 Higashioi Shinagawa-ku, Tokyo 140-8522	Masaharu Shinkai	24-Feb-21	NA
Japan	4312	Rakuwakai Otowa Hospital Institutional Review Board 2 Otowachinji-cho Yamashina-ku Kyoto-shi Kyoto 607-8062	Yuko Wada	18-Feb-21	NA

Mexico	Central: 4901	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	Central: 4902	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	Central: 4903	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001

Mexico	Central: 4904	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	4905	Comité de Etica en Investigación de Médica Sur S.A.B de C.V Puente de Piedra No. 150 Colonia Toriello Guerra Tlalpan Ciudad de México 14050	Dr. Norberto Carlos Chávez Tapia Dra. Varenka Julieta Barbero Becerra Dra. Eva Juarez Hernandez	18-Jan-21	01-2021-CEI-30
Mexico	4906	Comité de Etica en Investigación del Hospital Universitario "Dr. José Eleuterio González" Francisco Ignacio Madero y Avenida Gonzalitos S/N	José Gerardo Garza Leal Dr. C. Guillermo Elizondo Riojas	07-Jan-21	PI21-00005

		<p>Colonia Mitras Centro Monterrey , Nuevo León</p> <p>64460</p>	<p>Dr. Mario Alberto Campos Coy</p>		
Mexico	4907	<p>Comité de Etica en Investigación del Instituto Nacional de Enfermedades Respiratorias Ismael Cosío Villegas Calzada de Tlalpan #4502 Colonia Sección XVI Tlalpan</p> <p>Ciudad de México</p> <p>14080</p>	<p>Lic. Adriana Espinosa Jove</p> <p>Dra. en C. Blanca Margarita Bazán Perkins</p> <p>Dr. Edgar Enrique Sevilla Reyes</p>	05-Jan-21	INER/CEI/083/2021
Mexico	Central: 4908	<p>Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica</p> <p>Penitenciaria #20</p> <p>Colonia Centro, Guadalajara, Jalisco</p> <p>44100</p>	<p>Mtra. Bertha Alicia Ochoa Sanchez</p> <p>Dr. Liliana Faviola de la Cerda Trujillo</p> <p>Dr. Luis Enrique Colunga Lozano</p>	06-Jan-21	CEI-000001
Mexico	Central:	<p>Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica</p>	<p>Mtra. Bertha Alicia Ochoa Sanchez</p>	06-Jan-21	CEI-000001

	4909	Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano		
Mexico	Central: 4910	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	Central: 4911	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Poland	Central:	Komisja Bioetyczna przy Dolnoslaskiej Izbie Lekarskiej Kazimierza Wielkiego 45	Dr n. med. Włodzimierz Bednorz	08-Apr-21	Resolution no. 22/04/2021

	5704	Wroclaw 50-077			
Poland	Central: 5706	Komisja Bioetyczna przy Dolnoslaskiej Izbie Lekarskiej Kazimierza Wielkiego 45 Wroclaw 50-077	Dr n. med. Włodzimierz Bednorz	08-Apr-21	Resolution no. 22/04/2021
Russian Federation	6201	LEC of "Medical Research Institute" Legal: 25A Koli Tomchaka Str. Location:148D Moskovsky prosp. Saint Petersburg 196084	Yuhno Mihail	24-Feb-21	VV-TMF-005749760
Russian Federation	6202	St. Pt. State Institution of Health "City polyclinic No 109, Oleko Dundicha Street, 8 building 2 Saint-Petersburg 192283	Zhagrin Valeri	24-Feb-21	VV-TMF-005749962

Russian Federation	6205	Independent Ethics Committee at Joint-Stock Company "Group of Companies Medsi" 16, Krasnaya Presnya str. Moscow 123242	Igor Abramov	05-Mar-21	VV-TMF-005842991
Russian Federation	6206	Ethics committee, Pokrovskiy Hosp 85, Bolshoy prospect V.O. St.-Petersburg 199106	Balyabin Aleksandr	24-Feb-21	VV-TMF-005791088
Russian Federation	6208	IEC of LLC Clinic OsNova Serebristiy boulevard, 20 Saint-Petersburg 197227	Daria Adiatullina	01-Apr-21	VV-TMF-005969985
Russian Federation	6209	IEC Bayandin Murmansk Regional Clinical Hospital	Viktoria Dolinina	09-Mar-21	VV-TMF-005793049

		6 Pavlova ul. Murmansk 183047			
Russian Federation	6210	LEC of Ltd "Astarta" Nakhimova Street, 11 Saint-Petersburg 199226	Stroyev Yuri	01-Mar-21	VV-TMF-005796218
Spain	Central: 7001	CEIM Provincial de Malaga Ethic Comitee Provincial de Málaga Ethic Comitee Provincial de Málaga Avda. Carlos Haya s/n Malaga 29010	Dr. Manuel Herrera Gutiérrez	12 Apr 2021	NA: There is no approval ID itself
Spain	Central: 7003	CEIM Provincial de Malaga Ethic Comitee Provincial de Málaga Ethic Comitee Provincial de Málaga Avda. Carlos Haya s/n Malaga	Dr. Manuel Herrera Gutiérrez	12 Apr 2021	NA: There is no approval ID itself

		29010			
Spain	Central: 7004	CEIM Provincial de Malaga Ethic Comitee Provincial de Málaga Ethic Comitee Provincial de Málaga Avda. Carlos Haya s/n Malaga 29010	Dr. Manuel Herrera Gutiérrez	12 Apr 2021	NA: There is no approval ID itself
Ukraine	7705	EC of "Central city clinical hospital of Ivano-Frankivsk city council"114, Mazepy str. Ivano-Frankivsk 78018	O.V. Tsikhon	18-May-21	Nr 59
Ukraine	7706	EC of Communal Non-profit Enterprise 'Kherson City Clinical Hospital n.a. Ye.Ye. Karabelesh'22/1, Ushakova Str. Kherson, 73000	O. I. Demediuk	13-May-21	Nr 10-СП

Ukraine	7707	EC of ME Dnipro Multifield Clinical Hospital #4, 31, Blyzhnya street Dnipro 49102	M.D. Shynkarenko	13-May-21	Nr 11
United Kingdom	Central: 2804	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central: 2816	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central: 2817	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central:	The Old Chapel	Professor Catherine Urch	06-Jan-21	

	2819	Royal Standard Place, Nottingham NG1 6FS			REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central: 2821	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central: 2823	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United States of America	Central: 7801	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7802	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA

United States of America	Central: 7805	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7806	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7807	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7810	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7811	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA

United States of America	Central: 7812	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7814	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7815	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7816	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7818	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA

United States of America	Central: 7821	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7825	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7826	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7827	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7829	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA

United States of America	Central: 7831	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7833	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7834	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7835	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7836	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA

United States of America	Central: 7837	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7838	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA

IEC independent ethics committees, *IRB* institutional review board.