

OFICIO 3000-0511-24

Bogotá D.C., mayo de 2024

Asunto: Acuso Recibo de Eventos Adversos Serios

Dando cumplimiento a lo estipulado en la Resolución No. 2011020764 del 10 de junio de 2011 “*Por la cual se establece el reglamento relativo al contenido y periodicidad de los reportes de eventos adversos en la fase clínica con medicamentos en humanos de que trata el artículo 146 del decreto 677 de 1995*”, la Dirección de Medicamentos y Productos Biológicos del **Invima**, da acuso de recibo de la información allegada con los siguientes radicados, correspondientes al reporte de eventos adversos serios nacionales e internacionales y otros documentos relacionados. El Invima en cualquier momento y como parte del proceso de análisis de la información, podrá requerir datos adicionales, para efectos de Inspección, Vigilancia y Control.

Eventos Adversos Serios Nacionales

RADICADO	FECHA RADICADO	PATROCINADOR o CRO	CODIGO INVIMA
20211021657	2021-02-10	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211021623	2021-02-10	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211022154	2021-02-10	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211022391	2021-02-11	Bayer S.A.	PI-BH-773
20211022656	2021-02-11	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023029	2021-02-11	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023034	2021-02-11	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211023042	2021-02-11	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023051	2021-02-11	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023060	2021-02-11	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023133	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023137	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023163	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023185	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023198	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023241	2021-02-12	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211023273	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023291	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023323	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023356	2021-02-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211023398	2021-02-12	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267

20211023424	2021-02-12	Apellis Pharmaceutical, Inc. / Intriols S.A.S.	PI-AL-1304
20211023511	2021-02-12	Bayer S.A.	PI-BH-773
20211017066	2021-02-03	Bayer S.A.	PI-BH-1012
20211023583	2021-02-12	Abbvie S.A.S.	PI-ABS-1321
20221177966	2022-08-10	Regeneron Pharmaceuticals, Inc. / Parexel International de Colombia S.A.S.	EO-PA-230
20211024390	2021-02-15	Bayer S.A.	PI-BH-1012
20211024405	2021-02-15	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211024493	2021-02-15	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211024511	2021-02-15	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211024532	2021-02-15	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211024562	2021-02-15	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211024577	2021-02-15	Bayer S.A.	PI-BH-773
20211024590	2021-02-15	Clínica CES	PI-CES-1410
20211025672	2021-02-16	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211023074	2021-02-11	Bayer S.A.	PI-BH-773
20211026194	2021-02-16	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211026591	2021-02-17	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211026597	2021-02-17	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211027524	2021-02-17	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211027530	2021-02-17	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211027532	2021-02-17	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211028308	2021-02-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211028484	2021-02-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211028500	2021-02-18	Bayer S.A.	PI-BH-773
20211028757	2021-02-19	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211028765	2021-02-19	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211028774	2021-02-19	Clínica CES	PI-CES-1410

20211028783	2021-02-17	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20241003699	2024-01-09	Sanofi Pasteur Inc. / Parexel International Colombia S.A.S.	PI-SA-1513
20211028904	2021-02-19	Bayer S.A.	PI-BH-773
20211028902	2021-02-19	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211028920	2021-02-19	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211029429	2021-02-19	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211035646	2021-02-26	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211035668	2021-02-26	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211035700	2021-02-26	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211035734	2021-02-26	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211035753	2021-02-26	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211036773	2021-03-01	Bayer S.A.	PI-BH-1012
20211036822	2021-03-01	Bayer S.A.	PI-BH-1012
20211035813	2021-02-26	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211035829	2021-02-26	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211035958	2021-02-26	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211035961	2021-02-26	Clínica CES	PI-CES-1410
20211036318	2021-03-01	Bayer S.A.	PI-BH-1012
20211036333	2021-03-01	Bayer S.A.	PI-BH-991
20211036359	2021-03-01	Bayer S.A.	PI-BH-773
20211036368	2021-03-01	Bayer S.A.	PI-BH-991
20211036593	2021-03-01	Apellis Pharmaceutical, Inc. / Intriads S.A.S.	PI-AL-1304
20211036696	2021-03-01	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211036801	2021-03-01	GlaxoSmithKline Biologicals SA	PI-GS-1287
20211036853	2021-03-01	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211036860	2021-03-01	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211037504	2021-03-02	Abbvie S.A.S.	PI-ABS-1321
20211037513	2021-03-02	Bayer S.A.	PI-BH-1012

20211037528	2021-03-02	Clínica CES	PI-CES-1410
20211037544	2021-03-02	Clínica CES	PI-CES-1410
20211038159	2021-03-02	Clínica CES	PI-CES-1410
20211038172	2021-03-02	Clínica CES	PI-CES-1410
20211038259	2021-03-02	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211038372	2021-03-02	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211038401	2021-03-02	Clínica CES	PI-CES-1410
20211038424	2021-03-02	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211038717	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211038782	2021-03-03	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211038855	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211039157	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211039174	2021-03-03	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211039278	2021-03-03	Bayer S.A.	PI-BH-1012

20211039296	2021-03-03	Bayer S.A.	PI-BH-1012
20211039313	2021-03-03	Bayer S.A.	PI-BH-1012
20211039353	2021-03-03	Clínica CES	PI-CES-1410
20211039707	2021-03-03	Bayer S.A.	PI-BH-1012
20211039721	2021-03-03	Bayer S.A.	PI-BH-1012
20211039369	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211039400	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211039408	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211039424	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211039637	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211039731	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211039743	2021-03-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211040148	2021-03-03	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211040354	2021-03-04	Clínica CES	PI-CES-1410
20211028932	2021-03-03	Syneos Health	PI-BT-1255

20211029558	2021-03-03	Alvarez Gotuzo Asociados S.A.S	PI-FT-433
20211036325	2021-03-03	PRA Health Sciences	PI-TI-1278
20211036383	2021-03-03	COVANCE SOLUTIONS MADE REAL	PI-BI-1275
20211036732	2021-03-03	Syneos Health	PI-GR-1429
20211038441	2021-03-03	Resolution Latin America	PI-SA-1425
20211040114	2021-03-03	Syneos Health	PI-UL-1281
20211040118	2021-03-03	PPD Colombia S.A.S	PI-ALN-1440
20211040211	2021-03-03	PPD Colombia S.A.S	PI-DI-1032
20211040227	2021-03-03	PPD Colombia S.A.S	PI-ST-1324
20211040234	2021-03-03	PPD Colombia S.A.S	PI-AC-1227
20211040307	2021-03-03	PPD Colombia S.A.S	PI-CC-1166
20211040665	2021-03-03	PPD Colombia S.A.S	PI-BG-1104
20211044720	2021 -03-03	Syneos Health	PI-DT-1138
20211044747	2021- 03 -03	IQVIA RDS COLOMBIA SAS	PI-APH-1370
20211044755	2021-03-03	IQVIA RDS COLOMBIA SAS	PI-APH-1409
20211044859	2021-03-03	IQVIA RDS COLOMBIA SAS	PI-CC-1155

20211044903	2021-03-03	IQVIA RDS COLOMBIA SAS	PI-MEI -1331
20211044711	2021-03-10	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211044729	2021-03-10	Abbvie S.A.S.	PI-ABS-1321

Eventos Adversos Serios Internacionales

RADICADO	FECHA RADICADO	PATROCINADOR o CRO	CODIGO INVIMA
20211013594	29-01-2021	COVANCE SOLUTIONS MADE REAL	PI-BI-1172
20211014680	01-02-2021	BAYER S.A.	PI-BH-991
20211017127	03-02-2021	JJS Medical Research Latam S.A.S.	PI-OB-1171
20211017233	04-02-2021	Chemo Research S.L.	PI-CH-1303
20211022158	11-02-2021	Resolution Latin America	PI-IB-1386
20211022446	11-02-2021	Abbvie S.A.S.	PI-ABS-1099 -PI-ABS-1096
20211023117	12-02-2021	Abbvie S.A.S.	PI-ABS-1016
20211023125	12-02-2021	Abbvie S.A.S.	PI-AB-909
20211036297	01-03-2021	Lat Research S.A.S	PI-IS-1456

20211022422	2021-02-11	Boehringer Ingelheim Colombia S.A./ IQVIA RDS COLOMBIA SAS	PI-LBI-1121
20211023065	2021-02-11	Novo Nordisk A/S	PI-NN-1250
20211023120	2021-02-12	Abbvie S.A.S.	PI-ABS-1211
20211023123	2021-02-12	Abbvie S.A.S.	
20211023176	2021-02-12	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1013
20211023213	2021-02-12	CSL Behring LLC (CSLB) / Fortrea Colombia Ltda (antes Labcorp Colombia Services Ltda).	PI-CS-1244
20211023226	2021-02-12	GlaxoSmithKline Colombia S.A.	PI-GS-1414
20211023244	2021-02-12	PAREXEL International S.A.S. anteriormente SANOFI-AVENTIS DE COLOMBIA S.A. / IQVIA RDS Colombia S.A.S.	PI-SA-1295
20211023414	2021-02-12	AstraZeneca / RPS Colombia LTDA (Compañía del grupo PRA Health Sciences).	PI-AZ-1170
20211023438	2021-02-12	AstraZeneca / PRA Health Sciences Colombia Ltda.	PI-AZ-1129
20211026606	2021-02-17	Bayer S.A.	PI-BH-1012
20211027539	2021-02-17	Bayer S.A.	PI-BH-1004

20211027542	2021-02-17	Bayer S.A.	PI-BH-1012
20211028797	2021-02-19	EirGenix Inc. / PSI CRO Colombia S.A.S.	PI-EG-1297
20211028881	2021-02-19	H.Lundbeck, A/S / ICON Clinical Research	PI-HL-1108
20211028918	2021-02-19	Instituto Kirby / Alvarez Gotuzzo Asociados S en C	PI-IK-1193
20211029518	2021-02-19	Boenringer Ingelheim.S.A./ PAREXEL International Colombia S.A.S.	PI-LBI-1357
20211028848	2021-02-19	Bayer S.A.	PI-BH-1012
20211036622	2021-03-01	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / AbbVie Inc	PI-ALL-1336
20211036757	2021-03-01	Regeneron Pharmaceuticals Inc. / PAREXEL International Colombia S.A.S.	PI-RPH-1361
20211037509	2021-03-02	Chengdu Kanghong Biotechnology Co., Ltd / Syneos Health Colombia Ltda.	PI-CK-1269
20211037515	2021-03-02	Bristol Myers Squibb de Colombia S.A	PI-BM-990
20211037523	2021-03-02	Bristol Myers Squibb de Colombia S.A	PI-BM-1023

20211037539	2021-03-02	Bristol Myers Squibb de Colombia S.A	PI-BM-1332
20211038189	2021-03-02	Bristol Myers Squibb de Colombia S.A	PI-BM-1158
20211038206	2021-03-02	Bristol Myers Squibb de Colombia S.A	PI-BM-1202
20211038207	2021-03-02	Merck KGaA / IQVIA RDS COLOMBIA SAS	PI-MC-1044
20211039188	2021-03-03	Laboratorios Sophia S.A de C.V.	PI-LSO-1135
20211039333	2021-03-03	Bristol Myers Squibb de Colombia S.A	PI-BM-1202
20211040027	2021-03-04	AstraZeneca	PI-AZ-1337
20211040045	2021-03-04	Shire Human Genetic Therapies, Inc. (Shire) / PPD Colombia S.A.S	PI-SH-1218
20211040057	2021-03-04	Shire Human Genetic Therapies, Inc. (Shire) / PPD Colombia S.A.S	PI-SH-1218
20211040072	2021-03-04	Shire Human Genetic Therapies, Inc. (Shire) / PPD Colombia S.A.S	PI-SH-1218
20211040162	2021-03-04	AstraZeneca / IQVIA RDS COLOMBIA SAS	PI-AZ-1245
20211040186	2021-03-04	KINEX PHARMACEUTICALS INC. / ATHENEX – CIDAL COLOMBIA S.A.S.	PI-KP-1106

20211040210	2021-03-04	Shire Human Genetic Therapies, Inc. (Shire) / PPD Colombia S.A.S	PI-SH-1218
20211040337	2021-03-04	Acerta Pharma, BV / PPD Colombia S.A.S	PI-ACE-1000
20211040371	2021-03-04	CureVac AG / RPS Colombia Ltda. / PRA Health Sciences Colombia Ltda.	PI-CV-1459
20211040393	2021-03-04	GlaxoSmithkline Research & Development Limited / PPD Colombia S.A.S.	PI-GS-1132
20211040411	2021-03-04	Bristol Myers Squibb de Colombia S.A.	PI-BM-1144
20211040420	2021-03-04	Aptevo BioTherapeutics, LLC. / PSI CRO Colombia S.A.S	PI-ABT-1334
20211040680	2021-03-04	P-(MP) Millennium Pharmaceuticals, Inc. / PPD Colombia S.A.S	PI-MP-969
20211040709	2021-03-04	Biogen Idec Reserch Limited / IQVIA RDS Colombia S.A.S	PI-BG-1313
20211041995	2021-03-05	Novartis de Colombia S.A. / PAREXEL International Colombia S.A.S.	PI-NO-1277
20211044616	2021-03-05	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211044620	2021-03-09	Eli Lilly and Company / PPD Colombia S.A.S	PI-EL-1312
20211044624	2021-03-09	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271

20211044629	2021-03-09	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211044632	2021-03-09	Esperion Therapeutics, Inc / IQVIA RDS COLOMBIA SAS	PI-ET-1127
20211044692	2021-03-10	Human Genome Sciences, Inc. / IQVIA RDS COLOMBIA SAS	PI-HGS-723
20211044699	2021-03-10	Akebia Therapeutics, Inc. / IQVIA RDS COLOMBIA SAS	PI-AT-1142
20211044753	2021-03-10	Eli Lilly and Company / PPD Colombia S.A.S	PI-EL-1312
20211044774	2021-03-10	Novo Nordisk A/S	PI-NN-1309
20211044820	2021-03-10	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211044837	2021-03-10	R-Pharm / IQVIA RDS COLOMBIA SAS	PI-RPH-1085
20211044927	2021-03-10	GENFIT / Labcorp Colombia Services LTDA.	PI-GF-1078
20211045812	2021-03-11	AstraZeneca / Fortrea Colombia Ltda. (antes Labcorp Colombia Services Ltda).	PI-AZ-1399

20211045828	2021-03-11	Productos Roche S.A.	PI-RO-1343
20211045839	2021-03-11	Productos Roche S.A.	PI-RO-1175
20211045845	2021-03-11	Productos Roche S.A.	PI-RO-1343
20211045878	2021-03-11	P-(FH) F. Hoffmann- La Roche Ltd / IQVIA RDS COLOMBIA SAS	PI-FH-975

Atentamente,

SANDRA MARÍA MONTOYA ESCOBAR

Director Técnico de Medicamentos y Productos Biológicos

Proyectó: Grupo de Investigación Clínica