

OFICIO 3000-0460-23

Bogotá D.C., mayo 2023

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
20231077312	27/03/2023	Sanofi Pasteur S.A.	PI-SAP-1513
20201162109	11/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201162097	11/09/2020	Bayer S.A.	PI-BH-1012
20201164599	15/09/2020	Pfizer Inc. / ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-PF-899
20201166757	17/09/2020	Bayer S.A.	PI-BH-1012
20201166823	17/09/2020	Bayer S.A.	PI-BH-1012
20201166927	17/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201166940	17/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201162107	11/09/2020	Bayer S.A.	PI-BH-1012
20201167825	18/09/2020	Bayer S.A.	PI-BH-1012
20201167848	18/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201162105	11/09/2020	Bayer S.A.	PI-BH-1012
20201167906	18/09/2020	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211225586	26/10/2021	Janssen Vaccines & Prevention B.V. / IQVIA	PI-JC-1419

20201166672	16/09/2020	Pfizer Inc. / ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-PF-899
20221122586	22/06/2022	Bayer S.A.	PI-BH-1408
20201167840	18/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201165629	16/09/2020	Fundación Valle de Lili	PI-FV-1376
20211212927	13/10/2021	Janssen Vaccines & Prevention B.V./ IQVIA RDS COLOMBIA S.A.S	PI-JC-1445
20201162278	11/09/2020	Fundación Valle de Lili	PI-FV-1376
20201166783	17/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201167929	18/09/2020	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20201167956	18/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201168924	21/09/2020	Colegio Mayor Nuestra Señora del Rosario	PI-CMR-1377
20201168957	21/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201167854	18/09/2020	Centro de Estudios en Infectología Pediátrica S.A.S.	PI-CEIP-1390
20201168930	21/09/2020	Bayer S.A.	PI-BH-773
20201169011	21/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201160943	09/09/2020	Bayer S.A.	PI-BH-1012
20201169049	21/09/2020	Bayer S.A.	PI-BH-1012
20201169066	21/09/2020	Bayer S.A.	PI-BH-1012
20201169088	21/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201169118	21/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201169175	21/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115

20201170140	22/09/2020	Novartis de Colombia S.A. / PAREXEL International Colombia S.A.S.	PI-NO-1280
20201170342	22/09/2020	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20201170359	22/09/2020	Bayer S.A.	PI-BH-991
20201170359	22/09/2020	Bayer S.A.	PI-BH-991
20201170399	22/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201170425	22/09/2020	Chengdu Kanghong Biotechnology Co., Ltda. / Syneos Health Colombia Ltda.	PI-CK-1269
20201170454	22/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201171200	22/09/2020	Centro de Estudios en Infectología Pediátrica S.A.S.	PI-CEIP-1390
20201171244	23/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201171246	23/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201171248	23/09/2020	Bayer S.A.	PI-BH-1012
20201171250	23/09/2020	Bayer S.A.	PI-BH-773
20201171252	23/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201171262	23/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201171270	23/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201171275	23/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201171566	23/09/2020	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1312
20201171590	23/09/2020	Bayer S.A.	PI-BH-1012
20201172582	24/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201172705	24/09/2020	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201172761	24/09/2020	Bayer S.A.	PI-BH-1012
20201172810	24/09/2020	Bayer S.A.	PI-BH-773
20201172830	24/09/2020	Bayer S.A.	PI-BH-1012

Eventos Adversos Serios Internacionales

RADICADO	FECHA RADICADO	PATROCINADOR o CRO	CODIGO INVIMA
20201162122	11/09/2020	Bayer S.A.	PI-BH-991
20201164639	15/09/2020	Allievex Corporation / Labcorp Colombia Services LTDA	PI-BI-1275
20211227664	28/10/2021	Icahn School of Medicine at Mount Sinai / LA Research SAS	PI-IS-1456
20201166846	17/09/2020	I.R.I.S (institut de recherches internationales servier) / PAREXEL International Colombia S.A.S.	PI-IRI-852
20201158749	08/09/2020	Allergan Sales, LLC. / PAREXEL International Colombia S.A.S.	PI-ALL-1264
20201206176	05/11/2020	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20201166860	17/09/2020	Boehringer Ingelheim Colombia S.A. / IQVIA RDS COLOMBIA SAS	PI-LBI-1121
20201168866	20/09/2020	Novo Nordisk A/S	PI-NN-1250
20201168868	20/09/2020	Astrazeneca AB / RPS Colombia Ltda (Compañía del grupo PRA Health Sciences).	PI-AZ-1170
20201166871	17/09/2020	Bayer S.A.	PI-BH-773
20201154635	02/09/2020	Amgen Inc, / IQVIA RDS Colombia S.A.S.	PI-AG-1323
20201168850	20/09/2020	Abbvie S.A.S.	PI-ABS-1211
20201168853	20/09/2020	Abbvie S.A.S.	PI-AB-909
20201168870	20/09/2020	AstraZeneca / PRA Health Sciences Colombia Ltda.	PI-AZ-1129
20201169025	21/09/2020	EirGenix Inc. / PSI CRO Colombia S.A.S.	PI-EG-1297
20201169149	21/09/2020	H.Lundbeck, A/S / ICON Clinical Research	PI-HL-1108
20201169131	21/09/2020	H.Lundbeck, A/S / ICON Clinical Research	PI-HL-1108

20201170323	22/09/2020	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1312
20201170378	22/09/2020	Allergan Sales, LLC. / AbbVie Inc.	PI-ALL-1336
20201171254	23/09/2020	Bayer S.A.	PI-BH-1012
20201171256	23/09/2020	Bayer S.A.	PI-BH-1012
20201171277	23/09/2020	Bristol Myers Squibb de Colombia S.A.	PI-BM-831
20201171414	23/09/2020	Tricida, Inc. / RPS Colombia Ltda (Compañía del Grupo PRA Health Sciences)	PI-TI-1278
20201171486	23/09/2020	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1312
20201171506	23/09/2020	Bristol Myers Squibb de Colombia S.A.	PI-BM-1215
20201171576	23/09/2020	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1312
20201172594	24/09/2020	Boehringer Ingelheim Colombia S.A.	PI-LBI-1121
20201172614	24/09/2020	Amryt Research, Ltd. / INC Research Colombia	PI-AR-1208
20201172637	24/09/2020	Aurinia Pharmaceuticals, Inc. / Worldwide Clinical Trials Sucursal Colombia	PI-API-1258
20201172667	24/09/2020	Galapagos NV / INC Research Colombia Ltda.	PI-GAL-844
20201172682	24/09/2020	Bristol Myers Squibb de Colombia S.A.	PI-BM-1202
20201172726	24/09/2020	Bristol Myers Squibb de Colombia S.A.	Patrocinador
20201172731	24/09/2020	Bristol Myers Squibb de Colombia S.A.	PI-BM-1332
20201172744	24/09/2020	Human genome Sciences, Inc. / PAREXEL International Colombia S.A.S.	PI-HGS-726

20201172849	24/09/2020	Human genome Sciences, Inc. / PAREXEL International Colombia S.A.S.	PI-HGS-726
20201172784	24/09/2020	Regeneron Pharmaceuticals, Inc. / ICON Holdings Clinical Research International Limites Sucursal Colombia	PI-RPH-1089
20201172894	24/09/2020	Bristol Myers Squibb de Colombia S.A.	PI-BM-1202
20201172888	24/09/2020	GlaxoSmithkline Research & Development Limited / PPD Colombia S.A.S.	PI-GS-1132
20201173962	25/09/2020	Janssen Research & Development LLC. / PRA Health Sciences Colombia Ltda.	PI-JC-1120
20201173998	25/09/2020	Biogen MA Inc. / IQVIA RDS COLOMBIA SAS	PI-BG-1104
20201174005	25/09/2020	Actelion Pharmaceuticals Ltd./ PPD Colombia S.A.S.	PI-AC-1227
20201174014	25/09/2020	P-(MP) Millennium Pharmaceuticals, Inc. / C-(PPD) PPD Colombia S.A.S.	PI-MP-969
20201174022	25/09/2020	Windtree Therapeutics Inc. Antes Discovery Laboratories Inc. / PPD Colombia S.A.S.	PI-DI-1039
20201174035	25/09/2020	Celgene Corporation / PPD Colombia S.A.S	PI-CC-1166
20201174048	25/09/2020	Shire Human Genetic Therapies Inc. / PPD Colombia S.A.S.	PI-SH-1226
20201174077	25/09/2020	Shire Human Genetic Therapies Inc. / PPD Colombia S.A.S.	PI-SH-1238
20201174087	25/09/2020	Biogen MA Inc. / IQVIA RDS COLOMBIA SAS	PI-BG-1313
20201174100	25/09/2020	Genzyme Corporation / PPD Colombia S.A.S.	PI-GE-1365
20201174111	25/09/2020	Akebia Therapeutics, Inc. / IQVIA RDS COLOMBIA SAS	PI-AT-1055

20201175068	28/09/2020	Takeda Vaccines, Inc. / PPD Colombia S.A.S.	PI-TAK-982
20201175076	28/09/2020	MedImmune, LLC. / IQVIA RDS Colombia S.A.S.	PI-MEI-1330

Atentamente,

SINDY PAHOLA PULGARÍN MADRIGAL

Asesora de la Dirección General

Coordinadora Grupo de Investigación Clínica - Dirección de Medicamentos y Productos Biológicos (DMPB)

Proyectó: Grupo de Investigación Clínica