



OFICIO 3000-0245-21

Bogotá D.C., abril de 2021

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
20201007390	16/01/2020	Bayer S.A.	PI-BH-1012
20201010899	21/01/2020	Bayer S.A.	PI-BH-1012
20201012601	23/01/2020	Pfizer S.A.S.	PI-PF-899
20201012604	23/01/2020	Pfizer Inc.	PI-PF-1146
20201012772	23/01/2020	Amgen Inc.	PI-AG-1115
20201013950	23/01/2020	Bayer S.A.	PI-BH-1012
20201013954	23/01/2020	Bayer S.A.	PI-BH-1012
20201013957	24/01/2020	Bayer S.A.	PI-BH-1010
20201010834	21/01/2020	Novartis de Colombia S.A.	PI-NO-1296
20201032865	19/02/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201032869	19/02/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201032871	19/02/2020	Boehringer Ingelheim Colombia	PI-LBI-1121



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		S.A	
20201032873	19/02/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201034628	20/02/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201034633	20/02/2020	Amgen Biotecnológica S.A.S	PI-AG-1115
20201034763	20/02/2020	Eli Lilly Interamérica Inc.	PI-EL-1257
20201035268	21/02/2020	Janssen Cilag S.A.	PI-JC-1225
20201036016	21/02/2020	Bayer S.A.	PI-BH-1010
20201036023	21/02/2020	Bayer S.A.	PI-BH-1010
20201044925	02/03/2020	Amgen Biotecnológica S.A.S	PI-AG-1115
20201045064	02/03/2020	Novartis de Colombia S. A	PI-NO-1241
20201045772	03/03/2020	Merck S.A	PI-MC-1044 PI-MC-1113 PI-EMD-998
20201047267	03/03/2020	Bayer S.A.	PI-BH-1012
20201047270	03/03/2020	Bayer S.A.	PI-BH-1010
20201047274	03/03/2020	Bayer S.A.	PI-BH-773
20201047280	03/03/2020	MSD	PI-MS-1260 PI-MS-1261
20201050374	04/03/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201050377	04/03/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201051369	04/03/2020	Amgen Biotecnológica S.A.S	PI-AG-1115
20201051516	04/03/2020	Bayer S.A.	PI-BH-1010
20201051529	04/03/2020	Bayer S.A.	PI - BH-773
20201047260	03/03/2020	Bayer S.A.	PI-BH-1010
20201026989	12/02/2020		
20201007229	16/01/2020	Eli Lilly and Company	PI-EL-1257



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20201047262 CO2000046212	03/03/2020 27/02/2020	Bayer S.A.	XOFIGO
20201061525 20201047267	04/03/2020 03/03/2020	Bayer S.A.	PI-BH-1012
20201051528 20191254916	04/03/2020 19/12/2019	Bayer S.A.	PI-BH-1012
20201052010	05/03/2020	Bristol-Myers Squibb de Colombia S.A.	PI-BM-1282 PI-BM-1001 PI-BM-1065 PI-BM-1158 PI-BM-1081 PI-BM-1095 PI-BM-1325 PI-BM-1320 PI-BM-1201 PI-BM-1202
20201004428	13/01/2020	Amgen Biotecnológica S.A.S	PI-AG-1115
20201004607	13/01/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201004694	13/01/2020	ABBVIE	PI-ABS-1259
20201004707	13/01/2020	Bayer S.A.	PI-MS-1299 PI-MS-1235 PI-MS-1299 PI-MS-1299 PI-MS-12-61 PI-MS-12-61



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			PI-MS-1235 PI-MS-1248 PI-MS-1299 PI-MS-1273 PI - BH-773
20201006271	15/01/2020	MSD	
20201006490	15/01/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201006632	15/01/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201006634	15/01/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20201010905	21/01/2021	Bayer S.A.	PI-BH-1012
20201011873	22/01/2021	Bayer S.A.	PI-BH-1004
20201011876	22/01/2021	Bayer S.A.	PI-BH-1004
20201012838	22/01/2021	Novartis de Colombia S.A.	PI-NO-1277
20201013850	22/01/2021	Novartis de Colombia S.A.	PI-NO-1277
20201014839	27/01/2020	Boehringer Ingelheim Colombia S.A.	PI-LBI-1121
20201015972	28/01/2020	Bayer S.A.	PI-BH-1012
20201016805	29/01/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201016924	29/01/2020	Bayer S.A.	PI-BH-991
20201016927	29/01/2020	Bayer S.A.	PI-BH-991
20201018526	31/01/2020	Boehringer Ingelheim Colombia S.A.	PI-LBI-1121
20201018529	31/01/2020	Boehringer Ingelheim Colombia S.A.	PI-LBI-1121
20201019690	03/02/2020	Pfizer S.A.S.	PI-PF-899
20201019934	03/02/2020	Amgen Biotecnológica SAS	PI-AG-1115



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20201020138	03/02/2020	Bayer S.A.	PI-BH-1012
20201016929	29/01/2020	Bayer S.A.	PI-BH-1012
20201018800	31/01/2020	Novartis de Colombia S.A.	PI-NO-1277
20201021555	25/02/2020	OPKO Biologics Ltda	PI-OB-1171
20201010834	21/01/2020	Novartis de Colombia S.A.	PI-NO-1277
20201024841	10/02/2020	Bayer S.A.	PI-BH-991
20201024849	10/02/2020	Bayer S.A.	PI-BH-1010
20201024852	10/02/2020	Bayer S.A.	PI-BH-1010
20201025537	11/02/2020	Pfizer Colombia S.A.S.	PI-PF-899
20201025828	11/02/2020	Bayer S.A.	PI-BH-1012
20201025829	11/02/2020	Bayer S.A.	PI-BH-773
20201025856	11/02/2020	Merck Sharp & Dohme Colombia S.A.S.	PATROCINADOR
20201026907	12/02/2020	Eli Lilly and Company	PI-EL-1257
20201026989	12/02/2020	Bayer S.A.	PI-BH-1010
20201027689	13/02/2020	Pfizer S.A.S.	PI-PF-1146
20201027908	13/02/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201028022	13/02/2020	Bayer S.A.	PI-BH-1012
20201028028	13/02/2020	Bayer S.A.	PI-BH-1010
20201029274	14/02/2020	Bayer S.A.	PI-BH-773
20201029293	14/02/2020	Bayer S.A.	PI-BH-1012
20201030324	17/02/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201030461	17/02/2020	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1273
20201031297	17/02/2020	Pfizer Colombia S.A.S.	PI-PF-899
20201031659	18/02/2020	Merck Sharp & Dohme Colombia S.A.S.	PATROCINADOR
20201024837	10/02/2020	Bayer S.A.	PI-BH-991



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20201024854	10/02/2020	Bayer S.A.	PI-BH-1012
20201028047	13/02/2020	Bayer S.A.	PI-BH-1010
20201029195	14/02/2020	Novartis de Colombia S.A.	PI-NO-1277
20201029350	14/02/2020	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1273
20201036046	21/02/2020	Bayer S.A.	PI-BH-1012
20201036054	21/02/2020	Bayer S.A.	PI-BH-1010
20201036144	21/02/2020	Merck Sharp & Dohme Colombia S.A.S.	PATROCINADOR
20201037035	21/02/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201037838	25/02/2020	Pfizer Colombia S.A.S.	PI-PF-899
20201038278	25/02/2020	Bayer S.A.	PI-BH-1012
20201038283	25/02/2020	Bayer S.A.	PI-BH-1010
20201038288	25/02/2020	Bayer S.A.	PI-BH-773
20201038294	25/02/2020	Bayer S.A.	PI-BH-1010
20201039881	26/02/2020	Pfizer Colombia S.A.S.	PI-PF-1146
20201039939	26/02/2020	Novartis de Colombia S.A.	PI-NO-1277
20201040037	26/02/2020	Bayer S.A.	PI-BH-1012
20201040039	26/02/2020	Bayer S.A.	PI-BH-1012
20201040042	26/02/2020	Bayer S.A.	PI-BH-1012
20201040045	26/02/2020	Bayer S.A.	PI-BH-1010
20201040047	26/02/2020	Bayer S.A.	PI-BH-1010
20201040445	27/02/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201040448	27/02/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201040679	27/02/2020	Pfizer Colombia S.A.S.	PI-PF-899
20201040838	27/02/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201040840	27/02/2020	Amgen Biotecnológica SAS	PI-AG-1115
20201040852	27/02/2020	Sanofi Pasteur S.A.	PI-SAP-1033



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20201040869	27/02/2020	Sanofi Pasteur S.A.	PI-SAP-1033
20201041016	27/02/2020	Bayer S.A.	PI-BH-1012
20201042120	27/02/2020	Bayer S.A.	PI-BH-1012
20201042123	27/02/2020	Bayer S.A.	PI-BH-1012
20201042135	28/02/2020	Merck Sharp & Dohme Colombia S.A.S.	PATROCINADOR
20201036027	21/02/2020	Bayer S.A.	PI-BH-1010
20201036030	21/02/2020	Bayer S.A.	PI-BH-1010
20201036060	21/02/2020	Bayer S.A.	PI-BH-1010
20201036728	24/02/2020	Bayer S.A.	PI-BH-1012
20201036732	24/02/2020	Bayer S.A.	PI-BH-1010
20201038282	25/02/2020	Bayer S.A.	PI-BH-1012
20201036737	24/02/2020	Bayer S.A.	PI-BH-1010
20191139576	29/07/2019	Boehringer Ingelheim Colombia S.A.	PI-LBI-1121
20201053932	06/03/2020	Bayer S.A.	PI-BH-1010
20201053954	06/03/2020	Bayer S.A.	PI - BH-773
20201054101	06/03/2020	Productos Roche SA	MN39889
20201055303	09/03/2020	Bayer S.A.	PI - BH-773
20201055138	09/03/2020	Amgen Biotecnológica S.A.S	PI-AG-1115
20201055306	09/03/2020	Bayer S.A.	PI-BH-1010
20201053924	06/03/2020	Bayer S.A.	PI-BH-1010
20201047270	03/03/2020		
20201055183	09/03/2020	Syneos Health Colombia Ltda.	PI-DT-1138
20201056360	10/03/2020	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1273 PI-MS-1261 PI-MS1261 PI-MS-1314



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Eventos Adversos Serios Internacionales

RADICADO	FECHA	PATROCINADOR o CRO	CODIGO INVIMA
20201004612	13/01/2020	Daiichi Sankyo Inc.	PI-DSK-1194
20201004617	13/01/2020	Esperion Therapeutics , Inc	PI-ET-1127
20201004618	13/01/2020	Human genome Sciences, Inc	PI-HGS-723
20201022013	02/02/2020	Abbvie S.A.S.	PI-AB-909
20201022018	05/02/2020	Abbvie S.A.S.	PI-ABS-1016
20201022030	05/02/2020	Abbvie S.A.S.	PI-ABS-1096
20201007229	16/01/2020	Eli Lilly and Company	PI-EL-1257
20201040963	27/02/2020	Bristol-Myers Squibb de Colombia S.A.	Bristol-Myers Squibb de Colombia S.A.
20201040965	27/02/2020	Bristol-Myers Squibb de Colombia S.A.	Bristol-Myers Squibb de Colombia S.A.
20201041915	28/02/2020	I.R.I.S (Institut de Recherches Internationales Servier)	PI-IRI-852
20201034709	20/02/20	MSD	MSD
20201050290	04/03/2020	Daiichi Sankyo/IQVIA	DU176b-D-U312
20201050292	04/03/2020	Gilead Sciences International /Syneos	PI-GAL-844
20201050298	04/03/2020	Kowa Research Institute/IQVIA	PI-KW-1124
20201050301	04/03/2020	IQVIA RDS COLOMBIA SAS	BEL 205646
20201050354	04/03/2020	PAREXEL en nombre de GSK	PI-HGS-726
20201051452	04/03/2020	ICON CLINICAL RESERACH	PI-RPH-1185
20201051928	05/03/2020	ACADIA Pharmaceuticals Inc/Worldwide Clinical Trials - Colombian Branch /PAREXEL International Colombia S.A.S	PI-ADP1270



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		(Safety Reports)	
20201051931	05/03/2020	ACADIA Pharmaceuticals Inc/Worldwide Clinical Trials - Colombian Branch /PAREXEL International Colombia S.A.S (Safety Reports)	PI-ADP1271
20201060305	04/03/2020	IQVIA RDS COLOMBIA SAS	161403
20201060310	04/03/2020	IQVIA RDS COLOMBIA SAS	161505
20201050312	04/03/2020	IQVIA RDS COLOMBIA SAS	PI-TAK-982
20201050383	04/03/2020	Boehringer Ingelheim Colombia S.A	PI-LBI-1197
20201051789	04/03/2020	Laboratorios SOPHIA S.A DE C.V	PI-LSO-1135
20201052571	05/03/2020	Bristol-Myers Squibb de Colombia S.A.	BMS-663068
20201052573	05/03/2020	GSK	PI-GS-1287
20201002787	09/01/2020	Productos Roche S.A.	PI-RO-1031
20201002789	09/01/2020	Roche S.A	PI-RO-701
20201002790	09/01/2020	Roche S.A	PI-RO-789
20201002793	09/01/2020	Productos Roche S.A.	PI-PR-1233
20201002795	09/01/2020	Roche S.A.	PI-RO-656
20201002800	09/01/2020	Roche S.A.	PI-RO-1116
20201002953	09/01/2020	Novartis de Colombia S.A	PI-NO-1229
20201003895	13/01/2020	P-(MP) Millennium Pharmaceuticals, Inc	PI-MP-969
20201018475	31/01/2020	Pfizer Colombia S.A.S.	PI-PF-899



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20201021850	05/02/2020	Boehringer Ingelheim Colombia S.A.	PI-LBI-1121
20201022026	05/02/2020	Abbvie S.A.S.	PI-ABS-1143
20181263257	18/03/2018	H.Lundbeck, A/S	PI-HL-1108
20181263259	20/12/2018	H.Lundbeck, A/S	PI-HL-1108
20181263260	20/12/2018	H.Lundbeck, A/S	PI-HL-1108
20201039980	26/02/2020	Bristol Myers Squibb de Colombia S.A.	PI-BM-831
20201040537	27/02/2020	PUMA BIOTECHNOLOGY. INC	PI-LW-357
20201040904	27/02/2020	BioMarin Pharmaceutical Inc.	PI-BI-1275
20201040957	27/02/2020	Bristol Myers Squibb de Colombia S.A.	PI-BM-1282
20201044742	02/03/2020	KINEX PHARMACEUTICALS INC	PI-KP-1106
20201045099	02/03/2020	Bristol Myers Squibb de Colombia S.A.	PI-BM-1202
20201046898	03/03/2020	Astellas Pharma Global Development, Inc	PI-AS-1267
20201046974	03/03/2020	Astrazeneca	PI-AZ-1245
20201047163	03/03/2020	Amryt Research limited	PI-AR-1208
20201050285	03/03/2020	Celgene Corporation	PI-CC-1155
20201003863	13/01/2020	Shire Human Genetic Therapies Inc.	PI-SH-1226
20201003873	13/01/2020	Nektar Therapeutics	PI-NT-1291
20201003868	13/01/2020	Shire Human Genetic Therapies Inc.	PI-SH-1218
20201003875	13/01/2020	P-(ALL) ALLERGAN	PI-ALL-996



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20201003888	13/01/2020	Shire Human Genetic Therapies Inc.	PI-SH-1216
20201003876	13/01/2020	ACERTA PHARMA, BV	PI-ACE-1000
20201003879	13/01/2020	Celgene Corporation	PI-CC-1166
20181268451	27/12/2018	Gilead Sciences, Inc.	PI-GIS-1032
20191095022	21/05/2019	Allergan Inc.	PI-ALL-1019
20191126232	04/07/2019	Regeneron Pharmaceuticals, Inc.	PI-RPH-1089
20191139735	23/07/2019	Bayer S.A.	PI-BH-1237
20191140971	24/07/2019	BioMarin Pharmaceutical Inc.	PI-BI-1172
20191139732	28/07/2019	Bayer S.A.	PI-BH-1139
20191221883	12/11/2019	Bristol Myers Squibb de Colombia S.A.	PI-BM-1001
20191161860	22/08/2019	Tricida, Inc.	PI-TI-1278
20191168582	30/08/2019	Kezar Life Sciences	PI-UL-1281
20191171253	03/09/2019	Regeneron Pharmaceuticals	PI-RPH-1089
20191196883	07/10/2019	AstraZeneca	PI-AZ-1170
20191196888	07/10/2019	AstraZeneca	PI-AZ-1129
20191203802	17/10/2029	Lundbeck	PI-HL-1196
20191214034	30/10/2019	Kezar Life Sciences	PI-UL-1281
20191217439	05/11/2019	AstraZeneca	D3250C00057
20191219419	07/11/2019	Gilead Sciences International	PI-GAL-
20211150773	06/08/2019	AstraZeneca	D1680C008019
20191156267	14/08/2019	Kezar Life Sciences	PI-UL-1281



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20191192593	01/10/20019	Amgen Inc / RPS Colombia Ltda (PRA Health Sciences)	PI-AG-1169
20191198555	09/10/2019	Syneos Health	PI-BT-1255
20191207590	22/10/2019	Tricida Inc/ RPS Colombia Ltda (PRA Health Sciences)	PI-TI-1278
20201052614	05/03/2020	Amgen Inc / RPS Colombia Ltda (PRA Health Sciences)	PI-AG-1323 PI-AG-1322
20201052620	05/03/2020	Amgen Inc / RPS Colombia Ltda (PRA Health Sciences)	PI-AG-1075 PI-AG-1163
20201054087	09/03/2020	Productos Roche SA	PI-RO-1175
20191120845	26/06/2019	Gilead Sciences, Inc.	PI-GIS-1032
20191150771	06/08/2019	Astrazeneca	PI-AZ-1129

Atentamente,

GUILLERMO JOSÉ PÉREZ BLANCO

Director Técnico de Medicamentos y Productos Biológicos

Proyectó: Grupo de Investigación Clínica