



La salud
es de todos

Minsalud

OFICIO 3000-5655-20

Bogotá D.C., 30 de noviembre de 2020

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
20191222110	12/11/2019	Bayer S.A	PI-BH-773
20191174504	09/09/2019	Roche S.A	PI-RO-701
20191174507	09/09/2019	Productos Roche S.A.	PI-RO-994
20191222112	12/11/2019	Bayer S.A	PI-BH-773
20191222796	13/11/2019	Pfizer S.A.S	PI-PF-1146
20191222799	13/11/2019	Pfizer S.A.S	PI-PF-899
20191223156	13/11/2019	Boehringer Ingelheim S.A	PI-LBI-1121
20191200512	11/10/2019	Pfizer S.A.S	PI-PF-1146
20191200909	11/10/2019	Bayer S.A	PI-BH-1010
20191200914	11/10/2019	Bayer S.A	PI-BH-773
20191210766	25/10/2019	Bayer S.A	PI-BH-1012
20191210787	25/10/2019	Bayer S.A	PI - BH-773
20191210794	25/10/2019	Bayer S.A	PI-BH-1012
20191210796	25/10/2019	Bayer S.A	PI-BH-1012



La salud
es de todos

Minsalud

20191210790	25/10/2019	Bayer S.A	PI - BH-773
20191210820	25/10/2019	Bayer S.A	PI - BH-1010
20191210811/ 20191197998	25/10/2019/ 08/10/2019	Bayer S.A	PI-BH-1010
20191210814/ 20191174447	25/10/2019/ 06/09/2019	Bayer S.A	PI-BH-1010
20191210817/ 170080241	25/10/2019/ 28/07/2017	Bayer S.A	PI-BH-1010
20191200921/ 20191192772	11/10/2019/ 1/10/2019	Bayer S.A	PI-BH-1012
20191200923/ 20191110067	11/10/2019/ 11/06/2019	Bayer S.A	PI-BH-1237
20191200925/ 20191170251 20191171352	11/10/2019/ 2-3/09/2019	Bayer S.A	PI-BH-1237
20191200927/ 20191185047	11/10/2019/ 20/09/2019	Bayer S.A	PI-BH-773
20191210823/ 20191193596	25/10/2019/ 02/10/2019	Bayer S.A	PI-BH-1004
20191210826/ 20191196831	25/10/2019/ 07/10/2019	Bayer S.A	PI-BH-112
20191210829/ 20191191671	25/10/2019/ 30/10/2019	Bayer S.A	PI-BH-1004
20191210833	25/10/2019	Bayer S.A	PI-BH-1012
20191210833	28/10/2019	Bayer S.A	PI-BH-773
20191211274	28/10/2019	Bayer S.A	PI-BH-773



La salud
es de todos

Minsalud

20191211276	28/10/2019	Bayer S.A	PI-BH-1010
20191211278	28/10/2019	Bayer S.A	PI-BH-773
20191222650	13/11/2019	Bayer S.A	PI-BH-1237
20191223158	13/11/2019	Boehringer Ingelheim S.A	PI-LBI-1121
20191223241	13/11/2019	Merck Sharp & Dohme	PI-MS-1130 PI-MS-941 PI-MS-1261 PI-MS-1260 PI-MS-1003 PI-MS-1279
20191223278	13/11/2019	Covance Colombia Services LTDA	PI-BI-1172
20191225579	15/11/2019	Bayer S.A	PI-BH-1010
20191225581	15/11/2019	Bayer S.A	PI-BH-1004
20191225587	15/11/2019	Bayer S.A	PI-BH-1010
20191225588	15/11/2019	Bayer S.A	PI-BH-1012
20191198737	09/10/2019	Sanofi Aventis de Colombia S.A.	PI-QC-425
20191199791	10/10/2019	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20191199800	10/10/2019	Amgen Inc	PI-AG-1115
20191199923	10/10/2019	Bayer S.A	PH-BH-773
20191196434	07/10/2019	Bayer S.A.	PI-BH-773
20191195538	04/10/2019	Bayer S.A.	PI-BH-773
20191195730	04/10/2019	Merck Sharp & Dohme	PI-MS-1260
20191196437	07/10/2019	Bayer S.A.	PI-BH-1012
20191196446	07/10/2019	Bayer S.A.	PI-BH-773
20191195549	04/10/2019	Bayer S.A.	PI-BH-773
20191196451	07/10/2019	Bayer S.A.	PI-BH-1237
20191196454	07/10/2019	Bayer S.A.	PI-BH-1012



La salud
es de todos

Minsalud

20191195544	04/10/2019	Bayer S.A.	PI-BH-1012
20191197990	08/10/2019	Bayer S.A.	PI-BH-1010
20191197991	08/10/2019	Bayer S.A.	PI-BH-1010
20191197995	08/10/2019	Bayer S.A.	PI-BH-1012
20191197998	08/10/2019	Bayer S.A.	PI-BH-1010
20191198002	08/10/2019	Bayer S.A.	PI-BH-1010
20191195536	04/10/2019	Bayer S.A.	PI-BH-1010
20191198735	09/10/2019	Sanofi Pasteur S.A.	PI-SAP-1033
20191218479	06/11/2019	MSD	PI-MS-1235/PI-MS-1261/ PI-MS-1260/PI-MS- 1203/PI-MS-1130/PI-MS- 941/PI-MS-1203
20191202804	16/10/2019	Pfizer Colombia S.A.S.	PI-PF-899
20191200928	11/10/2019	Bayer S.A.	PI-BH-1012
20191201630	16/10/2019	Pfizer Colombia S.A.S	PI-PF-899
20191201903	15/10/2019	Amgen Inc	PI-AG-1115
20191202054	15/10/2019	Merck Sharp & Dohme Colombia S.A.S	PI-MS-1151
20191202798	16/10/2019	ICON Clinical Research	PI-PF-1146
20191203715	17/10/2019	Pfizer Colombia S.A.S	PI-PF-899
20191203958	17/10/2019	Boehringer Ingelheim Colombia S.A.	PI-LBI-1121
20191211281	28/10/2019	Bayer S.A.	PI - BH-1010
20191211283	28/10/2019	Bayer S.A.	PI-BH-1012
20191195541	19/10/2019	Bayer S.A.	PI-BH-1012
20191211558	28/10/2019	Pfizer Colombia S.A.S	PI-PF-899
20191212489	28/10/2019	Pfizer Colombia S.A.S	PI-PF-899
20191213602	30/10/2019	Pfizer Colombia S.A.S	PI-PF-899
20191213906	30/10/2019	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1261



La salud
es de todos

Minsalud

20191218200	06/11/2019	Syneos Health Colombia Ltda	PI-DT-1138
20191219563	07/11/2019	IQVIA	N/A
20191224276	14/11/2019	Laboratorios Sophia S.A de CV/ Laboratorios Sophia de Colombia Ltda	PI-LSO-1135
20191220452	08/11/2019	Pfizer S.A.S / ICON Clinical Research representado en Colombia por ICON Holdings Clinical Research International Sucursal Colombia	PI-PF-1146
20191220887	08/11/2019	MSD	PI-MS-1082
20191220956	08/11/2019	Bayer S.A	PI - BH-1010
20191220960	08/11/2019	Bayer S.A	PI-BH-1012
20191220964	08/11/2019	Bayer S.A	PI - BH-773
20191221818	12/11/2020	Amgen Biotecnológica S.A.S	PI-AG-1115
20191220890	08/11/2019	MSD	PI-MS-1260
20191220774	08/11/2019	NOVARTIS	NR
20191229146 20191229149 20191229151 20191229155 20191229158 20191229166 20191229169	20/11/2019	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20191229197	20/11/2019	Amgen Biotecnológica S.A.S	PI-AG-1115
20191229360	20/11/2019	Bayer S.A	PI-BH-1004
20191229367 20191229373	20/11/2019	Bayer S.A	PI-BH-1010
20191227649	19/11/2019	Pfizer S.A.S / ICON Clinical Research representado en Colombia por ICON Holdings Clinical Research International Sucursal Colombia	PI-PF-1146
20191227885	19/11/2019	Amgen Biotecnológica S.A.S	PI-AG-1115



La salud
es de todos

Minsalud

20191211285	28/10/2019	Bayer S.A	PI-BH-1012
20191211288	28/10/2019	Bayer S.A	PI-BH-1010

Eventos Adversos Serios Internacionales

RADICADO	FECHA RADICADO	PATROCINADOR o CRO	CODIGO INVIMA
20191220476	08/11/2019	ACADIA Pharmaceuticals Inc./PAREXEL International Colombia S.A.S	PI-ADP-1271
20191219463	07/11/2019	Windtree Therapeutics Inc. Antes Discovery Laboratories Inc./PPD Colombia S.A.S.	PI-DI-1039
20191219466	07/11/2019	Biogen MA Inc/PPD Colombia S.A.S.	PI-BG-1104
20191219471	07/11/2019	Vaccine Research Center (VRC)/PPD Colombia S.A.S.	PI-VR-1154
20191220492	08/11/2019	Ipsen Innovation/ Covance Colombia Services Ltda	PI-II-1097
20191209484	24/10/2019	Bristol-Myers Squibb	N/A
20191210505	25/10/2020	PAREXEL /Allergan Sales, LLC.	PI-ALL-1265 PI-ALL-1263 PI-ALL-1264
20191210506	25/10/2020	PAREXEL /PUMA Biotech.	NR
20191210509	25/10/2020	PAREXEL /Allergan Sales, LLC.	PI-ALL-1265 PI-ALL-1263 PI-ALL-1264
20191210510	25/10/2020	PAREXEL /Allergan Sales, LLC.	PI-ALL-1265 PI-ALL-1263 PI-ALL-1264



La salud
es de todos

Minsalud

20191210557	25/10/2020	Covance Colombia Services LTDA	PI-BI-1275
20191210574	25/10/2020	Bristol-Myers Squibb	NR
20191211808	28/10/2019	Bristol-Myers Squibb	NR
20191217283	05/11/2019	Kowa Research Institute	PI-KW-1124
20191217286	05/11/2019	Human genome Sciences, Inc/ IQVIA RDS COLOMBIA SAS	PI-HGS-723
20191211278	05/11/2019	Kinex Pharmaceuticals/CIDAL	PI-KP-1106
20191218007	06/11/2019	IQVIA	PI-RPH-1133
20191195492	04/10/2019	Abbvie S.A.S.	PI-ABS-1173
20191219454	07/11/2019	Nektar Therapeutics / PPD Colombia S.A.S	PI-NT-1291
20191232427	25/11/2019	Bayer S.A	PI-BH-1237
20191236747	29/11/2019	Chendu Kanghong Biotechnology Co., Ltd / Syneos Health	PI-CK-1269
20191236751	29/11/2019	Pfizer S.A.S	PI-PF-1146 PI-PF-899
20191239644	3/12/2019	Bayer S.A	PI-BH-1034
20191237944	02/12/2019	Instituto Kirby	PI-IK-1193
20191239647	03/12/2019	Bayer S.A	PI-BH-991
20191195498	04/10/2019	Abbvie S.A.S.	PI-ABS-1210
20191195500	04/10/2019	Abbvie S.A.S.	PI-ABS-1016
20191196895	07/10/2019	CSL Behring LLC (CSLB)	PI-CS-1244
20191179546	13/09/2019	H. Lundbeck A/S (Lundbeck)	PI-HL-1196
20191182014	17/09/2019	Population Health research Institute- Astrazeneca	PI-PHR-836
20191182453	18/09/2019	Allergan Inc.	PI-ALL-1019
20191182733	14/09/2019	GENFIT	PI-GF-1078
20191182878	18/09/2019	CSL Behring LLC (CSLB)	PI-CS-1244
20191183659	19/09/2019	GlaxoSmithKline Biologicals SA	PI-GS-1287



La salud
es de todos

Minsalud

20191191215	30/09/2019	Pfizer Colombia S.A.S	PI-PF-899
20191196778	07/10/2019	Sanofi Aventis de Colombia S.A.	PI-SA-981
20191193910	09/10/2019	Instituto Kirby	PI-IK-1193
20191194434	03/10/2019	Novo Nordisk A/S	PI-NN-1250
20191194572	03/10/2019	Bayer S.A.	PI-BH-1034
20191194575	03/10/2019	Bayer S.A.	PI-BH-773
20191195479	04/10/2019	Abbvie S.A.S.	PI-ABS-1099
20191195486	04/10/2019	Abbvie S.A.S.	PI-AB-909
20191195492	04/10/2019	Abbvie S.A.S.	PI-ABS-1173
20191195498	04/10/2019	Abbvie S.A.S.	PI-ABS-1210
20191195500	04/10/2019	Abbvie S.A.S.	PI-ABS-1016
20191219436	07/11/2019	Regeneron Pharmaceuticals	PI-RPH-1185
20191219431	07/11/2019	Acerta Pharma, BV / PPD Colombia S.A.S	PI-ACE-1000
20191219437	07/11/2019	Shire Human Genetic Therapies Inc. / PPD Colombia S.A.S	PI-SH-1216
20191219481	07/11/2019	Eli Lilly and Company	N/A
20191219545/ 20191218003	07/11/2019	IQVIA	N/A
20191219554	07/11/2019	Daiichi Sankyo/ IQVIA	N/A
20191220041	08/11/2019	Janssen Cilag S.A.	N/A
20191219429	07/11/2019	Actelion Pharmaceuticals Ltda	PI-AC-1227
20191219432	07/11/2019	P-(MP) Millennium Pharmaceuticals, Inc.	PI-MP-969
20191219433	07/11/2019	Celgene Corporation	PI-CC-1166
20191220474	08/11/2019	ACADIA Pharmaceuticals Inc/Worldwide Clinical Trials - Colombian Branch /PAREXEL International Colombia S.A.S	NR
20191220777	08/11/2019	Novartis De Colombia S.A	N/A



La salud
es de todos

Minsalud

20191220814	08/11/2019	Amgen	PI-AG-1115
20191220819	08/11/2019	Amgen	PI-AG-1115
20191220823	08/11/2019	Amgen	NR
20191220855	08/11/2019	GlaxoSmithKline	PI-BM-968
20191220938	08/11/2019	Productos Roche SA	NR
20191220939	08/11/2019	Productos Roche SA	NR
20191241443	05/12/2019	Boehringer Ingelheim Colombia S.A	PI-LBI-1121
20191242285	06/12/2019	Sanofi Aventis de Colombia S.A.	N/A
20191242304	06/12/2019	BioMarin Pharmaceutical Inc./Covance Colombia Services Ltda.	PI-BI-1172
20191242309	06/12/2019	CSL Behring LLC (CSLB)/Covance Colombia Services Ltda.	PI-CS-1244
20191242790	06/12/2019	GlaxoSmithKline	PI-GS-1153
20191242885	06/12/2019	MSD	MSD
20191246148	11/12/2019	Allergan Sales, LLC/ PAREXEL International Colombia S.A.S.	PI-ALL-1264
20191246152	11/12/2019	Allergan Sales, LLC/ PAREXEL International Colombia S.A.S.	PI-ALL-1265
20191246154	11/12/2019	Allergan Sales, LLC/ PAREXEL International Colombia S.A.S.	PI-ALL-1263
20191256894	20/12/2019	Bayer S.A	PI-BH-1012 PI-BH-1010
20191249051	13/12/2019	EirGenix Inc./PSI CRO Colombia S.A.S.	PI-EG-1297
20191219445	07/11/2019	Shire Human Genetic Therapies Inc. / PPD Colombia S.A.S	PI-SH-1218
20191219450	07/11/2019	Shire Human Genetic Therapies Inc. / PPD Colombia S.A.S	PI-SH-1226
20191221907	12/11/2019	Boehringer Ingelheim Colombia	PI-LBI-1197



La salud
es de todos

Minsalud

		S.A.	
20191228232	19/11/2019	Bayer S.A.	PI-BH-1139
20191228716	20/11/2019	Allergan Inc.	PI-ALL-1019
20191174508	06/09/2019	F. Hoffmann- La Roche Ltda	PI-RO-789
20191176192	10/09/2019	Aurinia Pharmaceuticals, Inc.	PI-API-1147
20191176201	10/09/2019	Aurinia Pharmaceuticals, Inc.	PI-API-1147

Atentamente,

DIANA MILENA CALDERON NOREÑA

Director Técnico de Medicamentos y Productos Biológicos

Proyectó: Grupo de Investigación Clínica