



OFICIO 3000-0497-21

Bogotá D.C., agosto 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 |
|----------------------------|-------------------------|----------------------|---------------|
| 20201227947 20211045514 | 3/12/2020 10/03/2021 | Universidad Nacional | PI-UN-1391 |
| 20201068918 | 03/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201068922 | 03/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201069608 | 03/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201069610 | 6/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201069613 | 6/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201069616 | 6/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201068968 | 1/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201069618 | 6/04/2020 | Bayer S.A. | PI-BH-1010 |
| 20201069619 | 6/04/2020 | Bayer S.A. | PI-BH-1010 |
| 20201069620 | 6/04/2020 | Bayer S.A. | PI-BH-1010 |
| 20201070207 | 1/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201080539 | 30/04/2020 | Bayer S.A. | PI-BH-1010 |
| 20201080543 | 30/04/2020 | Bayer S.A. | PI-BH-1010 |
| 20201080544 | 30/04/2020 | Bayer S.A. | PI-BH-1012 |
| 20201080546 | 30/04/2020 | Bayer S.A. | PI-BH-1004 |



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|-------------|------------|---------------------------|------------|
| 20201094878 | 29/05/2020 | Amgen Inc. | PI-AG-1115 |
| 20201094902 | 29/05/2020 | Amgen Inc. | PI-AG-1115 |
| 20201095706 | 01/06/2020 | Eli Lilly and Company | PI-EL-1257 |
| 20201096250 | 01/06/2020 | Amgen Inc. | PI-AG-1115 |
| 20201102172 | 11/06/2020 | Novartis de Colombia S.A. | PI-NO-1296 |

Eventos Adversos Serios Internacionales

| RADICADO | FECHA | PATROCINADOR o CRO | CODIGO INVIMA |
|-------------|------------|--|---------------|
| 20201054110 | 06/03/2020 | Genetech, Inc. | PI-GNT-1087 |
| 20201056329 | 10/03/2020 | Ipsen Innovation | PI-II-1097 |
| 20201061420 | 17/03/2020 | Allergan Sales, LLC | PI-ALL-1263 |
| 20201061422 | 17/03/2020 | Allergan Sales, LLC | PI-ALL-1264 |
| 20201063650 | 19/03/2020 | Bayer S.A. | PI-BH-1139 |
| 20201068914 | 03/04/2020 | Bayer S.A. | PI-BH-773 |
| 20201068915 | 3/04/2020 | Bayer S.A. | PI-BH-1034 |
| 20201070002 | 5/04/2020 | Novo Nordisk A/S | PI-NN-1250 |
| 20201061425 | 17/03/2020 | Allergan Sales, Llc | PI-ALL-1263 |
| 20201063653 | 19/03/2020 | Bayer S.A. | PI-BH-1237 |
| 20201067484 | 31/3/2020 | P-(MEI) MedImmune LLC | PI-MEI-939 |
| 20201068925 | 03/04/2020 | Bayer S.A. | PI-BH-991 |
| 20201075774 | 21/04/2020 | H. Lundbeck, A/S (Lundbeck) | PATROCINADOR |
| 20201077289 | 24/04/2020 | Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un Socio de Allergan) | PI-ALL-1336 |
| 20201077290 | 24/04/2020 | PUMA BIOTECHNOLOGY. INC | PI-LW-357 |



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| 20201078188 | 27/04/2020 | Bristol Myers Squibb de Colombia S.A. | PI-BM-990 |
| 20201078189 | 27/04/2020 | Bristol Myers Squibb de Colombia S.A. | PI-BM-1230 |
| 20201078193 | 27/04/2020 | Bristol Myers Squibb de Colombia S.A. | PI-BM-1282 |
| 20201078194 | 27/04/2020 | Bristol Myers Squibb de Colombia S.A. | PI-BM-831 |
| 20201079553 | 29/04/2020 | Boehringer Ingelheim Colombia S.A. | PI-LBI-1121 |
| 20201079879 | 29/04/2020 | Merck Sharp & Dohme Colombia S.A.S. | PI-MS-1261 |
| 20201080515 | 30/04/2020 | I.R.I.S (institut de recherches internationales servier) | PI-IRI-852 |
| 20201084215 | 08/05/2020 | ACADIA Pharmaceuticals Inc. | PI-ADP-1270 |
| 20201084230 | 08/05/2020 | ACADIA Pharmaceuticals Inc. | PI-ADP-1271 |
| 20201091581 | 22/05/2020 | Merck Sharp & Dohme Colombia S.A.S. | PI-MS-1261 |
| 20201081280 | 04/05/2020 | Bristol Myers Squibb de Colombia S.A. | PI-BM-1202 |
| 20201099657 | 08/06/2020 | Merck Sharp & Dohme Colombia S.A.S. | PI-MS-1248 |
| 20201084505 | 11/05/2020 | Merck KGaA | PI-MC-1044 |
| 20201081913 | 05/05/2020 | Astellas Pharma Global Development, Inc. | PI-AS-1267 |
| 20201082259 | 05/05/2020 | Human genome Sciences, Inc | PI-HGS-824 |
| 20201083824 | 08/05/2020 | Novartis de Colombia S.A. | PI-NO-1296 |
| 20201084239 | 08/05/2020 | Bristol Myers Squibb de Colombia S.A. | PI-BM-1202 |
| 20201084247 | 08/05/2020 | Novo Nordisk A/S | PI-NN-1309 |



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| 20201087253 | 14/05/2020 | Aptevo BioTherapeutics, LLC. | PI-ABT-1334 |
| 20201087355 | 14/05/2020 | GENFIT | PI-GF-1078 |
| 20201087371 | 14/05/2020 | Novartis de Colombia S. A. | PI-NO-1241 |
| 20201089264 | 19/05/2020 | Amgen Inc. | PI-AG-1323 |
| 20201089317 | 19/05/2020 | Amgen Inc. | PI-AG-1115 |
| 20201089399 | 19/05/2020 | Amgen Inc. | PI-AG-1163 |
| | 19/05/2020 | Amgen Inc. | PI-AG-1315 |
| 20201090077 | 20/05/2020 | Amgen Inc. | PI-AG-1206 |
| 20201092496 | 26/05/2020 | Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un Socio de Allergan) | PI-DT-1138 |
| 20201092533 | 26/05/2020 | AstraZeneca | PI-AZ-447 |
| 20201092919 | 26/05/2020 | Bayer S.A. | PI-BH-1010 |
| 20201094835 | 29/05/2020 | AstraZeneca | PI-AZ-1337 |
| 20201094863 | 29/05/2020 | Amryt Research limited | PI-AR-1208 |
| 20201094921 | 29/05/2020 | AstraZeneca | PI-AZ-1245 |
| 20201095107 | 29/05/2020 | BioMarin Pharmaceutical Inc. | PI-BI-1275 |
| 20201095139 | 29/05/2020 | BioMarin Pharmaceutical Inc. | PI-BI-1172 |
| 20201095154 | 29/05/2020 | Chengdu Kanghong Biotechnology Co., Ltda. | PI-CK-1269 |
| 20201095170 | 29/05/2020 | Boston pharmaceuticals, Inc. | PI-BT-1255 |
| 20201095218 | 29/05/2020 | Kezar Life Sciences | PI-UL-1281 |
| 20201095294 | 30/05/2020 | Teva Branded Pharmaceutical | PI-TB-1253 |



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| | | Products R&D, Inc. | |
| 20201095301 | 30/05/2020 | Teva Branded Pharmaceutical Products R&D, Inc. | PI-TB-1254 |
| 20201095312 | 30/05/2020 | Regeneron Pharmaceuticals, Inc, | PI-RPH-1089 |
| 20201095315 | 30/05/2020 | Bayer S.A. | PI-BH-1010 |
| 20201095536 | 01/06/2020 | Productos Roche S.A. | PI-RO-1175 |
| 20201095597 | 01/06/2020 | Bayer S.A. | PI-BH-1012 |
| 20201097411 | 03/06/2020 | CHEMO , SL | PI-CH-1303 |
| 20201097495 | 03/06/2020 | OPKO Biologics Ltda. | PI-OB-1171 |
| 20201097511 | 03/06/2020 | Sistema general de regalías, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio de Bogotá | PI-JS-1249 |
| 20201097966 | 04/06/2020 | Novo Nordisk A/S | PI-NN-1250 |
| 20201102643 | 12/06/2020 | Novo Nordisk A/S | PI-NN-1309 |

Atentamente,

GUILLERMO JOSÉ PÉREZ BLANCO

Director Técnico de Medicamentos y Productos Biológicos

Proyectó: Grupo de Investigación Clínica