



**OFICIO 3000-0778-22**

Bogotá D.C., noviembre de 2022

**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**

<b>RADICADO</b>	<b>FECHA RADICADO</b>	<b>PATROCINADOR o CRO</b>	<b>CODIGO INVIMA</b>
20221501455	3/02/2022	Janssen Cilag S.A / IQVIA	PI-JC-1419
20221501456	3/02/2022	GlaxoSmithKline Biologicals S.A.	PI-GS-1457
20221501457	3/02/2022	GlaxoSmithKline Biologicals S.A.	PI-GS-1457
20221501478	24/03/2022	OMS	PI-OMS-1536
20221501481	24/03/2022	Janssen Cilag S.A / IQVIA	PI-JC-1419
20221501482	24/03/2022	GlaxoSmithKline Biologicals S.A.	PI-GS-1457
20221501483	24/03/2022	GlaxoSmithKline Biologicals S.A.	PI-GS-1457
20221501540	3/02/2022	Sanofi Pasteur	PI-SAP-1513
20221501513	24/03/2022	Eli Lilly and Company/PPD Colombia S.A.S.	PI-EL-1257
20221501515	24/03/2022	Janssen Cilag S.A / IQVIA	PI-JC-1419
20221501516	24/03/2022	Sanofi Pasteur S.A.	PI-SAP-1319
20221501521	24/03/2022	Sanofi Pasteur S.A.	PI-SAP-1513



20221501529 20221501532 20221501533 20221501535	25/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501574	25/03/2022	Sanofi Aventis de Colombia S.A.	PI-SA-1465
20221501575	25/03/2022	Sanofi Pasteur	PI-SAP-1319
20221501484	25/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501576	25/03/2022	Sanofi Pasteur S.A.	PI-SAP-1513
20221501503	24/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501505	24/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501509	24/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501510	24/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501511	24/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501542	24/03/2022	Bayer S.A.	PI-BH-1408
20221501544	24/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501561	24/03/2022	Bayer S.A.	PI-BH-1408
20221501578	25/03/2022	Astellas Pharma Global Development, Inc/ PAREXEL International Colombia S.A.S.	PI-AS-1267
20221501876	30/03/2022	GlaxoSmithKline Colombia S.A.	PI-GS-1457
20221501878	30/03/2022	Sanofi Pasteur S.A.	PI-SAP-1513
20221501879	30/03/2022	Bayer S.A.	PI-BH-1408
20221501880	30/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501881	30/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419



20221501882	30/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1445
20221501894	31/03/2022	Astellas Pharma Global Development, Inc/ PAREXEL International Colombia S.A.S.	PI-AS-1267
20221501896	31/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501898	31/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501900	31/03/2022	Sanofi Pasteur S.A.	PI-SAP-1513
20221501598	28/03/22	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501821	30/03/22	AstraZeneca	PI-AZ-1337
20221501822	30/03/22	Bayer S.A.	PI-BH-1408
20221501823	30/03/22	Bayer S.A.	PI-BH-1408
20221501824	30/03/22	Bayer S.A.	PI-BH-1408
20221501826	30/03/22	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501863	30/03/22	Baxalta Innovations GmbH/IQVIA RDS Colombia SAS	PI-BIG-1180
20221501864	30/03/22	Astellas Pharma Development/ PAREXEL International Colombia S.A.S.	PI-AS-1267
20221501865	30/03/22	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501866	30/03/22	Bayer S.A.	PI-BH-1408
20221501867	30/03/22	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221501868	30/03/22	Bayer S.A.	PI-BH-1408
20221501869	30/03/22	Eli Lilly and Company/PPD Colombia S.A.S.	PI-EL-1257
20221501871	30/03/22	GlaxoSmithKline Colombia S.A.	PI-GS-1457
20221501872	30/03/22	Hamilton Health Sciences/ Population Health Research	PI-HHS-1474



		Institute-PHRI Fundación Cardioinfantil-Instituto de Cardiología	
20221501875	30/03/22	Janssen Cilag S.A / IQVIA	PI-JC-1445
20221501850	1/4/2022	Inovio Pharmaceuticals, Inc/Icon Clinical Research	PI-IPI-1524
20221501937	1/4/2022	Inovio Pharmaceuticals, Inc/Icon Clinical Research	PI-IPI-1524
20221501943	1/4/2022	GlaxoSmithKline Colombia S.A.	PI-GS-1457
20221501852	01/04/2022	Janssen Vaccines & Prevention B.V./ IQVIA	PI-JC-1419
20221501989	04/04/2022	Sanofi Pasteur S.A.	PI-SAP-1513
20221501933	31/03/2022	Parexel International Colombia SAS	PI-ADP-1271
20221501931	31/03/2022	Inovio Pharmaceuticals, Inc	PI-IPI-1524
20221501935	01/04/2022	Janssen Cilag S.A / IQVIA	PI-JC-1419
20221501908	31/03/2022	Inovio Pharmaceuticals, Inc	PI-IPI-1524
20221501909	31/03/2022	Inovio Pharmaceuticals, Inc	PI-IPI-1524
20221501929	30/03/2022	Janssen Vaccines & Prevention B.V./IQVIA	PI-JC-1419
20221506331	05/04/2022	Janssen Vaccines & Prevention B.V./ IQVIA	PI-JC-1419
20221506373	05/04/2022	Sanofi Pasteur S.A.	PI-SAP-1513



20221506375	05/04/2022	Janssen Vaccines & Prevention B.V./ IQVIA	PI-JC-1419
20221506376	05/04/2022	Janssen Vaccines & Prevention B.V./ IQVIA	PI-JC-1419
20221506377	05/04/2022	Sinocelltech Ltda / PAREXEL International Colombia S.A.S.	PI-SL-1493
20221506400	06/04/2022	Janssen Vaccines & Prevention B.V./ IQVIA	PI-JC-1419
20221506638	06/04/2022	Abbvie S.A.S.	PI-ABS-1259
20221506639	06/04/2022	Janssen Vaccines & Prevention B.V./ IQVIA	PI-JC-1419
20221506681	07/04/2022	Janssen Vaccines & Prevention B.V./ IQVIA	PI-JC-1419
20221506698	07/04/2022	Janssen Vaccines & Prevention B.V./ IQVIA	PI-JC-1445
20221506724	07/04/2022	Bayer S.A.	PI-BH-1408



**Eventos Adversos Serios Internacionales**

<b>RADICADO</b>	<b>FECHA RADICADO</b>	<b>PATROCINADOR o CRO</b>	<b>CODIGO INVIMA</b>
20221500073	16/02/2022	Boehringer Ingelheim	N/A
20221500711	03/03/2022	IQVIA RDS Colombia S.A.	PI-MLP-1351
20221500709	03/03/2022	IQVIA RDS Colombia S.A.	PI-CC-1155
20221500710	03/03/2022	IQVIA RDS Colombia S.A.	PI-RPH-1133
20221500730	04/03/2022	IQVIA RDS Colombia S.A.	PI-CC-1155
20221500731	04/03/2022	IQVIA RDS Colombia S.A.	PI-MLP-1351
20221500732	04/03/2022	IQVIA RDS Colombia S.A.	PI-RPH-1133
20221500957	08/03/2022	Laboratorios SOPHIA de Colombia LTDA	PI-LSO-1135
20221500999	09/03/2022	AstraZeneca Colombia	PI-AZ-1337
20221501058	11/03/2022	Mirum Pharmaceuticals Inc.	PI-MPI-1345 PI-MPI-1471
20221501453	24/03/2022	Edesa Biotech Research Inc. / JSS Medical Research Latam SAS	PI-EB-1453
20221501454	24/03/2022	MSD	PI-MS-1479 PI-MS-1372
20221501479	24/03/2022	OPKO Biologics LTD/ JSS Medical Research Latam SAS	PI-OB-1171
20221501480	24/03/2022	Chemo Research S.L.	PI-CH-1303
20221501514	24/03/2022	Astellas Pharma Global Development, Inc/PAREXEL International Colombia S.A.S.	PI-AS-1267
20221501517	24/03/2022	ACADIA Pharmaceuticals Inc./ PAREXEL International Colombia S.A.S.	PI-ADP-1270
20221501518	24/03/2022	ACADIA Pharmaceuticals Inc./ PAREXEL International Colombia S.A.S.	PI-ADP-1271
20221501519	24/03/2022	Allergan Sales, LLC/ PAREXEL International Colombia S.A.S.	PI-ALL-1336
20221501520	24/03/2022	Sinocelltech Ltda/ PAREXEL International Colombia S.A.S.	PI-SL-1493
20221501522	24/03/2022	BAYER S. A	PI-BH-773
20221501523	24/03/2022	BAYER S. A	PI-BH-1412



20221501569	25/03/2022	AstraZeneca Colombia	PI-AZ-1337
20221500070	16/02/2022	Boehringer Ingelheim S.A.	PI-LBI-1511
20221501571	25/03/2022	Synairgen Research Ltd. /PAREXEL International Colombia S.A.S.	PI-SR-1484
20221501572	25/03/2022	UCB Biopharma SRL/ PAREXEL International Colombia S.A.S.	PI-UCB-1416
20221501573	25/03/2022	Argenx BV/ PAREXEL International Colombia S.A.S.	PI-BV-1509
20221501485	24/03/2022	Veru, Inc. / Worldwide Clinical Trials Colombia S.A.S.	PI -VI-1546
20221501495	21/03/2022	AstraZeneca	PI-AZ-1427
20221501506	24/03/2022	Bristol Myers Squibb de Colombia S.A	PI-BM-1202
20221501507	24/03/2022	Bristol Myers Squibb de Colombia S.A	Patrocinador
20221501508	24/03/2022	Bristol Myers Squibb de Colombia S.A	PI-BM-823
20221501512	24/03/2022	Regeneron Pharmaceuticals Inc / PAREXEL International Colombia S.A.S.	PI-RPH-1361
20221501543	24/03/2022	Laboratoios LITAPHAR.S.L.	PI-LL-1415
20221501547	24/03/2022	CSL Behring LLC (CSLB) / Labcorp Colombia Services LTDA	PI-CS-1244
20221501563	25/03/2022	Bristol Myers Squibb de Colombia S.A	PI-BM-1282
20221501564	25/03/2022	Bristol Myers Squibb de Colombia S.A	Patrocinador
20221501565	25/03/2022	Bristol Myers Squibb de Colombia S.A	PI-BM-1554
20221501577	25/03/2022	Inovio Pharmaceuticals, Inc/ Icon Clinical Research	PI-IPI-1524
20221500356	22/02/2022	H. Lundbeck, A/S /Icon Clinical Research	PI-HL-1108
20221500357	22/02/2022	H. Lundbeck, A/S /Icon Clinical Research	PI-HL-1508



20221500358	22/02/2022	H. Lundbeck, A/S /Icon Clinical Research	PI-HL-1109
20221501579	25/03/2022	Eli Lilly and Company/PPD Colombia S.A.S.	PI-EL-1257
20221501580	28/03/22	Eli Lilly and Company/PPD Colombia S.A.S.	PI-EL-1312
20221501599	28/03/22	Bayer S.A.	PI-BH-1466
20221501862	29/03/22	Icahn School of Medicine at Mount Sinai/LA Research SAS	PI-IS-1456
20221501941	1/4/2022	Pfizer S.A.S	Pfizer S.A.S
20221501998	04/04/2022	Kinex Pharmaceuticals INC. / Athenex – Cidal Colombia S.A.S.	PI-KP-1106
20221501999	04/04/2022	Laboratoios LITAPHAR.S.L.	PI-LL-1415
20221506300	04/04/2022	Galapagos NV / INC Research Colombia Ltda	PI-GAL-844
20221506328	05/04/2022	Amryt Research limited / INC Research Colombia	PI-AR-1208
20221506329	05/04/2022	GEDEON RICHTER Pcl / Syneos Health Colombia Ltda	PI-ALL-1428
20221506330	05/04/2022	Apellis Pharmaceutical, Inc. / CTI Clinical Brasil Serviços de Pesquisas e Comercio Ltda	PI-AL-1489
20221506328		Amryt Research limited / INC Research Colombia	PI-AR-1208





	05/04/2022		
20221506329	05/04/2022	GEDEON RICHTER Pcl / Syneos Health Colombia Ltda	PI-ALL-1428
20221506332	05/04/2022	AstraZeneca / Labcorp Colombia Services LTDA	PI-AZ-1399
20221506334	05/04/2022	Pharma Mar S.A. / Labcorp Colombia services Ltda	PI-PM-1514
20221506335	05/04/2022	Merck KGaA / IQVIA RDS COLOMBIA SAS	Patrocinador
20221506353	05/04/2022	OPKO Biologics Ltda. / JSS Medical Research Latam SAS	PI-OB-1171
20221506354	05/04/2022	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un Socio de Allergan) / Syneos Health Colombia Ltda.	PI-DT-1138
20221506355	05/04/2022	Gedeon Richter Plc. / Syneos Health Colombia Ltda	PI-GR-1429
20221506374	05/04/2022	Allievex Corporation / Labcorp Colombia Services LTDA	PI-BI-1275
20221506605	06/04/2022	Tricida, Inc / RPS Colombia Ltda (Compañía del Grupo PRA Health Siciences)	PI-TI-1278
20221506615	06/04/2022	EirGenix Inc. / PSI CRO Colombia S.A.S	PI-EG-1297
20221506616		Abbvie S.A.S.	PI-ABS-1211



	06/04/2022		
20221506617	06/04/2022	Abbvie S.A.S.	Patrocinador
20221506682	07/04/2022	Boehringer Ingelheim Colombia S.A. / PAREXEL International Colombia S.A.S.	PI-LBI-1197
20221506688	07/04/2022	Bayer S.A.	PI-BH-1004
20221506717	07/04/2022	Basilea Pharmaceutica International Ltda. / PSI CRO Colombia S.A.S.	PI-BPR-1474
20221506720	07/04/2022	Biogen Idec Reserch Limited / IQVIA RDS Colombia S.A.S.	PI-BG-1313
20221506721	07/04/2022	Clover Biopharmaceuticals AUS Pty Ltda / IQVIA RDS Colombia S.A.S.	PI-BG-1448
20221506722	07/04/2022	Bayer S.A.	PI-BH-1408
20221506692	07/04/2022	Acerta Pharma, BV / PPD Colombia S.A.S.	PI-ACE-1000
20221506696	07/04/2022	Acerta Pharma, BV / PPD Colombia S.A.S.	PI-ACE-1000
20221506697	07/04/2022	Acerta Pharma, BV / PPD Colombia S.A.S.	PI-ACE-1000
20221506700	07/04/2022	Alnylam Pharmaceuticals INC. / PPD Colombia S.A.S.	PI-ALN-1440
20221506701	07/04/2022	Laboratorio Boehringer Ingelheim / Parexel International Colombia S.A.S	PI-LBI-1511
20221506702	07/04/2022	Alnylam Pharmaceuticals INC. / PPD Colombia S.A.S.	PI-ALN-1440
20221506723	07/04/2022	Clover Biopharmaceuticals AUS Pty Ltda / IQVIA RDS COLOMBIA S.A.S	PI-BG-1448
20221506725	07/04/2022	Acerta Pharma, BV / PPD Colombia S.A.S.	PI-ACE-1000
20221506726	07/04/2022	Acerta Pharma, BV / PPD Colombia S.A.S.	PI-ACE-1000



20221506727	07/04/2022	P-(MP) Millennium Pharmaceuticals, Inc. / C-(PPD) PPD Colombia S.A.S.	PI-MP-969
20221506728	07/04/2022	Celgene Corporation / PPD Colombia S.A.S.	PI-CC-1166
20221506729	07/04/2022	Celgene Corporation / PPD Colombia S.A.S.	PI-CC-1166
20221506730	07/04/2022	Anylam Pharmaceuticals INC. / PPD Colombia S.A.S.	PI-ALN-1440
20221506731	07/04/2022	Novo Nordisk A/S	PI-NN-1250
20221506732	07/04/2022	Novo Nordisk A/S	PI-NN-1436
20221506733	07/04/2022	Anylam Pharmaceuticals INC. / PPD Colombia S.A.S.	PI-ALN-1440
20221506741	07/04/2022	Anylam Pharmaceuticals INC. / PPD Colombia S.A.S.	PI-ALN-1440
20221506742	07/04/2022	Anylam Pharmaceuticals INC. / PPD Colombia S.A.S.	PI-ALN-1440

Atentamente,

**JUDITH DEL CARMEN MESTRE ARELLANO**

Director Técnico (E) de Medicamentos y Productos Biológicos

Proyectó: Grupo de Investigación Clínica