No. de Convenio: CM3-INCMN/107/8/PI/34/15

AMENDMENT #3
(Budget Amendment)

(For Use in Spanish Speaking Countries)

This is an Amendment ("THE AMENDMENT") to the Cooperation Agreement number **INCMN/107/8/PI/34/15** to carry out Projects or Protocols for Scientific Research in the Field of Health ("THE MAIN AGREEMENT") dated June 23rd, 2015; is constituted as an amendment to the **Protocol MSD-021-INF-1589-15-18-2 named "A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subject"** hereafter **"THE PROTOCOL"** by and among INSTITUTO NACIONAL DE CIENCIAS MÉDICAS Y NUTRICIÓN "SALVADOR ZUBIRÁN", hereinafter called "THE INSTITUTE", MERCK SHARP & DOHME COMERCIALIZADORA, S. de R.L. de C.V., represented by ALEXANDRA GUADALUPE BARAJAS OLIVAS, MD, under request of Merck Sharp & Dohme Corp., hereinafter called "THE SPONSOR" and BRENDA ELOISA CRABTREE RAMÍREZ, M.D., researcher in Sciences part of the Infectious Diseases Department of "THE INSTITUTE" hereinafter called "THE RESEARCHER", who together will be called "THE PARTIES".

BACKGROUND

On June 23rd, 2015, "THE PARTIES" celebrated the agreement INCMN/107/8/PI/34/15, according to which "THE INSTITUTE" and "THE INVESTIGATOR" commit themselves to carry out "THE PROTOCOL" of HIV-1 in adults and adolescents, which aims to contribute to the advancement of scientific knowledge, as well as to the satisfaction of the country's health needs, through scientific and technological development, in biomedical, clinical , medical and epidemiological areas, in accordance with what is strictly established in "THE PROTOCOL", through the resources provided by "THE SPONSOR". According to the Fourth Clause of the Main Agreement, its validity was agreed indefinitely as of its signature.

On November 29th, 2018, "THE PARTIES" celebrated the Amendment #2 to "THE MAIN AGREEMENT", whose purpose was to modify the Attachment C - Budget for MK-1439A-021-0804; "A

ENMIENDA # 3
(Enmienda al Presupuesto)

(Para uso en los Países de lengua Hispana)

Esta es una enmienda ("LA ENMIENDA") al Convenio de Concertación número **INCMN/107/8/PI/34/15** para llevar a cabo Proyectos o Protocolos de Investigación Científica en el Campo de Salud ("EL CONVENIO PRINCIPAL") de fecha 23 de junio de 2015; se constituye como una enmienda al **proyecto MSD-021-INF-1589-15-18-2 denominado "Un Estudio Clínico de Fase III, Multicéntrico, en Doble Ciego, Randomizado, Controladó con Comparador Activo para Evaluar la Seguridad y Eficacia de MK-1439A Administrado Una Vez al Día Frente a ATRIPLA™ Administrado Una Vez al Día en Participantes Infectados por VIH-1 sin Contacto Previo con Tratamientos"** en adelante **"EL PROTOCOLO"**, celebrado por una parte por el INSTITUTO NACIONAL DE CIENCIAS MÉDICAS Y NUTRICIÓN "SALVADOR ZUBIRÁN", en adelante "EL INSTITUTO", y por la otra parte MERCK SHARP & DOHME COMERCIALIZADORA, S. de R.L. de C.V. actuando en su nombre la DRA. ALEXANDRA GUADALUPE BARAJAS OLIVAS, a solicitud de Merck Sharp & Dohme Corp., en adelante "EL PATROCINADOR", y por una tercera parte la DRA. BRENDA ELOISA CRABTREE RAMÍREZ, investigadora en Ciencias, adscrita al Departamento de Infectología de "EL INSTITUTO" en adelante "EL INVESTIGADOR", a quienes en conjunto se les denominará "LAS PARTES"..

ANTECENDENTES

El día 23 de junio de 2015, "LAS PARTES" celebraron el convenio INCMN/107/8/PI/34/15, conforme al cual "EL INSTITUTO" y "EL INVESTIGADOR" se comprometen a llevar a cabo "EL PROTOCOLO" de investigación en materia de VIH-1 en adultos y adolescentes, que tiene como objeto contribuir al avance del conocimiento científico, así como a la satisfacción de las necesidades de salud del país, mediante el desarrollo científico y tecnológico, en áreas biomédicas, clínicas, socio médicas y epidemiológicas, conforme a lo a lo establecido estrictamente en "EL PROTOCOLO", mediante los recursos que le proporcione "EL PATROCINADOR". De acuerdo a la cláusula Cuarta del Convenio Principal, su vigencia se pactó indefinida a partir de su firma.

Con fecha 29 de Noviembre de 2018, "LAS PARTES" celebraron la Enmienda 2 a "EL CONVENIO PRINCIPAL", cuyo objeto fue modificar el Anexo C – Uso de los Recursos (o presupuesto) del Convenio de

Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subject" ("THE PROTOCOL").

Concertación para la realización del estudio MK-1439A-021-0804; "Un Estudio Clínico de Fase III, Multicéntrico, en Doble Ciego, Randomizado, Controlado con Comparador Activo para Evaluar la Seguridad y Eficacia de MK-1439A Administrado Una Vez al Día Frente a ATRIPLA™ Administrado Una Vez al Día en Participantes Infectados por VIH-1 sin Contacto Previo con Tratamientos" ("EL PROTOCOLO").

STATEMENTS

I. THE INSTITUTE states through its General Director:

I.1 That Dr. David Kershenobich Stalnikowitz, General Director of "The INSTITUTE" accredits his position by appointment dated June 18, 2017, issued by Dr. José Ramón Narro Robles, Secretary of Health, which was protocolized in the act number one hundred and forty-seven thousand one hundred and five, dated July 17, 2017, granted before the faith of Lic. Ignacio Soto Borja y Anda, Holder of the Notary Public No. 129 of the Federal District, today Mexico City, so that in such character has the power to represent the "INSTITUTE" in this act, in accordance with the provisions of Article 19, section I of the National Institutes of Health Law.

II. THE SPONSOR STATES THROUGH ITS LEGAL REPRESENTATIVE

II.1 That Alexandra Guadalupe Barajas Olivas M.D. in her capacity as Legal Representative, has the faculties to sign this agreement, in accordance with the power of attorney granted by "MERCK SHARP & DOHME COMERCIALIZADORA" limited liability company of variable capital; stated in the act ninety-one thousand eight hundred seventy tree, dated May 4, two thousand and eighteen, granted before the faith of Mr. MAURICIO GALVEZ MUNOZ, holder of the notary number thirty-nine of Mexico City. So it has the power to represent "EL SPONSOR" in this act, which have not been modified or restricted in any way, revoking in this act Yvonne Aboitiz Slim, who signed the "THE MAIN AGREEMENT".

II.2 MERCK SHARP & DOHME COMERCIALIZADORA, S. de R.L. de C.V. with address at Av. San Jerónimo, 369, La Otra Banda, Ciudad de México, México, 01090 and acting in its own name and right at the request of Merck Sharp & Dohme Corp., having a place of business at 2000 Galloping Hill Road, Kenilworth, NJ 07033 USA

DECLARACIONES

I. "EL INSTITUTO" POR CONDUCTO DE SU DIRECTOR GENERAL DECLARA:

I.1 Que el Dr. David Kershenobich Stalnikowitz, Director General de "El INSTITUTO" acredita su cargo mediante nombramiento de fecha 18 de junio de 2017, expedido por el Dr. José Ramón Narro Robles, Secretario de Salud, mismo que fue protocolizado en el acta número ciento cuarenta y siete mil ciento cinco, de fecha 17 de Julio de 2017, otorgada ante la fe del Lic. Ignacio Soto Borja y Anda, Titular de la Notaria Pública No. 129 del Distrito Federal, hoy Ciudad De México, por lo que en tal carácter tiene facultades para representar en este acto a "El INSTITUTO", de conformidad con lo dispuesto en el Artículo 19 fracción I de La Ley de los Institutos Nacionales de Salud.

II. "EL PATROCINADOR" POR CONDUCTO DE SU APODERADA LEGAL DECLARA:

II.1 Que la Dra. Alexandra Guadalupe Barajas Olivas, en su calidad de Apoderada Legal, cuenta con facultades para suscribir el presente convenio, de conformidad con el poder notarial otorgado por "MERCK SHARP & DOHME COMERCIALIZADORA" sociedad de responsabilidad limitada de capital variable; que consta en la escritura noventa y un mil ochocientos setenta y tres, de fecha cuatro de mayo de dos mil dieciocho, otorgada ante la fe del Lic. MAURICIO GALVEZ MUNOZ, titular de la notaria numero treinta y nueve de la Ciudad de México. Por lo que tiene facultades para representar en este acto a "EL PATROCINADOR", mismas que no le han sido modificadas ni restringidas en forma alguna, revocando en este acto a la Dra. Yvonne Aboitiz Slim, quién suscribió "EL CONVENIO PRINCIPAL".

II.2 Que MERCK SHARP & DOHME COMERCIALIZADORA, S. de R.L. de C.V. tiene su domicilio en Av. San Jerónimo, 369, La Otra Banda, Ciudad de México, México, 01090 y que se encuentra actuando en su nombre a solicitud de Merck Sharp & Dohme Corp. con domicilio en 2000 Galloping Hill Road, Kenilworth, NJ 07033, Estados Unidos de América.

III. "THE PARTIES" STATE

III.1 Which ratify each and every one of the statements made in "THE MAIN AGREEMENT".

WHEREAS, the parties wish to modify the terms of Atachment C of "THE AGREEMENT" as stipulated in this document.

NOW AND THEREFORE, considering the important object included in the present and with the intention of being legally bound, the parties agree the following:

CLAUSES

FIRST. SUBJECT MATTER.- "THE PARTIES" agree that "THE AGREEMENT" for Protocol MK-1439A-021-0804: "A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subject" ("THE PROTOCOL") is hereby amended again as follows:

- Addition of visits to Extension Study

SECOND.- The Budget is amended in accordance with the new budget terms set forth in Attachment C to this AMENDMENT that will be an integral part of "THE MAIN AGREEMENT" from the execution of this amendment and replaces the previously agreed amounts.

THIRD. TERM.- This amendment shall take effect and shall become effective from the date of the last signature captured by those involved in its execution and until the term of "THE MAIN AGREEMENT".

It is understood and agreed that all other provisions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, having read this agreement and being aware of it, the "PARTIES" involved in this act, and also aware of its scope and content, they sign and ratify it in four counterparts in Mexico City on February 28th, 2019.

III. LAS PARTES DECLARAN:

III.1 Que ratifican todas y cada una de las declaraciones vertidas en "EL CONVENIO PRINCIPAL".

POR CUANTO, las partes desean modificar los términos del Anexo C del CONVENIO como se estipula en el presente documento.

AHORA Y EN VIRTUD DE LO CUAL, considerando la importante contraprestación que se incluye en el presente y con la intención de estar legalmente vinculados, las partes acuerdan las siguientes:

CLAÚSULAS

PRIMERA. OBJETO.- "LAS PARTES" contratantes convienen en que el Convenio de Concertación para la realización del estudi, MK-1439A-021-0804; "Un Estudio Clínico de Fase III, Multicéntrico, en Doble Ciego, Randomizado, Controlado con Comparador Activo para Evaluar la Seguridad y Eficacia de MK-1439A Administrado Una Vez al Día Frente a ATRIPLA™ Administrado Una Vez al Día en Participantes Infectados por VIH-1 sin Contacto Previo con Tratamientos" ("EL PROTOCOLO") se modifica de nueva cuenta por la presente Enmienda de la siguiente manera:

- Adición de visitas en el estudio de Extensión

SEGUNDA.- El Presupuesto se modifica de acuerdo con las nuevas condiciones del presupuesto consignadas en el Anexo C, el cual se adjunta a la presente ENMIENDA, y formará parte integrante de "EL CONVENIO PRINCIPAL" a partir de la firma del presente instrumento y sustituye los montos pactados con anterioridad en el Anexo C.

TERCERA. VIGENCIA.- La presente enmienda surtirá efectos o iniciara su vigencia a partir de la fecha de la última firma plasmada por las personas que en su formalización intervienen y hasta la vigencia de "EL CONVENIO PRINCIPAL".

Queda entendido y convenido que todas las demás disposiciones del presente Contrato se mantendrán en plena vigencia y efecto.

EN FE DE LO CUAL, Leído el presente instrumento y enteradas "LAS PARTES" que intervienen en este acto sobre su alcance y contenido, lo firman y ratifican por cuadruplicado en la Ciudad de México a 28 deFebrero del 2019.

No. de Convenio: CM3-INCMN/107/8/PI/34/15

INSTITUTO NACIONAL DE CIENCIAS MÉDICAS Y NUTRICIÓN "SALVADOR ZUBIRÁN"

BY _____

NAME Dr. David Kershenobich Stalnicowitz

TITLE Director General.

DATE 6-3-2019

INSTITUTO NACIONAL DE CIENCIAS MÉDICAS Y NUTRICIÓN "SALVADOR ZUBIRÁN"

FIRMA _____

NOMBRE Dr. David Kershenobich Stalnicowitz

TÍTULO Director General.

FECHA 6-3-2019

MERCK SHARP & DOHME COMERCIALIZADORA, S. de R.L. de C.V.

BY _____

NAME Alexandra Guadalupe Barajas Olivas, M.D.

TITLE Legal Representative

DATE 19 FEB 2019

MERCK SHARP & DOHME COMERCIALIZADORA, S. de R.L. de C.V.

FIRMA _____

NOMBRE Dra. Alexandra Guadalupe Barajas Olivas

TÍTULO Representante Legal

FECHA 19 FEB 2019

THE RESEARCHER

BY _____

NAME Brenda Eloisa Crabtree Ramírez, M.D.

DATE _____

EL INVESTIGADOR

FIRMA _____

NOMBRE Dr. Brenda Eloisa Crabtree Ramírez

FECHA FEB 21, 2019

Instituto Nal de Ciencias Médicas y Nutrición "Salvador Zubirán" Crabtree MK-1439A-021-0804 Amend3
Budget Amendment Template (English-Spanish) 1-22-13

GLOBAL AGREEMENTS Virginia Gilbert

12 February 2019

Attachment C - Budget

Anexo C – Uso de los recursos (Presupuesto)

PID:138437 SiteNo:804

MSD Study Site Budget
MK-1439A-021-05

Alexandra Barajas Olivas, MD
Exec.Clinical Research Director
GCTO-Mexico

30-Jan-2019

PI Name: Brenda Eloisa Crabtree Ramirez

Institution (Site): Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran

The target number of patients for your site is 11. For the purpose of trial planning and management, this Budget encompasses an enrollment range between 11 and 20. However, as you approach your target of 11 if you wish to continue to enroll, you must be proactive & contact the CRA for approval to continue enrolling up to 20. If you wish to continue to enroll beyond 20, a Budget Amendment will be issued to finalize the authorization of any potential increase in subject numbers beyond 20. The budget will be adjusted if the study design is modified and has a financial impact. Sponsor reserves the right to decrease or increase the number of patients at any time during the enrollment period without renegotiating based on the costs listed in this budget. Such notification shall be in writing from a person authorized by the Sponsor.

Per Patient Visit Cost: *BASE STUDY*

Per Patient Visit Costs	SCREENING	DAY 1 RAND	WEEK 4	WEEK 8	WEEK 16	WEEK 24	WEEK 36
	Mex$ 9,061.39	Mex$ 8,030.01	Mex$ 6,180.08	Mex$ 6,654.84	Mex$ 5,934.52	Mex$ 6,261.94	Mex$ 5,165.08

Per Patient Visit Costs	WEEK 48	WEEK 60	WEEK 72	WEEK 84	WEEK 96	DISCONTINU	FOLLOW-UP
	Mex$ 6,425.65	Mex$ 5,165.08	Mex$ 5,165.08	Mex$ 5,165.08	Mex$ 5,165.08	Mex$ 5,934.52	Mex$ 4,984.99

Per Patient Visit Costs							Total / Patient
							Mex$ 85,293.34
						Total Estimated number of Randomized Patients	16
						Total Per Patient Visit Cost based on Estimated Patients	Mex$ 1,364,693.44

Per Patient Visit Cost: *Extension*

Per Patient Visit Costs	WK100	WK116	WK132	WK148	WK164	WK180	WK192
	Mex$ 6,675.00	Mex$ 6,675.00	Mex$ 6,675.00	Mex$ 6,675.00	Mex$ 6,675.00	Mex$ 6,675.00	Mex$ 6,675.00

Per Patient Visit Costs	WK208	WK224	WK240	WK256	WK272	EX2/ED	EX2/FU
	Mex$ 3,645.00	Mex$ 3,645.00	Mex$ 3,645.00	Mex$ 3,645.00	Mex$ 3,645.00	Mex$ 3,645.00	Mex$ 3,483.00
Per Patient Visit Costs							Total / Patient
							Mex$ 72,078.00
						Total Estimated number of Randomized Patients	16
						Total Per Patient Visit Cost based on Estimated Patients	Mex$ 1,153,248.00

GCTO Mexico
Georgina Castillo
30 ENE 2019

- The Per Patient Visit Cost includes study-related costs for each patient as required in the Protocol, including procedure costs, site personnel fees (including electronic data entry), administrative fees during performance of the study (copying, shipping preparation, labels, etc.), lab draws, patient stipends (if elected), and indirect costs and overhead. All of the study related costs are included in the costs outlined above. The Per Patient Visit Costs section of the budget represents procedures required to be performed on every patient. The Site Costs are outlined below and include: Additional procedures which are required by the Protocol for specific events and approved by the Sponsor, procedures that are required by the Protocol for a sub-set of patients, and costs which may be incurred by the Site in support of initiating and supporting the study at the Site until completion of all patients and documentation.

- A Central Laboratory will be used for this study. No processing fees will be incurred by the Site other than lab collection fees already contained in the budget.

- Supplies sourced from Sponsor that are licensed or have a value greater than USD $100 per Sponsor calculations at study close-out will be either returned to Sponsor or purchased at current market value, or disposition as instructed by Sponsor.

- For randomized patients who do not complete the study, the Site will be paid according to the per visit schedule noted above for those completed visits documented by electronic data capture or other approved data input.

SITE COSTS *	TOTAL NOT TO EXCEED:	Mex$ 583,733.05

*** Site Costs will be paid upon receipt of an invoice with documentation from the third party, when applicable, or upon receipt of other acceptable documentation.**

	Quantity	Per Occurrence	NOT TO EXCEED
Study Start-Up Fee/Site Set-Up Fee Sponsor agrees to reimburse the site a Study Start-up Fee upon execution of the contract agreement.	1	18,030.00	Mex$ 18,030.00
Site Validation* Sponsor agrees to reimburse the site validation fee upon receipt of the site validation form. The amount listed is the maximum amount. Actual reimbursement will be calculated upon receipt of the site validation form.	1	7,447.65	Mex$ 7,447.65
Study Coordinator - Chart review per hour*	40	454.00	Mex$ 18,160.00
Contingency Allotment, Site/Patient* Sponsor agrees to pay for unexpected costs for the patient upon prior approval by Sponsor and upon receipt of an invoice or acceptable documentation	1	15,000.00	Mex$ 15,000.00
Serious adverse events (SAE)* Sponsor agrees to reimburse the site for providing documentation and reports related to Serious Adverse Events for patients at your site upon receipt of invoice. Costs will be reviewed and approved through Sponsor.	30	760.00	Mex$ 22,800.00
Advertising*	1	34,026.00	Mex$ 34,026.00

GCTC-Mexico/COM
Georgina Castillo

30 ENE 2019

Sponsor agrees to reimburse the site for Advertising costs specific to this study upon receipt of a vendor invoice and appropriate supporting documentation.

Screen Failures:	10	3,862.54	Mex$ 38,625.40
Unscheduled Visits - maximum of 3 per patient*	48	2,930.00	Mex$ 140,640.00
Sponsor agrees to reimburse the site for each unscheduled visit upon receipt of an invoice and appropriate documentation. Costs will be reviewed and approved through Sponsor.			
Virologic Failure Confirmation (VFC) Visit*	16	2,930.00	Mex$ 46,880.00
Sponsor agrees to reimburse the site for each unscheduled visit upon receipt of an invoice and back up documentation. Costs will be reviewed and approved through Sponsor.			
Extension Re-consent, informed consent performed again with the same patient*	25	748.00	Mex$ 18,700.00
Extension Inclusion/Exclusion criteria for those patients entering extension*	16	704.00	Mex$ 11,264.00
Patient Reimbursement, Expenses, Patient Travel - Per Visit, includes Unscheduled Visits (for sites not participating ClinCard)**	330	302.00	Mex$ 99,660.00
Office Supplies/Admin Supplies - Printing (CRF), Stationary, Photocopy, Fax, Mailing, Telephone* (from May 2017 2017 to Apr 2018)	1	27,500.00	Mex$ 27,500.00
Office Supplies/Admin Supplies - Printing (CRF), Stationary, Photocopy, Fax, Mailing, Telephone* (From May 2018 to LSLV)	24	2,000.00	Mex$ 48,000.00
Additional Patient travel *DO NOT EXCEED*	5	7,400.00	Mex$ 37,000.00

Mileage, travel round trip and / or other travel expenses (ground transport, ex taxi)	1,400.00
Hotel stay, 1 night/visit	2,000.00
Round trip Airfare	4,000.00
Total Estimated Budget:	**Mex$ 3,101,674.49**

GCTC Medical COM
Georgina Castillo

30 ENE 2019

PAYMENT SCHEDULE: Per patient visit costs shall be due and payable as follows:

Payments will be made in monthly or bimonthly installments based on the number of completed visits per randomized patient. Patient visit data is obtained in-house according to information provided by the Electronic Data Capture System (EDC). The final payment will be withheld from the monthly installments until study completion.

Study Start-Up Fee / Site Set-Up Fee (listed above in the Site Costs).	Mex$ 18,030.00	Payment will be made upon agreement execution.
Final Payment: a withheld amount of the Total Per Patient Visit Costs.	Mex$ 251,794.14	Final payment will be sent to Site upon receipt by Sponsor of all completed case report forms and transferred data, and study database lock.

Remittance for the applicable amount is generally issued by Sponsor within 60 days.

Invoice Submissions:

Please direct all invoices to the Sponsor Payment Coordinator assigned to this study.

Institution shall submit invoices to Sponsor within 90 days of work performed. Invoices submitted beyond 90 days may be subject to additional verification by Sponsor which may delay payment.

Sponsor Payment Coordinator

Name:	**Dulce Hurtado**
Phone #	**52 55 54-81-97-53**
Fax #:	**NA**
e-mail:	dulce.hurtado@merck.com
Address	**Av. San Jerónimo No. 369, Col. La Otra Banda, C.P. 01090 México D.F.**

Payee Details

Payee Name :	**Instituto Nacional de Ciencias Médicas y Nutrición "Salvador Zubirán"**
Payee Address :	**Av. Vasco de Quiroga No. 15**
	Col. Sección XVI
	P.P. 14080 CDMX
	Mexico
Attention :	**Dra. Brenda Eloisa Crabtree Ramírez**

Georgina Castillo

30 ENE 2019

Alexandra Barajas Olivas, MD
Exec.Clinical Research Director
GCTO-Mexico

30 Jun 2019

Records / ABC HCP Engagements (Child Workflows)

2018-00030557-0001 : MK-1439A-021-0804 CRABTREE INCMCSZ

UPLOAD DOCUMENT TO CHILD ... | CANCEL CHILD WORKFLOW

Summary News Related Actions

HCP Due Diligence Review | More Information Required | Approved | Completed | Cancelled | Not Approved

Activity Details 6/23/2015

Activity Name:	MK-1439A-021-0804 CRABTREE INCMCSZ	**Creation Date**	16-Oct-2018
Workflow Created By:	Castillo, Georgina	**Requestor Country:**	Mexico
Franchise or Business Area of the Activity:	Research Activities -MRL/CMD only	**Division**	MRL
Type of Activity	Clinical Trial	**Objectives of Activity**	Clinical Trial research Agreement MK-1439A-021-0804 INCMCSZ
Activity Start Date	23-Jun-2015	**Product / Therapeutic Area**	doravirine (+) lamivudine (+) tenofovir disoproxil fumarate / Antiviral
Activity End Date	17-Mar-2022	**Activity Country**	All
Expert/HCP role in activity		**Additional Information**	
Reason for selection of HCP		**HCP Information**	CRABTREE RAMIREZ, BRENDA ELOISA
Topic of Lecture(s)		**Master Workflow**	2018-00030557

Benefits provided (expenses) for CRABTREE RAMIREZ, BRENDA ELOISA

Currency	MEXICO PESO	**Meals**	0.00
Hotel	0.00		
Travel (air, rail, ground, etc.)	0.00		
Other	0.00		

Honoraria provided for BRENDA ELOISA CRABTREE RAMIREZ

Currency	MEXICO PESO
Total proposed honoraria	1.00
Honoraria Details	

Aggregate Spend Summary

Currency	MEXICO PESO	**In Progress Total Planned Benefits**	0.00
Fiscal Year	2015	**In Progress Total Planned Honoraria**	0.00
Threshold Reached	No	**Approved Benefits Total**	0.00
Combined Threshold	500,000.00	**Approved Honoraria Total**	0.00
Honoraria Threshold	400,000.00		

Details

Fiscal Year	Child Workflow Number	Type of Activity	Start Date	End Date	Travel (air, rail, ground, etc.)	Hotel	Meals	Registration Fees	Total proposed honoraria	Other (Common Benefits)	Other (HCP Specific)	Status
2018	20180001245 0003	Sponsorship of attendees to a congress or Company organized program (OUTSIDE HCP country/region based on local SOP)	7/23/2018	7/27/2018	65,000.00	35,000.00	0.00	18,000.00	0.00	0.00	0.00	Approved

HCP Profile

Merck Unique ID	13788068	**Local ID**	AJIA-3VWAPD
Western First Name		**First Name**	BRENDA ELOISA
Western Last Name		**Last Name**	CRABTREE RAMIREZ
Primary Employer	HOSP INST NAC DE CS MEDICA Y NUTRICION SALVADOR ZUBIRAN	**Employer Address Line 1**	
Employer Department		**Employer Address Line 2**	
Employer Title		**Employer Address Line 3**	
		Employer City	CIUDAD DE MEXICO
		Employer State/Province	
		Employer Country	Mexico

HCP Due Diligence for BRENDA ELOISA CRABTREE RAMIREZ

Government Affiliation / Role of the Individual	Employed by the government only (e.g., hospital employee)	**Comments**	
HCP Due Diligence Effective Date	17-Aug-2018	**HCP Due Diligence Expiration Date**	17-Aug-2019
DDQ Document		**Organization Address Line 1**	
HCP Documentation	HCP Documentation - 138521 - 5_2_2018 6_01 PM GMT+00_00 - Victor Hugo Pastor	**Organization Address Line 2**	
		Organization Address Line 3	
Organization HCP is affiliated with as a Government Official (if different than Primary Employer)			
Role of HCP with this Organization			

Delegation Action

Delegator User	Delegee User	Comments
No items available		

Approver(s) Action

Approval Stage	Approved By	Approval Date	Approval Decision	Comments	More Information Comments
No items available					

Task Report

No results found

Uploaded Documentation

Event Documentation

Other Documentation

Records / ABC: HCP Engagements (Child Workflows)

2019-00004043-0001 : Clinical Trials perfmormed at Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán

UPLOAD DOCUMENT TO CHILD... | CANCEL CHILD WORKFLOW

Summary News Related Actions

HCP Due Diligence Review | More Information Required | Pending Tier 3 Approval | Pending Tier 3 Managing Director | Approved | Completed | Cancelled | Not Approved

Activity Details 7/30/2014

Activity Name:	Clinical Trials perfmormed at Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán	**Creation Date**	13-Feb-2019
		Requestor Country:	Mexico
		Division	MRL
Workflow Created By:	Castillo, Georgina	**Objectives of Activity**	Clinical Trial Research Agreements
Franchise or Business Area of the Activity:	Research Activities -MRL/CMO only	**Product / Therapeutic Area**	Several
		Activity Country	All
Type of Activity	Clinical Trial	**Additional Information**	
Activity Start Date	30-Jul-2014	**HCP Information**	Kershenobich, David
Activity End Date	30-Nov-2024	**Master Workflow**	2019-00004043
Expert/HCP role in activity			
Reason for selection of HCP			
Topic of Lecture(s)			

Benefits provided (expenses) for Kershenobich, David

Currency	MEXICO PESO	**Meals**	0.00
Hotel	0.00		
Travel (air, rail, ground, etc.)	0.00		
Other	0.00		

Honoraria provided for David Kershenobich

Currency	MEXICO PESO
Total proposed honoraria	1.00
Honoraria Details	

Aggregate Spend Summary

Currency	MEXICO PESO	**In Progress Total Planned Benefits**	109,070.80
Fiscal Year	2014	**In Progress Total Planned Honoraria**	209,997.60
Threshold Reached	No	**Approved Benefits Total**	0.00
Combined Threshold	500,000.00	**Approved Honoraria Total**	0.00
Honoraria Threshold	400,000.00		

Details

Fiscal Year	Child Workflow Number	Type of Activity	Start Date	End Date	Travel (air, rail, ground, etc.)	Hotel	Meals	Registration Fees	Total proposed honoraria	Other (Common Benefits)	Other (HCP Specific)	Status

Fiscal Year	Child Workflow Number	Type of Activity	Start Date	End Date	Travel (air, rail, ground, etc.)	Hotel	Meals	Registration Fees	Total proposed honoraria	Other (Common Benefits)	Other (HCP Specific)	Status
2018	2018-00002590-0004	Speaker / Lecturer, Workshop Moderator or Chairperson	5/11/2018	5/12/2018	13,855.31	1,264.65	0.00	0.00	51,143.76	0.00	0.00	Approved
2017	2017-00018961-0002	Input / Advice provided to our Company (single meeting)	9/18/2017	9/20/2017	8,790.03	6,440.04	0.00	0.00	53,816.48	0.00	0.00	In Progress
2017	2016-00084704-0004	Speaker / Lecturer, Workshop Moderator or Chairperson	5/12/2017	5/13/2017	0.00	3,685.93	0.00	0.00	56,627.47	0.00	0.00	Approved
2015	2015-00008278-0001	Global Therapeutic Experts Forum (GTEF)	5/7/2015	5/9/2015	89,372.16	4,468.61	0.00	0.00	48,409.92	0.00	0.00	In Progress

HCP Profile

Merck Unique ID 3631722
Western First Name David
Western Last Name Kershenobich
Primary Employer HOSP CLIN LOMAS ALTAS-QUIROFANO
Employer Department
Employer Title

Local ID 261348
First Name David
Last Name Kershenobich
Employer Address Line 1
Employer Address Line 2
Employer Address Line 3
Employer City CIUDAD DE MEXICO
Employer State/Province
Employer Country Mexico

HCP Due Diligence for David Kershenobich

Government Affiliation / Role of the Individual All other affiliations higher than hospital formulary
HCP Due Diligence Effective Date 18-Oct-2018
DDQ Document DDQ Document - Other - DDQ DAVID KERSHENOBICH STALNICOWITZ Vigencia 12Feb20 - 2_13_2019 3_26 PM GMT+00_00 -

Comments
HCP Due Diligence Expiration Date 18-Oct-2019
Organization Address Line 1
Organization Address Line 2
Organization Address Line 3

	Georgina Castillo - 2_13_2019 4_37 PM GMT+00_00 - Lourdes Estela Portillo
HCP Documentation	HCP Documentation - FCPA David Kershenobich - 2_1_2018 9_10 PM GMT+00_00 - Victor Hugo Pastor HCP Documentation - FCPA Kershenobich - 12_22_2016 6_47 PM GMT+00_00 - Victor Hugo Pastor
Organization HCP is affiliated with as a Government Official (if different than Primary Employer)	
Role of HCP with this Organization	

Delegation Action

Delegator User	Delegee User	Comments

No items available

Approver(s) Action

Approval Stage	Approved By	Approval Date	Approval Decision	Comments	More Information Comments
Additonal Approval	Esteban, Alexandra	19-Feb-2019	Approved to Proceed	1. HCP is not receiving any direct payment of benefit 2. This due diligence is done due to his role of Director of the Institution (Center) where the clinical trial is going to be conducted. 3. HCP will be signing the agreement on behalf the Center.	
MD Approval	Holmer, Per Christian	19-Feb-2019	Approved to Proceed		

Task Report

No results found

Uploaded Documentation

Event Documentation	Other - DDQ DAVID KERSHENOBICH STALNICOWITZ Vigencia 12Feb20 - 2_13_2019 3_26 PM GMT+00_00 - Georgina Castillo
Other Documentation	