

AMENDMENT #3
(Budget Amendment)

(For Use in Spanish Speaking Countries)

This is an Amendment ("THE AMENDMENT") to the Cooperation Agreement number INCMN/107/08/PI/039/14 to carry out Projects or Protocols for Scientific Research in the Field of Health ("THE MAIN AGREEMENT") dated July 30th, 2014; is constituted as an amendment to the Protocol named "A phase 3 Randomized Study of the Efficacy and Safety of Posaconazole versus Voriconazole for the Treatment of Invasive Aspergillosis in Adults and Adolescents (Phase 3; Protocol No. MK5592-069)" 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 LUIS ALFREDO PONCE DE LEÓN GARDUÑO, 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 July 30th, 2014, "THE PARTIES" celebrated the agreement INCMN/107/08/PI/039/14, according to which "THE INSTITUTE" and "THE INVESTIGATOR" commit themselves to carry out "THE PROTOCOL" of aspergillosis 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 June 19th, 2017 and June 28th, 2018, "THE PARTIES" celebrated the Amendment #1 and #2 to "THE MAIN AGREEMENT", whose purpose was to modify the Attachment C - Budget for MK-5592-069-0172; "A phase 3 Randomized Study of the Efficacy and Safety of Posaconazole versus Voriconazole for the Treatment of Invasive Aspergillosis in Adults and Adolescents (Phase 3;

ENMIENDA # 3
(Enmienda al Presupuesto)

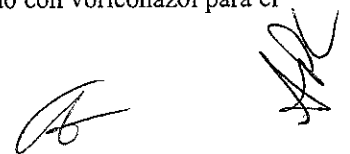
(Para uso en los Países de lengua Hispana)

Esta es una enmienda ("LA ENMIENDA") al Convenio de Concertación número INCMN/107/08/PI/039/14 para llevar a cabo Proyectos o Protocolos de Investigación Científica en el Campo de Salud ("EL CONVENIO PRINCIPAL") de fecha 30 de julio de 2014; se constituye como una enmienda al proyecto denominado "Un estudio randomizado de Fase 3, de la eficacia y seguridad de posaconazol comparado con voriconazol para el tratamiento de las aspergilosis invasiva en adultos y adolescentes (Fase 3, protocolo No. MK5592-069)" 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 DR. LUIS ALFREDO PONCE DE LEÓN GARDUÑO, investigador en Ciencias, adscrita al Departamento de Infectología de "EL INSTITUTO" en adelante "EL INVESTIGADOR", a quienes en conjunto se les denominará "LAS PARTES".

ANTECEDENTES

El día 30 de julio de 2014, "LAS PARTES" celebraron el convenio INCMN/107/08/PI/039/14, conforme al cual "EL INSTITUTO" y "EL INVESTIGADOR" se comprometen a llevar a cabo "EL PROTOCOLO" de investigación en materia de aspergilosis 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 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 19 de Junio de 2017 y 28 de Junio de 2018, "LAS PARTES" celebraron la Enmienda 1 y 2 a "EL CONVENIO PRINCIPAL", cuyo objeto fue modificar el Anexo C - Uso de los Recursos (o presupuesto) del Convenio de Concertación para la realización del estudio MK-5592-069-0172; "Un estudio randomizado de Fase 3, de la eficacia y seguridad de posaconazol comparado con voriconazol para el



Protocol No. MK5592-069) ("THE PROTOCOL").

tratamiento de las aspergilosis invasiva en adultos y adolescentes (Fase 3, protocolo No. MK5592-069)" ("EL PROTOCOLO").

STATEMENTS

DECLARACIONES

I. THE INSTITUTE states through its General Director:

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

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.

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. THE SPONSOR STATES THROUGH ITS LEGAL REPRESENTATIVE

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

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.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 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

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. LAS PARTES DECLARAN:

III.1 Which ratify each and every one of the statements

III.1 Que ratifican todas y cada una de las declaraciones



made in "THE MAIN AGREEMENT"

WHEREAS, the parties wish to modify the terms of Attachment 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-5592-069-0172: "A phase 3 Randomized Study of the Efficacy and Safety of Posaconazole versus Voriconazole for the Treatment of Invasive Aspergillosis in Adults and Adolescents (Phase 3; Protocol No. MK5592-069)" ("THE PROTOCOL") is hereby amended again as follows:

- Number of patients originally considered in visit costs: 25. (Site can enroll up to 30 with the same budget)
- Radiologist – Per Hour is increased from 72 to 150 hours
- Study Coordinator, EDC – Per Hour is increased from 60 to 150 hours
- Copies of Diagnostic Films is increased from 55 to 75

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 November 08th, 2018.

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 estudio, MK-5592-069-0172; "Un estudio randomizado de Fase 3, de la eficacia y seguridad de posaconazol comparado con voriconazol para el tratamiento de las aspergilosis invasiva en adultos y adolescentes (Fase 3, protocolo No. MK5592-069)" ("EL PROTOCOLO") se modifica de nueva cuenta por la presente Enmienda de la siguiente manera:

- Número de pacientes considerados en Costos de visitas: 25. (El sitio puede seguir enrolando hasta 30 pacientes sin necesidad de enmendar el presupuesto)
- Se incrementan las horas de radiólogo de 72 a 150
- Se incrementa las horas de coordinación de captura de datos (EDC) de 60 a 150 horas
- Se incrementan las copias de los discos de diagnóstico de 55 a 75

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 08 de Noviembre del 2018.

INSTITUTO NACIONAL DE CIENCIAS MÉDICAS Y NUTRICIÓN "SALVADOR ZUBIRÁN"

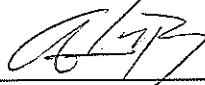
BY 

NAME Dr. David Kershenobich Stalnicowitz

TITLE Director General.

DATE 23 / JANUARY / 2019

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

BY 

NAME Alexandra Guadalupe Barajas Olivas, M.D.

TITLE Legal Representative

DATE 03 Dic 2018

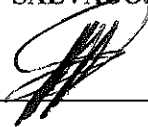
THE RESEARCHER

BY 

NAME Luis Alfredo Ponce de León Garduño, M.D.

DATE 10 JAN / 2019

INSTITUTO NACIONAL DE CIENCIAS MÉDICAS Y NUTRICIÓN "SALVADOR ZUBIRÁN"

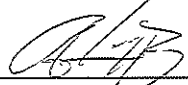
FIRMA 

NOMBRE Dr. David Kershenobich Stalnicowitz

TÍTULO Director General.

FECHA 23 / ENERO / 2019

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

FIRMA 

NOMBRE Dra. Alexandra Guadalupe Barajas Olivas

TÍTULO Representante Legal

FECHA 03 Dic 2018

EL INVESTIGADOR

FIRMA 

NOMBRE Dr. Luis Alfredo Ponce de León Garduño

FECHA 10 / JAN / 2019

Instituto Nacional de Ciencias Médicas y Nutrición "Salvador Zubirán" Ponce MK-5592-069-0172 Amend3
Budget Amendment Template (English-Spanish) 1-22-13



26-Nov-18

No. de Convenio: CM3-INCMN/107/08/PI/039/14

Attachment C - Budget

Anexo C – Uso de los recursos (Presupuesto)

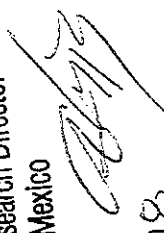




PID:521669
SiteNo:172

MSD Study Site Budget
MK-5592-069-03

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



PI Name: Luis Alfredo Ponce de Leon G

25 Oct 2018

Institution (Site): Inst Nac de Ciencias Medicas y Nutricion

The target number of patients for your site is 20. For the purpose of trial planning and management, this Budget encompasses an enrollment range between 20 and 30. However, as you approach your target of 20, if you wish to continue to enroll, you must be proactive & contact the CRA for approval to continue enrolling up to 30. If you wish to continue to enroll beyond 30, a Budget Amendment will be issued to finalize the authorization of any potential increase in subject numbers beyond 30. 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:

Per Patient Visit Costs	V1/SV	V2/D1	V3/D3	V4/WK1	V6/WK2	V6/WK4	V7/WK6
	Mex\$ 35,587.80	Mex\$ 16,610.40	Mex\$ 18,777.60	Mex\$ 36,111.00	Mex\$ 44,606.80	Mex\$ 74,436.00	Mex\$ 27,360.40

Per Patient Visit Costs

Per Patient Visit Costs	V8/WK12/EOT	V9/FU1	V10/FU2	Total / Patient
	Mex\$ 30,065.40	Mex\$ 9,008.40	Mex\$ 2,056.20	Mex\$ 294,609.00
Total Estimated number of Randomized Patients				25
Total Per Patient Visit Cost based on Estimated Patients				Mex\$ 7,365,225.00

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.

- Supplies sourced from Sponsor (or at the Sponsor's expense) 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 *

* 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.

Site Validation*	Quantity	Per Occurrence	TOTAL NOT TO EXCEED:
	1	3,653.00	Mex\$ 2,892,261.07
			NOT TO EXCEED Mex\$ 3,653.00

24 OCT 2018
GCTO-Mexico
Clinical Center

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	18,030.00	Mex\$ 18,030.00
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Study Start-Up Fee

Sponsor agrees to reimburse the site a Study Start-up Fee upon execution of the contract agreement.

48	4,000.00	Mex\$ 192,000.00
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Pharmacy: Set-Up Fee per month*

Sponsor agrees to reimburse the site a monthly Pharmacy Fee, upon receipt of an invoice.

24	898.97	Mex\$ 21,575.28
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Add Electrocardiogram, routine ECG (EKG) with at least 12 lead ECG: tracing, interpretation, and report. Blood draw for Electrolyte testing handled separately.*

56	4,727.01	Mex\$ 264,712.56
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Add Bronchoscopy biopsy(s), single or multiple sites; diagnostic*

40	9,245.98	Mex\$ 369,839.20
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Add High Resolution Computed Tomography (HRCT), thorax, chest, lung, rate includes report & interpretation*

75	375.05	Mex\$ 28,128.75
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Copies of Diagnostic Films, Complex (e.g. high technology, video recordings, compact discs, CDs) - Per Copy*

368	2,441.34	Mex\$ 873,999.72
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IV Infusions Post-Day 28 (max. add 12IVs/pt), rate includes pharmacy prep, administration & vitals*

48	330.00	Mex\$ 15,840.00
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Collection of addl PK samples, single Post-dose, Pt ages 13-17, (max 6/pt)*

30	202.00	Mex\$ 6,060.00
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Collection of addl PK samples, single Post-dose Week 1 visit, adult patients on IV therapy*

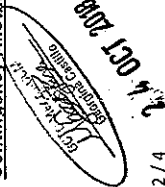
1	20,000.00	Mex\$ 20,000.00
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Contingency Allocation, Patient, includes addl tests and repeat labs as needed (such as mycology, hematology, serum chemistry, electrolytes, scans, etc.)*

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	20,000.00	Mex\$ 20,000.00
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Contingency Allocation, Site*



[Handwritten signature]

Sponsor agrees to pay for unexpected costs for the site upon prior approval by Sponsor and upon receipt of an invoice or acceptable documentation

480	454.02	Mex\$ 217,929.60
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Study Coordinator - Per Hour, Database Chart Review*

1	6,391.96	Mex\$ 6,391.96
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Document Storage, Archiving Total Cost*

Sponsor agrees to reimburse Document Storage at the end of the study to Sites that enroll patients upon receipt of invoice.

3	29,657.00	Mex\$ 88,971.00
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Screen Failures:

The Sponsor agrees to reimburse the site for screen failures at a rate of 1:2 in accordance with number of randomized patients. For each SF, your site will be paid \$29,657.00 at V1. A screen failure is a patient who has entered the study with a signed consent form and was not randomized into the active treatment period due to failure to meet y/e inclusion/exclusion criteria as specified in the protocol.

50	7,507.00	Mex\$ 375,350.00
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Unscheduled Visits Includes PE, EORTC, Conirmeds, AE & Patient stipends*

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.

16	1,005.00	Mex\$ 16,080.00
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Re-informed consent 2 per patient*

150	1,382.00	Mex\$ 207,300.00
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Radiologist - Per Hour*

150	336.00	Mex\$ 50,400.00
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Study Coordinator, Electronic Data Capture (EDC) - Per Hour*

48	2,000.00	Mex\$ 96,000.00
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Office Supplies/Admin Supplies in general and Telephone and/or Internet for EDC/IVRS*

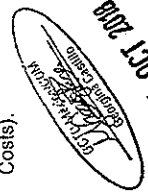
Total Estimated Budget: Mex\$ 10,257,486.07

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

Payments will be made in monthly 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.

Mex\$ 18,030.00 Payment will be made upon agreement execution.

Study Start-Up
Fee / Site Set-
Up Fee (listed
above in the Site
Costs).



Final Payment: a withheld amount of the Total Per Patient Visit Costs.

Mex\$ 736,522.50

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 and invoice inquiries to the Sponsor Payment Coordinator assigned to this study. On all submissions and inquiries, please include Study #, Site # and Principal Investigator Name in the subject line of your email and on the invoice.

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.

The final invoice from Institution must be submitted to Sponsor within 90 days after the study close-out visit.

Sponsor Payment Coordinator

Name:	Beatriz Rodriguez
Phone #	54819600 ext. 19550
Fax #:	NA
e-mail:	beatriz_rodriguez@merck.com
Address	Av. San Jerónimo No. 369 Col. La Otra Banda CP 01090 CDMX

Payee Details


Payee Name :	Inst Nac de Ciencias Medicas y Nutricion
Payee Address :	Vasco de Quiroga No. 15 Sección XVI CP 14000 CDMX
	Professional License # (US only):
	State of License (US only):
	Mexico
Attention :	Luis Alfredo Ponce de Leon G



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

[Signature]
25 Oct 2018

2018-00033218-0001 : MK-5592-069-0172 PONCE / INCMNSZ

 UPLOAD DOCUMENT TO CHILD...	CANCEL CHILD WORKFLOW
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Summary News Related Actions

HCP Due Diligence Review	More Information Required	Approved	Completed	Cancelled	Not Approved
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Activity Details 7/30/2014

Activity Name: MK-5592-069-0172 PONCE / INCMNSZ	Creation Date: 07-Nov-2018
Workflow Created By: Castillo, Georgina	Requestor Country: Mexico
Franchise or Business Area of the Activity: Research Activities -MRL/CMO only	Division: MRL
Type of Activity: Clinical Trial	Objectives of Activity: Clinical trial Research Agreement
Activity Start Date: 30-Jul-2014	Product / Therapeutic Area: POSACONAZOLE / Antibacterial/Antifungal
Activity End Date: 10-Jan-2020	Activity Country: All
Expert/HCP role in activity:	Additional Information:
Reason for selection of HCP:	HCP Information: PONCE DE LEON GARDUNO, LUIS ALFREDO
Topic of Lecture(s):	Master Workflow: 2018-00033218

Benefits provided (expenses) for PONCE DE LEON GARDUNO, LUIS ALFREDO

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

Honoraria provided for LUIS ALFREDO PONCE DE LEON GARDUNO

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: 2014	In Progress Total Planned Honoraria: 573,637.40
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 (Commission Benefits)	Other (HCP Specific)	Status
2018	2018-000207-26-0001	Speaker / Lecturer Workshop Modera	8/16/2018	8/16/2018	0.00	0.00	0.00	0.00	59,790.00	0.00	0.00	Approved



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 (Comm on Benefits)	Other (HCP Specific)	Status
2018	2018-00014257-0001	Workshop Moderator or Chairperson	6/18/2018	6/21/2018	0.00	0.00	0.00	0.00	94,050.00	0.00	0.00	Approved
2018	2018-00007212-0024	Sponsorship of attendees to a congress or Company organized program (OUTSIDE HCP country /region based on local SOP)	10/3/2018	10/7/2018	10,000.00	36,000.00	0.00	24,100.00	0.00	2,000.00	2,000.00	Approved
2018	2018-00000623-0004	Workshop Moderator or Chairperson	3/3/2018	3/3/2018	85,087.02	988.92	0.00	29,667.72	39,556.96	0.00	0.00	Approved
2017	2017-00027597-0006	Input / Advice provided to our Company (single meeting)	12/5/2017	12/6/2017	100,477.50	1,103.35	0.00	0.00	72,351.05	0.00	0.00	Approved
2017	2017-00024919-0001	Speaker / Lecturer / Workshop Moderator	8/10/2017	8/10/2017	0.00	0.00	0.00	0.00	36,920.00	0.00	0.00	Approved



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 (Commission Benefits)	Other (HCP Specific)	Status
2017	2017-00020206-0001	Chairperson Scientific Input Engagement (SIE) (single meeting)	8/4/2017	12/31/2017	0.00	0.00	0.00	0.00	105,424.10	0.00	0.00	Approved
2017	2017-00010481-0007	Input / Advice provided to our Company (single meeting)	5/9/2017	5/9/2017	0.00	0.00	0.00	0.00	9,472.21	0.00	0.00	Approved
2017	2017-00002536-0001	Speaker / Lecturer Workshop Moderator or Chairperson	3/30/2017	3/30/2017	0.00	0.00	0.00	0.00	41,480.00	0.00	0.00	Approved
2017	2017-00001375-0005	Speaker / Lecturer Workshop Moderator or Chairperson	4/8/2017	4/8/2017	56,671.09	2,509.96	0.00	0.00	31,115.17	0.00	0.00	Approved
2016	2016-00078257-0005	Sponsorship of attendees to a congress or Company organized program (OUTSIDE HCP country /region based on local SOP)	10/26/2016	10/30/2016	14,000.00	5,800.00	0.00	17,000.00	0.00	0.00	0.00	Approved
2016							0.00	0.00		0.00	0.00	

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 (Commission Benefits)	Other (HCP Specific)	Status
	2016-000782 46-0011	Input / Advice provided to our Company (single meeting)	12/2/2016	12/2/2016	144,535.00	2,426.71			48,534.27			Approved
2016	2016-000608 27-0004	Workshop Moderator or Chairperson	6/25/2016	6/25/2016	7,006.20	1,694.77	0.00	0.00	34,943.65	0.00	0.00	Approved

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HCP Profile

Merck Unique ID	13795505	Local ID	AJA-3W0CM2
Western First Name		First Name	LUIS ALFREDO
Western Last Name		Last Name	PONCE DE LEON GARDUNO
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 LUIS ALFREDO PONCE DE LEON GARDUNO

Government Affiliation / Role of the Individual	Employed by the government only (e.g., hospital employee)	Comments	
HCP Due Diligence Effective Date	26-Jan-2018	HCP Due Diligence Expiration Date	26-Jan-2019
DDQ Document	DDQ Document - FCPA Ponce de Leon - 10_6_2016 4_28 PM GMT+00_00 - Victor Hugo Pastor	Organization Address Line 1	
HCP Documentation	HCP Documentation - FCPA Ponce del Leon Garduno - 1_22_2018 3_57 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	Deegee User	Comments
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No items available



Delegator User

Delegee User

Comments

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)

2018-00026850-0002 : MK-7655A-014-0300 Ponce de León

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
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Activity Details 2/23/2017

Activity Name: MK-7655A-014-0300 Ponce de León Workflow Created By: Castillo, Georgina Franchise or Business Area of the Activity: Research Activities -MRL/CMO only Type of Activity: Clinical Trial Activity Start Date: 23-Feb-2017 Activity End Date: 31-Dec-2019 Expert/HCP role in activity: Reason for selection of HCP: Topic of Lecture(s):	Creation Date: 13-Sep-2018 Requestor Country: Mexico Division: MRL Objectives of Activity: MK-7655A-014-0300 CTRA Product / Therapeutic Area: Infectious Activity Country: All Additional Information: HCP Information: Kershenobich, David Master Workflow: 2018-00026850
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Benefits provided (expenses) for Kershenobich, David

Currency: MEXICO PESO Hotel: 0.00 Travel (air, rail, ground, etc.): 0.00 Other: 0.00	Meals: 0.00
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Honoraria provided for David Kershenobich

Currency: MEXICO PESO Total proposed honoraria: 1.00 Honoraria Details:
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Aggregate Spend Summary

Currency: MEXICO PESO Fiscal Year: 2017 Threshold Reached: No Combined Threshold: 847,515.00 Honoraria Threshold: 847,515.00	In Progress Total Planned Benefits: 109,070.80 In Progress Total Planned Honoraria: 153,370.20 Approved Benefits Total: 3,685.93 Approved Honoraria Total: 56,627.47
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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 (Commission Benefits)	Other (HCP Specific)	Status
2018	2018-00002590-0004	Speaker / Lecturer Workshop Moderator	5/11/2018	5/12/2018	13,855.31	1,264.65	0.00	0.00	51,143.76	0.00	0.00	Approved

