



SERVICIOS DE SALUD  
DE DURANGO

REVISADO POR:

No. 027/2021

**DIRECCIÓN  
JURÍDICA**

**Trial Information**

**Trial Name:** Sanofi Pasteur\_SPTS2340-S2340  
**Project:** SPTS2340-S2340  
**Protocol Number:** VAT00008  
**Protocol Version:** 2.0 (dated 16 April 2021)  
**Phase:** III  
**Title:** A parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults 18 years of age and older

**Budget Information**

**Location:** Mexico  
**Currency:** MXN - Mexican Peso  
**Total Cost per Patient Main Arm:** 65,883.66  
**Total Cost per Patient Reactogenicity Subset Arm:** 69,346.51  
**Subset Arm:**

**PI Name:** Juan Carlos Tinoco Favila  
**Site Name:** Hospital General de Durango  
**Overhead Percent:** 22.00%

Main Arm					
Visit Name	Visit Cost Subtotal	Overhead at 22%	Total Cost Per Visit	Visit Quantity	Cumulative Visit Cost
V01 (D01)	12,558.00	2,762.76	15,320.76	1.00	15,320.76
V02 (D22)	8,250.00	1,815.00	10,065.00	1.00	10,065.00
V03 (D43)	5,691.00	1,252.62	6,943.62	1.00	6,943.62
V04 (D78)	5,377.00	1,182.94	6,559.94	1.00	6,559.94
V05 (V134)	5,377.00	1,182.94	6,559.94	1.00	6,559.94
V06 (D202)	5,377.00	1,182.94	6,559.94	1.00	6,559.94
V07 (D292)	5,377.00	1,182.94	6,559.94	1.00	6,559.94
V08 (D387)	5,996.00	1,319.12	7,315.12	1.00	7,315.12
Conditional Visits					
CLB1	3,905.00	859.10	4,764.10	1.00	4,764.10
CLB2	2,167.00	476.74	2,643.74	1.00	2,643.74
CLB3	2,167.00	476.74	2,643.74	1.00	2,643.74
CLB4	2,167.00	476.74	2,643.74	1.00	2,643.74
Safety Follow-up Call (for Early Discontinued Subjects)	3,738.00	822.36	4,560.36	1.00	4,560.36
<b>Total Cost per Patient</b>					<b>65,883.66</b>

Reactogenicity Subset Arm					
Visit Name	Visit Cost Subtotal	Overhead at 22%	Total Cost Per Visit	Visit Quantity	Cumulative Visit Cost
V01 (D01)	12,524.00	2,843.28	15,367.28	1.00	15,367.28
V02 (D22)	9,486.20	2,086.96	11,573.16	1.00	11,573.16
V03 (D43)	6,927.20	1,523.98	8,451.18	1.00	8,451.18
V04 (D78)	5,377.00	1,182.94	6,559.94	1.00	6,559.94
V05 (V134)	5,377.00	1,182.94	6,559.94	1.00	6,559.94
V06 (D202)	5,377.00	1,182.94	6,559.94	1.00	6,559.94
V07 (D292)	5,377.00	1,182.94	6,559.94	1.00	6,559.94
V08 (D387)	5,996.00	1,319.12	7,315.12	1.00	7,315.12
Conditional Visits					
CLB1	3,905.00	859.10	4,764.10	1.00	4,764.10
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CLB3	2,167.00	476.74	2,643.74	1.00	2,643.74
CLB4	2,167.00	476.74	2,643.74	1.00	2,643.74
Safety Follow-up Call (for Early Discontinued Subjects)	3,738.00	822.36	4,560.36	1.00	4,560.36
<b>Total Cost per Patient</b>					<b>69,346.51</b>

Invoiceable Procedures and Other Direct Costs	Selected Cost	Overhead at 22%	Total Cost	Considerations
COVID-19-Linked Illness (CLI) Initial and Follow-Up Telephone Calls (per call)	1,226.50	269.83	1,496.33	Invoiceable if contact is not performed via eDiary.
Passive Surveillance Telephone Calls (per call) (max. 3 per patient)	125.00	27.50	152.50	Invoiceable for calls actually received from patients experiencing symptoms of a COVID-19-like illness. Not to exceed 3 calls per patient without prior Sponsor approval.
(Weekly) Active Surveillance Calls (per call)	342.50	75.35	417.85	Invoiceable for telephone calls conducted successfully, if active surveillance contact is not performed via eDiary.
Daily Follow-Up Telephone Calls/Contacts for Patients Experiencing COVID-19-Like Illness (CLI)(per patient per occurrence of CLI)	3,425.00	753.50	4,178.50	Invoiceable per patient per occurrence of COVID-19-like illness to cover all daily telephone calls/contacts performed from onset through the end of illness.
Nasopharyngeal and Anterior Nasal Sample Collection	144.00	31.68	175.68	Invoiceable for repeat swab collection, as needed.
Screen Failure(s)	8,900.50	1,958.11	10,858.61	Screen Failures will be reimbursed as a flat fee inclusive of Informed Consent, Inclusion/Exclusion Criteria, Collection of Demographic Data, Urine/Serum Pregnancy Test, Initial Outpatient Visit, Nasopharyngeal and Anterior Nasal Sample Collection, Preparation, Handling and Shipment of Swabs to Central Laboratory, Patient Travel Reimbursement, Complex Physician Fee, Complex Nurse Fee and Administrative/Personnel Costs, on receipt of a detailed invoice. The Site must document all Screening procedures completed prior to Screen Failure and must ensure that the subject has signed an Informed Consent Form. Sponsor will not pay for any procedures carried out after the subject has failed Screening. Screen Failures are capped at 10% of total site enrollment. Screen Failures in excess of this amount may be invoiced with prior Sponsor approval.

Invoiceable Site Administrative Fees	Unit Cost (inclusive of OH, if applicable)	Estimated No. of Occurrences	Total Cost	Considerations
Site Start-Up Fee (inc. Pharmacy Set-Up)	28,281.00	1	28,281.00	upon invoice
Site Close-Out Fee (inc. Pharmacy Close-Out)	24,493.00	1	24,493.00	upon invoice
Archiving and Document Storage, 25 Years	161,095.00	1	161,095.00	upon invoice with supporting documentation
PPE reimbursement	39,730.00	1	39,730.00	Will be paid according to the invoice, once and no more than the stated here.
<b>Estimated Total Site Administrative Fees</b>			<b>253,599.00</b>	