



महाराष्ट्र MAHARASHTRA

2024

DA 310126



उप कोषागार अधिकारी
कल्याण

NOVARTIS HEALTHCARE PRIVATE LIMITED (FIRST PART)

110 MAR 2025

AND

Swami Rama Himalayan University (SRHU) (SECOND PART)
(For Himalayan Institute of Medical Sciences)

AND

Dr. Kunal Gurunani (THIRD PART)

K. Gurunani

07/06/2025

Kunal

Dr. Kunal Gurunani
Regn.No. UKMC-967

27695

मुद्रांक विक्री नांदवही अनु क्रमांक

मुद्रांकाचा प्रकार

दस्त नोंदणी करणार आहेत का.

मिळकतीचे थोडेवयात वर्णन

मुद्रांक विकृत पैसा-याचे नांव

हस्ते असल्यात लक्ष्ये ना दिसतात व लक्ष्ये

दुस-या पक्षकः ॥ १ ॥

मुद्रांक शुल्क रु. १००/-

परवानाधारक मुद्रांक विज्ञापन रवींद्र सदन, भानुशाला

परवाना क्रमांक २५५५ यु.०५

विक्रीचा टिकाण / पन्ना १३

प्रतिष्ठान नं. ०५, छत्तर भवन.

2025

2020-21, 2021-22, 2022-23, 2023-24, 2024-25, 2025-26, 2026-27, 2027-28, 2028-29, 2029-30, 2030-31, 2031-32, 2032-33, 2033-34, 2034-35, 2035-36, 2036-37, 2037-38, 2038-39, 2039-40, 2040-41, 2041-42, 2042-43, 2043-44, 2044-45, 2045-46, 2046-47, 2047-48, 2048-49, 2049-50, 2050-51, 2051-52, 2052-53, 2053-54, 2054-55, 2055-56, 2056-57, 2057-58, 2058-59, 2059-60, 2060-61, 2061-62, 2062-63, 2063-64, 2064-65, 2065-66, 2066-67, 2067-68, 2068-69, 2069-70, 2070-71, 2071-72, 2072-73, 2073-74, 2074-75, 2075-76, 2076-77, 2077-78, 2078-79, 2079-80, 2080-81, 2081-82, 2082-83, 2083-84, 2084-85, 2085-86, 2086-87, 2087-88, 2088-89, 2089-90, 2090-91, 2091-92, 2092-93, 2093-94, 2094-95, 2095-96, 2096-97, 2097-98, 2098-99, 2099-00, 2100-01, 2101-02, 2102-03, 2103-04, 2104-05, 2105-06, 2106-07, 2107-08, 2108-09, 2109-10, 2110-11, 2111-12, 2112-13, 2113-14, 2114-15, 2115-16, 2116-17, 2117-18, 2118-19, 2119-20, 2120-21, 2121-22, 2122-23, 2123-24, 2124-25, 2125-26, 2126-27, 2127-28, 2128-29, 2129-30, 2130-31, 2131-32, 2132-33, 2133-34, 2134-35, 2135-36, 2136-37, 2137-38, 2138-39, 2139-40, 2140-41, 2141-42, 2142-43, 2143-44, 2144-45, 2145-46, 2146-47, 2147-48, 2148-49, 2149-50, 2150-51, 2151-52, 2152-53, 2153-54, 2154-55, 2155-56, 2156-57, 2157-58, 2158-59, 2159-60, 2160-61, 2161-62, 2162-63, 2163-64, 2164-65, 2165-66, 2166-67, 2167-68, 2168-69, 2169-70, 2170-71, 2171-72, 2172-73, 2173-74, 2174-75, 2175-76, 2176-77, 2177-78, 2178-79, 2179-80, 2180-81, 2181-82, 2182-83, 2183-84, 2184-85, 2185-86, 2186-87, 2187-88, 2188-89, 2189-90, 2190-91, 2191-92, 2192-93, 2193-94, 2194-95, 2195-96, 2196-97, 2197-98, 2198-99, 2199-00, 2200-01, 2201-02, 2202-03, 2203-04, 2204-05, 2205-06, 2206-07, 2207-08, 2208-09, 2209-10, 2210-11, 2211-12, 2212-13, 2213-14, 2214-15, 2215-16, 2216-17, 2217-18, 2218-19, 2219-20, 2220-21, 2221-22, 2222-23, 2223-24, 2224-25, 2225-26, 2226-27, 2227-28, 2228-29, 2229-30, 2230-31, 2231-32, 2232-33, 2233-34, 2234-35, 2235-36, 2236-37, 2237-38, 2238-39, 2239-40, 2240-41, 2241-42, 2242-43, 2243-44, 2244-45, 2245-46, 2246-47, 2247-48, 2248-49, 2249-50, 2250-51, 2251-52, 2252-53, 2253-54, 2254-55, 2255-56, 2256-57, 2257-58, 2258-59, 2259-60, 2260-61, 2261-62, 2262-63, 2263-64, 2264-65, 2265-66, 2266-67, 2267-68, 2268-69, 2269-70, 2270-71, 2271-72, 2272-73, 2273-74, 2274-75, 2275-76, 2276-77, 2277-78, 2278-79, 2279-80, 2280-81, 2281-82, 2282-83, 2283-84, 2284-85, 2285-86, 2286-87, 2287-88, 2288-89, 2289-90, 2290-91, 2291-92, 2292-93, 2293-94, 2294-95, 2295-96, 2296-97, 2297-98, 2298-99, 2299-00, 2300-01, 2301-02, 2302-03, 2303-04, 2304-05, 2305-06, 2306-07, 2307-08, 2308-09, 2309-10, 2310-11, 2311-12, 2312-13, 2313-14, 2314-15, 2315-16, 2316-17, 2317-18, 2318-19, 2319-20, 2320-21, 2321-22, 2322-23, 2323-24, 2324-25, 2325-26, 2326-27, 2327-28, 2328-29, 2329-30, 2330-31, 2331-32, 2332-33, 2333-34, 2334-35, 2335-36, 2336-37, 2337-38, 2338-39, 2339-40, 2340-41, 2341-42, 2342-43, 2343-44, 2344-45, 2345-46, 2346-47, 2347-48, 2348-49, 2349-50, 2350-51, 2351-52, 2352-53, 2353-54, 2354-55, 2355-56, 2356-57, 2357-58, 2358-59, 2359-60, 2360-61, 2361-62, 2362-63, 2363-64, 2364-65, 2365-66, 2366-67, 2367-68, 2368-69, 2369-70, 2370-71, 2371-72, 2372-73, 2373-74, 2374-75, 2375-76, 2376-77, 2377-78, 2378-79, 2379-80, 2380-81, 2381-82, 2382-83, 2383-84, 2384-85, 2385-86, 2386-87, 2387-88, 2388-89, 2389-90, 2390-91, 2391-92, 2392-93, 2393-94, 2394-95, 2395-96, 2396-97, 2397-98, 2398-99, 2399-00, 2400-01, 2401-02, 2402-03, 2403-04, 2404-05, 2405-06, 2406-07, 2407-08, 2408-09, 2409-10, 2410-11, 2411-12, 2412-13, 2413-14, 2414-15, 2415-16, 2416-17, 2417-18, 2418-19, 2419-20, 2420-21, 2421-22, 2422-23, 2423-24, 2424-25, 2425-26, 2426-27, 2427-28, 2428-29, 2429-30, 2430-31, 2431-32, 2432-33, 2433-34, 2434-35, 2435-36, 2436-37, 2437-38, 2438-39, 2439-40, 2440-41, 2441-42, 2442-43, 2443-44, 2444-45, 2445-46, 2446-47, 2447-48, 2448-49, 2449-50, 2450-51, 2451-52, 2452-53, 2453-54, 2454-55, 2455-56, 2456-57, 2457-58, 2458-59, 2459-60, 2460-61, 2461-62, 2462-63, 2463-64, 2464-65, 2465-66, 2466-67, 2467-68, 2468-69, 2469-70, 2470-71, 2471-72, 2472-73, 2473-74, 2474-75,

જ્યા કામાસાઠી જ્યાંની મુત્રાંક ધરેલો ઘોસા ત્યાંની ત્યાચ કારણાસાઠી

मुद्रांक खरेदी केल्यापासुन ६ महिण्यात वापरणे बंधनकारक आहे.

3 MAR 2025

FIRST AMENDMENT TO CLINICAL TRIAL AGREEMENT

 This first Amendment is made at Mumbai and entered into on 25 day of May, 20²⁵ by and between;

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Indian Companies Act, 1956 and having its registered office at Inspire BKC, 7th Floor, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as “**Novartis**”, which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the First Part;

AND

Swami Rama Himalayan University (SRHU), a University established under section 2(f) of the UGC Act and enacted vide Uttarakhand State Act (**For its constituent academic unit Himalayan Institute of Medical Sciences**) having its registered office at Swami Ram Nagar, Jolly Grant, Doiwala, Dehradun, Uttarakhand 248016, represented by Registrar **Commander Challa Venkateswar** hereinafter referred to as (“**Institution**”) which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Kunal Gurunani as clinical practitioner in the field of **Cardiology** acting in the role of principal investigator, hereinafter referred to as (“**Principal Investigator**”) which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

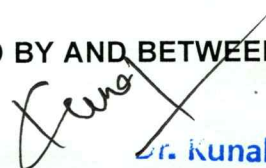
(Novartis, Principal Investigator, and Institution may hereinafter be individually referred to as ‘**Party**’ and are collectively referred as ‘**Parties**’).

WHEREAS

A. By a Clinical Trial Agreement dated 07 July 2023 entered into between the Parties hereto (“**Agreement**”), the Principal Investigator and the Institution have agreed to provide certain Clinical Trial related services to Novartis on the terms and conditions contained in the Agreement.

B. Now by this first Amendment, the Parties are desirous of modifying and restating the sub-clause on ‘Use of Trial Drug’, and ‘PUBLICATION’ and ‘TRANSPARENCY/DISCLOSURE’, Modifying Annex-1 (Payment of telephonic visit) ‘clause to amend the Agreement on the terms and conditions herein after appearing.

NOW THIS AMENDMENT WITNESSETH AND IT IS HERE BY AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:



Dr. Kunal Gurunani
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1. Clause 5.2 (Use of Trial Drug) of the Agreement is modified, and the revised clause 5.2 is as set forth below:

5.2 Novartis shall provide the Trial Drugs (as defined hereunder) in sufficient quantity to conduct the Trial, unless specified in Protocol that one or more drugs is supplied locally. If the Drugs are supplied locally, Novartis Shall reimburse the Institution. Trial Drugs shall be defined as any investigational drug referred in the Protocol, which can include active ingredient, comparator, or placebo. For purposes of this Agreement only, the Trial Drugs shall be free of charge to the Institution. In all events, the Trial Drug shall remain the sole property of Novartis.

2. Clause 13.1, 13.3, 13.5 and 13.9 are added to the Agreement and the additional clauses are set forth as below:

13.1 The term 'publications' is used interchangeably to refer to peer-reviewed scientific manuscripts (e.g. primary and secondary manuscripts, submitted to scientific or medical journals), scientific congress abstracts, and corresponding posters and oral presentations.

13.3 Novartis follows the ICMJE authorship guidelines (www.icmje.org). All authors must therefore fulfill all four ICMJE authorship criteria during publication development to be included as authors on the publication, as follows:

- (a) Substantial contributions to conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- (b) Drafting the work or revising it critically for important intellectual content; AND
- (c) Final approval of the version to be published; AND
- (d) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

13.5 Authors will not receive remuneration for their writing of a publication, either directly from Novartis or through a professional medical writing agency.

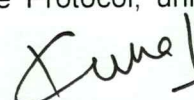
13.9 Novartis and its agents may list participating investigators and their institutional affiliations in the acknowledgement section of the manuscript or abstract submitted for publication according to the journal or congress guidelines.

3. Clause 13.4 of the Agreement is modified, and revised clause is set forth as below:

13.4 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement prior to drafting the publication.

4. Clause 13.7 of the Agreement is modified and the revised clause 13.7 is as set forth below:

13.7 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise



agreed in writing by all the Principal Investigators involved in the Trial and by Novartis.
Publication of partial data sets shall not be made until the full data is released.

5. Clause 24.3 is modified and revised clause is as set forth below: *(Added 24.3) amur*

24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy

6. This amendment shall be effective from 25 March 2025 and shall be coterminous with the agreement read with the prior addendums/amendments for all intents and purposes.
7. Save and except to the extent aforesaid, all other terms and conditions of the Agreement shall continue to remain unaltered, valid and binding upon the Parties. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

R. M. J.

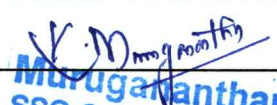
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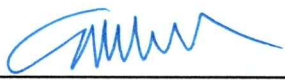
Dr. Kunal Gururani
Regn.No. UKMC-967

IN WITNESS WHEREOF, the Parties to this Amendment have caused their duly authorized representatives to enter into and execute this Amendment.

Novartis Healthcare Private Limited

By: 
Name: Murugananthan K.
Title: SSO Country Head
Date: 25 May 2025

Swami Rama Himalayan University
(For Himalayan Institute of Medical Sciences)

By: 
Name: Commander Challa Venkateswar (Retd)
Title: Registrar
Date: 07 / 06 / 2025

Principal Investigator

By: 
Name: **Dr. Kunal Gurunani**
Title: MBBS, MD Internal Medicine, DM Cardiology
Date: 20-05-2025

Dr. Kunal Gurunani
Reg. No. UK110507

Annex1: Payment (and Equipment) Schedule

(Addendum)

STUDY NUMBER: CKJX839D12302

STUDY NAME: A randomized, double-blind, placebo-controlled multicenter study to evaluate the effect of inclisiran on preventing major adverse cardiovascular events in high-risk primary prevention patients (VICTORION-1 PREVENT)

Investigator's Name: Dr. Kunal Gururani

Institute Name: Himalayan Institute of Medical Sciences

Payee Name: Institution-Scientific & Industrial Research

Pan Card Number: AAAJH0463L

GSTIN: 05AAAJH0463L1ZC

Committed Number of Study Subjects: 10

List of Equipments provided to Institution / Principal Investigator:

- Thermo-hygrometer- to be retrieved back post DBL

STUDY BUDGET

(Added to the Table under Payment Schedule)

VISIT NAME		Investigator fees (in INR)	Study Coordinator Fees (in INR)	Institutional Overhead (20%) (in INR)	Total cost per visit (in INR)
Telephonic visit	TMED	2636	1531	833	5000

**After the subject treatment discontinuation, every telephonic visit will be paid as per above table and all the visit cost will be replaced by the telephonic cost as per the above table.

07/06/2025

Dr. Kunal Gururani
Regn.No. UKMC-967