Executive Summary

JURI MOON
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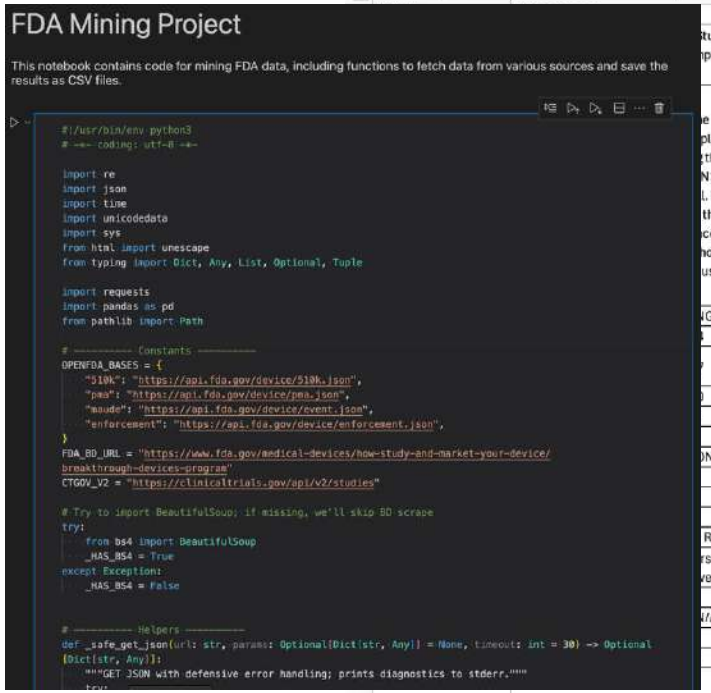
I specialize in regulatory affairs and clinical operations, building automation tools and cross-functional workflows that streamline FDA compliance, trial readiness, and documentation.

1) **Personal Project:**
    1) Documentation Optimization Tool
    2) FDA- Data Mining & Competitor Intelligence Tool
2) **Segmentation Automation Tool on 3D Vagas Nerve**
3) **Clinical Trial Consulting – Skin Care Research Center**
4) **Regulatory Affairs Experience – NovelMed Therapeutics**
5) **Manufacturing Experience – Olon, USA (API Facility)**

1.1 FDA Data Mining & Clinical Trial Benchmarking

Developed an FDA data-mining pipeline and comparative analytics dashboard to benchmark clinical trials on any company



FDA Mining Project

This notebook contains code for mining FDA data, including functions to fetch data from various sources and save the results as CSV files.

```
#!/usr/bin/env python3
# -*- coding: utf-8 -*-

import re
import json
import time
import unicodedata
import sys
from html import unescape
from typing import Dict, Any, List, Optional, Tuple

import requests
import pandas as pd
from pathlib import Path

# ---------- Constants ----------
OPENFDA_BASES = {
    "510k": "https://api.fda.gov/device/510k.json",
    "pma": "https://api.fda.gov/device/pma.json",
    "maude": "https://api.fda.gov/device/event.json",
    "enforcement": "https://api.fda.gov/device/enforcement.json",
}
FDA_BD_URL = "https://www.fda.gov/medical-devices/how-study-and-market-your-device/
breakthrough-devices-program"
CTGOV_V2 = "https://clinicaltrials.gov/api/v2/studies"

# Try to import BeautifulSoup; if missing, we'll skip BD scrape
try:
    from bs4 import BeautifulSoup
    _HAS_BS4 = True
except Exception:
    _HAS_BS4 = False


# ---------- Helpers ----------
def _safe_get_json(url: str, params: Optional[Dict[str, Any]] = None, timeout: int = 30) -> Optional
[Dict[str, Any]]:
    """GET JSON with defensive error handling; prints diagnostics to stderr."""
```

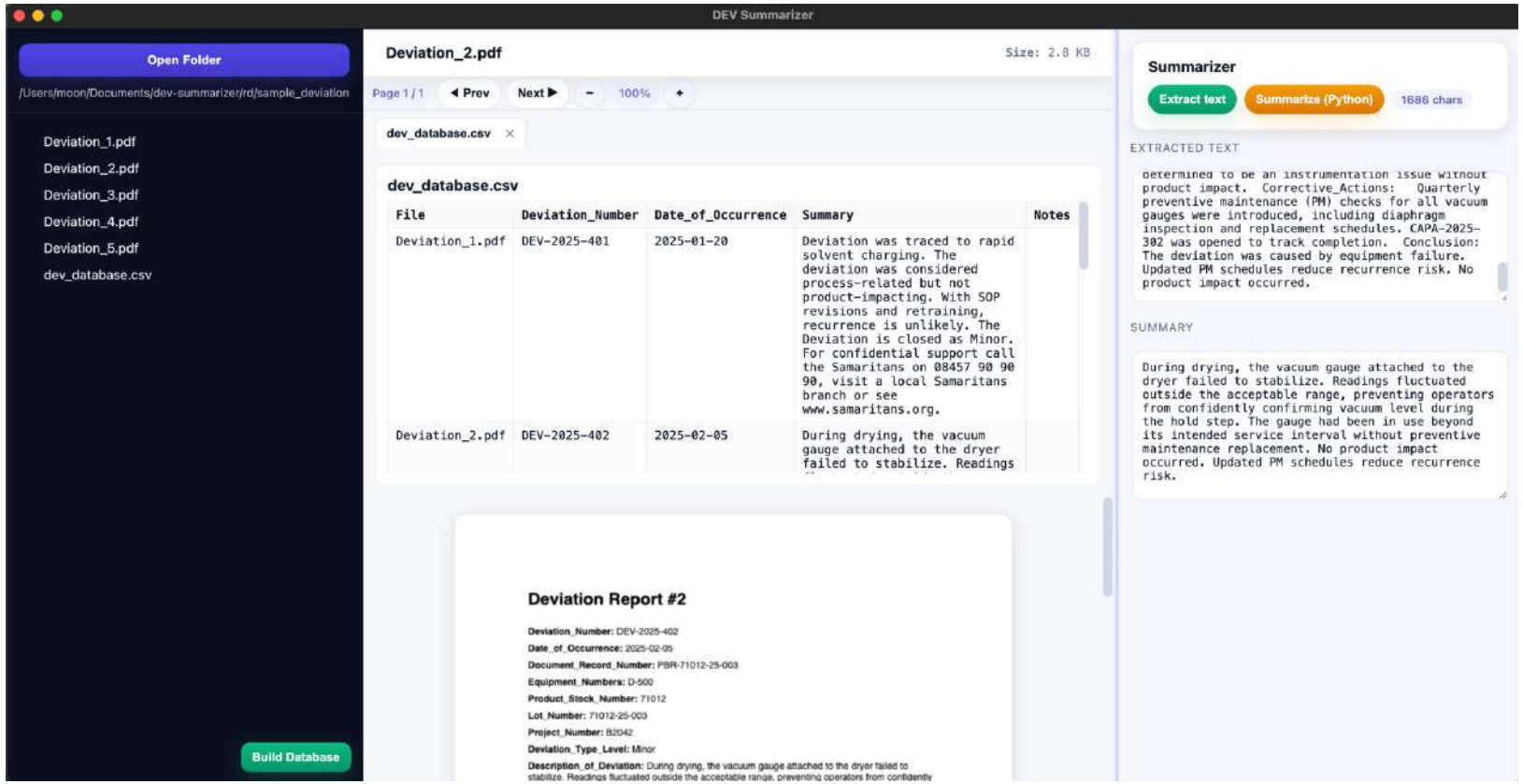
C6 | 2026-11

	A	B	C	D	E	F	G
			NCT06992596	**NCT06710626**	**NCT06429735**	**NCT07127172**	
		tudy of a Precise nputer Interface for the	UAE-PRIME: A Feasibility Study of a Precise Robotically Implanted Brain-Computer Interface for the Control of External Devices	CONVOY: An Early Feasibility Study of Neural Control of Assistive Devices Via Brain-Computer Interface Technology	PRIME: An Early Feasibility Study of a Precise Robotically Implanted Brain-Computer Interface for the Control of External Devices	GB-PRIME: An Early Feasibility Study of a Precise Robotically Implanted Brain-Computer Interface for the Control of External Devices	
		e safety and plant and R1 Robot in their arms and legs N1 Implant is a small, . It connects to tiny the R1 Robot, which is a ce these threads. This how well the implant and use....	The UAE-PRIME Study is a feasibility study designed to assess the initial clinical safety and functionality of the Neuralink N1 Implant and R1 Robot. This study involves participants who have tetraparesis, tetraplegia, or a diagnosis that may lead to these conditions. The N1 Implant is a wireless, rechargeable device mounted on the skull, connected to electrode threads that are inserted into the brain by the R1 Robot, which is a robotic device specifically designed for this procedure....	The CONVOY Study is a clinical trial designed to explore the feasibility of participants from the PRIME Study (NCT06429735) using the N1 Implant to control various assistive devices. The main goal is to determine whether participants can successfully modulate their brain activity to control devices, such as an Assistive Robotic Arm (ARA). This study will assess the effectiveness, consistency, and safety of neural control using the ARA and other assistive devices....	The PRIME Study is a first-in-human early feasibility study to evaluate the initial clinical safety and device functionality of the Neuralink N1 Implant and R1 Robot device designs in participants with tetraparesis or tetraplegia. The N1 Implant is a skull-mounted, wireless, rechargeable implant connected to electrode threads that are implanted in the brain by the R1 Robot, a robotic electrode thread inserter....	The GB-PRIME Study is an early feasibility study designed to assess the clinical safety and functionality of the Neuralink N1 Implant and R1 Robot. This study involves participants who have tetraparesis, tetraplegia, or a diagnosis that may lead to these conditions. The N1 Implant is a wireless, rechargeable device mounted on the skull, connected to electrode threads that are inserted into the brain by the R1 Robot, which is a robotic device specifically designed for this procedure....	
		NG	RECRUITING	ENROLLING_BY_INVITATION	RECRUITING	RECRUITING	
			5/9/25	11/25/24	1/9/24	7/31/25	
			2026-11	5/25/31	2026-01	2028-01	
			2027-11	5/25/31	2031-01	2031-02	
			6/5/25	6/5/25	8/28/25	8/17/25	
			NA	NA	NA	NA	
		ONAL	INTERVENTIONAL	INTERVENTIONAL	INTERVENTIONAL	INTERVENTIONAL	
			N/A	N/A	N/A	N/A	
			N/A	N/A	N/A	N/A	
			N/A	N/A	N/A	N/A	
		Robot	N1 Implant, R1 Robot	Assistive Robotic Arm	N1 Implant, R1 Robot	N1 Implant, R1 Robot	
		rse Events (AE), The Rate verse Events (AE)	The Rate of Device-Related Adverse Events (AE), The Rate of Procedure-Related Adverse Events (AE)	Ability of participants to modulate brain activity for controlling an assistive device via the N1 Implant.	Device-Related Adverse Events (AE), Procedure-Related Adverse Events (AE)	The Rate of Device-Related Adverse Events (AE), The Rate of Procedure-Related Adverse Events (AE)	
			10	3	10	7	
		N/A	18 Years - N/A	N/A - N/A	22 Years - 75 Years	18 Years - N/A	
			ALL	ALL	ALL	ALL	
			FALSE	FALSE	FALSE	FALSE	
	Inclusion_Criteria	* Severe quadriplegia (tetraplegia) due to spinal cord injury or amyotrophic lateral sclerosis (ALS) for at least 1 year without improvement, where quadriplegia is defined as having very limited or no hand, wrist, and arm movement and all levels below * Life expectancy ,â• 12 months. * Ability to communicate in English * Presence of a stable caregiver	* (a) A diagnosis of a spinal cord injury (\>12 months), stroke (\>12 months), or other neurological condition causing the participant to experience bilateral upper limb motor impairment, with no expectation of recovery. OR (b) A diagnosis of Amyotrophic Lateral Sclerosis (ALS) or other progressive neurological condition where the natural history of the disease is well understood and where there is tetraparesis and the expectation, in the view of the participant's treating neurologist, that the disease will progress such that the participant will meet criteria 1a within 1 year of recruitment.	* Continued enrollment in the PRIME Study. * Implanted with the N1 Implant....	* Severe quadriplegia (tetraplegia) due to spinal cord injury or amyotrophic lateral sclerosis (ALS) for at least 1 year without improvement, where quadriplegia is defined as having very limited or no hand, wrist, and arm movement and all levels below * Life expectancy ,â• 12 months. * Ability to communicate in English * Presence of a stable caregiver	* (a) A diagnosis of a spinal cord injury, brain stem stroke, or other neurological condition causing the participant to be non-ambulant and with bilateral upper limb motor impairment with no expectation of recovery that significantly or completely impairs the participant's ability to manually control a computer, smartphone or tablet with their hands. OR (b) A diagnosis of Amyotrophic Lateral Sclerosis (ALS) or other progressive neurological condition where the natural history of the disease is well understood and where there is tetraparesis and the expectation in the view of the participants treating neurologist that the	

Personal Project: Regulatory Documentation Tool

1.2 Automated Deviation Classification Tool Using LLMs

Developing Software to automate the extraction, summarization, and risk classification of deviation reports using a custom Large Language Model pipeline.



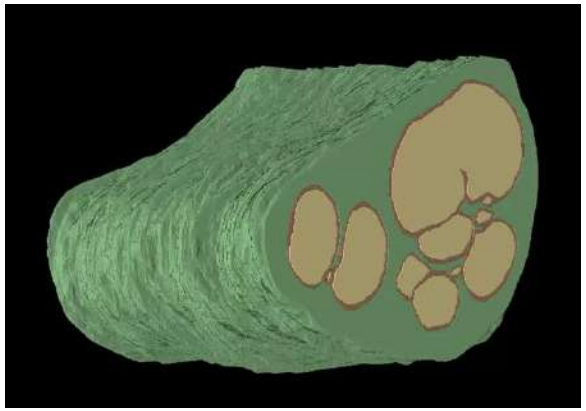
* Dummy Deviation Example

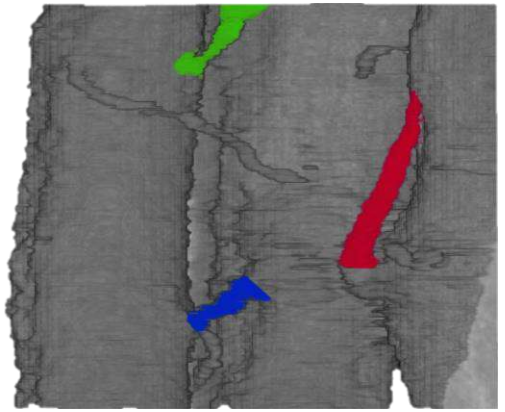
Personal Project: Regulatory Documentation Tool

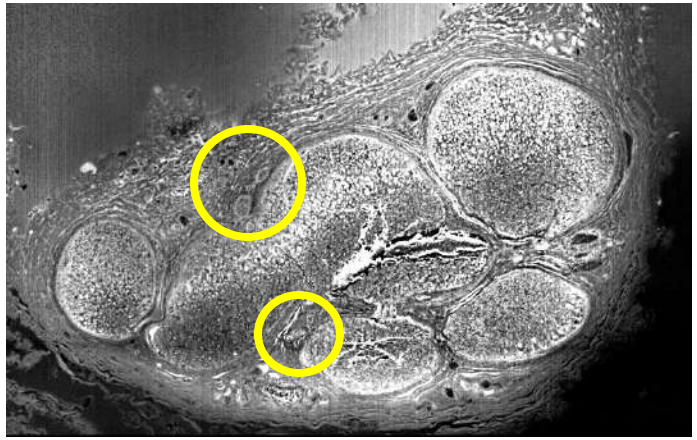
2 Deep Learning Tool – 3D Vagas Nerve Segmentation

Built annotation pipelines to reduce from 5 to 2 days through computer vision pipeline using SAM fine-tuning and adaptive retraining on nerve image data.

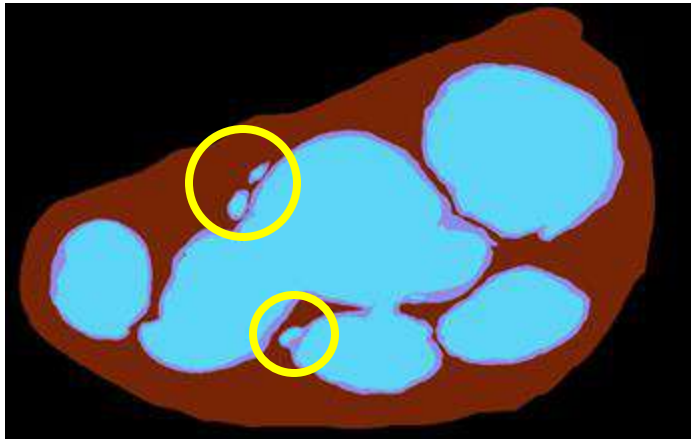
Sample	Images	Train	Test	Dice
1	1000	40	10	0.93 ± 0.05
2	1000	80	20	0.87 ± 0.10
3	435	30	5	0.87 ± 0.08
4	352	20	5	0.85 ± 0.10



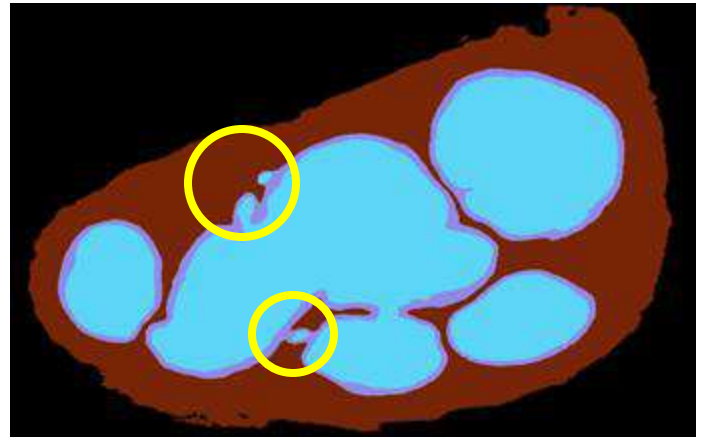




Original Image



Ground Truth

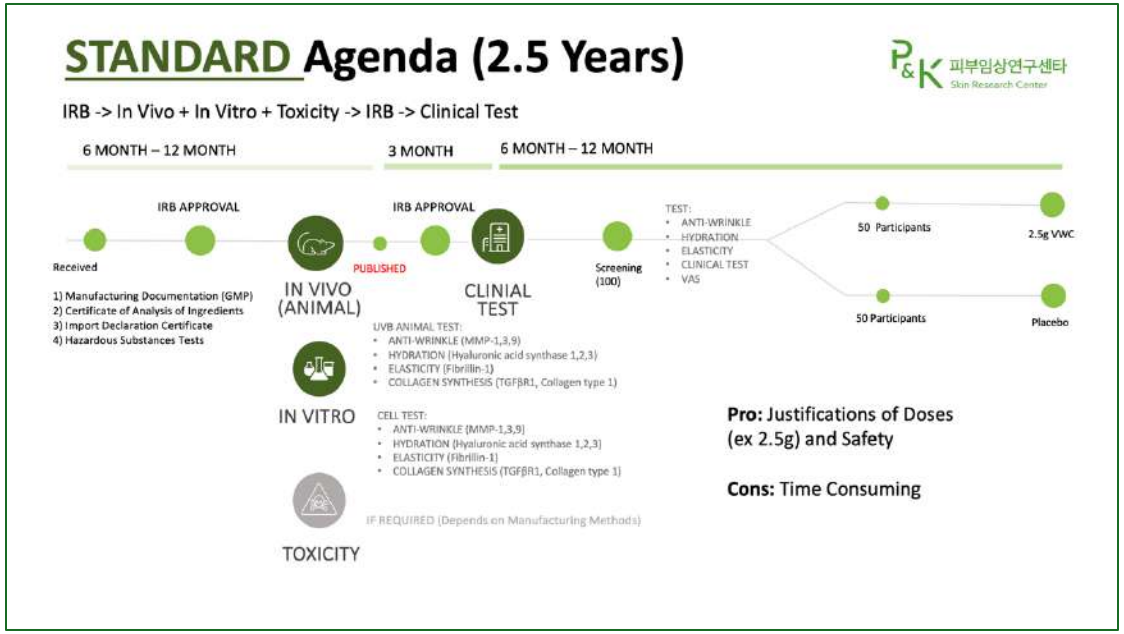


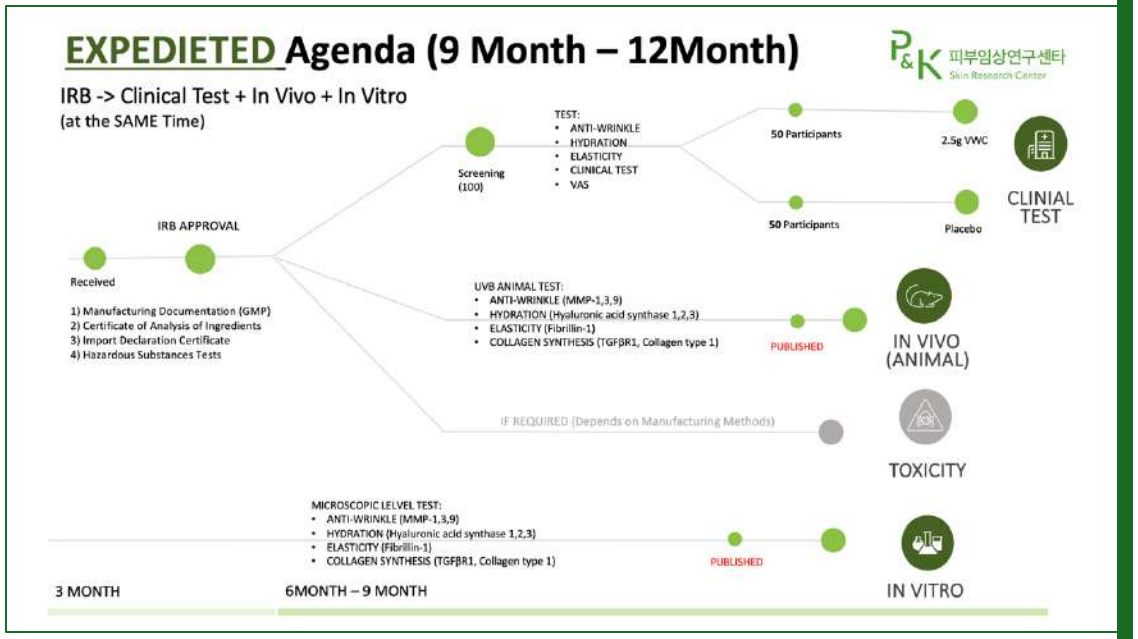
Research: Reconstructing Vagal Nerve

3. Clinical Trial Design

P&K 피부임상연구센타 Skin Research Center

Acted as the main liaison between sponsors, CROs, and research centers to design, adapt, and deliver multiple clinical trial agendas tailored to regulatory timelines and sponsor needs.





Clinical Trial Project Consultant

3. Clinical Trial Design

P&K 피부임상연구센타 Skin Research Center

Led protocol design and biomarker strategy for a 12-week placebo-controlled skin efficacy trial supporting international collagen peptide registration.

STUDY SYNOPSIS

Sponsor: [redacted]	**Name of Ingredient** [redacted]

Title
A randomized, double-blinded, placebo-controlled, parallel study to evaluate the effects of a fish collagen peptide on skin elasticity, wrinkles and moisturizing effect

Objectives
Evaluate the efficacy [redacted] skin health and quality (wrinkles, elasticity, hydration) in female participants aged 45-60 after consuming 2.5g of [redacted] for 12 weeks

Investigational Product
[redacted] is a hydrolyzed collagen powder derived from *Pangasius hypophthalmus*, a tropical and sustainable freshwater fish (Vinh Hoan Corporation)

Number of Participants
Approximately 50-60 participants (25-30 in each group). Participants who drop out of the study will be replaced.

Study Period
12 Weeks

Dose and Mode of Administration
Group A will be the control Group. Participants will receive matching placebo powder containing only inactive ingredients. Group B will receive 2.5g of [redacted]der.

Both Group A and Group B will receive either [redacted] powder daily or a placebo powder once daily, in the morning, dissolved in water as a drink on an empty stomach for 12 Weeks. The powder should be dissolved in at least 100 mL of water.

Group A	Group B
Placebo Powder	2.5g of [redacted]

Study Duration
Participants will be assessed in total 4 visits, at screening, baseline (day 0), day 42, and end-of-study (day 84) to evaluate the study's objectives.

Participants will be screened within a period not to exceed 14 days before Study Day 1.

Eligibility Criteria for Inclusion

1. Females aged 45 to 60 years
2. BMI between 20.0-29.9 kg/m2
3. Gave voluntary, written, informed consent to participate in the study
4. Displayed visible signs of natura and photoaging in the face
5. Agreed to avoid prolonged xposure to UV radiation for the duration of the Study
6. Female participant was not of child bearing potential, defined as females who have had a hysterectomy or oophorectomy, bilateral tubal ligation, or were post-menopausal (natural or surgically with > 1 year since last menstruation) OR Females of childbearing potential agreed to use a medically approved method of birth control and have a negative urine pregnancy test result. A minimum of 3 months stable dose was required for females on a hormonal birth control. Acceptable methods of birth control included:
   a. Hormonal contraceptives including oral contraceptives, hormone birth control patch (Ortho Evra), vaginal contraceptive ring (NuvaRing), injectable contraceptives (Depo-Provera, Lunelle), or hormone implant (Norplant System)
   b. Double-barrier method
   c. Intrauterine devices
   d. Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s)
   e. Vasectomy of partner (shown successful as per appropriate follow-up)

Eligibility Criteria for Exclusion

1. Women who were pregnant, breastfeeding, or planning to become pregnant during the trial
2. Acute or chronic skin disease (i.e. atopic dermatitis, eczema, rosacea, psoriasis) or dermatological disorders (scars, sunburns, moles) near the test sites
3. Topical medications used near the test area within 6 weeks prior to baseline
4. Use of tretinoin, adapalene, tazarotene or other topical medications for the treatment of skin aging near the test site during the 12 weeks preceding baseline
5. Application of topical alpha hydroxyl acids near the test site within 28 days of baseline
6. Use of, or planning to use, systemic corticosteroids within 28 days of baseline or during the study
7. Use of natural health supplements for improving the skin (specifically high concentrations of vitamin A, to be assessed on an individual basis)
8. Planned or unavoidable exposure to intense ultraviolet (UV) radiation during the study (such as sun tanning salons, vacations in a sunny climate or outdoor worker)
9. Botulinum toxin A (Botox) injection treatment near the test sites within 2 years of baseline or plan to receive this treatment during the study

Efficacy Assessments

1. Anti-Wrinkle test
2. Inner-Outer Elasticity test
3. Inner-Outer Skin Moisture Test
4. Wrinkle Imaging
5. Skin Tightening vector

Confidential and Proprietary

Biomarkers for indication of 'Skin Protection' from UV

Classification	Biomarkers	Measurable Research Types		
		in vitro	in vivo	Human
Skin Protection Mechanisms	MAPK, AP-1, p-38,c-Fos, c-Jun, JNK	o	o	
	MMPs	o	o	o
	Ki-(7, 8-OHdG cells		o	
	Thickness of epidermis-dermis		o	o
	MED		o	o
	SOD, GSH-Px, CAT	o	o	
	Cytokine	o	o	
	COX-2	o		
Clinical Improvement	Skin Wrinkle		o	o
	Skin Elasticity		o	o

Biomarkers for indication of 'Skin Hydration'

Classification	Biomarkers	Measurable Research Types		
		in vitro	in vivo	Human
Skin Structure and Function Maintenance	Ceramide		o	o
	Procollagen	o		o
	Collagen Fibers		o	o
	Collagen Synthesis Genes	o		o
	Collagen-I		o	
	Elastin	o		o
	Fibrillin Content			o
	Hyaluronic Acid Content	o	o	
	Hyaluronic Acid Synthesis Enzymes			o
	Collagenase Inhibition Activity	o	o	
	Elastase Inhibition Activity	o		
Clinical Improvement	Skin Moisturization level		o	o
	Transepidermal Water Loss (TEWL)		o	o
	Stratum Corneum Flexibility		o	o
	Skin Roughness			o
	Skin Elasticity		o	o

Clinical Trial Project Consultant

3. Clinical Trial Design Bench Marking

P&K 피부임상연구센타 Skin Research Center

Compiled competitor trial designs across 8 companies to benchmark formulation, dosing, biomarkers, and efficacy endpoints for regulatory strategy.

NO	Company/ Registered Date	Functional Content	Daily Intake	Raw Material	Substance	Manufacturing Process	Trial Test Subjects	Trial Results	In Vivo Testing
1	Amorepacific Corporation 2010.05.20	Hydration/ UV	1,000 ~ 1,500 mg / day	NA	NA	NA	NA	NA	NA
2	CJ Cheil Jedang 2012.09.21	Hydration	2 g/ day	NA	NA	NA	NA	NA	NA
3	NewTree 2013.10.17	Hydration/ UV/ Bone, Joint Strength	Hydration/ UV : 1-3g day / Bone,Joint Strength: 3-4 g/ day	NA	NA	NA	KL grade 1-2, VAS 3/10 or higher, 40-75-year-old adult men and women, 80 participants	1) Significant reduction in total WOMAC score and subcategories (pain, physical function) compared to the control group 2) Significant reduction in total WOMAC score, subcategories (pain, physical function), and VAS score compared to the control group	In a degenerative arthritis-induced animal study, a histopathological evaluation of joints and cartilage (OARSI) showed a decrease in inflammatory markers (IL-1β, IL-6) and an increase in cartilage composition markers (Aggrecan, Collagen Type 2).
4	JUYEONG NS 2019.08.29	Hydration/ UV	3,270 mg/ day	Tilapia - Scales	Gly-Pro-Val-Gly-Pro-Ser (mg/g): 0.83 (80-120% of the indicated amount)	Raw Material → Gelatin Extraction → Enzymatic Hydrolysis → Citric Acid Addition → Spray Drying → Final Product	79 women aged 30-60 with wrinkles and dryness	1) Significant increase in skin moisture levels and skin elasticity indicators (R2, R5, R7) 2) Significant decrease in transepidermal water loss (TEWL)	In an animal study with UV exposure, there was an increase in the expression of hyaluronic acid synthase, filaggrin, and involucrin. Additionally, hyaluronic acid content and skin moisture levels increased while the expression of hyaluronidase and transepidermal water loss (TEWL) decreased.
5	NONGSHIM TAEKYUNG 2019.08.13	Hydration/ UV	1.65 g/day	Nile Tilapia - Scales - Origin: Thailand	Gly-Pro dipeptide: 45 (80-120% of the indicated amount)	Collagen Raw Material → Extraction/Enzymatic Hydrolysis → Filtration → Concentration → Sterilization → Spray Drying → Selection → Final Product	Men and women aged 25-60 with dry skin and a moisture index of 49 or below, and visual assessment of eye wrinkles at grade 3	1) Significant increase in skin moisture levels, eye wrinkles (Ra, R-max, Rz, Rp, Rv), and skin elasticity (KM CoR, Area) 2) Significant decrease in skin keratin levels (forearm area)	In a UV-treated cell experiment, the expression of skin damage-inducing proteins (MMP-1, MMP-3) decreased, and the production of collagen (Type I) increased. In a UV-induced skin dryness animal model, there wa a reduction in wrinkle area, wrinkle count, and transepidermal water loss (TEWL), along with an increase in moisture retention.
6	SuHeung 2022.1.28.	Hydration / UV	2 g/day	Nile Tilapia - Scales, Gelatin	Val-Gly-Pro-Hyp-Gly-Pro-Ala-Gly (mg/g): 0.93 (80-120% of the indicated amount)	Dissolution → Hydrolysis/Heating → Deodorization → Filtration → Sterilization → Dried Raw Material	84 adult men and women aged 35-60 with eye wrinkles L16 or above and bilateral cheek moisture levels of 49 AU or below	1) Significant increase in skin moisture levels compared to the control group 2) Significant decrease in skin wrinkles and transepidermal water loss (TEWL) compared to the control group	In a UVB-treated animal (mice) experiment, there was an increase in skin moisture levels and moisture-related factors (e.g., fibrillin1), as well as a increase in collagen synthesis-related factors (TGFβR1, procollagen type 1, collagen type 1). Additionally, there was a decrease in wrinkle-related factors (MMP-1, MMP-3, MMP-9) and skin thickness.
7	Gettech 2022.1.28.	Hydration / UV	2 g/day	Nile Tilapia - Scales, Gelatin	Val-Gly-Pro-Hyp-Gly-Pro-Ala-Gly (mg/g): 0.93 (80-120% of the indicated amount)	Dissolution → Hydrolysis/Heating → Deodorization → Filtration → Sterilization → Dried Raw Material	84 adult men and women aged 35-60 with eye wrinkles L16 or above and bilateral cheek moisture levels of 49 AU or below	1) Significant increase in skin moisture levels, etc., compared to the control group 2) Significant decrease in skin wrinkles and transepidermal water loss (TEWL) compared to the control group	In a UVB-treated animal (mice) experiment, there was an increase in skin moisture levels and moisture-related factors (e.g., fibrillin1), as well as a increase in collagen synthesis-related factors (TGFβR1, procollagen type 1, collagen type 1). Additionally, there was a decrease in wrinkle-related factors (MMP-1, MMP-3, MMP-9) and skin thickness.
8	CJ Wellcare 2023.2.15	Hydration / UV	2 g/day	NA	NA	NA	NA	NA	NA

Clinical Trial Project Consultant

3. Market Scraper for Collagen Products on Amazon & Coupang

P&K 피부임상연구센타 Skin Research Center

Built a Python scraper to extract pricing, rating of 100+ collagen supplements across major e-commerce platforms for competitor benchmarking.

```
#·Create·DataFrame·and·drop·rows·with·missing·titles
coupang_df·=·pd.DataFrame.from_dict(d)
coupang_df·=·coupang_df.dropna(subset=['Title'])

#Save·to·CVS
output_path='coupang_collagen_data.csv'
coupang_df.to_csv(output_path,header=True,index=False)

coupang_df.head()
```

Python

	Title	Price	Rating_Count	Rating_Num	Sellers	Ingredients	Nutritions	Links	Manufacturer
0	에버콜라겐 타임 비오틴 50포, 150g, 2개	79,900원	45,141	5.0		N/A	N/A	http://www.coupang.com/vp/products/7235454776?...	NA
1	홀리데이즈 프리미엄 콜라겐, 120정, 2개	19,900원	28,941	4.5		N/A	N/A	http://www.coupang.com/vp/products/6283668167?...	NA
2	닥터스베스트 콜라겐 타입 1 앤 3 500mg 캡슐, 240정, 1개	23,460원	4,888	4.5		N/A	N/A	http://www.coupang.com/vp/products/2527891?ite...	NA
3	에버콜라겐 타임 비오틴 50포, 150g, 2개	79,900원	45,141	5.0		N/A	N/A	http://www.coupang.com/vp/products/7235454776?...	NA
4	에버콜라겐 타임 비오틴, 150g, 1개	40,830원	45,141	5.0		N/A	N/A	http://www.coupang.com/vp/products/7235454776?...	NA

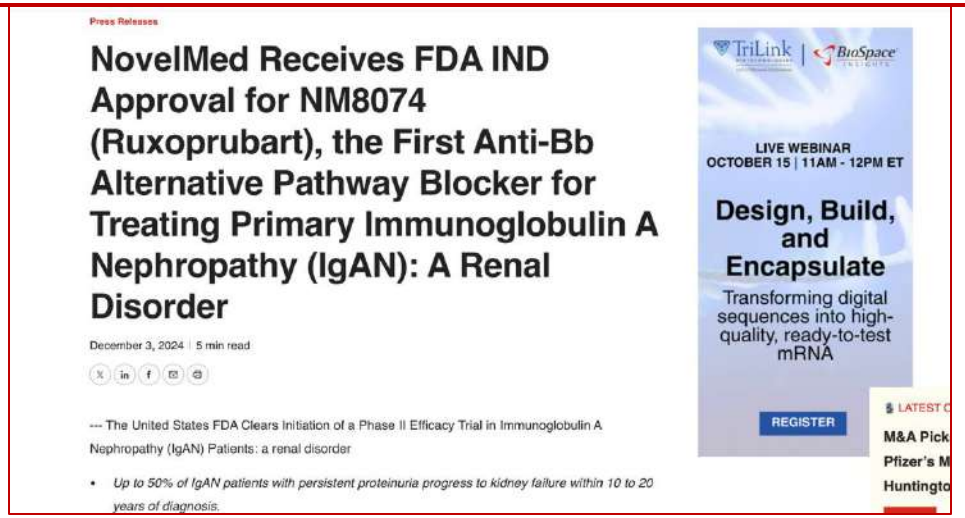
Title	Price	Rating_Count	Rating_Num	Li
에버콜라겐 타임 비오틴 50포, 150g, 2개	79,900원	45,141	5.0	ht
홀리데이즈 프리미엄 콜라겐, 120정, 2개	19,900원	28,941	4.5	ht
닥터스베스트 콜라겐 타입 1 앤 3 500mg 캡슐, 240정, 1개	23,460원	4,888	4.5	ht
에버콜라겐 타임 비오틴 50포, 150g, 2개	79,900원	45,141	5.0	ht
에버콜라겐 타임 비오틴, 150g, 1개	40,830원	45,141	5.0	ht
[서울대 위바이옴] 식약처 인정 국내 최대함량 3270mg 저분자	132,000원	356	4.5	ht
에버콜라겐 인앤업플러스, 84정, 1개	33,490원	8,673	5.0	ht
뉴트리원 비비랩 저분자 콜라겐 비타민C, 100g, 2개	39,900원	10,633	5.0	ht
여에스더 어린콜라겐 비오틴플러스 비오틴콜라겐 (+에스더포뮬	114,640원	1,224	4.5	ht
에버콜라겐 타임 비오틴, 150g, 1개	40,830원	45,141	5.0	ht
뉴트리원 비비랩 저분자 콜라겐 비타민C, 100g, 2개	39,900원	10,633	5.0	ht
비비랩 더 콜라겐 파우더S, 100g, 3개	62,900원	11,935	4.5	ht
오니스트 트리플콜라겐 오렌지, 280g, 1개	34,320원	763	5.0	ht
순수식품 석류 저분자 콜라겐 젤리 스틱, 300g, 10개	62,820원	26,796	4.5	ht
세비톨 멀티 퍼펙트 저분자 피쉬 콜라겐 펩타이드, 99g, 30개	16,500원	8,331	5.0	ht
비타할로 피쉬 콜라겐 석류맛, 180g, 1개	16,390원	15,589	4.5	ht
보뚜 저분자 콜라겐 C, 180g, 1개	15,540원	13,139	4.5	ht
로엘 히알루론산 콜라겐정, 60정, 1개	9,900원	15,564	4.5	ht
닥터스베스트 콜라겐 타입 1 앤 3 500mg 캡슐, 240정, 1개	23,460원	4,888	4.5	ht
네오셀 Neocell 마린 콜라겐 콜라겐/히알루론산, 120정, 1개	21,690원	13,731	4.5	ht
바이탈뷰티 슈퍼콜라겐 앰플 30일분, 750ml, 1개	55,700원	11,345	5.0	ht
네오셀 Neocell 마린 콜라겐 콜라겐/히알루론산, 120정, 3개	59,960원	13,731	4.5	ht
닥터스베스트 콜라겐 타입 1 앤 3 500mg 캡슐, 240정, 2개	44,250원	4,888	4.5	ht
늘삽 석류 콜라겐 젤리스틱 레디퀸	23,900원	0	0.0	ht
비타할로 석류 콜라겐 스틱 30개, 600g, 2개	24,990원	13,069	4.5	ht
네오셀 Neocell 마린 콜라겐 콜라겐/히알루론산, 120정, 1개	21,690원	13,731	4.5	ht
홀리데이즈 프리미엄 콜라겐, 120정, 1개	10,900원	28,941	4.5	ht
로엘 히알루론산 콜라겐정, 60정, 1개	9,900원	15,564	4.5	ht
비비랩 저분자 콜라겐 비오틴 플러스 50p, 100g, 2개	41,900원	4,716	5.0	ht
[6개월분] 건강헤아림 저분자 피쉬 어린 콜라겐 펩타이드 비오틴	46,760원	926	5.0	ht

Clinical Trial Project Consultant

4. Regulatory Affair Experience

Key Role

- Phase II Clinical Trials Management
- CRO / SMO Coordination
- AE / SAE Monitoring
- Deviation Management
- FDA Submission – Protocol Writing
- CMC (Chemistry, Manufacturing, and Controls) Data Management
- Trial Master File (TMF)
- Risk Mitigation
- Inspection Readiness
- Trial Disruption Prevention



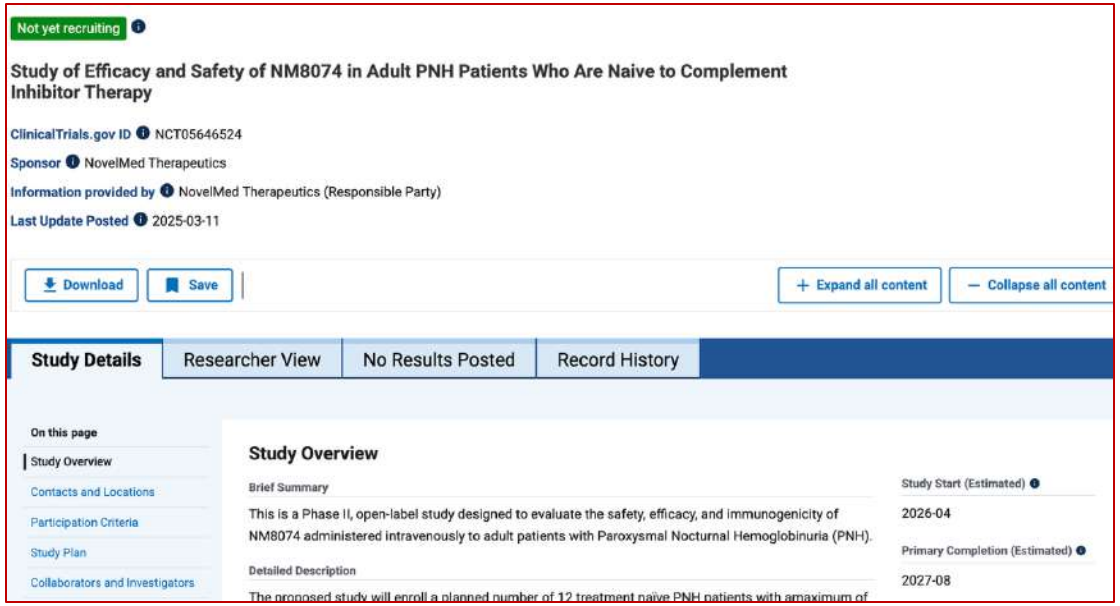
Press Releases

NovelMed Receives FDA IND Approval for NM8074 (Ruxoprubart), the First Anti-Bb Alternative Pathway Blocker for Treating Primary Immunoglobulin A Nephropathy (IgAN): A Renal Disorder

December 3, 2024 | 5 min read

--- The United States FDA Clears Initiation of a Phase II Efficacy Trial in Immunoglobulin A Nephropathy (IgAN) Patients: a renal disorder

- *Up to 50% of IgAN patients with persistent proteinuria progress to kidney failure within 10 to 20 years of diagnosis.*



Not yet recruiting

Study of Efficacy and Safety of NM8074 in Adult PNH Patients Who Are Naive to Complement Inhibitor Therapy

ClinicalTrials.gov ID NCT05646524
Sponsor NovelMed Therapeutics
Information provided by NovelMed Therapeutics (Responsible Party)
Last Update Posted 2025-03-11

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Study Details | Researcher View | No Results Posted | Record History

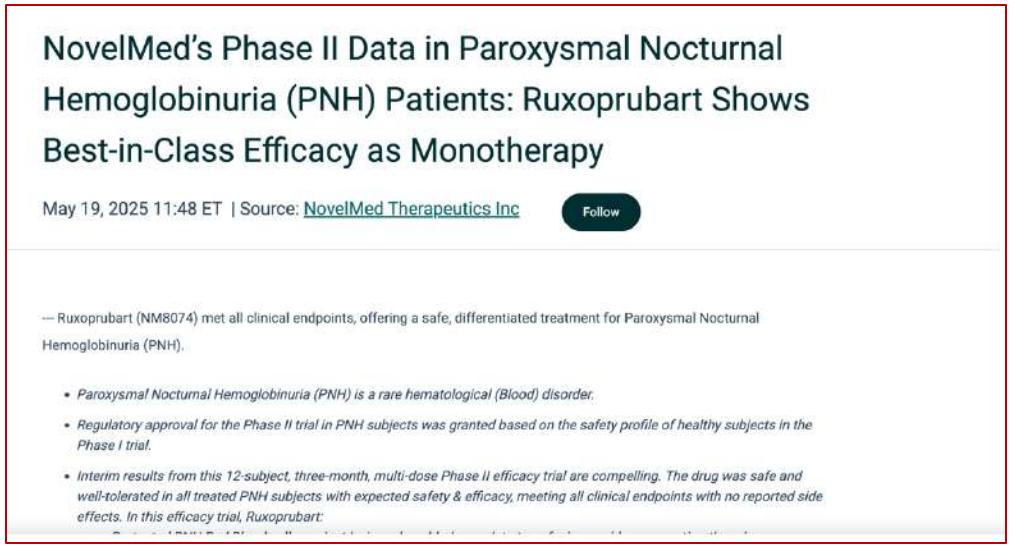
On this page
- Study Overview
- Contacts and Locations
- Participation Criteria
- Study Plan
- Collaborators and Investigators

Study Overview

Brief Summary
This is a Phase II, open-label study designed to evaluate the safety, efficacy, and immunogenicity of NM8074 administered intravenously to adult patients with Paroxysmal Nocturnal Hemoglobinuria (PNH).

Detailed Description
The proposed study will enroll a planned number of 12 treatment naïve PNH patients with amaximum of

Study Start (Estimated) 2026-04
Primary Completion (Estimated) 2027-08



NovelMed's Phase II Data in Paroxysmal Nocturnal Hemoglobinuria (PNH) Patients: Ruxoprubart Shows Best-in-Class Efficacy as Monotherapy

May 19, 2025 11:48 ET | Source: NovelMed Therapeutics Inc

--- Ruxoprubart (NM8074) met all clinical endpoints, offering a safe, differentiated treatment for Paroxysmal Nocturnal Hemoglobinuria (PNH).

- *Paroxysmal Nocturnal Hemoglobinuria (PNH) is a rare hematological (Blood) disorder.*
- *Regulatory approval for the Phase II trial in PNH subjects was granted based on the safety profile of healthy subjects in the Phase I trial.*
- *Interim results from this 12-subject, three-month, multi-dose Phase II efficacy trial are compelling. The drug was safe and well-tolerated in all treated PNH subjects with expected safety & efficacy, meeting all clinical endpoints with no reported side effects. In this efficacy trial, Ruxoprubart:*

Regulatory Affair Intern, NovelMed Therapeutics

5. Manufacturing Experience at Active Pharmaceutical Ingredients Facility

olon USA

Key Role

- FDA PAI Readiness Support
- Exception Summary Reports
- Batch Record Review
- Commercial API Support
- Equipment Qualification
- cGMP Compliance

Manufacturing - Process and Development Olon USA