



ORTHO MEDICO

C L I N I C A L T R I A L

ORTHOMEDICO Inc.

Research Study Group and Outcome Development





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Company Introduction



Company Profile

Company Name ORTHOMEDICO Inc.

Establishment 2005/06

Capital Stock 75M yen

President Kazuo Yamamoto

Staff members Full-time: 50
Part-time: 75

Address 〒112-0002
2F Sumitomo Fudosan Korakuen Bldg., 1-4-1 Koishikawa, Bunkyo-ku,
Tokyo, Japan

Website <https://www.orthomedico.jp/english.html>

Area of business

1. Clinical Trial
2. Agent for submission of notifications
3. Participant recruitment
4. Market Research
5. Research Study Group Organization
6. Outcome Development
7. Overseas Business



山本和雄
Kazuo Yamamoto
President/ CEO



A Brief History of ORTHOMEDICO

- 人 In 06/2005, ORTHOMEDICO was created as a subdivision in Tokyo Medical and Dental University.
 - Sole purpose was to **evaluate food safety**
- 人 Over the years, ORTHOMEDICO has evolved enormously from a small division in a university to a **major company** with numerous clients both locally and internationally.

**Our passion for ensuring food safety has remained unchanged.
Sparing no effort in proving the safety of our clients' food products!**



Overseas Enterprise



Support to overseas enterprise

- Acquisition of scientific evidence of Asian population
- Agent for notification as food with functional claims
- Organization of study groups and seminars to promote clients' products /idea.
- Expansion of business to the Japanese market

Japanese Enterprise



Support to local enterprise

- Acquisition of scientific evidence of overseas non-Asian population
- Expansion of business to overseas market



Research Study Group Organization

Research Study Group Organization



*HAJIKEN is a contraction of the original Japanese name "はじめての研究会" (Hajimete no kenkyukai), meaning "first study group".



**Now is the time to
get global !!**

- 人 In Orthomedico, we help businesses and researchers spread the words of their nutritional or medical researches, while advertising their products or sharing their research ideas through
- Establishing study groups
 - Organizing seminars, workshops, symposiums and conferences
 - Providing financial support to businesses / researchers

6 steps from enquiry to organization

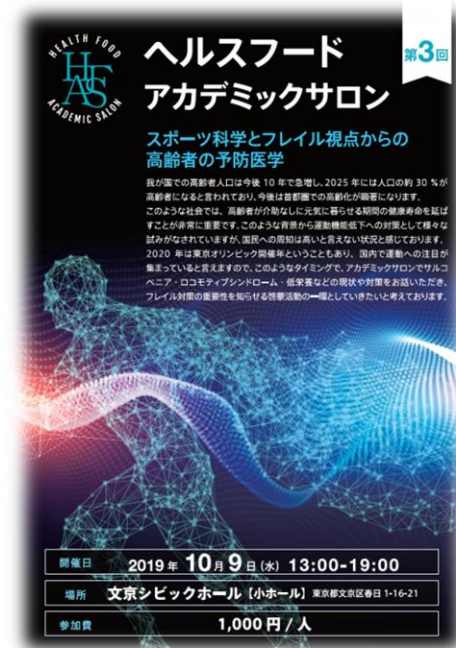
Total Support from seminar objective establishing, lecturer selection, scale estimation, timing suggestion, to setting up of venue after initial enquiry!





Examples of academic events held

Health Food Academic Salon



Event example A

No. of lecturers

4

No. of participants

Approx. 50 ~ 100

Planning and operating cost

Approx. 2,000,000 yen

プログラム | 12時30分 受付

講演



【13:00~14:00】

「生涯現役のための運動医科学」

講師：森谷 敏夫 先生 京都大学 名誉教授

講演



【14:00~14:45】

「スポーツの競技力向上とヘルスフード」

講師：澤木 啓祐 先生 順天堂大学 特任教授／名誉教授

講演



【14:45~15:30】

「国家戦略としてのフレイル対策－健康長寿 鍵は“食力”－」

講師：飯島 勝矢 先生 東京大学 高齢社会総合研究機構 教授

休憩 15:30~16:00 (名刺交換等)

ディスカッション



【16:00~17:30】

講演後、演者によるパネルディスカッションを予定しております。

座長：矢澤 一良 先生 早稲田大学 ナノ・ライフ創新研究機構 規範科学総合研究所ヘルスフード科学部門 部門長

懇親会



【18:00~19:00】 文京シビックホール【スカイホール】

講師の先生方への質問や名刺交換の場としてご活用ください。

懇親会は会場のお席に限りがございますので、お早めにお申し込みください。

Researchers in the field of sports science were invited to give speeches



Examples of academic events held

International Vitamin K2 Symposium



Event example B

No. of lecturers

6

No. of participants

Approx. 150~200

Planning and operating cost

Approx. 5,000,000 yen



The 1st Vitamin K2 health function and application challenges
Speaker



Presentation time 12:35 - 13:05 —
Progress in Vitamin K2 Research and
Its New Health Functionality in
Japan
Graduate School of Agricultural
Science, Tohoku University
**Prof. Dr. Hitoshi
Shirakawa**



Presentation time 14:20 - 15:00 —
Effects and Related Mechanisms of
Vitamin K2 Supplementation on
Diabetes
Harbin Medical University, Public Health
Prof. LI YING



Presentation time 13:05 - 13:35 —
Discovery of Novel Bioactive
Substances by Derivatization of
Vitamin K
Faculty of Bioscience and Engineering,
College of Systems Engineering and
Science, Shibaura Institute of
Technology
**Prof. Dr. Yoshitomo
Suhara**



Presentation time 15:00 - 15:40 —
New Insights on Menquinone-7
Effects in Vascular Calcification and
Stiffness
Southwest Jiaotong University
Hospital, The Third People's Hospital of
Chengdu, Hematology
Prof. TAN JING



Presentation time 13:35 - 14:05 —
From Japan! Health Function of
Natural Fermented Vitamin K2
(Menaquinone-7)
Assistant director, Food Design Center,
J-OIL MILLS, Inc.
Mr. Toshiro Sato



Presentation time 15:55 - 16:35 —
Relationship between the inhibitory
effect of calcium migration by
vitamin K2 and inflammatory factors
Shenyang Pharmaceutical University,
Life Sciences and Biological Pharmacy
Prof. XU FENG

* Depending on the control of COVID-19, there is a possibility of changes to the program or suspension of the event. Your understanding would be much appreciated.

Japanese and Chinese researchers gathered
to share their Vitamin K research results.



Best Life Award (BLA)



What is the Best Life Award ?

- ◆ It is basically a 30M yen research support fund dedicated for individuals and organizations such as local small businesses to plan and conduct their QOL-improving researches.



Objective

- ◆ Help/ provide assistance to individuals or organizations who are engaged in developing ways to improve people's QOL, and realize their underused/unused ideas.



General flow

- ◆ Upon receiving applications, applicants and their projects will be reviewed by a selection committee before the selected applicants are finalized and awarded.





Best Life Award (BLA)



Target areas:

Food (Raw material)

Food raw materials that are seen as potential candidates in the contribution of maintenance and promotion of health and beauty.

Food (Final product)

Food products that are seen as potential candidates in the contribution of maintenance and promotion of health and beauty (products which are sold already or scheduled for sale)

Epidemiological Survey

National survey that aims at development of health maintenance

Confectionaries

Food products that are seen as potential candidates in disease prevention and health promotion (confectioneries and snacks)

Daily necessities

Products and technologies such as bathtub, toilets, sanitary, and textiles (clothing) that are seen as potential candidates in the contribution of improvement of QOL when used in living spaces

Health device Sporting equipment

Healthcare device and sporting equipment that support the understanding of health status and lifestyle, or support the practice of health promotion

Specialty foods from Japan

Specialty foods within prefectures of Japan



Best Life Award (BLA)

Here are some of the awardees of the 1st Best Life Award



Activity Supported:

- Clinical Trial

Research Topic:

- Study on the development of food with functional food for the prevention of Metabolic Syndrome and frailty



Activity Supported:

- Dietary/Nutrition Questionnaire (CAND)

Research Topic:

- Impact of health literacy instructional interventions on the nutritional status among students enrolled in registered dietitian programme



BEST LIFE AWARD

2nd BEST LIFE AWARD

Now open for entry

Entry Deadline: 31st July, 2022 12:00JST



Outcome Development

Outcome Development

- 人 In a clinical trial for functional food, **healthy individuals** are usually set as the main target for studying. Thus, it is often difficult for clinical outcomes used by pharmaceutical studies to be applied on such studies of food product.
- 人 With that in mind, clinical **outcomes** are proactively being studied here to increase the aim of the accuracy of evaluation of food product in clinical studies, in ORTHOMEDICO.



Clinical outcome and preclinical research service developed we can offer



CAND[®]
Calorie And Nutrition Diary

Calorie And Nutrition Diary (CAND)



ニュートリゲノミクス
サービス

Nutrigenomics Service

Calorie And Nutrition Diary (CAND)

What is CAND?

- CAND is a novel dietary questionnaire developed by ORTHOMEDICO for quick and easy recording and assessment of dietary habits of test subjects.*
- Designed to allow individuals who are not accustomed to meal preparation to answer with ease.
- Currently, CAND is being utilized in the following areas.
 - In university lectures and researches
 - In local food education activities
 - Self-health management of employees
 - Enquiry to the nutritional values of one's meal



CAND[®]
Calorie And Nutrition Diary

CANDの記入について
1日に食べた食事の量を記入欄には、食品/1人分ガイドと日本食品標準成分表の分類に基づき、8つに分類(分類1)しています。

分類	分類2	分類3
主食	ご飯・パン・麺・雑穀・その他穀類食品	31単位
副食	サラダ・野菜・いも類・大豆以外の豆類・その他野菜・海藻類	17単位
主菜	肉類・魚介類・卵類・大豆・大豆製品	26単位
牛乳・乳製品	---	3単位
豆類	---	1単位
植物油	---	1単位
菓子	---	3単位
嗜好飲料	---	4単位
その他	中華料理・エスニック・スープ類(湯・粥)	22単位

* N Suzuki, et al. A novel dietary questionnaire: The Calorie and Nutrition Diary (CAND)
New Food Industry 2019;61(10):721-732.

Calorie And Nutrition Diary (CAND)

- When conducting nutrition survey using CAND, details of meal is recorded through selection of dishes from list of names of dishes
- The amount of food consumed (number of servings) is estimated using the size of the hand when playing “Gu, choki and par” (A Japanese version of “Paper, rock and scissors”) as a reference
- Answers are recorded on a mark sheet

一測定から記入の流れー
マークシートの記入方法 [1]

前項までの食べた料理の該当箇所が確認できましたら、目安量 (グーまたはパー) を基に換算した摂取量 (人前) をマークシートへ記入します。

食べ物	朝	昼	夜	CANDへの記入
ごはん	1	1	2	
サラダ (肉なし)	—	—	1	1
鮭の塩焼き	1	—	—	1
ステーキ (牛ロース)	—	—	1	1
みそ汁	1	—	—	1
幕の内弁当	—	1	—	1

例) マークシートの塗りつぶしについて

1101 ① ② ③ ④ ⑤ ← 良い例

1102 ① ② ③ ④ ⑤ ← 悪い例

1103 ① ② ③ ④ ⑤

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一測定から記入の流れー
マークシートの記入方法 [2]

・ごはんの場合

ごはん (p.13参照ください) の回答番号は **1101** です。

食べ物	朝	昼	夜	CANDへの記入
ごはん	1	1	2	

1101 ① ② ③ ④ ⑤

1日に2人前を食べていますので、②を塗りつぶします。

・サラダ (肉なし) の場合

サラダ (p.17参照ください) の回答番号は **2101** です。

食べ物	朝	昼	夜	CANDへの記入
サラダ (肉なし)	—	—	1	1

2101 ① ② ③ ④ ⑤

1日に1人前を食べていますので、①を塗りつぶします。

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一測定から記入の流れー
マークシートの記入方法 [3]

・鮭の塩焼きとステーキ (牛ロース) の場合

鮭の塩焼きとステーキ (牛ロース) (p.19参照ください) の回答番号は、鮭の塩焼きが **3202**、ステーキ (牛ロース) が **3103** となります。

食べ物	朝	昼	夜	CANDへの記入
鮭の塩焼き	1	—	—	1
ステーキ (牛ロース)	—	—	1	1

3202 ① ② ③ ④ ⑤

3103 ① ② ③ ④ ⑤

1日にそれぞれ1人前を食べていますので、いずれもの①を塗りつぶします。

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一測定から記入の流れー
マークシートの記入方法 [4]

・みそ汁と幕の内弁当の場合

みそ汁 (p.25参照ください) と幕の内 (p.27参照ください) の回答番号は、みそ汁が **9201**、幕の内弁当が **9401** となります。

食べ物	朝	昼	夜	CANDへの記入
みそ汁	1	—	—	1
幕の内弁当	—	1	—	1

9201 ① ② ③ ④ ⑤

9401 ① ② ③ ④ ⑤

1日にそれぞれ1人前を食べていますので、いずれものを塗りつぶします。

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CAND

食べ物	朝	昼	夜	CANDへの記入
ごはん	1	1	2	
サラダ (肉なし)	—	—	1	1
鮭の塩焼き	1	—	—	1
ステーキ (牛ロース)	—	—	1	1
みそ汁	1	—	—	1
幕の内弁当	—	1	—	1

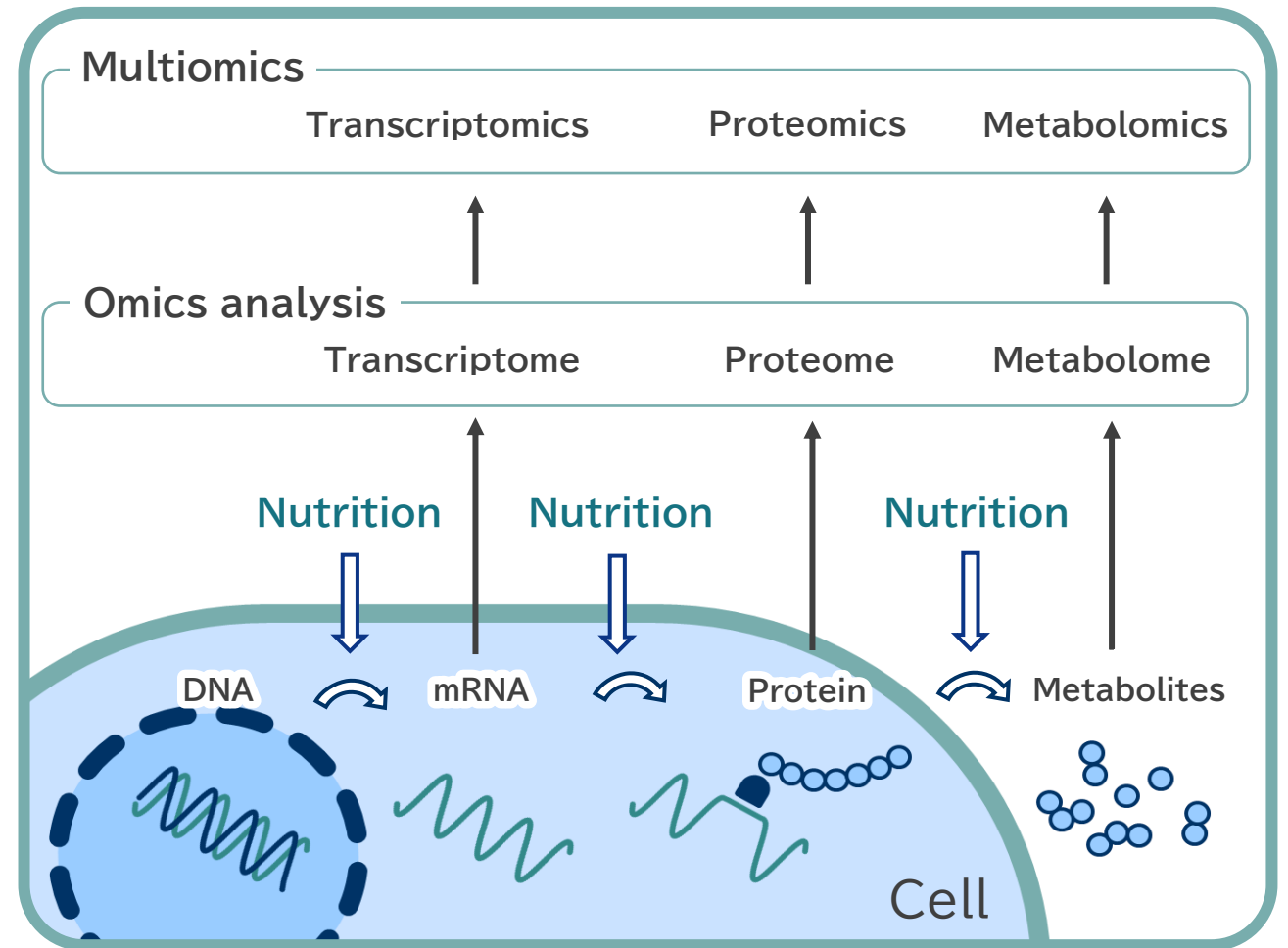
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* N Suzuki, et al. A novel dietary questionnaire: The Calorie and Nutrition Diary (CAND) *New Food Industry* 2019;61(10):721-732.



Nutrigenomics service

- ⤴ Nutrigenomics service is a preclinical analysis service provided with the support from Professor Taichi Hara, an expert of food science from Waseda University
- ⤴ Service scheme: To analyze and demonstrate the changes on gene expression that occur when a food material is added to specific cells, and consequently examine and define the functionality of that food material in human beings



 Please feel free to contact us if you have any enquiry !

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International Support Division



RICHARD SUN KWONG, LAI

Bachelor of Pharmacy, The University of Hong Kong

Registered Pharmacist of HKSAR

Considerable clinical experience as a pharmacist



XUN, LIU

Bachelor of Science, Tianjin Medical University

Master of Medical Science, University of Tsukuba

Ph.D., The University of Tokyo



Looking forward to working with you!
Thank you very much!!

