Fuji Keizai
Marketing Research &
Consulting Group

Survey on the trends in overseas expansion by Japanese clinical testing companies -Comprehensive analysis-

<Survey report>

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Survey overview

1. Topic of the survey

Survey on the trends in overseas expansion by Japanese clinical testing companies -Comprehensive analysis-

2. Purpose of the survey

- ✓ Infectious diseases that threaten the health of the poor around the world such as malaria, tuberculosis, and neglected tropical diseases (NTDs) keep spreading. Under such circumstances, the GHIT Fund has been working on the development of new drugs for infectious diseases such as NTDs to contribute to global health with Japanese technologies and innovations since its foundation in 2013. From exploratory research (drug discovery) to clinical testing and at each stage of regulatory approval, it invests in continuous product development to promote the adoption of innovations in R&D by domestic and overseas related industries and academia in the real world.
- ✓ The GHIT Fund actively invests in late-stage product development (late-stage clinical projects) to pave the way for delivering therapeutic drugs, vaccines, and diagnostics to those most in need more quickly.
- ✓ The GHIT Fund promotes the co-creation of products through international cross-industrial joint research with Japanese and overseas academia, research institutions, pharmaceutical companies, SMEs, and start-ups. It establishes a technological network to respond to global pandemics and climate change and explores technological seeds.
- ✓ The GHIT Fund also plans to comprehensively explore technological seeds for diagnostics and medical devices.
- ✓ In Japan, many companies self-manufacture diagnostics. Infectious disease testing using immunoassays, in particular, is a field where it is more likely that the technologies of Japanese companies can be delivered to overseas countries more quickly since many Japanese companies have entered the market.
- ✓ In this survey, a comprehensive analysis was conducted based on the results of the interview with Japanese diagnostics manufacturers for diagnostic reagents. The purpose of this survey is to analyze the candidate companies Fuji Keizai selected based on the open call strategies of the GHIT Fund and the movements of the eligible companies and the current challenges and needs to provide data that will contribute to your development of diagnostics for NTDs.

3. Survey method

Category	Detail
Comprehensive survey	The comprehensive survey report is created by our professional researchers

4. Survey period

✓ March 2025

5. Research organ

✓ Life Science Division, Fuji Keizai Co., Ltd.

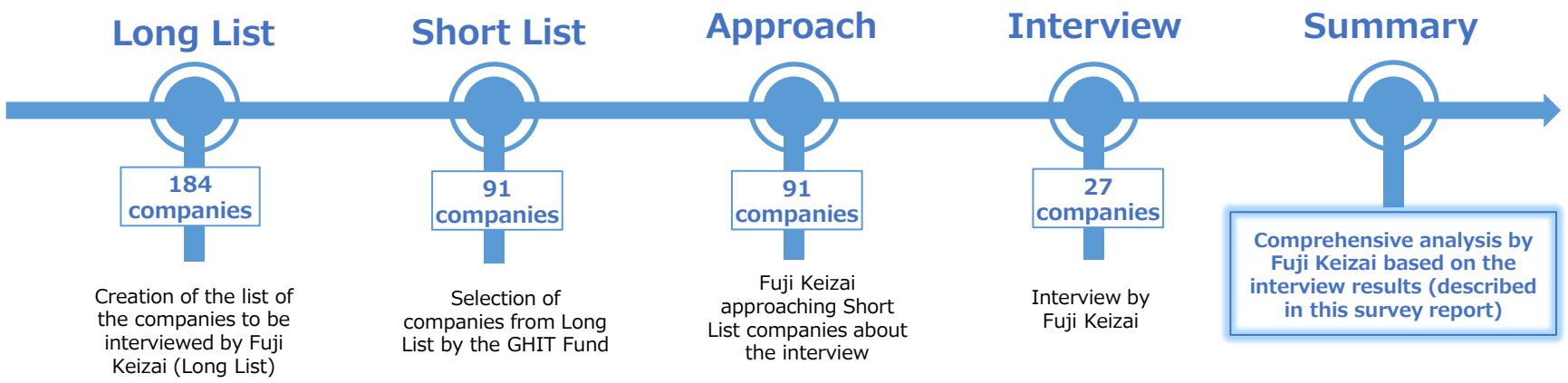
Table of Contents

I. Overview of the survey

Surveyed companies

Group	Classification of the interviewed companies
Group 1	(i) Manufacturers of in vitro diagnostics for infectious disease testing using immunoassays (lateral flow assays (with or without reader)), POC immunoassays (device type/cartridge type) (ii) Leading raw material manufacturers related to immunoassay technology (iii) Leading contract manufacturers related to immunoassay technology (iv) Smart auscultation tool manufacturers (digital stethoscopes, cough analyzers, etc.) (v) Major raw material manufacturers of molecular assays using PCR (oligonucleotide, PCR enzymes, etc.) (vi) Manufacturers of portable X-ray/ultrasound devices and skin imaging devices (vii) Manufacturers of point-of-care (POC) molecular assays & devices
Group 2	(i) Companies providing blood culture solutions for decentralized medical environments (device-based or manual) (ii) Major manufacturers of raw materials for molecular assays using nucleic acid amplification methods other than PCR (oligonucleotide, enzymes for nucleic acid amplification methods other than PCR, etc.) (iii) Companies providing POC Dx solutions for diabetes (standard BGM, noninvasive or minimally invasive BGM, continual BGM, HbA1c)
Group 3	(i) Companies owning sequencing technologies (devices and software) (ii) POC blood testing device manufacturers (Hg, 3-5 DIFF, platelets)

Flow of the survey



I. Overview of the survey

Summary of the results of the approach to the companies about the interview

	Technological category	No. of Long List companies	No. of Short List companies	No. of companies Fuji Keizai approached about the interview	No. of companies interviewed	No. of companies that declined the interview
Group 1	**(i) Manufacturer of in vitro diagnostics for infectious disease testing using immunoassays** (Lateral flow assays (with or without readers)), POC immunoassays (device type/cartridge type)	66	37	37	**15**	15
	(ii) Leading raw material manufacturers related to immunoassay technology	9	3	3	**1**	0
	(iii) Leading contract manufacturers related to immunoassay technology	11	4	4	**2**	1
	(iv) Smart auscultation tool manufacturers (digital stethoscopes, cough analyzers, etc.)	7	1	1	0	1
	(v) Major raw material manufacturers of molecular assays using PCR (oligonucleotide, PCR enzymes, etc.)	5	1	1	0	0
	(vi) Manufacturers of portable X-ray/ultrasound devices and skin imaging devices	16	3	3	0	3
	(vii) Manufacturers of point-of-care (POC) molecular assays and devices	6	1	1	0	0
Group 2	**(i) Companies providing blood culture solutions for decentralized medical environments** (device-based or manual)	2	2	2	0	1
	(ii) Major manufacturers of raw materials for molecular assays using nucleic acid amplification methods other than PCR (oligonucleotide, enzymes for nucleic acid amplification methods other than PCR, etc.)	8	8	8	**3**	3
	(iii) Companies providing POC Dx solutions for diabetes (Standard BGM, noninvasive or minimally invasive BGM, continual BGM, HbA1c)	18	11	11	0	3
Group 3	**(iv) Companies owning sequencing technologies** (devices and software)	27	14	14	**4**	2
	(v) POC blood testing device manufacturers (Hg, 3-5 DIFF, platelets)	9	6	6	**2**	1
	Total	184	91	91	27	30

*After creating the list of Group 1 companies and interviewing them, the lists of Group 2 and Group 3 companies were created, and their interviews were held. So, some companies that had been included in the list of Group 1 companies and then interviewed were included in the lists of Group 2 and Group 3 companies and interviewed again. However, we do not take such duplication into consideration.

Answers, such as "The infectious disease area is not the area we focus on," and "What we can do in our technological fields does not match what we should do in the project," accounted for a large percentage as the main reasons for declining the interview.

I. Overview of the survey

Tabulation of the answers to the interview questions

*The answers to the major interview questions that can be tabulated are tabulated below. As for the number of companies that answered the questions, the answers of SYSMEX and Sekisui Medical, which had been interviewed twice, were not counted for each interview, but just for one. SYSMEX and Sekisui Medical are classified into Group 1 for the sake of convenience. In addition, the percentages shown are the proportions of the number of companies that chose the answers to the number of companies that answered the questions.

Quality Management System obtained

Category/QMS	ISO 13485	Other
Group 1	17	13
Group 2	1	3
Group 3	2	4
Total number of companies that chose this answer	20	20
Number of companies that answered this question	25	25
Percentage	**80.0%**	**80.0%**

*Multiple answers allowed

The vast majority of companies, mostly in-vitro diagnostics manufacturers, obtained ISO 13485 certification.
"ISO 9001" accounted for a large portion of "Other" answers.

Whether or not having overseas achievements in the technological category

Category/ Whether or not having overseas achievements	Yes	No
Group 1	17	1
Group 2	3	0
Group 3	3	1
Total number of companies that chose this answer	23	2
Number of companies that answered this question	25	25
Percentage	**92.0%**	**8.0%**

Many companies have overseas achievements and operate globally.

I. Overview of the survey

Methods of overseas expansion in the technological category

Category/expansion method	In-house marketing	Outsourced marketing	Contract manufacturing	Raw material supply	Other
Group 1	11	5	4	5	3
Group 2	1	0	1	3	0
Group 3	1	1	1	1	3
Total number of companies that chose this answer	13	6	6	9	6
Number of companies that answered this question	25	25	25	25	25
Percentage	**52.0%**	**24.0%**	**24.0%**	**36.0%**	**24.0%**

*Multiple answers allowed

Product sales through sales subsidiaries or agencies accounted for a large portion of “Other” answers.

Level of promotion of overseas operations

Category/Level of promotion	High	Relatively high	Normal	Relatively low	Low
Group 1	8	7	3	0	0
Group 2	1	0	1	0	1
Group 3	1	1	2	0	0
Total number of companies that chose this answer	10	8	6	0	1
Number of companies that answered this question	25	25	25	25	25
Percentage	**40.0%**	**32.0%**	**24.0%**	**0.0%**	**4.0%**

“High” and “relatively high” account for 72.0% of the answers to the question on the level of promotion of overseas operations, showing that more companies focus on promoting overseas operations.

I. Overview of the survey

Level of interest in NTDs

Category/Level of interest	High	Relatively high	Normal	Relatively low	Low
Group 1	4	6	3	3	2
Group 2	0	0	0	0	3
Group 3	0	0	3	1	0
Total number of companies that chose this answer	4	6	6	4	5
Number of companies that answered this question	25	25	25	25	25
Percentage	**16.0%**	**24.0%**	**24.0%**	**16.0%**	**20.0%**

"High" and "relatively high" accounted for 40.0% of the answers to the question on the level of interest in NTDs.

I. Overview of the survey

Level of awareness of the GHIT Fund

Category/Level of awareness	Highly aware	Aware to a certain degree	Slightly aware	Have heard of it	Do not know
Group 1	6	1	1	4	6
Group 2	0	0	0	1	2
Group 3	0	0	1	0	3
Total number of companies that chose this answer	6	1	2	5	11
Number of companies that answered this question	25	25	25	25	25
Percentage	**24.0%**	**4.0%**	**8.0%**	**20.0%**	**44.0%**

Fujirebio and Eiken Chemical, which are funding partners and sponsors of the GHIT Fund, chose “Highly aware.”

[Reference] Level of awareness of the GHIT Fund (companies other than funding partners and sponsors of the GHIT Fund in Group 1)

Category/Level of awareness	Highly aware	Aware to a certain degree	Slightly aware	Have heard of it	Do not know
(i) Manufacturer of in vitro diagnostics for infectious disease testing using immunoassays (Lateral flow assays (with or without readers)), POC immunoassays (device type/cartridge type)	4	1	1	3	4
(ii) Leading raw material manufacturers related to immunoassay technology	0	0	0	1	0
(iii) Leading contract manufacturers related to immunoassay technology	0	0	0	0	2
(iv) Smart auscultation tool manufacturers (digital stethoscopes, cough analyzers, etc.)	0	0	0	0	0
(v) Major raw material manufacturers of molecular assays using PCR (oligonucleotide, PCR enzymes, etc.)	0	0	0	0	0
(vi) Manufacturers of portable X-ray/ultrasound devices and skin imaging devices	0	0	0	0	0
(vii) Manufacturers of point-of-care (POC) molecular assays and devices	0	0	0	0	0
Total number of companies that chose this answer	4	1	1	4	6
Number of companies that answered this question	16	16	16	16	16
Percentage	**25.0%**	**6.3%**	**6.3%**	**25.0%**	**37.5%**

As for the companies of Group 1 with the highest number of companies interviewed (manufacturers of in vitro diagnostics for infectious disease testing using immunoassays, etc.), the level of awareness of the GHIT Fund is relatively high among non-funding companies.

I. Overview of the survey

Level of interest in the GHIT Fund

Category/Level of interest	High	Relatively high	Normal	Relatively low	Low
Group 1	10	5	2	1	0
Group 2	0	0	3	0	0
Group 3	0	2	2	0	0
Total number of companies that chose this answer	10	7	7	1	0
Number of companies that answered this question	25	25	25	25	25
Percentage	**40.0%**	**28.0%**	**28.0%**	**4.0%**	**0.0%**

Fujirebio and Eiken Chemical, which are funding partners and sponsors of the GHIT Fund, chose “High.”

II. Analysis of the companies Fuji Keizai recommends

Summary

- Among the interviewed companies, **Fujirebio, Sysmex, Eiken Chemical, Shino-Test, Medical & Biological Laboratories, and Arkray** answered that **their levels of interest in the GHIT Fund, promotion of overseas operations, and interest in NTDs were high** (high, relatively high).
- All these companies are major companies in the in vitro diagnostic market and clinical laboratory instrument market and many of them have been developing products related to the three major infectious diseases.
- Some companies are currently funding partners and sponsors of the GHIT Fund, and others engage in the GHIT Fund's projects or participated in the GHIT Fund in the past.

The companies that answered that their levels of interest in the GHIT Fund, promotion of overseas operations, and interest in NTDs were high (high, relatively high).

Selected companies	Level of interest in the GHIT Fund	Level of promotion of overseas operations	Level of interest in NTDs	Noteworthy technologies, know-how, and achievements	Remarks
FUJIREBIO Inc.	High	High	Relatively high	✓ Having experience in developing many products for NTDs, the three major infectious diseases, and emerging and re-emerging infectious diseases in cooperation with AMED and other organizations as a major in vitro diagnostic manufacturer.	Funding partner and sponsor of the GHIT Fund
SYSMEX CORPORATION	High	High	Relatively high	✓ Selling analytical equipment that detects red blood cells infected with malarial and other parasites and measuring their ratio and the eight items to be measured in a CBC in the hematology field where it has strength. ✓ Acquired 100% ownership of Astrego Diagnostics, a Swedish company with the technology for rapid drug susceptibility testing, in 2022	Participated in the GHIT Fund in the past
Eiken Chemical Co., Ltd.	High	Relatively high	High	✓ Providing products for NTDs using the LAMP method, a unique nucleic acid amplification technique that it developed. ✓ Taking the most advanced to NTDs among the Japanese companies	Funding partner and sponsor of the GHIT Fund
Shino-Test Corporation	High	Relatively high	Relatively high	✓ Developing test drugs for rare diseases that are not handled by other manufacturers ✓ Can handle small-lot production of test drugs for rare diseases that other major testing companies cannot handle due to the unprofitability because it has its own laboratory.	-
MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.	High	Relatively high	Relatively high	-	Working on the GHIT Fund project for schistosomiasis and onchocerciasis
ARKRAY, Inc.	High	High	High	-	-

II. Analysis of the companies Fuji Keizai recommends

1. Companies highly willing to form a partnership with the GHIT Fund

- High (high and relatively high) accounts for **68.0%** of the answers to the question on the level of interest in the GHIT Fund, which shows that the majority of the companies are highly interested.
- Among the companies that chose "high" and "relatively high," the companies that chose "high" are more willing to form a partnership with the GHIT Fund and consist mostly of **major in vitro diagnostic manufacturers** that sell their products globally. In addition, judging from their initiatives, many of these **companies have been working on the development of products for infectious tropical diseases**.
- Among them, **Fujirebio, Sysmex, Eiken Chemical, Medical & Biological Laboratories, and Arkray have experience in joint development with public agencies**.

Level of interest in the GHIT Fund

Category/Level of interest	High		Normal	Low	
	High	Relatively high		Relatively low	Low
Group 1	10	5	2	1	0
Group 2	0	0	3	0	0
Group 3	0	2	2	0	0
Total number of companies that chose this answer	10	7	7	1	0
	17			1	
Number of companies that answered this question	25	25	25	25	25
Percentage	**40.0%**	**28.0%**	**28.0%**	**4.0%**	**0.0%**
	68.0%			**4.0**	

*The percentages shown are the proportions of the number of companies that chose the answers to the number of companies that answered the question.

Companies that chose "high" and are more willing to form a partnership with the GHIT Fund than the companies that chose "relatively high"

*The highlighted companies are funding partners and sponsors of the GHIT Fund.

Company that chose this answer	Category	Initiatives on tropical infectious diseases
FUJIREBIO Inc.	In vitro diagnostic manufacturer	✓ Having experience in developing products for dengue fever and Zika fever ✓ Launched a measurement device that can test HIV test items
TAUNS Laboratories, Inc.	In vitro diagnostic manufacturer	✓ Having experience in developing antibodies for in vitro diagnostics for dengue fever, launched antibody kits for tuberculosis
SYSMEX CORPORATION	Manufacturer of clinical laboratory instruments and in vitro diagnostics	✓ Launched products for malaria and HIV
Eiken Chemical Co., Ltd.	In vitro diagnostic manufacturer	✓ Launched products for Chagas disease, leishmaniasis, trypanosomiasis, and dengue fever
Shino-Test Corporation	In vitro diagnostic manufacturer	-
NICHIREI BIOSCIENCES INC.	In vitro diagnostic manufacturer	-
MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.	In vitro diagnostic manufacturer	✓ Developed products for schistosomiasis and onchocerciasis
ARKRAY, Inc.	Manufacturer of clinical laboratory instruments and in vitro diagnostics	✓ Selling products related to malaria, tuberculosis, and HIV
artience Co., Ltd.	Manufacturer of raw materials for in vitro diagnostics	-
Cosmo Bio Co., Ltd	Life science-related trading company	-

2. Companies with noteworthy technologies, know-how, and achievements

- **Major Japanese in vitro diagnostic manufacturers**, such as Fujirebio and Eiken Chemical, **have a track record of working on NTDs, the three major infectious diseases, and emerging and re-emerging infectious diseases.**
- The strength of Toyobo and Takara Bio is **their mass production systems for high-quality enzymes, antibodies, and antigens for in vitro diagnostics**, and they are expected to contribute to the value chain of the project in terms of the supply of raw materials.
- Cosmo Bio is expected to contribute to the development of simple test products to be used in developing countries by applying the new **point-of-care testing technology** that it has adopted. Varinos is one of the few companies that utilize NGS for clinical testing and is expected to contribute to **the bacterial flora analysis for NTDs and the analysis of drug-resistant bacteria**.

Notable companies and their topics

In vitro diagnostic manufacturer

Eiken Chemical Co., Ltd.

- ✓ Providing products for NTDs using the LAMP method, a unique nucleic acid amplification technique that it developed.
- ✓ Taking the most advanced to NTDs among the Japanese companies

FUJIREBIO Inc.

- ✓ Having experience in developing many products for NTDs, the three major infectious diseases, and emerging and re-emerging infectious diseases in cooperation with AMED and other organizations as a major in vitro diagnostic manufacturer.

Shino-Test Corporation

- ✓ Developing test drugs for rare diseases that are not handled by other manufacturers
- ✓ Can handle small-lot production of test drugs for rare diseases that other major testing companies cannot handle due to the unprofitability because it has its own laboratory.

Manufacturer of clinical laboratory instruments and in vitro diagnostics

SYSMEX CORPORATION

- ✓ Selling analytical equipment that detects red blood cells infected with malarial and other parasites and measuring their ratio and the eight items to be measured in a CBC in the hematology field where it has strength.
- ✓ Acquired 100% ownership of Astrego Diagnostics, a Swedish company with the technology for rapid drug susceptibility testing, in 2022

Raw material manufacturers

TOYOBO Co., Ltd.

- ✓ Its strength is the development and mass production of high-quality raw enzymes and antibodies.
- ✓ Possibility as a player that supplies raw material

TAKARA BIO INC.

- ✓ Its genetic engineering and cell engineering technologies are its core competence, and its strength is the rapid mass production of PCR enzymes.
- ✓ Possibility as a player that supplies raw material

Life science-related trading company

Cosmo Bio Co., Ltd

- ✓ Have recently introduced Smart ELISA (tentative name), which is the technology developed by the National Institute of Advanced Industrial Science and Technology, and have been looking for ways to apply this technology to new businesses
- ✓ Likely to contribute to the development of simple test kits

Contract NGS analysis company

Varinos Inc.

- ✓ One of the few companies that utilize NGS for clinical purposes
- ✓ Conducts an intrauterine flora analysis using NGS, which may be applied to a bacterial flora analysis for NTDs

3. Companies with a solid track record in overseas operations

- "High" and "relatively high" account for **72.0%** of the answers to the question on the level of promotion of overseas operations.
- Among the companies that chose "high" and "relatively high," the companies that chose "high" and showed a higher level of promotion of overseas operations consisted mostly of **major companies that have their business bases globally**.
- Whereas Arkray's business centers around diabetes in Japan, its overseas business **mainly comprises in vitro diagnostics for infectious diseases, and it sells rapid test kits for the three major infectious diseases and NTDs at its business bases around the world.**

Level of promotion of overseas operations

Category/ Level of promotion	High		Normal	Low	
	High	Relatively high		Relatively low	Low
Group 1	8	7	3	0	0
Group 2	1	0	1	0	1
Group 3	1	1	2	0	0
Total number of companies that chose this answer	10	8	6	0	1
	18			1	
Number of companies that answered this question	25	25	25	25	25
Percentage	**40.0%**	**32.0%**	**24.0%**	**0.0%**	**4.0%**
	72.0%			**4.0%**	

*The percentages shown are the proportions of the number of companies that chose the answers to the number of companies that answered the question.

The companies that chose "high" and showed a higher level of promotion of overseas operations among the companies that chose "high" and "relatively high"

*The highlighted companies are funding partners and sponsors of the GHIT Fund.

Company that chose this answer	Form of overseas expansion	Background to the promotion of overseas operations
FUJIREBIO Inc.	Contract manufacturing, raw material supply	✓ Focusing on the CDMO business with major overseas in vitro diagnostic manufacturers
TAUNS Laboratories, Inc.	In-house marketing	✓ Aiming to increase the ratio of overseas sales in the future
SYSMEX CORPORATION	In-house marketing	✓ Mainly selling equipment and reagents related to hematological testing at global business bases
SEKISUI MEDICAL CO., LTD.	In-house marketing	✓ One-third of its sales are from overseas sales
TOYOBO Co., Ltd.	Raw material supply	✓ Focusing on supplying raw materials for in vitro diagnostics
TAKARA BIO INC.	In-house marketing, contract manufacturing	✓ Focusing on the in-house marketing of reagents for research and the manufacturing of customized products
ARKRAY, Inc.	In-house marketing	✓ Mainly selling in vitro diagnostics for infectious diseases at its global business bases ✓ Sixty percent of its sales are from overseas sales
Cosmo Bio Co., Ltd	In-house marketing	✓ Selling reagents for research mainly in the U.S. and Europe
Oriental Yeast Co., Ltd.	Raw material supply	✓ Selling biochemical products (enzymes, coenzymes, and substrates)
Varinos Inc.	Contract testing	✓ Expanding its contract testing service taking the whole world into consideration

II. Analysis of the companies Fuji Keizai recommends

4. Companies with high levels of interest in and focus on testing of infectious diseases, such as NTDs

- "High" and "relatively high" accounts for **40.0%** of the answers to the question on the level of interest in NTDs.
- Among the companies that chose "high" and "relatively high," the companies that chose "high" and showed a higher level of focus consist of **companies that have a track record of working on NTDs, the three major infectious diseases, and emerging and re-emerging infectious diseases, those that anticipate that NTDs will spread in Japan in the future and consider it as a business opportunity, and those with a corporate culture that encourages employees to attempt to develop new products.**

Level of interest in NTDs

Category/Level of interest	High		Normal	Low	
	High	Relatively high		Relatively low	Low
Group 1	4	6	3	3	2
Group 2	0	0	0	0	3
Group 3	0	0	3	1	0
Total number of companies that chose this answer	4	6	6	4	5
	10			9	
Number of companies that answered this question	25	25	25	25	25
Percentage	**16.0%**	**24.0%**	**24.0%**	**16.0%**	**20.0%**
	40.0%			**36.0%**	

*The percentages shown are the proportions of the number of companies that chose the answers to the number of companies that answered the question.

The companies that chose "high" and showed a higher level of interest among the companies that chose "high" and "relatively high"

*The highlighted companies are funding partners and sponsors of the GHIT Fund.

Company that chose this answer	Category	Background of taking interest in NTDs
Eiken Chemical Co., Ltd.	In vitro diagnostic manufacturer	✓ Signed the Kigali Declaration ✓ Launched products for Chagas disease, leishmaniasis, trypanosomiasis, and dengue fever ✓ Developed and launched a diagnostic reagent for Chagas disease using the funding from the GHIT Fund.
NICHIREI BIOSCIENCES INC.	In vitro diagnostic manufacturer	✓ Have a high level of interest in NTDs since they are thought to be infectious diseases that will spread even in Japan someday
KANTO CHEMICAL CO., INC.	In vitro diagnostic manufacturer	✓ Have a high level of interest in NTDs since the company culture encourages researchers to pursue what they want to do or to take on the challenge in developing products that can contribute to society
ARKRAY, Inc.	Manufacturer of clinical laboratory instruments and in vitro diagnostics	✓ Already selling rapid test kits for filariasis, which is an NTD ✓ Have a track record of supplying products to international health organizations

1. Needs for support and challenges related to forming a partnership with the GHIT Fund and applying for its open calls, identified by domestic clinical testing companies

- As for forming a partnership, most companies **want more detailed information** regardless of the size of the companies and their business and the groups of the interviewed companies.
- The companies that had formed a partnership with the GHIT Fund and participated in its projects gave feedback based on their experience.

◎Information companies lack when applying for an open call

(i) About the full details of the business scheme

- We would like to know the full details of the business scheme, including what companies will undertake which parts of the project, ranging from R&D to manufacturing and marketing.
- We would like to know in detail about the investment structure and the pattern of commitment.
- We would like to know which case of the following is assumed. Do you expect to support the creation of new seeds for infectious disease testing technologies, or do you intend to provide support to develop existing groundbreaking infectious disease testing technologies, such as the LAMP method possessed by Eiken Chemical, to more practical stages in developing countries?

(ii) About information on the disease areas that the GHIT Fund would like companies to develop

- If there is a disease area that the GHIT Fund would like us to develop, we would like the fund to specify with the reasons.
- We would like detailed information, such as the test items, testing methods, and necessary antibodies for the target diseases, as well as the required amounts of annual production and supply.

(iii) About product needs

- It would be easier for us to develop products that meet the needs if we could obtain detailed information on requirements and challenges about such products as those that are more sensitive than current testing products and low-cost products.

(iv) About the growth rate of the market in the future

- We would like to know the future marketability. We would like to have a demand forecast of the market scale in 10 and 20 years in particular.

◎ Feedback on how to make it easier and more meaningful for companies to participate in projects of the GHIT Fund

- What about the fund collecting information about projects from university professors, finding projects for which there are great needs, planning a pipeline, and opening a call for companies?
- We hope public institutions would be able to collect the voices from researchers in academia so that project information could be passed on to companies that may form a partnership or cooperate with the GHIT Fund.
- As the GHIT Fund has started providing new services, such as market research and support for the acquisition of regulatory approval, we suppose that it would be easier for companies to participate in projects if this support is widely informed.
- We feel that companies could easily form a partnership if there were a precedent, such as the development of a pharmaceutical initiated by the GHIT Fund first.

◎Challenges found from other angles

- Requirements for applying for open call projects are so strict that it is difficult to make a plan that can meet such requirements.

2. The needs for support and challenges that domestic clinical testing companies have in relation to research, development, manufacturing, distribution, and marketing of in vitro diagnostics for NTDs and other elements

- Most interviewed companies mentioned the **necessity of financial assistance** regardless of the size of the companies and their business and the groups of the interviewed companies. Financial support is essential for continuous development.
- Many in vitro diagnostic manufacturers mentioned the **securing of samples and an organization that will evaluate their reagents** as the challenges they face in relation to research, development, and manufacturing.
- Some **SME companies** mentioned the **securing of a connection with researchers in academia** as a challenge they face. Since distinguished researchers have already teamed up with major companies, it is important for SMEs that do not have personal connections to receive support, such as referrals to researchers and support for relationship building with them.

Financial assistance/research, development, and manufacturing

Financial assistance

- Since it is difficult to maintain a production system without continuous demand, we hope to have financial support for continuous development.
- All depend on subsidies for overall development of raw materials.
- The more financial support we can get, the better.
- It is desirable that we receive subsidies for material costs and the process to keep real-time PCR data and fixtures and equipment in the laboratory.
- Our concern is funding only.
- If we can see the exit stage of the development and receive subsidies or other forms of assistance, we believe that it is possible to actually proceed with development.

Research Development Manufacturing

- It is difficult for us to enter the NTD diagnostics market on our own, and we need support for the securing of samples and an organization that will evaluate our reagents.
- If we assume the demand for border control measures in Japan, we could proceed with this business smoothly on the condition that we could get regulatory approval on a priority basis.
- With pipeline for development and business tool support, it will be possible for us to be responsible for development and manufacturing.
- We believe the gap between large companies and small and medium-sized enterprises is connections. Distinguished professors have already teamed with leading companies, and it is quite difficult to find the right professors. If we have a relationship with researchers, we assume that we would be able to secure samples efficiently in a short period of time and shorten the development period by years. In order to increase the chance of success for a business, we would like to have support, such as referral to researchers and support for relationship building with them.
- A number of technological patents have been filed in the infectious diseases area. Our company would be able to promote efficient development if the fund would purchase or otherwise provide access to such patents.

2. The needs for support and challenges that domestic clinical testing companies have in relation to research, development, manufacturing, distribution, and marketing of in vitro diagnostics for NTDs and other elements

- Many companies, excluding companies that have subsidiaries in the areas where NTDs occur and those that have already expanded into such areas and established sales channels there, mentioned the **securing of a supply chain** as the challenge they face. Distribution support is also needed.
- As for marketing, many companies would like **the country or the GHIT Fund to purchase their products** to recover the costs for their business.
- Some companies would like to receive **consistent support from development to local marketing** as it will be difficult for a single company to enter the NTD diagnostics market.

Distribution/marketing

Distribution

- We consider that the building of distribution networks in cooperation with local governments is required.
- It is necessary to secure the method of transporting the kits to the countries and areas where testing will be carried out.
- If there is a clear vision to the supply chain, it is easier to make an internal decision for participation.
- There are many supply logistics available, but it is hard for a company to research them alone. Therefore, if clear instructions on the place of supply would be provided, it would be easier for companies to engage in a project. It seems difficult for companies to raise their hands unless they can see the path to get their products delivered to the end users.
- How to provide treatment after getting positive test results is important, and it is necessary to develop appropriate distribution networks that include therapeutic drugs in cooperation with local governments and healthcare professionals.
- Since we cannot find sales channels for a product that we have developed, we would like to receive assistance on the supply side.

Marketing

- If the government or a foundation takes the initiative to purchase stock, it would be possible for us to launch the product on the market.
- There are various purchase systems offered, but we feel that they are technical and difficult to use. It would be helpful if the potential of the market, such as expected purchase volume of each country, would be presented.
- As a commercial company, it is important for us to recover the costs incurred to manufacture products. As for emerging infectious diseases, even if we develop and sell reagents while they are spreading, as demand decreases once they subside, we have to shift to make-to-order manufacturing. It would be best if a certain degree of cost recovery were guaranteed through such methods as purchases by the government.

Consistent support

- The process does not end at the development of product. We would like to have consistent support for the entire scheme from development to spread and delivery to local destinations. It would be best if support by purchasing products could be provided.
- We would like to have a support that covers the whole flow evenly.
- It will be difficult for a single company to enter the markets, and therefore financial assistance and tie-ups between companies will become necessary.

3. Recommendations from Fuji Keizai (important points in providing support for domestic clinical testing companies in initiatives on in vitro diagnostics for NTDs, etc.)

- Even among the companies that are willing to form a partnership with the GHIT Fund, **there is no company that can do everything from development to local distribution on its own**. Some support from the fund, such as funding and distribution support, is necessary.
- In Group 1, many companies are aware of the GHIT Fund, and the level of their interest in the fund is also high. **The companies that responded that their willingness to form a partnership with the fund was high** are **concentrated in Group 1.** Though each company places importance on support, such as the provision of more detailed information and the securing of sales channels to participate in projects, answers differ between in vitro diagnostic manufacturers and manufacturers that develop raw materials and antibodies.
- **In Group 2 and Group 3, the level of awareness of the GHIT Fund was low in the first place, and many companies declined the interview.** Even the interviewed companies are not that willing to form a partnership with the fund. As for the Group 2 and Group 3 companies, we need to start by informing them of the fund and discovering candidate companies based on the opinions from Group 1 companies.

Needs for support and important points

Common needs among all the groups

(i) Financial assistance for development
(ii) Securing of a supply chain after product development

Common important points in providing support to all the groups

- Support that should be provided on a top-priority basis is financial assistance. Since the NTD diagnostic market is small, no single company can enter it on its own. So, continuous support from development to marketing is required.
- Then, support for securing a supply chain, including sales channels to deliver products to the countries and areas where they are needed and the method of supplying them there, is required.

Group 1

Needs of in vitro diagnostic manufacturers

(i) Securing of samples and an organization that will evaluate their reagents
(ii) Securing of connections with researchers in academia and clinicians
(iii) Purchase of developed products

Important points in providing support

- Unique support for developing NTD in vitro diagnostics, such as the securing of samples and reagents, should be provided to develop in vitro diagnostics for NTDs as few NTDs occur in Japan.
- Since many companies consider selling end products, it is important that their products are purchased for the stability of their business.

Needs of manufacturers that develop raw materials and antibodies

(i) Purchase of technological patents
(ii) Confirmation of the ratio of patents owned for raw materials and antibodies (If a company has a high ratio, such raw materials and antibodies can be used for other diseases as substitutes.)

Important points in providing support

Since many companies have unique technologies, it is desirable that patents for developed technologies and antibodies be purchased, or they be allowed to be used for other diseases.

Challenges in Group 2 and Group 3

(i) The level of awareness of the GHIT Fund is low
(ii) The level of interest in the NTD area is low
(iii) Companies are not interested in partnership projects as the NTD area does not match their business field.

Important points in solving the challenges

- Since many companies that were not interested in the NTD in vitro diagnostic market or forming a partnership with the fund were categorized in Group 2 and Group 3, it is necessary to change the categorization or start by discovering companies that may be eligible.

- It is also important to inform companies of the GHIT Fund based on the opinions from the Group 1 companies.

3. Recommendations from Fuji Keizai (important points in providing support for domestic clinical testing companies in initiatives on in vitro diagnostics for NTDs, etc.)

- Among the 17 companies of Group 1 that chose “high” and “relatively high” and are willing to form a partnership with the GHIT Fund, **the types of partnerships they would like to form differ depending on whether they are in vitro diagnostic manufacturers, raw material suppliers, or manufacturers that develop antibodies**. It is required that the types of partnerships that are suitable for each company be promoted.
- In Group 2 and Group 3, no company responded that their willingness to form a partnership was “high” and the 2 companies (Varinos and A&T Corporation) that belonged to Group 3 chose “relatively high.” Both companies responded that they might be able to cooperate in some way if we could engage in co-development utilizing the technologies they owned, although NTDs did not match their business fields. In addition, in Group 2, no company responded that their willingness to form a partnership was “high” or “relatively high.”

Important points in forming a partnership

Group 1

Important points in forming a partnership with in vitro diagnostic manufacturers

Since many companies would like to be engaged in the entire process from development to manufacturing and marketing of end products, it is desirable to form an alliance.

Important points in forming a partnership with manufacturers that develop raw materials and antibodies

Since many companies would like to form a partnership in the areas that they specialize in such as the development of raw materials and antibodies, it is desirable to provide them with partial contract projects.

Group 3

Varinos Inc. (Contract NGS analysis company)

Since the advantage of NGS is that it can comprehensively analyze all bacteria and a comprehensive analysis is required to detect unknown bacteria, it is desirable that the company cooperate with projects with analyses using NGS.

A&T Corporation (Blood analysis device & system company)

It is desirable that the company engage in co-development using its own technologies such as blood coagulation analyzers, electrolyte analyzers, laboratory information system (LIS), and laboratory automation system (LAS).

Among the Group 1 companies, the companies that Chose “5: high” or “4: relatively high” in the questions about their levels of (i) interest in the GHIT Fund, (ii) promotion of overseas operations, and (iii) interest in NTDs

Responding company/category	(i)	(ii)	(iii)	Remarks
FUJIREBIO Inc. (In vitro diagnostic manufacturer)	5	5	4	✓ It is desirable to form an alliance. ✓ As the company also supplies reagents in cooperation with a local Indian company, it can obtain samples of some NTDs.
SYSMEX CORPORATION (Manufacturer of clinical testing equipment and in vitro diagnostics)	5	5	4	✓ Since the company acquired 100% ownership of Astrego Diagnostics, a Swedish company with the technology for rapid drug susceptibility testing, in 2022, the number of the technologies we can utilize in the field of infectious diseases has been increasing.
Eiken Chemical Co., Ltd. (In vitro diagnostic manufacturer)	5	4	5	✓ The company has developed and launched a diagnostic reagent for Chagas disease in collaboration with the GHIT Fund.
Shino-Test Corporation (In vitro diagnostic manufacturer)	5	4	4	✓ Since the company owns its own testing center called Shino-Test Science Laboratories , it can conduct testing of rare diseases in small lots that major testing companies cannot handle economically. ✓ It is desirable to form a partnership where the company provides contract manufacturing and development.
MEDICAL & BIOLOGICAL LABORATORIES CO., LTD. (In vitro diagnostic manufacturer)	5	4	4	✓ The company has developed products for schistosomiasis and onchocerciasis in collaboration with the GHIT Fund. ✓ Since the company has a high-volume production capacity, it is desirable that it participate in projects in the field of manufacturing.
TAKARA BIO INC. (Manufacturer that supplies raw materials)	4	5	4	✓ Since the company can mass-produce PCR enzymes rapidly, it is desirable to form a partnership where it supplies raw materials.
ARKRAY, Inc. (Manufacturer of clinical testing equipment and in vitro diagnostics)	5	5	5	✓ The company would like to develop simple genetic testing products for tuberculosis if it can receive support from the GHIT Fund.