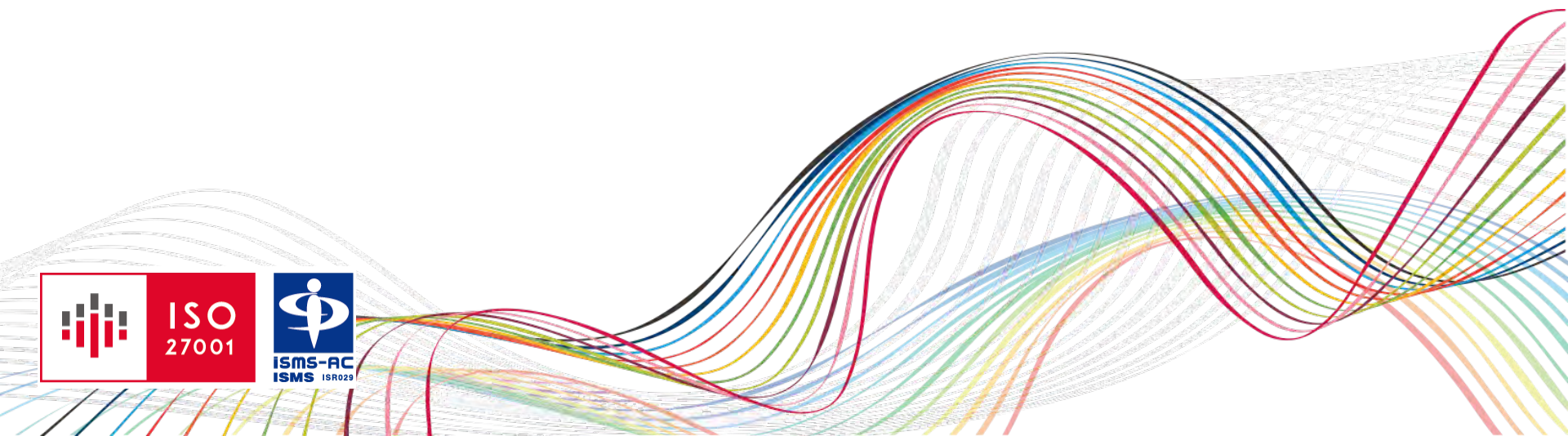


# 3H Medi Solution Capabilities



# Agenda

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**3H Group**

**Patient Centric Services**

**Oncology & Orphan Disease**

**In Home Clinical Trial**

**Asian Network**

# 3H Group Introduction

## 3H medi solution

CEO: Ando Sho  
Founded: 2009

### Planning · Management · Consulting · Sponsor contact

- First in Japan Consulting CRO specializing in patient recruitment
- Provide unique patient recruitment strategy
- Feasibility service using IT such as Google Map (PASSMAP) and database
- Highly accurate area and site selection service
- A system (REGUSYS) to prevent dual entry of the patient
- Vendor management by patient recruitment specialists

## 3H clinical trial

CEO: Takizawa Hiroataka  
Founded: 2005

### Recruitment · Database · Call center

- Japan's largest patient recruitment company
- Holds patient database of over 820,000 nationwide
- Over 300 diseases and symptoms database suitable for clinical trials
- 90+ seats call center specializing in clinical trials
- Online and offline recruitment strategies to connect with potential patients
- Oncology one of its kind in Japan which provide the solution for Oncology Clinical Trial.

## 3H CTS

CEO: Takahashi Yoshinori  
Founded: 2015

### SMO

- Japan only SMO able to recruit patients
- Provide solutions to sponsors and sites needs
- Patient community enables the SMO to maximize the enrollment with less sites
- Enrollment planning for out-patients and referral patients
- Using the Clinical Trial database increases enrollment with lower cost.



# 3H Milestone

some pretty spectacular statistics..

3H is providing its services to **15/TOP 20** Global Pharma



3H has worked with **26/TOP 30** Japanese pharma



We have referred the patients to more than

**2,500 sites**



We support clinical trials/year

**695**



Subjects enrolled in last 5 years.

**60,000**



Our patient recruitment supports contributed to reduce the clinical trial

timeline by **5 months**  
(Max)





## 生活向上WEB

- Japan's largest healthcare information and monitoring information website
- 840,000 member databases that would like to participate in monitors
- **More than 200 disease categories**
- **More than 100,000 clinical data**
- **More than 150,000 dosing information**
- **More than 10,000 monitor referrals per year**
- **Able to make disease awareness ads and advertise clinical trials**
  - Steering Company 3H Clinical Trials K.K.
  - Media Name "Seikatsu Kojo Web"
  - URL <http://www.seikatsu-kojo.jp/>
  - Ratio of male to female: 1:1
  - Monthly PV count 2 million PVs
  - Number of monthly visitors 300,000
  - 10,000 patients enrolled per month



94,000 people



138,000 people



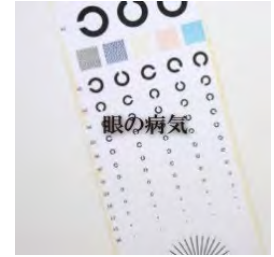
14,300 people



102,000 people



15,200 people



8,800 people



71,000 people



35,000 people



26,000 people



18,000 people



880,000 people



14,900 people



73,500 people



1,800 people



38,500 people



6,800 people



5,300 people



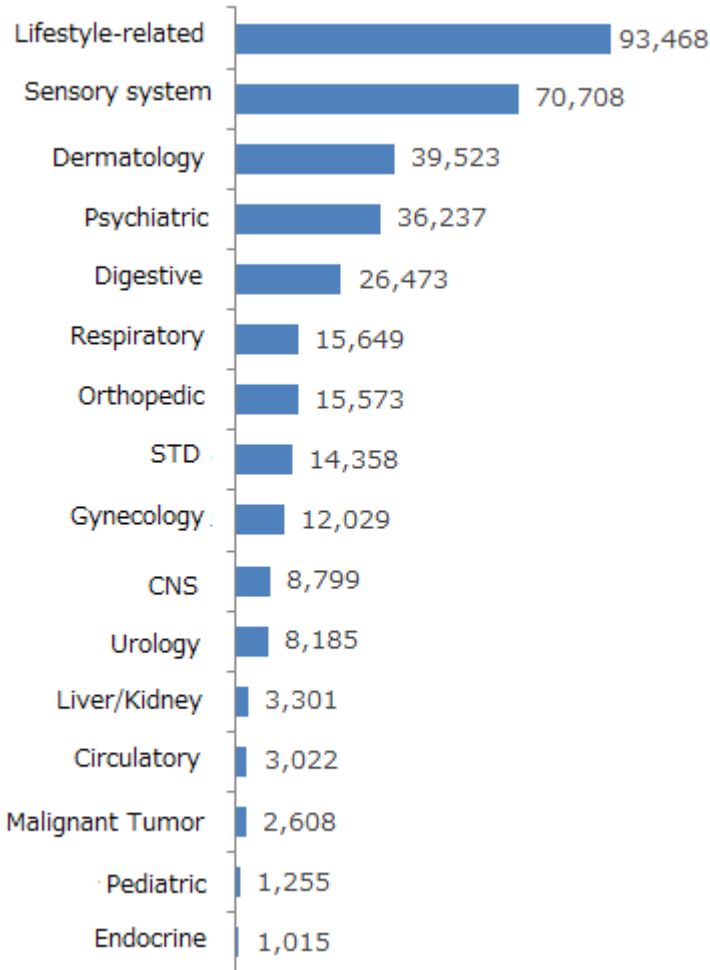
694,000 people

# Registered different conditions

Database  
(880,000 Patients)

## Registered conditions

### Disease by categories



### Registered Conditions TOP50

RANK	Disease Name	# Registered	RANK	Disease Name	# Registered
1	Hypertension	37,681	26	Appendicitis	2,700
2	Seasonal Allergy	33,775	27	Iron-deficient Anemia	2,654
3	Hyperlipidemia	27,202	28	Allergic Conjunctivitis	2,602
4	Allergic Rhinitis	19,686	29	Sinusitis	2,527
5	Insomnia	15,145	30	Endometriosis	2,470
6	Depression	13,659	31	Chronic Urticaria	2,463
7	Bronchitis	12,846	32	Dysmenorrhea	2,392
8	Atopic Dermatitis	12,043	33	Glaucoma	2,091
9	Acne	11,456	34	Type I Diabetes	2,086
10	Type II Diabetes	9,679	35	Panic Attack	1,910
11	Uricemia (Gout)	9,237	36	BPH	1,709
12	Venous Thrombosis	9,151	37	Angina Pectoris	1,632
13	Tinea Pedis	7,967	38	IBS	1,611
14	Back Pain	6,371	39	Schizophrenia	1,563
15	Dry Eye	5,880	40	Carpal Tunnel	1,516
16	Constipation	5,757	41	Rheumatoid Arthritis	9,447
17	Hypertriglyceridemia	5,568	42	Menopause	1,374
18	Uterine Fibroids	4,554	43	Cataracts	1,342
19	Peptic Ulcer	4,355	44	Chronic Gastritis	1,325
20	Overactive Bladder	4,277	45	Myocardial Infarction	1,194
21	GERD	4,225	46	Pneumonia	1,165
22	Osteoporosis	4,195	47	Arrhythmia	1,105
23	Alzheimer	4,011	48	Dysautonomia	997
24	Shingles	3,698	49	Joint Deformation	974
25	Duodenal ulcer	3,071	50	Seborrheic Dermatitis	939

# Membership information data in possession

Item	Contents
Age/Sex	Male/female age
Address	National prefectures/national municipalities
Date of birth	Day of birth
Height/Weight/BMI	Height (cm)/Weight (kg)
Date of completion	Date Month Year
Occupation	Students, company officers, officials, civil servants, self-employed, non-employed, freeters, housewives, etc.
Drinking/Smoking	Drinking (yes/no) Smoking (yes/no)
Desired information	Clinical trials, beauty care, cosmetics and health foods
Desired guidance method	Telephone, e-mail, fax, and direct mail
Desired contact time	Weekdays, Saturdays, Sundays, and Hours
Medical information	<b><u>Disease information, blood test data, medication information, etc.</u></b>

Hematology parameters		
WBC count	Total Bilirubin	Uric acid
Red blood cell count	AST(GOT)】	Nitrogen urate
Hemoglobin content	ALT(GPT)】	Creatinine
Hematocrit	ALP	Na
MCV	LDH	K
MCH	γ-GT	Cl
MCHC	CPK	LDL cholesterol
Platelet count	Fasting plasma glucose	Hemoglobin A 1 C
TP	Total cholesterol	Systolic blood pressure (top)
A/G	HDL-Cho	Diastolic blood pressure (bottom)
ALB	Triglyceride	Time of data extraction

Area	Disease name * All disease categories are more than 300
Endocrine metabolic disease	Type 1 diabetes mellitus, type 2 diabetes mellitus, suspected diabetes mellitus, obesity, hyperuricemia, hypercholesterolemia, pediatric, etc.
Cardiovascular disease	Hypertension, atrial fibrillation, angina pectoris, heart failure, venous thrombosis, etc.
Digestive disorder	Ulcerative colitis, reflux esophagitis, gastric ulcer, Crohn's disease, irritable bowel syndrome, taste disorder, etc.
Respiratory disease	Bronchial asthma, pneumonitis, chronic obstructive pulmonary disease, respiratory infection, COPD, pediatric, etc.
Orthopedic disease	Low back pain, osteoporosis, rheumatoid arthritis, osteoarthritis of the knee, etc.
Neurologic disorders	Sleep disorder, sleep apnea syndrome, Alzheimer's dementia, other dementia, Parkinson's disease, Restless syndrome, cerebral infarction, pediatric, etc.
Psychiatric disorders	Schizophrenia, depression, social-anxiety disorder, anorexia, PTSDs, panic disorder, epilepsy, bipolar disorder, pediatric, etc.
Renal, hepatic, and biliary diseases	Renal impairment, hepatitis B/C, tumor, cirrhosis, liver dysfunction, etc.
Skin disease	Acne vulgaris, psoriasis vulgaris, atopic dermatitis, chronic urticaria, tinea unguium, herpes zoster, seborrheic dermatitis, pediatric, etc.
Allergy	Chronic rhinitis, pollinosis, drugs, foods, animals, metals, sesame, fish, wheat flour, children, etc.



# Patient Insight

Collection of patient voices from our 856,000 database members using: internet, contact center, mail surveys, face-to-face, communities...etc., Segmented data relating to diseases, lab stats, drug administration are also attainable.



856,000 members

>583 disease categories

- Disease data  
250,000
- Laboratory data  
150,000
- Drug use data  
350,000



## Internet Research

On patients with specific diseases is possible even with a low budget over a short period



## Phone Research

Member hearing conducted nationwide by specialized communicators



## Mail Research

Most suited towards elderly members  
Original copy of survey can be kept for records



## Community Research

Best method for observational day-to-day records such as patient occasion and disease status



## Depth Interview

For hearing the patient's real voice which may be sometimes difficult with surveys (insight research)



## Group Interview

Conduct insight research efficiently through open-discussion forums with patients

Quantitative  
Research

Qualitative  
Research



# Past and Current Studies (Patient Survey)

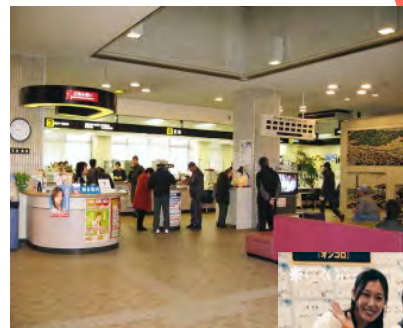
Client	Research Theme	Survey Contents	Sample Size	Method	Date
Domestic Pharma	Quantitative Research of Ulcerative Colitis Patients	Quantitative survey on selection and acceptability of treatment methods for the patients with ulcerative colitis.	300s	WEB Survey	2018
Global Pharma	Patient survey of OA (knee) · CLBP (low back pain)	Interview survey to grasp the Patient Journey Map as well as on intent to use drug during development.	16s	Qualitative interview (IDI)	2018
Global Pharma	Quantitative survey of cancer patient	Quantitative survey on the actual condition and consultation of pain and anxiety for cancer patients and consultation partners.	300s	WEB Survey	2018-19
Global Pharma	Qualitative survey of Prostate cancer	Interview survey on communication with medical staff on fatigue / malaise during treatment.	10s	Qualitative interview (Tel)	2018-19
Global Pharma	Quantitative research of Lung Cancer Patients	Quantitative survey on IC contents, selection factors, IC satisfaction level etc. in drug selection of lung cancer patients	100s	WEB Survey	2018-19
Global Pharma	Acne Patients Survey	Quantitative Survey for concerning troubles and countermeasures for patients with mild acne (Reasons to visits / non-visits the hospital)	300s	MROC	2019
Domestic Pharma	Anaemia Patient Survey	Survey to grasp the benefits of new drugs vs current therapies targeting Anaemia patients	50s	MROC	2019
Domestic Pharma	Anaemia Patient Survey	Clinical CS survey for patients with Anaemia	Quant:100s Quality: 5s	WEB Survey (IDI)	2019

# Recruitment outreach (Online/Offline)



## Media outreach

- Study specific page
- Online Media outreach
- Offline Media Outreach
- KOL study session, lecture, seminar
- Disease awareness events
- Physicians referral
- Pharmacy outreach
- Direct Mail



Event



About 220,000



About 1,410,000



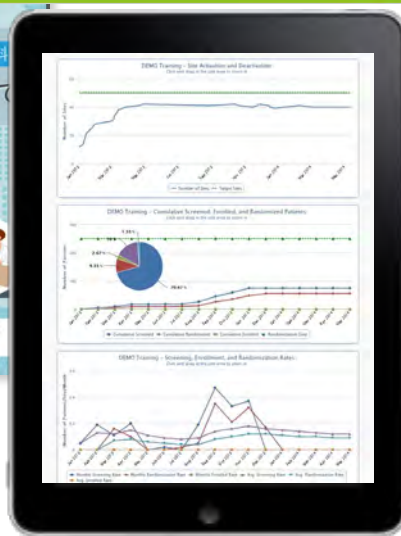
About 3,000,000



About 2,300,000



# Site Supporting Tools



## Site supports

- Poster
- Brochure
- Pocket Protocol
- Newsletter to physicians
- Video tool
- iPad tools
- KOL Video
- **Recruitment Training to site staffs**

Recognition of the study at sites increase by providing materials and tools that will motivate study coordinators and site staffs

100  
KOLs

50+  
Research

1 Million  
Accesses

20,000  
Patients



150  
Events

80+  
Trials

# KOL (Key Opinion Leader) agreeing with Oncolo Team



**100+**  
KOLs

Over 100 cancer specialists support  
Many professors/deans

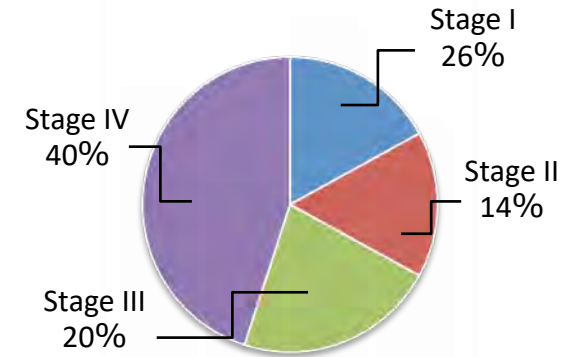
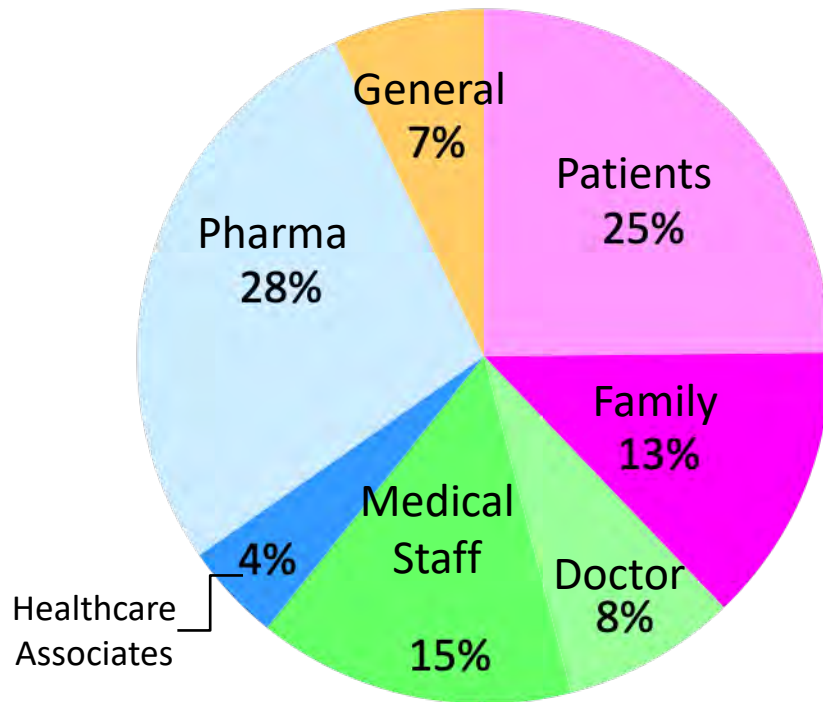
## **Oncolo Medical Supporter**

A medical representative who agreed to cooperate with 3H Oncolo information site.



# E-mail members

1 Million Users Visit ONCOLO<sup>®</sup> per Month.



Lung Cancer	21.5%	Cervical Cancer	1.4%
Breast Cancer	17.8%	Neuroendocrine Tumor	1.2%
Colorectal Cancer	7.9%	Thyroid Cancer	1.2%
Stomach Cancer	7.0%	Brain Tumor	1.2%
Ovarian Cancer	4.5%	Malignant Mesothelioma	1.2%
Pancreatic Cancer	3.7%	Melanoma	0.6%
Prostate Cancer	2.7%	Laryngeal Cancer	0.4%
Kidney Cancer	2.7%	Malignant Lymphoma	2.5%
Uterine Body Cancer	2.3%	Leukemia	2.1%
Liver Cancer	2.1%	Multiple Myeloma	1.2%
Canteen Cancers	2.1%	Other	11.2%
Bladder Cancer	1.6%		

ONCOLO がんと、ひとと、つなぐ

サイト内を検索する

0120-974-268

がんの種類 ▶ ニュース ▶ 臨床試験 ▶ リサーチ ▶ 体験談/患者会 ▶ オンコロとは ▶

がんイベント ▶ がんの用語辞典 ▶ 薬剤用語辞典 ▶ がん立ち啓発 ▶

※1/25条件変更しました※ステージ3非小細胞肺癌対象インタビュー協力をお願いします

希少がん Meet the Expert 2019 参加者募集!

ONCOLOが主催する、がん情報充溢のセミナー「まれながん」のことを「希少がん」といい、人口10万人6人未満のがんのこと...

参加費無料 日時: 毎月第1 / 第3金曜日 19:00~20:30

場所: 国立研究開発法人 国立がん研究センター 中央病院 1F 希少がんセンター10号室

詳細を見る ▶

Our website is visited not only by patients, but also by many pharmaceutical/medical related staffs



**トリプルネガティブ乳がんの方対象**

免疫チェックポイント阻害薬  
PD-1抗体の治験のご案内

Triple-negative breast cancer

**初期膀胱がん対象**

免疫チェックポイント阻害剤の治験のご案内

Muscle layer non-invasive bladder cancer

**頭頸部がん**

- ・口唇・口腔(舌、歯肉)
- ・中咽頭・下咽頭
- ・喉頭(声門)

免疫チェックポイント阻害薬の治験  
にご協力ください

Head and neck squamous cell carcinoma

胆道癌 胸膜中皮腫  
小細胞肺癌 唾液腺癌  
甲状腺癌 神経内分泌腫瘍  
子宮頸癌 子宮内膜癌  
肛門癌 外陰癌

免疫チェックポイント阻害薬  
10種の希少がんの治験にご協力ください

Rare cancer (basket)

膀胱・腎盂・尿管がん

免疫チェックポイント  
阻害剤の治験

詳細はコチラ ▶

Muscle-invasive bladder cancer

**食道がん対象**

免疫チェックポイント阻害薬  
の治験のご案内 ▶

小野薬品工業株式会社

Esophageal cancer

免疫チェックポイント阻害薬

**小細胞肺癌**  
の治験のご案内 ▶

Bristol-Myers Squibb

Small-cell lung cancer

**乳がんの方対象**

PARP阻害薬の治験にご協力ください

アストラゼネカ株式会社

BRCA breast cancer

濾胞性リンパ腫 (FL) / 小リンパ球性リンパ腫 (SLL) / 辺縁帯リンパ腫 (MZL) など

再発または治療抵抗性の  
**低悪性度非ホジキンリンパ腫対象**  
新薬治験のご案内

Low-grade Non-Hodgkin lymphoma

医師主導治験

消化管間質腫瘍の  
方を対象とした  
治験にご協力ください

オンコロ

GIST

前立腺がん

の治験にご協力ください

Janssen

Non-metastatic castration-resistant prostate cancer

悪性胸膜中皮腫の  
治験にご協力ください。

Malignant pleural mesothelioma

**Achievement (include plans) : More than 80 trials:** Brain tumor : 2、 Head and neck cancer : 1、 Salivary gland cancer : 1、 Non-small cell lung cancer : 9、 Small-cell lung cancer : 3、 Breast cancer : 5、 Malignant pleural mesothelioma : 5、 Esophageal cancer : 2、 Gastric cancer : 2、 Hepatocellular carcinoma : 1、 Renal cell carcinoma : 2、 Bladder cancer : 3、 Colorectal cancer : 1、 GIST : 1、 Prostate cancer : 1、 Malignant lymphoma : 6、 Leukemia : 7、 Multiple myeloma : 1、 Rare cancer basket study : 1、 Melanoma : 2、 Unknown primary cancer : 1、 Solid cancer : 1、 Bone metastasis sarcoma : 1、 uterine carcinosarcoma : 1、 Small intestine adenocarcinoma : 1、 Glioma : 1

- Ads for hematologic cancer are increasing and has a very high responsive rate
- Ads for immune checkpoint inhibitor is decreasing but has a high responsive rate
- Connections with sites go up and medical investigator trials are increasing as well



- ◆ Rare disease information site RareS.
- ◆ URL : <https://raresnet.com/>
- ◆ since : 2018 Feb～
- ◆ Relation : NPO incurable disease network
- ◆ page views : 20,000/month
- ◆ active users : 1,000/month
- ◆ Patient Organization : 109

- latest news : Collect and publish news related to rare diseases
- various types of rare diseases : designated rare diseases + rare cancers, pediatric chronic specific diseases
- clinical trial information : posting information about studies which are recruiting participants.
- event information : information on national events held by various organizations.
- Incurable disease medical liaison council・Posting information on updates of these organizations

# 3H Group Features & Digitization Activities

『A specialized company that recruits subjects』



Volunteers

856,000

Networks

- Oncology
- Rare Disease
- Pharmacy



『**Approach** : "Patient-centered / Digitizing" for Virtual clinical trial』

Virtual-ct

▶ Planning with the **University of Tokyo**

Home Visit -ct

▶ Home visit clinical trial 's with **Physicians**

App

▶ Development method reflecting **patient opinion**

IoT

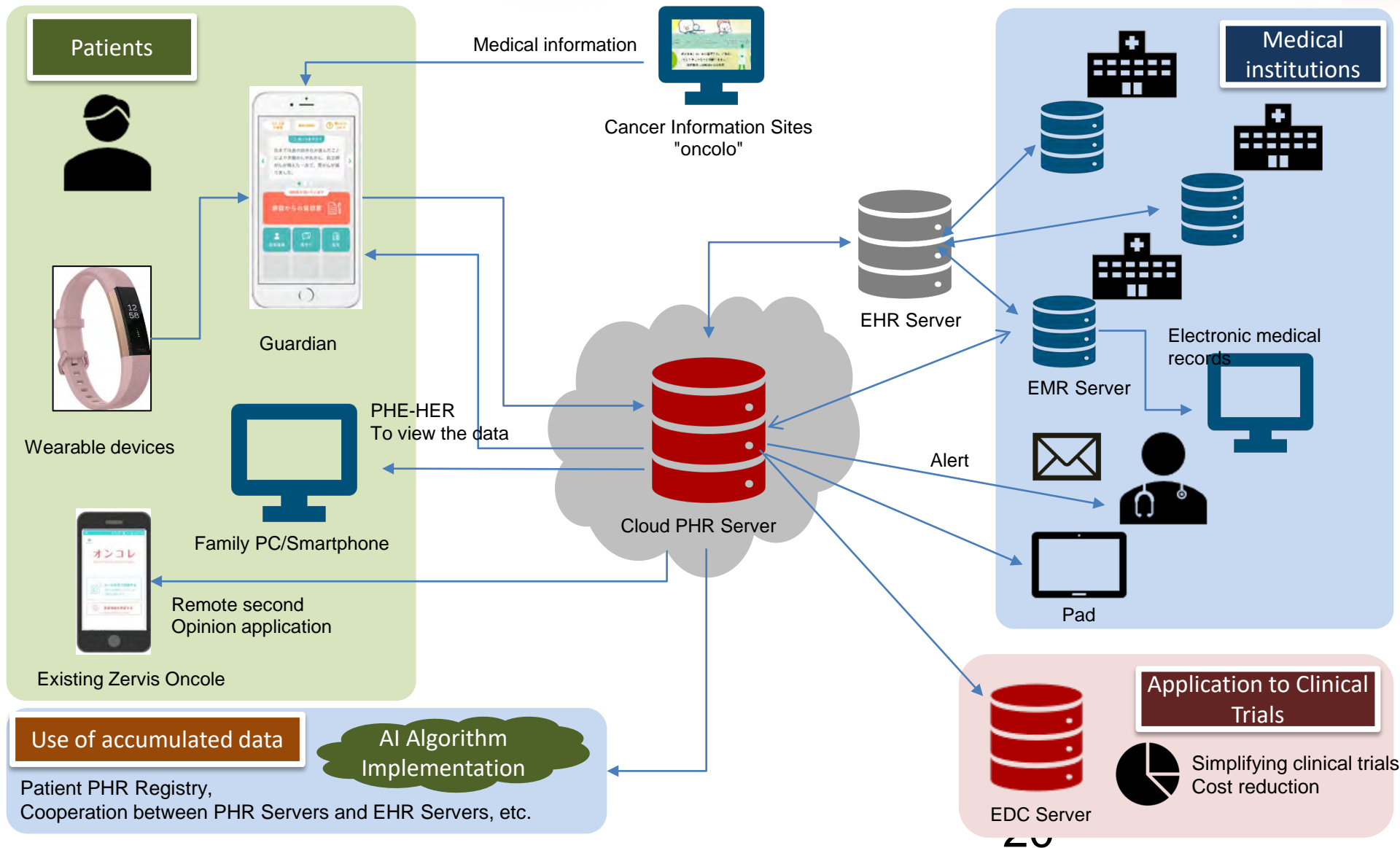
▶ **Introducing IOT for Patient Centricity**

Provisioning

▶ Device delivery management (**Japan's only mechanism**)

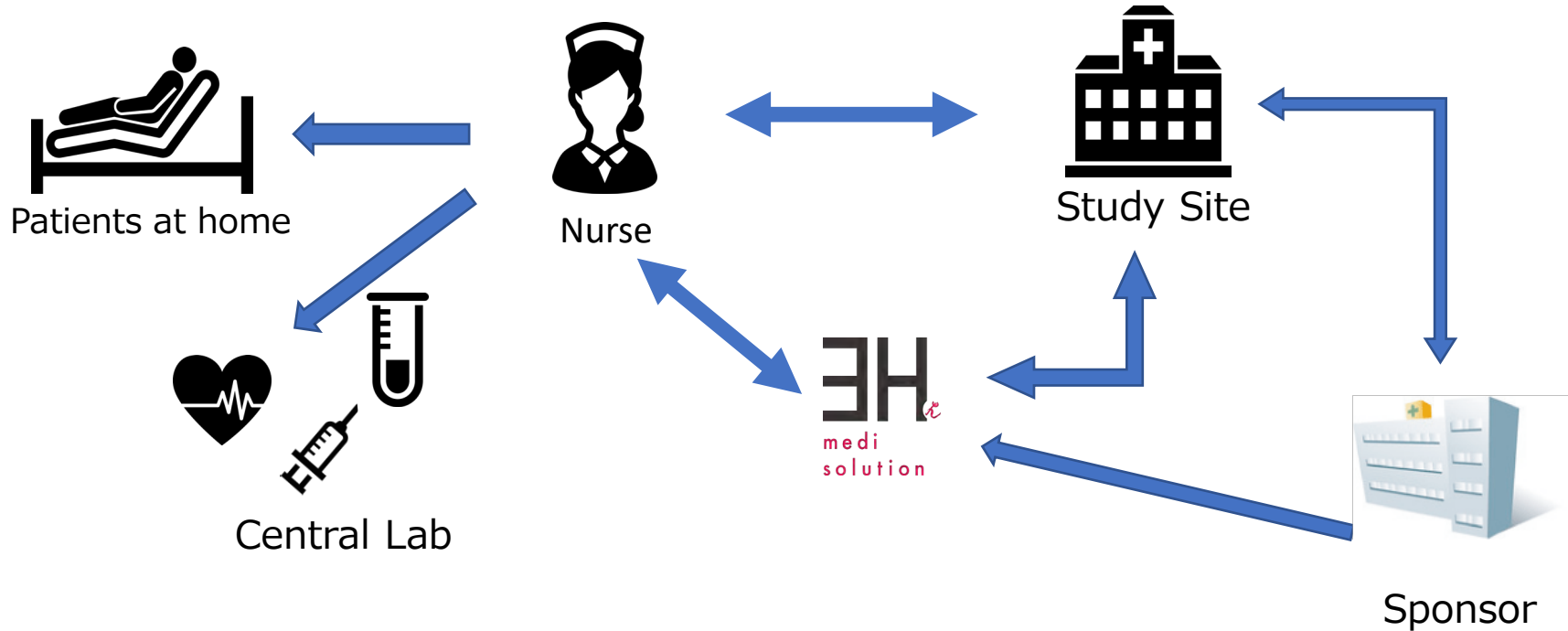
Recruitment

▶ Web **contents for each disease** / contents for IC support





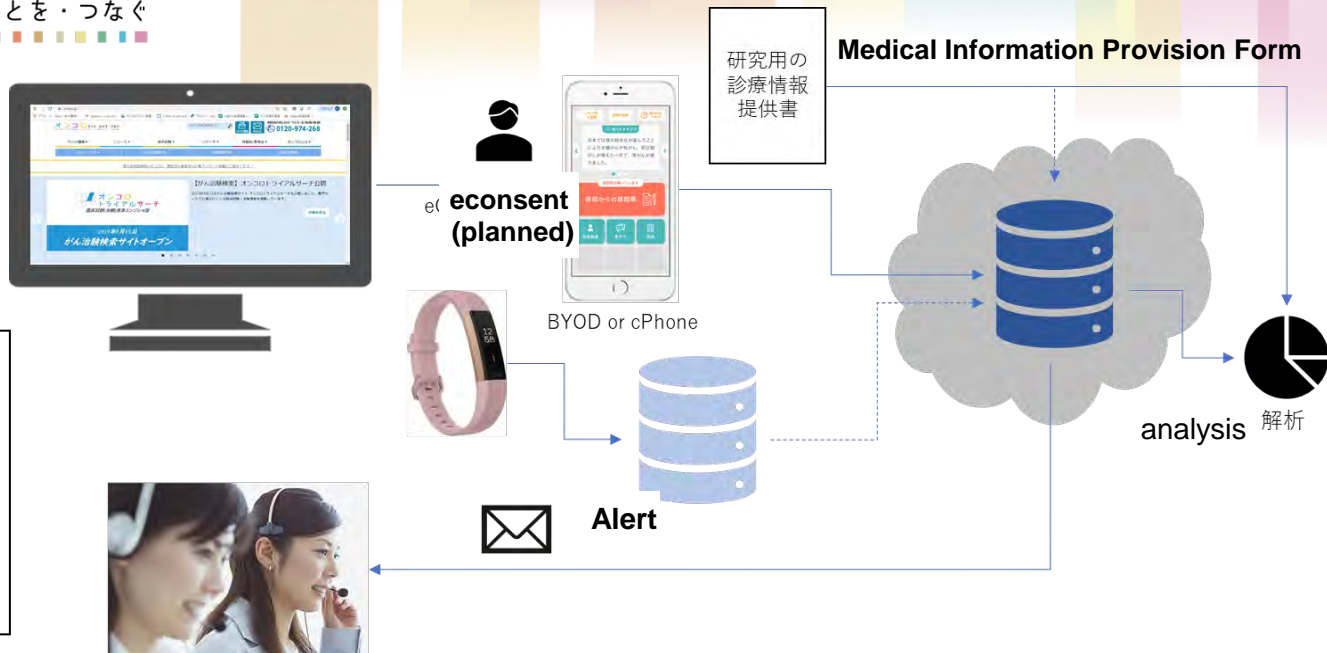
## 3H In-Home Clinical trial Support Model for Japan



Following services are based on RFP request.

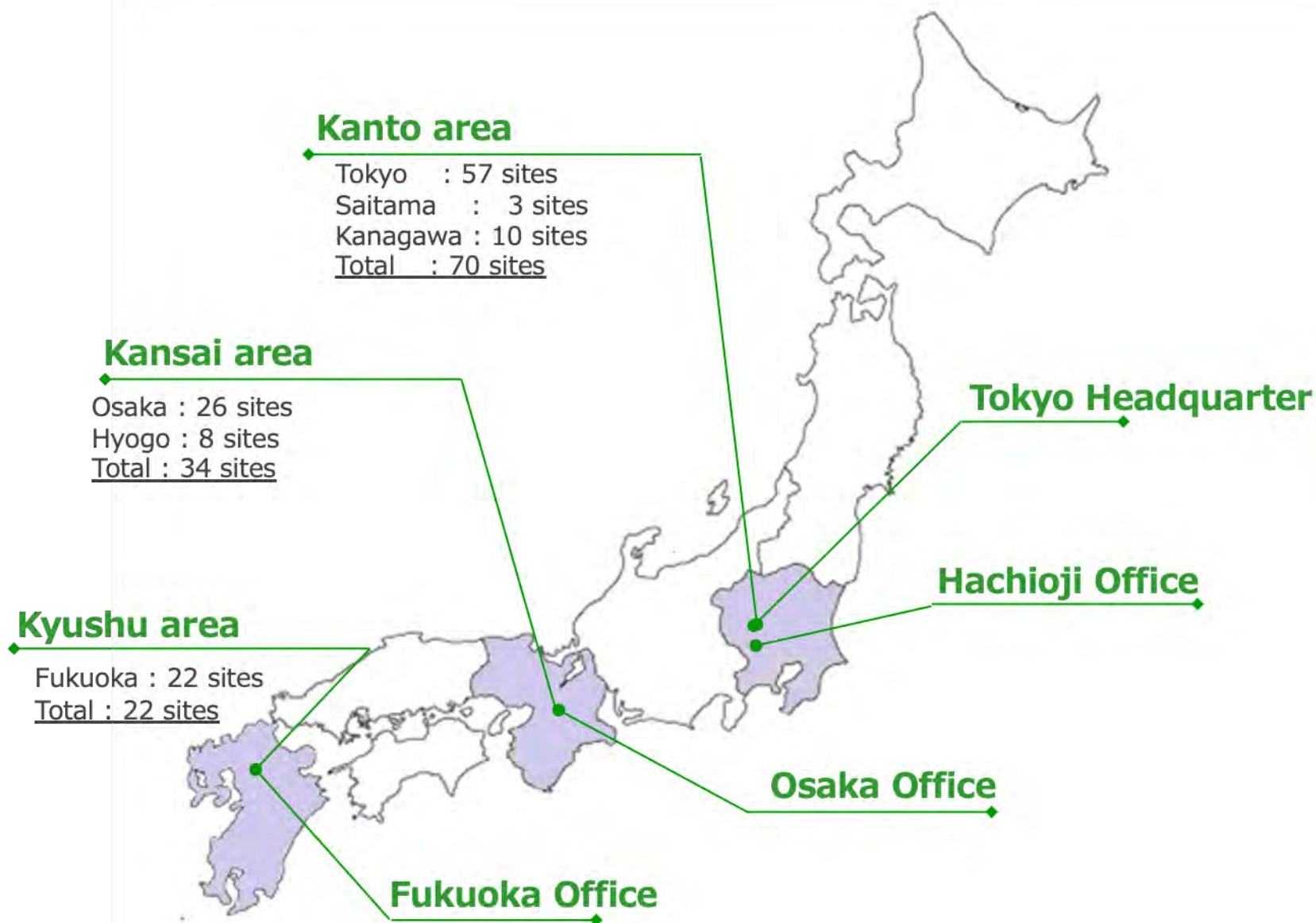
- Study set-up
- In home materials, Site set up, IM
- In-home visits
- Nurse setup & training
- Visit coordination & management

**Completed  
Virtual  
Study for  
ONCOLOGY**



**Study Details:** Siteless Virtual Study of Adverse Event Monitoring Applications in Cancer Patients  
 site less Virtual Study for Validation of Adverse Events Monitoring Application in Oncology  
**Indication:** Projected number of subjects with advanced cancer  
**Patients:** 100 subjects  
**Study Period:** November 2019 to March 2020  
**Objectives:** P-Guardian Systems Validation and Exploration of Changes in Patients' Quality of Life  
**Scheduled scale:** PRO-CTCAE(Weekly), FACT-G(Monthly)  
**Sensor-Acquisition Scale:** Activity (Calorie, METs), SpO2, Heart Rate, Sleeps

# Offices and affiliated Investigational Sites



\*The site number above represents our core sites

\*The actual number of sites we have made contracts as investigational site is over 300

# Clinical Study Support by 3H Asian Network

1. Conduct Patients Feasibility in each country
2. Conduct cultural adaptive tactics in each country
3. Single Contract support in 7 countries



## Main Services

- Feasibility study
- Patient Recruitment
- Site Support Activities
- Call Center
- SMO Services
- Patient Retention



# Merit behind 3H medi solution



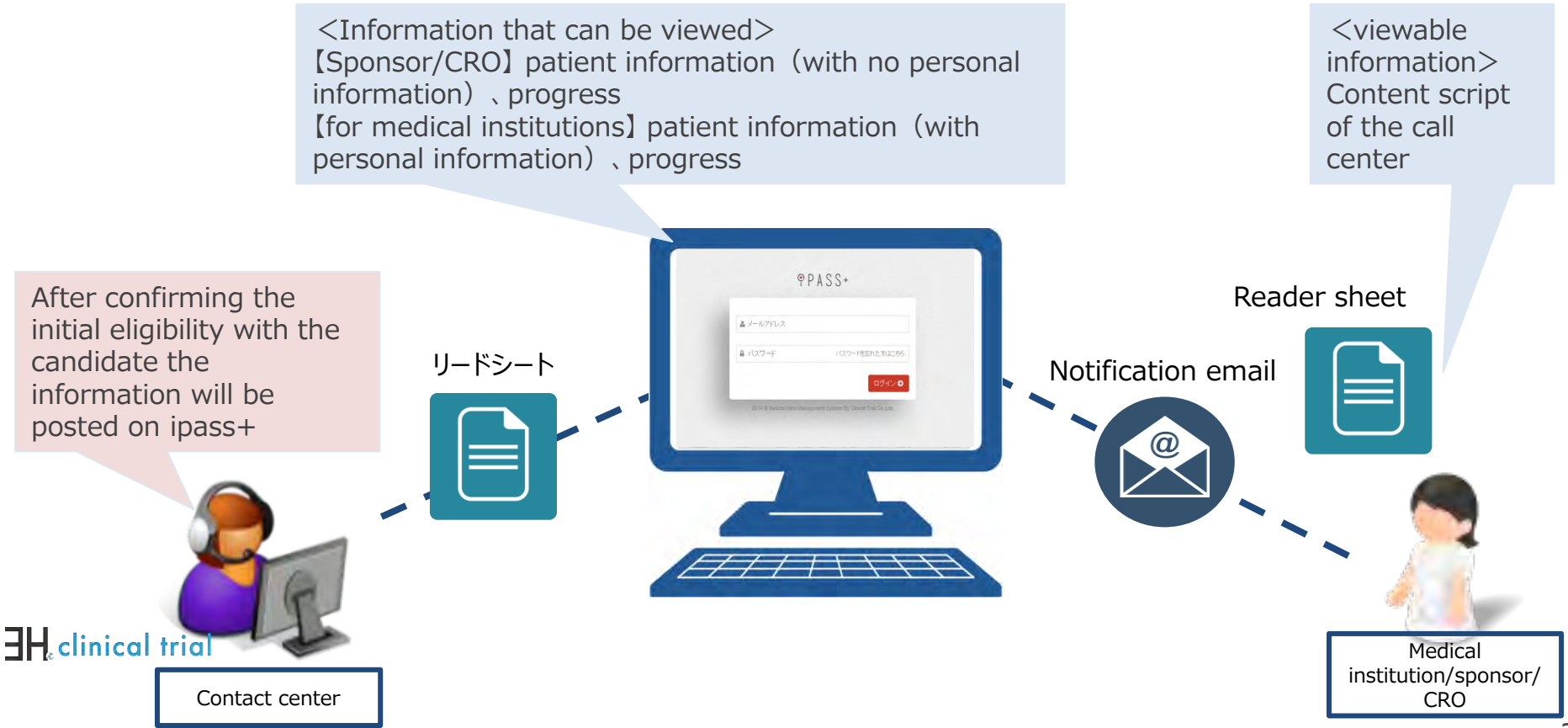
Asian Network



1. Covering all the necessary tactics for patient recruitment with local Vendors/Support.
2. Inculcating local vendors with the Know-how of Japanese PRO and Quality.
3. Our local vendor are well-versed in local clinical trial regulations and culturally affluent.
4. Multiple country project management by 3H medi solution Global professional of patient recruitment
5. Managing the referred patients at sites from Referral to Randomization by referral management system (iPASS+)

# What can be done from iPASS+

- ① By entering the progress information, you can share the information in real time basis
  - ② The notification mail function allows you to know that information has posted on ipass+( patients has been introduced to sites by the contact center)
  - ③ CRC can access the call script answers given by the potential participants through the reader sheet.
- ※since the reader sheet contains personal information, it is available only to SMO staff.
- ④ It is possible to exchange personal information of the candidates securely through ipass+(an account will be granted for each user)





# Thank you

3H Global Contact at: [imran@3h-ms.co.jp](mailto:imran@3h-ms.co.jp)