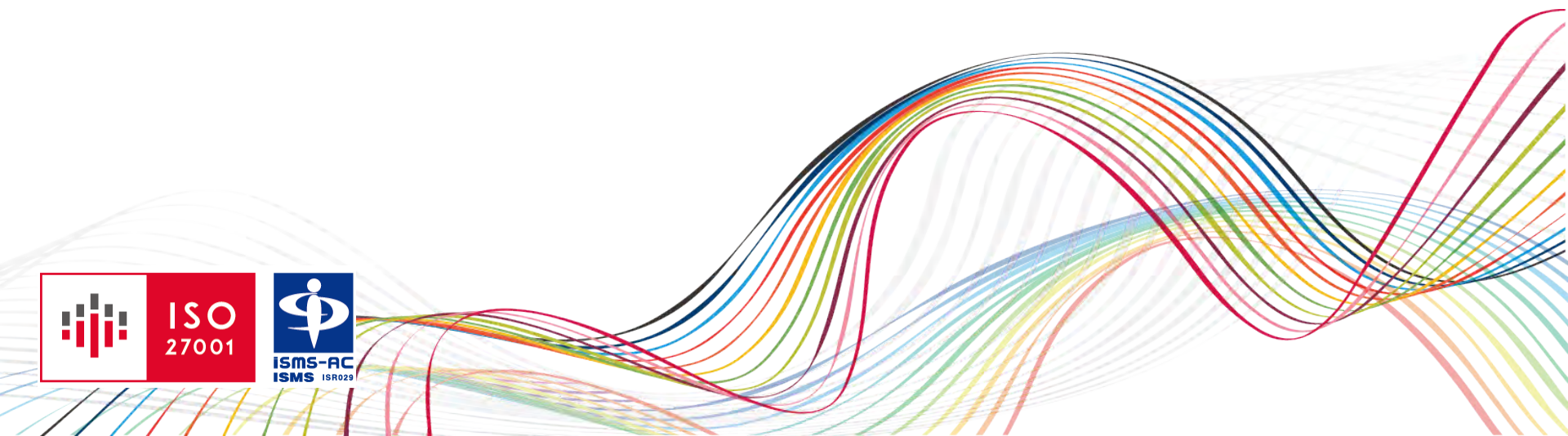


3H Medi Solution Global Capabilities



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



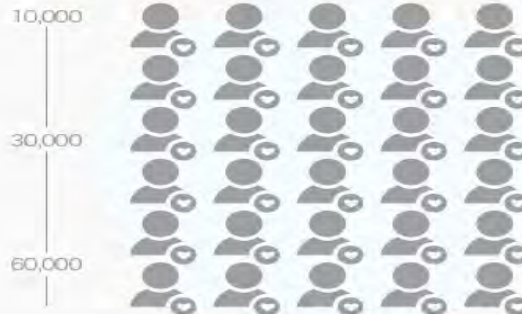
We support clinical trials/year

695



Subjects enrolled in last 5 years.

60,000



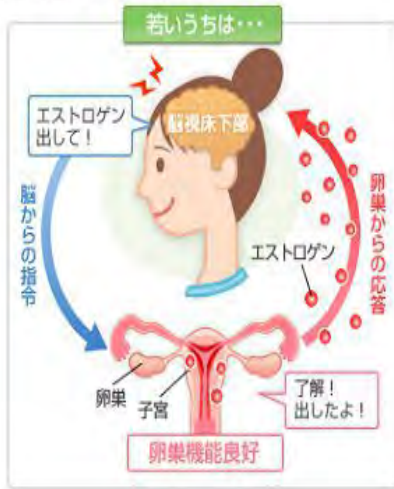
Our patient recruitment supports contributed to reduce the clinical trial

timeline by **5 months**
(Max)



Phase II Study // Hot Flash/Menopausal Syndromes

[更年期障害の仕組み]



Expert Analysis //

Hot flash is said to occur in around 10% of women in Japan. Despite the high incidence rate, only 50% of patients got diagnosed and receive treatment because it is the disease that makes it difficult for patients to realize that they are the patients of the disease and to encourage themselves to go the hospital.

For this study, CROee decided to plan the campaign very strategically, because the planning in a situation where there was not affluent information on the potential patients visiting the medical institution as well as recruiting the mild to moderate hot flash or menopausal syndromes patients by the set of online campaign as well as Newspaper Inserts.

Project Summary //

Sponsor	Japanese Pharma
Support from CROee	Patient recruitment advertisement
Timing of consultation	Throughout trial
Target	Hot Flash/ Menopausal Syndromes
# of site	17
Target area	All Japan
Medias used	DB, Web ,Newspaper Inserts

Impressive Number //

50 Hot Flash becomes more prevalent with old age, and more than half of those are over 50 years of age with this symptom. However, 50% of people try to endure the symptoms without receiving treatment, and 50% of people even after having severe climacteric disorders do not do anything. As a countermeasure, they take supplements, do exercise or take herbal medicine and without going to hospital. So we targeted the group of this 50% mainly and succeeded in recruiting the patients. Newspapers inserts and call centre script made with the help of gynaecologist expert patient recruitment specialist played the vital role to convince the patient to go to the hospital and try the new medication which was the one of the main sources to enrol the patient. Enrolling only from the sites would have not been that much successful.

Phase-III Study// OA

Expert Analysis//

Many people with OA do not get seen by a doctor, and many will use medications only when they cannot bear the pain. Therefore, the number of people who visit doctors regularly is low. CROee's recruitment advertisements focused on recruiting those who are troubled by pain rather than on whether they were receiving treatment for OA or not. Also, to reduce the burden of first visit charge and referral form charge, we suggested transportation fee reimbursement. As a result, we could get more patient to participate and achieved 180% of the planned number of randomizations

Project Summary //

CROee Support	Patient recruitment advertisement
Timing of consultation	During Clinical Trial
Target	Knee OA, Hip Joint OA
Sites	67
Target Area	All Japan
Tactics	DB, Newspaper · Inserts, Web

Impressive Number

60 OA becomes more prevalent with old age, and more than half of those over 40 years of age are troubled by pain. However, 60% of people try to endure the pain without receiving treatment, and 60% of people are not satisfied with their treatment outcome. CROee used newspaper advertisements to target these 60%, and lead many people to consider doctor visits or new treatment options. This lead to the successful recruitment of a patient group that could not have been recruited within sites.

Plan vs Result //

	Plan	Result
Recruitment Period	7 Months	7 Months
Referrals	668	1,295
Registered	35	63

Phase III Study //Alcoholism



Expert Analysis //

Although this is a condition with many potential patients, we had no information regarding patient profile for those that visit hospitals (severe disease) and those that are our recruitment targets (mild ~ moderate disease). Therefore, we ran a pilot plan to test our hypothesis on a small scale, and used the result to characterize the second screening. The recruitment plan was modified twice during the recruitment period. Through strategical planning and optimization, we achieved 115% of the achievement target within 4 months.

Project Summary //

CROee Support	Patient recruitment advertisement
Timing of consultation	Before the Trial
Target	Alcoholism
Sites	80
Target Area	All Japan
Tactics	DB, Inserts, Web

Impressive Number

2 Alcohol dependence is called the “disease of denial”, and it is difficult for patients to realize their disease and receive treatment. Patient eligibility was confirmed through the call centre in two steps, the second step being a hearing held by qualified staff such as clinical psychologists (2ndscreening). This allowed us to successfully recruit for alcohol dependence, which was considered a very challenging project.

Plan vs Result //

	Plan	Result
Recruitment Period	14 Months	10 Months
Referrals	1,996	1,079
Registered	500	575



Expert Analysis //

An example of successful site selection. The sites selected for this study were all very favourable for the referred patients in terms of location and time slots for visits. Especially 95% of the sites were within 10 minutes walking distance. The visit rate of referred patients was 76.6%, which is significantly higher than the average of 40~60%. Also, by being stringent with the selection criteria for referrals, less than the anticipated number of referrals were made, resulting in decreased burden for sites.

Project Summary //

CROee Support	Patient recruitment advertisement
Timing of consultation	Before the Trial
Target	OAB wet
Sites	107
Target Area	All Japan
Tactics	DB, Inserts, Web

Impressive Number //

76.6 When the number of referrals are high, sites cannot handle contacts with the subjects in a timely manner, resulting in increased numbers of unresponsive patients or cancellations. The contact center helped with coordinating the first visit and passed on information about the patient onto sites, resulting in a high first visit rate after referral and an effective path to randomizations.

Plan vs Result //

	Plan	Result
Recruitment Period	6 Months	6 Months
Referrals	1,579	684
Registered	500	473

Phase II Study // Endometriosis



Expert Analysis //

We started with advertisement strategies that are said to be the gold-star standard for patient recruitment, but few patients meeting the inclusion criteria showed up. Advertisement design and messages also had influence on the type of patients that ended up responding, which had mostly mild symptoms. Halfway through the study, we altered the advertisements and brought the surgery criteria to the forefront. This resulted in an increased number of patients that met the criteria, but was not sufficient for us to recover before the recruitment period ended.

Project Summary //

Support from CROee	Patient recruitment advertisement
Timing of consultation	Throughout trial
Target	Endometriosis
# of site	15
Target area	All Japan
Medias used	DB, Web

Impressive Number //

10 Endometriosis is said to occur in 5-10% of women. Despite the high incidence rate, only 10% of patients receive treatment. For this study, only patients diagnosed by laparoscopy and laparotomy were eligible. Under this inclusion criteria, CROee's feasibility research revealed that only 10% of endometriosis patients would be eligible. Depending on the inclusion criteria, diseases with high incidence rate may require strategies as vigorous as those for rare diseases.

Plan & Results //

	Plan	Result
Recruitment Period	3 months	5 months
Referrals	68	39
Registered	24	1



Expert Analysis //

Follow-up with patients over the long span of 2 years to monitor changes in their disease state is something that could only have been done because of our volunteer database. By regularly following-up with patients, the communicator built a trust relationship with the patient. Because of this, the patient was willing to call us to and report changes in their disease symptoms, which made it possible for them to clear the difficult criteria of visiting the site during an acute exacerbation.

Project Summary //

CROee Support	Patient recruitment advertisement
Timing of consultation	During the Trial
Target	schizophrenia
Sites	13
Target Area	All Japan
Tactics	DB, Web

Impressive Number //

2 Schizophrenia has a bipolar nature which consists of “on” and “off” periods. This study’s targets were patients who were experiencing an acute episode of “on”. Because it was difficult to predict when patients would have an episode, we recruited patients who were stable and followed-up with them biweekly so that we would be able to catch them when they were close to having an episode and refer them. This was a strategy that required communication and trust between the communicator and schizophrenic patient..

Plan vs Result //

	Plan	Result
Recruitment Period	27 Months	24 Moths
Referrals	—	8
Registered	4	3

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



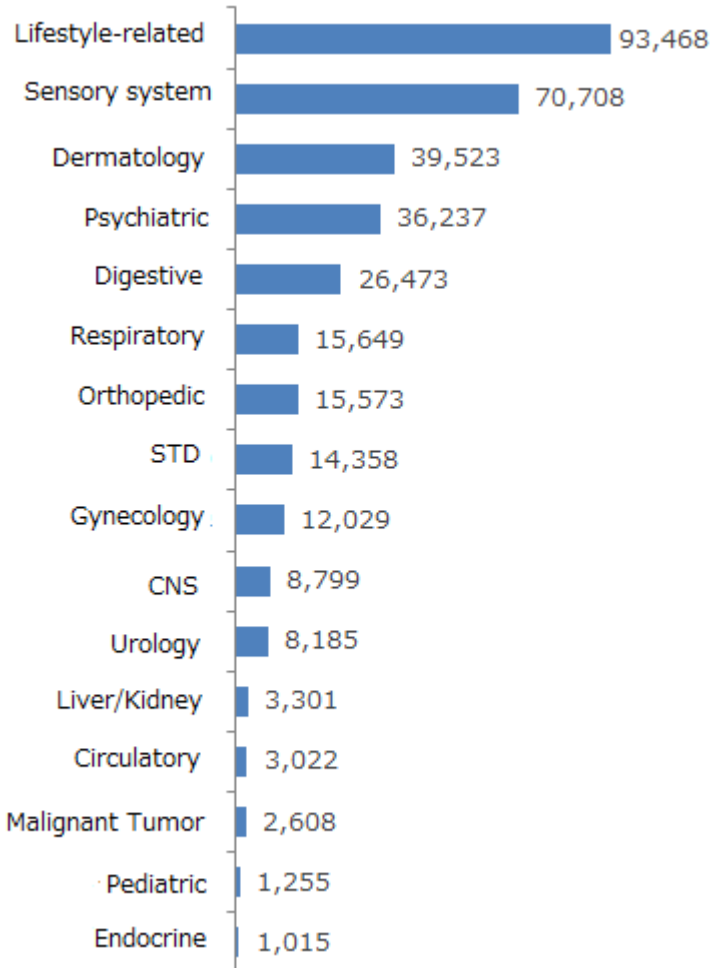
694,000 people

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	<u>Disease information, blood test data, medication information, etc.</u>

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

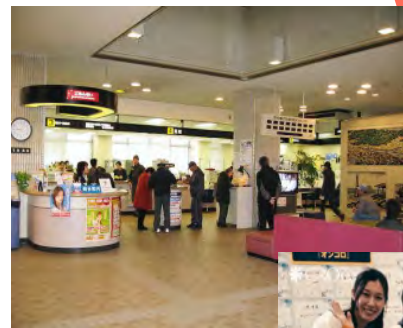
Area	Disease name * All disease categories are more than 300
Endocrine metabolic disease	Type 1 diabetes mellitus, type 2 diabetes mellitus, suspected diabetes mellitus, obesity, hyperuricemia, hypercholesterolemia, pediatric, etc.
Cardiovascular disease	Hypertension, atrial fibrillation, angina pectoris, 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.

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

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

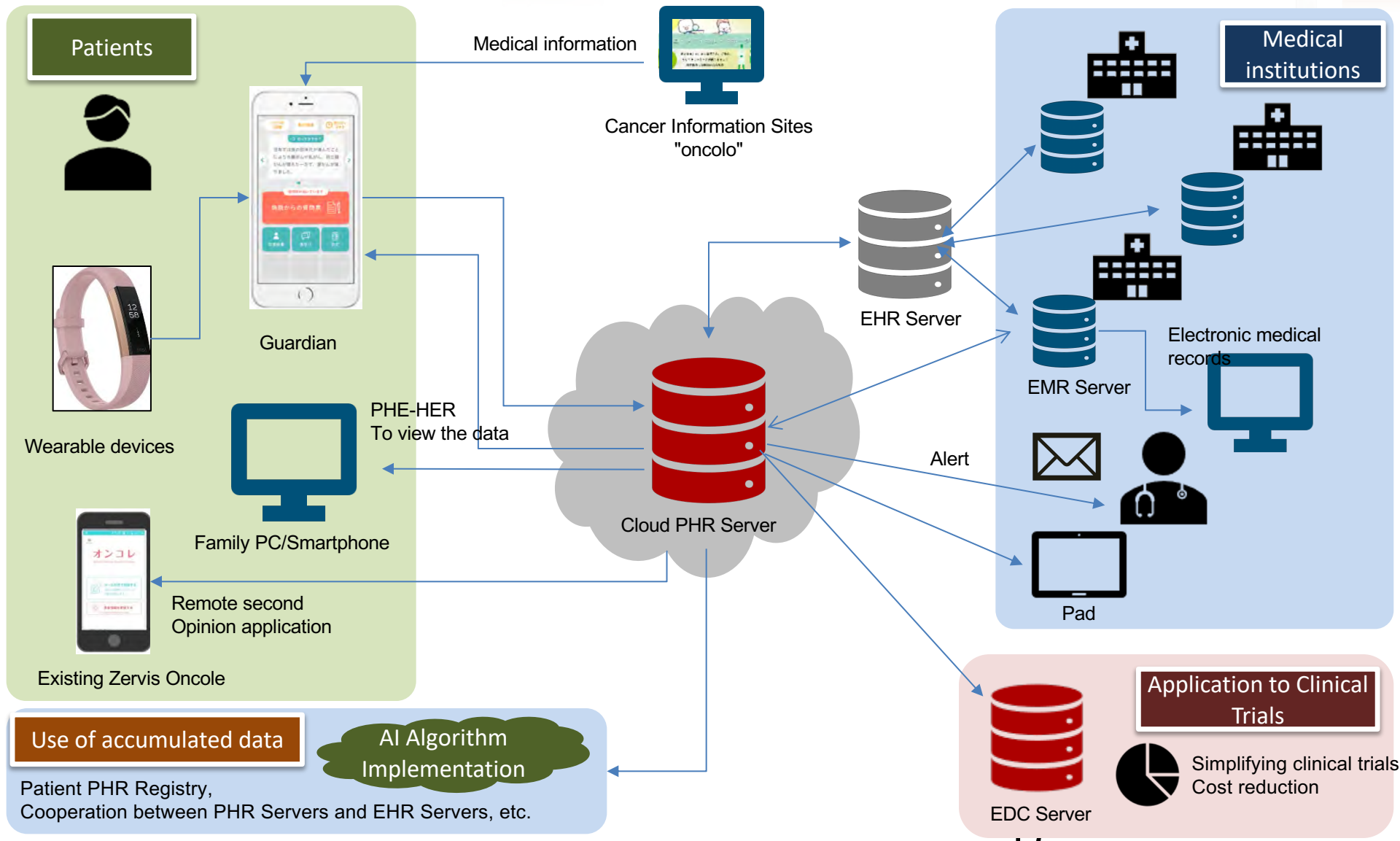
▶ **Introducing IOT for Patient Centricity**

Provisioning

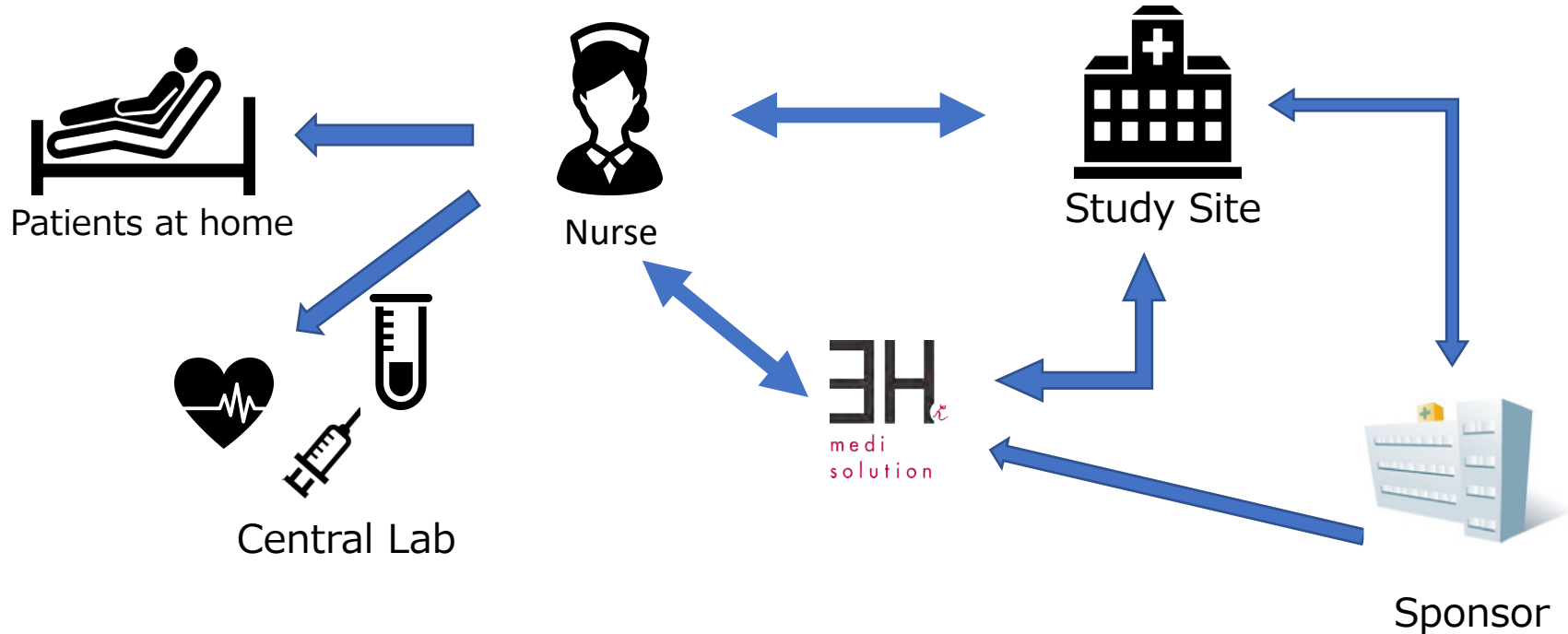
▶ Device delivery management (**Japan's only mechanism**)

Recruitment

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



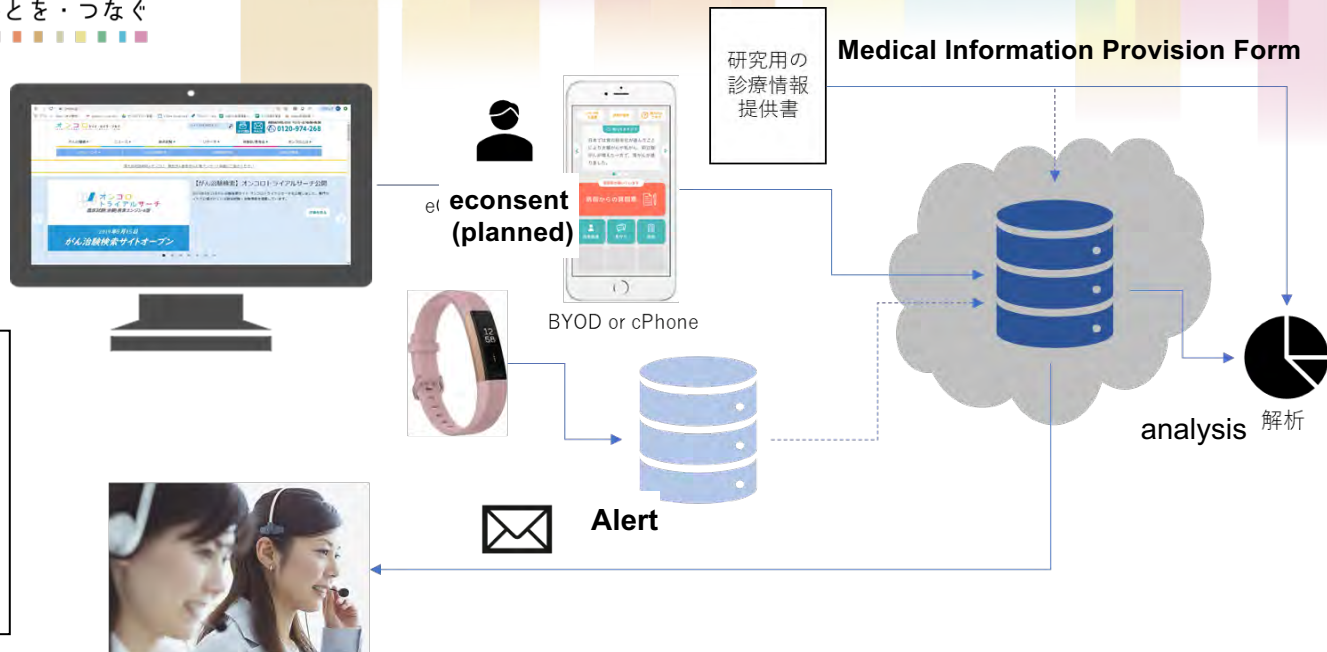
3H In-Home Clinical trial Support Model for Japan



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

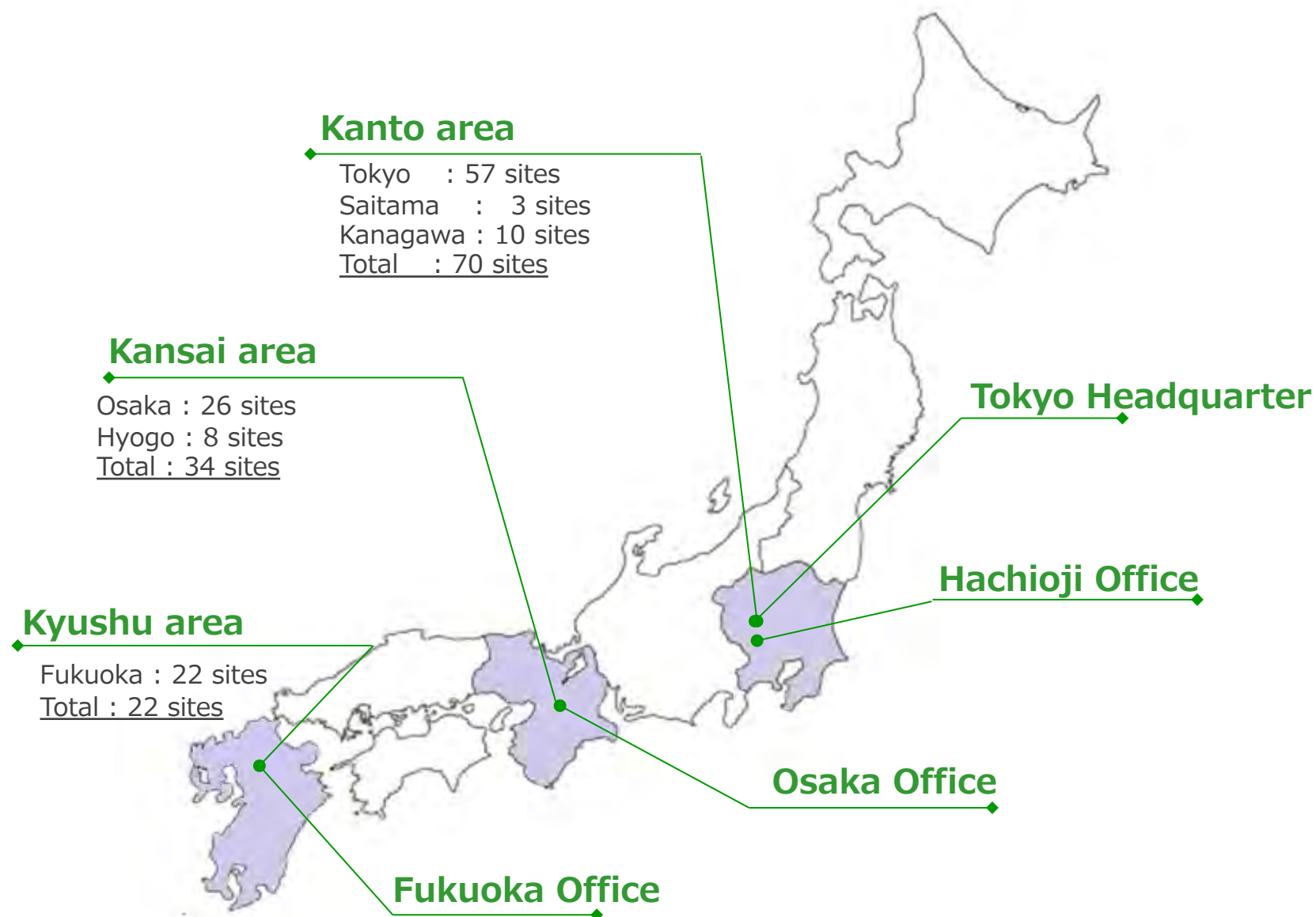
Study Period: November 2019 to March 2020

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+)

Referral Management System: iPASS+

Referral

First Visit

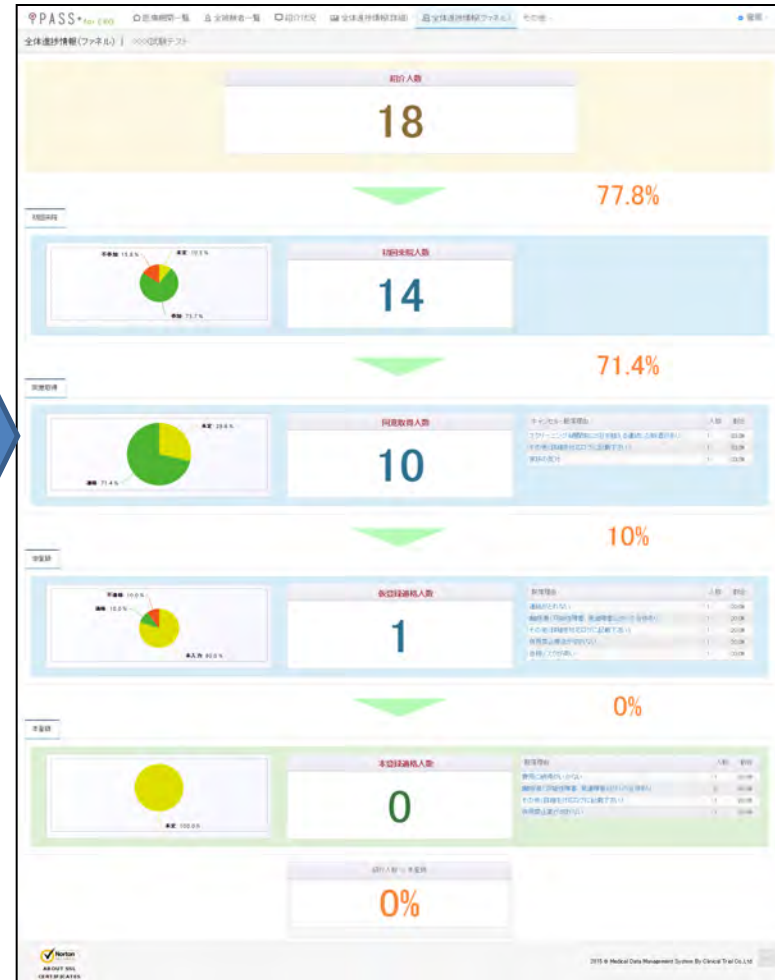
IC

Randomization

Recruited

累計登録者数: 47人
 登録日:
 登録日:
 標準日の日付: 12年05月18日(木)
 本日 登録>> 2件続>>
 CSV導出

予約受付日(yy/mm/dd)	予約日	ID番号	電話 SCR	SCR 中	SCR 結果	ICB	観測期 結果	投与予定日 (yy/mm/dd)	投与日(yy/mm/dd)	終了日(yy/mm/dd)	最新更新日
10/12/02	---	251516	●	●	▼	---	---	---	---	---	2012-01-30 19:05:09
10/12/06	---	42248	●	●	●	11/03/29	●	11/4/12	11/4/12	11/5/24	2011-08-04 21:00:01
11/02/02	---	42293	●	●	●	---	---	---	---	---	2012-01-30 19:13:48
11/08/17	---	192092	●	△	△	---	---	---	---	---	2011-09-02 12:08:17
10/07/27	10/07/30(金) 14:00	268654	●	●	▼	---	---	---	---	---	2010-08-04 17:30:41
10/11/01	10/11/04(木) 10:00	291371	●	●	●	---	---	---	---	---	2012-04-02 11:30:46
10/12/06	10/12/08(水) 15:00	73763	●	●	●	11/06/02	●	11/7/01	11/7/01	11/8/26	2011-10-29 17:54:12
10/12/08	10/12/16(水) 14:30	256579	●	△	△	---	---	---	---	---	2011-01-28 12:02:10
10/12/06	10/12/18(土) 11:00	86981	●	●	●	---	---	---	---	---	2012-04-02 10:53:32
10/12/06	10/12/27(月) 10:30	133783	●	●	▼	---	---	---	---	---	2012-01-30 18:59:23
11/01/26	11/02/01(水) 15:00	269780	●	●	▼	---	---	---	---	---	2011-09-15 12:41:07
11/01/25	11/02/04(金) 15:30	270682	●	●	▼	---	---	---	---	---	2011-09-15 12:41:51
11/02/04	11/02/10(水) 15:00	259186	△	△	△	---	---	---	---	11/2/07	2011-02-07 15:47:35
11/02/05	11/02/17(水) 14:30	182092	●	△	△	---	---	---	---	11/2/02	2011-09-02 11:06:35
11/02/10	11/02/18(金) 14:30	318207	△	△	△	---	---	---	---	11/2/14	2011-02-14 11:30:05
11/02/05	11/02/18(金) 16:00	316209	△	△	△	---	---	---	---	11/2/06	2011-02-06 13:47:46
11/01/25	11/02/19(土) 11:00	279534	●	●	▼	---	---	---	---	---	2011-04-06 20:27:41
11/02/08	11/02/23(水) 10:30	236034	●	●	▼	---	---	---	---	---	2011-09-15 12:42:46
11/02/10	11/03/05(土) 08:30	230432	●	●	▼	---	---	---	---	---	2012-03-27 20:57:49
11/02/24	11/03/07(月) 10:30	133995	●	●	▼	---	---	---	---	---	2011-03-22 14:45:26
11/03/07	11/03/17(水) 10:30	321068	●	●	▼	---	---	---	---	---	2011-04-06 20:19:51
11/03/23	11/03/30(水) 15:30	320833	●	△	△	---	---	---	---	---	2011-04-06 20:19:51
11/03/24	11/03/30(水) 16:00	280260	△	△	△	---	---	---	---	11/3/27	2011-03-27 11:57:26
11/04/07	11/06/15(金) 14:30	323714	△	△	△	---	---	---	---	11/4/12	2011-04-12 11:59:13
11/04/01	11/04/18(月) 08:30	195884	●	●	▼	---	---	---	---	---	2011-08-04 21:00:32
11/03/31	11/04/23(土) 10:30	322258	●	●	▼	---	---	---	---	---	2012-03-27 20:59:51
11/04/18	11/04/25(月) 08:30	325486	●	●	▼	---	---	---	---	---	2012-01-31 18:40:56
11/04/28	11/05/14(水) 08:30	43376	●	●	▼	---	---	---	---	---	2012-03-23 16:01:31



iPASS+ is a system to provide referrals information to the site securely. All the referrals from our advertisement will be screened through our call centre. All the information about referrals will be uploaded to iPass+ Each site can log in to the iPASS+ with ID & password to view referral information.

Thank you

To know more please contact: imran@3h-ms.co.jp