



- For children opening up the future -

# 小児治験ネットワーク

## Pediatric Clinical Trials Network

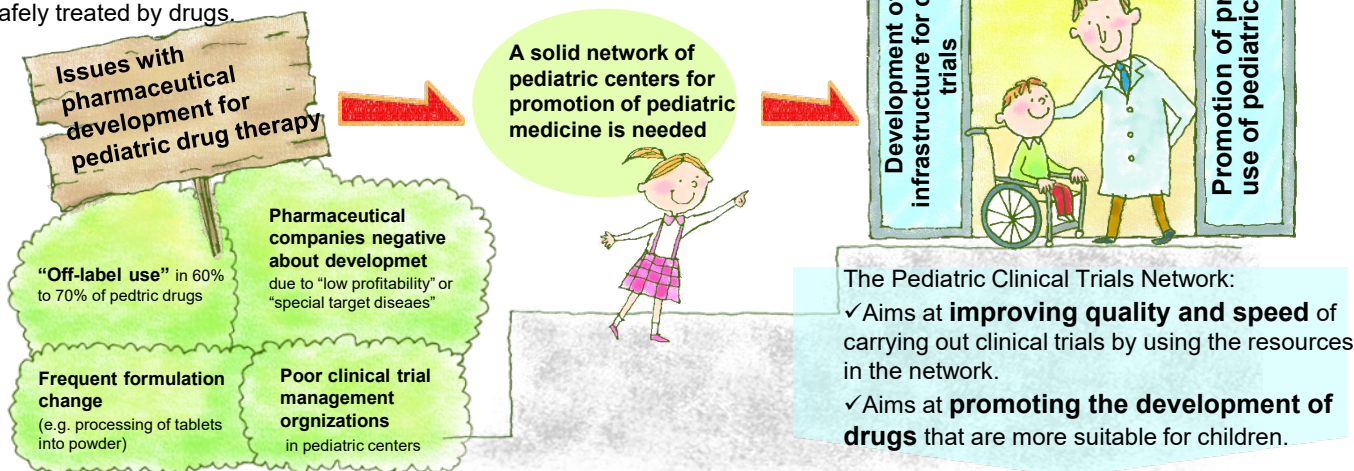
### What Is Pediatric Clinical Trials Network?

**Network specific to the pediatric field**, centered on the member medical institutions of the Japanese Association of Children's Hospitals and Related Institutions.

### Background of Establishment (Established in 2010)

The environment surrounding pediatric drugs has many issues.

The Pediatric Clinical Trials Network, a network formed by pediatric centers across Japan, is committed to supporting the promotion of pharmaceutical development for children in order to improve the environment that children can be safely treated by drugs.



### Member Medical Institutions

55 member medical institutions

6,900 pediatric hospital beds in the network

All 55 institutions that are able to conduct feasibility studies

Thirty-nine institutions (marked with ●) that are capable of following the review process by the central IRB

University hospital	18 sites
NHO hospital*	11 sites
General hospital	9 sites
Children's hospital	17 sites

\* NHO : National Hospital Organization

1	● Hokkaido Medical Center for Child Health and Rehabilitation
2	● NHO Hirosaki General Medical Center
3	● Miyagi Children's Hospital
4	● Ibaraki Children's Hospital
5	● Dokkyo Medical University Hospital
6	● Jichi Medical University Hospital
7	● Gunma Children's Medical Center
8	● Saitama Children's Medical Center
9	● Chiba Children's Hospital
10	● National Center for Child Health and Development
11	● Tokyo Metropolitan Children's Medical Center
12	● Chiba Children's Hospital
13	● Chiba Children's Hospital
14	● Chiba Children's Hospital
15	● Chiba Children's Hospital
16	● Chiba Children's Hospital
17	● Chiba Children's Hospital
18	● Chiba Children's Hospital
19	● Chiba Children's Hospital
20	● Chiba Children's Hospital
21	● Chiba Children's Hospital
22	● Chiba Children's Hospital
23	● Chiba Children's Hospital
24	● Chiba Children's Hospital
25	● Chiba Children's Hospital
26	● Chiba Children's Hospital
27	● Chiba Children's Hospital
28	● Chiba Children's Hospital
29	● Chiba Children's Hospital
30	● Chiba Children's Hospital
31	● Chiba Children's Hospital

16	● Japanese Red Cross Aichi Medical Center Nagoya Daiichi Hospital
17	● Aichi Children's Health and Medical Center
18	● Aichi Developmental Disability Center Central Hospital
19	● NHO National Mie Hospital
20	● Shiga Medical Center for Children
21	● University Hospital Kyoto Prefectural University of Medicine
22	● NHO Minami Kyoto Hospital
23	● Osaka Women's and Children's Hospital
24	● Osaka City General Hospital
25	● Takatsuki General Hospital
26	● Osaka Habikino Medical Center
27	● Hyogo Prefectural Kobe Children's Hospital
28	● Kobe University Hospital
29	● Nara Prefecture General Medical Center
30	● Wakayama Medical University Hospital
31	● Tottori University Hospital
32	● NHO Okayama Medical Center
33	● Kawasaki Medical School Hospital
34	● Hiroshima Prefectural Hospital
35	● NHO Fukuyama Medical Center
36	● Fukuyama City Hospital
37	● NHO Shikoku Medical Center for Children and Adults
38	● Fukuoka Children's Hospital
39	● Kyushu Hospital
40	● NHO Kumamoto Medical Center
41	● NHO Beppu Medical Center
42	● Okinawa Prefectural Nanbu Medical Center & Children's Medical Center

# Activities of the Pediatric Clinical Trials Network

## Feasibility study for clinical trials

- Feasibility studies and studies on numbers of patients are free of charge.
- Studies across all the pediatric field can be conducted.
- Study results are available in about 10 days.

I would like to conduct a feasibility study. Which institutions are subject to the study?

All institutions that are members of the network.

## Central Institutional Review Board

Centralized review of multiple institutions is performed.  
Centralized review contributes to reduction of costs for review and efficient review process.

I would like to ask for review by central IRB. How many institutions are covered by the central IRB?

39 institutions. Please make sure "Member Medical Institutions" for further information.

## Standardization of necessary procedures for clinical trials

- Procedures or cost calculations are standardized.
- Some of activities of clinical trial offices are centrally performed, including standardization of informed consent forms or assent forms.

I am not familiar with preparing assent forms.

You can use a template of assent forms that are publicly available on our website.

## Efficient clinical trials using ICT technology

- An information management system is used to drive digitization of the documents for clinical trials.
- Multi-center conferences to promote subject enrollment are held by using web conference system, if necessary.

What is an information sharing and management system?

It is an original document management system designed for easy use in our Network.

## On-demand clinical trials

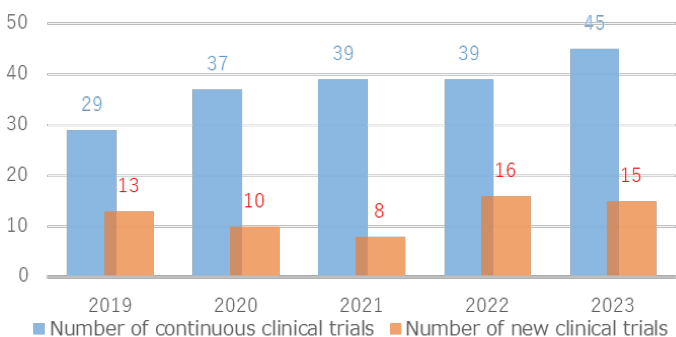
In the case of rare diseases, a contract for preparation for conducting clinical trials can be made with medical institutions potentially enrolling subjects. This enables swift site initiation and results in cost reduction when candidate subjects emerge.

## Promotion of pediatric drug development

Aiming at promoting pediatric drug development, following three activities are ongoing. One is to collect the information on dosage forms suitable for children, the second one is to provide support activities to promote clinical researches, and the last one is to collect the information on adverse drug reactions to enhance safety measures of drug use in children.

## Achievements

Number of clinical trials per year



Number of approved medicines/devices

### Grand Total 37 products

Approved in Apr 2023 – Mar 2024	Indication (Including expansion of indications)
E Keppra	Epilepsy
Feburic	Hyperuricemia
Sogroya	Short stature due to growth hormone deficiency
Growject	Short stature due to SHOX disorder
SYNFOLIUM	Sheet for tissue reconstruction in surgery for congenital heart disease
Xarelto	Thromboprophylaxis after Fontan surgery
Genotropin	Body composition abnormalities in Prader-Willi syndrome
Entresto	Heart failure
FASENRA	Asthma
Mitchga	Atopic dermatitis

## Human Resource Development Specific to Pediatric Clinical Trials

Clinical research in children, including clinical trials, involves ethical considerations or efforts different from those in the adult field and knowledge on development of children because it targets children. For this reason, educational programs for developing CRCs specialized in pediatric fields have been developed and annual classroom training sessions have been held in summer.

More practical hands-on training is provided to the trainees if required.



Scene of CRC classroom training

## Contact Information

[Office for the Pediatric Clinical Trials Network] Network Promotion Unit, Department of Multicenter Collaboration, Clinical Research Center, National Research and Development Agency, National Center for Child Health and Development

Contact: TEL: +81-3-5494-7297 (dial-in) / FAX: +81-3-3415-6230

E-mail: jctn@ncchd.go.jp (Pediatric Clinical Trials Network office)

URL: <https://pctn-portal.ctdms.ncchd.go.jp/>

Address: 2-10-1 Okura, Setagaya-ku, Tokyo, 157-8535, Japan