

New Paediatric Clinical Trials Network in Japan

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- The views and opinions expressed in the following PowerPoint slides include those of the individual presenter and should not be attributed to the Japanese Children Trials Network (JCTN)
- This is a private point of view

Japanese Children Trials Network (JCTN)

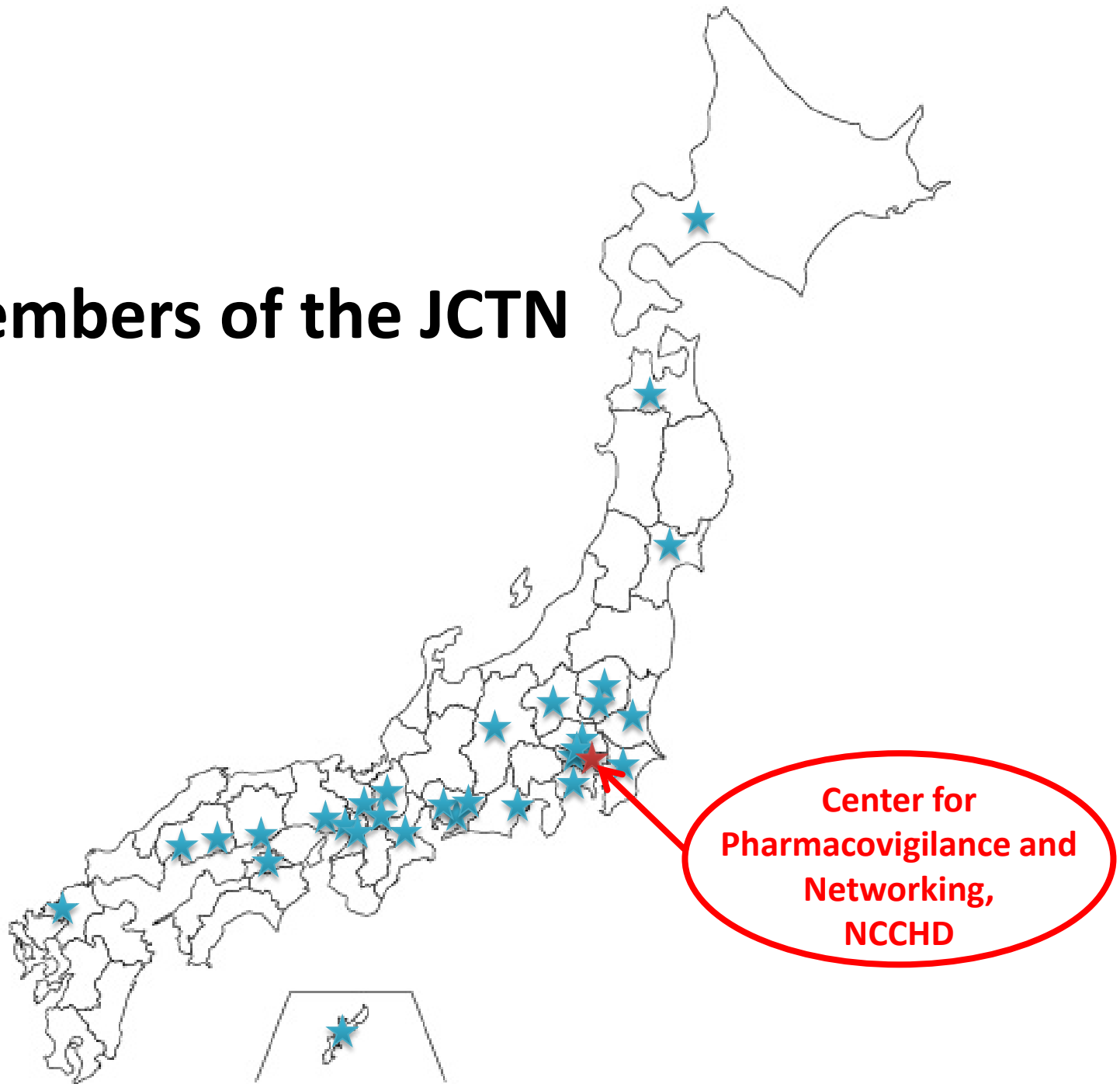
- **Japanese Children Trials Network (JCTN)** is a new paediatric clinical trials network
- Established in 2010
- National Network
- Parent organization of the JCTN is the Japanese Association of Children's Hospitals and Related Institutions (JaCHRI, since 1968)
- Head office of the JCTN is in the **Center for Pharmacovigilance and Networking** of the **National Center for Child Health and Development (NCCHD)**

JCTN aims to fulfill its mission by:

JCTN has the almost **same objectives as the Enpr-EMA and its members**

- fostering **high-quality ethical research on the safety and effectiveness of medicines for children**;
- facilitating a Japanese paediatric research with expertise in performing trials in the paediatric population;
- efficient inter-network and stakeholder collaboration, to build up the necessary competences at GCP level, and to avoid unnecessary duplication of studies;
- informing parents, careers, children and young people about clinical trials, and encouraging their participation;
- raising awareness among healthcare professionals of the need for clinical trials in all ages of children, and supporting their involvement in such studies;
- assisting and entering into dialogue with ethics committees on issues relevant to research and clinical trials in children !!!

31 Members of the JCTN



Outcome of the JCTN in fiscal 2011

Feasibility assessment and Implementation status

No.	対象疾患等	剤形	調査種別	実施時期	調査施設	回答施設	可能施設	選定施設	治験受託状況
1	免疫不全	注射	実施可能性	H23. 4	23	19	5	2	施設単独で受託
2	小児強直間代発作	内服 (DS)	実施可能性	H23. 5	15	13	6	1	施設単独で受託
3	小児強直間代発作 (国際共同治験)	内服 (錠剤)	実施可能性	H23. 11	26	25	4	1	施設単独で受託
4	強迫性障害	内服 (錠剤)	Feasibility	H23. 11	27	22	—	—	—
5	家族性 高コレステロール血症	内服 (錠剤)	実施可能性	H23. 12	26	25	4	0	—
6	自閉症 (易刺激性)	内服 (液剤)	実施可能性	H24. 1	21	21	2	1	施設単独で受託
7	Nerurogenic detrusor overactivity	Oral (Tablets)	実施可能性	H24. 2	19	18	5	2	JCTN (Global industrial- Initiated) 2012-
8	Pulmonary arterial hypertension	Oral (Tablets. Granules)	実施可能性	H24. 2	20	19	6	3	JCTN (Industrial- initiated) 2012-
9	脆弱X症候群 (FXS)	—	Feasibility	H24. 3	27	25	—	—	—

Outcome of the JCTN in fiscal 2012, 2013

Feasibility assessment and Implementation status

No.	対象疾患等	剤形	調査種別	実施時期	調査施設	回答施設	可能施設	選定施設	治験受託状況
1	統合失調症	内服（錠剤）	実施可能性	H24.4	25	22	0	—	—
2	Giant congenital nevocellular nevi	Cultured epithelial autograft	Feasibility	H24.4	29	27	—	—	JCTN (Investigator-initiated) 2012-
3	血管腫	注射	Feasibility	H24.5	29	27	—	—	—
4	Noonan syndrome (Short stature)	Subcutaneous Injection	実施可能性	H24.6	24	23	8	—	JCTN (Investigator-initiated) 2013-
5	ダウン症候群の急激退行	内服（錠剤）	実施可能性	H24.8	24	20			Under consideration
6	難治性部分てんかん発作を有する結節硬化症	内服（錠剤）	実施可能性	H24.8	23	20	10	1	施設単独で受託
7	小児肺動脈性肺高血圧症	内服（錠剤）	実施可能性	H24.9	30	27	10		Under consideration
8	2 Trials of ADHD	Oral (Tablets)	実施可能性	H24.10	24	21	6		JCTN (Investigator-initiated) 2013-
9	小児クローン病	注射	実施可能性	H24.12	23				Under consideration
10	小児潰瘍性大腸炎	注射	実施可能性	H24.12	23				Under consideration
11	小児経腸栄養剤	内服（液剤）	Feasibility	H25.1	31				—

Thank you for your attention.

- In the near future we would like to work together with you as a member of Enpr-EMA
- I hope this presentation was informative for you
- I really appreciate your time

