



Paeditric clinical trials in Poland – future Polish Network

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Why CTs in Poland? CROM Report 2014

- Poland is the largest market of clinical trials in the Central Eastern European region, conducting approximately 20 % of all trials.
- Poland holds the 10th position in the world and first among emerging markets in terms of the number of CTs as well as the 7th place in Europe in terms of the number of patients participating in clinical trials (407 CTs approved in 2014)
- Most of CTs in Poland are managed by CROs (70% in terms of volume and 53% in terms of value).





Why CTs in Poland? CROM Report 2014

CROM

White Paper

CLINICAL RESEARCH IN POLAND

- About 40,000 patients participate in clinical trials in Poland each year. The year 2008 was a record year for our market, with more than 51.000 patients enrolled.
- Enrollment to clinical trials in Poland is typically faster than in many other countries. This may be due to a number of factors, which are described below:

Poland has a relatively large population (38 millions) presence of specialized medical centers provides access to patients in all therapeutic areas, particularly oncology, rheumatology, cardiology and **paediatrics**.



Why CTs in Poland? CROM Report 2014

CROM

White Paper

CLINICAL RESEARCH IN POLAND

- High motivation for patients in Poland to become involved in CTs. This is because patients participating in trials in Poland expect better medical care, free drugs and diagnostic procedures.
- CTs are also attractive to investigators because of possibility to test new treatment standards, exchange information with foreign experts and the opportunity to have co-authored publications in medical journals.



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CROM

White Paper

CLINICAL RESEARCH IN POLAND

- cost per trial in Poland is nearly 30% less than the cost in the U.S.
- costs of a clinical trial conducted in Poland are relatively low due to a high rate of patient recruitment and excellent quality of data, leading to a reduced number of rejected clinical trials recordings and time-efficient proceedings.
- comparison of the number of the FDA audit site inspections carried out between 1997 and 2008 in various countries worldwide showed that Poland has a high standard of CTs procedures and provides good quality clinical trial data.



The Children's Memorial Health Institute

- The Children's Memorial Health Institute is the largest and most modern tertiary referral pediatric hospital in Poland. It is also a research institute contributing to modern pediatrics.
- Our mission is to provide the highest standards of treatment and care through understanding the needs of the Patients and their Families, based on the latest scientific achievements in pediatrics and the experience of the best medical personnel.





Children's Memorial Health Institute - basic figures

- Tertiary paediatric hospital
- 560 beds including 150 surgical and 50 intensive beds (PICU, SICU, NICU)
- Each year approx.
 - 40 000 admissions
 - 170 000 out-patients consultations
 - 12 000 general anaesthesia
 - 4000 major surgical operations
 - annual budget 75 000 000 Euros





The Children's Memorial Health Institute – EU funded projects in 2015

Nr kontraktu/ umowy	Data rozpoczęcia	Data zakończenia	Kierownik projektu	Tytuł projektu	Akronim
261060	2011-01-01	2017-06-30	Marek Migdał	Global research in pediatrics - GRIP	GRIP
277984	2011-11-01	2015-10-31	Tomasz Kmiec	Treat Iron-Related Childhood-Onset Neurodegeneration	TIRCON
289346	2012-02-01	2017-01-31	Dariusz Gruszfeld	Long-term effects of early nutrition on later health	EarlyNutrition
305373	2012-10-01	2017-03-31	Maria Szarras-Czapnik	Clinical European study on the outcome of surgical and hormonal therapy and psychological intervention in disorders of sex development (DSD)	DSD-Life
602391	2013-11-01	2018-10-31	Sergiusz Jóźwiak	Long-term, prospective study evaluating clinical and molecular biomarkers of epileptogenesis in a genetic model of epilepsy - tuberous sclerosis complex	EPISTOP

Nr kontraktu/ umowy	Data rozpoczęcia	Data zakończenia	Kierownik projektu	Tytuł projektu	Akronim
677024	2015-06-01	2018-05-31	Małgorzata Krajewska-Walasek	Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases	RD-ACTION

Nr kontraktu/ umowy	Data rozpoczęcia	Data zakończenia	Kierownik projektu	Tytuł projektu	Akronim
POIG.02.03.00-14-085/13	2014-03-01	2015-12-31	Robert Szkop	Naukowe Centrum Danych Pediatricznych	NCDP





The Children's Memorial Health Institute – 35 on-going international clinical trials in 2015

Lp.	Nr protokolu
1	M06-807
2	EP00-401 EP00-402
3	CRAD001M2302 (EXIST2)
4	HOS
5	BO20924 (BERNIE)
6	CRAD001A2314

7	PMR-EC-1206
8	PMR-EC-1206
9	BI1218.56
10	AGAL19110/MS12711
11	BO25041C (HERBY)
12	H6D-MC-LVIG
13	PMR-EC-1207

14	905-CL-047
15	LAL-CL02
16	905-CL-074
17	AC-056C501
18	CRAD001MIC03 (TOSCA)
19	ALX-MCD-502
20	CNT0148UCO1001
21	CRAD001M2304 (EXIST3)

22	SPD476-319
23	LUM001-304
24	V118_05
25	178_CL-202
26	20130173
27	XM02-ONC-201
28	2819-CL-0202

29	1VIT13036 (LUPIDA)
30	LTS14116
31	CT-ORZY-NPC-001
32	LUM001-501
33	V00400SB302
34	SAG/0211PFC-1131
35	CT-P13 4.3



The Children's Memorial Health Institute – 16 clinical trials planned to start in 2016

Lp.	Nr protokolu
1	HEP002
2	PMR-EC-1207
3	H6D-MC-LVHV
4	Ewing 2008
5	CRAD001M2305 EXIST-LT
6	TAK390MR_108
7	KF5503/65
8	KF5503/73

9	SAG/0211PFC- 11S1
10	178_CL-203
11	XM22-08
12	MK-0517- 044_0221
13	KF5503/65
14	14VR4

15	TAK-390MR-204
16	TAK-390MR-205



SMART project



The main objective of the **TWINNING Coordination and Support action** is to spread excellence and widen IPCZD participation in paediatric medicines research through:

- Raising IPCZD staff's research profile and increasing their research capacity
- Creating a training program based on specific Knowledge's needs
- Supporting IPCZD in developing and adopting innovative approaches for paediatric research
- Increasing the global Scientific & Technological capacity of the whole partnership



SMART project



A composite training programme

Three internationally-leading research institutions

- CVBF in Italy,
- UCL in the United Kingdom
- Marseille University in France

To provide high-level specific expertise in paediatric clinical trial management, M&S and Extrapolation applications, new formulation generation





Future Polish Network

MINISTERSTWO ZDROWIA
ul. Miodowa 15
00-952 Warszawa
tel. centr. 634-90-00

Warsaw, 23rd February, 2015

To whom it may concern,

This is to certify that Polish Ministry of Health approves the application of The Children's Memorial Health Institute, Warsaw, Poland, for participation in European Paediatric Clinical Trials Research Infrastructure (EUPCTRI).


PODSEKRETARZ STANU
w Ministerstwie Zdrowia

Anna Lukasik



Thank you



TEDDY EUROPEAN NETWORK OF EXCELLENCE
FOR PAEDIATRIC CLINICAL RESEARCH

Scientific Meeting and General Assembly

**The paediatric theme in the
forthcoming clinical research scenario**

