

HOW TO REACH WARSAW



By plane

Warsaw Chopin Airport is the airport of Warsaw. The airport is just 10 km south west of Warsaw in Okęcie, and the journey time by bus is usually around 25 minutes. The 175 and 188 bus lead into the city centre and take a ride every ten minutes. Airport Info: +48 22 650 4220 • +48 22 650 1111 • www.lotnisko-chopina.pl

By train

Warszawa Centralna (Warsaw Central) is the main railway station in Warsaw. There is also an underground system in Warsaw. intercity.pl • www.pkp.pl • www.metro.waw.pl

Taxi

ELE SKY TAXI	+48 22 811 11 11	www.eletaxi.pl
SUPER TAXI	+48 22 578 98 00	www.supertaxi.pl
SAWA TAXI	+48 22 644 44 44	www.sawataxi.com.pl

Course venue

Hall 119 block F (1st floor), the Children's Memorial Health Institute, Warsaw, Al.Dzieci Polskich 20



GIANNI BENZI FOUNDATION

The Gianni Benzi Pharmacological Research Foundation (FGB) is a registered not-for-profit scientific research organisation aimed at promoting research on the medicines and other products for human use. Besides research, its activities are addressed to high-level educational initiatives mainly in the field of Regulatory Sciences.

FGB is partner of Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) and collaborates with many national, local and international scientific organisations.

Other activities at FGB include setting up of research grants and scholarships, as well as dissemination of research results and promotion of editorial initiatives.



CHILDREN'S MEMORIAL HEALTH INSTITUTE

The Children's Memorial Health Institute (CMHI) is the largest and most modern tertiary paediatric hospital in Poland and also a research institute contributing to modern pediatrics.

The CMHI has 560 beds including 150 surgical and 48 intensive beds with approximately 40.000 admissions/year and 170.000 out-patients consultations/year.

In 2014, it has been involved in 13 EU funded research projects, 24 national research grants and 32 clinical trials with medicinal products in paediatric population.

The Polish Ministry of Health appointed the CMHI to coordinate the establishment of a European Paediatric Clinical Trial Research Infrastructure (EPCTRI) at Polish level.



GRiP NETWORK OF EXCELLENCE

The Global Research in Paediatrics - Network of Excellence (GRiP) is a EU-funded project (<http://www.grip-network.org>), aimed at stimulating and facilitating the development and safe use of medicines in children.

The GRiP consortium is achieving this goal through the development of an International training programme on paediatric medicines development and evaluation; the validation and harmonisation of research tools specific for paediatrics; the sharing of best practices, strategies and plans. In the GRiP context, Work Package 4 "New methods for clinical studies in paediatrics", led by CVBF-TEDDY, is aimed at the implementation of alternative designs for clinical trials in children to be included in paediatric medicines developmental plans.

COURSE DIRECTORS

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SCIENTIFIC SECRETARIAT

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The VIII Foresight Training Course "Regulatory and Practice in Paediatric Trials and Studies" is organised by the Gianni Benzi Pharmacological Research Foundation (FGB, Italy) and the Children's Memorial Health Institute (CMHI, Poland) in collaboration with the GRiP Network (Global Research in Paediatrics) - Work Package 4, led by CVBF-TEDDY



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VIII FORESIGHT TRAINING COURSE REGULATORY AND PRACTICE IN PAEDIATRIC TRIALS AND STUDIES

22-23 SEPTEMBER 2015
WARSAW



BACKGROUND

All the participants of this FTC edition have a different long-standing experience with paediatric clinical research and training activities.

To date, several issues are expected to dramatically impact on paediatric clinical research:

1. The entry into force in Europe of new rules regulating clinical research will obviously reflect on paediatric research. In May 2016 the new Regulation on clinical trials will be applied. In particular we will analyse how the provisions of the 2008 European Paediatric Recommendations will be implemented in the Regulation.
2. The debate on the impact of the Paediatric Regulation after 10 years from its entry into force is ongoing. By January 2017, a report on the experience from rewards and incentives measures will be issued. This means that our initiative, involving several qualified stakeholders from different countries, should contribute to collect opinions and data supporting the maintenance of a strong EU paediatric initiative.
3. New supporting forms, e.g. research infrastructures and global networks, are developing to promote paediatric clinical research. A proposal for a European Paediatric Clinical Trials Research Infrastructure (EPCTRI) addressing paediatric research all across Europe, with innovative scientific and methodological strategies, has been recently submitted and is in the evaluation process. For the first time, an IMI (Innovative Medicines Initiative) call will specifically address the paediatric research theme. Valuable efforts are also dedicated at global level to create new research platforms, such as the International Neonatal Consortium or the Global Pediatric Clinical Trial Network.

Suitable expertise to develop and exploit these instruments should be adequately trained. This Course will provide an opportunity for this aim.



day 1 22 September 2015

2:00 pm - 6:30 pm

THEME 1 - HOW TO PLAN AND CONDUCT PAEDIATRIC TRIALS

Chairs: Fedele Bonifazi, Marek Migdal

The Paediatric Regulation and main applicable guidelines

Agnes Saint-Raymond

Effects of the new Clinical Trial Regulation on paediatric issues: what is new and what is still uncovered

Viviana Giannuzzi

Data collection and data exchange among stakeholders involved in paediatric trials including IRBs/ECs and concerned Authorities

Steven Hirschfeld

Multi-national/multi-centre paediatric trials: current experience

Carlo Giacchino

Free discussion

THEME 2 - INNOVATIVE STUDY DESIGNS TO IMPLEMENT PAEDIATRIC RESEARCH

Chairs: Adriana Ceci, Steven Hirschfeld

Examples from the current practice (to be provided by the speakers)

Oscar Della Pasqua

Massimo Cella

Marek Migdal

The need to implement innovative designs in selected sectors:

- orphan drugs *Bozena Dembowska-Baginska*

- off-patent drugs *Adriana Ceci*

- innovative drugs *Enrico Bosone*

Free discussion

23 September 2015 day 2

9:00 am - 1:30 pm

THEME 3 - FROM THE PROTOCOL TO THE TRIAL CONDUCT

Chairs: Evelyne Jacqz-Aigrain, Mark Turner

Paediatric studies submission and approval: the role of the national authorities

Anna Cieslik

To make practical paediatric clinical trials easier, faster and more effective: the experience in the Nordic area

Kalle Hoppu

Recruitment and trial management issues in EU and non-EU paediatric trials

Donato Bonifazi

Involvement of patients and patient groups in research

Elin Haf Davies

Free discussion

THEME 4 - FUTURE OF THE PAEDIATRIC RESEARCH IN A GLOBAL CONTEXT

Chairs: Kalle Hoppu, Marek Migdal

Global initiatives for paediatric research

Mark Turner

Actions needed at national level. Examples from:

- Albania *Linda Pustina*

- France *Evelyne Jacqz-Aigrain*

- Italy *Adriana Ceci*

- Japan *Hidefumi Nakamura*

Closing remarks

SPEAKERS' LIST

Donato Bonifazi

Chief Executive Officer of Consorzio per Valutazioni Biologiche e Farmacologiche; DEEP project manager - Italy

Fedele Bonifazi

Vice president of Gianni Benzi Pharmacological Research Foundation; GRIP Network project manager - Italy

Enrico Bosone

Director of Patient Access Policy EMEA, Celgene - Italy

Adriana Ceci

President of the Gianni Benzi Pharmacological Research Foundation, Scientific Director of Consorzio per Valutazioni Biologiche e Farmacologiche - Italy

Massimo Cella

Expert at Consorzio per Valutazioni Biologiche e Farmacologiche; GRIP WP4 Innovative Study design Working Group - Italy

Anna Cieslik

Office for Registration of Medicinal Products, Head Documentation Assessment Department - Poland

Elin Haf Davies

Director at Enabling Research - Empowering Children - United Kingdom

Oscar Della Pasqua

Professor of Clinical Pharmacology & Therapeutics, University College London - United Kingdom

Bozena Dembowska-Baginska

European Medicines Agency, Member of COMP; Head of Department of Oncology at Children's Memorial Health Institute - Poland

Viviana Giannuzzi

Coordinator of R&D area, Consorzio per Valutazioni Biologiche e Farmacologiche - Italy

Carlo Giaquinto

GRIP Network Coordinator, President of Fondazione Penta - Italy

Steven Hirschfeld

Associate Director for Clinical Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development Chief Medical Officer Rapid Deployment Force PHS-1 - United States of America

Kalle Hoppu

Director at Poison Information Centre, HUCH Emergency Care, Helsinki University Hospital - Finland

Evelyne Jacqz-Aigrain

Head of the department of Pediatric Pharmacology and Pharmacogenetics-Hopital Robert Debré - France

Marek Migdal

Deputy Head of Paediatric Intensive Care Unit in the Children's Memorial Health Institute - Poland

Hidefumi Nakamura

Chief, Division for Clinical Trials, Clinical Research Center; National Center for Child Health and Development, Tokyo - Japan

Linda Pustina

Director of Higher Education and Science, Albanian Ministry of Education and Sport - Albania

Agnes Saint-Raymond

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Mark Turner

Neonatal Consultant at Liverpool Women's NHS Foundation Trust and Senior Lecturer in Neonatology at the University of Liverpool - United Kingdom