



HEXAL Children's
Medication Initiative



Istituto G. Gaslini

Present

the Second Expert Workshop

**Can the “in silico Child” help to develop
better medicines for our children?**

September 28th – 29th 2010

Programme

Scientific Committee

*Arthur J. Atkinson, Jeffrey S. Barrett, Ornella Della Casa Alberighi,
Jessica Dominguez-Hirschi, Stephanie Læer,
Bernd Meibohm, Gérard Pons*

Organizing Secretariat

Manuela Aloe, Lena Cosulich

C.I.S.E.F. Germana Gaslini
c/o Direzione Scientifica – Ist. G. Gaslini
L.go G. Gaslini, 5
16147 Genova (Italia)
tel.: +39010 5636.554/.805; fax: +39010 3776590
e-mail: manuelaaloe@ospedale-gaslini.ge.it
lenacosulich@ospedale-gaslini.ge.it
website: www.sispge.com

VENUE and Organizing Secretariat:

*C.I.S.E.F.- Germana Gaslini International Centre
For Studies and Training,
Badia Benedettina della Castagna,
Villa Quartara
Genova–Quarto, Italy*



CISEF
CENTRO INTERNAZIONALE DI STUDI E FORMAZIONE
GERMANA GASLINI

Dear Colleagues,

The expert workshop is aimed at providing knowledge basis on modelling and simulation techniques to paediatricians, scientists, and clinical pharmacologists involved in planning and executing clinical trials in Paediatrics and in paediatric drug development especially for European grant applications.

The interdisciplinary science of modelling and simulation continues to show value for quantifying safety and efficacy tradeoffs, for optimizing drug dose, and for improving the confidence of drug development decisions helping to guide pharmacotherapy in future.

Model-based methods are particularly useful to support paediatric drug development because they provide a means to leverage knowledge from adult clinical studies, enabling efficient data collection and minimizing the number of infants and children required in clinical trials.

The application of model-based simulations in paediatric pharmacotherapy will contribute to optimize medication use in children and enable to support paediatricians and care givers in providing personalized medicine to children.

Stephanie Läer and Ornella Della Casa Alberighi
Meeting Chairs

GENERAL INFORMATION

The course is addressed to Paediatricians, Scientists, and Clinical Pharmacologists.

Registration fee:

€300,00 VAT INCLUDED - participants from Pharmaceutical Companies

€150,00 VAT EXCLUDED - participants from Public Institutions

The fee covers:

- entrance to scientific sessions
- abstract volume and CD
- working lunches, coffee breaks and conference dinner
- certificate of attendance

Deadline for registration: September 10th, 2010

The registration fee must be paid upon confirmation of acceptance by the Organizing Secretariat

Phone: +39 010.5636.554/805

E-mail: manuelaaloe@ospedale-gaslini-ge-it
lenacosulich@ospedale-gaslini.ge.it

The course will be limited to a maximum of 25 participants.

GERMANA GASLINI INTERNATIONAL CENTRE FOR STUDIES AND TRAINING (CISEF)

Director of CISEF: Antonio Infante

Directors of the course: Ornella Della Casa Alberighi & Stephanie Läer

FACULTY

BARRETT JS, Philadelphia, U.S.A.
BIONDI A, Monza, Italy
BODDY A, Newcastle, U.K.
BREITKREUTZ J, Düsseldorf, Germany
DELLA CASA ALBERIGHI O, Genoa, Italy
DELLA PASQUA O, Leiden/Amsterdam, The Netherlands
GREK V, Paris, France
GREVEL J, Nottingham, U.K.
HULPKE-WETTE M, Göttingen, Germany
KERN S, Basel, Switzerland
KHALIL F, Düsseldorf, Germany
LÄER S, Düsseldorf, Germany
MARTINOLI C, Genoa, Italy
MEIBOHM B, Memphis, U.S.A.
MELIOLI G, Genoa, Italy
MESCHINI S, Rome, Italy
PAUL T, Göttingen, Germany
PONS G, Paris, France
RAMUSOVIC S, Düsseldorf, Germany
ROSOLEN A, Padua, Italy
RUPERTO N, Genoa, Italy
VERRINA E, Genoa, Italy
VICINI P, San Diego, U.S.A.

HOW TO REACH THE COURSE VENUE

Course Venue

Badia Benedettina della Castagna
via Romana della Castagna 11 A
16147 Genova (Italia)

Plane: From the International Airport “Cristoforo Colombo”, shuttle bus n. 100 (runs every hour) takes you to Genova Principe railway station. First service from Genova Airport at 6:05 a.m. last service at 23:20 p.m.. Catch the bus immediately outside the arrivals terminal. Ticket price (purchased on board): € 4,00. From Genova-Principe railway station take a train or bus n. 33 to reach Genova-Brignole railway station.

Train: Participants arriving in Genova by train should bear in mind that there are two major stations in the city: Genova-Brignole and Genova-Principe. Not all the trains – particularly from northern Italy (e.g., Milano) - pass through Genova-Brignole: therefore, make sure that your train does indeed stop at Genova-Brignole. From Genova-Brignole railway station, take bus n. 17 (eastwards) and get off in Corso Europa, in front of AC Hotel (see bus).

Bus:
From downtown, take bus n. 17 (eastwards) and get off in Corso Europa, in front of Hotel AC (see car).
From Genova-Nervi, take bus n. 17 (westwards) and get off in Corso Europa, in front of AC Hotel; cross the road and turn to your left (see car)

Car: Motorway exit Genova-Nervi, take Corso Europa westwards, take the overpass and drive eastwards, pass Hotel AC and ESSO gas station on the right; after 50 mt. turn right into Via Romana della Castagna, go straight 80 mt., enter the gate on the right leaving the church on the left and follow signs for parking.

Tuesday, September 28th, 2010

8:15 Registration

8:45 Welcome and Introduction
O. Della Casa Alberighi and S. Läer

I. Integrating science into paediatric clinical drug development by simulation techniques

9:00 Regulatory vision of modelling and simulation in paediatric applications:

How the Paediatric Committee (PDCO) is currently using modelling and simulation in the requests for modifications of the Paediatric Investigation Plan (PIP)
G. Pons, Paris, France

9:30 Discussion

10:00 Methodology: Top down versus bottom up approach in modelling and simulation: what can we achieve with which method?
B. Meibohm, Memphis, US

10:30 State of the art: Modelling and simulation in paediatric protocol design development, e.g. number of patients and blood samples
JS. Barrett, Philadelphia, US

11:00 Coffee Break

11:30 Multiscale and statistical modelling in obstetric-fetal pharmacology and paediatrics: accomplishments and prospects
P. Vicini, San Diego, US

12:00 Model-based drug development: an opportunity for paediatrics
J. Grevel, Nottingham, UK

12:30 Applying physiological and biochemical concepts to optimize biological agent development
S.Kern, Basel, Switzerland

13:00 Lunch Break

14:30 Does the paediatric formulation have an influence on PK/PD results? Integration of the paediatric formulation into the PIP
J. Breitzkreutz, Dusseldorf, Germany

15:00 Proof of concept in paediatrics
O. Della Casa Alberighi, Genoa, Italy

15:30 Simulation techniques for optimizing medication use in children
S. Läer, Dusseldorf, Germany

16:00 Coffee Break

II. Examples of successful applications using modelling and simulation techniques from FP7

16:30 The European Paediatric oncology Off-patent medicine Consortium (EPOC) project on PK and PD of doxorubicin
A. Boddy, Newcastle, UK

The LOULLA & PHILLA project on development of oral liquid formulations of methotrexate and 6-mercaptopurine for paediatric acute lymphoblastic leukaemia
V. Grek, Paris, France

III. Projects from workshop participants

- 17:30 **Projects in paediatric rheumatology**
- Bottom up approach: advances in ultrasound and MRI - functional imaging and new tools for data quantification in juvenile idiopathic arthritis**
C. Martinoli, Genoa, Italy
- Outcome measures in paediatric rheumatology**
N. Ruperto for the Paediatric Rheumatology INternational Trials Organisation (PRINTO), Genoa, Italy
- 18:10 **Discussion**
- 20:00 **Conference Dinner at Villa Quartara**

Wednesday, 29th of September 2010

III. Projects from workshop participants – cont'

- 8:30 **Projects in paediatric cardiovascular diseases**
- Essential hypertension in children – when and how to treat?**
M. Hulpke-Wette, Göttingen, Germany
- Paediatric drug trials and clinical practice – pros and cons**
T. Paul, Göttingen, Germany
- Paediatric drug trials and clinical practice – challenges for clinical pharmacists**
F. Khalil and S. Ramusovic, Düsseldorf, Germany

9:30

Projects in paediatric oncology

- Drug development in paediatric oncology: issues and opportunities**
A. Biondi, Monza, Italy
- Biomarkers in paediatric oncology**
A. Rosolen, Padua, Italy
- Modelling from *in vitro* data with a new anticancer agent**
S. Meschini, Rome, Italy

10:30

Coffee Break

11:00

- Project in paediatric nephrology**
Getting the cinacalcet dose right in secondary hyperparathyroidism
E. Verrina for the Italian Registry of Paediatric Chronic Dialysis, Genoa, Italy

11:20

- Projects in paediatric infectious diseases**
Paediatric dose selection through pharmacokinetic/ pharmacodynamic modelling and simulation
O. della Pasqua, Leiden/Amsterdam, The Netherlands, and Greenford, UK

11:40

- Projects in paediatric clinical pathology**
Assessment of biomarkers reference values in paediatrics
G. Melioli, Genoa, Italy

12:00

Selected presentations

12:45

- Wrap-up and Conclusions**
S. Läer and O. Della Casa Alberighi



ISTITUTO G.GASLINI

REGISTRATION FORM



CISEF
CENTRO INTERNAZIONALE DI STUDI E FORMAZIONE
GERMANA GASLINI

Please fill in and return to the Organizing Secretariat by September 10th, 2010

Tel: +39 010 5636.805/554, Fax: +39 010 3776590

e-mail: manuelaaloe@ospedale-gaslini.ge.it, lenacosulich@ospedale-gaslini.ge.it

TITLE: Can the “in silico Child” help to develop better medicines for our children?

ID OF THE EVENT: 937

VENUE: Badia Benedettina della Castagna, Genoa

DATE: September 28th-29th, 2010

Personal data:

NAMEFAMILY NAME.....

Private address:

ZIP code.....Town.....Country.....

Tel...../.....Mobile.....Fax...../.....

e-mail.....

Institute.....

Work address:.....

ZIP code.....Town.....Country.....

Tel...../.....Mobile.....Fax...../.....

For purposes of Continuing Medical Education accreditation, please provide the following information:

Date of birth:

Place of birth:

Codice

Fiscale

(Italian only):

Profession:

Discipline:

REGISTRATION FEE

For Italian participants: Enti Pubblici esenti IVA come disposto dall'art. 14, c. 10, l. 537/93:

The registration fee of **300,00 €* VAT INCLUDED** for pharmaceutical companies and of **150,00 €* VAT EXCLUDED** for public institutions must be paid within 5 days after the confirmation of acceptance by the Organizing Secretariat.

Payment can be made by:

<p style="text-align: center;">ISTITUTO G.GASLINI</p>	<h1 style="color: green;">REGISTRATION FORM</h1>	 <p style="font-size: small;">CISEF CENTRO INTERNAZIONALE DI STUDI E FORMAZIONE GERMANA GASLINI</p>
---	--	--

A) **Bank transfer** to: CISEF “Germana Gaslini” cc 11413/80, IBAN IT23B0617501455000001141380, SWIFT/BIC CODE: CRGEITGG442

Please specify on the transfer **“AFR - Registration for “In silico Child” on behalf of (registrant’s name).**

Please send (preferably by fax) copy of the transfer once it has been ordered

All related banking costs are at the registrant’s expenses

B) **Check** payable to Istituto Giannina Gaslini and sent to the Organizing Secretariat with this form duly signed

*** The registration fee can be reimbursed only with a 5 days notice before the beginning of the event.**

INVOICE/RECEIPT

The invoice/receipt of your payment will be made out to the public or private subject who makes the payment. Please indicate the full data for the invoice:

The invoice should be made out to

.....
 address.....N°.....
 Zip code.....Town.....P.IVA/CF.....
 and sent to the attention of

Privacy policy; (Art.13, Italian law 196/2003)

Your data will be stored in the optical archive of the Istituto G. Gaslini. CISEF will make use of the data provided exclusively for the purpose of the present event including the Italian Continuing Medical Education programme procedures. They will be forwarded to the Italian CME National Commission, stored in the CISEF database and used to keep you informed on relevant CISEF forthcoming events and in case of your future attendance at CISEF events.

Please tick the box if you wish we erase your data from the CISEF database.

The Centro Internazionale di Studi e Formazione “Germana Gaslini”, via Romana della Castagna, 11, 16147 Genova is the holder of the data.

Date..... Signature.....