Università di Roma Tor Vergata

Bambino Gesù OSPEDALE PEDIATRICO

GRIP Global Research in Paediatrics

MASTER

of Science in

Paediatric Medicines

Development and Evaluation

Master of Science in Paediatric Medicines Development and Evaluation

Coordinating University:

University of Rome "Tor Vergata" School of Paediatrics in collaboration with the Children's Hospital Bambino Gesù and the EU Project Global Research in Paediatrics (GRiP).

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INTRODUCTION and BACKGROUND

It is widely known that pharmacological treatment of children poses unique efficacy and safety challenges for children and health professionals in all countries worldwide.
The use of off-label drugs is a public health problem.
Indeed, in Europe over 50% of children admitted to hospital or primary care will receive an unlicensed or off-label medicine. Such drug use is associated with increased risk of reduced efficacy as well as medications errors.
According to the National Patient Safety Institute, at least 60,000 children suffer from medical errors every year in the US.
The largest category of mistakes, involving about 10,000 children and babies, is related to medication.
The heart of the problem remains the absence of clinical trials that examines the optimal dosage in children and the absence of formulations adapted to young patients.
One strategy to address this is to adequately educate current and future generations of health professionals to be able to conduct robust paediatric clinical trials aimed to ensure Marketing Authorization with specific Paediatric Therapeutic Indications.

In 2010, a consortium of 21 universities and research groups of scientists was awarded a European Commission (EC) grant to implement the Network of Excellence **Global Research in Paediatrics** (GRiP **www.grip-network.org**). GRiP aims to stimulate and facilitate the development and safe use of medicines in children.
Part of this EC project is the development of a **Master of Science (MSc) Programme in "Paediatric Medicines Development and Evaluation"**, targeting health professionals with work experience in the field.

THE MASTER PROGRAMME-AIMS

The curriculum of the **MSc on Paediatric Medicines Development and Evaluation** has two important aims:

1. To educate the next generation of researchers, paediatricians, physicians and health professionals in paediatric pharmacology and trial design in order to conduct robust clinical drug trials in the paediatric population.

2. To stimulate continuing professional development of practicing physicians and pharmacists to acquire additional competences in all the specific aspects of paediatric pharmacology, drug evaluation, trial design and conduct, as well as the regulatory requirements for the in-label use of medicines.

SYLLABUS

The MSc programme on Paediatric Medicines Development and Evaluation is a two-year programme with 60 ECTS, awarded by the University of Rome Tor Vergata. The programme is based on ten modules to be taken in a sequenced manner (see table below). Almost all theoretical education is offered online through the GRiP Virtual Learning Environment **https://fronter.com/grip/**. Students are required to attend face-to-face lessons during the Freshers' and Re-Freshers' meetings and during their work placement and/or training stages. **The start of the programme is 19th of November 2014** with a face-to-face "Freshers' Meeting" to be held at Villa Mondragone, the conference site belonging to the University of Rome Tor Vergata, Italy. The Freshers' Meeting is a three day obligatory "get-together" with the aim to give an overview of the course, organization, methodology, learning objectives and to demonstrate how to use the Virtual Learning Environment.

Module nr and abbreviation	Module title	Responsible GRiP Partner/Faculty Member	Affiliation	ECTS
	Start of the Master: Fresher's meeting (19-21 Nov 2014)	**Paolo Rossi**	**University of Rome Tor Vergata** Conference site: Villa Mondragone	1
Module 1 MED	**Introduction to Paediatric Medicines**	**Paolo Rossi** Viviana Moschese	**University of Rome Tor Vergata**	4
Module 2 DEV	**Developmental Pharmacology Pharmacokinetics**	**Evelyne Jacq Aigrain** John Van Den Anker	**INSERM/Universitè Paris Diderot-Paris 7** University Children's Hospital Basel	4
Module 3 RET	**Regulatory and Ethical Issues Regarding Paediatric Medicines Research**	**Agnes Saint Raymond**	**European Medicines Agency (EMA), London**	4
Module 4 EXP	**Experimental Drug Evaluation in Paediatrics**	**Adriana Ceci** Paola Baiardi Gerard Pons	**Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF), Pavia** University Paris Descartes PRES Sorbonne Paris Cité	4
Module 5 FOR	**Paediatric Drug Formulations**	**Tony Nunn** Catherine Tuleu	**University of Liverpool** University College London (UCL) School of Pharmacy, London	4
Module 6 TRI	**Paediatric Clinical Trial Management**	**Mark Turner** John Van Den Anker	**University of Liverpool** University Children's Hospital Basel	4
Module 7 PPP	**Post-Licensure Paediatric Drug Evaluation: Pharmacovigilance & Pharma-coepidemiology**	**Miriam Sturkenboom** Katia Verhamme Sabine Straus Agnes Saint Raymond	**Erasmus University, Rotterdam** European Medicines Agency (EMA)	4
Module 8 PREG	**Pharmacology in Pregnancyand and Neonates**	**Evelyne Jacq-Aigrain**	**INSERM/Universitè Paris Diderot-Paris 7**	4
Module 9 BIO	**Biomarkers and Innovative Tools in Paediatric Clinical Pharmacology**	**Oscar Della Pasqua** Adriana Ceci Paola Baiardi	**University College London (UCL) School of Pharmacy, London,** Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF)	4
Module 10 VAC	**Paediatric Vaccines**	**Jan Bonhoeffer** John van den Anker Miriam Sturkenboom	**University Children's Hospital Basel;** Erasmus University, Rotterdam	4
Work placement and/or training stages and Thesis				19
				60

By the end of this program, the student will be able to do the following

		1	2	3	4	5	6	7	8	9	10
1	Demonstrate an understanding for the need and application of individualized/optimized medicines therapy in paediatric diseases.	●	●			●		●	●	●	●
2	Demonstrate an understanding of medicines development for a paediatric population.	●	●	●	●	●			●	●	
3	Describe various study designs and their advantages and challenges in relation to paediatric population.				●			●		●	●
4	Critically appraise existing paediatric medicines studies.	●			●	●		●			●
5	Demonstrate an understanding of regulatory environment pertaining to paediatric medicines studies.			●		●	●	●	●	●	●
6	Develop a study protocol for a paediatric medicines study.			●	●		●	●	●		●
7	Conduct a scientifically robust and ethical paediatric medicines study.	●	●	●	●		●				
8	Develop a report of a paediatric medicines study.			●	●		●				●

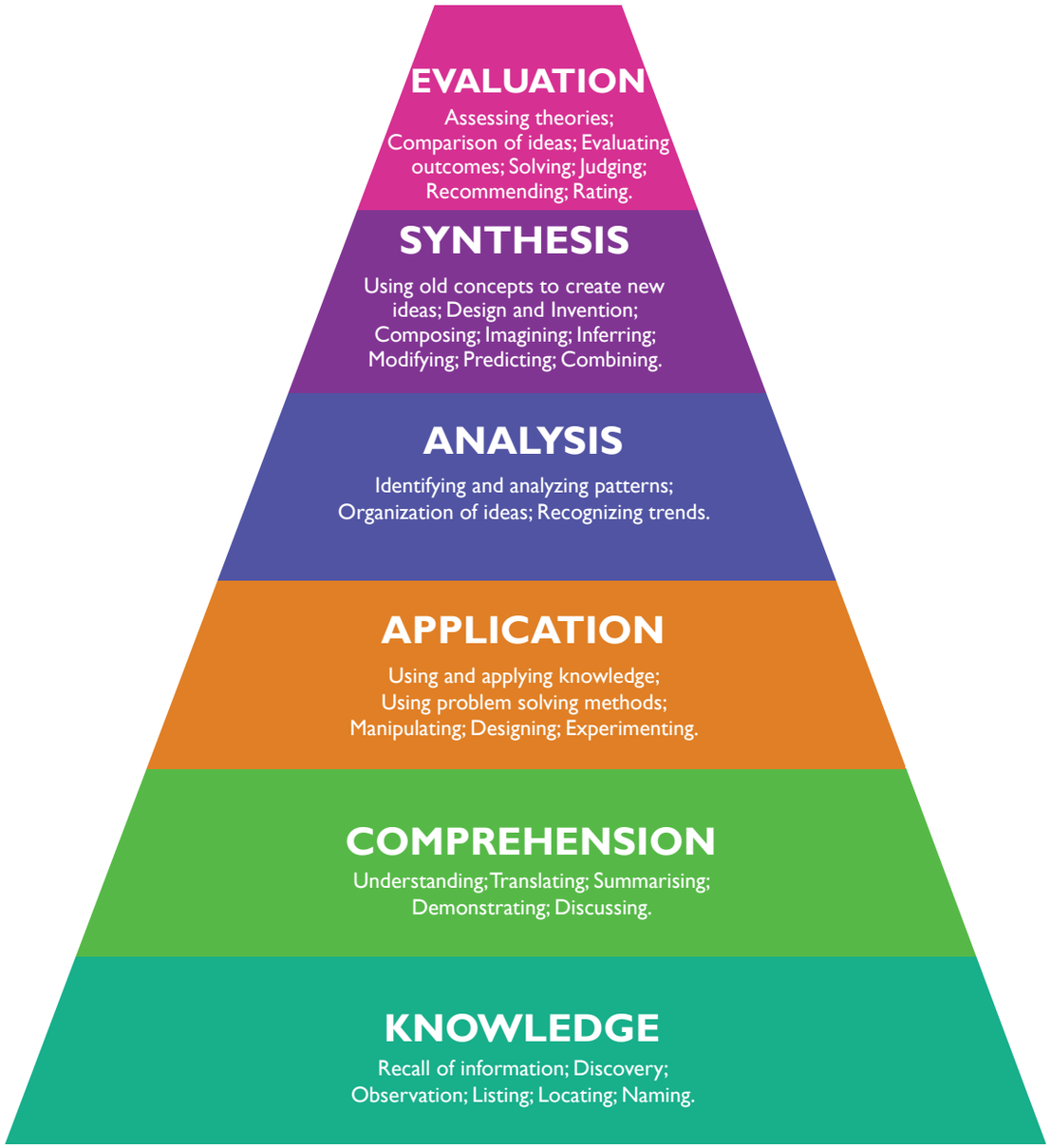
Full description of the Syllabus and of single modules content is available on the following links:
http://www.scuolaaltaformazione.com
http://www.grip-network.org

SCIENTIFIC COLLABORATORS

The twenty-one collaborating partners/entities participating in the EC project GRiP, together with other professionals external to GRiP consortium, are acting as teachers and/or tutors in this **MSc Programme in Paediatric Medicines Development and Evaluation**.

BLOOM'S TAXONOMY

The instructional methods are chosen by each Module Leader to foster student learning towards reaching the objectives.
According to Bloom's levels, training content has been organized at many levels of expertise and taken different and appropriate forms.
Bloom's Taxonomy is the agreed way to teach students.
The table below defines each cognitive level from higher to lower order thinking and list the Bloom's levels of expertise:



MASTER ORGANIZATION

Freshers' Meeting

This is one of the few face-to-face occasions in this Master Course since almost all the education takes place on-line. The Freshers' Meeting is an obligatory event.
This will introduce the teachers to the students and they will learn how the course is organized.
The face-to-face-meeting will take place at Villa Mondragone, which is one of the Tuscolana Villas in the Frascati area in the suburb of Rome **http://www.villamondragone.it**

The Training Sessions

Training activities are composed of one or several of the following:

• **The teaching sessions** consist of lectures, tutorials or dedicated seminars, all using English as the main language.

• **A tutorial** is a session of exercises, guidance and discussion/ correction with a teacher. Tutoring is provided through interactive sessions through e-learning platform tools.

• **The home exercise sessions** consist of home exercises such as scientific publication review and appraisal, case studies, case based-learning, study proposals, quizzes.

• **Module validation session** assessment consists of the evaluation of the trainee's progress by different type of tests according to the Bloom's level of the topic, (e.g. multiple choice test, open questions test, case study evaluation).

• **Work-placement or training stage sessions**
A 19 ECTS work-placement or training stages are required. The thesis can be prepared at the premises of one of the GRiP partners or at another third party location.
The student who wishes to write their thesis at a third party location has to get approval of their thesis location from the Joint Quality Committee.

Virtual Learning Environment (VLE)

The educational activities are mostly made on-line with the help of Fronter learning platform.
For each student, a tutor will be appointed from the participating GRiP partners, whom the student may consult for advice or assistance during the course. An IT expert will be available to assist students in their activity on the VLE platform if needed.

Thesis

A thesis is part of the Master degree. The student has to write the thesis under guidance of a tutor.

SELECTION CRITERIA

All individuals are selected and treated based on their relative merits and abilities.
Requirements to enter the International Master are:

Degree in:
- Medicine and Surgery
- Biology and Biotechnology
- Pharmacy
- Chemistry
- Nursing

- Bachelors' degree (180 ECTS credits) or equivalent of relevant professional experience to be validated by the Master Selection Committee.
- English proficiency corresponding to a minimum IELTS 6.5

The Master Selection Committee will select the students on the basis of their:
- relevant academic background;
- convincing letter of motivation;
- work experience and professional qualifications (if applicable);
- results of any interviews (if applicable).

REGISTRATION

The enrolment is available on-line via the following link:
https://delphi.uniroma2.it/totem/jsp/index.jsp?language=EN

Student Section, in Section A select: Postgraduate courses
1: Specialization Courses-Master
2: Enrollment to the Admission Test for the Master/Specialization Courses
3: Start application procedures
4: Faculty of Medicine and Surgery
5: Paediatric Medicines Development and Evaluation-PNG

Deadline for registration is: 29/10/2014

Students will be enrolled at the University of Tor Vergata when:
- They have paid the first instalment of the annual Master degree fee.
- Students can also register to study one or more modules only, in that case only a certificate of completion or participation will be awarded for each module.

REGISTRATION FEE

EU students' admission fee is 4.000 €, non EU-students' fee is 8.000 €. The fee can be paid in two instalments (50% per instalment) with deadlines for academic year 1:
17th November 2014 and 31st January 2015

Deadline for academic year 2:
16th January 2015 and 31st January 2016

If you choose to take separate module(s) only, the registration fee is 600 €/module.
If the student is unable to fulfil his/her programme the fee cannot be repaid.
The registration fee includes the following services:
- Enrolment in the teaching units and modules delivered by the University of Rome Tor Vergata.
- Free access to library, document centres and related services at the University of Rome Tor Vergata provided that the local rules are respected.
- Examination, diploma and/or certificate.

The fees do not include costs relating to accommodation, food, international travel or travel onsite. Additional costs other than the tuition fee may be requested for re-examination, or late registration.

ASSESSMENT and VALIDATION-CERTIFICATES

In order to be awarded the Master of Science degree in Paediatric Medicines Development and Evaluation, the student must have completed all parts of the programme with the required number of ECTS:
- Pass grades for all module assessments. The successful student has earned 40 ECTS credits with the modules.
- Satisfactory participation in and attendance at research meetings and seminars in the research department or during the work placement.
- Successful completion of the workplacement or training stages.
- Defence of a Master thesis in front of the Educational Steering Committee.
- Before the degree can be awarded, all tuition fees must be paid.

Certificates
- At the end of each module, the module leader will assess and validate the completion of the required tasks before the student can proceed to next module.
- If the student has registered for taking separate module(s) only, the student will not receive a degree but a certificate only from the University of Rome Tor Vergata for each completed individual module.

Information

For more information you can contact:

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