II LEVEL MASTER
IN PRECLINICAL AND CLINICAL RESEARCH

COORDINATOR
Susanna Esposito
Full Professor
Department of Medicine and Surgery
University of Parma, Parma (Italy)
PROFESSORS AND TEACHERS

UNIPR
University of Parma, Parma

Alberto Argentiero
Research Fellow UNIPR

Antonio D’Aloia
Full Professor of Administrative Law

Daniele Del Rio
Associate Professor of Human Nutrition

Rossana Cecchi
Full Professor of Legal Medicine

Susanna Esposito
Full Professor of Pediatrics

Leonardo Fogassi
Full Professor of Physiology

Lorella Franzoni
Associate Professor of Pharmacology

Matteo Goldoni
Associate Professor of Medical Statistics

Marcello Giuseppe Maggio
Full Professor of Geriatrics

Giovanni Roti
Researcher in Hematology

Francesca Scassina
Associate Professor of Human Nutrition

Nicola Sverzelli
Associate Professor of Radiology

Marcello Tiseo
Associate Professor of Oncology

0.U. FORMAZIONE POST-LAUREAM
University of Parma, Parma

Caterina Mantovani
Giovanna Corazza

0.U. DEPARTMENTAL ADMINISTRATION
University of Parma, Parma

Giorgetta Leporati

PARMA HOSPITAL

Caterina Caminiti
OU Innovation and Research, Director

Corrado Confalonieri
Ethics Committee Secretariat

Giuseppe Maglietta
OU Innovation and Research, Biostatistician

Alessandra Zanardi
Hospital Pharmacy Director

EXTERNAL TEACHERS

Stefania Ballarini
Vifor Pharma, Geneva, Switzerland

Maria Lisa Calzetti
Associazione per l’Auto ai Giovani con Diabete (AGD) Parma, Parma

Nella Capretti
Associazione Noi per Loro, Parma

Giovanni Checcucci Lisi
Medical Director Sanofi, Rome

Andrea Esposito
Radiology Unit, IRCCS Policlinico Hospital, Milan

Laura Fabbi
Head of Neonatology Clinical Unit, Chiesi, Parma

Stefano Lagravinese
ClinOpssHub srls, Brindisi

Cinzia Marano
Medical Director, GSK Vaccines, Verona

Luigi Notarangelo
National Institute of Allergy and Infectious Diseases, NIH, Washington DC, USA

Anna Odone
Full Professor of General and Applied Hygiene, University of Pavia, Pavia

Palmina Perri
Lega Italiana Fibrosi Cistica (LIFC) Emilia, Parma

Prisco Piscitelli
Euro-Mediterranean Biomedical Scientific Institute, ISBEM, Brindisi

Gian Marco Prandi
Assoc. Dir. Medical Affairs Vaccines, MSD Italia, Roma

Stefano Valente
Medical Affairs Vaccines, Director MSD Italy, Roma
**DECEMBER**

**WEEK 1 ➤ DECEMBER 4th, 2020**

S. Esposito
Welcome to the course

S. Esposito
Introduce yourself

S. Esposito
Why bother with doing clinical research?

L. Fogassi
From the animal model to the clinical practice

G. Roti
The phases of preclinical research

**WEEK 2 ➤ DECEMBER 11th, 2020**

L. Franzoni
Pharmacokinetics, pharmacogenetics and pharmacogenomics

**WEEK 3 ➤ DECEMBER 18th, 2020**

A. D’Aloia
Ethics of preclinical research

**JANUARY**

**WEEK 4 ➤ JANUARY 8th, 2021**

G. Roti
Drug discovery in oncology

L. Fabbri
Drug design and development of new pharmaceutical formulations

**WEEK 5 ➤ JANUARY 15th, 2021**

R. Piscitelli
From genetics to epigenetics

**WEEK 6 ➤ JANUARY 22nd, 2021**

A. Zanardi
Equivalent drugs and biosimilars

**FEBRUARY**

**WEEK 7 ➤ FEBRUARY 5th, 2021**

A. Argentiero
Methodology and phases of clinical research

M. Tiseo
Special focus on phase 1

**WEEK 8 ➤ FEBRUARY 12th, 2021**

S. Esposito
How to set up a non-profit clinical trial

G. Maglietta
The importance of study design

M. Tiseo
The importance of networks in clinical research

**WEEK 9 ➤ FEBRUARY 19th, 2021**

S. Lagravinese
Good Clinical Practice

**WEEK 10 ➤ FEBRUARY 26th, 2021**

L. Fabbri
Monitoring in clinical trials

L. Fabbri
Collection, management and data quality

R. Cecchi
Informed consent and legislative criticalities in clinical research
<table>
<thead>
<tr>
<th>WEEK 11</th>
<th>MARCH 5th, 2021</th>
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<tbody>
<tr>
<td>S. Ballarini</td>
<td>Drug development for registration purposes and IMP management</td>
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<th>WEEK 12</th>
<th>MARCH 12th, 2021</th>
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<tbody>
<tr>
<td>C. Confalonieri</td>
<td>The Ethics Committees: role and function</td>
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<tr>
<th>WEEK 13</th>
<th>MARCH 19th, 2021</th>
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<tbody>
<tr>
<td>C. Caminiti</td>
<td>How to draw up a protocol</td>
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<tr>
<td>G. Maglietta</td>
<td>Special focus on sample size</td>
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<tr>
<th>WEEK 14</th>
<th>MARCH 26th, 2021</th>
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<tbody>
<tr>
<td>A. D’Aloia</td>
<td>Principles of bioethics in human studies</td>
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<tr>
<th>WEEK 15</th>
<th>APRIL 2nd, 2021</th>
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<tbody>
<tr>
<td>C. Caminiti</td>
<td>The role of professional figures and health structures</td>
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<tr>
<th>WEEK 16</th>
<th>APRIL 9th, 2021</th>
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<tbody>
<tr>
<td>G.M. Prandi</td>
<td>Investigator initiated study and company sponsored study: role of the CRO and of the pharmaceutical company in the management of adverse events</td>
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<tr>
<td>S. Valente</td>
<td>Development cycle of vaccines and other drugs: from medical needs to implementation of marketed product</td>
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<tr>
<th>WEEK 17</th>
<th>APRIL 16th, 2021</th>
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<tbody>
<tr>
<td>L.D. Notarangelo</td>
<td>Inborn errors of immunity: advances in treatment</td>
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<tr>
<td>G. Checcucci Lisi</td>
<td>Signal detection and management in pharmacovigilance: from theory to practice</td>
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<tr>
<th>WEEK 18</th>
<th>APRIL 23rd, 2021</th>
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<tbody>
<tr>
<td>A. Odone</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>D. Del Rio</td>
<td>Food and health: from laboratory research to the consumer</td>
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<tr>
<th>WEEK 19</th>
<th>APRIL 30th, 2021</th>
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<tbody>
<tr>
<td>C. Marano</td>
<td>Value of vaccination and communication against vaccine hesitancy</td>
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<tr>
<td>C. Marano</td>
<td>Therapeutic innovation and post-marketing surveillance</td>
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<tr>
<th>WEEK 20</th>
<th>MAY 7th, 2021</th>
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<tbody>
<tr>
<td>S. Esposito</td>
<td>Artificial intelligence and telemedicine in pediatrics</td>
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<tr>
<th>WEEK 21</th>
<th>MAY 14th, 2021</th>
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<tbody>
<tr>
<td>F. Scazzina</td>
<td>Food, health and sustainable development</td>
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<tr>
<th>WEEK 22</th>
<th>MAY 21st, 2021</th>
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<tbody>
<tr>
<td>A. Esposito, N. Sverzellati</td>
<td>Application of artificial intelligence in radiology: comparison between Centers</td>
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MODULE 2

OCTOBER

WEEK 23 ▶ OCTOBER 1st, 2021
L. Fabbri
Clinical trials in neonatology

WEEK 24 ▶ OCTOBER 8th, 2021
S. Esposito
Child is not a small adult

WEEK 25 ▶ OCTOBER 15th, 2021
M. Maggio
Clinical trials in the elderly
G. Checcucci Lisi
Vaccine development in high risk patients
M.L. Calzetti, N. Capretti, P. Perri
The role of patients and their associations

WEEK 26 ▶ OCTOBER 22nd, 2021
M. Goldoni
Bibliographic research, systematic review and meta-analysis
M. Goldoni
Basics of biostatistics
S. Esposito
From the protocol to the publication of a scientific article

CERTIFICATION ISSUED: Certificate
PROPOSING STRUCTURE: Department of Medicine and Surgery
DURATION: 12 months
TEACHING PROVISION: E-learning
COST: 2,000,00 euro
COST FOR LISTENERS: 500,00 euro
ATTENDANCE % REQUIRED: 75
STAGE: 500 hours

FURTHER INFORMATION:
ctu.pediatriaparma@gmail.com

DEADLINE FOR REGISTRATION: OCTOBER 23rd
WITH INTERVENTIONS OF SPEAKERS FROM:

- Bill & Melinda Gates Foundation, Seattle, WA, USA
- Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA
- European Centre for Disease Prevention and Control (ECDC), Solna (Stockholm), Sweden
- European Medicines Agency (EMA), Amsterdam, The Netherlands
- Fondazione Penta
- ICON
- INCiPIT network
- IQVIA
- IRCCS Ospedale Pediatrico Bambino Gesù
- Istituto Superiore di Sanità
- Ministero della Salute
- Organizzazione Mondiale della Sanità, Ginevra, Svizzera
- Parexel
- PPD
- UNESCO