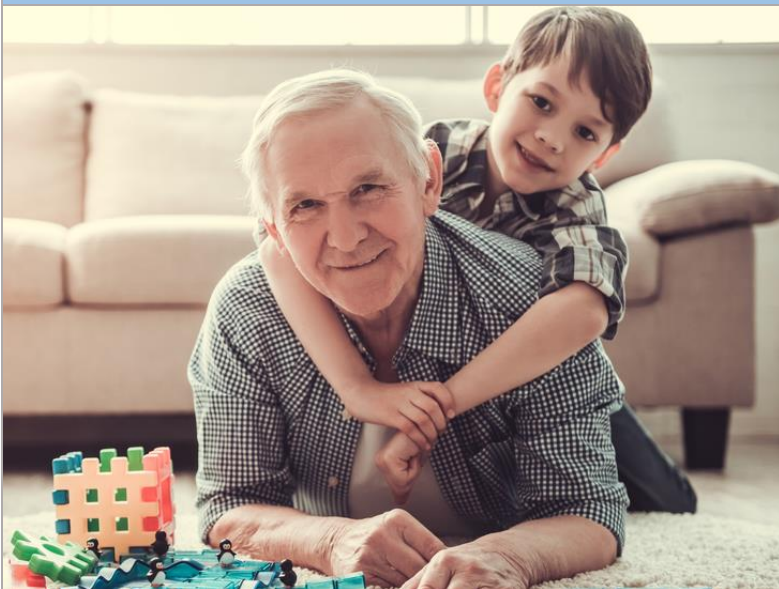


**EFGCP Children's Medicines &  
Geriatric Medicines Working Parties  
Multi-Stakeholder Workshop on  
Facilitating Medicines Development  
for Youth and the 'Young at Heart':  
Learning for Intergenerational  
Strategies**



**21 November 2017**

**CentrEd at Excel  
London  
United Kingdom**

*Organised by*



where science and ethics meet

*With the support of*

British Geriatrics Society  
Improving healthcare for older people

**Autumn meeting  
overview**

22 - 24 November 2017  
ExCel, Platinum Suite London

**BGS**

**[conferences@efgcp.eu](mailto:conferences@efgcp.eu) - [www.efgcp.eu](http://www.efgcp.eu)**

## Workshop Rationale

The development of drugs is evolving and much effort is being put into understanding in special populations like children and older people. The two ends of life can be viewed separately, but at the same time they share many common elements like frailty, or vulnerability. These common aspects were the main components which brought together the EFGCP Children's and Geriatric Medicines Working Parties in preparing this workshop. The agenda reflects important topics like the special ethical considerations that can affect the informed consent process, evaluation of the safety parameters which is dependent of the adequate reporting of adverse events and interpretation of the adverse drug reactions and proper use of modelling of simulation to bring value to the drug development process.

The objective of this workshop is to share challenges, to detect possible synergies and to learn from each other in order to improve and to facilitate and promulgate high quality ethical clinical research and drug development for these important populations across whole Europe.

## Programme Committee (from the EFGCP Children's Medicines & the Geriatric Medicines Working Parties)

<b>Simonetta Alvino</b>	INC Research/inVentiv Health Italy
<b>Dimitris Athanassiou</b>	MDA Hellas & United Parent Projects Muscular Dystrophy, European Forum for Good Clinical Practice (EFGCP), Greece
<b>Denisa Chirita</b>	Bayer, Germany
<b>Solange Corriol-Rohou</b>	AstraZeneca, France
<b>Martine Dehlinger-Kremer</b>	SynteractHCR, Germany; European Forum for Good Clinical Practice (EFGCP), Belgium & EUCROF, The Netherlands
<b>Claudio Fracasso</b>	Pfizer, Italy
<b>Laurence Hugonot-Diener</b>	Broca Hospital Paris & European Forum for Good Clinical Practice (EFGCP), France
<b>Marianne Maman</b>	Novartis Pharma, Switzerland
<b>Thomas Severin</b>	Novartis Pharma, Switzerland
<b>Anthea Tinker</b>	King's College London, United Kingdom
<b>Florian von Raison</b>	Novartis Pharma, European Forum for Good Clinical Practice (EFGCP), Switzerland

## Faculty

<b>Dimitris Athanassiou</b>	MDA Hellas & United Parent Projects Muscular Dystrophy, European Forum for Good Clinical Practice (EFGCP), Greece
<b>Claudio Fracasso</b>	Pfizer, Italy
<b>Denisa Chirita</b>	Bayer, Germany
<b>Eleni Gaki</b>	Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom
<b>Laurence Hugonot-Diener</b>	Broca Hospital Paris & European Forum for Good Clinical Practice (EFGCP), France
<b>Anthea Tinker</b>	King's College London, United Kingdom
<b>Florian von Raison</b>	Novartis Pharma, European Forum for Good Clinical Practice (EFGCP), Switzerland
<b>Ingrid Klingmann</b>	Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Brussels
<b>Simonetta Alvino</b>	INC Research/inVentiv Health Italy
<b>Flora Musuamba Tshinanu</b>	EMA and Federal Agency for Medicines and Health Products (Belgium)
<b>Amy Cheung</b>	AstraZeneca, UK
<b>Adalsteinn Gudmundsson</b>	Consultant in Geriatric Medicine, Landspítali University Hospital, Reykjavik, Iceland and a member of the Geriatric Expert Group at EMA.

## Workshop Language

The language of the workshop will be English.

## Workshop Venue

**CentrEd Excel**  
One Western Gateway  
Royal Victoria Dock  
London E16 1XL  
United Kingdom

## Registration & Information

OPEN EVENT

E-mail [conferences@efgcp.eu](mailto:conferences@efgcp.eu) or visit [www.efgcp.eu](http://www.efgcp.eu)

# Agenda

**08:15**      *Registration & Welcome Coffee*

**09:00**      **Introduction**  
*Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Brussels*

## PLENARY SESSION 1: Ethical & Regulatory Considerations

**Chairpersons:** *Dimitris Athanassiou, MDA Hellas & United Parent Projects Muscular Dystrophy, European Forum for Good Clinical Practice (EFGCP), Greece*  
*Simonetta Alvino, INC Research/inVentiv Health, Italy*

**09:05**      **Ethical issues when comparing research on children and older people**  
*Anthea Tinker, King's College London, United Kingdom*

**09:30**      **EMA guidelines about the definition of physical frailty for baseline stratification in the older clinical trial population**  
*Adalsteinn Gudmundsson, Consultant in Geriatric Medicine, Landspítali University Hospital, Reykjavik, Iceland and a member of the Geriatric Expert Group at EMA.*

**10:00**      *Coffee Break*

## PLENARY SESSION 2: Pharmacovigilance at both ends of life

**Chairpersons:** *Denisa Chirita, Bayer, Germany & Claudio Fracasso, Pfizer, Italy*

**10:30**      **Paediatric Data Generation through real life experience or clinical trial**  
*Eleni Gaki, Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom*

**11:00**      **Geriatric Data Generation through real life experience or clinical trial**  
*Laurence Hugonot-Diener Broca Hospital Paris, France & European Forum for Good Clinical Practice (EFGCP)*

**11:30**      **Good vigilance practice at both ends of life**  
*Speaker Invited, Health Authority*

**12:00**      **Panel Discussion**

**12:30**      *Lunch*

### PLENARY SESSION 3:

## Modelling and Simulation in Drug Development for Younger and Old People Issues or Solutions for both?

- Chairpersons:** *Solange Rohou, AstraZeneca, European Forum for Good Clinical Practice (EFGCP), France & Florian von Raison, Novartis, European Forum for Good Clinical Practice (EFGCP), Switzerland*
- 13:30**      **Modelling and simulation, Need for new international guidance?**  
*Solange Rohou, AstraZeneca, France*
- 14:00**      **Modelling and simulation in paediatric development. A case study**  
*Amy Cheung, Senior Clinical Pharmacometrician, Early Clinical Development AstraZeneca, UK*
- 14:30**      *Coffee break*
- 14:45**      **Modelling and simulation in geriatric development: A case study**  
*Speaker Invited*
- 15:15**      **Modelling and simulation in older or younger people. Quo Vadis from regulatory standpoint**  
*Flora Musuamba Tshinanu, EMA and Federal Agency for Medicines and Health Products (Belgium)*
- 15:45**      **Panel discussion: Modelling and simulation. Can geriatrics learn from paediatrics?**  
**Panelists:**  
*Dimitris Athanassiou, MDA Hellas & United Parent Projects Muscular Dystrophy, European Forum for Good Clinical Practice (EFGCP), Greece*  
*Amy Cheung, Flora Musuamba Tshinanu, Solange Rohou, & Florian von Raison*
- 16:15**      **Wrap up / Closing Remarks**  
*Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Brussels*
- 16:30**      *End of meeting*