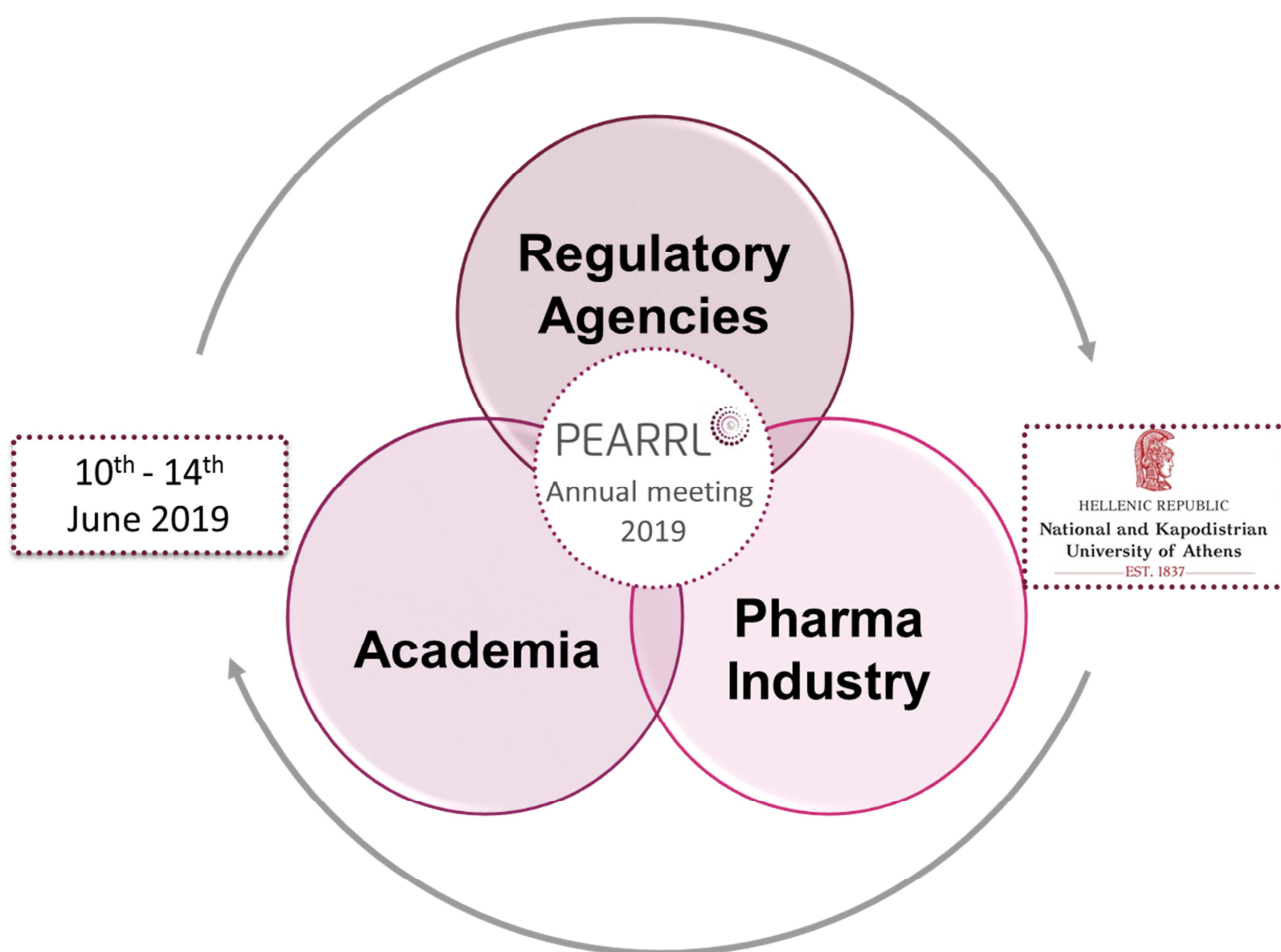


## *3<sup>rd</sup> PEARRL Annual Meeting*

### *Model Informed Drug Development*



*10<sup>th</sup> – 14<sup>th</sup> June 2019*

National and Kapodistrian University of Athens,  
Department of Pharmacy, Greece

<http://www.pearrl.eu/am2019.html>

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## Programme

<b>H2020 ITN</b>	PEARRL project (no.674909)    PEARRLs of Wisdom Week 2019 <a href="https://www.pearrl.eu/am2019.html">https://www.pearrl.eu/am2019.html</a>
<b>Date</b>	10 <sup>th</sup> – 14 <sup>th</sup> June 2019
<b>Theme of Annual meeting</b>	Model Informed Drug Development
<b>Schedule</b>	<p><b>Day 1</b>    Science Slams – ESR research presentations</p> <p><b>Day 2</b>    Science Slams – ESR research presentations</p> <p><b>Day 3</b>    Symposium  <b>Session I</b> – Drug discovery / development interface  <b>Session II:</b> Model informed pre-clinical development</p> <p><b>Day 4</b>    Symposium  <b>Session III:</b> Model informed Clinical Pharmaceutical Development  <b>Session IV:</b> Emerging trends in pharmaceutical product lifecycle management</p> <p><b>Day 5</b>    Transferable skills workshop</p>
<b>Networking events</b>	<p><b>Sunday</b> Pre-Conference Get-Together (PIs and ESRs)</p> <p><b>Day 1</b>    Informal networking</p> <p><b>Day 2</b>    ESRs activity   Acropolis museum</p> <p><b>Day 2</b>    PIs and ESRs dinner</p> <p><b>Day 3</b>    PIs, Speakers and ESRs dinner</p> <p><b>Day 4</b>    Informal networking</p> <p><b>Day 5</b>    ESRs activity   Cape Sounion, Archaeological Site</p>
<b>Location</b>	<b>Athens, Greece</b>
<b>Address</b>	National and Kapodistrian University of Athens, Main Building Panepistimiou 30, 10679 Athens
<b>Wi-Fi access</b>	EDUROAM access available Additional Username & Password will be provided on site

## Welcome Note

Dear PEARRL participant – Welcome to the 3<sup>rd</sup> annual PEARRLs of Wisdom Week!

Following to the previous two very successful meetings in Cork (2017) and Frankfurt (2018) we hope you will also enjoy our 2019 meeting in Athens.



Cork 2017 Annual Meeting



Frankfurt 2018 Annual Meeting

With the help of our coordinator (Brendan Griffin), WP1 leader (Martin Kuentz) and WP3 leader (Jennifer Dressman), we have tried to put together an exciting program both from the scientific and networking points of view. In particular, the external invited speakers for our open two-day symposium are among the top scientists in the field of oral drug product development at least in Europe. We would like to thank them all for their kind contribution. We would also like to thank the National and Kapodistrian University of Athens and Pharmathen S.A. for their support.

We hope you will all enjoy your stay in Athens!

Christos Reppas and Maria Vertzoni

## About Athens



### Sightseeing

Athens takes the fuss out of sightseeing. It is a user-friendly town thanks to the pleasant demeanor of the English-speaking Athenians and the easy to use and manageable transportation system. The visitor can see a lot in one day. Archaeological Sites & Classical Greek Monuments, Byzantine Monuments & Ottoman Monuments, Museums, Art Galleries, street performances, festivals. Needless to say, The Acropolis remains a "must see"...

You may explore Athens [here](#)



### Getting around

A state-of-the-art metro system, wide avenues, an efficient public transportation system and a compact city center, all make moving around Athens easy and convenient. The Athens transportation network now includes new buses, pollution-free trolleys, tram and a revamped electric railway system that connects to two metro lines. Piraeus's port, in short distance from the Athens city center, serves national and international sea lines. The modern highways make driving to and from the city, a pleasant experience.

### Gastronomy

Gourmet and traditional Greek cuisine, in the past decade, has become one of the most popular in the world as it has been proven to provide a flavourful healthy and balanced diet. Culinary aficionados are encouraged to delight in the myriad of sophisticated restaurants that boast tastes and interiors inspired from all parts of the world. The local and traditional outdoor seaside taverns and cafes are plentiful and a cultural mainstay.

### Shopping

Shopping in Athens - a showcase for its traditional and modern culture and lifestyle - can be a fascinating and satisfying experience for all. Amidst the many well-known international name brand outposts and traditional Greek art and folklore shops, are hundreds of chic boutiques and specialty stores blossoming with great fashion finds for every taste and budget. Make sure to stop in at one of the many wonderful year-round outdoor cafés and restaurants to make your experience of shopping in the Athenian way, complete!

### Sea & Sun

Athens is the only European city surrounded by pristine beaches, where you can swim for many months during the year. Visit a beach in Athens and you are likely to feel like you're on a Greek island, as you are greeted with stretches of crystal sands, fine pebbles and breathtaking, blue clean waters. Some beaches boast barren rocks and cliffs that carve caves and coves you can explore. Other beaches have floating bars, music and seaside spas, while others are secluded for romance. Most offer beach amenities, such as lounge chairs, umbrellas, lifeguards, fun playgrounds, restaurants and water sports for all ages.

In Athens, enjoying a sunset stroll or a seaside meal is a part of daily life. Walk on the many Athenian esplanades lined by tropical palm trees. Beach hopping is made possible by the new tramway. Hop-in from the center of Athens and watch the sunset over the Saronic Gulf.

### Athens City Facts

**Weather:** Athens is an ideal year-round destination with comfortable and favourable climate conditions for travel and sightseeing. Rainfall is minimal and the summers (June through August) are dry and hot with temperatures ranging, on average, from 78° to 94°F or 20° to 34°C. The Mediterranean climate makes for mild winters and even milder autumns in low-lying areas, with the coldest temperatures reported in January at a very temperate 41° to 55° F or 5° to 13°C.

**Language:** Most Athenians speak English and those in the hospitality industry are likely to speak French and German too. Signage, menus and transportation signs are written in Greek and English.

**Currency:** Euro €

**Shopping Hours:** Major outlets Monday-Friday. 9:00-21:00; small shops Monday, Wednesday 9:00 to 15:30; Friday, 9:00 to 20:30; Saturday 9:00 to 15:30.

**The airport:** The new award winning Athens International Airport, Eleftherios Venizelos, serves 83 international destinations. Its close proximity to the city centre, 30 minutes by car and 40 minutes by train, makes Athens easily accessible.

For more information, you may visit the official site of the [Athens International Airport](http://www.athens-airport.gr/)

**Transportation:** Network includes new buses, pollution-free trolleys, tram and a revamped electric railway system that connects to the metro lines. Taxis are inexpensive by European standards.

More information can found here [http://www.stasy.gr/index.php?id=1&no\\_cache=1&L=1](http://www.stasy.gr/index.php?id=1&no_cache=1&L=1)



## Hotels recommended by the Organizers

### Titania Hotel

52, Panepistimiou Ave., Athens, 10678, Greece

<http://www.titania.gr/>

Room prices: 130-160 €/night

350 m from the National and Kapodistrian University of Athens (main building), 4 min walking distance. The hotel is 300 m from Panepistimio metro station and 12 minutes walk from Syntagma metro station.

### Ilisia Hotel

25, Mihalakopoulou St., Athens, 11528, Greece

<http://www.ilisiahotel.gr/>

Room prices: 100-110€/night

We would be happy to make the reservation for you at a special rate for PEARRLers (80€, breakfast and all taxes are included). Please send us your full name, preferred room (single or double), check in and check out dates and we will book the room for you ([vertzoni@pharm.uoa.gr](mailto:vertzoni@pharm.uoa.gr)).

2.5 km from the National and Kapodistrian University of Athens (main building), 10 min metro ride from Megaro Mousikis metro station.



## Location of Venue

**Monday 10<sup>th</sup> June through Thursday 13<sup>th</sup> June**

National and Kapodistrian University of Athens (main building),

Argyriadis Lecture Room

Address: Panepistimiou 30, 10679 Athens

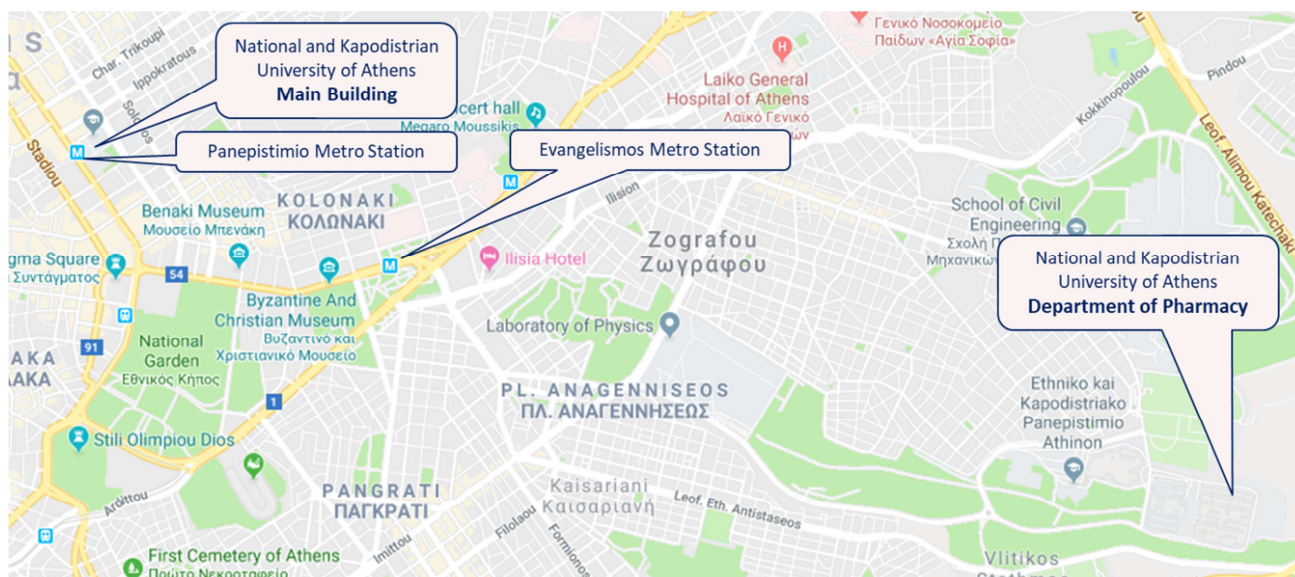


**Friday 14<sup>th</sup> June**

National and Kapodistrian University of Athens, Panepistimiopolis Campus

Department of Pharmacy, New Lecture Room of Pharmaceutical Technology Section

The room can be reached with public but transportation (Bus line 250, from Evangelismos metro station)

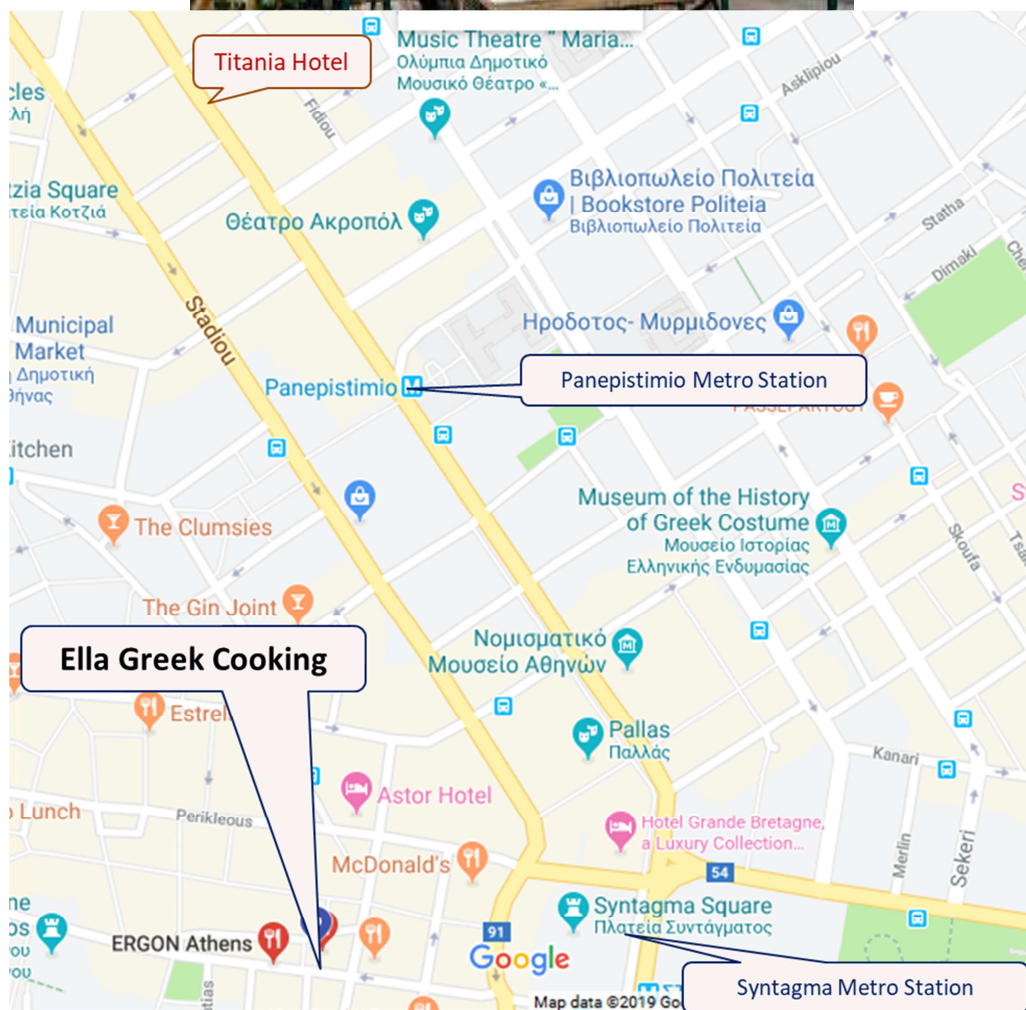




## Pre-Conference Get-Together | Pls and ESRs

Sunday, 9<sup>th</sup> June 2019 || 20:00

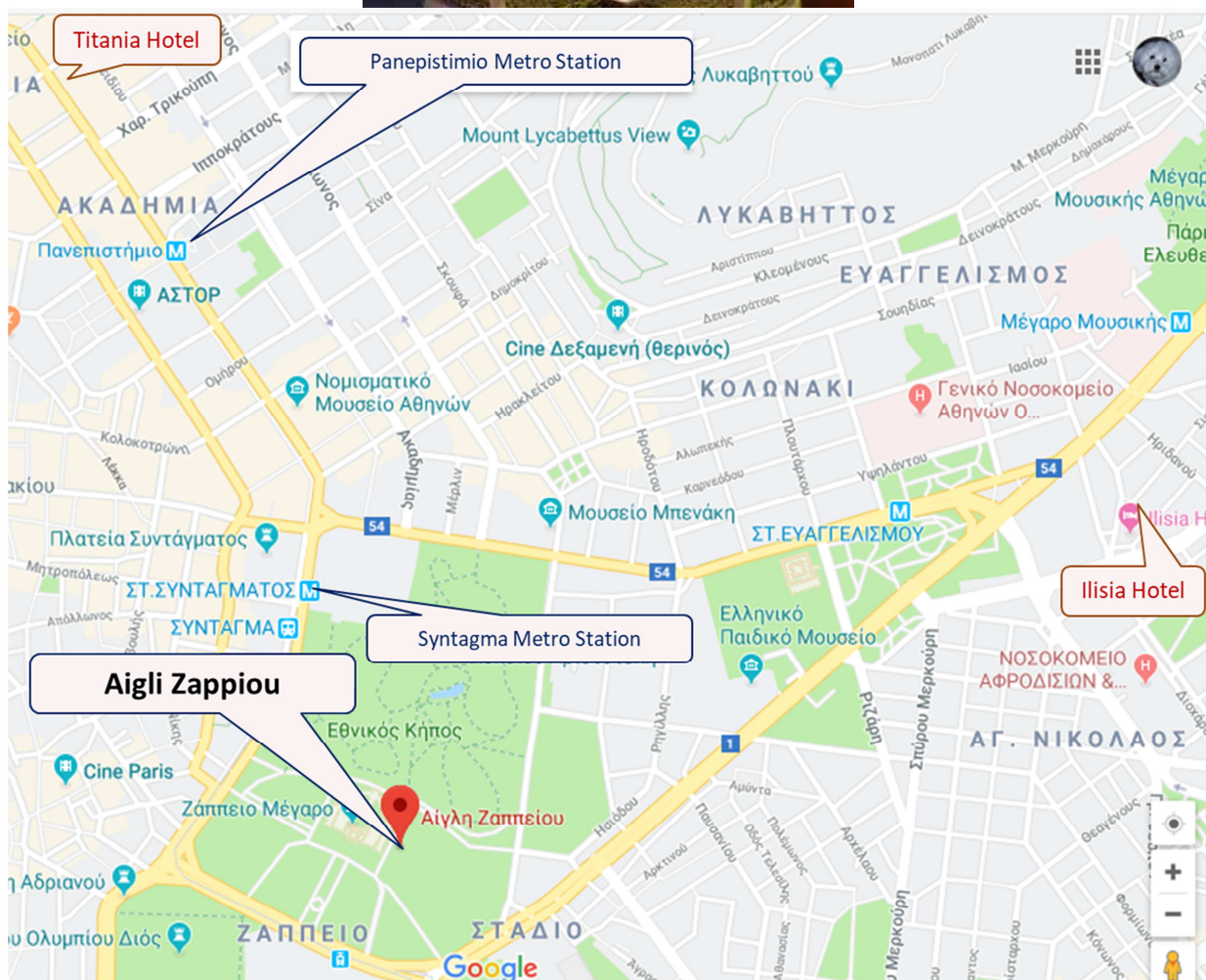
Ella Greek Cooking, Mitropoleos 26, Athens 10563, Tel 210 3315547, <https://www.ellagreekcooking.gr/>



## PEARRL Dinner | Speakers and Pls

Tuesday, 11<sup>th</sup> June 2019 || 20:00

Aigli Zappiou, Zappion, Athens 105 57, Tel 2103369364, [www.aeglizappiou.gr](http://www.aeglizappiou.gr)

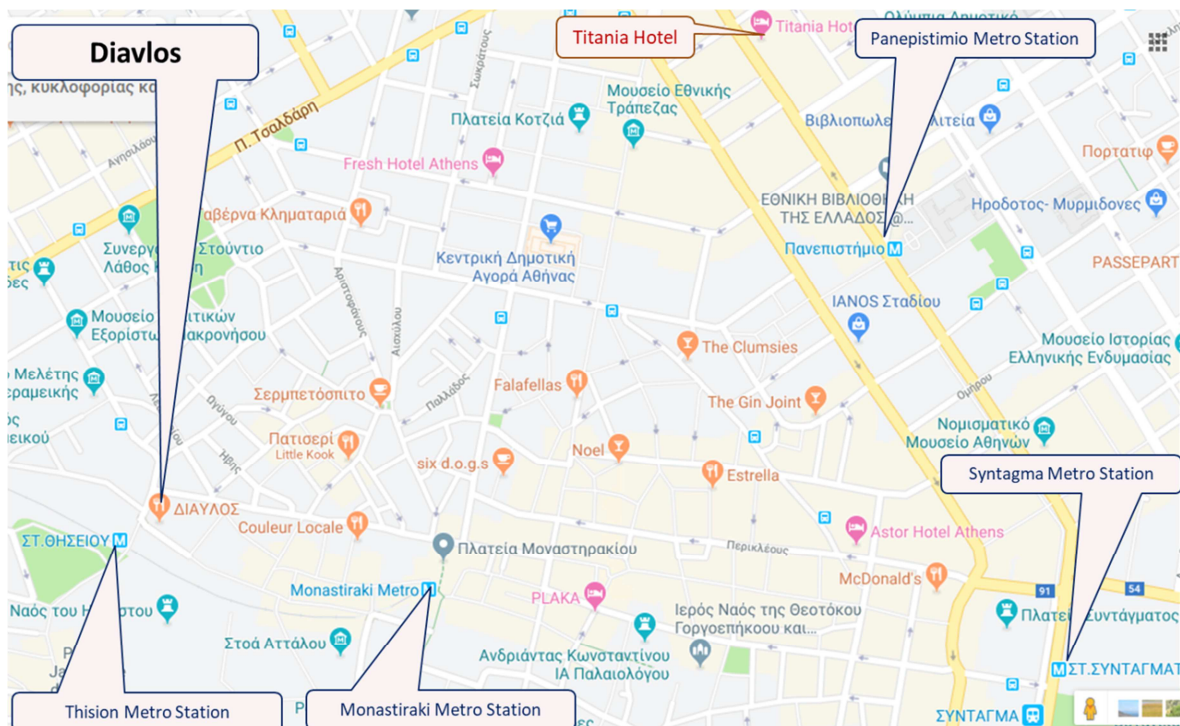




## PEARRL Dinner | ESRs

Tuesday, 11<sup>th</sup> June 2019 || 20:00

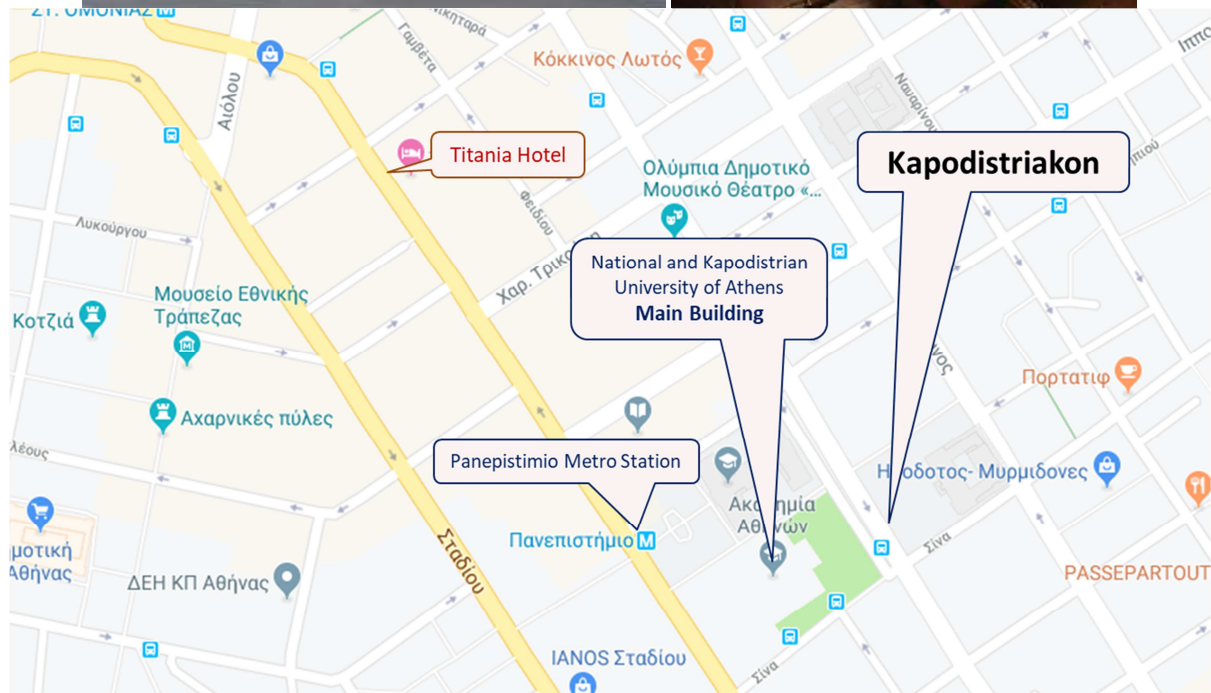
Diavlos, Andrianou 1, Athens 105 55, Tel 21 0325 0944, <http://www.diavlosathens.gr/en/>



## PEARRL Symposium Dinner | Speakers, Pls and ESRs

Wednesday, 12<sup>th</sup> June 2019 || 20:00

Kapodistriakon Restaurant, Kostis Palamas Building, Akadimias 48, Athens 106 79, Tel 21 0368 8711,  
<https://www.facebook.com/EstiatorioToKapodistriakoKterioKostesPalamas>





## Participants list for the Scientific Program

#	Short name	Organisation	Name(s)	Attendance checklist				
				Day 1 10 <sup>th</sup>	Day 2 11 <sup>th</sup>	Day 3 12 <sup>th</sup>	Day 4 13 <sup>th</sup>	Day 5 14 <sup>th</sup>
B1	UCC	University College Cork	Brendan Griffin					
			Caitriona O'Driscoll					
			Niklas Köhl (ESR1)					
B2	JWGU	Johann Wolfgang Goethe University	Jennifer Dressman					
			Edmund Kostewicz					
			Chara Litou (ESR6)					
			Rafael Paraiso (ESR8)					
			Ioannis Loisios-Konstantinidis (ESR13)					
B3	UoA	National and Kapodistrian University of Athens	Christos Reppas					
			Mira Symillides					
			Maria Vertzoni					
			Christina Pentafragka (ESR7)					
			Marina Statelova (ESR11)					
B4	UBAH	University of Bath	Nikoletta Fotaki					
			Mariana Guimarães (ESR12)					
			Angela Effinger (ESR15)					
B5	FHNW	University of Applied Sciences and Arts Northwestern Switzerland	Martin Kuentz					
			Georgios Imanidis					
			Felix Ditzinger (ESR2)					
			Sandra Jankovic (ESR5)					
B7	Merck	Merck KGaA	Anita Nair					
			Christoph Saal					
			Daniel Price (ESR3)					
B9	Pharmaten	PHARMATHEN SA	Lida Kalantzi					
			Georgia Tsakiridou (ESR4)					
B10	Sirius	Sirius Analytical	Karl Box					
			Patrick O'Dwyer (ESR10)					
B11	Janssen	Janssen	Rene Holm					
			Roxana Ilie (ESR14)					

#	Short name	Organisation	Name(s)	Attendance checklist				
				Day 1 10 <sup>th</sup>	Day 2 11 <sup>th</sup>	Day 3 12 <sup>th</sup>	Day 4 13 <sup>th</sup>	Day 5 14 <sup>th</sup>
P1	BfArM	<b>Bundesinstitut für Arzneimittel und Medizinprodukte</b>	Jobst Limberg					
P5	ACCEL	<b>accelopment AG</b>	Jeanette Müller					
P6	BioREL	<b>Biorelevant.com Ltd. (BioRel)</b>	Daryl Leigh					
P7	UCB	<b>UCB Biopharma SPRL (UCB)</b>	Pascal Somville					
P10	Pfizer	<b>Pfizer Ltd.</b>	Mark McAllister					
S1		<b>University of Pavia</b>	Carla Caramella					

## Day 1 – 10<sup>th</sup> June 2019 – Science Slams

Theme: Science & Technology

Attendees: PEARRL Beneficiaries

Time	Session	Speaker	Session Title
9:00 – 11:00	ESR presentations (WP1)	Chair: M. Kuentz (WP1 Leader) ESR1 – Niklas Köhl ESR2 – Felix Ditzinger ESR3 – Daniel Price	ESR presentations
11:00-11:15	Coffee		
11:15-13:15	ESR presentations (WP1)	Chair: M. Kuentz (WP1 Leader) ESR4 – Georgia Tsakiridou ESR5 – Sandra Jancovic ESR14 –Roxana Ilie	ESR presentations
13:15-14:00	Lunch		
14:00 – 16:00	ESR presentations (WP2)	Chair: C. Reppas (WP2 Leader) ESR7 – Christina Pentafragka ESR10 – Patrick O’Dwyer ESR11 – Marina Statelova	ESR presentations
16:15-16:30	Coffee		
16:30 – 17:45	ESR presentations (WP3)	Chair: J. Dressman (WP3 Leader) ESR13 – Ioannis Loisios-Konstantinidis ESR6 – Chara Litou	ESR presentations

## Day 2 – 11<sup>th</sup> June 2019- Science Slams

Theme: Science & Technology

Attendees: PEARRL Beneficiaries

Time	Session	Speaker	Session Title
9:00 – 11:00	ESR presentations (WP3)	Chair: J. Dressman (WP3 Leader) ESR8 – Raphael Paraiso ESR12 – Mariana Guimarães ESR15 – Angela Effinger	ESR presentations
11:00-11:15	Coffee		
Chair: B. Griffin and J. Dressman			
11:15-12:15	‘PEARRLS of Wisdom’	Team/group presentation on Regulatory science topic. Questions from industry, regulatory and academic representatives	<ul style="list-style-type: none"><li>• ‘The BCS is outdated – we need to move on!’</li><li>• ‘PK studies in pre-clinical species is outdated- we need to move on!’</li><li>• ‘Lipinski was right – if it doesn't fit, change the furniture, don’t rebuild the house!’</li></ul>
12:15-13:00	WP1,2 & 3 wrap up and planning	All	
13:00-14:00	Lunch		
Chair: B. Griffin			
14:00-15:00	Management	Management Board (PMB)	Project Management, Deliverables and Milestones,  Discuss the status of publications and score cards and finalize format / contents (e.g. commentaries? E.g. for WP2 could be <i>in vivo</i> vs. <i>in vitro</i> tools for evaluating absorption?)  Discuss the webinar for March 2020
15:00-16:00		Supervisory Board (PSB)	Project status, WP info, Training Programme, FAQ
16:00-16:30	Coffee		
16:30-17:30	Management	Supervisory Board (PSB)	Update and discussion with Professor Carla Caramella (Member of the Scientific Advisory Board) on Project Status



## Invited Speakers



**Dr. Bertil Abrahamsson**  
AstraZeneca R&D  
Mölndal, Sweden



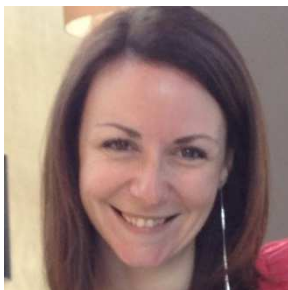
**Apostolis Aivaliotis**  
Pharmathen S.A.  
Marousi Attica, Greece



**Dr. Jochem Alsenz**  
F. Hoffmann- La Roche  
Ltd. Basel, Switzerland



**Dr. James Butler**  
GlaxoSmithKline  
Ware, UK



**Sandy Van Hemelryck**  
Janssen Pharmaceutica  
Belgium



**Dr. Masoud Jamei**  
Certara  
United Kingdom



**Dr. Essam Ahmed  
Ghazaly Kerwash** The  
Medicines and  
Healthcare Products  
Regulatory Agency  
(MHRA), United Kingdom



**Ian Flawn Orpana**  
Verto Pharma AB, SE



**Neil John Parrott**  
F. Hoffmann- La Roche  
Ltd., Basel, CH



**Dr. Christian Wagner**  
Merck Group  
Darmstadt, Germany

## Day 3 – 12<sup>th</sup> June 2019 – Open scientific symposium on Model Informed Drug Development

Theme: Lead optimisation through to pre-clinical development

Attendees: PEARRL Beneficiaries, Partners and External invites

Time	Topic	Speaker	Presentation Title
08:30	Registration		
08:45	Welcome address	C. Reppas   B. Griffin	PEARRL
Session I – Drug discovery/development interface Chair: B. Griffin, UCC			
09:00	Pharmaceutical Profiling	Jennifer Dressman (UGoethe, Germany)	Pharmaceutical Profiling in the pharmaceutical industry
09:45	Drug candidate lead optimisation	Martin Kuentz (FHNW, Switzerland)	Digital approaches from drug candidate selection to computational pharmaceuticals
10:30	PEARRL approaches to predicting formulation design	Dan Price (Merck, Germany)	COSMOquick as a predictor of drug/excipient interactions in enhanced dosage forms
10:45	Coffee		
11:15	High throughput biopharmaceutical screening	Jochem Alsenz (Roche, Switzerland)	High throughput biopharmaceutical screening
12:00	PEARRL approaches to Biorelevant in vitro screening	Patrick O’Dwyer (Pion, UK)	A guide to small scale screening for drug-specific questions
12:15	PEARRL approaches to predicting formulation design	Felix Ditzinger (UNWS, Switzerland) Georgia Tsakiridou (Pharmathen, Greece)	Solid dispersions based on a modelling rationale
12:45	PEARRL approaches to predicting formulation design	Niklas Koehl (UCC, Ireland) Roxana Ilie (J&J, Belgium)	A guide to bioenabling formulation selection in development: focus on lipid based approaches
13:15	Lunch		
Session II – Model informed pre-clinical development Chair: J. Dressman (UGoethe)			
14:15	Role of rDCS in guiding preclinical pharm development	James Butler (GSK, UK)	Role of rDCS in guiding preclinical pharm development
15:00	Role of PBPK in guiding preclinical pharm development	Christian Wagner (Merck, Germany)	Role of PBPK in guiding preclinical pharm development
15:45	Coffee		
16:15	Role of animal modelling in preclinical pharm development	Sandy Van Hemelryck (J&J, Belgium)	Preclinical Bioavailability Strategy for Decisions on Clinical Drug Formulation Development
17:00	PEARRL approaches to biorelevant in vitro screening	Chara Litou (UGoethe, Germany)	The role of biorelevant testing in formulation development
17:15	PEARRL approaches to biorelevant in vitro screening	Christina Pentafragka (UoA, Greece)	Using luminal data for modelling absorption in the fed state
17:30	End of Day 1		

## Day 4 – 13<sup>th</sup> June 2019 - Open scientific symposium on Model Informed Drug Development

Theme: Clinical development through to pharmaceutical product lifecycle management

Attendees: PEARRL Beneficiaries, Partners and External invites

Time	Session/Topic	Speaker	Presentation Title
Session III – Model informed clinical development C. Reppas (UoA)			
09:00	Formulation for first in man studies	James Butler (GSK, UK)	Formulation for first in man studies
09:45	Transitioning to the final formulation. What are the challenges?	Bertil Abrahamsson (AZ, Sweden)	Transitioning to the final formulation. What are the challenges?
10:30	Coffee		
11:00	PBPK modelling of food effects	Neil Parrott (Roche, Switzerland)	PBPK modelling of food effects
11:45	PBPK modeling of DDIs	Masoud Jamei (Certara, UK)	Applications of PBPK modelling in predicting complex DDIs
12:30	PEARRL approaches to predicting in vivo outcomes using in silico tools	Angela Effinger (Bath, UK)	Targeting GI diseases
12:45	PEARRL approaches to biorelevant <i>in vitro</i> screening	Mariana Guimaraes (UBath, UK))	<i>In vitro</i> evaluation of drugs/drug products for paediatrics
13:00	PEARRL approaches to predicting in vivo outcomes using <i>in silico</i> tools	Marina Statelova (UoA, Greece	<i>In silico</i> evaluation of drugs/drug products for paediatrics
13:15	Lunch		
Session IV – Emerging trends in pharmaceutical product lifecycle management Chair: M. Kuentz (FHNW)			
14:00	Developing generic products	Lida Kalantzi (Pharmathen, Greece)	Modelling and simulation in the development of generics
14:45	A regulatory perspective on PBPK modelling	Essam Ahmed Ghazaly Kerwash (MHRA, UK)	Regulatory perspective on the use and qualification of PBPK modelling
15:30	Coffee		
16:00	Manufacturing and Quality Control	Ian Flawn Orpana (Verto Pharma AB, Sweden)	Statistical Process Control (SPC) in Manufacturing and Quality Control of Drug Products
16:45	PEARRL approaches to predicting formulation design	(Sandra Jankovic (UNWS, Switzerland)	Emerging process analysers in pharmaceuticals
17:00	PEARRL approaches to predicting in vivo outcomes using in silico tools	Ioannis Loisios (UGoethe, Germany)	Establishing virtual bioequivalence trials simulation using population-based PBPK modelling
17:15	PEARRL approaches to predicting in vivo outcomes using in silico tools	Raphael Paraiso (UGoethe, Germany)	The role of <i>in vitro</i> and <i>in silico</i> tools to support bioequivalence studies
17:30	End of Day 2		

## Day 5 – 14<sup>th</sup> June 2019 - Transferable skills workshop and Network event

Theme: Generic and Transferable skills training

Attendees - ESRs

Time	Session	Speaker	Title
Chair: C. Reppas			
9:00	Innovation in the pharmaceutical industry	Mark McAllister, Pfizer	Leveraging S&T for innovative product and process design
10:00	Entrepreneurship and commercial start up for pharma	Daryl Leigh (Biorelevant.com Ltd.)	Entrepreneurship and commercial start up for pharma
11:00	Coffee		
11:30	Patent related topic	Apostolos Aivaliotis (IP Senior Manager, Pharmathen)	Managing Intellectual property for commercial success
12:30	EU Funding Opportunities and Proposal Writing	Jeanette Muller (accelopment AG)	Overview of opportunities in Horizon 2020 and other funding schemes.
13:30	Lunch		

14:30 Departure to Cape Sounion

Departure from the Department of Pharmacy

[http://odysseus.culture.gr/h/3/eh352.jsp?obj\\_id=2390](http://odysseus.culture.gr/h/3/eh352.jsp?obj_id=2390)

