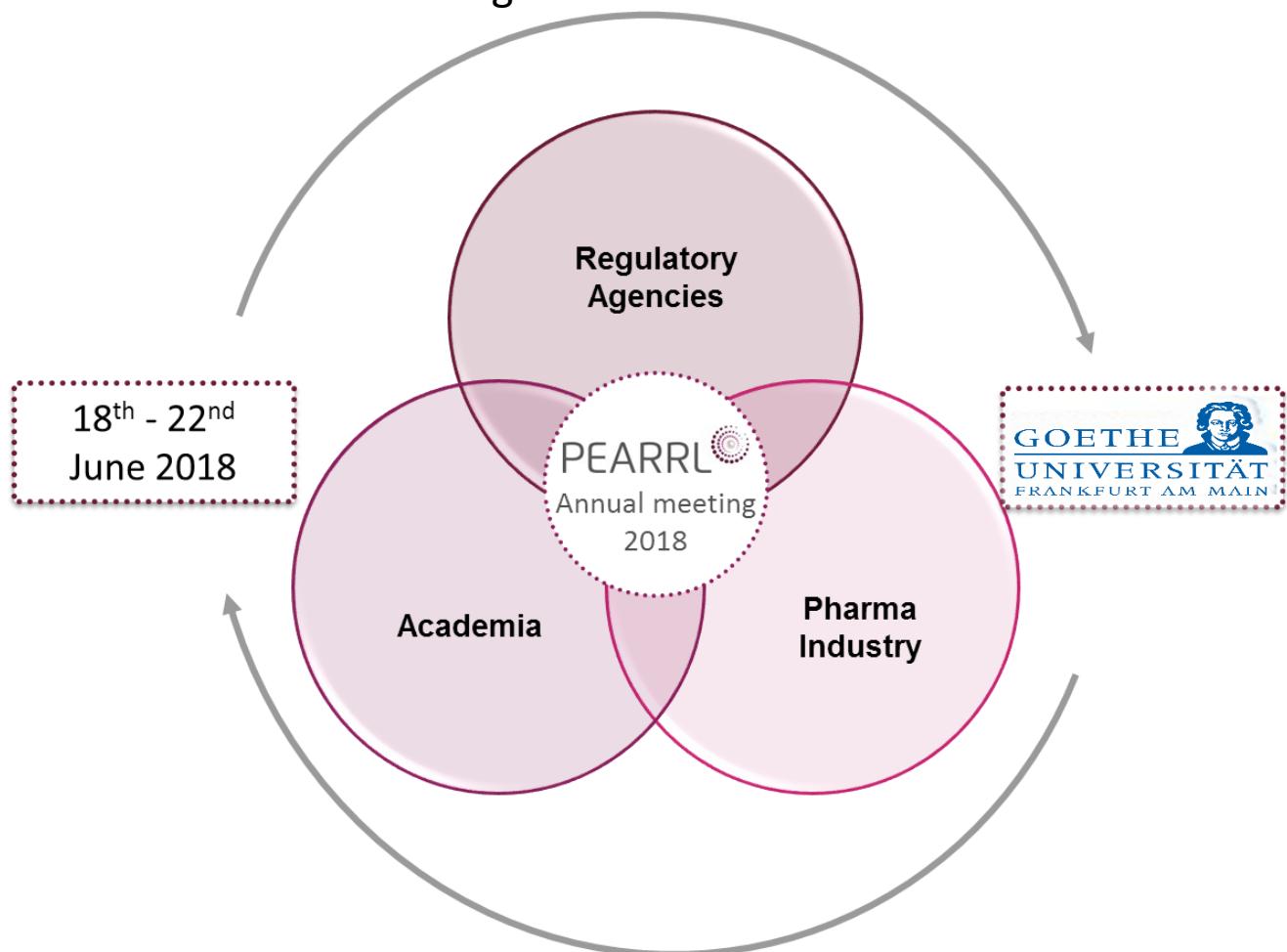




Pharmaceutical Education And Research with Regulatory Links
European Training Network

2nd PEARRL Annual Meeting

Programme of events



18th - 22nd June 2018

Johann Wolfgang Goethe University, Frankfurt

<http://www.pearrl.eu/2ndannualmeeting.html>



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 674909.

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Programme

H2020 ITN

PEARRL project (no.674909) PEARRLs of Wisdom Week 2018

<http://www.pearrl.eu/first-poww.html>

Date

18th– 22nd June 2018

Schedule

- Day 1** Regulatory Science Workshop ‘Applications of PBPK modelling for Oral Drug Delivery’
- Day 2** Regulatory Science Symposium ‘Tools for investigating oral dosageforms with regulatory applications’
- Day 3** Science Slams – ESR research presentations
- Day 4** Science Slams – ESR research presentations
- Day 5** Transferable & career skills workshop

Networking events

- Sunday** Pre-Conference Get-Together (All)
- Day 1** Conference (All)
 - Social Event (PIs and conference speakers)
 - Laser-Tag Teambuilding (ESRs)
- Day 2** Conference and Conference Dinner (All)
- Day 3** informal networking
- Day 4** Dialog museum Tour (ESRs)
- Day 5** -

Location

Frankfurt am Main, Germany

Address

Johann Wolfgang Goethe University
Campus Westend (Mon & Tue)
 Conference Room 1.801 (Renate-von-Metzler-Saal) in the Casino Building, Goethe University, Theodor-W.-Adorno-Platz 1, 60323 Frankfurt

Campus Riedberg (Wed, Thu & Fri)
 Seminar Room N100-114, Biozentrum, Goethe University, Max-von-Laue Straße. 9, 60438 Frankfurt

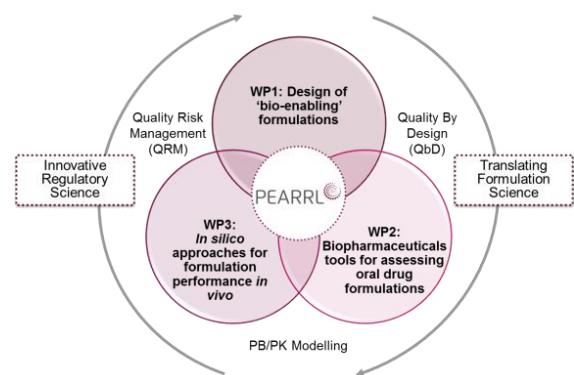
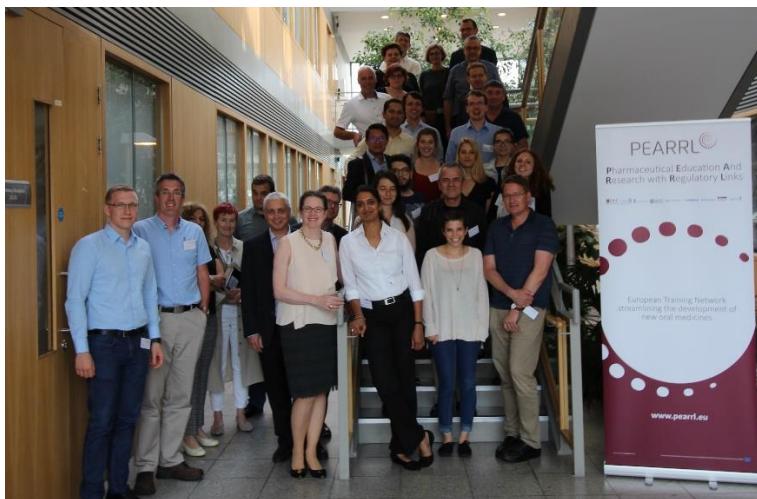
Wi-fi access

Username & Password will be provided during the meeting

Welcome Note

Dear PEARRL participant,
Welcome to Frankfurt for our second annual PEARRLs of Wisdom Week.

PEARRL is a Marie Skłodowska-Curie European Training Network offering a comprehensive training program addressing the challenges of developing emerging drug candidates into new licensed medicines with innovative drug formulation strategies and *in vitro* and *in silico* development tools tailored to facilitate earlier access to medicines.



PEARRL brings together European pharmaceutical industry, academia and regulatory agency partners together as a multi-sectorial team to deliver a unique research and training programme for 15 Early Stage Researchers (ESR).

The main research objectives of the PEARRL programme are to develop novel bio-enabling formulations and new biopharmaceutics tools to predict their *in vivo* performance as a means to improve efficiency and cost competitiveness in drug development, thus facilitating earlier access of patients to "breakthrough therapies". PEARRL will create innovation in all three areas (bio-enabling formulations for oral administration, biopharmaceutics tools and patient-tailored PBPK models) to ensure streamlined molecule-to-market time-lines for poorly soluble drugs and thus ensure the future competitiveness of Europe's Pharma industry. Outcomes will benefit the Pharma industry and, in particular, our industry partners. PEARRL interactions will facilitate collaboration with and among regulatory bodies, including our Partner Organisations EMA, HRPA, BfArM and MHRA, and our joint research will further strengthen Europe's excellence in academic science at our Universities.

We hope this network-wide training event will be a rewarding experience for all those attending the meeting and a first step in a successful career for the Early Stage Researchers.

Welcome to the PEARRLs of Wisdom Week 2018!

Professor Jennifer Dressman



About Frankfurt

Glistening with glass, steel and concrete skyscrapers, Frankfurt am Main is the focal point of the greater Frankfurt Rhine-Main metropolitan area, with 770,000 residents in Frankfurt and almost 6 million in the region. "Mainhattan", as it is referred to by some, is home to one of the world's largest stock exchanges and the headquarters for the European Central Bank. The city has existed as a trading centre for centuries and hosts some of the world's most important trade shows including the Frankfurt Auto Show, Achema and the Frankfurt Book Fair.

Amongst the skyscrapers, which are unique to Frankfurt in Europe, are the half-timbered buildings clustered in the quaint medieval "Altstadt" (old town). During World War 2, 90% of all buildings in Frankfurt were reduced to rubble by Allied bombing, with only 5 buildings surviving from the middle ages intact. Restoration of the historical city has been ongoing with the latest project reconstructing the old town quarter between the Römerberg square and the Frankfurt Cathedral (Dom-Römer-Project) penned for completion in late 2018.

Frankfurt has also earned a national reputation as a city of the arts, given its large variety of museums and galleries numbering approximately 60 centres in total. One of the city's most famous literary sons is Johann Wolfgang von Goethe, born in 1748 and after whom the Goethe University was named.

The University was founded in 1914, and currently has approximately 46,000 students distributed across the four main campuses within the city. Pharmacy was originally based at the central Bockenheim Campus but was relocated to the current location in Riedberg in 1994. The 2nd PEARRL Annual Meeting will be held both in central Frankfurt at the *Westend* Campus and at the *Riedberg* Campus located at northern boundary of the city.



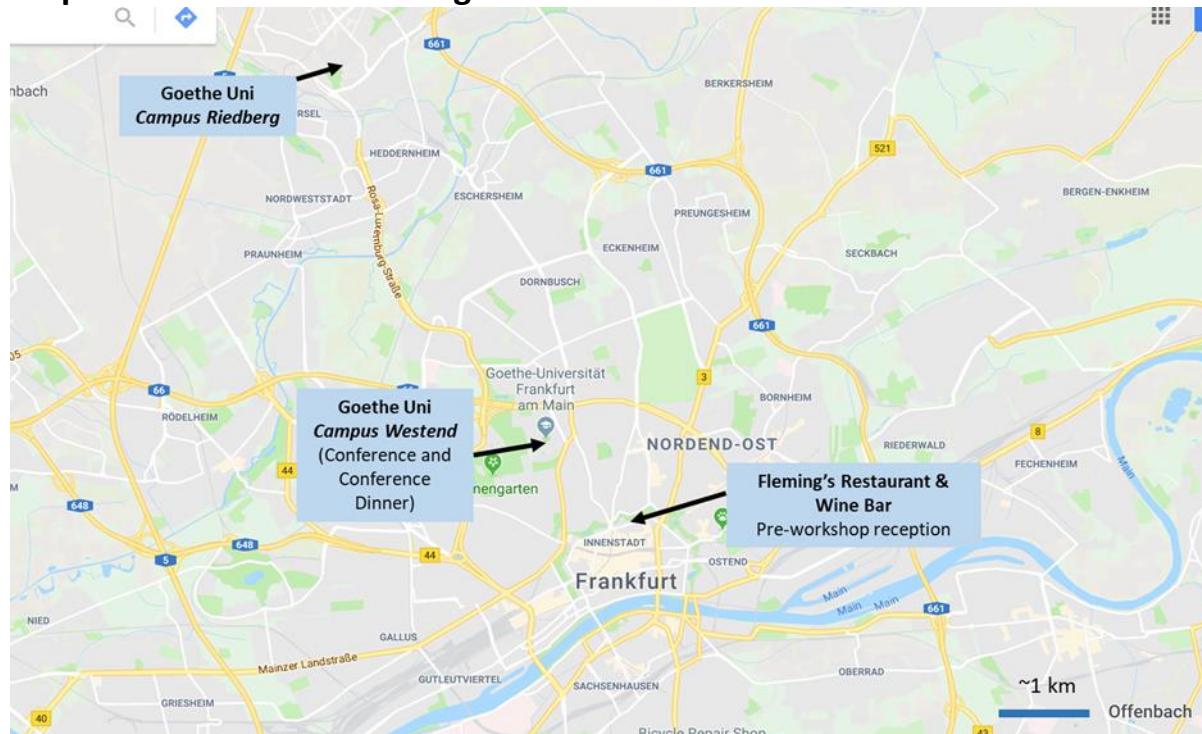
How to get to Conference Location Campus Westend and Campus Riedberg

The U-Bahn (subway) can be used to transit to both the Westend (**U** 1,2,3 or 8, alight at the “**Holzhausenstrasse**” station) and the Riedberg (**U** 8, alight at the “**Uni Campus Riedberg**” station) Campuses of Goethe University.

For U-Bahn timetable and route information refer to the RMV website or download the RMV App

<http://www.rmv.de/auskunft/bin/jp/query.exe/en>

Map of various venues during POWW 2018



Pre-conference Get-Together – Sunday Evening

The venue will be:

Fleming's Club Frankfurt

Eschenheimer Tor 2

60318 Frankfurt am Main

The Get-Together will be in the bar on the 7th floor (Fleming's Club) and will run from 7 till 9 p.m.

Everyone is invited to purchase his/her drinks and snacks.

PI and Speakers Dinner – Monday Evening

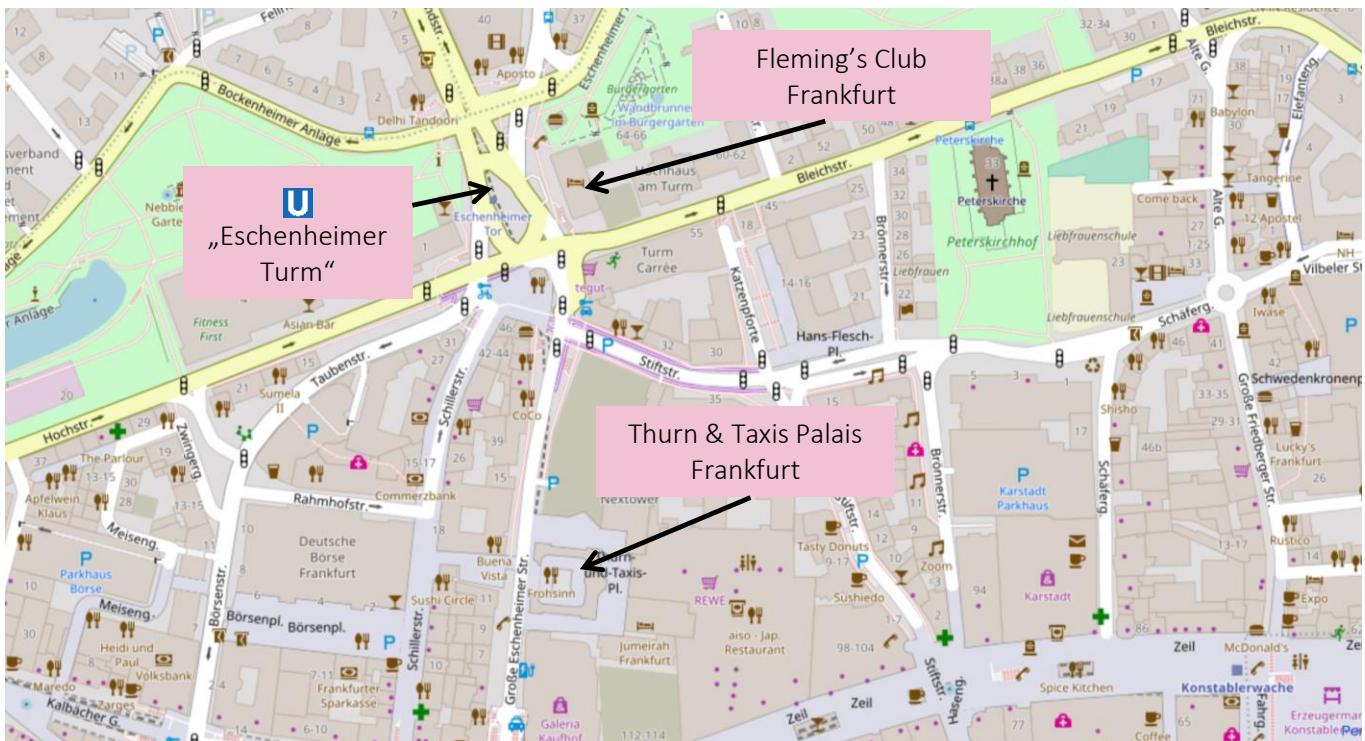
The venue will be:

TNT- Thurn 'N Taxis Palais

Thurn und Taxis Platz 1

60313 Frankfurt am Main

The dinner will begin at 7 pm and will be paid for all speaker at the Symposium



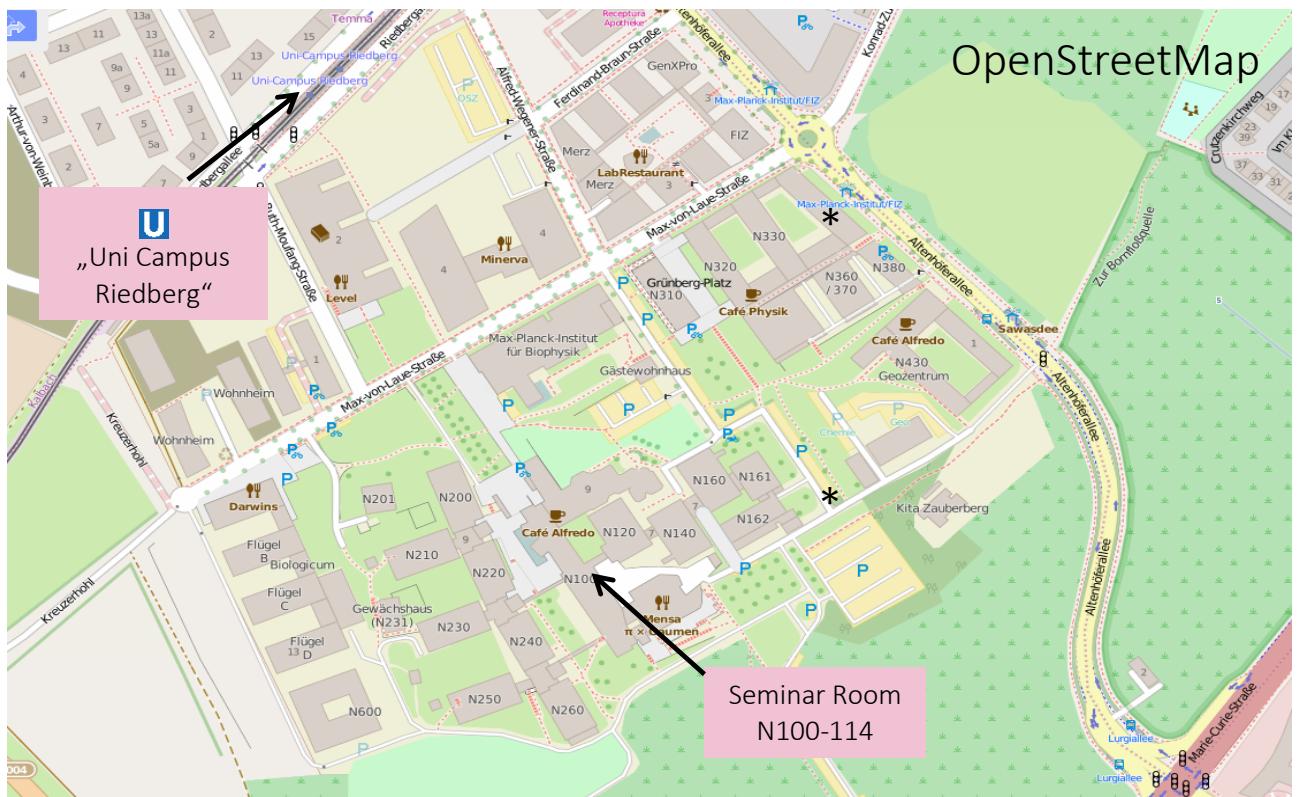
Campus Westend – Monday and Tuesday

How to get to conference venue “Conference Room 1.801” and conference dinner at “Sturm & Drang” (Tues 7.00 pm) at Johann Wolfgang Goethe University



Campus Riedberg – Wednesday, Thursday and Friday

How to get to conference venue “Seminar room N100-114” at Johann Wolfgang Goethe University



Conference Dinner

**Tuesday evening 7:00 – 10 pm at Restaurant “Sturm und Drang”
at Johann Wolfgang Goethe University -Westend Campus**

Theodor-W.-Adorno-Platz 5, 60323 Frankfurt am Main;

<http://cafe-sturm-und-drang.de/>



Hotel Suggestions Close to Campus Riedberg

1. Relexa hotel Frankfurt/Main (*limited availability!!!*)

Lurgiallee 2
60439 Frankfurt am Main
+49 69 - 95778 0

<https://www.relexa-hotel-frankfurt.de/en>

Please ask for the Goethe University rate when making the booking either by phone or email, standard room: 99€ (single), 122€ (double), business room: 125€ (single), 151€ (double). Breakfast included, Wi-Fi is free in the hotel lobby

500 m walk to **U "Riedwiese/Mertonviertel"**:

Westend Campus: 13 minute U-Bahn ride on U2 (direction Südbahnhof Frankfurt) and disembark at "**Holzhausenstraße**";

Riedberg Campus: 800 m walk/taxi ride to University conference room

2. Hotel Heddernheimer Hof (*limited availability!!!*)

Heddernheimer Landstrasse 82
60439 Frankfurt am Main
+49 69 951 176 00

<http://www.heddernheimerhof.eu/en/>

Room prices are 83€ (small single); 88€ (standard single) and includes breakfast and Wi-Fi

670m walk to **U "Heddernheimer Landstrasse"**:

Westend Campus: 10-minute U-Bahn ride on **U1/U2/U3** (direction Südbahnhof Frankfurt) and disembark at "**Holzhausenstraße**";

Riedberg Campus: 5-minute U-Bahn ride **U9** (direction "Nieder-Eschbach") and disembark at "**Uni Campus Riedberg**"

3. Motel Plus Frankfurt am Main

Erich-Ollenhauer-Ring
Heddernheim, 60439 Frankfurt am Main
+49 69 95 11 472-0

<http://www.motelplus-frankfurt.de/>

Room rates: Single room 63€, double room 73€ - including breakfast and wifi

Direct 3-minute walk to **U "Nordwestzentrum"**:

Westend Campus: 21 minute U-Bahn ride on U1 (direction Südbahnhof Frankfurt) and disembark at "**Holzhausenstraße**";

Riedberg Campus: 8-minute U-Bahn ride on **U9** (direction Nieder-Eschbach) and disembark at U-Bahn station "**Uni Campus Riedberg**"

4. Hotel & Restaurant Sandelmühle (limited availability!!!)

An der Sandelmühle 35
 60439 Frankfurt am Main
 +49 69 – 951 547 68

<http://www.sandelmuehle.eu/2015/buchung.html>

Room rates: single room 69€, double room 108€, including breakfast and Wi-Fi.

700m walk to **U “Sandelmühle”:**

Westend Campus: 10 minute U-Bahn ride on the U1/U2/U3 & U8 (direction Südbahnhof Frankfurt) and disembark at “**Holzhausenstraße**”;

Riedberg Campus: 4-minute U-Bahn ride on U2 (direction Bad Homburg), disembark at U-Bahn station “**Kalbach**”, transfer onto U-Bahn U9 (direction “Frankfurt Ginnheim”) 5 minute U-Bahn ride and disembark at “**Uni Campus Riedberg**”

5. Darmstädter Hof

Hotel & Restaurant
 An der Walkmühle 1
 60437 Frankfurt am Main – Nieder-Eschbach
 +49 69 - 509 109 0

<http://www.hoteldarmstaedterhof-frankfurt.de/darmstaedterhof-zimmer.htm>

Please ask for the Goethe University rate when making the booking either by phone or email, rate for standard single or double room is 82€ or 102€ includes breakfast and Wi-Fi

270m walk to **U “Nieder-Eschbach”:**

Westend Campus: 20 minute ride on the **U2** (direction Südbahnhof Frankfurt) and disembark at “**Holzhausenstraße**”;

Riedberg Campus: 9 minute U-Bahn ride on **U9** (direction “Frankfurt Ginnheim”) and disembark at “**Uni Campus Riedberg**”

Hotel Suggestions Close to Campus Westend (Central Frankfurt)

1. Fleming's - Selection Hotel Frankfurt-City

Eschenheimer Tor 2
60318 Frankfurt am Main
+49 69 427 232-0

<https://www.flemings-hotels.com/en/hotels-residences/frankfurt/flemings-selection-hotel-frankfurt-city/hotel>

Room rates: Single room from 145€ including breakfast and wifi

190m walk to **U “Eschenheimer Tor”:**

Westend Campus: 2 minute ride on the **U1/U2/U3/U8** (direction city outbound) and disembark at “**Holzhausenstraße**”;

Riedberg Campus: 24 min ride on U8 (direction Riedberg) and disembark at “**Uni Campus Riedberg**”

2. Hilton Frankfurt City Centre

Hochstraße 4,
60313 Frankfurt am Main
+49 69 133800

<http://www3.hilton.com/en/hotels/hesse/hilton-frankfurt-city-centre-FRAHITW/accommodations/index.html>

Room rates: Single room from 199€

190m walk to **U “Eschenheimer Tor”:**

Westend Campus: 2 minute ride on the **U1/U2/U3/U8** (direction city outbound) and disembark at “**Holzhausenstraße**”;

Riedberg Campus: 24 min ride on U8 (direction Riedberg) and disembark at “**Uni Campus Riedberg**”

3. Turm Hotel Frankfurt

Eschersheimer Landstraße 20,
60322 Frankfurt am Main
+49 69 154050

<http://www.turmhotel-fra.de/gb/reservierung.html>

Room rates: Single room from 145€

290m walk to **U “Grüneburgweg”:**

Westend Campus: 1 minute ride on the **U1/U2/U3/U8** (direction city outbound) and disembark at “**Holzhausenstraße**”;

Riedberg Campus: 23 min ride on U8 (direction Riedberg) and disembark at “**Uni Campus Riedberg**”

Participant list

#	Short name	Organisation	Name(s)	Attendance checklist				
				18 th	19 th	20 th	21 st	23 rd
B1	UCC	University College Cork	Brendan Griffin Caitriona O'Driscoll Niklas Köhl (ESR1) Laura Henze (ESR9)					
B2	JWGU		Jennifer Dressman Edmund Kostewicz Chara Litou (ESR6) Rafael Paraiso (ESR8) Ioannis Loisios-Konstantinidis (ESR13)					
B3	UoA		Christos Reppas Maria Vertzoni Christina Pentafragka (ESR7) Marina Statelova (ESR11)					
B4	UBAH		Nikoletta Fotaki Mariana Guimarães (ESR12) Angela Effinger (ESR15)					
B5	FHNW	University of Applied Sciences and Arts Northwestern Switzerland	Martin Kuentz Felix Ditzinger (ESR2) Sandra Jankovic (ESR5)					
B7	Merck		Anita Nair Christoph Saal Daniel Price (ESR3)					
B9	Pharmaten		Lida Kalantzi Georgia Tsakiridou(ESR4)					
B10	Sirius	Sirius Analytical	Karl Box Patrick O'Dwyer (ESR10)					
B11	Janssen		Rene Holm Ruzica Kolakovic Roxana Ilie (ESR14)					

#	Short name	Organisation	Name(s)	Attendance checklist				
				18 th	19 th	20 th	21 st	23 rd
P1	BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte	Jobst Limberg					
P2	EMA	European Medicines Agency	Evangelos Kotzagiorgis					
P3	HPRA	Health Products Regulatory Authority	Una Moore					
			Niall MacAleenan					
			Nick Lee					
			Peter Kiely					
			Laurence O'Dwyer					
			Jayne Crowe					
P4	MHRA	Medicines and Healthcare products Regulatory Agency	Sean Jones					
			Daniel O'Connor					
			Martin O'Kane					
			Manika Azad					
			Stefania Ragone					
			Colm Reddington					
P5	ACCEL	accelopment AG	Jeanette Müller					
			Julia Götz					
P6	BioREL	Biorelevant.com Ltd. (BioRel)	Daryl Leigh					
P7	UCB	UCB Biopharma SPRL (UCB)	Jérôme Mantanus					
			Pascal.Somville					
P10	Pfizer	Pfizer Ltd.	Dr. Mark McAllister Sharon Page Irena Tomaszewska					

EXTERNAL

#	Short name	Organisation	Name(s)	Attendance checklist				
				1	2	3	4	5
		Marie Curie Project Officer (BD)	Patricia Rischitor					

Day 1 - 18th June 2018 – In silico tools to support Regulatory applications

Theme: Regulatory science -Applications of PBPK modelling for Oral Drug Delivery

Attendees: PEARRL Beneficiaries and Partner organisations

Time	Session	Speaker	Session Title
08:45	In silico tools for Regulatory applications	J. Dressman & N. Fotaki	Welcome address
09:00		Rodrigo Cristofoletti	Nuts and bolts of PBPK Modeling for oral drug absorption
09:45		Oliver Hatley	How PBPK is set up to describe DDI
10:30	Coffee		
11:00	In silico tools	Andrea Edginton	Pediatric PBPK: growth and maturation, model development workflow and regulatory aspects
11:45	In silico tools	Mehul Mehta	Applications of PBPK at the FDA
12:30	Lunch		
14:00	Case studies	J. Dressman	Understanding food effects
14:45		David Turner	Understanding precipitation of weak bases in the GIT
15:30	Coffee		
16:00	Case studies	Rodrigo Cristofoletti	Prediction of clinically based BE: case example ibuprofen, ibuprofen salts
16:45		Andrea Edginton	Extrapolating the healthy adult dose-exposure relationship to special populations using PBPK
17:30	Panel discussion		

Day 2 – 19th June 2018 - In vitro tools to support Regulatory applications

Regulatory Science Symposium: "Overview of Tools for investigating dosage form behaviour in vitro that can be used in regulatory applications"

Attendees: PEARRL Beneficiaries and Partner organisations

Time	Session	Speaker	Session Title
08:45	In vitro tools with Regulatory applications	C. Reppas & K.Box	Welcome address
09:00		Mehul Mehta, FDA, USA	Biopharmaceutics and Clinical Relevance: The FDA point of view
09:45		Mark McAllister, Pfizer, UK	Industrial perspectives on the use of predictive biopharmaceutics tools
10:30	Coffee		
11:00	In vitro tools	K. Box, Pion	Small scale models: Usefulness, challenges and their potential for implementation by regulatory authorities
11:45	In vitro tools	E. Kostewicz, Goethe University	The transfer model for evaluation of supersaturation and precipitation in the small intestine after oral drug product administration: Usefulness, challenges and its potential for implementation by regulatory authorities
12:30	Lunch		
14:00	In vitro tools	M. Vertzoni, National and Kapodistrian University of Athens	The BioGIT model for evaluating the impact of gastrointestinal transfer on luminal concentrations in the fasted state: Usefulness, challenges and its potential for implementation by regulatory authorities
14:45	In vitro tools	Werner Weitschies, University of Greifswald	Experiences with the simulation of gastric (hydro)dynamics with a view in the development of a useful in vitro tool
15:30	Coffee		
16:00	In vitro tools	Anette Müllertz, University of Copenhagen	The Dynamic Gastric System in the evaluation of oral drug products: Usefulness and Challenges
16:45	In vitro tools	Richard Barker, AstraZeneca, UK	The use of TIM-1 system for the evaluation of oral drug products in a regulatory setting
17:30	Panel discussion		

Detailed Agenda for Scientific Programme

Day 3 – 20th June 2018 – Science Slams

Theme: Science & Technology

Attendees: PEARRL Beneficiaries

Time	Session	Speaker	Session Title
9:00 – 11:00	ESR presentations (WP1)	ESR1 – Niklas Köhl ESR2 – Felix Ditzinger ESR3 – Daniel Price	ESR presentations
11:00-11:15	Coffee		
11:15-13:15	ESR presentations (WP1)	ESR4 – Georgia Tsakiridou ESR5 – Sandra Jancovic ESR14 – Roxana Ilie	ESR presentations
13:15-14:00	Lunch		
14:00 – 16:00	ESR presentations (WP2)	ESR7 – Christina Pentafragka ESR9 – Laura Henze ESR10 – Patrick O'Dwyer	ESR presentations
16:15-16:30	Coffee		
16:30 – 17:45	ESR presentations (WP2)	ESR11 – Marina Statelova ESR13 – Ioannis Loisios-Konstantinidis	ESR presentations

Day 4 – 21st June 2018- Science Slams

Theme: Science & Technology

Attendees: PEARRL Beneficiaries

Time	Session	Speaker	Session Title
9:00 – 11:00	ESR presentations (WP3)	ESR6 – Chara Litou ESR8 – Raphael Paraiso ESR12 – Mariana Guimarães	ESR presentations
11:00-11:15	Coffee		
11:15-12:00	ESR presentations (WP3)	ESR15 – Angela Effinger	ESR presentations
12:00-13:00	WP1,2 & 3 wrap up and planning	All	
13:00-14:00	Lunch		
14:00-15:00	Management	Management Board (PMB)	Project Management, Deliverables and Milestones, Reporting and Finances, Supervision and Secondments, Dissemination and Outreach, Preparation PSB/SAB
15:00-16:00		Supervisory Board (PSB)	Meeting/Webinar Project status, WP info, Training Programme, FAQ

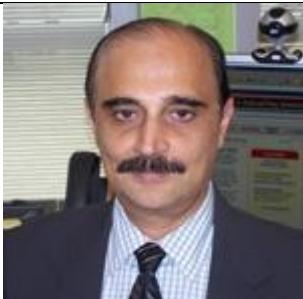
Day 5 – 22nd June 2018 - Transferable skills workshops

Theme: Generic and Transferable skills training

Attendees - ESRs

Time	Session	Speaker	Session Title
9:00-12:00		Ms. Lena Wolf	Public speaking and stage presence: Theatre-based training to present with impact (GRADE)
12:00-13:00	Lunch Break		
13:00-16:00		Ms. Lena Wolf	Continue... Public speaking and stage presence: Theatre-based training to present with impact (GRADE)

Invited Speakers



Dr. Mehul Mehta

Director, DCP I (Division of Clinical Pharmacology I), OCP (Office of Clinical Pharmacology), in CDER (Center for Drug Evaluation and Research), FDA; USA



Dr. Andrea Edginton

Associate Professor, Programmatic Assessment Officer, School of Pharmacy, University of Waterloo, Canada



Prof. Werner Weitschies

Department of Biopharmaceutics and Pharmaceutical Technology, University of Greifswald, Germany



Dr. Richard Barker

Pharmaceutical Development Biopharmaceutics, AstraZeneca, United Kingdom



Dr. Rodrigo Cristofoletti

National Health Surveillance Agency (ANVISA), Brazil



Prof. Anette Müllertz

Pharmaceutical Design and Drug Delivery, University of Copenhagen, Denmark



Dr David Turner

Simcyp Limited (A Certara Company)
Sheffield, United Kingdom



Dr Oliver Hatley

Simcyp Limited (A Certara Company)
Sheffield, United Kingdom

PEARRL Annual meeting: Networking Events

Arrival day: and location	Partici pation	Information
Saturday 16th June		
Evening 8 p.m.	ESRs only	Welcome Drinks Location to be announced
Sunday 17th June		
Morning 11am	ESRs only	Brunch at "Toffis" Berger Straße 30, 60316 Frankfurt am Main http://www.toffis.de (6,80€ all you can eat buffet breakfast, excluding drinks)
Evening 7-9 pm	All	Preconference Get-Together Fleming's Club Frankfurt (Rooftop bar) Eschenheimer Tor 2 60318 Frankfurt am Main https://www.flemings-hotels.com/hotels-residences/frankfurt/flemings-selection-hotel-frankfurt-city/restaurant
Monday 18th June		
Evening 7pm	PI and Speakers	TnT Thurn und Taxis Palais Thurn-und-Taxis-Platz 1, 60313 Frankfurt am Main https://tntpalais.com/restaurant
Evening 7pm	Only ESRs	LaserTag games Borsigallee 18 60388 Frankfurt am Main https://www.laserzone.de/de/frankfurt/die-lasertag-arena-das-spiel Dinner in Bornheim

Tuesday 19th June

Arrival day: and location	Participation	Information
Evening 7.00 pm – 10 pm	All	Conference Dinner "Sturm & Drang" Restaurant/Café-Bistro Sturm und Drang Theodor-W.-Adorno-Platz 5 (formerly Grüneburgplatz 1) 60323 Frankfurt http://cafe-sturm-und-drang.de/

Wednesday 20th June

		Individual networking
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Thursday 21st June

Afternoon 3pm	ESRs only	Dialog Museum - 90-minute tour Hanauer Landstraße 145 60314 Frankfurt am Main http://dialogmuseum.de/?lang=en
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Friday 22nd June

Evening	ESRs only	Informal get-together for those not departing Friday afternoon
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