

Second All WGs UNGAP Meeting 12th – 13th February 2019



Sofia, Bulgaria





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Word of Welcome	1
Local organizing committee	2
Program overview	3
Conference halls	5
Detailed program of the meeting	7
Poster presentations	13
Transportation to and from Sofia Airport	18
Sightseeing in Sofia	20
Participants list	24

Dear participants,

We are pleased to welcome you in Sofia, the capital of Bulgaria, for the second meeting of the European Network on Understanding Gastrointestinal Absorption-related Processes (UNGAP). We hope to sustain the high standards set by the first meeting in Leuven, Belgium, which was attended by more than 110 participants and included 19 lectures and 40+ posters by renowned experts. The scientific discussions that were initiated during the first meeting will continue in the framework of the four major challenges that UNGAP aims to address in the different working groups (WGs): differences between specific patient populations (WG1), regional differences along the gastrointestinal tract (WG2), the intraluminal behaviour of advanced formulations (WG3), and the food-drug interface (WG4). Expert talks by UNGAP members and external invited scientists will provide insight into the latest advancements on the topics of interest, whereas separate work group sessions and poster presentations will offer a platform for focused discussions on specific problems. PhD students will have the opportunity to present their work and network with top experts in their field. These activities are aimed to stimulate the cross-field dissemination of knowledge and thereby advance our understanding of drug absorption in the gut.

Keynote lectures relevant to WGs will take place in Vitosha hall on Tuesday (12th February) morning, followed by a light lunch in the poster area. The participants will then split into 4 groups for the parallel WG sessions (halls inside the hotel) and will reconvene in the afternoon for an all-WG discussion in Vitosha hall. The official conference dinner will be held in the restaurant of hotel Vitosha on Tuesday evening. On Wednesday (13th February), hot-topic presentations by all WGs will be presented in Vitosha hall.

UNGAP would not have been possible without the support of the European Cooperation in Science and Technology (COST) program, for which we are very grateful.

We hope that you will have fruitful discussions during the meeting and will enjoy your visit in Sofia!

Welcome to Sofia and to the UNGAP community!

The organizing committee

Local organizing committee



Zahari Vinarov Chair Organizing Committee



Liliya Vinarova Registration, Booklet



Fatmegyul Mustan Registration, Booklet



Savina Paunova Registration



Nelly Stanoeva Registration



Delyan Krustev Booklet



Vladimir Katev Registration



Yohan Georgiev Registration

Tuesday, 12th February

8:30 Registration

9:00 Welcome

9:15 – 12:30 Keynote lectures (All Work Groups)

Vitosha hall, outside the Hotel

12:30 – 14:00 Lunch & Poster session

Vitosha hall, outside the Hotel

14:00 – 16:00 Parallel Work Group sessions

Halls *inside* the Hotel

16:30 – 17:30 Pearls of Wisdom: discussion on "gastroretention doesn't work?"

Moderator: Prof. Clive Wilson

Vitosha hall, outside the Hotel

19:00 Official dinner, Vitosha Hotel Restaurant

Wednesday, 13th February

Venue: Vitosha Hall (outside the Hotel) all day, all WGs

8:30 – 10:00 WG1 meeting: How the differences in GI absorption of special populations impact the stages of drug product development

Chair: Dr. Katarina Vucicevic

10:15 – 11:45 WG2 meeting: Regional differences along the GI tract

Chair: Prof. Maria Vertzoni

11:45 – 12:45 Lunch & Poster session

12:45 – 14:15 WG3 meeting: Intraluminal behaviour of advanced formulations

Chair: Prof. Caitriona O'Driscoll

14:30 – 16:00 WG4 meeting: Food-drug interface

Chair: Prof. Maura Corsetti

16:00 – 16:30 General discussion and Wrap up of meeting

Prof. Christos Reppas

The main hall where most of the UNGAP meeting and events will take place is **Vitosha Conference Hall**. This hall is located in a building across the street, right next to the hotel (1-2 min walking distance). One can get there easily by exiting the hotel, turning right and walking to the building across the street, where **Vitosha Conference Hall** is located (see the map below).

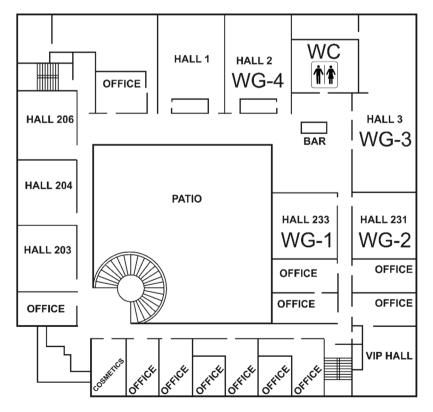
How to get there: Vitosha Hall location



Conference rooms for the parallel WG sessions (Tuesday, 12th February, after lunch)

On Tuesday (12th February) after lunch, the parallel WG sessions will take place **on the second floor of the Hotel**, which can be accessed by stairs and elevator. Signs will indicate the location of the conference rooms inside the hotel.

WG1 – Hall 233 WG2 – Hall 231 WG3 – Hall 3 WG4 – Hall 2



Tuesday 12th February (morning session)

Vitosha Conference Hall (outside the hotel)					
8:30 – 17:00	Registration				
9:00 – 9:15	Welcome and introduction Prof. Patrick Augustijns, Prof. Peter Kralchevsky				
9:15 – 10:00	Effect of food structure on nutrients release and lipid digestion Dr. Myriam Grundy (Reading University; Infogest)				
10:00 – 10:45	Administering oral drug products in specific populations <i>Dr. Hannah Batchelor</i> (School of Pharmacy, University of Birmingham)				
10:45 – 11:00	Coffee break				
11:00 – 11:45	The challenges and opportunities of drug development for multimorbid patient populations <i>Prof. Sven Stegemann</i> (Graz University of Technology)				
11:45 – 12:30	Challenges and future perspectives of amorphous solid dispersions Prof. Guy Van Den Mooter (University of Leuven)				
12:30 - 14:00	Light Lunch & poster session (Vitosha Hall) "Meet the expert" lunch for PhD students				

Tuesday 12th February (afternoon session)

Parallel WG sessions:					
WG1, Hall 233 WG3, Hall 3					
WG2, H	Hall 231	WG4, Hall 2			
	These halls are	inside the hotel!			
14:00 – 14:05	Introduction by	WG leads			
14:05 – 15:05		y PhD students; (WG1, WG2, WG3)			
15:05 – 15:35	 Small group discussions related to the WG future: > Best practices > Short-term scientific missions (STSMs) > Research collaborations > New project proposals 				
15:35 – 15:50	5:35 – 15:50 Presentation of the results of the small group discussions				
15:50 – 16:00	50 – 16:00 Preparation of WG summary to be presented on Wednesday				

All-WG session						
	Vitosha Hall, outside the hotel					
16:00 – 16:30	Coffee break					
16:30 - 17:30	Pearls of Wisdom: discussion on "gastro- retention doesn't work?" Moderator. Prof. Clive Wilson					
19:00	Official dinner Vitosha Hotel Restaurant					

Wednesday 13th February (morning session)

<u>All-WG session</u> Vitosha Hall (outside the hotel)					
WG1 meeting: How the differences in GI absorption of special populations impact the stages of drug product development Chair: Dr Katarina Vucicevic					
	Beyond the pill: How the differences in GI absorption of special age populations impact the drug product design Dr Mine Orlu, School of Pharmacy - UCL				
8:30 - 10:00	Beyond the pill: How the differences in GI absorption of special age populations impact the drug exposure and response Dr Katarina Vucicevic, Faculty of Pharmacy, University of Belgrade				
	Update on current and future WG activities				
10:00 – 10:15	Coffee break				
WG2 Mee	ting: Regional differences along the GI tract				
	Chair: Prof. Maria Vertzoni				
10:15 – 11:45	Physicochemical characteristics, viscosity, and volumes along the GI lumen of humans vs. dogs and the usefulness of canine data in the development of oral drug products for humans and for dogs <i>Prof. Christos Reppas</i> , Faculty of pharmacy, University of Athens				
	Regional intestinal permeability in humans: implications for modified-release dosage forms Dr. David Dahlgren, Uppsala University				
	Update on current and future WG activities				

Wednesday 13th February (afternoon session)

11:45 – 12:45	Light Lunch & poster session							
	"Meet the expert" lunch for PhD students							
WG3 Meetir	WG3 Meeting: Intraluminal behavior of advanced formulations							
	Chair: Prof. Caitriona O'Driscoll							
The impact of excipient-bile interactions on the solubility of poorly-water soluble drugs Dr. Zahari Vinarov, Faculty of Chemistry and Pharmac Sofia University								
12:45 – 14:15	Oral protein delivery-learning from the TRANSINT EU Consortium Dr. Matilde Duran							
	Update on current and future WG activities							
14:15 – 14:30	Coffee break							
	WG4 Meeting: Food-drug interface							
	Chair: Prof. Maura Corsetti							
	The utility of a pig model for predicting food dependent oral bioavailability in humans <i>Dr. Brendan Griffin</i>							
14:30 – 16:00	What do we know about the gut response to a meal in humans Prof. Maura Corsetti							
Update on current and future WG activities								
16:00 – 16:30	General discussion and meeting wrap up Prof. Christos Reppas							



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No.	Firstname	Lastname	WG	Poster title			
	WG1: Differences between specific patient populations						
1	Marija Jovanovic WG1 Application of population pharmacokinetic modeling approach in the assessment of drug exposure in special patient populations						
2	Marton	Kiss	WG1	Drug dosing optimisation using pediatric intestinal tissue			
3	Malgorzata	Sznitowska	WG1	Oral paediatric antibiotics - the need for better pharmaceutical care			
4	Maiara	Montanha	WG1	Reduced oral bioavailability of Amoxicillin tablets compared to suspensions in RYGB bariatric subjects			
5	Anna	Stachowiak	WG1	The assessment of the pharmacokinetics of tramadol and its active metabolite (O-desmethyltramadol) in extremely obese patients.			
6	Erik	Wollmer	WG1	A novel patient-specific in vitro drug release model incorporating physiological features relevant to oral drug absorption in Parkinson patients			
7	Lisa	Freerks	WG1	A toolbox for simulating gastrointestinal conditions in children: I. Media to simulate typical paediatric breakfasts			
40	Maja	Kristensen	WG1	Application of microcontainers for targeting intestinal lesions found in inflammatory bowel disease			

	WG2: Regional differences along the gastrointestinal tract					
8	J. Arturo	García- Horsman	WG2	Animal SPECT/CT and drug absorption. (Preliminary)		
9	Elena	Toader	WG2	Drug absorption and therapeutic implications in inflammatory bowel disease		
10	Sarinj	Fattah	WG2	Effect of a stimulated intestinal fluid on permeability of [3H]-octreotide across human and rat intestinal tissue		
11	Christian	Jede	WG2	Implementation of biorelevant bicarbonate buffer in a GI transfer model		
12	Fiona	McCartney	WG2	Investigation of different intestinal permeation enhancers ex vivo and in vivo		
13	Mare	Oja	WG2	Logistic classification models for pH-permeability profile to improve prediction of absorption in gastrointestinal tract		
14	Khaled	Heissam	WG2	Measuring fasted state gastric motility before and after a standard BA/BE 8 oz drink of water: validation of new MRI imaging protocols against concomitant perfused manometry in healthy participants		
15	Margherita	Falavigna	WG2	Mucus-PVPA: an in vitro permeability screening tool for the investigation of intestinal drug absorption		

16	Glenn	Lemmens	WG2	Pharmacokinetic disposition of COXIBS for the prevention/treatment of colorectal cancer	
17	Marlies	Braeckmans	WG2	The influence of gastric motility on intraluminal drug behavior	
43	Natashia	Larsen	WG2	Achieving targeted release of freeze-dried probiotic strains by granulation, extrusion, spheronization and fluid bed coating	
		NG3: Intralu	minal	behaviour of advanced formulations	
18	Caroline	Alvebratt	WG3	A Dissolution-Digestion-Permeation Assay to Investigate the Performance of Advanced Drug Delivery Systems	
19	Grzegorz	Garbacz	WG3	Bio-predictive dissolution testing of nicotinic acid	
20	Mette Sloth	Bohsen	WG3	Co-existing colloidal phases of human duodenal aspirates: Intraindividual fluctuations and interindividual variability in relation to molecular composition	
21	Vladimir	Katev	WG3	Albendazole Solution Formulation via Vesicle-To-Micelle Transition of Phospholipid-Surfactant Aggregates	
22	Ann-Christin	Jacobsen	WG3	High-throughput dissolution/permeation screening of enabling formulations: Testing a novel two-compartment microtiter plate approach	
23	Linas	Petkevičius	WG3	Mathematical modelling of drug release from multi-layer capsules	

24	Niklas	Koehl	WG3	New insights into using lipid based suspensions for 'brick dust' molecules: case study of Nilotinib	
25	Jana	Kubackova	WG3	Oral delivery of oligonucleotides for local treatment of inflammatory bowel disease	
26	Gaohua	Lu	WG3	PBPK Application Examples	
27	Jadwiga	Paszkowska	WG3	Predictive dissolution testing - novel methodology	
28	Flavia	Laffleur	WG3	Smart and advanced polymeric formulations	
29	Janneke	Keemink	WG3	The in vitro lipolysis-permeation assay predicts in vivo performance of carvedilol administered with lipids in dogs	
39	Jens	Ceulemans	WG3	Early development of a poorly-soluble oncology drug candidate: proceeding with a conventional or enabling formulation?	
44	Georgia	Tsakiridou	WG3	A simple rheological method for polymer selection in amorphous drug solid dispersions	
			WG4:	The food-drug interface	
30	Radić	Kristina	WG4	Comparison of different in vitro tools for prediction of intestinal permeability of olive derived nutraceuticals	
31	Annalisa	Maruca	WG4	Drug-food interactions evaluated by computational methods	

33	Hulya	Buyukkestelli	WG4	Effect of food on oral drug absorption and bioavailability	
34	Raffaella	Catalano	WG4	Food-drug interactions evaluated by computational methods	
35	Tjaša	Felicijan	WG4	Glass-bead flow through dissolution system: design and applicability	
36	Visnja	Stepanic	WG4	In silico predictions of ADME/Tox features of herbicides	
37	Simone	Hansmann	WG4	Integrating <i>in vitro</i> data into an <i>in silico</i> model to predict the influence of formulation changes: a Merck case example	
38	Aleksandar	Cvetkovski	WG4	Screening for nutraceutical-drug interactions toward the noncovalent interactions of their solid binary systems (Case study on Piperine)	
41	James	Butler	WG4	How effective are biopharmaceutics classification systems (BCS, DCS, BDDCS) at predicting food effects?	
42	Michael	Grimm	WG4	The application of MRI to study gastric emptying in the fed state	

Transportation to and from Sofia Airport

Inter-Terminal Transfer



Sofia Airport provides free-of-charge transportation between Terminal 1 and Terminal 2 at every 30 minutes between 07:00 and 19:00 local time, with no intermediate stops on the route. The shuttle bus stops in front of both terminals are indicated with signage and marking on the road pavement.

Transportation from Terminal 2 to Park Hotel Vitosha via Metro

The metro station at Sofia Airport is located in the eastern part of Terminal 2. You can reach it by following the floor markings in blue at the public area of Terminal 2. The nearest stop to your Hotel is GM Dimitrov, and after that you have a 15 min walk to the hotel.



Transportation to Park Hotel Vitosha organized by the hotel

Airport-to-hotel transfer is included in the room price for participants that have booked a room in hotel Vitosha by sending an e-mail to <u>reservations@vitoshaparkhotel.com</u> and have mentioned the booking reference "COST-UNGAP 11-13.02.2019" in the body text of the e-mail.

Note that airport-to-hotel transfer will be provided only to participants who have sent their flight information to <u>reservations@vitoshaparkhotel.com</u> and have received official confirmation for the transfer from the hotel staff.

Getting to and from the airport by Taxi

For your comfort and safety, we recommend the services of the taxi operator OK Supertrans AD as contractual partner of Sofia Airport. You can request the service at the offices of **OK Supertrans** in the Arrivals of Terminal 1 and Terminal 2. And the floor markings in yellow will lead you to the taxi stand area.



+359 2 973 2121 www.oktaxi.net

IMPORTANT!

We recommend that you do not use taxi services offered outside the office of the taxi operator or in front of the terminal to avoid the risk of abuse.

When you are checking out of the Hotel and heading to the Airport, you can ask the Hotel Reception to call you a taxi.

The cost of a Taxi should be under 15 Levs BGN (7.50 EUR) *1 EUR = 2 Bulgarian Levs*

For more transportation options to and from the Airport, you can check: https://www.sofia-airport.bg/en/passenger

Please note that the costs for transport by taxi are <u>NOT REFUNDED</u> by COST, unless in special circumstances (see COST Vademecum)

Sightseeing in Sofia

The beginning of your tour of Sofia starts at the Metro station "Sofia University Kliment Ohridski". You can go there by going to Metro station "GM Dimitrov" (see page 28) and getting on a train for "Obelya" for 3 stops. Also a Taxi is always an option, the cost should be under 10 BGN (5 EUR).

When you get there the first thing you will see the main building of Sofia University.



The University was founded in 1888 and was originally named after the brothers Evlogi and Hristo Georgiev who donated the land and funds for the construction of the university building. Their statues are seated outside the main entrance. The international design competition was originally won by Henri Breansson in 1907, his designs were however later modified by Yordan Milanov. Nowadays only part of the actual university campus is based here, with many faculties located around the city.

1. Then you will head to Alexander Nevsky Cathedral

Named after Alexander Nevski, a Russian Tsar who saved Russia from invading Swedish troops in 1240 and the patron saint of Tsar Alexander II, who was also referred to as Bulgaria's Tsar Osvoboditel (Liberator), since it was his troops that finally brought about Bulgaria's liberation from Ottoman rule. Some of Russia and Bulgaria's best artists of the time worked on the interior



with its five aisles and three altars. Built between 1904-1912 in the Neo Byzantine style, typical for Russian churches in the 19th century, the cathedral is 76 metres long and 53 metres wide and is said to hold up to 7000 people. The belfry is 52 metres high and houses 12 bells. <u>Working hours: 7:00 – 18:00</u>

2. Your next stop is Tsar Osvoboditel (Liberator) Monument and the Parliament

This fine bronze statue portrays the Russian Tsar Alexander II on horseback and is a gesture of gratitude to the Russian Tsar and his troops. In front of the bronze statue is the building of the National Assembly.



3. On your way to Metro station "Serdika" you will pass through a couple of landmarks.

The Russian Church

This small decorative church with its golden onion domes was built between 1912 and 1914, (by many of the same workers from the nearby Nevski Cathedral) to appease a Russian diplomat afraid to worship in Bulgarian churches. The church is named after St. Nikolai 'the miracle maker'. To this day wishes are written on slips of paper and placed in the wooden box by the white marble sarcophagus of Bishop Serafim (1881 – 1950), who is buried in the crypt.



The Bulgarian Presidency

Today the Bulgarian president has his official chambers here facing the archaeological museum and his guard of honor has been photographed by many a tourist. The guards change every hour on the hour but if you want the full pomp and ceremony be here on the first Wednesday of the month at 12:00 when you can see the official changing of the guards complete with music, shouting and weapon brandishing.



Complex Ancient Serdika

The Church of St George is an Early Christian red brick rotunda that is considered the oldest building in Sofia, the capital of Bulgaria. It is situated behind the Sheraton Hotel, amid remains of the ancient town of Serdica.

Built by the Romans in the 4th century, it is a cylindrical domed structure built on a square base. It is believed that it was built on the site of a pagan temple, though the

original purpose of the building was for public use. The building is famous for the 12th-, 13th- and 14th-century frescoes inside the central dome. Three layers of frescoes have been discovered, the earliest dating back to the 10th century. Magnificent frescoes of 22 prophets over 2 metres tall crown the dome. Painted over during the Ottoman period, when the building was used as a mosque, these frescoes were only uncovered and restored in the 20th century.

Saint Sofia Statue

Towering above the intersection of Maria Louisa Blvd and Todor Alexandrov Blvd in the commercial heart of the city, Sofia was erected in 2001 - not without some controversy - replacing Lenin's monument, which was removed from the same spot at the time of the democratic changes. Eight meters in height, the copper and bronze statue by the sculptor Georgi Chapkanov, stands on a 16 meter high

pedestal. Adorned with the symbols of power (crown), fame (wreath) and wisdom (owl), the crown is also a reference to the Goddess of Fate – Tjuhe, inspired by the old emblem of Sofia dating back to 1900.

4. Your last stop on the tour is St. Kyriaki Church (St. Nedelya)

From here you can explore the different cafes and restaurants on Vitosha Boulevard, which is the main pedestrian street in the heart of Sofia. If you want to see more of Sofia, at the end of Vitosha Boulevard there is a park across the street in which you can find the National Palace of Culture.

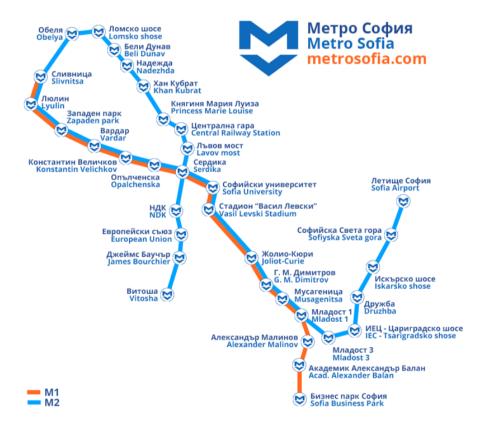
To go back to the Hotel you can get a Metro from Serdica Station Line 1 to Mladost, your stop is the 4th – GM Dimitrov Station.





To get a Metro from the National Palace of Culture, go to NDK station, which is at the intersection where you crossed from boulevard Vitosha to the park, and get a train to Obelya for one stop (Serdica Station), this is Line 2 of the Metro, so you will have to transfer to Line 1 and get a train to Mladost for four stops to GM Dimitrov Station.

The price of the Metro is 1.60 Levs, tickets can be bought at the vending machines at every entrance or at the cashiers boot next to the barriers. Also you can buy a daily pass from the cashier for 4 Levs.



No.	Last name	First name	E-mail	Affiliation	Country
1	Alsenz	Jochem	Jochem.Alsenz@roche.com	F. Hoffmann-La Roche AG	Switzerland
2	Alvebratt	Caroline	caroline.alvebratt@farmaci.uu.se	Uppsala University	Sweden
3	Augustijns	Patrick	patrick.augustijns@kuleuven.be	University of Leuven	Belgium
4	Batchelor	Hannah	h.k.batchelor@bham.ac.uk	University of Birmingham	UK
5	Beloqui Garcia	Ana	ana.beloqui@uclouvain.be	University of Leuven	Belgium
6	Bermejo Sanz	Maria del Val	mbermejo@goumh.umh.es	Universidad Miguel Hernandez	Spain
7	Bogataj	Marija	marija.bogataj@ffa.uni-lj.si	University of Ljubljana	Slovenia
8	Bogdanova	Svetla	svbogdanova@gmail.com	Sofia University	Bulgaria
9	Bohsen	Mette Sloth	bohsen@sdu.dk	University of Southern Denmark	Denmark
10	Boltnarová	Barbora	boltnarb@faf.cuni.cz	Charles University	Czech Republic
11	Braeckmans	Marlies	marlies.braeckmans@kuleuven.be	University of Leuven	Belgium
12	Brandl	Martin	mmb@sdu.dk	University of Southern Denmark	Denmark
13	Butler	James	james.m.butler@gsk.com	GlaxoSmithKline	UK
14	Catalano	Raffaella	catalano@unicz.it	University Magna Graecia of Catanzaro	Italy
15	Ceulemans	Jens	jceulem3@its.jnj.com	Janssen Pharmaceutica	Belgium
16	Code	Christian	christian.code@sund.ku.dk	University of Copenhagen	Denmark
17	Corsetti	Maura	maura.corsetti@nottingham.ac.uk	University of Nottingham	UK
18	Cvetkovski	Aleksandar	aleksandar.cvetkovski@ugd.edu.mk	Goce Delcev University	Macedonia, FYR
19	Dahlgren	David	david.dahlgren@farmaci.uu.se	Uppsala University	Sweden
20	De Wildt	Saskia	Saskia.deWildt@radboudumc.nl	Radboud UMC	The Netherlands

21	Denkov	Nikolai	nd@lcpe.uni-sofia.bg	Sofia University	Bulgaria
22	Devold	Tove	tovede@nmbu.no	Norwegian University of Life Sciences	Norway
23	Dou	Liu	ucnvdou@ucl.ac.uk	UCL School of Pharmacy	UK
24	Dupont	Didier	didier.dupont@inra.fr	INRA, STLO	France
25	Durán-Lobato	Matilde	matilde.duran.lobato@gmail.com	Universidad de Santiago de Compostela	Spain
26	El	Sedef Nehir	sedef.el@ege.edu.tr	Ege University	Turkey
27	Falavigna	Margherita	margherita.falavigna@uit.no	UiT The Arctic University of Norway	Norway
28	Fattah	Sarinj	sarinj.fattah@ucd.ie	University College Dublin	Ireland
29	Felicijan	Tjaša	tjasa.felicijan@ffa.uni-lj.si	University of Ljubljana	Slovenia
30	Flaten	Gøril Eide	Goril.flaten@uit.no	UiT The Arctic University of Norway	Norway
31	Fotaki	Nikoletta	n.fotaki@bath.ac.uk	University of Bath	UK
32	Freerks	Lisa	lisa.freerks@uni-greifswald.de	University of Greifswald	Germany
33	Garbacz	Grzegorz	g.garbacz@physiolution.pl	Physiolution	Poland
34	García-Horsman	J. Arturo	arturo.garcia@helsinki.fi	Univerisity of Helsinki	Finland
35	Gavins	Francesca	Francesca.gavins.13@ucl.ac.uk	UCL School of Pharmacy	UK
36	Georgiev	Yohan	j.georgiev94@abv.bg	Sofia University	Bulgaria
37	Gjorgieva Ackova	Darinka	darinka.gorgieva@ugd.edu.mk	Goce Delcev University	Macedonia, FYR
38	Griffin	Brendan	brendan.griffin@ucc.ie	University College Cork	Ireland
39	Grimm	Michael	grimmm@uni-greifswald.de	University of Greifswald	Germany
40	Grundy	Myriam	m.m.grundy@reading.ac.uk	University of Reading	UK

				MIGAL – Galilee	
41	Gutman	Roee	roeeg@migal.org.il	Research Institute	Israel
42	Hansmann	Simone	Simone.hansmann@merckgroup.com	Merck KGaA	Germany
43	Heissam	khaled	khaled.heissam@nottingham.ac.uk	University of Nottingham	UK
44	Holas	Ondrej	ondrej.holas@faf.cuni.cz	Charles University	Czech Republic
45	Holm	Rene	rholm@its.jnj.com	Janssen Pharmaceutica	Belgium
46	Holmstock	Nico	nholmsto@its.jnj.com	Janssen Pharmaceutica	Belgium
47	llyasoglu Buyukkestelli	Hulya	hulyailyasoglu@gmail.com	Ege University	Turkey
48	Jacobsen	Ann-Christin	acj@sdu.dk	University of Southern Denmark	Denmark
49	Jede	Christian	Christian.jede@external.merckgroup.com	Merck KGaA	Germany
50	Jovanović	Marija	marijaj@pharmacy.bg.ac.rs	University of Belgrade	Serbia
51	Kalyan Chirumamilla	Siri	jordan.thomas@certara.com	Certara UK	India
52	Káňová	Kristýna	astriik@gmail.com	Institute of Microbiology, Czech Academy of Science	Czech republic
53	Katev	Vladimir	vk@lcpe.uni-sofia.bg	Sofia University	Bulgaria
54	Keemink	Janneke	janneke.keemink@farmaci.uu.se	Uppsala University	Sweden
55	Kersiene	Milda	milda.kersiene@ktu.lt	Kaunas University of Technology	Lithuania
56	Kirilov	Bogdan	Bogdan.Kirilov@bda.bg	Bulgarian Drug Agency	Bulgaria
57	Kiss	Marton	marton.kiss@radboudumc.nl	Radboud UMC	The Netherlands
58	Klein	Sandra	Sandra.Klein@uni-greifswald.de	University of Greifswald	GErmany
59	Koehl	Niklas	niklas.koehl@ucc.ie	University College Cork	Ireland

60	Koskinen	Mikko	mikko.koskinen@orionpharma.com	Orion Pharma	Finland
			0 1		
61	Koziolek	Mirko Maja	mirko.koziolek@uni-greifswald.de	University of Greifswald	Germany
62	Kristensen	Nørgaard	maja.kristensen@sund.ku.dk	University of Copenhagen	Denmark
63	Kristl	Albin	kristla@ffa.uni-lj,si	University of Ljubljana	Slovenia
64	Krustev	Delyan	Dk@lcpe.uni-sofia.bg	Sofia University	Bulgaria
65	Kubačková	Jana	kubackja@faf.cuni.cz	Charles University	Czech Republic
66	Kuentz	Martin	martin.kuentz@fhnw.ch	FHNW, School of Life Sciences	Switzerland
67	Laffleur	Flavia	Flavia.Laffleur@uibk.ac.at	University of Innsbruck	Austria
68	Lemmens	Glenn	glenn.lemmens@kuleuven.be	University of Leuven	Belgium
69	Lu	Gaohua	gaohua.x.lu@gsk.com	GSK	UK
70	Madla	Christine	christine.madla.16@ucl.ac.uk	UCL School of Pharmacy	UK
71	Maran	Uko	uko.maran@ut.ee	University of Tartu	Estonia
72	Maruca	Annalisa	maruca@unicz.it	University Magna Graecia of Catanzaro	Italy
73	Matias	Ana	amatias@ibet.pt	iBET	Portugal
74	Matilainen	Laura	laura.matilainen@orionpharma.com	Orion Pharma	Finland
75	Matos	Melanie	melanie.matos@ibet.pt	iBET	Portugal
76	McCartney	Fiona	fiona.mccartney@ucd.ie	University College Dublin	Ireland
77	Melendez-Martinez	Antonio	ajmelendez@us.es	Universidad de Sevilla	Spain
78	Miljus	Goran	goranm@inep.co.rs	INEP Institute, University of Belgrade	Serbia
79	Moens	Frédéric	frederic.moens@prodigest.eu	ProDigest	Belgium
80	Montanha	Maiara	maiara.teofilos@gmail.com	University of Lisbon	Portugal

81	Mullertz	Anette	anette.mullertz@sund.ku.dk	University of Copenhagen	Denmark
82	Mustan	Fatmegyul	fm@lcpe.uni-sofia.bg	Sofia University	Bulgaria
83	O'Driscoll	Caitriona	caitriona.odriscoll@ucc.ie	University College Cork	Ireland
84	Oja	Mare	mare.oja@ut.ee	University of Tartu	Estonia
85	Orlu	Mine	m.orlu@ucl.ac.uk	UCL School of Pharmacy	UK
86	Pappinen	Sari	sari.pappinen@orionpharma.com	Orion Pharma	Finland
87	Paszkowska	Jadwiga	j.paszkowska@physiolution.pl	Physiolution	Poland
88	Paunova	Savina	sp@lcpe.uni-sofia.bg	Sofia university	Bulgaria
89	Petkevičius	Linas	linas.petkevicius@mif.vu.lt	Vilnius University	Lithuania
90	Pinto	Joana	joana.pinto@rcpe.at	RCPE	Austria
91	Ponchel	Gilles	gilles.ponchel@u-psud.fr	Université Paris-Sud Université Paris Saclay	France
92	Rades	Thomas	thomas.rades@sund.ku.dk	University of Copenhagen	Denmark
93	Radić	Kristina	kradic@pharma.hr	University of Zagreb	Croatia
94	Reppas	Christos	reppas@pharm.uoa.gr	National and Kapodistrian University of Athens	Greece
95	Ruiz Picazo	Alejandro	alejandroruizpicazo@gmail.com	Miguel Hernandez University	Spain
96	Sassene	Philip	pjsa@novonordisk.com	Novo Nordisk	Denmark
97	Semjonov	Kristian	kristian.semjonov@gmail.com	University of Tartu	Estonia
98	Skupin-Mrugalska	Paulina	p_skupin@wp.pl	Poznan University of Medical Sciences	Poland
99	Smilkov	Katarina	katarina.smilkov@ugd.edu.mk	Goce Delcev University	Macedonia, FYR
100	Stachowiak	Anna	stachowiak.an@gmail.com	Poznan University of Medical Sciences	Poland

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101	Stanoeva	Nelly	ns@lcpe.uni-sofia.bg	Sofia University	Bulgaria
102	Stepanic	Visnja	stepanic@irb.hr	Rudjer Boskovic Institute	Croatia
103	Sznitowska	Malgorzata	msznito@gumed.edu.pl	Medical University of Gdansk	Poland
104	Tcholakova	Slavka	sc@lcpe.uni-sofia.bg	Sofia University	Bulgaria
105	Tekin	Hamdi	hamditekin@arel.edu.tr	Istanbul Arel University	Turkey
106	Teleki	Alexandra	alexandra.teleki@farmaci.uu.se	Uppsala University	Sweden
107	Thijs	Tim	tim.thijs@kuleuven.be	University of Leuven	Belgium
108	Toader	Elena	toader.elena@yahoo.com	University of Medicine and Pharmacy	Romania
109	Tran	Thuy	thu-thuy.tran@servier.com	Technologie Servier	France
110	Tsakridou	Georgia	gtsakiridou@pharmathen.com	Pharmathen S/A and National and Kapodistrian University of Athens	Greece
111	Uslu	Mehmet Emin	m.eminuslu@mail.com	Manisa Celal Bayar University	Turkey
112	Valentová	Kateřina	kata.valentova@email.cz	Institute of Microbiology of the Czech Academy of Sciences	Czech Republic
113	Van den Mooter	Guy	guy.vandenmooter@kuleuven.be	University of Leuven	Belgium
114	Vertzoni	Maria	vertzoni@pharm.uoa.gr	National and Kapodistrian University of Athens	Greece
115	Vinarov	Zahari	zv@dce.uni-sofia.bg	Sofia University	Bulgaria
116	Vinarova	Liliya	li@dce.uni-sofia.bg	Sofia University	Bulgaria

30

117	Vitali Čepo	Dubravka	dvitali@pharma.hr	University of Zagreb	Croatia
118	Vucicevic	Katarina	kacav@pharmacy.bg.ac.rs	University of Belgrade	Serbia
119	Wilson	Clive	clivegwilson@mac.com	Strathclyde University	UK
120	Wolf	Julian Dominik	j.wolf@thiomatrix.com	ThioMatrix GmbH	Austria
121	Wollmer	Erik	erik.wollmer@uni-greifswald.de	University Greifswald	Germany
122	Yde Larsen	Natashia	natashia.larsen@sund.ku.dk	University of Copenhagen	Denmark





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