



**6° DEEP General Assembly
6° Scientific Coordination Meeting
4° Ethics Board Meeting
3° Open Meeting**

Hotel Tirana International
May 18th-20th 2015 - Tirana, Albania

AGENDA

Day 1, May 18th, 2015

08.30	REGISTRATION	
	OPENING SESSION	
08.45	Welcome address	A. Godo D. Bonifazi
09.00	SESSION I PHARMACOKINETIC EVALUATIONS Chair: <i>A. Ceci</i>	
	DEEP-1 trial conduction and results	G. C. Del Vecchio
	Comparison of results with existing data	M. Spino
	Model-based evaluation of chelation therapy	O. Della Pasqua
	Planning the PK Evaluation in the DEEP-2 clinical trial	B. Pantaleo
11.00	COFFEE BREAK	
11.30	SESSION II STATISTICS AND ECONOMICS Chair: <i>M. Spino</i>	
	DEEP-2 Statistical Plan	P. Baiardi
	Report on current and future market and budget impact	F. Bonifazi
	Pharmacoeconomics and HTA report	P. Folino
13.00	LUNCH	



14.00	SESSION III – OPEN MEETING CLINICAL RESEARCH IN ALBANIA Chair: <i>A. Godo – A. Manastirliu</i>	
	The Albanian Clinical Trial Regulation: first step in fostering clinical research and innovation	K. Rjepaj
	Critical issues in developing paediatric trials	G. Kuli-Lito
	Paediatric pharmaceutical formulation in rare diseases	C. D. Altomare
	Collaborative efforts in medicine and research	V. Dattoli
	The role of Albanian Universities in supporting clinical research: expectations and needs	A. Como
	International Cooperation: Universities of Tor Vergata and Buon Consiglio	A. Brancati
	CVBF: a Contract Research Organization for GCP clinical trials in Albania	S. Alvergna
	Medical Education in Albania: Challenges and Opportunities	E. Shehu
16.00	DISCUSSION	
16.30	COFFEE BREAK	



	SESSION IV – OPEN MEETING	
17.00	NETWORKS AND PROJECTS IN A GLOBAL CONTEXT Chair: <i>A. Altavilla – D. Bonifazi</i>	
	Proposal of a new European Research Infrastructure for Paediatric Clinical Trials (EPCT-RI)	A. Ceci
	Paediatric studies to reduce the off-label use	P. Baiardi
	DEEP-2 Study in Albania	M. Kreka
	Pharmacoepidemiology from Global to Local	I. Wong
	Participating in an international research network: the experience of Mother Teresa University Hospital in the GAPP Project	A. Hoxha
	Ethics and Paediatrics in light of the New European Regulation	V. Giannuzzi
	Laboratory Good Standards and SOPs for clinical research: the DEEP experience	E. Refatllari
	European Projects in Cooperation with the Mediterranean countries: the Egyptian Experience	A. El-Beshlawy
19.00	DISCUSSION	
19.30	END OF THE MEETING	



Day 2, May 19th, 2015

9.00	SESSION V - ETHICS BOARD MEETING Chair: <i>L. Brunetta</i>	
	Research in younger patients and other issues in Cyprus	G. Papanikolaou
	How to export blood samples from Egypt	L. Ragab
	Material and procedure for the information consent and assent in UK	H. Devlieger
	Supply of deferiprone 80 mg/ml after the DEEP-2 trial: regulatory and ethical aspects	J. Connelly
11.00	COFFEE BREAK	
11.30	SESSION VI – INVESTIGATOR MEETING DEEP-2 THE SAFETY-EFFICACY CLINICAL TRIAL * Chair: <i>A. Maggio</i>	
	DEEP-2 Study Protocol and the experience of Italian centres	M. Casale
	DEEP-2 Study in Egypt	M. El-Tagui
	DEEP-2 Study in Greece	A. Kattamis
	DEEP-2 Study in Cyprus	S. Christou
	Assuring Clinical Research Quality	S. Morgagni
13.30	LUNCH	



14:30	SESSION VII DEEP-2 EMERGING ISSUES <i>Chair: A. El-Beshlawy</i>	
	Patient recruitment plan: critical point for the success of the clinical trial	D. Bonifazi
	The FERRISCAN Protocol for the Evaluation of Liver and Cardiac Hemosiderosis used for the DEEP II Project	S. Gotsis
	First feedback on the subjects safety from DSMC	S. Fattoum
	Overview on the study: progresses and open issues	A. Ceci
16.30	COFFEE BREAK	
17:00	SESSION VIII DEEP-2 CRAs TRAINING	
	Structure and content of site visit reports	S. Morgagni
	Document collection and transmission to TMF responsible	S. Morgagni
	Handling of critical issues	S. Morgagni
19.00	END OF THE MEETING	

* Individual training sessions on GCP, e-CRF and drug management will be available during the Meeting.



Day 3, May 20th, 2015

	SESSION IX	
09:00	DEEP-3 LONG-TERM SAFETY STUDY *	
	<i>Chair: C. Putti</i>	
	Overview on DEEP-3: progresses and open issues	M. Felisi
	ADR Assessment	S. Botzenhardt
	Updates from Cairo: More than one hundred patients evaluated	M. Ghamrawy
10.30	COFFEE BREAK	
11.00	DEEP GENERAL ASSEMBLY	
	<i>Chair: E. Nastas</i>	
	Towards the review of the project committed by the EC: next steps and timelines	A. Ceci
	A critical evaluation of the deliverables submitted	M. Casale
	Dissemination of the project results	M. Lupo
	New budget approval	D. Bonifazi
13.00	END OF THE MEETING	

* Individual training sessions on e-CRF will be available during the Meeting.