



**GAPP General Assembly**  
**June 30<sup>th</sup> - July 1<sup>st</sup>, 2016**  
**Erasmus MC**  
Wijtemaweg 80, 3015 CN - Rotterdam

**AGENDA**

**Day 1, Thursday June 30<sup>th</sup>, 2016**

13.00	<b>REGISTRATION</b>	
13.30	<b>OPENING SESSION</b>	
	Welcome address	D. Tibboel
	Meeting Objectives	A. Ceci
14.00	<b>SESSION I - CLINICAL STUDIES update</b> <i>Chair: D. Tibboel</i>	
	WP5: Gabapentin new liquid formulation specifications	M. Gentile
	WP5: Gabapentin Market Analysis and HTA	F. Bonifazi
	WP7: GABA-1 final protocol presentation and patient eligibility	F. Kaguelidou
	WP8: GABA-2 final protocol presentation and patient eligibility	S. De Wildt
	WP3: GABA-1 and GABA-2 submission update and study initiation timings	L. Tagliavacca
	WP9: GABA-3 study presentation	O. Della Pasqua
17.00	<b>COFFE BREAK</b>	
17.30	<b>SESSION II - GAPP General Assembly</b> <i>Chair: D. Bonifazi</i>	
	Project status update	L. Mangiarini
	Amendment to the Grant Agreement and to the Consortium Agreement	V. Lomonaco
	GAPP project dissemination activities and publications	M. Lupo
19.00	<b>END OF THE WORKING DAY</b>	
20.00	<b>DINNER</b>	



## Day 2, Friday July 1<sup>st</sup>, 2016

08.15	<b>REGISTRATION</b>	
08.30	<b>SESSION III – GABA-1 Study management procedures</b> <i>Chair: L. Mangiarini</i>	
	Study Procedure Manual presentation	
	<ul style="list-style-type: none"> <li>• Consent/Assent</li> <li>• Patient screening</li> <li>• Randomisation</li> <li>• Pain assessment</li> <li>• Patient diary</li> <li>• Drug titration</li> <li>• Blood sampling and processing</li> <li>• SAE handling/Pharmacovigilance</li> </ul>	<p>L. Tagliavacca F. Kaguelidou J. van Rosmalen F. Kaguelidou F. Kaguelidou P. Healy P. Healy C. Manfredi</p>
	Discussion on site-specific requirements	ALL
11.00	<b>COFFEE BREAK</b>	
11:30	<b>SESSION IV – GABA-1 Study enablers</b> <i>Chair: F. Kaguelidou</i>	
	Good Clinical Practice Training Course presentation	M. Lupo
	Trial Management and Monitoring Plan	D. Bonifazi
	GABA-1 eCRF Presentation	A. Centonze
13.00	<b>LUNCH</b>	
14.00	<b>SESSION V – GABA-1 CRF simulation</b> <i>Chair: T. M. van der Zanden</i>	
	Patient inclusion simulation	T. G. de Leeuw A. Centonze
	Questions and answers	ALL
15.00	<b>FINAL REMARKS</b>	D. Tibboel
15.30	<b>END OF THE MEETING</b>	