

Model-Informed Drug Development in Cardiac Safety
18-22 January 2016, AstraZeneca, Mölndal

Time	Monday 18 Jan	Tuesday 19 Jan	Wednesday 20 Jan	Thursday 21 Jan	Friday 22 Jan
8					
	Course intro	Repository (CK)	Presentation of results	Cont' Importance of cardiac safety in drug development - preclinical evaluation (CD/CP)	Regulatory considerations for cardiac safety in drug development (CD/CP)
9	DDMore Overview (CK)				
	Coffee/Tea Break	Coffee/Tea Break	Coffee/Tea Break	Coffee/Tea Break	Coffee/Tea Break
10	MCL/MDL-IDE Intro (ZPG)	Repository	Introduction to Simulx (CK/ZPG)	HO MIDD (preclinical): Guinea pig PKPD modeling & selection of best LO candidate (TC/LB)	HO QT modeling in phase I - prediction of TQT study (UW-H/ÅJ)
		DDMoRe IT Platform			
11	MCL GD + HO: Data/Parameter Object (CK/ZPG)	TEL (ZPG)	Simulx HO (CK/ZPG)		
12	LUNCH				LUNCH with wrap- up and feedback
13	MCL GD + HO: Model/Task Object (CK/ZPG)	TEL HO (CK/ZP-G)	Introduction to Cardiac Physiology & Physiopathology (CD/CP)	Importance of cardiac safety in drug development - clinical evaluation (CD/CP)	
14					Coffee/Tea Break
15	MCL GD + HO: Model/Task Object	Coffee/Tea Break	Coffee/Tea Break	HO MIDD (dog to human translation) – modeling of QT effects in dog & prediction of QT effect in human (JP/LB)	
16	Presentation of Results	TEL HO , Cont'	Importance of cardiac safety in drug development - preclinical evaluation (CD/CP)	Dog translation into human results (JP/LB)	
	Standardised Output				
17	Wrap-up & feedback				
			Social evening event?		

	Lecture
	Hands-on exercise
	Group discussion
	Lecture with guided demo

Presenters & Tutors

TC- Teresa Collins CK - Charlotte Kloft
AC - Amy Cheung
CD - Corina Dota
CP - Chris Pollard
JP - Joanna Parkinson
LB - Linnea Bergenholm
UW-H - Ulrika Wählby-H.
ÅJ - Åsa Johansson
ZPG - Zinnia Parra Guillen