30 September 2015
EMA/462579/2015

EMA expert workshop on extrapolation across age groups

30 September 2015, meeting room 3E

Background

The primary rationale for extrapolation is to avoid unnecessary studies in the target population for ethical reasons, for efficiency, and to allocate resources to areas where studies are the most needed.

Additionally, in situations where the feasibility of studies is restricted, extrapolation principles may be applied for rational interpretation of the limited evidence in the target population in the context of data from other sources.

As per the published EMA Concept paper on extrapolation of efficacy and safety in medicine development, there is the need to develop a framework for extrapolation approaches that are considered scientifically valid and reliable to support medicine authorisation. The framework shall set out a structured approach to be followed for each extrapolation exercise to improve interactions with stakeholders and to standardise the decision making across EMA committees.

In addition the revision of the ICH E11 (Clinical Investigation of Medicinal Products in the Paediatric Population) is ongoing with a focus on extrapolation and the workshop may inform the ongoing reflection.

Thus, it is important to provide drug developers clear and compatible guidance with considerations specific to global product development and licensing of paediatric medicines.

Objectives of the workshop

The workshop will discuss the role of extrapolation and how it should be evaluated within a regulatory framework through the product development life cycle.

The goal of the meeting is to come with recommendations for a framework on which clinicians, modellers and statisticians agree that will result in an explicit and systematic approach for decision making alongside the life cycle; hence optimising the chances for successful development and approval.

The outcome of the workshop should allow for progress in the drafting of the Extrapolation drafting paper by agreeing on a toolkit of methods available allowing for a better informed system data from every source according to the increasing level of evidence across the life cycle.

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Programme

Programme details (Chair: Rob Hemmings; EMA: Cécile Ollivier)		
8:00	Registration	
8:30	Opening statement (P. Tomasi)	10 minutes
	Session 1: Extrapolation framework: Common principles and challenges	
	• Introduction (C. Male)	15 minutes
	• When do clinicians usually extrapolate in their practice? (D. Brasseur)	15 minutes
	• Extrapolation is epilepsy (G. Pons and C. Chiron (TC))	15 minutes
	• How modelling and simulation can address gaps in knowledge when planning a paediatric development? (I.S. Rusten)	15 minutes
	• Statisticians perspectives on extrapolation (D. Wright)	
	Discussion: All	45 minutes
	• Lead discussants: D. Mentzer, F. de Andrés Trelles	
10:30	Coffee break – 15 min	15 minutes
10:45	**Session 2:** Structure, methods and decision criteria for extrapolation	
	• What should be the source data when considering a paediatric development? (G. Burckart, V. Sinah, S. Cole)	25 minutes
	• How to weight the strength of prior information and clarify the expected level of evidence? (G. Hlavin, M. Posch)	15 minutes
	• Dealing with risk and uncertainties (A. Nordmark)	15 minutes
	Discussion: All	45 minutes
12:30	Morning wrap up – R. Hemmings	30 minutes
13:00	Lunch break	45 minutes
13:45	**Session 3:** Case studies	
	• Extrapolation in antibacterial agents: M. Cortizo, I. Lutsar, J. Standing, J. Gulbinovic	30 minutes
	• Dapagliflozin: J. Karres, J. Standing, N. Benda	30 minutes
14:45	Coffee break	
	• Everolimus: A. Koch, K. Weber, F. Tshinanu, R. Mačiulaitis	30 minutes
	• What should the European framework for extrapolation look like?	30 minutes
16:00	Afternoon wrap-up and next steps – R. Hemmings	30 minutes
16:30	Closing remarks	