

21 August 2026

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Draft agenda – Workshop on advancing proof-of-concept data in paediatric oncology drug development

21 September 2026, 13:00-16:00 (Teams)

Chair: Karen Van Malderen

Item	Draft agenda	Mins
1.	Welcome / Introductions Overview of the agenda <i>Afmps: Karen Van Malderen</i>	5 min
2.	Comments collected during the public consultation on the Concept Paper <i>EMA: Maria Sheean</i>	30 min
3.	Stakeholders' views on the proposed weight of evidence framework and on the future process to support collaboration <i>Academic translational research: Jan Molenaar</i> <i>Academic clinical research: Pam Kearns</i> <i>Industry: Gesine Bejeuhr and George Kirk</i> <i>Regulators: Dominik Karres</i>	60 min
4.	Panel discussion Speakers and: <i>FDA: Martha Donoghue</i> <i>Academics: Malcolm Smith, Elizabeth Fox</i> <i>Patient advocate: tbc</i>	30 min
Coffee Break		15 min
5.	Going beyond oncology – learnings and next steps: <u>Mechanism of action under the New Legislation</u>	30 min

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Item	Draft agenda	Mins
	<i>European Commision / DG Sante: tbc</i> • <u>Vision and education</u> <i>EnprEMA: tbc</i> • <u>Scientific content and decision making</u> <i>EMA: Sabine Scherer</i>	
6.	Closing remarks	10'