Pediatric Device Consortia (PDC)/Chief Medical Officer for Pediatrics and Special Populations/Innovator (PCI) Meeting Minute Checklist

The goal of the Food Drug Administration (FDA)'s Pediatric Device Consortia (PDC) Grants Program is to facilitate the development, production, and distribution of pediatric medical devices through funding of nonprofit consortia. FDA's Center for Devices and Radiological Health (CDRH) funds the PDC Grant's Program, which is overseen and directed by the Office of Orphan Products Development (OOPD). The consortia provide expert advising and support services to innovators of medical devices intended for children.

For many medical device developers supported by the PDCs, enhanced understanding of regulatory pathways and programs may facilitate devices being designed, developed and labeled for children. OOPD and CDRH seek to augment this potential via the PCI meeting.

The PCI meeting is an informal conversation between the Office of Orphan Products Development (OOPD), CDRH's Chief Medical Officer for Pediatrics and Special Populations and innovators to facilitate an improved understanding by the innovator regarding regulatory options that support and advance pediatric device development while respecting all other existing Center review processes. The intent is to provide innovators with the opportunity to gather additional information regarding the regulatory options that support pediatric IFUs and labelling by engaging in a high-level, non-binding regulatory discussion. We strongly encourage engaging CDRH in the pre-submission process.

Sponsor Name:

Medical Device:

Date of Meeting:

FDA Attendees			
Name	**Title**	**Contact Information**	✓
Erika Torjusen, M.D., M.H.S.	Director- Rare Pediatric Disease (RPD) Designation Program, Humanitarian Use Device (HUD) Designation Program, Pediatric Device Consortia (PDC)	Office of the Commissioner Office of Orphan Products Development 301-796-2278 erika.torjusen@fda.hhs.gov	
Vasum Peris, M.D., M.P.H.	Chief Medical Officer and Director for Pediatrics and Special Populations	Center for Devices and Radiological Health Office of Strategic Partnerships and Technology Innovation 301-796-6089 vasum.peiris@fda.hhs.gov	
Catherine Park	PDC Program Analyst	Office of the Commissioner Office of Orphan Products Development 240-402-4296 catherine.park@fda.hhs.gov	
	PDC Project Officer	Office of the Commissioner Office of Orphan Products Development XXX-XXX-XXXX @fda.hhs.gov	

Innovator Team Attendees			
Name	**Title**	**Contact Information**	✓

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Checked boxes are the topics we covered during the call. Other topics listed are additional information that may be helpful to know.

✓	Discussed
Pediatric Device Development and Labeling https://www.fda.gov/media/85233/download https://www.fda.gov/media/73510/download	
Additional Comments	

	Discussed
Investigational Device Exemption (IDE) https://www.fda.gov/medical-devices/device-advice-investigational-device-exemption-ide/ide-application	
Additional Comments	

	Discussed
510(k) Submissions https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k	
Additional Comments	

	Discussed
De Novo Classification Process (Evaluation of Automatic Class III Designation) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation	
Additional Comments	

	Discussed
Humanitarian Use Device (HUD) and Humanitarian Device Exemption (HDE) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-use-device-hud-designations https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program	
Additional Comments	

	Discussed
Pre-Market Approval (PMA) https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma https://www.fda.gov/medical-devices/premarket-approval-pma/pma-guidance-documents	
Additional Comments	

	Discussed
Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program	
Additional Comments	

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-Schedule pre-submission meeting with CDRH first to find out what the best regulatory pathway should be

	Discussed
Breakthrough Devices Program https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program	
Additional Comments	

	Discussed
Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions https://www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-uncertainty-making-benefit-risk-determinations-medical-device-premarket-approvals-de	
Additional Comments	

	Discussed
Early Feasibility Studies (EFS) Program https://www.fda.gov/medical-devices/device-advice-investigational-device-exemption-ide/early-feasibility-studies-efs-program	
Additional Comments	

	Discussed
Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices https://www.fda.gov/regulatory-information/search-fda-guidance-documents/leveraging-existing-clinical-data-extrapolation-pediatric-uses-medical-devices	
Additional Comments	

	Discussed
Real World Evidence (RWE) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices	
Additional Comments	

	Discussed
3D Printing https://www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices https://www.fda.gov/files/medical%20devices/published/Technical-Considerations-for-Additive-Manufactured-Medical-Devices---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff.pdf	
Additional Comments	

	Discussed
Medical X-Ray Imaging Devices Conformance with IEC Standards https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-x-ray-imaging-devices-conformance-iec-standards	

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Additional Comments

	Discussed
Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices	
Additional Comments	

	Discussed
Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket	
Additional Comments	

	Discussed
Reporting of Computational Modeling Studies in Medical Device Submissions https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reporting-computational-modeling-studies-medical-device-submissions	
Additional Comments	

	Discussed
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices	
Additional Comments	

	Discussed
Content of Premarket Submissions for Management of Cybersecurity in Medical Devices https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0	
Additional Comments	

	Discussed
Emergency Use Authorizations for Medical Devices (EUAs) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices	
Additional Comments	

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Additional Helpful Links

Device Advice: Comprehensive Regulatory Assistance
Humanitarian Use Device (HUD) Designation: OOPD
Pediatric Device Consortia Grants Program
CDRH: Pediatric Medical Devices Homepage

Division of Industry and Consumer Education (DICE) Contact Information

Email: DICE@fda.hhs.gov
(800) 638-2041
(301) 796-7100