Should and could my trial be fit for filing

ACCELERATE Webinar

PANEL MEMBERS BIOGRAPHIES
Bram De Wilde is a paediatric haemato-oncologist at Ghent University Hospital. He has a clinical and research expertise in pediatric solid tumors in general and neuroblastoma in particular. He also runs an ITCC accredited phase I/II pediatric oncology trials unit. As a part time professor at Ghent university and a FWO clinical mandate holder, his research focus is in translational research into biomarkers and novel treatment concepts for children with cancer.
Professor Pam Kearns is Chair of Clinical Pediatric Oncology at the University of Birmingham and an Honorary Consultant Pediatric Oncologist at Birmingham Children’s Hospital. She is Director of the University’s Institute of Cancer and Genomic Sciences and Cancer Research UK Clinical Trials Unit (CRCTU), for which she leads the research strategy for one of UK’s largest cancer trials unit, including the National Trials portfolio for children and young people with cancer. She has served on the Board of SIOP Europe since 2013 and was President from 2019 to 2021. She is an Executive Board Member for Innovative Therapies for Children with Cancer’ (ITCC) and the International multi-stakeholder platform ‘ACCELERATE’.
Dr. Fox leads regulatory and clinical trial operations as well clinical research prioritization and strategy at St Jude Children’s Research Hospital. Nationally, she is the vice-chair of Developmental Therapeutics for the Children’s Oncology Group and the Pediatric Early Phase Clinical Trials Network. Dr. Fox has expertise in quantitative clinical and pre-clinical pharmacology, pediatric clinical oncology, and clinical research and trial design including response and toxicity biomarker endpoint development. She applies an integrative approach to clinical drug development utilizing animal models, pre-clinical and clinical pharmacology to evaluate new agents and novel trial designs.
DONNA LUDWINSKI

Donna's son Erik was diagnosed with neuroblastoma in 1991 at age 6, relapsed after 13 years, and died in 2010 after almost five years of treatment at age 24. Donna has been involved in the patient/parent community for more than 17 years and is the Director of Research Advocacy at Solving Kids' Cancer based in NYC, and Family Support Advocate for SKC UK. She serves on the Parent Advisory Council for New Approaches to Neuroblastoma Therapy (NANT), FDA Patient Representative, and the NCI Pediatric Central Review Board (CIRB). Donna has a BS in Chemical Engineering, raised 4 children, now lives in Virginia with her husband, and spends all her free time with her 7 grandchildren.
MARTHA DONOGHUE

Martha Donoghue, MD is a board-certified pediatric hematologist/oncologist who serves as the Deputy Director of the Division of Oncology 2 in the Office of Oncologic Diseases and the Acting Associate Director of Pediatric and Rare Cancer Drug Development in the Oncology Center for Excellence at the U.S. Food and Drug Administration (FDA). Prior to joining FDA in 2009 as a clinical reviewer, Dr. Donoghue completed a fellowship in pediatric hematology and oncology at the Children’s National Medical Center after working for several years as a general pediatrician in private practice.
DOMINIK KARRES

Dominik received his medical degree from the University Erlangen, Germany, followed by a MD in paediatric drug development. He held a training post in paediatric haematology/ oncology (University Hospital Muenster) and worked in paediatric oncology and paediatric oncology drug development in Germany and the UK (Royal Marsden Hospital & Institute of Cancer Research UK). In 2014 he joined the UKs medicines regulatory agency (MHRA) with positions in the Licensing and Post-marketing Division. Since 2018 he has been working as Scientific Officer at the EMAs Paediatric Medicines Office. Dominik is supporting the agency’s efforts further fostering paediatric oncology drug development. In this capacity he is also the EMAs nominee to the ACCELERATE Steering Committee.
KIM PIETSC

Dong Ho Kim Pietsch is currently seconded as National Expert to the Inspections office within the European Medicines Agency (EMA). Kim joined the Paul-Ehrlich-Institut (PEI) in 2012 as a GCP inspector and has conducted over 100 GCP inspections in relation to marketing authorization applications all around the globe and contributed to various guidelines and publications in relation to GCP as part and outside of this membership of the EU GCP Inspectors Working Group.
Elly Barry is a board-certified pediatrician and pediatric hematologist/oncologist with over 15 years of experience in drug development, currently serving as the Senior Vice President and Head of Clinical Development at Day One Biopharmaceuticals, a company focused on developing medicines for childhood cancer. Prior to Day One, Elly worked for 7-years at Pfizer as the Global Clinical Lead for Pediatric Oncology and head of the Pfizer’s Pediatric Oncology Leadership Team, overseeing pediatric oncology clinical development and responsible for developing and implementing strategy and deliverables related to pediatric oncology development plans.
Dr. Kieran is currently the VP of Clinical Development at Day One Biopharmaceutics, a company focused on the development of targeted drugs for children. He received a PhD in Immunology from the University of Alberta, Canada in 1983 and his MD in 1986 from the University of Calgary. After a post-doctoral fellowship in the Department of Molecular Biology at the Pasteur Institute in Paris, France where he cloned the regulatory molecule NFkB, he completed a pediatric residency at McGill University in Montreal and a pediatric oncology fellowship at Boston Children’s Hospital. Dr. Kieran became Director of Pediatric Neuro-Oncology at the Dana-Farber Cancer Institute in 1998 focused on targeted, gene, immune modulatory and antiangiogenic therapies for pediatric brain tumor patients and other rare cardiac and premature aging diseases.