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Consortium, networks dedicated to improving treatments for neonates

by from the Food and Drug Administration Office of Pediatric Therapeutics and Division of Pediatric and Maternal Health

The International Neonatal Consortium (INC) is a global collaboration of academic and clinical neonatologists and nurses, regulators, drug developers and patient advocacy groups working to accelerate the development of safe and effective therapies for neonates.

Launched in May 2015, INC is facilitated by the Critical Path Institute. Its working groups have published a white paper on neonatal clinical pharmacology and an article considering new endpoints for bronchopulmonary dysplasia studies.

Ongoing projects include establishing data standards for neonatal studies, defining normal hemodynamic parameters for preterm and term neonates, developing a state-of-the art white paper to guide retinopathy of prematurity studies, and publishing a protocol to guide trials of neonatal seizure therapies.

INC's work products are intended to be used by trial networks and drug developers to improve efficiency and consistency in neonatal trials. (See <https://c-path.org/programs/inc/>.)

Networks and consortia that promote high-quality research on the safety and efficacy of therapeutic products for neonates include the following:

- The Neonatal Research Network (<https://neonatal.rti.org/>) of the National Institute of Child Health and Development (NICHD) was established in 1986, and its academic sites conduct neonatal clinical trials.
- The NICHD-supported Pediatric Trials Network (<https://pediatrictrials.org/>) has been studying neonatal therapeutics since its inception in 2010.
- The nonprofit Institute for Advanced Clinical Trials in Children (<https://www.iactc.org/>) was launched in 2017 to engage public and private stakeholders in the development of pediatric clinical trials.
- The European Network of Paediatric Research at the European Medicines Agency (<http://bit.ly/2FwDQ5h>) is a network that facilitates pediatric studies.

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