

Advancing Neonatal Drug Development: Celebrating Progress on World Prematurity Day

On this occasion of **World Prematurity Awareness Day**, we reflect on the immense progress we have made together and recognize the vital role you have played in advancing neonatal drug development. At the International Neonatal Consortium (INC), our mission is clear: to improve outcomes for preterm infants and their families through collaboration, innovation, and research.

This day reminds us of the challenges premature infants face and strengthens our resolve to address their unique needs through actionable solutions and groundbreaking initiatives.



INC's Journey and Transformative Impact

Over the years, INC has united a diverse global community of clinicians, researchers, regulatory authorities, industry leaders, and patient advocates, advancing neonatal drug development through collaborative, pre-competitive efforts. Our achievements include:

- **Revolutionizing Safety Reporting with NAESS:** The Neonatal Adverse Event Severity Scale (NAESS) has standardized adverse event reporting, enabling consistent safety evaluations in clinical trials and receiving FDA recommendation as a key tool in drug development.
- **Developing the ROP Activity Scale:** This scale has transformed how Retinopathy of Prematurity (ROP) is assessed, supporting regulatory submissions and enabling the successful development of new interventions.
- **Establishing the Real-World Data Analytics Platform (RW-DAP):** By curating over 380,000 neonatal records across 30 global datasets, RW-DAP supports natural history studies and predictive modeling, enabling groundbreaking insights into diseases like Bronchopulmonary Dysplasia (BPD).
- **Guiding Regulatory Standards:** INC's work has directly influenced FDA and EMA guidelines, shaping critical pathways for safer and more effective neonatal drug trials. Key contributions include adaptive trial designs, pharmacokinetics-driven dosing recommendations, and long-term neurodevelopmental outcome assessments.
- **Optimizing Neonatal Therapies:** INC's initiatives, such as tailored seizure trial designs and standardized blood pressure protocols, have provided actionable tools that directly enhance neonatal care and advance therapeutic innovation.

Why This Work Matters

Neonates, particularly those born preterm, are among the most vulnerable patients, and their unique needs demand dedicated research and therapeutic strategies. While much has been accomplished, **significant gaps remain**. For example, despite decades of research, **no treatment for Bronchopulmonary Dysplasia (BPD) has been approved in the last 30 years**, and devastating conditions like **Necrotizing Enterocolitis (NEC)**, **neonatal brain injury**, and many other neonatal diseases still lack effective therapies. These unmet needs

highlight the urgency of INC's mission.

Without robust, neonatal-specific data, clinicians often rely on therapies not optimized for this population. INC's work in addressing these gaps has not only shaped regulatory practices but also transformed neonatal care standards. By fostering collaboration among diverse stakeholders, INC is building a future where neonates benefit from therapies that are **safer, more effective, and tailored to their specific needs**. Together, we are committed to **changing this landscape** and ensuring every preterm infant has access to life-saving innovations.

A Call to Action: Join Us in Advocating for Change

As we honor World Prematurity Awareness Day, we invite you to **recommit to this mission**. Whether by supporting research initiatives, engaging in ongoing projects, or helping us connect with potential partners, your contribution is vital. By fostering collaboration, we can expand our impact and inspire innovative solutions to ensure a brighter future for preterm infants.

Spread the Message

Help amplify our mission by sharing our work within your networks. Together, we can raise awareness, inspire action, and drive meaningful change for neonates and their families.

On behalf of everyone at INC, thank you for your unwavering dedication to neonatal health. If you'd like to learn more about INC or join our efforts, please reach out to us at incinfo@c?path.org.

Let's continue working together to ensure every preterm infant has the best possible start in life.