



# **INC COMMUNICATIONS TOOLKIT FOR REGULATORS**

*Last Updated October 2021*

## How to Use this Guide

The key messages, logos, one pagers and social graphics contained or linked in this guide are intended to be used **as is** to keep messages about INC and its topics, i.e., NAESS, long-term outcomes, neonatal seizures, etc. consistent. If you'd like to make modifications, please email [incinfo@c-path.org](mailto:incinfo@c-path.org) with your requests/ideas.

The sample social copy included in the **Social Toolkits** can be modified to be written in your "voice" as needed. Please reach out with any questions. Thank you.

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## Challenge

The last drug that significantly impacted survival in preterm neonates was approved more than 30 years ago and, to this day, neonates continue to be treated as therapeutic orphans, underserved by the drug development community and continually lacking safe and effective therapies. Currently, less than one percent of registered trials are in neonates and the vast majority of drugs – approximately 60 to 90 percent – in this population are used off-label, greatly impacting any objective evaluation of their safety and efficacy. Providing much needed treatments for this neglected subset of the population requires the engagement of the global neonatal community – families, health care providers, academic scientists, regulators, pharmaceutical investigators, advocacy organizations and funders – to focus on the needs of the neonate by sharing their data, knowledge and expertise in order to advance medical innovation and regulatory science.

## Need

With the collaboration of stakeholders within the neonatal community, practical tools can be developed and incorporated into clinical trials, which will then lead to more successful, efficient trials, providing this population with significantly increased and higher-quality treatments.

## Objective & Specific Aims

Our mission is to communicate the work of C-Path's International Neonatal Consortium (INC) to the larger neonatal communities in support of a positive research culture and inclusivity of multiple stakeholder perspectives in the NICU.



Communicate INC progress within INC and to the larger neonatal community



Amplify and support the perspective of all stakeholders



Promote positive research culture for neonates as we address their unmet drug development needs



Measure, revise, refine and iterate

## Communications Strategy



Develop key messages for the global neonatology community using the content of INC's impact from the perspective of each stakeholder group:

### Stakeholders include:

- Parents
  - Advocacy groups
- Nurses
  - Societies/Professional Groups/Partners
- Neonatologists
  - Societies/Professional Groups/Partners
- Regulatory Agencies
- Industry Representatives

### Key Messages for Stakeholders:

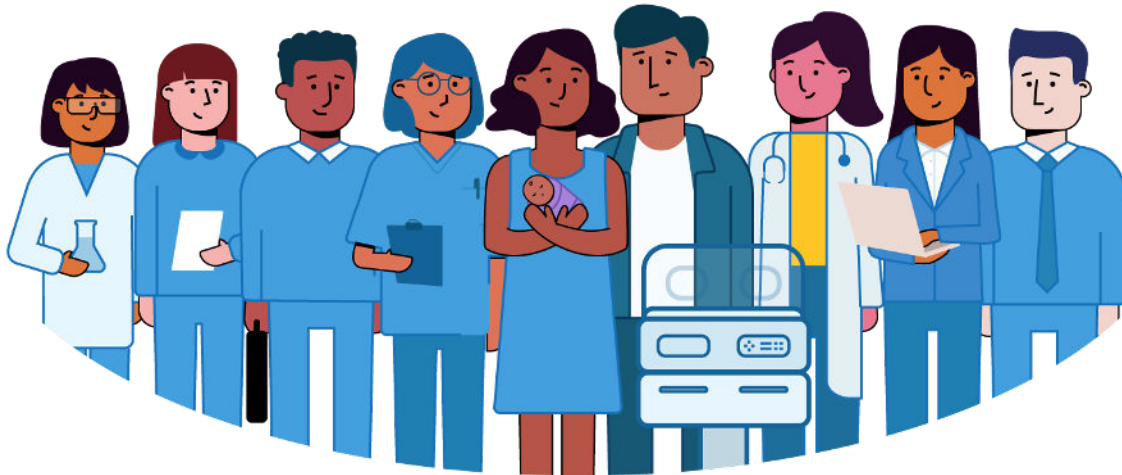
- NAESS
- Assessment of long-term neurodevelopmental outcome (LTO) following trials of medicinal products in newborn infants
- Recommendations for the design of therapeutic trials for neonatal Seizures

## Target Audience: Global Neonatal Community

- **Parents**
  - NICU Parent Network (US-based)
  - EFCNI (EU-based)
  - Others, such as Irish Neonatal Health Alliance, Alliance for Black NICU Families and other smaller groups, but most fit under the other two umbrellas.
  - thezaky.com
- **Nurses**
  - COINN (LinkedIn, Facebook, Twitter)
  - NANN
  - AWHONN

- ANN.Healty Newborn Network
- Chifa Listerve
- ALIGNN
- **Neonatologists**
  - Neonatal research networks in different countries / regions.
  - NICHD, Neonatal Research Network
  - NICHD, Pediatric Trials Network
  - Vermont Oxford Network
  - EuroNeoNet: European Neonatal Network
  - EFCNI: European Foundation for the care of newborn infants
  - Society for Pediatric Research
  - European Society for Pediatric Research
  - iNEO: International Network evaluating Neonatal Outcomes
  - Australia-New Zealand Neonatal Network (ANZNN)
  - Canadian Neonatal Network (CNN)
  - Israeli Neonatal Network (INN)
  - Neonatal Research Network of Japan (NRNJ)
  - Swedish Neonatal Quality Register (SNQ)
  - UK Neonatal Collaborative (UKNC)
  - American Academy of Pediatrics, Section of Neonatal Perinatal Medicine (similar sections of other pediatric associations)
  - American Academy of Pediatrics, Section of Clinical Pharmacology and Therapeutics and Section on Advances in Therapeutics and Technology
- **Regulatory Agencies**
  - Registered Lobbyists US/EU
  - Pediatric Cluster (FDA/EMA)
- **Industry Representatives**
  - For trade associations with active pediatric work groups, send one pager to staffer who is point person for pediatric work group
    - BIO
    - EFPIA
  - For trade associations without pediatric working groups the approach would be ask if their members would like to self-select into an email distribution group for INC publication/project key message
    - PhRMA
    - IFPMA
    - JPPMA
- **Societies/Pro Groups/Partners**
  - American Society for Pharmacology and Experimental Therapeutics
  - American Society for Clinical Pharmacology & Therapeutics
  - Canadian Society for Pharmacology and Therapeutics

## Communication Resources



## Key Messages - Regulators



### Neonatal Adverse Event Severity Scale (NAESS)

- NAESS emphasizes that neonates are different and describes neonatal morbidity helping to differentiate disease and intervention-related events

- NAESS defines a better language, common to all parties involved in the care of the neonate and their enrollment in a study/trial
- NAESS is aligned with [MedDRA](#) and NIH to meet regulatory needs for submissions. This provides more complete picture of risk, benefit and causality assessment and informs pharmacovigilance, pediatric safety reports/summaries, benefit/risk discussion and labeling.

### Long-term Outcomes

- The [publication](#) puts forth an expert consensus on the neurodevelopmental safety assessments recommended following neonatal trials of medicinal products.
- It provides a framework for the planning of long term neurodevelopmental safety and efficacy evaluations associated with neonatal medicinal product trials.
- The document provides expert consensus on the minimum time for follow-up of neonates following clinical trials for medicinal products.
- Promoting retention without undue burden to research participants and parents must be considered, while ensuring systematic, interpretable and adequate safety follow.

### Neonatal Seizures

- The [publication](#) puts forth multidisciplinary consensus on the design of neonatal therapeutic trials for anti-seizure drugs (ASDs) to facilitate development of a protocol.
- It specifies key study population considerations including enrollment of neonates with EEG-confirmed seizures, addressing various etiologies of neonatal seizures in analysis plans, and inclusion of preterm infants only when supported by available safety and pharmacokinetic data.
- The document provides expert consensus on the recommended efficacy endpoints for neonatal seizure trials including reduction of seizure burden (primary), seizure recurrence (co-primary or secondary), administration of rescue ASDs (secondary), and demonstration of improved long-term neurologic outcomes (secondary).

- Other key design elements include defining study procedures to ensure that timing to administration of study drug does not delay anti-seizure treatment, use of a usual care (phenobarbital) comparator, incorporation of neonatal-specific adaptive trial designs, and inclusion of neurodevelopmental assessment at a minimum age of 18-24 months as both, a safety and an efficacy measure.

## INC Logo & Images

- [Logo & Brand Guidelines](#)
- [Graphic Assets](#)

## General Talking Points

### International Neonatal Consortium

- In 2015, C-Path, launched the International Neonatal Consortium, INC, to bring together multidisciplinary stakeholders in a pre-competitive way to serve unmet drug development needs in neonates, with the common cause of developing safe and effective medical products for neonates.
- Critical Path Institute's International Neonatal Consortium, INC's, mission is to accelerate the development of safe and effective therapies for neonates.

### Neonatal Adverse Event Severity Scale (NAESS)

- The Neonatal Adverse Event Severity Scale, NAESS, is the first neonatal-specific adverse event severity grading instrument.
- NAESS is the first tool to provide a standardized, infant-specific framework to consistently assess severity of the most commonly reported events experienced among critically ill infants.
- The NAESS is a valuable tool that can help inform pharmacovigilance reviews, pediatric safety reports, and benefit/risk assessments.
- NAESS mapping to MedDRA terms allows for standardized and consistent safety comparisons between medications and across trials throughout the world.



- The NAESS is designed to allow for revisions and expansion of terms as utilization increases and progress is made in systematizing the assessment of AEs in newborns.

### Long-term Neurodevelopmental Outcomes (LTO)

- Currently, there is significant uncertainty over the role of assessment of long-term neurodevelopmental outcome in neonatal clinical trials.
- INC has developed a framework to determine the need, nature, and duration of LTO assessments in trials involving newborn infants and outline assessments for outcomes as direct or indirect consequence of intervention.
- This framework calls for the strategic involvement of parents and patient advocates aimed at balancing benefits, costs and burdens of assessments to the researcher and families.

### Design of Therapeutic Trials for Neonatal Seizures

- Seizures, one of the most common neurologic emergencies in neonates, are associated with significant mortality and neurodevelopmental disability. In fact, seizures are more common in neonates than any other age group.
- There is a critical need for safe and effective treatments for seizures in neonates.
- The INC publication, [Recommendations for the design of therapeutic trials for neonatal seizures](#), includes comprehensive recommendations for clinical trial design components for anti-seizure medications in neonates with valuable input from clinical care providers, researchers, parents, nurses, industry, and regulatory agencies. This coordinated approach of stakeholder input can encourage the development of medications that are effective to specifically treat neonatal seizures.
- New parents may be surprised to hear that there are very few clinical trials designed specifically for neonates and even fewer for neonatal seizures. Clinical trials for new anti-seizure medications are essential and NICU graduate parents provided important input.

- Parent's shared experiences and opinions regarding trial safety, long-term outcomes and caregiver burden were incorporated into each study recommendations.

## FAQs

- Find FAQs on C-Path's INC website, <https://c-path.org/inc>

## Social Media & Social Media Toolkits

- **C-Path Social Page Tags**
  - **LinkedIn:** @Critical Path Institute (C-Path) (auto populates)
  - **Facebook:** @Critical Path Institute (auto populates)
  - **Twitter:** @CPathInstitute
  - **YouTube:** <https://www.youtube.com/c/CriticalPathInstitute>
- **Social Media Hashtags:** #CPath #INC #NAESS #longtermoutcomes #seizures #neonatal #neonatology #nicu #preemie #premature #healthcare #neonatologist #collaboration #pediatric #clinicaltrials #consortium #globalhealth
- **Toolkits**
  - [Parents](#)
  - [Nurses](#)
  - [Neonatologists/Physicians](#)
  - [Regulators](#)
  - [Industry](#)

## Email Campaigns

Example emails would go out to INC members and INC master stakeholder list. The call to action (CTA) to stakeholder groups is that they share it with their networks, but for ease this would be one message that fits all.

### EXAMPLE

As a **[stakeholder group]** member, working with the [Critical Path Institute's International Neonatal Consortium](#) (a global collaboration formed to forge a predictable regulatory path for evaluating the safety and effectiveness of therapies for neonates), **[I/we]** would like **[you/organization name]** to be aware of resources developed by INC to support the development of therapies for neonates.

*Linked please find the recently published [Neonatal Adverse Event Severity Scale](#) paper additional resources to help amplify our message, including social media toolkits at [c-path.org/inc/resources](https://c-path.org/inc/resources).*

If possible, please cascade to your [\[network/members\]](#) that would also be interested in this information, as applicable. If distribution is prohibited, please consider querying your membership for their interest to opt-in to an email distribution list, to be used by INC to distribute relevant industry papers and high-level message summaries regarding development of neonatal therapies as they become available.

Please contact the INC team at [incinfo@c-path.org](mailto:incinfo@c-path.org), if you have questions.

Kind regards,  
Mary Short

## INC PPT Slides

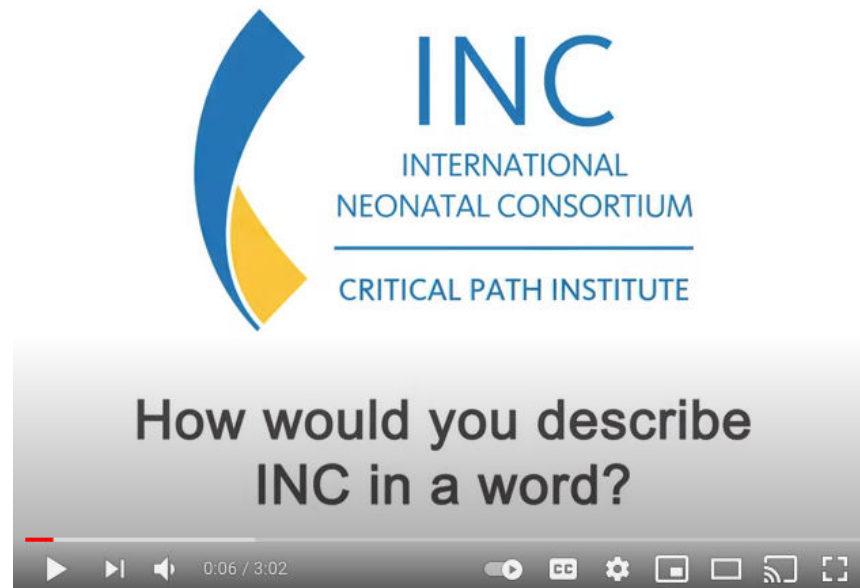
- [Regulators Key Messages Slides](#)

## Videos

- [INC Overview Video](#)

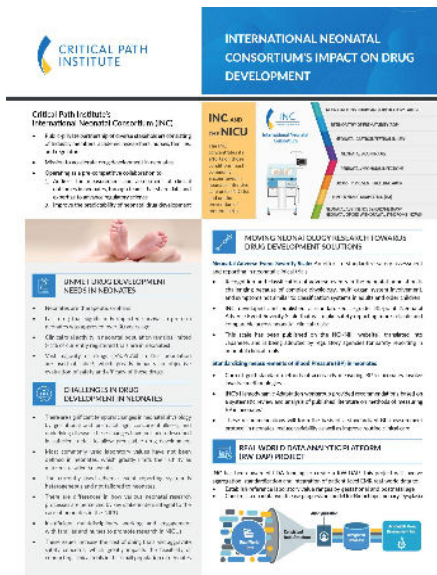


- [INC "In a Word" Video](#)

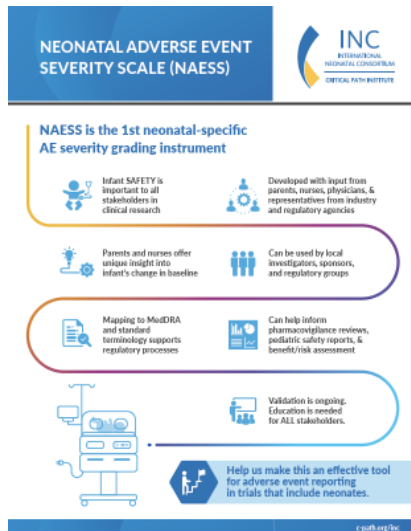


## One Sheets

- INC One Sheet



- INC NAESS One Sheet



## Papers/Publications:

- [Inter-rater reliability of the neonatal adverse event severity scale using real-world Neonatal clinical trial data](#)
- [Method of Blood Pressure Measurement in Neonates and Infants: A Systematic Review and Analysis](#)
- [Necrotizing Enterocolitis: Using Regulatory Science and Drug Development to Improve Outcomes](#)
- [Antenatal and perinatal factors influencing neonatal blood pressure: a systematic review](#)
- [Assessment of long-term neurodevelopmental outcome following trials of medicinal products in newborn infants](#)
- [Recommendations for the design of therapeutic trials for neonatal seizures](#)
- For additional publications, visit: <https://c-path.org/inc/>.

## Communications Timeline Planning & Measurement

### Creating an Outreach Effort and Timeline for Messaging

The following table is a list to plot moments, events and ideas to track the people and places/events that can help us get the word out. Think about the next 12 months where as a group we can consider creating communications amplification opportunities:

*Could the moment provide a good opportunity to reach our target audiences with a key message about INC?*

**Planning Tips:**

- Review the opportunities table below
  - Are you attending/presenting at any of these events?
  - Is there awareness you can share with your networks around a particular event or awareness week, i.e., National Nurses Week, etc.
- Give yourself time to plan and select materials from the toolkit
- Focus on the opportunities that are a match for the stakeholder key message you are using
- Share your plans to use our toolkit materials with the INC Communications WG
- Track your communications here: [bit.ly/plan\\_inc\\_comms](https://bit.ly/plan_inc_comms)

The opportunities below will help to inform a short term and then longer term communications plan for INC. If you have additional opportunities to add, you may do so [here](#).

**Opportunities Table:**

Date	Event	Organization	Location
SEPTEMBER 2021			
	<a href="#">FDA Meetings, Conferences and Workshops</a>	FDA	
9/7-9	<a href="#">Giving Voice to the Silent Burden: Maternal Mental Health Technical Consultation</a>	Healthy Newborn Network	Virtual event
9/8 -11	<a href="#">Fall 2021 National Neonatal, Advanced Practice, &amp; Mother Baby Nurses Conferences</a>	Academy of Neonatal Nursing	
9/11	<a href="#">Virtual neonatal minicon</a>		Virtual event
9/ 10 - 11	<a href="#">20th International Attachment Conference, virtual conference</a>		Virtual event

9/14	<a href="#"><u>4th Congress of joint European Neonatal Societies (jENS)</u></a>		Athens, Greece
9/13 - 19	<a href="#"><u>Neonatal Nurses Week</u></a>		
9/13 - 15	<a href="#"><u>NANN's VIRTUAL 37th Annual Conference</u></a>	NANN	Virtual event
9/14 - 18	<a href="#"><u>jENS 2021 congress</u></a>	ESPR	Virtual event
9/15 - 16	<a href="#"><u>Postpartum Hemorrhage CoP Virtual Annual Meeting</u></a>	Healthy Newborn Network	Virtual event
9/21 - 22	<a href="#"><u>Global Breastfeeding and Lactation Symposium</u></a>		
9/22	<a href="#"><u>Focus on Pharmacology Virtual Series</u></a>	ASPET	
9/24 - 25	<a href="#"><u>Unpacking the NICU Parent Leader Journey</u></a>	NICU Parent Network	Virtual event
9/28	<a href="#"><u>Strengthening capacity for health innovation in Africa</u></a>	H3D-F and IFPMA partnership	Virtual event
OCTOBER 2021			
	<a href="#"><u>Pediatric Academic Societies (PAS) Meeting</u></a>		
10/5 - 21	<a href="#"><u>2021 Newborn Screening Symposium</u></a>	Association of Public Health Laboratories	Virtual event
10/8 - 12	<a href="#"><u>AAP National Conference &amp; Exhibition</u></a>	American Association of Pediatrics	Philadelphia, Pennsylvania
10/9 - 13	<a href="#"><u>AWHONN convention</u></a>	AWHONN	Virtual event

10/18 - 19	<a href="#"><u>International Conference on Neonatology</u></a>		Paris, France
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10/18 - 21	<a href="#"><u>Council of International Neonatal Nurses, INC (COINN)</u></a>	COINN Alliance of Global Neonatal Nursing	
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10/19 - 20	<a href="#"><u>2021 INC Scientific Workshop</u></a>	INC	Virtual event
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10/27 - 28	<a href="#"><u>BIO Patient &amp; Health Advocacy Digital Summit</u></a>	BIO	Virtual event
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#### NOVEMBER 2021

11/8 - 10	<a href="#"><u>Neonatal Pharmacology Conference 2021</u></a>	Medical University of South Carolina	Charleston, South Carolina
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11/11 - 12	<a href="#"><u>Advances and Controversies in Neonatal Medicine</u></a>	Vanderbilt University Medical Center	Nashville, Tennessee
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11/15 - 17	<a href="#"><u>Miami Neonatology 2021</u></a>	University of Miami Miller School of Medicine	Miami, Florida
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11/16 - 19	<a href="#"><u>SBER21 and AER21</u></a>	PRIM&R	Virtual event
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11/17	<a href="#"><u>World Prematurity Day</u></a>	World Prematurity Day	
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#### DECEMBER 2021

12/5 - 8	<a href="#"><u>Hot Topics in Neonatology</u></a>	Nemours Children's Health System	National Harbor, MD
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#### 2022

#### JANUARY 2022

1/2 - 6	<a href="#"><u>37th Annual Obstetrics, Gynecology, Perinatal Medicine, Neonatology, and the Law</u></a>	Center for Human Genetics	Orlando, Florida
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1/10 - 14	<a href="#"><u>BIO Partnering at JPM</u></a>	BIO	Virtual event
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FEBRUARY
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2/23 - 25	<a href="#"><u>NEO Conference</u></a>	Mednax	San Diego, CA
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MARCH
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3/15	<a href="#"><u>iCAN 2022 Summit</u></a>	iCAN	Lyon, France
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3/16 - 19	<a href="#"><u>American Society for Clinical Pharmacology and Therapeutics</u></a>	ASCPT	Gaylord Rockies Resort & Convention Center Denver, CO
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3/29 - 31	<a href="#"><u>Drug Information Association - Europe meeting</u></a>	DIA - EU	Hybrid/Brussels
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April 2022
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4/21 - 4/25	<a href="#"><u>PAS Meeting</u></a> <a href="#"><u>Pediatric Academic Societies (PAS) Meeting</u></a>	International Biomedical	Denver, CO
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MAY 2022
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5/4 - 6	<a href="#"><u>Neonatal &amp; Pediatric Airborne Transport Conference</u></a>	International Biomedical	Austin, Texas
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JUNE 2022
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5/19 - 23	<a href="#"><u>Drug Information Association - Global Annual Meeting</u></a>	DIA	Hybrid
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SEPTEMBER 2022
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	<a href="#"><u>EFPIA events</u></a>	EFPIA	
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OCTOBER 2022
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	<a href="#"><u>EFPIA events</u></a>	EFPIA	
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10/7 - 11	<a href="#"><u>American Academy of Pediatrics National Conference &amp; Exhibition</u></a>	AAP-NCE	Anaheim, CA
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10/12 - 15	<a href="#"><u>22nd Annual International Perinatal Bereavement Conference (IPBC)</u></a>	Pregnancy Death and Infant Loss Alliance (PLIDA)	Denver, Colorado
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10/16 - 20	<a href="#"><u>2021 Newborn Screening Symposium</u></a>	Association of Public Health Laboratories	Tacoma, Washington
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NOVEMBER 2022			
11/14 - 18	<a href="#"><u>PRIM&amp;R Annual Conference</u></a>	PRIM&R	Salt Lake City, UT

LINKS OF INTEREST
<a href="#"><u>Alliance for Black NICU Families</u></a>
<a href="#"><u>The Zacky</u></a>
<a href="#"><u>ASPET</u></a>
<a href="#"><u>ASCPT American Society for Clinical Pharmacology &amp; Therapeutics</u></a>
<a href="#"><u>PhRMA</u></a>
<a href="#"><u>JPMA</u></a>
<a href="#"><u>March of Dimes</u></a>
<a href="#"><u>ESDPP European Society for Developmental Perinatal and Paediatric Pharmacology</u></a>
<a href="#"><u>EFPIA events</u></a>

## Measurement:

- Reports Showing INC Web Content Engagement
- Social Media Engagement Reports
- Email Campaign Results
- **INC members: The INC Communications Workgroup** would like to track your communications activities regularly. If you plan to use any materials on social media, at a meeting, for a blog, etc., please send an email to [incinfo@c-path.org](mailto:incinfo@c-path.org) with the following information:
  - Date of Activity

