Pediatric clinical trials: Navigating evolving regulations successfully with the right partner

Gone are the days when pediatric patients were considered simply as miniature adults. Drug developers and regulators alike agree that younger patients, with their developing bodies, are bound to respond differently to pharmaceutical products. To ensure that this younger cohort receives safe and effective treatment, regulations governing clinical trials are evolving, creating new challenges for drug developers. Working with the right partner can help you navigate the road ahead.

Old challenges, new regulations

Collecting clinical data on pediatric patients has always proved quite difficult: how do you find and enroll the appropriate patients in the first place? Then, how do you collect blood safely and manage blood sample volumes for such a vulnerable group?

Current Pediatric Age Classifications (ICH Guidance E11*) identify five separate categories, as per table below:

Age Group	Category
Born at < 37 weeks gestation	Pre-term, newborn infants
< 0 day	Pre-term, newborn infants
0-27 days	Term newborns
28 days-23 months	Infants and toddlers
2-11 years	Children
12 to 16-18 years, depending on region	Adolescents

**International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human use*

However, testing these groups will no longer be confined to specific pediatric clinical trials. New regulations now demand that pediatric data be collected in all clinical trials for new therapies. As regulators will be intent on showing how seriously they take young patients, sponsors must expect to operate in a more stringent enforcement environment.

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You need to be prepared to meet these complex demands and it is therefore critical that you find a clinical testing partner with a proven mix of pediatric capabilities. Covance can offer you a thorough understanding of the pediatric regulatory landscape, expertise in protocol design and implementation and insight to identify and support high-performing investigator sites and staff.

Having to perform pediatric clinical trials to meet these new requirements can be rather daunting, especially if you are new to them. Experience counts and you can count on ours: building on the 169 studies we have performed, i.e. more than 20 percent of all pediatric studies conducted in the US since 2008, we have gained insights that will help you deliver results you can act on.

Pediatric Experience 2008-YTD 2013		
	Covance Pediatric Studies	Covance Studies with Peds
0-3 yrs	47	30
3-6 yrs	52	45
6-10 yrs	62	72
10-12 yrs	54	65
12-18 yrs	57	91
Total Studies	93	169

[1]*www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm190622.htm*

Accelerated clinical trial with end-to-end support

As your research partner, we will support you throughout and devise new strategies to accelerate your pediatric clinical trials. Every sponsor has unique needs and our central laboratories will carry out customized testing to optimize your clinical plan, as well as tailored blood collection assessments. In the event of a short draw, we will perform analytes following protocol/SOW order of priority. Your blood collections will be safe, as we provide transport tubes for serum or plasma and special transfer pipettes or other tubes if required.

Working with you, our specialist teams, comprising M.D. subject matter experts, blood volume specialists, medical technologists, technical administrators and project managers, will bring the right mix of pediatric skills to deliver the high-quality study data you expect.

Innovative approaches to blood volumes and collection for greater precision

When it comes to some of the most challenging areas of a pediatric trial, such as blood volume and collection, Covance can introduce you to new methods and customized solutions, providing end-to-end support: assisting with your Institutional Review Board (IRB) submissions; devising ways to minimize blood volume while meeting protocol needs; adhering to rigorous SOPs for collection; following best practices for specimen handling, and developing effective strategies for handling other critical tasks.

The blood sample collection itself requires special care with pediatric patients. Using appropriate systems - adapted to delicate bodies and veins - and delivering precision to avoid redraws, calls for efficient and flexible instruments. Our teams conduct pediatric blood sampling using the high-quality Sarstedt S-Monovette® blood collecting system, chosen for its significant benefits: small but easy to hold, it allows for blood to be drawn using a butterfly needle and guide sleeve holder and does not require a tube extender. It can fit in a standard centrifuge, be used as a regular vacuum tube and also offers the option of use as a syringe. As investigator site personnel find the system comfortable and easy to operate, redraws can be minimized and you benefit from more reliable results.

Sarstedt pediatric tube sizes:	
EDTA	1.2 mL and 2.7 mL
Clot tube with gel	1.1 mL
Clot tube with no gel	1.2 mL and 2.7 mL
Glucose, fluoride	1.2 mL and 2.7 mL
Lithium heparin with gel	1.1 mL
Lithium heparin with no gel	1.2 mL and 2.7 mL
Sodium citrate (coag)	1.4 mL and 3.0 mL

Novel approaches, rigorous processes and reliable equipment go hand in hand with competent investigator site personnel and we also ensure that they are supported at all stages to deliver results that will inform your decisions.

Proactive and rigorous support for high-performing investigator sites

High-performing investigator sites are the foundation of your successful pediatric trial. With our experience, we understand and anticipate the unique needs of the investigator site team and are able to meet them in a proactive fashion. Every site receives comprehensive training and materials including manuals, quick reference guides, and videos. To ensure that investigators easily understand each step of your study and adhere to your protocol, we provide customized clinical trial kits. We also apply rigorous SOPs featuring best practices for managing all study supplies. We believe that a well-trained team will deliver quality results that translate into more effective and productive trials.

Challenging as pediatric clinical studies may appear to you at first, why not view them as an opportunity to transform your data into confident results? With Covance as your experienced partner, you can deliver quality data and be assured of your patients' safety. Together we can take your drugs to market faster, making your trials more productive while creating hope for more young patients.

Learn more about our drug development solutions at **www.covance.com**

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The Americas + 1.888.COVANCE + 1.609.452.4440
Europe / Africa + 00.800.2682.2682 **Asia Pacific** + 800.6568.3000

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