DRIVING INNOVATION IN PEDIATRIC CLINICAL TRIALS
OUR PEDIATRIC INSIGHTS DELIVER RESULTS YOU CAN COUNT ON

Pediatric patients are not simply miniature adults. Their developing bodies can respond very differently to pharmaceutical products. To respond to their unique needs, the pharmaceutical regulatory landscape is shifting—and creating challenges for drug developers.

Together with the right partner, you can successfully navigate the road ahead.

PEDIATRIC AGE CLASSIFICATIONS (ICH GUIDANCE E11*)

- Pre-term, newborn infants
- Term newborns (0 to 27 days)
- Infants & toddlers (28 days to 23 months)
- Children (2 to 11 years)
- Adolescents (12 to 16-18 years—dependent on region)

*International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use
ANTICIPATING CHALLENGES WITH INSIGHT AND COMPASSION

Pediatric patients can be very challenging:
- Identifying and enrolling the appropriate patients
- Blood sample collection
- Managing blood sample volume

Pediatric data are now required in all clinical trials for new therapies—simply avoiding this cohort is not an option. And with greater visibility comes a more robust enforcement environment.

You need to be ready to meet these complex challenges. Your clinical testing partner must possess pediatric-specific experience and capabilities.

Covance offers:
- A deep understanding of the pediatric regulatory environment
- Expertise in pediatric protocol design and implementation
- Insight to identify and support high-performing investigator sites

NO SUBSTITUTE FOR EXPERIENCE

In pediatric trials, experience counts. We have it, and we’re ready to put it to work for you.

<table>
<thead>
<tr>
<th>Pediatric Experience 2008–YTD 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covance Pediatric Studies</td>
</tr>
<tr>
<td>0–3 yrs</td>
</tr>
<tr>
<td>3–6 yrs</td>
</tr>
<tr>
<td>6–10 yrs</td>
</tr>
<tr>
<td>10–12 yrs</td>
</tr>
<tr>
<td>12–18 yrs</td>
</tr>
<tr>
<td>Total Studies</td>
</tr>
</tbody>
</table>

Breakdown of studies completed between September 27, 2007 and November 18, 2013

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>BPCA</th>
<th>BPCA &amp; PREA</th>
<th>PREA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy/Safety</td>
<td>43</td>
<td>31</td>
<td>200</td>
<td>274</td>
</tr>
<tr>
<td>PK/Safety</td>
<td>9</td>
<td>37</td>
<td>20</td>
<td>66</td>
</tr>
<tr>
<td>PK/PD</td>
<td>14</td>
<td>8</td>
<td>9</td>
<td>31</td>
</tr>
<tr>
<td>Safety</td>
<td>6</td>
<td>4</td>
<td>25</td>
<td>35</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>6</td>
<td>21</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>86</td>
<td>275</td>
<td>436</td>
</tr>
</tbody>
</table>

BPCA — Best Pharmaceuticals for Children Act
PREA — Pediatric Research Equity Act

SUCCESSFUL PEDIATRIC TRIALS BEGIN WITH THE RIGHT PARTNER

Trial acceleration strategies emerge when you have end-to-end lab support.

▶ Customized testing to optimize your clinical plan
▶ Tailored blood collection assessments
▶ The ability to perform analytes following protocol/SOW order of priority in the event of a short draw
▶ Collection and transport supplies for small volumes
▶ Special transfer pipettes and/or other tubes as needed

THE RIGHT TEAM FOR THE RIGHT RESULTS

When you partner with Covance, we become part of the same team, working together to meet your needs at every stage of your trial.

Your support team includes:
▶ MD subject matter experts
▶ Blood volume specialists
▶ Medical technologists
▶ Technical administrators
▶ Project managers

BLOOD VOLUME AND COLLECTION: OUR UNIQUE APPROACH

Blood volume and collection may be the most challenging aspect of your pediatric trial. You need a partner with broad experience, specialized expertise and customized solutions that go far above and beyond traditional approaches.

With our support, you can explore—and enact—new ways to solve your challenges. That includes Institutional Review Board (IRB) submissions, strategies to minimize blood volume while meeting protocol needs, rigorous SOPs for collection and best practices for specimen handling.
PEDDIATRIC BLOOD DRAWS ARE EASIER WITH OUR TEAM

Your pediatric blood sampling will be conducted with the high-quality Sarstedt S-Monovette® blood collecting system that offers:

▶ Reliable draws using a butterfly needle and guide sleeve holder
▶ No tube extender required
▶ Fits in a standard centrifuge
▶ Use as regular vacuum tubes
▶ Capability to draw blood as a syringe

INVESTIGATORS THRIVE WITH THE RIGHT SUPPORT

High-performing investigator sites are the foundation of your successful pediatric trial. We understand the needs of the entire investigator site team, and our attention to detail translates into productive, efficient site performance—which positively impacts your clinical and economic metrics.

Every site receives:

▶ Comprehensive training and materials including manuals, quick reference guides and training videos
▶ Customized clinical trial kits that drive protocol adherence
▶ SOPs ensuring best practices for managing all study supplies

YOUR PEDIATRIC TRIAL POSSIBILITIES, REDEFINED

Your study represents an opportunity to transform pediatric clinical data into confident results—and commercial success.


<table>
<thead>
<tr>
<th>Sarstedt Pediatric Tube Sizes</th>
<th>1.2 mL and 2.7 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA</td>
<td>1.2 mL</td>
</tr>
<tr>
<td>Clot tube with gel</td>
<td>1.1 mL</td>
</tr>
<tr>
<td>Clot tube with no gel</td>
<td>1.2 mL and 2.7 mL</td>
</tr>
<tr>
<td>Glucose, fluoride</td>
<td>1.1 mL</td>
</tr>
<tr>
<td>Lithium heparin with gel</td>
<td>1.2 mL and 2.7 mL</td>
</tr>
<tr>
<td>Lithium heparin with no gel</td>
<td>1.2 mL and 2.7 mL</td>
</tr>
<tr>
<td>Sodium citrate (coag)</td>
<td>1.4 mL and 3.0 mL</td>
</tr>
</tbody>
</table>
Learn more about our
drug development solutions at
www.covance.com

Covance is an independently held company with headquarters in Princeton, New Jersey, USA. Covance is the marketing name for Covance Inc. and its subsidiaries around the world.

The Americas + 1.888.COVANCE + 1.609.452.4440
Europe / Africa + 800.2682.2682
Asia Pacific + 800.6568.3000

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