Designing a safe and effective pediatric digital health platform for the US market

**About Gabi Smartcare**

Gabi Smartcare offers out-of-hospital medical monitoring of newborns and children thanks to its miniaturized monitoring bracelet and digital platform accessible to clinicians. The cloud-based Gabi Analytics platform processes and structures collected data, detects health events, and provides healthcare professionals with a personalized and predictive health assessment.

- **Pediarity™**

**The opportunity**

- **Respiratory disease** is a leading cause of death in children under the age of 5, accounting for **25% of all pediatric hospitalizations** each year.
- Remote, medical-grade monitoring solutions showed a reduction in adult ER visits and hospitalizations, but there is a lack of digital health tools for the pediatric population.

**The challenge**

- Due to high development costs and a limited commercial market, there is a dearth of FDA-authorized medical devices for children.
- Multi-fold challenges exist with developing pediatric digital health products. It is critical to recognize the unique anatomical and physiological differences from adults and utilize specialized design and testing to ensure product compatibility and effectiveness.
- Navigating regulatory guidance for adults and applying insights to the pediatric population adds complexity for developers, in addition to carefully navigating unique ethical considerations.

**The approach**

- Gabi originally started their product journey via a non-regulated route. However, upon recognizing the importance of addressing growing pediatric needs in the US and bringing their product to market with appropriate product claims, they began their regulatory journey.
- The team requested a series of pre-submission meetings with the FDA to discuss clinical aspects of the product in development, with a focus on understanding the requirements of the agency across different pediatric age groups: neonates (0-28 days), infants (28 days to 2 years), and children (2 years to 12 years).
- As a company based in Belgium, Gabi learned that getting real-world clinical data accepted by the FDA required them to conduct a gap analysis with the justification of the differences between European and US populations vs. conducting testing directly in the US population. They opted for the latter.

**The success**

- With an exempt user application fee for a pediatric device, Gabi received a **510(k) clearance for their Pediarity™ product**, bringing a new safe and effective medical device to the US market.
- They are currently working with **30+ children’s hospitals across the US**.
- Gabi is on a mission to keep children out of hospitals by using screening methods and remote patient monitoring platforms to prevent unnecessary admissions and readmissions to the hospital.

> “FDA's 510(k) clearance of our solution opens the gateway to a key medical sector. It gives us access to our first high-value-added market – the 'hospital at home' – where we have strong traction. We are the only digital pediatric solution that enables home monitoring with remote follow-up.”

— Jonathan Baut

CEO, Gabi SmartCare