

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