Meet Laura,

The CEO of SmartBytes, an Italian start-up that has developed an innovative algorithm based on neural networks called "CyrcAIdian" which monitors people's sleep-wake cycle.

Age: 36
Profession: Founder and CEO of SmartBytes
Education: PhD in Clinical Research
Previous professional experiences: 5 years as postdoc researcher
Tech savviness: medium
Legal savviness: low
Business savviness: medium
Languages: Italian (native), English (C1)

Goals & Opportunities

Laura wants to commercialize CyrcAldian on the Italian market.

If the AI system is commercialized as a medical device, it would need to respect the **stringent requirements for high-risk AI systems**.
This is challenging and costly, but also promising, e.g., directly selling CyrcAldian to hospitals would mean **lower initial financial investments** than promoting it in a congested consumer market. This would also **satisfy those SmartBytes' employees** who would prefer to see their algorithm used for healthcare purposes.

On the other hand, a strategy of commercialization to consumers may be more scalable and thereby **cover a larger market size**. Moreover, **compliance with the AI Act would be simplified**.

Needs

Laura needs to:
a) **understand the AI Act's requirements** for CyrcAldian **and the obligations** that apply to SmartBytes
b) **decide if it will be more convenient** to commercialize CyrcAldian as a fitness tracker or as a medical device.

To do so, she needs **an easy-to-use, low-cost solution** that helps her to find out the compliance obligations of SmartBytes and that considers other factors to **better inform the organizational and financial strategy** of the start-up.

Barriers

Laura is **worried** because she and her colleagues have no legal expertise, apart from having some basic notions on patents.

SmartBytes **does not dispose of in-house legal advice**, while external consultants are costly. Moreover, Laura is **very busy** in setting and executing the organizational strategy of SmartBytes - she can't possibly set aside time and energies to become an expert in AI law!

Laura has looked online for solutions but what she found is **too abstract, legalistic and general** to be of actual use.

They are engineers after all! They need **clear instructions to follow**, whereas they are left unsure of what they need to do to commercialize CyrcAldian safely.

SmartBytes and CyrcAIdian

SmartBytes is a **start-up** funded in 2021, that started as a spin-off of the University of Bologna.

Leveraging the research results obtained at the Insomnia Research Lab, Laura and some academic colleagues developed "**CyrcAIdian**", an algorithm that analyzes the raw data collected through actigraphs, which are accelerometers integrated into **wearable activity trackers** commonly used for monitoring physical activity.

CyrcAidian measures quantity and quality of sleep and elaborates statistics that can be **used by the individual** to learn more about their sleep patterns, as well as by **medical personnel** for diagnostic and therapeutic purposes related, for instance to monitor their patients' sleep quality and to evaluate the effectiveness of therapies.

SmartBytes' employees

Pietro, CEO Background in Biomedical Engineering

Andrea, Lead Data Scientist, Background in AI engineering

Irene, Intern and Master Student in Biorobotics

Elia, Data Scientist Background in Medicine

Samya, Data Scientist Background in Computer Science

Sara, Communication and Marketing