

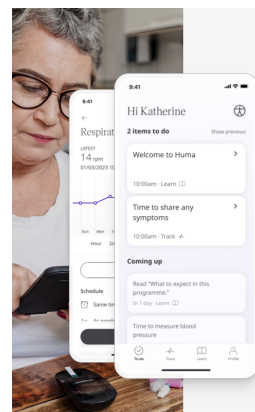
Huma: Clinical evidence transferability



About Huma

Huma is a global digital health company that offers digital platforms to enhance patient care, improve outcomes, and enable personalized health solutions across various therapeutic areas.

Relevant product: Huma's condition-agnostic remote patient monitoring platform advances connected care for patients and accelerates research and therapies. It has received regulatory clearances in Europe (Class IIb), India, Middle East, and United States (Class II).



Strategy & approach

- Huma's strategy includes using data from its peer-reviewed publications – including prospective and retrospective, longitudinal, experimental, and quasi-experimental study designs – to gain regulatory approvals globally.
- The company builds regulated medical devices that support care as it's meant to be delivered: via condition-agnostic platforms, as opposed to in isolated silos.
- Huma's approach is based on a thorough understanding of the similarities and differences in healthcare across populations, geographies, and therapeutic areas.
- It has successfully navigated complex regulatory environments by carefully selecting and justifying data from different regions and integrating them cohesively.



National engagement

- Regulators appreciate Huma's acknowledgment of its studies' strengths and limitations, which has fostered trust between Huma and regulatory agencies.
- By leveraging its clinical and scientific teams, which have deep expertise in academia and health transformation, Huma successfully demonstrates that clinical evidence from its condition-agnostic platform can be generalized across different geographies.



Key takeaways

- ✓ Prior to this, there were no Class IIb condition-agnostic certifications in Europe.
- ✓ This demonstrates that regulators can approve broad intended uses when underpinned by the right evidence strategy.

“Regulations are there to protect patients – we've shown these don't need to be a barrier to innovation.”

— Dr. Arrash Yassaee

Former Global Clinical Director, Huma