

# Real-World Evidence for Pharmaceutical Innovation



## THE DRUG DEVELOPMENT BOTTLENECK

The numbers don't lie, and the hesitation is no longer defensible. Recent analysis from Tufts and the Digital Medicine Society (DiMe), working alongside leaders from Johnson & Johnson, Roche, Genentech, UCB, Bayer, Takeda, GSK and, MindMed, has made the economics crystal clear.

## DEPLOYING DIGITAL ENDPOINTS IN PHASE 2 AND 3 TRIALS CAN:



Shorten timelines  
by **3-5**  
months



Generate  
**\$27-48M**  
in value



Deliver  
**4-7x**  
ROI

## THE ECONOMIC REALITY PHARMA FACES:

- Average cost to bring a drug to market: **\$879M to \$1.3 billion** (with capitalized costs reaching \$2.6B)
- **90% of clinical trials fail** to meet endpoints, often due to inadequate patient monitoring
- Post-approval Phase 4 studies cost **\$39-48 million** per study
- Patient adherence issues cause **\$100-\$300 billion** in avoidable costs annually and obscure true drug efficacy
- Lack of continuous monitoring limits ability to identify **responders vs. non-responders early**, inflating trial costs

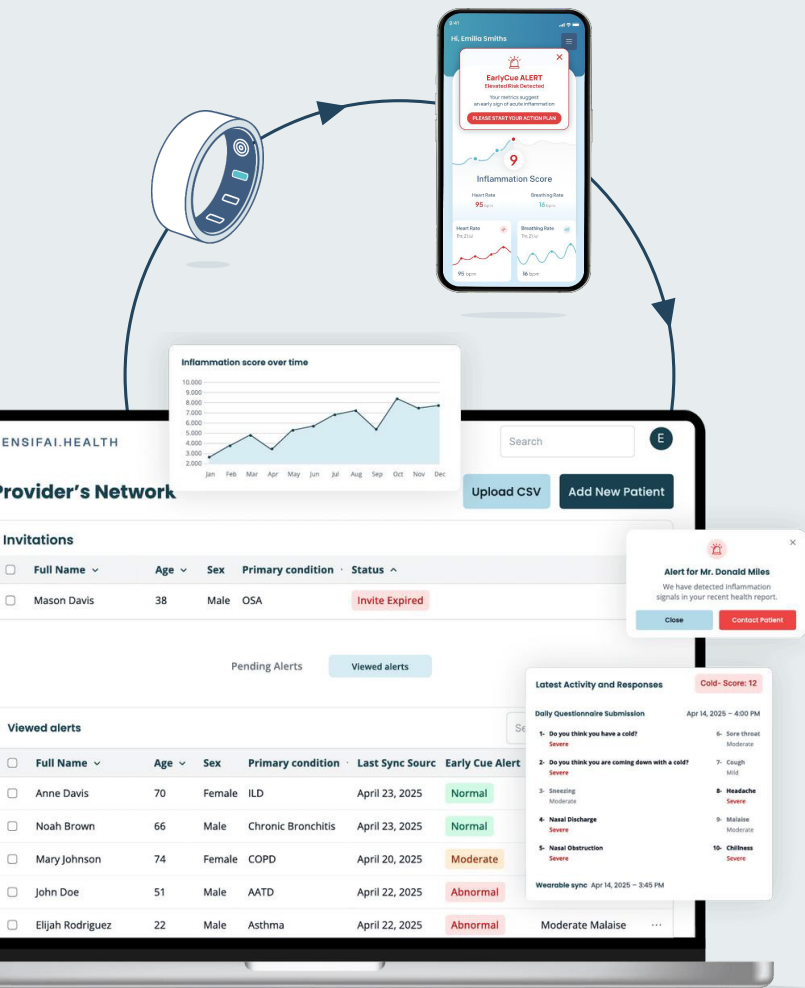


# THE SENSIFAI ADVANTAGE

Non-invasive immune monitoring through everyday wearables that transforms drug development economics **across the entire lifecycle.**

## CLINICALLY VALIDATED TECHNOLOGY:

- **90% accuracy** in detecting immune signals before symptoms appear
- Non-invasive monitoring through consumer wearables (no blood draws, no clinic visits)
- Currently deployed in chronic lung disease patients, expanding to other chronic diseases and immune response identification
- Real-time inflammation detection enables early intervention and precise response protocols



## OUR PLATFORM DELIVERS:

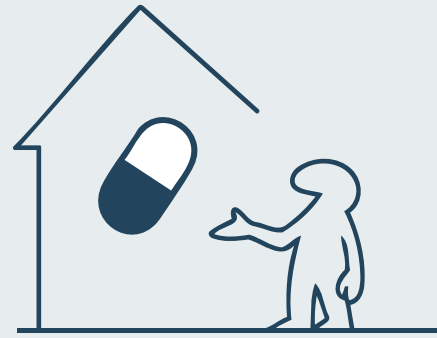
- **Phase II-III:** Real-time immune monitoring to trigger effective intervention and measure efficacy using novel digital biomarker endpoints that reduce trial duration and improve success rates
- **Post-Market:** Continuous real-world evidence for label expansion and companion app enabling at-home diagnostics and treatments

## MEASURABLE ECONOMIC IMPACT

**Clinical Trial Optimization:** Support adaptive trial designs with continuous data collection and immediate immune event identification - increasing signal (events) vs. noise ratio.

## POST-MARKET VALUE CREATION:

- Personalized precision medicine approaches: Generate new markets for at-home prescription of drugs that were ineffective in the past (for example, early detection and automatic prescription deployment for antivirals or anti-inflammatory interventions)
- Generate real-world evidence more efficiently than traditional observational studies (Phase 4 studies average **\$39-\$48M** in costs)

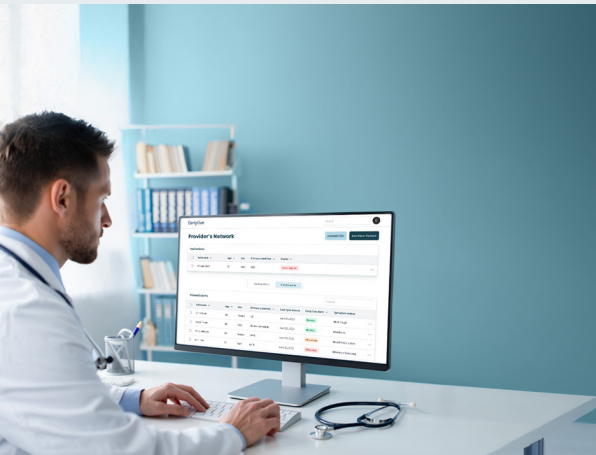


## COMPETITIVE ADVANTAGE

While pharma faces unprecedented pressures; rising costs, declining success rates, and shrinking timelines, the solution is within reach. In an era where real-world evidence drives regulatory decisions, reimbursement, and clinical adoption, non-invasive AI platforms like Sensifai offer pharma continuous immune monitoring via consumer wearables, addressing industry pain points for both timeline and cost while improving trial success and quality. Real-time patient monitoring with personalized AI is shifting from optional to essential.

Digital biomarkers aren't just about innovation;  
they're about efficiency in an increasingly competitive landscape.

**The tools are here. The validation exists. The ROI is proven.**



Companies that integrate continuous health data into their development and commercialization strategies will:

- Launch drugs faster with more robust evidence
- Demonstrate value more convincingly to payers and providers
- Identify new opportunities and patient populations earlier
- Defend market position more effectively with real-world data

## ABOUT SENSIFAI HEALTH

SensifAI Health is a pioneering HealthTech startup at the forefront of bioconvergence, employing AI to translate physiological data from wearable biometric sensors into actionable immunological insights. SensifAI's innovative approach allows for the early detection of systemic inflammation in individuals with chronic conditions, facilitating timely medical interventions that can significantly improve health outcomes for those most vulnerable.