Are you implementation ready?
An alternative patient and healthcare system-centered model for pharma

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Background

The pharmaceutical industry continues working in silos, with development teams focusing on trial completions and commercial teams focusing on launch execution. This process is effective at delivering products to market, but not necessarily to patients. Healthcare system (HCS) and patient needs are typically addressed late, resulting in suboptimal integration into clinical practice.

Here we introduce the concept of **Implementation Readiness** (IR), describing **the need to deliver a product effectively into the clinical care pathway by launch and beyond**.

Addressing the multifaceted needs of patients, HCPs, payers and HCS through implementation readiness ensures a higher degree of patient and HCS centricity is built into the innovation and the way it reaches healthcare systems by launch.

Introducing 'Implementation Readiness'

Implementation Readiness is defined as a product's ability to be used in clinical practice starting from launch. It calls for coordinated planning across pharma functions - R&D, medical, commercial, market access - towards a shared IR goal. Key elements include implementation science, treatment optimization studies, and generation of evidence on diagnosis, referral pathways, HCP behaviour, and patient preferences *before* launch.

Being implementation ready means that: (a) patients agree on the benefits and risks of the drug and see it as an improvement over the standard of care; (b) HCPs agree on how and when to use the drug; (c) payers recognize the added benefit in the designated patient population and; (d) the HCS itself is suited to the challenges of delivering the drug to patients.

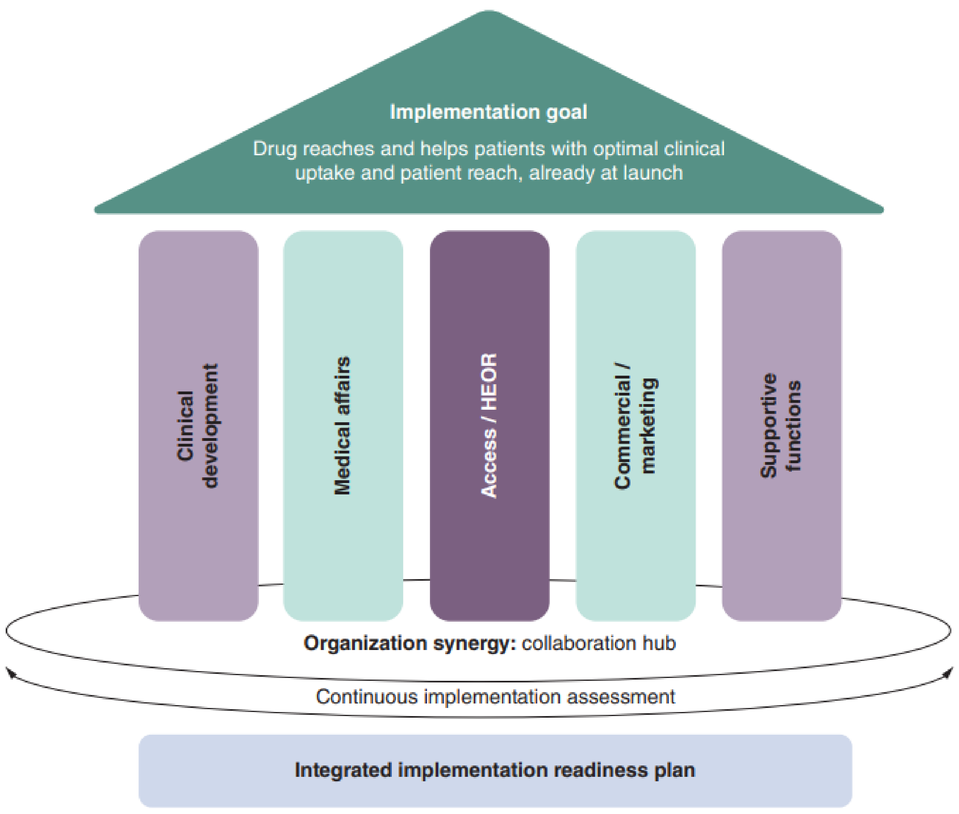

Figure 1. A new pharma model where all the functions work from a shared integrated implementation readiness plan, toward a common implementation goal, ensuring seamless product adoption at lunch.

Impact

IR would require the HEOR function to transform from supporting market access close to launch to identifying and addressing real-world implementation barriers early. While IR involves greater pre-launch investment and risk, it can enable faster uptake and greater patient reach.

A simulated analysis shows a 24-50% increase in 10-year area under the curve (AUC) for patient adoption compared to traditional strategies. The IR framework also aligns with the evolving EU HTA Regulation, which demands evidence on real-world clinical practice and system impact, not just regulatory endpoints.

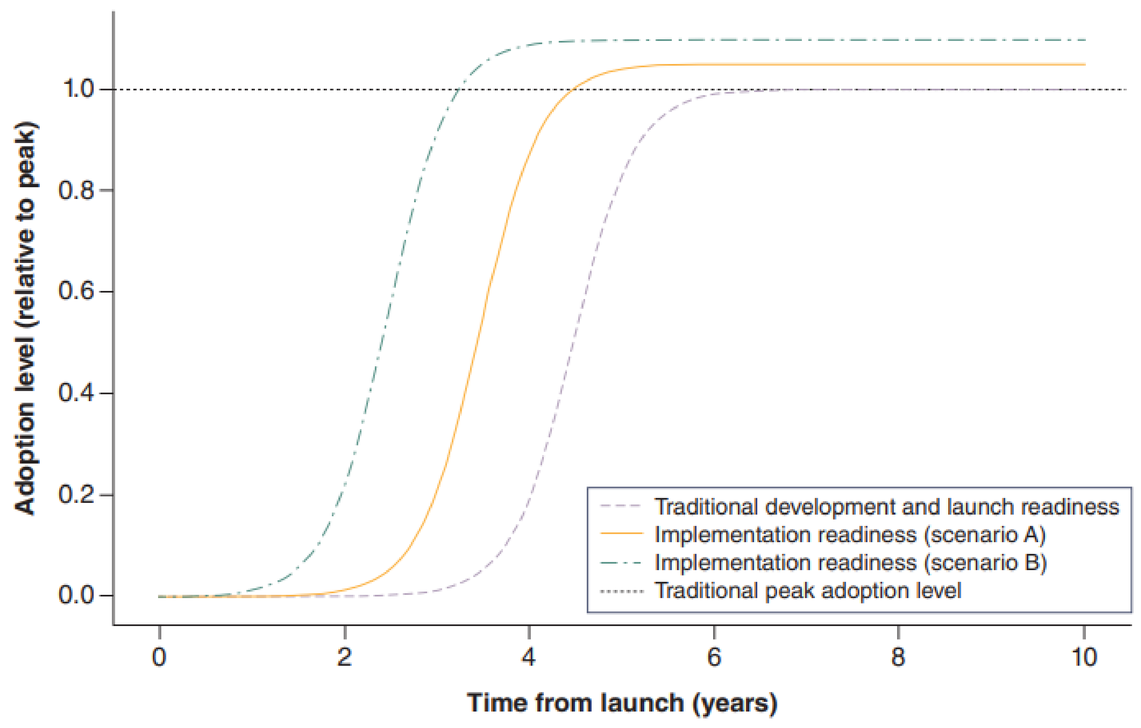

Figure 2. Impact of implementation readiness on lunch uptake: comparison of traditional development and lunch readiness (purple dashed), scenario A with a 1-year earlier and 5% higher peak (orange solid), and scenario B with a 2-year and 10% higher peak (green dash-dot).
The dotted horizontal line represents the traditional peak adoption level. Implementation readiness leads to faster and greater uptake, with the AUC over 10 years increasing from 5.53 (traditional) to 6.86 in scenario A and 8.28 in scenario B, representing a +24% and +50% increase, respectively.

Conclusion

- **Implementation Readiness** offers a **new optimization** target for pharma, focused on **patients actually receiving the innovation** as opposed to only regulatory approval and reimbursement;
- It requires **organizational change**: shared KPIs, early stakeholder co-creation, and cross-functional accountability;
- By rethinking what it means to be "ready" for launch, IR promotes a more **integrated** and **patient-centric approach** - better meeting all stakeholder expectations.

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Acronyms

EU HTA	European Health Technology Assessment	**HCS**	HealthCare System
AUC	Area Under the Curve	**IR**	Implementation Readiness
HEOR	Health Economics and Outcomes Research	**KPI**	Key Performance Indicator
HCP	HealthCare Professional	**R&D**	Research and Development