



Dear Valued Client,

Welcome to the October edition of ANSEA Insights. As we move through late 2025, the healthcare landscape continues to evolve at an unprecedented pace, driven by digital innovation, regulatory harmonization, and strategic collaborations. This edition highlights emerging trends such as digital-drug combination therapies, integrated care platforms, and patient-centric treatment models that are reshaping the way pharma and med tech companies deliver value.

At ANSEA, we are committed to providing you with timely, actionable intelligence. Alongside insights into FDA approvals, breakthrough therapies, and royalty transactions, we examine the implications of these developments for companies navigating innovation, partnerships, and market expansion across Asia and beyond. Whether you are optimizing your portfolio, exploring strategic alliances, or preparing for next-generation care models, we aim to offer valuable context to guide your decisions.

As always, we appreciate your continued engagement and look forward to supporting your efforts to drive meaningful impact and innovation in healthcare worldwide.

Healthcare Trends to Watch

The healthcare landscape is evolving through digital technology, pharmaceuticals, and innovative business models. Key trends, Digital-Drug Combination Therapies, Ecosystem-Based Coordinated Care, and Strategic Partnerships, enable personalized, data-driven care, improve outcomes, and create growth opportunities. By integrating digital tools with traditional therapies and fostering cross-sector collaboration, organizations are moving from episodic treatment to continuous, patient-centric care.

1. Digital-Drug Combination Therapies & Prescription Digital Therapeutics

This trend combines pharmaceuticals with digital tools—apps, sensors, and therapeutic software, for integrated behavioural and clinical interventions. Regulatory guidance from the FDA and EMA supports validation and reimbursement when patient benefits are proven. These therapies enhance adherence, enable remote monitoring, provide real-time data, and drive personalized care, with the market growing due to chronic disease prevalence and patient-centric models.

- **Akili Interactive – EndeavorRx:** *Akili Interactive’s EndeavorRx is the first FDA-authorized prescription digital therapeutic for children (8–12) with ADHD, delivered as an immersive video game. Using adaptive algorithms, it targets neural systems to improve attention, supported by five clinical studies, including a Lancet Digital Health RCT, showing significant improvements in attention and reductions in ADHD-related impairments.*
- **Medidata and Click Therapeutics:** *Medidata and Click Therapeutics are advancing software-enhanced drugs (SE Drugs) that combine digital therapeutics with pharmaceuticals into co-packaged products. Leveraging existing workflows and real-world evidence, the partnership integrates AI-powered trial management with FDA-regulated digital therapy expertise to enhance clinical outcomes and transform patient care. Backed by recent FDA draft guidance on PDURS, the collaboration aims to set a new standard in patient-centric drug development.²*

2. Healthcare Digital Integration & Coordinated Care Planning

Digital ecosystems connect patients, providers, payers, pharma, and medtech, enabling seamless, scalable care. By unifying data, services, and stakeholders, they support real-time collaboration across diagnostics, therapeutics, telehealth, remote monitoring, and pharmacy services. This approach enhances outcomes, efficiency, and engagement, while creating sustainable

revenue and shifting competition from asset ownership to data-driven ecosystem leadership.

- **Philips Health + UnitedHealth Group:** *Philips Virtual Care Management is a multi-modal platform delivering comprehensive virtual chronic disease management including diabetes, hypertension, heart disease, chronic kidney disease, COPD, and gestational programs. It integrates condition-specific protocols, connected devices, and engagement tools on a secure cloud-based platform. The program is customizable and scalable to meet health system and payer needs.*³
- **Tempus:** *Tempus operates a cloud-based precision oncology ecosystem leveraging data and AI to personalize cancer care. It aggregates clinical and molecular data to provide actionable insights for oncologists, enhancing diagnosis, treatment decisions, and clinical trial matching. The platform integrates genomic sequencing, electronic health records, and real-world data to support precision medicine and improved outcomes in oncology care.*⁴

3. Strategic Partnerships & Market Expansion

Pharma and medtech companies increasingly partner with startups, academia, and industry peers to accelerate innovation, reduce risks, and enter high-growth markets. These collaborations improve clinical trial efficiency, strengthen supply chains, support health system transformation, and enable rapid integration of digital, AI, and precision medicine capabilities, becoming key drivers of competitive advantage.

- **Medtronic + Brainomix:** *Medtronic Neurovascular partners with Brainomix to enhance stroke care in Western Europe. Brainomix's AI-powered 360 Stroke platform interprets brain scans in real time, supporting faster, more accurate diagnoses and treatment decisions. Integrated with Medtronic devices, it aims to improve thrombectomy rates, streamline workflows, and enable timely, life-saving interventions.*⁵
- **Microsoft:** *Novartis maintains a foundational alliance with Microsoft, providing the enterprise-wide AI infrastructure and cultural foundation. This collaboration spans AI empowerment of associates, exploration of complex computational challenges in drug discovery and therapy optimization, and deployment of Microsoft Azure and Copilot tools for company-wide AI integration.*⁶

Emerging trends drive differentiation, improved outcomes, and new revenue streams. Digital-drug combination therapies and PDTs enhance pharmaceutical value, while ecosystem-based care models integrate data, services, and stakeholders into scalable, patient-centric networks. Strategic partnerships and market expansion accelerate innovation, AI adoption, and

access to high-growth markets, helping companies move beyond product-centric approaches toward continuous, holistic care and leadership in digital, precision healthcare.

Pharma M&A Activity: Recent Deals and Insights

In 2025, major acquisitions and royalty deals highlight pharmaceutical priorities in innovation, market expansion, and growth. Royalty Pharma, Pfizer, and Johnson & Johnson made targeted investments in oncology, metabolic diseases, and neuroscience, emphasizing royalty financing, pipeline expansion, and therapeutic diversification to capture high-potential assets and long-term revenue.

- Royalty Pharma Acquisition of Royalty Rights on BeOne's IMDELLTRA:** Royalty Pharma acquired global (excluding China) royalty rights to Amgen's IMDELLTRA (tarlatamab) for up to \$950 million, including an \$885 million upfront payment and up to \$65 million in sales-contingent royalties. Targeting ~7% of net global sales through 2038–2041, IMDELLTRA is a bispecific T-cell engager for extensive-stage small cell lung cancer. BeOne Medicines retains China rights, while Royalty Pharma focuses on global markets, aligning with its strategy of investing in royalties on promising, low-risk therapeutics.
- Pfizer Acquisition of Metsera Inc for \$4.9 Billion:** Pfizer acquired Metsera Inc for an estimated \$4.9 billion to bolster its obesity and cardiometabolic portfolio. Metsera's innovative therapies address high-burden metabolic conditions, expanding Pfizer's pipeline and competitiveness in the growing obesity treatment market. The deal aligns with Pfizer's focus on chronic metabolic diseases and complements its existing cardiovascular and metabolic products, highlighting its commitment to pipeline diversification and high-growth areas.
- Johnson & Johnson Acquisition of Intra-Cellular Therapies for \$14.6 Billion:** Johnson & Johnson completed the acquisition of Intra-Cellular Therapies for \$14.6 billion, paying \$132 per share in cash, finalizing the deal in April 2025. The acquisition strengthens J&J's neuroscience segment with Caplyta (lumateperone), an oral atypical antipsychotic approved for schizophrenia and bipolar depression. Caplyta also has an FDA review underway for supplemental approval as adjunctive treatment for major depressive disorder (MDD), potentially expanding its market. In 2024, Caplyta generated \$680.5 million in sales, up 47% from 2023, with a projected \$758 million in 2025.⁹
- Hologic Acquisition by Blackstone & TPG for up to \$79 per Share:** Hologic will be acquired by Blackstone and TPG for \$76 per share in cash plus up to \$3 per share in contingent value rights tied to Breast Health revenue milestones, representing a 46% premium. Minority investments come from ADIA and GIC.

The deal strengthens Hologic's leadership in women's health and accelerates growth. Closing is expected in H1 2026, subject to approvals, with Hologic's stock to be delisted post-transaction.

These strategic transactions highlight ways for pharma and healthcare companies to drive growth and portfolio value. Royalty acquisitions like IMDELLTRA generate long-term revenue with lower operational risk, while pipeline acquisitions such as Metsera emphasize targeting high-growth areas with unmet needs. By identifying complementary assets and balancing risk with innovation, companies can diversify portfolios, strengthen competitive positioning, and accelerate patient access to transformative treatments.

Regulatory Updates

In 2025, regulators in the UK, US, Singapore, and Australia are accelerating access to innovative therapies and AI-enabled healthcare while maintaining patient safety. Initiatives include MHRA–FDA collaboration, precautionary quality controls in Singapore, and updated manufacturing and AI regulations in Australia. These actions reflect a global shift toward harmonized standards, faster market entry, and stronger oversight of medical products and digital health solutions.

- UK–US Regulatory Collaboration: Accelerating Innovation Through AI and Reliance Routes:** *In 2025, the UK's MHRA and US FDA strengthened collaboration to accelerate patient access to innovative medical technologies and AI-driven healthcare. The National AI Commission, including experts and tech leaders like Google and Microsoft, ensures safe, transparent AI use. International reliance routes allow the UK to accept FDA-approved devices, reducing duplication and speeding market entry, supporting new UK medical technology regulations in 2026 and reliance routes in 2027 for a more harmonized regulatory environment.¹⁰*
- Singapore Regulatory Updates: Focus on Quality, Precision Medicine, and Immunotherapies:** *Singapore's Health Sciences Authority (HSA) maintains high standards for drug quality and safety, exemplified by the precautionary recall of five Bepraz batches. Simultaneously, approvals under Project Orbis and related frameworks, such as Enhertu, Opdivo, Tremfya, Abrysvo, and Onivyde, expand access to precision oncology, immunotherapies, and targeted treatments, highlighting Singapore's commitment to patient-centric care.¹¹*
- Australia Regulatory Updates: Strengthening Manufacturing Standards and AI Integration:** *Australia's TGA has updated Good Manufacturing Practice (GMP) guidelines, adopting the PIC/S Guide with a focus on sterile products. The agency is also consulting on AI and digital integration in manufacturing and has enhanced the GMP dashboard for timely, transparent*

compliance information, strengthening oversight and supply chain confidence.¹²

Global regulatory developments offer pharma, medtech, and healthcare companies' opportunities to accelerate product launches, leverage international approvals, and safely integrate digital health and AI solutions. Aligning with AI and precision medicine trends can create competitive advantages while ensuring patient safety and trust.

Recent Drug Approvals: Advancing Patient Care

In 2025, several breakthrough therapies are expected to gain FDA approval, offering new treatments for rare genetic diseases, oncology, and other serious conditions. These drugs mark significant advances in precision medicine and patient care¹³:

- **Anzupgo (delgocitinib, LEO Pharma, Jul 23):** Chronic hand eczema; targeted topical therapy.
- **Sepience (sepiapterin, PTC Therapeutics, Jul 28):** Hyperphenylalaninemia; precision metabolic therapy.
- **Vizz (aceclidine, LENZ Therapeutics, Jul 31):** Presbyopia; first aceclidine eye drop improving near vision.
- **Modeyso (dordaviprone, Jazz Pharmaceuticals, Aug 6):** Diffuse midline glioma; first-in-class protease activator.
- **Hernexeos (zongertinib, Boehringer Ingelheim, Aug 8):** HER2-mutant NSCLC; oral targeted therapy.
- **Brinsupri (brensocatib, Insmed, Aug 12):** Non-CF bronchiectasis; DPP-1 inhibitor improving lung function.
- **Dawnzera (donidalorsen, Ionis, Aug 21):** HAE prophylaxis; RNA-targeted therapy reducing attacks by up to 90%.
- **Wayrilz (rilzabrutinib, Sanofi, Aug 29):** Chronic immune thrombocytopenia; oral reversible BTK inhibitor.
- **Keytruda Qlex (pembrolizumab + berahyaluronidase, Merck, Sep 19):** Solid tumors; enhanced immunotherapy penetration.
- **Forzinity (elamipretide, Stealth BioTherapeutics, Sep 19):** Barth syndrome; restores mitochondrial function.
- **Inluriyo (imlunestrant, Eli Lilly, Sep 25):** ER+, HER2-, ESRI-mutated breast cancer; oral estrogen receptor antagonist.
- **Palsonify (paltusotine, Crinetics, Sep 25):** Acromegaly; oral SST2 agonist.
- **Rhapsido (remibrutinib, BeiGene, Sep 30):** Chronic spontaneous urticaria; oral BTK inhibitor.

- **Jascayd (nerandomilast, Boehringer Ingelheim, Oct 7):** IPF; preferential PDE4B inhibitor slowing lung function decline.

Implications for Pharma and Med Tech Companies

The shift toward continuous, coordinated, patient-centric care offers pharma and medtech companies' opportunities to redefine value. Digital-drug combination therapies and PDTs enhance clinical outcomes, adherence, and real-time data collection, while ecosystem-based care models, like Philips Virtual Care Management and Tempus, connect patients, providers, payers, and devices into scalable, data-driven networks. Strategic partnerships, market expansion, and regulatory harmonization accelerate innovation, AI adoption, and access to high-growth markets. Together, these trends enable companies to move beyond product-centric approaches toward holistic care, strengthen relationships, unlock new revenue, and lead in digital, precision, and patient-centered healthcare.

ANSEA supports organizations in navigating this transformation, helping them unlock value through strategic insights, grounded analysis, and a deep understanding of the healthcare environment.

About ANSEA

ANSEA is a global healthcare consulting firm dedicated to improving patient outcomes for public and private sector institutions. Our expertise ranges from Commercial Planning, Market Access, Health Systems Research, Stakeholder Engagement and Health Economics and Outcomes Research. We provide innovative solutions and local insights to support clients worldwide.

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