Best-in-Class Beyond the Pill Solutions: How Pharma Should Evaluate and Select BtP Vendor Partners

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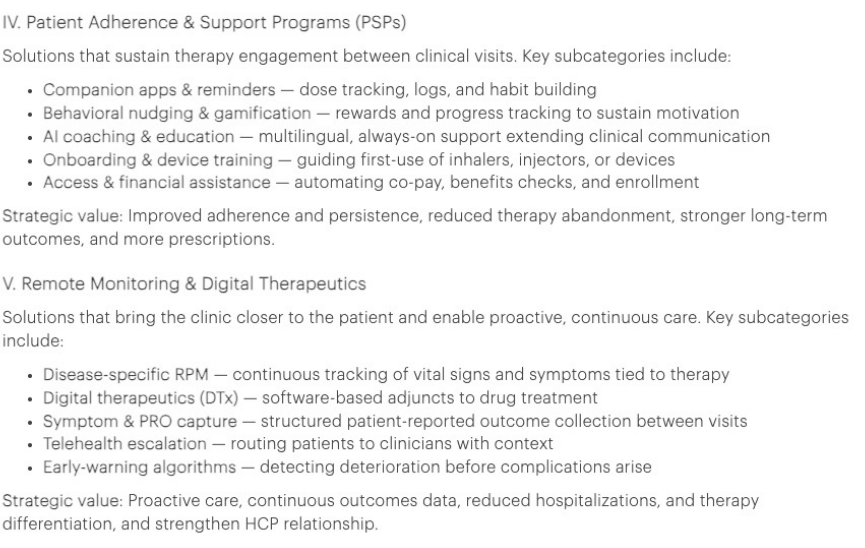
The term "beyond-the-pill" has become widely used across the pharmaceutical industry, yet its definition remains inconsistent and often misrepresented. Vendors position a broad range of digital solutions under this label, making direct comparisons difficult and complicating vendor selection for pharma companies. The absence of a standardized classification framework further limits transparency around capabilities and differentiation. Establishing clear categories and defining "best-in-class" criteria are therefore critical to support structured evaluation and informed partnership decisions. To address this gap, R2GConnect will showcase leading beyond-the-pill solutions in an online pitch event on April 14, highlighting best-in-class solution providers for BtP.

What Does "Beyond the Pill" Mean?

Beyond the Pill (BtP) refers to digital solutions that extend pharma's value proposition beyond the drug itself. A solution qualifies as Beyond the Pill if it meets one of two criteria:

1. It supports HCPs beyond the prescription and strengthen the HCP/Pharma relationship — helping clinicians engage with the right information, identify eligible patients, make better clinical decisions, and reduce administrative burden.
2. It supports patients beyond the drug — helping patients stay adherent, manage their conditions, replace the drug, change health behaviors, and generate real-world data that demonstrates therapy value.

Together, they form the core of the BtP ecosystem. Many other solution exists which use the Beyond the Pill label, whenever it helps their sales and marketing efforts.



The Five BtP Categories

R2GConnect organizes BtP solutions into five categories covering the full therapy lifecycle:

I. Digital HCP Engagement Platforms

Solutions that help pharma engage healthcare professionals more effectively and intelligently. Key subcategories include:

- Next-best-action detailing — AI-driven recommendations for message, channel, and timing per HCP
- Medical information on-demand — compliant, instant answers to drug queries via NLP/LLMs
- Virtual CME & advisory boards — accredited education and expert feedback at scale
- KOL mapping & engagement — data-driven identification and nurturing of scientific leaders
- Field force targeting & territory optimization — improved rep productivity and coverage

Strategic value: Optimized HCP engagement, stronger advocacy networks, and deeper prescriber insights.

II. Patient Identification & Diagnosis Enablement

Solutions that help find the right patients faster and support earlier diagnosis. Key subcategories include:

- Undiagnosed case finding — mining EHR/claims data to surface unrecognized patients
- Biomarker & genomic eligibility scoring — matching molecular profiles to targeted therapies
- Clinical trial matching — aligning patient data with study inclusion criteria
- Care-gap closure analytics — identifying missed screenings or therapy opportunities
- Switch-risk & churn prediction — forecasting therapy discontinuation or switching

Strategic value: Expanded patient pool, faster diagnosis, accelerated recruitment, and improved therapy precision.

III. Clinical Decision Support & Workflow Automation

Solutions that help HCPs make faster, safer treatment decisions while reducing administrative burden. Key subcategories include:

- Therapy selection navigators — ranking treatment options based on guidelines and patient factors
- Dosing & titration optimization — suggesting safe dose adjustments over time
- Toxicity & AE management — guiding clinicians through evidence-based interventions
- Diagnostic image & signal triage — flagging suspicious findings from imaging/waveforms
- Prior-authorization automation — streamlining reimbursement and reducing time-to-therapy

Strategic value: Streamlined workflows, improved prescribing accuracy, faster therapy initiation, and strengthen HCP relationship.

IV. Patient Adherence & Support Programs (PSPs)

Solutions that sustain therapy engagement between clinical visits. Key subcategories include:

- Companion apps & reminders — dose tracking, logs, and habit building
- Behavioral nudging & gamification — rewards and progress tracking to sustain motivation
- AI coaching & education — multilingual, always-on support extending clinical communication
- Onboarding & device training — guiding first-use of inhalers, injectors, or devices
- Access & financial assistance — automating co-pay, benefits checks, and enrollment

Strategic value: Improved adherence and persistence, reduced therapy abandonment, stronger long-term outcomes, and more prescriptions.

V. Remote Monitoring & Digital Therapeutics

Solutions that bring the clinic closer to the patient and enable proactive, continuous care. Key subcategories include:

- Disease-specific RPM — continuous tracking of vital signs and symptoms tied to therapy
- Digital therapeutics (DTx) — software-based adjuncts to drug treatment
- Symptom & PRO capture — structured patient-reported outcome collection between visits
- Telehealth escalation — routing patients to clinicians with context
- Early-warning algorithms — detecting deterioration before complications arise

Strategic value: Proactive care, continuous outcomes data, reduced hospitalizations, and therapy differentiation, and strengthen HCP relationship.

Best-in-Class Criteria: Six Must-Have Requirements

Beyond solution category and functional scope, six non-negotiable requirements determine whether a BtP solution is strategically viable for pharma partnership. These criteria form the foundation of R2GConnect's evaluation framework and define what separates best-in-class platforms from tactical point solutions.

I. Clear Business Model Aligned with BtP Definition

A best-in-class BtP solution must have a business model that directly and transparently connects to its role in the therapy lifecycle — either supporting HCPs beyond the prescription or supporting patients beyond the drug.

The vendor must clearly articulate which of the two BtP streams it serves and how its revenue model reflects value delivered within that stream. A patient adherence tool should demonstrate how its pricing ties to measurable adherence outcomes. A clinical decision support tool should show how its model integrates into clinical workflows and reimbursement pathways.

The business model must be pharma-compatible: structured for enterprise B2B agreements with clear deliverables, defined service-level agreements, and transparent cost components. Best-in-class vendors offer flexibility across multiple contracting models — SaaS subscription, per-patient/per-user pricing, project-based implementation fees, and outcome-linked performance components — because different pharma partners and therapy areas require different structures.

Red flags include vendors whose core revenue comes from consumer or hospital contracts and who treat pharma as a secondary or undefined revenue stream. The business model must demonstrate that pharma is a primary, strategically considered customer segment.

II. Proven Pharma Collaboration and Clear Pricing for All Stakeholders

A best-in-class BtP solution must have demonstrated experience working with pharmaceutical companies — not just a stated intention to do so. Prior pharma collaboration is the strongest signal that a vendor understands the regulatory, compliance, and commercial requirements unique to pharma partnerships.

This includes understanding of pharma's cross-functional decision-making (brand, medical affairs, IT, compliance, regulatory, and market access teams all have a stake), experience with medical-legal review processes and pharmacovigilance requirements, familiarity with pharma procurement cycles and enterprise contracting norms, and the ability to navigate multi-stakeholder environments where the payer, the prescriber, and the patient may all be different entities.

Equally important, a best-in-class vendor must present clear, defensible pricing models not only for pharma but for all parties in the value chain. Many BtP solutions operate in multi-payer environments, contracting simultaneously with pharma, health systems, and payers. The vendor must articulate pricing for each stakeholder clearly — including how costs scale with user volume, geography, therapeutic area, and integration complexity.

Best-in-class indicators include named pharma partnerships (ideally multi-year), published case studies from pharma-sponsored programs, and a pricing model refined through actual pharma contracts rather than theoretical proposals.

III. Clinical Evidence Generation

A best-in-class BtP solution must demonstrate measurable clinical or commercial impact through validated evidence — not just platform metrics or engagement statistics.

The evidence hierarchy matters:

- Peer-reviewed published studies (ideally RCTs with meaningful sample sizes) represent the strongest evidence.
- Third-party validated data (outcomes validated by independent research organizations, health economics firms, or academic partners) represents strong evidence.
- Controlled pilot data with defined endpoints is acceptable for earlier-stage solutions.
- Vendor commercial claims without external validation represent the weakest tier.

Best-in-class solutions go beyond demonstrating that their platform is used to demonstrating that it changes outcomes: quantified improvements in clinical endpoints (adherence rates, hospitalization reduction, adverse event detection), health-economic impact (cost savings per patient, per therapy cycle), or real-world evidence supporting regulatory submissions, payer negotiations, or label-expansion strategies.

IV. Regulatory & Compliance Maturity

A best-in-class BtP solution must meet the regulatory and data governance requirements appropriate to its function and target markets. Pharma cannot assume regulatory risk from its vendor partners.

Data privacy compliance is non-negotiable. Solutions operating in the United States must demonstrate HIPAA compliance, including Business Associate Agreements, data encryption, access controls, and audit trails. Solutions operating in the European Union must demonstrate GDPR compliance, including lawful basis for processing, data minimization, right to erasure, and Data Protection Impact Assessments. Solutions targeting global deployment must demonstrate compliance with both frameworks plus any additional local requirements.

Medical device classification must be clear and appropriate. The required regulatory posture depends on the solution's function. Solutions that provide clinical decision support, diagnostic triage, dosing recommendations, or therapeutic interventions typically fall under medical device regulation and require CE marking under the EU Medical Device Regulation (MDR) or FDA clearance as Software as a Medical Device (SaMD) in the United States. The specific classification (Class I, IIa, IIb, or III under MDR; Class I, II, or III under FDA) depends on the risk level and intended use.

Best-in-class vendors clarify their device classification status, hold relevant certifications (ISO 13485 for quality management, ISO 27001 for information security), have undergone cybersecurity audits, and can demonstrate pharmacovigilance integration processes. Solutions positioned solely as consumer wellness products without regulatory defensibility lack the credibility required for global pharma partnerships.

The regulatory landscape is evolving rapidly. The EU AI Act classifies AI-enabled medical devices as high-risk, with compliance obligations taking effect in 2026–2027. In the US, the FDA has introduced Predetermined Change Control Plans for AI/ML devices and lifecycle management guidance for AI-enabled software. Vendors must demonstrate awareness of and preparedness for these evolving requirements.

V. Integration Capability

A best-in-class BtP solution should integrate seamlessly into the healthcare ecosystem rather than operating as a standalone tool. Standalone solutions face declining engagement over time and fail to deliver the continuous data flows that pharma needs for evidence generation and commercial insight.

Integration can span across multiple dimensions:

- Technical interoperability — support for FHIR, HL7, and other healthcare data standards enabling data exchange with EHRs, clinical decision support systems, and laboratory information systems.
- CRM and commercial system connectivity — for HCP-facing solutions, integration with platforms such as Veeva or Salesforce is essential.
- Patient ecosystem connectivity — for patient-facing solutions, integration with pharmacy systems, payer portals, wearable devices, and connected medical devices.
- Workflow integration — the solution must fit naturally into how clinicians, patients, and care teams already work, rather than requiring them to change behavior. Minimal training, simple onboarding, and structured outputs that clinicians can act on within existing workflows.

VI. Proven Usage & Scalability

A best-in-class BtP solution must demonstrate that its platform is actively being used by HCPs, patients, or both — and that it can scale across the geographies, therapy areas, and patient volumes that pharma operates in.

Proven usage means the vendor can show that the solution has been adopted and is being used in real-world settings — not just downloaded or deployed. For HCP-facing solutions, this means demonstrating active clinician engagement: how many HCPs use the platform regularly, how it integrates into their daily practice, and what impact it has on their workflow. For patient-facing solutions, this means demonstrating sustained patient engagement: retention rates (30-day, 90-day, 6-month), daily or weekly active usage, and evidence that patients continue using the solution long enough to achieve meaningful outcomes.

Engagement metrics alone are not sufficient — best-in-class vendors connect usage data to outcomes. High retention rates are valuable only if they correlate with improved adherence, better clinical endpoints, or measurable health-economic impact.

Scalability means the solution can expand from a single-country pilot to a multi-market, multi-brand deployment without re-engineering. This requires:

- Cloud-native infrastructure supporting global deployment and enterprise-grade uptime
- Modular architecture allowing therapy-specific customization without rebuilding the core platform
- Multi-language capability (best-in-class solutions support at least 5–6 languages)
- White-label or co-branding options for pharma to deploy under its own brand
- Regulatory scalability — the ability to navigate MDR/IVDR in the EU, FDA SaMD in the US, and local frameworks in other markets
- Enterprise-grade SLAs covering uptime, data security, incident response, and update governance

R2GConnect's Partner Fit Scoring Framework

The evaluation and selection process of a Beyond the Pill solution vendor is complex and time consuming. We recommend a Partner Fit Scoring Framework, a weighted evaluation model that produces a composite score (0–100) for each vendor. Weights need to be adjusted at the beginning of each vendor selection process:

1. Evidence Level (20%): Peer-reviewed RCT or published study with meaningful sample size scores 100. Third-party validated pilot with independent data scores 75. Vendor claims with internal data only scores 50. No evidence or purely conceptual scores 25.
2. Technical Maturity/Innovation Level (20%): FDA-cleared, CE-marked (IIa or higher), or enterprise-deployed across multiple sites scores 100. CE Class I with active deployments or validated MVP with paying customers scores 50–75. Prototype or pre-launch concept scores below 50.
3. Regulatory & Compliance (10%): Full HIPAA and GDPR compliance with relevant medical device classification (CE MDR or FDA SaMD as appropriate), ISO 13485, ISO 27001, and completed cybersecurity audits scores 100. Partial compliance (e.g., GDPR only, or Class I without higher classification where required) scores 60–80. No regulatory posture, no data privacy compliance, or consumer-wellness-only positioning scores below 50.
4. Integration Flexibility (10%): FHIR/HL7 interoperability plus proven EHR and CRM integration across multiple systems scores 100. Partial integration (API-based but limited to specific systems) scores 60–80. Standalone solution with no integration pathways scores 30–50.
5. Market Reach & Proven Usage (10%): Multi-country pharma deployments with demonstrated HCP or patient adoption, sustained retention metrics, and enterprise SLAs scores 100. Regional deployment with pilot-stage usage data scores 60–80. Single-market, no demonstrated real-world adoption scores 30–50.
6. Therapeutic Relevance (10%): Multi-therapy or chronic disease platform applicable across pharma portfolios scores 100. Deep single-specialty with demonstrated expansion potential scores 70–80. Narrow single-use application with limited pharma applicability scores 50.
7. Team fit (20%): Vendor team quality and motivation are critical selection criteria, particularly given that partnerships typically extend over a minimum of one to two years. During this time, challenges and operational barriers are inevitable. Pharma companies therefore require partners who not only deliver technical capabilities, but also demonstrate resilience, proactive communication, and the ability to sustain collaboration and performance during more demanding phases of the partnership.

Takeaway

Beyond-the-pill (BtP) solutions can generate measurable value for pharmaceutical companies; however, vendor selection remains complex due to the lack of a consistent definition. The broad and often inaccurate use of the BtP label allows healthtech companies to position offerings within this category even when BtP is not a core capability or when value claims are not substantiated for relevant use cases.

To mitigate this, pharma companies need to clearly define the specific outcomes and value drivers they expect from a BtP partnership and assess potential vendors against a structured, best-in-class set of criteria. R2GConnect's BtP vendor selection framework addresses this need by enabling decision-makers to systematically identify, benchmark, and select the most suitable partners across five solution categories—ensuring cross-functional alignment and measurable, outcome-driven impact.

For more information about R2GConnect's BtP vendor selection framework, contact hello@research2guidance.com or visit https://www.r2gconnect.com/innovation-scouting

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