Aptar
digital health

Branded or Unbranded: What Options for Commercial Digital Health Solutions in Pharma?

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Across specialty medicine, many innovative therapies can benefit from the added value of a digital health solution to improve the experience of patients with their treatment. Pharmaceutical companies have several options regarding how these digital health solutions can be marketed in relation to drug brands. To implement the appropriate branding strategy for these new digital assets, pharma decision-makers must answer multiple questions:

- Will the new solution be paired with the drug?
- Is it unique to the drug or to a drug class?
- How will it be integrated with other services to providers and patients treated with the drug?
- How does it relate to regulatory pathways?

Choosing between the different branding options has consequences on the market access strategy and the way the digital solution can generate value for the pharma company. In this white paper, we will review the different branding options available to pharmaceutical companies, review the strategic rationale behind each option and illustrate how these options may apply to different types of digital health solutions.

One solution, multiple branding options

Five levels of relationship exist between a digital solution and a drug brand from the most indirect to the strongest: unbranded, company-branded, drug-branded, drug-specific, and drug-paired solutions. It is important to note that across different geographies, the level of relationship may vary, according to local regulations and market access strategies.

Unbranded digital solutions are not related to a specific entity or product. They offer several advantages to pharmaceutical companies as they may be distributed with or by third parties. They can provide more balanced health information, support patients more holistically and therefore potentially improve diagnosis, disease management, and/or treatment outcomes without direct product promotion. As they are not tied to a specific drug, they generally target a broader patient population, and their market adoption potential is higher. However, their development and distribution can be complicated when compared to drug-specific solutions as unbranded approaches usually require stronger alignment between multiple stakeholders that may have different

DRUG-PAIRED
The digital solution is marketed and distributed with the drug (e.g., co-packaging or combination product)

DRUG-SPECIFIC
The digital solution is designed for patients treated by the drug and restricted to this population

DRUG-BRANDED
The digital solution uses the drug brand but may be used by other patients affected by the corresponding solution

COMPANY-BRANDED
The digital solution uses the company brand but is not specific to its drug

- Drug-paired
- Drug-specific
- Drug-branded
- Company-branded
- Unbranded
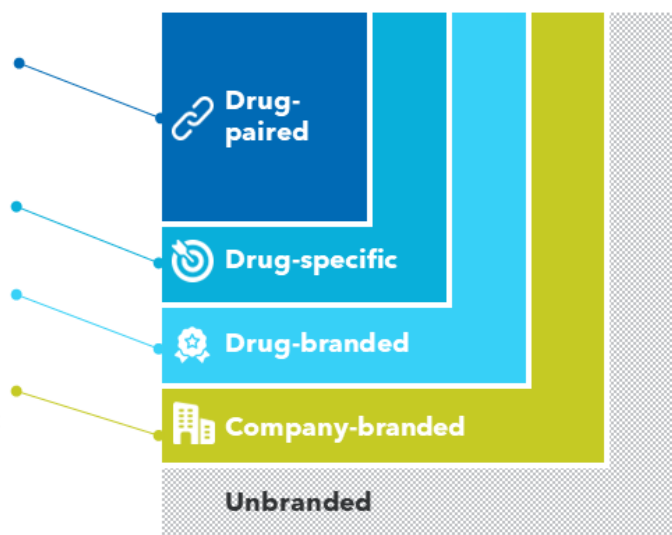
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priorities. Finally, they are sometimes the only available option in markets where promotion is restricted.

Company-branded digital solutions use the company brand but are not specific to its drug. An example of a company-branded solution would be Insulia®, a prescription-only medical device that recommends basal insulin doses for adults with type 2 diabetes based on the treatment plan created by the healthcare provider. Insulia® is not tied to specific basal insulin and is not branded as such. However, its brand is associated with the manufacturer, Voluntis, part of Aptar Digital Health. Our experience has shown that to avoid using multiple systems in parallel, prescribers tend to prefer solutions that are not tied to a specific drug but are as broad as possible.

Drug-branded solutions uses the drug brand but may be used by other patients affected by the corresponding condition. When allowed by local regulation, such digital

solutions can be leveraged to enhance brand differentiation and deliver a unique treatment experience to patients. While the services offered through the solution might not be unique to a drug (i.e., these features are in practice drug-agnostic), they may be offered primarily or exclusively to patients treated with the company drug. They can oppose drug-agnostic solutions that benefit their end-users regardless of their treatment plan in the same therapeutic area. Drug-specific solutions can build barriers to competition, but their market potential can be reduced. The target user population is smaller and they are less eligible for reimbursement, especially in Europe where public reimbursement is more complicated to achieve for branded digital solutions. To counter this, some pharma may consider developing solutions that can be used in tandem with several drugs in their portfolio, like the Abbvie Complete program. This program works with several brands such as Humira and Skyrizi and provides Patient Support Program-like support, answers to treatment and insurance questions

DRUG-PAIRED The digital solution is marketed and distributed with the drug (e.g. co-packaging or combination product)		▪ **Betaseron® Betaconnect AutoInjector** ▪ **Propeller / Novartis co-packaging on Enerzair Breezhaler**
DRUG-SPECIFIC The digital solution is designed for patients treated by the drug and restricted to this population		▪ **Takeda/Shire MyPKFiT™ for Advate®** ▪ **Eli Lilly Trulicity® app**
DRUG-BRANDED The digital solution uses the drug brand but may be used by other patients affected by the corresponding condition		▪ **Abbvie COMPLETE**
COMPANY-BRANDED The digital solution uses the company brand but is not specific to its drug		▪ **Insulia® digital companion for people with T2 diabetes**

Insulia® is a prescription-only software medical device intended for use by healthcare professionals and their type 2 adult diabetes patients treated with long-acting insulin analogs as an aid in the management of diabetes. Insulia® should not be used for basal dose recommendations with intermediate-acting insulin (NPH – Neutral Protamine Hagedorn) nor with premixed insulin. Insulia® is not intended for use by people who are pregnant, non-adult patients or patients that are treated with a basal-plus or a basal-bolus regimen (i.e., including multiple mealtime insulin injections per day or insulin pump therapy). Insulia® is only indicated for use with insulin detemir (Levemir® U-100) once or twice daily, insulin degludec (Tresiba® U-100) once daily and insulin glargine (Lantus® U-100, Toujeo® U-300, Semglee® U-100 and Basaglar® U-100) once daily. Please carefully read product instructions before use available in the About & Help tab of the app. For more information, please visit: www.insulia.com/

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and provides a dedicated Nurse Ambassador. Other pharma companies may also consider the benefits of branded digital solutions to positively contribute to discussions on drug pricing.

Drug-specificity refers to digital solutions designed for patients treated by the drug and restricted to this population. It is usually the case when they address challenges that are unique to the drug compared to other therapeutic options for the same condition: these challenges can be specific to the administration mode, the dosing of the drug or its safety profile. As an example of a drug-branded solution, Takeda/Shire developed and achieved clearance for myPKFiT™ for Advate®. It is a free web-based software used to generate pharmacokinetic profiles for hemophilia A patients 16 and older, weighing at least 45 kilograms and treated with Advate®. We can also quote as another example the Trulicity® app, developed by Eli Lilly and Company . This app aims at helping patients with Type 2 diabetes gain confidence in using their medication. It includes features such as medication reminders, Instructions for Use (IFU) and specific support related to Trulicity®.

Even more tied are Drug-paired solutions. These digital solutions are marketed and distributed with the drug (e.g., co-packaging or combination product). Sometimes, the type of features that are provided by the solution is so unique and necessary to the drug utilization that the digital solution is distributed with the drug as a co-packaged solution or a combination product. While the regulatory pathway seems more complex to navigate, these solutions can make for a

simpler business case. The value proposition of digital solutions is so close to the drug strategy and unique challenges that value generation models are more streamlined, if the solution meets regulatory and payer expectations. An example of paired digital solutions would be Betaconnect Autoinjector for Betaseron® users. Betaseron® is a prescription medicine used to treat relapsing forms of multiple sclerosis and Betaconnect is the auto-injector used by patients to take their drug themselves. It operates in tandem with a software component composed of myBETAapp™ and the BETACONNECT Navigator™. The mix of medicine, device, mobile and cloud-based health technology was approved by the FDA as a combination product in 2017 . Another relevant example is the European collaboration between Novartis and Propeller Health , where the Propeller digital health platform is co-packaged and prescribed alongside Enerzair Breezhaler to treat uncontrolled asthma.

Customized digital solutions to meet specific business needs

To address the growing diversity of business objectives for digital health solutions, Aptar Digital Health has built its offering around 3 major archetypes.

Digital Patient Support Programs (PSPs) are brand-specific digital solutions for patients, connected with Patient Support Programs, to improve onboarding and adherence. They target the onboarding experience, eventually including accessibility such as financial support. They are generally non-regulated, brand-specific extensions to PSPs and are rarely interventional.

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Digital PSP/ Companion apps

Brand-specific digital solutions for patients, connected with Patient Support Programs, to improve onboarding and adherence.

Software-as-a-Medical Device

Software addressing pain points in the treatment journey (e.g., dosing, toxicity, self-administration). They can be interventional, usually through clinical or patient decision-support and are generally drug-specific.

Disease Management

Comprehensive drug-agnostic solutions elevating standards of care for chronic conditions through holistic approach.
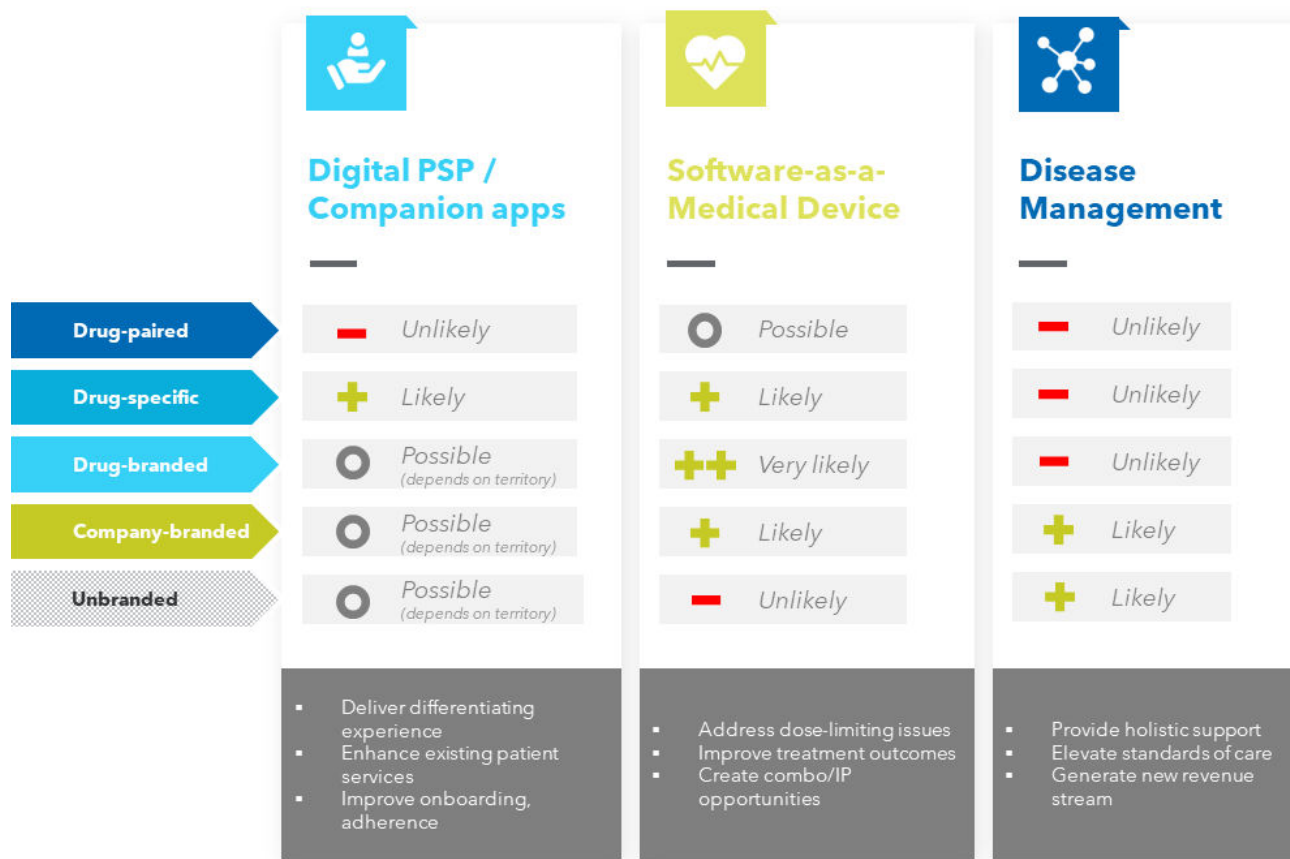
Digital Therapeutics are software addressing pain points in the treatment journey (e.g., dosing, toxicity, self-administration). They can be interventional, usually through clinical or patient decision-support. As such, they are regulated Software-as-a-Medical Device and are generally drug-specific.

Disease Management Platforms are comprehensive drug-agnostic solutions elevating standards of care for chronic conditions through a holistic approach. They consider the patient journey in the broadest sense, including diagnostic, education, ePRO, telehealth, symptoms, and trigger tracking. They support real-time remote monitoring of adherence and outcomes. Part of these solutions can be regulated, and they are generally drug agnostic, and eligible for reimbursement.

While there is no ultimate go-to-market strategy for digital health solutions, combining these models can help pharma companies achieve different business objectives. If there is a strong need to support the brand in its market and increase its competitiveness through value-adding services, digital PSPs and companion apps may be the best fit. A Digital Therapeutic strategy may be more suitable if the goal is to address drug-related issues while improving outcomes. A Disease Management Platform would be the best candidate to provide holistic support to patients, focus on adherence and target reimbursement of the solution.

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	Digital PSP / Companion apps	Software-as-a-Medical Device	Disease Management
Drug-paired	Unlikely	Possible	Unlikely
Drug-specific	Likely	Likely	Unlikely
Drug-branded	Possible (depends on territory)	Very likely	Unlikely
Company-branded	Possible (depends on territory)	Likely	Likely
Unbranded	Possible (depends on territory)	Unlikely	Likely
	• Deliver differentiating experience • Enhance existing patient services • Improve onboarding, adherence	• Address dose-limiting issues • Improve treatment outcomes • Create combo/IP opportunities	• Provide holistic support • Elevate standards of care • Generate new revenue stream

Conclusion

Pharmaceutical companies considering digital solutions to support their drugs must navigate the complex waters of branding and market relations between the two components. Over the past decade, numerous models have been implemented across therapeutic areas, each tailored to specific business objectives, regulatory pathways, and local market access constraints.

At Aptar Digital Health, we believe that a diversified approach to branding digital solutions can lead to the best possible outcomes for the appropriate patient population.
We are commited to design the right solution to answer our pharma partners' challenges.

About Aptar Digital Health

Aptar Digital Health is a leader in integrated health solutions and services with a mission to elevate patient experiences at every stage of their treatment journey. Our suite of end-to-end, patient-centric digital solutions leverages our unmatched expertise and diverse, industry-leading product portfolio to deliver differentiating experiences and more positive outcomes.

Aptar Digital Health is a division of Aptar Pharma, which is part of AptarGroup, Inc., a global leader in the design and manufacturing of a broad range of drug delivery, consumer product dispensing and active material science solutions and services.

To learn more about how we enhance patient experiences
with our partners, visit:
www.aptardigitalhealth.com

1. https://www.skyrizi.com/skyrizi-complete/about-skyrizi-complete
2. https://www.takeda.com/newsroom/shire-news-releases/2017/abhvp5
3. Google Play Store (link), consulted on 13/APR/23
4. Bayer Receives FDA Approval of myBETAapp™ and BETACONNECT Navigator™ (link) consulted on 09/MAR/23
5. https://pharmaceuticalmanufacturer.media/pharma-manufacturing-news/novartis-partnership/