

# Business Case for Digital Inhalation Devices

**A platform provider's perspective on creating a compelling user experience and driving adoption**

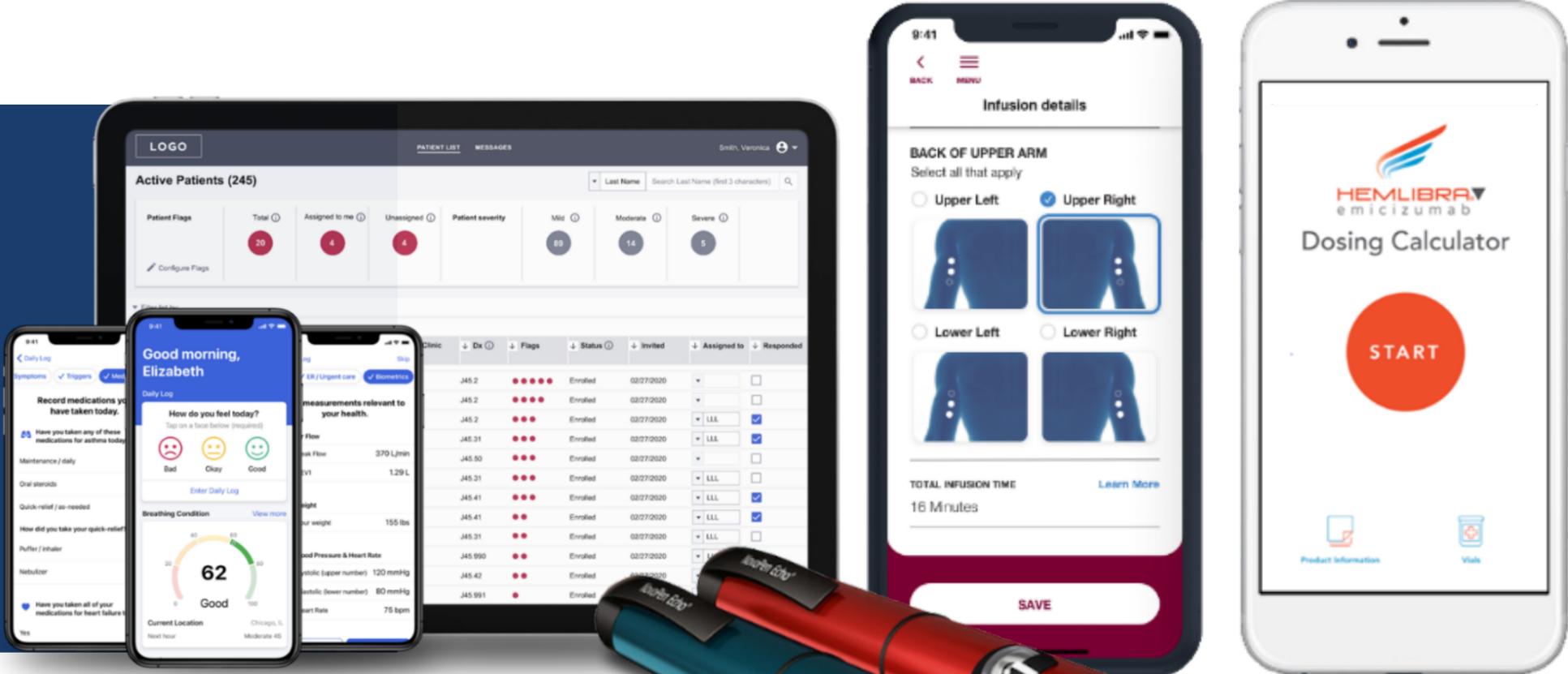
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# BrightInsight is a Global Platform for Biopharma & Medtech, Supporting Regulated Digital Health Solutions

We help companies accelerate time to market for regulated Software as a Medical Device (SaMD) digital health offerings; including apps, algorithms, medical devices and combination products.



**CSL Behring**



# Digital Health Solutions are Delivering Value Across the Patient Journey



**BRIGHTINSIGHT  
USE CASES  
(EXAMPLES)**

**PATIENT DIAGNOSIS**  
Leverage powerful algorithms to diagnose patients more quickly and accurately when early intervention matters.

**PATIENT SELECTION**  
Give providers the tools they need to quickly and accurately match individual patients with the right therapies.

**DOSE MANAGEMENT**  
Ensure optimal drug dosing and filtration through the integration of diagnostic/wearable data and regulated dose recommendation algorithms.

**PATIENT ADHERENCE**  
Unlock better patient adherence with innovative digital drug comparison apps and/or connected combination products.

**CARE PATHWAY INTEGRATION**  
Improve outcomes for patients with chronic conditions and complex comorbidities through data integration, lifestyle support and telemedicine.

# Devices are Playing a Central Role in Delivering these Digital Health Use Cases

*“How can I maintain a healthy lifestyle?”*



## Consumer Products (wearables, smartphones)

- Primary patient interface (patient reported outcomes, lifestyle advice)
- "proxy" outcomes measures (e.g. movement)
- Primary cloud gateway

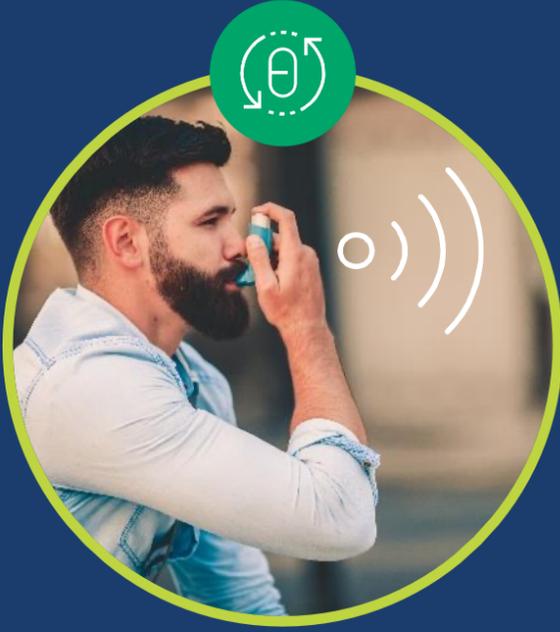
*“Is my therapy working?”  
“What dose should I take?”*



## Medical Biometric Monitors (IVD, wearables)

- Direct clinical outcomes measures (e.g. point of care IVD, BP, ECG, etc.)

*“Did I take my meds correctly?”*



## Adherence Monitors (Combination products)

- Dose event logging
- Correct use confirmation

# Despite Encouraging Clinical Data, Connected Inhalers are not Gaining Traction in the Market... Why?

## EVIDENCE OF CLINICAL BENEFIT



12-month electronic adherence monitoring data and patient dose reminders **reduces the number of courses of oral steroids and hospital admissions** for children aged 6-16.<sup>1</sup>

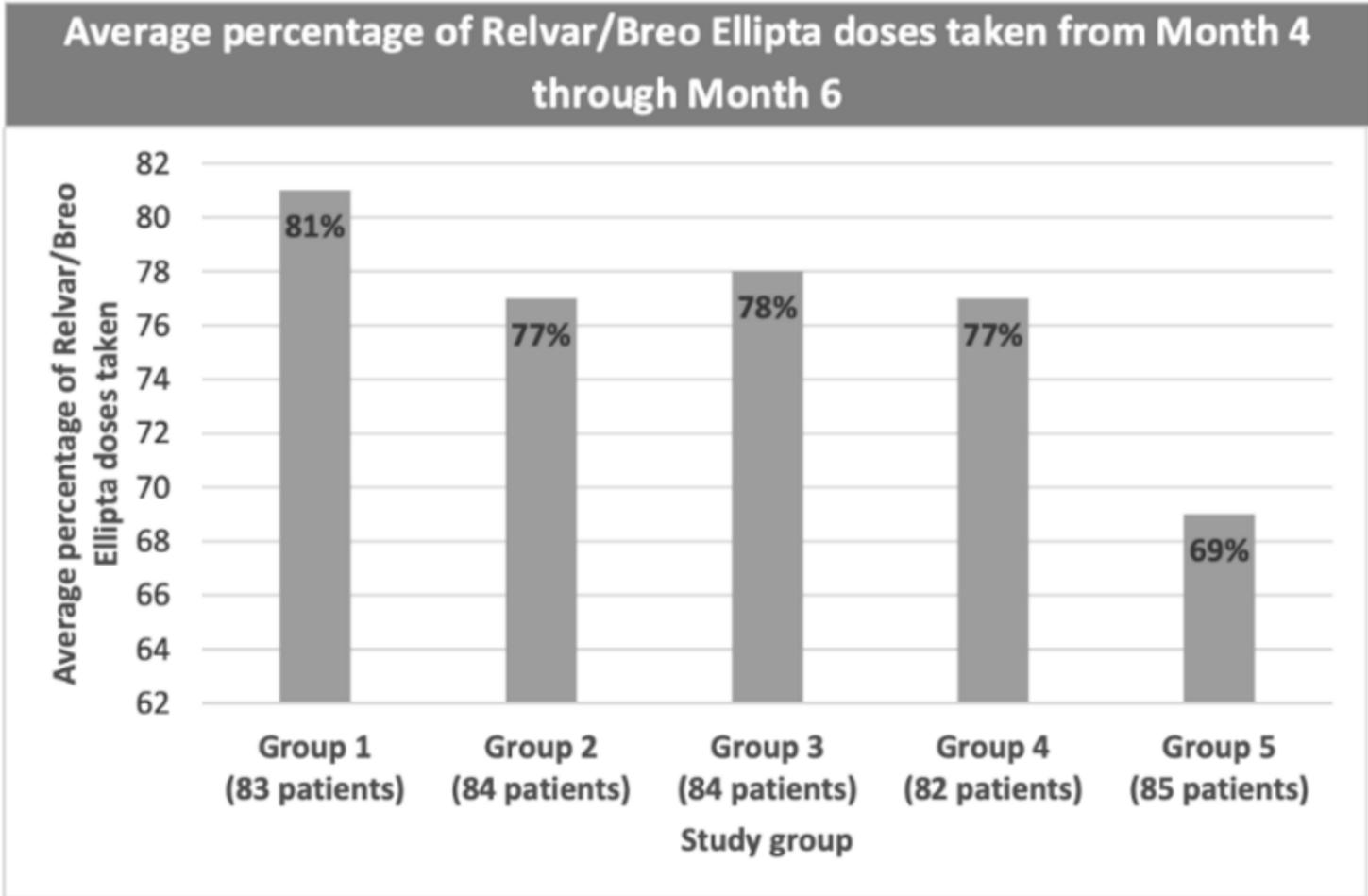


2900 patient study using smart inhalers across eight countries has found **significant improvement in adherence and patient control of allergic rhinitis and asthma** (CARAT) test scores.<sup>2</sup>



437 patient study by GSK using sensor dose logging of inhaler events and display of dose inhalation to both clinicians and patients (group 1 opposite) showed a **12% adherence increase relative to the non-digital control group** (group 5 below) and **reduced rescue medication** use in patients with uncontrolled asthma.<sup>3</sup>

## GSK TRIAL DATA ON SMART INHALERS<sup>3</sup>



References

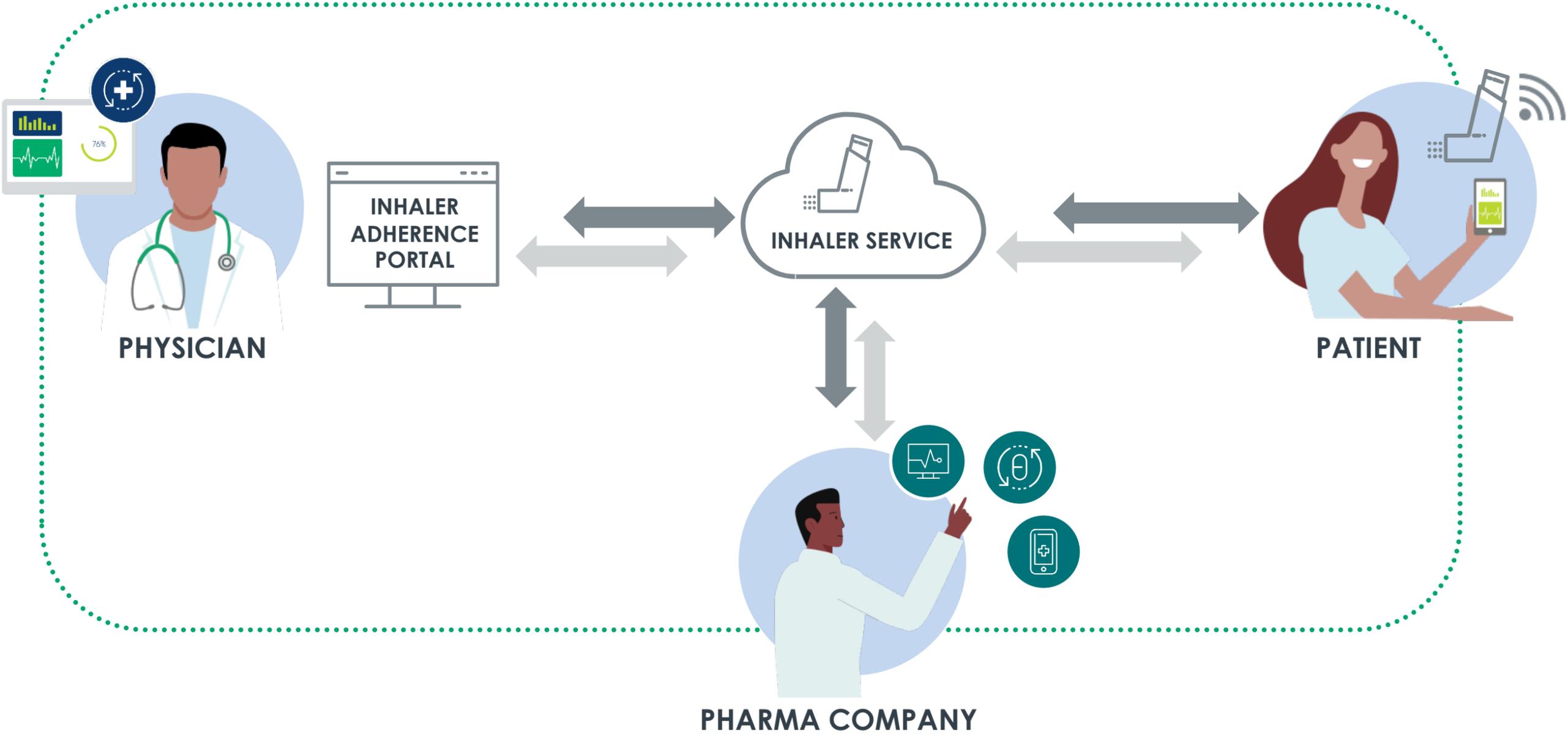
<sup>1</sup>Morton, RW, Elphick, HE, Rigby, AS, et al STAAR: a randomised controlled trial of electronic adherence monitoring with reminder alarms and feedback to improve clinical outcomes for children with asthma. Thorax 2017; 72: 347-354.

<sup>2</sup><https://ispe.org/pharmaceutical-engineering/july-august-2019/improving-pharmaceutical-connections-patients>

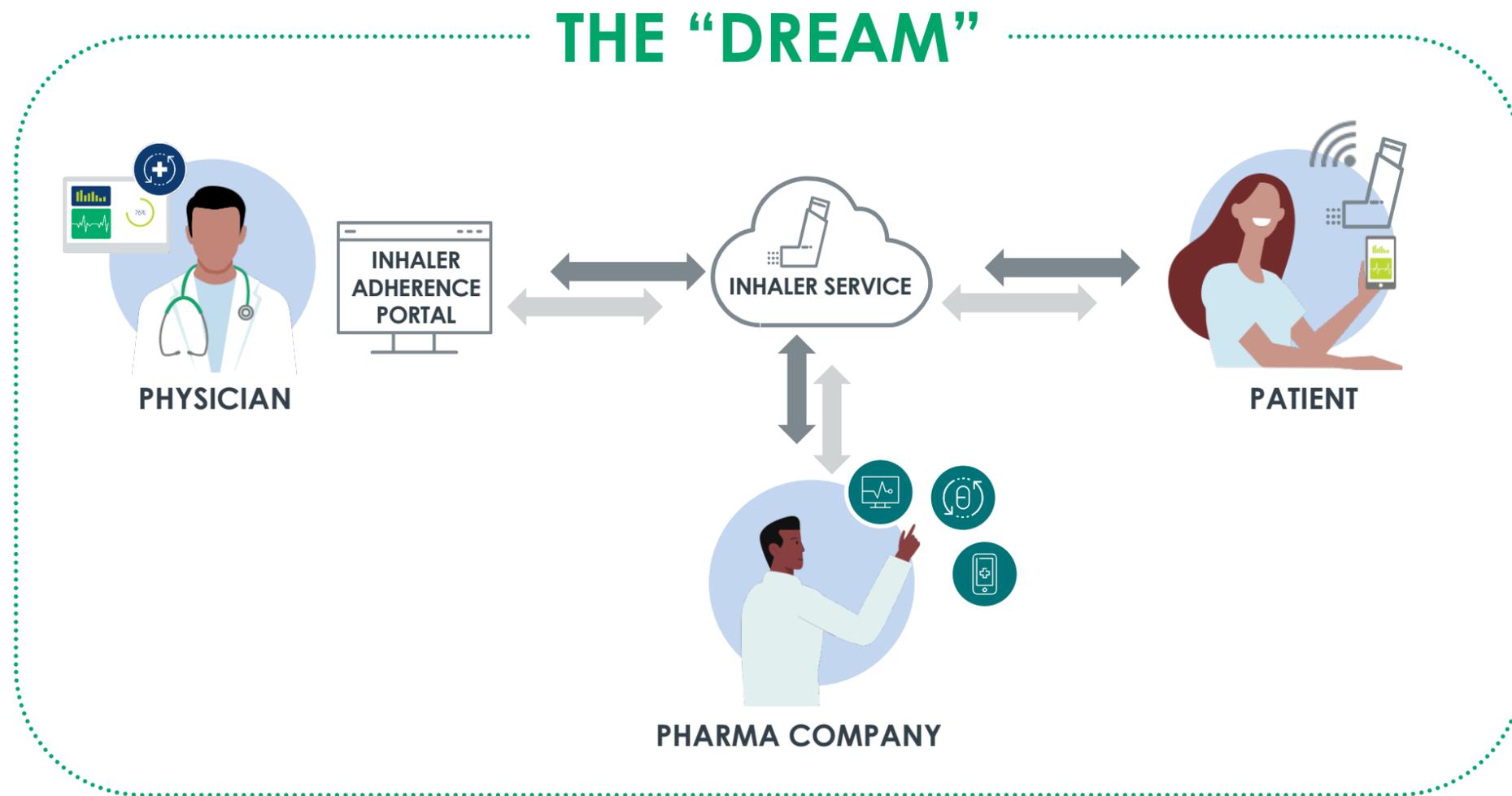
<sup>3</sup><https://www.gsk-studyregister.com/en/trial-details/?id=207040> and European Respiratory Journal 2020; DOI: 10.1183/13993003.03103-2020

# Traditionally, Biopharma has Offered Connected Combination Products as a Closed Ecosystem

## THE "DREAM"

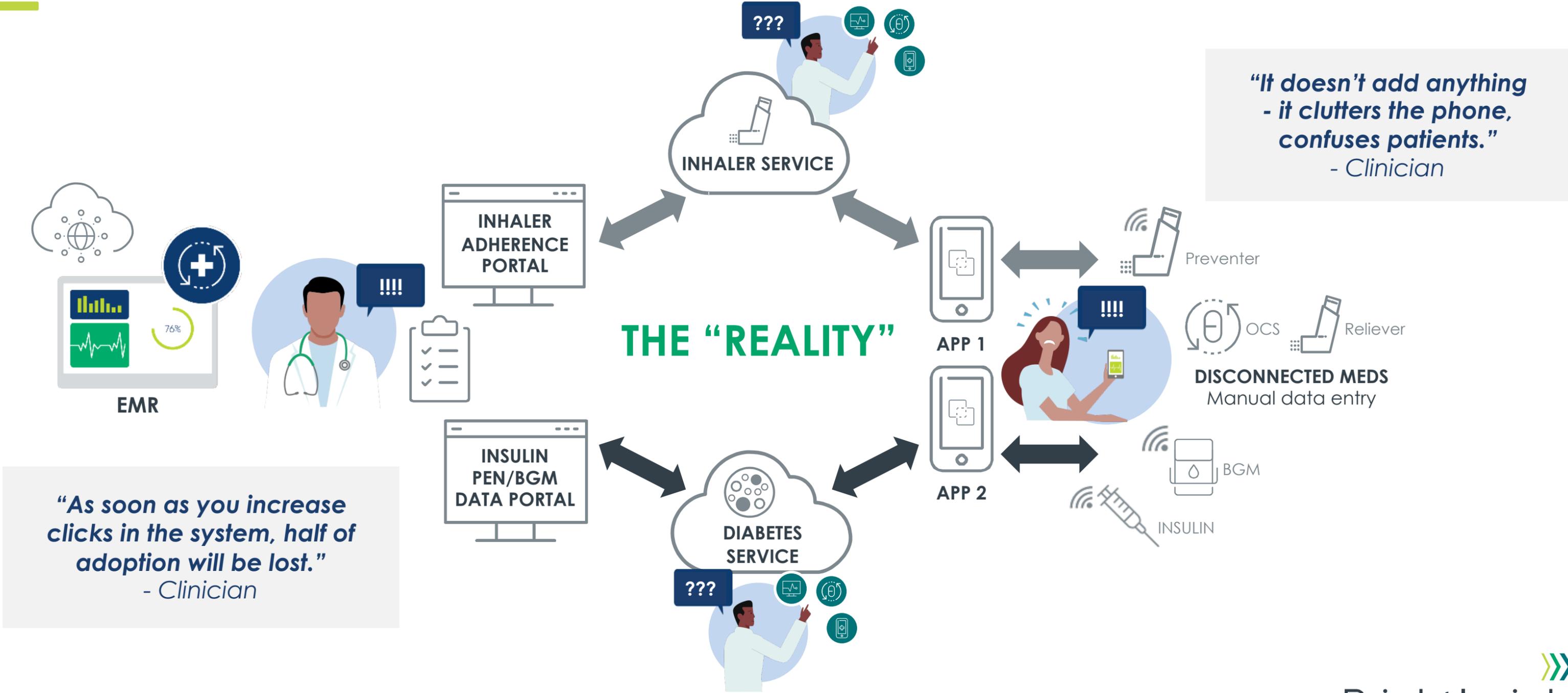


# Traditionally, Biopharma has Offered Connected Combination Products as a Closed Ecosystem



- **Patient Benefit – Specificity:** Focused companion solution (support designed for a specific treatment)
- **Physician Benefit - Support:** Remote driver of compliance and data collection to better manage specific treatment
- **Pharma Benefit – Differentiation:** Offering to drive value to key stakeholders and enable future pharma innovation based on data

# These Single-point Solutions Fail to Meet the Pain Points of Both Physicians & Patients



## CHALLENGE:

# Closed Ecosystems Compromise Engagement & Limit Impact for All Parties – Including Pharma



### PATIENT EXPERIENCE



“I have an app for tracking my symptoms, calendar notifications reminding me about my meds, emails from my doctor via their health system portal...and that’s just for my asthma”



### CLINICIAN EXPERIENCE



“I received a message from the patient in EHR, and now I need to login to the brand’s treatment portal in a separate screen, then have my nurse call the patient to triage the issue then fax in a benefits verification”

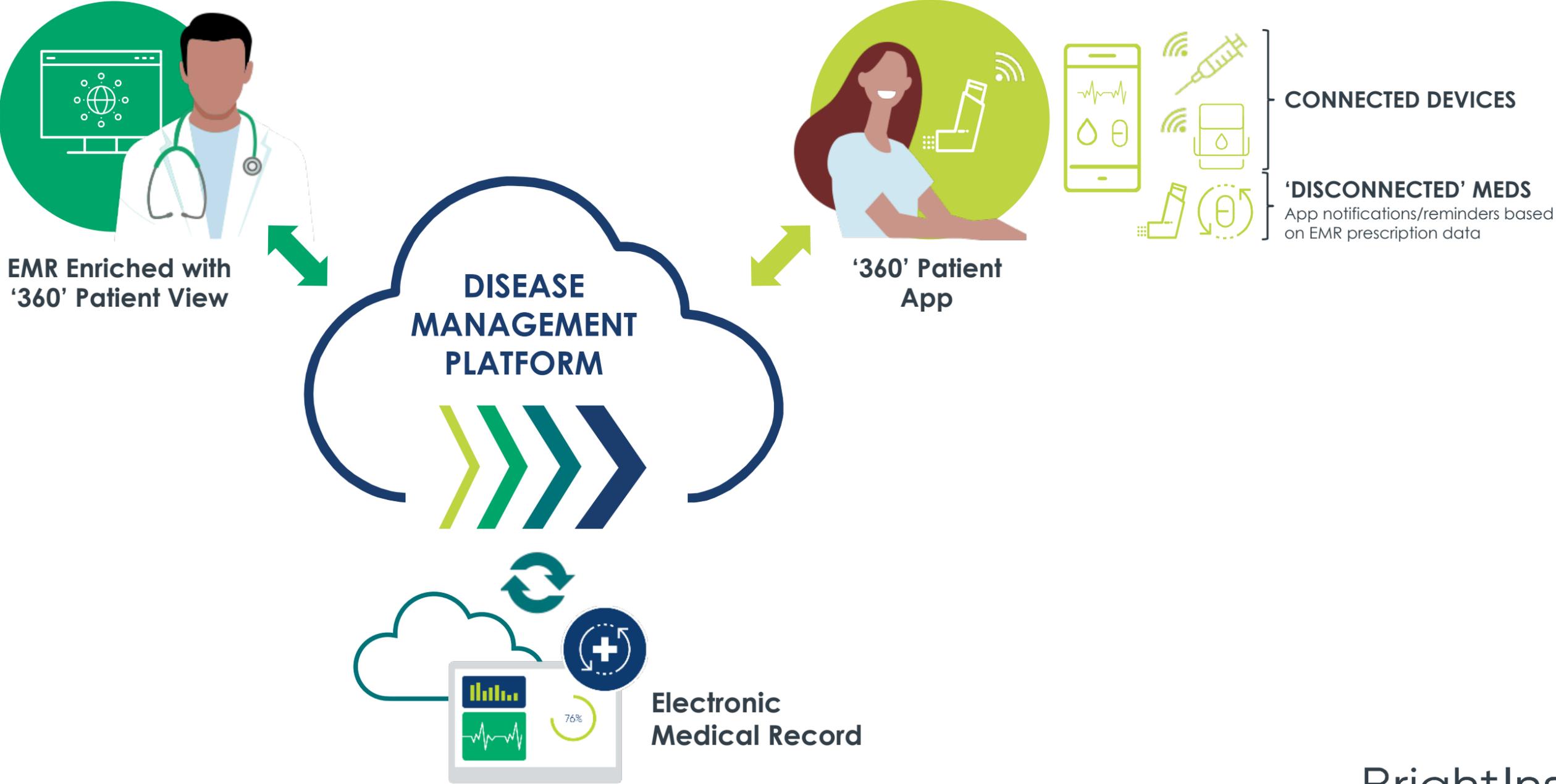


### PHARMA EXPERIENCE

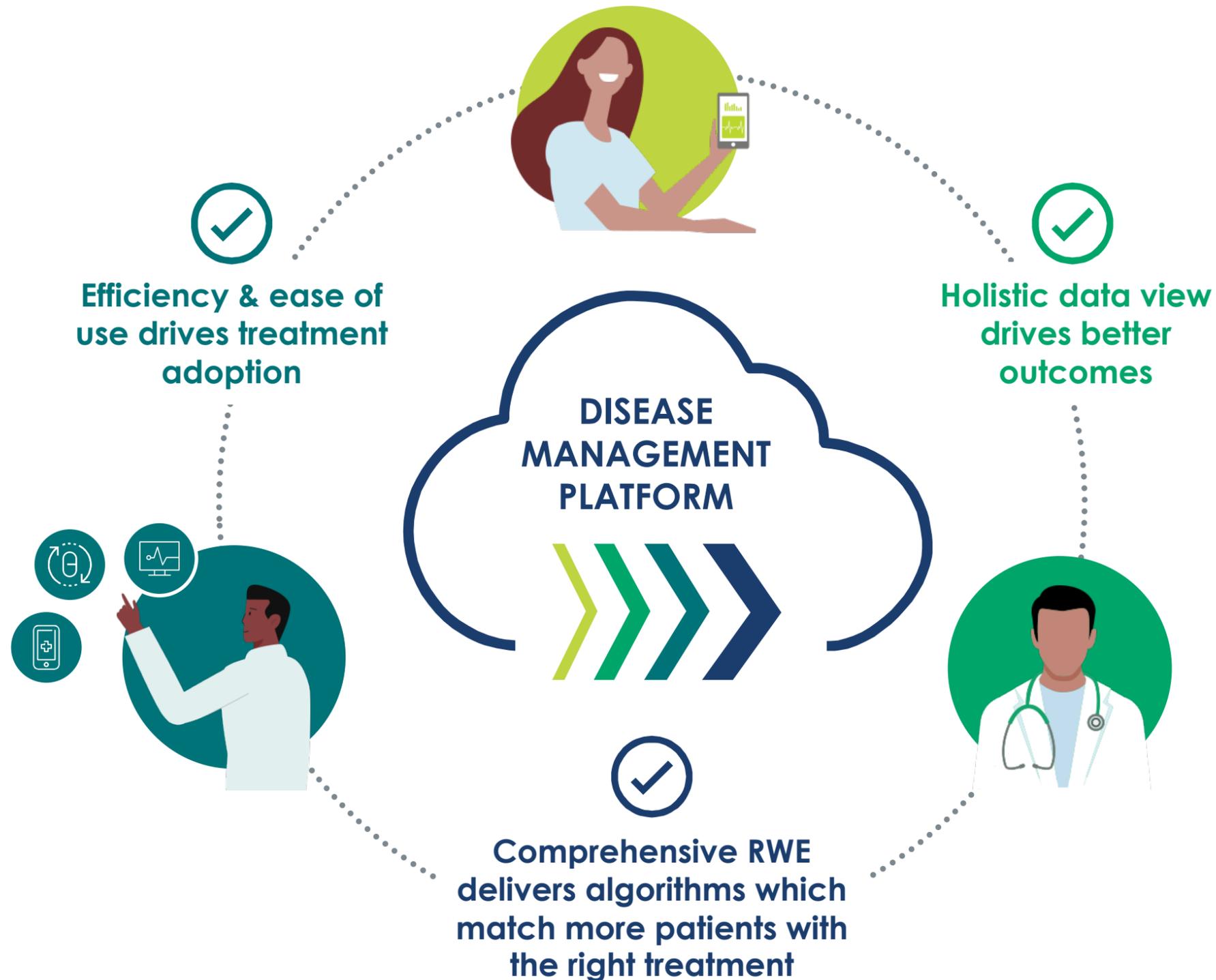
“We know everything about how our device is being used...but how is it linked to outcomes? How are comorbidities and competitors impacting adoption?”

**SOLUTION:**

# Simplified User Experience via Disease Management Platforms - One Login Giving a '360' View of the Patient



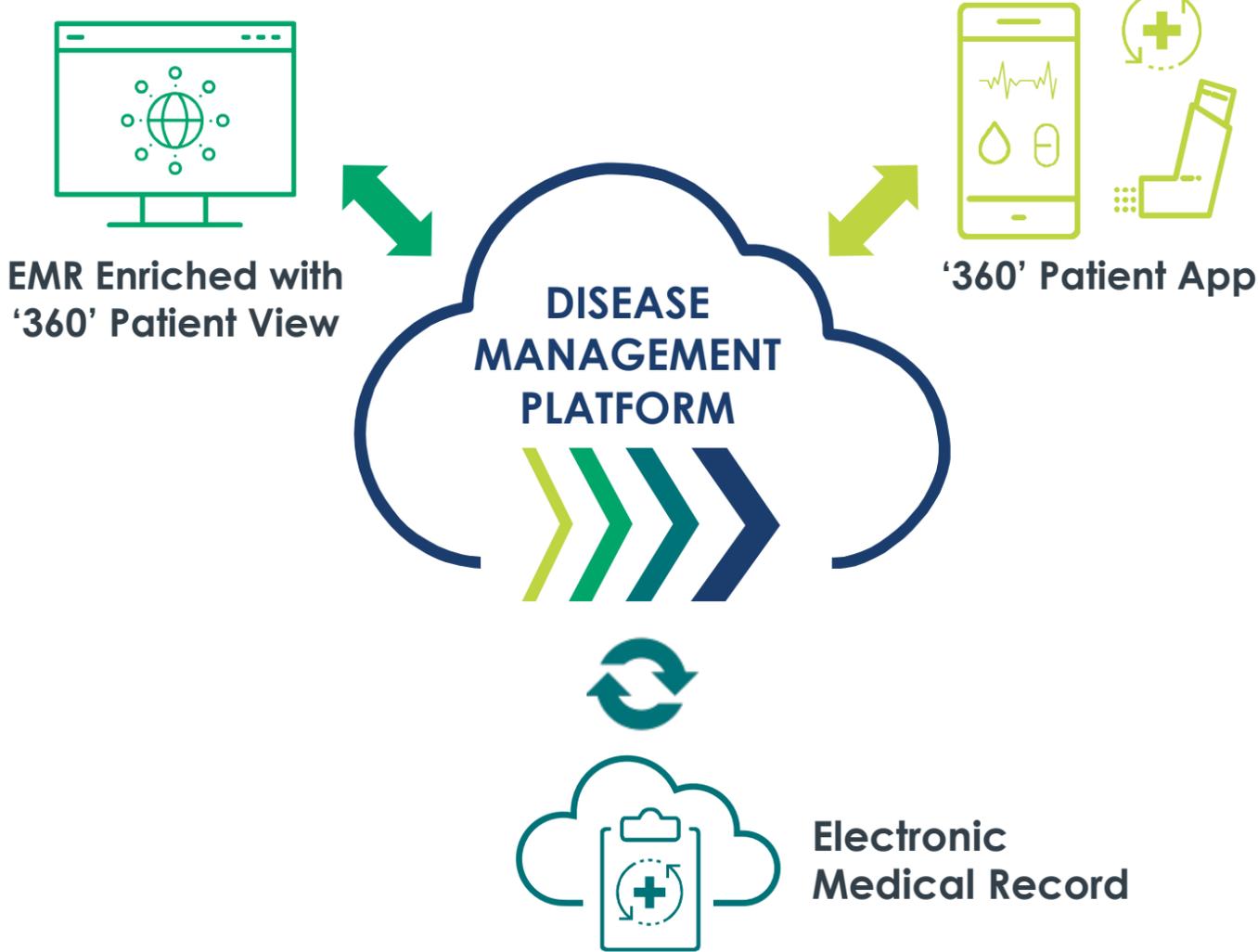
# Simplified User Experience Aligns Stakeholders & Enhances Impact – More Data, More Actionability



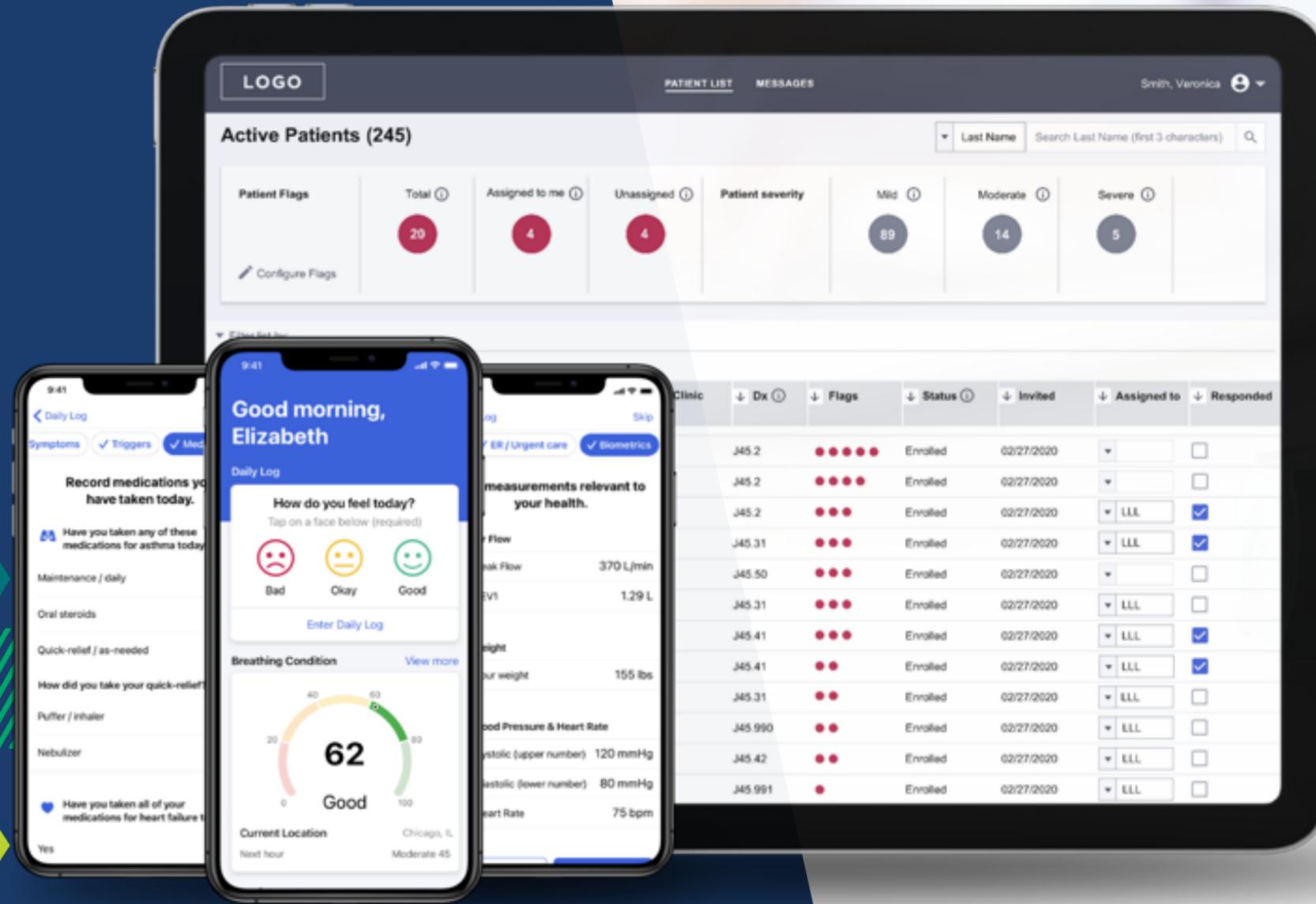
# Where You Invest Ultimately Depends on Your Objectives



PHARMA COMPANY GOAL	SOLUTION
<p><b>Increase # prescriptions of your therapy</b></p>	<p><b>DMP with embedded algorithms:</b> Drug/device agnostic DMP which tracks disease progression and flags higher risk patients. Device integrations (including yours) are a secondary consideration.</p>
<p><b>Increase adherence to your therapy</b></p>	<p><b>DMP provided by 3<sup>rd</sup> parties:</b> Your priority here is driving device adoption/use, meaning you should provide an “open source” device solution for other DMPs.</p>
<p><b>Real World Data to support your therapy as the standard of care</b></p>	<p><b>DMP data deal:</b> Data access deal with 3<sup>rd</sup> party DMPs are often sufficient to capture RWD, but pharma-funded solutions may be needed in certain niche therapy areas.</p>



# CASE STUDY: AstraZeneca's AMAZE Platform



# Recommendations

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## **Seamless user experience is paramount**

Multiple single point apps per user drive cognitive overload, a poor user experience and low adoption.

## **Design the system not the device**

Your combination product must be embedded into a holistic disease management platform.

## **Pharma DMP integration strategy will vary**

depending on whether you are looking to capture new patients (algorithms), retain existing ones (adherence devices) or collect RWD (data partnerships)