# Business Case Considerations in Inhaler Device Dtx — a Pharma company perspective

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### WHY DIGITAL THERAPUTICS IN INHALED RESPIRATORY MEDICINE?

Digital solutions can improve adherence, reduce user errors and inform disease management – leading to improved clinical outcomes and effective use of medicines

- ...Disease Management
- ...Adherence improvement
- ...User error mitigation
- ...Treatment management (e.g inform tx escalation)
- ...Real World Evidence generation





## BUSINESS MODELS — ARCHETYPES (EXAMPLES)

Business model	Simple Static Low involvement Low clinical value Low cost (and investment)			Complex Dynamic High involvement High clinical value High cost (and investment)
Market archetype	Low priced a/o non-reimbursed markets Low priced products			High priced a/o reimbursed markets Premium priced products
	Level of connectivity and engagement			
Features	QR-code Web/app Reminder Static IFU	Connected inhaler Seamless App	Connected inhaler Seamless App Disease management Dynamic IFU Adherence	Connected Ecosystem (inhaler, biomarkers, ePEF) Seamless App Disease management Dynamic IFU
Endpoints	Onboarding Adherence (?)	Adherence (policing) Lung function	HCU User errors Exacerbations	HCU Exacerbations Disease control



### What have to be true to make it a Business Case?

A positive business case (NPV/ROI) will depend several key factors

Value drivers

Days on Treatment (adherence)

Share of Market (better offering)

Retention to program/treatment

Financing model; reimbursement -> evidence -> clinical outcomes

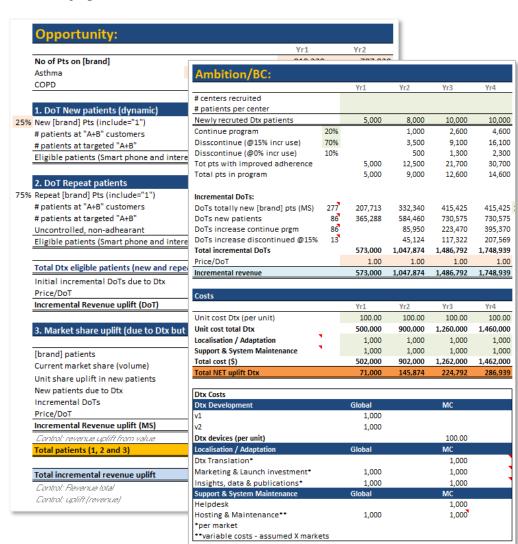
Market size (scale)

Critical mass to carry the fixed costs (software, hardware, data management)

Scale for acceptable unit cost

COGs (unit cost)

Scale, reusable/disposable, sensors, battery



### WHAT IS AN ATTRACTIVE PRODUCT?

A user interface is like a joke. If you have to explain it, it's not that good



#### Patient user interface

**Human Factor** 

Zero flaws; once lost is lost forever

Necessary, value adding, features only (keep simple)

Onboarding; seamless and intuitive

Sustainable





#### HCP user interface

Integrated with Health Care Systems
Local, country, region
Seamless



## CHALLENGES; NAVIGATING BARRIERS TO SCALE



- Patient experience
- Privacy
- Ease of use (accessibility, add-on/integrated)



- Payer acceptance of premium price point
- Approvals and reimbursement
- Regulatory classification



- Workflow integration
- Remote management



- Operations investment
- COGs impact
- Sustainability commitments



#### RECOMMENDATIONS

Keep it simple (critical features only and patient centric)

Decide on Business model

Seamless and intuitive (onboarding)

Spend significant time on the Payer perspective

Targeting patient groups

Be aware of the challenges

Digital Product



