Trends in Industry

Moderator

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Announcements

▸ The archived recording will be available a shortly after the webinar on the BMES website.

▸ You may submit questions throughout the webinar by using the online chat function. Your questions will be addressed after the speaker presentation.

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BMES
BIOMEDICAL ENGINEERING SOCIETY™

Speaker

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Biopharma, Digital, Device Convergence

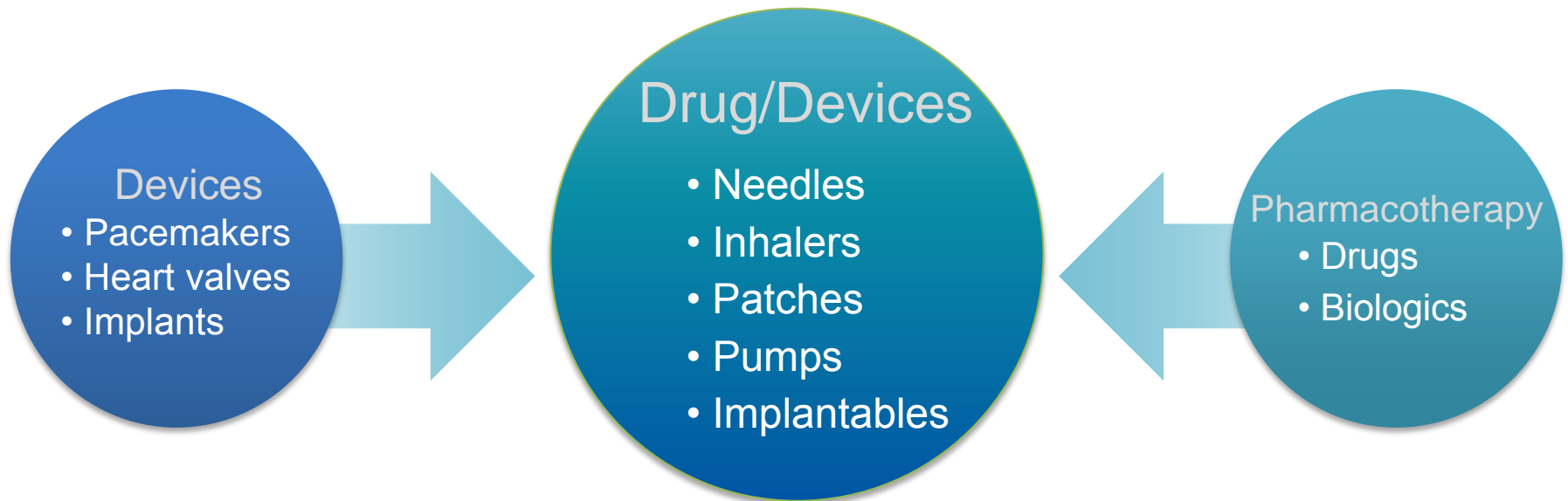September 2016

Adrienne Lovink | Partner

Discussion Agenda

1. **MacroTrends and Drivers Enabling Biopharma, Digital, Device Convergence**
   › With a focus on *Technology Evolution and Accessibility*
   › *Investment Trends in Digital Health*
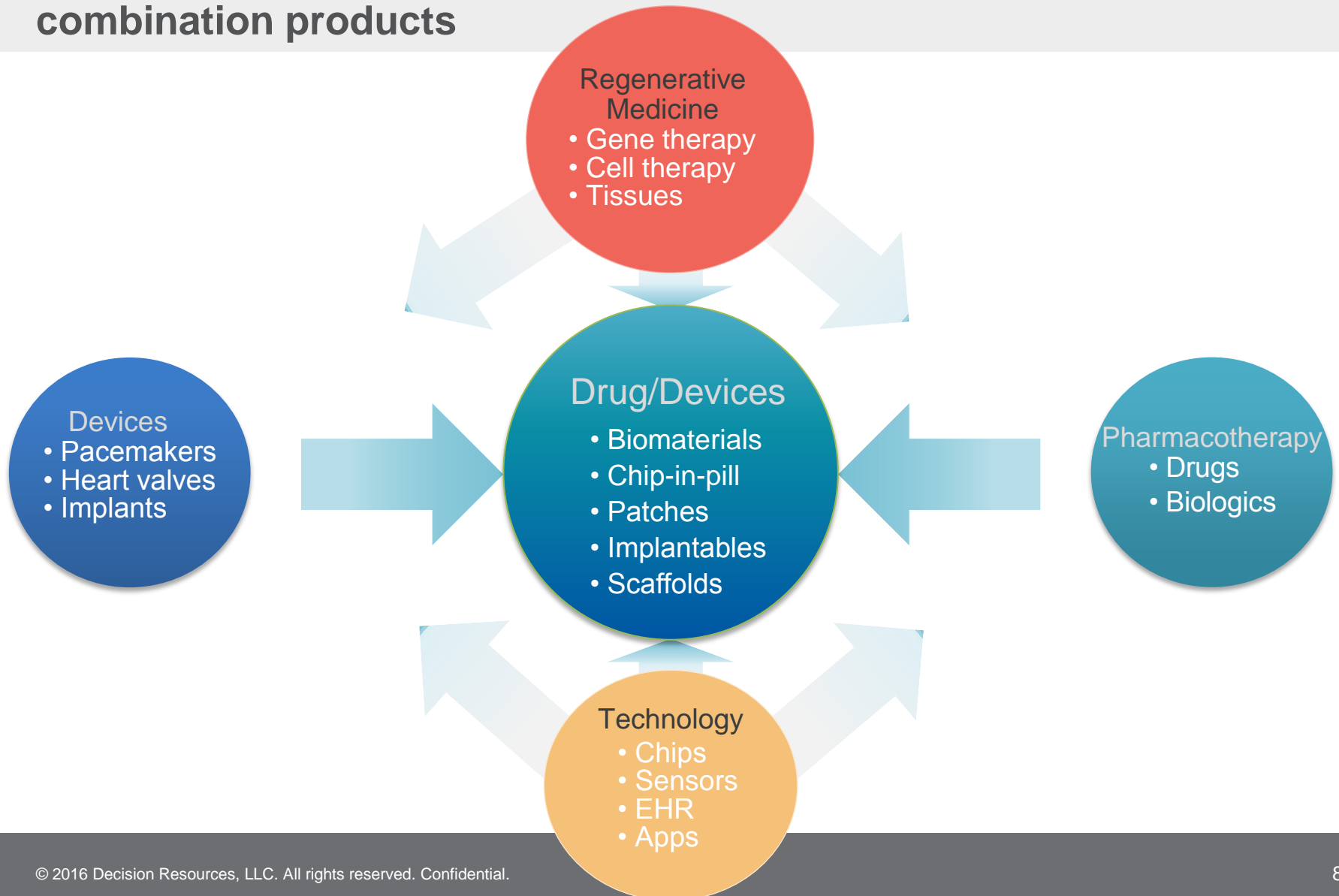
2. **Stakeholder Readiness for Digital Engagement**
   › With a focus on *Patients, Physicians, Health System Decision Makers and Regulators*

3. **DRG's Strategic Framework for Digital Health Valuation**
   › With a focus on *Digital-Device Analogs*
   - Asthma-COPD Medication and Disease Management
   - Smartphone Enabled Continuous Glucose Monitoring (CGM)

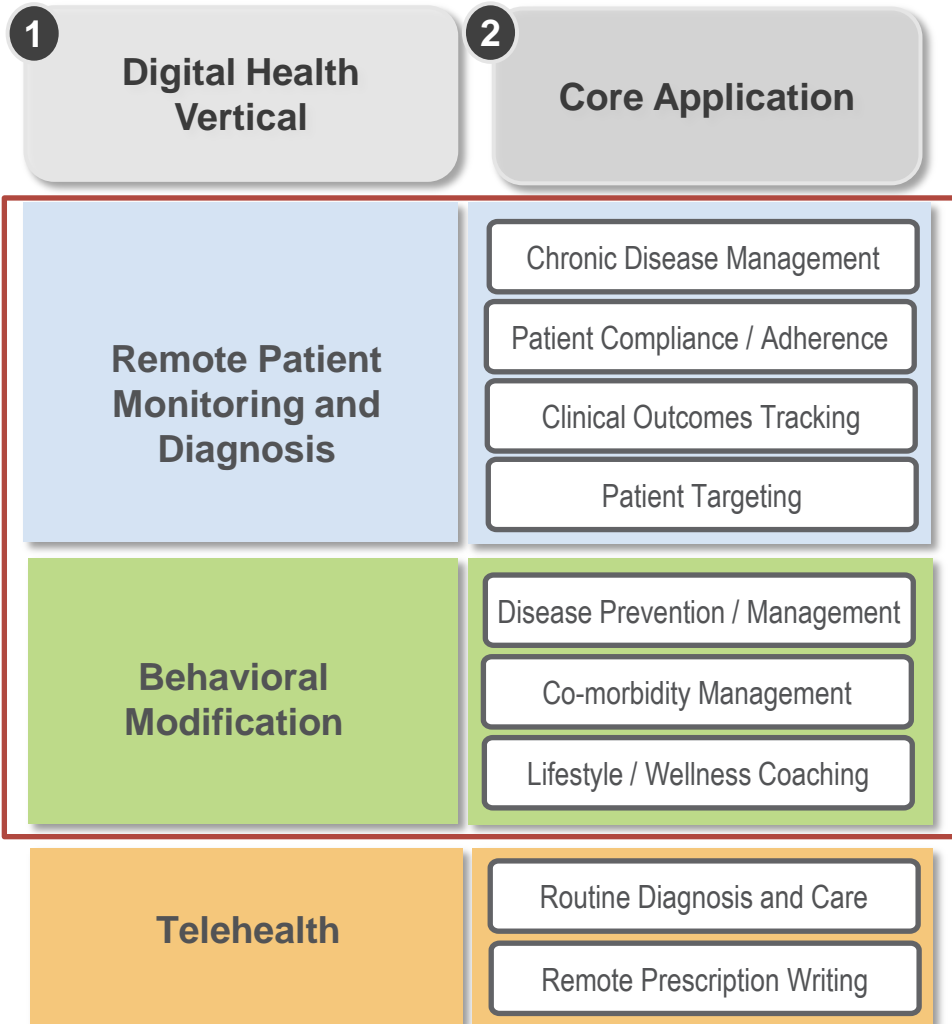# Drug device combinations are an established segment of the diagnostic and therapeutic landscapes

Devices
- Pacemakers
- Heart valves
- Implants

Drug/Devices
- Needles
- Inhalers
- Patches
- Pumps
- Implantables

Pharmacotherapy
- Drugs
- Biologics

Convergence is changing the landscape and the demand for novel combination products

Regenerative Medicine
- Gene therapy
- Cell therapy
- Tissues

Drug/Devices
- Biomaterials
- Chip-in-pill
- Patches
- Implantables
- Scaffolds

Devices
- Pacemakers
- Heart valves
- Implants

Pharmacotherapy
- Drugs
- Biologics

Technology
- Chips
- Sensors
- EHR
- Apps

DRG's View of the Digital Health Landscape

1 Digital Health Vertical

2 Core Application

Remote Patient Monitoring and Diagnosis
- Chronic Disease Management
- Patient Compliance / Adherence
- Clinical Outcomes Tracking
- Patient Targeting

Behavioral Modification
- Disease Prevention / Management
- Co-morbidity Management
- Lifestyle / Wellness Coaching

Telehealth
- Routine Diagnosis and Care
- Remote Prescription Writing

Chronic Disease Management sits at the bullseye of the digital-device convergence opportunity

Cloud-based CDM Program

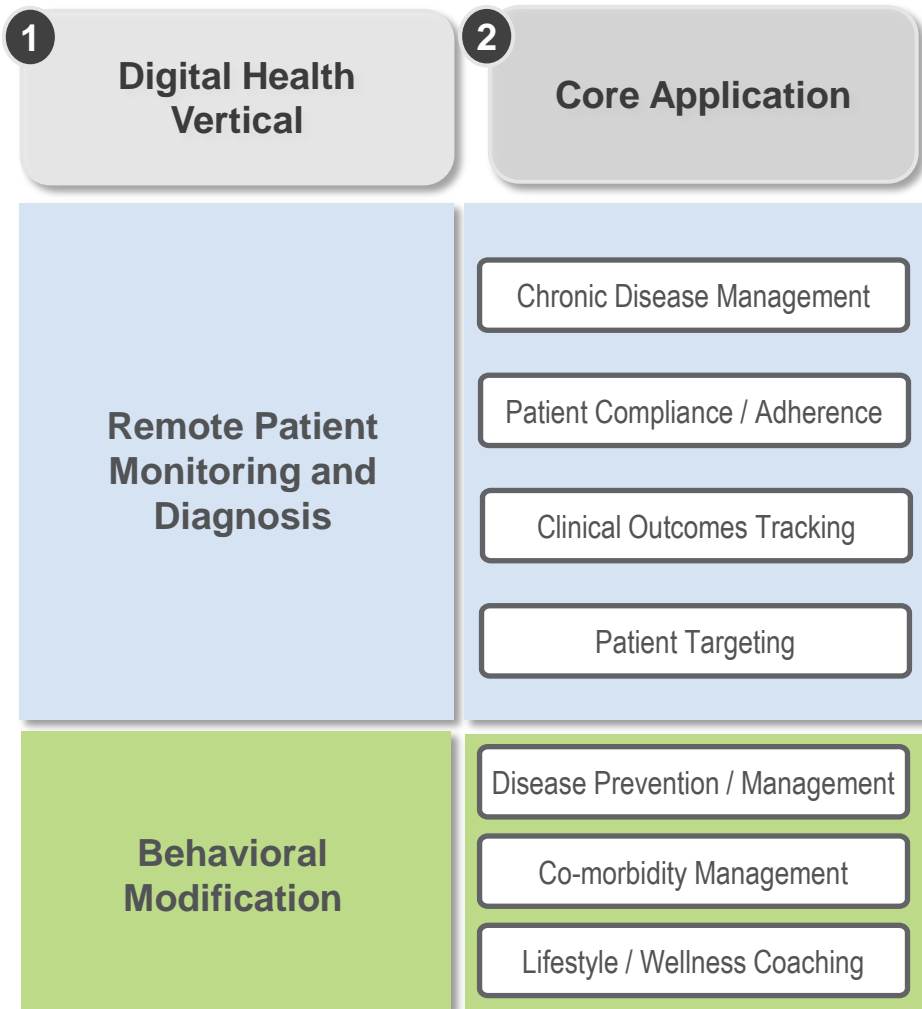Mobile Asthma/COPD Management

Mobile CardiacTelemetry

Remote CGM System

Smoking Cessation and Obesity Apps

The combined commercial opportunity for digital remote monitoring and behavior modification is estimated at over $20B*

1 Digital Health Vertical

2 Core Application

Remote Patient Monitoring and Diagnosis

- Chronic Disease Management
- Patient Compliance / Adherence
- Clinical Outcomes Tracking
- Patient Targeting

Behavioral Modification

- Disease Prevention / Management
- Co-morbidity Management
- Lifestyle / Wellness Coaching

> "
> The **number of remotely monitored patients grew by 51 percent to 4.9 million in 2015**. The number of remotely monitored patients should grow at a compound annual growth rate **(CAGR) of 48.9 percent to reach 36.1 million by 2020.**
>
> - Berg Insight

Smartphones, connected medical accessories and apps have been underutilized by the healthcare industry. **In 2016 care will begin to shift into the palms of consumers' hands**, helping to drive down costs, increase access and fulfill the public's desire for 'anywhere, anytime' monitoring, diagnosis and treatment."

- Kelly Barnes, US Health Industries and Global Health Industries Consulting Leader, PwC

Macrotrends Enabling Digital-Device Convergence

Growth and evolution of the technology sector has enabled paradigm shifts in how key decision makers solve healthcare delivery challenges

Technology Evolution and Accessibility

- ↑ Supply of and Demand for Data
- Miniaturization and Continued Adoption of MI* approaches
- Development and Approval of Disruptive Technologies
- Growth in Personalized Medicine and Companion Diagnostics
- Tech Firm Investment in Digital Health Technologies
- Stakeholder Readiness for Digital Adoption

Enabling

Evolving stakeholder engagement models

- IT Enabled Engagement Across the Care Continuum
- Increase in Patient-Driven Decision Making
- Shift from Point-in-Time to Coordinated, Continuous Care
- New Physician Practice Models

Value-based decision making with a focus on health outcomes

- Shift from FFS to Value-based Reimbursement
- Market Commoditization
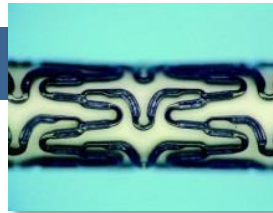- Health Informatics and Population Health Management
- Manufacturer drive to Demonstrate a Value Premium

*MI = Minimally Invasive

Emerging products increasingly incorporate digital component(s) aimed toward patient monitoring and/or behavior modification

Traditional Combination products
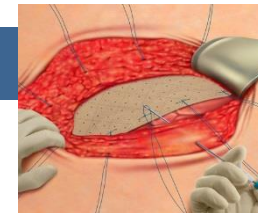
Drug + device-enabled delivery

Device + drug

Drug-eluting stents

Drug-coated balloons

Active Transdermal patches
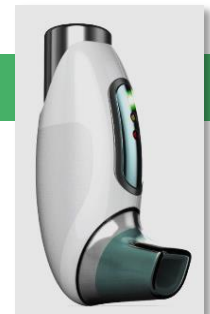
Emerging products

Device + drug + app

Wearable Vital Sign Monitoring

Sensor-enabled Knee Implant

Sensor-based asthma medication compliance monitor

Digitization of medical devices has implications on the approval pathway, and changes the skill sets required for successful product development and commercialization

Body worn sensors to gather complex physiological data

Biocompatible 3D Printed Tissues

Mobile Prescription Therapy (MPT) for T2 Diabetes

AI* driven adherence apps

*AI = Artificial Intelligence

14

Data-driven partnerships are creating a machine learning-driven ecosystem to improve outcomes, control costs and improve upon value-based healthcare

› Medical management company

› **$2.6B acquisition** to flesh out Watson's core focus on cloud based healthcare and analytics

› Physician-led population health management software

Medical device companies are also partnering with payers to demonstrate differential value and improved outcomes via digital solutions

UnitedHealthcare®

OPTUM Labs™

Boston Scientific

› OptumLabs is UnitedHealth's **healthcare research and innovation group**
› Co-founded by the Mayo Clinic, and Optum, UnitedHealth's health IT and services unit

› Collaboration will identify points in the patient care continuum where existing or new BS products and services can improve the efficiency and value of care, care delivery and overall population health
› Initial focus on **Heart Failure and Diabetes**

aetna®

Medtronic

› **Numerous Health IT acquisitions** for products including mobile health symptom checker **iTriage**, private information exchange **Medicity** and **Active Health**, a population health clinical decision/workflow management tool to improve engagement and outcomes
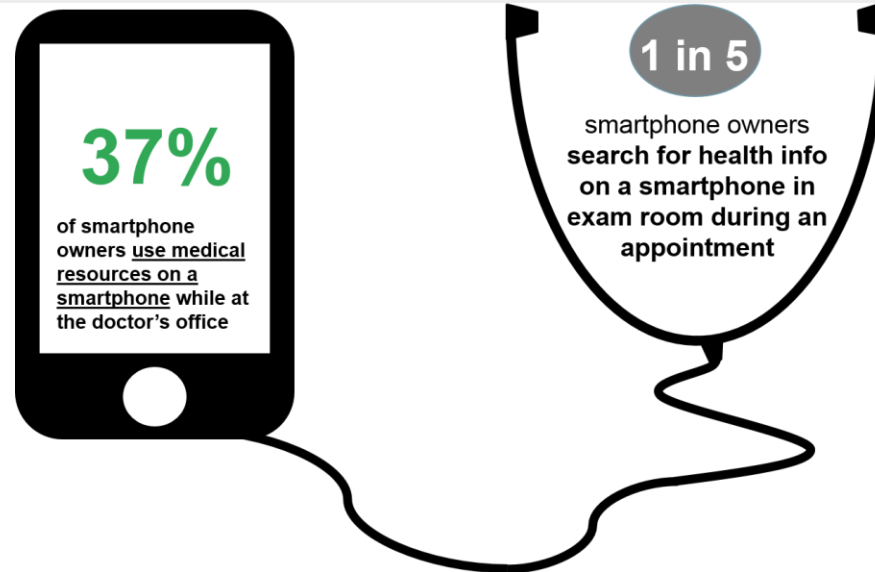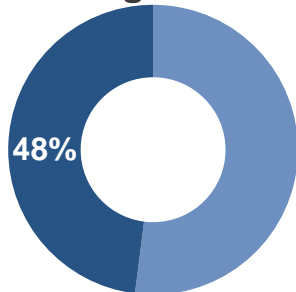
› Identify patients via remote patient monitoring that would trigger the use of Medtronic's fluid status monitoring device for **Heart Failure** patients before the need for hospitalization arises
› Collaboration will also target **Diabetes**

Stakeholder Readiness for Digital Engagement

Patients are using digital resources, including smartphones at critical decision points during the course of their care

37%

of smartphone owners <u>use medical resources on a smartphone</u> while at the doctor's office

1 in 5

smartphone owners **search for health info on a smartphone in exam room during an appointment**

When experiencing new symptoms before seeing a doctor

48%

After receiving a treatment plan from a doctor

25%
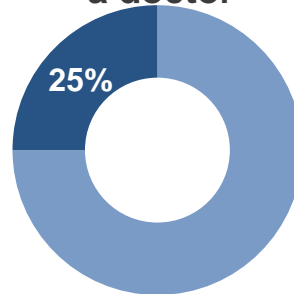
When considering switching to a new drug

35%
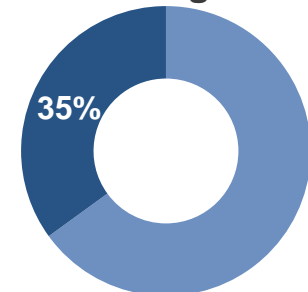
1/3 of patients believe that wearables, smart watches and other digital technologies have enormous potential to help them manage their health

Patient Interest in Using a Digital Solution to Improve Their Health, 2015

Category	Percentage
Wearable device	36%
Smartwatch	28%
Sensors	22%
Ingestible device	18%
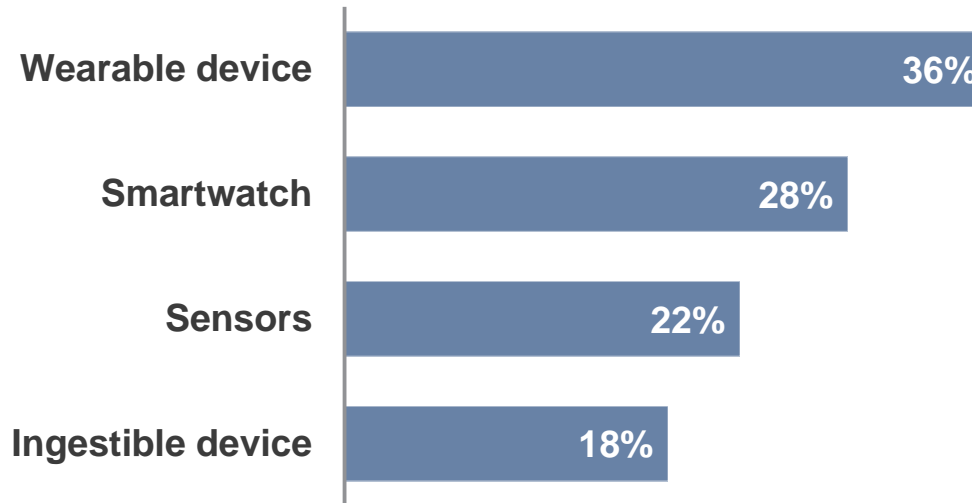
proteus®
DIGITAL HEALTH
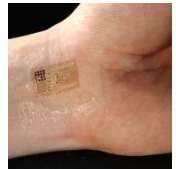
Motivators for using a wearable, sensor etc. to treat your condition

› 45% If it was free
› 42% If doctor recommended it
› 34% If I receive an incentive for using them (e.g. lower deductible)

Reasons for not using or buying a wearable, sensor, etc.

› 50% Too expensive
› 30% Privacy concerns
› 22% Don't like being monitored

Wearable owners are more likely to engage remotely with their care team than non-owners

Patient Interest in Using a Digital Solution to Improve Their Health, 2015

I would prefer to do routine visits remotely rather than in person
- Wearable owners: **35%**
- Online consumers: **21%**

I want my care team to monitor my health remotely, but my doctor doesn't provide these services
- Wearable owners: **33%**
- Online consumers: **15%**

My doctor has recommended that I use technology (e.g. smartphone, wearable etc.) to monitor my health remotely
- Wearable owners: **31%**
- Online consumers: **10%**

■ Wearable owners ■ Online consumers

" The global wearables market is projected to grow from 19 million units (2014) to 112 million (2018).

Physicians are increasingly relying on digital technologies to facilitate treatment planning and better outcomes

"**I rely on the information I receive via digital communication** from my patients to **develop my treatment plans**."
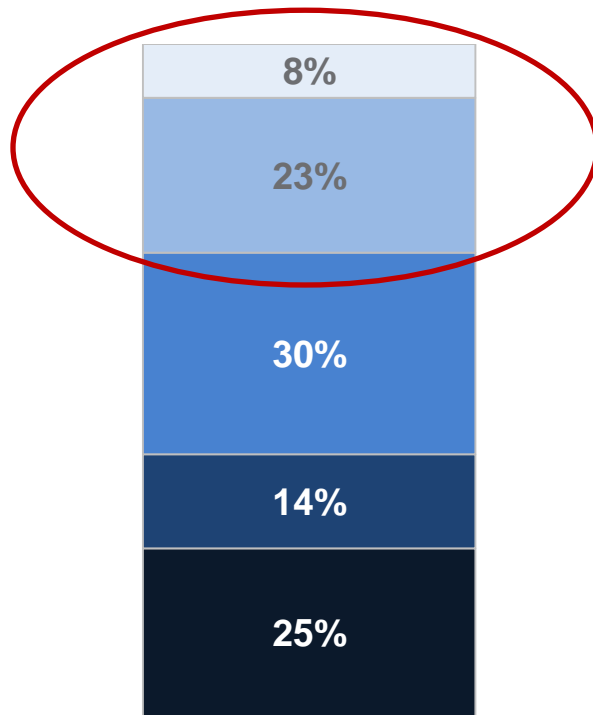
"**I believe using digital technologies** to **communicate with my patients remotely** will drive better outcomes**.**"
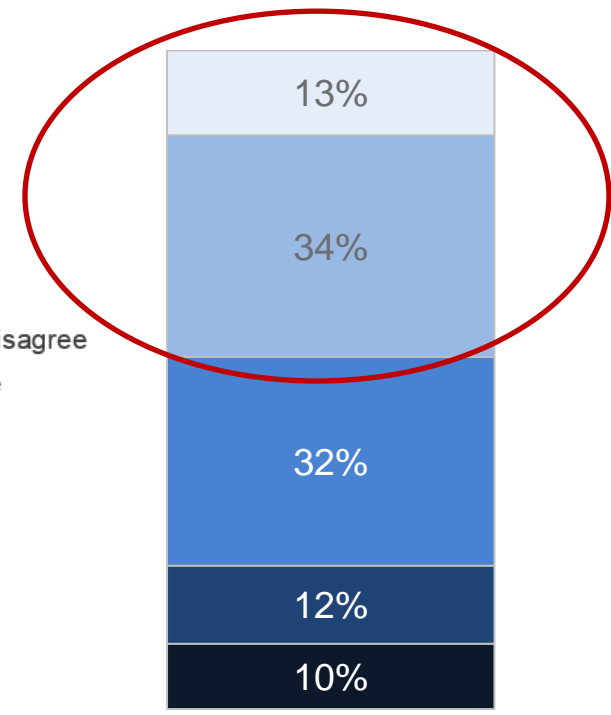
- 5 - Strongly agree
- 4 - Somewhat agree
- 3 - Neither agree nor disagree
- 2 - Somewhat disagree
- 1 - Strongly disagree

Left chart (US Physicians):
- 8%
- 23%
- 30%
- 14%
- 25%

US Physicians

Right chart (US Physicians):
- 13%
- 34%
- 32%
- 12%
- 10%

US Physicians

Improved patient outcomes where adherence is an issue is the top influencer in positively impacting a drug's formulary placement

**Factors Influencing HSDM When Considering the Blue
Star Device as a Companion App to the Drug**

It has improved outcomes for a patient population which drives costs
- Hospital: 52%
- MCO: 58%

It has improved outcomes for a patient population for which adherence is a key issue
- Hospital: 51%
- MCO: 69%

It has improved metrics for a patient population whose success is tied to payment incentives
- Hospital: 39%
- MCO: 58%

Legend:
■ Hospital
■ MCO
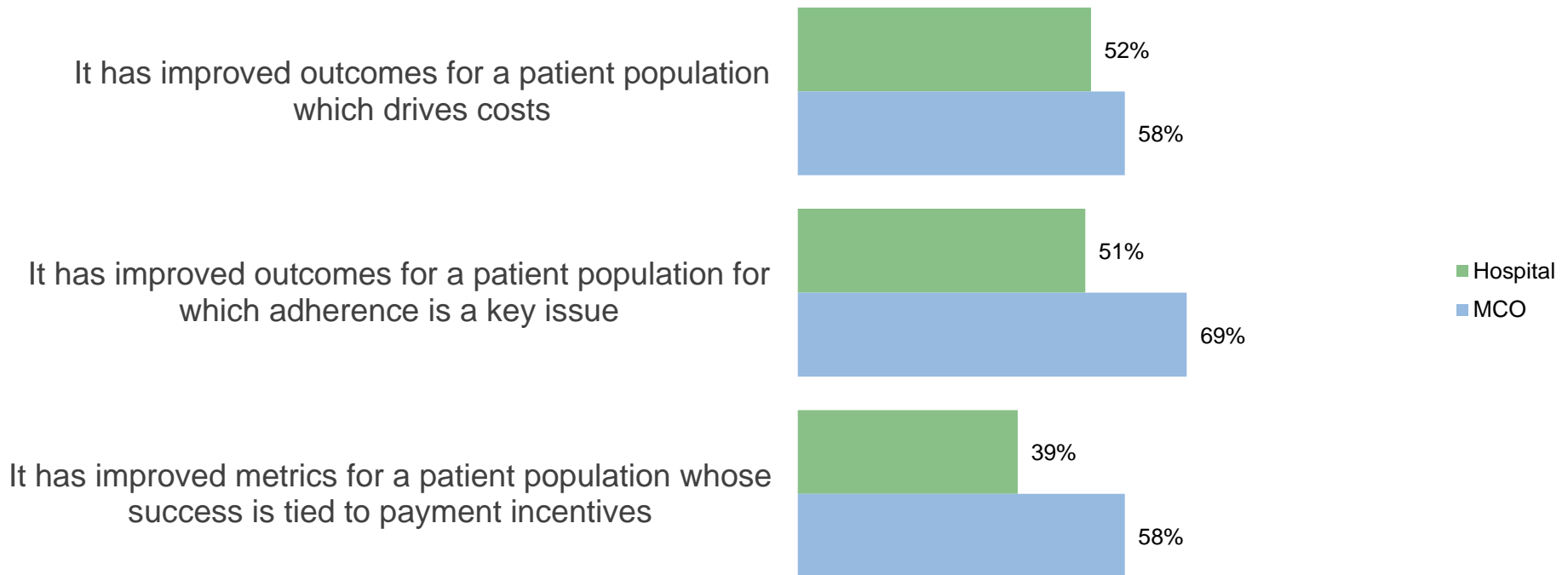
Digital-Device Technology Analogs

DRG's Strategic Framework for Digital Health Valuation

1 Digital Health Vertical	2 Core Application	3 Monetization Strategy/ Manufacturer Value	4 Relevant Stakeholders
Remote Patient Monitoring and Diagnosis	Chronic Disease Management Patient Compliance / Adherence Clinical Outcomes Tracking Patient Targeting	Sold or Licensed to Drive Quality Outcomes and/or Cost Reduction Incremental Share/Revenue via Increased Value Higher Price and/or Utilization via Improved Reimbursement Sold or Licensed to Increase Value of Claims and/or HEOR Sold or Licensed for Patient Targeting Clinical Trials Disease Insight for Industry Marketing	Primary Care Physicians Specialists Pharmacists Health Systems/Hospitals Accountable Care Organisations (ACO) Payers (Government, Private) Patients / Caregivers
Behavioral Modification	Disease Prevention / Management Co-morbidity Management Lifestyle / Wellness Coaching		
Telehealth	Routine Diagnosis and Care Remote Prescription Writing		

Asthma-COPD Medication and Disease Management

Company	PROPELLER HEALTH
Technology Profile	› Small sensor attaches to the top of a patient's existing inhaler device › Tracks medication use, recording time and location of use, as well as air quality › Data syncs wirelessly to companion app › Based on data collected, feedback is given to patients to assist them with better understanding and managing their disease › Data can also be transmitted to HCPs and industry clinical researchers
End Goal	› Symptom control and exacerbation prediction in patients who experience frequent acute episodes that would normally drive the patient to hospital › Ability to study population-based adherence patterns for more precise correlation of adherence with safety, efficacy, and economic outcomes

Partners / Collaborators

Industry – Device/Pharma	✔	Boehringer Ingelheim GSK	**Health System**	✔	Dignity Health Wyckoff Heights Medical Arizona Care Network
Industry – Tech	✔	AMC Health	**Government**	✔	City of Louisville
Payer	✔	Amerigroup Florida	**Societies**	✔	American Hospital Association

Propeller continues to collaborate with different types of organizations to reduce costs and improve the management of asthma and COPD

| May 2014 | July 2014 | September 2014 | April 2016 |

Helpouts

Propeller expands its digital health platform and services to include real-time inhaler technique coaching video consultations via Helpouts by Google

ACN | Arizona Care Network

Arizona Care Network is the first ACO to offer the Propeller platform to its members with COPD

SAFEGUARD

Safeguard Scientifics, a capital provider that targets healthcare companies, helped Propeller to raise $14.5M in Series B financing to accelerate product development

Boehringer Ingelheim

BI announces pilot program of Propeller Health's sensor technology with their Respimat Inhaler looking to gain information about patient adherence

gsk GlaxoSmithKline

Propeller's sensor technology will be used in clinical studies with the Ellipta inhaler to study adherence patterns across patient populations

AMC Health — Advancing Monitored Care

Propeller teams up with remote patient monitoring company to roll out a program focused on improving drug adherence in patients with COPD

Through its diverse portfolio of partnerships, Propeller is able to monetize its sensor via multiple channels

Monetization Strategy/ Manufacturer Value

Sold or Licensed to Drive Quality Outcomes and/or Cost Reduction

Incremental Share/Revenue via Increased Value

Higher Price and/or Utilization via Improved Reimbursement

Sold or Licensed to Increase Value of Claims and/or HEOR

Sold or Licensed for Patient Targeting

Clinical Trials

Disease Insight for Industry

Marketing

› **Improved clinical outcomes:**
  - >80% improvement in adherence
  - 50% decline in uncontrolled asthma
  - >70% improvement in symptom control

› **These outcome have led to reductions in:**
  - Hospitalizations
  - ER visits
  - Unscheduled office visits

› Propeller **contracts with a network of payers/providers** to:

  - Deliver care to patients who command an outsized portion of spending dollars*.

› In some cases, takes a **stake in the well-being of the patient**, negotiating a contracted rate at which to share the savings*

› Both **Boehringer Ingelheim and GSK have utilized the Propeller Health sensor** to enable remote monitoring and tracking of specific patient sub-populations **during clinical trials** to gather population health statistics (e.g. **adherence metrics**)

› Identification of patient and/or disease characteristics associated with **high frequency exacerbators** (e.g. highly symptomatic patients) offers the ability to develop **tailored treatment regimes and patient support programs**

Smartphone Enabled Continuous Glucose Monitoring (CGM)

Company	DEXCOM® One Step Ahead
Technology Profile	› Percutaneous disposable sensor for measuring glucose levels; a transmitter on the sensor sends data wirelessly to smart phone or receiver › Tracks daily activities that influence glucose trends › CLARITY™ app generates cloud-based reports to support diabetes management by sharing data with healthcare providers › SHARE™ component, which is compatible with Apple Watch, enables sharing of data with family/friends
End Goal	› Real-time glucose monitoring in a discrete / private fashion on a smart phone or watch to improve diabetes control › Patient empowerment › Displace the standard of care (finger sticks) in glucose monitoring › Ultimate goal: CGM transmitter in a Band-Aid-sized electronics configuration that a patient can peel off and throw away, that is very cost effective.

Partners / Collaborators						
	Industry – Device/ Pharma	✓	JnJ, Asante, Isulet, Tandem Diabetes	**Payer**	✘	
				Health System	✘	
	Industry – Tech	✓	AppleWatch, Google/Verily Data Platform Management (Diasend SweetSpot, Tidepool)	**Government**	✘	
				Societies	✓	JDRF, ADA

Through multiple industry partnerships, Dexcom has leveraged opportunities for driving cost reductions and the potential to further increase market share beyond its current 60%

Monetization Strategy/ Manufacturer Value

- Sold or Licensed to Drive Quality Outcomes and/or Cost Reduction
- Incremental Share/Revenue via Increased Value
- Higher Price and/or Utilization via Improved Reimbursement
- Sold or Licensed to Increase Value of Claims and/or HEOR
- Sold or Licensed for Patient Targeting
  - Clinical Trials
  - Disease Insight for Industry
  - Marketing

› **CLARITY™ cloud-based reports** and **SHARE™ function** enables healthcare practitioners to monitor and provide **improved diabetes management support** leading to **improved outcomes:**
  - Dexcom has demonstrated significant improvements in overall glycemic control with their technology for both T1 and T2 diabetes

› **Partnership with Google** will drive device miniaturization and reduced costs

› **Mobile CGM has been a successful reimbursement story**:
  - Established CPT codes; broad coverage within the payer community

› **Commercial insurance plans:**
  - Majority have written positive coverage decisions for both personal and professional use of Dexcom CGM

› **Medicare:**
  - Provided a benefit category and coverage for CGM and related therapies as of March 2015. This will also support access for artificial pancreas technology as it becomes available

› Identification of patient and/or disease characteristics associated with poorly controlled diabetes offers the ability to **develop tailored treatment regimes and patient support programs**

Questions?