Digital Therapeutics:
Combining Technology and Evidence-based Medicine to Transform Personalized Patient Care
DIGITAL THERAPEUTICS

Benefits and Value of DTx Products
The expanding digital health landscape includes products such as:

**Digital Therapeutics**
Digital therapeutics deliver evidence-based therapeutic interventions to patients to prevent, manage, or treat a medical disorder or disease.

**Mobile Health (mHealth)**
*Examples include:*
- Wellness, fitness trackers, and nutrition apps
- Consumer health information
- Medication adherence apps

**Health Information Technology (HIT)**
*Examples include:*
- Electronic medical record systems
- Electronic prescribing and order entry
- Consumer health IT applications

**Devices, Sensors, and Wearables**
*Examples include:*
- Wearable and wireless devices
- Biometric sensors
- Diagnostic products

**Personalized Healthcare**
*Examples include:*
- Patient reported outcomes
- Predictive analytics
- Clinical decision support

**Telehealth**
*Examples include:*
- Telemedicine virtual visits
- Remote patient monitoring
- Remote care programs
What Is a Digital Therapeutic?

Digital therapeutics (DTx) deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

DTx products incorporate advanced technology best practices relating to design, clinical validation, usability, and data security. They are reviewed and cleared or approved by regulatory bodies as required to support product claims regarding risk, efficacy, and intended use.

Digital therapeutics empower patients, healthcare providers, and payers with intelligent and accessible tools for addressing a wide range of conditions through high quality, safe, and effective data-driven interventions.
Foundational Industry Principles

Principles all digital therapeutics must adhere to:

- Prevent, manage, or treat a medical disorder or disease
- Produce a medical intervention that is driven by software
- Incorporate design, manufacture, and quality best practices
- Engage end users in product development and usability processes
- Incorporate patient privacy and security protections
- Apply product deployment, management, and maintenance best practices
- Publish trial results inclusive of clinically-meaningful outcomes in peer-reviewed journals
- Reviewed and cleared or approved by regulatory bodies as required to support product claims of risk, efficacy, and intended use
- Make claims appropriate to clinical validation and regulatory status
- Collect, analyze, and apply real world evidence and/or product performance data
Targeted Disease States Across the Industry

- Asthma
- Attention-Deficit/Hyperactivity Disorder
- Autism Spectrum Disorder
- Chronic Obstructive Pulmonary Disease
- Concussion
- Chronic Pain
- Depression
- Diabetes
- Epilepsy
- Gastrointestinal Disorders
- Hypertension
- Insomnia
- Motor, speech, and cognitive dysfunction

- Multiple Sclerosis
- Neurologic disease and injury
- Obesity
- Oncology
- Opioid Use Disorder
- Panic Disorders
- Parkinson's Disease
- Post-traumatic stress disorder
- Schizophrenia
- Sleep Disorders
- Stroke Rehabilitation
- Substance Use Disorder
- Traumatic Brain Injury
**DTx Product Categories**

<table>
<thead>
<tr>
<th>ADDRESS A MEDICAL CONDITION</th>
<th>MANAGE OR PREVENT A MEDICAL DISORDER OR DISEASE</th>
<th>OPTIMIZE MEDICATION</th>
<th>TREAT A MEDICAL DISEASE OR DISORDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory enforcement discretion (without explicit oversight)</td>
<td>Third-party validation of efficacy and safety claims by regulatory or equivalent national body</td>
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<tr>
<td>No efficacy claims regarding a medical disorder or disease</td>
<td>Low to medium risk claims (e.g., reduce rate of disease progression)</td>
<td>Medium to high risk claims (e.g., improve efficacy of adjunctive therapies)</td>
<td>Medium to high risk claims (e.g., direct efficacy claims on clinical outcomes)</td>
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**Product claims related to a medical disorder or disease...**

**Clinical evidence generation...**

**Patient access to product...**

**Relationship to concurrent therapies...**

**To support product claims of risk, efficacy, and intended use...**

Clinical trials and ongoing evidence generation required

Direct-to-Consumer (Prescription not required)

Works independently OR Indirectly supports another therapy

Over-the-Counter OR Prescription required

Monotherapy OR Directly supports a concurrent treatment

Prescription required

Monotherapy OR Directly supports a concurrent treatment
What is NOT a digital therapeutic?

‘Digital Health’ products that do not claim to prevent, manage, or treat a disease are not subject to the same standards and best practices as digital therapeutics. It is therefore important to differentiate which products are and are not a digital therapeutic.

Products considered to NOT be a digital therapeutic include:

- Health and wellness apps
- Medication adherence tools
- Diagnostic products
- Telehealth and telemedicine platforms
- Clinical decision support and/or predictive analytic products
- Use of digital tools to support drug trials
- Digitization of healthcare processes

What is a digital therapeutic?
Delivers evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease.
Value of Digital Therapeutics

Accounting for the diversity of products across the DTx industry, individual digital therapeutics have the potential to:

• Provide patients, providers, and payers with novel therapy options for unmet medical needs
• Be used independently or in conjunction with other therapies
• Enhance and support current medical treatments
• Reduce reliance on certain pharmaceuticals or other therapies
• Integrate into medical guidelines and best practices
Benefits for Patients & Caregivers

- Deliver reliable, evidenced-based interventions with a high control of quality
- Increase access to therapies that are clinically demonstrated as safe and effective
- Personalize care based on individual patients’ needs and abilities
- Administer therapeutic interventions in an engaging and convenient way
- Provide care independent of a patient’s schedule and in the privacy of their own environment (e.g., home, office, on-the-go, etc.)
- Reduce stigma associated with the delivery of certain traditional therapies
- Provide patients, caregivers, and select healthcare providers with secure progress updates on personalized goals and outcomes
Benefits for Healthcare Providers

- Improve clinical and health economic outcomes at the patient and population levels for a large range of physical, behavioral, and mental disorders and diseases
- Facilitate analysis of population health outcomes
- Provide ubiquitous access to evidence-based treatment options for conditions that previously have been untreated or undertreated by traditional medications and therapies
- Increase patient population exposure to effective and engaging treatments without potentially requiring an equivalent workforce expansion
- Decrease the economic burden of medical conditions by reducing overall costs
Benefits for **Payers**

- Integrate into healthcare delivery systems in accordance with industry best practices and guidelines
- Be prescribed to patients by qualified healthcare providers independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes
- Provide secure data regarding patient engagement and response to therapy that is integrable into provider portals and clinical data warehouses
- Enable intelligent data-driven care management and clinical decision making
- Deliver clinically-proven therapies that provide patients with effective self-management therapeutic options
- Expand access to evidence-based medical therapies locally, nationally, and globally
PRODUCT COVERAGE

Coverage Examples of Digital Therapeutics
Sleepio and the NHS

Sleepio has been evaluated by the National Institute for Health and Care Excellence (NICE).

Sleepio is a fully automated online sleep improvement programme for insomnia, which delivers tailored and engaging advice, 24/7. It is clinically proven to improve sleep, mental wellbeing and productivity.

Developed by Professor Colin Espie from the University of Oxford, Sleepio is backed by gold-standard scientific evidence, which includes 33 published papers and 8 randomised controlled trials. Further information about our evidence can be found here.
CIGNA EXPANDS PERSONALIZED DIABETES PREVENTION PROGRAM IN COLLABORATION WITH OMADA HEALTH

18 September 2018

- Acclaimed digital lifestyle program delivers convenient, personalized experience to help people avoid the onset of diabetes and other chronic disease
- Expanded collaboration provides integrated, value-based health services to employers and customers

BLOOMFIELD, Conn., 18 September, 2018 - Global health service company Cigna (NYSE: CI) is expanding its Diabetes Prevention Program (DPP) in collaboration with Omada Health. The new program is designed to deliver an expanded suite of personalized, user-friendly digital health tools to help people prevent the onset of diabetes and other chronic diseases, and will be available to Cigna's national and regional employer clients effective January 2019.

Using the digital lifestyle program, participants enrolled in a Cigna-administered health plan may be empowered to make impactful and sustainable behavior changes under the guidance of a personal health coach and with the support from a peer group.

Individual customers will have access to a fully integrated experience, with the Omada program synchronized with other Cigna health services including access to a discount gym-membership program with a national network of more than 9,000 fitness facilities, the participation of Cigna Health Coaches to encourage program participation, and convenient program accessibility via...
Local Payer: Highmark, Inc.

Highmark Inc. Adds Coverage For Medical Innovations In Treatment Of Panic Attacks [...]

POSTED ON SEPTEMBER 24, 2018

PITTSBURGH, Pa. (Sept. 17, 2018) — A new, non-pharmaceutical treatment, Freespira, and non-invasive diagnostic technology, Heartflow FFRct (fractional flow reserve), were added to Highmark’s medical policy in 2018 following positive results from a program that fast-tracks medical innovations to the marketplace.

Freespira, an in-home digital therapeutic device for panic disorder and panic attacks occurring with other
Propeller and Express Scripts Partnership Offers Innovative Digital Respiratory Care to Improve Health for People with Asthma or COPD

press release

11.16.17

Today, Propeller Health and Express Scripts (NASDAQ: ESRX) announced a strategic partnership to provide Propeller’s FDA-cleared digital solution to Express Scripts members using inhaler sensors and a mobile app to manage asthma or COPD. This collaboration is the largest respiratory digital health deployment with a pharmacy benefit manager to date.

Propeller’s digital sensors enable remote monitoring for patients enrolled in Express Scripts’ Pulmonary Care Value ProgramSM (PCV), which combines specialized pulmonary pharmacist clinical support, patient engagement and quality-based...
DIGITAL THERAPEUTICS ALLIANCE

Mission, Members & Initiatives
Digital Therapeutics Alliance

Founded in 2017, the Digital Therapeutics Alliance (DTA) is a non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. DTA maintains an international industry focus and is headquartered in the United States.

Mission
We seek to broaden the understanding, adoption, and integration of clinically-evaluated digital therapeutics into healthcare through education, advocacy, and research.

Vision
DTA works to enable expanded access to high quality, evidence-based digital therapeutics for patients, clinicians, and payers in order to improve clinical and health economic outcomes.
DTA’s Primary Focus

Our goal is to engage with patients, clinicians, payers, and regulators in order to provide them with the necessary tools to properly recognize, evaluate, and utilize digital therapeutics.
### DTA Priority Initiatives

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<th>Incorporating digital therapeutics into clinical guidelines</th>
<th>Enabling expanded access to high quality digital therapeutics</th>
<th>Promoting consistency and cohesion in regulatory oversight</th>
<th>Improving clinical and health economic outcomes</th>
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<td>Framing the pathways for ‘evidence-based’ and ‘clinically validated’ DTx products</td>
<td>Constructing frameworks for product development, implementation, and scalability</td>
<td>Supporting cohesive regulatory oversight models and DTx quality standards</td>
<td>Developing meaningful assessment and value frameworks</td>
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#### Priority Issues

- Academia & Industry
- Providers & Patients
- Regulatory & Notified Bodies
- Healthcare Decision Makers
Digital Therapeutics Alliance Members*

*As of June 2019
DTA’s International Focus

The Digital Therapeutics Alliance’s 30-plus members represent 10 countries, across four continents*

Australia
Canada
England
France
Germany
Ireland
Israel
Spain
Switzerland
United States

*As of June 2019
Envisioning the Future

In a world where patients may be using five digital therapeutics at one time...

- Dashboard of actionable data from multiple DTx products for healthcare providers and patients?
- Standardized process to integrate DTx products into clinical guideline and workflow processes?
- Identification of interactions between two DTx products (akin to drug-drug interactions)?
- Real World Evidence generation models and attributed to clinical outcomes?
- Identifying potential synergistic benefits of being on multiple therapies?
- Centralized patient experience across multiple DTx products?
- Formulary and medication reconciliation process inclusion?
- Consistent integration process across health-systems?
- Wholesale distribution model for digital therapeutics?
- Scalable prescription and dispensing processes?
For more information, visit:
www.dtxalliance.org

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