

# The Digital Health Opportunity



# What is Digital Health?

CATEGORIES	Apps*	Telehealth	Devices	Wearables**	ΙοΤ	Chatbots	AR/VR	RPM
Therapeutics	15,000+	150						
Advanced wellness	100,000	400						
Basic wellness	175,000	200						
Instructional/ Education	10,000+	50						
TOTAL NUMBERS	300,000+	800	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown

\*Mobile apps and web apps (often called ehealth and mhealth)

\*\* includes smart watches, rings, armbands, straps, clothing, etc

A few facts:

- Digital Therapeutics (at the top here) are regulated by the FDA (but less than 100 are fully approved as of July 2022)
- Digital Health is a collective term for all digitized health and healthcare solutions-other terms are mobile health & virtual care
- This entire product/tool/solution set covers consumer or patient facing (B2C) and Provider/Clinician facing (B2B)
- The entire 'universe' of digital health tools is estimated to be around 400,000 as of July 2022 but is growing at a rate of 1,000 a week or 50,000 a year -80% of these do not meet minimum standards





# **The Digital Health Opportunity**

# Since COVID-19



Today 5 million people download a health app every day – 25% higher than before COVID-19.

(45%

Age is no barrier to digital adoption - **65%** of Baby Boomers and **50%** of over-75s were willing to receive virtual healthcare from traditional providers.



Calm meditation app is valued at **\$2bn** with 4M active users and attracts stars such as Matthew McConaughey, LeBron James and Kate Winslet. Digital Health solutions are increasingly recognized as being a major aid to managing and improving population health.

The evidence for the benefits of health Apps and related solutions is growing fast, and the economic benefits in terms of demand reduction across health care systems are becoming increasingly clear.

There are lots of products out there and population uptake is positive. In addition, the policy environment is also supportive with digital activation targets being incorporated into many aspects of care.



# Where is impact observed?

The evidence for Digital Health is growing. It is now recognized as a major aid to managing and improving population health.

The evidence for digital health includes improving health and service efficiencies. The Return on Investment (ROI) is increasingly clear.



## Weight management

Remote locations and difficulty in accessing incumbent services mean digital health improves equity in access



## Diabetes

Waiting times for face-to-face services are high, apps can start providing support today



## Sleep

It's hard to recall your symptoms from yesterday, let alone two or even four weeks ago. When you do receive F2F care, augment it with accurate real-world data

## COPD

Digital health provides a veil of anonymity, for those not quite ready to talk face-to-face.



# The Digital Health Challenge Uptake issues in key populations

Despite positive evidence of growth, the digital health revolution is in reality a little less well established. Only **16%** of downloads in the health and fitness space are for Apps that support specific conditions. Less than **7%** of Diabetes sufferers use an App to support their condition and the figures for COPD (less than **2%**) and Migraine (less than **0.2%**) paint a similar picture.

## Despite over **300,000 apps** being available "Just **41 Apps** account for over **83%** of downloads in the health and care App space. More than **80%** of health and care Apps do not achieve more than **5,000** downloads"

## Health App Use

Overall Condition Specific	16%
Diabetes	8%
COPD	<b>3</b> %
Migraine	0.2%



# The Breadth of the Challenge - Not all Apps are the same!

## 01. Preventative / Pathway Independent

These Apps are designed to work independently of traditional health and care services and treatment pathways. They can be supportive of those services and pathways or focussed on prevention and the wider wellbeing agenda.

- This is the largest group of Apps in overall health and fitness and medical categories.
- Examples include: Inhaler Technique, Stress Management, Fitness, and Diet Apps.

#### **03. Pathway Replacement**

These Apps aim to replace traditional steps in a clinical pathway entirely. They are designed to be integrated into the pathway or process and to deliver 'services' directly to the patient/user or healthcare professional.

- Very likely to be Medical Devices and/or Clinical Services requiring CQC oversight.
- Examples include: 'Mole Checkers', App based ECG solutions, Full Service CBT Apps.



#### 02. Integrated / Pathway Support

These Apps are designed to support existing clinical/healthcare pathways in some way. Typically this might include supporting communications between users and professionals around symptom/condition monitoring.

- These Apps typically require some form of 'integration' with existing processes and systems.
  - Examples include: Symptom Checkers, Condition Monitoring, 'Mood Diaries'.

#### 04. Administrative Support

These Apps provide an alternative or supportive solution for key administrative tasks such as Appointment Management, Prescription Management, Service Sign-Posting, and Personal Care Record Management.

Often fully integrated into existing clinical systems – eg GPSoc.

Examples include: GP Services Apps, Electronic Personal Care Records, Service Catalogues.

# What are the Major Blockers?





Market Scale – c300k Products and Services available across 100's of condition and category areas



Pace of Change – Agile Development techniques deliver constant updates of previously assessed products



Unknown Risks and Liabilities – these are untested and can be an inhibitor without systems to protect and manage this risk



Range of Assessment Disciplines or Domains – from technical to clinical the breadth of assessment skills required is considerable



Regulatory and Technology Change - new standards and regulations are emerging constantly and new technologies - such as AI require constant assessment iteration



**Regulation v Innovation** - striking the right balance between these two elements and maintaining the innovation energy in Digital Health is key



# THE DIGITAL HEALTH MISTAKE

NOT LEARNING FROM OTHER AREAS

In all other areas of health and care we have the critical infrastructure in place for safe decision making and distribution...

...there is no coordinated infrastructure in place for digital health



E-prescribing to distribute and track medicines, with PBMs to manage reimbursement

The Orange Book to list approved drugs on formulary

ICER to assess impact and effectiveness



FDA to approve and licence drugs

CENTER FOR DRUG EVALUATION & RESEARCH



# **ORCHA** THE DIGITAL HEALTH SOLUTION

HAVING THE RIGHT INFRASTRUCTURE IN PLACE



## **ORCHA** DIGITAL HEALTH ASSESSMENT FRAMEWORKS THE STARTING POINT, NOT THE END POINT

FDA through the Breakthrough Device Program (BDP), e.g. 510(K), are strictly limited to Digital Therapeutics, accounting for 5-10% of the market of digital technologies

Few exist outside of the FDA and there is little consensus

Outside of the US, there are multiple frameworks globally to help national authorities to assess a digital solutions

They include universal regulations and specific measures developed for digital health

It is costly and time intensive to create standards from scratch and get baseline data and critical mass

Self-certification doesn't have the consistency and objectivity

The standards can take significant time to complete

ORCHA have pulled together the areas of 'baseline' consensus into the new US Digital Health Assessment (US DHA) framework





## ORCHA ASSESS AGAINST THESE INTERNATIONAL SCHEMES

HAVING HELPED CREATE MANY OF THEM

	US Digital Health	EU ISO 82304-2	NHS DTAC	Canadian MHCC	German DiGA	Netherland GGZ/Mind	5 NORDIC Nations	NZ -Health Navigator
Enhanced Review	Assessment							
Enhanced Evidence Analysis		<b>O</b>			<b>O</b>			<b></b>
Commercial and Financial								
Interoperability								
Clinical Safety		<b>O</b>	<b>O</b>		<b>O</b>			$\bigcirc$
Technical Stability	$\bigcirc$	<b>O</b>		<b>O</b>	<b>O</b>			
Security	<b>O</b>	<b>O</b>		<b>O</b>	<b>O</b>		<b></b>	
Enhanced Data Analysis			$\bigcirc$	<b>O</b>				
User Experience	<b>O</b>					<b>O</b>	<b></b>	
Clinical Assessment				<b>O</b>			<b>O</b>	
ORCHA Baseline Review								
Clinical Assurance		0		<b>O</b>	<b>O</b>	$\bigcirc$	<b>O</b>	<b>Ø</b>
Usability & Accessibility		0	<b>O</b>	<b>O</b>	<b>O</b>	<b>O</b>	<b>O</b>	<b></b>
Data & Privacy	<b>Ø</b>	0	<b>O</b>	0	<b>O</b>	<b>O</b>	<b>O</b>	<b>O</b>
ORCHA Rapid Assessment	0	0						

# The Regulatory Landscape What Applies to what?

The Regulatory landscape can be very confusing for Digital Health providers as 'old' regulations and standards are being 'adapted' to meet the very different scenarios that these solutions throw up. Healthcare Regulators globally are wrestling with how to provide a suitable regulatory regime for these innovative products and services.

#### Data & Privacy

In the EU, Apps are now largely governed by GDPR/HIPPA Regulations. However emerging standards around the additional requirements to support System Interoperability will undoubtedly add more layers. Key areas of focus will be the 'model of consent' and authentication solutions.

## **Clinical Assurance**

This is an area that is packed with regulations, standards and policy requirements depending on the jurisdiction in question. Key regulations include, Medical Device Regulations, CQC Registration, Clinical Safety standards, and requirements around evidence of effectiveness and impact.



#### Security

This is Digital Assessment around security on compliance with OWASP best practice guidelines for Apps and Web based solutions. Whilst existing accreditation regimes such as Cyber Essentials and ISO27001 are relevant, the need to demonstrate 'security by design' and suitable vulnerability testing is also becoming key.

## User Experience

This is currently the area that is least impacted by Regulation. There are some standards around usability and accessibility, but true User Experience metrics or KPIs are hard to come by, with the primary user feedback mechanisms highly prone to misuse.



# **5 Levels of Digital Health Tools\***



An app/tool is placed at the highest tier any part of its functionality sits at. If an app had both 3b and 2a functionality, the app would be expected to establish evidence at a 3b tier.

Requirements are cumulative, meaning an app at Tier 3a would need to have all those assurance/evidence required of all the below tiers.

DIGITAL HEALTH. UNLOCKED.

\*Although Apps dominate digital health tools or solutions, this also includes digital devices (such as VR), Telehealth solutions, wearables, IoT solutions, remote patient monitoring systems, etc.)





# **The Human ORCHA Team**



30 Professional Digital health Tool Assessors

The team reviews 250 new digital health tools a month\*



15 clinical leads (13 of these physicians) under a Chief Medical Officer The team re-reviews 100 digital health tools a month



6 Subject matter Experts (HIPPA, Hi Trust, SOC2 etc) The team creates 3 insights reports a month

\*Only around 80% of these meet minimal standards

DIGITAL HEALTH. UNLOCKED.

# **Dissemination & Activation Approaches**

Digital Health Assessment is a means to an end, not an end in itself.

It is one of the key foundations to wider Digital Health adoption and use, but to be effective it needs to be accessible to those who need it.

Libraries, catalogues and formularies, are all manifestations of the Assessment Output and provide a trusted resource for end users to utilize.

There can never be too much promotion of these outputs and different audiences will be attracted to different sites and will require different messaging and levels and type of information

To be truly effective an Assessment 'System' will provide the Assessment outputs in a range of flexible ways to enable a coordinated and consistent eco-system of 'approved' or 'trusted' Digital Health solutions to develop.



# The Importance of Search and App Matching



## Health Condition or Category

We have over 180 health and care conditions or categories to support a wide array of health and wellbeing needs.



#### **Key Features**

We capture over 15 distinct functions and features to help users find the capabilities that they need help and support with.

## Individual Characteristics

Our review process identifies a range of key characteristics that an App has been designed to support. These range from target age to physical and cognitive capabilities.



#### **Technical Preferences**

Whether it is iOS or Android, Garmin or FitBit, or Strava or MapMyRun, the technical world users inhabit is a key element of an App's 'stickability'.

# What are the Benefits of Driving Strongly towards the Adoption of Safe, High Quality and Efficacious Digital Health?

- We get to lower costs for delivering care (often substantially)
- We get rigorously reviewed/assessed and constantly reviewed/re-assessed digital health solutions to ensure they give clinicians and other providers 'peace of mind' and give patients/consumers, and their caregivers trust/faith in the solution they are using
- If done carefully we curate only safe and high-quality digital health solutions in a targeted library to give consumers an easy way to know a tool is fit for purpose and adds tangible value in their wellness journey or treatment and/or recovery from illness or disease
- We considerably lessen the time and effort needed to qualify and 'vendor manage' digital health tool suppliers
- By assessing for quality, we reduce the risk of lawsuits and damages related to the use of digital health tools
- We enhance the reputation and brand of the organization when it deploys a library of safe and high-quality digital health solutions
- We provide more flexibility in care options to end users, which help them to feel better (and reduce stress and anxiety, time off work and even boost personal wellbeing and productivity)





# **DISCOVERY AND INSIGHTS**

FROM THE WORLD'S LARGEST DATA SET

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Alternatively, or in addition, ORCHA delivers one-off reports that use ORCHA's data set and wider research to create a detailed analysis of a particular area of digital health

- Produced by our extensive research team
- Health Economic Researchers, data scientists and academics

## **WORCHA SUMMARY** DELIVERING DIGITAL HEALTH INFRASTRUCTURE NEEDS THROUGH OUR END-TO-END PLATFORM

