



***UNLOCKING THE  
POWER OF DIGITAL  
HEALTH***

DIGITAL HEALTH. UNLOCKED.

# THE DIGITAL OPPORTUNITY

Health-focused consumers have embraced digital health



## Since COVID-19



Healthcare providers see the benefit with **93%** of clinicians believing digital technologies can help.



Age is no barrier to digital adoption - **55%** of over 55s and **52%** of over-65s were willing to receive digital healthcare from traditional providers.



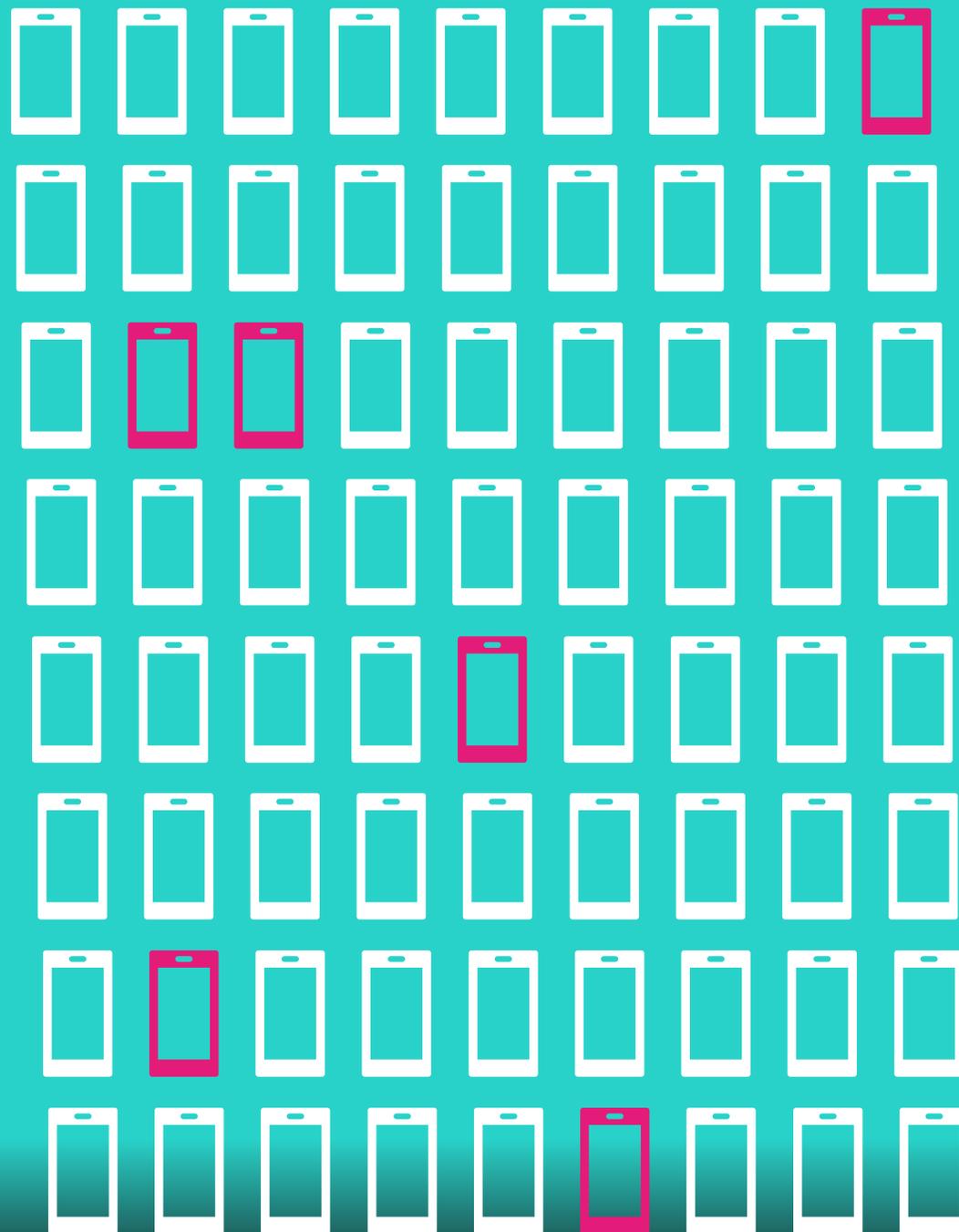
The world's 10 largest English-language mental wellness apps saw 10 million downloads in April 2020. And more than **858,000** people downloaded the Couch to 5K app in 2020 - a **92%** increase over 2019.

**5** million

Today 5 million people download a health app every day - 343% higher than before COVID-19 ([see our paper in BMJ](#))

But, with **365,000** digital health products to choose from, how do you know which are safe, effective, and suited to your client?

*Imagine if the same were true for medication.*



# 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...

...why do we think digital health is different?



E-prescribing to distribute and track medicines



The BNF to know when and how to prescribe



NICE to assess impact and effectiveness

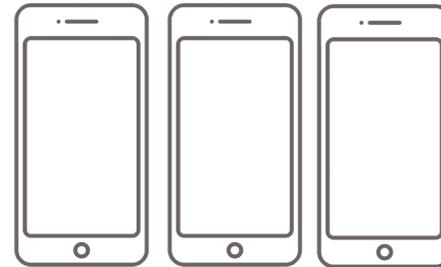


MHRA to approve and licence drugs



# THE DIGITAL HEALTH SOLUTION

Having the right infrastructure in place



## GOVERNANCE

GOVERNANCE AND REIMBURSEMENT INFRASTRUCTURE

## ACCESSIBILITY

RECOMMENDATION INFRASTRUCTURE

## AWARENESS

TRAINING AND ASSESSMENT INFRASTRUCTURE

## TRUST

REGULATORY INFRASTRUCTURE



DATA AND  
INTELLIGENCE  
PLATFORM



DIGITAL  
FORMULARY

x100



ASSESSMENT /  
TRAINING  
AT SCALE



DTAC  
ISO 82304

DIGITAL HEALTH  
STANDARDS /  
FRAMEWORKS



**But, it all starts with trust**



# 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 EPIC and Cerner
- ✓ Examples include: GP Services Apps, Electronic Personal Care Records, Service Catalogues.

# THE REGULATORY PUZZLE: WHAT APPLIES TO WHAT?

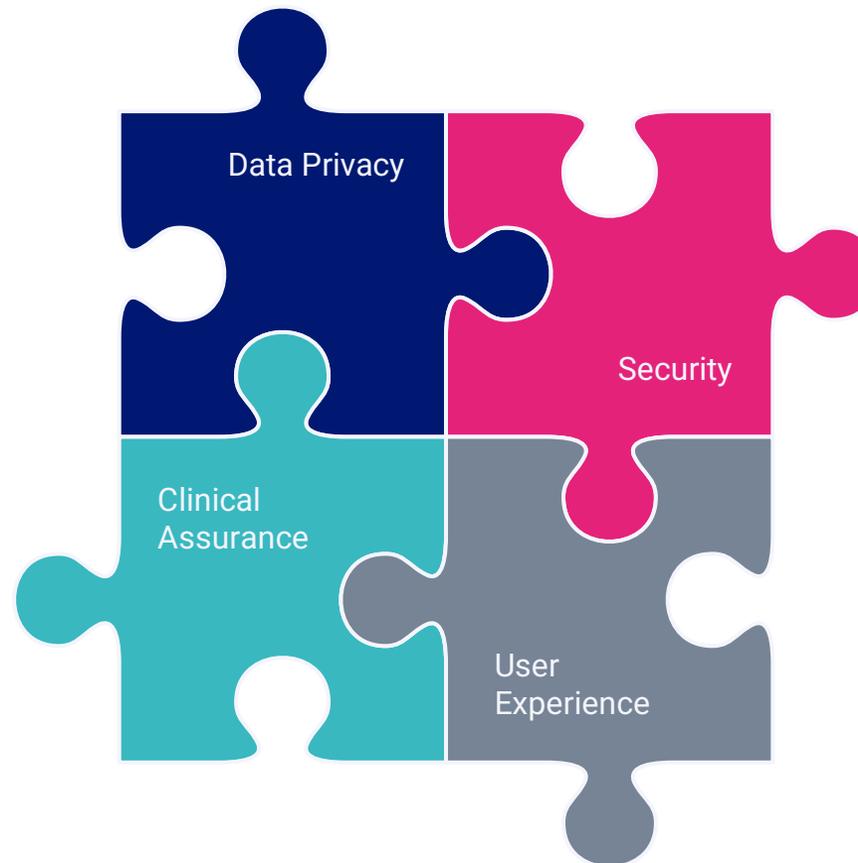
The Regulatory landscape can be very confusing for Digital Health providers as 'old' regulations and standards are being 'adapted' to meet the very different scenarios that these solutions throw up. Healthcare Regulators globally are wrestling with how to provide a suitable regulatory regime for these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

## Data & Privacy

In the EU, Apps are now largely governed by GDPR Regulations. However emerging standards around the additional requirements to support System Interoperability will undoubtedly add more layers on top of the base GDPR position. 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 (with major changes coming into force shortly), CQC Registration, Clinical Safety standards, and requirements around evidence of effectiveness and impact.



## Security

NHS Digital have focussed their 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.

There are multiple frameworks to help national authorities to assess a digital solution

They include universal regulations and specific measures developed for digital health

There are a lot of common requirements for:

- Data and privacy
- Usability and accessibility

There is less consensus and convergence in areas:

- Clinical assurance
- Security assessment

User experience and clinical analysis is largely un-assessed

**ORCHA have pulled together the areas of consensus into the ORCHA Baseline Review (OBR)**

**NICE**  
National Institute for  
Health and Care Excellence

NICE ESF



The DTAC



Medical Devices  
Regulations



ISO-82304-2



Mindex



DiGA



mHealth Belgium -  
Validation Pyramid



NORDIC Baseline  
Review





# ACTIVATION AND ASSURANCE THROUGH **DIGITAL PRESCRIPTIONS**

- Expand and accelerate digital health transformation
- Deliver choice for patients and match the technology to their needs
- Provide a digital formulary for healthcare professionals to recommend and prescribe
- Support with a Digital Health Academy to upskill the workforce
- Manage risk, liability, assurance and continued compliance through ORCHA



**To truly support the digital patient and professional, we must provide the technology and the infrastructure...**



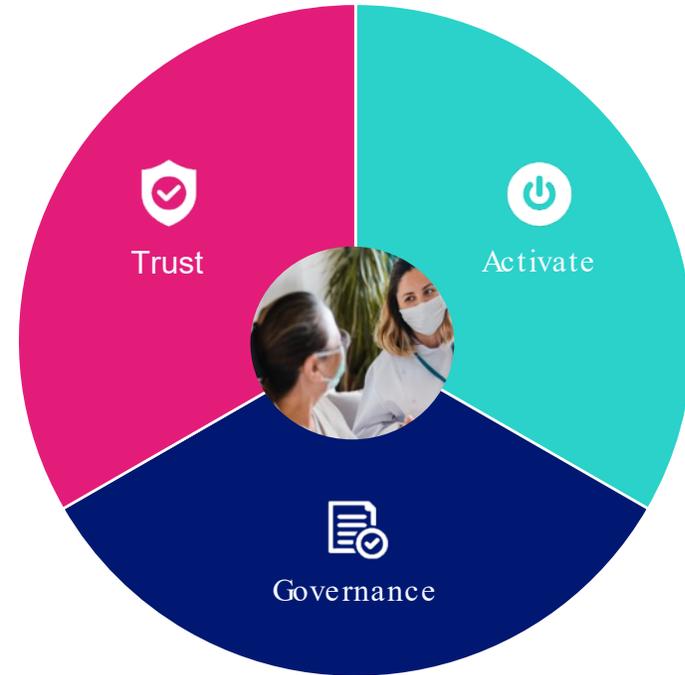
Trust in digital health



Overcome awareness and access barriers to deliver activated Health Care Professionals and patients



Have strong governance and risk management



# ***ABOUT ORCHA***

Improving the lives of people through technology





## WE WORK ACROSS 12 LEADING HEALTHCARE COUNTRIES

**7,000+**

Professionals on the platform

**17,000+**

Health app assessments conducted

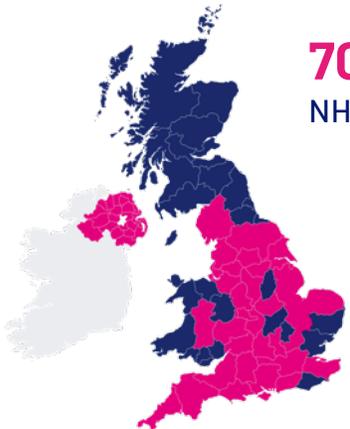
**500+**

Individual assessment components cover all major standards and regulations



**70%**

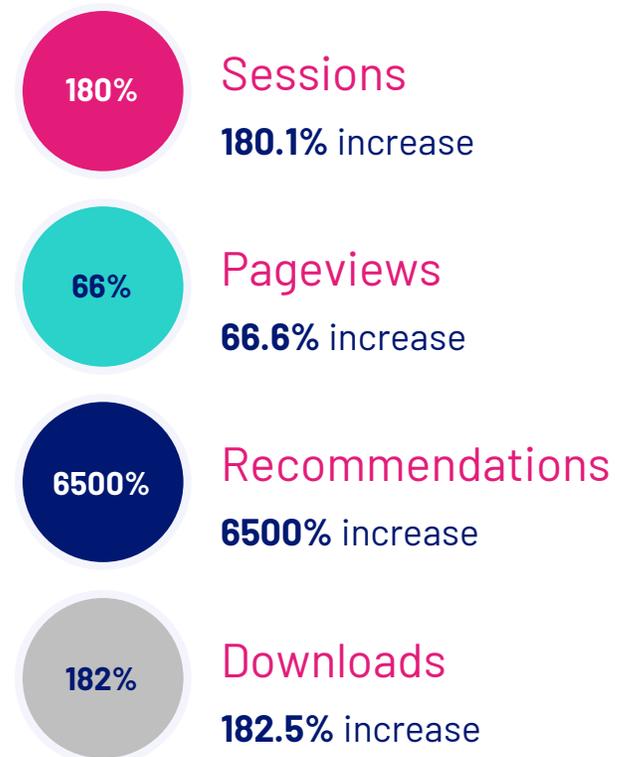
NHS regions covered by ORCHA





# AND FINALLY...**NOW IS THE TIME**

The use of digital is accelerating and our need is growing, let's meet the challenge...





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**Any questions?**