UNLOCKING THE POWER OF DIGITAL HEALTH
The Digital Opportunity

Health-focussed 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.

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

Sources:
Imagine if the same were true for medication.

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

**Assessment / Training at Scale**

**Digital Health Standards / Frameworks**

Having the right infrastructure in place
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.

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’.

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.

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 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)**
## ORCHA Assess Against These International Schemes

**Having Helped Create Many Of Them**

<table>
<thead>
<tr>
<th></th>
<th>NHS DTAC</th>
<th>EU ISO 82304-2</th>
<th>US Digital Health Assessment</th>
<th>Canadian MHCC</th>
<th>German DiGA</th>
<th>Netherland GGZ/Mind</th>
<th>5 NORDIC Nations</th>
<th>NZ - Health Navigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhanced Evidence Analysis</td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial and Financial</td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interoperability</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Clinical Safety</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Technical Stability</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Security</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Enhanced Data Analysis</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>User Experience</td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
<td>✔️</td>
</tr>
<tr>
<td>Clinical Assessment</td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
<td>✔️</td>
</tr>
</tbody>
</table>

### ORCHA Baseline Review

**Clinical Assurance**

- ✔️

**Usability & Accessibility**

- ✔️

**Data & Privacy**

- ✔️

### ORCHA Rapid Assessment

- ✔️
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

[Image of ORCHA logo]
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 covering all major standards and regulations

70%
NHS regions covered by ORCHA
The use of digital is accelerating and our need is growing, let’s meet the challenge...

- **Sessions**: 180.1% increase
- **Pageviews**: 66.6% increase
- **Recommendations**: 6500% increase
- **Downloads**: 182.5% increase

**AND FINALLY...NOW IS THE TIME**
Main Office
Sci-Tech Daresbury, Vanguard House,
Keckwick Lane, Daresbury, WA4 4AB

Telephone
+44 (0) 1925 606542
Email
hello@orcha.co.uk

London
ORCHA, Spaces, 307 Euston Road,
London, NW1 3AD

Amsterdam
Orcha Health, B.V. Stadsplateau,
73521 AZ. Utrecht

Boston, United States
ORCHA Health Inc., CIC, 50 Milk St
Boston, MA

Any questions?