



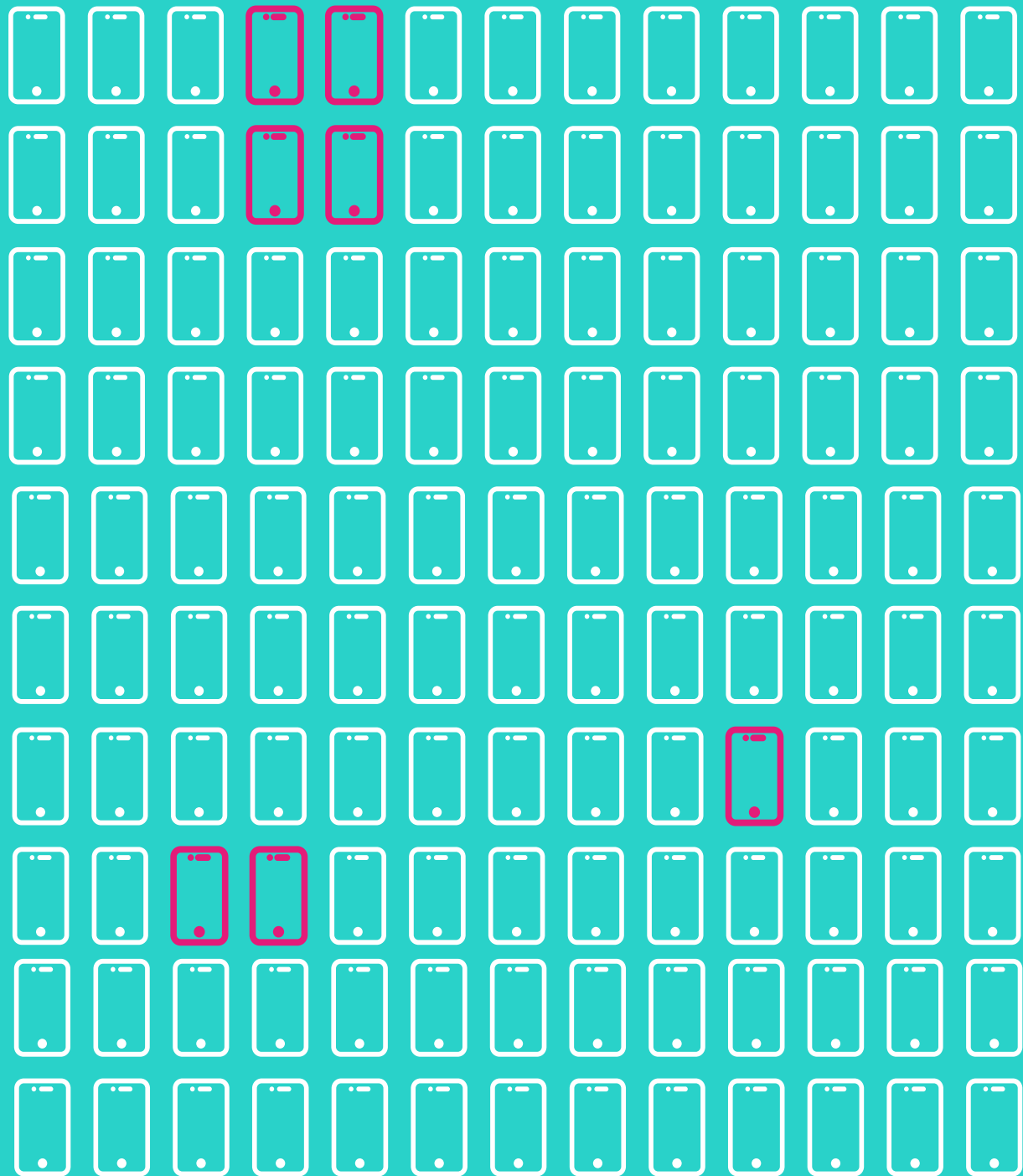
THE FUTURE OF REGULATION

Liz Ashall-Payne, CEO, ORCHA

DIGITAL HEALTH. UNLOCKED.

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.



Healthcare providers are seeing the opportunity

With escalating demands, COVID-19, and national policy, health providers have made huge advances.



Believe health technologies can reduce the number of visits to doctor offices



Believe that these apps can improve patients' health



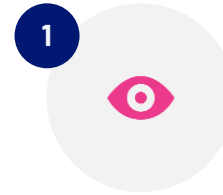
The first G20 report in area of digital health was announced in advent of the G20 Summit in December 2020.



80% of professionals are using smartphones & medical apps



What are the main barriers to using digital health apps?



Awareness

Apps are not yet part of the day-to-day management of health and care related conditions.



Accessibility

Finding and matching Apps to support your needs or those of your service users is very difficult.



Trust

The lack of a suitable quality indicator inhibits the embracing of Apps by end users and professionals in health and care space.



Governance

The lack of clarity around the regulatory landscape and the appropriate governance foundations delivers organisational uncertainty.



It all starts with trust

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

This are focuses 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.

DIGITAL HEALTH ASSESSMENT FRAMEWORKS

There are multiple frameworks to help NHS and local authorities to assess a digital health solution.

They include universal regulations and specific measures developed purely 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 and evidence evaluation
- Security assessment

User experience and clinical analysis is largely un-assessed.



NICE ESF



Medical Devices Regulations



The DTAC



ISO-82304-2



Mindex



DiGA



mHealth Belgium - Validation Pyramid



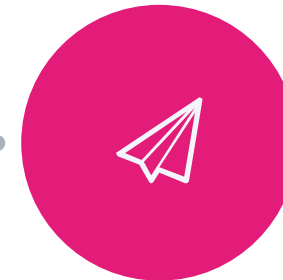
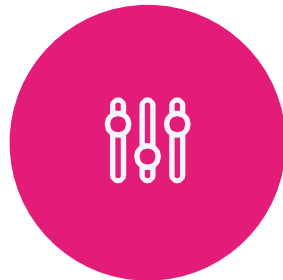
NORDIC Baseline Review

The ORCHA Baseline Review Process

A revolutionary approach to technology assessment

Auto Filtering

We filter out apps not available in relevant languages and apps that haven't been updated for over 18 months. We auto-categorise those remaining Apps into over 250 condition and category areas.



Developer Checks

We notify developers of our review findings ahead of publication and allow them 10 days to challenge any area of the review.

Publication & Further Monitoring

Following the developer check period, the review is published on all relevant platforms and we start to gather further information for our 'Advanced Review' phase.

Weekly Monitoring

We monitor all of the apps in this space on a weekly basis to identify new apps, apps that have new releases and apps that have become out of date.

350 Point Evaluation PLUS

Our reviewers analyse each app through a 350+ point evaluation which assesses an app's compliance with relevant standards, regulations and best practice.

	Netherland	NORDIC Nations	Canada	NHS DTAC	ISO 82304-2	NZ Health Navigator
Enhanced Evidence Analysis					✓	✓
Commercial and Financial						
Interoperability		✓				
Clinical Safety				✓	✓	✓
Technical Stability			✓	✓	✓	
Security		✓	✓	✓	✓	
Enhanced Data Analysis			✓	✓		
User Experience	✓	✓				
Clinical Assessment		✓	✓			
ORCHA Baseline Assessment						
Clinical Assurance	✓	✓	✓	✓	✓	✓
Usability & Accessibility	✓	✓	✓	✓	✓	✓
Data & Privacy	✓	✓	✓	✓	✓	✓
ORCHA Rapid Assessment	✓	✓	✓	✓	✓	✓



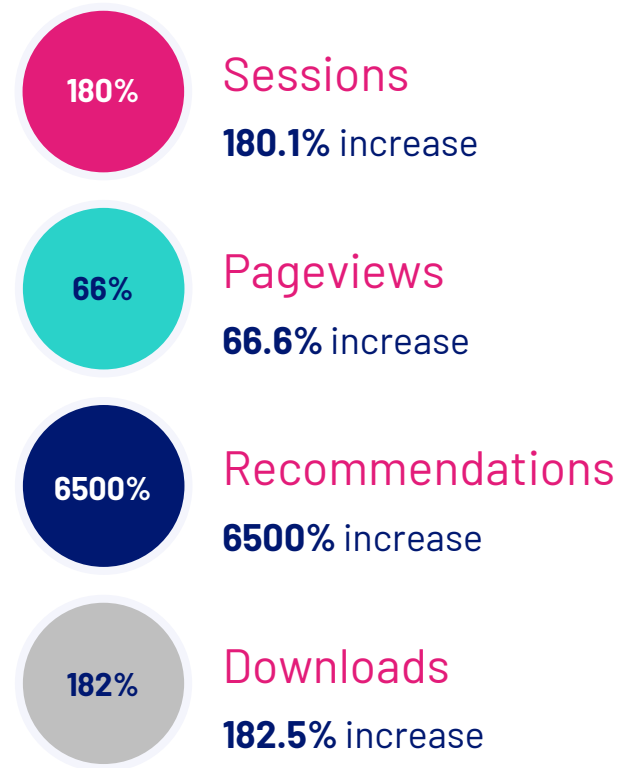
Digital Health Libraries and recommending the best!





NOW IS THE TIME

Searching for, finding and recommending digital health apps since COVID-19



To truly support the digital patient, we must:



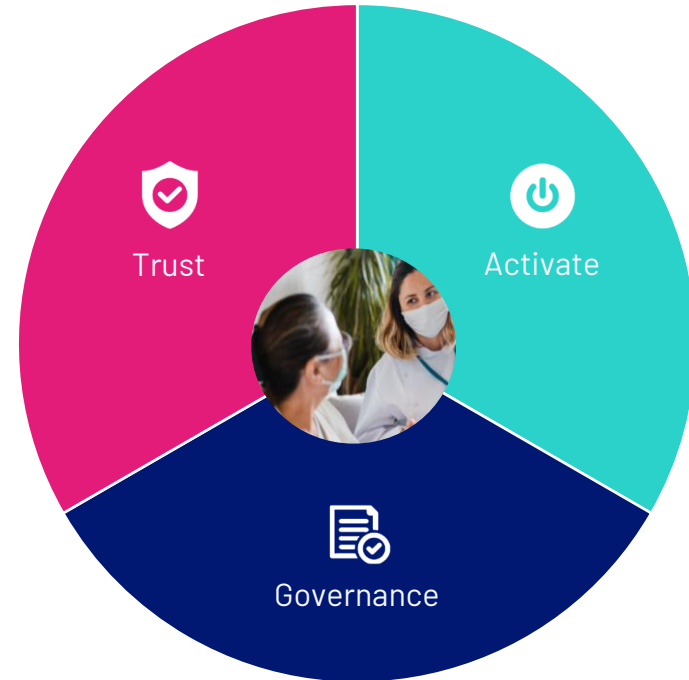
Trust in digital health



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



Have strong governance and risk management





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



@OrchaHealth



@Orcha



@Orcha