

***CLINICAL ASSURANCE  
& SAFETY DOMAIN***



# ***THE DIGITAL HEALTH ASSESSMENT FRAMEWORK***



## **Key components:**

### **Data & Privacy**

- Adherence to federal laws designed to protect the rights and freedoms of individuals.
- A deeper dive into laws that are specific to individual products, such as the need for HIPAA compliance and COPPA

### **Clinical Assurance & Safety**

- Is the app safe and effective? This is by reference to the NICE Evidence Standard Framework , where requirements vary based on the functionality of the app
- For patient safety, is the app a medical device as outline by FDA Digital Health Requirements?

### **Usability & Accessibility**

- Design and development; accessibility; usability; user support
- Compliance with design standards

### **Technical Security & Stability**

- App was built in compliance with the secure coding practice guidelines of the OWASP (Open Web Application Security Project)

# ***HOW IS CLINICAL ASSURANCE AND SAFETY EVALUATED***



- The Clinical Assurance and Safety domain is largely based on the Evidence Standards Framework (ESF) published by NICE. The amended ESF categorizes digital apps (or DHTs) into tiers based on functionality and integration with other systems. Apps designated at higher tiers have a higher threshold of assessment regarding clinical evidence and safety.
- The Tier system is outlined into Tier A, Bi, Bii, Ci and Cii.
- The assessment includes a review of published data, quality of the studies if they exist, and evidence of involvement by appropriate professionals or professional organizations.

## Evidence & Assurance of Effectiveness



### Proportionality

Conduct proportional assessment linked to functions and features of App.

### Necessity

What type of evidence is necessary: effectiveness, safety or both?

### Appropriateness

Evidence must be conducted with an appropriate sample or via appropriate means

### Quality

If an App has provided appropriate evidence, quality must be assessed

# Evidence Standards Framework (ESF)



Why refer to the ESF?



Tier A → Tier Bi → Tier Bii → Tier Ci → Tier Cii

# ESF Requirements



**This goes beyond traditional evidence...**

- Supporting Evidence
- Endorsement
- Assurance

ESF requirements are cumulative. To pass Tier Cii, the DHT must pass Tier Ci, Bii, Bi, A

# ESF Tiers & Examples

Tier A → Tier Bi → Tier Bii → Tier Ci → Tier Cii

## An DHT is a Tier A if it

- Has no measurable patient outcomes but provides services to a health or social care system

E.g. maintenance app or admin app which acts as a healthcare system / service

## What are the requirements?

- Supporting Evidence (Survey, Pilot Study, Meta-analysis, RCT, Observational or Other indicated user acceptance/benefit)

And it also needs **one** of the following:

- Evidence of a relevant professional involved in the development team
- Relevant organisational credentials
- Evidence of endorsement by a relevant body

Tier A is the lowest Tier and identifies DHTs with the lowest risk.  
This is why Tier A apps can pass the ESF with just two criteria.



# Tier A Example - Attensi



A DHT is a Tier A if it

→ **Has no measurable patient outcomes but provides services to a health or social care system**

E.g. maintenance app or admin app which acts as a healthcare system / service

Description

Attensi specializes in gamified simulation training. As a global leader in the field, and our solutions combine advanced 3D modelling with deep insight into human behaviour and psychology, **training employees** in authentic situations that involve human interaction and operation of critical software and systems.

# Tier A Example - Attensi



## Attensi

- "91% said completing Attensi Process helped them in their real-life work."
- Professional involved in development in relation to creating simulations

Does it pass its ESF Tier?



- **Supporting Evidence** (EE02 - Survey, Pilot Study, Meta-analysis, RCT, Observational or Other indicated user acceptance/benefit)

And it also needs **one** of the following:

- **Evidence of a relevant professional involved in the development team**
- Relevant organizational credentials
- Evidence of endorsement by a relevant body

## A DHT is a Tier Bi if it

- Provides information or guidance
- Allows a healthcare professional to provide clinical advice, as opposed to the app providing it
- Provides information, resources, or activities to the end user
- Provides two-way communication between patients, citizens or healthcare professionals
- Is a simple self-management app

## What are the requirements?

- Evidence that the info, advice or guidance is validated with appropriate academic studies or academic expert input
- Evidence of safeguarding measures being in place for any communication functions
- The app has evidence of accrediting expertise

Please note: For a DHT to pass its Tier it must also pass all the Tiers below it.  
Tier Bi must pass its own requirements AND Tier A requirements.

# Tier Bi Example - Calm



## A DHT is a Tier Bi if it

- **Provides information or guidance**
- Allows a healthcare professional to provide clinical advice, as opposed to the app providing it
- **Provides information, resources, or activities to the end user**
- Provides two-way communication between patients, citizens or healthcare professionals
- **Is a simple self-management app**

## Description

*"Our **guided meditations** are available in lengths of 3 to 25 minutes, so you can choose the perfect length to fit your schedule. We offer a new 10-minute Daily Calm every day, Sleep Stories narrated by well-known voices like Matthew McConaughey.*

*Calm saves your meditation and sleep sessions to your Apple Health app."*

# Tier Bi Example - Calm



## Criteria Evidence

- Meets the requirements of Tier A
- Tamara Levitt has studied meditative practices for 30 years

## Does it pass its ESF Tier?



- **Evidence that the info, advice or guidance is validated with appropriate academic studies or academic expert input**
- Evidence of safeguarding measures being in place for any communication functions **NA**
- **The app has evidence of accrediting expertise**

## A DHT is a Tier Bii if it

- Is a standard self-management app

## What are the requirements?

- Evidence that the Developer has validated the info, advice or guidance
- Evidence of safeguarding measures being in place for any communication functions
- Evidence of accrediting expertise

And either...

- Evidence of an endorsement by a relevant body OR
- Supporting evidence (at least a meta analysis, or an observational study/RCT with a significant p value) OR
- Evidence of implementation into a relevant healthcare organization.

Please note: For a DHT to pass its Tier it must also pass all the Tiers below it. Tier Bii must pass its own requirements AND Tier A & Bi requirements.

# Tier Bii Example - Pathway through Pain

A DHT is a Tier Bii if it

- **Is a standard self-management app**  
The App collects condition specific data over time which can be reviewed and accessed by the user.

Description

*“This accessible web-based course is NHS commissioned and delivers significant and often life-changing results for individuals seeking to better self-manage chronic musculoskeletal pain. This is achieved through the practice of **chronic pain self-management** and cognitive approaches learnt throughout the course.*

*Participants report their progress using self-assessment tools throughout the course. Progress and outcomes are reported to their sponsor via a Management Portal.”*

# Tier Bii Example - Pathway through Pain



## Criteria Evidence

- Meets the requirements of Tier A, Bi
- This accessible web-based course is NHS commissioned.
- Observational study with p values that demonstrate significance
- The information is validated with references and sources
- Sarah Germany has 10 years of experience in the Occupational Health sector

## Does it pass its ESF Tier?



- **Evidence that the Developer has validated the info, advice or guidance**
- Evidence of safeguarding measures being in place for any communication functions **NA**
- **Evidence of accrediting expertise**

And either...

- **Evidence of an endorsement by a relevant body**
- OR
- **Supporting evidence** (at least a meta analysis, or an observational study/RCT with a significant p value)
- Evidence of implementation into a relevant healthcare organization.



## A DHT is a Tier Ci if it

- Is a complex self-management app
- Has preventative behaviour change within the app
- Has a recognised (not novel) clinical calculator

## What are the requirements?

- Supporting evidence (RCT/Observational which has a significant p value)
  - ◆ Significant p value
  - ◆ Comparator OR validated comparator

Please note: For a DHT to pass its Tier it must also pass all the Tiers below it.  
Tier Ci must pass its own requirements AND Tier A, Bi & Bii requirements.

# Tier Ci - Oviva

## A DHT is a Tier Ci if it

- Is a complex self-management app
- **Has preventative behaviour change within the app**
- Has a recognised (not novel) clinical calculator

## Description

*“The Oviva app is used to communicate with your dietitian or health professional, who can support you to learn more about managing your health. Receive regular support and advice to give you the knowledge and skills to improve your confidence in achieving your goals. You will discuss your personal aims and concerns with your dietitian, make a personalised plan, and set goals using the app. Snap photos of your meals, **manage your goals through our tracking functions, and receive feedback and support. This will include personalised tips, recipes and nutrition information tailored to you.** You can also connect with the Health app, to conveniently share your health data.*”

## Criteria Evidence

- Meets the requirements of Tier A, Bi, Bii
- Observational Study which demonstrates significance and has a comparator which is validated

## Does it pass its ESF Tier?



- **Supporting evidence** (RCT/Observational which has a significant p value)
  - ◆ **Significant p value**
  - ◆ **Validated comparator**

## A DHT is a Tier Cii if it

- Diagnoses a condition
- Contains a novel clinical calculator
- Automatically measures/records and transmits health data to 3rd party without input from user
- Provides treatment
- Guides the treatment of a condition
- Alleviates the symptoms of an existing condition

## What are the requirements?

- Evidence of an RCT
  - ◆ Significant p value
  - ◆ A validated comparator

Please note: For a DHT to pass its Tier it must also pass all the Tiers below it. Tier Cii must pass its own requirements AND Tier A, Bi, Bii & Ci requirements.

# Tier Cii - FibriCheck

A DHT is a Tier Cii if it

- Diagnoses a condition
- **Contains a novel clinical calculator**
- Automatically measures/records and transmits health data to 3rd party without input from user
- Provides treatment
- Guides the treatment of a condition
- Alleviates the symptoms of an existing condition

Description

*“Then check your heart rhythm and heart rate with FibriCheck, the medically certified health app on your smartphone. Keep an eye on the health of your heart, **detect cardiac arrhythmias in good time, and avoid complications such as a stroke.** PPG is a technology with ECG quality that uses light to detect cardiac arrhythmias. It measures changes in the volume of your blood vessels by using the flash of your smartphone camera. These signals can be used to determine your heart rhythm and heart rate.”*

Criteria Evidence

- Meets the requirements of Tier A, Bi, Bii, Ci
- Randomised Control Trial which demonstrates significance and has a validated comparator which is validated

Does it pass its ESF Tier?



- Evidence of an RCT
  - ◆ **Significant p value**
  - ◆ **A validated comparator**

# Conclusions



**The DHAF Evidence Standards Framework provides an approach based on:**

- Proportional assessment linked to functions & features
- Necessity for evidence of effectiveness and/or safety based on Tiers
- Appropriateness of sample size
- Quality with reference to p-values & comparators