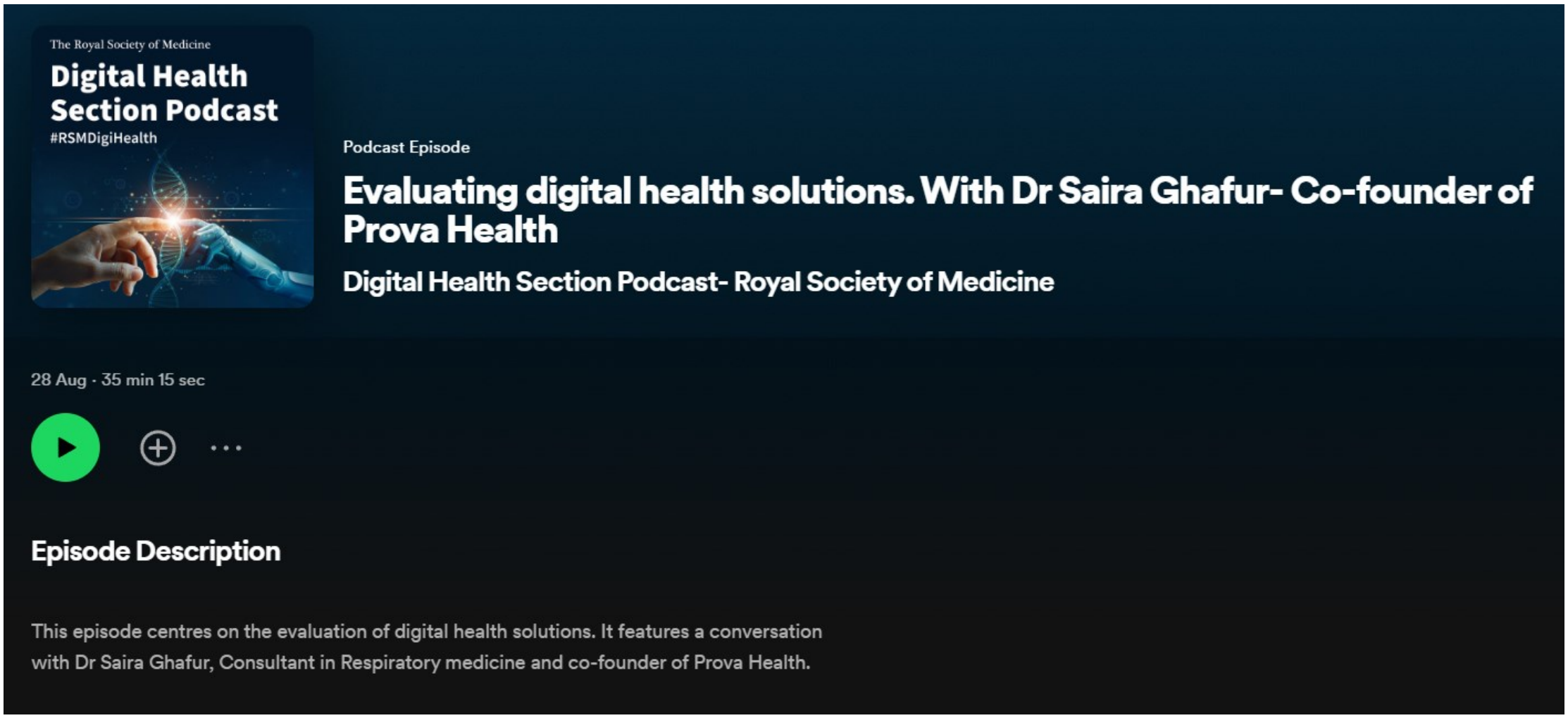
CLINICAL EVIDENCE GENERATION

A PRACTICAL GUIDE FOR HEALTHTECH COMPANIES

This carousel has been adapted from the following podcast:



Available here:

https://open.spotify.com/episode/65Bud3UaUSrNUXtX4S0wmm?si=USqdZ2K7S3eiuU0n7-OF9A

“We know that our traditional methodology of doing evidence generation in healthcare is the gold standard - **Randomized Controlled Trial**.

And as innovators, we know that **this is not always possible.**

It's not always the right thing to do either.

So we need to think of more **pragmatic** and innovative ways of being able to generate this evidence **at different stages** of the evolution of a tech product.”

Dr. Saira Ghafur

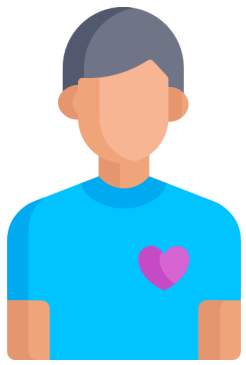
Co-Founder, Prova Health

QUESTION 1:

Consider who is this evidence for?

The first thing an innovative needs to think about is **who are you trying to demonstrate value to?**

Is it for:



Patients?

Clinicians?

Health Systems?

Investors?

And very quickly, then that kind of tells you **the type of evidence** that you may need to produce.

QUESTION 2:

What type of evidence do you want?

And then the next thing is what type of evidence are you trying to produce?

Is it **clinical**?

Is it **financial**?

Is it **operational**?

Is it **user experience**?

And this will differ based on the **kind of stakeholders** that you're trying to reach out to.

QUESTION 3:

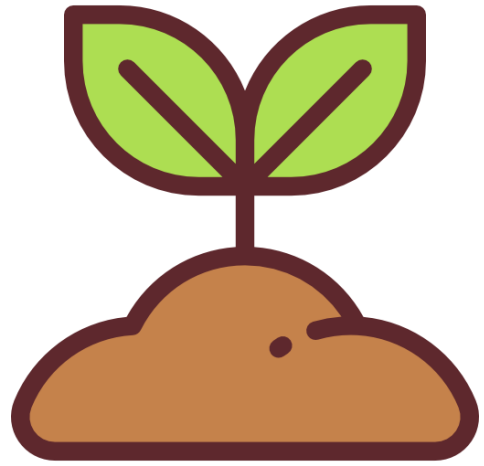
What stage of product development are you at?

Are you at the:

- **Early stage** when you're just kind of starting off and you've got lots of different iterations of the product or the **MVP stage**?

- **Later stage** when you're kind of looking more at safety, performance or security issues for **regulatory approval**?

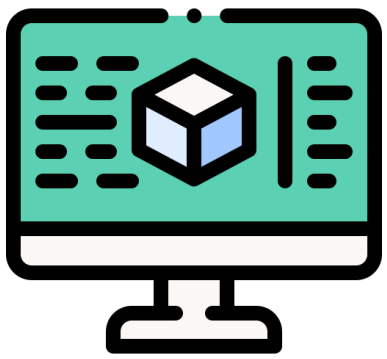
- **Post deployment phase** where you require **post-market surveillance** and using your real world data that you're generating to either stay in the market or improve the product?



EARLY STAGES OF PRODUCT DEVELOPMENT

For an early stage company who is trying to get to the stage **where they've got an MVP** and is looking for kind of a proof of concept study -

You can look at **simulation studies** looking at user feedback and that user can be either clinicians or it can be patients at that point in time.



Multiple different sites can be replicated quickly.

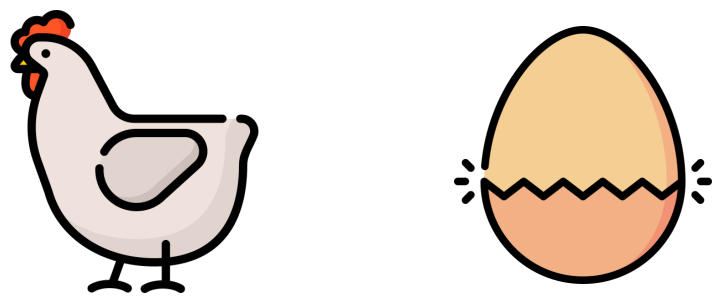
You've got the **qualitative data**, but also you can collect some **quantitative data** there as well and really helps you quickly iterate that product from that user feedback.

Tips for Simulation Studies

. Make sure you've got really **robust use cases**.

. Use the kind of synthetic patient data populate the different cases and really **make it as realistic as possible.**

. **You can do this remotely**, in lots of different geographical locations as well and collect that different qualitative and quantitative data.



Simulation is useful to overcome the **chicken and egg situation** where health system ask for evidence before the MVP is even deployed or tested, **but you cannot generate evidence** without deployment.

To note for early stage products:

At this stage that the real emphasis has to be on **generating evidence quickly**.

It's about really **working out what the problem is for your users**, it's about finding that product market fit.

It's **less about having really robust research methodology** in terms of having collective studies or having really high quality data because at this point, **that's not the focus** of the evidence generation.

What you want to make sure is high quality is **your ability to solve the user problem.**

LATER STAGES OF PRODUCT DEVELOPMENT

After developing a product that meets a need,

You will need to start generating evidence for regulatory approval, ultimately focusing on **clinical safety and performance.**

Looking at any technical documentation that you need to file, you should assess:

- What **class (MHRA/FDA)** is this technology.
- What **regulatory documentation** do I need for this.
- What type of **studies might I need to do** or what **evidence needs to be present** for that technical documentation.
- What **security and data standards** are needed.

Clinical Evaluation

If you are set within **class 2 to 2a devices** (as per the MHRA), you've got to really look at your **clinical outcomes data** and making sure that you have that **positive effect and care**, which you are stating that it does to obtain regulatory approval.

The type of studies that traditionally generates such data include:

- **Randomised controlled studies.**
- **Platform trials**
- **Cohort Studies.**
- **Case-control studies.**
- **Observational studies.**

Key considerations

- Consider **how much funding** do you have to run any of these studies.
- Is it something that's going to be deployed **across multiple centres**?
- Will it require **multiple arms** of study?
- What **data** do you have access to?
- How many **patients or end users** do you have access to?

These are factors to consider whether you have got the right study and the right fit for that study.

The key is **choosing the right type of study** for the kind of clinical outcome that you are trying to demonstrate.

DEMONSTRATING VALUE TO CLIENTS.

The type of evidence **required by purchasers** within the healthcare system is generally different from that required from regulatory bodies.

The key questions they may have include:

. How is this tool going to **improve the service** at this health care system.
. How are we going to demonstrate any **return of investment**.
. Is it going to be cheaper for me to deploy this **versus X, Y or Z**?

But of course, they will definitely consider the clinical evidence and safety as well.

In the backdrop of a limited budget,

A good economic evaluation which demonstrate the improvement in efficiency and return of investment of your tool is invaluable.

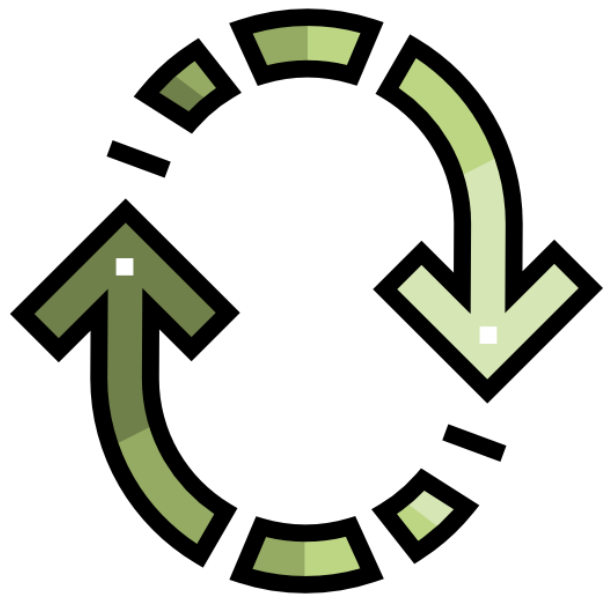
Having said that, this is a **challenging bit of evidence to generate** because it's very hard to know how a technology will impact a system in a workflow

When

Often those **workflows need to be transformed** in order to incorporate that technology effectively.

Therefore

It is important that we utilise **real world evidence** and **real world data** to demonstrate how a product works in reality.



CONTINUOUS MONITORING (POST-MARKET)

As part of the regulatory process, you are required to do **continuous monitoring** of products.

While there are no stipulated ways in which this has to be done, it is worth considering:

- What kind of **clinical outcomes** you're trying to demonstrate.
- What **type of study** you can potentially run.
- Are you using **comparing your data** to something such as a national repositories of data.
- What data you want to use **to inform change**.
- What kind of **time period** are you able to do this under as well

To note:

An important point here as well is that we need to **think quite reactively** about the step before it gets to deployment.

So, for example, a digital technology that's deployed within an NHS trust **may need ongoing access** to that trust data in some format in order to be monitoring that product effectively.

Therefore,

There needs to be a collaborative effort there and perhaps some kind of **data sharing agreements** long term to make sure that the adequate data is being pulled out.

So it's just something **that needs to be thought about in advance** rather than once a product is deployed.

PROVING POTENTIAL TO INVESTORS

“People are **scrutinizing things** an awful lot more than what would have been the case probably **two or three years** ago.”

Again, it's **back to the basic thing** of does this see what it does in the tin is this clinical outcome validated.

And some kind **financial evidence** or projection of how this innovation may save cost and:

This is how it will **improve outcomes**.
This is how it will **improve processes**.

“I think investors are scared as well because, you know, there's been a **massive shake up** in the market.

As I said, less money to go around and **people are being a lot more diligent about evidence** that they're looking for now as well.”

Hope you all found this helpful!

This is part of a series to help HealthTech founders access better resources for their projects.

Just our small way of trying to help!