Evidence for Effectiveness

How did this project come about?

The Evidence for Effectiveness (EfE) project sits within the context of a cross-government project to develop a 'code of conduct' for the digital health marketplace.

The EfE project will focus on how to produce evidence of clinical-effectiveness, impact on behaviour change, and produce economic value.

The goal is to create advice on the evidence needed and related standards, which will support innovators to know what and when to develop evidence for their innovation. This will streamline the current pathway and save time for commissioners and innovators by promoting the 'kill quick' philosophy for unviable innovations.

Who is doing this?

This project brings together key stakeholders in this space; led by Indra Joshi (NHS England) and including Sam Roberts (NHS England), Neelam Patel (MedCity), Axel Heitmuller (DigitalHealth.London), Alexia Tonnel (NICE), Mark Salmon (NICE) and Felix Greaves (Public Health England).

Executive sponsors of the project are Simon Eccles – Chief Clinical Information Officer for Health and Care, DHSC, NHSE, NHSI and Gillian Leng – Deputy Chief Executive, NICE.

Why are we doing this?

Therapeutic digital tools such as health apps and algorithms have developed with increasing pace over the last decade - mobile health apps and wearables' sales are predicted to grow by 35% in 2018 alone. Digital health provides great opportunities; however, some of the problems with digital health innovations at present include:

- Demonstrating the effectiveness of digital health tools with appropriate evidence
- Manufacturers are not clear what evidence they need to produce
- Commissioners are unclear as to what they are looking for
- Pilots and trials in the innovation space are developed with little 'at scale' implementation of such tools.

What are we developing?

This project aims to develop advice and a set of standards to enable innovators to develop effective technologies that meet patient and NHS demand. This includes:

- A **trusted and respected source of advice** on what evidence to produce; allowing innovators to produce better evidence, faster and more cost-effective, and in turn allow the NHS to commission, deploy and scale clinically and cost-effective digital health tools that meet demand.

- **Related standards** on how to produce evidence of effectiveness, economic impact and compliance with other standards.

What will this be based on?

The tool and standards will be developed in collaboration with industry and the NHS, and evolve through an iterative process – start simple, test model, and keep updating.

We will develop a classification matrix for digital health tools, taking into account three broad dimensions: risk, cost and functionalities. The tool advising on appropriate evidence will be based on these classifications and will include clear requirements for data standards, information governance and technical safety standards, as well as guidelines on how the effectiveness of digital therapeutic products are evidenced and evaluated.

What's in it for digital health companies?

Companies will be able to design and build a product knowing what the standards are for clinical effectiveness and cost-effectiveness, which will:

- Enable a more streamlined pathway for product and evidence development, saving them time and money
- Save innovator time in seeking advice
- Provide them with early advice as to whether their innovations are viable.

What's in it for commissioners?

Commissioners will be able to provide early advice and support and save time in receiving applications for products which are not viable. It will:

- Enable a more streamlined pathway for product and evidence development, resulting in more targeted, meaningful evidence generation for evaluators, saving the health system time and money
- Save commissioners time in giving advice/signposting.
- Ensure they receive quality applications for digital health programmes, for example in the Innovation Technology Tariff, NHS England received 270 applications and none of them had sufficient evidence.
- Promote the 'kill quick' philosophy for those innovations that are not viable.
- Promote England as the place to manufacture and develop quality innovations.

When will this be delivered?

This project runs from May to December 2018, involving key parties to feed into and assist in developing the framework, testing, and piloting. The framework will launch in January 2019 and it will be embedded within the ecosystem as standard practice for evidence generation.

How can companies / commissioners be involved?

We are hosting a number of workshops for innovators and commissioners in Manchester and London, to contribute initial thoughts and help design this Evidence for Effectiveness

framework. Stakeholder input will be crucial in helping us better understand the evidence innovators need to generate and in helping commissioners identify the evidence they should be looking for.

We will also be hosting wider roundtables with stakeholders and engaging with digital health innovators and commissioners to pilot the frameworks.

If you would like to be involved in the process, please get in touch with Neelam Patel, Chief Operating Officer, MedCity, at neelampatel@medcityhq.com