Developers guidance

Using data during your digital technology lifecycle

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This is required guidance

It is legally required and it is an essential activity.

This Guide covers:

- England

From:

- Health Research Authority (HRA)

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Reviewed by: Health and Care IG Panel

At each stage of your technology's lifecycle, you will need to use data.

Proof-of-concept (pre-development)
This involves generating evidence to show that a technology idea, design or concept is workable.

Technology development
This includes the following stages:

- **Testing in the health or care environment** (technology conceptualisation)
  Before you can deploy your technology in clinical care, you must show it is safe and effective to use. You might need to test this in a live health or care environment
- **Direct care** (technology rollout once placed on market) (deployment)
  Direct care (also known as individual care) is any clinical, social or public health activity concerned with the prevention, investigation and treatment of illness and the alleviation of suffering of individuals. More guidance relating to the use of data for direct care and the direct-care concept can be found on the NHS Transformation Directorate IG Portal. To be part of the direct care team, you must have a legitimate relationship with the patient or service user, such that the individual would reasonably expect you to have access to their records to provide them with individual care
- **Service evaluation and post-market surveillance** (post-rollout)
  Once you have rolled out your technology, you will have to monitor it for safety and efficacy

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