UNDERSTANDING VALIDATION

Forensic Capability Network

Validation may seem time-consuming and challenging, but the process is vital for underpinning evidence within the Criminal Justice System (CJS). These education materials aim to explain what validation is, why it's important, and how it all works.

WHAT IS VALIDATION?

Validation is a scientific study to show that a method is fit for purpose. This is achieved by conducting a series of objective tests.

Validation studies help to give the public confidence in forensic results. Should forensic evidence be challenged in court, or when UKAS carries out assessments, validated procedures will demonstrate robust scientific methodology.

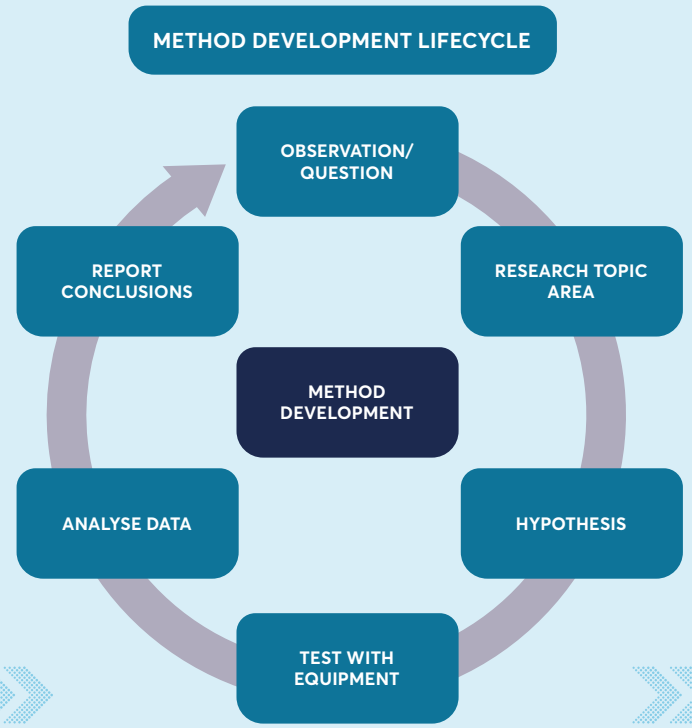
METHOD DEVELOPMENT VS VALIDATION

Method development and validation are two completely different processes, and they shouldn't be confused.

Method development is for when a new method is introduced or for an existing method if user requirements change. If your intended method is not well-defined or understood, you may need to consider method development before you begin validation.

Method development is a stage all about gathering data and ideas to discover an appropriate method that satisfies your end user requirements.

Validation only takes place once the method has been fully developed and finalised. If any changes are made to the method after validation, the end user requirements and specification need to be reviewed against the new requirements which may lead back to method development again.



HOW IT ALL WORKS

METHOD DEVELOPMENT: ASK YOURSELF THESE QUESTIONS

You will need to ask the below questions to gather data prior to validation:

1. WHO IS YOUR END USER?

The ultimate end user is the Criminal Justice System (CJS) as a whole. This includes, but isn't limited to, the following:

a. The investigative agencies (e.g. the police, practitioners, investigation teams, forensic units, PCSOs, Forensic Service Providers).

b. The prosecution authorities (e.g. the Crown Prosecution Service).

c. The defence.

d. The judiciary.

e. The reviewing authorities (e.g. the Criminal Cases Review Commission).

f. The public (including those serving as jurors).

What might these groups expect from the method's operation and output? Asking yourself this will help to ensure your method is fit for purpose.

2. WHAT ARE THE END USER REQUIREMENTS?

What are the essential things that the user needs to complete their tasks satisfactorily? For example, end users may require access to software or hardware so they can log on securely. This requirement can then be translated into more technical detail via the specification.

3. WHAT IS YOUR SPECIFICATION?

The specification details what the requirement actually means and what is going to be tested. This covers what the method is, the configuration, and even what the method can and cannot be used for – for example, the above requirement may then mean that the end user needs to log onto the system using a unique username and password.

4. WHAT IS YOUR ACCEPTANCE CRITERIA?

This is set before validation and defines what requirements must be met, considering all of the aforementioned points. The criteria must be clearly stated, measurable, and define set tolerances (taking into account any risks that could negatively affect CJS outcomes).

5. WHAT IS YOUR TEST?

Tests in validation are objective experiments to test that the method is fit for purpose. Remember to include challenging variables that stress test the limits of your method so that end users are aware of the method's constraints.

6. WHAT IS YOUR REPEATABILITY AND REPRODUCIBILITY?

In validation, repeatability is shown through a series of tests conducted by the same person repeatedly using the same method and equipment obtaining the same results as previous tests.

Reproducibility, on the other hand, is shown through a series of tests conducted by different people repeatedly using the same method and equipment obtaining the same results as previous tests.

7. WHAT IS YOUR RISK ASSESSMENT?

This is needed to identify any potential risks which may result in inaccurate, unreliable, misleading or unclear results that could impact the CJS. The code recommends using a Failure Mode and Effects Analysis (FMEA) template for this.

VALIDATION EXERCISE

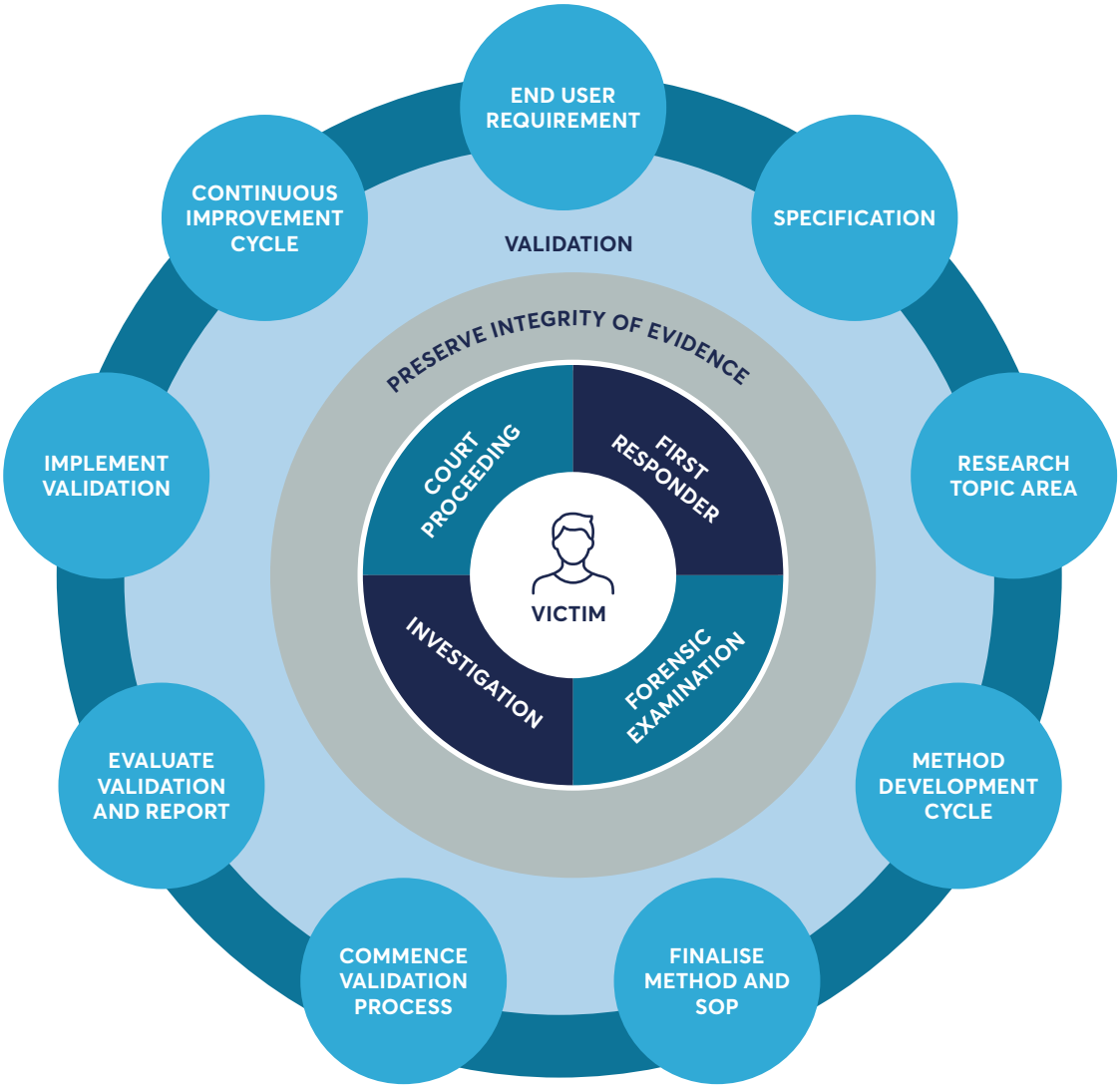
Once you've finalised the method you can complete the validation plan and start the validation exercise.

This involves conducting experiments to test against everything laid out in your validation plan and then documenting the results.

You'll have to repeat the test to be sure the results are repeatable and reproducible.

Validation should only be carried out by people deemed competent in the method.

If the experiment passes your acceptance criteria, then your method has passed validation!



VERIFICATION

Verification is for when you want to adopt a validated method that's already in use elsewhere, with the exact same variables, equipment, tools, and procedures.

Verification demonstrates that the method works consistently for you. Any deviations to the method may require revalidation.

WHAT ARE THE BENEFITS OF VALIDATION?

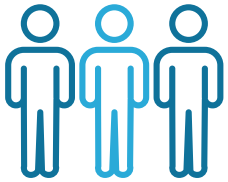
Continuous improvement of forensic methods

Robustly tested scientific processes that instil trust in policing

Removing any doubt around potential bias

Ensuring compliance with Quality Standards

Allowing evidence to withstand scrutiny or challenge



Giving practitioners confidence in the deployment of methods

WHAT TO DO NEXT...

1.

Read the FSR Code, ILAC G19 and FSR guidance documents.

2.

Get advice from FCN or others who have already completed validation.

3.

Document everything you do and share knowledge with your colleagues.

4.

Don't underestimate how long it takes to complete both method development and validation. Typically, validation should be completed at least six months prior to your UKAS assessment to embed the method, carry out any training and demonstrate three months in a steady state.

If you're finding validation challenging, remember you are a part of a wider forensic community, and the FCN is here to help.

ABOUT US: FORENSIC CAPABILITY NETWORK

The Forensic Capability Network (FCN) is a membership organisation for the forensic science community. Following investment by the Home Office, FCN is operated by the policing community on behalf of police forces and law enforcement organisations in England and Wales. Amongst other things, the FCN provides a knowledge base, development programmes and support to forensics practitioners.

To find out more, just visit the FCN and FSR websites | www.fcn.police.uk | www.gov.uk/government/organisations/forensic-science-regulator