Hardian Health

Innovate UK

Health Innovation Network South London

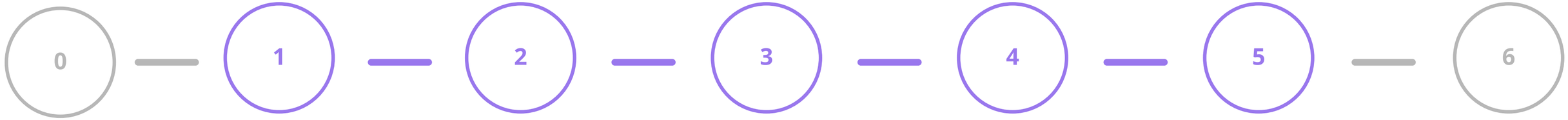
Module 6: Clinical Evaluation of VR/XR Devices

Objectives for Module 6

1. Outline the 5 key steps of clinical evaluation (10 minutes)
    a. Intended Use
    b. Scientific Validity
    c. Analytical Validity
    d. Clinical Validity
    e. Post-Market Clinical Evaluation

2. Multiple choice questions (5 minutes)

Clinical Evaluation Process - Overview



0	1	2	3	4	5	6
Define Value	**Conceptualise**	**Scientific Validity**	**Analytical Validity**	**Clinical Validity**	**Post Market**	**Deliver Value**
Define Unmet Need Value Proposition	Define Intended Use (target market, condition, users)	Literature review Proof-of-concept studies	Bench testing Usability testing Internal validation	External validation Clinical Investigations	Post Market Surveillance Post Market Clinical Follow-up	Demonstrate Economic Value

Step 1: Conceptualisation

Conceptualisation	Scientific Validity	Analytical Validity	Clinical Validity	Post Market
Define Intended Use (target market, condition, users)	Literature review Proof-of-concept studies	Bench testing Usability testing Internal validation	External validation Clinical Investigations	Post Market Surveillance Post Market Clinical Follow-up

Step 1: Define your Intended Use

Document the following

Intended medical indication

Intended patient population

Intended user groups (primary and secondary)

Intended part of the body

Intended use environment (physical and digital)

Operating principle (clinical and technical)

Articulate the *clinical benefit* you are intending to provide

Meaningful, measurable, patient relevant clinical outcomes related to diagnosis, or a positive impact on patient management

Step 2: Scientific Validity

Conceptualisation	Scientific Validity	Analytical Validity	Clinical Validity	Post Market
Define Intended Use (target market, condition, users)	Literature review Proof-of-concept studies	Bench testing Usability testing Internal validation	External validation Clinical Investigations	Post Market Surveillance Post Market Clinical Follow-up

Step 2: Scientific Validity

Is there a valid association between the outputs of your tech, and the clinical/biological target?

What evidence is already available to support this (literature review)

What evidence have you developed (proof-of-concept studies)

Step 3: Analytical Validity

Conceptualisation

Define Intended Use (target market, condition, users)

Scientific Validity

Literature review
Proof-of-concept studies

Analytical Validity

Bench testing
Usability testing
Internal validation

Clinical Validity

External validation
Clinical Investigations

Post Market

Post Market Surveillance
Post Market Clinical Follow-up

Step 3: Analytical Validity

Does your candidate product perform as expected in a controlled environment?

Bench testing (hardware)

Unit testing (software)

Integration testing (software +/- hardware)

Formative usability testing (IEC 62366-1)

Don’t forget if you have hardware:

Functional / electrical safety testing

Electromagnetic compatibility (EMC) testing

Radiofrequency testing (e.g. for bluetooth)

Battery safety testing (e.g. for wearables)

Step 4: Clinical Validity

Conceptualisation	Scientific Validity	Analytical Validity	Clinical Validity	Post Market
Define Intended Use (target market, condition, users)	Literature review Proof-of-concept studies	Bench testing Usability testing Internal validation	External validation **Clinical Investigations**	Post Market Surveillance Post Market Clinical Follow-up

Step 4: Clinical Validity

Conduct a *pivotal clinical investigation*

An investigation in line with current gold standards to demonstrate your claims

Using independent, representative validation data

Only one may be needed for regulatory approval, if designed well

You must prove all clinical claims you make for your software, based on its intended use

Conduct summative usability testing

Investigation design

Design depends on the claims being made in the Intended Use

Are you claiming to be better than the current standard of care? An adjunct? Non-inferior?

Therapeutic interventions/recommendations

Comparator arm, likely prospective (+/- blinding and randomization)

Improving diagnostic/detection accuracy

Compare to ground truth, may be retrospective

Special Cases

AI for augmenting user performance: multi-reader, multi-case (MRMC) design

Crossover design studies

Case control studies

Step 5: Post Market

Conceptualisation

Define Intended Use (target market, condition, users)

Scientific Validity

Literature review
Proof-of-concept studies

Analytical Validity

Bench testing
Usability testing
Internal validation

Clinical Validity

External validation
Clinical Investigations

Post Market

Post Market Surveillance
Post Market Clinical Follow-up

Post Market Surveillance and Post Market Clinical Follow-Up

Post Market Surveillance (PMS)

User feedback

Surveillance for safety and adverse effects

Complaints

Post Market Clinical Follow-up (PMCF)

Check that performance is maintained in the real world

Monitor for performance drift

Assessing for variability between deployment sites/populations

Summary

Conceptualisation	Scientific Validity	Analytical Validity	Clinical Validity	Post Market
Define Intended Use (target market, condition, users)	Literature review Proof-of-concept studies	Bench testing Usability testing Internal validation	External validation Clinical Investigations	Post Market Surveillance Post Market Clinical Follow-up

Contact:

ankeet@hardianhealth.com

hin.mindset@nhs.net

Hardian Health

Clinical | Digital | Consulting

www.hardianhealth.com

@HardianHealth

Innovate UK

Health Innovation Network South London