HRC-DDR TECHNOLOGY ROADMAP

- End user review of the technology.
- Completed at an early stage.
- Informs the future directions/ design of a technology and indications /contraindications of use.
- No REC/ HRA or MHRA approval required.

Expert Review

- Hands-on session using technology with real end users.
- Completed at early stage technology development.
- Informs future design/ features/ use of a technology within intended environment.
- No REC/ HRA or MHRA approval required.

Formative Usability Testing

1 **TRL 1-2 Basic Research** 2 3 **TRL 3-6 Pre-Clinical Research** 5

First In Human

6 **TRL 6-7 Clinical Research** 7 8 **TRL 8-9 Regulatory Clearance & Market Prepration** 9 10 **TRL 10 Post Launch**

Summative Usability Testing

- Hands-on session using technology with real end users.
- Completed typically at the end of technology development.
- For use within the technical file.
- De-risks device in regards to safe use by end users.
- Typically no REC/ HRA or MHRA approval required

- Assessment of essential safety and performance of technology.
- Required for medical device approval (CE/ UKCA marking)
- Conducted with the final version of technology device.
- REC/ HRA approval and MHRA required (via IRAS submission).

Post-Market Research

- Completed post-regulatory approval.
- Assesses correct, safe and ergonomic use of technology with end users within a real clinical environment.

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Expert Review

Stage of Development:
- Early in technology development.
- Can be an idea with drawings, does not need to have been physically mocked up.
- Can be conducted repeatedly throughout the project.

Aims & Purpose:
- To establish an unmet clinical need.
- To identify indications and contraindications of a device.
- Understand key design features for and areas of future development.

What's involved?
- Set-up: Protocol preparation and recruitment of intended end users.
- Delivery: Remotely - MS Teams
- Output: Report summarising discussions and feedback/ recommendations for proposed technology.

Approvals:
- No approvals required.

Why is it important?
- Gathers opinions from end users to validate the concept.
- Identifies where the technology could provide patient/healthcare benefits and where within the patient pathways the technology could be implemented & adopted.

What can the results be used for?
- Early evidence to support grant applications.
- Precursor to usability testing and generates a document trail within a products technical file.

Formative Usability Study

Stage of Development:
- Early in technology development or after any significant design change.
- Can be an early prototype device which is not fully functional.

Aims & Purpose:
- To explore design features and device errors.
- Assesses how real end users interact with the device in a simulated clinical environment.
- Feedback generates future device development and modifications to reduce use error risk.

What's involved?
- Set-up: Protocol preparation and recruitment of intended end users.
- Delivery: Usability testing in MD-TEC or externally dependant upon intended environment.
- Output: Report summarising discussions and feedback/ recommendations for proposed technology alongside edited video footage.

Approvals:
- No approvals required.

Why is it important?
- To avoid costly longer term design errors.
- Determines additional functions/applications to gain market advantage.

What can the results be used for?
- To identify use errors and incorporate end user suggestions for design improvements.
- Essential aspect of early documentary evidence for risk assessment and quality management.
- Evidence to support grant applications.

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Summative Usability Study

Stage of Development:
- Typically conducted at the end of the development process where only minor changes should be made afterwards.

Aims & Purpose:
- Evaluates product effectiveness, efficiency, and satisfaction by measuring user interactions and outcomes within a simulated clinical environment.
- Gives final validation of the intended design, training and user instructions.

What's involved?
- Set-up: Protocol preparation and recruitment of intended end users.
- Study Delivery: Usability testing in MD-TEC or externally dependant upon intended environment.
- Output: Report summarising discussions and feedback for proposed technology alongside edited video footage.

Approvals:
- No approvals required, unless the device is being used on a human where MHRA, REC and HRA approvals are required.

Why is it important?
- Used to demonstrate safe and effective use of the device in preparation of regulatory approval.

What can the results be used for?
- Identify hazards and risk assessment.
- Supports technology readiness to proceed to a first in human clinical investigation.
- Pitching for investment.

First In Human Clinical Investigation

Stage of Development:
Final version of the device.

Aims & Purpose:
- Assesses the essential safety & performance of the device.

What's involved?
- Set up: Document preparation - protocol development, participant-facing documents, and documents required for IRAS submission. Completion of IRAS questions and submission. Recruitment of intended end users.
- Study Delivery: Normally in the clinical research facility at University Hospitals Birmingham.
- Output: Report summarising discussions and feedback for proposed technology alongside edited video footage.

Approvals:
- HRA and REC approval
- MHRA - Letter of no objection.

Why is it important?
- Acts as a pilot study to demonstrate that the device can be used safely in a clinical context.
- Required for medical device approval (CE/ UKCA marking).
- Can be used to generate an initial data set for future validation.

What can the results be used for?
- Demonstrates essential safety and performance.
- Supports development of subsequent clinical investigations and/or clinical adoption of the technology.
- Results can help to build credibility by generating preliminary real-world evidence.
- Commercialisation of the device.

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Patient & Public Involvement

HealthTech
PUBLIC ADVISORY GROUP

Stage of Development: Complete early in technology development and throughout product development.

Aims & Purpose:
- Understand patient/public perspectives
- Evaluate public acceptability
- Learn about, and seek to address, patient/carer accessibility needs, including those from diverse backgrounds
- Gain insights to inform the development of technology/research study
- Work with members of the public to improve technology, patient-facing communication and study information
- Understand and endeavour to mitigate against, health inequalities pertaining to the technology

What's involved?
- Set up: Advice and guidance from PPIE Manager to inform approach.
- Delivery: Innovator-led engagement sessions/public involvement group facilitation with a group/s of patients/members of the public to inform the project. There may be opportunities to attend the HRC's HealthTech Public Advisory Group for a 50-minute engagement session to support delivery.
- Output: A public engagement plan and a written record of feedback from engagement with HealthTech Public Advisory Group (where applicable)

Approvals:
- No approvals required.

Why is it important?
- PPIE ensures research is relevant, ethical, and impactful by incorporating the perspectives and experiences of those who will be using the technology.

What can the results help to provide?
- To inform the development of technology to ensure it is beneficial and accessible to the diverse patient population.

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Health Economics

Stage of Development: Applicable from early concept (TRL 2–3) through clinical evaluation (TRL 6–7) and market preparation/post-market (TRL 8–10). The focus shifts from early value proposition and target price ("headroom") to trial-ready economic endpoints, and budget impact for adoption modelling using real-world data.

Aims & Purpose:

- Define a clear value proposition versus the current standard of care.
- Derive ceiling price/target price using the headroom approach and identify the minimum effectiveness and maximum deliver-to-patient cost that sustain cost-effectiveness.
- Estimate cost-effectiveness (ICER/INB) at relevant decision thresholds (e.g., UK £/QALY).
- Quantify budget impact and affordability under realistic uptake scenarios.
- Map evidence gaps and design an evidence-generation plan (trial/RWE) to de-risk adoption.

What's involved?

- Use-case & pathway definition: Care pathway mapping, comparators, perspective, time horizon, and discounting.

Parameterisation:

- Effectiveness/utility: literature synthesis, or structured expert elicitation with translation of clinical outcomes (e.g., pain/function) to QALYs.
- Costs: device price options, training, consumables, monitoring, adverse events, and downstream resource use/savings.

Why is it important?

- Health-economic analysis translates technology performance into payer-relevant value, for example, as assessed by NICE and other relevant bodies. It informs go/no-go decisions in the case of early economic evaluations, as well as the benefits of the technology compared to its costs, including design choices, pricing, and market sequencing. These factors have direct implications on the likelihood of adoption and reimbursements in the real world.

What can the results help to provide?

- A concise value proposition with clear quantifiable benefits at target thresholds.
- Target/ceiling price for the technology at which it remains cost-effective
- Budget impact and uptake-linked affordability for healthcare systems.
- A staged evidence-generation plan, from pre-market to post-market, aligned to usability, clinical, and regulatory milestones in the roadmap.