**Potential Operational Effectiveness Evaluation Report for Medical Devices (POpERR)**

**Tech title:**

**Clinical Application:**

**Date of Review:**

**Reviewer (name and role):**

**Review requested by:**

|  |  |
| --- | --- |
| **Questions** | **Answers/Comments** |
| Parameters Measured/Monitored: |  |
| Is it CE-Marked – to what Directive/Regulations (State classification): |  |
| To what IEC/TSO Standards does it conform: |  |
| Date first marketed in Europe: |  |
| Date first marketed elsewhere: |  |
| Version history of the device: |  |
| Is this device a software application: |  |
| Is this a hardware device which can work independent of an app/software platform: |  |
| Is this a hardware device which can work dependent on an app/software platform: |  |
| How is data transmitted (Bluetooth, wireless, hardwire, usb...)? |  |
| Are there pilot sites? If so, where? |  |
| Are there reference sites? |  |
| Literature Review summary related to the device in the context of this clinical application: |  |
| Literature Review summary related to this or similar device in other clinical applications: |  |
| ***Data*** |  |
| * What patient data is captured: |  |
| * Where is the data stored: |  |
| * How is the data backed-up: |  |
| * Who can access the data: |  |
| * What level of data loss is sustainable without risk to the patient: |  |
| * How is the data accessed: |  |
| * Who will review the data (existing professional?) |  |
| * How is patient data shown? |  |
| * What are the options for data analytics and associated reporting? |  |
| * How is the data incorporated into the patient’s record? |  |
| * Does the system incorporate automated diagnosis or clinical decision support? If so outline features and whether or not these can be disabled; |  |
| ***Usability Summary:*** |  |
| * Infrastructure Requirements (remote and central): |  |
| * Operating System requirements: |  |
| * Initial set-up: |  |
| * Ease of use - hardware (remote and central): |  |
| * Ease of use: data management |  |
| * Ease of use: data analysis |  |
| * Give an opinion of the quality of the Instructions for Use? Is there a brief set-up guide and a long-version; are instructions clear? |  |
| ***Technical/User Support availability:*** |  |
| * How is this provided: |  |
| * How will training be provided? |  |
| Security or Known Issues: Has this product any history at a national press level in terms of security or adverse incidents? If so, please outline these including approximate dates. |  |
| General Performance Summary: |  |
| State likely duration of this solution (max 3 years to account for technological advances): |  |
| ***Costs:*** |  |
| * Initial outlay - central |  |
| * Initial outlay – remote (per patient) |  |
| * Service contract costs? |  |
| * Annual or Monthly licence costs? State if these are per patient. |  |
| * State discount options available |  |
| * State any other cost involved and state if this is per patient or based on time. |  |
| ***Benefits (outline):*** |  |
| * Admission avoidance? |  |
| * ED above? |  |
| * Shorter Length of Stay? |  |
| * Improved self-management? |  |
| * Precision out-patient scheduling? |  |
| * Reduced out-patient attendance? |  |
| * Reduced PPE demands? |  |
| * Safer care? |  |
| * More compassionate patient care? |  |
| * Improved quality of life for the patient? |  |
| * Clinical risk reduction? |  |
| * Access to clinical expertise, if necessary, which cannot be accessed with previous pathways? |  |
| * Facilitation of clinical decision support (eg through AI)? |  |
| * Facilitation of data/evidence driven service improvement? |  |
| * Increased healthcare delivery efficiency? |  |
| * Operational risk reduction (eg automated records)? |  |
| * Other |  |
| State the likely benefits of implementation of this solution. Include the minimum level of engagement to achieve value for money. |  |
| Include a risk assessment for introduction of this technology/device |  |
| Any other pertinent information: |  |
| Preliminary Business Case Summary: |  |