

## **Appendix 2: list of requirements needed for MHRA self-certification**

- Adverse event reporting Standard Operating Procedure (SOP)
- Detailed project plan
- Results of clinical evaluation (testing of app on 100 randomly selected retrospective cases)
- Clinical risk assessment
- Essential requirements document
- Formal rationale for device classification
- Summary report of software testing
- Evidence of registration of quality improvement projects with NHS trusts
- Completion of University of Manchester information governance checklist

Once we had received MHRA self-certification, in order to be able to introduce the app and dashboard to the NHS Trusts, we were required to provide them with the documentation above, and in addition, further documentation (listed below) was also required:

- Privacy impact assessment
- Data sharing agreement
- Contract between University of Manchester and each NHS trust to cover the loan of equipment (2 Android tablets per trust).

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The information in this report/brochure is correct at the time of printing.