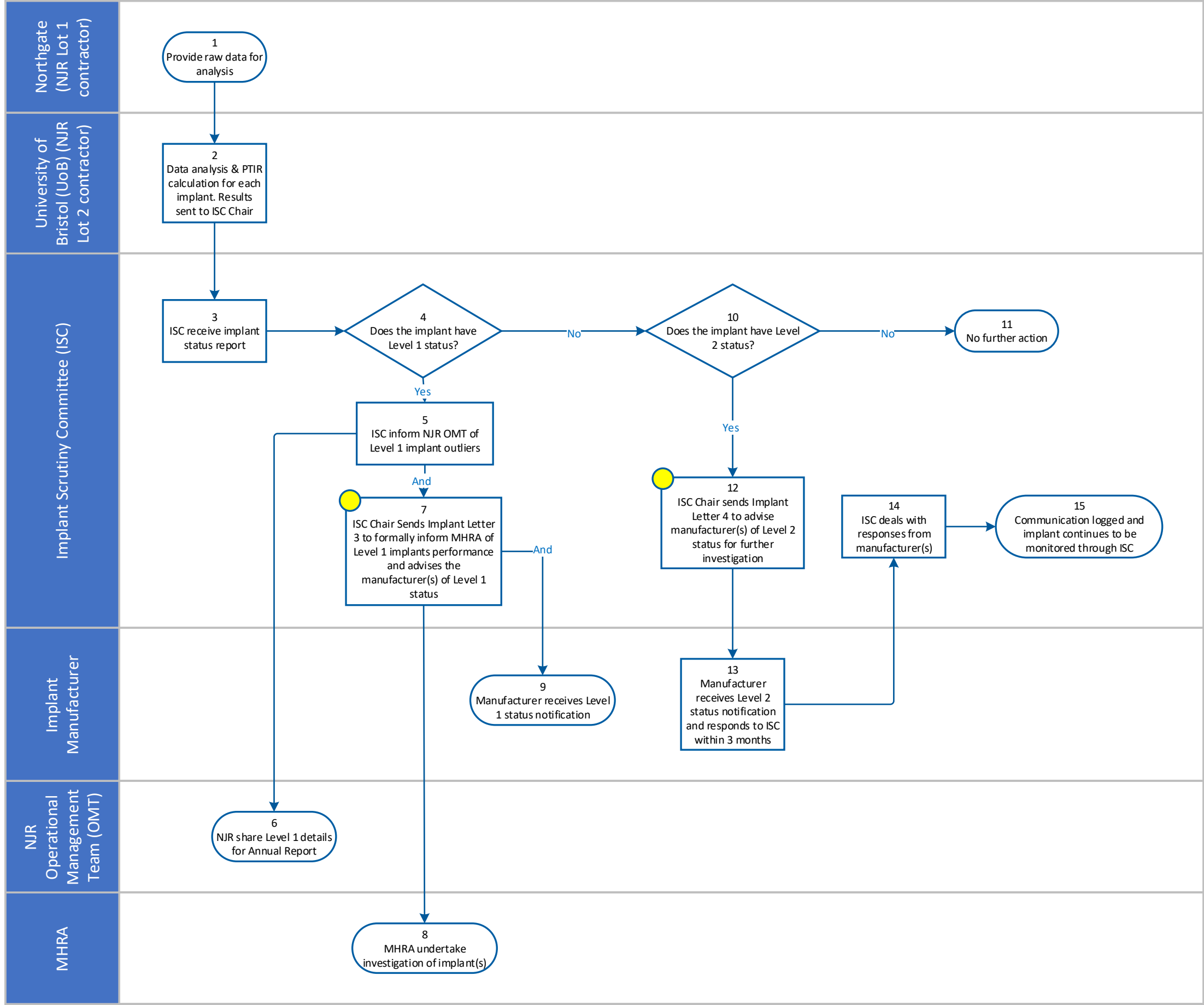


7. Implant Outlier Process

Version 1.0



Key

- Process step (rectangle)
- Data (parallelogram)
- Start/End (oval)
- Decision (diamond)
- Sub Process (double-line rectangle)
- Document (wavy-bottom rectangle)
- To mark a process that relates to updating the Outlier Management System (yellow circle)
- PTIR – Patient-Time Incidence Rate
- ISC – Implant scrutiny Committee
- MHRA – Medicines and Healthcare products Regulatory Agency
- NJR OMT – NJR Operational Management Team

Note:

Patient-Time Incidence Rate (PTIR) - The total number of events (e.g. first revisions) divided by the total of the length of time the patients were at risk. It is calculated with 95% confidence intervals. It is then compared to the overall PTIR for all implants of that type.

Level 1 status: Does the implant have a PTIR at least two times the overall PTIR with >100 primary operations within NJR?

Level 2 status: Does the implant have a PTIR at least two times the overall PTIR with <100 primary operations within NJR or does the implant have a PTIR 1.5 times the overall PTIR with >100 primaries on the NJR?

The Implant Outliers progress report is updated & reviewed at ISC. The findings of any investigations are recorded in the report.