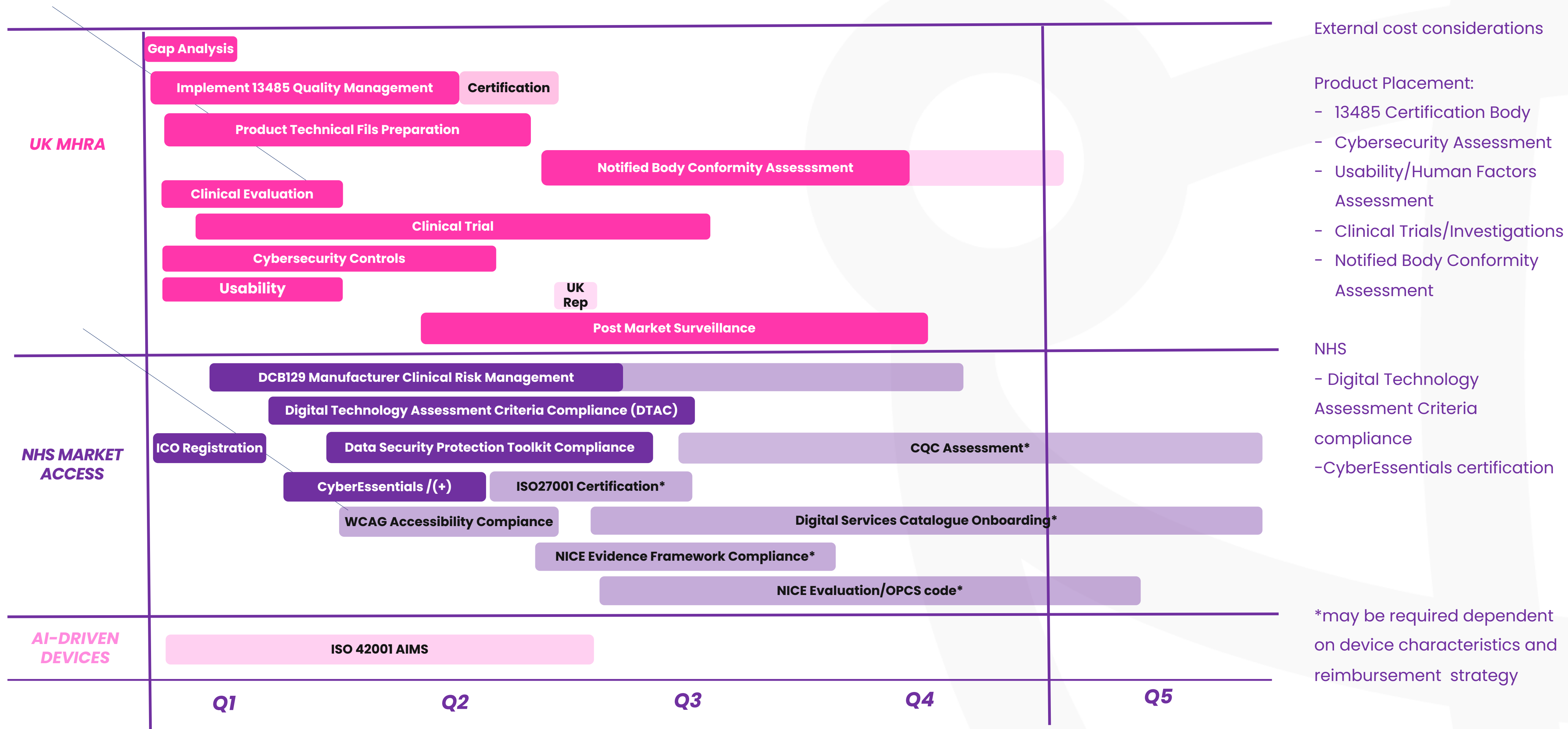


UK Market Access

EXAMPLE PATHWAY SEQUENCE & TIMELINE



External cost considerations

- Product Placement:
- 13485 Certification Body
 - Cybersecurity Assessment
 - Usability/Human Factors Assessment
 - Clinical Trials/Investigations
 - Notified Body Conformity Assessment

- NHS
- Digital Technology Assessment Criteria compliance
 - CyberEssentials certification

*may be required dependent on device characteristics and reimbursement strategy