Data Access

MUST
- Follow the Data Protection Regulation (DPR, General Data Protection Regulation (GDPR), Common Law duty of Confidentiality and Caldicott principles.
- Consider the legal basis for processing data

SHOULD
- Consider if your product will be classed as a medical device or in vitro diagnostic medical device or none of the above.
- Consider guidance on borderline medical devices.
- Consider the risk classification of the device.

SHOULD
- Start considering questions around Intellectual Property and its potentially apportioning

SHOULD
- Consider complying with the Department for Health and Social Care's Code of conduct for data-driven health and care technology.

Idea generation

Healthcare Professional · Patients · Private sector · Academia

MUST
Consider if your idea is:
- feasible
- has a clear intended use
- viable
- state of the art
- innovative

Statutory bodies & ALBs: NICE · NHS England · NHS Clinical Commissioning Group
Other stakeholders: GP practices & Trusts · Charities · The AHSN Network · Innovate UK · Patients & carers group

SHOULD
- Consider who the payor and the end user of the innovation will be.
- Establish early dialogue and engagement with commissioners and other stakeholders to identify funding and reimbursement routes
- Consider using interactive tools like the "Navigating the Innovation Pathway tool"

COULD
- Consider surveying the market for CE-marked and FDA approved products through repository tools like Healthskouts

Data Access

What?

Identifiable
- Personal identifiable
- Pseudonymised
- De-identified
- Other individual level 'anonymised' data (particularly if linked/dated)

Examples: medical records, staff schedules, appointments, medical images, lab results

Anonymous
- Open data
- Statistics (aggregated)

Examples: stock of medical supplies, estates return information collection, national statistics on healthcare

How?

Data access request

If access request approved:
- NHS digital process: (1) Data sharing Framework Contract (2) Data sharing agreement
- Other standard process: (1)Strategic research agreement (2) Data processing agreement & processing protocol

Where?

Where to ask for data?

NB. Non-exhaustive lists
- NHS trusts
- GP practices
- Clinical Commissioning Groups
- National registries
- NHS Digital
- Clinical Practice Research Datalink
- Public Health England
- Digital Innovation Hubs
- Biobank

Online tools to find health data:
- NIHR's Health Data Finder
- HDR UK's Gateway

Regulators: ico. · General Medical Council · Health Research Authority
Statutory bodies & Arm's Length bodies (ALBs): National Data Guardian · NHS Digital · NHS England and NHS Improvement
Other stakeholders: NHS X · Patients & carers group

MUST
- Consider the type of data being accessed as the type of data dictates what you can do to it and if you need to seek for consent or section 251 support

SHOULD
- Think of data needs, both for testing and validating & minimum amount of data needed
- Consider doing a Data Protection Impact Assessment or System Level Security Policy through NHS Digital
- Consider using the "Model Clinical Investigation Agreements" templates produced by UK Clinical Research Collaboration when drawing up collaboration agreements with NHS trusts.

COULD
- Consider various types of privacy preserving technologies (Privacy Enhancing Technologies, federated learning, synthetic data)

Regulatory Sandbox: ico.

Proof of concept

COULD
- Consider engaging with notified body for a pre-submission assessment. This might entail a cost to the manufacturer

Regulators: MHRA · Health Research Authority
Statutory bodies and ALBs: NIHR National Institute for Health Research · NHS Research and Development Forum
Other stakeholders: HDR UK · Notified bodies

Preliminary Research

Assessment of governance, legal compliance and ethics

Pre-clinical studies: Feasibility studies/Observational studies /Initial usability testing

Internal validation of solution

Assess evidence needs: This is dependent on risk classification of medical device or in-vitro diagnostic medical device

Ongoing risk assessment

SHOULD
- Consider testing for biases in product

Peer Review Publication and dissemination if an academic study

Research for Medical devices

Regulators: MHRA · Health Research Authority
Statutory bodies and ALBs: NIHR National Institute for Health Research · NICE National Institute for Health and Care Excellence
Other stakeholders: World Health Organization · Notified bodies

Pre-CE: Medical Devices Intended For Clinical Investigation

Provide MHRA wit h advanced notice of intention to submit a clinical investigation

Complete the Clinical Investigation Application form on via the Integrated research Application System (IRAS)

Submit Clinical Investigation Application Form & supporting information to the MHRA

60 day assessment period for the MHRA to review the safety and performance of device and the design of the investigation.

Manufacturer receives 'objection' or 'no objection' notice from the MHRA regarding the investigation

Clinical investigation is carried out

MUST
- Consider that under specific circumstances, manufacturers do not need to notify the MHRA of a clinical investigation (e.g medical devices manufactured in-house). If the manufacturer wishes to sell the product outside of the trust which obtained the in-house exemption they will have to seek a CE-mark

Research for in-vitro diagnostic medical devices

Pre-CE: Performance evaluation & clinical evidence for in-vitro diagnostics

Compile Performance Evaluation Plan (Annex XIII section 1.1 IVDMR)

Scientific Validity Report (Annex XIII section 1.2.1 IVDMR)

Analytical Performance Report (Annex XIII section 1.2.2 IVDMR)

Clinical Performance Report (Annex XIII sections 1.3.1 and 2.3.3 IVDMR)

If performed, produce Clinical Performance Study Plan (CPSP) (Annex XIII section 2.3.2 IVDMR)

Create Performance Evaluation Report and submit documentation

MUST
- Consider that IVD devices for performance evaluation studies are not subject to CE marking procedures (e.g IVD devices manufactured in-house)

Evidence generation for commissioning and reimbursement

Pre-CE mark compile clinical evidence through other routes
(e.g. critical assessment of the scientific literature on safety, performance, design; scientific questionnaires, cross-referencing of data gathered from use of CE-marked medical device with patient/clinician questionnaires, etc)

NICE classification
- Tier 1
- Tier 2
- Tier 3a
- Tier 3b

Evidence generation reimbursement and commissioning purposes

Complete contextual questions

Carry out assessment
- Evidence Standards
- Economic Impact Standards

NICE assessment

Identify funding sources → Discuss commercial model

Funding bodies
Not an exhaustive list.
Digital health London accelerator · The AHSN Network · CATAPULT · Innovate UK · NIHR National Institute for Health Research · NHS England · MRC Medical Research Council · HDR UK · Wellcome

Regulatory compliance

Regulators: MHRA · ico.
Other stakeholders: Notified bodies
Statutory bodies & ALBs: NHS Digital · NICE · Standards bodies

MUST
When the New Medical Device Regulation (MDR) 2020 and In-Vitro Diagnostic Medical Devices Regulation (IVDR) 2022 will come into place, you will need to appoint at least one person responsible for regulatory compliance with responsibilities that cover:
- Quality management (compliance with ISO:13485 & IEC 62304)
- Regulatory documentation
- Post-market surveillance
- Vigilance reporting

SHOULD
- Check how transition period will affect your device certification (transitional provision article 120 of the MDR)

Regulatory compliance

Medical devices regulation

Carry out conformity assessment based on risk class (link)
- Class I
- Class IIa
- Class IIb
- Class III

Declaration or certification of conformity depending on risk class

Apply CE marking

In-Vitro Diagnostic Medical Devices

Carry out conformity assessment based on risk class (link)
- General IVDs
- IVDs for self-testing
- IVDs in annex II list B
- IVDs in annex II list A

Declaration or certification of conformity depending on risk class

Apply CE marking of in-vitro diagnostic medical devices

Clinical acceptability testing (pre-deployment)

Completing administrative tasks (e.g. contracts, etc.) → Data access request to test on real data → Testing on real data

MUST
- Manufacturer must provide training and show that the training leads to effective use of the device

Deployment

Implementation

Post-market surveillance

PROACTIVE MECHANISMS
- Manufacturer's post-market surveillance system, plan, report, period safety update report & vigilance (MDR articles 83-89 & IVDR 78-84)
- Post-market clinical follow-up
- Data registries (e.g. national joint registry…) used for post-market surveillance of medical devices excluding software

REACTIVE MECHANISMS
- Yellow Card Scheme
- National Reporting and Learning System
- ICO investigation
- CQC inspection

MUST
- Comply with post-market surveillance requirements
- Consider what your known unknowns are during post-market surveillance and closely monitor them

Ongoing product improvement & risk assessment

Service delivery

Regulatory Sandbox: CareQuality Commission · ico.

Real world evidence
There is no single definition but can be generally understood as: evidence generated from real world data collected outside of the context of randomised controlled trials

MUST
- Make sure that if two devices are used in combination both have a separate & valid CE mark & their intended use includes the use of the other device. If not and there is no evidence of safety & effectiveness of the devices used in combination, the combination itself becomes a NEW device in its own right

Reimbursement, procurement and commercial models

Reimbursement, procurement and commercial models

Identify reimbursement and procurement routes → Develop the commercial model → Commissioning and adoption

Statutory bodies & ALBs: NICE · NHS Supply Chain · Business Services Authority · NHS Digital · The AHSN Network · GOV.UK
Other stakeholders

SHOULD
- Consider that commissioning decisions are made at CCG/ local authority level. Innovators will need to engage with CCGs and local authorities individually.
- Consider NHSE's Innovation and Technology Payment Programme

Sandbox: HDR UK